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BIOTECHNOLOGY AND FOOD

The use of biotechnology in food production evokes media-induced images of 'Frankenstein' foods that pose potential threats to the environment and human health. However, while the scientific evidence to support this view may be limited the perception of risk from genetically modified foods (GM) is very real. This paper considers the use of biotechnology in food production and describes the regulatory processes for commercialisation of GM crops in the EU. It also describes the concepts of the 'Precautionary Principle' and 'Substantive Equivalence' in the regulatory process.

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1. INTRODUCTION

2003 saw the 50th anniversary of the discovery of the double helix structure of DNA, often popularly referred to as the 'blueprint' for life. The subsequent years since its discovery have seen huge developments in the field of molecular biology such as the mapping of the human genetic sequence[i], cloning of mammals[ii], and the manipulation of plant genes to develop herbicide and insecticide-resistant crops[iii]. Accompanying the scientific advances have been debates on the ethics of gene technology, implications for trade, and the impacts on human health and the environment to name but a few. In addition, and importantly, it has necessitated the development of new regulations that provide the framework for governing food safety issues in relation to genetically modified food (GM).

The debate on the pros and cons of GM food tends to be polarised. One side would argue that the risks – to human health and the environment – are unknown yet potentially serious and therefore outweigh any potential benefits; while the other would say that the risk is exaggerated and the benefits have yet to be exploited. However biotechnology is simply that, another technology which may present both benefits *and* risks to society. It could be argued that one aspect of biotechnology, the genetic modification of crops has, to date, focussed on the benefits to the farmer and on improving agricultural economics; and possibly embedded at least partial ownership of the food chain within multi-national corporations. It is not clear however what the benefits to *wider* society may be nor is it clear whether these would outweigh the risks from introducing novel crops to the environment or 'modified' food products to the market. Given that there is no such thing as a risk-free food this last issue is key i.e. is there sufficient benefit – or potential benefit – to the consumer from these foods, compared to conventional foods, to run the risk of damage to the environment and/or to human health?

This paper considers the issues relating to biotechnology and food production, specifically the cultivation of crops, and attempts to rationally describe the pros and cons of such technology. It also considers how GM food is regulated and describes the role of such concepts as the 'Precautionary Principle' and 'Substantial Equivalence' in the regulatory process.

2. PERCEIVED RISKS FROM GM FOOD

The impact of genetic modification on human health and on the environment has become the two main areas of concern among the general public throughout Europe on this issue. Within the UK a national debate[iv] confirmed that people are generally uneasy about GM foods for broad social and political reasons, and more direct issues such as impacts on the environment and food safety concerns[1]. This generally refers to a belief that there are risks to the environment and to human health that are as yet unknown but might include potential *direct* impacts e.g. the introduction of allergenic material to previously non-allergenic products or crops (allergenicity); and *indirect* effects such as the increased development of antibiotic resistance (gene transfer). In relation to impact on the environment some are concerned about the possible detrimental effects if GM crops are widely cultivated[2]. Broadly speaking these effects can be categorized into two major possible risks from GM crops[3]:

[i] The Human Genome Project
[ii] Dolly the sheep in the UK.
[iii] For example, Bt cotton.
[iv] GM Nation? The Findings of the Public Debate

- the transference of genes from the GM crop into other species – cross pollination – conferring to them the traits of the modified variety or increased invasiveness of the plant itself;

- negative effects on the arable ecosystem and its associated wildlife.

Contamination by modified varieties either by cross-pollination or by mixing of crops post-harvest could also *theoretically* have an indirect effect on food safety resulting in possible health risks to humans and/or animals from eating genetically modified food/feed from these crops. However, it is simply not possible to make general statements about the safety of *all* GM foods given that there is a range of GM organisms that contain different genes inserted in different ways. The safety of each therefore should be assessed on a case-by-case basis.

2.1 EXAMPLES OF GM SAFETY ISSUES

2.1.1 BRAZIL NUTS AND SOYBEANS

Potential allergenicity is one of the key concerns relating to GM safety. Allergens are most commonly proteins or segments of proteins. There is concern that insertion of genes into crops will produce a protein, whose aim will be to confer a particular trait e.g. herbicide resistance, but might also induce an allergic reaction in humans if ingested. Perhaps the most notable case of allergenic transfer relates to the transfer of Brazil nut genes to soybeans intended for cattle consumption. The aim was to increase the level of sulphur-containing amino acids in soybeans by using the gene(s) from Brazil nuts and therefore improve the quality and value of the feed. However, laboratory experiments showed that the protein subsequently produced was allergenic to humans. Despite the fact that the product was never intended for human consumption it was never brought to market[4].

