

Thermal Processing of Foods
Professor R. Anandalakshmi
Department of Chemical Engineering
Indian Institute of Technology Guwahati
Lecture 30
Regulatory Considerations

Good morning everyone. So, in the last class we have discussed about what are all the sanitation regulatory agencies are available and standards are available and after that we have also seen about the various food contacting surfaces, what are all the sanitation requirements they must fulfill and non-contacting food surfaces are as well. So, today we are going to see about the regulatory considerations which are followed or which requires to be followed in the food processing industry and also safety requirements for the of food.

So, first we will discuss about the regulatory considerations in India and even though these regulatory considerations are vary country to country. There are international food laws that has to be complied for all the countries which are involved in food processing and food manufacturing and food import and export so that also we are going to see about.

(Refer Slide Time: 01:50)

Current Scenario in India

- Food Safety and Standards Authority of India (FSSAI) is the apex food regulator.
- It is empowered by and functions under the Ministry of Health and Family Welfare, Government of India.
- The FSSAI implements and enforces food regulations as prescribed in the Food Safety and Standards Act, 2006 (FSS Act). The FSS Act is an Act of Parliament, popularly known as the Food Act.
- Number of food legislations have been consolidated in the FSS Act and became effective in 2011 with FSSAI as its regulatory body.
- Though the Act continues to evolve, it needs to be further harmonized with standards of international agencies for global parity.

The first one we are going to talk about the current scenario in India. So, in India the Food Safety and Standard Authority of India which is nothing but FSSAI is the apex food regulator and it is empowered by the functions under Ministry of Health and Family Welfare, Government of India.

So, this particular Food Safety and Standards Authority of India is empowered by Ministry of Health and Family Welfare, Government of India and also it functions under the same ministry.

So, this FSSAI implements and enforces the food regulations as prescribed in the Food Safety and Standards Act, 2006 so we call it as a FSS Act. So, this Act is an Act of Parliament and popularly known as the Food Act. So, this FSSAI implements and enforces the food regulations as prescribed by the Food Safety Standards Act so which is nothing but FSS Act and this Act is an Act of Parliament in India and which is popularly known as Food Act.

So, the number of food legislations have been consolidated in the FSS Act and became effective in 2011 with FSSAI as its regulatory body. And though Act continues to evolve, it needs further harmonized with the standards of international agencies for global parity so this is what I told. So, though we are saying that the FSSAI is the regulatory body for the Food Safety and Standards in India. So, in the Act also intermittently amended with a certain modifications to further harmonize with the standards of international agencies as per with the global scenario.

(Refer Slide Time: 03:56)

Standardized and Non-standardized

- FSSAI standardized 380 articles of food in 16 categories and any other foods require product approval if they are not listed among these 380 food items. (2015)
- The standardized food products are those for which standards are prescribed and do not require product approval prior to manufacture, sale, distribution, or import.
- The first time manufacturer or importer of standardized foods only requires an FSSAI license to begin a food business.
- Non-standardized food products do not have standards as their safety parameters are either not known or not yet ascertained.
- FSSAI works to standardize more foods in harmonization with Codex Alimentarius.

And FSSAI standardized 380 articles of food in 16 categories and any other food requires the product approval if they are not listed among these 380 food items. So, this is the scenario about 2015 and there is a another amendment in the 2017 so that is implemented from January first 2018 onwards. So, till then the FSSAI standardized almost 380 articles of food in almost 16

categories and if any other food which requires the product approval which is not standardized already.

So, if they are not listed so under these standardized food items they need a special approval. The standardized food products are those for which standards are prescribed and do not require any product approval prior to manufacture, sale, distribution or import. So, if any of the food products are listed among these 380 articles of food in 16 categories they do not require a product approval prior to manufacture, sale, distribution or import.

So, the first time manufacturer or importer of standardized food so which is already there in FSSAI only requires an FSSAI license to begin a food business. So, they do not require the product approval but the same time the non-standardized food products do not have standards as their safety parameters or either not known or not yet ascertained. So, there may be of new food items or new food formulations so they do not come under the already listed standardized food under FSSAI.

So, there may be two reasons for that, one is they come up with the new of food formulation or not yet ascertained. For the new food formulations there may not be any safety parameters which is already known or they are not yet ascertained. So, FSSAI works to standardized more foods in harmonization with Codex Alimentarius. So, this I talked about in the sanitary requirements itself,

So, this we are going to see what it is, So, this is the international agency. So, as of now in the sense before this last amendment around 2015. So, FSSAI standardized almost 380 articles. So, the standardized and non-standardized food items came into existence based on this standardization of articles under FSSAI. So, standardized food means so they are already they are their safety parameters and their formulation and their level RDA they call it as.

So, recommended dietary allowances, so all the information were listed in the FSSAI. So, in such case those standardized food items do not require any prior permission or prior product approval for manufacture, sale, distribution or import. If the products are not listed under this FSSAI category so then they need a product approval before the license. So, that means their safety parameters are either not known or not yet ascertained.

So, already if the food item is standardized under FSSAI, so then what we require is only license for any food business and also this FSSAI is working to standardized more foods in harmonization with Codex Alimentarius.

(Refer Slide Time: 07:50)

Standardized and Non-standardized

- Traditional foods also do not require product approval as they are being consumed for centuries in India.
- The ingredients and preparation methods are well known and this guarantees their safety.
- If, however, traditional foods use any new ingredients or food additive or new technologies in preparation, they need product approval.
- Foods Imported into India have to follow the FSS Act, Rules & Regulations
- If the food articles are standardized, the importer only needs a FSSAI license to import them. The importer also needs to comply with FSSAI regulations for sale and distribution of the food products.

The traditional foods in India, so they also do not require product approval because they are already being consumed for centuries in India. And the ingredients and the preparation methods are well known for those traditional foods and this guarantees their safety but if however the traditional foods use any new ingredients other than the traditional methodology or traditional ingredients or food additives or new technologies in preparation they need a product approval.

Sometimes what happens? So, based on the current rent they may require some food additives, for example, certain traditional foods the self-life of them is only one or two days, if so if we want to increase bit further for a week. So, we may require some food additives to be added in the traditional food. So, any such case, any modification in the process or any modifications in the ingredients of the traditional foods so they require a product approval.

The foods imported into India imported into India have to follow the FSS Act, rules and regulations. And if the food articles are standardized, the importer only needs a FSSAI license to import them. The importer also needs to comply with FSSAI regulations for sale and distribution of the foods. So, it is not only for the food processing or food sale or distribution in India.

So, if the importer, importer of the foods also need a FSSAI license and as well as the approval for any sale distribution of their food products in India. So, if the food articles whatever the imported food articles are already standardized under FSSAI so they require only license but if not they also require the product approval, before getting license. So, that means the importer also comply with the FSSAI standards acts and rules regulations so for any sale, distribution of their food products in India.

(Refer Slide Time: 10:05)

Standardized and Non-standardized

- If a new or unknown food article is introduced for import, it is considered non-standardized and requires product approval under the Section 22 of the FSS Act, 2006.
- The FSS Act, 2006 does not apply to foods being exported out of India.
- Exporters do not require FSSAI product approval as these food products are not sold to Indian consumers.
- Non-standardized food products, awaiting product approval, are assessed for safety in four categories.
- To expedite product approval, a 90-day outer limit is now in place for completion of the application review process. May be more, if the product is referred to the Scientific Panel for further scrutiny, the time limit could be extended. On approval they can immediately apply for license.

If a new or unknown food article is introduced for import, so if any new of unknown food article, so that means non-standardized one. It is considered non-standardized and requires the product approval under Section 22 of the FSS Act, 2006. So, the FSS Act, 2006 does not apply to foods being exported out of India because why? So, they do not require the product approval because it is not sold to Indian customers.

