FOOD SCIENCE AND TECHNOLOGY

Lecture40

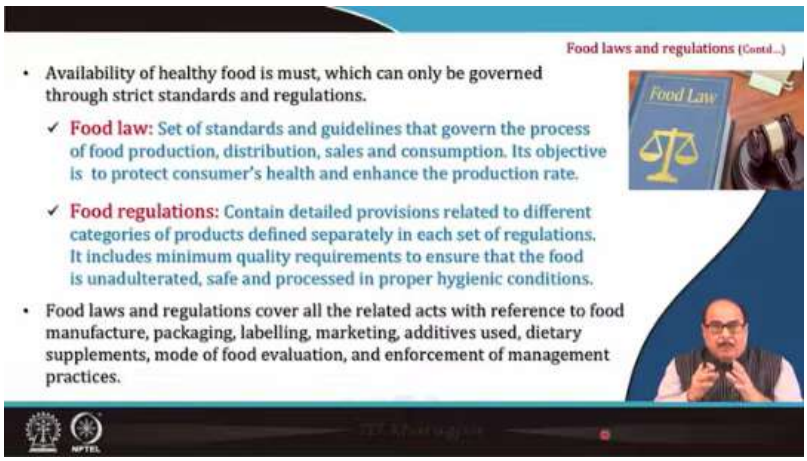
Lecture 40: International Regulations on Food Additives

Hello everyone, Namaste.

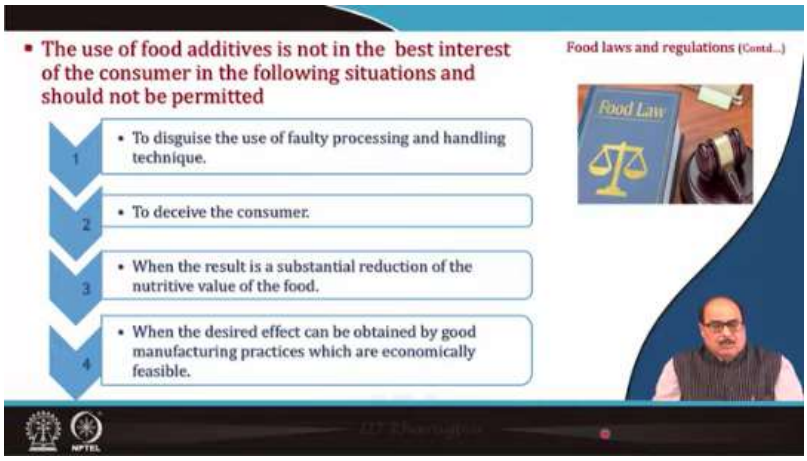
In this lecture today, we will talk about international regulations on food additives.

We will discuss the various food laws and regulations, Indian food laws, FSSAI guidelines, and standards on food additives. WHO and FAO guidelines on food additive applications, and finally, we will also briefly talk about the Codex Alimentarius Commission.

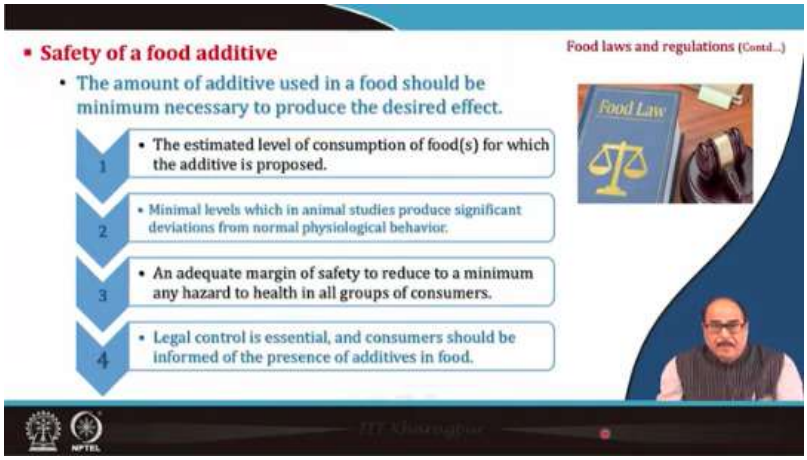
So, let us see what the food laws and regulations are. You know that having good-quality food, safe food to eat is a concern for every individual. And here, to meet this requirement—that the food given to the public is safe and of good quality— the government, food industry, and consumers all need to share the responsibility. The government's responsibility is to ensure that food quality and safety requirements are appropriate and adequately supported within the framework of the national food policy and that safety legislation and regulations are clearly communicated to the industry and consumers. The government must also provide efficient food control administrations, adequate and reliable food inspection and food analysis services, to ensure that the quality and safety requirements of the food are met by all. The food industry must ensure the quality and safety of its products through the implementation of quality assurance programs, including food safety programs based on the Hazard Analysis and Critical Control Point system. Compliance with all relevant regulations and so on. Even consumers must apply correct food handling practices. This is to avoid food quality and safety problems at the household level during consumption. So, everyone must take responsibility to ensure that the food is of good quality and safe to consume.



