

**GOVERNMENT OF INDIA  
MINISTRY OF HEALTH AND FAMILY WELFARE  
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**RAJYA SABHA  
UNSTARRED QUESTION NO.2054  
TO BE ANSWERED ON 10<sup>th</sup> MARCH, 2026**

**INCIDENTS OF FOOD CONTAMINATION AND COUGH SYRUP  
CONTROVERSY**

**2054. SHRI VIVEK K. TANKHA:**

Will the **Minister of HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether the repeated incidents of food contamination and the recent cough syrup controversy exposes serious regulatory lapses and how the Union Government assesses the effectiveness of the national food and drug safety framework in preventing adulteration and protecting public health;
- (b) the number of inspections, sample tests, prosecutions, and licence cancellations initiated under the Food Safety and Standard (FSS) Act in the last three years, State-wise;
- (c) the mechanisms being used by Government and FSSAI to monitor and audit State enforcement capacity and laboratories; and
- (d) the concrete reforms proposed to strengthen early detection, independent testing, accountability of manufacturers, and deterrence against large-scale adulteration across the country?

**ANSWER**

**THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY  
WELFARE  
(SHRI PRATAPRAO JADHAV)**

(a) to (d): Food Safety and Standards Authority of India (FSSAI) is mandated to lay down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption. The implementation and enforcement of the Food Safety and Standards (FSS) Act, 2006 is a shared responsibility between the Central and State Governments.

Further, the manufacturing, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and rules thereunder. The regulatory

control over the manufacture, sale and distribution of drugs in the country is exercised through a system of licensing and inspection by the State Licensing Authorities (SLAs). Compliance with the conditions of licence granted under the said Act and Rules is mandatory for manufacture, sale and distribution of drugs in the country. SLAs are legally empowered to take action against violation of provisions of the said Act and Rules.

While the FSSAI, is responsible for laying down science-based standards and ensuring overall coordination, the State Food Safety Authorities are primarily responsible for enforcement at the field level. Designated officers (DOs) and Food Safety Officers (FSOs) under the Commissioner of Food safety in the States/UTs are entrusted with the responsibility of enforcing the provisions of FSS Act, 2006.

To ensure compliance with the set standards, limits, & other statutory requirements under the Act, 2006 and Food Safety & Standards Regulations (FSSR), FSSAI, through State/UT food safety authorities and its four (04) regional offices, conducts regular localized/targeted special enforcement and surveillance drives including National Annual Surveillance Plan (NASP), inspections and sampling activities throughout the year. If any deviations from the standards or violations to the FSSR are observed, the defaulting Food Business Operators (FBOs) are subjected to regulatory actions, including punitive measures, as stipulated under the FSS Act, 2006 and rules and regulations made thereunder.

State wise details of food samples analysed and action taken against the defaulting Food Business Operators for non-compliance for last three years are attached at **Annexure-I, II and III** respectively.

As per the requirements of ISO/IEC 17025:2017 mandated by the Food Safety and Standards (Recognition and Notification of Laboratories) Regulations, 2018, FSSAI Notified Laboratories including State Food Testing Laboratories are required to obtain and retain National Accreditation Board for Testing and Calibration Laboratories (NABL), which includes periodic surveillance assessments and re-assessments to verify continued conformity with the prescribed standards and regulatory provisions.

In addition, FSSAI extends financial and technical assistance for the up-gradation and strengthening of State Food Testing Laboratories (SFTLs). Periodic and systematic reviews of their functional status, infrastructure adequacy, human resource availability and capacity gaps are conducted through structured field visits, technical evaluations by assessing

performance through Monthly Progress Reports and during Central Advisory Meeting (CAC).

FSSAI has facilitated rapid food testing methods to reduce the screening time of the food products at the field level and accelerate surveillance as well as monitoring activities. RAPID Kits are advanced, easy to use, portable and handheld devices and they don't require any sophisticated equipment or conventional reagents to conduct the tests. Currently, 86 RAFT Kits are approved by FSSAI.

