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Labeling genetically modified food: Comparative law studies from consumer's perspective

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Article

Labeling Genetically Modified Food – Comparative Law Studies from Consumer's Perspective

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This article focus on the genetically modified food and labelling requirement. The relatively new technology raises some concerns over the safety of food containing genetically modified substance. The "substantial equivalent" doctrine, adopted by the U.S., and the "precautionary" doctrine, taken by the EU, represent two contradictory approaches to reconcile new biotechnology and consumer protection, a difference influenced by politics or food industry rather than by consumer attitudes. In this article, we argue that consumers cannot make their own choices and exercise market power without a certain degree of disclosure of information. However, even though food labelling is an effective way to convey information, it is by no means a perfect solution. This article will consider several ways to label genetically modified food and the costs or benefits so as to illustrate the best way to disclose information to consumers by way of labelling.

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CONTENTS

I. INTRODUCTION

For thousands of years, food is always an important part of human life. Through the history, human beings tried every method to improve agricultural productivity. Conventional breeding, hybridization, etc. are just some examples. The most recent development is the use of biotechnology, which was called "green revolution" or "biotechnological revolution" by some people.[1]

No doubt, biotechnology can bring lots of benefits for human beings, including increasing crop yields, reduce pesticide use, enhancing herbicide resistance, improving efficiency of farming and crop adaptability to growing conditions, cheaper and more nutritious foods, etc.[2] In the recent decade, sales of genetically modified crops rose dramatically.[3] According to European Union, cultivation of genetically modified crops rose from 28 million hectares worldwide in 1998 to 53 million hectares in 2001.[4] Research also shows that, in the year of 1998 alone, one-third of corns and 45% of soybeans planted in the U.S. were genetically modified,[5] and definitely the figure would continue to rise as time goes by.

While people seemed comfortable with traditional methods to improve foods, on the contrary, it seems that people reserve more on those genetically modified food ("GM food").[6] Some worry about risks created by new biotechnology while some reject GM food for ethical or religious reasons. In the regulatory level, how to deal with those new risks along with maintaining benefits is a difficult policy issue. In this article, we will discuss certain concerns about GM food from end users' point of view, possible regulatory regime and examine the present regulations in several countries.

In Part II of this article, we will examine theoretical background for consumer regulation on GM food. We will discuss consumer's right-to-know theory and consumer's freedom of choice. We will also cover asymmetric information problem on GM food and other concerns about GM food from consumer's point of view. At the end of this part, we will explore whether market itself can work out the solution for

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1. Julian Kinderlerer, *Genetically Modified Organisms: Colloquium Article Genetically Modified Organisms: A European Scientist's View*, 8 N.Y.U. Envtl. L.J. 556, 557 (2000).
2. Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. Mich. J.L. Ref. 403, 409-415 (2002).
3. McGarity, *id*. *See also* Kinderlerer, *supra* note_ **錯誤! 尚未定義書籤。**,557-558.
4. *Life Sciences and Biotechnology – A Strategy for Europe*, COM(2002) 27 final, 2002/C 55/07.
5. Matthew Franken, *Fear of Frankenfood: A Better Labeling Standard for Genetically Modified Foods*, 1 Minn. Intell. Prop. Rev. 5, 104-105 (2000).
6. For consumer polls, *see infra* section IV.A.2.

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information problem and why certain degree of regulations are required.

In Part III, we will introduce present regulations in various countries. The first group is represented by the United States and the attitude of Food and Drug Administration. This group virtually stands for the "substantially equivalence principle". In contrast, the second group, represented by the European Union, takes "precautionary principle" as the cornerstone, and has relatively tighter regulation on GM food than the first group. Between the two extremes, there are some middle grounds. Regulations in Taiwan and in Japan are best examples.

In the last part, we will compare regulations in different jurisdictions described in Part III and will explore reasons for such difference. We will also examine whether present regulations can solve information problems for consumers and what other choices we have other than labeling GM food.

II. GENETICALLY MODIFIED FOOD AND CONSUMER SUPREMACY

A. *Why We Should Disclose Information to Consumers?*

1. *Consumer's Right to Know*

The first theory of regulating and labeling GM food is based on "consumer's right to know". "At the core of this theory is the notion that the public has a basic right to know any fact it deems important about a food or commodity before making a purchasing decision".[7] However, the "right to know" theory involves not only conceptual issues but also its constitutional foundation in each jurisdiction. In theoretical level, where can we derive this "right to know" from? How wide does this right-to-know can cover? What can consumers claim to know under their "right to know"? It is not the purpose of this article to discuss all these details. However, those issues should be resolved in order to construct a solid ground if we determine to build GM food regulation on the basis of consumer's right to know.

Consumer's right to know theory also involves constitutional law debates, best illustrated in the United States. In *International Dairy Foods Association v. Amestory*[8], the Second Circuit struck down Vermont's law on labeling milk that used recombinant Bovine Somatotropin ("rBST"), which is "a synthetic growth hormone that increases milk production by cows" and which was approved by Federal Food and Drug Administration

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7. Alicia T. Simpson, *Buying And Eating In the Dark: Can the Food And Drug Administration Require Mandatory Labeling of Genetically Engineered Foods?*, 19 Temp. Envtl. L. & Tech. J. 225, 227 (2001).

8. 92 F.3d 67 (2nd Cir. 1996).

("FDA") in 1993[9], where "FDA has determined that there is no significant difference between milk from treated and untreated cows."[10] In 1994, the State of Vermont enacted a statute requiring that "if rBST has been used in the production of milk or a milk product for retail sale in this state, the retail milk or milk product shall be labeled as such."[11] Plaintiffs filed law suit in 1994 seeking to enjoin enforcement of this statute based on First Amendment and on Commercial Clause. While the District Court rejected their claims, part of this judgment was reversed by the Second Circuit on the ground of First Amendment. The Second Circuit held that plaintiffs' freedom of speech was infringed by Vermont statute.

In applying the four-part analysis established in Central Hudson[12], the Second Circuit held that "Vermont has failed to establish the second prong of Central Hudson test, namely that its interest is substantial."[13] In this case, Vermont did not claim health or safety concerns "but instead defends the statute on the basis of strong consumer interest and the public's right to know" (emphasis added).[14] Although the court admitted that the "demand of its citizenry for such information is genuine", "we conclude that it is inadequate. We are aware of no case in which consumer interest alone was sufficient to justify requiring a product's manufacturers to publish the functional equivalent of a warning about a product method that has no discernable impact on a final product."[15] The judge further stated that "although the Court is sympathetic to the Vermont consumers who wish to know which products may derive from rBST-treated herds, their desire is insufficient to permit the State of Vermont to compel the dairy manufacturers to speak against their will."[16] We should also notice that the dissenting judge in International Dairy case thought that Vermont's interest was substantial enough to overcome First Amendment protection on commercial speech.[17]

Besides the First Amendment argument in the United States, the notion of consumer's right-to-know seems to be accepted as a basic concept in some jurisdictions. For example, in a speech given by Prime Minister Tony Blair (of the United Kingdom) in 2000, he simply stated

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9. *Id.* at 69.
10. *Id*. at 70.
11. *Id* at 69.
12. The four-part test include: (1)whether the expression concerns lawful activity and is not misleading; (2) whether the government's interest is substantial; (3) whether the labeling law directly serves the asserted interest; and (4) whether the labeling law is no more extensive than necessary. *Id.* at 72 (citing *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557, 566 (1980)).
13. *Supra* note 8, at 73.
14. *Id*.
15. *Id.*
16. *Id*. at 74.
17. *Id.* at 77-78.

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that "anyone eating in a restaurant has a legal right now to ask whether the food they serve contains GM ingredients." [18] (emphasis added) The "fundamental right to know" claim is also the most convenient vehicle that consumer groups can employ to request more information. [19] However, the problem with the "right to know" theory is the ambiguity as to its width and application. Although it could be a policy ground in certain countries, this theory is far from universally accepted.

2. *Consumer Choice, Political Process and Market Power*

The informed choice theory seems to be a better foundation. The basic idea is no longer whether consumers have a legal right to request information but whether consumers consider certain information as important. This strategy can be best described by the European Union's attitude.

In its communication to European Parliament in 2000 [20], the Commission of European Union ("Commission") stated that "Europe has also taken clear positions on the importance of freedom of choice for consumers as well as for economic operators with respect to GM food ..." [21] Informed choice, which should facilitate demand-driven applications, has been listed as one of five main action lines by the Commission. [22] The State of New York, in its proposed bill concerning GM food, also recognizes that "it is important that consumers of this state have an opportunity to make informed choices as to whether to purchase and consume food and food products that are genetically modified". [23]

This theory is also related to political process. If most consumers consider certain information as important or necessary, they can voice through political process to form new regulation. They may also face the challenge of different interest groups. In fact, as to GM food, there is no absolute right or wrong in imposing labeling requirements. If people in one jurisdiction agree that they need labeling or even require more stringent regulation, and if it is passed through democratic process, it is the will of people. This is a very rough description of political process and there are certain limitations and variations as to what the political process could achieve. It is not accurate to state that consumers can do whatever

18. Ved P. Nanda, *Genetically Modified Food and International Law – the Biosafety Protocol and Regulations in Europe*, 28 Denv. J. Int'l L. & Pol'y 235, 239 (2000).

19. For one statement from a consumer union, *see* Karen A. Goldman, *Labeling of Genetically Modified Foods: Legal and Scientific Issues*, 12 Geo. Int'l Envtl. L. Rev. 717, 720 (2000).

20. *See supra* note 4.

21. *Id.* at 55/13.

22. *Id.* at 55/11.

23. 2003 Bill Text NY A.B. 4458.

they want to do by way of political process. However, on the other hand, we should not ignore the power of voice by consumers that could influence the direction of regulation in one jurisdiction.

In addition, consumers also can exercise their market power. Through market competition, considering all disclosed risk, benefit and price, if certain GM food fails appeal to consumers, producers will have less benefit on planting and producing GM food, and then naturally that GM food will be squeezed out of the market. On the other hand, if certain GM food survives the competition, that means it is accepted by some, if not all, consumers. Thus, market competition can be a proxy for policy makers. If GM food price is higher than traditional food price and it still survives in the market, that means there is demand for such GM food. On the other hand, given the fact that GM food is normally cheaper than traditional food or organic food, if GM food is still losing market share under this condition, it means that consumers choose more non-GM food than GM products. In the meantime, we should notice that upstream food supplies and technology development will be influenced by downstream market. This is what European Union's demand-driven strategy would like to address.[24]

Indeed, consumers should have the freedom to choose the food they want. However, as in other consumer products, the whole question surrounds the information problem and relevant transaction costs. The soundness of political process theory and market theory all rely on an informed decision by consumers. Without such information, choice is meaningless. We will discuss information costs and market function under by consumers based on insufficient information in the following sections.

