INDIAN DRUG MANUFACTURERS' ASSOCIATION

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INDIAN PHARMACEUTICALS FOR GLOBAL HEALTH

January 13, 2015

13/1/15

Hon'ble Shri Jagat Prakash Nadda ji,
Union Minister for Health & Family Welfare,
Government of India,
Nirman Bhavan,
New Delhi 110 001.

Subject: Comprehensive proposal for amendments in FSS Act 2006

Respected Sir,

Greetings from Indian Drug Manufacturers' Association.

This has reference to our delegation meeting with your goodself on 22nd December 2014.

Sir, it is respectfully submitted that FSSAI (Food Safety & Standards Act of India) operations and activities in last two and a half years were of high concern area which has severely disturbed the established operations of FBOs.

We are submitting herewith our comprehensive proposal of proposed changes/alterations to the Food Safety & Standards Act 2006.

We request your kind consideration.

With kindest regards,

S.V. Veerramani
President

Dr. R.K. Sanghavi
Chairman – Nutraceutical Subcommittee

Cc to: Shri Lov Verma,
Secretary to the Government of India,
Ministry of Health & Family Welfare,
Nirman Bhawan, New Delhi.

13/01/2015

Food Safety & Standards Act, 2006, [Rules, 2011; Regulations, 2011]

PROPOSED CHANGES / ALTERATIONS BY STAKEHOLDER INDIAN DRUGS MANUFACTURERS' ASSOCIATION (IDMA)

[In response to circular of December 2014 issuedby the Ministry of Food Processing Industries stating that Ministry of Health and Family Welfare has constituted a Committee to undertake comprehensive review of Food Safety and Standards Act, Rules and Regulations.]

KEY: What is crossed is suggested for deletion; what are marked in red are the alterations / additions suggested in the sentence / paragraph)

SERIAL NO	PAGE NO & DETAILS	CLAUSES AS PER GUIDELINES	CHANGES SUGGESTED	REASONS
1.	Page No: 4 Chapter I, Sec 3, **Definitions.**Subpoint (z)	"label" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, graphic, perforated, stamped or impressed on or attached to container, cover, lid or crown of any food package and includes a product insert;	"label" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, graphic, perforated, stamped or impressed on or attached to container, cover, lid or crown of any food package;~~and includes a product insert;~~	Package insert cannot be considered as part of label.
2.	Page No: 4 Chapter I, Sec 3, **Definitions.** Subpoint (zf) (A) (i)	"misbranded food" means an article of food – (A) if it is purported, or is represented to be, or is being – (i) offered or promoted for sale with false, misleading or deceptive claimseither; (a) upon the label of the package, or	"misbranded food" means an article of food – (A) if it is purported, or is represented to be, or is being – ~~(i) offered or promoted for sale with false, misleading or deceptive claimseither;~~ ~~(a) upon the label of the package, or~~	This needs to be separately defined as "miscommunication" as a separate subpoint (zza) could be inserted for the same.

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		(b) through advertisement, or	~~(b) through advertisement, or~~	
3.	Page No: 5 Chapter I, Sec 3, **Definitions.**Subpoint (zf) (A) (ii) (iii)	(ii) sold by a name which belongs to another article of food; or (iii) offered or promoted for sale under the name of a fictitious individual orcompany as the manufacturer or producer of the article as borne on the package or containing the article or the label on such package; or	(i) sold by a name which belongs to another article of food; or (ii) offered or promoted for sale under the name of a fictitious individual orcompany as the manufacturer or producer of the article as borne on the package or containing the article or the label on such package; or	Since point (i) is suggested to be separated, the subsequent two points have been re-numbered.
4.	Page No: 6 Chapter I, Sec 3, **Definitions.** Subpoint (zq)	(zq) “risk management” means the process, distinct from risk assessment, ofevaluating policy alternatives, in consultation with all interested parties consideringrisk assessment and other factors relevant for the protection of health of consumersand for the promotion of fair trade practices, and, if needed, selecting appropriateprevention and control options;	(zq) “risk management” means the process, distinct from risk assessment, of evaluating food safety measures within the scope of the act~~policy alternatives~~, in consultation with all interested parties including healthcare industry experts~~considering risk assessment and other factors relevant for the protection of health of consumers and for the promotion of fair trade practices, and, if needed,~~	Food safety measures, as a policy for risk management needs to be undertaken with the consensus of each and every stakeholder.

