

NON - SPECIFIED FOOD PRODUCT APPROVAL SYSTEM

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What are Non specified Food products?

“Non-specified food” means any food other than proprietary food or food ingredients, including additives, processing aids and enzymes for which standards have not been specified in any regulation made under the Act.

..... as specified under Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017

Why this definition came?

- Definition came because of section 22

22. Genetically modified foods. organic foods. functional foods. proprietary foods. etc. Save as otherwise provided under this Act and regulations made thereunder, no person shall manufacture, distribute, sell or import any novel food, genetically modified articles of food, irradiated food, organic foods, foods for special dietary uses, functional foods, nutraceuticals, health supplements, proprietary foods and such other articles of food which the Central Government may notify in this behalf.

FSSAI is mandated under law to regulate/approve
Proprietary and novel foods

Set of Advisories released to effectively regulate Proprietary food and Novel food

Office Memorandum dated 29th September 2014 regarding renewal of license for which NOCs/PNOCs has been issued by Product Approval Division (Uploaded on: 01-10-2014)

Office Memorandum (PDF)

FAQs on Product Approval(Uploaded on: 14-10-2014).

procedure ,PDF (14-10-2014)

September 2014

Food Product Approval System (FPAS) online launched (Uploaded on: 11-09-2014).

Procedure ,PDF (11-09-2014)

May 2013

Guidelines to be followed for Product Approval Procedure(Uploaded on: 17-05-2013).

procedure ,PDF (17-05-2013)

December 2012

Procedure regarding new product approval(Uploaded on: 11-12-2012).

procedure ,PDF (11-12-2012)

November 2012

Advisory of Product Approval (Uploaded on: 07-11-2012)

May 2012

Continuation to the Advisories of Product Approval (Uploaded on: 02-05-2012).

Continuation to the Advisories ,PDF (02-05-2012)

March 2012

The procedure adopted by FSSAI for approval of proprietary products/ ingredient already being manufactured under erstwhile Acts/ Orders (PFA, FPO, MMPO, MFPO etc.) or imported – reg. (Uploaded on: 23-03-2012).

The procedure adopted by FSSAI ,PDF

February 2012

Clarification relating Product Approval Procedure (Uploaded on: 14-02-2012)

Clarification relating ,PDF

January 2012

Applications for Approval of new Product/Ingredient.(Uploaded on: 30-01-2012)

Announcement (PDF)

Applications for Approval (PDF)



Building Healthy India with Safe
Food



Food Product Approval System Version 1.0

List of NOCs/PAs Issued in the Year 2012

Sl.No.	Applicant	Product	Date of NOC/PA Issue
1	M/s Apex Laboratories, B-23, SIDCO Pharmaceuticals Complex, Alathur, Kancheepuram District- 603110	Zincovit Drops	30.04.2012
2	M/s Apex Laboratories, B-23, SIDCO Pharmaceuticals Complex, Alathur, Kancheepuram District- 603110	Zincovit Syrup	30.04.2012
3	M/s Apex Laboratories, B-23, SIDCO Pharmaceuticals Complex, Alathur, Kancheepuram District- 603110	Zincivit Tablet	30.04.2012
4	M/s Apex Laboratories, B-23, SIDCO Pharmaceuticals Complex, Alathur, Kancheepuram District- 603110	Actilife Tablets	02.05.2012
5	M/s Jagdale Industries Limited, 782, 15th Cross, 1st Phase, J.P. Nagar, Bangalore- 560078	Mulmin Drops	07.05.2012
6	M/s Jagdale Industries Limited, 782, 15th Cross, 1st Phase, J.P. Nagar, Bangalore- 560078	Mulmin Pro	07.05.2012
7	M/s Jagdale Industries Limited, 782, 15th Cross, 1st Phase, J.P. Nagar, Bangalore- 560078	Mulmin Syrup	07.05.2012

F.No.P-15025/SCJ/2015-PA/FSSAI
Food Safety and Standards Authority of India
(A Statutory Authority established under Food Safety and Standards Act, 2006)
(Product Approval Division)
FDA Bhawan, Kotla Road, New Delhi

Dated, the 26th August, 2015

It is no longer possible for the FSSAI to continue with process of Product Approvals which was facilitated through the Advisory dated 11.05.2013 in view of the order dated 19.08.2015 of the Hon'ble Supreme Court whereby the judgement and order dated 01.08.2014 of the Hon'ble Bombay High Court has gained finality and the said Advisory has ceased to remain operative.

