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Webinar: "Draft Regulations on Nutra & Health Supplements and Others"

September 11, 2015
Starts at 3 pm IST

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Today's Speakers

- Dr. Pawan Vats
- Dr. Saurabh Arora

Dr. Pawan Vats

- Vice President (Food Safety) at Auriga Research Ltd
- Ph.D in Chemistry, Post Graduate in Foods & Drugs Analysis
- Previously with Department of Food Safety, Government of NCT of Delhi
- Training of Food Safety Officers, Designated Officers, Adjudicating Officers, PGDFSQM for IGNOU
- Review of Food Safety Act & rules, Delhi PFA rules
- Food Safety and Standards Act, Rules & Regulations with different industry bodies
- Third Party Auditor-BRC Global Standard for Food Safety

Dr. Saurabh Arora

- Ph.D in Pharmaceutics
- Founder: FoodSafetyHelpline.Com
- Director: Auriga Research Ltd
- Director: Arbro Pharmaceuticals Ltd (Arbro Analytical Division being one of the largest food testing laboratories in India)
- Leading the services business of Arbro and Auriga for over 9 Yrs
- Managing 5 food testing labs and a team of over 300 people

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What now after PA?

Are these draft regulations the way forward?

What is the validity of these regulations ?

Why these regulations stand where the PA system via advisories failed?

Structure of the Food Safety & Standards Act, 2006

- Food Safety & Standards Act, 2006
- Food Safety & Standards Rules, 2011
- Food Safety & Standards Regulations, 2011

Food Safety & Standards Regulations

- **Food Safety and Standards (Licensing and Registration of Food businesses) Regulation, 2011.**
- **Food Safety and Standards (Packaging and Labelling) Regulation, 2011.**
- **Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011**
- **Food Safety and Standards (Prohibition and Restriction on sales) Regulation, 2011.**
- **Food Safety and Standards (contaminants, toxins and residues) Regulation, 2011.**
- **Food Safety and Standards (Laboratory and sampling analysis) Regulation, 2011.**
- Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical purpose, Functional Foods, and Novel Food) Regulations, 2015

Supreme Court's Say on Product Approval Advisory Dated May 11, 2013

- To Govern Section 22, FSSAI Issued advisory
- Challenged in Bombay High Court
- Bombay High Court's Stay on PA advisory
- Supreme Court Upholds Bombay High Court's Order
- FSSAI stopped Product Approval Process

Section 22

- As per Section 22 of the Food Safety and Standards Act, 2006 (FSSA), “no person shall manufacture, distribute, sell or import any novel food, genetically modified articles of food, irradiated food, organic food, foods for special dietary uses, functional foods, neutraceuticals, health supplements, proprietary foods and such other articles of food which the Central Government may notify in this behalf, Except as per the FSS Act and the Regulations made thereunder

What all is broadly covered in the draft regulations?

Draft Regulations on Nutraceuticals

Food Safety and Standards (Food or Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical purpose, Functional Foods, and Novel Food) Regulations, 2015

Important points

- First Draft
- Objections & Suggestions to be submitted till September 23, 2015
- Wide Definition for Food Products covered under Section 22
- Composition of Food Products
- List of Additives to be used
- Specific Labelling Requirements/Declarations
- Food Authority's prior approval still required in certain conditions

Regulation 2 - Definitions

- Foods containing prebiotic ingredients
- Foods containing Probiotic Ingredients
- Foods for Special Dietary Uses (FSDU)
- Food or health supplements
- Foods for Special Medical Purposes
- Nutraceuticals
- Novel Foods
- Specialty Foods containing ingredients based on Ayurveda, Unani and Siddha and Traditional Health Systems of India

Essential Compositions

Regulation 3: Foods for Special Nutritional purposes or dietary uses

- Foods intended for normal consumption by their special composition
- Foodstuffs must differ significantly from the composition of normal foods of comparable nature
- Shall be manufactured specifically as supplements to regular diet either for general maintenance of health or in certain physiological or disease conditions
- Shall fulfill the characteristics as laid down in these Regulations

