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FSSAI Publishes Guidelines on Product Approvals

Report Categories:
Sanitary/Phytosanitary/Food Safety
Food and Agricultural Import Regulations and Standards - Narrative
Exporter Guide
Sugar
Dairy and Products
Livestock and Products
Beverages
Poultry and Products
Grain and Feed
Vegetables
Tree Nuts
Fresh Fruit
Oilseeds and Products
Trade Policy Monitoring

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Report Highlights:

The Government of India's (GOI) Food Safety and Standards Authority of India (FSSAI) published on their website guidelines on product approvals. The document takes the reader through a complete journey and status of product approval.

Executive Summary:

FSSAI published guidelines on the food product approval system to explain the entire process of product approval. These guidelines have been published with a cover note addressed by the CEO, FSSAI, wherein he emphasizes the stakeholders to fill in the product approval application with due diligence and avoid any unnecessary delays in the approval process. Important highlights include information on (a) vertical and horizontal food standards; (b) product approvals in respect of proprietary food; (c) the working of product approval system; (d) statistics on product approval; (e) future roadmap and action plan; (f) online food product approval system (FPAS); and (h) new standards and regulations.

General Information:

On May 11, 2015, FSSAI published guidelines on product approvals. These guidelines explain the entire process of product approval and also include annexures to provide explanatory notes for each of the points included in the prescribed format of the product approval application. Statistics compiled by FSSAI show a total of 304 applications received in the online system during January 1 to March 31, 2015. The important features of the guidelines are highlighted below.

- The food products falling in category of genetically modified foods have not been notified as yet for India.
- Though the food industry is opposing the current product approval system for proprietary food, only about 30-40% of the application for product approval fall in this category.
- A Task Force was constituted in August 2014 to work on the issue of product approval and suggest a draft regulation for the process of product approvals. The Task Force has submitted its report on April 22, 2015 and their recommendation are being examined.
- The court matter related to the advisory of May 11, 2013, challenged by certain groups from the industry and the Indian Drugs Manufacturers Association in the High Court of Bombay is still pending before the Supreme Court.
- An Action Plan has been prepared for timely processing of application. Under the plan, all product approval applications have been divided into two categories: (1) those filed/received until December 31, 2014 and (2) those filed from January 1 to March 31, 2015. Both the categories will be reviewed and a decision reached latest by July 31, 2015. The status of pending application for product approvals at different points is given in the table below.

No. of Apps. received	Product Approvals/ NOCs Issued	Referred to Scientific Panel	Apps. Closed (being incomplete/ non-responsive)	Under Closure	Rejected	Pending (including under back reference)	Files complete for the PA&SC	Pending Scrutiny with FSSAI	Pending with FBOs for clarifications
As on 31.01.2014 (the day when the High Court of Mumbai stayed the Advisory dated 11th May 2013)									
3565	522	-	241	-	147	2655	-	-	1063
As on 13.08.2014 (the day when the Hon'ble Supreme Court stayed the order of High Court of Mumbai									
3999	522	-	241	-	147	3089	-	-	1063
Status of Applications filed / received up to 31.12.2014									
As on 31.12.2014									
4541	763	-	551	-	184	**3043**	-	-	-
As on 15.02.2015									
4541	885	-	835	840	202	**1779**	-	-	-
As on 31.03.2015									
4541	1004	145	1338	367	244	**1443**	-	-	-
As on 30.04.2015									
4543	1059	200	1926	0	444	**914**	213	530	171
No. of Applications filed in On-line Mode from 01.01.2015 to 31.03.2015									
304									

- Processing of Applications filed/ received on or after 01.01.2015 shall start after the disposal of applications received up to 31.12.2014.
- All efforts are being made to dispose off the applications received up to 31.12.2014 by 30.06.2015.
- It is also planned to dispose off all completed applications received up to 31.03.2015 by 31.07.2015.

