

**Minutes of the 13<sup>th</sup> meeting of the Food Authority held on January 31, 2014 at 1100 hrs. at FDA Bhavan, New Delhi**

The thirteenth meeting of the Food Safety and Standards Authority of India (FSSAI) was held on January 31, 2013 at 1100 hrs. at FDA Bhavan, Kotla Road, New Delhi under the Chairmanship of Shri K. Chandramouli, Chairperson, FSSAI. The list of participants present in the meeting is as per **Annexure**. Leave of absence was granted to the members who could not attend.

Chairperson welcomed the members of the Authority to the meeting and recalled that the last meeting was held on 29.8.2013. He mentioned that the Authority meetings should be held once in three months. However, the present Authority meeting is being held late due to the important on-going work of the two sub-groups formed during the last Authority meeting. He drew attention of the members towards the important developments that have taken place from the last Authority meeting viz., increasing pace of licensing and registration, visits to some states, improved coordination with states. Some states have responded well and the on-line licensing and registration work has gathered momentum, with a large number of States/UT's adopting on-line licensing application (FLRS) willingly. It is important to encourage E-Governance initiatives for transparency and effectiveness.

He informed the members that the States/UTs government are responsible not only for State licensing and registration work but also the enforcement of the Act. It was informed that the Authority will expedite the monitoring/surveillance process, strengthen the regional offices and pursue the standardization work vigorously. Presently, the number of proposals of standardization going to panels is less and this needs to be increased. In this context, he informed the members about the proposed Amendment in the Act as approved by the cabinet for simplification in notification process. On the point raised by one of the member on pending notifications it was informed that the status of all pending notifications may be taken up as an agenda item henceforth, for information in all the forthcoming Authority meetings. Action taken report for previous meeting should also be presented in the next meeting. The Chairperson also informed that we are in touch with members on a regular basis and they are free to contact any time. Thereafter, Chairperson, FSSAI requested CEO, FSSAI to conduct the proceedings of the meeting.

### **Item No. 1: Disclosure of interest by members**

All the members present during the meeting signed the "Specific Declaration of Interest" in respect of the agenda items to be considered in the meeting, before the start of the proceedings.

### **Item No. 2: Confirmation of the minutes of the last meeting held on 29<sup>th</sup> August, 2013**

The Authority confirmed the minutes of the twelfth meeting of the Food Authority held on 29th August, 2013. While adopting the minutes, it was informed that the consolidated status of all the pending agenda items discussed in the previous meetings will be informed in the next Authority meeting and thereafter Action Taken Report (ATR) of previous meeting will be a regular feature in the Authority meetings. On one of the point raised by a member on previous Authority meeting minutes, it was informed that malt extract and dairy whitener have been referred to expert group on milk and lactic acid food grade standard has been revised as per expert group recommendation. Hence, out of the 10 BIS Standards approved in the last Authority meeting, eight would be processed for draft gazette notification excluding malt extract and dairy whitener.

### **Item No. 3: Chief Executive Officer's report**

CEO welcomed all the distinguished members and briefed about the activities undertaken by FSSAI after the last Authority meeting with respect to: enforcement activities including the number of Central licenses and State registration/ licenses issued by the States; training and Capacity Building; IEC activities; Scientific Committee/ Scientific Panels meetings and the progress in work on the Standard Setting; harmonization of Standards with Codex; Laboratory Up gradation; Codex activities and International cooperation. So far as trainings were concerned it was informed that almost all States/UT's have been covered except few states. One day training programme for about 500 street food vendors was conducted in Delhi on the World Food day. FSSAI also participated in IITF, 2013 and the National exhibition and the conference on Packaging held in January 2014. The members of the Authority were also informed about the various notifications regarding fixing standards for food articles that have been issued finally or as drafts.

