Legal and Regulatory Issues in Biotechnology
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Module - 03
Biotech Product commercialization: Regulatory Approval Process
Lecture - 12
Cartagena Protocol

Hello. Welcome back to the course again. So, this is in continuation with our earlier discussion for the Regulatory framework for GM crops. So, in this discussion we would discuss about the Cartagena Protocol which is one of the international obligations for India to adopt different mechanisms where the transboundary movement of the living organism can be regulated and safely assessed.

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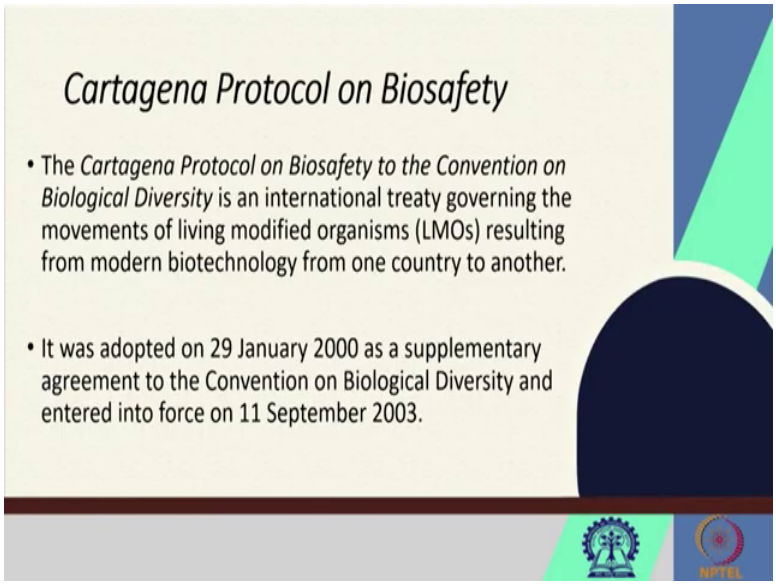

So, this is the current set of legislation. So, since 1976 onwards we have lot of development; we have lot of regulations, guidelines everything in place to now control. But how did it started? So, one of the international obligations which India also followed was the obligation with respect to the Biosafety Protocol or adopting Biosafety guidelines. Because of this protocol which is known as the Cartagena Protocol on Biosafety.

So, this Cartagena Protocol on the Biosafety is basically a part to the Convention of the Biological Diversity which is an international treaty. And this Cartagena Protocol on the Biosafety basically governs the movement of the living modified organisms or the LMOs resulting from the modern biotechnology from one country to other.

So, initially when the research started being international, when you wanted to bring certain genetic resources to your country or give it to other country. Then there was need of this movement of the living modified organism and the inherent risk was also there. Suppose, if there is a loss of the organism or if it is accidentally released into the environment, then, who will be responsible? And if you do not get the intended one and there is certain other negative results or so, there may be lot of consequences.

So, for that reason in order to have a controlled movement and an informed decision on whether or not to bring any genetically modified organism to own country, we needed certain Biosafety assessment.

So, this Cartagena Protocol was enacted for that reason only. And this protocol was adopted on 29th January 2000 as a supplementary agreement to the convention of the biological diversity (CBD) and it entered into force on 11th of September 2003.