B. *Information Problem from Consumer's Perspective*

1. *Where Does Genetically Modified Food Go?*

Before discussing various regulatory schemes, it is vital to understand how GM food enters into market in order to make adequate regulations. The earliest stage occurs in laboratories. Scientists use biotechnology to insert gene(s) into or modified gene(s) of certain organism ("GMO"). In this stage, it is still far from consumer's direct concern. However, government might have some interests in monitoring scientific researches in order to control its future development.

Afterward, those genetically modified products will be employed by farmers through pesticide containing GMOs, through feeding animals with GM feed, or through planting crops from GM seeds. For consumers,

24. *Supra* note 4, at 55/13.

the greatest risk in this stage is the use of pesticide. Unlike traditional pesticide, modern technology can produce genetically modified pesticide in order to enhance its resistance for certain insects. Let alone the agricultural and environmental problems, it does create a risk that consumer might eat GM pesticide along with foods.[25]

Besides pesticide, one primary kind of GM food comes from animals. The first source is meat of those genetically modified animal, such as GM beef. The second source are products of those genetically modified animals, like eggs and milk. The third source is meat or products of normal animals feeding with animal feeds containing GMOs. The fourth kind of animal food product is from animals which are injected with recombinant Bovine Somatotropin ("rBST") to increase its milk production.[26]

As to GM crops, part of them will enter into market directly for consumption. Some of them will be processed in factories and sold in the market in different packages. Some will be used as animal feeds and transform into other types of food products. The use of genetically modified animal feeds creates a risk of mixture with human foods. The well-known StarLink case is the best example. In September 2000, a variety of corns approved for human uses was found containing Cry9C, a protein toxic to certain insects. Cry9C was approved by the Environmental Protection Agency ("EPA") for animal feed and industrial uses but for human consumption.[27] The product in question was recalled by producers.[28] This case was also followed by product liability law suits.[29]

On the downstream market, consumer can buy GM foods in supermarkets or anywhere selling them, either in their original form (ex. corn) or as processed products (ex. soybean milk). However, this is not the only source that consumer can gain access to GM food. Consumers may also eat food through restaurants. Restaurants buy foods from the market as ordinary consumers, but restaurants will cook the food and mix foods they bought into dishes. Consumers might have no chance to know where the foods come from in a restaurant.

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25. For information on the GM pesticide and human health, *see generally* McGarity, *supra* note 2, at 417-418.

26. *See* A. T. Simpson, *supra* note 7, at 232.

27. *See* Raymond Formanek, Jr., *Proposed Rules Issued for Bioengineered Food*s, from <http://www.fda.gov/fdac/features/2001/201_food.html> (visited on March 7, 2004).

28. *Id.*

29. *See e.g. In re Starlink Corn Products Liability Litigation*, 2002 U.S. Dist. LEXIS 21677 (N.D. Ill. Oct. 2, 2002)

2. *Information Costs*

From the above description, we can easily find a puzzle for consumers: How can they know one food is genetically modified or not? Policy makers need to consider: What kind of information consumers want? How to transfer information to consumer at least costs? Can consumers digest all the information?

First, what kind of information do consumers want? In the simplest form, which food is GM food? Apparently, this is not the only answer we want. This information simply gives consumers an opportunity to reject GM food. However, it does not deliver a clearer idea on what GM food is. Some consumers may be interested in the advantages and disadvantages of GM food, like additional nutrition, longer preservation time, etc., while some consumers may desire to know any potential negative effect on their health once they eat GM food.

However, information is not free. Generating useful information for consumers or regulatory agencies is costly. There is also cost on delivering information to consumers. Moreover, once we delivery information to consumers, we cannot guarantee that consumers can fully understand those information. The process of deciding which information is necessary (in terms of both quantity and quality) also creates costs. Moreover, we cannot ignore the enforcement costs as well as the potential errors and frauds accompanying the production and delivery of information.

C. *Other Consumer Concerns for Genetically Modified Food*

1. *Attitude Toward Risk: Substantial Equivalence v. Precautionary*

When we face a new product created by new technology, we always wish to know "how different is it?" Is it the same as traditional food? Is the chance of hazard higher than ordinary food? Those questions are related to the attitude toward new technology, and answers to them involve the conflict between "substantial equivalence principle" and "precautionary principle".

The substantial equivalence principle was first established by the Organization for Economic Cooperation and Development ("OECD") in 1992. "The concept of substantial equivalence embodies the idea that existing organisms used as food, or as a source of food, can be used as the basis for comparison when assessing the safety of human consumption of a food or food component that has been modified or is new."[30] "If the

30. OECD, *Safety Evaluation of Foods Derived by Modern Technology: Concept and*

new or modified food or food component is determined to be substantially equivalent to an existing food, then further safety or nutritional concerns are expected to be insignificant."[31] "Such foods, once substantial equivalence has been established, are treated in the same manner as their analogous conventional counterparts."[32] "Where a product is determined not to be substantially equivalent, the identified differences should be the focus of further evaluations."[33]

On the other hand, the precautionary principle requires that, "in the face of scientific uncertainty or lack of knowledge, it is better to err on the side of protecting human and environmental safety than to err on the side of the 'risks'".[34] In short, the basic idea is "if you are not sure of the consequences, do not proceed."[35]

The two principles represent two different regulatory philosophies. When facing a new technology, what attitudes should we have? The same conflict appears not only in GM food but also in human cloning or other aspects of new biotechnology. The conflict also illustrates different attitudes toward how to deal with risk. On the one hand, the substantial equivalence principle bases its argument on present scientific proofs. On the other, the precautionary principle takes a more risk-adverse position and requests most evidence than present ones before moving on. There is no absolute right or wrong in adopting either principle. However, the attitude does influence the decision of government and consumers when facing new genetically modified food. The result will affect not only domestic market but also international trade.[36]

In addition, we should notice that substantial equivalence principle is relatively easier to apply than precautionary principle. Under precautionary principle, the extent to which regulations are sufficient in terms of precaution is not quite clear. We cannot develop the whole regulation regime simply from the concept of "precautionary principle". Which procedures or requirements are necessary for precaution needs to be considered in each jurisdiction.

Principle 11 (1992).

31. *Id.*

32. *Id.* at 11-12.

33. *Id.* at 12.

34. McGarity, *supra* note 2, note 489 (citing Royal Society of Canada, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada: Expert Panel Report of the Future of Food Biotechnology* 17 (2001), at 194).

35. Kinderler, *supra* note 1, at 558.

36. *See* speech of Robert Coleman (Director General Health and Consumer Protection Directorate European Commission) on "The US, Europe, and Precaution: A Comparative Case Study Analysis of the Management of risk in a Complex World", from <http://europa.eu.int/comm/dgs/health_consumer/library/speeches/speech139_en.pdf> (visited on Mar 1, 2003)

2. *Agricultural Policy and International Trade*

Regulation on GM food also involves international trade issue, which comes from the fact that United States is the biggest exporter of GM food in the world and that any restriction on GM food in one country might influence not only domestic industry but also other countries. Under the present World Trade Organization ("WTO") structure, disputes should be resolved in the Dispute Settlement Body of WTO. As to GM food, first we have to look at the Agreement on Agricultural Trade.[37] Labeling requirement of GM food is relevant to sanitary measures under GATT and the Agreement on the Application of Sanitary and Phytosanitary Measures. It may also raise problems under Technical Barrier to Trade Agreement ("TBT Agreement").[38]

In 1997, EU and the U.S. already had a dispute over EU's regulation on hormone food.[39] Recently, European Union banned importation of certain American made GM farm products into European market. Estimated loss for American farmers is nearly 300 million US dollars.[40] US government is now considering whether to file suits in WTO.[41] Similar disputes arose not only between the U.S. and EU but also between China and the U.S.[42]

International trade dispute influences not only technology advanced countries but also some African countries under threat of starvation as well. Those countries worry that the introduction of GM crop into their territories might influence local ecosystem. They are also afraid that planting GM crop may influence their future opportunity to export crops to Europe.[43]

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37. Mark King, *The Dilemma of Genetically Modified Products at Home and Abroad*, 6 Drake J.Agric. L. 241, 248 (2001).

38. *See generally* John S. Fredland, *Unlabel Their Frankenstein Foods!: Evaluating A U.S. Challenge to the European Commission's Labeling Requirements for Food Products Containing Genetically-Modified Organisms*, 33 Vand. J. Transnat'l L. 183, 196 (2000); King, *id.*

39. *See* <http://europa.eu.int/comm/food/fs/him/him_index_en.html> (visited on March 10, 2003).

40. International World Watch, *EU Official Calls for Truce in Biotech Dispute*, 1/31/03 WSJ A8.

41. Norman E. Borlaug, *Science v. Hysteria*, 1/22/03 WSJ A14; Neil King Jr., *U.S. Trade Chief Wants To Take Food Case to WTO: White House is Undecide*, 1/10/03 WSJ A8; Neil King Jr., *Trade Suits Is Possible in Biotech-Crop Battle for Big Markets in Asia and Elsewhere*, 12/2/02 WSJ A4; Scott Miller, *U.S. Farmers Want WTO Review of GMO Dispute With Europe*, 11/25/02 WSJ A13.

42. Peter Wonacott, *U.S., Chinese Officials Say Progress Is Being Made, Particularly on Agriculture*, 7/31/02 WSJ A12.

43. *See supra* note 38.

3. *Environmental Effects*

One major concern about GMOs is their environmental effect. Some people concern the potential negative effect on biodiversity by displacing native species through spreading new genes into the environment or threat to beneficial insects and pests.[44] Also, non-GM crop farmers also worry that adjacent GM crop farms may have impact on their farms.[45] Some also concern about herbicide resistance or about the resistibility of insects.[46]

4. *Food Safety and Health Concerns*

For consumers, the most important issue is the safety of GM food. Unfortunately, up to now, there is no clear evidence showing that GM food has health or safety hazard for human beings.[47]

One of the biggest health concerns is on allergens. "Although sensitive persons can usually minimize the risk of allergenic responses by avoiding particular foods, they may be caught unawares if GM food manufacturers transfer the genes with allergenic proteins from one plant to another."[48] However, there are thousands of proteins existing in all food products. Different people may have different reaction to different protein. How can we be certain that it is the modified gene that creates problem?