Before concluding the CEO drew attention of all the members towards some significant judgements given by the Hon'ble Supreme Court and various High Courts in the intervening period. In particular, attention was drawn to the judgement by the Hon'ble Supreme Court in

Centre for Litigation Vs. UOI. In this case, the Hon'ble Supreme Court has in the judgement emphasized the following "*We may emphasize that any food article which is hazardous and injurious to public health is a potential danger to the fundamental right to life guaranteed under Article 21 of the Constitution of India. A paramount duty is cast on the States and this Authority to achieve an appropriate level of protection to human life and health which is fundamental right of all the citizens under Article 21 read with Article 47 of the Constitution of India*". The Hon'ble Supreme Court also held that many food articles are available in the market and contain insecticides and pesticides residues, beyond the tolerable limits causing serious health hazards. Fruit based soft drinks contain pesticides residues in alarming proportion. The Hon'ble Court has directed the Food Safety and Standards Authority of India to gear up their resources with their counterparts with all States and Union Territories and conduct periodical inspection and monitoring of major fruits and vegetable markets, so as to ascertain whether they conform to such standards set by Act and the Rules. In Swami Achuyutanand Tirth & Others Vs. Union of India, the Hon'ble Supreme Court has emphasized that the non-implementation of the Provisions of Act violates the rights of health and safety of the human being guaranteed under Article 21 of the Constitution of India and directed the States to explain to the Court how they are functioning and what effective steps have been taken to implement the Act and accountability. The Hon'ble High Court Jammu & Kashmir in Sheikh Mohammed Ayoub Vs. State of J&K and Others imposed on one milk manufacturer, one turmeric manufacturer and one Saunf powder manufacturer fine of Rs. 10 crores each and directed them to deposit the amount with Director SKIMS, Soura Srinagar for adulterating the said products. In the same judgement, directions were given that the respondents State shall take all necessary steps for enforcing Food Safety and Standards Act, 2006 and Rules made thereunder with reasonable promptitude.

The Hon'ble High Court of Himachal Pradesh in Indian Biscuit Manufacturer Vs. UOI has held that the State has to enforce provisions of FSS Act, 2006 and regulation framed thereunder and the HP non-Biodegradable Garbage (Control) Act, 1955. The Hon'ble High Court of Delhi in M/s Trevo India Pvt. Ltd. Vs. Food Safety and Standards Authority of India has disposed of the writ petition and all pending application after stating that the Scientific Panel has considered the product in detail, wherein the panel found that in the absence of such safety data, in the larger interest of consumer safety who will otherwise blindly consume it based on label claims, the panel recommended not to approve the product in its present form of application.

In the light of the above judgements, delivered by the Hon'ble Supreme Court and various High Courts the Food Safety and Standards Authority of India as well as the State Food Safety Authorities will have to gear up their resources to effectively implement the provisions of the Act, the Rules and the Regulations.

Shri Thanglura, Member Authority raised the point regarding inadequate Food laboratory infrastructure in North-East and whether Authority can consider having consumer protection fund on the lines of SEBI, TRAI etc. It was also emphasised that financial support is a must to the State governments for the effective implementation of the Act.

Dr. Arun Panda, Joint Secretary, Ministry of Health & Family Welfare responded by informing the Authority that Ministry was able to convince the Department of Expenditure, Ministry of Finance that there is an urgent need to give support to States/UT governments for effective implementation of the Act at the ground level. An outlay of 1500 Crore has been proposed for the Centrally Sponsored Scheme and the funds would be utilised for setting up of the infrastructure, salaries, trainings, IEC activities and the Upgradation of Food testing laboratory infrastructure. A MoU is proposed to be signed with the State Governments by clearly laying down the deliverables and the timelines for effective monitoring. Similarly, Rs. 850 Crore has been approved by EFC for the Central Sector Scheme, which will be utilised for strengthening FSSAI at HQ, regional offices, and other activities. Special focus has to be on surveillance and E-governance initiatives during the 12<sup>th</sup> Plan period. Ms. Anuradha Prasad, Joint Secretary, Ministry of Food Processing Industries also informed that Ministry of Food Processing Industries is operating a scheme on Upgradation of the food testing laboratories and assistance is given to government, government run food testing laboratories too. It was also informed that assistance is also given for two technical persons for a period of two years.

The Authority took note of CEO's report. CEO also placed on record the thanks and appreciation to the two sub-groups that worked on the draft nutraceutical and food recall Regulations for their excellent work.