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			~~selecting appropriate prevention and control options~~;	
5.	Page No: 8 Chapter I, Sec 3, **Definitions.** Subpoint (zza)	"miscommunication" means an article of food – (A) if it is purported, or is represented to be, or is being – (i) offered or promoted for sale with false, misleading or deceptive claims either: (a) upon the label of the package, or (b) through advertisement, or	"miscommunication" means an article of food – (A) if it is purported, or is represented to be, or is being – (i) offered or promoted for sale with false, misleading or deceptive claims either: (a) upon the label of the package, or (b) through advertisement, or	"miscommunication" separated form "misbranded food".
6.	Page No: 9 Chapter II, Sec 5, **Composition of Food Authority and qualifications for appointment of its Chairperson and other Members** Subpoint (1) (d)	(d) three eminent food technologists or scientists;	(d) three eminent food technologists or scientistsincluding1 dietician and 1 qualified medical doctor with relevant experience;	It is very essential to have dietician and qualified medical doctor since health supplements are also regulated by the FSSA.
7.	Page No: 9 Chapter II, Sec 5, **Composition of Food Authority and qualifications for appointment of its Chairperson**	(f) two persons to represent farmers' organisations;	(f) Chief Executive Officer, FSSAI and a representative of Association of Food Scientists and Technologists as well as two persons from healthcare industry;	Farmers and fishermen are excluded from the purview of the FSSA and hence should not be members of the Food Authority. Representation from healthcare industry /

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	and other Members Subpoint (1) (f)			association crucial to governing the health-related products & claims.
8.	Page No: 9 Chapter II, Sec 5, **Composition of Food Authority and qualifications for appointment of its Chairperson and other Members** Subpoint (3)	(3) The Chairperson shall be appointed by the Central Government from amongst thepersons of eminence in the field of food science or from amongst the persons from theadministration who have been associated with the subject and is either holding or has held theposition of not below the rank of Secretary to the Government of India.	(3) Health Minister, Government of India shall be Ex-Officio Chairperson of the Authority. Else, the chairperson shall be appointed by the Central Government from amongst the persons of eminence in the field of food science only.	The Chairperson should not be from Administration. In the present scenario, the chairperson is a retired Secretary of Government of India to whom the posting is evidently not appropriate.
9.	Page No: 12 Chapter II, Sec 9, **Officers and other employees of Food Authority.** Subpoint (1)	(1) There shall be a Chief Executive Officer of the Food Authority, not below the rank of Additional Secretary to the Government of India, who shall be the Member-Secretary of the Authority, to be appointed by the Central Government.	(1) There shall be a Chief Executive Officer of the Food Authority, who shall be a Senior Food Technologist having experience in industry and~~not below the rankof Additional Secretary to the Government of India,~~ who shall be the Member-Secretary of the Authority, to be appointed by the Central Government.	Officer of the rank of Additional Secretary to the Government of India with knowledge in food science are rare. Inappropriate decisions have already been experienced when officer of the rank of Additional Secretary to the Government of India having no knowledge of food science have been

