

International Biosafety Legal Provisions and Application—Focusing on the Conflict between the Cartagena Protocol on Biosafety and the WTO rules

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Keywords: Biosafety, Genetic-Modification, CPB, WTO

Abstract: The current international biosafety regulatory system presents the form of co-construction of environmental regulations centered on the Cartagena Protocol on Biosafety and trade regulations under the framework of World Trade Organization. Analyzing the environmental regulations and trade regulations on biosafety, it can be seen that there are many conflicts and contradictions between the two, which is due to the differences between the purposes of legislation and core principles of the two. Looking at China's legislation on biosafety, there is also room for improvement. Each country should incorporate the basic principles of good faith, mutual support, cooperation and coordination into the formulation of their respective domestic laws, so as to ensure that the legislation of the domestic law can minimize the possible conflict between the CPB and the WTO rules.

1. Definition of the concept

1.1 Biosecurity

The concept of "biosecurity" has not yet been defined in a uniform and clear manner by the academic community. In the Chinese context, "biosecurity" is generally categorized into a broad definition and a narrow definition. The broad definition of biosecurity refers to all safety issues related to biosecurity, including biodiversity conservation, endangered species, invasive alien species, biotechnology safety, human health, etc. The implementation of the PRC Biosafety Law adopts this definition.^[1] The narrow definition of "biosafety" refers to the safety of genetically modified organisms (GMOs), which is adopted in the Cartagena Protocol on Biosafety (hereinafter referred to as CPB).^[2]

This paper will focus on the conflict between the CPB and WTO regimes, and therefore will adopt a narrow definition of "biosafety". This section of Chinese legislation will also focus more on legislation related to genetically modified technology in the biosafety law.

1.2 Living Modified Organisms (LMO)

The system design of CPB is basically centered on LMO (Living Modified Organisms), compared with the well-known GMO (Genetically Modified Organism), LMO emphasizes more on the "living" characteristic of being able to transfer or replicate genetic material.

2. International biosafety-related legal content

In the 1960s, GATT members began to start negotiations on non-tariff barriers (NTBs), and in 1979, more than 20 members reached a plurilateral agreement, namely, the Agreement on Technical Barriers to Trade (hereinafter referred to as TBT). In the early 1990s, the United States led the negotiation of the Agreement on the Application of Sanitary and Phytosanitary Measures (hereinafter referred to as SPS), which was formed on the basis of the TBT. After the establishment of the WTO in 1995, both the TBT and the SPS were transformed into multilateral agreements, and together with the General Agreement on Tariffs and Trade 1994 (hereinafter referred to as GATT 1994), the international trade regime on biosafety was constructed.

On the other hand, since the 1980s, the international community's concern for biosafety has been increasing, and worries about genetically modified (GM) technology have also intensified, and biosafety was mentioned in Agenda 21 and the Convention on Biological Diversity (hereinafter referred to as the CBD), which were signed after the UNCED. After several twists and turns, the four-year-long negotiations on the CPB were concluded in January 2000, and the CPB was born as a protocol to the CBD, forming a body of law in the field of biosafety in international law.

2.1 The International Environmental Legislation System with CPB as the Core

2.1.1 Elements of biosafety in CBD

The CBD provisions related to biosafety are mainly Article 8 and Article 19. ^[3] The provisions on biosafety in these three articles are relatively principled and general. Article 8(g) requires States Parties to control the unfavorable influence in the environment, biological diversity and humans that might result from using or releasing of LMOs. Article 19 (3), which suggests that States Parties may consider adopting a protocol to provide for appropriate procedures for the transporting, processing and using of LMOs, is the most important reason for the creation of the CPB.

2.1.2 Key elements of CPB

2.1.2.1 Objectives and scope of application

According to Article 1 of the CPB, the objective of the CPB is to adopt protective measures to enable the safe of transporting, processing and using of LMOs in accordance with the preventive principle in a manner that has no impact on the conservation and sustainable use of biodiversity, considering possible impacts on human health and paying more attention on the transborder. According to the provisions of Article 4 "Scope" and Article 5 "Drugs", the scope of application of the CPB is the cross-border movement, passing through, processing and use of all LMOs that may have unfavorable influence on mankind's health and biological diversity. However, it does not include LMOs of drugs for human use.

