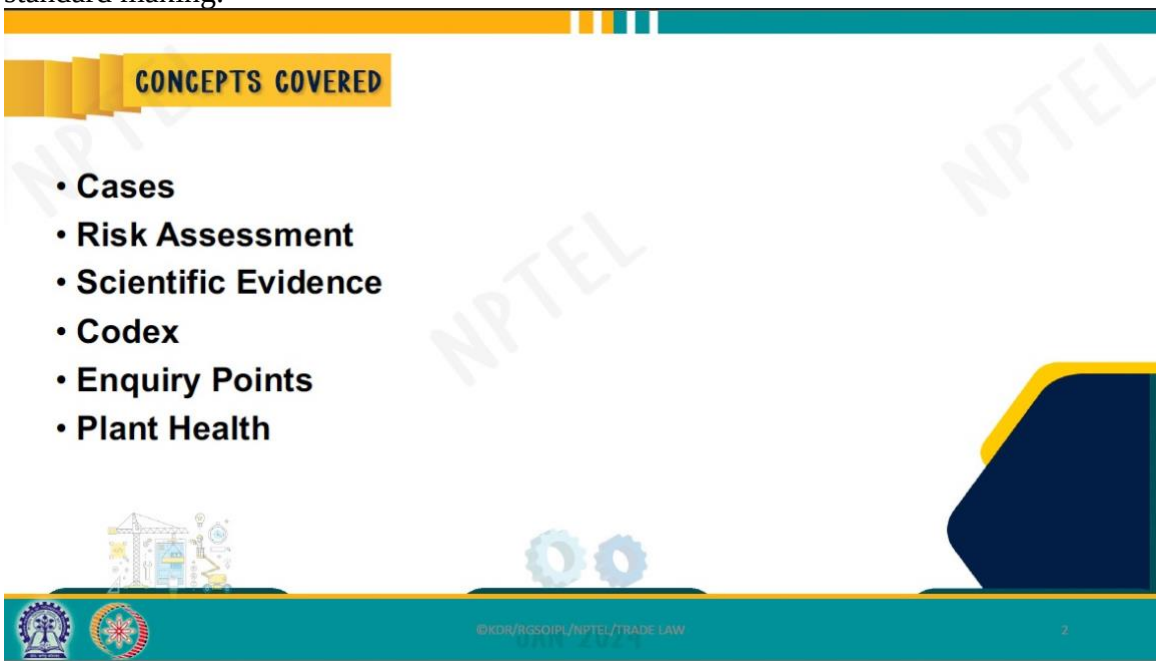
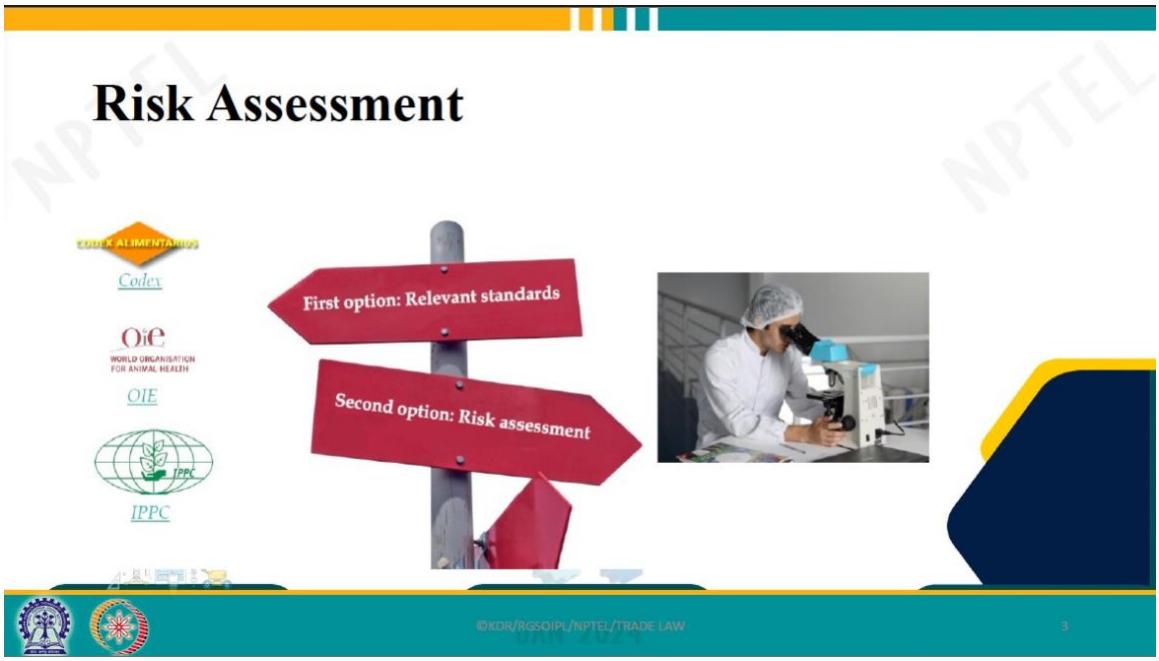
Lecture 13: Assessment of Risks, Codex and Standards

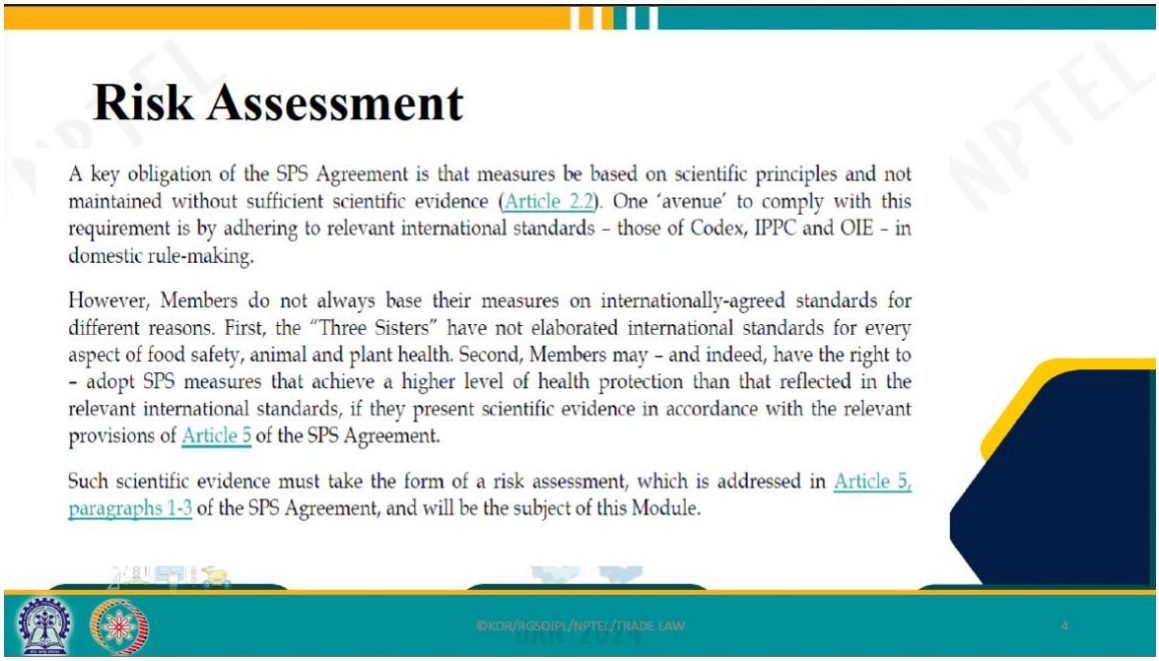
Dear students, in this particular lecture we are going to elaborately discuss about the risk assessment. So, the risk assessment: we said that in the last class the entire SPS measure is based on scientific evidence and risk assessment. So, it is important to see what exactly do you mean by this risk assessment, how the risk assessment is made and the intricacies of risk assessment and how it is affecting or how it is going to affect the international standard making.



And what are its implications also, we will see some of the cases, the case laws which are decided by the panel and other agencies. And also most importantly, we will also see that as a part of the transparency process, the enquiry points, what are the enquiry points in India, what are the other agencies in India dealing with the SPS Agreement. And also, we will see what is the function of the Codex, what this Codex is, what is their function and how they make standards.

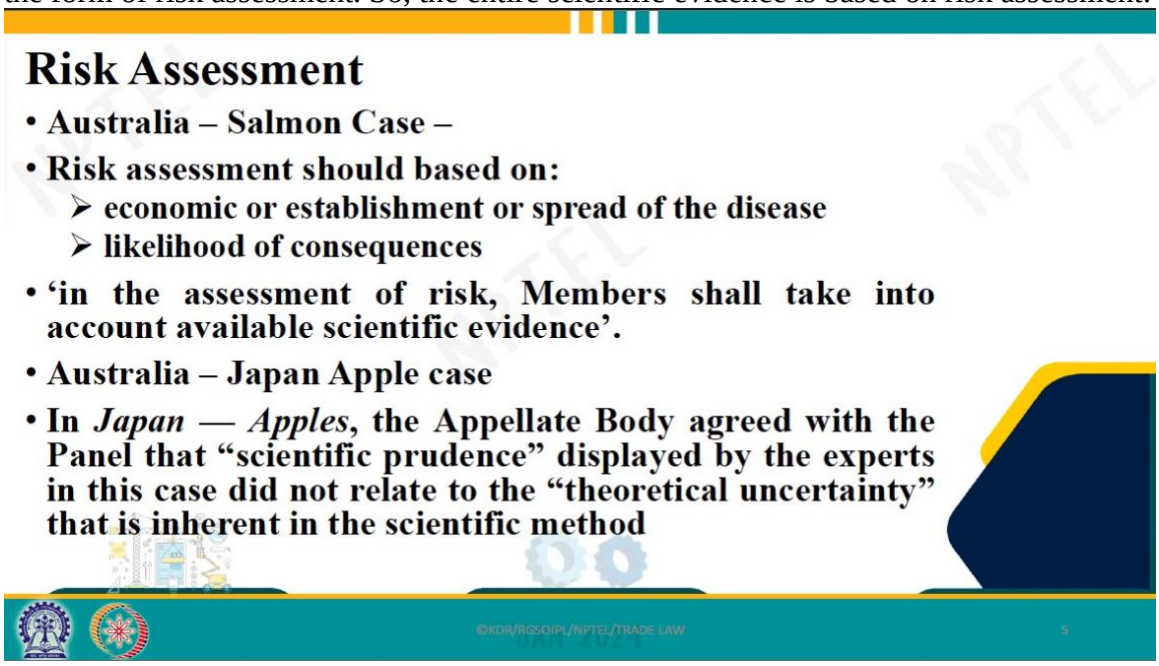


So, let us first see or discuss about the risk assessment. So, risk assessment: you can see that we saw that there are three international organizations which make standards, how do they make the standards? They make the standards based on risk assessment. So, the Codex Alimentarius, which forms food standards, and OIE, which forms the standards for animal health, then IPPC, which forms standards for plant health. So, these are the three international organisations which are making international standards, mainly based on risk assessment.

