

GOVERNMENT OF INDIA  
MINISTRY OF FOOD PROCESSING INDUSTRIES  
**LOK SABHA**  
**UNSTARRED QUESTION No. 357**  
ANSWERED ON 19<sup>TH</sup> NOVEMBER, 2019

APPLICATION OF NEW FPIs

**357. DR. AMOL RAMSING KOLHE:  
SHRI SUNIL DATTATRAY TATKARE:  
DR. SUBHASH RAMRAO BHAMRE:  
SHRIMATI SUPRIYA SULE:  
SHRI KULDEEP RAI SHARMA:  
SHRI A.K.P. CHINRAJ:**

Will the Minister of FOOD PROCESSING INDUSTRIES be pleased to state:

- (a) the time duration taken to give approval for a new product put up by entrepreneurs in the field of Food Processing Industry;
- (b) the details of number of applications of food processing unit pending with the competent authorities during each of the last three years and the current year;
- (c) whether there is a big problem in getting a new product approved by entrepreneurs in the field of Food Processing Industry, if so, the details thereof and the reasons therefor;
- (d) whether the Government has devised any solution to the problem of delays faced by the entrepreneurs in obtaining product approval from the authorities concerned, if so, the details thereof and if not, the corrective steps taken in this direction; and
- (e) the other steps taken by the Government to expedite the clearance of approvals?

**ANSWER**

THE MINISTER OF STATE FOR FOOD PROCESSING INDUSTRIES  
(SHRI RAMESWAR TELI)

(a): Food Safety and Standards Authority of India (FSSAI) under Ministry of Health and Family Welfare, has the mandate for dealing with the matters relating to Food Safety and Standards.

As per information provided by FSSAI, the Food Safety and Standards

(Approval of non-specified food and food ingredients) Regulations, 2017 were notified in the Gazette of India on 11th September, 2017 for the approval of non-specified food/ food ingredients including novel food /food ingredients. The time duration taken to grant a new product approval under the said Regulations is approximately 4 to 6 months from the date of submission of the application depending on the completeness of the information submitted by the applicant. However, it may take a longer time, if sufficient information on safety and efficacy of the product is not available.

(b): The details of the applications received under the said regulations, as per information shared by FSSAI, are as follows:

(i)	Total Number of applications received till date:	<b>290</b>
(ii)	Number of applications processed and disposed of:	<b>174</b>
(iii)	Number of applications that is under process:	<b>116</b>

The year-wise break up of pending 116 applications under process is as below:

I. 2017:	03
II.2018:	40
III.2019:	73

(c): FSSAI has informed that as per requirements of the Food Safety and Standards (Approval of non-specified food and food ingredients) Regulations, 2017, any new product approval application needs to provide complete information regarding its safety and efficacy. These new products need to undergo risk assessment process before approval and placing the same in the market. The absence of safety data and efficacy data regarding the product will hamper grant of new product approval.

(d) & (e): To reduce the burden of product approval and facilitate the clearance of new food products, FSSAI took various measures. These include:

(i) amendment to Regulation 2.12 on proprietary food under the Food Safety and Standards (Food Products and Food Additives) Regulations, 2011.

This amendment shifted the clearance of new foods from recipe based approach to the ingredient based approach on the principles that a food would be safe for human consumption if the standardized ingredients are used in preparation of such food. This has resulted in a drastic reduction in the need of product approval.

(ii) The list of permissible food additives has also been increased under these regulations. In addition, several new product standards/regulations have also been developed.

(iii) The Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods and Novel Food) Regulations, 2016 covering eight categories of food, namely, Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purposes, Specialty Foods containing plants or botanicals, Foods containing probiotics, Foods containing prebiotics and Novel Foods have been notified which has further reduced the need for any product approval.

(iv) A separate Expert Committee has been constituted to examine the applications received under the Food Safety and Standards (Approval of non- specified food and food ingredients) Regulations, 2017 to facilitate and expedite the process of approval.

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