So, the exporters do not require FSSAI product approval as these food products are not sold to Indian consumers, so the exporters. Non-standardized food products awaiting for product approval or assessed for safety in four categories. So, when we apply for product approval how the process goes, because if it is a non-standardized food. So, we supposed to get approval from the FSSAI so what is the procedure?

So, the expedite product approval, a 90 days outer limit is now in place for completion of the application review process. So, it is like every other process in India so it has got 90 day window

limit. So, in this 90 days window limit it goes for various level of reviewing processes and if the product is referred to the scientific panel for further scrutiny then it maybe more, more than 90 days.

If there are any certain standards to be checked by the scientific panel so then it may require more than 90 days, the time limit could be extended more than 90 days if the product has to be sent to scientific panel. On approval they can immediately apply for license. So, till now what we have seen? So, in the current regulations or scenario in India what we are saying? So, as far as India is concerned the Food Safety Standards Authority of India is the apex body and the first FSS Act came into existence on Food Safety and Standards Act as a Food Safety and Standard Act in 2006 and it is an Act of Parliament and popularly known as Food Act.

(Refer Slide Time: 12:33)

Standardized and Non-standardized

- FSSAI standardized 380 articles of food in 16 categories and any other foods require product approval if they are not listed among these 380 food items. (80%)
- The standardized food products are those for which standards are prescribed and do not require product approval prior to manufacture, sale, distribution, or import.
- The first time manufacturer or importer of standardized foods only requires an FSSAI license to begin a food business.
- Non-standardized food products do not have standards as their safety parameters are either not known or not yet ascertained.
- FSSAI works to standardize more foods in harmonization with Codex Alimentarius.

So, till then almost in till 2015 almost 380 articles are categorized in almost 16 categories. So, based on that there are two major categories of the food product, one is standardized food products, non-standardized food product. Standardized food products only require product license to manufacture, sale, distribute or import and non-standardized food items first has to get the product approval.

So, that takes almost 90 days window but for any case it has to be submitted before the scientific panel then it may require more than 90 days. So, after once they get the product approval and they may go for immediately license and based on the standardized, non-standardized food item

the importer exporter also has to comply to the standards of FSSAI body because the importer needs the same process, first a product approval and then license for their sale and distribution.

So, if their products are already standardized they can go for license. If there are non-standardized food, they have to get approval and then go for license but exporters, so they do not require the FSSAI product approval because these food products are not sold to Indian customers.

(Refer Slide Time: 13:50)

New Draft Regulations

- Special interest is Section 22 of the FSS Act, which deals with “Nutraceuticals, Functional Foods, Novel Foods and Health Supplements.” For the first time regulations have been proposed for this category of foods.
- If these products propound nutritional or medicinal benefits they need to have sound scientific evidence. The products must not contain either steroids or psychotropic drugs.
- Ingredients like vitamins and minerals must conform to the recommended dietary allowances for Indians, as proposed by the Indian Council of Medical Research. (RD)

So, then the new draft regulations. So, as I said, the amendment was recently implemented in 2017 and it got into the practice from January 2018. So, in that the special interest is the Section 22 of the FSS Act which deals with “Nutraceuticals, Functional foods, Novel foods and Health supplements.” For the first time regulations have been proposed for these categories of foods.

So, when we were talking about Nutraceuticals also so I specially told you about this FSS Act. If these products propound Nutritional or Medicinal benefits they need to have a sound scientific evidence. So, to get the product approval we supposed to submit the scientific evidence and these products must not contain either Steroids and Psychotropic drugs so this is also important.

Anyway we are going to see the FDA regulations on these Nutraceuticals and what are all the Nutraceuticals already into the regulations based on the scientific evidence we are going to see. The ingredients like vitamins and minerals must confirm to the recommended dietary allowance

so this is what we call it as a RDA for Indians as proposed by the Indian Council of Medical Research.

So, in such Nutraceuticals, the vitamins and minerals must confirm to the recommended dietary allowances for Indians as proposed by Indian Council of Medical Research, ICMR.

(Refer Slide Time: 15:23)

Regulations for Licensing and Registration of Food Businesses

- According to the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011, it is mandatory for all food businesses operators, manufacturers, importers, distributors, wholesalers, retailers, hotels, restaurants, eateries, as well as petty food businesses to have an FSSAI registration/license so they are in compliance with the FSS Act.
- Food businesses with an annual turnover up to INR 12,00,000 need a registration certificate. Food businesses, with an annual turnover above this amount, need a license.
- There are two types of licenses: Central license and state license
- The central license is issued on the basis of manufacturing capacity, as well as turnover. Those operating food businesses within an Indian state need a state license that is also based on capacity or turnover.

And according to Food Safety and Standards so which is nothing but Licensing and Registration of food Businesses Regulation, 2011, it is mandatory for all businesses operators, manufacturers, importers, distributors, wholesalers, retailers, hotels, restaurants, eateries, as well as the petty food businesses to have an FSSAI regulation license so that they are in compliance with the FSS Act.

So, in India the food businesses operators, manufacturers, importers, distributors, wholesalers, retailers, hotels, restaurants, eateries, as well as the petty food businesses to have an FSSAI regulation and license so that they are in compliance with the FSS Act. So, there may be a confusion, I mean what is a food business? So, what is the limit? So, for then the food businesses with an annual turnover up to Indian rupees of 12,00,000 need a registration certificate from the FSSAI also if the turnover is above than this amount then they need a license as well.

So, if it is up to 12,00,000 then they may require the registration certificate under FSSAI and if the turnover is more than that they need a license to do their business. The license is of two

category, one is central license, another one is state license. So, this is well known, central means an issued by the central government and state means issued by the state government. The central licenses issued on the basis of manufacturing capacity as well as the turnover as we seen here.

Those operating food businesses within Indian state need a state license that is also based on capacity and turnover. So, one particular state if you are running that particular business we need a state license as well.

(Refer Slide Time: 17:29)

Regulations for Licensing and Registration of Food Businesses

- Those that operate businesses in two or more states require an additional central license for head office/registered office and separate license/registration for other locations they operate in.
- Only transporters need a singular license/registration for all vehicles an individual transporter runs.
- Those food business operators that deal with non-standardized products have to first apply for the product approval and only then they can obtain a license under the licensing and registration regulations.
- All importers and exporters have to obtain a central license from FSSAI.

And those operate businesses in two or more states require an additional central license for head office, head office there is a central license and registered office and separate license registration for other locations they operate in. So, if the businesses running between state or two or more states so they require a additional license from central government for their head office or registered office and also they need separate registration and license to the locations wherever they are doing the state businesses.

Only transporters need a singular license or registration for all vehicles and individual transporter runs. So, if the food businesses require the vehicle so then they may require particular license and registration for those vehicles as well. So, those food business operators that deal with non-standardized food. So, which requires the further product approval and license have to first apply for the product approval only then they can obtain a license under the licensing and registration

regulations. All importers and exporters have to obtain a central license from FSSAI so that is important.

(Refer Slide Time: 18:50)

Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulation, 2017 ✓

- Food Safety and Standards Authority of India (FSSAI) - Official gazette of India with reference to microbiological requirements for fish and fishery products. ↑
- Regulation:
 - ✓ Revised microbiological necessities for sea foods ✓
 - ✓ New varieties of fish and fisheries products ✓
 - ✓ Maximum allowable limits of hygiene indicator organisms ✓
 - ✓ Safety indicator organisms in a wide range of fish and fishery products other food items namely oils, fats, oats and pasta
 - ✓ Sampling plan and reference test methods for microbiological limits. ✓
- These standards have been finalized and come into force on 1st January, 2018.
- The revised microbiological standards aim at guaranteeing quality and food safety of sea food produce in the domestic market.

