

[A draft notification prohibiting the admixture of mustard oil with other edible oils was issued on 18.11.2020.](#) However, through an order dated 04.12.2020, the draft amendment has been withdrawn. The order states that the draft has been withdrawn after due representations made by the stakeholders. The reason for both introduction and withdrawal is unclear.

[Draft notification on the changes in labelling of multi sourced or blended vegetable oil.](#)

[A major change of far reaching consequence has been proposed in Import Regulation.](#) The draft regulation, if it comes through in the present form, will place greater restriction on import food products and food categories which are considered to be “High Risk”, which is not presently defined but will be specified from time to time. Manufacturing units situated outside India and wishes to export

such “High Risk” foods must get their manufacturing unit registered with FSSAI. Audit of the manufacturing unit by FSSAI or its authorized representatives is a pre requisite to grant of registration. The application can be made online. Timelines for audit is not specified. No indication with regard as to who will bear the cost of the audit, etc. As “High Risk” is not defined, any product or product category may be included at a later date. In my opinion, FSSAI must restrict itself to the registration of such facilities.

[Draft notification proposes amendments in Fortification Regulation It introduces fortification requirements for milk powder, amends the requirement of iodine in salt.](#)

Advisories and Orders, Guidance Notes and Others

[An order operationalizing the use of additional colours in alcoholic beverages.](#)

[FSSAI vide its order dated 04.12.2020 has extended the tenure of Hygiene Rating Agencies of food establishment.](#)

[Revised manual for the estimation of Mycotoxins.](#)

[FSSAI extends the validity of the operationalized regulation on the incidental presence of khesari dal in food grains up to 2%, till the publication of final regulation.](#)

[In June 2020, FSSAI issued an order that consignment of certain categories of foods \(Cereals, Pulses, Oilseeds, etc\) to be accompanied by a GM or GMO free certificate from January 2021. This deadline has now been extended to 31 March 2020.](#)

[Draft Regulation setting limits for formaldehyde, etc has been operationalized.](#)

REGULATORY AFFAIRS COMMITTEE MEETING REPORT



AUTHOR
Seles Gupta,
Food Technologist,
PFNDAI

Protein Foods & Nutrition Development Association of India organised an online regulatory affairs committee meeting on 10 November 2020. The invitations were sent to all the PFNDAI members and nominees.

The objective of this meeting was to discuss the Food Safety & Standards (Amendment) Bill 2020, to gain an understanding of its purpose and provisions, and to

gather inputs for improvements in the drafted bill. On the panel, we had Mr Bhupinder Singh (Chairman, PFNDAI), Dr Shatadru Sengupta (Vice Chairman, PFNDAI), Dr Joseph Lewis (Vice Chairman, Regulatory Affairs

Committee, PFNDAI), Dr Jasvir Singh (Regulatory, Scientific & Government Affairs Leader – South Asia DuPont), Dr Prabodh Halde (Head Regulatory- Marico Ltd.), Mr K.K. Joshi (Head Regulatory Affairs, Policy & Advocacy, ITC Food Division), Dr KD Yadav (Sr Vice President (Technical) - AAK Kamani), Ms. Rini Sanyal (Director Regulatory & Government Affairs, Herbalife), Ms Meenu Yadav (Manager, Scientific and Regulatory Affairs, Mondelez India),

Mr. Rajendra Dobriyal (Director, Scientific & Regulatory Affairs, Coca Cola India) & Mr. Abhinav Srivastava (Head of Regulatory Policy & Intelligence, Amway India).

The meeting included an introduction of all the speakers and panellists by Ms SwechhaSoni (Manager- Food & Nutrition, PFNDAI), opening remarks by Dr Jagadish Pai (Executive Director, PFNDAI), welcome address by Mr Bhupinder Singh, presentation on “FSSA Amendment Bill 2020” by Dr Shatadru Sengupta, remarks on the bill by Dr Lewis, a panel discussion moderated by Dr Lewis, Q & A round and feedback collection through Google forms.

Dr Shatadru Sengupta opened the discussion on the FSSA Amendment Bill 2020 by providing an overview of significant changes that have been introduced in the act. Few of the important proposed changes that were discussed and analysed are as follows:



I. In the preamble, on page 2, it is written “An act to consolidate the laws relating to food and feed to establish the Food Safety & Standards Authority of India” and “to ensure availability of safe and wholesome food for human consumption and animal feed”. Analysis- With the inclusion of words - animal feed and export, we can now expect FSSAI to regulate animal feed and food exports. If FSSAI intends to regulate animal feed, regulations regarding irrigation

water, irrigation soil and fertilisers may also need to be drafted and included. When it comes to regulating exports, the implementation of regulations might be challenging as the foreign countries already have their regulations in place and these regulations might not align with Indian regulations.

