

FOOD ADDITIVES - SAFETY & QUALITY: REGULATORY NORMS

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Food additives are chemicals, biochemical, ingredients etc., which are added to food products for their technological benefits. These benefits may be to preserve the quality of food, to maintain and improve its appeal, to ensure its nutritional value and to provide innovations in new products with consumer appeal and satisfaction. Additives are also added to maintain uniform quality and to enhance quality parameters such as flavour, colour, texture etc. in large-scale production. They and their by-products ultimately become part of the food that is consumed and so they must be safe.

Additives may be direct additives, which are added deliberately to improve its sensory quality, nutritive value, stability, ease in processing and retention of quality during handling and retailing. There are also indirect additives, which are not added intentionally but get included into foods incidentally during handling, processing and packaging.

There are some guiding principles for the use of food additives. They should be justified for their technological effectiveness and purpose. They should be safe for use. There should be maximum adequate levels, absolutely necessary levels of usage and ADI (Acceptable Daily Intake) properly evaluated while considering its safety and permitted usage levels in foods. They should not be added with the intention of misleading consumers about quality. They should also not significantly affect adversely the nutritional quality of food products.

Following are the Classes of Food Additives

- **Preservatives**
- **Food Colours**
- **Food flavours and flavouring agents**
- **Emulsifying, Stabilizing, Anti caking and Antifoaming agents**
- **Antioxidants**
- **Sequestering and Buffering agents/ Acidulants**
- **High intensity / low calorie sweeteners**
- **Vitamins and minerals**
- **Processing Aids**
- **Nutraceuticals**
- **Probiotics/Prebiotics**
- **Functional additives**

Consumer Concerns and Issues

Consumers today are quite aware of certain issues concerning food processing and additives are concerned about some aspects with respect to additives. Of primary importance is the issue of safety. Some additives have been banned because of their safety problems. This worries consumers and they are skeptical about many additives. They sometimes wonder whether there are health hazards associated of any of the additives over prolonged usage. Some media reports and activists who write about ill effects of some additives. This makes them more concerned about the safety issues.

Quality is another concern regarding use of additives. There have been reports in the past of use of some additives to hide poor quality. They feel that additives are added to misguide them about the quality of food products. Although this may be possible in some low quality products, most of the organized industry uses additives to improve the sensory quality but not to misguide consumers in that respect. However, this doubt gives rise to another issue and that is 'need to know'. They would like label declaration about additives so they can make a choice, between kinds of additives or without any additives.

Since there are additives that are natural and synthetic, and consumers feel natural are safe, these concerns regarding synthetic additives is also quite significant.

Among other concerns are packaging and the value for the money spent on packaged food products. Branded products have made a definite impact on consumers and many are willing to spend extra for branded, packaged food products although some may not. Another big concern about packaged foods is the claims on the labels. Some misleading and fraudulent claims in the past have created a negative image about claims. Consumers constantly are on guard about the claims.

Food Safety

Food safety in India is ensured by Government of India's Ministry of Health under the provisions of Prevention of Food Adulteration Act & Rules. They are responsible for Food Laws and the rules therein. State government Food & Drug Administration (FDA), which carries out surveillance using food inspectors, does the enforcement. There are food analysis labs, both state and central, which verify the authenticity of food products.

Any food safety legislation or standard, requires involvement of several aspects including Research & Development, Information & Documentation, Education & Training, Quality Assurance Program, Codex & International Norms, Advisory System, Planning, Enforcement and Surveillance. Various activities take place at different places such as education & research institutions, government laboratories, data bases including international & national, industry production and quality evaluation centers, and finally state level enforcement and surveillance departments. Due to the complex nature, any change in standards and enforcement has to be properly planned and executed after careful consideration of all these factors.

Food Additives: Approval Process

Any new additive before approving must undergo rigorous toxicity studies, including acute and chronic studies involving biochemical evaluation, teratogenic studies, reproductive studies besides the LD₅₀ tests. In the US, Delaney Clause governs the approval of any food additive, under which the additive is banned if found to be carcinogenic, under any condition or level, a very difficult zero risk condition.