2. Every endeavour will be made to expedite the Regulations governing section 22 products.
3. We regret the inconvenience.



(Dr. Sandhya Kabra)
Director (Product Approval)

2016: New Proprietary food regulations notified and made operational

Food Safety and Standards (Food Product Standards and Food Additives) Regulation 2011 and /or Standards for food additives that have been operational through the notice of 23 December 2015

F.No. 11/12/Reg/Prop/FSSAI-2016(Part-I)
Food Safety and Standards Authority of India
(A statutory Authority under the Ministry of Health and Family Welfare, Govt. of India)
FDA Bhawan, Kotla Road, New Delhi-110002

The 22nd August, 2016

Subject: Direction under Section 16(5) of Food Safety and Standards Act, 2006 regarding operationalisation of standards for proprietary food.

Revised standards of proprietary food under Regulation 2.12 of the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 were operationalised on 13.01.2016. Subsequently, these revised standards were notified on 19.04.2016 and uploaded on the FSSAI website on 27.04.2016 inviting suggestions and comments from various stakeholders.

2. The draft regulations were reviewed taking into considerations the comments and suggestions received from various stakeholders and are under process of final notification. These finalised standards of proprietary food as enclosed herewith have been made operational w.e.f 22.08.2016. These standards will supercede the standards of proprietary food which were previously operationalised on 13.01.2016.

3. It is directed that the enforcement officials in States/UTs be instructed to implement the above mentioned standards of proprietary food till the issuance of final notification in this regard.

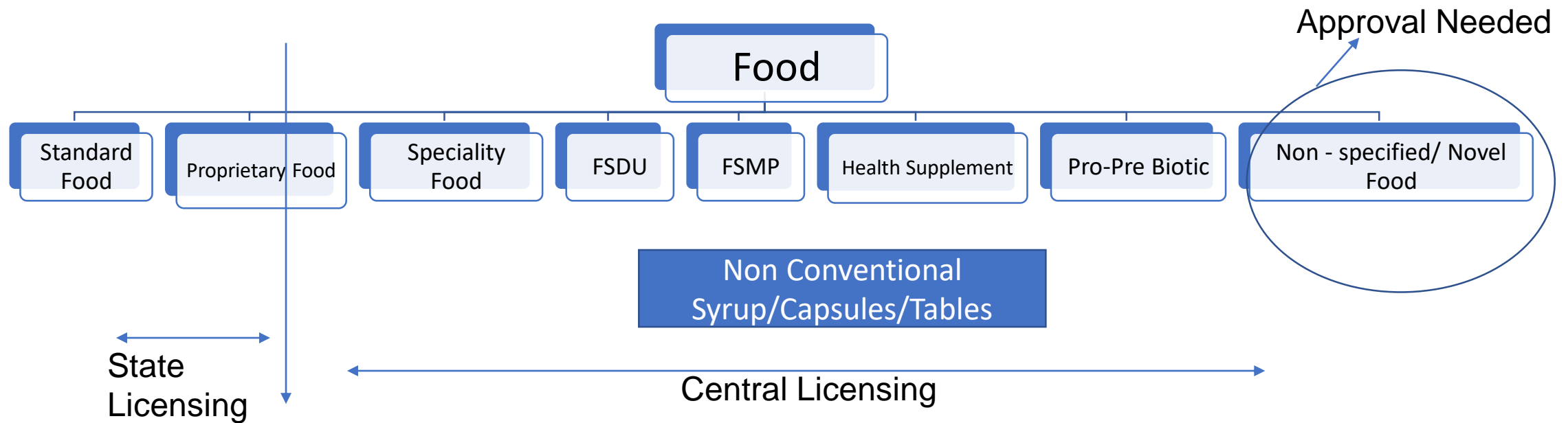
4. This issues with the approval of the Competent Authority in exercise of the power vested with Food Authority under clause 5 of Section 16 of the Food Safety and Standards Act, 2006.