In addition, there are some doubts on the risk caused by changes in host plant metabolism and some people also worry about new chemicals not formerly present through new gene technology.[49] A further concern is on antibiotic resistance problem, whereas some scientists fear that antibiotic resistance genes may recombine with certain natural bacteria, which will pose hazard of antibiotic resistance.[50]

5. *Food Preference and Ethical Concerns*

People may have ethical concern on GM food because of its relatively

44. *See* Denise M. Lietz, *Comment: A Precautionary Tale: The International Trade Implication of Regulating Genetically Modified Foods In Australia and New Zealand*, 10 Pac. Rim L. & Pol'y 411, 415 (2001).

45. Kinderlerer uses the size of farms as an explanation to why United States and European Union have different regulatory cultures. *See* Kinderlerer, *supra* note 1, at 561-562.

46. Henrique Souza, *Genetically Modified Plants: A Need for International Regulation*, 6 Ann. Sury. Int'l & Comp. L. 129, 138-139 (2000).

47. Kinderlerer, *supra* note 1, at 560.

48. McGarity, *supra* note 2, at 419.

49. *Id.* at 420-422.

50. *Id*. at 424; Sarah, Kirby, *Genetically Modified Foods: More Reasons to Label Than Not*, 6 Drake J. Agric. L. 351, 361 (2001).

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artificial feature. Another concern comes from putting animal genes into vegetables so that some people might worry that vegetables are no longer purely suitable for "vegetarians", which may cause a problem in Buddhists countries. However, food preference is not necessarily connected with vegetarians. Some people just don't like to eat any genetically modified foods at all. There is no right or wrong for such preference. How much can this attitude influence regulation in one jurisdiction partly depends on how much it is presented in political process.

6. *Scientific Development*

One might also concern about relationship between regulation and development of technology. More stringent regulation might lead to higher R&D costs, and thus might reduce the total amount of new scientific discoveries that may help to improve human life. This effect cannot be ignored if we consider the potential benefit of advanced technology and competitiveness of a country in a global economy.[51] On the other hand, one can also argue whether we really want or need such benefits, or whether the technology development broadens the gap between developing countries and developed countries. The real impact is still not so clear and needs to accessed with caution, especially if we take patent system into account. However, we can expect that it will influence scientific research if EU and the U.S. continue to adopt different levels of regulation and one country offers more promising profitable future for agriculture industry.

Not all the policy concerns described above have direct impact on consumers. However, as consumers are the end users of food products, all effects will come back to them eventually. Policy standpoint and scientific development may influence future life of consumers. International trade dispute may limit choices of consumers. Needless to say about the potential disastrous effect on the environment. Nevertheless, as we will argue below, though labeling cannot solve all these problems, it can inform consumers and establish a public policy forum to determine what we should do to GM food in the future.

51. Even in European Union, the European Commission tried to balance different interests and to make a sound strategy. *See generally supra* note **錯誤! 尚未定義書籤。**. *See also* Mathew Franken, *Fear of Frankenfoods: A Better Labeling Standard for Genetically Modified Foods*, 1 Minn. Intell. Prop. Rev. 5, 122 (2000) (Arguing that "the mandatory European labeling requirement may also inhibit the development of new biotech products.").

D. *Can Market Distinguish GM Food Without Regulation?*

As we discussed above, there is no absolute right or wrong for GM food, as the controversy continues to grow. If consumers are willing to accept it, GM food can survive. However, above analysis is based on the premise that consumers know it is GM food. Supposed that there is no regulation on GM food at all, can the market digest bad GM food and kick them out of the market? Can the market for GM food distinguish bad lemons from good ones?

First of all, without adequate disclosure mechanism, consumers might not know which food contains GMOs. There is serious asymmetric information here. Without such information, consumers cannot make comprehensible choices. For an ordinary common knowledge consumer, he cannot even tell GM food simply from its outlook. Furthermore, consumer's ability to generate information is also restricted. Thus, we cannot solely rely on consumer's market power to distinguish GM food from non-GM food, or distinguish bad GM food from good GM food.

Secondly, given the benefit of GM food and the relatively unknown nature of the hazard, there is no strong incentive for GM food manufacturers to disclose information voluntarily. On the contrary, some manufacturers may want to disclose that their food is non-GM food in order to attract some consumers. Whether they will disclose it or not still depends on the costs and benefits of manufacturers. If the use of non-GM product and voluntarily disclosure can bring them more profits than costs, they will do so. However, we should notice that, unless market condition permits, one cannot infer that a food is GM food simply from the fact that it doesn't bear the label of "non-GM food". In addition, GM food is not like bad lemons. Whether it is bad or not still requires further researches. Therefore, we cannot fully compare the GM food market with lemon market.

Moreover, dissemination of information is another problem. Market cannot function well without an effective way to distribute relevant information to consumers. In securities disclosure system, listing companies are forced for disclosure material information and punished for its non-disclosure through civil or even criminal penalties. However, even with the mandatory disclosure system, it is still arguable that whether the price of a security really reflects the information disclosed. Multimedia might be a vehicle for distributing information on misfortunate event flowing from GMOs, albeit how much information they can transfer is still in doubt. Obviously we cannot solely rely on multimedia since they might select a few cases to report and cannot give consumers whole idea

about what happens.[52]

In sum, without adequate regulation to disclose information, market power cannot work smoothly. Thus, like ordinary food ingredients or nutrition, labeling becomes the most direct vehicle to inform consumers. However, we should contend that labeling is not the only method that can generate information and to inform consumers. The effectiveness of labeling is also in doubt.

III. COMPARATIVE LAW STUDIES

A. *American Approach*

> "*FDA believes that the new techniques are extensions at the molecular level of traditional methods and will be used to achieve the same goals as pursued with traditional plant breeding*." — Statement of Policy: Foods Derived From New Plant Varieties, by FDA[53]

1. *Overview*

Present regulation in the United States reflects the passive attitude of regulation on GM food. However, we should not misunderstand that United States has no regulation on GM food at all. In general, we can divide the U.S. regulation on GM food into three levels. First, the U.S. Department of Agriculture ("USDA") is in charge of the release of GMOs through its Animal Plant and Health Inspection Service ("APHIS"). "Those developing a new GMO plant must submit a petition to APHIS showing that ... the plant is safe and poses no risks as a plant pest. APHIS's task is to conduct an environment assessment to determine the GMO's possible effects on human health and the environment."[54]

Secondly, the Environmental Protection Agency ("EPA") enjoys primary authority to regulate pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA").[55] Under FIFRA, one cannot sell, distribute or receive a pesticide unless it has been registered with the

52. As one author analyze the problem that "as time grows more valuable, and consumers are faced with a vast array of information resources that often provide conflicting information, consumers will rely more heavily on brief news stories and "sound bites" of information for guidance with respect to health and nutrition." "The media outlets that provide this type of information consequently will gain power and influence, particularly given the different (and generally regarded as more lenient) standards that apply to the media versus traditional product labeling and advertising." Richard .S. Silverman, *Report on the future of Food Regulation*, 55 Food Drug L.J. 11, 12 (2000).

53. 57 FR 22984.

54. Nanda, *supra* note 18, at 244-245.

55. McGarity, *supra* note 2, at 464.

EPA.[56] For this purpose, the applicant must submit extensive information required by the EPA, which includes pesticide's identity, its environmental fate, potential health influence, etc.[57]

Thirdly, the Food and Drug Administration ("FDA") has authority over GM food under Federal Food, Drug and Cosmetics Act ("FDCA"). However, there is no special regulation designed for GM food in the United States. In the federal level, the whole question surrounds how FDA interprets FDCA and applies "substantially equivalent" principle in treating GM food. In state level, some states have legislative bills on GM food, though none of them has been passed yet. In the following sections, we will respectively discuss the present regulation under FDCA, FDA's actions and some state legislative movements.

2. *Regulation under Federal Food, Drug, and Cosmetics Act*

Under the Federal Food, Drug and Cosmetic Act, FDA has three angles to approach GM food: food additive, adulteration, and misbranding.

(a) Food Additive and Adulteration

First, section 402(a)(1) of FDCA[58] provides ample authority for FDA to ensure the safety of foods. The standard of review is whether the added substance "may render it injurious to health". Secondly, according to Section 402(a)(2)(C), a food shall be deemed adulterated if it bears or contains any food additive that is unsafe within the meaning of section 409[59]. However, under section 409 of FDCA, "the term 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food ..., if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures ... to be safe under the conditions of its intended use".[60] (emphasis added) Therefore, a food additive is subject to premarket approval process of section 409 only if it is not "generally recognized as safe" ("GRAS"). The GRAS status must be evidenced through scientific procedures conducted by qualified experts. Thus, the question FDA faces is whether GM food "may render it injurious to health" and whether GM food deserves the GRAS status. If GM food may render it injurious to health, it would be deemed adulterated and would be

56. *Id.*
57. *Id.*
58. 21 USCS § 342.
59. 21 USCS § 348.
60. 21 USCS § 321(s).

subject to relevant sanctions, including injunction, criminal penalties, seizure and civil penalties.[61] If GM food is not GRAS, premarket approval is required.

In 1992, FDA issued a statement of policy concerning foods derived from new plant varieties ("1992 Statement")[62], whereas FDA dealt with the application of FDCA to GM food. As to the application of section 402(a)(1), FDA left it for food producers to evaluate whether it "may" be injurious to health and FDA encouraged informal consultation between producers and FDA scientists.[63] As to food additive and GRAS status, FDA stated that "generally FDA does not anticipate that transferred genetic material would itself be subject to food additive regulation" and that "such material is presumed to be GRAS".[64] Therefore, under FDCA, FDA decides not to actively exercise its authority over GM food.

