

Regulatory Practices: Interpretation and Compliance

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What Is Regulation?

- Any measure or intervention implemented under government authority
- Acts to control the behaviour of individuals or groups that come within the ambit of that authority.

Regulation Includes

- The primary laws (Act)
- Subordinate instruments
- and the rules/ guidelines/ advisory etc

Five Principles of Good Regulatory Practice -

- Good governance
- Rigorous impact assessment
- Scientific basis and proportionality
- Open consultation
- Minimal restrictiveness -

- Standards and regulations are well-designed to achieve their intended objectives.
- They can be effectively enforced.
- Regulations that are poorly designed and implemented can create unnecessary technical barriers to trade. (Leighton-ASEAN)

The APEC Guidelines for the Preparation, Adoption and Review of Technical Regulations

Simple but effective analytical tool.

The checklist

1. Has the problem been clearly identified?

2. Have all the options to address the problem been considered?

Has the design and implementation of technical regulations been considered ?

Have performance-based regulations and/or standards been considered?

- Have international standards and obligations been considered?
- Have compliance mechanisms been considered?
- Have provisions for review and monitoring of the technical regulation been considered?

- Has consultation taken place?
- These Guidelines have been endorsed by APEC Senior Officials and referred to other APEC fora for consideration and use where appropriate.

Tools for Regulatory Analysis

Cost-benefit analysis is a useful tool to decide whether a particular regulatory response is the most appropriate in a given situation.

It enables decision-makers to make judgements about the reasonableness of a regulation and the practicalities for those who will be required to comply.

It also allows regulations to be designed so that they impose the lowest costs and yield the greatest benefits.

A major consideration when undertaking a cost-benefit analysis is the assessment of risk

... the direct results of inappropriate regulation are likely to be higher costs, higher prices, misallocation of resources, a lack of product innovation and poor service quality. OECD

NO ADDED MSG

***Example 1**

- The product shall bear a statement, **“This product is not intended to diagnose, treat, cure or prevent any diseases.”**
- Minimum viable numbers of probiotics strain at the level at which the efficacy is claimed and at the end of the shelf-life; ($\geq 10^8$ / CFU/g)

* Example 2
FSSAI draft regulation -
Probiotics

- PS: These organisms may be used either singly or in combination but must be declared on the label with full information and has to be non-GMO.

* RDA as a limit for
addition of nutrients

* Example 3

Example 4

NO Added Sugar- Label

- Added sugar is chemically identical to sugars naturally found in the foods
- **Food companies will have to utilize calculations to determine the amount of added sugar**
- Manufacturers to keep records verifying the amount of added sugars present in each step of processing for each food product .
- Jennifer and Slavin: Nutrients 2015

- A study conducted by the Turner Research Network, asked consumers to look at food labels and determine the total amount of sugar in the product.

- According to preliminary data, participants who were shown a label that only had “sugars” listed, 92% were able to accurately identify the total amount of sugar.
- When “added sugars” was added below the “sugars” category, only 55% accurately identified the amount of total sugar. Jennifer and Slavin: Nutrients 2015

- Notably, 52% of participants thought that the “added sugars” were in addition to the total amount of sugars listed on the label .
- The inclusion of the “added sugars” category appears to make interpreting the Nutrition Facts label more difficult and may actually be doing the opposite of what the FDA had hoped to do.
- Jennifer and Slavin: Nutrients 2015

EFSA Panel on Dietetic Products,
Nutrition, and Allergies (NDA);

Scientific Opinion on Dietary Reference
Values for carbohydrates and dietary
fibre.

EFSA Journal 2010; 8(3):1462 [77 pp.]

The term “added sugars” refers to sucrose, fructose, glucose, starch hydrolysates (glucose syrup, high-fructose syrup) and other isolated sugar preparations used as such or added during food preparation and manufacturing.

Sugar alcohols (polyols) such as sorbitol, xylitol, mannitol, and lactitol, are usually not included in the term “sugars”.

_However, they are partly metabolised and included in “carbohydrates” according to the European legislation.

Main dietary sources of sugars

- Fruits, berries, fruit juices, some vegetables,
- **Milk and milk products,**
- Foods containing added sucrose and starch hydrolysates (e.g., glucose syrup, high- fructose syrup) such as carbonated beverages and sweets.

Sugars

Frequent consumption of sugar-containing foods can increase risk of dental caries,

Available data do not allow the setting of an upper limit for intake of (added) sugars on the basis of a risk reduction for dental caries

Caries development related to consumption of sucrose and other cariogenic carbohydrates does not depend only on the amount of sugar consumed

- The evidence relating high intake of sugars (mainly as added sugars), compared to high intakes of starch, to weight gain is inconsistent for solid foods.
- Some evidence that high intakes of sugars in the form of sugar-sweetened beverages might contribute to weight gain.
- The available evidence is insufficient to set an upper limit for intake of (added) sugars based on their effects on body weight.

Observed negative associations between added sugar intake and micronutrient density of the diet are mainly related to patterns of intake rather than to intake of added sugars *per se*.

The available data are not sufficient to set an upper limit for (added) sugar intake.

Some evidence that high intakes (>20 E%) of sugars may increase serum triglyceride (TG) and cholesterol concentrations

and >20 to 25 E% might adversely affect glucose and insulin response

Available data are not sufficient to set an upper limit for (added) sugar intake.

(WHO now recommends 10% E Max)

Glycemic index and glycemic load

Experimental evidence that a reduction of the dietary glycemic index and glycemic load may have favorable effects on some metabolic risk factors such as serum lipids,

Evidence for a role in weight maintenance and prevention of diet-related diseases is inconclusive.

Thank you