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New Food Regulatory Regime – Changes, Challenges and Way Ahead

*Critique of the Food Safety and Standards Act, 2006 (FSSA) by **Minakshi Sharma Dabas, Advocate, Corporate Law Group, New Delhi***

As countries witness a growth in International food trade, development of complex food types, processes and handling, there has been a parallel rise in the level of awareness on different food and water borne diseases. Food safety is becoming a growing global concern with regulatory regimes worldwide being faced with the challenge of minimizing, or rather, curtailing food safety risks.

Indian food industry is all set to be a major international force in the near future. The Ministry of Food Processing Industries has formulated the 'Vision 2015' Action Plan which targets trebling the size of the food processing industry, increasing value addition from 20 % to 35%, and enhancing India's share in global food trade from 1.5% to 3%. Also, according to a recently published report titled 'Indian Food and Drinks Market: Emerging Opportunities' by market research firm RNCOS, the Indian food and beverages market is projected to grow at a compound annual growth rate (CAGR) of about 7.5 per cent during 2009-13 and would touch US\$ 330 billion by 2013.

With all eyes set on the nation, India is steadily garnering up to ensure safe and wholesome food to its citizens by setting up a single unified empirical standard. The Government established the Food Safety and Standards Authority of India (FSSAI) under the Food Safety and Standards Act, 2006 (FSSA) with the mandate to lay down science based standards for food products and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food. While the Ministry of Health and Family Welfare notified the Food Safety and Standards Rules, 2011 in the Gazette of India vide G.S.R.No.362-(E) dated May 5th, 2011 (which shall come into force from August 5th, 2011), it is in the final stages of notifying the Food Safety and Standards Regulations 2010. Necessary steps are being taken to ensure a smooth transition from the Prevention of Food Adulteration (PFA) Act, 1954 to the new FSS despite many challenges. As the implementation part will be done by the Central as well as the State Governments, municipalities and panchayats, the State governments are scaling up operations and resources for the changeover. With the nationwide enforcement of the new consolidated Act, the PFA and varying overlapping legislations pertaining to food sector will be repealed. Besides, procedural delays and confusion due to overlapping turfs of as many as eight ministries is expected to be removed.

One of the primary changes that FSSA would bring about is imposing the responsibility of food safety on the manufacturer for the first time (under the PFA regime, it was the Food Inspector responsible for examination and prosecution). With the introduction of the supply chain concept under the FSSA, the focus will not be on inspection, but on each person in the chain-sourcing, manufacturing, storing, distributing- assessed by Food Safety Officers (FSOs). FSSA prohibits the manufacture, import, storage, sale or distribution of any such article of food which is unsafe, i.e., food whose nature, substance or quality is injurious to health. There are specific responsibilities laid down under the FSSA for the Food Business Operators (FBO) for ensuring the safety of food

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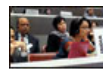
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articles. FSSA extends its jurisdiction to all persons by whom food business is carried on or owned under the definition of FBOs. The FBOs are strictly liable for any article of food which is unsafe under the FSSA. The FSSA also provides for food recall procedures whereby an FBO is required to immediately inform the competent authorities and co-operate with them, if the food which he has placed in the market is unsafe for the consumers. FSSAI has recently notified the draft Regulations on Food Recall Procedure to provide guidance to the FBOs for carrying out food recall for food that does not adhere to the food safety standards. It is also aimed to establish an effective and efficient follow-up action/ post-recall report system.

The FSSA has also provided for appointment of a Designated Officer (rank of a Sub Divisional Officer) by the Commissioner of Food Safety to be in charge of food safety administration for a specific district whose duties shall include issuing or canceling licences of FBOs, serving 'improvement notices', prohibiting sale of food articles violating prescribed standards, receiving reports and samples of food articles from FSOs and getting them analysed, sanction or launch prosecutions and get investigated any complaint against any contravention of the Act or against the FSOs. Other major reforms in the pipeline to ensure safe food articles by FBOs are mandatory compliance with Good Agricultural Practices (GAP) for big retailers, organic food certification, stricter labelling and claims regulations covering the entire range of health foods, such as health drinks, packaged food products as well as nutraceuticals including dietary supplements etc.