2.1.2 FIELD PEAS

Researchers at Australia's Commonwealth Scientific and Industrial Research Organisation (CSIRO) who were working to develop a GM field pea that would be resistant to the pea weevil discontinued the research after they showed that the GM peas caused an immune response in mice. The pea weevils live on starch in the pea seed and they need a specific enzyme to digest the starch. The scientists introduced a gene from beans which inhibits production of this enzyme. Therefore the pea weevils are unable to digest the protein. However, while this inhibitor is also present in beans, which have been consumed for years by humans, it appears to undergo unexpected changes when it is made in the pea. It appears these changes are responsible for the allergenic response in mice[5]. On the basis of these results, and following discussion on the potential implications for ingestion of these GM peas initiating an immune response in humans, the development of the GM pea was discontinued.

This last example highlights what is a key issue in the approach to evaluating the safety of GM crops; that is, that scientists assume that a protein produced in a GM plant will behave exactly as the same protein produced naturally in another plant. However, it has also been argued that this research highlights the robustness of the case-by-case approach to safety evaluation of GM crops[6].

2.2 Crop Contamination

The majority of GM crops have been genetically modified for one or both of two traits:

- herbicide tolerance (63% of GM crops planted in 2008); or
- insect resistance (15%)[7].

However this has given rise to concerns about conventional crops being contaminated by GM crops. The GM Contamination Register Report 2007 by GeneWatch UK and GreenPeace International stated that there were 39 new instances of crop contamination over that year[8]. The contamination of conventional crops could pose a serious threat to the integrity of the food supply. The contamination of a crop could therefore be either cross-pollination which, as noted above, could potentially result in GM traits being transferred to non-GM varieties that are grown commercially or contamination post-harvest.

Hails (2000)[9] considered three categories of GM crops where inserted genes conferred resistance:

- Herbicide;
- Insect; and
- Viral.

Arguing on the basis of ecological fitness and selective advantage she proposed that on a risk assessment scale[v], herbicide-tolerance was the lowest risk while virus-resistance was the greatest risk. This is based on the observation that traits such as insect and virus resistance are more likely to confer a selective advantage in a wild population. Large-scale release of genetically modified herbicide tolerant (GMHT) oilseed rape also showed no increased invasiveness over conventional types[10] and, indeed that these GM herbicide resistant types do not survive for long outside cultivation[11]. The risks of a range of GM crops have been studied since the PROSAMO project (Planned Release of Selected and Modified Organisms) was established in the late 1980s. The results of this project indicate that the GM plants studied (GMHT oilseed rape, maize and sugar beet and insect resistant potato) were neither more invasive nor more persistent in semi-natural habitats.

A study commissioned by English Nature concluded that 'gene stacking'[vi] could occur in the UK if plants containing different herbicide tolerance genes were planted commercially[12]. However, ACRE (Advisory Committee on Releases to the Environment) indicated that this was unlikely to result in 'super-weeds' but was a management issue in relation to planting and control of such crops[13]. This last point is in agreement with the conclusions of the researchers who conducted the UK field studies, described below. There are however examples of glyphosate[vii]-resistant weeds. A glyphosate-resistant Johnsongrass (*Sorghum halepense* (L.)) appeared in Argentina in 2001 and was identified in at least 10,000 ha at that time[14]. It is now estimated that at least 120,000 ha are affected[15]. A study has confirmed that the Johnsongrass survival in glyphosate-treated soybean field in northern Argentina is due to evolved glyphosate resistance[16]. Glyphosate resistance would mean more

[v] Risk to the environment.
[vi] This means that multiple traits are conferred to a plant e.g. resistance to a number of different herbicides.
[vii] This is a broad-spectrum herbicide produced by Monsanto that has become the world's largest selling crop-protection product.

glyphosate and/or additional chemicals would have to be used to reduce the spread of Johnsongrass.
Crop contamination could also refer to contamination *post*-harvest. Regulation (EC) No. 1829/2003 on Genetically Modified Food and Feed states that genetically modified food and feed cannot be placed on the EU market until it undergoes a safety assessment and is then authorised under the Regulation. Unauthorised GM material is not allowed *in any amounts* in food or feed in Europe.

