

Unease of doing business

Regulatory Committee Meeting

19 Dec. 2018

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Vice Chairman:

Regulatory Affairs Committee PFNDAI

Changing the Indian state from bully to ally

. . . much of India’s regulatory cholesterol for employers is not driven by economic justifications—consumer protection, market failures, information asymmetry and externalities—but reflects what economist Cass Sunstein calls expressivism; where values rather than facts are used to make policy.

The toxic regulatory cholesterol

Changing regulations frequently makes life miserable for MSMEs and breeds informality

	Possible annual compliances	Possible filings every year	Changes last year
Labour/HR	27,191	1,890	288
Finance	9,871	797	3,725
Environment, health & safety	2,534	86	10
Corporate laws	1,490	44	168
Commercial laws	5,530	355	293
Sebi	3,043	18	326
RBI	1,545	64	62
FSSAI	1,647	8	72
Other regulators	7,891	120	87
TOTAL	60,472	3,382	5,031

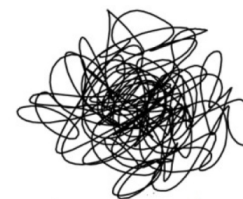
Source: Avantis Regtech database

Business and regulation drafts . .

✧ **Unease in** business . . .

✧ anxiety over complexity of texts

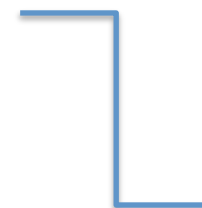
✧ unsure of compliance traps



✧ **Ease of doing** business . . .

✧ minimal operational difficulty

✧ predictable process



Serving size

Starts from the Labelling “Notice”

Serving size: “or”

Regulation No FSSR- (PL)2011: (2.2.2.3)

- ✧ Nutritional Information per 100 g or 100ml or per serving . .
- ✧ Where declaration per serving, the amount in gram (g) or milliliter (ml) shall be included beside the serving measure

Nutritional Information		
Servings per package: 3		
Serving Size: 150g		
	Quantity per serving	Quantity per 100g
Energy	608kj	405kj
Protein	4.2g	2.8g
Fat, total	7.4g	4.9g

Shows how much of the nutrient is in one serving. The serving size is determined by the manufacturer

Use the 'per 100g' column to compare foods

NUTRITION INFORMATION		
Serving per package: 4		
Serving size: 250 mL (1 glass)		
	Per serving	Per 100 mL
Energy	63 kcal	25 kcal
Protein	0 g	0 g
Total Fat	0 g	0 g
Saturated Fat	0 g	0 g
Carbohydrate	15.7 g	6.3 g

Easier to compare nutrients of two similar products

Nutrients you would get from 1 serving of food

Serving size: the issue with “and”

Notice Notice (LD)2018: 4.2.(3)(b): Nutrition Information

- ✧ Information per 100g or 100ml of the product **and** per serve percentage (%) contribution to RDA
- ✧ Amount of food in gram(g) or ml(ml) beside the serving measure **and**
- ✧ the number of servings in the package

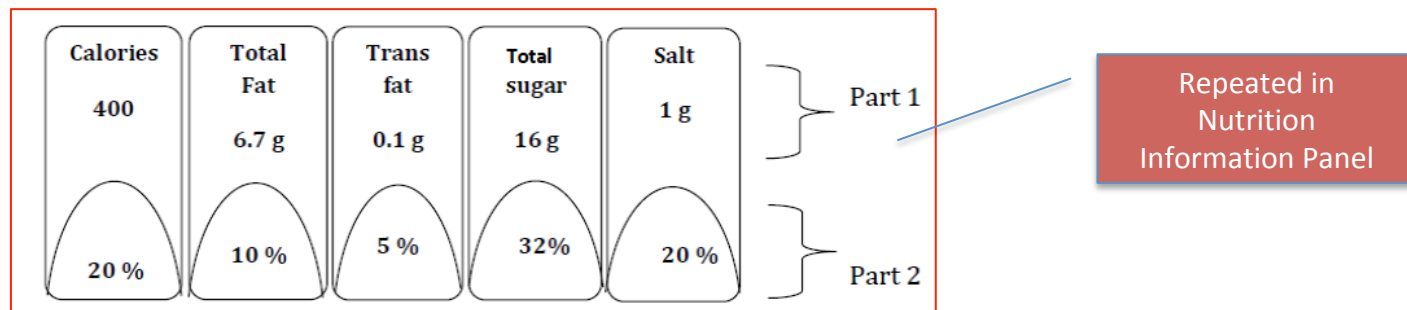
Nutrition Information		
Serving size: 1 Tbsp (17g)		
Servings about: 29		
	100g	% RDA
Energy (kcal)	88	4
Protein (g)	0	0
Carbohydrate	24	2
Sugars	24	8
Total Fat (g)	0	0
Saturated fat (g)	0	0
Trans fat (g)	0	0
Cholesterol (mg)	0	0
Salt (g)	2.4	8



