3 years of implementation of Nutra Regulation – a snapshot

PFNDAI Regulatory Meeting

14th June, 2019, Mumbai

The Positives

From ambiguity to a evolving regulatory framework

Defined categories, their nutrients, ingredients and additive requirements, conditions

Specific labelling, declarations and claims as per category

FAQs – help in implementation

General methods of sampling & analysis for testing of parameters

FSMS – GMP for manufacturing

ReCHaN – dedicated Resource Centre for Health Supplements & Nutraceuticals

Compliance related training for both industry and Regulators

Evolution from Dec 2016 – release of Gazette Notification

- The Nutra regulation came into force on the date of its release (except certain provisions)i.e. 23rd Dec 2016, however, compliance with the regulation was kept for 1st January 2018 – close to a gap of one year
- Compliance date extended for certain conditions
- Number of directions, orders, notices and drafts followed to address certain ambiguities and also ease implementation

Additional approval of New Ingredients - 2017

34th meeting of Scientific Panel discussed the suggestions for inclusion of new ingredients on 7th Feb, 2017

The panel also advised to create a Working Group (WG) to review the representations etc. the same was created on 23rd May, 2017

The WG met few times and recommended following inclusion in

Sch I: Coral calcium, Tocotrienols, Copper oxide and its forms not exceeding RDA i.e. 2mg / day, Selenium

Sch II: amendment of foot note : "suitable esters, derivatives, isomers and salts of amino acids"

Sch VI(Part A): 12 new ingredients including Glutathione, Colostrum etc. were included. American Ginseng extract gets into the approved list. **Part B** included Cranberry extract

Sch VII: 2 new probiotic strains added

Sch IV: added Dandelion(leaf, root and whole plant with a permissible range). There were few more plant / botanicals added

Implementation order : 29th Dec, 2017

For Sub regulation 21, the same shall be substituted:

- " Mere combinations of vitamins, including use of single vitamin, in dosage formats such as tablets…..at levels equal to 1 RDA or below shall be covered under these regulations", however,

further orders including latest extension dated 10th May, 2019 restricted that

- FBOs are allowed to continue with the formulation containing mere combinations of vitamins and minerals only up to 1RDA level in dosage formats, till 30th June, 2019 or till further orders, whichever is earlier,

Note: *1st one was never implemented and the second amendment was never discussed, however, released as Implementation order*

After sub regulation(4), following sub regulation shall be inserted, namely:

(5)No Food Business Operator shall advertise FSDU for general public.

Observation

Incongruity in the process of evolution

- **Proposed amendment vs subsequent orders**

Journey during 2017 - 2018

Important changes suggested in the implementation order – once again released for stakeholders comments-

- Mere combination of vitamins and minerals including single vitamin in dosage forms within 1RDA – to be governed under Food as Health Supplements
- Few ingredients like natural calcium sources, Tocotrienols, chondroitin, glucosamine, cranberry etc.
- Permissible usage range defined for most of the plants and botanicals
- Inclusion of ' suitable esters and salts of vitamins and salts, chelates of minerals may be used'
- Products containing vitamins including single vitamins at levels equal to or below RDA shall be permitted under FSDU and FSMP
- (5) No Food Business operator shall advertise FSDU for general public

Journey continues

- Specified usage of nutrients in HS and Nutraceuticals from various schedules
- Under FSDU, in Sub regulation (2), for clause (iv), provides

" a food business operator may add the quantity of the nutrients up to 50% of Tolerable Upper Level or up to 1 RDA, whichever is higher". In case, where TUL is not specified, FBOs shall not exceed 1RDA"

Schedule III: inclusion of Iron Oxide

Specific mention of compliance with general Packaging & labelling, Contaminants, Toxins etc. Methods of sampling and analysis and **Food Hygiene**

Food Hygiene: Compliance with Schedule IV

Observation:

- Inconsistency related to permissible RDA

Implementation order: 29th June, 2018

In suppression of the direction dated 29th Dec, 2017

- Blanket approval for use of ingredients(as per Annexure 1) under various schedules came under restriction
- Data submitted for certain ingredients earlier were found insufficient for safety, FBOs were advised to discontinue use of such ingredients
- Further, FBOs were advised to stop using 14 different ingredients listed in the annexure with immediate effect due to inadequate safety data. No further manufacturing till further assessment and approval
- FBOs were allowed to continue manufacturing of formulations containing mere combination of vitamins and minerals up to 1RDAfor a period of 6 months from the date of this direction
- FSDU products were allowed to continue without declaration of energy on the Nutritional panel

Implementation order : 31st Dec, 2018

In continuation of the direction dated 29th June, 2018, the order further added

- Vit D 3 from lichen as veg source
- The order directed discontinuation of few more ingredients with a clear deadline of one month (30days) from the date of publication to clear the already manufactured / imported products
- Safety data : 15years in India and 30 years place of origin
- Further extension of 3 months provided for mere combinations of vitamins and minerals up to 1 RDA

Observation

- Conflicts on use of ingredients – " safety"

2019 – few more additions

New requirements / conditions

- (30) any single purified chemical entity listed in these regulations, except extracts of botanicals to be sold as HS or Nutraceuticals/ FSDU / FSMP, shall not be permitted without **prior approval of Food Authority**
- Regulation shall not apply to infants (age group 0 – 6months)
- HS / Nutraceuticals / Specialty products containing safe plant or botanicals or probiotics for age group of 7 to 24 months not permitted without prior approval of Food authority
- Safety data should include history of safe use of at least 15 years in India and 30 years in the country of origin
- Proposed inclusion of Camellia sinensis in different forms with usage range
- Proposed inclusion of Caffeine with a limit of 3mg /kg of body weight. Single dose not more than 200mg
- Few more pro biotic micro organisms were suggested for inclusion in Sch VII

Issues which needs attention / amendments

- Restriction on use of Nutra ingredients (Sch VI) in formulating Health Supplements
- Mere Combination of Vitamins including single vitamins to be governed under food
- RDA restriction for Health Supplements / Nutraceuticals
- Safety & Efficacy of ingredients - combinations
- New Ingredients and computation of History of safe use
- Format for Nutritional Declaration
- Tolerance / rounding off

- Thank you / any questions?