#### Agenda Items

#### **1. Approval of draft final notification of Standards for Caffeinated beverages and Standards of blue tint.**

The Food Authority noted and approved the draft final notification of Standards for Caffeinated beverages and Standards of blue tint in packages of five litres and above

used for packaged mineral water and packaged drinking water. The upper limit of caffeine 320mg/l (320 ppm), the restriction on per day consumption (consume not more than 500 ml per day), and the labelling requirements of caffeinated beverages were agreed by the Food Authority.

The colour blue tint as per the BIS standard IS 9833 was agreed towards the standards of blue tint in packages of packaged mineral water and packaged drinking water.

## **2. Report of the Sub-Group on the draft Nutraceuticals Regulations**

The Authority noted the report of the sub-group on the draft Nutraceutical as given as Agenda item No. 2 and the revised draft regulation. It was brought to the notice of the Authority that two issues were still open for discussion as given below:

- i) Issue pertaining to usage of more than 1 RDA in case of food and health supplements.
- ii) Probiotic and pre-biotic category: In line with Indian Food Code, foods containing probiotic and pre-biotic ingredients shall not be treated as separate category of foods.

With regard to the point pertaining to more than one RDA it was brought to the notice that Section 22 of the FSS Act, 2006 restricts the use of minerals or vitamins or proteins or their compounds or amino acids in amounts not exceeding the Recommended Daily Allowance (RDA) for Indians. Moreover, it was noted that to take care of special needs, RDA in the Food for Special Dietary Use and the Food for Special Medical Purpose has been kept more than 1 RDA. It was also brought to the notice that Chair of the Sub-group had requested the other members for any published data on Indian population for more than one RDA. Keeping in view the concerns raised by some of the members it was decided that the revised Draft Food/Health supplement, Nutraceutical Regulation will be considered by the Authority and for the point pertaining to more than 1 RDA, the issue will be referred to Indian Council of Medical Research (ICMR), the body that lays down the RDA for Indian population.

With regard to probiotic and pre-biotic categories, it was decided that they will remain separate categories as given in the draft regulation.

Thus, the Authority approved the revised Food/Health supplement, Nutraceutical Regulation as circulated in the meeting with the issue of more than one RDA in Food/Health supplements referred to ICMR.

The Authority placed on record its appreciation of the work done by the Sub-group.

### **3. Report of the Sub-Group on the draft Food Recall Regulation**

The Authority discussed the revised draft Food Recall Regulation prepared by sub-group and noted some of the salient points with regard to the classification of food recall, inclusion of definition of "food under recall" and other points pertaining to recall of imported food etc. There were discussions on the guidelines prepared and annexed as part of the draft Regulation.

It was agreed by the Authority that draft Food Recall Regulation as circulated is approved but the Sub-group may revisit the 'Guidelines for food recall' after consultation with a small committee of Food Safety Commissioners of State/UT. The guidelines will be a separate document for the guidance of the Central and State Food Authorities.

The Authority placed on record its appreciation of the work done by the Sub-group.

### **4. Ingredients approved in the meetings of the Panel for Functional foods, Nutraceuticals, dietetic products and other similar products and the Scientific Committee**

#### **i) Use of plant sterols (phytosterols) as food ingredient**

It was noted that the Scientific Panel had recommended that the labelling declaration must indicate that 'the product is to be used under the Medical supervision'. However, the Scientific Committee in its recommendations has not included this point. Two of the members also suggested to modify the labelling declaration as:

- 'people who want to lower blood cholesterol level' to 'helps in reducing blood cholesterol' aligning it with claim declaration of other countries.
- To replace 'breast feeding women' with 'lactating women'.

- 'CONSUMPTION OF MORE THAN 3g. PER DAY OF STEROL/STENOLS MUST BE AVOIDED' to 'CONSUMPTION OF MORE THAN 3g. PER DAY OF STEROL/STENOLS IS NOT RECOMMENDED' (as per draft notification 2006).

The Food Authority considered the agenda item and referred it back to the Scientific Committee/Panel for Functional foods, Nutraceuticals, dietetic products and other similar products for looking into the above points.

