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GMOs in food, the basis of regulation and the EU-US trade dispute

1. Introduction

Few trade issues have caused such bitter divisions between the governments of the USA and EU states as that of genetic modification in agriculture. Differences over the authorisation of commercial growing of GM crops and the conditions under which GM food can be traded have continued for many years, notably since the EU's *de facto* moratorium' on GM crops came into effect in 1998.

There have been significant developments in this area in the last 12 months. In August 2003 the US took the issue to a WTO Dispute Panel after the failure of initial consultations following the matter first being taken to the WTO. In addition the EU has introduced new legislation regarding the production, labelling and traceability of GM crops.

The dispute raises a number of important issues regarding the regulation of production and trade in GM food. These include the role and validity of 'substantial equivalence' as the starting point for the authorisation of GM crops, the role of the precautionary principle in regulation, the status of social science alongside 'sound science' in risk assessment and management and, fundamentally, about whether 'process' rather than 'product' is an acceptable basis for regulation.

This paper discusses these issues and assesses the implications for the continuing US-EU trade dispute of the new EU regulations on GM food and feed, their traceability and labelling. New evidence from a survey of the UK public regarding their preferences for different forms of GM food provides insights regarding whether product or process is the appropriate basis for regulation of GMOs in food.

2. GM Food and the US-EU Trade Dispute

GM Food Regulatory Approaches in the US and EU

Given that the US and EU comprise the largest bilateral trading relationship on the planet, a dispute regarding the way in which agricultural commodities are authorised for production and traded was always going to lead to significant friction. However in the 1980s and early 1990s there was little indication of the serious problems that were about to emerge.

As biotechnology developed, regulators on both sides of the Atlantic were faced with important decisions on how to regulate the new crops that were being pioneered. Essentially, although somewhat crudely, the different approaches taken in the EU and the US were those of 'process-based' and 'product-based' regulation respectively. The former means that the process of production is the focus of legislation whereas the latter means that only the product is the subject of scrutiny. In the case of GM technology, a 'process-based' approach may be based on a view that there may be new risks to health, the environment or both associated with the modification process.

The EU's adoption of a process-based legislative approach allowed it to pursue a harmonised system of control across the various member states (House of Lords, 1999) rather than attempting to ensure identical laws regarding health and the environment were in place across them. The

result was that all stages of the GM process from research and testing through to market release were scrutinised.

The US product-based approach means that the regulation of development through to commercialisation is done under existing legislation. That is, legislation concerning genetic modification specifically is not required. It should be noted that, as Senker and van Swanenberg (2000) point out:

> "The distinction in principle between product-based and process-based forms of regulation refers mainly to the preferred administrative arrangement for regulation (and, from the industry's perspective, the stigma of identifying a particular technology as requiring specific regulatory oversight) rather than any necessary difference in the regulatory burden." (2000: 12)

Substantial Equivalence

This point regarding the similarities still possible in the process- and product-based approaches becomes clearer when one considers the concept that has been at the heart of the EU's assessment of GM products for which authorisation is sought. More specifically, authorisation in the EU has been based on the concept of 'substantial equivalence'. Substantial equivalence has three levels and crops and their derivative food products can (Tait and Bruce, 2001) be categorised as:

1. substantially equivalent to a conventional counterpart;
2. substantially equivalent to a conventional counterpart apart from a few clearly defined differences;
3. not substantially equivalent to a conventional counterpart.

If a new product is 'substantially equivalent' then new testing of the crop is not required, whereas if it is not substantially equivalent, then additional testing is required.

Whilst in the EU a regulatory system specifically for biotechnology products has developed, the fact that the starting point for the assessment of new varieties for the market is substantial equivalence means that in practice there have been similarities regarding the authorisation process on both sides of Atlantic. In the US, GM crops do not require special regulatory approval as long as the constituents of the food are not significantly different from those in other foods

The use of substantial equivalence as the starting point for regulation of GMOs in food is contested. Millstone *et al*., (1999) argue that the concept is never clearly defined, that is, it is not clear how substantial the differences must be before two products are not equivalent. They argue that as biotechnology developed new foods in the 1990s it was not clear how they should be regulated. On option was to treat GM foods as novel chemical compounds with the need for detailed toxicological tests which would be expensive and take a great deal of time. The use of substantial equivalence enabled, they argue, GM foods to be regarded as novel enough to allow Intellectual Property Rights (IPRs) to be generated and protected but not sufficiently novel to require toxicological testing. Hence Millstone *et al*., argue that:

> "Substantial equivalence is a pseudo-scientific concept because it is a commercial and political judgement masquerading as if it were scientific. It is, moreover, inherently anti-scientific because it was created primarily to provide an excuse for not requiring

biochemical or toxicological tests. It therefore serves to discourage and inhibit potentially informative scientific research." (1999: 526)

This view is strongly contested. Kearns and Mayers respond that substantial equivalence is a guiding principle and not a substitute for a safety assessment:

> "It stresses that an assessment should show that a GM variety is as safe as its traditional counterparts. In this approach, differences may be identified for further scrutiny, which can involve nutritional, toxicological and immunological testing. The approach allows regulators to focus on the differences in a new variety and therefore on safety concerns of critical importance. Biochemical and toxicological tests are certainly not precluded." (1999: 640)

The Evolution of EU Regulation

EU regulation of biotechnology in agriculture began with two regulations in 1990 which concerned contained use (Directive 90/219) and deliberate release (Directive 90/220) of GMOs. Under Directive 90/220, 14 GM plant varieties were eventually authorised for release or sale within the EU by the time the 1998 *de facto* moratorium came into effect. However the Directive did permit member states to restrict GM crops, despite approval, if they were justifiably deemed to pose a health or environmental risk.

The labelling regime was modified in 1997 through the Novel Foods and Novel Food Ingredients Regulation (Directive 258/97). The EU regulatory regime regarding the placing on the market of GMOs was refined in 2002 through Directive 2001/18. This Directive required field testing at the research and development stage in ecosystems which could be affected by their use. The process of market authorisations was a stepped one after a case-by-case environmental risk assessment. All products placed on the market would require labelling on the understanding that a further labelling Directive would follow in 2003.

Directive 2001/18 also required an "obligation to implement a monitoring plan in order to trace and identify any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment of GMOs as or in products after they have been placed on the market."

3. The Moratorium

In 1996 imports of Monsanto's glyphosate tolerant GM soybeans began to enter the EU without segregation or labelling. At this time, prompted in part by these imports GM soybeans, the issue of genetic modification became an increasingly mainstream political issue within certain parts of the EU. Calls grew from some for bans on these GM imports, while major EU trade organisations called for segregation and labelling of the imports.

Discontent and opposition regarding GMOs in the EU developed, albeit unevenly, from 1996. In 1997 Austria and Luxembourg banned a series of GM varieties despite their having been authorised under Directive 90/220. Additional bans on approved crops followed in Austria as well as Greece, Italy and Germany. A number of states made it clear in 1998 that they would block further authorisations in the absence of a new labelling regime for GM crops. This block accounted for sufficient votes to prevent a qualified majority at the Council of Ministers from approving new GM products. Hence the *de facto* moratorium came into effect in 1998.

It is interesting to note that the ban by EU states on crops which had previously been authorised under Directive 90/220 (such as Austria's 1997 ban on Bt176 maize) meant that they could be challenged by the Commission in the European Court of Justice. The fact that such action was not forthcoming probably encouraged the bans that followed from other EU nation states. Such action would have forced these states to put their case regarding the 'justifiable' concerns they had regarding the risk posed by the GM crops to health or the environment.

Impacts of the Moratorium on US-EU Trade

Among the most important field crops in the USA are maize, soybeans and cotton. These crops are used in food and animal feed and derivatives of them feature extensively in food processing also (Pew Institute, 2003). By 2003 81% of soybeans, 73% of cotton and 40% of maize in the US was genetically modified. The effects of the moratorium have been uneven across commodities as is illustrated in Tables 1 and 2.

The total value of US exports has fallen by nearly a quarter between 1998 and 2002. The decline for soybeans is of a similar magnitude and it is reported that US producers have been reluctant to plant varieties of GM soybean other than the one approved by the EU prior to the moratorium (Pew Institute, 2003).

The baseline value of cotton exports to the EU was much lower, at $115 001, than that for soybeans but the decline of 39% in this value is marked. The most severe decline has been in terms of maize, where the value of US exports to the EU has fallen by 92% between 1998 and 2002. Table 2 shows that this dramatic decline in US-EU maize shipments is relatively minor in terms of the overall US export flow, given that the EU only accounted for 4% of US maize exports.

