

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

**RAJYA SABHA  
UNSTARRED QUESTION NO.1073  
TO BE ANSWERED ON 12<sup>th</sup> DECEMBER, 2023**

**REGULATIONS OF NUTRACEUTICAL AND HEALTH SUPPLEMENTS**

**1073. SHRI SHAKTISINH GOHIL:**

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

- (a) whether it is a matter of fact that there is no Gazetted Notified Regulations in the country for regulating the nutraceutical and health supplements;
- (b) whether it is a fact that Food Safety and Standard Authority of India (FSSAI) has repealed the earlier regulations on their own with the approval of Government, if so, then why Government has not taken action in the matter so far; and
- (c) the manner in which all the manufacturing units of Nutraceutical products have been brought under the mandatory ambit of Central FSSAI License without amending the Regulations or the Act, what was the objective of this decision when FSSAI has only 36 Central FSOs for the entire country?

**ANSWER  
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY  
WELFARE  
(DR. BHARATI PRAVIN PAWAR)**

(a) and (b): The Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 was notified in the Gazette on 26.12.2016.

To remove ambiguity and bring more clarity, Food Safety and Standards Authority of India (FSSAI) overhauled the Nutra 2016 regulation and drafted a new framework called as Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022. As the above draft regulations were in the process of draft publication and their final notification would take time, therefore FSSAI issued directions to operationalize the provisions of the draft regulations. The draft Regulation has been notified in the Gazette on 28.06.2022.

(c): It was observed that licenses were inadvertently issued by State Licensing Authorities for non-standardised and non-compliant products due to complexities of Nutraceutical regulations and lack of explicit understanding of the State Authorities in respect of these regulations.

As per clause 3 of sub-regulation 2.1.2 of regulation 2.1 of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011, Food Authority may through a notification make such changes or modify the list given in the schedule I (List of food business falling under the purview of Central Licensing Authority) as considered necessary.

With the approval of Food Authority, an Order was issued to allow only Central Licenses for manufacturers of Food Products covered under Nutraceuticals Regulations and implementation of the said provision through Food Safety Compliance System.

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