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				appointed as the Chief Executive Officer of FSSAI.
10.	Page No: 12 Chapter II, Sec 9, **Officers and other employees of Food Authority.** Subpoint (2)	(2) The Food Authority may, with the approval of the Central Government, determine the number, nature and categories of other officers and employees required to the Food Authority in the discharge of its functions.	(2) The Food Authority may, with the approval of the Central Government, appoint food technologist/ scientists / medical doctors in the technical posts.~~Determinethe number, nature and categories of other officers and employees required to the FoodAuthority in the discharge of its functions.~~	Since FSSAI is a food science based organizationno Bureaucrat shall be appointed for technical posts.It is the recommendation of the 150th Joint Parliamentary Standing Committee also to depute subject specialist only for international meetings/ Training programs in contrast to current practices of deputing officials with no food science background which is inappropriate, including even for the image of the country.
11.	Page No: 13 Chapter II, Sec 11, **Central Advisory Committee.** Subpoint (2)	(2) The Central Advisory Committee shall consist of two members each to represent the interests of food industry, agriculture, consumers, relevant research bodies and food laboratories and all Commissioners of Food Safety,	(2) The Central Advisory Committee shall consist of two members each to represent the interests of food industry, healthcare industry, agriculture, consumers, relevant research bodies and food laboratories and all Commissioners of Food	It is important to have representation of healthcare industry since health supplements are also regulated by the FSSA.

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		and the Chairperson of the Scientific Committee shall be ex officio member.	Safety, and the Chairperson of the Scientific Committee shall be ex officio member.	
12.	Page No: 15 Chapter II, Sec 13, **Scientific Panels.** Subpoint (4)	(4) The Food Authority may from time to time re-constitute the Scientific Panels by adding new members or by omitting the existing members or by changing the name of the panel as the case may be.	(4) The Food Authority ~~may from time to time~~shall re-constitute the Scientific Panels every three years byadding new members or by omitting the existing members or by changing the name of the panel as the case may be.	The Food Authority may reconstitute the scientific panels every three years to maintain transparency. There is no dearth of Food Scientists in the country. Members should have industrial experience and Present system of pick and choose method for selection of scientific panel members should be stopped. Even the 150th Joint Parliamentary Standing Committee also recommended not to engage pure academicians.
13.	Page No: 15 Chapter II, Sec 14, **Scientific Committee.**Subpoint (1)	(1) The Food Authority shall constitute Scientific Committee which shall consist of the Chairpersons of the Scientific Panels and six independent scientific experts not belonging or affiliated to any of the	(1) The Food Authority shall constitute Scientific Committee which shall consist of the Chairpersons of the Scientific Panels and six independent subject relevant scientific experts	Experts with relevant experience are to be included in the Scientific Committee for providing appropriate guidance.

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		Scientific Panels.	not belonging or affiliated to any of the Scientific Panels.	
14.	Page No: 16 Chapter II, Sec 16, **Duties and functions of Food Authority.** Subpoint (1)	(1) It shall be the duty of the Food Authority to regulate and monitor the manufacture, processing, distribution, sale and import of food so as to ensure safe and wholesome food.	(1) It shall be the duty of the Food Authority to regulate as per the provisions of the act for~~and~~ monitoring the manufacture, processing, distribution, sale and import of food so as to ensure safe and wholesome food.	FSSAI is empowered to regulate as per the provisions of the FSS Act.
15.	Page No: 19 Chapter II, Sec 16, **Duties and functions of Food Authority.** Subpoint (4)	(4) The Food Authority shall make it public without undue delay –	(4) The Food Authority shall make it public without undue delay as per the set and committed timeframe–	Timely feedback is essential to ensure availability of healthcare supplements for the consumer / public health.
16.	Page No: 19 Chapter II, Sec 16, **Duties and functions of Food Authority.** Subpoint (5)	(5) The Food Authority may from time to time give such directions, on mattersrelating to food safety and standards, to the Commissioner of Food Safety, who shall bebound by such directions while exercising his powers under this Act;	(5) The Food Authority may from time to time give such directions within the scope of the act, on matters relating to food safety and standards, only to the respectiveState & Union Territory Commissioner of Food Safety, who shall be bound by such directions while exercising his powers under this Act;	This will enable the FSS Act to be implemented in its true spirit uniformly across India.
17.	Page No: 20 Chapter II, Sec 17, **Proceedings of Food Authority.** Subpoints (4) & (5)	(4) All orders and decisions of the Food Authority shall be authenticated by the Chief Executive Officer. (5) The Chief Executive Officer shall take part in the meetings of the Food Authority	~~(4) All orders and decisions of the Food Authority shall be authenticated by the Chief Executive Officer.~~ ~~(5) The Chief Executive Officer shall take part in the meetings of the Food Authority~~	These two points should be deleted since the Chief Executive Officer has been proposed to be a member of the Authority.