Availability of healthy food: It is a must and can only be governed by strict standards and regulations. So, food laws are basically a set of standards and guidelines that govern the process of food production, distribution, sales, and consumption. Their objective is to protect consumers' health. And enhance the production rate, manufacturing rate, or availability of food to the people. Food regulations contain detailed provisions related to different categories of products defined separately in each set of regulations. It includes minimum quality requirements to ensure that the food is unadulterated, safe, and processed under proper hygienic conditions. So, food laws and regulations cover all the related acts with reference to food manufacturing, packaging, labelling, marketing, additives used, dietary supplements, the mode of food evaluation and even the enforcement of management practices. So, all these are covered under the food laws and regulations.



So, we come to a specific topic: food additives. The use of food additives is not in the best interest of consumers in various situations. In those situations, it should not be permitted. So, what are those situations? Earlier, when we were discussing food additives and functional food additives, etc., we also shed some light on this aspect: the addition of any chemical to food should not be permitted if it results in disguising the use of faulty processing and handling techniques. if it deceives the consumer, or if the result is a substantial reduction in the nutritive value of the food. For example, if you add a chemical to preserve the food and extend its shelf life, its shelf life might get extended, but if its nutritional value is lost in the process, significantly, then there is no point in using such a chemical to extend the shelf life. Finally, when the desired effect is the effect which you want to get by adding the chemical, if it can be obtained by good manufacturing practices which are economically viable, then the addition of chemicals should be avoided.

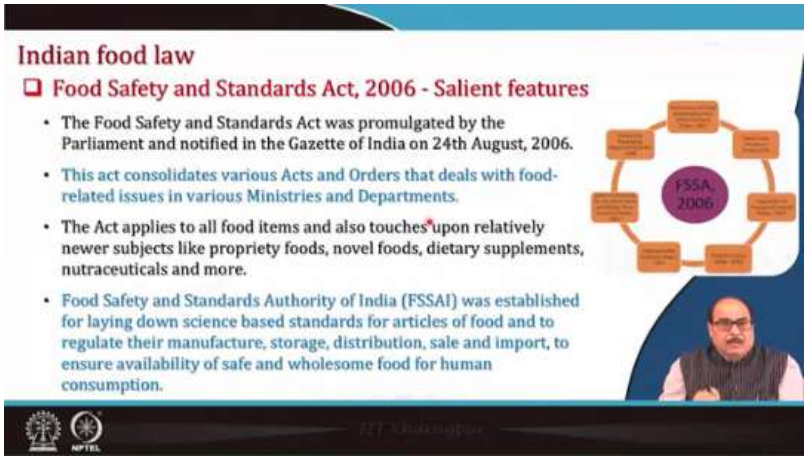


Then, the safety of the food additive, which is the chemical added to the foods, is very, very important. It must be safe. Its safety is the very major concern of all the regulators, industry, and even the consumers. So, the amount of additive used in food should be the minimum necessary to produce the desired effect and how that is the minimum necessary amount is obtained is estimated and based on the estimated level of consumption of foods for which additive is proposed that is how much likely a person is likely to consume that particular food daily or in 6 months or in a year. So, in all the data collected, and that is in the process of food, how much chemical is likely to be ingested or taken by the consumers? So, the minimum level in animal studies produces significant deviations from normal physiological behaviour. So, that should be taken into account even an adequate margin of safety to reduce to a minimum any hazard to health in all groups of consumers. Legal control is essential, and consumers should be informed of the presence of additives in the food.

Then, let us talk specifically about the laws and regulations for food additives. Regulations are food additives, which usually appear as a subsidiary instrument under the main food

legislation. regulations on food additives, which usually appear as subsidiary instruments under the main food regulation, should list the minimum requirement for their composition and quality. The additives may be used to exclude others. The foods in which they may be used and the maximum levels that can be used. So, all these things in formations must be included in the food additive regulations. And there are for example, the FDA monitors the safety of additives that is for example, one by hundred of the amount of an additive found to be safe in the lab animal. FDA has also given there is a GRAS list that all these chemicals which are recommended for use in food additives should appear on the GRAS list, which is the GRAS means generally recognized as safe. Then there are several chemical items may be 670 even more than that are recognized as GRAS chemicals by WHO and FAO or joint committee etcetera. So, it must be taken into account that these chemicals should be GRAS chemicals.