(b) Labeling and Misbranding

Although there is no special labeling requirement for GM food under the FDCA, GM food is still subject to general requirements. A label would be deemed to be misbranded if its labeling is false or misleading in any particular.[65] Labels should bear the common or usual name of its ingredient and an appropriate description.[66] In addition, the Nutrition Labeling and Education Act of 1990 requires complete nutrition labeling.[67] Without such information required on the label, it will be deemed as misbranded.[68] Meanwhile, pursuant to section 201(n) of FDCA, "if an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account ... the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article ...".[69] (emphasis added)

In its 1992 statement, FDA noticed that "consumers must be informed, by appropriate labeling, if a food derived from a new plant variety differs from its traditional counterpart such that the common or usual name no longer applies to the new food, or if a safety or usage issue exists to which consumers must be alerted."[70] However, FDA also believed that "the new techniques are extensions at the molecular level of

61. *See* 21 USCS § 332-334 and 335b.
62. 57 FR 22984.
63. *Id.* at 22990.
64. 21 USCS § 343(a).
65. 21 USCS § 343(a)(1).
66. 21 USCS § 343(i).
67. Frederick H. Degnan, *The Food Label and the Right-to-know*, 52 Food Drug L.J. 49, 54 (1997).
68. 21 USCS § 343(q).
69. 21 USCS § 321(n).
70. 57 FR at 22991.

traditional methods and will be used to achieve the same goals as pursued with traditional plant breeding." "For this reason, the agency does not believe that the method of development of a new plant variety is normally material information within the meaning of 21 the U.S.C. 321(n) and would not usually be required to be disclosed in labeling for the food".[71]

Furthermore, in 1994, FDA issued a guideline regarding milk produced with the use of rBST.[72] "The agency found that there was no significant difference between milk from treated and untreated cows and, therefore, concluded that under the Federal Food, Drug, and Cosmetic Act, the agency did not have the authority in this situation to require special labeling for milk from rBST-treated cows."[73] Moreover, in the same guideline, FDA mentioned also "rBST-free" labeling. "Because of the presence of natural bST in milk, no milk is "bST-free," and a "bST-free" labeling statement would be false." Even if labeled as "from non-rBST treated cows", FDA still recommended that producers attached a statement "No significant difference has been shown between milk derived from rBST-treated and non-rBST-treated cows" in order to avoid any misleading.[74]

3. *New Development and State Law Movement*

Apparently, FDA applied the "substantial equivalent" test when making the 1992 policy statement. In principle, FDA treated GM food (or food from a new plant variety) the same as traditional food. Unless otherwise proved, FDA does not require GM food to be labeled different from ordinary food, and the lack of such information on food label would not constitute misbranding. There are pros and cons about this attitude. Some people argue that there is no need to require special labeling for GM food.[75] On the other hand, some people object to FDA's position by arguing that FDA should consider whether consumers think GMO as material,[76] by arguing the soundness of substantial equivalence principle,[77] or by comparing with the regulation of irradiated foods.[78]

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71. *Id.*

72. *Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatotropin*, 59 FR 6279 (FDA 1994).

73. *Id.* at 6280.

74. *Id.*

75. *See* J. Howard Beales III, *Modification and Consumer Information: Modern Biotechnology and the Regulation of Information*, 55 Food Drug L.J. 105 (2000).

76. Lara B. Winn, *Special Labeling Requirements for Genetically Engineered Food: How Sound Are the Analytical Frameworks Used by FDA and Food Producers?*, 54 Food Drug L.J. 667, 670 (1999); Similar argument *see also* Frederick H. Degnan, *Biotechnology and the Food Label: A Legal Perspective*, 55 Food Drug L.J. 301, 308-310 (2000).

77. Winn, *id.* at 670-672.

78. For regulation on irradiated foods, see 21 C.F.R. §179.26. *See also* Degnan, *supra* note

Eight years after the 1992 statement, in *Alliance for Bio-Integrity v. Shalala*[79], plaintiffs tried to challenge the 1992 statement, but their claims were rejected. The court upheld FDA's interpretation on presuming GRAS status for GM food.[80] It also upheld FDA's decision that there is no material change of GM food because the decision was not made arbitrarily or capriciously.[81][82] However, even though the court upheld its policy statement, in 2001, FDA issued a "Proposed Rules Issued for Bioengineered Foods" and guidelines for "Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering"[83]. Although there is still no compulsory labeling proposed in this proposed guideline, FDA does notice the problem of misleading information about GM food.

On the other hand, some congressmen, both in Senate and House, tried to introduce bills which impose labeling requirements on GM food.[84] Several states also have proposed legislature on genetically modified food. In Hawaii, New York and Rhode Island, there are proposed legislatures concerning GMO labeling in current session.[85] As in *International Dairy Foods Association v. Amestory*[86], one can predict that those new proposals will meet strong objection from food industry, either in legislative or judicial context.

B. *European Approach*

> "*The Community provisions governing novel foods have to be tightened and streamlined*". — From the White Paper on Food Safety[87] in 2002.

1. *Overview*

Unlike the United States, Europeans are known for their hostility toward GM food. Regulations on GMOs in the European Union have relatively longer history than other countries. From 1990, Council

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錯誤! 尚未定義書籤。, at 306.

79. 116 F.Supp.2d 166 (D.C.C., 2000).
80. *Id.* at 177-178.
81. *Id.* at 178-179.
82. For comments on this decision, see Simpson, *supra* note **錯誤! 尚未定義書籤。**, at 237.
83. See <http://www.cfsan.fda.gov/~dms/biolabgu.html> (visited on November 15, 2002).
84. Sarah L. Kirby, *Notes: Genetically Modified Foods: More Reasons to Label Than Not*, 6 Drake J.Agric. L. 351, 367 (2001).
85. For Hawaii, see 2003 HI H.B. 1033and 2003 HI S.B. 601; For New York, 2003 NY A.B. 176, 2003 NY A.B. 4206 and 2003 NY A.B. 4458 , 2003 NY S.B. 1824 and 1834; For Rhode Island, see 2003 RI S.B. 264.
86. *See supra* note 8.
87. COM (1999) 719 Final, at 26.

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Directive 90/220/EEC (amended by Commission Directive 97/35/EC for labeling requirement) began the regulation of GMOs through authorization process and labeling requirements. In 1997, "Regulation concerning Novel Foods and Novel Food Ingredients" ("1997 Regulation")[88] came into effect. In 2002, a new Council Directive 2001/18/EC[89] ("2002 Directive") repealed the old 1990 Directive and launched a revised system of the authorization process. New proposals for Regulation on labeling of GMO food is under legislative process.[90]

The whole regulatory structure of EU regulations on GMOs can be divided into two parts: horizontal and vertical. Horizontal regulation deals with introducing a GMO into environment and market. According to Article 2(2) of 2002 Directive, GMO means "an organism[91], with exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination".

Vertical regulation deals with products derived from GMOs, such as ketchup made from GM tomatoes, which concerns with more concrete food or food ingredients. Article 1 of 1997 Regulation declares that "this Regulation concerns the placing on the market within the Community of novel foods or novel food ingredients." (Article 1.1) Section 2 of Article 1 provides six categories of food or food ingredients regulated under this Regulation.[92] We should notice that the 1997 Regulation use the term "novel" instead of directly using "GM food". Apparently GM food is part of novel food, but new legislative proposals will separate GM food from novel food. If the new law comes into effect, definition and regulatory structure of GM food will be different from 1997 Regulation.[93]

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88. Regulation (EC) 258/97, 1997 O.J. (L043) 1.

89. *Directive on the Deliberate Release Into the Environment of Genetically Modified Organisms*, 2001/18/EC, 2001 OJ (L 106) 1.

90. *See* <http://europa.eu.int/comm/food/food/biotechnology/gmfood/index_en.htm> (visited on March 12, 2004).

91. According to Article 2(2) of 2002 Directive, "organism" means any biological entity capable of replication or of transferring genetic material.

92. Six categories include: (a) foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220/EEC; (b) foods and food ingredients produced from, but no containing, genetically modified organisms; (c) foods and food ingredients with a new or intentionally modified primary molecular structure; (d) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae; (e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use; (f) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

93. *See Discussion Paper: Implementation of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients*, released on July. 2002. Downloaded from <http://europa.eu.int/comm/food/fs/

Therefore, in sum, the 2002 Directive deals with upstream level of GM food (concerning GMOs) and the 1997 Regulation deals with downstream food and food ingredients.

2. *Structure of EU Regulation on GMOs and Foods Containing GMOs*

According to 2002 Directive and 1997 Regulation, the control over GMOs in the market can be divided into several parts: notification and consent before entering into market, labeling in the product and postmarket monitoring and safeguard:

(a) Authorization

The 2002 Directive deals with carrying out the deliberate release into the environment of genetically modified organisms for the purpose of placing on the market or for any other purposes within the Community.[94] "Placing on the market" means "making available to third parties, whether in return for payment or free of charge"[95].

Before placing GMOs into market for the first time, the person who wants to do it ("notifier") should submit notification competent authority of Member State (Article 12, and Article 2 for whose purpose is other than placing on market) in order to acquire the consent of that authority. The notification shall include "environment risk assessment and conclusions", which should be conducted in pursuant to Annex II of this Directive, and some other requirements listed in Article 13 (for GMOs whose purpose is other than placing on market, see Article 5).

After notification, the competent authority should make assessment report and decide whether the GMOs in question could be allowed to appear in the market, which is termed as "consent" (Article 19). The consent can be given for a maximum period of 10 years (Article 15) and be renewed (following procedures in Article 17). The consent can specify the scope, period of validity and conditions for placing into market as well as labeling and monitoring requirements (Article 19).

As to food and food ingredients, the 1997 Regulation adopts similar steps as the 2001 Directive. Those who wants to place the product on market for the first time have to submit a "request" to Member State, which includes an "initial assessment" and relevant documents listed in Article 4 and 6. If necessary, competent authority can order additional assessment (Article 6(3), 7(1) and 9). The decision made should define "the scope of authorization" and, where appropriate, should establish

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novel_food/discussion_en.pdf> (visited on March 10, 2003).

94. *See* Article 1 of 2001/18/EC.

95. *See* Article 2(3) of 2001/18/EC.

conditions of use, designation its specification and specific labeling requirement (Article 7(2)).

(b) Labeling

As to labeling, the notifier should include a proposal for labeling in his notification (Article 13(2) of 2002 Directive). The 2002 Directive explicitly requires that the "labeling shall clearly state that a GMO is present", with words "This product contains genetically modified organisms." This phrase should appear either on a label or in a document accompanying the product (Article 19(3)(e), 21 and 26).

The 1997 Regulation also imposes labeling requirements (Article 8). The first thing we need to notice is that labeling of GMOs is "additional" to the existing food labeling (Article 8(1)). Secondly, the target of labeling is "final consumer". However, some part of labeling requirement is not so clear. There are four kinds of information which should be included in the labeling:

(a) If the GMOs render a novel food or food ingredient "no longer equivalent" to an existing food or food ingredient, "any characteristic or food property, such as composition, nutritional value or nutritional effects and intended use of the food", should be included in the label. The key factor in this paragraph is "no longer equivalent".

The second paragraph of Article 8.1(a) deems a food or food ingredient to be "no longer equivalent" "if scientific assessment ... can demonstrate that the characteristics assessed are different in comparison with a conventional food or food ingredient, having regard to the accepted limits of natural variations for such characteristics." "The labeling must indicate the characteristics or properties modified together with the method by which that characteristic or property was obtained" (Article 8.1(a), third paragraph).