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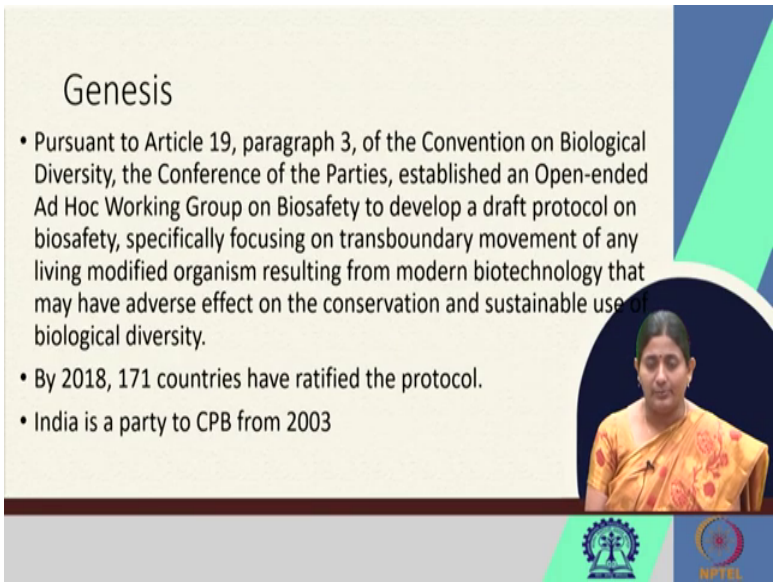

So, if you see the development of this Cartagena Protocol on the Biosafety it is named based on the place on which that treaty was signed- Cartagena. Cartagena in the Columbia.

So, as per the Article 19 of paragraph 3 of this Convention of the Biological Diversity the member countries established an Open-ended Ad Hoc Working Group on the Biosafety to draft the protocol on the Biosafety, particularly focusing on the transboundary movement of the genetically modified organisms derived from the biotechnological process. And which may have adverse effects on the conservation as well as the sustainable use of the biological diversity.

So, finally, that gave us this Cartagena Protocol. And by 2018 nearly 171 countries have ratified this protocol so far. India is also a party to the convention of the biological diversity like this Cartagena Protocol from the year 2003.

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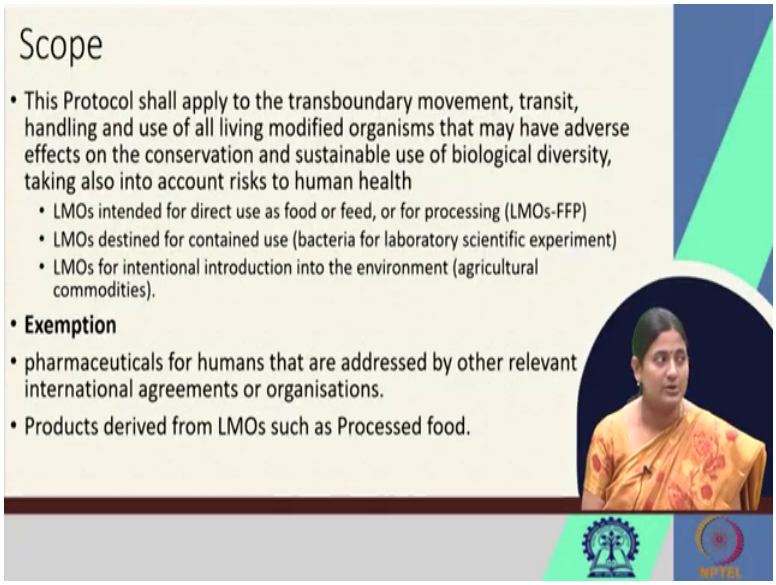

So, what this protocol is all about? This protocol is basically, as mentioned, is for the transboundary movement of the genetically modified organism or living modified organism as defined in that protocol LMOs. So, depending on the risk associated with the different kinds of the product, they have classified this whole LMOs into three categories and they have tried to play certain Biosafety measures or how to control this movement in these three categories.

So, first category is the LMOs or the living modified organisms intended for direct use as food or feed or for processing FF. And there is a second category, LMOs for a destined or contained use, means the bacteria or any other modified organism will be generally used in the experiments in the laboratory scale. Then, we have the third category LMOs for intentional introduction into the environment. For example this Bt cotton or any other genetically modified plant which have the intention to be introduced into the environment.

So, there are three different levels of or three different categories of the modified substances which can be used. So, all these are regulated under this Cartagena Protocol. However, there are certain exemptions, so for something for the pharmaceuticals which are derived from the living modified organism, different proteins or different antibodies are also being derived from the genetically modified plants.

