DRAFT FOOD REGULATIONS HAVE BEEN RELEASED FOR CONSULTATION

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The Draft Food Safety and Standards Rules, 2009 (**"Rules"**), Draft Food Safety and Standards Regulations, 2009 and the Annexure (**"Regulations"**) have been released by the Food Safety and Standards Authority of India (**"FSSAI"**). The Food Safety and Standards Act, 2006 (**"Act"**) was passed by the Parliament with the intention to converge all present food laws into one and to have a single regulatory body. Accordingly, FSSAI was established under the Act with the mandate to lay down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale, and import, to ensure availability of safe and wholesome food for human consumption.

The Draft Rules have been prepared in consultation with various stake holders and after thorough deliberations in a series of meetings in the FSSAI. The Rules include qualification of the enforcement agencies, manner of sampling, determination of cases for referring to appropriate courts, time frame for such determinations, procedure to be followed in adjudication of cases, qualification of the Presiding Officer of the Tribunal and rules on other issues enumerated under section 91 of the Act. The Regulations broadly reproduces the Prevention of Food Adulteration Rules, 1955 and contains separate Annexure for appendix A, B, and C which includes standards for food colour, list of additives and microbiological requirements etc., which have been reproduced from the rule without any change.

PSA view – The Act was a welcome step and the FSSAI, since its inception has been trying to regulate the various facets of food industry be it manufacturing, processing, distribution, sale or import of food. Due to the absence of the corresponding rules, the Act was not serving the very purpose it was enacted for. The Rules and the Regulations are a concrete step towards creating uniformity in food regulations in India. In exercise of the powers conferred by section 92 (o) read with section 31 of the Act, the FSSAI has also made a separate regulations for Licensing/Registration of Food Businesses which reflects the commitment of FSSAI to ensure safe and wholesome food for human consumption in India.

Biomedical Research Human Subjects Promotion and Regulation Bill – in action again!

Biomedical Research Human Subjects Promotion and Regulation Bill (**"Bill"**), which has been in the pipeline for a long time since it was cleared by the Law Ministry in 2006, is currently being modified by the Indian Council of Medical Research (**"ICMR"**) to bring it in line with the prevailing requirements. The modified draft will be sent to the Union Health Ministry for final approval before introducing it in the Parliament this year. In its present form, provisions pertaining to punishment are not severe. The modified Bill will spell out stringent punishment for offenders as a deterrent, which will be at par with international laws.

PSA view – Research on human subjects is a sensitive issue and has always called for uniform ethical guidelines. It has acquired a new sense of urgency as more and more pharma companies are undertaking research on humans, clinical trials on new drugs, introducing diagnostic procedures, and therapeutic interventions in India. Though regulations such as the Good Clinical Practices, ICMR Code are in force (which emphasize upon following ethical principles and uniform practices), ultimately, these are guidelines which lack enforceability. Hence, the Bill, if implemented effectively, will go a long way in keeping a check on research performed on humans and also be enforceable in a court of law. Hopefully, the Bill will see the light of the day very soon!

ICMR issues guidelines on probiotic foods

ICMR has issued draft guidelines which specifically pertain to regulation of the probiotic foods introduced into the Indian market. Presently, probiotic foods are categorized as general food and are subject to minimal regulation. The guidelines introduced by the ICMR, which will most likely be implemented in the early half of 2010, aim to guarantee product safety, reliability and quality along with a level playing field for all companies in this segment of the pharmaceutical sector. The draft guidelines provide that probiotic food manufacturers will also have to establish safety and efficacy of probiotic foods through clinical trials, just like drugs.

Further, the guidelines also provides that probiotic food to be marketed in India will first have to be clinically tried and approved in India on Indian subjects irrespective of whether they have been clinically tried abroad. This is due to the geographical difference between consumers on whom the probiotic food have been tested and the Indian consumer. The ICMR through the guidelines support stringent labeling norms to prevent misuse and misleading the general public.

PSA view – Given the nature of the product and the implications it can have on human health, coupled with the fact that at present, there is minimal regulation governing the marketing and manufacture of the product, the guidelines are a welcome move. The guidelines, once approved by the Drug Controller General of India, will help in reducing any false generalized claims relating to probiotic foods. Considering the sizeable market for probiotic foods in India, and its exponential growth potential *(approximately 40% annually)*, the guidelines are a must for protecting the consumers, as well as for giving all companies a level playing field in this sector.

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