(b) The second requirement is "the presence in the novel food or food ingredient of material which is not present in an existing equivalent food stuff and which may have implications for the health of certain sections of the population." To some extent, this paragraph is quite unclear as what kind of "implications" can we use.

(c) The third is "the presence in the novel food or food ingredient of material which is not present in an existing equivalent food stuff and which gives rise to ethical concerns."

(d) The final requirement is "the presence of an organism genetically modified by techniques of genetic modification ..."

(c) Monitor and Safeguard

EU also establishes monitoring and safeguard measures for GMOs. In consenting GMOs into market, competent authority can impose certain monitoring requirements, including obligations to report to the Commission and competent authorities (Article 19(3)(f)). If new

information has become available, with regard to the risks of GMOs, "notifier should immediately take measures necessary to protect human health and the environment, and inform competent authority (Article 20). The 2002 Directive also allows Member States to establish safeguard measures to cope with severe risk and emergency (Article 23). To the extent of not breaching confidentiality, the information with regard to notification and consent should also be made public (Article 24).

3. *Other Countries Adopting Precautionary Principles*

EU is not the only region that adopting precautionary principle as the cornerstone.[96] Australia, New Zealand and Switzerland adopt similar regulatory regime, with approval process as well as labeling requirement.[97]

Take Switzerland as an example. Swiss law adopts similar structure to EU with some variation on labeling. Swiss law requires pre-market approval of GMOs for food products and release of GMO crops into environment.[98] Swiss law also imposes labeling requirement. A food product must be labeled "produced with GMOs" if any of its ingredients contain more than 1% of GMOs.[99] A food product may be labeled "produced without genetic engineering" if certain conditions are met.[100] Finally, it is not permitted to label "GMO free" under Swiss law because it is difficult to guarantee that a product is 100% free from GMOs.[101]

C. *East Asian Countries*

1. *Taiwan*

(a) Overview

Generally, regulation on genetically modified food in Taiwan can be divided into three parts. On the upstream, the National Science Council ("NSC") is in charge of scientific researches on genes. The scope of regulation covers wide range of gene-related researches, including GMOs

96. *See* Lietz, *supra* note 44, at 418-419.

97. *Id.* at 421-423. *See also* <http://www.gmcommission.govt.nz/RCGM/rcgm_report_appendix1.html>.

98. Franz X. Perrez, *Genetically Modified Organisms: Colloquium Article Taking Consumers Seriously: The Swiss Regulatory Approach to Genetically Modified Food*, 8 N.Y.U. Envtl. L.J. 585, 596 & 598 (2000).

99. *Id.* at 597.

100. Three conditions include: 1) no GMOs were used during the production and processing of the food or its ingredients; 2) none of its ingredients contain more than one percent GMOs; 3) a similar GM food product or ingredient which may be used for the production of this product has been approved for the Swiss market. *Id.*

101. *Id.* at 598.

and GM food. In the mid-stream, the Council of Agriculture ("COA") is in charge of test planting of genetically modified crops. However, COA cares only about agricultural industry. As the product leaves the hands of farmers, it is no longer within the jurisdiction of COA.

On the down stream, the Bureau of Food Sanitation ("BFS") under Department of Health ("DOH") is in charge of regulating manufacturing and distributing of food products into market and all kinds of food examination. DOH and BFS play an important role in controlling GM food after it enters into market.

(b) Three Sources of Law Concerning Genetically Modified Food

(i) Prohibition on Unknown Food

The authority of DOH to regulate GM food comes from the Food Sanitation Management Act ("FSMA"). First, article 11(9) of FSMA requires that food or food additives, "which have never been provided for human consumption and [never been] proven to be harmless to human health", shall not be manufactured, processed, prepared, packaged, transported, stored, sold, imported, exported, presented as a gift or publicly displayed.[102] (emphasis added)

So far, there is no hint that DOH would treat GM food as "never been provided for human consumption" and "never been proven to be harmless". However, in conceptual level, since it is disputable whether GM food is different from traditional specie of same crop, it is not absolutely certain whether GM food can be treated as "never been provided for human consumption". Moreover, as to the "harmless" test, although there is no strong positive scientific report showing that GM food is harmful to human beings, there is also no data showing that it is "harmless". Therefore, the whole question still depends on DOH's policy decision.

(ii) Special Permission for Listed Food Products

The second authorization comes from article 14 of FSMA. Paragraph 1 of article 14 states that "None of the foods, food additives, food cleansers, food utensils, food containers and food packaging which are designated by the central competent authority in a public notice shall be manufactured ... without product registration filed with and a license procured from the central competent authority. Any change in the material facts being registered shall be subject to the prior approval of the central competent authority." (emphasis added) There is no further limitation on

102. Article 11(9) of Food Sanitation Management Act:
"Foods or food additives under any of the following circumstances shall not be manufactured, processed, prepared, packaged, transported, stored, sold, imported, exported, presented as a gift or publicly displayed:
9. those that have never been provided for human consumption and proven to be harmless to human health." (translation acquired from <http://www.doh.gov.tw/dohenglish/Laws/Laws_Content.asp?No=92&ClassName=&ClassNo=L03>) (visited on November 15, 2002).

power of designation by "central competent authority" (i.e. Department of Health) in the FSMA. Therefore, under present law, the DOH can designate any kind of food or food additive and subject it to registration requirement (but of course, subject to limitation in constitution, administrative law or any other general legal principles).

There was no designation on genetically modified food until the year of 2001. In February 22 2001, DOH issued the Public Notice No. 0900011745[103] ("745 Notice) subjecting genetically modified corn and genetically modified soybean to the registration requirement under article 14. We should notice that registration requirement is not simply paper work. It must pass through some safety review in order to be permitted to register. Safety assessment should be conducted according to the Guidance of Safety Assessment for Genetically Modified Foods issued by DOH.[104]

(iii) Labeling

The third authority is about food labeling, prescribed in article 17 of FSMA. Section 1, paragraph 6 of this article requires that pre-packaged foods or food additives shall conspicuously indicate in Chinese and common symbols the following material facts on the container or packaging other material facts designated by the central competent authority in a public notice. This is a blank authorization to DOH, and it has issued Announcement[105] No. 0900011746[106] ("746 Notice") describing the labeling requirement of genetically modified corn and soybean (which was issued on the same day as the 745 Notice). We will discuss details of labeling requirement below.

(c) Present Regulation on GM Food Labeling

(i) Definition of Genetically Modified Food

The 745 Notice is the first and by far the only time that government makes an explicit definition of "genetic modification". According to this Notice, "[g]enetic modification means techniques that apply genetic engineering or modern biotechnology to transfer or insert genetic material into a living cell or organism resulted in genetic modification of the cell

103. Department of Health Gazette, Volume 30, No. 709, 2001. *See* <http://websrv.doh.gov.tw/DocGuest/OpenList.asp?DocID=678> (visited on November 15, 2002).

104. *See* <http://food.doh.gov.tw/life/default_genefood_declared.htm> (visited on November 15, 2002).

105. One should notice that there is no single official translation for legal terms within Taiwanese government. It's very normal to see two different terms refering to the same thing. As to public notification requirement under Art 14 and 17, the statute translation uses "public notice", but the official translation of No. 746 notice uses "announcement". Hereby I use "announcement". The English translation of 746 announcement can be retrieved from the following page: <http://food.doh.gov.tw/life/default_genefood_declared.htm> (visited on November 15, 2002).

106. Department of Health Gazette, Volume 30, No. 709, 2001. *See* <http://websrv.doh.gov.tw/DocGuest/OpenList.asp?DocID=677> (visited on November 15, 2002)

or organism. The technique does not include conventional breeding, cell fusion, protoplast fusion, hybridization, induced mutagenesis, ex vivo fertilization, somatic mutation, and polyploidy induction".[107]

(ii) Limited to Corn and Soybean

So far, 745 Notice and 746 Notice are the only two notices that DOH made against GM food, and those two notices apply only to two kinds of crops: corn and soybean (which are referred in the Notices respectively as "genetically modified corn" and "genetically modified soybean").

(iii) Method of Labeling

First, the labeling requirement applies only to food products which contain ingredient of genetically modified soybean or corn more than five percent (5%) by weight of finished product.[108] If the ingredient is less than 5%, there is no labeling requirement. One may wonder why "5%". There is no direct explanation in official documents. Another problem is that "[s]oy sauce, soybean oil (salad oil), corn oil, corn syrup, and corn starch etc. made of GM soybean or corn are exempted from the GM labeling requirement".[109] Since soy sauce is a very important ingredient in Chinese food and is widely used in everyday life in every family and restaurant, excluding soy sauce from labeling requirement might greatly lessen effect of labeling. One possible reason of this exclusion is that soy sauce is highly processed.[110] However, DOH still doesn't tell us why highly processed food item can be different from other food items.

Secondly, if a food product contained GM corn or soybeans which is more than 5% of total weight of that product, that food product should be labeled with the wording of "Genetically Modified" (GM) or "Containing Genetically Modified".[111] The size of those words should not be less than 2 mm (around 0.008 inch) and it should be labeled immediate after "the name of the product or the ingredient, or other conspicuous places in the labeling".[112] In fact, it is really small.

Thirdly, voluntary labeling is encouraged beginning from January 1, 2001. As to mandatory labeling, DOH takes a progressive method. From January 1, 2003, mandatory labeling applies to soybean and corn products in the raw agricultural form, including soybean meal (flour), corn grit/meal (flour). Beginning from January 1, 2004, it will apply to primarily processed soybean and corn products, including tofu, dried tofu, soy milk, soy curd, frozen corn, canned corn, and soy protein products. In January 1, 2005, it will apply to all other processed soybean and corn

107. *Supra* note 103, Item 1.
108. *Supra* note 106, Item 1.
109. *Id.* at Item 4.
110. *Id.* at Item 6(3).
111. *Id.* at Item 1 and 4. We need to notice that the label should be written in Chinese rather than in English.
112. *Id.* at Item 5.

products with the exception of those highly processed food items including soy sauce, soybean oil (salad oil), corn oil, corn syrup, and corn starch etc. which do not contain fragment of transgene or its protein.[113]

2. *Japan*

In Japan, the whole regulation on GM food can be divided into two parts: (1) the Ministry of Agriculture, Forestry and Fisheries issued guidelines for field tests and the use of GMO in food industry[114]; and (2) the Ministry of Health, Labor and Welfare ("MHLW") is in charge of safety assessment and labeling of GM food. Here we will focus on the safety assessment and labeling requirements.

