Page 1056 - 1060

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Implications of Genetically Modified Food on Global Health: A Comparative analysis of the Regulations in USA and EU

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ABSTRACT

The scientific developments that are taking place in genetic engineering are pioneering and are playing a key role in shaping the future of the world. Genetically Modified (GM) foods are certainly advancements that have taken over the food chain and have very much become an inextricable part of our food consumption. This paper will attempt to analyze the implications of GM foods in the context of global health. A comparison of the contrasting regulatory framework of USA and EU will be undertaken.

Despite the tremendous potential these foods have in eradicating issues such as malnutrition and world hunger, yet they pose threats that are inconceivable and could even be catastrophic. In a globalized world that we live in it is impossible to control and contain the transcending and cross- boundary effects any advancement might have. It is not possible to retract a GMO once released and could create havoc. Therefore, it becomes crucial to ensure that all GM foods undergo rigorous scientific assessments and studies before being released and disbursed. Having a robust regulatory mechanism is the need of the hour. It is imperative to develop a uniform and standardized mechanism by having a global conversation. While USA has a very lax system in place with minimum labelling requirements and a product focused approach, EU on the other hand is quite stringent with strict process focused assessments and labelling requirements heavily rooted in the precautionary principle. The way forward seems to draw from the system in EU so as to develop a global framework based on the precautionary principle.

I. INTRODUCTION

In the 21st century, it is near impossible to imagine a world sans GMOs. GM crops and genetically engineered food have become deeply entrenched in our food chain and consequently an integral part of our lifestyle. Even though these scientific advancements have the potential of eradicating a plethora of global concerns including world hunger and malnutrition[2], they however pose the threat of being very

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[2] Manish Shukla, Khair Tuwair Al-Busaidi, Mala Trivedi & Rajesh K. Tiwari , *Status Of Research, Regulations And Challenges For Genetically Modified Crops In India*, GM Crops & Food, 9:4, (2018), 173-188

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dangerous and could even be catastrophic. They can cause irreversible damage leading to a host of health conditions and environmental concerns. The major issue that persists is the difficulty in ascertaining the consequences and effects of GMOs.[3] Even though over time there has been a considerable progress in how the risk is assessed, however it is still impossible to fully predict the future or how the GMOs will interact with the environment or the long-term effects. This paper will attempt to understand the implications of genetically engineered food in the larger global health context. The focus will be on understanding how different jurisdictions have dealt with the risks attached to such scientific advancements and how the Risk assessment has been incorporated in pursuance to the precautionary principle. A comparison of the contrasting frameworks of USA and European Union will be undertaken through this paper.

II. ANALYSIS

"Genetically modified (GM) foods are foods derived from organisms whose genetic material (DNA) has been modified in a way that does not occur naturally."[4] The purpose of GMOs is to introduce new genetic characteristics that are desirable in order to improve the utility and value of the particular organism.[5] For example, the genetic structure of a tomato plant is modified so that the plant is more resistant to pests and has a longer shelf life.

The, for or against GMO, debate has been a long ongoing one and seems like it will so continue for a while in the near future. It is quite apparent over years of studies that there are both advantages as well as disadvantages of GMOs. It is not prudent to look at them in strictly binary terms. There are advocates constantly pushing forward their respective stance and trying to justify their position, however it is not possible to adjudge the validity of such claims and reach to a conclusive decision. It is rather be fruitful to monitor and regulate this aspect of science so as to minimize the risk and maximize the benefits.

It is important to acknowledge that regulation of GMOs is a global concern. In this day and age of globalization, nothing that happens in a location is restricted and contained within that space. The boundaries have been blurred and the effects are far-reaching. There are a plethora of aspects that must be taken into account which have a global impact, including but not restricted to trade liberalization, rapid economic developments, migration etc, all of these contribute to the rapid spread and circulation of various products across the globe directly or indirectly.[6] To think of these issues narrowly is not an option because the stakes are very high. It will inevitably affect masses and damage the environment irreversibly if not treated very cautiously.[7]

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[3] Sophia Kolehmainen, Precaution *before Profits: An Overview of Issues in Genetically Engineered Food and Crops*, Virginia Environmental Law Journal 20 Va. Envtl. L. J. 267 (2001)

[4] *Food, Genetically Modified*, WHO, http://www.who.int/topics/food_genetically_modified/en/?

[5] Katharine Gostek, *Genetically Modified Organisms: How The United States' And The European Union's Regulations Affect The Economy*, Michigan State International Law Review,Vol. 24.3, (2016)

[6] Lawrence O. Gostin, *Global Health Law: A Definition and Grand Challenges,* Public Health Ethics Volume 1, Number 1, (2008), pg 53–63

[7] Sophia Kolehmainen, *Precaution before Profits: An Overview of Issues in Genetically Engineered Food and*

Additionally, it is extremely difficult to control external factors. Once the GM food and crops are released into the environment then it is impossible to retract them. It could potentially change the entire species if the gene is strong and could ultimately lead to extinction of certain species. It is not possible to control the nature and hence it is beyond anyone to control the trans-boundary effects. To add to all of this it is impossible to predict how it could interact with other substances in the environment. These are only a few consequences among the myriad of challenges. When there is so much uncertainty that exists and the repercussions are of a great magnitude it is very crucial to proceed with extreme caution. It is important to ensure that the potential risks are ascertained before releasing any such GMOs into the open.