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		but without a right to vote.	~~but without a right to vote.~~	
18.	Page No: 20 Chapter II, Sec 17, **Proceedings of Food Authority.** Subpoint (7)	(7) No act or proceedings of the Food Authority shall be questioned or invalidated merely on the ground of existence of any vacancy or defect in the constitution of FoodAuthority.	(7) No act or proceedings of the Food Authority shall be questioned or invalidated merely on the ground of existence of any vacancy provided the same does not impact the decision on the subject matter and the same is minuted~~or defect in the constitution of Food Authority~~.	The changes suggested ensures transparency in the decision making process.
19.	Page No: 20 Chapter III, Sec 18, **General principles to be followed in Administration of Act.** Subpoint (1) (c)	(c) where in any specific circumstances, on the basis of assessment ofavailable information, the possibility of harmful effects on health is identifiedbut scientific uncertainty persists, provisional risk management measuresnecessary to ensure appropriate level of health protection may be adopted,pending further scientific information for a more comprehensive riskassessment;	(c) where in any specific circumstances, on the basis of assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures,within the scope of the act, necessary to ensure appropriate level of health protection may be adopted, pending further scientific information for a	Risk management measures should be implemented as per the provisions of FSSA.

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			more comprehensive risk assessment;	
20.	Page No: 21 Chapter III, Sec 18, **General principles to be followed in Administration of Act.** Subpoint (2) (a) (iii)	(iii) stakeholders' concern that the framed regulations and standards may impose trade barrier;	(iii) stakeholders' concern that the framed regulations and standards may impose trade barrier;	This additional point needs to be inserted since there have been serious disregard to overseas trading and a state of uncertainty with regards especially to imports.
21.	Page No: 23 Chapter IV, Sec 20, **Contaminants, naturally occurring toxic substances, heavy metals, etc.**	No article of food shall contain any contaminant, naturally occurring toxic substancesor toxins or hormone or heavy metals in excess of such quantities as may be specified byregulations.	No article of food shall contain any contaminant, naturally occurring toxic substances or toxins or hormone or specific harmful heavy metals – but not including beneficial minerals, in excess of such quantities as may be specified by regulations.	Health providing minerals should not be considered to be a part of harmful heavy metals.
22.	Page No: 23 Chapter IV, Sec 22, **Genetically modified foods, organic foods, functional foods, proprietary foods, etc.**	Save as otherwise provided under this Act and regulations made thereunder, no personshall manufacture, distribute, sell or import any novel food, genetically modified articles of food, irradiated food, organic foods, foods for special dietary uses, functional	~~Save as otherwise provided under this Act and regulations made thereunder, no person shall manufacture, distribute, sell or import anynovel food,genetically modified articles of food, irradiated food, organic foods,~~Foods for special dietary uses, functional foods, n~~e~~utraceuticals, health	Sec 22 needs to differentiate between health supplements and similar products vis-à-vis novel, genetically modified and irradiated foods. Only novel foods, genetically modified foods and irradiated foods need to apply for approval of ingredients which do not have history of safe consumption of at least 1 year in India and / or at least 3 years in