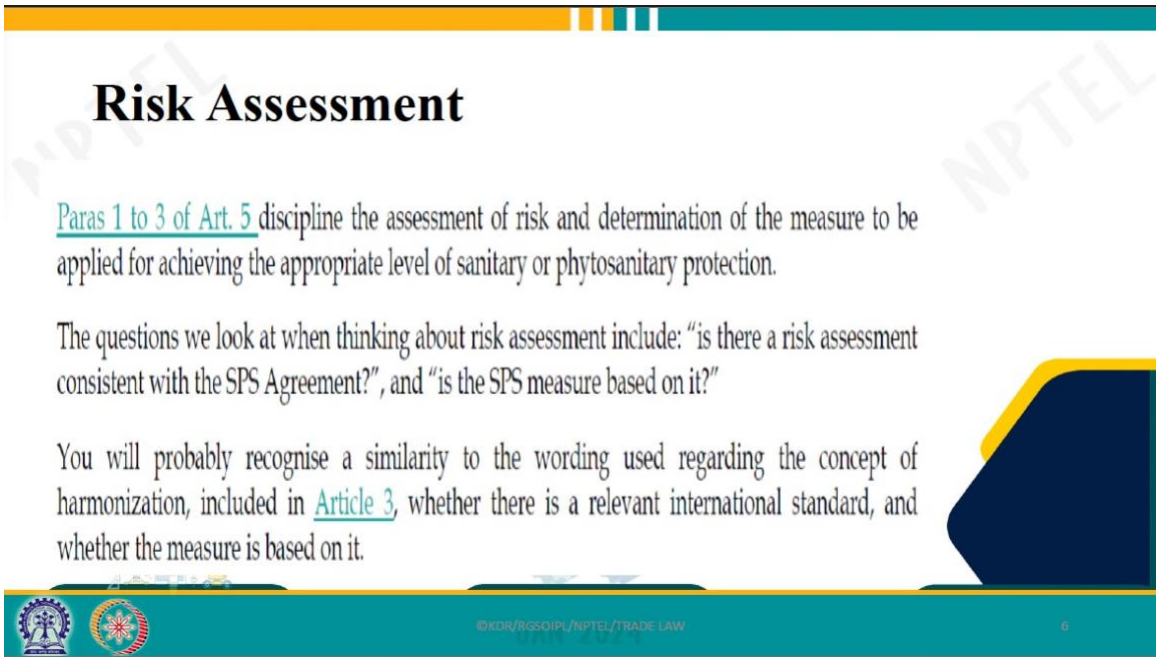


What exactly do you mean by the risk assessment? So, Article 2.2 of the SPS Agreement talks about and clearly says that any SPS measure be based on scientific principles and not be maintained without sufficient scientific evidence. So, who will determine the scientific evidence? So, yes, the members need to prove that these particular measures are

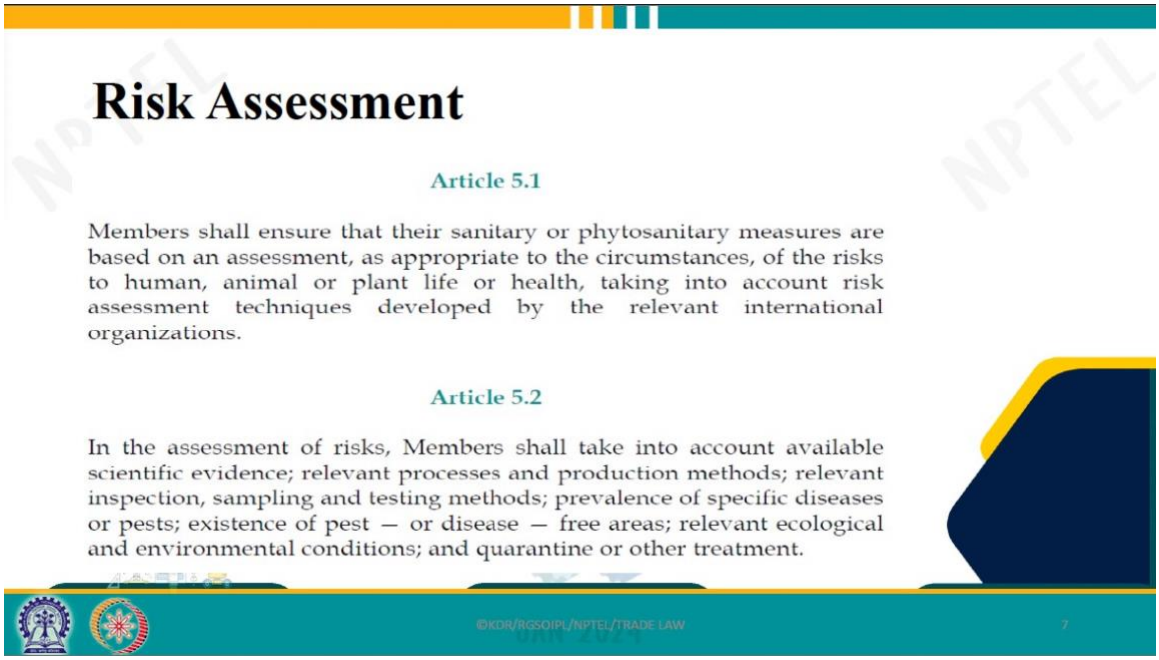
in accordance with scientific evidence, and this is the risk assessment which has been made. So, these standards, internationally standards can be different for different reasons for members. As I told you so you can see the three components; the food safety; animal and plant health. And also the members have the right to adopt SPS measures at a higher level, higher level of health protection than the international standards, but that should be again based on scientific evidence and risk assessment. So, scientific evidence must take the form of risk assessment. So, the entire scientific evidence is based on risk assessment.



And you can see that for the risk assessment in many cases there are rulings from the WTO panel and appellate body. For example, in the Australian Salmon case, the panel very clearly said that the risk assessment must be made based on the economic establishment or spread of the disease and the likelihood of consequences. And for the assessment of risk, the member should take scientific evidence. In Australia-Japan Apple case again the appellate body said scientific prudence, scientific evidence-scientific prudence must be displayed by the experts. So, theoretical uncertainty is not the problem of SPS, and scientific prudence and scientific evidence is the basis of all SPS measures.

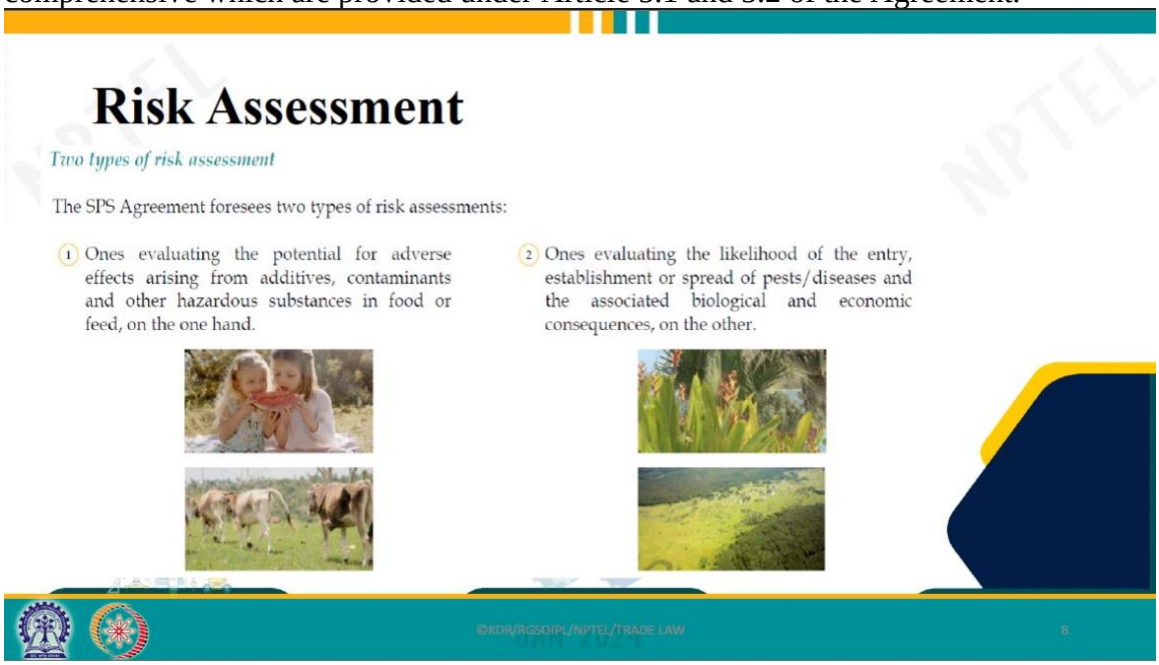


And also you can see the assessment part. How is it done? So, the assessment of risk, as I told you, for achieving a particular level of standard or achieving an appropriate level of Sanitary and Phytosanitary protection. This appropriate level should not exceed primarily to protect plant health, animal health or the food safety mechanism or human health. So, the risk assessment includes these, the risk assessment must be purely scientific in nature. And also you can see that the international standards are made by the international organizations purely based on a risk assessment. So, risk assessment is a part and parcel of the scientific evidence.



So, Article 5.1 of the SPS Agreement clearly says that the members shall ensure that their sanitary or phytosanitary measures are based on assessment, appropriate to circumstances and risk should be assessed to human, animal or plant life health taking into account the

risk assessment techniques developed by the relevant international organisation. So, the standard format is the risk assessment developed by the international organizations and they do a risk assessment and they come out with an international standard and mostly the countries adopt. So, for example, countries like India have not adopted the Codex standards, a very high standard. Rather, India adopted standards developed by its own agencies, and we will see those later in some of the lectures. So, Article 5.2 also supplements Article 5.1 and says that in the assessment of risk the members shall take into account scientific evidence and the process and production methods, the inspection methods, sampling and testing methods, special diseases or pests in a particular region or area, the ecological and environmental concerns and quarantine facilities and treatment. So, it is not very simple. The risk assessment and procedures are elaborate and comprehensive which are provided under Article 5.1 and 5.2 of the Agreement.



And what are the different types of risk assessment? So, the risk assessment and the risk to the human body, animals and plants are different. So, in the case of human beings you can see that the evaluating the potential for adverse effects arising from additives, contaminants and other hazardous substances in food. So, it may be a pesticide residue, it may be additives, it may be contaminants or it may be salmonella contaminants like salmonella, or it may even be named as filthy. So, this is a high risk to human beings, and then the entry of pests if you come to the plants, you can see the entry of pests and diseases to a country is a serious concern of every country. So, the new pests, the entry of new diseases have far reaching consequences on the environment as well. So, the risk assessment is all a part of the entire process.

Risk Assessment

Annex A.4

Risk assessment — The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the Sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences;

or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

So, the risk assessment specifically you can see that it looks into the evaluation of the likelihood of entry, establishment or spread of pests or diseases within a particular territory from the importing country, then adoption of certain SPS measures or other consequences, economic consequences or the evaluation of the potential adverse effect on human animal and plant due to the presence of additives, contaminants, toxins, disease-causing organisms, foods, beverages, foodstuffs etcetera. So, the contamination or contaminants, additives, toxins, all these categories will come under the risk assessment procedures.

Risk Assessment

Assessment of risks from pests and diseases

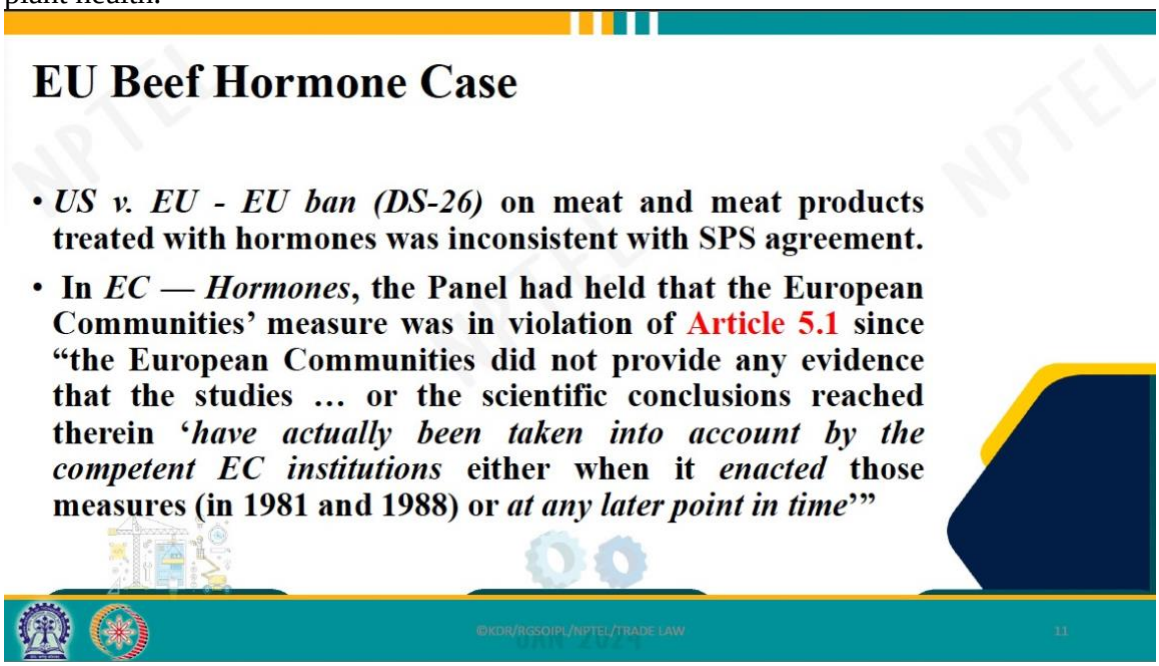
Example: *Australia – Salmon* (1998)

An assessment of pest or disease-risk involves an analysis of the likelihood of a pest or disease entering, establishing, and spreading; and of the associated potential biological and economic consequences.