Central Drugs Standard Control Organization (CDSCO) in recent years has taken several measures to ensure the quality and safety of medicines in the country, few are mentioned below:-

- i. In order to assess the regulatory compliance of drug manufacturing premises in the country, the CDSCO along with State Drugs Controllers (SDCs) have conducted Risk-Based Inspections of more than 960 premises since December, 2022 and based on findings, more than 860 actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses /product licenses, warning letters have been taken by the State Licensing Authorities.
- ii. More than 1100 cough syrup manufacturers have been subjected to intense audit in coordination with State authorities. Increased market surveillance sampling of syrup formulations by Central and State drugs regulators has also been done.
- iii. List of drugs of various companies, which are declared Not of Standard Quality/ Spurious/ Misbranded/ Adulterated by the Central Drugs Testing Laboratories is uploaded and available on the website of CDSCO under the heading of Drug Alert ([www.cdsc.gov.in](http://www.cdsc.gov.in)) and actions initiated.
- iv. The Drugs Rules, 1945 have been amended in year 2023 to mandate that manufacturers of the top 300 drug formulation brands listed in Schedule H2 shall print or affix a Bar Code or QR Code on the primary packaging label, or on the secondary label where space is insufficient, to store data readable through software applications for authentication. Similarly, the Rules have also been amended to require that every Active Pharmaceutical Ingredient (bulk drug), whether manufactured or imported, shall bear a QR Code on each level of packaging containing data readable through software applications to facilitate tracking and tracing.
- v. The Central Government has amended the Drugs Rules 1945 vide G.S.R. 922 (E) dated 28.12.2023 to revise the schedule M to the said rules related to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products. Revised Schedule M has become effective for the drug

manufacturers with turnover > Rs. 250 crores from 29.06.2024 and for manufacturers having turnover of less than Rs. 250 Cr from 01.01.2026.

- vi. In February 2024, CDSCO published regulatory guidelines for the sampling of drugs, cosmetics, and medical devices by Central and State Drugs Inspectors. These guidelines provide a structured approach to ensure the quality and efficacy of products available in the market through uniform drug sampling methodology.
- vii. An online portal, SUGAM labs is in place since September 2023 for integrating the drug testing labs of the CDSCO. It automates the entire workflow for testing of Medical Products (Drugs, Vaccine, Cosmetics & Medical devices) to meet the quality specification and tracing the testing status in the laboratories.

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## Annexure –I

## Details of food samples analysed and penal action taken during 2024-2025.

Details of Enforcement (2024-2025)						
S. No.	State/UT	No. of Samples Analysed	Civil Cases		Criminal Cases	Cancelled license
			Decided Penalty	with	No. of Convictions	
1	Andaman And Nicobar Islands	810		0	0	1
2	Andhra Pradesh	5984		464	8	15
3	Arunachal Pradesh	125		7	0	5
4	Assam	1705		0	0	19
5	Bihar	2863		25	0	7
6	Chandigarh	374		116	41	5
7	Chhattisgarh	2069		143	6	1
8	Dadra and Nagar Haveli & Daman & Diu	56		0	0	0
9	Delhi	2624		18	16	1
10	Goa	1172		11	0	0
11	Gujarat	12387		859	91	8
12	Haryana	2233		599	59	20
13	Himachal Pradesh	1587		471	0	3
14	Jammu & Kashmir	6955		1,239	29	17
15	Jharkhand	364		52	0	1
16	Karnataka	9371		283	32	34
17	Kerala	10767		1,088	206	40
18	Ladakh	417		38	0	0
19	Lakshadweep	0		0	0	0
20	Madhya Pradesh	13920		2,597	22	3
21	Maharashtra	5403		1,147	0	9
22	Manipur	126		2	0	1
23	Meghalaya	388		0	0	0
24	Mizoram	0		0	0	0
25	Nagaland	223		0	0	0
26	Orissa	2282		27	0	2
27	Puducherry	173		0	0	0
28	Punjab	4131		333	8	1
29	Rajasthan	13840		3,114	30	2
30	Sikkim	254		0	0	0
31	Tamil Nadu	18071		1,536	492	7
32	Telangana	3347		125	0	1
33	Tripura	123		0	0	0
34	Uttar Pradesh	30380		14,920	215	16
35	Uttarakhand	1509		256	4	1
36	West Bengal	14502		672	6	0
	<b>Total</b>	<b>170535</b>		<b>30142</b>	<b>1265</b>	<b>220</b>