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		foods,neutraceuticals, health supplements, proprietary foods and such other articles of food whichthe Central Government may notify in this behalf.	supplements, proprietary foods and such other articles of food which the Central Government may notify in this behalf can be manufactured as per the regulations of the act. Organic foods shall be certified by an accredited agency of Agricultural products export development agency and Proprietary foods shall be regulated by the standards of nearest category standardized products. Save as otherwise provided under this Act and regulations made thereunder, no person shall manufacture, distribute, sell or import any novel food,genetically modified articles of food and irradiated food. Ingredient approval of such foods containing articles is required if there is no history of safe consumption of at least 1 year in India, and / or at least 3 years in overseas regulated countries.	overseas regulated countries to ensure consumer benefits coupled with ensuring consumer safety, and is as per the prevailing global practices in most developed countries. Also classifying / regulating organic foods and proprietary foods must be specific.There is no difference between organic food and inorganic food except agricultural practices. Agricultural Products Exports Development Authority (APEDA), Ministry of Commerce, Government of India, have already authorized a few certification agencies for organic food. Proprietary food is entirely different from Novel food. As per Oxford Dictionary , the word proprietary relates to ownership of a company or person. All non-standardized food should not be considered as proprietary food. Hence proprietary food and novel food need to be *separately* redefined.
23.	Page No: 24 Chapter IV, Sec 22,	(ii) minerals or vitamins or proteins or metals or their	(ii) minerals or vitamins or proteins or metals or their	Recommended Daily Allowance is to indicate the

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	Genetically modified foods, organic foods, functional foods, proprietary foods, etc. Subpoint (1) (a) (ii)	compounds or aminoacids (in amounts not exceeding the Recommended Daily Allowance forIndians) or enzymes (within permissible limits);	compounds or amino acids ~~{~~[in amountsnot less than the minimum limit specifiedand which could exceed~~not exceeding~~ the Recommended Daily Allowance for Indians butnot surpassing known international maximum Upper Tolerable Limits (UTL) / Tolerable Upper Intake Levels (UL) and as specified on same basis by regulations~~}~~] or enzymes (within permissible limits)and excluding overages;	requirement of nutrients for healthy individuals. For particular physical or physiological condition or specific diseases and disorders vitamins, minerals, amino acids, other nutrients need to be provided as per the increased requirement not exceeding the *maximum* UTL / UL specified globally. United States Food And Drugs Administration (US FDA), European Food Safety Authority (EFSA) have fixed up both minimum and maximum level. RDA should be not less than minimum limits and not more than maximum limits which need to be defined in India and until such time the global specifications are to be adapted. It is the practice followed by US FDA also to allow 50 percent of the overage.
24.	Page No: 25 Chapter IV, Sec 22,	(4) “proprietary and novel food” means an article of food	(4) “proprietary ~~and novel~~ food” meansa product	Proprietary Food and Novel Food need to be

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	Genetically modified foods, organic foods, functional foods, proprietary foods, etc. Subpoint (4)	for which standardshave not been specified but is not unsafe: Provided that such food does not contain any of the foods and ingredientsprohibited under this Act and regulations made thereunder.	marketed under, and protected by, a registered trade name, and has a known ingredient or a blend of known ingredients with a history of safe human consumption.~~an article of food for which standards have not been specified but is not unsafe~~: Provided that such food does not contain any of the foods and ingredients prohibited under this Act and regulations made thereunderand thereby needs no prior approval.	separated and differently appropriately defined. Proprietary foods means an articles for which standards have not been specified till date by FSSAI but the ingredients as well as finished product are not unsafe.
25.	Page No: 25 Chapter IV, Sec 22, **Genetically modified foods, organic foods, functional foods, proprietary foods, etc.** Subpoint (5)	(5) “novel food” means an article of food containing ingredient/s for which standards have not been specified and whose safety is not established globally: Provided that such food does not contain any of the foods and ingredients prohibited under this Act and regulations made thereunder.	(5) “novel food” means an article of food containing ingredient/s for which standards have not been specified and whose safety is not established globally: Provided that such food does not contain any of the foods and ingredients prohibited under this Act and regulations made thereunder.	New subpoint (5) needs to be added under Section 22 of Chapter IV so as to define Novel Food differently fromProprietary Food. Approval shall be required only for novel food ingredient.
26.	Page No: 26 Chapter IV, Sec 23, **Packaging and**	(3) The label of any food could highlight the benefits or functionality provided by its	(3) The label of any food could highlight the benefits or functionality provided by its	This new subpoint (3) needs to incorporated under Section 23 of