With effect from July 1, 2015, a time line of 30 days will be followed for all product approval applications and the details are given in the table below.

First 30 days	Next 30 days	Next 30 days
From the date of receipt of application in the on-line system, the Product Approval Division shall seek any clarifications or ask for submission of deficient documents within 30 days. No clarifications to be raised after 30 days.	The FBO Applicant to respond to the query/ provide clarifications/ complete the documentation within next 30 days. If no response is received or incomplete response is received from the FBO, the application will be closed as being non-responsive.	The Product Approval and Screening Committee to complete the process of screening and decide the application i.e. • Grant approval/NoC; • Reject the application; • Close the non-responsive applications; • Refer to the concerned Scientific Panel for detailed examination. It is difficult to commit any time-lines for a decision by the Scientific Panel as this entails the FBO to submit an application with more data for safety/ risk assessment by the Panel.

- Once an application is submitted, the Authority does not allow any changes to be made in the application.
- The applications for intermediate food products is accepted in the manual mode as this functionality is yet to be developed and provided in the online system.
- The facility of 'Track Status' of application is available under the FPAS.
- The Authority is considering permitting and approving a range of ingredients in the product subject to the limits prescribed in the applicable vertical and horizontal standards. Wherever, the applicant would apply for a range, the same would be considered and allowed within a band of 10 percent subject to the upper and lower limits prescribed under the regulations without undertaking a fresh risk assessment. For a change in the composition of ingredients within an already approved product, the food business operator would be allowed the change in composition, subject to the limits prescribed, on a simple application containing the composition of the product and the label without payment of any fees and such an application will be cleared within 15 working days. Similar procedure will be followed for the introduction of different flavors of the already approved project. However, these facilities are not yet operational as the development of e-forms is still under process and will be launched only with effect from July 1, 2015.
- The timeline to review an existing standard or develop a new standard is provided in the table below.

Sr. No.	Steps	Estimated Time
(i)	Identification of the Food Product of which standard is to be reviewed or a new Standard is to be developed	Four Weeks – an ongoing exercise
(ii)	Reference to the concerned Scientific Panel	
(iii)	Consideration of the matter by the Scientific Panel	12 to 18 months
(iv)	Consultation process with experts, opportunity of hearing to the industry, data collection, reference to the Studies on the subject etc.	
(v)	Drafting of the Standard	
(vi)	Placing the Draft Standard before the Scientific Committee	03 months - Event based
(vii)	The Scientific Committee may refer it back for certain clarifications or requiring the panel to look into certain other related aspects	
(viii)	Approval of the Scientific Committee	
(ix)	Placing the agenda before the Food Authority for approval	01 to 03 months depending upon the timing of the meeting of the Food Authority
(x)	Revision of the Draft Regulation from legal angle after approval of the Food Authority	About one month
(xi)	Reference to the Ministry for its approval, legal vetting and publication of the Draft Regulation	Legal Vetting may take 1 to 3 months time
(xii)	Placement of the Draft regulation on the website after its publication in the Gazette inviting comments from the stakeholders	60 days running concurrent for notice to WTO and inviting comments/ suggestions from the stakeholders
(xiii)	Simultaneous Notification to the WTO for its comments	
(xiv)	After closure of 60 days period, the comments received are tabulated, and examined.	Appx. 30 to 45 days
(x)	A reference is made to the Scientific Panel to consider the comments received in response to the Draft Notification and furnish its considered recommendations	About 60 to 90 days
(xi)	The Draft Regulation, after attending to the	30 to 90 days linked with

Sr. No.	Steps	Estimated Time
	comments received during the consultation process, is placed before the Scientific Committee for validation, if required, and the Authority for its approval.	the scheduling of meetings of the Scientific Committee/ Food Authority
(xii)	The Final Regulation is sent to the Ministry of Health for its approval for Notification of the Final Regulation	30 days to 90 days
(xiii)	The Ministry forwards the same to the Legislative Department in the Ministry of Law for Legal Vetting and on receipt thereof accords its approval	
(xiv)	The Final Regulation is sent to the Controller of Publications for publication of the notification in the Government Gazette.	About 30 days

The progress and status on the finalization of draft standards/regulations on various areas is also outlined in the publication that includes the draft standards for alcoholic beverages.in the notification. A print screen shot of the same is provided below.

