CHALLENGES IN OBTAINING APPROVAL OF NON-SPECIFIED FOODS

WEBINAR REPORT BY

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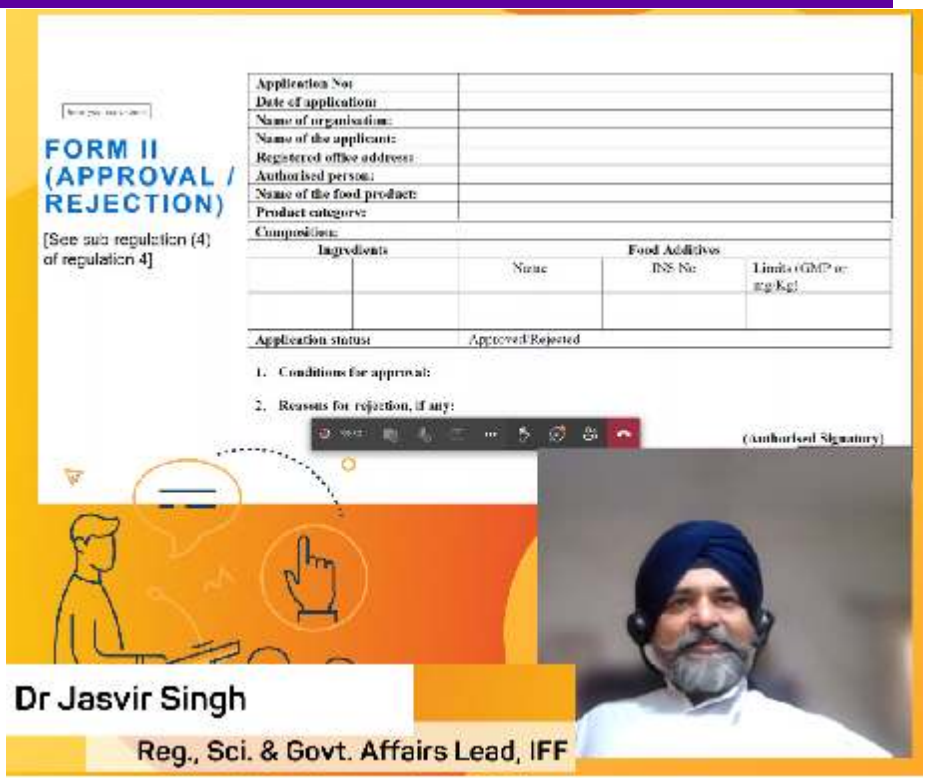
Protein Food And Nutrition Development Association of India (PFNDAI) conducted on 30th October 2021 a regulatory webinar on 'Challenges in Obtaining Approval of Non-Specified Foods'. The main objective of this webinar was to provide a platform to our participants for gaining knowledge about the approval of non-specified foods from experts in the field.

There were four presentations followed by a panel discussion. The speakers for the webinar were Dr. Jasvir Singh (Regulatory, Scientific & Government Affairs Lead, IFF), Ms. Sakshi Grover (Mgr. Strategic Services, Freyr Global Reg. Solutions & Services), Ms. Rini Sanyal (Director, Regulatory & Government Affairs, Herbalife Nutrition), and Ms. Meenu Yadav (Technical Reg. Affairs, Marico).

On the panel, there were Ms. Aparna Tandon Jain (Sr. Manager - Nutrition & NPD, Signutra), Ms. Shailesh Kumari (Senior Manager - Regulatory and Scientific Affairs, Nestlé), Mr. Phani Kumar (Head Quality & Regulatory, Zydus Wellness), and Dr. Akanksha (India Lead Scientific and Regulatory Affairs, Mars Petcare).

The webinar started with the welcome address by Dr. J. S. Pai (Executive Director, PFNDAI). The webinar was chaired and moderated by Dr. Joseph Lewis (Food Regulatory Consultant). He gave the opening remarks and introduced the participants to the topic of the webinar. In his remarks, he described the origin of this regulation by emphasizing the term "History of safe use'. Ms. Dolly Soni (Executive- Marketing & Digital, PFNDAI), introduced all the speakers before their respective presentations.