(a) Safety Assessment

One distinguished feature of Japanese regulation over GM food is its safety assessment requirement. Beginning on April 1, 2001, safety assessment of GM food is mandatory required.[115] "Importation and sale of these foods are legally prohibited if they have not been assessed for safety by the national government."[116]

Key points of the safety assessment requirement include: (1) Proteins produced by recombined genes must be easily decomposed; (2) Harmful or allergenic proteins must not be produced; and (3) Newly recombined genes must be safe.[117] MHLW also provided detailed standard for safety assessment as guideline and identity preserving handling procedure for producers or importers to follow.[118]

(b) Labeling

On the other hand, labeling of GM food is also required from April 1, 2001. MHLW provided some examples of labeling wording: (1) if a food is a GM food, it should be labeled as "Genetically Modified" (labeling is mandatory); (2) A food not handled according to identity preserved handling separating GM food and non-GM food must be labeled "Not Segregated from GM Product" (Labeling is mandatory.); (3) A non-GM food handled according to identity-preserved handling may be labeled "Not genetically modified." (Labeling is voluntary.)[119]

What kind of food products are subject to labeling requirement? So

113. *Id.* at Item 6 and 7.

114. *See* <http://www.s.affrc.go.jp/docs/sentan/eguide/eguide.htm> and <http://www.s.affrc.go.jp/docs/sentan/eintro/intro.htm> (visited on January 02, 2003).

115. *See* <http://www.mhlw.go.jp/english/topics/qa/gm-food/gm2.html> (visited on January 02, 2003).

116. *Id.*

117. *Id.*

118. *Id.*

119. *See* "Mandatory Labeling of Genetically Modified Foods and Foods Containing Allergens", <http://www.mhlw.go.jp/english/topics/qa/gm-food/gm4.html> (visited on January 02, 2003).

far, only "soybeans, corn, rapeseed, potatoes and cottonseed" are required for labeling. MHLW provide a rather detailed list of processed foods that need to be labeled and most of them are made of either soybeans or corns.[120] Therefore, virtually soybean and corns are two major targets of labeling requirement.

However, we should also notice that there are some exemptions from labeling requirement. "Exempted processed foods are products such as those in which recombinant DNA or proteins produced by such DNA are finally eliminated or broken down (for example, oil, cornflakes, etc.), and those in which soybean or corn is not a major ingredient (is not one of the three major ingredients, and does not account for 5% or more of total weight)."[121] Furthermore, MHLW established a monitoring and checking system in order to control the integrity of labeling.[122]

IV. COMPARISON

A. *Explanation for the Difference*

1. *Major Differences*

To some extent, one can say that there is great difference between EU and the U.S. However, the difference may not be as big as one imagines. In agricultural level, both EU and the U.S. require approval and field tests for GMOs. EU also has separate regulation over distribution certain seeds containing GMOs.[123] As to environmental regulation, both jurisdictions also require environmental assessment when introducing GMOs into use. Taiwan and Japan also have similar regulations. The major difference appears on the food safety and labeling issue.

The difference between EU and the U.S. can be regarded as the competition of two principles: substantial equivalence principle and precautionary principle. FDA of the United States adopts substantial equivalence principle. Therefore it treats GM food generally as conventional food. On the other hand, EU adopts the precautionary principle and it takes more cautious approach to allow GM food in the market. Either GMO or GM food should apply for authorization with initial or environmental assessment before entering into market. EU also imposes broader labeling requirements on GM food.

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120. *See* "FAQs on Labeling System for Genetically Modified Foods", <http://www.mhlw.go.jp/english/topics/qa/gm-food/gm1.html> (visited on January 02, 2003).

121. *Id.*

122. *Id.*

123. For example, *see* Coucil Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed, 2002 O.J. (L 193) p33-59; Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes, 2002 O.J. (L 193) p60-73.

Between the two extremes, Taiwan and Japan represent a rather restricted application of precautionary approach. In fact, the timing of launching GM food safety assessment and labeling requirement in Taiwan and in Japan are so close that it is hard to say whether Taiwanese law imitates Japanese law or Japanese law refer to Taiwanese law. One common feature in both countries is that those GM food subject to labeling requirement is designated by competent authority, and the scope is much more restricted than European Union regulations. Another common feature is the exemption of highly processed products. Both countries require safety assessment before GM food enters into market. Nevertheless, we should notice that safety assessment in both countries focuses more on food sources (like crops) rather than end products. We should also notice that Japanese regulation is subtler with regard to GMO-free or non-segregated food than Taiwanese law.

What is the main force for this difference? As we will argue in the following text, there is no such great difference on consumer attitude no matter in America, Europe or in Asia. Besides difference in statute wording, economic condition greatly influences the decision of authorities.

2. *Does Consumer Attitude Matter?*

Europeans are famous for their reserved acceptance to GM food. There might be several reasons for this attitude, such as occurrence of mad cow disease, cultural or religious reason, etc. Therefore, consumer attitude may be one reason why they are stricter in regulating GM food. Some people might guess Americans do not care about GM food. However, it is not the truth. As we will discuss below, the fear toward GM food is a worldwide phenomenon. The distrust on GM food can also be observed through the rise of organic food movement.[124]

In the United States, according to a poll conducted by ABCNEWS in June 2001, only 35% of people considered GM food as “safe”, while 52% of people thought it unsafe. 93% of people opined that the federal government should require labels on food stating whether it's been genetically modified. In addition, compared with attitude toward organic food, the difference is even clearer. Only 5% people had more willingness to buy a food if it is labeled as genetically modified, compared with 52% in food labeled as “organically raised”. On the contrary, 57% people said that they were less likely to buy GM food if it was so labeled, compared with only 10% for organic food. However, we should also notice that around 35% of people said “no difference” no matter it is GM food or

124. *See* Winn, *supra* note 76, at 358.

organic food.[125] This attitude is also confirmed by other similar surveys.[126]

In Europe, although no pan-European consumer poll yet, existing survey shows that Britons are generally against GM food.[127] A poll also shows that over 80% of consumers in Germany are opposed to GM food.[128] Situation in Asia is similar, too. In a government survey conducted in 2000 in Taiwan, 61.6% people worried about the safety of GM food. 48.4% people would choose non-GM food intentionally if they know it is GM food. It is also interesting to note that, according to this survey, even if the price of GM food is 50% cheaper than non-GM food, there are still nearly 65% people willing to buy non-GM food instead of cheaper GM food. Meanwhile, 73.5% Taiwanese people support mandatory labeling of GM food.[129] In Japan, in a survey in 2000, only 31% of Japanese are likely to support GM food and only 20% say they are willing to buy GM fruit.[130]

These data shows that almost all around the world most consumers are concerning about GM food. Therefore, consumer attitude cannot be an explanation for the difference.

3. *Other Influencing Factors*

Since there is not much difference on consumer attitude toward GM food, there must be other reasons why the U.S. adopts a rather laissez-faire attitude. The political influence of food industry might be a factor. The clue comes from the International Diary case.[131] As described above, this case was brought against the State of Vermont for its labeling regulation on rBST milk. In this case, all plaintiffs represented food industry's interests[132] and Vermont statute was struck down at the end. In

125. Gary Langer, "Behind the Label – Many Skeptical of Bio-Engineered Food", <http://abcnews.go.com/sections/scitech/DailyNews/poll010619.html> (visited on March 05, 2003).

126. *See* McGarity, *supra* note 2, at 475. Simpson, *supra* note 7, at 240. Michael A. Whittaker, *Reevaluating the Food and Drug Administration's Stand on Labeling Genetically Engineered Foods*, 35 San Diego L. Rev. 1215, 1222 (1998).

127. *See* Winn, *supra* note 76, at 679 note 68. Nanda, *supra* note 18, at 238 note17.

128. *See* <http://archive.greenpeace.org/~usa/reports/biodiversity/roundup> (visited on Mar. 1, 2003)

129. *See* <http://food.doh.gov.tw/life/default_genefood.htm> (visited on December 10, 2002)

130. Jill J. McCluskey et al., *Consumer Response to Genetically Modified Food Products in Japan*, at 3 (2001) Downloaded from <http://impact.wsu.edu/research/twp/01-101.pdf> (visited on March 10, 2003).

131. 92 F.3d 67 (2nd Cir. 1996).

132. Plaintiffs included International Diary Foods Association, Milk Industry Foundation; International Ice Cream Association, National Cheese Institute, Grocery Manufacturers of America and National Food Processors Association.

contrast, in Alliance for Bio-Integrity case[133], where plaintiffs were consumer groups, the court rejected their petition for regulation on GM food. Although this simple comparison neglects the difference of legal arguments in both cases and does not represent the whole truth, it reflects the fact that industry is quite powerful in influencing food regulation policy.

This perspective is also strengthened by the fact that the U.S. is the biggest GM food exporter in the world. According to Greenpeace's data, "60% of processed consumer food products contain soybean material—from margarine to baby food and chocolate bars. The U.S. produces most of the world's soybeans and exports about half of its crop to Europe and Asia".[134] Estimated 68% GM crop are produced in the U.S.[135] Exportation of soybean to Europe from the U.S. amounts to $2.5 billion a year[136], and "about 70% of soybeans and more than 25% of corn in the US are now grown from genetically modified seeds."[137] In contrast, according to BBC news, US corn sales to Europe shrank from 70 million bushels in 1997 to just 3 million in 1998 owing to consumer concerns on GM food.[138] The losing market of the U.S. farmers might be one reason why the U.S. and EU have trade disputes over GM food regulations.

On the other hand, situation in Taiwan may justify why Taiwanese government subjects only corn and soybean to regulation. 95% to 100% of corns and soybeans in Taiwan are imported from abroad[139] and United States of America is the biggest source for those crops imported to Taiwan. Nearly 98% of corns and 85% of soybeans are imported from the U.S.A.[140]. An unofficial estimate shows that 50% of imported soybean and 30% of corns imported are genetically modified.[141] Because soybeans and corns are widely used as animal feed and processed as other kind of food stuff like soy sauce, etc., it is reasonable for Taiwanese

133. 116 F.Supp.2d 166 (D.C.C., 2000).

134. *See* <http://www.greenpeaceusa.org/images/user/2/i237.pdf> (visited on March 12, 2003).

135. "Which generically modified foods are sold not – and where are they grown", <http://www.bionetonline.org/English/Content/ff_cont4.htm> (visited on March 12, 2003).

136. <http://www.geocities.com/Athens/1527/eubackoff.html> (visited on March 12, 2003).

137. Davis Teather, *US trade war threat as Europe bars GM crops*, <http://www.guardian.co.uk/Print/0,3858,4580537,00.html> (visited on March 12, 2003).

