Report of
Workshop on
Workshop on Recent Amendments & Regulations
23rd March, 2017

Welcome Note:

The welcome note was addressed by Dr. Jagdish Pai, Executive Director, PFNDAI. The last one year has witnessed a range of gazette notifications being notified by FSSAI. The most prominent among them were Gazette Notification on Propreitary foods, Nutraceuticals and Food Recall. The release of the notifications has certainly brought some relief to food business operators; however there are yet some clarifications and gaps in knowledge which had to be addressed. This workshop was therefore conducted to call upon prominent speakers from industry as well as regulatory body to share their insights and clarify doubts of food business operators.

Introduction to Seminar

The seminar was introduced by Mr. V. Mohan partner at Inttl Advocare and Chairman, Regulatory Affairs, PFNDAI. He started his address, by mentioning that Food Safety and Standard Act has completed 10 years since it was introduced on 24th August, 2006. Since then, the Food Safety and Standard Authority of India have been making efforts to shift the focus from adulteration to self-compliance. Within the Act are 12 regulations which include Licencing, Labelling, Contaminants and Recall. In an environment of information overload, and micromanagement; and added pressure of compliance with new slurry of new regulations, gaining a balanced view is becoming all the critical. Unlike past, wherein the focus was "getting things done", the new Act allows a level playing field for all stakeholders – industry, consumer and regulators, to scrutinise the new notifications with the ultimate aim of keeping consumer safety as ultimate priority. A participative approach of the present day is certainly better as compared to yesteryear times of trust deficit – wherein the focus used to be prosecution of food adulterators. Although the Act wants to ensure safe food for the consumer from wherever, it may come from, the focus as of today continues to be restricted on the 10 % of packaged food industry. However, people not only consume packaged food, they also consume food from roadside vendors to high end restaurants and local cafeteria. As regulations on nutraceuticals, functional food, food recall and Proprietary are enforced; the onus is on the food business operator as to how they navigate through the challenges that are posed in front them.

Presentation 1: State of Regulatory Affairs in Ease of Doing Business

The first presentation of the day was made by Dr. J. Lewis, Consultant to FSSAI, on "State of Regulatory Affairs in Ease of Doing Business". In the ecosystem of the food industry where there are food business operators, customer and food regulators, he compared FSSAI to keystone. Like a keystone which is a wedge shaped stone and is placed on top of an arch and keeps other stones in place due to its weight and position, FSSAI as a regulator has an integral role to play in maintaining a fine balance between public safety and enabling business for the food business operator. It is the core, principle or foundation of a policy, system on which everything else depends. Any regulation that is introduced can have two

outcomes – it can either cause ease or unease in doing business. An ease in doing business means that there aren't any difficulties and unease would bring with it some anxiety and unpredictability due to mental dissatisfaction. Dr. Lewis went on to define the time-lines of how Regulations on Nutraceuticals and Proprietary foods were introduced in last couple months to help bring ease in doing business. Nutraceuticals and functional foods which have been in market prior to the introduction of the Act in 2006, can continue to market products. The enforcement will start only from 1st January, 2018. The proprietary foods have laid down two aspects for ingredients – standardised or permitted for use in other standardised foods. The onus of safety lies with the manufacturer. Besides introducing regulations, FSSAI have tried to bring other food business operators within their purview by starting initiatives such as training of members in hotels and restaurants, street food vendors, HACCP training of Mid-day meal vendors, ease of import of FSMP; and Risk based Inspection System. In order to bring clarity on how new regulations have brought unease in doing business, he gave examples of the definition of label and nutraceuticals; and declaration. As per present label definition, there is no mention of word "sticker", instead there is a word "attached". The regulation states that every food article should carry "a label", so if there are two labels, one in front and one at the back, it is termed as violation. There is category distinctiveness between nutraceutical and food supplement, due to overlapping definition. Besides, declaration of "Not meant for medicinal use" has to be mentioned in all categories except for "food for medicinal purposes". Therefore, products like coconut water will also bear the declaration. This is clear example of overreaching regulation. To conclude, the regulation is meant to reform and bring relief only after carefully weighing the scientific evidence and take opinions from all stake holders.