Regulation 4: General conditions for manufacture and sale of foods

- The formulation of the foods shall be based on sound medical or nutritional principles
- No hormones or steroids or psychotropic ingredients shall be added in these foods
- The labels shall clearly mention the purpose, the target consumer group and the physiological or disease conditions which they address, apart from the specific labelling requirements

Regulation 4: General conditions for manufacture and sale of foods

- The labels, accompanying leaflets /or other labelling and advertising of all types of foods, referred to in these regulations shall provide sufficient information on the nature and purpose of the food as well as detailed instructions and precautions for their use and the format of information
- A food, which has not been particularly modified in any way but is suitable for use in a particular dietary regimen because of its natural composition, shall not be designated as “Food Supplements” or “Special Dietary” or “Special Dietetic” or by any other equivalent term and such food may bear a statement on the label that “this food is by its nature “X”

Regulation 5: Food or health supplements

Essential Composition

- Vitamins & Minerals as Specified in Schedule I

Schedule I – List of Vitamins & Minerals

- Should Be in forms as given in Schedule II

Schedule II – List of Vitamins & Minerals & Their Components

- Amino Acids as specified in Schedule III

Schdule III – List of Amino Acids

Regulation 5: Food or health supplements

Essential Composition

- Plants or Botanicals as specified in Schedule V

Schedule V – ASU ingredients (Plants or Botanical sources)

- Substances from Animal Origin as specified in Schedule VI

Schedule VI – ASU ingredients (Animal sources)

Minerals or Metal Sources as specified in Schedule VII

Schedule VII – ASU ingredinents (Minerals or Metal Sources)

Enzymes as specified in Schedule IX

Schedule IX – List of sources of Nutraceuticals

Regulation 6: Nutraceuticals

Essential Composition

- Vitamins & Minerals as Specified in Schedule I

Schedule I – List of Vitamins & Minerals

- Should Be in forms as given in Schedule II

Schedule II – List of Vitamins & Minerals & Their Components

- Amino Acids as specified in Schedule III

Schdule III – List of Amino Acids

Regulation 6: Nutraceuticals

Essential Composition

- Plants or Botanicals as specified in Schedule V

Schedule V – ASU ingredients (Plants or Botanical sources)

- Substances from Animal Origin as specified in Schedule VI

Schedule VI – ASU ingredients (Animal sources)

Enzymes as specified in Schedule IX

Schedule IX – List of sources of Nutraceuticals

Regulation 7: Foods for Special Dietary Uses

Essential Composition

- Vitamins & Minerals as Specified in Schedule I

Schedule I – List of Vitamins & Minerals

- Should Be in forms as given in Schedule II

Schedule II – List of Vitamins & Minerals & Their Components

- Amino Acids as specified in Schedule III

Schdule III – List of Amino Acids

Regulation 7: Foods for Special Dietary Uses

Essential Composition

- Plants or Botanicals as specified in Schedule V

Schedule V – ASU ingredients (Plants or Botanical sources)

- Substances from Animal Origin as specified in Schedule VI

Schedule VI – ASU ingredients (Animal sources)

Minerals or Metal Sources as specified in Schedule VII

Schedule VII – ASU ingredinents (Minerals or Metal Sources)

Enzymes as specified in Schedule IX

Schedule IX – List of sources of Nutraceuticals

Regulation 8: Foods for Special Medical Purposes

Essential Composition

- Amino Acids as specified in Schedule III

Schdule III – List of Amino Acids

- Vitamins & Minerals as per the level specified in Schedule IV

Schedule IV – Values for Vitamins, Minerals and Trace elements allowed to be used in FSMP other than those intended for use by infants

Regulation 8: Foods for Special Medical Purposes

Essential Composition

- Plants or Botanicals as specified in Schedule V

Schedule V – ASU ingredients (Plants or Botanical sources)