In 2006 rice products from China were found to have unauthorised genetically modified Bt63 rice. Despite subsequent reassurances from China about its rice and rice products being free of Bt63 it continued to be detected over the next two years. Emergency measures were introduced in April of 2008 which required imports of specified products to be *certified* as being free of the unauthorised genetically modified material. Such products would only be placed on the EU market if either

"they are accompanied by an original analytical report issued by an official or accredited laboratory which demonstrates that the product does not contain, consist of, or is not produced from the genetically modified organism 'Bt63'

Or

satisfactory results of analysis are received by the food authority at the point of entry to the European Union (EU), following sampling carried out by or under the supervision of that authority"[17].

In January 2009 Germany notified the Commission of a Border Rejection of unauthorised genetically modified (Bt63) rice vermicelli from China[18] and detected it again in rice macaroni in February.

2.3 Environmental Impact

The UK government commissioned an independent group of researchers to carry out the largest field trials of GM crops in the world. This was a four year programme in the UK aimed at studying the effects that the management practices associated with Genetically Modified Herbicide Tolerant (GMHT) crops might have on farmland wildlife, when compared with weed control used with non-GM crops[19]. The crops investigated were winter-sown oilseed rape, spring-sown oilseed rape, beet and maize.

The results showed that there were differences in the wildlife between GMHT and conventional spring rape, beet and maize. The report indicated that growing conventional beet and spring rape was better for many groups of insects than the GMHT beet and spring rape; for example, there were greater numbers of butterflies and bees around conventional crops. There were also a greater number of weeds which are important for shelter and a greater number of weed seeds which provide a source of food for birds. GMHT winter rape showed fewer bees and butterflies but no overall difference in the number of other insects, slugs and spiders. However, the converse was true for maize which saw greater numbers of butterflies and bees and more weed seeds at certain times of the year.

The important point that the researchers made themselves was that the differences did not arise because of genetic modification *per se* but rather because of the wider options they provide farmers in terms of weed control i.e. they can use different herbicides and apply them differently[20]. In addition it is likely that other factors may

influence the impact of GM crops on wildlife biodiversity such as how the land is cultivated, management of crop rotation and the area and distribution of the land farmed.

3. POTENTIAL BENEFITS OF GM

Ultimately, the potential benefits of GM crops can only be compared with conventional crops and whether these benefits outweigh the potential risks from GM. For example, does GM actually contribute to increased yields of crops and reduced use of pesticides? Does it contribute to reduction in hunger? Are they significantly better to warrant a more relaxed approach to regulation such as that in the USA and Canada?

The advocates for GM would point to the benefits that the technology brings to food production. GM technology does have the potential to make food more nutritious and therefore contribute to improved health status. The development of Golden Rice for example holds out the possibility of helping to prevent blindness in the developing world resulting from vitamin A deficiency[21]. This GM rice produces beta-carotene which is absent from polished rice. Consumption of this therefore offers the potential to address vitamin A deficiency. However, even this apparent positive aspect of GM is not without its detractors. Some varieties of unpolished rice contain beta-carotene in the outer layer of the seed but this is subsequently removed by milling to prolong its storage time prior to export[22]. This suggests that due to trade and economic pressures to satisfy *western* tastes the unpolished rice, produced by indigenous producers, that does contain beta-carotene is being replaced by a GM polished rice with beta-carotene. There are also considerable concerns over the apparently limited availability of this rice to those who need it most[23], relating to the seventy or so patents that are applicable to this product[24].

A recent venture between Monsanto and *Dow AgroSciences* (DAS) has produced a corn variety with eight different herbicide-tolerance and insect-resistant transgenic traits. Known as Smartstax, Monsanto claims that the corn is designed to give *"protection against a broader spectrum of above- and below-ground insects and the most comprehensive protection against established and emerging secondary pests".*[25] Japan, the world's leading corn importer, has already given full import and feed use approval for the corn[26].

The obvious potential benefits of such a crop are direct i.e. the crops themselves are insect-resistant and do not therefore require pesticides; and indirect – they allow farmers to modify their farm management practices such as their use of pesticides. This could mean a reduction in the volume of pesticide use. It has been estimated that the planted biotechnology-derived crops in 2006 resulted in a reduction in pesticide use of 110.06 million pounds[viii] in the USA[27]. The International Service for the Acquisition of Agri-biotech Applications (ISAAA) states that since 1996 there has been a reduction in pesticide use by farmers planting biotech crops by 6.3% or over 172.5 million kg[28]. Such figures are often questioned by GM opponents who cite such groups as ISAAA as being little more than fronts for the GM industry and. as noted in 2.2 above, the development of glyphosate-resistant crops could actually result in an increase in herbicide use.