So, all those pharmaceutical substances developed by the living modified organisms are exempted from this for which already relevant guidelines or relevant provisions are there, which is managing the Biosafety aspect or managing the risk assessment. So, those are exempted from this Cartagena Protocol. Further, the products derived from the living modified organism such as the processed food are also exempted from this Cartagena Protocol.

Only those three listed varieties which I mentioned earlier are regulated under the Cartagena Protocol.

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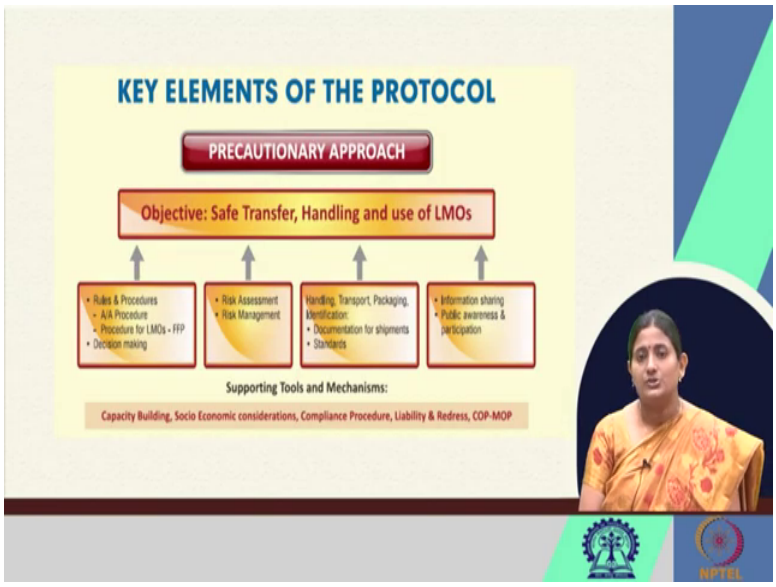

So, under this protocol the as mentioned, it regulates the transboundary movement. So, it acts on the precautionary approach as well. So, basic objective is to ensure safe transfer or ensure safe handling or ensure the proper use of the living modified organism.

So, to have overall effect or to achieve the aim of this Cartagena Protocol. So, if you go through this protocol it has nearly 40 Articles and these 40 Articles basically deals with the advanced information approval procedures. It have the elements of the risk assessment or risk management, it laid down certain procedures for the safe handling transport and packaging and the identification of the micro genetically modified organisms.

And how to transfer through the shipments and what should be the documentation procedure. And what should be the standards adopted for the transportation procedure. Then also it has the elements for information sharing and public awareness and participation program.

So, overall by placing proper regulation or proper procedure for the transport or handling of this thing; by aiming at capacity building; by taking into consideration the socioeconomic consideration, then different compliance procedure. This protocol has tried to achieve the objective of the safe transfer or handling of the living modified organism.

So, India being a party to this Cartagena Protocol also have adopted the standards and they have also adopted the different principle or the measures which are guided; which are provided in the protocol.

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So, I will just talk about two important provisions under this. So first, one of the important points with which the Cartagena Protocol has introduced is the advanced informed agreement or the AIA procedure. So, basically this AIA procedure ensures that the countries are provided with all the necessary information which is required to make an informed decision before agreeing to import of such organisms into the territory.

So, if India wants to import certain genetically modified organism, they should know about the inherent risk associated that how it operates in the environment or other hazards associated with that. So, through this an advance informed agreement can be possible.

So, basically subject to Article 5 and 6, the advance informed agreement procedure is given in Article 8 to 10 and Article 12 shall apply prior to the first international transboundary movement of the living modified organism. For the intentional introduction into the environment of the importing country it contains the reference for the precautionary approach and the reaffirms the precaution language in the principle 15 of the Rio Declaration of the environment and the development.

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So, as mentioned, this is basically to know about the inherent risk associated with the modified organism which you are importing. So, it ensures that you have sufficient information. So, that you can make an informed decision, means you know about the risk associated with the thing.