It becomes crucial that there is a proper system of regulation and monitoring. Across the globe, different countries have taken vastly varied positions to achieve the larger goal of ensuring food safety. However, ascertaining the efficacy and efficiency of these regulations is extremely difficult. Looking at the regulations in USA and EU, it is apparent that there is a huge disparity between both the jurisdictions. While USA has a relaxed framework and is the largest producer of GM crops, EU has a stricter and stringent framework so much so that certain countries in EU have completely banned GM food.[89] As of today, USA primarily focuses on the end 'product' and EU lays more emphasis on regulating the genetic engineering 'processes'.

Historically, USA had a more restrictive framework and EU was much more liberal. Over time due to multiple factors including the politics, culture and interest of people there has been a reversal in the regime. USA began giving primacy to scientific developments and technological advancements while EU grew more concerned about the environment, health and safety[10]. This kind of reversal has been quite drastic and has impacted the regulatory framework of both the regions.

In USA, if the composition of the conventional food and the corresponding GM food are similar then there are no elaborate assessments or regulations for the particular GM food. The GM foods are not subject to any special assessments just because they are genetically modified. Special labelling is also not required for GE foods. It is only required in case there is a "material" change from its conventional form. The procedures for import and export of GMOs across state borders are also very relaxed. The FDA, USDA, and EPA are the three regulatory bodies that are responsible respectively for food and feed safety, agricultural and environmental safety, and food and environmental safety related concerns. These government bodies are legally authorized over GE foods. The general idea is to allow products which seem to be innocuous and have no overt risks. However, once some risk is recognised then the

Crops, Virginia Environmental Law Journal 20 Va. Envtl. L. J. 267 (2001).

[8] J*essica La*, Same Science, *Different Policies: Regulating Genetically Modified Foods in the U.S. and Europe, Special Edition On Gmos*, August 9, 2015

[9] Katharine Gostek, *Genetically Modified Organisms: How The United States' And The European Union's Regulations Affect The Economy*, Michigan State International Law Review, Vol. 24.3, (2016)

[10] Diahanna Lynch, and David Vogel, *The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics*, Council on Foreign Relations Press, April 5, 2001.

products are withdrawn and the liability is high. The precautionary principle is not the foundation for the laws and regulations, but the economic benefit and scientific innovation are.

In EU, any process that is not conventional or naturally occurring require strict assessments. Only upon such approval are the products allowed to be released. Their approach is highly reliant on the precautionary principle[11]. Labelling is compulsory for all products which contain more than 0.9% of any GM material. EU treats all GMO crops, as "new food". These new foods are subject to the scrutiny and detailed scientific assessment by the European Food Safety Authority (EFSA). This body provides a report to the European Commission, which drafts a proposal for the further grant or refusal of the GM crop. The proposal is further submitted to the "Section on GM Food and Feed of the Standing Committee on the Food Chain and Animal Health". If approved then it is forwarded for further approvals and only upon satisfaction of all the responsible authorities is the product released in the market.There are strict pre-market approval and labelling requirements. Any food which has any amount of GM material must identify so. Throughout EU the minimum standards as afore mentioned need to be compulsorily complied with and it is left to the countries to draft guidelines and requirements as they deem appropriate. Several countries have completely banned the use of GM food in their country after adducing the requisite evidence.

Due to the lax regulations in USA a huge number of GM foods are approved and released into the market, much before they are in EU. The total land where GM food cultivation occurs in USA is also exponentially higher than in EU.[12] The markets in USA are over-flowing with GM products; up to nearly 60-70% of the products are estimated to be GM foods. Among these, soya and corn are the highest produce and are consumed widely. Unfortunately a majority of the population are not even aware of these realities. Due to the non-requirement of labelling in this respect it becomes all the more difficult to identify GM foods.

It is important to note that USA has been affected adversely due to the strict requirements and regulations of EU and certain other countries. The trade has greatly suffered post the imposition of the stricter regulations and restrictions on import and exports. Certain other countries followed suit and have made their frameworks more robust and stricter as that in EU. All this has been a bane especially for the developing and the least developed countries. USA has strategically diverted their products towards developing countries to compensate for the loss of business in the more regulated states. Developing countries have become the dumping ground for GM products due to their socio-economic position and are disproportionately affected by the effects of GMOs.

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[11] Didier Bourguignon, *The Precautionary Principle: Definitions, Applications And Governance*, European Parliament Think Tank, December 09, 2015; Accessed at: https://www.europarl.europa.eu/thinktank/en/document.html?reference=EPRS_IDA(2015)573876

[12] *Jessica La,* Same Science, *Different Policies: Regulating Genetically Modified Foods in the U.S. and Europe, Special Edition On Gmos,* August 9, 2015.

III. CONCLUSION

With rapid globalization the various sovereign states across the globe have become a single unit and no longer remain isolated. An action taken by one stakeholder in a remote corner of the world has far-reaching and transcending effects. International trade has greatly contributed in the mass production and unfettered circulation of the GM foods across the world. The developing and least developed countries are the worst affected of all and are breeding grounds for environmental and health related concerns. It is time that there is some sort of standardization and uniformity across the world. It seems like the approach taken by EU is more sustainable and effective. When the stakes are so high it only seems prudent to take a more cautious approach and not play around with the nature. It is erroneous to even think that the concerns following GMOs are restricted to a limited jurisdiction. This is a global health concern, and it is crucial to take measures which reflect in the global health laws and governance.[13]

Although there are obvious differences in both the regulatory frameworks, they do similar scientific studies for assessing the risk albeit at different stages. The product vs. process regulation debate is very pertinent. It seems like there needs to be a more global conversation that would obligate individual states to go for a cautious approach. The economic development must not be the sole consideration for any country, and it should be rather based on the precautionary principle.

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[13] Lawrence O. Gostin, *Global Health Law: A Definition and Grand Challenges,* Public Health Ethics Volume 1, Number 1, 2008, pg 53–63

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