



INDIAN DRUG MANUFACTURERS' ASSOCIATION

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INDIAN PHARMACEUTICALS FOR GLOBAL HEALTH

23rd January 2015

Smt. Anuradha Prasad,
Joint Secretary to the Government of India,
Ministry of Food Processing Industries,
Panchsheel Bhawan, August Kranti Marg,
Khelgaon, New Delhi.

Recd.
[Signature]
28/1/15

Dear Madam,

Ref.: Proposal for amendment in Section 22

This is in reference to our previous communication with your office with the dated **19th Jan'15** regarding concerns of our stakeholders and members who are severely affected in last 2 years due to complexity of **FSSAI** operations.

We understand that you are in the process of reviewing the **FSS Act** to carry out amendments for which you have invited proposal and representation from various associations across the industry sector and **IDMA** earlier in last week had already submitted the detailed proposal to your office and had requested for the appointment for representation.

However, we further understand that you are looking forward to specific proposal for amendments in **Section 22 of FSS Act**.

As desired, please note that we have reviewed the **Section 22** comprehensively within the committee of **IDMA Nutraceutical Subcommittee** as well as taken consultation of various healthcare associations and several other stakeholders representing **HealthCare Sector** operating under **Section 22** with history, experiences and establishment of business operations for several decades.

While reviewing and preparing a proposal, we have considered the balance interest of consumer safety, stakeholders' interest / protection and keeping Quality & Standards of Food Products.

Please find enclosed herewith proposal for amendment of **Section 22** from HealthCare sector. We are sure that our proposal will positively enlighten the **MOFPI** with our objective & balance approach for the **sectorial growth and development to support mission of our respected and honourable Prime Minister, - Make In India!**

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As you may be aware, **IDMA** organisation which is more than 53 Years old organisation and a Voice of National Sector has always and consistently worked towards interest of Consumer safety, stakeholders & flourishing our Nation with Industrialization, Development & Growth.

Respectfully to mention that our endeavour is to support the cause in all means and brings harmony in the **Healthcare sector** to flourish.

We sincerely look forward to your kind consideration of our proposal while carrying the amendment in **Section 22 of FSS Act**.

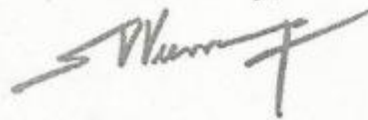
We have shared our balance and transparent views to bring the matter to rest and in harmony towards common objectives, including for the **HealthCare Sector**.

We would appreciate if while amending the **Section 22 of FSS Act**, proposal of **IDMA** is considered and would once again request you to kindly invite committee to represent our views and suggestions.

Thank you for your support and co-operation.

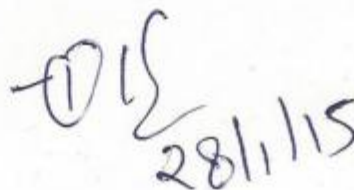
Look forward to work together and represent for "**Joint Mission Of our Nation - Make In India**"

Yours sincerely,



S Veerramani
President

- Cc: 1. **Hon'ble Shri. J P Nadda ji**,
Minister of Health and Family Welfare,
Nirman Bhawan, New Delhi
2. **Shri Lov Verma, IAS**,
Secretary (Health),
Nirman Bhawan, N.Delhi
3. **Shri Siraj Hussain, IAS**,
Secretary,
Ministry of Food Processing Industries,
August Kranti Marg, New Delhi
4. **Shri Navneet Singh Kang, IAS**,
Addl. Secretary & DG - CGHS,
Nirman Bhawan, New Delhi



Review: FSS ACT2006

Proposed Reformulation of Section 22

Section 22: Proprietary foods

(1) Proprietary food, means an article of food for which no food product standards are laid down.

(2) Proprietary foods shall comply with all applicable regulations made under this Act and shall not be unsafe.

Section 22A: Foods for special dietary uses or functional foods or nutraceuticals or health supplements

(1) FSSAI may by Regulations, specify the standards and guidelines in relation to manufacture, distribution, sale or import of foods for Foods for special dietary uses or functional foods or nutraceuticals or health supplements and such Regulations shall alone be applicable for the products falling under this sub-section 22A (1).

The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist and.

- (i) Are not represented for use as a conventional food
- (ii) Do not include a drug as defined in clause (b) and ayurvedic, sidha and unani drugs as defined in clauses (a) and (h) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and rules made thereunder;
- (iii) Do not claim to cure or treat any specific disease, disorder or condition (except for certain health benefit or such promotion claims) as may be permitted by the regulations made under this Act;
- (iv) Do not include a narcotic drug or a psychotropic substance as defined in the Schedule of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) and rules made thereunder and substances listed in Schedules E and EI of the Drugs and Cosmetics Rules, 1954; (New section to be inserted) Section 22A: Genetically modified foods, organic food, Novel Foods and irradiated.

Section 22B: Genetically modified foods, organic food, Novel Foods and irradiated foods FSSAI may by regulations, specify the standards and guidelines in relation to manufacture, distribution, sale or import of organic food, irradiated food, genetically engineered or modified foods and Novel foods.

The following definition maybe shifted under section 3

1. Organic food
2. Irradiated food
3. Novel Foods
4. Genetically engineered or modified food

Definitions to be included under Section 3:

1. “foods for special dietary uses or functional foods or nutraceuticals or health supplements” means:

(a) foods which are specially processed or formulated to satisfy particular dietary requirements or which exist because of a particular physical or physiological condition or specific diseases and disorders and which are presented as such wherein the composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist and may contain one or more of the following ingredients, namely:

(i) plants or botanicals or their parts in the form of powder, concentrate or extract in water, ethyl alcohol or hydro alcoholic extract, single or in combination;

(ii) minerals or vitamins or proteins or metals or their compounds or amino acids or enzymes, not exceeding established Upper Tolerable Limits as may be specified in the Regulations;

(iii) substances from animal origin;

(iv) a dietary substance for use by human beings to supplement the diet by increasing the total dietary intake;

and shall include such other categories or types of foods as may be notified by Regulations issued in this behalf.

2. “Novel Foods” means:

A novel food” means an article of food containing an ingredient which has no history of safe use in human.

3. “Genetically engineered or modified food means”:

Genetically engineered or modified food” means food and food ingredients composed of or containing genetically modified or engineered organisms obtained through modern biotechnology, or food and food ingredients produced from but not containing genetically modified or engineered organisms obtained through modern biotechnology;

4. “Irradiated Foods” to be defined as deemed appropriate.

5. “Organic Foods” to be defined as deemed appropriate.