138. "US farmers fear GM crop fallout", <http://news.bbc.co.uk/2/hi/science/nature/394301.stm> (visited on March 12, 2003).

139. Food Supply and Utilization 2001, at 194-195. Retrieved from <http://www.coa.gov.tw/statistic/90foodyearbook/food-3.htm> (visited on Feb. 20, 2003).

140. In the year of 2002, total importation of corns into Taiwan worthed $597,282.62 (in U.S. dollars) and $ 554,692.67 are imported from U.S.A. For soybeans, $466,546.08 out of 537,305.60 are from U.S.A. Data retrieved from <http://agrapp.coa.gov.tw:7001/TS2/TS2Jsp/TS20108.htm> (visited on March 12, 2003).

141. <http://food.doh.gov.tw/life/default_genefood.htm> (visited on March 15, 2003)

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government to pick up those two crops as the target of labeling requirement.

Moreover, there is no published evidence to show that GMOs in high processed food would be eliminated or destroyed during processing. However, most processed foods are manufactured by big food producers. We are not certain whether the decision to exempt those highly processed food products is based on scientific proof or political influence since we have no more explanation from both Taiwanese and Japanese government. There is always a possibility.

In sum, the relatively loose regulation by the U.S. government might just reflect the economic and political power of American food manufacturers. If the consumer surveys are true, sales of GM food might dramatically slump once it is labeled as containing GMOs. The decrease in sales in downstream market will influence upstream sales or production. Comparing consumer polls and economic data, GM food producers really have their reason to worry.

B. *Is Labeling A Satisfactory Way to Convey Information?*

1. *Information on Labeling*

The most important question for labeling is "which information should be included in the label?" The next question is "can consumer understand the information?" It is meaningless to cram all relevant information to consumers and hope that they can digest by themselves, either in the supermarket or at home. At the lowest label, we can require food manufacturers to tell consumers that this product contains GM food as ingredient. This information can give those who definitely don't want to take any GM food into their stomach a chance to make choice. However, for those who are risk-neutral or even risk-preference, this information is definitely not enough. Nevertheless, how much information is enough is still a problem. On the one hand, the more information put in the label, the higher the costs for manufacturers, the less chance that consumers will read and understand all.[142] It is a policy dilemma, and it exists in all kinds of labeling requirement in the market.

Up to now, European Union is the only place requiring further information besides "This product contains GMOs." According to Article 8 of 1997 Regulation[143], final consumer must be informed of any characteristic of such food, presence of material which is not present in an existing foodstuff which may have implication of health concern or giving

142. *See generally* Beales III, *supra* note 75, at 116.
143. Regulation (EC) 258/97, 1997 O.J. (L 043) 1.

rise to ethical concerns, and the presence of an organism genetically modified. If a GMO makes a food "no longer equivalent" to conventional food, producers not only have to disclose the presence of such GMO but also the "characteristic or food property" of such novel food. In contrast, Taiwan and Japan require only containing-GMO labeling. However, the use of such concept as "no longer equivalent" in EU regulation shows exactly the difficulty in drawing the line of information that should be published and which should not.

We can compare GM food labeling with labeling requirements on other products. On the one hand, GM food label is comparable with drug labels. Drug label would not simply state that "this is a drug" but contain more detailed information on how to use, what are the ingredients and relevant risks. It is impossible for food producers to do such detailed labeling since relevant risks are not clear at this moment. In addition, more or less drug itself has detrimental effect on human being, but as to GM food, it is still not certain in this regard.

On the other hand, we can also compare GM food label with ordinary food labels. Ordinary food labeling cannot tell consumers what calories or certain nutrition can do to human beings. To some extent one can argue that it should be enough if GM food label simply states that it contains GMOs or at most how much percentage of weight contained in that product. However, one distinction is that we all know and have easier access to know what calorie is and what is the negative effect of calorie through wide varieties of sources, but we only have limited access and information on how bad the GM food is, no mention that whether GM food is good or bad to human health is still not certain.

Moreover, we should also notice that detailed information of drugs comes from costly clinical research. Without such research, food producers might not have more information than government authorities, and any further information required on the label might not reflect the whole truth and might also create additional risk for consumers. Safety assessment in Japan and Taiwan or the initial assessment in Europe Union is simply "assessment" based on present knowledge. It cannot generate much more useful information through such assessment.

Finally, consumers might have various reasons to object GM food. Simply "containing GMO" labeling cannot satisfy some people's curiosity. However, if one rejects GM food simply because of religion, preference or whatever unknown reason, "containing GMO" labeling should be enough for them.

2. *GMO-free v. Containing GMO labeling*

Except the U.S., all countries with labeling requirement on GM food

require positive labeling. However, some producers may wish to label as "GMO-free" in order to attract consumers. There is no consistency as to regulation of this type passive labeling around the world.

As we have described above, Swiss law prohibits GMO-free labeling because it is difficult to guarantee 0% GMO in the food.[144] On the contrary, in Taiwan, there is no restriction on GMO-free labeling and the government even encourages producers to label as such. U.S government does not prohibit GMO-free labeling, but is now considering issuing guideline for such labeling. However, no matter in Taiwan or in the U.S., the GMO-free labeling must reflect the truth and it cannot contain any GMO inside, otherwise it will be treated as misbranding and be subjected to sanctions.

As Swiss legislators so concerned, one fundamental problem about GMO-free labeling is how to guarantee that there is absolutely no GMO in the food. Mixture of GM crop with non-GM crop can occur from the planting, processing, transportation to sales. Allowing GMO-free labeling means that not only should we look at the final product and make sure there is no GMO contained inside, but also we should establish a system to guarantee segregation of non-GM food from GM food from upstream to downstream. This will create additional costs.

Japanese law is more detailed in this regard. On the one hand, it creates the third category as "not segregated from GM product", besides GM food and non-GM food. On the other, Japanese government also issues practice guideline on identity preserving and handling procedure.[145] It is vital to enforce segregation rules, because if we cannot control segregation on foreign upstream production process, the integrity of non-segregation or non-GM food labeling is greatly in danger. However, if we apply those procedures to food importers, it will have extra-territorial effect on foreign food producers. This may lead to future trade disputes with other countries.

3. *Mandatory v. Voluntary Labeling*

Another issue is whether we should require food producers to reveal information, or just simply let producers to do it voluntarily. European Union's regulation is of the former type. Taiwan and Japan, too. On the contrary, although FDA does not impose mandatory labeling requirement in the U.S. right now, FDA does not forbid voluntary labeling, either.

First, in terms of potential misbranding or fraudulent behavior, there is no significant difference between the two. However, in mandatory

144. *See supra* III.B.3.
145. *See supra* III.C.2.

labeling regime, all producers using GMOs would bear the costs, while in voluntary labeling only those who want to label would bear the extra costs.

Secondly, given the fact that a lot of consumers would change their mind to buy non-GM food once they know that it contains GMOs, there will be less incentive for producers to label as "This food contains GMO". On the contrary, there will be more for producers to label their products as GMO-free under voluntary labeling system. To some extent it is similar to organic food.

This is relevant to the third question: Can voluntary labeling trigger market function to distinguish GM food, if no mandatory labeling is required? The answer relies on market conditions and consumer's attitude toward GM food. On one extreme, if consumers would treat those foods that do not bear GMO-free label as containing GMO, and if all consumers will not buy GM food once they know the fact, market power can work. However, market conditions are not as perfect as the above example. Foods that do not bear GMO-free label are not necessarily GM food. As discussed above, the success of GMO-free labeling relies on segregation of GM food from non-GM food from upstream to downstream. Therefore, segregation costs might prevent some food producers from labeling their products as GMO-free. In addition, there is also a possibility that food producers are not certain about whether crops or food ingredients they use include GMO or not. Under this circumstance, potential misbranding liability may also prevent them from making such labeling. In short, transaction costs in this situation greatly lessen the market function that voluntary labeling desires to trigger.

4. *Food in Restaurant*

As we discussed above, supermarket or traditional food market is not the only place where consumers can get food. Restaurant is also an important source to acquire food. However, throughout the world, all labeling requirements cannot solve the problem in the restaurant. Unless restaurant informs its customer, consumers have no way to know whether the food they buy in restaurant contains GM food or not. Like organic food restaurant, some restaurants might state that they don't use any GM food into cuisine. However, the integrity of that information relies heavily on the good faith of restaurant owners. Consumers are still in a disadvantageous position.

5. *Animals*

Animal food products are more controversial than GM crops. Facing

the threat of mad cow disease, Europeans were very cautious toward meat products.[146] EU also issued regulation on the use of hormone on meat and this created international trade dispute between the U.S. and EU.[147]

The first risk is raised by genetically modified animals. Like cloning animals, it is a highly controversial issue. In the foreseeable future, as biotechnology advances and is used by commercial entities, it will raise greater public debate. Under present EU regulation, GM meat should be labeled and the producers should apply for authorization beforehand. Therefore, EU needs not make special regulation to such GM meat if it comes into market one day. However, in Taiwan, there is no such rule designed for GM meat. Therefore, once GM meat appears in the market, government should decide whether to subject GM meat to safety assessment or labeling requirement.

Secondly, a less direct kind of influence on animal products is by way of GM animal feeds. The third risk is the use of hormone on animal food products. Again, the U.S. and EU express different regulatory ideas. In the U.S., so far there is no direct prohibition or restriction on the use of GM animal feed or hormone use on animals. The Food Safety and Inspection Service ("FSIS"), which is in charge of meat and poultry safety, never issued any regulation on potential genetically modified meat or eggs. Besides the 1994 policy statement[148], which rejected labeling of rBST milk, FDA also never issued any other regulation concerning GM animal feed or relevant animal products.

On the other hand, EU's approach is much more detailed. All the introduction of GMOs, no matter it is used in plants or on animal feeds should follow the authorization procedures and subject to labeling requirement under the 2002 Directive[149]. As to end products, if we look carefully at the wording of Article 8 of 1997 Regulation, we can find that meat or products from animals fed with GM feed are not subject to labeling requirement unless they contain such GMOs. New proposal of regulation will distinguish GM animal feed and GM food from present novel food definition.[150]

What's the difference of those animal by-products using biotechnology? As shown in FDA's 1994 statement, there is no difference between natural rBST and injected rBST. Just like unapproved health concern for human beings, there is also no certain proof showing that GM

146. *See* <http://europa.eu.int/comm/food/fs/bse/general_info_en.html#Overview> (visited on March 10, 2003).

147. *See* <http://europa.eu.int/comm/food/fs/him/him_index_en.html> (visited on March 10, 2003).