Table 1. U.S. Agricultural exports to the EU by value in US dollars

	1998 (US $m)	1999 (US $m)	2000 (US $m)	2001 (US $m)	2002 (US $m)	% change 1998-2002
Total U.S. Agric Exports to the EU	7849.1	6413.2	6243.6	6404.0	6144.5	-22%
Soybeans	1534.0	032.9	1154.7	1154.9	1153.8	-25%
Cotton	115.0	51.0	74.0	55.3	70.5	-39%
Maize	35.3	1.4	8.1	1.8	2.7	-92%

(source: Pew Institute , 2003)

Table 2. U.S. Agricultural exports to the EU by percentage of total US agricultural exports

	% Total US Agri.Exports Going to the EU				
	1998	1999	2000	2001	2002
Total U.S. Agric Exports to the EU	14	11	11	11	10
Soybeans	32	23	23	22	22
Cotton	4	4	3	2	3
Maize	4	1	0.1	0.1	<0.1

(source: Pew Institute , 2003)

The US Response to the Moratorium

The continued EU moratorium on growing and importing of GM crops led, eventually, to the US filing a complaint at the WTO in May 2003. The complaint, backed by Canada and Argentina and other nations, instigated a consultation period, of up to 60 days. However it was quickly apparent that no resolution was in sight and hence the U.S., Canada and Argentina formally requested a WTO Dispute Panel in August 2003. This request centred on three claims which, it is claimed, have breached WTO law and harmed the complainants exports to the EU. These claims are summarised (Busch *et al*., 2004: 10) as:

(1) "a moratorium on the approval of products of agricultural biotechnology" in which "the EC has suspended consideration of applications for, or granting of, approval of biotech products under the EC approval system";

(2) blocking of all "applications for placing [additional] biotech products on the market;"

(3) the maintenance by EC Member states of "national marketing and import bans on biotech products even though those products have already been approved by the EC for import and marketing in the EC."

The U.S., Canada, and Argentina argue that these sanctions by the EU contravene aspects of the SPS Agreement, GATT 1994, the Agreement on Agriculture, and the Technical Barriers to Trade (TBT) Agreement (Busch *et al*., 2004: 10).

Three points are worth noting about these developments. First, it is possible that the US's decision to take the matter to the WTO Dispute Panel may backfire regarding market development within the EU. The danger for the US being that distrust of GMOs in food will be exacerbated if a perception is created that these are being 'forced' in to the EU against the will of its governing bodies. Second, even if the Dispute Panel rules in favour of the US, the EU may choose to continue in its policies and simply face the penalties in terms of higher tariffs. This was the case with the rBST bovine growth hormone case (Pew Institute, 2003). Finally, the EU has repeatedly stated it would be dealing with the issues raised by the US via new regulations regarding labelling and traceability of GMOs in food, on the basis that the market development could only occur where a reasonable basis for consumer choice had been established.

The new labelling and traceability regulations are discussed in Section 5 and their possible effects on the trade dispute are discussed as well as evidence regarding the extent to which consumers in the UK appear to value the changes in the GM labelling regime.

4. Transboundary risk, regulation and governance

The EU-US trade dispute incorporates some rather fundamental differences regarding the way in which new technologies, such as genetic modification, are regulated. The dispute and the eventual ruling of the WTO Dispute Panel will have implications for the use of the precautionary principle as a legitimate part of regulation and the nature of risk assessment.

The Precautionary Principle

The EU regulatory framework regarding GMOs has always had a more precautionary basis than that of the US. This was partly a response to the experience regulating pesticides where there were delays in identify the toxic effects of, for example, organochlorines (Tait, 2001). The Royal Commission on Environmental Pollution (RCEP, 1989) report on *The Release of Genetically Engineered Organisms to the Environment* argued that "The opportunity exists to learn from the experiences and predictions of the past in order to build environmental foresight into any necessary regulation of these new products".

The inclusion of the precautionary principle within the regulatory framework created the possibility, however small, of ethical and value based judgements entering the process (Tait, 2001). It should be noted also that Directive 2001/18 on the release of GMOs was explicit that:

> "The precautionary principle has been taken into account in the drafting of this Directive and must be taken into account when implementing it."

and that:

> "Respect for ethical principles recognised in a Member State is particularly important. Member States may take into consideration ethical aspects when GMOs are deliberately released or placed on the market as or in products."

