

Liability Aspects Related to Genetically Modified Food under the Food Safety Legislation in India

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Abstract—The question of legal liability over injury arising out of the import and the introduction of GM food emerges as a crucial issue confronting to promote GM food and its derivatives. There is a greater possibility of commercialized GM food from the exporting country to enter importing country where status of approval shall not be same. This necessitates the importance of fixing a liability mechanism to discuss the damage, if any, occurs at the level of transboundary movement or at the market.

There was a widespread consensus to develop the Cartagena Protocol on Biosafety and to give for a dedicated regime on liability and redress in the form of Nagoya Kuala Lumpur Supplementary Protocol on the Liability and Redress ('N-KL Protocol') at the international context. The national legal frameworks based on this protocol are not adequately established in the prevailing food legislations of the developing countries. The developing economy like India is willing to import GM food and its derivatives after the successful commercialization of Bt Cotton in 2002. As a party to the N-KL Protocol, it is indispensable for India to formulate a legal framework and to discuss safety, liability, and regulatory issues surrounding GM foods in conformity to the provisions of the Protocol. The liability mechanism is also important in the case where the risk assessment and risk management is still in implementing stage. Moreover, the country is facing GM infiltration issues with its neighbors Bangladesh. As a precautionary approach, there is a need to formulate rules and procedure of legal liability to discuss any kind of damage occurs at transboundary trade. In this context, the proposed work will attempt to analyze the liability regime in the existing Food Safety and Standards Act, 2006 from the applicability and domestic compliance and to suggest legal and policy options for regulatory authorities.

Keywords—Commercialisation, food safety, FSSAI, genetically modified foods, India, liability.

I. INTRODUCTION

THE Genetically Modified (GM) technologies have increased international attention since its inception by Calgene researchers of United States in the year 1996. Since then, there was a tremendous increase in cultivation and commercialisation of GM across the world. As a result, the first and second generational GM crops followed in high succession, many developed, and developing countries began to give great importance to GM crops in their national food strategies. However, while the successful commercialization

of GM food provides certain benefits, there were widespread concerns about its effects on human health, environment, as well as ethical, social, cultural, and other concerns. Such concerns were not only confined to the GM crops and foods and at times, but concerns were expressed about the contamination of the conventional foods.

The liability associated with GM foods is increased in attention among the international community in recent years. [6] The pro-thinkers of GM considered that the GM food is equal to that of conventional counterparts and believe that the general laws on liability shall apply to GM food also. In countries like United States, New Zealand, Canada, and the UK, the issues arising out of damage and liability towards GM foods has been addressed in the existing food legislations. However, several antagonists believe that GM poses severe harm to biodiversity and, therefore, necessitates the significance of special liability regime to deal with such concerns. For instance, European Union formulated a stringent legislation, Directive 2004/35 applicable to the entire Community. As a result, the considerable attention is required to determine the procedures of legal liability for damage occurs during the time of introduction or import of GM food. There is a greater chance of contamination of approved GM events from the country of export to enter into importing country where a status of approval shall not be identical. In such a case, the developer is liable for the damages arising out of import of GM food and its derivatives. If a developer is not within the jurisdiction of the party where the damage has occurred, then the liability shall be channelized to any one of those listed as an operator involved in such transboundary movement. It brings the need of formulating a liability mechanism at the entry of import as well as introduction to markets. In addition, the incorporation of the liability mechanism is necessitated to prevent damages and to protect and compensate the victims in the event of damage to an ecosystem or human health. Moreover, the GM contamination Register run by certain anti-GM activist group has reported the cases of GM contamination in recent years.

After successful adoption of Bt Cotton in the year 2002, the developing countries like India in increasing its interest in importing GM foods in the form of additives. The research and development of GM food crops by both public and private sector enterprises has commenced in the year 2006. From 2007, the Food Safety and Standards Authority of India (FSSAI) derived its power of regulating GM food. It strengthened the power for FSSAI to decide on the GM food imports.

