

FOOD SAFETY AND STANDARDS ACT, 2006



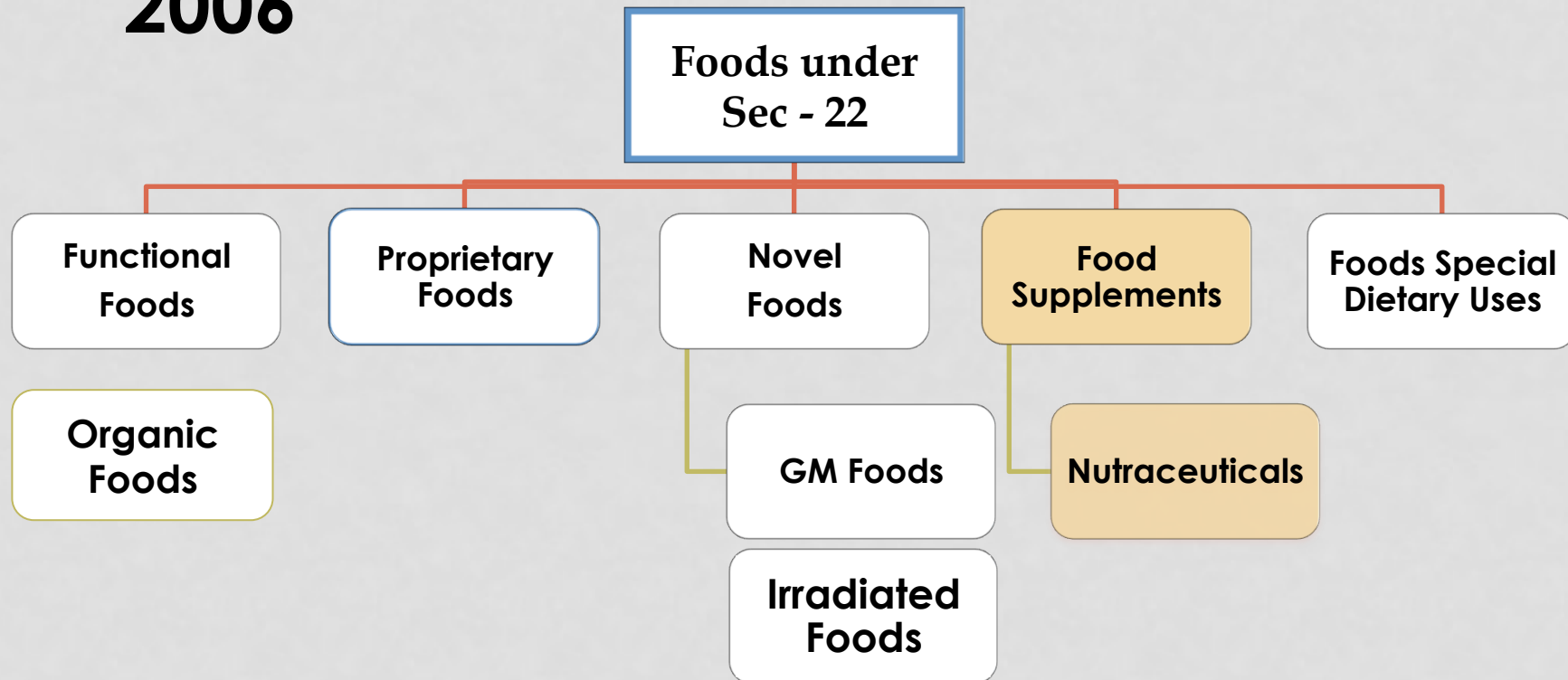
SECTION 22:

INDIA

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**IADSA Annual General Meeting
Prague
26 April 2016**

Food Safety and Standards Act 2006



- ❖ Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Food For Special Dietary Uses, Foods for Special Medical Purpose, Functional Foods and Novel Food) Regulation 2015
- ❖ Draft Notified: 30th July 2015; public comments

Definitions

“ Food or Health Supplements” means the foods which are intended to supplement the normal diet of a person and which are concentrated sources of one or more nutrients, like minerals, vitamins, proteins, mineral complexes, amino acids or enzymes, other dietary substances, plants or botanicals, substances from animal origin or other similar substances with know and established nutritional or beneficial physiological effect and which are presented as such and are offered or in combination , but are not drugs as defined in the Drugs & Cosmetics Act, 1940 and the rules made thereunder.

. . . marketed in single use packaging or in dosage form, namely forms such as capsules, tablets, pills and other similar forms, sachets of powder, etc., or any other similar forms of liquids and powders designed to be taken in measured unit quantities and . . .

“ Nutraceuticals” means a naturally occurring chemical compound having a physiological benefit or provide protection against chronic disease, isolated and purified from food or non-food source and may be prepared and marketed in the food format or granules, powder, tablet, capsule, liquid or gel and may be packed in sachet, ampoule, bottle, etc. and to be taken as measured unit quantities

Food Supplements & Nutraceuticals



Schedule	Description
I	List of Vitamins & Minerals EC 46/2002 <ul style="list-style-type: none"> ❖ 13 Vitamins ❖ 14 Minerals (except Fluoride)
II	List of Vitamins & Minerals and their components EC 46/2002
III	List of Essential Amino Acids <ul style="list-style-type: none"> ❖ Essential amino acids ❖ Non essential amino acids
V	ASU Ingredients: Plant or Botanical source <ul style="list-style-type: none"> ❖ Approx. 313 substances ❖ Part(s) to be used ❖ Extracts not mentioned
VI	ASU Ingredients: Animal Sources <ul style="list-style-type: none"> ❖ 9 sources: includes: milk, ghee, honey, etc
VII	ASU Ingredients: Mineral or metal <ul style="list-style-type: none"> ❖ Approx 19 sources; includes: gold, asphaltum, etc

Food Supplements & Nutraceuticals



Schedule	Description
VIII (a)	List of Food Additives for Food (some exceptions) Codex 13.6
VIII (e)	List of Food Additives to be used at GMP Codex: Table 3
IX	List of Nutraceuticals <ul style="list-style-type: none">❖ Approx. 300: Includes: Echinacea, ginkgo, Ginseng, glucosamine, hoodia, krill oil. CoQ10❖ Food Supplements - use of enzymes

AWAIT NOTIFICATIONS



- ❖ Expect a few more changes (comments under review)
- ❖ Product Approval regulation under preparation
 - ❖ Will be notified for comments.



THANK YOU