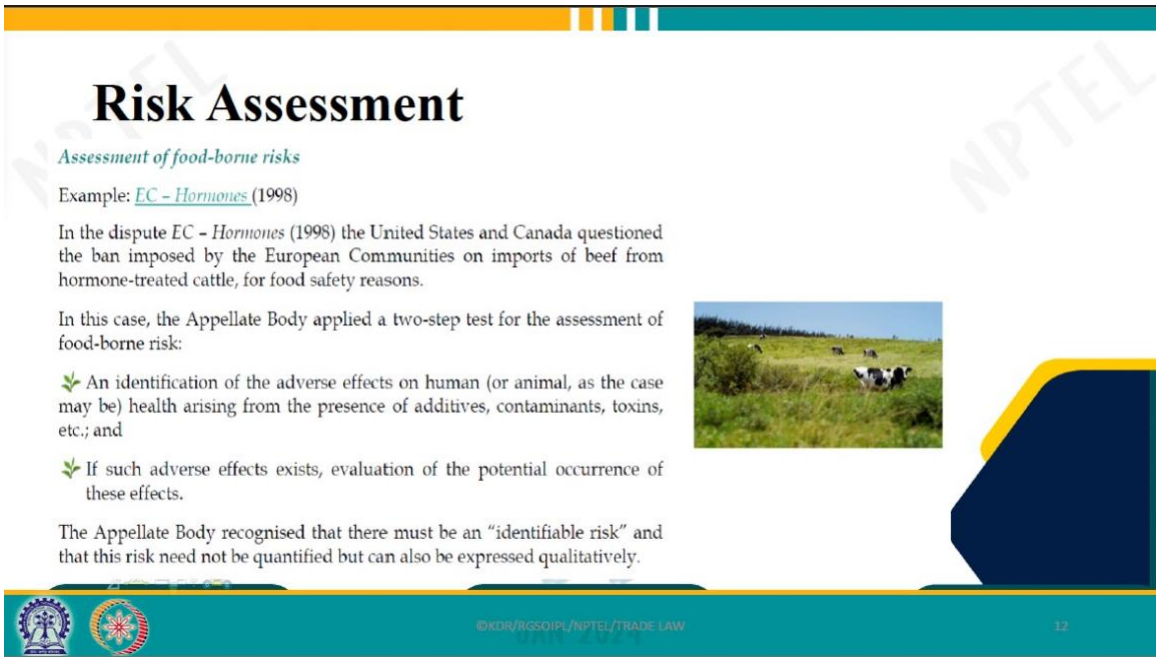
In the dispute *Australia – Salmon* (1998), the measure at issue was Australia's ban on the importation of fresh, chilled or frozen salmon, allegedly to protect the domestic salmon population from a number of diseases. Canada, the complainant, claimed that salmon imported for human consumption was unlikely to lead to the introduction of any such diseases.

And how the risk assessment from pests and diseases is done? So, we already mentioned about the Australia salmon WTO case in 1998. So, the panel and appellate body in different cases has made directives, directions or clarifications on how this risk

assessment is made. So, in the Australia salmon case, salmon, everybody knows is the fish. (1) The risk involved the likelihood of pest or disease establishing and spreading. So, the potential biological and economic consequences are to be taken into consideration for the risk assessment. And (2) can a particular country ban a particular fish or frozen fish by saying that it allegedly carries a number of diseases? So, you can see that Canada claimed that importation for human consumption was unlikely to lead to the introduction of any such disease. Always, the exporter will argue that there is no risk, but always, the importing country argues that there is risk. This has happened in US-EU Beef Hormone case also. So, the burden of proof is with the respondent or the exporting country to prove that, or it is the duty of the importing country to scientifically prove that it is harmful. So, whether it is fish, beef, or biotech products, It is for the importing country to scientifically prove that it is a risk. This is a risk to human health, or animal health, or plant health.



So, we talked too much about the EU Beef Hormone case. So, in this case, also, the appellate body very clearly said, the panel and the appellate body very clearly said that, the European communities did not provide any evidence that the studies or the scientific conclusion reached there in have actually been taken into account by the competent EC institutions either when it enacted those measures in 1981 to 1988 at any later point in time. It clearly says the meat products treated with hormones are not inconsistent with the SPS Agreement. So, that means, meat and products, meat and meat products treated with hormones should be allowed by the EU. So, the EU ban is inconsistent with the SPS Agreement. So, without scientific evidence, you cannot put a particular ban, a blanket ban on the import of any product, whether it is fish or it is beef.



And, we were talking about the hormone case. So, the beef is from hormone-treated cattle. So, the main argument of the European Union was that this causes a threat to human health. So, the appellate body of the WTO Dispute Settlement System has applied a two-step test for the assessment of foodborne risks. So, this entire jurisprudence is based on the risk assessment. So, (1) identification of the adverse effect on human or animal or plant health arising from the presence of particular additives, contaminants, toxins, etcetera. So, first, you have to identify the adverse effects on human beings or animals or plants. (2) such adverse effects exist, evaluation of the potential occurrence of these effects. So, the identifiable risk and that risk need not be qualified but can also be expressed qualitatively. So, the risk must be identifiable; otherwise, you cannot put a blanket ban on the import of any particular products from another WTO member country. So, the risk assessment and the production of scientific evidence always lies on the importing country.

Cases

- GMO case, US, Canada and Argentina v. EC – members cannot apply any ban without scientific evidence.
- Members can only apply measures necessary to protect human, animal or plant life or health.
- Precautionary principle
- Art.5 – scientific evidence should be based on risk assessment

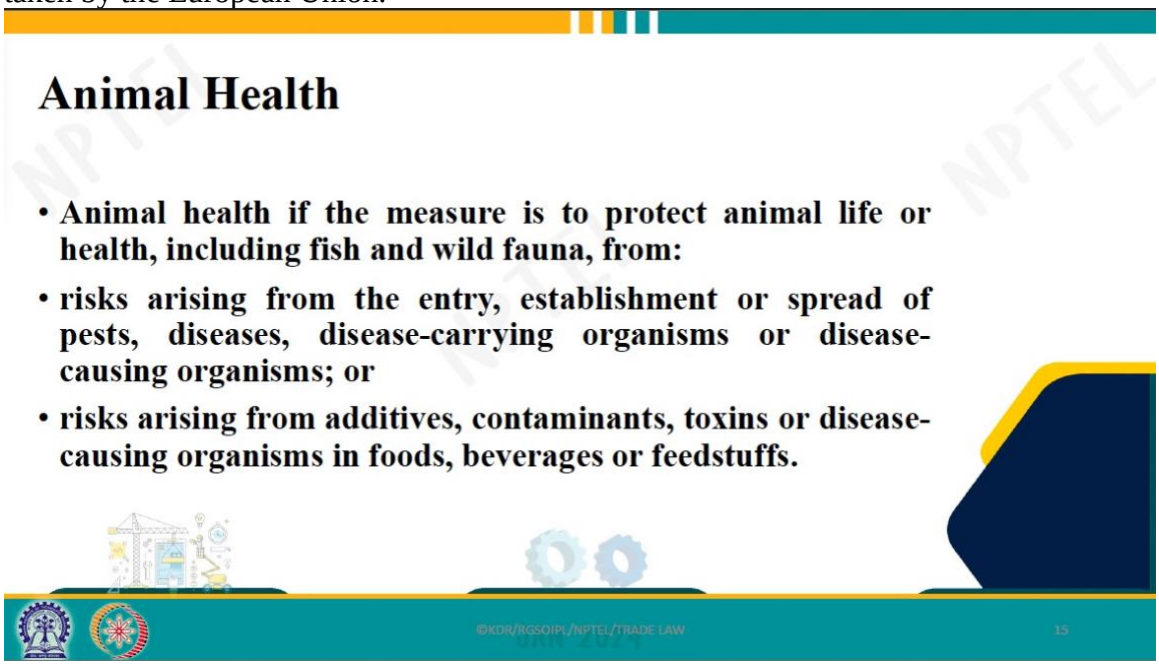
Another famous case is the (US, Canada and Argentina v. EC) Biotech/GMO case. So, the biotech producing countries like US, Canada, Argentina they have complained to the WTO the panel and appellate body saying that the EU has again placed a ban on the genetically modified organisms(GMO) especially food items. So, this was imposed by the European Union without scientific evidence. So, what is the limit? Definitely, the members can adopt standards, but not a blanket ban without scientific evidence and risk assessment. So, in this particular case also, the European Union lost the case because they were not able to produce sufficient scientific evidence.

Scientific Evidence

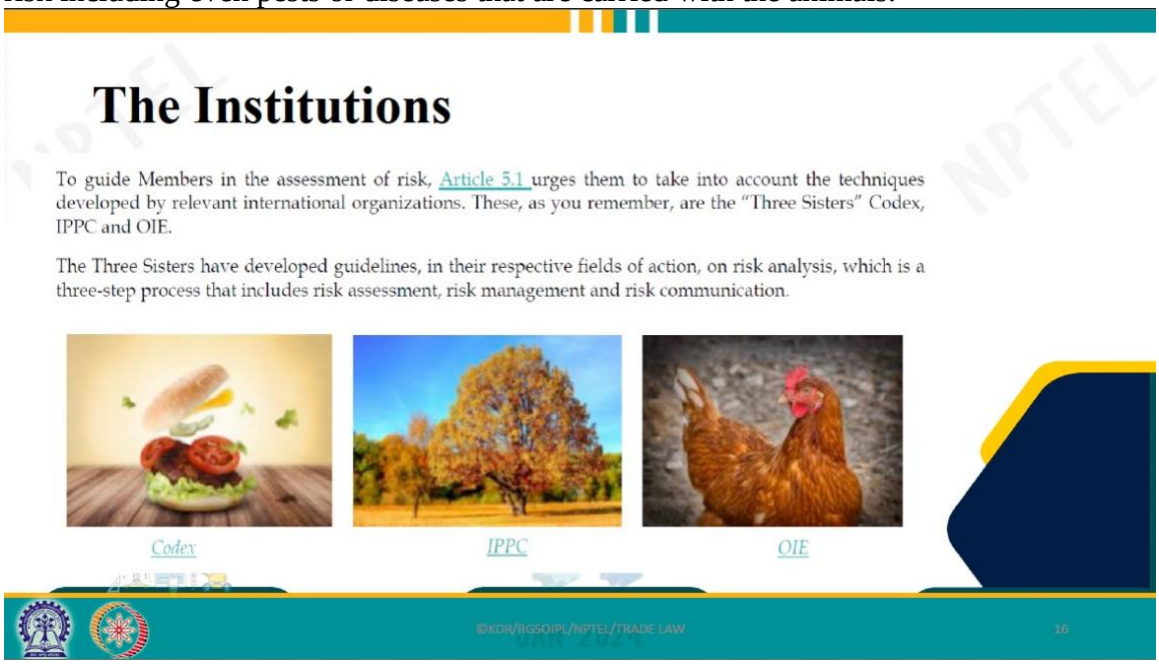
- Article 2 of the SPS Agreement stresses that Members have the right to adopt SPS measures to achieve their self-determined health protection level.
- This level, called the appropriate level of protection (ALOP) or the acceptable level of risk, represents a key feature of the SPS Agreement.