Standardized and Non-standardized

- If a new or unknown food article is introduced for import, it is considered non-standardized and requires product approval under the Section 22 of the FSS Act, 2006.
- The FSS Act, 2006 does not apply to foods being exported out of India.
- Exporters do not require FSSAI product approval as these food products are not sold to Indian consumers.
- Non-standardized food products, awaiting product approval, are assessed for safety in four categories.
- To expedite product approval, a 90-day outer limit is now in place for completion of the application review process. May be more, if the product is referred to the Scientific Panel for further scrutiny, the time limit could be extended. On approval they can immediately apply for license.

Regulations for Licensing and Registration of Food Businesses

- According to the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011, it is mandatory for all food businesses operators, manufacturers, importers, distributors, wholesalers, retailers, hotels, restaurants, eateries, as well as petty food businesses to have an FSSAI registration/license so they are in compliance with the FSS Act.
- Food businesses with an annual turnover up to INR 12,00,000 need a registration certificate. Food businesses, with an annual turnover above this amount, need a license.
- There are two types of licenses: Central license and state license
- The central license is issued on the basis of manufacturing capacity, as well as turnover. Those operating food businesses within an Indian state need a state license that is also based on capacity or turnover.

So, Food Safety and Standards Amendment Regulation, 2017 so this is what I have been talking about. So, it was the first FSSAI came into existence in 2006, FSS Act and in 2015 they started adding the standardized food varieties and categories them into standardized and non-standardized and they kept on adding these non-standardized food items once they got their approval and their license so then slowly they start adding into their standardized food items as well.

So, now the recent amendment in the regulation was happened in 2017. So, the Food Safety and Standards, so that means the Food Product Standards and Food Additives Amendment Regulation, 2017. So, it was again done under the regulatory body of Food Safety and Standards Authority of India FSSAI. So, this operates under Official gazette of India with reference to microbiological requirements for fish and fishery products so this got major concerned in 2017 amendment regulation.

So, the regulation considers the following criteria. The one is, revised microbiological necessities for sea foods and new varieties of fish and fishery products and maximum allowable limits of hygiene indicator organism and safety indicator organism in a wide range of fish and fishery products other food items namely oils, fats, oats and pasta and sampling plan and reference test method for microbiological limits.

So, these regulations even in the when we were discussing few slides earlier also we have discussed about this. So, the once the Act is made and then and there, there may be a revision

and there may be a amendment regulations and also while we are discussing about the past 3 session we also told. So, almost centuries back there was some other organism was target organism for past 3 session but after sometimes the target organism have been changed, organisms have been changed for many processes and same thing.

So, the past 10 lectures we were discussing about the recent developments in the food processing technology. So, for example the sensors, biosensors is a new area which is developing. So, these kind of test methods also then and there included in the Food Safety and Standards. So, that is why this particular act requires amendment then and there but how it is being done? We are going to see in couple of slides after.

These standards have been finalized and come into force on 1st January 2018 from then on this is being followed. The revised microbiological standards aim at guaranteeing quality and food safety of sea food produce in the domestic market. So, that is what I told that is done majorly for these sea products.

(Refer Slide Time: 22:01)

Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulation, 2017

- Through a notification dated 10 October, 2016, the FSSAI made changes to the Food Safety and Standards (Food Products Standards & Food Additives) Regulations, 2011
- With reference to 'Proprietary Foods', the existing regulation 2.12.1 has been altered and substituted with the new one
- The FSSAI considered objections and suggestions that it had invited from the public on 27 April 2016, on the draft regulation, and made this alteration.
- These regulations were considered as Food Safety and Standards (Food Products Standards and Food Additives) Ninth Amendment Regulations, 2016.

And so how it was done? So, when they thought about the amendments so what are the steps or at least in 2017 amendment regulations so what are all being followed? The through a notification dated October 2016 the FSSAI made changes to the Food Safety and Standards Regulations, 2011. So, the previous one is 2011 with reference to 'Proprietary Foods', the existing regulation of 2.12.1 has been altered and substituted with the new one.

The FSSAI considered objections and suggestion that it had invited from the public on 27 April 2016. So, the notification was done around October 2016 and before that objections and suggestions invited from the public also taken into account in their draft regulation and made this alteration and these regulations were considered as a Food Safety and Standards so otherwise food product standards and food additives Ninth Amendment Regulations in 2016.

(Refer Slide Time: 23:21)

Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulation, 2017

- FSSAI come up with the definition of proprietary food by offering the details as what is not to be integrated as proprietary food.
- Proprietary foods will therefore include foods that have not been standardized but will NOT include
 - ✓ New foods for special dietary usages
 - ✓ Foods for special medical purposes
 - ✓ Practical foods
 - ✓ Nutraceuticals
 - ✓ Health supplements
- Any deviation in quality parameters of a standardized food, as specified in the Food Safety and Standards Regulations under the FSSAI does not imply that the resulting product is a proprietary food.

So, then FSSAI come up with the definition of proprietary food by offering the details as what is not to be integrated as a proprietary food. The proprietary foods will therefore include foods that have not been standardized but will not include. So, it is not like all non-standardized items will come into that this category for product approval. So, the FSSAI come up with the definition for the proprietary food.

So, based on that the proprietary foods will therefore includes foods that have not been standardized. So, that means non-standardized foods but will not include the new foods for special dietary usages, foods for special medical purposes, practical foods, nutraceuticals and health supplements. Any deviation in the quality parameters of standardized food, as specified in the Food Safety Standards Regulations under FSSAI does not imply that the resulting product is the proprietary food.

So, there may be a chance. So, if the quality parameters of standardized food is not met so can I put it in a proprietary food? No, that should not imply that the resulting product is a proprietary food.

(Refer Slide Time: 24:44)

Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulation, 2017

- Other than additives other ingredients utilized in proprietary foods must either be standardized or permitted for usage in the preparation of other standardized food under these Regulations. However, FSSAI may specify from time to time the exclusion of definite ingredients.
- Proprietary food may also have vitamins and minerals in quantities not in excess of one RDA of the relevant micronutrients.
- Only those additives and at the levels that have been mentioned in Appendix A of these Regulations may perhaps be used in proprietary foods and according to the grouping and subcategory of foods they are mentioned in.
- FSSAI has also made it compulsory to mention on labels the food category or sub-category together with the generic name, nature and composition of the proprietary food namely oils, fats, oats and pasta.

Other than additives, other than ingredients utilized in the proprietary foods must either be standardized or permitted for usage in the preparation of other standardized food under these regulations. So, any additives or ingredients utilized in the proprietary food, must either be standardized or permitted for usage in the preparation of other standardized food under these regulations.

However, FSSAI may specify from time to time exclusion of define ingredients. So, that is why everywhere I am mentioning the time, date and month even year everything because then and there, there may be a changes and revisions based on the scientific evidences. So, based on that the FSSAI may specify time to time the exclusion of definite ingredients also. So, once it was standardized, so there may be a chance to remove them from the standardized condition based on the revisions and reports.

And proprietary foods may also have vitamins, minerals in quantities not in excess of one RDA of the relevant micronutrients so RDA is recommended dietary allowances. Only those additives and at the levels that have been mentioned in Appendix A so that we are going to see this is the

Appendix. Mentioned in Appendix A of these regulations may perhaps be used in the proprietary foods and according to the grouping and subcategory of foods they are mentioned in.

So, FSSAI has also made it compulsory to mention on the labels the food category or subcategory together with the generic name, nature and composition of proprietary a food namely oils, fats, oats and pasta. So, this proprietary food means like the ownership. So, only particular company will be manufacturing that particular food. So, that is the way the proprietary foods are categorized.

So, these proprietary foods also has got many additive which is already there in the standardized food item itself, but here what it is told? The FSSAI may specify from time to time the exclusion of that particular definite ingredients and also if they have any vitamins and minerals in quantities we should not be in excess amount already specified by the FSSAI for the relevant micronutrient level.