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	labelling of foods. Subpoint (3)	specific ingredients as documented.	specific ingredients as documented.	Chapter IV since where ever any ingredient has documentation of any benefit, the same can be mentioned on the label for the purpose of consumer awareness.
27.	Page No: 26 Chapter IV, Sec 24, **Restrictions of advertisement and prohibition as to unfair trade practices.** Subpoint (3)	(3) The advertisements done for any food could highlight the benefits or functionality provided by its specific ingredients as documented.	(3) The advertisements done for any food could highlight the benefits or functionality provided by its specific ingredients as documented.	This new subpoint (3) needs to incorporated under Section 24 of Chapter IV since where ever any ingredient has documentation of any benefit, the same can be used for the purpose of claim for a food by any means of communication for consumer awareness.
28.	Page No: 26 Chapter V, Sec 25, **All imports of articles of food to be subject to this Act.** Subpoint (3)	(3) Every imported food products shall be tested for relevant parameters only in accordance with Indian/ International testing process. Test results must conform to Certificate of Analysis issued by the exporting country.	(3) Every imported food products shall be tested for relevant parameters only in accordance with Indian/ International testing process. Test results must conform to Certificate of Analysis issued by the exporting country.	This new subpoint (3) needs to incorporated under Section 25 of Chapter V. **There are more than INR 22,000 crores affected because of unclear and ambiguous testing parameters under the shelter of consumer safety and regulations not being in harmony with global standards & practices.**
29.	Page No: 26 Chapter V, Sec 25, **All imports of articles of food to**	(4) Non-detachable stickers shall be allowed on imported food articles package, so as to comply with FSSA regulations,	(4) Non-detachable stickers shall be allowed on imported food articles package, so as to comply with FSSA regulations,	Exporter manufacture products for a number of countries and put common labels.

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	be subject to this Act. Subpoint (4)	if the sticker is pasted before shipment by the exporter.	if the sticker is pasted before shipment by the exporter.	Subsequently they put stickers according to the importing country. Since this is the international practice, stickers should be allowed.
30.	Page No: 29 Chapter VII, Sec 30, **Commissioner of Food Safety of the State.** Subpoint (1)	(1) The State Government shall appoint the Commissioner of Food Safety for the State for efficient implementation of food safety and standards and other requirements laid down under this Act and the rules and regulations made thereunder.	(1) The State Government shall appoint the Commissioner of Food Safety for the State for efficient implementation of food safety and standards and other requirements laid down under this Act and the rules and regulations made thereunder.He / She should be a full time Food Safety Commissioner having qualification not less than the prescribed qualification of a Food Safety Officer.	A separate Food Safety Department with budget is required in each state for effective implementation of the act. For this the Commissioner of Food Safety must be adequately and appropriately qualified.
31.	Page No: 30 Chapter VII, Sec 31, **Licensing and registration of food business.** Subpoint (4) Para 2	Provided that if a licence is not issued within two months from the date of making theapplication or his application is not rejected, the applicant may start his food business afterexpiry of the said period and in such a case, the Designated Officer	Provided that if a licence is not issued within two months from the date of making theapplication or his application is not rejected, the applicant may start his food business afterexpiry of the said period by using license application number or	Licensing of a manufacturing facility should follow Schedule 4 (General Hygiene & Sanitary Practices to be followed by food business operators) and not have any other prerequisite.