**ii) Astaxanthin as an antioxidant**

The Food Authority considered and approved the use of Astaxanthin (from *Haematococcus pluvalis*) as an antioxidant at a maximum level of 4mg/ day and its inclusion in the list of Nutraceuticals of the Draft Notification on Nutraceuticals, Nutritional, Functional and Novel.

**iii) Glucosamine HCl Boswellia**

The Food Authority considered the agenda item and referred it back to the Scientific Committee/ Panel for Functional foods, Nutraceuticals, dietetic products and other similar products to specify the usage levels of the ingredients.

**iv) Use of Spirulina as an ingredient**

The Food Authority considered and approved *Spirulina platensis* (*Arthrospira platensis*) usage as a Food supplement with the following composition: Protein (Minimum)-55 % (for *spirulina* only), Carbohydrates (Maximum)-30%, Fats (lipid) – not more than 10.0%, Minerals (Ash)-5.0 - 10%, Moisture-3.0 – 6.0 % (Also fatty acid profile to be mentioned on the package) and also its inclusion in the list of Nutraceuticals of the draft Food/Health supplement, Nutraceuticals Regulation .

**v) Use of Milk Thistle (70% Granular)**

The Food Authority considered and approved the use of Milk Thistle (*Silybummarianum*) 70% Granular as an ingredient and its inclusion in the list of Nutraceuticals of the Draft Notification on Nutraceuticals, Nutritional, Functional

and Novel foods with the following composition: Milk Thistle Extract – Native Extract: 90%; Excipients: Gum Arabic: 10%; Final Extraction ratio: 20:1; Solvent(s): Ethanol: 80%, Water: 20%.

**vi) Use of Carboxymethyl Starch (Sodium Starch Glycolate) as a source and ingredient (disintegrant) in the manufacture of the tablet Nutralite Garlic Heart Care**

The Food Authority considered and approved the use of Carboxymethyl Starch (Sodium Starch Glycolate) as a source and ingredient its inclusion in the list of Nutraceuticals of the Draft Notification on Nutraceuticals, Nutritional, Functional and Novel foods.

**5. Policy Decision: Approval for review of product formulation being administrated under the Integrated Child Development Scheme (ICDS) of the Ministry of Women and Child Development (MWCD).**

The Food Authority considered and approved the recommendations of Scientific Committee i.e. request Ministry of Women and Child Development (MWCD) to revise the ICDS guidelines as per National RDA and also include micronutrients like Zinc, Vitamin B<sub>12</sub> and Vitamin D<sub>3</sub> in new product formulations being administrated under the Integrated Child Development Scheme (ICDS) of the Ministry of Women and Child Development (MWCD).

**6. Note on Product Approval Procedure**

The Food Authority considered the note on the product approval procedure and it was informed that the endeavour is to simplify the process. In addition, the fee of Rs 25,000/- being charged when referring the product approval application to the Scientific Panels was also waived off w.e.f 4<sup>th</sup> September 2013. On the point raised by JS, MOFPI on the practicality of the procedure it was informed that the procedure laid down addresses the issue as has been brought out in the Note. Even the FAQs prepared on the product approval procedure bring to the fore the point that only non-standardized products need to apply for product approval. Majority of the food items of the daily need are already covered by the standardized food items and it is only a minuscule of the whole universe that needs to apply for product approval. It was also informed that traditional food was exempt from PA and only horizontal standards in



FSSR were applicable. Bulk of the applications being received for PA are related to food/health supplements and they need to be scrutinized as there is a definitional problem with regard to food vs. drug. The basic tenet behind the PA is to ensure the safety of the new ingredients that are reaching the market by following the due risk analysis process.

Some of the members informed that the PA procedure is hitting the companies operationally and the "proprietary food" under erstwhile regime of PFA were not meant to be covered under the process. It was decided that the concerns raised can be discussed together and any remaining issues can be resolved through discussions. It was also agreed that industry representatives will provide a list of daily use food items that need to be excluded from the PA procedure.