So, which is nothing but a recommended dosage allowance or recommended dietary allowance and also the proprietary food items should have the proper labeling. So, in that label the food category and subcategory together with the generic name, nature and composition of the proprietary food also to be mentioned.

(Refer Slide Time: 27:44)

Appendix A

Table 1
List of food additives for use in bread and biscuits ✓

Sl. No.	Name of additive	Bread	Biscuits
1	2	3	4
A.	Acidity regulators		
1	Sodium fumarate ✓	GMP	GMP
2	Potassium malate	GMP	GMP
3	Sodium hydroxide	GMP	GMP
4	Acetic acid or Lactic acid	2500 ppm max	GMP
5	Citric acid	-	GMP
6	Malic acid	-	GMP
7	Tartaric acid	-	GMP

So, this is one particular example I have taken from the regulations 2017. There are many tables under this Appendix A. So, this we are going to see and I will also show the other examples for other tables. The table 1 shows about the list of food additives for using bread and biscuits and so this is the category of the food like acidity regulators, the category of the food additives.

So, if it is a sodium fumarate it is general manufacturing GMP for the bread and if you are seeing the Acetic acid or Lactic acid so they have mentioned even 2500 ppm max. So, for biscuits it is under GMP regulations only.

(Refer Slide Time: 28:33)

Appendix A

- List of food additives for use in bread and biscuits ✓
- List of food additives for use in edible oils and fats ✓
- List of food additives for use in fish and fish products ✓
- List of food additives for use in thermally processed fruits ✓
- List of food additives in thermally processed vegetables ✓
- List of food additives for use in sugars and salt ✓

Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulation, 2017

- Other than additives other ingredients utilized in proprietary foods must either be standardized or permitted for usage in the preparation of other standardized food under these Regulations. However, FSSAI may specify from time to time the exclusion of definite ingredients.
- Proprietary food may also have vitamins and minerals in quantities not in excess of one RDA of the relevant micronutrients.
- Only those additives and at the levels that have been mentioned in Appendix A of these Regulations may perhaps be used in propriety foods and according to the grouping and subcategory of foods they are mentioned in.
- FSSAI has also made it compulsory to mention on labels the food category or subcategory together with the generic name, nature and composition of the proprietary food namely oils, fats, oats and pasta.

So, like this there are many tables under the same appendix. So, the list of food additives for use in bread and biscuits that we have seen and use in edible oils and fats and use in fish and fish products and to use in thermally processed fruits, thermally processed vegetables and use in sugars and salt almost 20 tables are there in appendix. So, you can them in the if you browse the Food Safety and Standards Amendment Regulation 2017 Appendix A. So, you will get to know about various categories and subcategory level of foods and their recommended allowances.

(Refer Slide Time: 29:10)

Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulation, 2017

- Food was mainly produced, sold and consumed locally. Over the last century the amount of food traded internationally has grown exponentially, and a quantity and variety of food never before possible travels the globe today.
- The C O D E X A L I M E N T A R I U S international food standards, guidelines and codes of practice contribute to the safety, quality and fairness of this international food trade.
- Consumers can trust the safety and quality of the food products they buy and importers can trust that the food they ordered will be in accordance with their specifications.
- Codex standards are based on sound science provided by independent international risk assessment bodies or ad-hoc consultations organized by FAO and WHO.
- WTO members that wish to apply stricter food safety measures than those set by Codex may be required to justify these measures scientifically.

The next one we already talked about the Codex Alimentarius, so we are going to see about this. The food was mainly produced, sold, consumed locally, but till the last century the amount of food traded internationally has grown exponentially. So, in ancient days so it is a local food market, they are produced, sold and consumed locally but last century the amount of food traded internationally has grown exponentially and a quantity and variety of food never before possible travels the globe today.

So, in such case it is not only the FSSAI Act. So, whatever we use in India so it also has to be of international standards otherwise we will not be able to export the foods which are prepared in India. So, in that line so we also supposed to review the international food laws and FDA regulations Food and Drug Administration regulations so for that only we are going to discuss about this.

So, in that case the Codex Alimentarius international food standards, guidelines and codes of practice contribute to the safety, quality and fairness of this international food trade. Consumers can trust the safety and quality of the food products they buy and importers can trust the food they ordered will be in accordance with their specifications. So, if it is coming under the whatever the food items the consumers, consumed or the importers can import.

So, if that is under the standards of Codex Alimentarius so they can purely trust those food items. The codex standards are based on sound science provided by independent international risk assessment bodies or ad-hoc consultations organized by FAO Food Agricultural Organization and WHO World Health Organization. So, the both consumers as well as importers can blindly trust the Codex standards because they are based on sound science provided by independent international risk assessment bodies or ad-hoc consultations organized by Food Agricultural Organization as well as World Health Organization.

And also the World Trade Organization members if they wish to apply any stricter food safety measures then those set by Codex may be required to justify these measures scientifically. So, that means the trust level is that much. So, even if some of the WTO members that means the World Trade Organization members wish to apply any stricter food safety measures then those set by the codex they may required to justify those measures scientifically. So, that means the Codex Alimentarius Standards are internationally accepted standards.

(Refer Slide Time: 32:11)

FSSAI Compliance Criterion for Import of Food Products to India

- Food articles imported to India from foreign countries and distributed in India need to conform to the FSSAI regulations or suffer restrictions on import.
- The FSSAI also has stringent regulations for packaging and labeling under Food Safety and Standards (Packaging and Labeling) Regulation, 2011.
- Ex: All chocolates, as defined in the Food Safety and Standards (Food Product Standards and Food Additives) Regulation, 2011 are to be prepared from milk.
- They cannot contain any vegetable oil or fats. Labels need to mention artificial flavors used to comply with FSSAI regulations.
- If these guidelines are not adhered to then chocolates are not permitted
- Global chocolate manufacturing giants are suffering a huge loss as a consequence.

So, then next one is the FSSAI compliance criterion for import of food products in India. So, the food articles imported to India from foreign countries and distributed in India need to confirm to the FSSAI regulations or suffer restrictions on import. So, the whatever imported to India from foreign countries and distributed in India need to confirm to the FSSAI regulations or suffer restrictions on import.

The FSSAI has also made the stringent regulations for packaging and labeling under Food Safety and Standards so which comes under packaging and labeling category, so in 2011. So, FSSAI implemented stringent regulations for packaging and labeling also because when it is imported from the foreign countries you should be in the English language, because the foreign country language we may not know and in that case we may not be able to read what is written in the packaging as well.

So, the FSSAI Food Safety and Standards Regulation in 2011 also applied stringent regulations on packaging and labeling as well. So, example is all chocolates as define in the Food Safety and Standards are Food Products Standards and Food Additives Regulation, 2011 are to be prepared from milk only. So, they cannot contain any vegetable oils or fats, labels need to mention artificial flavors used to comply with the FSSAI regulations.

So, this is where many foreign chocolate companies were trapped because as per the FSSAI regulation the Food Safety and Standards Regulations, 2011 only the milk to be used and vegetable oil or fats should not be used in the chocolates and also their labels need to mention any artificial flavors they are used for that particular preparation of chocolates so that also should comply with the FSSAI regulations.

If these guidelines are not adhered then the chocolates are not permitted. The global chocolate manufacturing giants are suffering a huge loss as a consequence of this particular Food Safety and Standards Regulation in 2011.

(Refer Slide Time: 34:38)

Cadbury seeks Centre nod to use veg fat in chocolates

Mumbai, April 18 | Updated: Apr 19 2005, 06:00am hrs

Cadbury India, which is virtually synonymous with milk chocolates in India, is seeking a sop from the Union government that will give a boost to the entire industry. The company has made a representation to the Union government that milk chocolate manufacturers be allowed to use 5% vegetable fat content in the manufacture of chocolates as this will significantly bring down costs.

