

Proprietary foods ... freedom to innovate

GB Meeting:

Abbott Healthcare Pvt. Ltd. Mumbai

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Vice Chairman: Regulatory Affairs (PFNDAI)

Freedom to innovate means

✧ Freedom to use ingredients ...

✧ **Traditional** ✓

✧ **Novel**

✧ Freedom to market products

✧ **Consumer choice**

✓

✧ **Fair competition** ✓

Are freedoms shrinking 1984 ... 2016

Proprietary food defining 'enablers'

✧ **PFA - 1955 37-A (2)(3) 1984:** “a food which has

Not been standardized

✧ not been standardized under the PFA rules ⌘

✧ name of that food or category ⌘... on the label

✧ **FSSR -2011 (2.12):**

✧ not been standardized under these regulations”... shall also..

Propriety food Product

○ name describing as clearly and/or category ⌘;

○ the proprietary food product ⌘ shall comply with.....

Are freedoms shrinking

Proprietary food defining 'controllers'

✧ FSSA - 2006: ...

- an article of food ☹ ... standards not been specified
- but is not unsafe" ☹

Not been standardized ...

But excludes ...
standardized

✧ FSSR - 2016 [2.12.1(1)]:

- an article of food ☹ not been standardized☹,
- but does not include ☹ Novel foods, FSDU FSMP , HS & N
- and such other food articles which the CG may notify in this behalf

excludes

Propriety food is a Product

Propriety food 'article of food'

Are freedom to innovate shrinking

Proprietary food defining 'controllers' - only those ingredients

- ❖ either standardized ⌘; or
- ❖ permitted for use other standardized food ⌘;
- ❖ **under these Regulations** ⌘;
- ❖ except **the ingredients** ⌘... notified by Food Authority

Not been standardized ...

.. excludes ... standardized

... or permitted for use

FAQ(4): meaning of “ under these regulations” ?

- Permitted ⌘ under FSSR (FSA & FA) 2011; or
- Already approved ⌘ PA process.

Compendium (22.01.2019)*

- Food Safety Standards and Regulations ?
- Indian Food Composition Tables, 2017

← includes

Propriety food is a Product

Propriety food 'article of food'

Proprietary food... can it contain ?

By definition...
.... “does not include”

**but..... “ under Food Safety and Standards
Regulations.... can it contain ?**

FSS (Health Supplements, Nutraceuticals, FSDU,
FSMP, FF, Novel Food (2016)

EPA

VI:123 : omega-3 α-linolenic)

Lutein

VI:103

Glucosamin

VI: 77

γ - linolenic acid

VI: 72

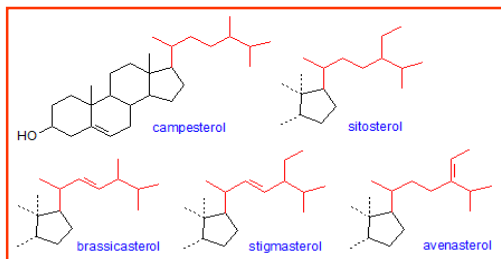
Psyllium husk (Isabgol)

IV: 305 as vegetable (5-10g)

VI: 146

Regulatory treatment - global practice

Phytosterols



Risk
Assessment
→

Novel food*

↓
Risk
Management

Authorizations for use in various foods....



Fat spreads
Nutraceutical



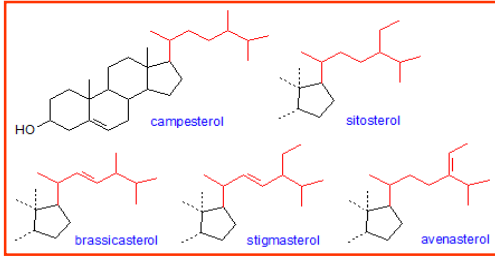
Yoghurt



* Commission Decision 2000/500/EC of 24 July 2000 on authorizing the placing on the market of 'yellow fat spreads with added phytosterol esters' as a novel food or novel food ingredient under Regulation (EC) No 258/97

Ambiguity versus Certainty

Phytosterols



Sc. Panel (Food Additives ..)