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		shall not refuse to issue alicence but may, if he considers necessary, issue an improvement notice, under section 32 andfollow procedures in that regard.	reference numberboth of which can be considered and used as License number for manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food till such license is granted. ~~and~~Also in such a case, the Designated Officer shall not refuse to issue alicence but may, if he considers necessary, issue an improvement notice, under section 32 andfollow procedures in that regard. A manufacturing facility / site should comply and satisfy critera as per Schedule 4 of the act and license to be issued solely on this basis.	
32.	Page No: 36 Chapter VII, Sec 36, **Designated Officer.** Subpoint (2)	(2) There shall be a Designated Officer for each district.	(2) There shall be a full time Designated Officer for each district whose qualification should not be less than the prescribed qualification of Food Safety Officer.	Judiciary already issued instructions to appoint full time adequately qualified Designated Officer.
33.	Page No: 36 Chapter VII, Sec 38, **Powers of Food Safety Officer.**	(b) seize any article of food which appears to the Food Safety Officer to be incontravention of this Act or	(b) seize any article of food which has resulted in proven unsafe consumption ~~appears to the Food Safety Officer to be in~~	The Food Safety Officer cannot have arbitrary powers to individually decide on the reasons for

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	Subpoint (1) (b)	the regulations made thereunder; and	~~contravention of this Act or the regulations made thereunder~~; and	seizing the articles of food unless otherwise proven unsafe.
34.	Page No: 36 Chapter VII, Sec 38, **Powers of Food Safety Officer.** Subpoint (1) (c)	(c) keep it in the safe custody of the food business operator such article of food after taking a sample; and in both cases send the same for analysis to aFood Analyst for the local area within which such sample has been taken:	(c) keep it in the safe custody of the food business operator such article of food after taking a sample; and in both cases send the same for analysis promptly to a Food Analyst for the local area within which such sample has been taken and procure & submit the analysis report from the Food Analyst within 14 days from the date seizure:	Since articles of food are perishable commodities and have specific assigned shelf life, there has to be a stipulated time frame for necessary action and revert.
35.	Page No: 36 Chapter VII, Sec 38, **Powers of Food Safety Officer.** Subpoint (2)	(2) The Food Safety Officer may enter and inspect any place where the article of foodis manufactured, or stored for sale, or stored for the manufacture of any other article of food,or exposed or exhibited for sale and where any adulterant is manufactured or kept, and takesamples of such articles of food or adulterant for analysis.	(2) The Food Safety Officer may enter and inspect any place where the article of food is manufactured, or stored for sale, or stored for the manufacture of any other article of food, or exposed or exhibited for sale and where any adulterant is manufactured or kept, and take samples of such articles of food or adulterant for analysis provided that the Food Safety Officer is so authorised in writing by not below the rank of Assistant Food Safety Commissioner and such written authorisation should be produced to the concerned FBO.	Entering and inspecting any manufacturing facility cannot be done by arbitrary selection of a FBO.
36.	Page No: 38 Chapter VII, Sec 40, **Purchaser may**	Provided that such purchaser shall inform the food business operator at the time	Provided that such purchaser shall inform the food business operator at the time	Purchasers intending to have food analyzed should not

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	have food analysed. Subpoint (1) Para 2	ofpurchase of his intention to have such article so analysed:	ofpurchase of his non-malafideintention to have such article of a specified batch number and manufacturing details (having proof of purchase)so analysed:	have malafide intent and should provide batch number, manufacturing details, proof of purchase and nature of complaint to address the issue appropriately and specifically.
37.	Page No: 39 Chapter VII, Sec 42, **Procedure for launching prosecution.** Subpoint (2)	(2) The Food Analyst after receiving the sample from the Food Safety Officer shallanalyse the sample and send the analysis report mentioning method of sampling and analysiswithin fourteen days to Designated Officer with a copy to Commissioner of Food Safety.	(2) The Food Analyst after receiving the sample from the Food Safety Officer shall analyse the sample and send the analysis report mentioning method of sampling, and analysis in compliance with product quality specification of food business operator within fourteen days to Designated Officer with a copy to Commissioner of Food Safety.	In analysis of articles of food, there are well-defined quality specifications on the basis of which the FBO manufactures and markets the same, especially if it is proprietary in nature.
38.	Page No: 45 Chapter IX, Sec 53, **Penalty for misleading**	(a) falsely describes any food; or (b) is likely to mislead as to the nature or substance or quality	(a) falsely describes any food; or (b) is likely to mislead as to the nature or substance or	Add subpoint (c) under Section 53 of Chapter IX. Misleading advertisement leading to injury could be