The key ingredients in a milk-chocolate are milk, sugar and cocoa. Vegetable oil can be a substitute for cocoa bean derivative cocoa butter.

Significantly, a chocolate to qualify as one has to have cocoa as an ingredient.

Cadbury India managing director Bharat Puri told FE, Worldwide, 5% vegetable fat is allowed to be used in chocolate. In India, however, this is not so. We have represented to the government that if be done ~~as this will result in cost savings.~~ To put matters in perspective, the Malaysian price of Palmolein moved in the band of \$390 per tonne to \$413 per tonne for the period March 14, 2005 to April 15, 2005. The African prices of cocoa butter, on the hand, moved in the price band of \$4,378 per tonne to \$5,458 per tonne. Cadbury Indias representation assumes significance as it enjoys a near 63% volume marketshare and a 69% value market share in the Rs 750 crore chocolate industry.

Courtesy:
Financial Express

So, I just put a example here. So, it is taken from Financial Express Newspaper on April 18th 2005, the Cadbury seeks center not to use vegetable fat in chocolates. So, it is said that the Cadbury India Managing Director Bharat Puri told Financial Express, world over 5 percentage vegetable fat is allowed to be used in chocolate, in India however this is not so. So, we have got stringent regulations in that.

So, that is why they were mentioning about the how much dollars they are losing per ton. So, here only the key ingredients what is allowed in India is milk, sugar and cocoa and sometimes a chocolate to qualify one has to have cocoa as an ingredient. So, we cannot use the vegetable fats or vegetable oils in that. So, this is just to tell you about that.

(Refer Slide Time: 35:35)

FSSAI Compliance Criterion for Import of Food Products to India

- FSSAI stipulates that all ingredients, including additives need to be mentioned on labels in descending order of their composition by weight and volume, which for alcoholic beverages, is not always possible.
- Liquor imports have therefore fallen, since labels that fail to mention additives, like color, water, flavoring, and preservatives are all withheld at ports.
- Another stipulation for food products is to have “inseparable labels” and not stickers.
- Food products with detachable labels are withheld.
- To ensure consumer safety, as some of these stickers are only in Chinese and Japanese so consumers cannot understand what’s written. These reasons have compelled many foreign companies to withdraw from India.

So, then the same FSSAI compliance criteria for import of food products in India. So, FSSAI stipulates that all ingredients including additives need to be mentioned on labels in descending order of their composition by weight and volume. So, the additives needs to be mentioned on the labels of the food in descending order by their composition as well as by weight and volume which for alcoholic beverages is not always possible.

So, if that is the case so the import of any alcoholic beverages must suffer with this stringent regulation. The liquor imports have therefore fallen, since labels that fail to mention additives like color, water, flavoring, preservatives are all withheld at ports itself. So, these import liquor have therefore fallen because they cannot mention the composition, composition like color, water, flavoring, preservatives etcetera and their label so they cannot be sold in India.

Another stipulation for food products is to have inseparable labels not as a stickers. So, the label should be inseparable it is not like a stickers. Food products with detachable labels are also withheld when it comes to ports. To ensure consumer safety as some of these stickers are only in Chinese and Japanese so consumers cannot understand what is written. So, these reasons have compelled many foreign companies to withdraw from India.

So, another FSSAI strict regulation is that the label should be printed in English language and Chinese, Japanese most of the labeling is will be done in their language either Chinese or


Japanese so that also problem with this FSSAI. So, because of that those imported companies were compelled to withdraw from India.

So, the compliance criteria wise one is in chocolates there should not be any vegetable fat and oils that we have seen and also the labeling it should not be a stickers it should be a inseparable labels and the label should have got the additives and ingredients in descending order of their composition which one is low in the end, which one is higher the top by their composition weight and volume.

And for alcoholic beverages since this particular categorization of their ingredients and additives based on their weight and volume is not possible so they are fail to meet the standards of FSSAI in India and another thing is the label should be of English language because of that certain companies also withdrawn their import from India.

(Refer Slide Time: 38:28)

FSSAI Compliance Criteria for Labeling of Imported Food

- Language on labels must be in English as per FSSAI Regulations, 2011
- “[✓]Vegetarian” or “[✓]Non-Vegetarian” must be declared by affixing the symbol for “Vegetarian” or “Non-Vegetarian” on packages 
- Mention name and complete address of the importer in India
- Mention net weight or number or measure of volume of contents
- Mention batch number or lot number or code number, and FSSAI license number

There are certain compliance criteria so we are going to discuss certain things and I request you as always, I request you to read further for any further compliance criteria for labeling of imported food in India. The language on labels must be in English as per FSSAI Regulations, 2011. The “Vegetarian”, “Non-Vegetarian” must be declared by a fixing the symbol for “Vegetarian” and “Non-Vegetarian” on packages, thus you might have seen certain that red symbol is for non-veg and green symbol is for vegetarian.

Mention name and complete address of the importer in India and mention net weight or number of measures of volumes of contents and mention batch number or lot number or code number and FSSAI license number as well.

(Refer Slide Time: 39:18)

FSSAI Compliance Criteria for Labeling of Imported Food

- Mention month and year in which the commodity is manufactured or prepared
- Declare “Best Before” date on the package
- Mention nutritional information or nutritional facts per 100 grams or 100 milliliter per serving of food product on the label
- Name and address of the manufacturer should be mentioned on the label and FSSAI logo and license number of the importer should be available on the label

And month, year and which the commodity is manufactured or prepared and declare “Best Before” date of the packaging. Mention nutritional information, nutritional facts per 100 grams or 100 milliliter per serving of food product on the label this also we have seen in Aseptic Processing lecture the a products, the sterilized milk product how it was defined in the labeling.

So, it is defined in the descending order and also it was done for 100 grams probably 100 ml. And name and address of the manufacturer should be mentioned on the label and FSSAI logo and license number of the importer should be available on the label. So, these are all certain compliance criteria for labeling of imported food product so there are lot many so I request you to further refer the references which is given at this end of this lecture.

(Refer Slide Time: 40:19)

Indian Regulations Compare with Global Standards

- The Indian food safety regulations are primarily based on the Codex Alimentarius.
- The Codex was formed with the collaborative efforts of the WHO and the FAO, two eminent United Nations health and food bodies.
- The Codex Alimentarius international food standards, guidelines and codes of practice contribute to the safety and quality of the food that reaches consumers.
- FSSAI regulations adhere to international standards.
- Other international standards formulated by global agencies like the European Food Safety Authority, Food Standards Australia New Zealand, and the USFDA have also to some extent been assimilated, integrated, and harmonized into the Indian standards, thereby bringing them almost at par with the global standards.

The Indian food safety regulations are primarily based on the Codex Alimentarius to meet the international standards. The Codex was formed with the collaborative efforts of WHO as well as FAO to eminent United Nations health and food bodies. The Codex Alimentarius international food standards, guidelines and codes of practice contribute to the safety and quality of the food that reaches the consumers and FSSAI regulations adhere to international standards as well to make certain export businesses.

And other international standards formulated by global agencies like the European Food Safety Authority, Food Standards Australia, New Zealand and the USFDA Food and Drug Administration from US have also to some extent being assimilated, integrated and harmonized into Indian Standards thereby bringing them almost at par with the global standards. So, even though we are discussing now about the FSSAI, so this is also the standards are also derived based on the global standards.

So, that we will not face any problem in terms of standards and safety and it is said that the global agencies like European Food Safety Authority, Food Standards Australia, New Zealand and USFDA Food Drug Administration have also contributed some extent in the assimilation, integration and harmonization of Indian Standards thereby bringing them almost at par with the global standards.

So, actually in that line so we also will review quickly about the FDA regulations and also some of the European regulations so which has also got great impact on the Indian Standards.