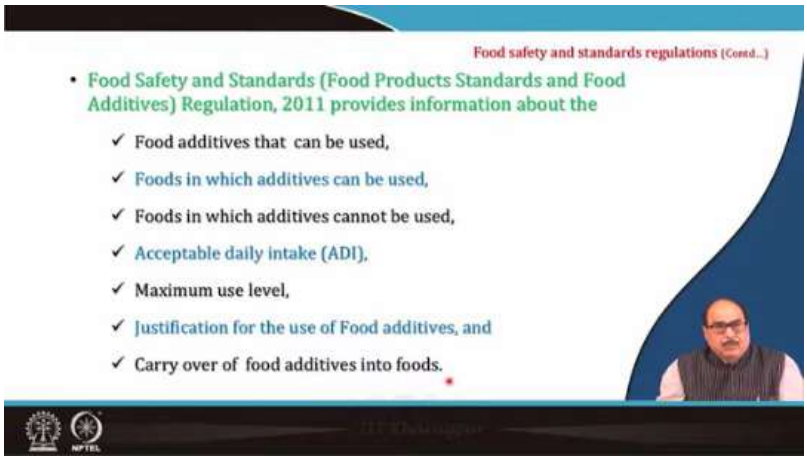
Therefore, every country should establish its own food regulatory framework depending upon the needs of the food sector and whether it adopts international standards developed by the Codex Alimentarius Commission and the Food and Agriculture Organization of the United Nations. In India, food additives are regulated by the Food Safety and Standards Act (FSSA) 2006 and the Food Safety and Standards, Food Products Standards and Food Additives Regulation 2011.



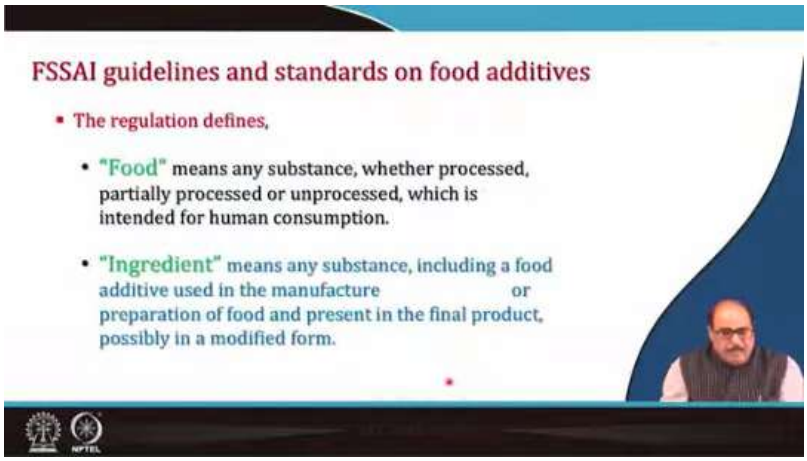
So, Indian food law—what are the salient features of the Food Safety and Standards Act of 2006? That is, in fact, this act—the Food Safety and Standards Act—was promulgated by the Parliament and notified in the Gazette of India on 24th August 2006. This act consolidates various acts and orders that deal with food-related issues in various ministries and departments. For example, earlier, when this FSSA act was not promulgated, there were various acts existing in various departments, and it was really causing a problem for the industry as they had to go to several ministries and departments to take permissions and enforcement, etc. So, to address this issue and provide a conducive environment for the industry, this FSSA act was promulgated, which is controlled by the Ministry of Health. And all the earlier regulations, like the Edible Oil Packaging Regulation Order of 1988, Prevention of Food Adulteration Act of 1954, Control Order 1967, Meat Food Products Order, Vegetable Oil Products Control Order, Fruit Products Order, Milk and Milk Products Order, and even Solvent Extracted Oil, De-oiled Meal, and Edible Flour Control Order. So, all these were brought under one umbrella in the FSSA 2006 Act. So, this act applies to all food items under this act. In fact, FSSA 2006 applies to all food items and also touches upon relatively newer subjects, such as proprietary foods, novel foods, dietary supplements, nutraceuticals, and many more. The Food Safety and Standards Authority of India (FSSAI), which is popularly known as it was established to lay down science-based standards for articles of food and to regulate their manufacture, storage, distribution, sale, and import to ensure the availability of safe and wholesome food for human consumption.