## Annexure-II

## Details of food samples analysed and penal action taken during 2023-2024

Details of Enforcement (2023-24)					
S. No.	State/UT	No. of Samples Analysed	Civil Cases	Criminal Cases	Cancelled license
			Decided with penalty	Decided with Fine and Imprisonment	
1	Andaman And Nicobar Islands	0	0	0	0
2	Andhra Pradesh	6439	646	8	40
3	Arunachal Pradesh	501	2	0	25
4	Assam	1139	0	0	0
5	Bihar	2806	79	0	10
6	Chandigarh	311	87	52	1
7	Chhattisgarh	1373	86	2	0
8	Dadra and Nagar Haveli & Daman & Diu	185	0	0	0
9	Delhi	3412	36	12	1
10	Goa	599	17	0	1
11	Gujarat	15841	1701	65	7
12	Haryana	3485	593	47	15
13	Himachal Pradesh	1618	376	2	6
14	Jammu & Kashmir	9057	1612	22	19
15	Jharkhand	384	59	0	2
16	Karnataka	5492	75	16	50
17	Kerala	10792	854	134	137
18	Ladakh	638	19	0	1
19	Lakshadweep	0	0	0	0
20	Madhya Pradesh	13998	1938	46	10
12	Maharashtra	5087	154	0	4
22	Manipur	168	0	0	0
23	Meghalaya	123	0	0	0
24	Mizoram	0	0	0	0
25	Nagaland	138	3	0	1
26	Orissa	2003	0	0	24
27	Puducherry	31	0	0	0
28	Punjab	6041	1204	102	0
29	Rajasthan	18536	2181	12	0
30	Sikkim	231	0	0	0
31	Tamil Nadu	18146	2195	478	36
32	Telangana	6156	425	0	6
33	Tripura	87	0	0	0
34	Uttar Pradesh	27750	14627	163	9
35	Uttarakhand	1998	332	0	1
36	West Bengal	5948	285	0	2
	<b>Total</b>	<b>170513</b>	<b>29586</b>	<b>1161</b>	<b>408</b>

## Details of food samples analysed and penal action taken during 2022-2023

<b>Details of Enforcement (2022-23)</b>					
S. No.	Name of State/UT	No. of Samples Analysed	Civil Cases	Criminal Cases	Cancelled license
			Decided with penalty	Decided with fine & Imprisonment	
1	Andaman& Nicobar Islands	1200	58	0	0
2	AndhraPradesh	3607	339	12	64
3	ArunachalPradesh	258	0	0	20
4	Assam	602	0	0	0
5	Bihar	2935	39	0	10
6	Chandigarh	473	27	8	4
7	Chhattisgarh	1468	119	8	0
8	Dadra Nagar Haveli & Daman & Diu	164	13	0	0
9	Delhi	3133	86	10	0
10	Goa	699	11	0	4
11	Gujarat	14562	547	24	15
12	Haryana	4445	915	35	25
13	Himachal Pradesh	2720	93	1	9
14	Jammu & Kashmir	13502	1592	15	42
15	Jharkhand	943	44	8	1
16	Karnataka	3416	191	15	56
17	Kerala	8533	454	33	90
18	Ladakh	220	23	0	0
19	Lakshadweep	0	0	0	0
20	MadhyaPradesh	12507	1908	71	22
21	Maharashtra	11077	198	5	17
22	Manipur	169	0	0	3
23	Meghalaya	409	0	0	0
24	Mizoram	140	0	0	0
25	Nagaland	109	0	0	1

26	Odisha	1368	47	0	40
27	Puducherry	0	0	0	1
28	Punjab	8179	1404	5	1
29	Rajasthan	13184	2435	4	1
30	Sikkim	279	4	0	0
31	Tamil Nadu	24188	3714	678	47
32	Telangana	4809	315	0	9
33	Tripura	31	0	0	0
34	Uttar Pradesh	30140	13148	251	50
35	Uttarakhand	1839	507	5	1
36	West Bengal	6203	233	0	0
	<b>Total</b>	<b>177511</b>	<b>28464</b>	<b>1188</b>	<b>533</b>