So, scientific evidence is an important component, very important component in risk assessment. And we said that the countries can adopt an appropriate level of protection or acceptable level of risk or even a higher standard based on risk assessment and scientific

evidence and they cannot be adopted as a means of trade barrier. So, in the biotech case and also the US-EU Beef Hormone case, the panel and appellate body said that the European Union used these measures as a trade barrier and struck down the measures taken by the European Union.

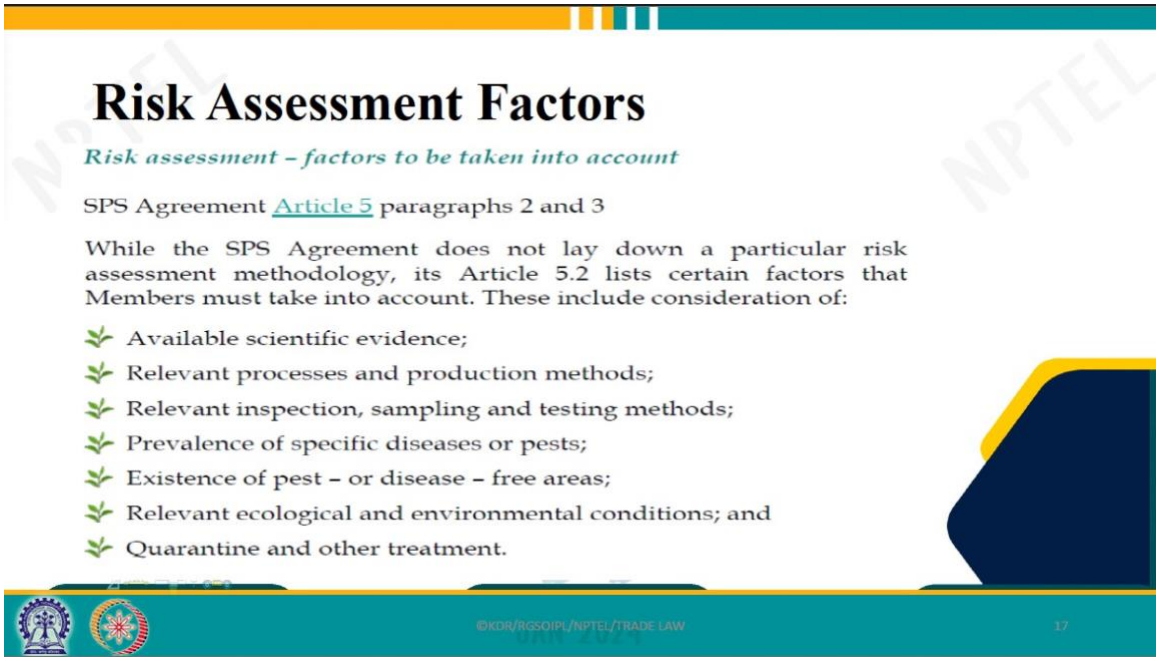


So, when it comes to the animal health, we know that animal health, whether it is the Sardine case, Australia's salmon case which we already discussed about, fish, fauna and flora and risk from injury spread of diseases or disease-causing organisms, all these are a risk including even pests or diseases that are carried with the animals.

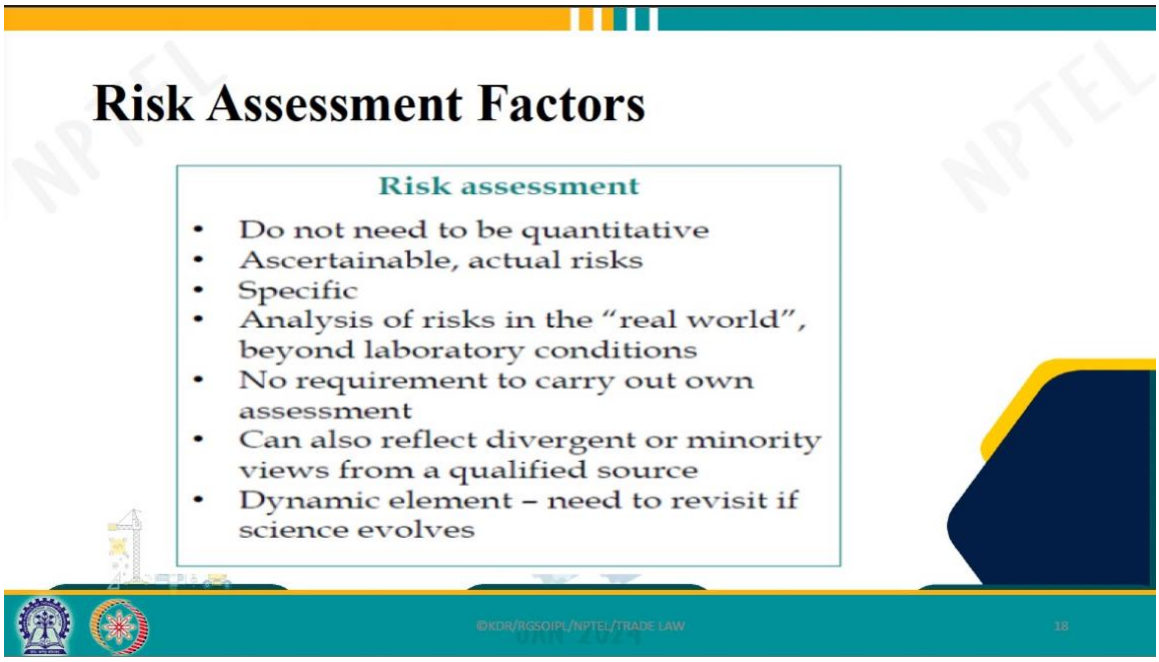


So, we talked about these three organisations, including about the Codex. So, the WTO SPS Agreement urges the members to adopt the international standards adopted by three sisters that is Codex, IPPC and OIE with regard to food standards, plant standards and

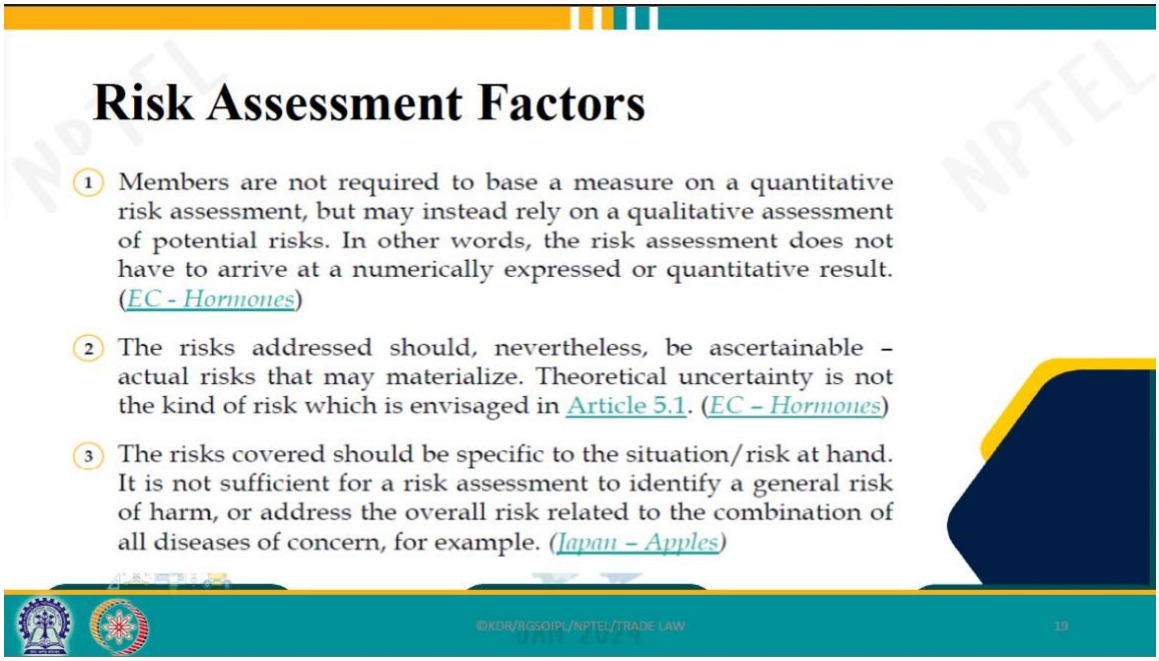
animal standards. So, these international organisations develop international guidelines on risk analysis. So, risk assessment, risk management and risk communication; three-step process which have been developed by these international organisations with regard to risk assessment.



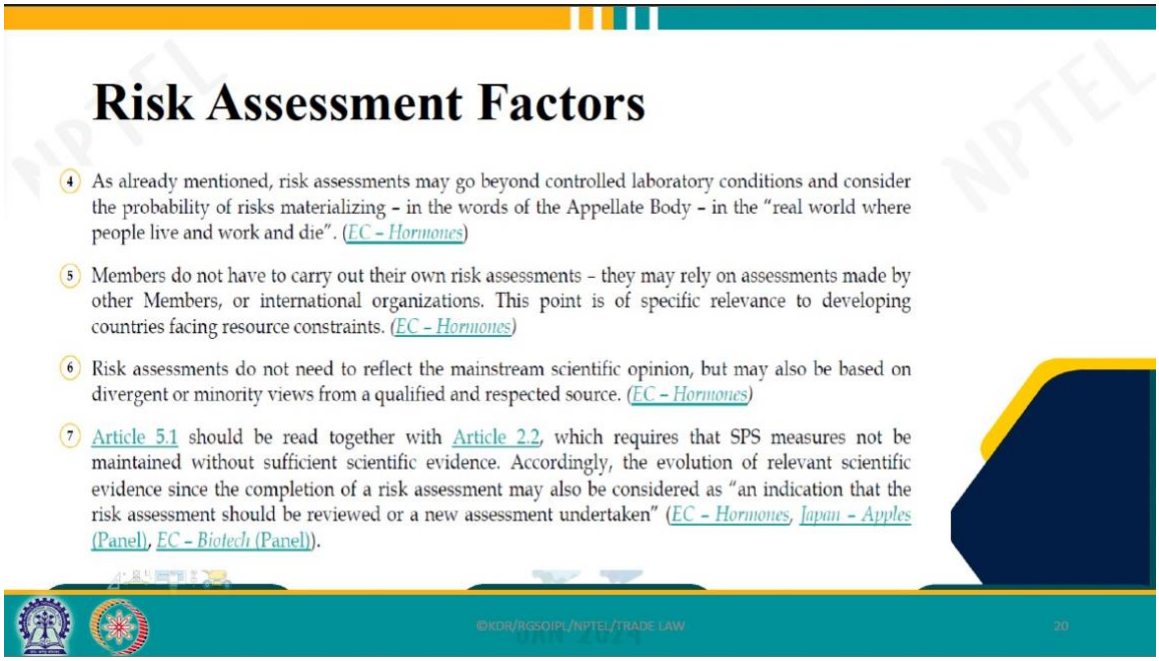
So, what are the risk assessment factors? The risk assessment factors in the SPS Agreement do not prescribe any particular risk assessment methodology, but in Article 5.2, you can find certain factors to be taken into consideration by the members in the risk assessment. What are those factors? Available scientific evidence, relevant process and production methods, inspection methods, sampling and testing methods, relevance of the specific diseases or pest, existence of pest disease or free areas, ecological and environmental conditions, then quarantine facilities or quarantine and other treatment facilities. These are the factors to be taken into consideration for risk assessment which is mentioned under the Article 5, but I said that Article 5 does not prescribe a particular methodology for risk assessment.



And these are the factors. And also, in the risk assessment factors certain measures are to be taken into consideration. What are those measures or certain things to be taken into consideration? They are and do not need to be quantitative in nature. The risk assessment need not be quantitative in nature. So, it must be an ascertainable actual risk. So, it must not be a future risk. It must be an ascertainable and actual risk. It should be specific. It should not be general. So, analysis of the risk in the real world means beyond the laboratory conditions. So, there is no requirement to carry out one's own assessment, and divergent minority views from qualified sources are also acceptable. Then the need to revisit if science evolves. So, science evolves, which means the reasoning involved in the scientific investigation can also be different. So, the risk assessment, these risk assessment factors to be taken into consideration.