The new regulations have also acknowledged the broader precautionary aspect of GMO regulation, hence Regulation 1829/2003 states that:

> "It is recognised that, in some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and that other legitimate factors relevant to the matter under consideration may be taken into account."

What then are the legitimate factors mentioned that can be taken into account; do such factors include the ethical and value issues of the public? The European Parliament had included the precautionary principle in earlier drafts of the Regulations but it was eventually removed although, as Scott (2003) explains, this has not led to its total exclusion:

> "Contrary to an earlier draft (itself amended following pressure from the European Parliament), there is, as things stand, no explicit reference to the precautionary principle in the GM food and feed proposal. Nonetheless… Article 1 refers to the general principles

> laid down in the EFSA [European Food Safety Authority] regulation, and consequently the precautionary principle…will enter through the backdoor"

The basis on which the precautionary principle may be invoked by member states to block imports or growing of GM crops is unclear. The ruling of the European Court of the First Instance concerning the withdrawal of EU approval for antibiotics in livestock indicates an acceptance that in the presence of uncertainty it is legal to act before the severity of the risk is clear. Whilst zero and purely hypothetical risk were deemed as an unacceptable basis for action, the ruling was that "Institutions are entitled to act before the relevant research aimed at obtaining evidence of risk is completed, and before quantitative evidence of the extent of the problem is available" (Scott, 2003)

These issues of the regulatory system's incorporation of risk, values and ethics are complicated by the fact that one may distinguish between two different forms of risk associated with products like GM food. Tait and Bruce (2001) propose a distinction between product-based and production system-based risk. The product-based risk associated with GM food or food with pesticide residues is the perceived health risk associated with consumption of the good. For production-system based risks the product is only emblematic of the risk associated with the production system as a whole. While some have concerns about eating GM food, it is clear that for many such goods are emblematic of perceived broader production system based risks, for example with respect to biodiversity effects. That is, these goods represent production systems about which they have value-based or ethical concerns.

If one is regulated by the WTO then this is a problem:

> "Despite the more open approach to decision making adopted recently by regulatory bodies such as the WTO, formal risk-regulation processes, national or transboundary, do not yet accommodate value-based perspectives. This leads to what are often described as irrational public responses to risk issues when demands are made that appear to go far beyond what could be justified on a purely scientific basis". (Tait and Bruce, 2001)

This raises issues about what issues, values and evidence can then feature in the assessment and management of risk. That is, of what can be "justified on a purely scientific basis".

Risk, Science and Values

Busch *at al*., (2004) argue that the US submission to the WTO reflects and restates the conventional understanding of risk assessment, that it should be scientifically based, objective and value free. Hence such an assessment should involve specification of the possible damages that may be caused to health or the environment and then an assessment of the probability of such damages occurring.

In this context, the values and concerns of the public or special interest groups do not feature in classical risk assessment. Such subjective elements may instead enter into the next stage of the process: risk management. Busch *et al* (2004) argue that, in the absence of certainty regarding the relevant knowledge base and the lack of consensus on the key parameters, the US position is flawed. They argue that the US position misunderstands the extent to which national scientific and cultural contexts help determine which analytic foci are valid for risk assessment. This is particularly the case when the scientific knowledge base is relatively new and small. Further,

their view is that "wider background assumptions and value commitments that are unavoidably embedded within scientific knowledge generated for policy applications".

Hence risk is not just about identifying a hazard but also the conceptual lenses through which the issue is seen. On this basis, they argue, the process undertaken by the EU has not involved unreasonable delay and acted as an illegal restraint on trade. Differences in the process between the US and EU do not imply one process is right or wrong, they reflect cultural and social differences. Risks are defined within social and political contexts and so the different standards and emphases one observes across different countries may be entirely justified rather than one or more of them inevitably being unscientific or irrational.