The CPB's focus on transboundary movements is due to the fact that each country's attitude towards LMOs is very different, as evidenced by the great divergence of interest groups during the negotiation process of the Protocol's conclusion and the difficult and protracted nature of the negotiations. It is impossible to reach a global unified attitude towards LMOs, so the Protocol finally focuses on the transboundary movement of LMOs.

2.1.2.2 Advance Informed Agreement Procedure and its application

According to the provisions of articles 6 to 12 of the CPB, before LMOs reach an importing country's environment for the first time, the exporting Party shall provide the importing Party the

notification in writing. But if these LMOs are in transit, being used in containments, being directly used in food or feed, or being processed, and have been determined by the Conference of the Parties not to pose a threat to public health, the notification can be exempted. In order for the importer to acknowledge receipt of the notification, it must do so in writing within 90 days of receiving it and specify the conditions under which the transboundary movement is permitted, and within a maximum of 270 days shall take a written decision: import approval, import prohibition, additional information request, or postponement. It is important to note, however, that failure to communicate the import Party's decision within 270 days of receiving the notification does not imply consent. The Biosafety Clearing House must be notified within 15 days of any decision by the Parties regarding the import of LMOs for food, feed, or processing.

Advance Informed Agreement Procedure (hereinafter referred to as AIA) is the core procedure of the CPB, which is divided into general imported LMOs and imported LMOs directly use as food, feed or for processing, the latter being more complex than the former due to human health considerations. The latter is more complex than the former due to human health considerations, with the additional requirement that parties not only communicate their decisions through the Biosafety Clearing House, but also develop and communicate the corresponding management measures to these parties.

Particularly noteworthy is the provision in the AIA that even if the importing Party does not have the scientific basis for the underlying unfavorable impacts of LMOs on biodiversity protection and sustainable utilization, it can still make a decision not to import in order to maximize the avoidance of potential adverse impacts. The existence of this provision greatly protects the interests of the importing party, gives the importing party a great deal of discretionary power, and creates a potential for conflict.

2.1.2.3 Risk estimation and control

Risk estimation and control in the CPB is concentrated in Articles 15, 16 and Annex 3. Generally speaking, risk estimation should be done in scientific principles, and the importing country may request the exporting country to do the risk estimation and bear the relevant costs. At the same time, parties should formulate control measures for LMOs based on the risk estimation.

Risk estimation and control is inherently an important part of the AIA process because the exporter has the duty to notify prior to the transshipment of the LMO, and therefore the risk estimation of the importing party should begin automatically upon receipt of the notification. And because the importing country can request the exporting country to conduct a risk estimation, the burden of risk estimation is no longer on the importing party to prove that the LMO is potentially hazardous, but on the exporting party to prove that the LMO is not potentially hazardous. It is also because of the inverted burden of proof, the importing party in the AIA program has the right to no clear scientific evidence to prove that the LMO has the potential for harm can still make the decision to refuse imports. However, the principle of "substantial equivalence" is still used in the international arena, under which most of the components of LMOs and traditional living organisms are equivalent, making it difficult to be adequate useful in risk estimation and control.

2.1.2.4 Shipping, Packaging and Marking Requirements

According to Article 18 of the CPB, LMOs have to be packed and delivered beneath protected states, taking into account worldwide guidelines and requirements. For LMOs introduced into the environment in general and LMOs used in containment, the Protocol requires that they must be accompanied by a document clearly identifying them as "living modified organisms". Modified organisms to be used directly as food or feed or for processing should be along with a document

clearly mentioning they may have LMOs and are no longer meant for the introduction into the environment.

2.2 Biosafety rules under WTO framework

2.2.1 Regulations on Biosafety in GATT 1994

According to article 20 (b) and (g) of GATT 1994, States parties may adopt measures in protecting human-being, other creature health and limited resources. These measures should not compose discrimination or a hidden restraint of commerce in favor of countries in the same situation.

This provision grants contracting States the "right of environmental exception".^[4] They may take measures to safeguard their own interests, contrary to their obligations and even to the benefits of other countries, in cases where the wellness of human-beings, other creatures, or the resources of the country are likely to be jeopardized. However, the criteria of no-discriminating and no-constituting a hidden restraint on commerce also restricts this right. Meanwhile, Article 20(b) of GATT 1994 is also the foundation of the biosafety content in TBT and SPS.