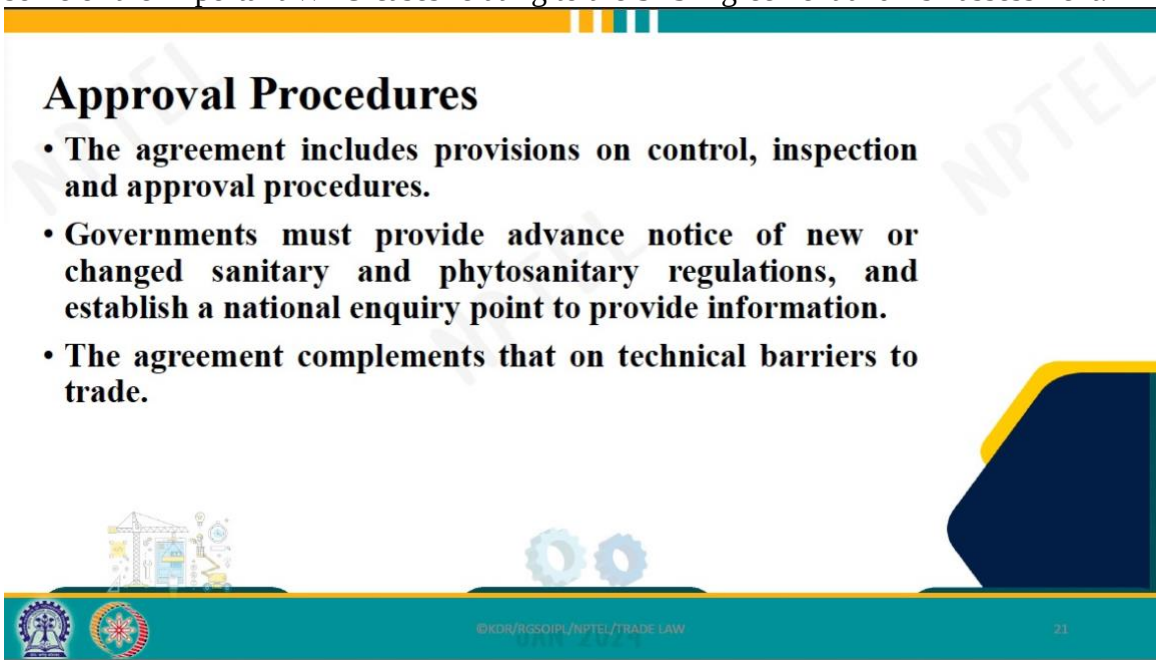


So, we talked about risk assessment factors under Article 5, and in the US-EC Beef Hormone case, the panel and appellate body clearly said that the members were not required to base their measure on quantitative risk assessment. Qualitative risk assessments of potential risks are more than enough. So, that means, a numerical expression or quantitative result is not required under the risk assessment. So, this was held in US-EC Beef Hormone case. And also you can see that ascertainment of actual risk is to be assessed. The theoretical future risk is not the kind of risk which they are looking under Article 5.1 and also you can see that the risk cover should be specific to the situation - risk at hand and it is not sufficient for risk assessment to identify a general risk and general risk is not the subject of SPS Agreement, a specific risk is to be there, identification of a specific risk or a harm and addressing that risk. And this was held in Japan-Apple case. So, the panel and appellate body are also clear with regard to the clarification of points on what exactly constitutes the risk assessment and risk assessment factors.

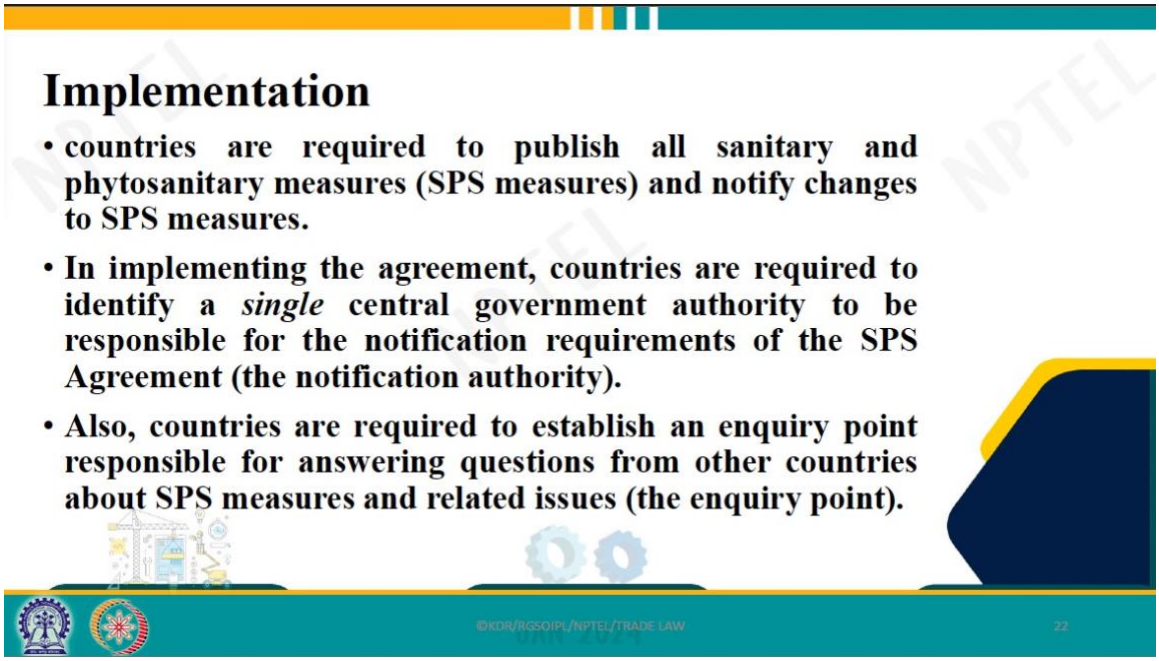


And you can see some of the points sheard by the panel and appellate body. So, they said that it should be the actual conditions, and it may not be in the laboratory conditions. So, the risk may be different in the laboratory, and risk may be different in real-world situations. So, (1) the real-world situations are only taken into consideration, not the laboratory situations. So, (2) And every member is free or they do not also need to carry assessments and the assessments done by other members also can be adopted or the risk assessment done by the international organizations can be adopted by any members. So, every country does not need to do a complete or elaborate risk assessment. If other countries have done it they can adopt it or if the international organizations have done it then they can adopt the international standards and also. So, the mainstream scientific opinion: there can be divergent scientific opinions, a minority opinion from well-qualified person also should be respected and should be taken into concentration and then again, SPS measure cannot be maintained without sufficient scientific evidence. So, that means scientific evidence and risk assessment, should be together, and you cannot impose any SPS measure without scientific evidence and without undertaking a risk

assessment. So, all these points are clarified by the panel and appellate body in US-EC Beef Hormone case and then in the Japan-Apple case and EC-Biotech case. So, these are some of the important WTO cases relating to the SPS Agreement and risk assessment.

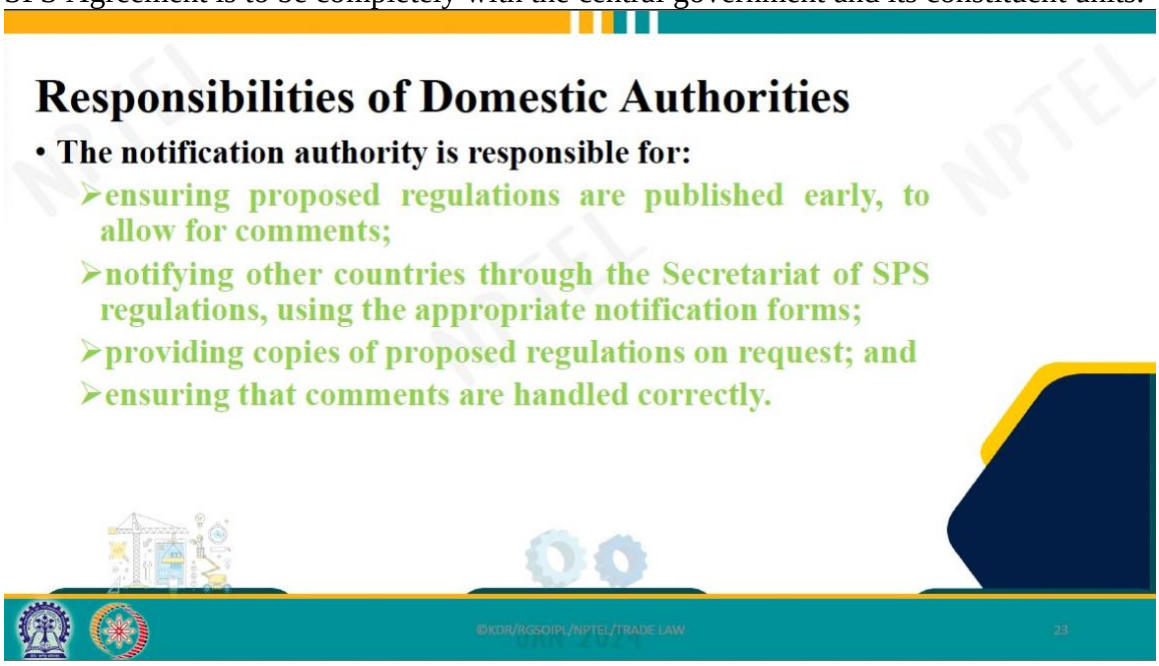


Then approval procedures; so every government must have a testing facility, inspection facility and approval procedures. So, sanitary and phytosanitary regulations and there must be enquiry points for disseminating information. There must be enquiry points for SPS and TBT for the dissemination of information, and specific offices should be designated as SPS offices and TBT offices, and we will see the addresses of Indian offices.

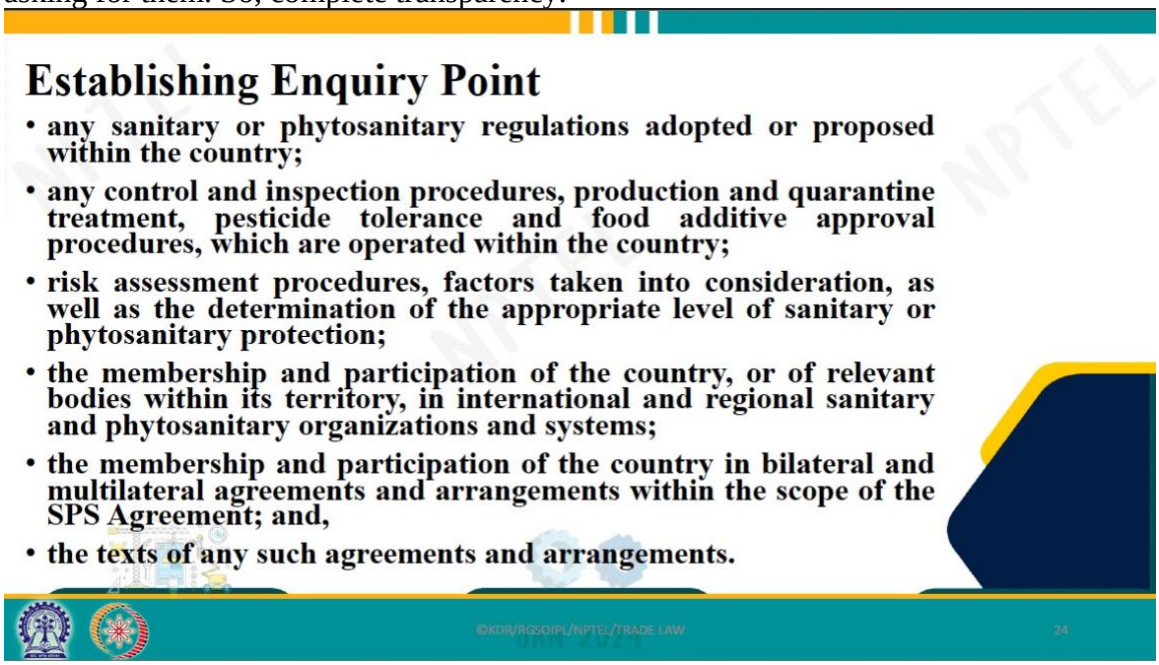


So, the implementation is specifically given to the central governments of every member country because different standards may be adopted by the constituent units of a state at

the lower level, but the implementation is to be done by the central government. So, the implementation is to be done by the central government at the domestic level at all levels, in the entire country they have to be implemented. So, the enquiry point is to be made by the central government, and a notification is to be made. So, the implementation of the SPS Agreement is to be completely with the central government and its constituent units.