5. The New EU Regulations on GM Food and Feed and Traceability and Labelling

As discussed in Section 5 the EU's position for many years was that the moratorium would only be lifted when the processes by which crops were authorised, for growing or importation, and labelled had been overhauled. The 2002 refinement of GM regulations (Directive 2001/18) was on the understanding that a new system of GM food labelling would follow. The significance of the new labelling and traceability regulation was made clear in EU responses to the US's commencement of WTO proceedings. Hence David Byrne, EU Commissioner for Health and Consumer protection, stated:

> "We have been working hard in Europe to complete our regulatory system in line with the latest scientific and international developments. The finalisation process is imminent. This is essential to restore consumer confidence in GMO's in Europe….Unless consumers see that the authorisation process is up to date and takes into account all legitimate concerns, consumers will continue to remain sceptical of GM products."

EU Commissioner for the Environment, Margot Wallstrom, commenting on the US move to the WTO Dispute Panel noted that:

> "This US move is unhelpful. It can only make an already difficult debate in Europe more difficult. But in the meantime, the Commission strongly believes that we in Europe should move ahead with completing our legislation on traceability and labelling and on food and feed, currently before the European Parliament"

So the new legislation on traceability and labelling was seen as potentially defusing the US-EU dispute. The new requirements regarding the labelling and traceability of GM food that Byrne and Wallstrom refer to are now briefly outlined and their implications discussed. Rather than helping to resolve the dispute, it seems that they are likely to make things more problematic.

The Latest EU Regulations: Labelling and Traceability

In July 2003 the Council and the European Parliament adopted two new Regulations to come into effect in April 2004:

- Regulation on GM food and feed (**Regulation 1829/2003**)
- Regulation on traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs (**Regulation 1830/2003**)

Under the rules of the new Regulation on traceability, business operators must transmit and retain information about products that *contain* or are *produced from* GMOs at each stage of the placing on the market. In this system records must be created and maintained throughout the food chain.

In practice a company selling GM seed must inform purchasers that it is genetically modified (including information allowing the specific GMO to be identified) and the cultivating farmer would have to inform purchasers of the crop that it is genetically modified and keep a register of those to whom he/she has sold. These traceability requirements apply to all GMOs that have received EU authorisation for placement in the market.

A crucial change to the regulatory framework is the extension of the current labelling provisions to genetically modified food or feed, *regardless of whether it contains detectable modified DNA or protein*. Any food or feed which *consist of, contain* or are *produced from* GMOs will require a label. For example, this includes tomato paste and ketchup produced from a GM tomato or starch, as well as oil or flour produced from GM maize.

This represents a significant change from the requirement before April 2004 which was based on the detectability of genetically modified DNA or protein in the final food product. A range of highly processed foodstuffs derived from GM material will now need to be labelled. These include common products such as soya oil, vegetable oil, lecithin and hydrolysed vegetable protein, modified starch, cornflour, maize starch, and maize oil. Genetically modified feed will also need to be labelled along the same principles to give livestock farmers accurate information on the composition and properties of feed.

However there are some notable continued exceptions from these labelling requirements. Products that are not food ingredients such as processing aids and enzymes (for example chymosin, used in the production of cheese) are exempt. Also exempt are products such as meat, milk or eggs obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products.

IN addition, the new legislation introduces a stricter threshold for *adventitious presence*. Specifically, the Regulations lower the threshold for non-labelled accidental presence of approved GM varieties from 1% to 0.9%. For those GMOs which have been assessed as not posing a danger but awaiting final approval the threshold at which labelling and traceability are enforced is 0.5%.

Table 3 summarises the main implications of the new regulations on labelling food and feed.

Table 3. Labelling of GM-Food and GM-Feed – Examples[1]

GMO-type	**Example**	**Presence of Genetically Modified DNA or protein?**	**Labelling Required Before April 2004?**	**Labelling Required April 2004?**
GM plant	Chicory[2]	Yes	Yes	Yes
GM seed	Maize seeds	Yes	Yes	Yes
GM food	Maize, Soybean sprouts, Tomato	Yes	Yes	Yes
Food	Maize flour	Yes	Yes	Yes
Produced	Highly refined maize oil, soybean oil, rape seed oil	No	No	Yes
From GMOs	Glucose syrup produced from maize starch	No	No	Yes
Food from animals fed on GM feed	Eggs, meat, milk	No	No	No
Food produced with the help of a GM enzyme	Cheese produced with the help of chymosin	No	No	No
Food additive/flavouring produced from GMOs	Highly filtered lecithin extracted from soybean oil used in chocolate	No	No	Yes
GM Feed	Maize	Yes	Yes	Yes
Feed produced from a GMO	Corn gluten feed, Soybean meal	No	No	Yes
Feed additive produced from a GMO	Vitamin B2 (riboflavin)	No	No	Yes

[1] Rigby et al., (2004)
[2] Once chicory has been approved for breeding purposes under Directive 90/220/EC, but not for food use.