The role of the Food Safety and Standards Authority of India is to frame rules and regulations to provide procedures and guidelines for risk assessments, render scientific advice to central and state governments in framing policy, capacity building for enforcement officials, and general awareness on food safety. So, it works basically in three domains, like standard settings; that is, there are even other agencies in India. Like FSSAI is again, and there is another Bureau of Indian Standards. and DMI, but the Bureau of Indians is the BIS and DMI; that is, although they are government agencies, they are voluntary. But FSSAI standards are mandatory, that is, every person who is in the food business, every individual or organization or that is an establishment who is in the food business, they are food business operators, then they must take the FSSAI, that is, the FSSAI approval, they must take. Then, FSSAI also deals with the policy, that is, the rules and regulations and the importance of enforcement and surveillance. That is enforcement and surveillance of the rules and guidelines and whether the industry is producing good quality and safe foods or not, which consumers are serving with all the surveillance and enforcement, etcetera, is again done by a state FSSAI with the state governments with the help of state governments and union territories.

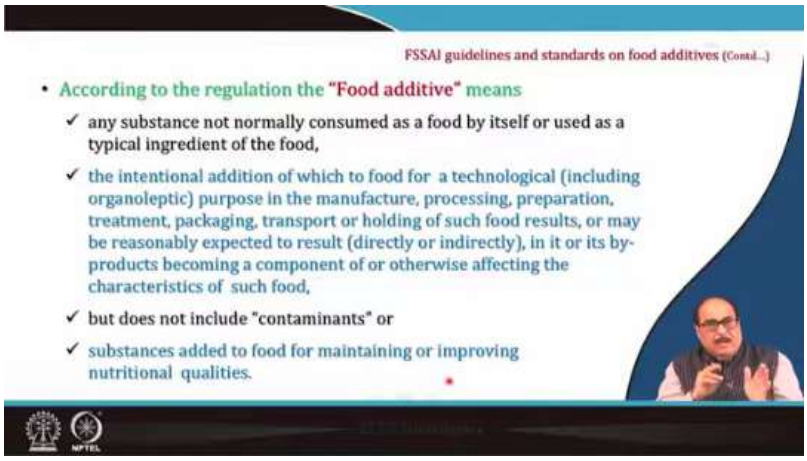
So, the Food Safety and Standard Regulations is how it works; FSSAI has a scientific committee and 21 scientific panels to provide scientific opinions and develop science-based standards. These panels assess the risk and offer expertise on topics such as food additives, flavourings, processing aids, food contact materials, pesticide residues, GMOs and biological hazards, packaging and almost all aspects related to food production, processing and distribution, etc. So, Food Safety and Standards Food Products Standards and Food Additive Regulation 2011 outline the provisions and requirements for the use of additives, flavourings, processing aids and materials in contact with the food.



Food safety and Standards that Food Products Standards and Food Additive Regulation 2011 provides information about the food additives that can be used, foods in which additives can be used, foods in which additives cannot be used, acceptable daily intake of these additives, maximum use level justification for the use of food additives and carryover of food additives into the foods. So, all these aspects are the regulations and guidelines and all these are provided in the food safe products standards and food additive regulation of 2011. Obviously, these regulations are also reviewed and updated from time to time.

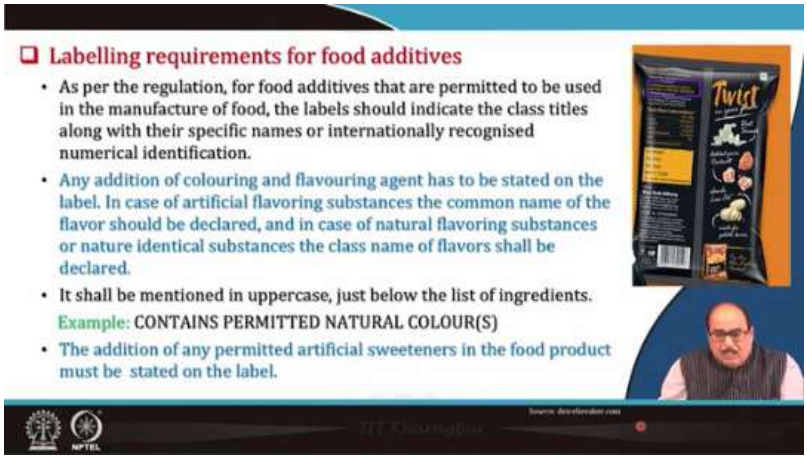


Then, the guidelines and standards for food additives that are food regulations. So, it defines even what the food is, what the ingredients are, what the additives are, etcetera. So, food, as per this regulation, means any substance, whether processed, partially processed, or unprocessed, which is intended for human consumption. So, that is the food in the FSSAI regulations. Ingredient means any substance, including a food additive, used in the manufacture or preparation of food and present in the final product, possibly in a modified form. So, that is the ingredient in the regulation.