#### **7. E- Governance initiatives of the Authority**

The Food Authority considered the agenda item on E- Governance initiatives of the Authority viz Online Food Licensing/ Registration System (FLRS), Online Food Import Clearance System (FICS), Food Inspection Prioritization System (FIPS) and proposed Food Product Approval System along with the financials of various projects being executed as different projects by National Institute of Smart Governance (NISG), a Section 25 company of the Department of Information Technology, Government of India on nomination basis. It was informed by CEO that first those areas are being considered under E-Governance activities wherein there is interface with the external stakeholders viz. the public to ensure transparency. It was also informed that the endeavour is to keep the organisational structure lean with more emphasis on IT based applications. Thus, there is outlay specified specifically for E-governance activities both in the Central as well as the Centrally sponsored Schemes of the 12<sup>th</sup> Plan. The Authority took on record the note on E-governance initiatives.

#### **8. Current Status of Harmonization of India's Food Standards with Codex Standards and other International Best Practices**

The Food Authority noted the Current Status of Harmonization of India's Food Standards with Codex Standards and other International Best Practices which was put up as an information agenda item.

**9. a) Changes in the composition of Scientific Panel for Fish and Fisheries Products**

The Food Authority considered and approved the inclusion of Dr. A. Gopalakrishnan (Director, CMFRI, Kochi) as a new member in Scientific Panel for Fish and Fisheries Products in place of Dr. G. Syda Rao (Former Director, CMFRI, Kochi).

**b) Changes in the composition of Scientific Panel for Functional foods, nutraceuticals, dietetic products and other similar products and Scientific Panel for Method of Sampling and analysis**

The Food Authority considered and approved the inclusion of (i) Dr. V D Sattigeri, Former Director CFL, CFTRI, Mysore in Scientific Panel for Functional foods, Nutraceuticals, dietetic products and other similar products; and (ii) Dr. SK Verma, Senior Scientist, CCMB, Hyderabad in Scientific Panel for Method of Sampling and Analysis.

**10. Proposed amendment in FSSAI (Procedure for Transaction of Business of the Central Advisory Committee) Regulations, 2010 for fixing of time period and replacement of non-active members.**

The Food Authority considered and approved the amendment in FSSAI (Procedure for Transaction of Business of the Central Advisory Committee) Regulations, 2010 for fixing of time period and replacement of non-active members as under:

**(a) 14. Appointment of members**

The members from the food industry, agriculture, consumers, relevant research bodies and food laboratories with relevant expertise shall be appointed by the Food Authority for a period of 3 years from the date of publication of such notification in the official gazette and shall be eligible for the reappointment for a further period of 3 years.

(b) In Regulation 16 to reimbursement of expenses, for the number "16" the number "15" shall be substituted.

**11. Revision of standard for blended edible vegetable oil with respect to unsaponifiable matter.**

The Food Authority considered and approved the proposed amendment to the Clause 2.2.1. (24) of 'Food Safety and Standards (Food Products Standards & Food Additives) Regulation, 2011', after (4) (ii), addition of:

Nature of oil	Acid value
(iii) Blended with physically refined rice bran oil	Not more than 4.0 percent by weight; provided that oryzanol content be minimum of 0.20% (by weight) with rice bran oil at 20% level and with an increment of 0.05% with every 5% rise in rice bran oil content in the blend.

**12. Harmonization of Iodine Value in imported Cotton Seed Oil with Codex Standards.**

The Food Authority considered and approved the proposed amendment of clause 2.2.1.2 of 'Food Safety and Standards (Food Products Standards & Food Additives) Regulation, 2011', as:

Replacement of 'Iodine value 98-112'  
with 'Iodine Value 98-123'

Dr. AR Sharma, Member Authority also pointed out that other points as discussed in the meeting of the expert group on fats and oils held on 07.05.2013 relating to enzymatic degumming and removal of mandatory certification of Agmark may also be considered. It was assured that the same will be examined for consideration in the next Authority meeting.