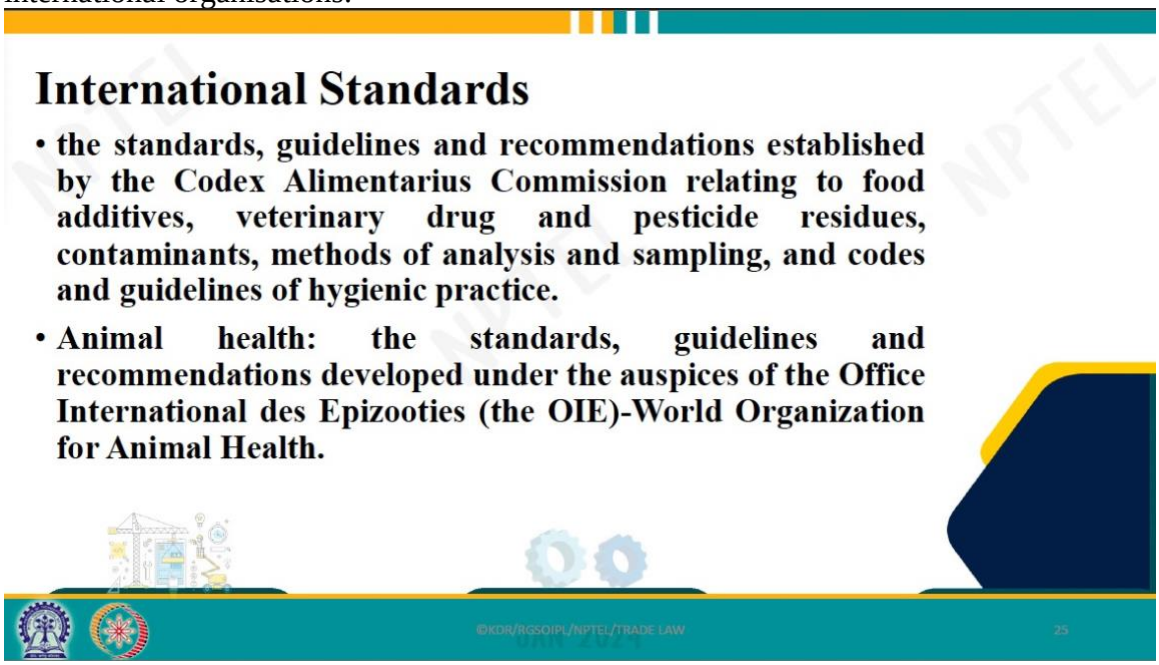


So, the domestic authorities must publish all regulations and all notifications relating to the SPS Agreement, and they should report to the SPS committee. Also, the copies to be provided for such regulations and then the copies to be given to the people who are asking for them. So, complete transparency.

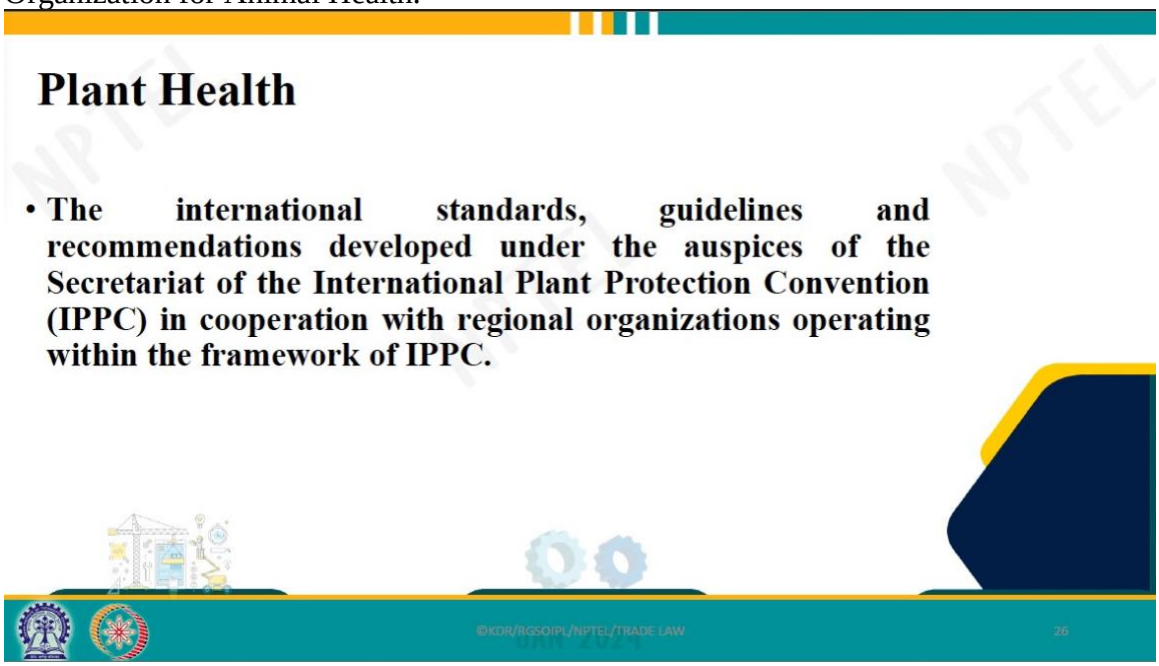


Enquiry points: The objective of the enquiry points is very clear. This is a part of transparency and also designated authorities, designated officials mainly relating to those

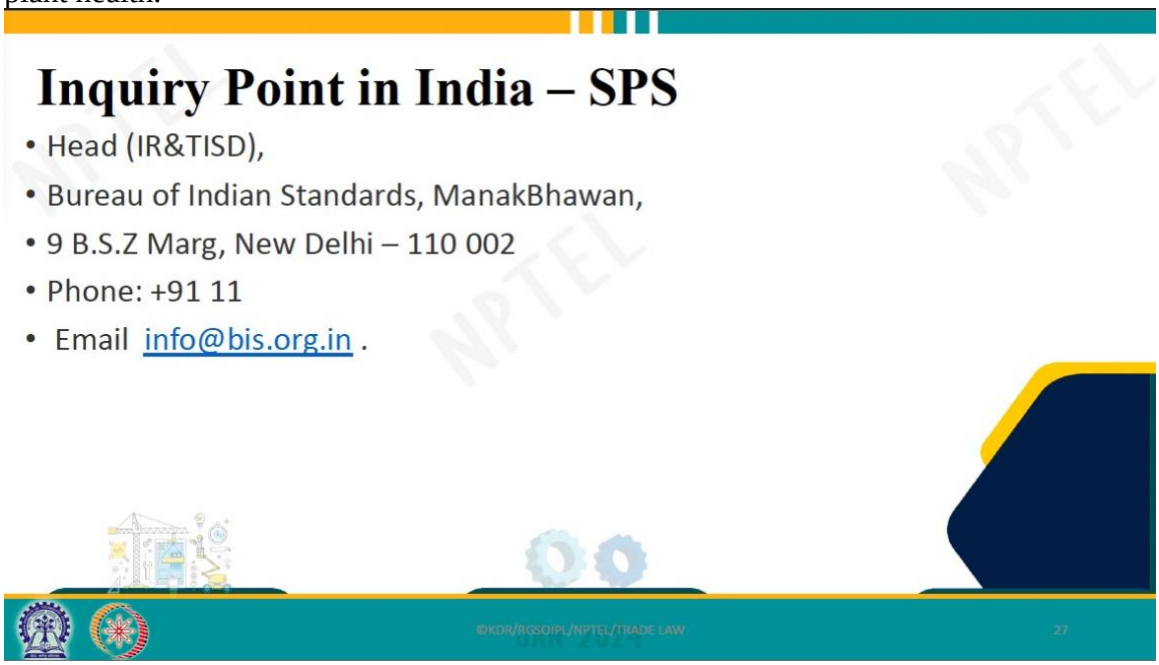
people who want to know about the risk assessment procedures and also other processes, which they have to follow, and also for following the international standards or dissemination of information with regard to international standards developed by the international organisations.



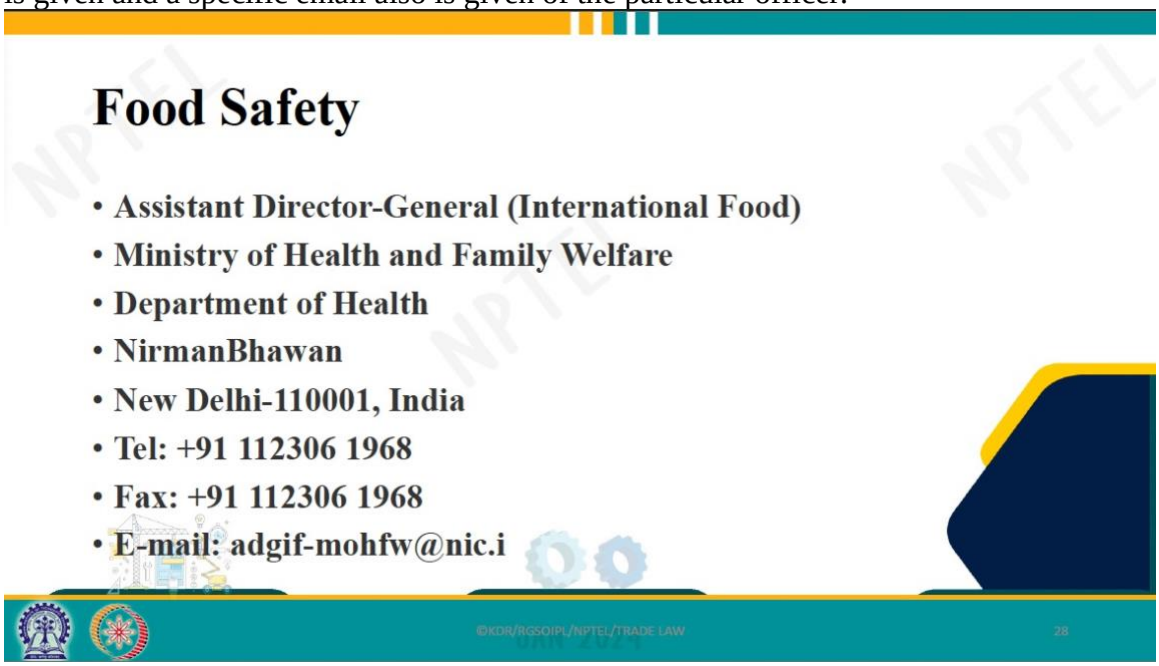
So, we talked about international standards, the three sisters organizations: we have already talked about them and they talk about standards, food standards, additive standard, veterinary drug standards, pesticide residues, contaminants, method of analysis of sampling and guidelines for hygienic practices. So, all these are done by the organisations like Codex and OIE *Office International des Epizooties*, World Organization for Animal Health.