Presentation 2: Nutraceuticals & Food Supplements

Ms. Rini Sanyal made a presentation on Regulations of Nutraceuticals and Foods supplements. She introduced the topic by stating some facts on how India is facing a double burden of malnutrition. On one hand nearly 50% of infants below age of three are underweight and on the other hand the number of obese adults is increasing at a dramatic pace. Good health is a function of 30 % genes and 70 % lifestyle. Recognising this fact, the market for Food or Health supplements. FSDUs, Nutraceuticals etc. have witnessed a tremendous growth in India in recent years due to their potential in providing health benefits. They cannot be compared to conventional foods, because supplementary nutrition is focussed to provide and reduce the dietary gap of micronutrients and other nutrients in normal diet. Section 22 of Food Safety and Standard Act covers foods which are specifically processed or formulated to satisfy particular dietary requirements thus covers food that may be used even in certain diseased conditions. The Gazette Notification of Food Safety and Standards (Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purposes, Functional Foods and Novel Food) Regulations, 2016 was notified on 23rd December 2016. The compliance of existing as well as new products needs to be done latest by 1st January, 2018. She went on to describe the ingredients, additives, nutrients, plants and botanicals and label declarations for nutraceuticals and health supplements. A comparision of nutraceuticals and health supplements was made, in order to address the incongruities. She concluded by providing suggestions for usage of spices, plant and botanical extracts; how there is need to simplify claims and declarations in order to make the regulation unambiguous and implementable legislation.

Presentation 3: Labelling and Claims

A presentation on "Labelling and Claims" was made by Mr. Shaminder Pal Singh, Director, Scientific and Regulatory Affairs, PepsiCo India. The focus of his presentation was the second draft of Labelling and Claims of FSSAI. He introduced the topic by stating how the product label and claims fulfil a consumer's need for information, industry's need to market their products and government's objective to ensure individual health and safety. He went on to compare the label particulars of India with Americas, Europe and Codex; which clearly showed that India's label requirements are the best in the world. The new draft on labelling aims to cover food soft through websites, mobile phones and direct selling; it will introduce new class of ingredients; and declaration of ingredients known to cause hypersensitivity. The key positive changes are that there is a definition for "non retail packs", natural claim and removal of duplications on label, for eg. Non-scientific declaration like "contains artificial sweetener" in case of sweeteners shall not be used. Conditions for making nutritional claims and health claims have been given which is mostly in line with Codex. Tolerance criteria for declared nutrients at 80 – 120% within declared shelf-life has been provided in the new draft. However, the declared value of nutrients may vary due to various factors which have not been accounted for in the provided limits of 80 to 120%. Therefore, the industry has proposed the limits in line with best practises of EU. Mr. Singh concluded his presentation by stating that everybody must work together to develop a broader frame work for scientific substantiation of food claims.

Presentation 4: Foods for Special Dietary Use (FSDU) & Foods for Special Medical Purpose (FSMP)

Mr. Kiran Desai, Regulatory Affairs manager, Mead Johnson India, described the regulation on FSDU and FSMP by giving their definition, scope, composition, labelling, and identity standards. In the regulation, FSDU has been formulated by clubbing category 13.4 -Dietetic formulae for slimming purposes and weight reduction and 13.5 Dietetic foods (e.g., supplementary foods for dietary use) of CODEX. Based on review, scientific experts are of the opinion that because of the wide diversity of such foods and the rapidly evolving scientific knowledge on which they are based, it is not appropriate to lay down detailed compositional rules of FSMS. He also highlighted the discrepancy of limit of nutrients versus the Recommended Dietary Allowance (RDA). RDA cannot always serve as guideline for adding vitamins and minerals, as nutritional requirements for various conditions many vary. By giving a comparison of various categories of Nutraceuticals and Schedules of nutrients, Mr. Desai expressed his concerns by stating that the regulation is confusing and there are limitations on which ingredients can be used and how they are used.