2.2.2 Regulations on Biosafety in TBT [5]

According to the Preamble and Article 2(2) of the TBT, contracting parties may take necessary measures to meet their legitimate needs for the safety of human and other living organisms, the protection of the environment, the freedom from deception, or the protection of important national security interests. The contracting countries can take these measures as long as these measures will not bring undue barrier to international business and will not construct a means of dogmatic or unwarrantable discrimination between the similar contracting countries or implicit limitation in worldwide commerce.

The formulation of TBT actually constitutes a restatement of Article 20(b) of GATT 1994. In addition, in all the dispute cases in the history of the WTO that have referred to the TBT, none of the panels or the Appellate Body used the specific content in TBT as a direct basis for their decisions. It can be said that the TBT does not contain substantive obligations that can be directly invoked by the dispute settlement bodies, and none of its rules exceeds the content of the obligations explicitly stipulated in GATT 1994.^[6]

2.2.3 Regulations on Biosafety in SPS[7]

The preamble to the SPS reaffirms Article 20(b) of GATT 1994, which permits contracting countries to adopt actions to defend human-being, other creatures' life or health under the criteria of non-discrimination and disguised restriction. Article 2(2) of the SPS, on the other hand, sets out the "scientific principle", and all SPS actions should on the foundation of "scientific principle" and ought not to be carried out except enough scientific justification. According to SPS, LMOs and their products may be disease-carrying organisms that harm other creatures' lives, or they may contain toxins or disease-causing organisms in food, beverages or feed. So trade in LMOs between WTO member countries should comply with the SPS.

SPS applies to all sanitary and phytosanitary measures (hereinafter referred to as SPS measures) that may influence the international commerce, and is initially intended as a further interpretation of Article 20(b) of GATT 1994, so as to avoid SPS measures from becoming a pretext for trade protectionism. The most important is the "scientific principle" mentioned in the SPS, according to which the importer and exporter of LMO will bear the scientific burden of proof, that is, if the importer wants to make a decision to refuse imports, he must prove with scientific evidence that LMO may bring risk to human-being and other creatures' health.

3. Exploring the Conflict between CPB and WTO Rules and the Inherent Causes

From the above discussion on the biosafety system in the international environmental legislation system centered on the CPB and the biosafety system in the worldwide commerce legislation system under WTO, it is not difficult to see that there are obvious differences between the two systems of environmental protection and worldwide commerce, which may even lead to conflicts in the application of biosafety issues.

3.1 Conflicts between CPB and WTO rules

3.1.1 Prioritization of CPB vs. WTO rules [8]

With regard to the primacy of the CPB and WTO rules, we can get a glimpse from the preface of the CPB, which states that commerce and environment agreements have to be jointly supportive to accomplishing sustainable development, which seems to place the CPB on the same level as WTO rules. However, the next article also stresses that this Protocol does not intend to change the rights and duties of any existing treaty provisions of the State. The textual interpretation of which shows that the CPB affect none of the rights and duties that have already arisen according to WTO rules, and thus the prior treaty, i.e., the rules of WTO, should take precedence. But the last article of the preamble breaks this conclusion, saying that the above content is not meant to let this Protocol to be in a lower rank when comparing with other treaties. This means that the CPB has an independent status, and should not be subordinate to the existence of WTO rules. So the question of priority of the two has become ambiguous due to the reversal of the layers of these three articles.

3.1.2 Specific conflicts between CPB and GATT 1994, TBT, SPS

3.1.2.1 Conflict between CPB and GATT 1994

The CPB has made provisions that distinguish the cross-border transfer of LMO products from traditional products, which violates the criterion of no-discriminating in Article 13 of GATT 1994.^[9] GATT1994 makes several references to the concept of "like product", on which the criterion of no-discriminating is also based. The criterion of no-discriminating is also based on the concept that different treatment is permissible if the products are different. Considering the differences between LMO products and traditional products, these two products are in competition with each other, and at the same time, there are generally few differences in appearance. Some of the ingredients of these two products may have been eliminated during processing which makes it impossible to detect the difference between the GM-related ingredients and traditional ingredients. So it is likely that LMO products and traditional products are similar, and it is not in line with the principle of non-discrimination under the GATT 994 to treat the two products differently.^[9]

In addition, Article 11 of GATT 1994 stipulates that no prohibitions or restrictions shall be imposed by means of quotas, import or export licenses or other measures other than duties, taxes or other charges. There is also a clear conflict between the conditional import decisions taken under Article 10 of the CPB, which may impose prohibitions or restrictions in terms of quotas, licenses and other measures.