So, there are basically four components of this advance informed agreement; first, the notification by the exporter. So, that is a detailed written description of this living modified organism by the exporter well in advance of the first shipment. So, you have been given all the information well in advanced. And after that you as an importer country have to acknowledge the notification by the importing country. And then you have to take a decision. So, there is a duration in which you can take the decisions, its I think varies from 90 to 70 days anyway.

So, the decision procedure means whether you want to approve it or prohibit or you do not want to import those things or you know you or want to know more information. So, those decisions can be given back to the country. Then finally, there will be the review of the decision. So, these are the four steps through which the advance informed agreement take place.

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And the second most important aspect which is mentioned in this Cartagena Protocol is the establishment of a clearing-house mechanism or which is known as the Biosafety Clearing-House and information sharing mechanism. So, with respect to this Biosafety information Article 20 of paragraph 1; the Cartagena Protocol on the Biosafety, they have established this Biosafety Clearing-House as a part of the clearing house mechanism.

And basically, this is a what you call information exchange procedure where you can exchange the scientific, technical, environmental and other legal information regarding the living modified organisms. And this is very helpful in terms that it assists the parties in implementing the different protocol. And you can take into account the special need for the developing part in developing country. Means, all the relevant information regarding different traits, different organisms, different LMOs are given under this Biosafety clearinghouse mechanism.

So, they have a dynamic platform where the information is registered by different management centers and you can search the related information and accordingly conduct your thing. So, it requires that one national focal point has to be established. So, as I mentioned so, in India also we have a Biosafety Clearing-House under this DBT biosafety body. So, if you visit that site so, it has a platform where all the information has been provided.

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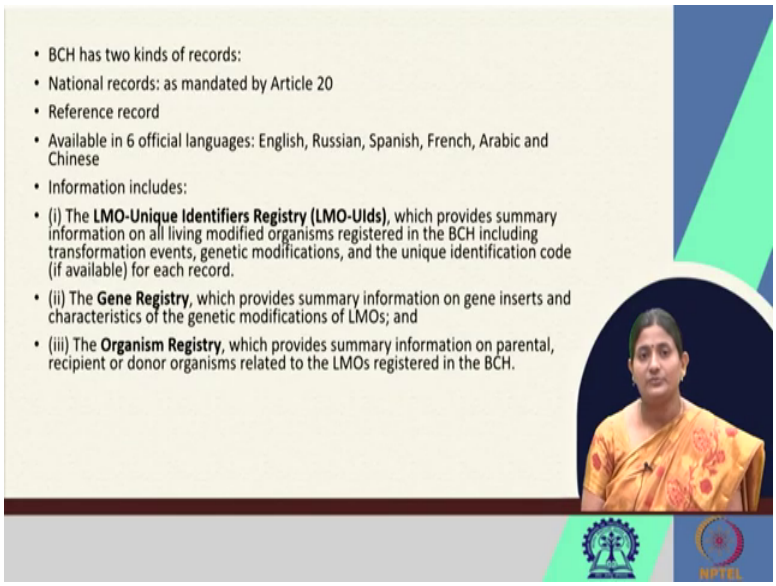

So, if you see the Biosafety Clearing-House, it has two kinds of records. First is the national record, where basically all the data related to the whatever is being developed there or information is with the national body or what are the bodies and other information are given in the portal. And other data are the known, as it is in the reference record.

So, as per the UN Mandate these information are also available in 6 languages like; English, Russian, Spanish, French, Arabic and Chinese. And you can find the LMOs for the unique identifier registry which basically provides you the summary information on all the living organisms registered in that BCH portal including the transformation event, the genetic modification, the unique identification code whatever is available the trade details.

Then we have the gene registry which provides the summary information on the different gene inserts and characteristics of the genetic modification. And the organism registry, which provides the summary information on the parental line use or the recipient or the donor organisms related to the LMO all these are registered in this Biosafety Clearing House mechanism.