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Being a party to the international instrument, it is necessary for India to formulate a legal framework on liability over GM foods. In addition to it, the country shall include the following elements such as causation of damage, standards of liability, channelization of liability, interim relief, exemptions, joint and several liability, apportionment of liability, limitation of liability to build a strong legal liability regime. Even though the N-KL Protocol has not specifically addressed these criteria, it is necessary for the country like India to include in its legislation and to deal with the liability aspects because of its intention to import GM food in the form of additives is expected soon. The Country initiated steps to develop the norms and procedures for dealing with risk assessment and risk management concerning GM foods. Therefore, the present study is to analyze the liability framework for GM foods in the prevailing Food Safety and Standards Act, 2006 of India. The study further attempts to examine the applicability and domestic compliance and to recommend legal and policy options for the regulatory authorities.

II. GM FOODS: PROSPECTS AND CONTROVERSIES

The GM perspectives have diversified among communities. The GM proponents argue that the GM product will alleviate poverty and world hunger. The advantages of GM foods are unable to deny for both farmer communities and consumers. Several Protagonists is of the belief that GM foods increase nutritional qualities, enhance taste and quality of food product, creates a resistance to insects, diseases and herbicides, a decrease in fruit ripening to extend shelf life and decrease use of pesticides. Also, WHO recent study commissioned the application of GM technology and recognized the benefits of GM in ensuring safe human health. [15] Despite these advantages, there are also risks related to the production, release into the environment, and consumption of GMOs. Several environmentalist, NGOs, and anti-GM activist argued that the GM technology is against nature and propounds that many risks involved in allowing such products for human consumption and animal feed. They are of the belief that the GM foods have the possibility of introducing allergens that are harmful to human beings, direct health effects(toxicity), tendencies to provoke allergic reaction (allergenicity) and genes from GM foods enters the gastrointestinal tract and adversely affect human health [3].

The human health damages could arise in the trade of GM products intended for direct use as food or feed. Therefore, the import of such GM products shall have the possibility to cause allergen reactions to the consumers from importing countries. The GM operators have their obligations and liabilities towards the products they are intended to import. Therefore, transparency should have been in place regarding the export of Genetically Modified Products. In such case, the respective member nations shall establish an appropriate system for identifying such products at the port of entry or needs to receive notification from the exporter or the exporting state.

III. INTERNATIONAL LIABILITY FRAMEWORK ON GM FOODS

A. CPB to N-KL Protocol: A Way Forward

The Cartagena Protocol on Biosafety (for short, Biosafety Protocol) is an international environmental agreement that established the global framework for the regulation of LMOs including GM food. It laid an important obligation to its member countries regarding the transboundary movement of GM food and derivatives. After several years of negotiation, the Biosafety Protocol has been adopted in the year 2000 and entered into force on 2003. As of 2015, 170 countries are the parties to the Biosafety Protocol. The main objective of the Biosafety Protocol was to ensure an adequate level of protection for the safe transfer, handling, and use of living modified organisms resulting from modern biotechnology that may possess adverse effects on the conservation and sustainable use of biological diversity with a special focus on transboundary movements. It is the only international instrument that specifically addresses the negative aspects of GM food and derivatives concerning human health and the environment. It provides a legal obligation to the member states to set their regulation to address the trade of GM foods. The Biosafety Protocol does not offer substantial provisions for liability and redress that would provide standards in case damages arising out of import or export of Genetically Modified Foods. Although, the legal mandate to develop the rules on liability and redress in relation with GM has found in Article 27 of the Cartagena Protocol on Biosafety. [13]

Article 27 reads as follows:

"The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years."

This enabling clause of the Biosafety Protocol deals with the liability and redress issues for the damages arising out of the transboundary movement of GM foods. It creates an obligation for the parties to establish procedures relating to liability and redress for the damages arising out of import and export of GM foods. Regarding Article 27, the procedures concerning liability and redress have to be developed within four years of its ratification.

On October 2004, the Secretariat of Convention on Biological Diversity convened a meeting of technical experts on liability and redress to commence the process of implementing Article 27. Based on Decision BS-I/8, an Open-ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress (Ad Hoc Working Group on Liability and Redress) has been established to discuss issues surrounding potential and actual damages concerning GM. The Ad Hoc Working Group on Liability and Redress had five working group meetings between 2005 and 2008. The Ad Hoc Working Group on Liability and Redress identified three

broad areas such as potential damage scenarios, application of international rules and procedures and elaboration of options for rules and procedures. Then, it has highlighted three types of damage such as damage to property, damage to human health and damage to the environment. Moreover, the socio-economic damages, cultural and religious damages have been much emphasized in the discussion.