There is a lot of confusion when it comes to non-specified foods. Hence, the objective of this webinar was to enlighten our participants about the challenges that occur while obtaining approval of non-specified foods. For achieving this goal, four eminent speakers from the



regulatory field were invited along with four experts from the field as panelists. Every speaker expressed a different perspective in their respective presentations.

The webinar proceeded as follows-

1. Framework & Overview of Regulation By Dr. Jasvir Singh

The first speaker for the webinar was Dr. Jasvir Singh. He enlightened the participants regarding the framework of the regulation and provided an overview. He also highlighted the changes that were adopted in the Food Safety and Standards (Approval for non-specified foods and food ingredients) regulation, 2017. Here are some of the important points from his presentation-

• This regulation has a great amount of history. At first, there were no regulations for foods that have not been standardized. Hence a regulation called proprietory foods regulation came in which included many such non-standardized products. but still,many food products did not come under the proprietary food category. These food products are called non-specified foods. Therefore a regulation for the approval of such non-specified foods was developed.

• The final regulation was issued on 11 Sep 2017. The first draft for the amendment was issued on 22 September 2021 which is open for any comments till 21 November 2021.

• Non-specified foods are defined as any food other than proprietory food or food ingredient, including additives, processing aids, and enzymes for which standards have not been specifiedin any regulation made under the act.

• Under this act, the procedure consists of two forms. Form-I needs to be filled by the manufacturer for approval and Form-II indicates the acceptance/rejection of the food ingredient.

• Safety data relevant to the Indian population is mandatory to be submitted.

2. Regulatory Route For Novel Foods Globally And Challenges With India FSSAI- By Ms. Sakshi Grover

She explained various approval systems that exist globally for non-specified foods. And also explained the challenges with the FSSAI, India regulation for approval of non-specified foods. Here are some of the highlights from her presentation-

• The size of the global market for health foods is increasing with the rapid rise in innovation in food science. This highlights the importance of the regulations for the approval of non-specified foods.

• Many countries have developed systems for the assessment and approval of novel foods e. g. Canada (Health Canada), US (new dietary ingredient approval under FDA), EU (EFSA), China (NHFPC),

Australia/New Zealand (FSANZ), India (FSSAI).

• When it comes to approval of novel foods with FSSAI certain challenges may occur. Following are the challenges with the FSSAI approval process-

1. Ambiguity in regulation and various categories have been clubbed under NSF
2. Takes a long time to hear back on the application
3. Safety data on the Indian population is mandatory
4. Manufacturers/importers of the same ingredient that has been approved have to apply again until that ingredient is included in the regulation.
5. Limited guidance on dossier requirement
6. The international manufacturers can not apply without a local importer.

Ms. Sakshi Grover concluded her presentation by suggesting that the novel foods should be a different category as they are different from NSF.

3. Obtaining approval of Non-specified Foods - By Ms. Rini Sanyal

She explained the process of obtaining approval of non-specified foods. Ms. Rini Sanyal highlighted the following points in her presentation-

• It is necessary to have prior approval of non-specified foods before getting the license/registration.

• The approval procedure involves five steps (application, scrutiny, approval, certificate submission, and post-approval).