So, this is a good interactive portal where you can search and find the different details.

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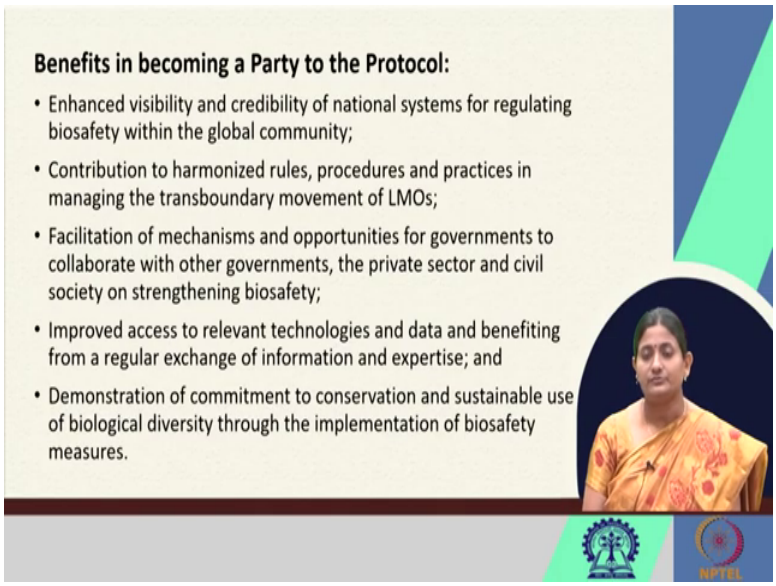

So, as I mentioned,India also became a party to this thing and according to that we have developed all this portal of this BCH act. As the BCH management portal is there, but all information are being exchanged. So, why should one be become party to this? So, what is the benefit which a country might get by being a party to such protocol?

If you see there are number of benefits being a party to this kind of protocol. India is a member of CDB and we also respect the principles of sustainability, access benefit sharing and protection of the bio resources. But if being a party to this kind of the protocol gives you further advantage in terms of an enhanced visibility and credibility of the national systems for regulating Biosafety within the global community.

And it also allows you to contribute to the harmonized rules procedures or the practices in managing the transboundary movement of the LMOs. And it also facilitates different mechanisms and opportunities for the governments to collaborate with other governments and the private sector, civil society for strengthening the Biosafety. And we have the improved access to relevant technologies and data which we can get through regular exchange of information and the expertise.

And it helps in demonstrating the commitment for conservation and sustainable use of the biological diversity through the implementation of this Biosafety measures.

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Further it gives us the ability to influence the implementation of the protocol and shape the further development through this participation in the decision making process of the conference of the parties and serving as meeting of the parties of the protocol. And developing country parties and parties with the economies in transitions are eligible for financial support from the global environment facilities as well.

So, it helps in capacity building and also in supporting other implementation of the protocol and participation process. So, there are number of benefits associated with the being a member to this protocol and India has successfully began implementing all these protocol throughout this time period from when it has joined. So, it is not only giving the visibility to India, but also enhancing our research credential in the area of the GM crops.

Though so far we have only one plant approved, but if you see the scale in which this is cultivated, particularly the DBT cotton crop, it is highly commendable. And hopefully, we have many there are many transgenic varieties which are under different phases of the trial. They might be released as soon as they get all the Biosafety clearances. And that would be overall helpful not only from the environmental point of view but also from the health as well as the food safety point of view.

So, this Cartagena Protocol is an important instrument which is related to our GM crop because you know all this Biosafety requirement or movement of this, not only GM crops but also other genetically modified organisms, because it is one of the protocol

which regulates the movement of the living organism or genetically modified organisms. So, it is also applicable for the development of the recombinant drugs sector also. So, we will study in the next segments.

So, this is all about the development of the genetically modified plants and its regulatory framework. So, you can get more information in the DBT Biosafety site, so more information is provided in the references.

So, thank you for being with me. So, we will meet again in our next chapter.

Thank you.