(Refer Slide Time: 42:22)

Agencies Responsible for Food

- Environmental Protection Agency (EPA) ✓
✓ Drinking water, pesticides
- Food and Drug Administration (FDA) ✓
✓ Food (not meat), drug, dietary supplements, cosmetics, medical devices, bottled water, seafood, wild game (exotic meat), eggs in shell, wine beverages with <7% alcohol
- Federal Trade Commission (FTC)
✓ Advertising ✓
- Alcohol and Tobacco Tax and Trade Bureau (TTB)
✓ Alcohol
- United States Department of Agriculture (USDA) ✗
✓ Grading of raw vegetables and fruit; meats; poultry; processing and grading of eggs

So, there should not be any confusion that why the international laws or US Regulations and European Regulations are discussed here in the Indian contexts but most of the Indian standards were also derived from them to make this as a global standards it is not only for India. So, the agencies responsible for food as Environmental Protection Agency in terms of drinking water and pesticides.

And Food and Drug Administration FDA, food not meat, drug, dietary supplements, cosmetics, medical devices, bottled water, seafood, wild game so that means exotic meat and eggs in shell, wine beverages with less than 7 percentage alcohol everything will come under the agency of Food and Drug Administration. Then Federal Trade Commission, which is for advertising. Alcohol and Tobacco Tax and Trade Bureau TTB which is for alcohol and United States Department of Agriculture USDA,

So, this takes care of the raw vegetables and fruits, meats, poultry, processing and grading of eggs. So, whatever left here, in food the meat is not come under the category of Food and Drug Administration. So, further the United States Department of Agriculture so which grades the raw vegetables, fruits, meats, poultry, processing and grading of eggs.

(Refer Slide Time: 43:47)

USDA

- FSIS division of USDA is responsible for meat and poultry inspection
- If a processing plant sells products in-state only, inspection can be performed by state inspectors
- Facilities can opt for federal or state inspection
 - ✓ A state's program must enforce requirements at least equal to those imposed by the Federal Meat and Poultry Products Inspection Acts
 - ✓ If inspected by state, product sale is limited to that state
- X CFR Y.Z(a): Title X, Section Y, Part Z, Sub-Part a

So, what is USDA regulations? The FSSAI so this is nothing but Food Safety and Inspection Services, FSIS is Food Safety Inspection Service division of USDA is responsible for meat and poultry inspection. If a processing plant sells products in-state only the inspection can be performed by a state inspectors. Facilities can opt for federal or state inspection, federal means centrally.

A state's program must enforce requirements at least equal to those imposed by the Federal Meat and Poultry Products Inspection Acts. So, the state cannot have its own regulations so they also should enforce the requirements at least equal to those imposed by Federal Meat Poultry Products Inspection Acts. If inspected by a state the product sale is limited to that particular state whatever we followed in India.

So, if the business is done by inter states through two or more states then we also told as per the FSSAI we supposed to take each states permission the same with USDA as well. So, the regulations says that so the X CFR federal regulations so X means title and this Y means section and Z is nothing but a part and a is nothing but a sub-part. So, this is the way the regulations were given.

(Refer Slide Time: 45:14)

FSIS Canning Regulations

- Achieve commercial sterility: Using scheduled process determined by process authority
- 9CFR318.300: Canned meat products ✓
- 9CFR381.300: Canned poultry products ✓
- 7CFR 52: Standard for grades (for certain fruits & vegetables) - Administered by Agricultural Marketing Service of USDA ✓
(AMS)

And FSIS Canning Regulations. So, here we are going to see only the important things. So, to achieve commercial sterility using scheduled process determined by processing authority so this we have discussed in earlier Thermal Processing lectures itself. So, for example 9CFR318.300 which is for canned meat products and 9CFR381.300 which is for canned poultry products these are FSIS Canning Regulations.

Then 7CFR 52 these are standards for grades for certain fruits and vegetables. So, they are Administered by Agricultural Marketing Service of USDA so this is called AMS. So, this I have just a put as a example for FSIS Canning Regulations.

(Refer Slide Time: 46:09)

FDA Regulations

- 21 CFR 1-99: General regulations for the enforcement of FD&C Act, FPLA, and Color Additives
- 21 CFR 100-169: Food standards, GMPs, low-acid foods, acidified foods, and food labelling
- 21 CFR 170-199: Food additives
- 21 CFR 101: Food labeling (Principal display panel)
- 21CFR 108: Emergency Permit Control: Acidified foods: 21CFR 108.25; Low-acid foods: 21 CFR 108.35
- 21 CFR 110: Current GMPs ✓ C GMP
- 21 CFR 113: Low acid foods ✓
- 21 CFR 114: Acidified foods ✓

Agencies Responsible for Food

- Environmental Protection Agency (EPA) ✓
✓ Drinking water, pesticides
- Food and Drug Administration (FDA) ✓
✓ Food (not meat), drug, dietary supplements, cosmetics, medical devices, bottled water, seafood, wild game (exotic meat), eggs in shell, wine beverages with <7% alcohol
- Federal Trade Commission (FTC)
✓ Advertising ✓
- Alcohol and Tobacco Tax and Trade Bureau (TTB)
✓ Alcohol
- United States Department of Agriculture (USDA) ✓
✓ Grading of raw vegetables and fruit; meats; poultry; processing and grading of eggs

USDA

- FSIS division of USDA is responsible for meat and poultry inspection
- If a processing plant sells products in-state only, inspection can be performed by state inspectors
- Facilities can opt for federal or state inspection
 - ✓ A state's program must enforce requirements at least equal to those imposed by the Federal Meat and Poultry Products Inspection Acts
 - ✓ If inspected by state, product sale is limited to that state
- X CFR Y.Z(a): Title X, Section Y, Part Z, Sub-Part a

FSIS Canning Regulations

- Achieve commercial sterility: Using scheduled process determined by process authority
 - 9CFR318.300: Canned meat products ✓
 - 9CFR381.300: Canned poultry products ✓
 - 7CFR 52: Standard for grades (for certain fruits & vegetables) - Administered by Agricultural Marketing Service of USDA
- (MS)

Then various FDA Regulations, Food Drug and Administration Regulations so this we have already seen here. So, what are all the foods covered under the category of FDA? So, here we have seen about the USDA Regulations. Here we have seen about FSIS Canning Regulations. So, here now FDA Regulations. So, the 21 CFR 1 to 99 talks about general regulations for the enforcement of FD and C Act, FPLA and Color Additives.

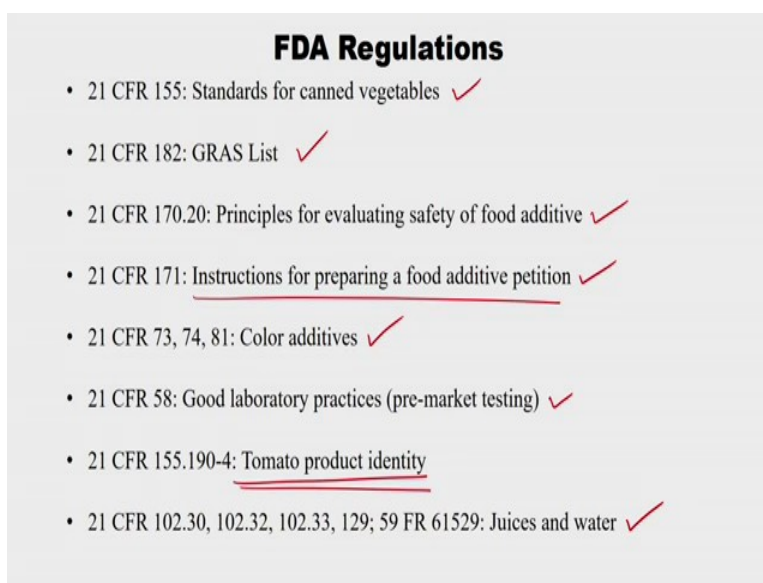
And 21 CFR 100 to 169 so they cover food standards, General Manufacturing Practices, low-acid foods, acidified foods and food labeling and 21 CFR 170 to 199 so they cover Food Additives and 21 CFR 1 naught 1 covers about food labeling principal display panel so this I

discussed for FSSAI Standards in India. So, this is the 21 CFR 1 part 1 under FDA so this talks about also the food labeling which is mainly on principal display panel.