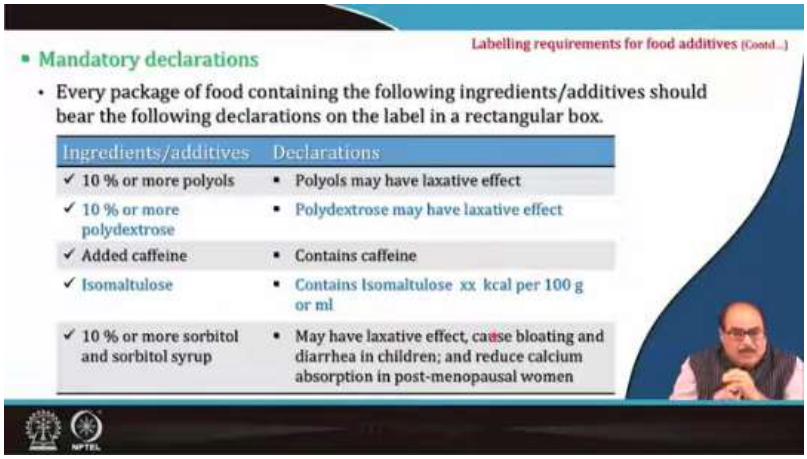
The food additive, according to this regulation, means any substance not normally consumed as food by itself or used as a typical ingredient of the food. The intentional addition of which to food for a technological, including organoleptic, purpose in the manufacture, processing, preparation, treatment, packaging, transport, or holding of such food results, or may be reasonably expected to result, directly or indirectly, in it or its byproducts becoming a component of, or otherwise affecting the characteristics of such food, but does not include contaminants. or even the additives, which are substances added to food to maintain or improve its nutritional quality.

So, under the Food Products Regulations by FSSAI (Food Additive Regulations), this authority under this regulation, the authority allows the use of more than 370 food additives along with their maximum permissible limits depending on the category of the food. And the list is again dependent upon these factors: there is a list, there is a scientific panel, then a scientific committee, etcetera. They regularly review these things, and where there is a need, something is added, some chemicals may be deleted, and all those things—it is a dynamic process. So, the regulation also emphasizes that additives must be of appropriate food-grade quality, prepared and handled like food ingredients, and conform to the applicable specifications. The standard regulation states that. The quantity of additive added to the food shall be limited to the lowest possible level necessary to achieve the desired effect—that is, it should be at a GMP level. The use of food additives is justified only when such use has an advantage and does not present an appreciable health risk or mislead the consumer and serves one or more of the technological functions.



Then, let us talk about labelling requirements for food additives as per the regulations for food additives. that are permitted to be used in the manufacture of foods. The label should indicate the class titles along with their specific names or internationally recognized numerical identification, as all these chemicals are food additives. They are assigned numerical identifications, which we have seen in earlier cases. Some of the chemicals have numerical identifiers, as we discussed regarding food additives. So, any addition of colouring and flavouring agents must be stated on the label. In the case of artificial flavouring substances, the common name of the flavour should be declared, and in the case of natural flavouring substances or nature-identical substances, the class name of flavours shall be declared and it shall be mentioned in uppercase just below the list of ingredients. For example, it should state: 'Contains permitted natural colors.' So, all this should be

written on the label. The addition of any permitted artificial sweeteners in the food product must be stated on the label.



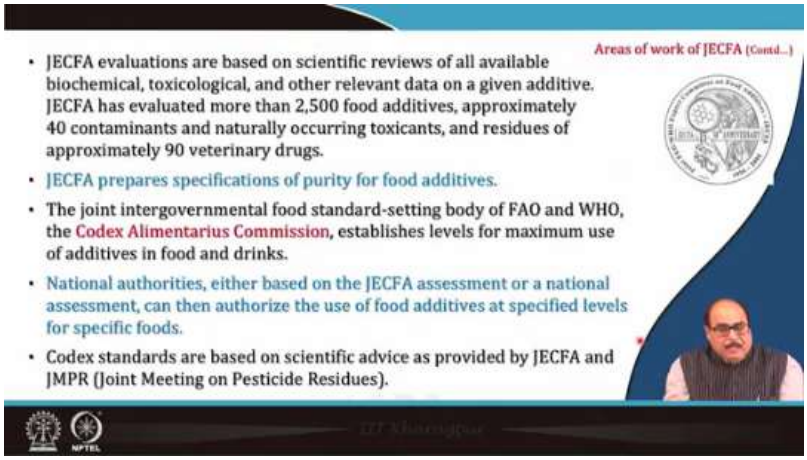
So, there are certain mandatory declarations under the regulation that every package of food containing the ingredients or additives should bear the certain declaration on the label in a regular box or in a rectangular box. For example, here I have listed some important ingredients and additives and what the declaration should be. Like for example, if a food is likely to have 10 per cent or more polyols, then in a rectangular box on the label, it should be written that polyols may have a laxative effect. In the case of 10 per cent or more polydextrose, it should be written that polydextrose may have a laxative effect. added caffeine, it should be written that it contains caffeine. For example, if it has isomaltulose, then the label should contain information that contains isomaltulose xx. This much particular amount or this much kilo calorie per 100 grams or per 100 mL or whatever the case may be. Then if the food contains 10 percent or more sorbitol and sorbitol syrup. Then the label must on the label it must be mentioned stated that this may have a laxative effect, cause blotting and diarrhoea in children and reduce calcium absorption in postmenopausal women.