Serving size: issue with “and”

Notice (LD)2018: 5.(4)(a, b, c): Principal Display Panel

✧ Front of Pack - declare **per serve** energy, total fat, trans fat, total sugar and salt to RDA as below:



- ✧ Part (1): Declares the amount of energy, total fat, trans fat, total sugar and salt (sodium chloride) **per serve**;
- ✧ Part (2): Declares the **per serve percentage** (%) contribution to RDA as provided under regulation 4.2 (3) (b);

Serving Size: FSSR (AC) 2018

4.(5)

General Principles

Claims shall specify number of servings of food per day for **claimed benefit**

- Nutrition Claims ✗
- Health Claims (Sch. III) ✓
- Health Claims (Sch. IV): Fortified foods - *per serving required ?*

Health Claims

7©

- a statement of the quantity of a nutrient or a substance that is the subject of the claim;
 - per 100g or 100ml **or per pack** (single consumption pack);

Serving Size: FSSR (AC) 2018

- Sch. III. 2(a)**
- Specified amount of nutrient/ingredient per serving (e.g. 1g);
 - Daily intake of the nutrient (e.g. 3g of nutrient X) for claimed benefit

-
- Sch. I
(6) & (15)**
- Nutrient Content Claims: per 100g or 100ml.
 - Free Trans Fat: food shall contain less than 0.2g per 100g/100ml
 - Source Probiotics: Contains $\geq 10^8$ CFU recommended servings per day

Definitions

Definition: Nutrient

means any substance normally consumed as a constituent of food: **(Notice: PD 2018)**

- ✧ provides energy ; or
- ✧ needed for growth and development and maintenance of healthy life; or
- ✧ a deficit of which will cause characteristic bio-chemical or physiological changes to occur.

Example- Vitamins, minerals & trace elements, protein, carbohydrate, fat, fiber, and substances which belong to or are components of one of these

means a constituent of food, which: **(FSSR-AC-2018)**

- ✧ provides energy ; or
- ✧ has specific metabolic or physiological functions; or

Dietary Fiber

Dietary Fiber

FSSR(LD) 2018

means carbohydrate polymers with a degree of polymerization (DP) **not lower than 3**, which are not hydrolyzed by the endogenous enzymes in the small intestine of humans.

Dietary fiber consists of one or more of

Dietary Fiber (dextrin soluble fiber)

FSSR (FPS/FA) 2016; 2.11.8

means glucose polymer of natural origin obtained by dextrinification, i.e. dry roasting acidified starch under specific conditions and further purified. The average degree of polymerization of Dietary Fiber (Dextrin – soluble fiber) **is from 12-25** compared to

several thousand for starch

Definition ?

“**balanced diet**” means a diet containing all essential (macro and micro) nutrients in **optimum** quantities and **in appropriate proportions** that meet the requirements;

“**equivalence claims**” means claims **that attempt to promote** the equality **in value**, amount **and importance** of one food attribute to another;

Several changes post public notice

Several changes

Final Notification: 19 Nov. 2018

Draft Notification: 13 Mar 2018

All disclaimers related to a claim shall be **conspicuous and legible.**

All disclaimers related to a claim shall appear in **the same field of vision.**

No advertisement shall be made for food products which is **deceptive to the consumers.**

X

The equivalence claims in form of phrases such as

X

✧ "contains the **same amount** of [nutrient] as a [food]"

✧ and "**as much** [nutrient] as a [food]"

Several changes

Final Notification: 19 Nov. 2018

Draft Notification: 13 Mar 2018

Non-addition of salt (**Sodium chloride**)

Non-Addition of **Sodium Salts**.-

- The food contains no ingredients that contain sodium salts that are used to substitute for added salt.

7.(1)(a);

physiological role of the **nutrient or substance***

physiological role of the **nutrient or substance**

*PFNDAl suggested definition of “ **other substance**” means a **substance other than a nutrient, that has a nutritional or physiological effect** (EC 1924/2006)*

NOT ACCEPTED ?

Several changes

Final Notification: 19 Nov. 2018

physiological role of the nutrient or substance*

Draft Notification: 13 Mar 2018

physiological role of the nutrient or substance

PFNDAI suggested - “other substance” (not defined) in regulation “

other substance” means a substance other than a nutrient, that has a nutritional or physiological effect (EC 1924/2006)

THE LOOKING-GLASS WORLD

"When I use a word," Humpty Dumpty said, in rather a scornful tone, "it means just what I choose it to mean – neither more nor less."

"The question is," said Alice, "whether you can make words mean so many different things."

"The question is," said Humpty Dumpty, "which is to be master – that's all."