Although some agreements have reached on some elements of an international regime, delegates did not reach "common ground" on certain important issues such as whether the regime should be legally binding and what kind of legal approach was necessary to address the liability and redress issue. At the final meeting of the Working Group, in the year 2008, the formation of the "Friends of the Chair Group" has been suggested to overcome the disagreements. It shall comprise six representatives each from the African Group, the Latin America and Caribbean Group (GRULAC), and Asia-Pacific Group; two representatives from the European Union; and one representative each from New Zealand, Norway, Switzerland, and Japan. The four informal meetings have held between 2008 and 2010.

The discussion on the legal approach to the international liability proved to be the most contentious issue. There were three options discussed: a binding instrument on civil liability, completely non-binding instrument, and the dual approach, i.e., a binding instrument on administrative approach and a non-binding civil liability instrument. [7]

During the negotiations, three lines of thought have been adopted respectively by three groups of parties. The first line of thought consists of Malaysia, Ethiopia, Colombia, Liberia, Burkina Faso, India, Namibia, Norway, and South Africa, and was for a binding international civil liability instrument. While Japan, Brazil, and Paraguay sitting on the other side argued for a non-binding instrument, the EU, New Zealand, and Switzerland chose a "middle" way by proposing for the binding instrument on administrative approach with a non-binding civil liability instrument. [11]

The two contentious issues such as the product of LMOs and financial security have discussed in the Friends of Co-Chairs Meeting in Nagoya. Brazil, Mexico, Paraguay, and South Africa argued to include financial security concept at the preambular reference rather in operative part. However, Malaysia rejected to it and necessitated the importance of inclusion of this provision inoperative part. Finally, through informal consultations, Malaysia agreed to a compromising language. The second contentious issue is about the definition of LMOs and product thereof. The Friends of the Co-chair decided to replace product thereof with products containing LMOs. The most important issue observed that the product thereof covers the living materials or dead materials. Japan, South Africa, Philippines, Brazil, Paraguay and China supported that the product thereof should contain only living materials or otherwise the scope of Supplementary Protocol have widened. But to contrary, Bolivia, Namibia and African Group with an exception of South Africa supported the concept of product thereof. [12]

The friends of Co-chair reached a final decision by including a different language (as mentioned in Article 3 of the Supplementary Protocol) instead of the term 'product thereof'. A decade after the adoption of the Biosafety Protocol, the Supplementary Protocol on Liability and Redress came into existence on 15th October 2010 at the 5th conference of COP-MOP. Finally, the Supplementary Protocol comprised a set of an administrative approach to providing that Parties have rights to deal with response measure in the event of damage caused by LMOs according to their domestic regulations.

B. Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress

After the Six years of negotiation under the purview of Cartagena Protocol on Biosafety, the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress (N-KL Supplementary Protocol) came into existence. [1] As of 2015, 31 member countries are parties to the N-KL Protocol and also needs nine more signatories to enter into force. The significant objective of the protocol is to lay internationally agreed rules and procedures to prevent and remedy damage to the biodiversity for the injury caused by the transboundary movement of LMOs including GM foods. The salient feature of the N-KL Supplementary Protocol includes response measure, administrative approach, civil liability and state responsibility have broadly discussed hereunder.

1) Response Measures

The response measure has envisaged in Article 5 of the N-KL Supplementary Protocol on Liability and Redress. According to it, the member countries shall lay measures for the operators to keep informed about the damage occurs during the transboundary movement of GM foods to the designated competent authority. The competent authority then evaluates the damage and takes appropriate measures to tackle with damages. The competent authority is under obligation to identify the operator that has caused the damage, and evaluate the damage and to find out the suitable measures that can be used by operators to deal with such damage. It might be appropriate to the intention of such a Protocol to protect biodiversity, which is dissimilar from conventional damage such as loss of property loss or human injuries. The operator or competent authority possibly will be in the most appropriate position to consider the procedures to deal with damages. The Response measures within the contemplation of the N-KL Supplementary Protocol include a complete choice of actions from defensive to restorative and it has implemented through domestic legislations.