And 21CFR 1 part 8 so that covers the Emergency Permit Control: acidified foods 21CFR 1 part 8.25; low acid food 21CFR 1 part 8.35. And 21 CFR 110 current GMPs the current GMPs is nothing but CGMP so this we discussed in Sanitation lecture itself. And 21 CFR 113 is for low acid food, 114 is for acidified foods. So, these two comes under here, food standards GMPs, low acid food, acidified food and labeling.

So, 110 is for current GMPs, 113 is for low acid food, 114 is for acidified foods. So, these are FDA Regulations. So, these you can browse if you put 21 CFR 113 so all the regulations which are being followed for low acid food will come. So, you can access the website www.fda.gov so in that you will get all these information.

(Refer Slide Time: 48:28)



FDA Regulations

- 21 CFR 155: Standards for canned vegetables ✓
- 21 CFR 182: GRAS List ✓
- 21 CFR 170.20: Principles for evaluating safety of food additive ✓
- 21 CFR 171: Instructions for preparing a food additive petition ✓
- 21 CFR 73, 74, 81: Color additives ✓
- 21 CFR 58: Good laboratory practices (pre-market testing) ✓
- 21 CFR 155.190-4: Tomato product identity
- 21 CFR 102.30, 102.32, 102.33, 129; 59 FR 61529: Juices and water ✓

And 21 CFR 155 are standards for canned vegetables, 182 for GRAS list Generally Recorded as Safe List and 21 CFR 170.20 so they are for principles for evaluating safety of food additive and 21 CFR 171 they are instructions for preparing a food additive petition and 21 CFR 73, 74, 81 are for color additives, 21 CFR 58 good laboratory practices. So, pre market testing and 21 CFR 155.190-4 so this is for tomato product identity and 21 CFR 1 part 2.30, 1 part 2.32, 1 part 2.33, 129; 59 FR 61529 everything is for juices and water.

So, different regulations they may be put in different categories. For example, if you go for 21 CFR 171 so it mainly talks about the instructions for preparing food additive petition but for juices and water there may be certain regulations told in different places of the FDA Regulations.

(Refer Slide Time: 49:42)

FDA Authorized Health Claims

- ✓ General regulations: 21 CFR 101.14
- ✓ Ca and Osteoporosis: 21 CFR 101.72
- ✓ Fat and Cancer: 21 CFR 101.73
- ✓ Sodium and Hypertension: 21 CFR 101.74
- ✓ Sat fat, chol and Coronary Heart Dis. (CHD): 21 CFR 101.75
- ✓ Fiber containing grains/fruits/veg and Cancer: 21 CFR 101.76
- ✓ Fiber containing grains/fruits/veg and CHD: 21 CFR 101.77
- ✓ Fruits & Vegetables and Cancer: 21 CFR 101.78
- ✓ Folic Acid and Neural Tube Defects: 21 CFR 101.79
- ✓ Sugar Alcohols and Dental Caries: 21 CFR 101.80
- ✓ Soluble Fiber from whole oats etc and CHD: 21 CFR 101.81
- ✓ Soy protein and CHD: 21 CFR 101.82
- ✓ Plant sterols, plant stanols and CHD: 21 CFR 101.83

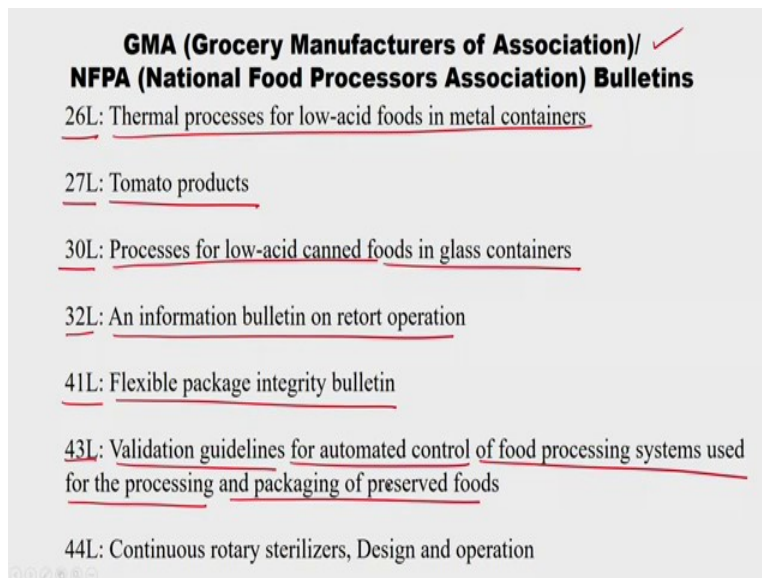
And this is another thing so when I was talking about the Nutraceuticals I told whatever the claim we are making here supposed to comply with the scientific evidences. So, based on the scientific evidences FDA authorized certain health claims of the products. So, those were listed here so it may be helpful for you to understand the Nutraceutical benefits here because it is approved by Food and Drug Administration.

The general regulations are given in 21 CFR 101.14. The calcium and Osteoporosis effect, so this is the disease. So, calcium effect on Osteoporosis is given under 21 CFR 101.72 and fat which is related to Cancer so those regulations were given in 21 CFR 101.73 and sodium level on Hypertension which is given in 21 CFR 101.74 and saturated fats, cholesterol and on Coronary Heart diseases which is given in 21 CFR 101.75.

Then fiber containing grains, fruits, vegetables on Cancer is given in 21 CFR 101.76 and fiber containing grains, fruits and vegetables on CHD Coronary Heart Diseases which is given in 21 CFR 101.77 and fruits and vegetables and on Cancer is given in 21 CFR 101.78 and folic acid and neural tube defects which is given in 21 CFR 101.79. Sugar, alcohols on dental caries so which is given in 21 CFR 101.80.

Soluble fiber from whole oats etcetera on CHD is given in 21 CFR 1 naught 1.81; soy protein on CHD is 21 CFR 1 naught 1.82; plant sterols, plant stenols on CHD is given in 21 CFR 1 naught 1.83. So, this is FDA authorized health claims based on the scientific evidence. So, these federal regulations comfortably discusses about the diseases and food components or dietary supplements against that particular diseases with based on scientific evidence provided to FDA. So, we can totally trust these composition on that particular diseases.

(Refer Slide Time: 52:23)



The next one is the GMA which is nothing but Grocery Manufactures Association in US and NFPA which is nothing but National Food Processors Association. So, they came up with certain bulletins as a regulations. 26L talks about thermal processes for low acid foods in metal containers; 27L talks about the tomato products and 30L talks about the processes for low acid canned foods in glass containers and 32L talks about an information bulletin on retort operation, 32L talks about the information bulletin on retort operation.

And 41L discusses about flexible packaging integrity bulletin and 43L gives the guidelines about the validation guidelines for automated control of food processing systems used for the processing and packaging of preserved foods and 44L talks about the continuous rotary sterilizers, design and operation. 43L talks about the validation guidelines for automated control of food processing systems used for the processing and packaging of preserved foods.

So, again here those bulletins are given as an example. So, there are lot many so you may refer based on your requirements or some of your working in particular industry. So, based on your needs you can browse in the Food Safety Standards or FDA to get to know more about all the bulletins or whatever the required bulletins for your industry.