- Substances from Animal Origin as specified in Schedule VI

Schedule VI – ASU ingredients (Animal sources)

- Minerals or Metal Sources as specified in Schedule VII

Schedule VII – ASU ingredinents (Minerals or Metal Sources)

- Enzymes as specified in Schedule IX

Schedule IX – List of sources of Nutraceuticals

Regulation 9: Food containing Probiotic Ingredients

Essential Composition

Only the probiotic cultures of specific strain of the microorganisms as specified in Schedule X

Schedule X – List of Strains as Probiotics (Live Micro-Organisms)

Regulation 10: Food containing Probiotic Ingredients

Essential Composition

Only Prebiotics specified in Schedule XI

Schedule XI – List of Prebiotic Compounds

Essential Composition

Foods & Health Supplements may contain ingredients used in Ayurveda, Siddha and Unani System Medicines as specified in Schedules V, VI, VII and Plants & Botanicals as specified in Scheduels V, VI and VII

Schedule V – ASU ingredients (Plants or Botanical sources)

Schedule VI – ASU ingredients (Animal sources)

Schedule VII – ASU ingredinents (Minerals or Metal Sources)

Novel Foods

Product Approval Required

Approval Process:

- the common name of the novel food;
- (ii) the name and address of the manufacturer **or** importer;
- (iii) a description of the novel food;
- (iv) details of the product;
- (v) ingredients used;
- (vi) technology and production process involved including method by which it is manufactured, prepared, preserved, packaged and stored;
- (vii) proposed claim or declarations to be made on the label along with sufficient scientific data;
- (viii) documents related to safety and efficacy of the food;
- (ix) information relating to its development;
- (x) method(s) of analysis;

Novel Foods

Approval Process:

- estimated shelf life of the product;
- (xii) adverse effect, if any;
- (xiii) details of the major change, if any, from conventional foods;
- (xiv) information relating to its intended use and directions for its preparation;
- (xv) information relating to its history of use as a food in a country other than India, if applicable;
- (xvi) information relied upon to establish that the novel food or ingredient or process is safe for consumption;
- (xvii) information relating to the estimated levels of consumption by consumers of the novel food;
- (xviii) the text of all labels to be used in connection with the novel food;
- (xix) the name and title of the person who signed the application and the date of signing;

Novel Foods

Approval Process

- the following information shall be included in any claimed novel foods, namely:-
- (a) chemical composition of the engineered food;
- (b) surface modification/ surface chemistry;
- (c) primary particle size;
- (d) solubility;
- (e) digestibility;
- (f) amount of nanomaterial if any in the food product;
- (g) specific claim, if applicable.

Labelling as per FSS (Packaging & Labelling) Regulations, 2011

Will prior approval still be needed?

Conditions where PA is required

- Any nutrient which is presented as that may result in certain nutritional and physiological benefits, but has no safe history and evidence
- Nutraceutical Product which does not have a data for safe history in India but safety has been established in other countries.
- In case where Health Claims are made, Documentation with valid evidence will be reviewed by the Food Authority
- If plant or mineral or any ingredient which does not have a safe history in India and not in the list specified under Schedule V, VI, VII, a prior approval is required
- Novel Food Products

RDA Limits

- The quantity of nutrients added shall not exceed the recommended daily allowance as per ICMR guidelines

- In case of foods for special medical purpose, if nutrients exceeds RDA limits then scientific evidence should be available, if the scientific data is not available then specific approval has to be obtained by Food Authority.

How will the quality of the products be controlled?

Purity Criteria

- Purity Criteria for Nutrients like Vitamins & MInerals shall be as determined and notified by the Food Authority

- Where the Purity criteria for nutrients like Vitamins & Minerals is not prescribed, the purity criteria from international bodies like Codex Alimentarius may be referred

- Must comply the requirements of regulations on contaminants.

- Microbiology?

Are there any new labeling requirements?