Here, you see that just a label has been given; that is, if food on a food label has some caffeine amount, like caffeine 0.03 per cent. Then the label must contain phrases like 'contains caffeine' and also 'high caffeine,' that is, 75 milligrams per 200 mL. It is not recommended for children, pregnant or lactating women, and persons sensitive to caffeine. Consume not more than 500 mL per day. So, all these statutory warnings, recommendations, etcetera, must be provided on the label under the regulations. Also, that is, suppose a food contains sweeteners; so, again here, there is maltitol, which is a polyol. So, it is written that the polyols may have a laxative effect. So, these things, accordingly, whatever we showed earlier, and this list is long, that is, almost such chemicals, etcetera, which might have some adverse effects, they are providing good effects, improving the—they might be improving the functional properties, etcetera, of the food, but if they are consumed beyond a certain level, they may cause health hazards. So, all these things must be declared on the labels.

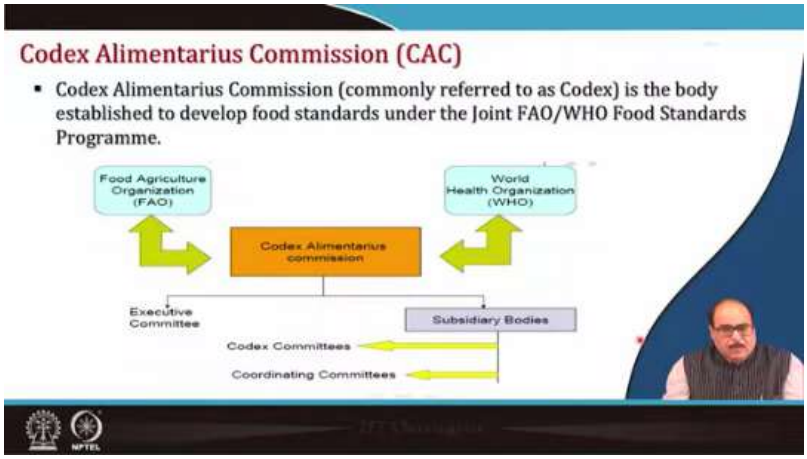
Now, let us talk about international regulation there is World Health Organization or food and agricultural organizations of the UN nation they also regulate the international food

trade according to the WHO food additives or substances primarily added to processed foods or other foods produced on an industrial scale for technical purposes and not normally used as a typical ingredient in the food. Mind it as a WHO. Additives must improve safety, increase the amount of time a food can be stored or modify the sensory properties of the food. The Joint FAO and WHO Expert Committee on Food Additives, popularly known as JECFA, is the international body responsible for evaluating the safety of food additives for use in foods that are treated internationally and traded internationally that is in the international food business. So, JECFA serves as an independent scientific committee that performs risk assessments and provides advice to the FAO, WHO, and other member countries of both organizations. Only food additives that have undergone a JECFA safety assessment and are found not to present an appreciable health risk to consumers can be used internationally.

Then, areas of the work of the Joint FAO-WHO Expert Committee on Food Additives is the risk assessment or safety evaluations of food additives, which are intentionally added chemicals, processing aids that are considered as food additives, flavouring agents by functional groups, residues of veterinary drugs in animal products, or contaminants and natural toxins. So, the risk assessment or safety evaluation for all these is done by the JECFA scientific committee. Also, exposure assessment of additives and contaminants, specifications and analytical methods, residue definition, MRL proposals, particularly for veterinary drugs, etcetera. and development of general principles for the safety evaluation of chemicals in food, it is all under JECFA. JECFA evaluations are based on scientific reviews of all available biochemical, toxicological, and other relevant data on a given additive.

