REGULATORY PRACTICES: INTERPRETATION AND COMPLIANCE

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Regulation has been defined as any measure or intervention implemented under government authority and acts to control the behaviour of individuals or groups that come within the ambit of that authority.

The regulations laid down under the Food Safety and Standards act is the authority and all Food Business Operators (FBO) are those who are regulated. Regulations include the following

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

Off these the Act is sacrosanct and cannot be changed unless it is done by the Parliament while all others could be changed or modified or removed etc through pre defined processes which would be mentioned in the act.

Regulation is not only as good as the act, rules and regulations but also the way in which they are executed. Execution depends on the following and these are defined as Good Regulatory Practices (GRP)

Five Principles of Good Regulatory Practice -

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

Good Governance is the manner in which the executive authority vested with the powers, manage the entity. Their motivation, understanding of the issues, reliance on good scientific advice, unbiased approach, management capacity and compliance with good practices followed elsewhere in the world decides the quality of governance.

Impact assessment- There has to be a continuous feed back on the impact of regulatory decisions and this leads to constant improvement in the regulatory processes. Every regulation is laid down with an objective and if such an objective cannot be achieved then the regulation needs to be re looked and redone to attain those objectives.

Scientific basis and proportionality: Food regulation is entirely based on scientific facts and evidences and not on perceptions of individuals or political views nor on peer reviewed opinions available from non authentic sources. Science itself keeps evolving and the same shall be applied to regulations as well. Sometimes regulations may be applicable in some situations and not applicable in another due to practical limitations hence there should be a scope for proportionality within each regulation.

Open consultation: This is generally followed in food regulation and is the cornerstone for evolving a good regulation. Opinions are likely to be highly varied but invariably the consumer, the FBO, scientists and the regulator should come to a common ground to achieve a meaningful regulation.

Minimal restrictiveness: Regulation facilitates trade with safety and benefits of the consumer in mind. It is never meant to be restrictive. Food Business needs innovation and novelty to provide the best benefit to consumers. Restrictive regulations will lead to

very standardized foods and leaves very little scope for improvement in food standards through innovations.

Design of standards

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

The APEC(Asia Pacific Economic Cooperation) have developed guidelines for the Preparation, Adoption and Review of Technical Regulations: A simple but effective analytical tool to make good regulations. This includes a check list which needs to be adhered to before framing the regulation.

1. Has the problem been clearly identified?
2. Have all the options to address the problem been considered?
3. Has the design and implementation of technical regulations been considered?
4. Have performance-based regulations and/or standards been considered?
5. Have international standards and obligations been considered?
6. Have compliance mechanisms been considered?
7. Have provisions for review and monitoring of the technical regulation been considered?
8. Has consultation taken place?

Cost- Benefit analysis of a new regulation (OECD)

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)

Examples of non enforceable regulations are

1. NO ADDED MSG on label when there are no analytical methods to differentiate between MSG inherent in foods and MSG which as been added as an additive
2. NO ADDED SUGAR – when we cannot differentiate between naturally present sugar and additional sugar.

Most regulations should be based on scientific evidences of a) Efficacy and b) A risk assessment process

Efficacy related check list:

1. Is there any benefit due to the product / an ingredient
2. If yes what are the biological/ chemical/ biochemical characteristics of the product / an ingredient
3. What is the minimum quantity and duration when you observe an effect
4. Is this available in a single serve or multiple, if multiple then how many servings are recommended per day
5. Can the benefit be quantified or identifiable through a marker
6. Are there any differences in the requirement in different physiological conditions
7. Is there a claim being made if yes then the nature of the claim and appropriate available scientific evidences to make such a claim

Risk Assessment check list
1. Is there a hazard if so what is the hazard
2. Can we quantify the risk and the probability of the risk(probability of such a adverse effect happening)
3. Is there a Lowest Adverse Effect Level (LOAEL)
4. Arrive at a No Observed adverse effect level
5. Is there an intake assessment and how likely is the 95 percentile intake to go beyond NOAEL
6. Is there any need for a risk communication on the label e.g. "Do not exceed two servings in a day"
7. If there is a risk due to excess what are the ways of managing such a risk.

Conclusion:

Good regulatory practices depend on regulations made out of good basic science, valid and published scientific evidences of efficacy and safety along with good management practices