15.2.1 Working through a period of last two years, the Food Authority has already finalized harmonization of **more than 11,000 standards of Additives with those of CODEX** and approved the same in its meeting held on 16.01.2015. The two members representing the Industry on the Authority had sought four weeks time for furnishing their comments before issuing the draft regulation qua these standards. Their request was accepted. The comments from the Industry representative members were received on 28.02.2015. Though the substantial comments have been referred to the concerned Scientific Panel for examination in the meantime, simultaneously the case is being prepared for issue of notification of the Draft Standards. The Draft Standards were submitted to the Ministry on 10th April 2015 and the Ministry forwarded the same to the Legislative Department of the Ministry of Law & Justice on the following day itself. These Draft Standards are presently under consultations with the Legislative Department.

15.2.2 The Authority has already finalized the **Draft Regulations for Nutraceuticals, Foods for Dietary Supplements and Foods for Special Medical Purposes etc.** These Draft Regulations were under discussions with the Legislative Department and have finally been forwarded to the Ministry on 31.03.2015. The Ministry is also learnt to have forwarded the same to the Legislative Department for legal vetting. These are also presently under consultations with the Legislative Department;

15.2.3 The Food Authority has also finalized the **Draft of Food Recall Regulations,** which have been through the process. These Draft Regulations have been published by the Controller of Publications in the Gazette on 22.04.2015 and are likely to placed on the FSSAI website by 15th May 2015 for inviting public comments;

15.2.4 Drafting of the **Import Regulations** is at advanced stage. It is planned to finalise the same by the end of May, 2015, resubmit the same to the Food Authority for its consideration and approval. The process of obtaining the approval of the Ministry of Health & Family Welfare and legal vetting would commence thereafter.

15.2.5 The draft **Standards for Alcoholic Beverages** have been finalised. Though initially planned to be finalised by end of July 2015, it has been possible to complete the work ahead of planned schedule. The Draft Standards/ Regulation for Alcoholic Beverages are being placed before the Food Authority in its ensuing meeting scheduled for the 18th May 2015. Once approved by the Food Authority, the process of issue of Draft Notification for inviting public comments would be put in motion;

15.2.6 As in the case of Alcoholic Beverages, considerable progress has been made towards finalisation of **Standards for Milk and Milk Products**. There are a few areas (like Dairy Milk Whitener and national Standards for FAT and SNF content of Milk) still left out in the absence of availability of scientific data/ evidence. However, it is proposed to complete this work within next four months **i.e. by the end of September this year**.

- A total of 7 new scientific panels on the following subjects have been proposed to be established by the Authority. Once this proposal is approved, each of the Scientific Panels will be requested to delineate its scope of work along with an action plan to develop/review the vertical standards in a fast track mode.

    - Milk and Milk products
    - Meat and meat products including poultry
    - Cereal, pulses and legumes and their products (including bakery)
    - Fruits and vegetables and their products (including dried fruits and nuts, salt, spices and condiments)
    - Oils and fats
    - Sweets, confectionary, sugar and honey
    - Water (including flavored water) and beverages)alcoholic and non-alcoholic)

The three annexures listed in the document are:

Annexure 1: Important Sections of the Food Safety and Standards Act, 2006 leading to the system of product approvals

Annexure 2: FSSAI guidelines dated May 11, 2013 for product approval procedure

Annexure 3: Explanatory notes on various points in the application for product approvals.

The full notification is available on FSSAI's website at http://www.fssai.gov.in/Portals/0/pdf/Comprehensive_Scheme_and_Guidelines_on_Product_Approvals.pdf