II. In section 3 (1) (oa) on page 3, the term “food contact material” has been included and it has been defined as “any material in contact with food or intended or reasonably expected to come in contact with food”.

Analysis- This is vague and wide in scope and could include any packaging, tiffin box, toys and cooking equipment. It needs more clarification.

III. In section 3 (1) (r), the definition of “food safety audit” has been amended and it states that “food safety audit means a systematic and independent examination of food safety measures adopted by food business”.

Analysis- In this new definition, the term “manufacturing units” has been replaced by “food business”. It seems that food safety audit could go beyond manufacturing operations and now, other departments like administration, marketing, etc could be subjected to the audit. This needs to be clarified and amended, and only activities directly related to food manufacturing should be audited.

IV. Under section 3 (1) (zd), the definition of “manufacturer” now, also includes brand owner.

Analysis- The brand owner may be a franchisor or owner of a trade mark which he has licensed out to an FBO. This new regulation will also make brand owners liable; this seems unreasonable as in some cases, brand owners may not have any control over the manufacturing process.

V. Section 18 (2) (d) gives FSSAI

powers to make regulations in case of emergencies.

Analysis- Currently, when it comes to drafting new regulations, FSSAI is under the supervision of the central government. With the proposed regulation, the power will transfer to FSSAI in emergencies. It is recommended that in case of emergencies if there is no prior approval, there should be a provision for a post facto approval.

Currently, FSSAI may only make regulations with previous approval of the Central Government and after previous publication by notification. Section 18(2)(d) ensures that there is an open and transparent public consultation during the preparation, evaluation and revision of regulations except where there is an urgency concerning food safety or public health. Through the amendment the Food Authority seeks to bypass the requirement of previous approval of the CG and previous publication by notification. The original text should be retained.

VI. Under section 22 (4), the definition of “proprietary food” has been amended. Earlier in the ingredients & additives that are not prohibited were allowed (i.e. not on a negative list). But with the amendment, only the ingredients and additives that are permitted will be allowed (i.e. are on a positive list).

Analysis- The shift from being not on a negative list to being on a positive list can stifle innovation in the food industry. Hence, this change should not be made.

VII. According to section 38 (1) (d), the food safety officer can seize any vehicle, equipment, packaging, labelling or advertising material linked with the food article which may be required as evidence in proceedings under the act. Further, this section states that the items that are seized will be kept in the custody of FBO or in custody of the authority.

Analysis- In case the items are kept in the custody of the authority, it can hamper the business of an FBO. More clarity on this part is needed in the bill, explaining how FBO should work to resolve the problem. Also, transport companies may not always be part of the FBO that is under proceedings. Even though it is the FBO that violates a rule, transport companies too may end up getting dragged in this problem and as a result, this will hinder their operations as well.

VIII. Section 40 (3) states that food testing should be carried out in labs that are recognised by food authority and that the information so collected shall be shared with food authority before releasing the same to the general public.

Analysis- This needs to be amended as the collected information should be shared with the FBO as well. This will allow the FBO to respond to the test results. Also, the test results and the data generated should be barred from being untruthful, disparaging, distorted or misleading.

IX. In Section 92 (2) (e), the deletion of word “guidelines” is proposed.

Analysis- With this change, FSSAI will be empowered to freely issue “guidelines” without any involvement of parliamentary procedures or any oversight from safeguards of the law-making process.

X. In Section 92A (2)(g), FSSAI is being empowered to make regulations about making regulations.

Analysis- This is excessive delegation of powers and it can result in usurping the powers of parliament as well as of central government.

Dr Shatadru also discussed how under various provisions, excessive delegation to FSSAI or to a Ministry is a breach of the Allocation of Business Rules, 1961, framed under the article 77 (3) of the Constitution of India. Then, he talked about the implications of using the word “fine” in various provisions in the act and suggested that it should be replaced with the word “penalty”.

Next, Dr Joseph Lewis presented his remarks on the amendments to FSSA. He discussed the transition from PFA to FSSA 2006. He explained how, earlier, we were working towards protecting human life, ensuring food safety and encouraging innovation in the Indian food industry, and that the section 18 in FSSA 2006 guaranteed businesses equal participation. But the amendment of section 18 (2) (d), doesn't provide stakeholders with the opportunity to participate.

He talked about how the amendment does not balance consumer protection with fairness to trade. Also, with the amendment of the “proprietary foods” category, we may end up creating unnecessary hurdles and stifling innovation. He insisted that when we want industry to grow, we need to work towards making regulations that are fair to all the stakeholders. Then, he concluded by emphasizing on the importance of consulting all stakeholders during preparation, examination and revision of

regulations.