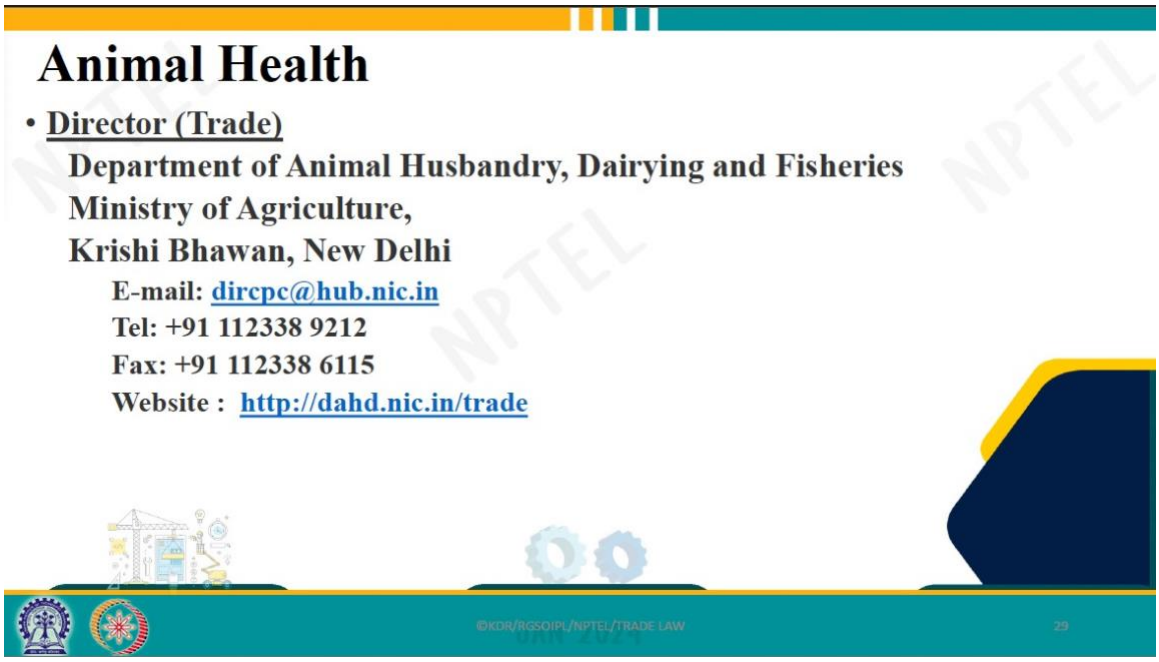
IPPC develops standards, guidelines and recommendations for everybody to protect the plant health.



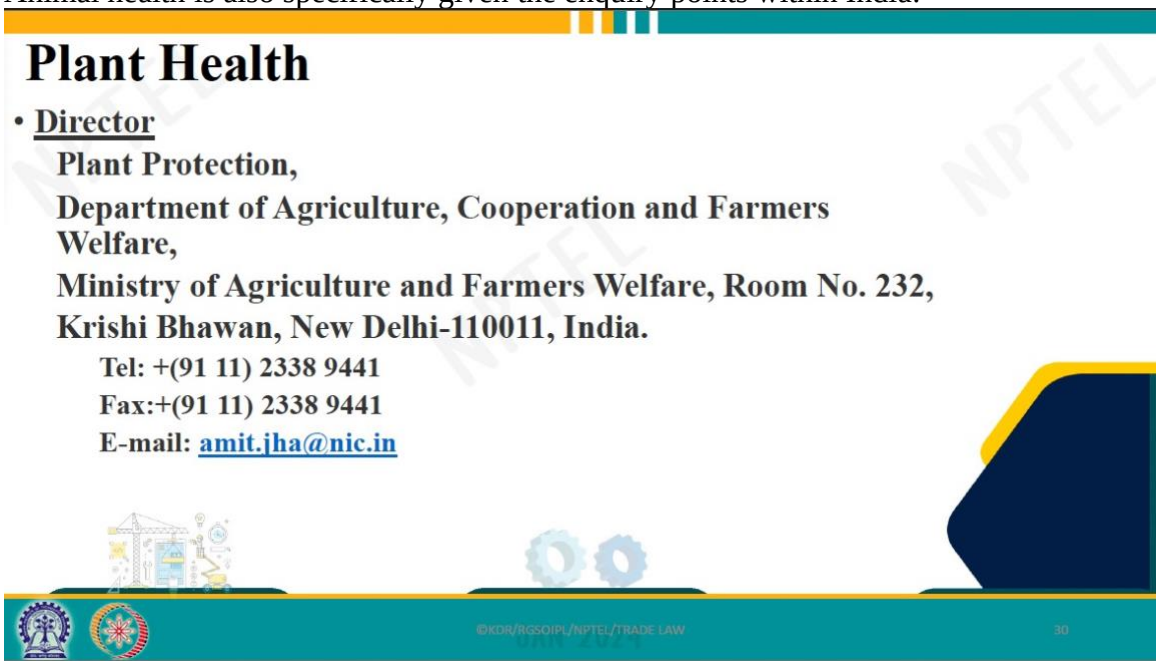
If you look into the enquiry points, you can see enquiry points for every office, every points for example, in India, the SPS office is, you can see the address, a specific address is given and a specific email also is given of the particular officer.



And if you look into food safety, the offices for international food safety are very clearly mentioned. So, what is the address, what are the phone numbers, and what are the email addresses for food safety?



Animal health is also specifically given the enquiry points within India.



And plant health; so, plant health is under another ministry, the Ministry of Agriculture, and there also - the specific person, address and enquiry point are also given.

Codex

- **Deputy Director & Liaison Officer**
  National Codex Contact Point
  Food Safety and Standards Authority of India
  (Ministry of Health and Family Welfare)
  FDA Bhawan, Kotla Road,
  New Delhi – 110002,
  India
  Tel: +91-11-23230997
  Email: codex-india@nic.in

And even you can see who is in charge of the Codex matters, international standard matters.

Risk Assessment

(1)

- **The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing country according to association with potential biological or economic consequences;**

Risk Assessment

(2)

- The evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

So, the government of India has now made different offices to take care of these particular risk assessments and related assessments or other standards or other processes which are relating to these SPS Agreements. And we have talked about risk assessment.

Animal Health

- Animal health and related issues: Director (Trade) (Shri S. K. Srivastava)

  Department of Animal Husbandry, Dairy & Fisheries
  G/SPS/ENQ/16 - 21 - Ministry of Agriculture Krishi Bhavan
  New Delhi 110001 India
  Telephone: +(91 11) 2338 9212 Telefax: +(91 11) 2338 6115
  E-mail/Internet: dircpc@hub.nic.in Website:

And animal health, for animal health also there is an office, a designated office as a part of the enquiry points which is mentioned.

Plant Health

- Plant health or phytosanitary issues:

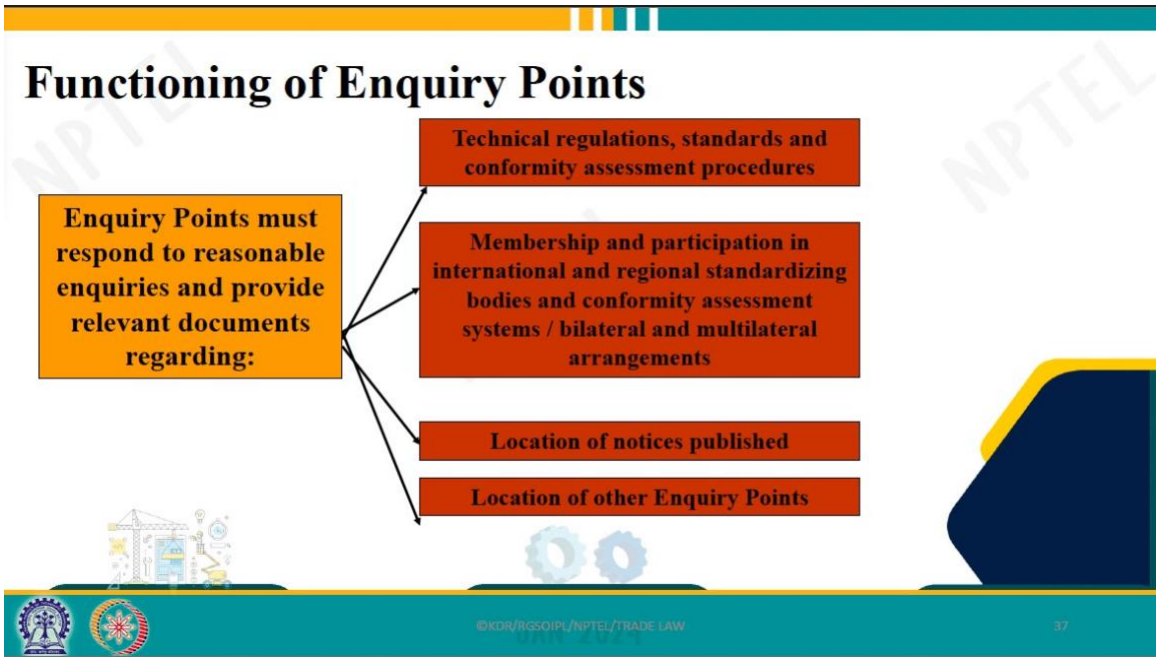
  Director (Mr Amit Jha) Plant Protection,
  Dept. of Agriculture & Cooperation Ministry of Agriculture
  Room No. 232 Krishi Bhavan New Delhi 110001 India
  Telephone: +(91 11) 2338 9441 Telefax: +(91 11) 2338 9441
  E-mail/Internet: amit.jha@nic.in

Plant health: we have already said that it is included.

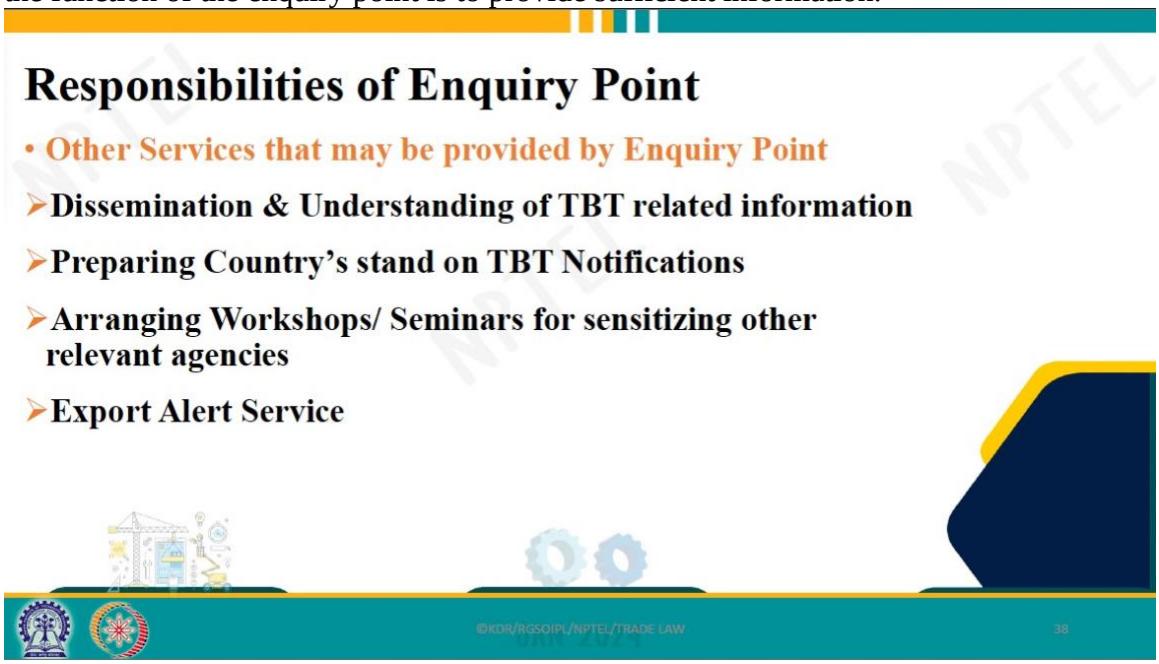
SPS v. TBT

- The scope of the two agreements is different. The SPS Agreement covers all measures whose purpose is to protect:
- human or animal health from food-borne risks;
- human health from animal- or plant-carried diseases;
- animals and plants from pests or diseases;

So, now we look into the SPS, so some of the risks are, we can see that, transgressing into the TBT, the packaging, the labelling and packaging side as well. So, we will discuss this in the coming classes about TBT.



