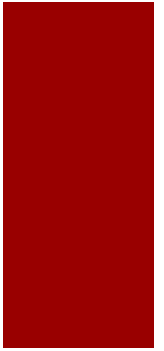


Regulatory thinking:

Proprietary foods and Product Approval



Protein Foods Nutrition Development Association of India (PFNDAI)
Hotel Vits, Mumbai

19th August, 2016

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26.08.2015: No longer able of continue product approval for products covered under S-22

Regulator stand -

- ❖ Adopted risk assessment towards non-standardized foods, . .
- ❖ Too many products within scope of S-22, to be standardized

Industry stand -

- ❖ The regulator does not have the power or authority to issue advisories

Dilemma: What is the crux of the issue ?

Industry says:

- ✧ Additives used in proprietary foods - safe. Hence no PA

Regulator reply:

- ✧ Single ingredient safety \neq product safety. Hence PA

Industry says:

- ✧ Where recipe is same for different FBO's. No PA

Regulator reply:

- ✧ Word 'proprietary' - means exclusive . Hence PA

What is the crux of the issue



1. Advisory/Notification?



Procedure

1. Safety ?



Risk Assessment

1. Standards?



Standardization

Risk Framework



SUBSTANCES
(added or present)



FOOD
FOOD PRODUCT
FOOD CATEGORY



FOOD
(Ingredients)

Sections 19-21

Food Additive

Processing Aid

Antibiotics,

Hormones,

Metal Contaminant

Microbial

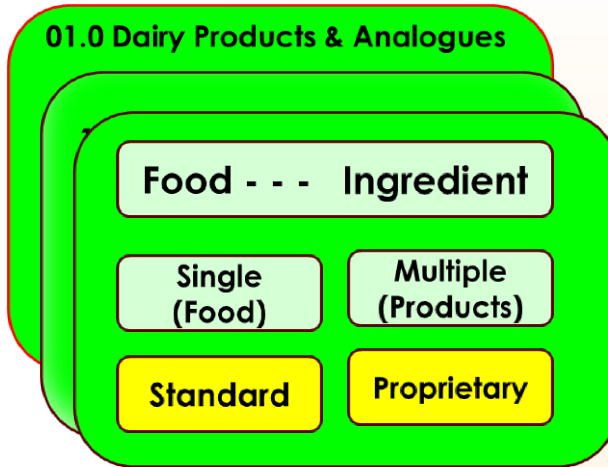
Toxins

Pesticide Residue



A
C
C
E
S
S

FOOD CATEGORIES (1-15)



A
C
C
E
S
S



Sections 22

History of Safe Use

Traditional

Novel

Technology

Traditional

Novel

Irradiation

GM, Nano



Ingredients not on Positive List: require Product Approval

| No | Name of Food/Category | Schedules: | Product Approval |
|----|---|--|------------------|
| 1 | Food Supplement | I, II, III, V, VI, VII, IX No history of safe use | PA |
| 2 | Nutraceuticals | I, II, III, V, VI, IX No history or safe use | PA |
| 3 | Foods for Special Dietary Uses (FSDU) | I, II, III, V, VI, VII, IX Any new nutrient | PA |
| 4 | Foods for Special Medical Purpose (FSMP) | III, IV, V, VI, VII, IX For any new nutrient | PA |
| 5 | Probiotics | Only probiotic cultures specified in X | PA |
| 6 | Prebiotics | Only those specified in XI | PA |
| 7 | Specialty Foods containing AYUS & TH Systems of India | if not specified in V, VI, VII. | PA |
| 8 | Novel Foods | No list provided | PA |



What is the gap?