[viii] Refers to weight

It is also the case that there are no GM drought-resistant or salt-tolerant crops on the market therefore any claims in respect of alleviating world hunger through planting of crops where it was not previously possible are still to be developed.

4. REGULATION OF GM FOOD

4.1 GLOBAL

The first generation of GMOs was developed for the international commodity market for feed, oil and processed foods and as a result both the market conditions of these products and the economic interests of the farm sector can be seen to influence the current policy frameworks internationally. Countries such as the USA and Canada, which export maize, soybean and canola, have developed a product-specific equivalence principle that is more permissive than Europe. In contrast the EU, which is the largest importer of soybean, have a much more cautious regulatory framework implementing a process-specific, precautionary principle[29]. The largest importer of canola and maize, Japan, initially used a framework similar to that of the USA and Canada however in 2001, for foods derived from crops developed using DNA recombination technology, it started a process-specific mandatory labelling system[30,ix]. Agricultural exporting countries such as Brazil, Chile, Indonesia and Thailand have also implemented mandatory labelling of GMOs[31].

Australia and New Zealand, under Standard 1.5.2 of the Australia New Zealand Food Standards Code – Food Produced Using Gene Technology – prohibit the sale and use of food produced using gene technology unless it has specifically been permitted[x]. Labelling is required if novel DNA or protein is present in the final food, and applies also to processing aids and food additives. Moreover it was concluded that lack of labelling would obstruct the consumer's right to act as they intend but that labelling would impede those GM products that offer little benefit in comparison to their conventional counterparts[32]. On the other hand the Food and Drug Administration (FDA) of the USA does not require foods produced from GM crops to be specifically labelled.

Food Standards Australia New Zealand (FSANZ) uses one of the most open and transparent assessment processes in the world. Two rounds of public consultation are undertaken during the assessment of applications and all data submitted (except commercial-in-confidence data) are available to the public[33].

Due to the increasing public concern about the impact of GM foods on human health and the environment it has become increasingly difficult to gain approval for market placement of GMOs in certain jurisdictions, especially the EU and Japan[34].

4.2 EUROPE

Regulation (EC) 178/2002[35] (EC, 2002c) lays down the principles of food[xi] law and procedures in food safety. This includes the role of the European Food Safety

[ix] Under the product-specific regulatory framework, a GM product is assessed within existing frameworks for safety and nutritional fitness, as long as the product is *substantially equivalent* to the conventional one.

[x] Gene technology is limited to recombinant DNA techniques, which alter the heritable genetic material of living cells or organisms.

[xi] In the general food law 'food' means any substance or product, whether processed, partially processed or unprocessed, intended to be or reasonably expected to be ingested by humans. 'Feed'

Authority - EFSA. EFSA is the key organisation regarding food and feed safety in Europe and its role is to assess and communicate on all risks associated with the food chain. A large part of its work therefore is to provide scientific advice to the EU Commission, the European Parliament and EU Member States.

Its' scientific work is carried out by a Scientific Committee and 11 panels comprised of experts in scientific risk assessment for specific areas including one on Genetically Modified Organisms (GMOs). The GMO Panel deals with genetically modified organisms and genetically modified food and feed. Its sole purpose is assessing risk. Its' assessments, formally known as opinions, are probably the most scrutinised of all the EFSA panels. It cannot take into consideration ethical issues or potential benefit of GMOs to society. Its' function is also separated from the risk managers and regulators and it has openness and transparency, and independence as two of its four key values[xii]. The members of these panels are also independent from EFSA, and must declare their interests. The GMO Panel for instance has 21 independent scientific members who are replaced every few years.

However, contrary to a widely held belief, EFSA does *not* have the authority to approve GMOs. Rather, a positive risk assessment of a GM crop is a prerequisite to *entering* the approval process. Once EFSA issues its' opinion on a GM product it is over to the risk managers – the Commission and relevant Committee – to reach a decision which is based, not just on EFSA's scientific assessment of risk to public health and to the environment from the product, but also takes into consideration wider social, (political) and ethical issues. Therefore on the basis of the EFSA opinion the Commission drafts a proposal for granting or refusing the authorisation. This must be approved by the section on GM food and feed of the Standing Committee on the Food Chain and Animal Health (SCFCAH). Also, within 30 days the public may make comments on EFSA's opinion which the Commission will also take into consideration when drawing up its paper for submission to SCFCAH.