Common Labelling

- General guidelines as per Food Safety & Standards (Packaging & Labelling) Regulations, 2011.
- Common name of the food product
- Product shall bear a statement, “This product is not intended to diagnose, treat, cure or prevent any disease
- Statement – To be stored out of reach of the children
- Warning for side effects, contraindication & product-drug interactions
- Label shall bear a statement – “NOT FOR MEDICINAL USE”

Specific Labelling Declarations

<u>For Health Supplements, following information on the label</u>

- "FOOD or HEALTH SUPPLEMENT"
- "Not to exceed the recommended daily dose"
- Statement indicating that 'food or health supplement should not be used as a substitute for varied diet

Specific Labelling Declarations

For Nutraceuticals, the following information on the label

- "NUTRACEUTICAL"
- Recommended Usage
- Warning for the risk of excess consumption

Specific Labelling Declarations

Foods for Special Dietary Uses, the following labelling declaration

- "FOOD FOR SPECIAL DIETARY USES"

- For weight management products, the following declaration

"For the Weight Control and Management"

Also, need to mention for the above that the product shall not be used by pregnant, nursing and lactating women.

- A prominent statement if the product is formulated for specific age group

Specific Labelling Declarations

Foods for Special Medical Purposes, the following labelling guidelines

- "FOODS FOR SPECIAL MEDICAL PURPOSE"
- The Statement, "RECOMMENDED TO BE USED UNDER MEDICAL ADVISE ONLY"
- The statement, "For the dietary management of ....."
- The Statement, "NUTRITIONALLY COMPLETE", if intended to be used for the purpose

Specific Labelling Declarations

Foods containing Probiotic Ingredients, the following guideline;

- "PROBIOTIC FOOD"
- Genus, species, strains, designation or International Culture Collection Number
- Recommended service size
- Proper storage temperature conditions

Specific Labelling Declarations

<u>Foods containing prebiotic ingredients, the following guidelines;</u>

- "PREBIOTIC FOOD"
- Recommended Serving Size

Specific Labelling Declarations

Speciality Foods Containing ingredients based on Ayurveda, Unani and Siddha and Traditional Health Systems in India

Labelling Guidelines as per FSS (Packaging & Labelling) Regulations, 2011

Prohibitions on labelling claims

For Nutraceuticals Products

- Cure of disease claims, e.g. “Prevents bone fragility in post menopausal women”
- Implied cures for disease claims through pictures, vignettes or symbols

Is any backup data needed for making claims?

Specific Labelling claims on valid data & evidence

For Nutraceutical Products

- For word ‘Shown’:

e.g.

Product(…name of the product) is shown to be helping in keeping your heart healthy”

For word ‘Proven’

e.g.

Product(…name of the product) is proven to make you loose weight

Can the authority ask for or evaluate supporting data?

Are there any grey areas after this regulation?

Still missing

The information the following food products is missing

- GM foods
- Proprietary foods
- Irradiated food
- Organic Foods
- The Microbiological Parameters have not been discussed

Way forward for industry

- Match product composition to these regulations
- Use the draft as basis for all new products
- Meet the labeling requirements
- Make sure supporting data is available
- Comply regulation on contaminants

How we can help You?

About ARBRO and AURIGA

'Arbro Analytical Division' is known to be among top 5 national level labs in India. Arbro is FSSAI approved and is accredited by NABL.

Auriga Research is an emerging multidisciplinary contract research and testing organization supported by an established analytical division, working with premier clients across all industries and around the world.

The analytical & CRO units are managed by highly qualified and skilled professionals and equipped with all the required instruments for the analysis of Pharma, Food and other articles on various parameters with using techniques like HPLC, HPTLC, GCMC and LCMSMS. Our services include client sample analysis, method development and validation, stability studies, etc