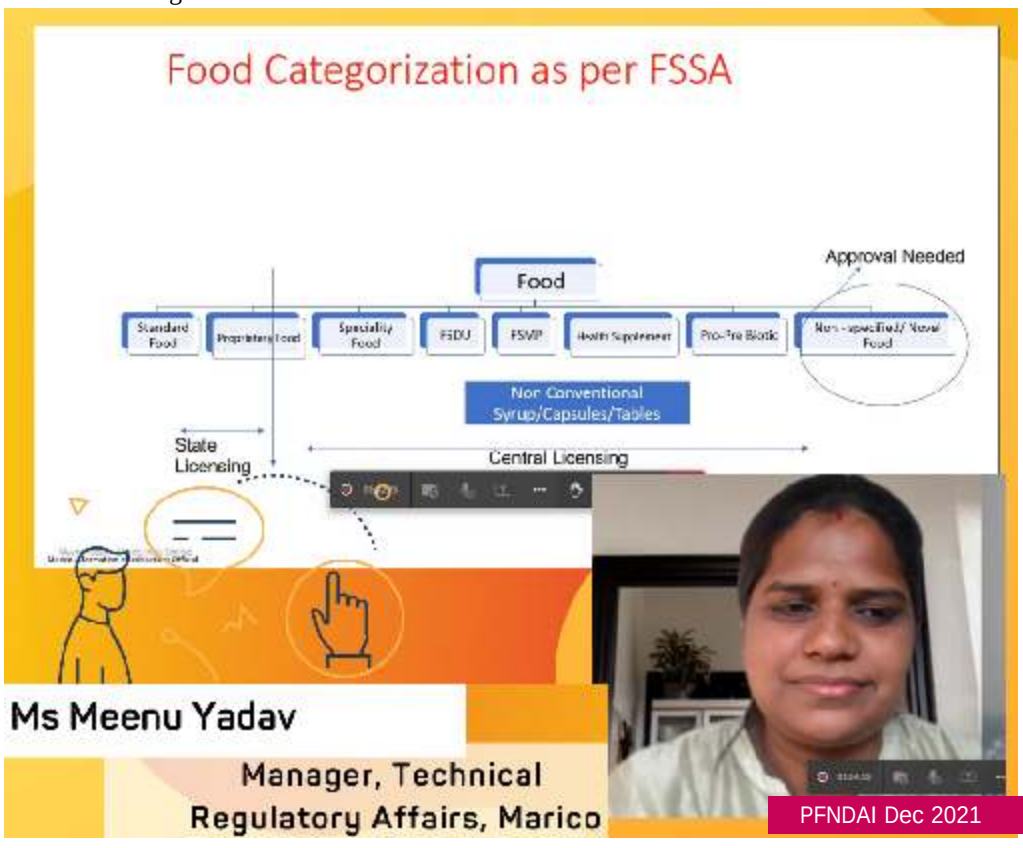
• Certain challenges may occur in the process of the non-specified food and food ingredients approval process like lack of infrastructure, documentation, non-specified timeline, inaccurate interpretation, and avertable requirements.

• Globally acceptable safe use should be used as a reference for including new ingredients

Ms. Rini Sanyal concluded her presentation by providing some resolutions to address the challenges that may occur with non-specified food approval.

4. Non-Specified Food Product Approval System- By Ms. Meenu Yadav

She enlightened the participants about the approval system for non-specified foods by sharing her views. Ms. Meenu Yadav highlighted the following points in her presentation- FSSAI is mandated under law to regulate/approve proprietory and novel food. So, to regulate effectively a set of the advisory was released.



Many challenges occur in the process of getting approval for non-specified foods. Following are the challenges that may occur-

1. Scope for the regulation of the non-specified food is not very clear
2. Repetitive approval is required for the same ingredient from different manufacturers.
3. Lack of a transparent and IT-enabled approval system
4. No specific timeline is provided for approval
5. All health and nutrient's claims need prior approval
6. A database management system is required for filtering out food as specified or non-specified

Ms. Meenu Yadav concluded her presentation by appreciating the efforts of FSSAI towards streamlining the approval process but also suggested that more efforts and changes are required.

Each presentation was followed by a question and answer session where the respective speaker answered the questions raised by the audience.

After the completion of all the expert talks, a panel discussion on the various aspects of Non-specified food approval was conducted. Pannel's discussion was moderated by Ms. Dolly Soni. In this panel discussion, the panel members shared their views about non-specified foods regulation and approval. Here are some of the topics which were discussed-

- Three types of permitted foods- standardized, proprietary, and non-specified foods
- Uncertainty of FBO's regarding product approval system for food products like citric acid
- Approval system for novel food and ingredients and processing aids in other countries
- The definition, examples, and the reason for regulating non-specified foods.

A short QnA sessional followed after the panel discussion to address some queries. The webinar concluded with the final remarks from Dr. Joseph Lewis anda vote of thanks by Ms. Dolly Soni.