So, what are these enquiry points actually doing? Enquiry points are the points for designated authorities to explain on all questions, reasonable enquiries and provide relevant documents, technical regulations, standards and conformity procedures with regard to SPS Agreement, whether it is food safety or food standards or animal safety or standards for veterinary drugs or even plant health; disease and disease-causing organisms. And these enquiry points are very clear so, they can participate in the regional standardizing bodies and assessment mechanisms and testing arrangements. So, basically, the function of the enquiry point is to provide sufficient information.



They do the dissemination of SPS and TBT-related materials, prepare the basic position of the country on these notifications, arrange workshops and awareness programs and also do training programs and also do alert services.

Notifications and Enquiry Points

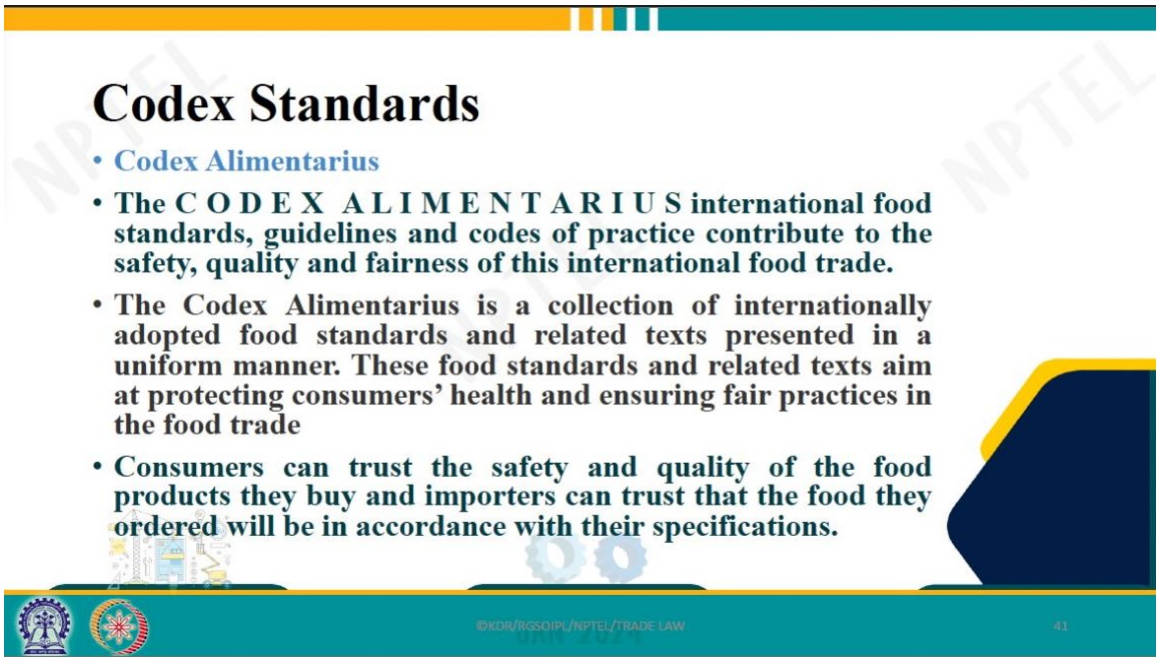
- The Draft Plant Quarantine (Regulation of Import into India) (Second Amendment) Order, 2007
- National Enquiry Point – ……., Director, Plant Protection,
  Department of Agriculture & Cooperation, Ministry of Agriculture,
  Room No. 232, Krishi Bhavan,
  New Delhi - 110 001, INDIA. Tele/Fax: 91-11-23381385
  Email: ……@nic.in

And enquiry points - we have already talked about this.

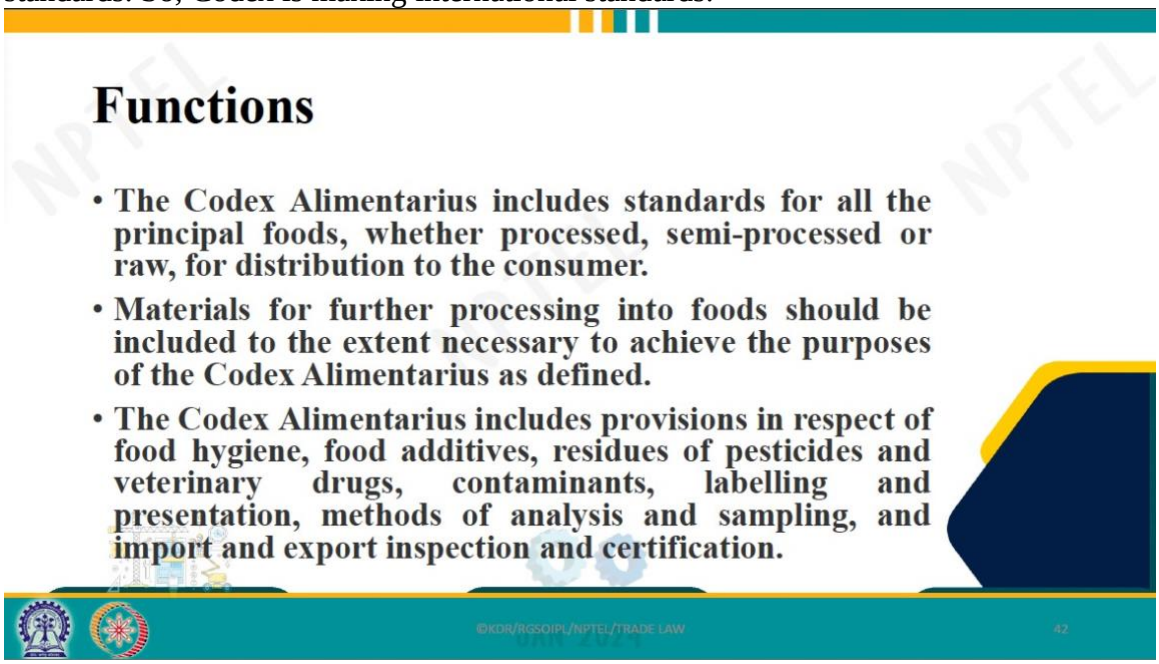
India – Notification Authority & Enquiry Points

- Department of Commerce, Ministry of Commerce- Notification Authority for India.
- Bureau of Indian Standards -Designated TBT Enquiry Point by Ministry of Commerce
- Ministry Of Health & Ministry of Agriculture- SPS Enquiry Points

And the departments concerned there are three departments concerned about the implementation in India that is the Department of Commerce and the Bureau of Indian Standards, the designated authority for the TBT enquiry point. Then, the Ministry of Health and Ministry of Agriculture are the SPS enquiry points. See these are the three ministries responsible for the implementation and other related matters on SPS.



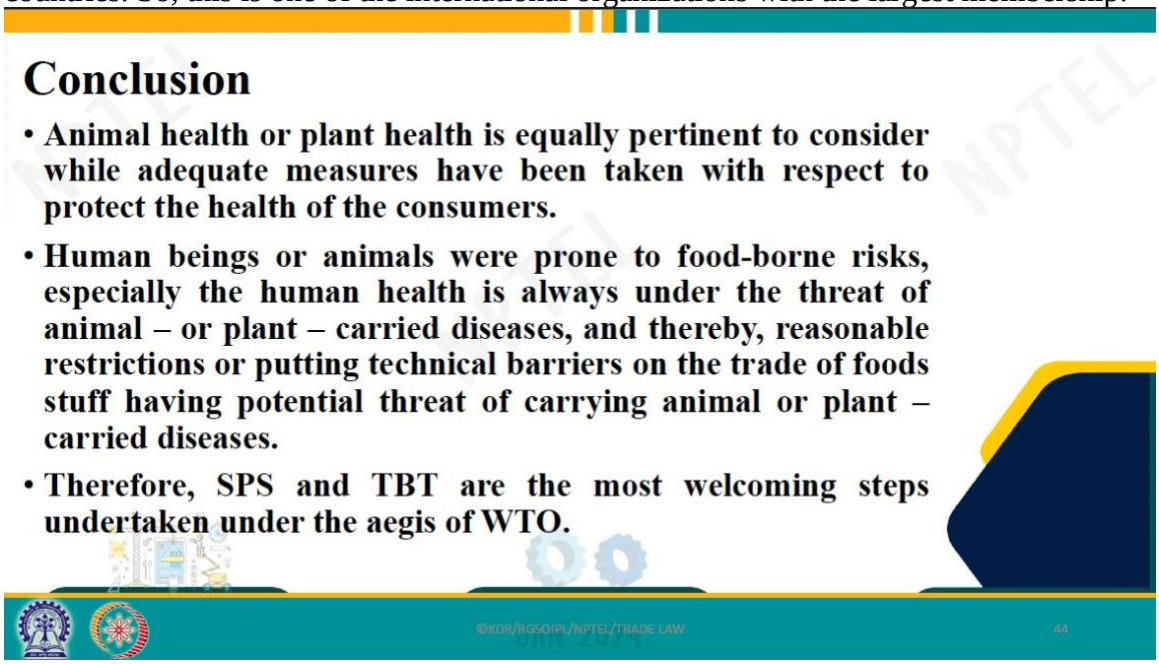
So, one more point which we have to see is the Codex. Why is the Codex important? The Codex Alimentarius Commission is the international standard-making agency for food items. So, they make standards, they make codes of practice, and they make quality standards and they also make international food standards. So, these Codex standards are widely adopted by the members, uniformly adopted, and these standards are made after an elaborate risk assessment, based on scientific evidence, and they form fair practices or good practices. So, the consumers can trust the safety if somebody has adopted the Codex standards. So, Codex is making international standards.



Standards for foods, processed foods, semi-processed foods, raw foods which are directly, the materials are directly distributed to the consumers. So, the Codex prepares the standard based on risk assessment. When it comes to other animals, you can see that

they not only talk about food hygiene but also food additives, residues, the maximum pesticide residues, veterinary ducts, contaminants, labelling and presentation, methods of analysis and sampling and also the import and export inspection and certification mechanisms. So, now every country has an export and inspection mechanism. India also has export inspection and certification mechanisms, still thousands of consignments are rejected every year. So, it shows a very pertinent question, the effectiveness of these particular organizations.

One of the largest membership is there in the Codex Alimentarius Commission with 189 Codex members. So, it is not 189, it is 188 plus the European Union and a bunch of other countries. So, this is one of the international organizations with the largest membership.



And in conclusion, I would say that the human health, animal health, plant health are very important health concerns of consumers. Because we saw in the beginning that there are a lot of consignment rejections, food-borne diseases, food-borne risks to human health and, threats to animals, threats to plants and, so there must be reasonable restrictions, reasonable barriers and reasonable standards in each and every country. So, I said in the last class that if you are not adopting a standard, higher standard, it is your problem, and you cannot impose on the importing materials a higher standard and a lower standard for domestic producers. So, the largest number of rejections shows that there are some problems, there are some problems in the standards, some problems in the risk assessment, and some problems in the certification and inspection schemes, which each and every member has to take into consideration. And SPS never imposes a uniform standard, it never imposes a uniform standard and every member country is free to adopt their own standards. So, we discussed elaborately about risk assessment. And risk assessment is an important factor, very important factor in scientific evidence for the making of SPS measures. So, whether it is the European Union or another country, if any SPS measure is not in accordance with or not complying with or has not produced sufficient scientific evidence and risk assessment procedures, then you cannot put any particular ban. You cannot ban any particular product from any country. So, we can find a number of cases, whether it is salmon case or it is apple case or it is EU Beef Hormone case, or it is EU Biotech case, and you can see a sizeable number of cases. That is why I said that thousands of SPS measures are reported by every country, every year. So, human health, animal health and plant health are very important for every country and everybody should adopt international standards. So, these risk assessment and scientific evidence is the core, the heart of the entire process and in the next class, we will talk about some of the other institutions and other processes related to the SPS Agreement.
Thank you.