3.1.2.2 Conflict between CPB and SPS risk assessment measures

As can be seen from the previous discussion of CPB risk assessment and SPS risk assessment, they present completely different provisions about the burden of proof. the CPB stipulates that the importing country can let the exporting country take the responsibility of risk assessment and bear

the assessment costs, which means that in the event that the exporting party is unable to provide accurate risk assessment to prove that the LMO does not pose potential risks, the importing party will still be justified in refusing to import or importing conditionally even if lacking scientific basis to prove that the risk exists.

The SPS is based on the scientific principle that a party intending to impose SPS measures should demonstrate the scientific basis of its measures. According to the SPS agreement, if the importing party does not have concrete scientific evidence of the risks in the LMO, it is not possible to implement trade-affecting sanitary or phytosanitary measures on this basis, let alone make a decision on refusal or conditions of importation.

3.1.2.3 Conflict between CPB and TBT on the package labeling

Article 18 of the CPB has mandatory requirements for LMOs and products to be clearly labeled as "LMOs" or "may contain LMOs" before transboundary movement. However, the mandatory requirement of CPB is only for LMOs and products transferred across the border, and there is no equivalent requirement for domestic products. For example, peanut oil imported from China with LMOs will be mandatorily labeled as "may contain LMOs", but peanut oil with the same type of LMOs produced domestically is not subject to such mandatory labeling because it does not need to be transferred across the border. It violates Article 2(1) of the TBT.^[10]

3.2 Exploring the causes of conflict

3.2.1 Different legislative purposes

For the CPB and WTO rules, they are completely different in terms of legislative purpose, the former for environmental protection and the latter for trade freedom. The WTO, as its name suggests, is first and foremost a trade organization, whose primary mission is to promote trade, lessen commerce obstacles, and obviate discriminatory treatment. The WTO's role in trade and environment is simply to harmonize the trade policies that have an impact on the environment with the environmental policies that have an impact on trade.^[11] Therefore, when the interests of the environment and trade are in conflict, the WTO will inherently favor the protection of trade interests. On the contrary, CPB, as an environmental convention, aims to protect biodiversity, ecosystems and the natural environment. Academics have the view that one of the basic concepts that most countries bring to the CPB negotiation table is that LMOs are inherently dangerous. This shows that the basic attitude of the two on the issue of biosafety is very different.

3.2.2 The core principles are different

As previously analyzed, the CPB applies the precautionary principle of risk, while the WTO rules apply the scientific principle.

The principle of science runs through the WTO rules. Starting from the rules of GATT 1994 Article 20 (b) (g), to the TBT in the reaffirmation of this rule, and even the SPS in the risk assessment of these objective requirements, are the embodiment of the principle of science. Under the scientific principle, countries importing LMO and its products need to prove with scientific evidence that there may be a risk that the party can take certain measures to restrict imports, for the importer is a more stringent responsibility, intended to promote worldwide commerce. According to the WTO panel and the Appellate Body in the Hormone Beef case, European asbestos imports and other cases in the same position, we can find that the WTO dispute settlement mechanism tend to hold the view that the principle of prevention of risk does not constitute international customary law. It shows the principle of prevention changes no rights or duties of member countries under SPS.^[12]

The preventive principle of the CPB is made clear in the preface saying that reiterating the preventive principle contained in the Rio Declaration. The precautionary principle is also reflected in the specific clauses of the Protocol, such as the risk assessment mechanism of the AIA and the protection of importing countries. Under the precautionary principle, if the exporting country of LMO and its products cannot prove that there is no possible risk, the importing country can make a more severe decision or even refuse to import, which is intended to protect environmental interests. In the process of signing the CPB, the risk Precautionary principle was the focus of intense negotiations between the consensus group with developing countries as the main body and the Miami Group with LMO exporting countries as the main body. Finally, with the collective efforts of the consensus group, the compromise group and the EU, the preventive principle was written into the CPB as a guiding principle, while the Miami Group collectively refused to sign and ratify the CPB.