(Refer Slide Time: 54:10)

EU and UK Regulations

- EU Food Laws
 - ✓ European Food Safety Authority (EFSA):
<http://www.efsa.europa.eu> ✓
- UK Food Laws
 - ✓ Food Standards Agency (FSA):
<http://www.food.gov.uk> ✓

**GMA (Grocery Manufacturers of Association)/ ✓
NFPA (National Food Processors Association) Bulletins**

26L: Thermal processes for low-acid foods in metal containers

27L: Tomato products

30L: Processes for low-acid canned foods in glass containers

32L: An information bulletin on retort operation

41L: Flexible package integrity bulletin

43L: Validation guidelines for automated control of food processing systems used for the processing and packaging of preserved foods

44L: Continuous rotary sterilizers, Design and operation

And there are EU and UK Regulations as well. The European Union Food Laws can be accessed in this particular website which is ww efsa europa dot eu and UK Food Laws can be accessed in www dot food dot government dot uk. So the food standards agencies FSA for UK food laws, for European food laws they have got European Food Safety Authority EFSA.

So, because we have already discussed enough about so again it will be a the regulation numbers and what it discusses about. So, I would like to give you as a home assignment to check for its various regulations implied by European Union as well as United Kingdom.

(Refer Slide Time: 55:10)

Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulation, 2017 ✓

- Food Safety and Standards Authority of India (FSSAI) - Official gazette of India with reference to microbiological requirements for fish and fishery products. ✓
↑
- Regulation:
 - ✓ Revised microbiological necessities for sea foods ✓
 - ✓ New varieties of fish and fisheries products ✓
 - ✓ Maximum allowable limits of hygiene indicator organisms ✓
 - ✓ Safety indicator organisms in a wide range of fish and fishery products other food items namely oils, fats, oats and pasta
 - ✓ Sampling plan and reference test methods for microbiological limits. ✓
- These standards have been finalized and come into force on 1st January, 2018.
- The revised microbiological standards aim at guaranteeing quality and food safety of sea food produce in the domestic market.

So, in this particular class we first discussed about the FSSAI Regulations so which is nothing but the Food Safety and Standards Authority of India. So, what should be the procedure to get the standards and safety check for the standardized food and non-standardized food and also what are all the regulations followed for imported and exported food.

And also we said that for imported food, so the FSSAI got stringent regulations and because of that certain companies also suffer quite a lot because of these stringent regulations but these are for Food Safety and Standards only. And also for exporters so they may be under the regulation acts but they do not require any food safety license because they do not sale or distribute their products in India and also we told about whatever the safety standards are drawn by FSSAI so that comes under this Codex Alimentarius Regulations, the Codex standards. So, to comply that Codex standards so it also has to be derived or it has also to be par with international Food Safety and Standard Laws.

(Refer Slide Time: 46:09)

FSIS Canning Regulations

- Achieve commercial sterility: Using scheduled process determined by process authority
- 9CFR318.300: Canned meat products ✓
- 9CFR381.300: Canned poultry products ✓
- 7CFR 52: Standard for grades (for certain fruits & vegetables) - Administered by Agricultural Marketing Service of USDA
(MS)

FDA Regulations

- 21 CFR 1-99: General regulations for the enforcement of FD&C Act, FPLA, and Color Additives
- 21 CFR 100-169: Food standards, GMPs, low-acid foods, acidified foods, and food labelling
- 21 CFR 170-199: Food additives
- 21 CFR 101: Food labeling (Principal display panel)
- 21CFR 108: Emergency Permit Control: Acidified foods: 21CFR 108.25; Low-acid foods: 21 CFR 108.35
- 21 CFR 110: Current GMPs ✓ C GMP
- 21 CFR 113: Low acid foods ✓
- 21 CFR 114: Acidified foods ✓

FDA Regulations

- 21 CFR 155: Standards for canned vegetables ✓
- 21 CFR 182: GRAS List ✓
- 21 CFR 170.20: Principles for evaluating safety of food additive ✓
- 21 CFR 171: Instructions for preparing a food additive petition ✓
- 21 CFR 73, 74, 81: Color additives ✓
- 21 CFR 58: Good laboratory practices (pre-market testing) ✓
- 21 CFR 155.190-4: Tomato product identity
- 21 CFR 102.30, 102.32, 102.33, 129; 59 FR 61529: Juices and water ✓

FDA Authorized Health Claims

- ✓ General regulations: 21 CFR 101.14
- ✓ Ca and Osteoporosis: 21 CFR 101.72
- ✓ Fat and Cancer: 21 CFR 101.73
- ✓ Sodium and Hypertension: 21 CFR 101.74
- ✓ Sat fat, cho~~l~~ and Coronary Heart Dis. (CHD): 21 CFR 101.75
- ✓ Fiber containing grains/fruits/veg and Cancer: 21 CFR 101.76
- ✓ Fiber containing grains/fruits/veg and CHD: 21 CFR 101.77
- ✓ Fruits & Vegetables and Cancer: 21 CFR 101.78
- ✓ Folic Acid and Neural Tube Defects: 21 CFR 101.79
- ✓ Sugar Alcohols and Dental Caries: 21 CFR 101.80
- ✓ Soluble Fiber from whole oats etc and CHD: 21 CFR 101.81
- ✓ Soy protein and CHD: 21 CFR 101.82
- ✓ Plant sterols, plant stenols and CHD: 21 CFR 101.83

So, in that line so we have discussed about the FDA Regulations. So, from US so whatever I have discussed other than India is mostly USDA regulation and FSIS Canning Regulations and FDA Regulations and also as we discussed in Nutraceuticals. So, we have also checked about the authorized health claims which is proposed by FDA on the Nutraceuticals.

(Refer Slide Time: 56:51)

GMA (Grocery Manufacturers of Association) ✓
NFPA (National Food Processors Association) Bulletins

26L: Thermal processes for low-acid foods in metal containers

27L: Tomato products

30L: Processes for low-acid canned foods in glass containers

32L: An information bulletin on retort operation

41L: Flexible package integrity bulletin

43L: Validation guidelines for automated control of food processing systems used for the processing and packaging of preserved foods

44L: Continuous rotary sterilizers, Design and operation

EU and UK Regulations

- EU Food Laws
 - ✓ European Food Safety Authority (EFSA):
<http://www.efsa.europa.eu> ✓
- UK Food Laws
 - ✓ Food Standards Agency (FSA):
<http://www.food.gov.uk> ✓

And also certain bulletins which are given by GMA which is nothing but Grocery Manufacturers of Association in US and National Food Processors Association US so that also we have seen about. And I have given you to check the European and UK Regulations so that because as we saw earlier the FSSAI also includes the International Food Safety and Standards and their laws to be par with international Food Safety and Standards. So, in that case we also have to know about the US standards, European Standards as well as the UK regulations to get to know more about them.

(Refer Slide Time: 57:38)

References and Additional Resources

- Fortin, N.D. 2009. Food regulation: Law, science, policy, and practice. John Wiley & Sons, Inc.
- Curtis, P.A. 2005. Guide to food laws and regulations. Blackwell Publishing.
- <https://www.foodqualityandsafety.com/article/food-regulations-what-is-the-current-scenario-in-india> [Last Accessed on July, 2019]

So, with this I will end this lecture and also these two books I have used for this particular lecture and for Indian food regulations, so that for that I have accessed this particular website which is last accessed on July to take some points. So, other than that for almost all these laws we have just put as a examples, as an example we discussed and to get to know more about that.

So, please refer their website as I told in the last class also, all these sanitation regulatory bodies also can be accessed on their particular website because now we have got lot of information in the webs and also the books what are all the disadvantages because as I said it needs revision and amendments within 2 years. So, in that case it would not be a wise idea to refer any books for the recent amendments so in that case so we will be able to get to know recent amendments in their website only.

So, in that case only I am urging you to refer their website or requesting you to refer their website for the recent amendments and the recent regulations which is improvised or which is modified to gain more knowledge on that, thank you.