Every GM variety is assessed by the Panel on a case-by-case basis. It also does so from scratch i.e. because a particular crop may be currently cultivated in another jurisdiction that does not mean the Panel will automatically give a positive risk assessment in respect of its cultivation in Europe. It will consider *all* the scientific data available on the crop and reach an assessment in due course. Also, even a positive risk assessment from EFSA does not mean that the Commission will necessarily support the cultivation of a crop or, as been seen in recent years, that individual Member States will abide by a positive opinion from the Commission. For example on the 14th April 2009 Germany became the latest in a line of European countries[xiii] to ban the cultivation MON 810 maize, a GM crop produced by Monsanto.
Member States were able to effectively ban the cultivation of MON 810 in their jurisdictions by invoking Article 16 (safeguard clause) of Directive 90/220/EEC on the deliberate release of genetically modified organisms (GMOs) into the environment.

What makes these bans all the more pertinent is that this GM maize has been authorised for commercial use across the EU since 1998. This highlights the general divergence between scientific opinion and political decision-making in Europe on issues related to biotechnology and food production and reflects the polarised nature of the debate across wider society on GM. The European Commission tried to force

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means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals.

[xii] The other two are Excellence in Science and Responsiveness.

[xiii] France, Austria, Greece, Hungary and Luxembourg are the other EU countries.

Hungary and Austria to allow the cultivation of GM maize on their territory but this was rejected by EU Environment Ministers[36].

EFSA recently completed a public consultation on the risk assessment of genetically modified plants and derived food and feed. By the close of the consultation period EFSA had received 357 submissions from 19 parties (NGOs, industry organisations, national assessment bodies and competent authorities)[37]. This document forms the basis for the establishment of a legal framework for EFSA's GMO assessment by the European Commission and Member States. EFSA has come under criticism for its risk assessment. Austria, for example, has been critical of the lack of transparency in how precaution/uncertainty has been dealt with in EFSA opinions as well as a range of other issues such as a lack of direct toxicity testing, and the use of indirect evidence to assess allergenicity[38].

Just recently 12 Member States wrote to the EFSA director about Monsanto's GM maize MON 810 to ensure that EFSA's reassessment of the maize covers all the concerns raised by each of the 12[39]. A reassessment is necessary in order that the licence is renewed for cultivation of MON 810 and in a recent decision by the EFSA GMO Panel on this reassessment it was concluded that MON 810 is *"as safe as its non-genetically modified counterpart with respect to potential effects on human and animal health or the environment"* and that it is *"unlikely to have any adverse effect on human or animal health or on the environment in the context of its intended uses"*[40]. This leaves an obvious gap between the decision of some national governments and the key risk assessment agency, in respect of food, in Europe.

On the 4th December 2008 the Council of European Environment Ministers agreed that long-term environmental risk assessment of GMOs should be improved and Member States be allowed to establish GM-free zones. The Council Conclusions on Genetically Modified Organisms (GMOs) also included the following[41]:

- It welcomed the commitment by the European Commission for a mandate to the EFSA to develop and update its guidelines on the environmental risk assessment of GMOs, in particular the long term environmental effects of pesticide-producing and herbicide-resistant GM plants;
- It invited Members States to collect and exchange relevant information on the socio-economic benefits and risks and agronomic sustainability of placing GMOs on the market by 2010;
- It emphasised the need to improve the use of Member State experts in the EFSA's safety evaluation of GMOs;
- fix Community thresholds for the presence of GMOs in conventional seeds;
- protect, on a case-by-case basis, sensitive and protected areas by establishing GMO-free zones.

4.2.1 THE PRECAUTIONARY PRINCIPLE

The publication of scientific articles on the toxicity of GM food is scarce[42]. However, the anti-GMO sector would argue that an absence of evidence of toxicity is not evidence of absence of toxicity. Rather the argument is made that long term studies are required to provide this evidence and that, in the absence of it, the Precautionary Principle (PP) should be adhered to. The PP is a key element in decision-making

concerning environmental protection and management and was first espoused at the Earth Summit in Rio in 1992[43] as principle 15 of the Declaration on Environment and Development:

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

The Precautionary Principle is also incorporated into a supplementary agreement to the Convention on Biological Diversity which entered into force on 29th December 1993. The Convention itself has 3 main objectives:

- To conserve biological diversity
- To use biological diversity in a sustainable fashion
- To share the benefits of biological diversity fairly and equitably[44].