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	advertisement. Subpoint (1)	of any food orgives false guarantee shall be liable to a penalty which may extend to ten lakhrupees.	quality of any food orgives false guarantee, shall in both cases be liable to a penalty which may extend to two ~~ten~~ lakh rupees. (c) is likely to be injurious to health shall be liable to a penalty which may extend to ten lakh rupees.	imposed a stiffer penalty.
39.	Page No: 61 Chapter XII, Sec 92, **Power of Food Authority to make regulations.** Subpoint (1)	(1) The Food Authority may, with the previous approval of the Central Government and after previous publication, by notification, make regulations consistent with this Act andthe rules made thereunder to carry out the provisions of this Act.	(1) The Food Authority may, with the previous approval of the Central Government and after previous publication, by notification, make regulations consistent with this Act andthe rules made thereunder to carry out the provisions of this Act. No regulations can be made if there is no provision of such matters in the act. Regulations must be in consistent with the act.	FSSAI has a power to make regulations these can never be for product approval**since there is no provision of product approval in the act.**
40.	Page No: 61 Chapter XII, Sec 92, **Power of Food Authority to make regulations.**	(2) In particular, and without prejudice to the generality of the foregoing power, suchregulations may provide for all or any of the following	(2) In particular, and without prejudice to the generality of the foregoing power, suchregulations only ~~may~~ provide for all or any of the	FSSAI has a power to make regulations with respect to subpoints (a) to (v) under subsection 2 of Section 92 of Chapter

SERIAL NO	PAGE NO & DETAILS	CLAUSES AS PER GUIDELINES	CHANGES SUGGESTED	REASONS
	Subpoint (2)	matters, namely:-	following matters, namely:-	XII of FSSA.
41.	Page No: 63 Chapter XII, Sec 93, **Laying of rules and regulations before Parliament.**	Every rule and every regulation made under this Act shall be laid, as soon as may beafter it is made, before each House of Parliament, while it is in session, for a total period ofthirty days which may be comprised in one session or in two or more successive sessions, andif, before the expiry of the session immediately following the session or the successivesessions aforesaid, both Houses agree in making any modification in the rule or regulation orboth Houses agree that the rule or regulation should not be made, the rule or regulation shallthereafter have effect only in such modified form or be of no effect, as the case may be; so,however, that any such modification or annulment shall be without prejudice to the validityof anything previously done under that rule or regulation.	Every rule and every regulation made under this Act shouldshall be laid, as soon as may be after it is made, before each House of Parliament, while it is in session, for a total period ofthirty days which may be comprised in one session or in two or more successive sessions, andif, before the expiry of the session immediately following the session or the successivesessions aforesaid, both Houses agree in making any modification in the rule or regulation orboth Houses agree that the rule or regulation should not be made, the rule or regulation shallthereafter have effect only in such modified form or be of no effect, as the case may be; so,however, that any such modification or annulment shall be without prejudice to the validityof anything previously done under that rule or regulation.	It is the underlying requirement of FSSA that rules and regulations have to be placed before and passed by both houses of parliament before the same is notified, gazetted and implemented.

SERIAL NO	PAGE NO & DETAILS	CLAUSES AS PER GUIDELINES	CHANGES SUGGESTED	REASONS
			If any rule or regulation does not exist in the Act as passed by both houses of Parliament, or is not notified nor gazetted, the same cannot be imposed under any pretext except as provided under the scope of the act.	

Note:

1. The changes in regulations must be consistent as per the rules as suggested / laid down in the Act.
2. The suggestions for the FSSA given are as per the existing details as appearing on: http://www.fssai.gov.in/portals/0/pdf/food-act.pdf as on 30th December 2014.

DR R K SANGHAVI
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30th December 2014