**13. Fixation of MRLs of 7 pesticides recommended by Scientific Panel on Pesticides and Antibiotic Residues of FSSAI**

The Food Authority considered and approved the MRLs of 7 pesticides on different crops viz. (I) Difenoconazole (Pomegranate, 0.01 \* ppm); (II) Methyl parathion (Rice (paddy), 0.01 \* ppm; Black gram, 0.01 \* ppm; Cotton, 0.01 \* ppm; Mustard oil, 0.01 \*


ppm); (III) Pendimethalin (Chilli, 0.05\* ppm); (IV) Ametocradin (Grapes, 0.05\* ppm); (V) Cyazofamid (Potato, 0.02\* ppm; Tomato, 0.02\* ppm; Grapes, 1 ppm); (VI) Clothianidin & its metabolites –Thiazolymethylguanidine (TMG), Thiazolymethylurea (TZMU), Methylnitroguanidine(MNG) (Tea, 0.02\* ppm) and (VII) Dinotofuran (Cottonseed Oil, 0.05\* ppm). (\*) - Limit of Quantification.

#### **14. Milestones and way forward approach under Food Import Clearance System (FICS)**

The Food Authority noted the Milestones and way forward approach under Food Import Clearance System (FICS), implementation of integrated IT-enabled imported food clearance system, draft food import regulations, designated port for food import, development of food inspection prioritization system (FIPS), pre-arrival document review under FIPS, single window clearance systems for customs and update on food laboratory infrastructure for imported food; which was put up as an information agenda item.

#### **15. Any other item with the approval of the Chairperson**

In the end Chairperson, FSSAI thanked all the Authority members for actively participating in the meeting and it was decided that the next Authority meeting can be convened in the third week of April 2014.

  
(Dillip Kumar Samantaray) 17/2/2014

**Chief Executive Officer**

List of participants

**Members of the Authority**

1. Shri K. Chandramouli, Chairperson, FSSAI
2. Shri D.K. Samantaray, Member Secretary
3. Dr. Arun Kumar Panda, Joint Secretary, Ministry of Health & Family Welfare, New Delhi.
4. Dr. Reeta Vasishta, Joint Secretary & Legislative Councillor, Ministry of Law, New Delhi.
5. Ms. Anuradha Prasad, Joint Secretary, Ministry of Food Processing Industries, Panchsheel Bhawan, New Delhi.
6. Dr. G. S. Toteja, Director, Desert Medicine Research Centre (DMRC), New Pali Road, ICMR Campus II, TAI, 3 Red Cross Road, New Delhi.
7. Dr. AR Sharma, CMD, M/s Ricelaa Health Foods Ltd. Village Manwala, Saron Road, Dhuri, Sangrur, Punjab.
8. Shri Vasudev K Thakkar, President, 'V' Care Right & Duty NGO. V. Care House Opp. Keval Farm, Karodia Road, Post-Bajwa, Vadodra, Gujarat.
9. Ms Shreya Pandey, All India Food Processors' Association, 206, Aurobindo Place Market, Hauz Khas, New Delhi.
10. Ms. Meetu Kapur, Confederation of Indian Industry (CII), India Habitat Centre, Core 4A, Ground Floor, Lodhi Road, New Delhi.
11. Shri Thanglura, Mizoram Consumers' Union, Lalat Chamber, Temple Square, Tuikual South, Aizawl, Mizoram.
12. Shri V. Balasubramaniam, General Secretary, Prawn Farmer Federation of India, 108/1, Rainbow Drive Layout, Sarjapur Road, Near – WIPRO, Corporate office, Bangalore.

13. Shri Abukalam, Madina Munavara Coffee Estate, Jayapura Koppa Taluk Chikmagalur, Karnataka.

#### **Officers of FSSAI**

1. Shri S. Dave, Advisor, FSSAI
2. Ms. Vinod Kotwal, Director (Codex), FSSAI
3. Col CR Dalal, Director (Surveillance), FSSAI
4. Dr. Meenakshi Singh, Scientist (Standards), FSSAI
5. Dr. Sandhya Kabra, Director (QA), FSSAI
6. Shri Rakesh Kulshrestha, JD(M), FSSAI
7. Shri Anil Mehta, DO( Northern Region), FSSAI
8. Shri Sanjay Gupta, AD (Enf.), FSSAI
9. Shri BG Pandian, AD (Imports), FSSAI
10. Shri PK Karthikeyan, AD (QA), FSSAI