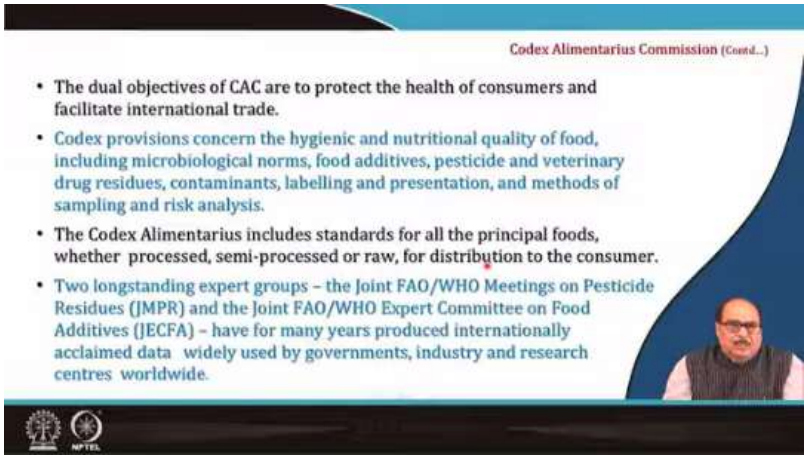


JECFA has evaluated more than 2500 food additives and approximately 40 contaminants and naturally occurring toxicants and residues of approximately 90 veterinary drugs. JECFA prepares specifications of purity for food additives. The joint governmental food standards are set by the FAO and WHO. The Codex Alimentarius Commission establishes the maximum levels for the use of additives in food and drinks. National authorities, either based on the JECFA assessment or a national assessment, can then authorize the use of food additives at specified levels for specific foods. Codex standards are based on scientific advice provided by JECFA and JMPR, which is the Joint Meeting on Pesticide Residues.

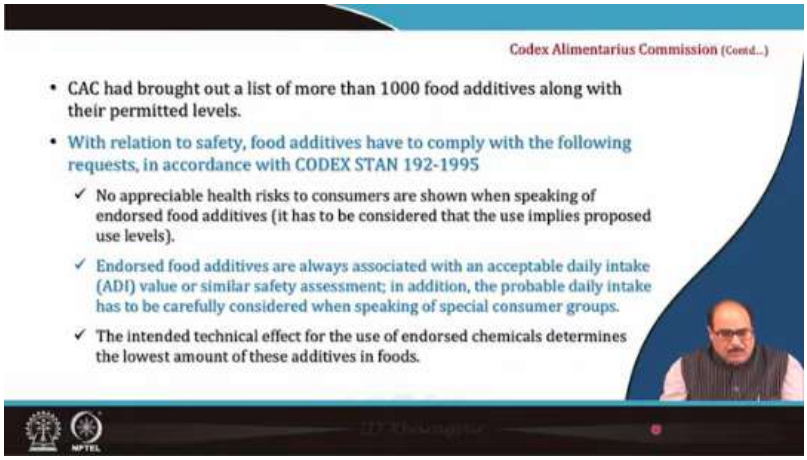


So, the Codex Alimentarius Commission, commonly referred to as Codex, is the body established to develop food standards under the joint FAO-WHO food standards program. So, the CSE, of course, is a joint committee or commission of the WHO and FAO, working within their framework guidelines. It has an executive committee and subsidiary bodies like Codex committees and coordinating committees. So, this is, you can say, the international agency which works widely as per the FAO and WHO norms and oversees

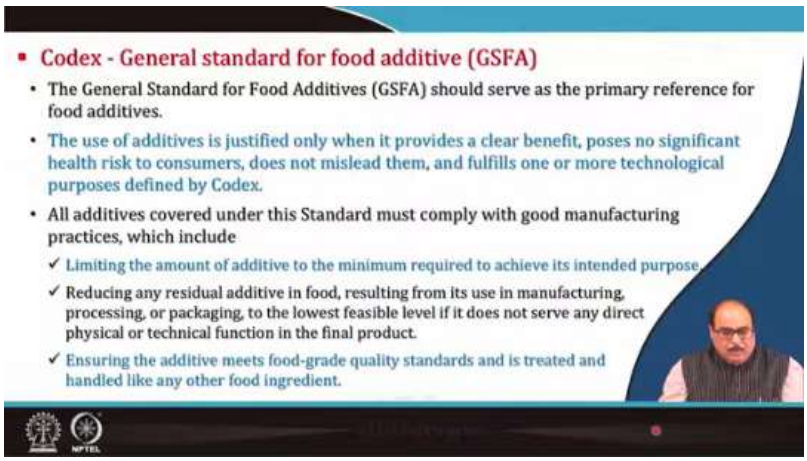
the food trade business, particularly the additive addition of chemicals, etcetera, in the foods.