(Sunil Bakshi)
Advisor (Regulations)

Enclosure: as above

Food Categorization as per FSSAI



And then on 11th September 2017, the final regulations came

MINISTRY OF HEALTH AND FAMILY WELFARE

(Food Safety and Standards Authority of India)

NOTIFICATION

New Delhi, the 11th September, 2017

F. No. 12/PA Regulation/Dir (PA)/FSSAI-2016.—Whereas the draft of the Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017 were published as required under section 92 of the Food Safety and Standards Act, 2006 (34 of 2006), vide notification of the Food Safety and Standards Authority of India number F.No. 12/PA Regulation/Dir (PA)/FSSAI-2016, dated the 31st January, 2017, in the Gazette of India, Extraordinary, Part III, Section 4, inviting objections and suggestions from the persons likely to be affected thereby, before the expiry of the period of thirty days from the date on which the copies of the Gazette containing the said notification were made available to the public;

And whereas copies of the said Gazette were made available to the public on 9th February, 2017;

And whereas objections and suggestions received from the public in respect of the said draft regulations have been considered by the Food Safety and Standards Authority of India;

Now, therefore, in exercise of the powers conferred by clause (v) of sub-section (2) of section 92 of the said Act, the Food Safety and Standards Authority of India hereby makes the following regulations, namely:—

Regulations

1 Short title and commencement.— (1) These regulations may be called the ‘Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017.’

(2) They shall come into force on the date of their publication in the Official Gazette.

Scope of this regulation

5. What food categories do these regulations cover?

These Regulations broadly cover the following articles of food or food ingredients:

- Novel food or novel food Ingredients or processed with the use of novel technology
- New additives
- New processing aids including enzymes
- Articles of food and food ingredients consisting of or isolated from microorganisms, bacteria, yeast, fungi or algae.
- Any other non specified food

Challenge 1:

Scope of Non specified food regulations should be very clear

Non-Specified
Food product

Vs

Proprietary
food

Vs

GM food

Vs

Nutraceuticals

Challenge 2:
*Why for a single
ingredient (from
different manufacturer)
we need repetitive
approvals*

	Capsure		Manufacturer
57	Coconut Testa Oil	76/Std/PA/FSSAI/2020 07.01.2021	M/s Vanakkam Oil. Coimbatore- 642120. Tamil Nadu.
57	Coconut Testa Oil	87/Std/PA/FSSAI/2020 27.07.2021	M/s Kairali Traders, Palakkad - 678762. Kerala.
58	Coconut Testa Oil	06/Std/PA/FSSAI/2021 02.08.2021	M/s Thekkanath Trading Company, Ernakulam- 683513. Kerala.
59	Coconut Testa Oil	07/Std/PA/FSSAI/2021 30.07.2021	M/s Surya Agencies, Thrissur- 680669, Kerala.

List of applications Approved/Rejected/Closed/Withdrawn/Status (under process) under FSS NSF Reg, 2017-Page 4 of 19

File No.F.No.01/Std/Audit(NSF)/FSSAI-2019

60	Coconut Testa Oil	08/Std/PA/FSSAI/2021 29.07.2021	M/s S.S. Traders, Kollam- 691301.Kerala.
61	Coconut Testa Oil	16/Std/PA/FSSAI/2021 29.07.2021	M/s P.K. Trading Company Malappuram- 679326. Kerala.
62	Coconut Testa Oil	71/Std/PA/FSSAI/2020 30.07.2021	M/s Aswathi Oil Industry, Calicut-673015. Kerala

Challenge 3:

A Transparent and an IT enabled system for approval process



Challenge 4:
*No specific timelines
defined for approvals*



Appreciate FSSAI for the efforts in streamlining the process but a lot more to be done

THANKS