2) Administrative Approach

The N-KL Supplementary Protocol obliges member countries to necessitate the appropriate operator to take action where there is a sufficient likelihood of damage and when the damage occurs. The operator must undertake a three-pronged action at the time of damage such as to report to the authority, evaluate the damage and to take appropriate response measures as mentioned in Article 5.1. From the language of

Article 5.3, it is clear that the operator has to take appropriate measures to avoid the occurrence of the damage during any sufficient likelihood of damage. [14] The competent authority shall itself put into operation suitable response measures where the operator fails to do so or in the case of the operator could not be reached. In such cases, the competent authority is entitled to recover the costs and expenses of the operator for their actions.

3) Civil Liability

Civil liability is the attachment of responsibility for any damage through the civil and distinctive from the administrative or criminal remedies. A designated administrative authority is entitled to implement the system under the administrative approach. Unlike criminal proceedings, the person alleging damage commence the process through an action against the person causing the damage without involving State as a party. The relief claimed shall be either compensation regarding money or injunction to restrain or to remove the source of the damage. In general, it is provided in every national legal system that the person has the right of recourse against the person accountable for the damage. Therefore, Civil liability is established through the judicial system of a country, where there is a contestation.

Article 12 of the N-KL Supplementary Protocol includes provisions on civil liability. [14] This Article provides an obligation for every member countries to include rules and procedures that addressing damage in their existing domestic legislations, or to formulate specific laws to deal with such damages or to develop a combination of both in general and specific rules and procedures.

4) State Responsibility

The N-KL Supplementary Protocol provides that state is accountable for any damage caused to other countries. In other words, it is considered as an established principle in international law that every country shall safeguard its boundaries without any disturbances from the neighboring states. Therefore, the state is liable for any transboundary environmental harm transmitted to the other countries in the process of trade. This mandate reflects in the N-KL Supplementary Protocol with the inclusion of Article 11 which necessitates the importance of State Responsibility as attributed as an important principle in Basel Convention. [10] Therefore, the N-KL Supplementary Protocol attempts to introduce a uniform liability regime at international level for addressing damages arising out of international trade of GM foods. On the contrary, the standards of liability shall be formulated by the domestic legislations of member countries that differ in their economic, social, and other political approaches. Therefore, it is necessary to analyze and examine the domestic legislations for addressing damage arising out of introduction and import of GM in this regard. [5]

IV. TRANSATLANTIC LIABILITY APPROACH TOWARDS GM FOODS

Being the largest producer and exporter of GM foods, the amount of the domestic food supply of US is high as compared to other major GM producing countries such as Argentina and Canada. The EU is the largest exporter and importer of food and drink, with total annual exports of EUR 85 billion and importer of EUR 89 billion. The food sector is an important component of EU economy. The United States adopted permissive approach surrounding GM food regulations and adopted a product-oriented approach to regulating GM foods for facilitating free trade, whereas EU adopted the process-oriented approach that is largely driven by the need for precaution. In the United States, three federal agencies such as United States Department of Agriculture, Food and Drug Administration and Environmental Protection Agency share the administrative duties related to agricultural biotechnology. Among these three organs, the Food and Drug Administration regulates transgenic crops as food or feed for the purpose of regulating the safety of these crops when consumed by humans or animals. Whereas in EU, the EFSA is a regulatory body for the activities involved with GM foods.

In US, the regulators consider that the GM food is equal to that of conventional counterpart and therefore the liability relating to GM food shall be covered in the general laws on liability. In the United States, the issues arising out of damage and liability towards GM foods has been addressed in the existing food legislations. There is no special law in US to address risk and liability issues. It has included in existing common law tort remedies, which are negligence, strict liability and nuisance. However, another line of thought is that GM poses several risks to human health and environment and, therefore, necessitates the importance of special liability regime to address such concerns. For instance, the European Union formulated a stringent legislation in the form of a directive that applies to the entire of its Community. A special legislation, i.e., the Directive 2004/35 is formulated to deal with environmental liability. This directive has based on the polluter pays principle and the precautionary principle. On the contrary to it, it fails to deal with traditional damage such as damage to human body, property and loss of life). Directive 85/374 is another product liability directive that provides strict liability in case of damage occurs during the process of trade in agricultural products.