However, exposure assessment is very important in determining the risk involving any additive under the modern practice of determining safety. The Risk Analysis, adopted nowadays involves, risk assessment, wherein the Hazard is identified & characterized, Exposure is assessed and thus risk is characterized. Once the Risk is assessed, it must then be managed so hazardous conditions do not arise. Finally the risk must then be communicated.

General Principles of Food Safety Risk Management

- 1: Risk management should follow a structured approach
- 2: Protection of human health should be the primary consideration in risk management decisions
- 3: Risk management decisions and practices should be transparent
- 4: Determination of risk assessment policy should be included as a specific component of risk management
- 5: Risk management should ensure the scientific integrity of the risk assessment process by maintaining the functional separation on risk management and risk assessment
- 6: Risk management decisions should include clear, interactive communication with customers and other interested parties in all aspects of the process
- 7: Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions

Risk Assessment Policy in JECFA and JMPR

In these policies, animal models are relied upon with certain assumptions to establish potential human effects. A 100-fold safety factor is used for many assumptions and variations between species. The policy does not assign any ADI to additives, drugs and pesticides that are found to be genotoxic carcinogens. This permits some of these contaminants to be at levels "as low as reasonably achievable" (ALARA).

It must be remembered that all substances (chemicals) are poisons. There is none that may not act as poison; only the right dose differentiates a poison and a remedy. Some of the known toxins are at times given as remedy and some of the nutrients and medicines at very high levels are toxic. No food substance is unequivocally safe or unsafe. The safety depends both on the amount in the diet and on level of its exposure. It is also important to know that both natural and synthetic additives must be considered from safety aspects.

Dietary Exposure

Dietary exposure of additives and other incidental chemicals is essential to evaluate exposure of some of the harmful chemicals. This requires a Dietary Intake Survey the design of which is very important in order to get an appropriate picture of total dietary exposure of various chemicals.

The Design of the Dietary Intake Survey should consider Target Population. Sometimes the survey is carried out to find out the intake of entire population in a particular region but many times it is restricted to Concerned Group, High Intake Group, Special Group like Children, Pregnant Women, Medical Target Group etc. While designing the survey, measurement of quantitative intake

is valuable. At times only certain special target products or specific brands are monitored to find out their intake and the exposure of chemicals through them.

The surveys may also be designed for shorter or longer duration. The shortest would be one day or one week study but at times study may be carried out for 90 days (sub-chronic) or even longer (chronic) especially when evaluating the safety of some of the chemicals. These are normally carried out with subjects being given specific amounts of chemicals/additives through food and then observing for any changes indicating effects. On the basis of these safety tests the ADI or MRL values may be decided after appropriate safety factors being taken for some exceptional cases.

Methods of Assessing Food Consumption

There are different methods of assessment of food consumption by a section of population. If the National consumption is to be assessed then all the food that is consumed is evaluated either by finding out domestic production and imports out of which the exports are deleted as well as losses due to spoilage or amounts which are stored for future. This will give total food consumed and dividing by the total population will give the individual average consumption.

The regional, household and individual consumption assessment requires more time, resources and expertise. The survey methods may include various forms or questionnaires, recording, estimation etc. and makes use of recall and/or diary kept by the subjects over a period of time. Once the amounts of various foods and products by individuals is estimated using food tables or by analysis, the exposure of food additives or chemicals through foods can be evaluated.

Food Additives: Regulations

There are different sets of regulations everywhere. Each country has its own set of rules for regulating food additives for example, US FDA Guidelines & Regulations gives the American regulations for food additives. Thus anyone producing and marketing food products in the US must abide by them. India has its own set of regulations under Prevention of Food Adulteration (PFA) Act & Rules. Each country has a set of regulations. When an Indian company wants to export to US, then it will have to follow the US regulations. When it wants to export to Australia their rules have to be followed. So there might be difficulties trying to follow many sets of regulations.

A group of countries may have a common regulation for example, European Union Directives, which give regulations for countries affiliated to it. This allows free exchange of food products across those EU countries. It avoids confusion because of many different regulations being followed for different countries. For international trade we have Codex, SPS, TBT regulations.