In 2000 the Conference of the Parties to the Convention on Biological Diversity (the Convention) adopted a supplementary agreement to the Convention. Despite strong opposition from the USA and other exporting countries (Canada, Argentina), the precautionary principle was incorporated into the text of the Biosafety Protocol of the Convention based upon affirmations from delegates of environmental agencies as opposed to trade ministers of the EU and developing countries[45]. This was the result of a dispute over the restriction outlined in the Agreement on Sanitary and Phytosanitary Measures (SPS) within the World Trade Organisation (WTO), which permits the restriction by nations on imports in the name of health or environmental protection, based on scientific evidence. In relation to the Biosafety Protocol, most developing countries desired a more cautious approach than that of the USA[46]. This agreement is known as the Cartagena Protocol on Biosafety. Although the term biosafety is not defined in the Protocol, in article 4 it states that

This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

In the preamble the Parties to the Protocol also reaffirm the *precautionary* approach as contained in article 15 of the Rio Declaration on Environment and Development. The Protocol also acknowledges the potential risks posed by living modified organisms[xiv] to biological diversity and seeks to protect it from these risks[47].

4.2.2 SUBSTANTIAL EQUIVALENCE

The central tenet of the safety assessment procedure for GM foods is '*substantial equivalence'.* This term was first used in 1993 in a report of the OECD Group of National Experts on Safety in Biotechnology[48]. The report stated that:

The concept of substantial equivalence embodies the idea that existing organisms used as foods, or as a source of food, can be used as the basis for comparison when

[xiv] This means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

assessing the safety of human consumption of a food or food component that has been modified or is new[49].

A compositional analysis of key components, such as nutrients and natural toxicants, is the basis of assessment of substantial equivalence as well as a phenotypic[xv] comparison[50]. The essential premise of this approach is that where a novel food or a novel food component is found to be substantially equivalent – as defined above – to an existing non-GM food then it can be treated in the same way, in terms of food safety, as the conventional food. However, questions have been raised as to the adequacy of this approach to provide evidence that GM foods are in fact safe[51] with the suggestion that the principle of substantial equivalence should be replaced by a programme of safety and toxicological testing similar to that for pharmaceuticals, food additives or pesticides[52]. Also, as noted in the example given in 2.1.2 above although the pea could be defined as being substantially equivalent to a conventional pea the insertion of the new genetic material resulted in the development of a pea with potentially allergenic properties.

A joint expert consultation organised by the FAO and WHO in 1996 endorsed this principle as an important component of the safety assessment process[53]. However, a later report by the OECD recommended that safety assessments of GM foods should be made more explicit and objective and that differences in the application of the principle of substantial equivalence, for example within member states of the EU, needs to be resolved[54]. The Royal Society has recommended that in order to pursue these objectives that *"research should be undertaken to develop modern profiling techniques and to define 'normal' compositions of conventional plants"[55].*

5. CONCLUSION

It is evident that about half the Member States of the European Union have concerns about the procedure used by EFSA for the assessment of the risk posed by GM foods. However, this in itself is not opposition to GM technology. The European consumer – and regulators – having experienced several food scares including BSE and dioxin contamination is likely to be more cautious about developments in food production than those say in the United States. Public attitudes to biotechnology also vary within and between countries. A survey of European attitudes to GM technology found that while 46% of respondents from the Czech Republic believed that GM should be encouraged only 21% of Germans felt the same way[56].

Currently, there is much controversy over the actual benefits of GM crops, the large majority of which are modified to be either herbicide- and/or pesticide-resistant. There is some debate over whether these GM crops actually produce greater yields. It is the case that the use of these crops may reduce yield *losses* but critics would say that this is not the same as increasing the yield of a crop *per se*. It is correct to say that no GM variety available today has been modified so as to *specifically* increase yield.

It is clear that the development of GM crops for commercialisation is only going to increase. The Institute for Prospective Technological Studies (IPTS), one of seven institutes of the Joint Research Centre (JRC) of the European Commission, has forecast that there will be over 120 GM "events[xvi]" by 2015[57]. This includes multiple

[xv] An organism's phenotype is a result of its genetic make-up and environmental influences.

[xvi] A term used to describe a trait conveyed by genetic modification

"events" ascribed to individual crops e.g. currently for soybeans only 1 GM event is available but by 2015 this is expected to increase to 17 different events. This will put considerable pressure on regulatory systems and potentially contribute to trade disputes due to asynchronous approval of such crops i.e. approval at different times in different countries. This potential creates an even greater problem between the countries of the European Union who have different positions on GM crops; and between the EU and third countries, such as the USA, Canada and Argentina who may want to import crops into the EU for food and feed.

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