The US Response to the new EU Regulations

The responses in the US to the new EU labelling and traceabiliy regime have been far from positive. This is reflected in the fact that the US decided to proceed to the Dispute Panel even when it was known that the EU regulations were imminent. Indeed, significant actors in the US regard the regulations as a new, illegal, barrier to trade. David Hegwood, Trade Advisor to the U.S. Department of Agriculture Secretary, said that the new regulations would "disrupt international trade without serving any legitimate food safety or environmental safety objectives." Ron Gaskill, from the American Farm Bureau Federation, said that the labelling and traceability rules are "just as inconsistent with the WTO agreement on technical barriers to trade and sanitary and phytosanitary measures as the moratorium itself is."

Richard Mills, of the US Trade Representative's office, concluded that the new regulations would not be sufficient for the WTO complaint to be resolved. Stating that the new labelling system should be non prejudicial and feasible he concluded "we are concerned that the proposed traceability and labeling does not meet this standard". Bob Stallman, President of the American Farm Bureau Federation, stated: "The EU has only made a bad situation worse. It's commercially impossible to comply with the rule, it's not justified by any scientific analysis, and it's just as WTO inconsistent as the biotech ban that the EU says it will replace."

A representative of the Biotechnology Industry Organization (BIO) reported that:

> "…our customers among the farming and food producing communities tell us the new traceability and labeling standards are impractical. Impartial observers can see they are not scientifically defensible…It seems more likely that the new regulations will drive food manufacturers to re-formulate to shun biotech derived ingredients altogether as their only effective means of avoiding the impractical burdens the new regulations would impose. If this happens, as we fear, the result would be to replace an overt moratorium with a technical barrier to trade that would be no less indefensible"

The US National Food Processors Association responded to the new regime with:

> "By finalizing these new requirements…. the EU has turned away from food science and food safety, and has established a serious trade barrier ….
>
> European consumers will see such labels on food products as 'warning labels..…Mandatory labeling should be based on the composition, intended use, and health and safety characteristics of a food product, not on the 'genetic process' from which it was derived. Moreover, the traceability requirements are a classic case of regulatory overkill, putting complex and detailed new requirements on food companies, *with no benefit for consumers*." [my italics]
> (NFPA Press Release 20/10/03)

The new labelling and traceability regime is, it is argued, unscientific, an illegal restraint on trade, as bad as the *de facto* moratorium, a barrier to choice. Being a rejection of food science and food safety, it is seen as serving no consumer interests. Evidently the new legislation has further stoked the trade dispute. While it may be a precursor to the lifting of the ban on US imports of GM crops and their derivatives, the conditions under which this trade will take place has been changed profoundly.

6. Assessing the Benefits of Process-Based Labelling

A number of studies of attitudes in the UK and mainland Europe have found that many consumers do not want to eat GM food and that the majority believe that, if such food is sold, it should be clearly labelled (see various Eurobarometer studies, for example). In this context the increase in the robustness and strictness of the EU labelling regime might, contrary to the NFPA statement above, be expected to offer significant gains to consumers. Of particular interest here is whether there are benefits attached to extending the labelling regime to include not only those foods containing modified genetic material but also those foods with ingredients *produced from* GMOs, such as maize and soy oil, despite the absence of modified DNA or protein.

In a study commissioned by the UK Department for Environment, Food and Rural Affairs (DEFRA), Rigby *et al*., (2004) investigate how consumers treat such foods containing ingredients derived from GM ingredients. The work employed both contingent valuation and choice modelling methods and used a simple good, bread, as the commodity of interest. In the survey the bread available could be of three forms

Table 4. GM, Non-GM and GM-Derived Bread

Made with non-GM ingredients	(Non-GM Bread)
Made with GM grains	(GM Bread)
Made with oils derived from GM crops but free from altered genetic material	(GM Derived Bread)

The choice modelling results allowed testing of whether, implicitly through their selection of bread options, the interviewees treated the bread containing GM-derived ingredients as equivalent to non-GM bread, or to bread with GM ingredients, or as a distinctly different product. Rigby *et al*., (2004) report that for the vast majority of those sampled, their choices indicated that they treated GM-derived ingredients as no different from GM ingredients.