Under the WTO agreements, common regulations have been arrived at for those countries signatories to the agreement and this allows the international trade without much problems. FAO/WHO have come up with Codex rules, which are accepted by these countries.

Purpose of Law

The Food Laws or Regulations are made in order to protect people consuming these foods from undue risks, which may arise from processing, transport, retailing and consumption of food products which may undergo contamination, spoilage, inclusion of harmful chemicals/microbes or at harmful levels. Besides safety, consumers are also protected by these laws with respect to quality, quantity and substance that the food products are supposed to represent. Finally, laws also aim to protect the consumers from Nutrition and Health considerations with special consideration being given to vulnerable group such as infants, pregnant women etc.

Regulatory Environment: India

The Indian law, Prevention of Food Adulteration Act, 1954 & Rules, 1955, address consumer and safety concerns. There is legislation, which created authority and infrastructure to govern and enforce the law and also provisions for Rules and standards for various products in which even the type and amounts of various additives allowed are given. This is the major law, but there are many others like Fruit Products Order (FPO), MFPO (Meat Food Products Order), Milk & Milk Products Order, Edible Oils Order etc. which deal with specific group of products. There is weights and measures regulations, which not only include food products but also the other non-food products.

All the above are the mandatory food laws. Besides there are some optional food laws or standards referred to as quality standards, e.g. those of Bureau of Indian Standards (BIS) and Agmark, which are used when products are said to be of those qualities. Thus India has a number of laws, which may govern the same food products.

India has abundant agro-resources and in many cases tops the countries of the world in production. India is among the first two largest producers of fruits, vegetables, milk, food grains, tea, spices, sugar, cashew, livestock etc. In spite of this distinction, value

addition is very low, just under 7% compared to China's more than 22%. We process hardly about 2% of our horticultural produce and our share in world food trade is abysmally low, less than 0.1%. The investors are shy of processing, partly because of a myriad of complex laws that inhibit innovation and discourages value addition.

Challenges Before the Indian Food Industry

There are many challenges and opportunities for Indian food industry. Globalisation has made available large number of choices of various products like fruit juices, beverages, biscuits, confectionery products etc. Many of the products are imported and some more are waiting. This scenario has both positive and negative aspects. People are ready for many new products so there is scope for industry. However, the imports will make domestic products to compete with them and at times superior imported product might dominate even with higher price. This presents a threat perception for Indian industry.

There are possibilities of exports for Indian products, but at the same time there is need for compliance with such WTO agreements like SPS and TBT as well as Codex standards. These impose additional quality parameters to the industry geared to Indian standards.

Science and technology is making advances at rapid rate especially in the fields of Biotechnology and Genetically Modified Foods are making appearance abroad as a result. These have superior properties both from agricultural points such as disease resistance, minimal susceptibility to damage during shipping, etc. as well as consumer view points like better flavour, colour, etc. They also may cost less to produce as the losses are less. There are other technologies like irradiation and packaging innovations also contribute to better quality and lesser losses. Those who take advantage of these will have greater advantage in the market. GM Foods are not allowed in many countries and these and their by-products may require authentication, which might be a negative point.

Consumers are also forcefully expressing their preferences and concerns about food products with respect to quality, safety, nutrition etc. These concerns also may make an impact on the market scenario. Since the markets have become connected due to globalisation, speed in marketing a new product is critical as competitors may quickly try to emulate a successful product.

What are the Limitations of current Food Laws?

While the market scenario is not very friendly but highly competitive although there are many opportunities, any lack of support due to limitation in food laws is bound to make a negative impact on the industry. At present, there are many laws for same food products are at times they overlap or contradict one another. Many of the laws and standards are quite rigid and inflexible. There are rules, which lay down standards for hundreds of products with very little scope for innovation. This denies consumers the choice, which then will be provided by imported products and the market will be lost for Indian industry.

There is also weak enforcement and at times the implementation is ad-hoc and not uniform. This creates uncertainty among the industry about compliance, which may result in unjust harassment and threat of prosecution. This is not a healthy state for good growth of industry.

Live Issues: Are we addressing them?