So, the dual objective of CAC is to protect the health of consumers and facilitate international food trade. Codex provisions concern the hygienic and nutritional quality of food. including microbiological norms, food additives, pesticides and veterinary drug residues, contaminants, labelling and presentation, and methods of sampling and risk analysis. The Codex Alimentarius Commission also includes standards for all the principal foods, whether processed, semi-processed or raw, for distribution to the consumer. So, for any type of food intended for distribution to consumers, the Codex Alimentarius decides it has the standard for that. Two long-standing expert groups of the Codex CSE or Codex Alimentarius Commission are the Joint WHO-FAO meetings on Pesticide Residues (JMPR) and the Joint FAO-WHO Expert Committee on Food Additives, that is the JECFA. So, JECFA and JMPR are the two. So, major committees or commissions work under this Codex Alimentarius Commission to discuss a deal with the various issues related to food additives and they have for many years produced internationally acclaimed data widely used by the government, industry, and research centers worldwide.

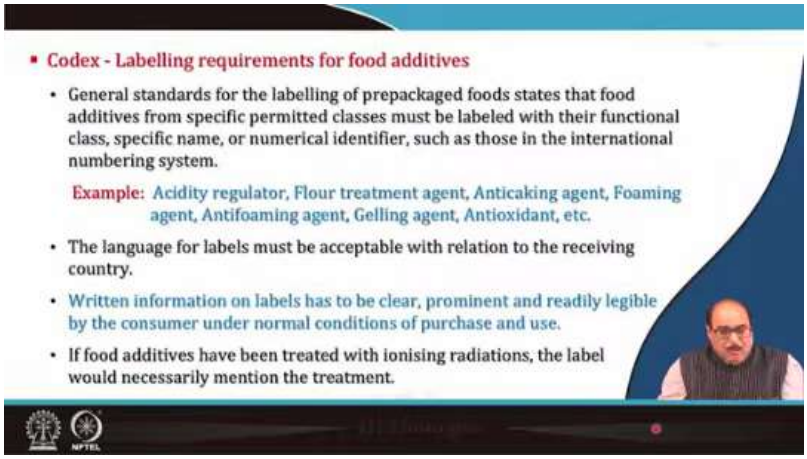


So, CAC has brought out a list of more than 1000 food additives along with their permitted levels in relation to food safety, food additives have to comply with certain requirements that are in accordance with the Codex Stan 192- 1995. What does it have to comply with? There is no appreciable health risk to consumers as shown when speaking of endorsed food additives. It has to be considered that the use implies the proposed use level. Endorsed food additives are always associated with an acceptable daily intake value or similar safety assessment. The probable daily intake has to be carefully considered when speaking of special consumer groups. The intended technical effect for the use of endorsed chemicals determines the lowest amount of these additives in food.



So, the Codex General Standard for Food Additives, popularly known as GSFA. This GSFS should serve as the primary reference for food additives. The use of additives is justified only when it provides a clear benefit, poses no significant health risk to consumers, does not mislead them, and fulfils one or more technological purposes defined by the Codex. All the additives covered under the standards must comply with good manufacturing practices, including limiting the amount of additive to the maximum

required to achieve its intended purpose or limiting the amount of additive to the minimum required to achieve its intended purpose. Reducing any residual additives in food resulting from its use in manufacturing, processing, or packaging to the lowest feasible level if it does not serve any direct physical or technical function in the final product. Also, it covers that GSFA ensures that additives meet food-grade quality standards and are treated and handled like any other food ingredients.



Codex labelling requirements for food additives, like general standards for the labelling of prepared or packaged or pre-packaged foods, state that food additives from specifically permitted classes must be labelled with their functional class, a specific name, or a numerical identifier. Such as those in the International Numbering System. For example, that is the So, they depend upon the functional application of the additive, It must be labelled as an acidity regulator, flour treatment agent, anti-caking agent, foaming agent, anti-foaming agent, gelling agent, antioxidant, or whatever functional properties it has. It should reflect the nature of the additive and must be listed under the Codex GSFA. The language for the label must be acceptable in relation to the receiving country, where the product is to be used. Preferably, the labelling should be in the local language. So that people can easily read the written information and the labels are clear. Prominent and readily legible by the consumer under normal conditions of purchase and use. If food additives have been treated with ionizing radiation, the label must mention the radiation treatment.

Finally, I will summarize this lecture by saying that the food additives are regulated by national and international bodies to ensure consumer safety. Indian food laws are governed by FSSAI, which enforces food safety regulations, including those for food additives. FSSAI provides a list of permitted additives, their maximum allowable limits, labeling requirements, and usage guidelines. So, any food business operators must obtain permission or that is, must take FSSAI approval for their business and their products. JECFA guidelines outline the safety evaluation, ADI, and conditions for the use of food additives. The Codex Alimentarius Commission establishes international food standards including those for food additives, to protect consumers' health and promote fair practices in the food trade worldwide.

These are the reference literature that was taken into account in this study.

I really thank you all very much for your patient hearing. Thank you.