148. *See supra* note 72.

149. *See supra* note 89.

150. *See* <http://europa.eu.int/comm/food/fs/afs/afs_marktlab_en.html> (visited on March 19, 2003).

animal feed is harmful to animals or to human beings. However, concerns for consumers remain. And to some extent consumers may worry more about animals with GM feed because of the lethal threat of some diseases.

In sum, given the proven risk of GM food, we believe that "containing-GMO" labeling is a cost-justified method of labeling, even though it is far from satisfactory. Second, both containing-GMO and GMO-free labeling involve different risks and costs. Third, we believe there is no strong incentive for some food producers to label as GMO-free, even though their products are really GMO free. Therefore, we cannot solely rely on voluntary labeling (plus GMO-free labeling) to invoke market power. Fourth, food in the restaurant creates another risk for those who don't want to take GM food, and the present labeling system cannot fully cope with this problem. Finally, animal food products or by-products are also subject to direct or indirect GMO contamination. We believe it will become the core problem as technology advances.

C. *Other Control Mechanisms*

As discussed above, labeling is not a perfect solution to disclose information. Here we will discuss if there is any substitute or supplement measure that can help to give consumer an opportunity of "informed choice" in least costs.

1. *Clinical Research and Premarket Control*

The first alternative is to require premarket approval process and clinical research in order to prove that certain GM food product has minimum standard of safety. In doing so, government will treat itself as proxy of consumer's market power. Clinical research is an effective way to generate information about safety and influence of GM food. How much information can be created depends on the scope of clinical research, and apparently, from the regulatory experiences in the United States, clinical research cannot generate all information. However, whatever useful or beneficial information clinical research can give, it is costly and very expensive.

Who should do clinical research, if we require? Obviously individual farmers cannot afford such an expensive regime. Farms operated by big food manufacturers might have more capital to conduct clinical research. However, food products are not like their highly profitable and patented pharmaceutical counterparts. Lacking potential profits as incentive, even big food producers might refrain from making GM food if clinical studies are required. It is also impossible to request those who use GM food into food (like restaurants) to do clinical research. Moreover, premarket

control is not wholly reliable. There is always new risk that was not found during clinical research. Even in the highly regulated pharmaceutical industry in the United States, premarket control is still not the only way FDA uses to ensure food safety.

The standard of reviewing is another problem. Zero risk is definitely an not a practical standard since clinical research cannot generate all information. Under the Federal Food, Drug and Cosmetic Act, FDA takes the GRAS standard ("generally regarded as safe).[151] However, there is a debate on how to define GRAS. To what extent can we say one GMO is "safe"? There is no perfect answer at this moment.

The cost-benefit analysis corresponds to present regulation of food industry and regulation of GM food in the world. In European Union, it requires environmental assessment rather than clinical research on human health, though additional assessment may be required if competent authority considers necessary. In Japan and Taiwan, although safety assessment is required, it is limited to upstream imported food products such as corns or soybeans rather than processed or end products. For example, in Taiwan, only genetically modified corn or soybean needs to do safety assessment but food product using GM corn or soybean only needs to be labeled. Meanwhile, safety assessment in Taiwan and Japan is far from a grand scale clinical research that can generate new information. It is simply an assessment based on present knowledge in order to make sure there is no allergenic effect on that GM crop. Government might also use other regimes to do clinical research, such as government-sponsored research project, etc. However, whether it is an efficient way to generate information require further evaluation.

If we require clinical research on GM food products, we can predict that only those highly profitable GM food products can survive (like drugs). However, is it what we want? Industry might not embrace the idea of premarket clinical research requirement. How about consumers? For those who don't like genetically modified product or those who are paranoid at any genetical modification eliminating all GM food from market seems to be a right and the only way we should go. However, if we take the potential economic benefit to human life into account, whether we should have such strong requirement is arguable.

2. *Post-market Monitor and Circulation Restrictions*

An effective reporting system is the key to the success of a post-market control system. In this regard, it seems that there is no difference from ordinary food safety control system. Food safety events

151. 21 U.S.C.S. § 348.

occur from time to time, no matter it is traditional or GM food. How can we know it is the modified gene that causes problem? However, compared with premarket method, postmarket approach is still less costly since government only has to focus on those foods that cause problems.

Obviously there is a time gap between the miserable event and discovering the real cause, especially what we face is "gene". Thus, the postmarket approach is not very effective on warning consumers of the hazard in the first hand. Moreover, what if it is not a massive food safety event? What the government should do when facing such a small hazard? If we are facing a massive negative allergic public reaction, apparently government can use its power to prevent further happening. However, if it is just a single case, how the government to notice potential harmed consumer is pretty tricky. On the one hand, government does not want to put public in panic, but on the other, it is not easy to specify a target group as well. In addition, inadequate publishing of information to consumers might also create externality on safe GM food. In sum, if a country already has a food safety reporting and warning mechanism, post-market approach is cheaper than premarket control approach. However, the effectiveness of postmarket control is also limited.

Besides post-market monitor, another kind of post-market control is the circulation restriction. With circulation restriction, it is easier for government to control the flow of GMOs of GM food. It may also be accompanied by a registration system. However, there will be some enforcement costs on circulation restriction. Not only does government should establish an efficient system to make this restriction effective, but also it should deal with potential circumventing behavior.

3. *Upstream Control and Authorization Process*

As a practical issue, regulation should start from the source rather than with end products, if we decide to put labeling requirement over GM food. Regulations in European Union, Taiwan and Japan all reflect this idea. On the one hand, it will be easier to control the circulation and use of GMOs in the market if we control from the source. On the other, since most GM crops in EU, Taiwan and Japan are imported, it is reasonable to regulate from the time it enters into the border. This method also reflects the precautionary principle.

More or less, all countries require certain kinds of upstream control, even in the U.S. In agricultural level, farmer cannot plant GM seed at will. All countries, including the U.S., require certain kinds of field tests requirement or environmental assessment. Once a GMO cannot pass this stage, it will not appear in retail market.

Upstream control or authorization process alone has nothing to do

with consumer choice. Government approval of GMOs or GM crop is far from being a guarantee of safety, either at present or in the future. Consumers still need information to make sound choices.

V. CONCLUSION

In this article, our theory is that consumers have freedom to choice and market competition can be an index to show what we should do in one jurisdiction about GM food. The appearance of GM food in the market brings great concerns for consumers. Some are relevant to consumers itself, such as food safety, health concern and safety issue. Some are in a rather public level, such as environment, trade policy and scientific development. Regulators need to consider all influencing factors to make judgments. However, we should not forget that all technology comes from human beings and is finally consumed by human beings. Consumer's intention should be respected. To allow consumers to make sound decisions, information plays a key role.

Difference between the U.S. and Europe reflect the difference of principles. Regulation in the U.S. reflects the substantial equivalence principle. Although it is based on present knowledge and is more favorable to food producers, this principle is easier to apply. On the other hand, such as in Europe or in Asia, regulations the precautionary principle. Governments in those regions take a more cautious approach. This article supports EU's point of view to construct a demand-driven environment for use of biotechnology. Delivering information from producers to consumers is an essential step for consumer's market power. However, how to convey information in a cheaper way without losing benefits of useful technology is the dilemma faced by every government.

Labeling is the most direct way to convey information from food producers to consumers. However, it is not a perfect solution. First, information in labeling is limited. Secondly, without adequate segregation measures, GMO-free labeling could be misleading. Thirdly, labeling cannot reach all situations, such as food from restaurants. Meanwhile, it is not reasonable to require food producers to conduct clinical research as pharmaceutical companies do. Postmarket control and monitor can strengthen food labeling but they should not be the only control mechanism.

In the comparative law level, the U.S. basically treats GM food as equivalent to conventional food, while European Union is on the end of the spectrum. Not only the definition of novel food in Europe is broader than simply GM food, but EU requires authorization and labeling from the beginning of introducing GMOs into environment to its use in consumer products. Regulations in Taiwan and Japan are more restricted in scope

compared with European Union. Both countries impose safety assessment and labeling requirements but only on those designated GM food, mostly corns and soybeans. Both countries also exempt some highly processed food products without persuading reasons. However, Japan created a third category of non-segregation food, which is not seen even in Europe.

The difference in above mentioned countries cannot be explained by consumer attitude. In fact, even in the United States, consumers show a lot of concern about GM food. Thus, consumer attitude cannot be an influencing factor on policy difference. On the other hand, we found that the U.S. is the biggest exporter of GM food in the world, and on the contrary, EU, Taiwan and Japan are all importers of GM food. This economic background can be shown into political process. Whereas food producers in the U.S. have more incentive to object consumer regulation, Europe provides a context that makes consumer's voice louder. However, this can never be the end of the story. Even in the U.S., some legislators and states propose to impose labeling requirements on GM food. The battle between food producers and consumers will continue

What should Taiwanese government do regulate GM food in the next step? Does the present regulation enough to protect consumers? What position should Taiwanese government take, European approach or American approach? Indeed, Taiwanese government is facing challenges. The truth is that most part of soybeans or corns used in Taiwan is imported from the U.S., the biggest exporter of GM crops. Any increase of regulation might not only hurt domestic industry who requires large amount of imported crops but also create international trade disputes with the U.S. that may have some negative impact on economy or politics. On the other hand, in domestic level, labelling requirement in Taiwan is not as wide as the EU thus leaves some doubts as to the protection of consumers from potential harm. Present regulations in Taiwan is flexible enough to cope with any new development in the future, either originated inside the island or any bulk importation of GM crops. Therefore, this article supports the standpoint of Taiwanese regulation, i.e. regulations on limited types of GM crops imported, given the fact that we are in most cases GM crops receivers than manufacturers. However, the potential risk of mixture of GM food with ordinary food cannot be ignored, and exemption of highly processed food made of GM corn or GM soybean also lacks powerful explanation to general public. As to the former point, absolute segregation is necessary to ensure the integrity of GM-free labelling, even if it is voluntary. Swiss law is sensible in prohibiting GM-free labelling. Japanese law seems to be a good model to learn from. If we do not ensure segregation from top to bottom, the effectiveness of the whole labelling system is in jeopardy. As to the latter point, most people might not feel strongly impacted if GM crops imported are not

going into their stomach directly. However, they might feel so if soybean sauce absorbed everyday contained GMOs. The 5% threshold shares similar problems. The Department of Health should provide more information to clear some clouds. After all, if we look at the bigger picture in the world of GM food, let's wait and see how the two giants – EU and the U.S. – figure out their disagreement, and how international standard, if possible, to be established in the future.