It was found that preferences regarding the GM nature of the bread differed by a number of socio-economic and demographic characteristics such as class, gender, age, attitudes, and the presence of children in the household. However analysis identified only one group of respondents in the sample, those aged between 16 and 24, who treated bread with GM-derived ingredients in the same way as non-GM bread. For all other groups, the choices revealed that GM and GM-derived ingredients were regarded as the same.

This would imply that regulation on the basis of process, rather than product, was valued by respondents. The critical issue appears to have been not whether the product contained detectable modified material, but the nature of the crop from which it was derived. Hence Rigby *et al,* (2004) conclude

> "The fundamental result from this first piece of analysis is that the vast majority of consumers regard the forthcoming extension of the labelling and traceability regime to include both GM ingredients and ingredients derived from GM products as highly desirable. With the possible exception of some of the youngest in the sample, the bread made with GM-derived ingredients was treated in the same manner as that made with ingredients containing detectable altered genetic material or protein. While the

introduction of the new labelling regime will no doubt generate additional costs for both industry, retailers and regulatory authorities, the evidence here is that the more robust and comprehensive labelling regime will deliver significant benefits for consumers."

7. Conclusions

In this paper the nature of the US-EU trade dispute regarding GMOs in food has been outlined. The origins of the dispute may be located in the differing bases for regulation which the two parties established as the biotechnology industry developed. In the US the desire to neither stigmatise nor unnecessarily impede the biotechnology industry led to a product-based approach to regulation. In the EU, partly as a result of being comprised of member states with differing national laws regarding human health and the environment, a process-based or horizontal approach to GMO regulation developed.

One of the first major EU Directives on GMO regulation permitted national states to restrict approved varieties of GM crops if they had 'justifiable reasons' because of risks to human health and the environment. In 1997 and 1998 a series of member states blocked EU-approved GM varieties leading to the 1998 *de facto* moratorium on GM crops in the EU.

The US repeatedly argued that this obstruction of approved varieties and non-approval of new GM varieties amounted to an illegal restraint on trade. Having not made what they considered as meaningful progress on this issue the US took the position to the WTO and in August 2003 a Dispute Panel was formed to address the issue.

The EU reiterated over a long period of time that the moratorium could not be lifted until the system for regulating the release, traceability and labelling of GMOs in food had been updated. In the absence of such a system, it was argued, consumer confidence regarding GM food could not be restored.

The new GMO traceability and labelling regime of the EU represents a rather fundamental shift in that the presence of altered genetic material is no longer the trigger for labelling. Ingredients derived from GM crops, but free of altered DNA or protein, will now require labelling. The shift away from only considering the product but also the process by which a food was produced is a shift that many sceptical of GM food will welcome.

The new system has been regarded with antipathy by US government and industry officials. They argue that it is unscientific and contrary to free trade. Whilst the new system may prove sufficient to lift EU's moratorium on GM food, it may well be the case that it leads to a new international trade dispute since, in the view of the US NFPA and others, the EU has created "yet another trade barrier that will keep many U.S. food products out of the European market".

The disputes at the WTO and between different constituencies within the EU regarding GMO production and trade have raised issues regarding risk, science and the basis on which one may restrict trade. Specifically, the role of ethics and values in the assessment and management of risk, the scientific basis upon which to assess GM varieties and the legitimacy or otherwise of invoking the precautionary principle are all being contested at present.

The new labelling and traceability regime for GMOs in the EU has created an impetus for further debate about the nature of regulation. The new regulation 1829/2003 creates a wider set of

concerns than had previously existed in the GM regulatory regime (Scott, 2003). Previously the issues were human health and the environment and the functioning of the market to which have now been added "animal health and welfare, environment and consumer interests"

Given that the presence of altered genetic material is no longer the criterion for labelling, this opens up the debate as to why other products which are also part of the genetic modification production process do not require labelling. In particular the labelling regime has been extended to include not only products comprising or containing GMOs but also products produced from GMOs. Excluded are those food items produced *with* GMOs, such as food produced with the help of modified enzymes and, more significantly, food produced using GM feed, such as eggs, meat and milk.

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