Dr Lewis' presentation was followed by a panel discussion where each panellist was invited to engage in the discussion and share three sections they feel are most important and should be reviewed critically. The discussion was moderated by Dr Lewis. Some of the key takeaways from the discussion were:

Dr Jasvir Singh talked about how we should take this opportunity to recommend changes in areas which already have been pain points for FBOs. He suggested that prescriptive limitations on RDA levels for products, in section 22, in existing act and prescriptions for solvents that one can use for making plant extracts (section 2 in the existing act has listed only 3 solvents) should be removed. He also discussed how the definitions of GMO, novel foods and proprietary foods need to be amended and improved.

- Dr K D Yadav discussed the need for change in section 18 (2) (d) in the amendment bill. He talked about how the proposed changes are less about science and more about giving powers to FSSAI. He insisted on the importance of having more transparency when it comes to making regulations.

- Mr Rajendra Dobriyal expanded on the inclusion of the word “export” in the preamble and discussed how other countries have the power to regulate what comes in their country. Hence, regulating exports may not be practical.



- Ms Meenu Yadav discussed how removing imprisonment in case of unsafe food, when it is not injurious to health, is a step in the right direction. She, then, talked about how risk assessment should be emphasized more in the FSSAI act. She also pointed out how the term “brand owner” is not defined in the act and it should not be included in the bill if the definition is not clear.

- Mr Abhinav Srivastva emphasized how regulations should be facilitating exports and not just regulating it. He also recommended changes to definitions of GMO and proprietary foods in the bill.

- Dr K.K. Joshi suggested that cause and effect analysis and cost and benefit analysis should be done before revising or introducing any regulations. He also talked about how before adding new elements in the act, we should analyse if we have the infrastructure to implement new regulations.

- Dr Prabodh Halde discussed how section 34 is an area of

concern for it may lead to corruption within the system. He also suggested that when we talk about unsafe food causing injury, we need to define the term “injury”.

- Ms Rini Sanyal pointed out that the definition of the term “consumer” in amendment is a little confusing and it either needs improvement or it should be taken from the Consumer Protection Act. She also suggested that if an FBO makes an error that is not jeopardizing the consumers’ health and if these errors can be rectified or controlled, the term “withdrawal” should be used instead of “recall”.

The panel discussion was followed by a Q & A session that was moderated by Swechha. Here are few of the questions that were raised:

Q1. Who is giving the powers to FSSAI? Should we not be going to that Authority rather than to FSSAI regarding this issue?

A- (by Dr Shatadru) The amendment has been issued by the Ministry of Health & Family Welfare. So yes, we can compile

all these suggestions and we should approach the Ministry.

Q2. From when will the new RDA become effective and will it be implemented by FSSAI?

A- (by Dr Jasvir) ICMR has already released their RDA values. When it comes to implementation, we need clarity on the timeline. Also, since these new RDA values will affect labelling of nutrition information and claims, FSSAI ought to settle this matter at the earliest.

Q3. Stevia is mentioned as an artificial sweetener. But it is plant based. So shouldn't it be under the category of natural sweeteners?

A- (By Mr Rajendra) FSSAI is currently working on this and now, we might have only two categories- caloric and non-caloric sweeteners. So instead of categorising sweeteners into natural and artificial, they will be categorised based on if they contribute to any calories or not.

The meeting concluded with a vote of thanks to all the participants by Ms Swechha.



Dr. Pai



Dr. Jasvir Singh



Dr. KD Yadav



Mr. Abhinav Srivastava



Dr. Lewis



Dr. Prabodh Halde



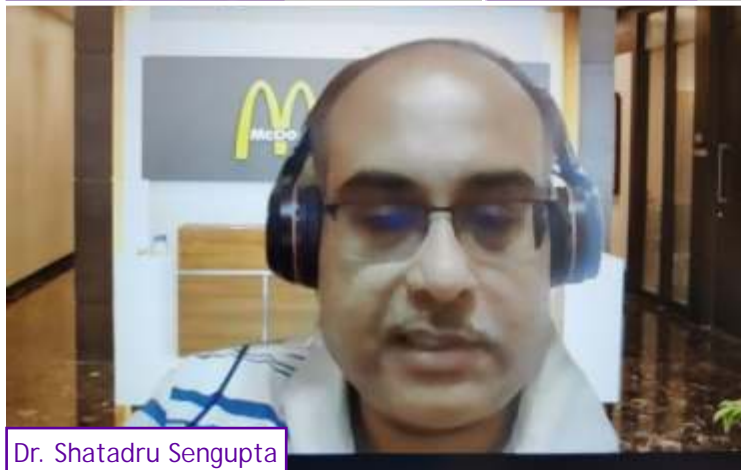
Mr. Rajendra Dobriyal



Ms. Meenu Yadav



Ms. Rini Sanyal



Dr. Shatadru Sengupta



Dr. Krishnakumar Joshi