4. China's Biosafety Legislation and Future Legislative Direction

The legislation on "biosafety" in China has a wide coverage but relatively general characteristics due to the widespread acceptance of a wider meaning of the word "biosafety". For example, the Biosafety Law of PRC only mentions the security of biotechnology exploration, advance and utilization, and does not contain provisions specifically regulating LMOs and products. Although China's biosafety law does not contain GM-related provisions, China's legislative history on GMOs began in 1993 with the Measures for the Safe Management of Genetic Engineering issued by the State Science and Technology Commission (SSTC), which mainly stipulated the safe management of biotechnology. In 2001, the State Council issued the "Regulations on the Safety Management of Agricultural Genetically Modified Organisms" (revised in 2016), which clearly regulated that agricultural genetically modified organisms should implement a security assessment system, labeling management system, production license system, business license system, and import safety approval system. The purpose is to enhance the security governance of agricultural GMOs, ensure human health and other creature safety, and preserve the eco-environment, promote research on technology of agricultural GMOs. On this basis, the Ministry of Agriculture and the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) have formulated five supporting regulations, namely, Measures for the Administration of Safety Evaluation of Agricultural Genetically Modified Organisms (GMOs), Measures for the Importation of GMOs, Measures for the Administration of the Labeling of Agricultural GMOs, Measures for the Approval of Agricultural GMOs Processing and Measures for the Administration of the Entry and Exit of Genetically Engineered Products in the Field. There are also provisions in the PRC Seed Law, the Law of the PRC on Agricultural Product Quality and Safety, and the Food Safety Law that are relevant to genetically modified seeds, agricultural products, and foods.

Looking at China's current biosafety legislation system, apparently it is dominated by administrative regulations and management measures. These regulations and measures are lower in terms of the order of effectiveness, and are scattered and less systematic. In terms of content, the regulation of agricultural GMO safety is relatively perfect, and there are specific provisions on the labeling of genetically modified agricultural products and processed products, but there are still large gaps in the legislation on genetically modified food and other related areas, which need to be improved. In addition, the current GM-related administrative regulations are mainly led by the Ministry of Agriculture. On one hand, China's GM-related problems are indeed concentrated in the agricultural sector, the system design has a certain degree of rationality; on the other hand, according to the relevant provisions of the CPB, the Ministry of Ecology and the Environment should be concerned about biosafety which is part of the international environment. The distribution of legislative responsibilities between the departments still need to be further adjusted.

Overall the conflict between CPB and WTO rules affects China's current biosafety legislation deeply. China has adopted a policy of partial labeling, i.e., mandatory labeling of agricultural GMOs that are on the agricultural GMO list, while organisms not on the list, even if they are GMOs, do not need to be labeled. It can be said that such a policy has, to a certain extent, taken into account risk prevention and trade freedom, and that the state has the flexibility to adjust the agricultural GMO list to avoid the imbalance between environmental and trade interests. The author believes that it is incorrect to hastily demand China to favor CPB or WTO rules, but there is still room for optimization and adjustment in China's current policies.

The current internationally accepted method of resolving conflicts between treaties is to interpret conflicting treaties according to Article 31(c) of the Vienna Convention on the Law of Treaties (VCLT)^[13], based on the basic international law principles of good faith, mutual support, cooperation and coordination. According to Professor Zhao Jingjing's view^[14], although this method has always been applicable only to international law, the implementation of international law must also rely on the enactment of domestic laws of each country, so it is reasonable for each country to incorporate the basic principles of good faith, mutual support, cooperation and coordination into the formulation of their respective domestic laws, so as to ensure that the legislation of the domestic law can minimize the possible conflict between the CPB and the WTO rules. Although the current application of this concept in national laws is not satisfactory, if it can be actively applied in the future, it may become a new customary law or practice, which will ultimately have a positive effect on the resolution of the conflict between CPB and WTO rules.^[15]

5. Conclusion

Genetically modified (GM) technology has both good and bad aspects: it can be a powerful tool for increasing food production and eradicating famine, while at the same time it can be a poison for genetic contamination and jeopardize the environment. It is precisely because the safety of genetically modified products have yet to be confirmed that the international community has adopted very different attitudes towards them, thus giving rise to the problem of the contradiction of environmental protection and free trade, which also affects the formulation and implementation of domestic laws. At present, the conflict can only be interpreted in accordance with the basic principles of international law and avoided as far as possible until the emergence of customary law. However, law is the reflection of society, and the conflict of values between environmental protection and free trade can only be resolved when the safety of genetic modification is solved from the source, which still depends on the future progress of biological science and technology.

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