Further, in addition to providing for compensation in cases of injury or death ranging from INR 1, 00, 000 to 5, 00,000, the FSSA lays down stringent penal provisions with regard to unsafe food. Any person who, whether by himself or by any other person on his behalf, manufactures for sale or stores or sells or distributes or imports any article of food for human consumption which is unsafe may be liable to be punished with a maximum imprisonment up to seven years or/and with a fine of up to INR 10,00,000. There are also provisions with differing culpability standards under the Indian Penal Code 1861 Consumer Protection Act, 1986 and Torts law. Also, to ensure speedy disposal of cases, FSSA provides for a difference between the not so serious cases (substandard food /misbranded food/ misleading advertisements about food products -not injurious to health) from those directly impacting health. If the violation does not have a direct impact on health, the adjudicating officer (rank of sub-divisional magistrate) shall penalize the violator without going to court. The state governments are mandated to establish Food Safety Appellate Tribunals to hear appeals from the decisions of the adjudicating officer. If the case is serious, it will go to court.

While implementation of the new law will go a long way in boosting consumer confidence and giving the much needed boost to the food processing sector, effective implementation is fraught with plentiful challenges. India presents a unique case of vastness and complexity. The very fact that the Act extends its jurisdiction to all persons by whom food business is carried on or owned under the definition of FBOs is a huge base to cover. Further, "Food Business" refers to any undertaking (profit or non-profit/public or private) carrying out any of the activities related to any stage of manufacture, processing, packaging, storage, transportation, distribution, import and includes food services, catering services, sale of food or food ingredients. Indian FBOs ranges from small time street hawkers to swanky high street food dealers with numerous intermediaries and complex processes and it is indeed a challenge to provide for regulatory oversight from farm to fork! Besides, currently there is limited number of Food Safety Officers, lack of funds with the State Governments coupled with shortage of quality laboratories lacking uniformity of standard.

Whilst formulating and implementing a single unified standard is a prodigious task, one of the major concerns of the industry which needs to be addressed by the government while finalizing the Food Safety and Standards Regulations 2010 is tuning in of international best practices with the domestic ground realities. Both the domestic and international industry is looking forward to FSSAI for the harmonization of Indian food standards for all food categories with the Codex Alimentarius Commission (CAC) standards. CAC is regarded as the world "Authority" on food standards (Joint FAO/WHO Food Standard Programme). Codex's focused objectives of (1) protecting consumers and (2) facilitating trade are shared by member countries and its standards based on scientific evidence and risk analysis principles, are followed and/or adopted partially or in totality by countries around the world. The WTO in its Sanitary and Phytosanitary Agreement recognizes the Codex standards as the global reference standards for consumers, food producers, processors, national food control agencies and all others involved in international food trade. The Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on Technical

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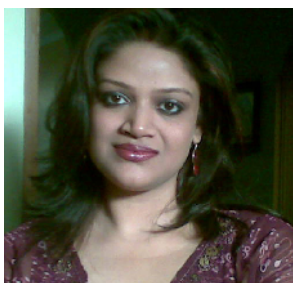
Global status report on noncommunicable diseases 2010



Barriers to Trade also encourage the international harmonization of food standards. Codex standards have thus become the benchmarks against which national food control measures and regulations are evaluated under the relevant provisions of the WTO Agreements.

With India being a member of the CAC since 1970, the Ministry of Health and Family Welfare (FSSAI acting as the National Codex Contact Point), has the primary responsibility for determination of government policy relating to food standards and enforcement of food control including national position on various issues relating to Codex. With the global food industry looking towards India as a food hot-spot, it is about time the national food legislation is aligned with Codex, encouraging innovation and facilitating trade without compromising consumer safety.

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Corporate Law Group's (CLG) Regulatory Practice spans across various sectors including food and beverages, wines and spirits, pharmaceuticals, biotechnology etc. CLG's clients include multinational companies, leading foreign law firms, public sector organizations as well as international organizations. The interdisciplinary Food and Drug Team includes lawyers and technical professionals having considerable experience across virtually all the industry sectors regulated by the food and drug administration.

A significant part of the firm's food and drug law practice is devoted to counseling clients concerning statutory and regulatory requirements. CLG's experts keep close tab of legal developments/upcoming regulations in the food sector and provide comments/suggestions for consideration on various issues and advise/assist its clients in making submissions related to food matters. CLG assists its clients in obtaining necessary regulatory licenses and statutory approvals with regard to product approval for marketing, manufacturing and safety issues, Good Clinical Practice (GCP) and Good Manufacturing Practice (GMP) requirements, regulatory strategies and life cycle management, labeling, advertising, import/exports clearances for biological and dual use materials, clinical investigation requirements, product liability, market protections and enforcement issues

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