Presentation 5: Food with added Prebiotic & probiotic ingredients

Dr. Prabhakar Kanade, Principal Consultant, M/s Supraks Consultant, gave a presentation on Regulation for Using Prebiotic and Probiotic Ingredients in Food. He briefly described various aspects of regulation by stating the conditions for using prebiotic and probiotic ingredients. The regulation describes definition, general requirements of usage and product requirements – description of culture and prebiotic substances, labelling requirements, permissible additives and requirements for making claims.

Q & A Session

Prior to lunch, speakers of first half of day answered to various questions from the audience. The session was chaired by Mr. Mohan.

Presentation 6: Food Recall

Mr. Kajal Debnath, Head- Regulatory Affairs, Mother Dairy Fruit & Vegetable Pvt. Ltd., presented on the recent notification of Food Recall which came into effect since 18th January, 2017. He started his presentation by citing some prominent instances of Food Recall that have taken place in past. As per Section 28 of FSS Act 2006, Food Authority notified food recall procedure regulations, which may prevent, reduce or eliminate a risk arising from a food. He further presented the definition of "unsafe food" as per the FSS Act, 2006. He also described in brief the various steps that are to be followed when a Food recall is initiated. He went on to highlight the challenges that food business operators experience if a food recall happens – this includes timely response to Food Authority, periodic status reports, having detailed forward and backward traceability. He briefly explained the recall process by giving example of Vitamin D fortified milk – from water/ farm resource to table. He concluded the presentation by stating as to how every organisation must have a recall team and should test their process from time-to-time by conducting a dummy recall. The batch number plays a critical role for recall success.

Presentation 6: Novel foods

Ms. Meenu Yadav, Manager, Scientific and Regulatory Affairs, Mondelez India, gave a presentation on Novel foods. She started the presentation by giving a list of various draft and final notifications released by FSSAI from January 2016 to January 2017. She went on describe the definition of Novel foods as per Wikipedia and as per Section 22 of FSS Act, 2006. After the Supreme Court judgement of August 2015 which deemed the Product approval process as illegal; final draft regulation of "Non Specified foods" which includes Novel foods was notified in January 2017. She further described the draft regulation which includes definitions, procedure for approval of novel ingredients, additives, technology and processing aid. She highlighted the challenges of the new regulation, with respect to timelines for scrutiny of applications, revoking of approval by authority without providing an opportunity to FBO to present their case and repeated ask of documents from FBO. One key challenge is overlapping of definition between proprietary foods and non specified foods which will create confusion.

Presentation 7: Harmonisation of Food Laws

Mr. Kevin Kenny,CEO, Decernis, USA, gave a presentation on Opportunities for Harmonization in Food/ Supplement Regulation. He introduced the topic by describing how there many Lists, food categories, usages and specifications in the world which are non-harmonized making international trade of food-related products difficult & expensive. He gave a brief snapshot of Codex Alimentarius (105 Countries), European Union (52 Countries), Eurasian Economic Union (5 Countries), SIECA (8 Countries), Mercosur (6 Countries), ASEAN (10 Countries) and GCC (6 countries), countries which fall under them, and the salient features of their regulations. He concluded the presentation by highlighting the trends, which show that substantial harmonization efforts are underway in various Regional Block. There is an ongoing intra-country overhaul of food regulations in China and India.

Panel Discussion:

Following the presentations, there was a panel discussion wherein queries of delegates which were received by email as well as during the course of seminar were answered to by the panelists. The Panel members were Dr. Shatadru Sengupta, Director-Legal at Hardcastle Restaurants Pvt. Ltd (Chair), Dr. Prabodh Halde Head Regulatory (Marico), Mr. Rajendra Dobryal Director – Regulatory Affairs (South Asia) (HUL), Mr. Sameer Barde, Senior Director, APCO, Ms. Shilpa Telang R&D Head (Gen Mills), and Mr. Sanjay Singh Head R&D for Consumer Brands Division (Ruchi).