In the US, the legal liability shall be categorized into three types: Civil Liability, Administrative Liability, and Criminal Liability. In the US, the action shall be taken in the form of the private lawsuit against the GM producers for the damage that has caused to human health or the environment. The plaintiff shall also initiate a suit for more than a cause of action, for which the plaintiff should have a reasonable basis to establish his case. [9]

One of the fascinating cases in the US, Star Link reported that the legal liability that dealt with GM contamination. Star Link is a GM corn approved for animal feed but not yet approved as food for human consumption. A clear case of contamination has found its trade as it has mixed with a

conventional variety of corn is meant for human consumption. Several farmers, elevators filed an individual suit against the developer of GM Corn, i.e., Aventis CropScience, US. The number of lawsuits has consolidated into a single class-action lawsuit that was decided by the US Federal Court for the Northern District of Illinois. Further, the court held for plaintiffs that the stored crop has contaminated with that of unapproved substance, and the defendant is held liable for their negligence, private nuisance and public nuisance.[4]

While Civil Liability is a liability arose from litigation between private individuals in ascertaining private claims, whereas Administrative Liability is a liability derived from legislative enactments. The legislative sanctions have delegated the obligations of administrative authority including implementation and enforcement. Moreover, the administrative liability is mainly concerned with the public liability, i.e., causes the violation of a statute. In addressing environmental concerns, the EU has developed an Environmental Liability Directive in the form of administrative liability to deal with damages caused to natural resources and biodiversity. Also, Operators of GM foods have been listed in Annexure III of the Directive, which possesses strict liability for damage to the environment.

The bifurcation between the US and the EU approach provides the greatest impact for the developing countries. While the EU justified Precautionary Principle in the entirety of regulating GM trade and its legislations, the US adopts substantial equivalence principle as it considers GM as equal to that of conventional counterpart. The transatlantic deviation in their approach, in fact, influences the choice of developing countries as many of them were the exporters of EU. If they choose to follow the US approach to regulating GM foods, the possibility for their products to be accepted by European counterparts shall not be hopeful. [8]

V. INDIA AND GM LIABILITY

The commercial approval for Bt-cotton has already raised a tremendous public concern regarding the traceability and regulatory issues. In India, cotton crop is the most important fiber crop that has severely infected by bollworm that reduces annual production. With the advent of Bt technology in 2002, the cultivation of Bt cotton has gradually increased to 11 million hectares of land in the year 2013. It represents one fourth of the global area of cultivation. Till date, 35 companies including public and private sector, subsidiaries of MNCs are engaged in the development and commercial cultivation of several varieties of Bt cotton in India.

The experience of India with GM crops holds importance for the countries where farmers of small society perform the agricultural activities. Most recently, India has shown the willingness to introduce GM food crops. Moreover, the research in GM food crops have already commenced in 2006 and since then the research and development have conducted by various public and private sector entities. The research activities are ongoing for the improvement of the major GM varieties in Brinjal, Cabbage, Castor, Cauliflower, Corn, Okra, Potato, Rice, Sorghum, Wheat, and Tomato.

The food industry in India is one of the largest industries which have huge potential for increasing agricultural economy, establishing large scale manufacturing units and export earnings. The food industries have regulated through several laws involving activities such as handling, package, storage, distribution, sale, labelling and import.

To avoid multiplicity of laws and regulations in the existing food laws and to focus on safety aspects of food, the Food Safety and Standards Act enacted in the year 2006. The twin fold objective of its enactment was to consolidate the laws relating to food and establish Food Safety and Standards Authority of India(FSSAI). The FSSAI is a statutory, regulatory body established to develop base science standards for food and to regulate and monitor the manufacture, processing, storage, distribution, sale, and import of food so as to ensure the food safety for human consumption. Recently, the power to regulate GM food was deregulated from GEAC and shifted to Food Safety and Standards Authority of India (FSSAI) through the notification issued by the Ministry of Environment, Forest and Climate Change in the year 2007. It provides power for FSSAI to make decisions on the import of GM food.

