The Folly and Risks of Over-Regulation

Insights into proposed regulation of Proprietary Food

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Today's agenda

1. What the Proprietary Food regulations are and are proposed to be, as available in the public domain

2. What the Proprietary Food regulations *may become*, not available in the public domain

3. The risks for FBOs

4. The way forward for FBOs

What we know and what we don't know

1. Proprietary Food notification of January 2016 *…known*

2. FAQs of March 2016 *… known*

3. Proprietary Food notification of April 2016 (draft only) *…known*
4. Corrigendum dated 15th June, 2016 to the FAQs *…known*
5. Mystery 20-page document *….unknown*

1. **Existing Regulation, as in the public domain, current and proposed**

Current : Notification dated 12th January 2016, live

Proposed : Notification dated 19th April, 2016, draft, not live

Sub-regulation (1)

<u>The *new* regulation (Notification dated 12th Jan, 2016)</u>

<u>(also, *draft* Regulation, Notification dated 19th Apr, 2016)</u>

2.12.1**: For the purpose of these regulations, -**

(1) Proprietary food means an article of food that has not been standardi~~z~~sed under these regulations, but does not include any novel food, food for special dietary use, functional food, nutraceuticals, health supplements and such other articles of food which the Central Government may notify in this behalf.

- What does ***standardized*** mean ?
  - Not defined in the Act
  - Not defined in the Regulations

- Vertical standards or horizontal standards ?

Sub-regulation (2)

(2) Proprietary food shall contain only those ingredients other than additives which are either standardised ~~in these Regulations~~ or permitted for use in the preparation of other standardised food under these Regulations.

- What is meant by *ingredients other than additives* ?
- Ingredients are ingredients. Additives are additives.
- Under the *Act*, ingredients *include* additives
- This leads to a paradox or irony

Sub-regulation (3)

(3) Proprietary food shall use only such additives as specified for the Category to which the food belongs and such category shall be clearly mentioned on the label along with its name, nature and composition.

- What is meant by *Category* ? Where defined ?
- How about sub-category and sub-sub category …?
- Not defined in the Act, nor in the Regulations
- Something in the FAQs, will discuss that separately

Sub-regulation (4)

4) Proprietary food product shall comply with the food additives provisions as prescribed in Appendix A and the microbiological specifications as prescribed in Appendix B of these Regulations and all other Regulations made under this Act.

- What is a ***Proprietary Food product*** **?
- Is this something different from ***Proprietary Food*** ?

** used in the singular !

Sub-regulation (5)

(5) The Food Business Operator shall be fully responsible for the safety of the proprietary food.

- *Which* Food Business Operator ? (note the *singular* and the use of the word *"The"*)
- What is the intention here ?
  - Manufacturer ?
  - Warehouse keeper ?
  - Distributor ?
  - Transporter ?
  - Retailer ?
- If one of the above is fully responsible, then none of the others is at all responsible !

FAQ conundrums

Puzzles in the FAQs

No deviations from standardized food !

- "Any deviation from a **standardized food** shall not qualify a food as proprietary food" (FAQ 2(ii))
- Why the **lens** of standardized food at all ?
- Who is the regulator to decide ? Deviation from *what* ?

- How is this compatible with the Constitution of India Article 19(1) (g) ?

  All citizens shall have the right to practise any profession, or to carry on any occupation, trade or business

Pre-cursor to Product Approval ?

Amended Regulation 2.12.1 (on proprietary food) is likely to be a precursor to Product Approval regulations

SHOW ME THE SCIENCE !

- Vitamins and minerals confined to 1 RDA (earlier 30% of RDA) (FAQ 4(iii))
- Is % of RDA now a risk measure ?
- Where is the science in this ? (Risk assessment, Sec 18, etc.)
- The long title of the Act says that the Act is : *An Act to consolidate the laws relating to food and to establish the Food Safety and Standards Authority of India for laying down* ***science based standards*** *for articles of food*

Technical issue

- “Special Purpose Foods” (FAQ 9)

No such phrase in the Act or the Regulations.

This is super-regulation

Technical issue

- Provision not made for FBOs that have not got product approvals in the past (FAQ 11)

- Discriminatory treatment !

Substantive issue

- In case of final product FBO should ensure that that the food does not contain any pathogenic organism at a level that could render it unsafe (FAQ 12)

The term "*unsafe food*" is already legally defined in Sec 3(1) (zz) of the Act, with 12 criteria (i) to (xii) mentioned therein. The addition of this new concept of the presence of *any pathogenic organism at a level that could render it unsafe* is a forced, thirteenth criterion over and above the Act. Keeping this text in the FAQ amounts to super-legislation !

Legality of FAQs

- There is no provision in the Act for issuing FAQs
- The FAQs do not mention any source of law or origin or basis or justification for their existence
- Recall the validity (or rather, the absence of validity) of “advisories”. Advisories suffered the same defect as FAQs do now.

2. **What the Proprietary Food regulations *may become*, not available in the public domain**

Things possibly regulated

- Final Products
- Ingredients
- Additives

Omnibus Product Approval Process in the works ?

Something new now …

"***<u>Pre – standardization permission</u>*** **for foods"**

The presumption is that not being standardized makes the food "bad" and therefore requires permission ?

Why PA Regulations at all ?

A negative list already exists ! Those Regulations exist !

Food Safety and Standards (Prohibition and Restrictions on sales) Regulations, 2011

So what is the gap in the existing Regulations that justifies new Regulations for Product Approval ?

Is there a mixing-up of the concepts of *standard* and *regulation*?

Various Application Forms (Forms A,B,C)

Proprietary Food will need approval

No timeline specified !

“Pre Market authorization”

“***Non-Standardized Food***”

“Traditional Food”

"***Identity Standards***"

(also referred to in FAQ 2(i))

"***Non-specified foods***"

"Exposure Assessment"

"Hazard Characterization"

"Food Safety Screening Committee"

“Post-market surveillance”

SHOW US THE LAW !

- What Section of the Act ?
- What Rule ?
- What Regulation ?
- What international precedent or global practice ??? (remember Sec 18 (2)(a) (ii) of the Act requiring FSSAI to take into account *international* practices)

Is it even necessary ?

- Regulations should be concerned with food safety
- Product approval regulation amounts to playing God with food product compositions, builds and market launches (unfettered powers to dictate business matters)
- There is a mix-up between identity and safety standards.
- Regulations should instead focus on safety hygienic practices, employee health, workplace health, HACCP, FSMS, and so on
- That is what the food industry really needs

Summing up…

The food industry *needs* all these proprietary food regulations like a *fish needs a bicycle*

3. The risks for all of us

Risks

1. Existing food is a question mark. Business continuity ?
2. New Product launches could be hit by delays
3. FSSAI licenses of FBOs and those of their suppliers up the chain could be not renewed ... Interruption of business ?
4. Uncertainty and unavailability could lead to Rs. crores' worth of damage to brands

4. The way forward for us

Way forward for us

- New Product launch *processes* to be rewritten ?
- Representations through scientific multi-FBO bodies
  - PFNDAI
  - Others
- Request a move to an *intimation and time-bound* regime, not an *approval and indefinite* regime (take the example of industrial licensing and automatic approvals from *1991*)

Q & A

THANK YOU !