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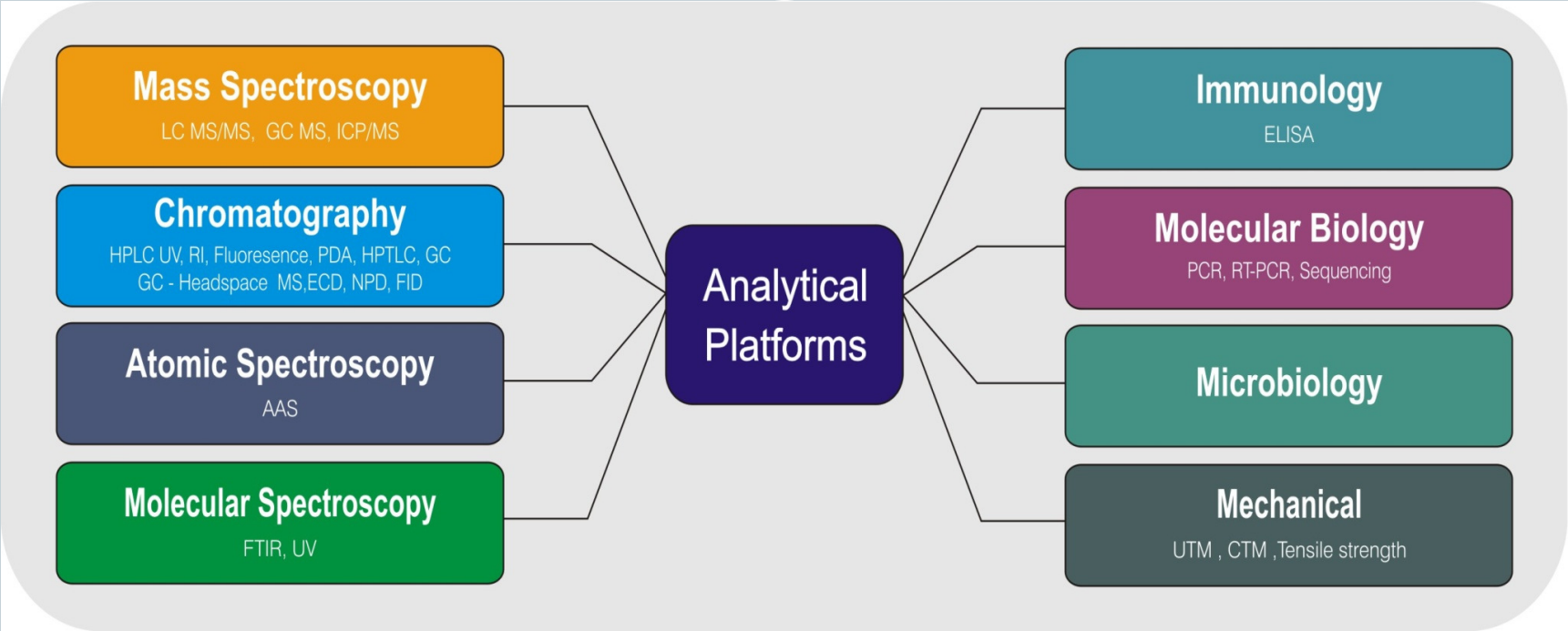
Our Strengths



professionals in 5 labs!

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Accreditations & Approvals

- FSSAI - 2012
- NABL – ISO\IEC 17025 : 2005 - 01-08-2003
- BIS - 10-01-2005
- R & D – DST - 01-06-1990
  (Dept. Of Science & Technology)
- Directorate of ISM & H - 05-02-2004
- APEDA (Agricultural and Processed Food Products Export Development Authority) - 15-01-2004
- AGMARK - 23-10-2008
- Approved by Russia – FSVPS - 03-05-2009
- ISO 9001:2008 - 12-02-1998
- Drug Control Dept. NCT, Delhi - 31-01-1995 - GLP
- Global Fund -Jan 2011
- Recently Awarded NABL for Bangalore Lab

Our Services

- Label Review Services
- Analysis Report for product and ingredients
- Shelf life studies
- Clinical studies to establish claims
- Training on various requirements for
- Development of FSMS Plan
- Self & Expert Inspection

Questions

Thank you!

Any Questions, contact us at:
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