Approved

Food Additive*

Nutraceutical ingredient**



Fat spreads
Nutraceutical



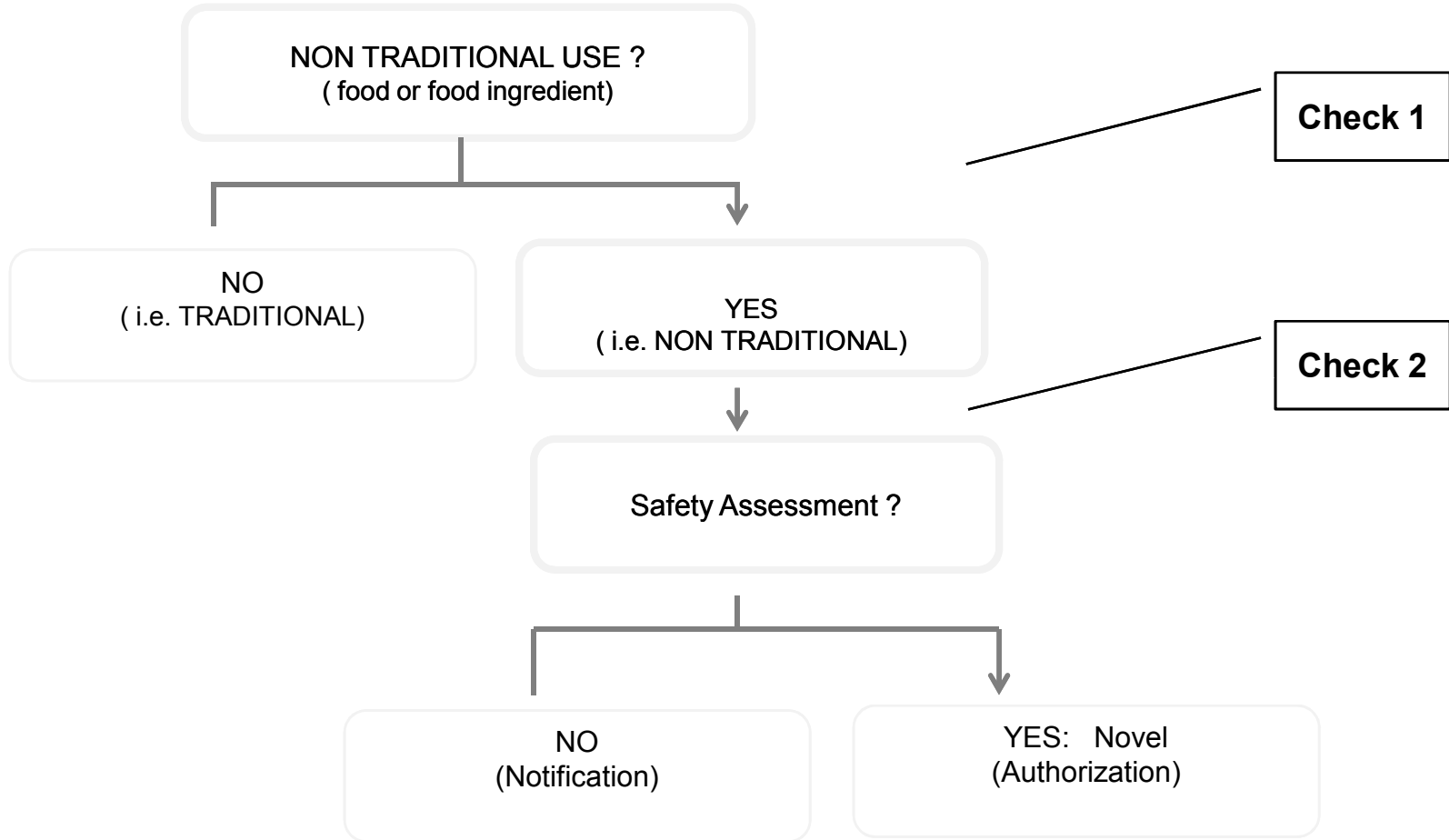
Yoghurt



* Food Safety and Standards (FPS+FA) 2016: 3.3.5

** FSS (HSN) Sch. VI: No. 168

Ingredient Use: Simple & transparent Process



Thank you