While the successful cultivation and commercialization of GM crops provides certain benefits, there are widespread global concerns on the effects of human health, as well as ethical, social, cultural and other concerns. GM contamination is a serious concern as the spread of GM cultivation raises in several countries in South Asia.[12] For instance, there are reports alleging that the border districts of West Bengal (India) infiltrated with Bt-Brinjal seeds from Bangladesh. It brings to light the predicament of these countries on many counts. One aspect is that agricultural production needs to increase with the support of GM technology. Another aspect is to ensure there are no risks posed by people and the environment. The Committee on Agriculture in its 37th report to Lok Sabha in the year 2012 and more specifically in para 3.3 indicates that FSSAI does not notify the implementing rules or regulations about GM food. ¹In 2013, the Committee on Agriculture was further constituted to analyse the Governmental actions based on recommendations of the 37th report of Committee on Agriculture. The report of the Committee suggested that the absence of monitoring mechanism under the FSSAI regarding safety aspects of GM food from import and domestically produced for instance cottonseed oil from Bt Cotton. It also highlighted the liability clause in the form of claim, compensation for any adverse effects on the health of consumers need to be worked out.

The liability framework for GM foods is very much essential for India in order to fulfill its international commitments. In addition to it, the country shall include the following elements such as causation of damage, standards of liability, channelization of liability, interim relief, and exemptions, joint and several liability, apportionment of liability, limitation of liability to build a strong legal liability

regime. The Food Safety and Standards Act, 2006(FSSA, 2006) has been enacted much before the N-KL Supplementary Protocol on Liability and Redress came into existence. [2]

A. Response Measures and FSSA, 2006

As envisaged in Article 5 of the N-KL Supplementary Protocol on Liability and Redress, India shall lay measures for the operators to keep informed about the damage occur during the transboundary movement of GM foods to the designated competent authority. However, the existing FSSA, 2006 does not have any provisions to deal with response measures rather it provides food recall procedures in Sec. 28 of the Act. Through this provision, the food business operator is entitled to initiate procedures for withdrawal of marketed food if he believes that the food he has processed, manufactured or distributed is not in compliance with this Act. The Operators shall exercise this provision only after informing the reasons for withdrawal to consumers. In addition to this provision, Sec. 34 of the FSSA, 2006 empowers the designated officers to issue emergency prohibition notice for imposing the prohibition against the health risk in respect of any food business. Therefore, the existing FSSA, 2006 does not have any appropriate procedure to deal with the damages caused by the transboundary trade of GM foods or remains silent towards incorporating the procedures relating to emergency response measures.

B. Civil Liability and FSSA, 2006

By Article 12 of the N-KL Supplementary Protocol on Liability and Redress, it necessitates the country to enact rules and procedures relating to liability and redress to deal with introduction and import of GM foods. The definition of damage, standards of liability, channeling of liability, interim relief, and related provisions has not adequately addressed in the existing legislation. Therefore, it must be incorporated into FSSA, 2006 or to develop a specific legislation. But the existing FSSA, 2006 do not discuss any provisions relating to civil liability rather the provisions relating to criminal liability is as enumerated in Sec. 48 to 67 of the Act.

VI. CONCLUSION

Presently, in India, the liability mechanism is very much necessitated because the guidelines in relation to risk assessment and risk management surrounding GM foods are in development stage. The national legal framework addressing the liability over GM foods is not adequately established in the existing FSSA, 2006. In addition to this, the country is persistently facing GM transboundary contamination issue with Bangladesh. The N-KL Supplementary Protocol on Liability and Redress has not specifically addressed the criteria such as a definition of damage, standards of liability, channelization of liability, interim reliefs, civil liability approach. However, it is necessary for the country like India to include in its legislation and to deal with the liability aspects because of its intention to import GM food in the form of additives is expected soon. Therefore, the rules and procedures dealing with liability for damages arising out

during transboundary trade of GM foods are very essential as a precautionary approach. Therefore, the new liability system shall be established in the existing FSSA, 2006 to deal with the damages arising out of introduction and import of GM foods with that of ideal international standards.

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