Besides having regulations and safety evaluation on Food Additives, other emerging concerns, which need to be addressed are as follows:

GM Foods	Organic Foods
Traceability	Nutritional Claims
Food Scares	BSE; Avian Flu
Allergens	Animal By-Products
Food waste	Food frauds
Media flares	Microbial concerns
Residues	Heavy metals
Crisis management	Product recall systems

Why Integrated Food Law?

Integrated Food Law is imperative for just and focused enforcement as well as for healthy growth of industry. Many countries have unified food laws including USA, Malaysia, Thailand, Indonesia and Pakistan. There are examples of groups of countries that have come together and formulated unified common food laws. Examples are Australia and New Zealand as well as European Union countries. They not only have integrated laws but also laws conducive for healthy industry producing safe and high quality products. In many of these there is focus on in-process quality control rather than product testing. Enforcement is more interested in

compliance than prosecution. Minor or technical violations are compounded. Even the possibility of analytical error is recognised by these laws. There is also protection given to manufacturing processes and trade secrets.

The New Food Bill: August 2006

The scope of the Act has been widened a little to take care of some of the lacunae in the PFA Act. In the new Act, packaged water has been included as previously only the bottled mineral water was included in the PFA. Secondly, foods for special dietary uses or functional foods or nutraceuticals or health supplements etc. have been included in the Act. Earlier there was confusion since the enforcing agencies included these under drugs and wanted the drug license for the manufacture and marketing of these products.

This new Act should ensure the orderly development of food industry, as well as consumer safety by setting appropriate standards and uniform enforcement at the state level. It specifies offences and penalties for these offences, which are quite distinct and specific when compared with PFA. In order the proper regulation of the Act a separate body called Food Safety & Standards Authority of India (FSSAI) will be created. This body will have a full-time chairperson and will have representatives from Central and state governments, scientific bodies like CSIR & ICAR, Food & Beverage industry, consumer organizations, with a third of it to be represented by women. Its functions include, considering and approving act, rules and regulations, lay down standards, evolve guidelines for enforcement and supervision of implementation.

Among other features of the Act, Central Advisory Committee will be created to ensure close cooperation between the Food Authority and the enforcement agencies. It will have a CEO, who will be the legal representative in the Food Authority (FSSAI). There will be several scientific panels created of the subject matter experts for products and for consultations. They will also accredit laboratories. Scientific committees will be created which will provide opinions on multi-sectoral issues falling within the competence of more than one scientific panel and on issues not falling within the competence of any scientific panel.

Besides the general provisions on food safety, the Act provides for guidelines on analysis of food and offences and penalties under the Act. There is also provision for adjudication and Food Safety Appellate Tribunal to look into disputes arising out of the above.

Food Safety Administration [FSA]

FSA will be created for evolving guidelines for implementation and uniform enforcement of the Act and Rules and will be headed by an administrator not below the rank of a Joint Secretary to the Government of India. FSA will create training modules for central and state level food law enforcement officers. It will also ensure standardisation of operating procedures and development of infrastructure of accredited labs and analytical systems.

Offences And Penalties

Under the new Act, wilful adulteration would attract deterrent punishment. Spurious foods manufacture would be deemed to be wilful adulteration and would attract financial penalties based on the principle of “unjust enrichment”. Penalties will also be commensurate with the gravity of offence committed.

A new feature would be differentiation between substandard: with no health hazard, substandard: harmful to health and wilful adulteration and accordingly penalties will vary. There will a provision made for Appellate Tribunal for disputes.

The Challenge From National Food Security to Global Food Dominance

After the opening of the borders at the conclusion of WTO talks, the race for Global Market share is hotting up. Indian markets hitherto not very easily accessible for international players are considering opportunity in India. Unless we move rapidly forward, we are not only going to miss opportunities now available in international trade but we may have problems in domestic markets too as there will be international players coming into the competition. Currently, our processing, especially of value added processing, is abysmally low with less than 2% and there are very high wastages.

India has the potential to the world’s largest producer of processed foods due to its vast resources in terms of agricultural produce. The existing food laws and regulatory framework impedes the growth of Indian food industry and stifles innovation. Regulatory mindset needs to shift from the current prescriptive vertical standards & regulations to horizontal norms and guidelines. We have the opportunity now to change for better or we may miss the bus.

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