Genetically modified food controversies

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The **genetically modified foods controversy** is a dispute over the use of food and other goods derived from genetically modified crops instead of from conventional crops, and other uses of genetic engineering in food production. The dispute involves consumers, biotechnology companies, governmental regulators, non-governmental organizations, and scientists. The key areas of controversy related to GMO food are: whether GM food should be labeled, the role of government regulators, the effect of GM crops on health and the environment, the effect on pesticide resistance, the impact of GM crops for farmers, and the role of GM crops in feeding the world population.

The starting point for assessing the safety of all GM food is to evaluate its substantial equivalence to the non-modified version. Further testing is then done on a case-by-case basis. Despite concerns over potential toxicity, allergenicity or gene transfer to humans from GM food, there is broad scientific consensus that food on the market derived from GM crops poses no greater risk than conventional food. There is no evidence to support the idea that the consumption of approved GM food has a detrimental effect on human health. Although labeling of genetically modified organism (GMO) products in the marketplace is required in many countries, it is not required in the United States and no distinction between GMO and non-GMO foods is recognized. In the United States, the Food and Drug Administration does not require labeling of GMO products in the marketplace, nor does it recognize a distinction between GMO and non-GMO foods.

Advocacy groups such as Greenpeace, The Non-GMO Project and Organic Consumers Association say that risks of GM food have not been adequately identified and managed, and have questioned the objectivity of regulatory authorities. Opponents say that food derived from GMOs may be unsafe and propose it be banned, or at least labeled. They have expressed concerns about the objectivity of regulators and rigor of the regulatory process, about contamination of the non-GM food supply, about effects of GMOs on the environment and nature, and about the consolidation of control of the food supply in companies that make and sell GMOs.

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Public perception

Social science surveys have documented that individuals are more risk averse about food than institutions. There is widespread concern within the public about the risks of biotechnology, a desire for more information about the risks themselves and a desire for choice in being exposed to risk. [8][8][9] There is also a widespread sense that social and technological change is speeding up and people feel powerless to affect this change; diffuse anxiety driven by this context becomes focused when it is food that is being changed. [8]

Religious groups have raised concerns over whether genetically modified food will remain kosher or halal. In 2001 no GM foods have been designated as unacceptable by Orthodox Rabbis or Muslim leaders. [10] However, there are Jewish groups that dispute this designation. [11]

Some groups or individuals see the generation and use of GMO as intolerable meddling with biological states or processes that have naturally evolved over long periods of time, while others are concerned about the limitations of modern science to fully comprehend all of the potential negative ramifications of genetic manipulation. Other people see genetic engineering as a continuation in the role humanity has occupied for thousands of years in selective breeding.

There is a concerted and organised effort from many environmental and other advocacy groups to impose moratoriums or ban GMO products from being commercialised. International organisations like Greenpeace $^{[14]}$ and Friends of the Earth $^{[15]}$ include genetic engineering as part of their environmental and political concerns. Other groups like GMWatch and The Institute of Science in Society concentrate mostly or solely on opposing genetically modified crops. $^{[16][17]}$

Reviews and polls

In 2006, the Pew Initiative on Food and Biotechnology made public a review of U.S. survey results from 2001-2006. [18] The review showed that Americans' knowledge of genetically modified foods and animals was low through the period. During this period there were protests against Calgene's Flavr Savr transgenic tomato that described the GM tomato as being made with fish genes, confusing it with DNA Plant Technology's Fish tomato experimental transgenic organism, which was never commercialized. [19][20]

A 2010 Deloitte survey found that 34% of U.S. consumers were very or extremely concerned about GM food, a 3% reduction from 2008. [21] The same survey found a strong gender difference in opinion: 10% of men were extremely concerned, compared with 16% of women, and 16% of women were unconcerned, compared with 27% of men. A 2009 review article of European consumer polls concluded that opposition to GMOs in Europe has been gradually decreasing. [22] Approximately half of European consumers accepted gene technology, particularly when benefits for consumers and for the environment could be linked to GMO products. 80% of respondents did not cite the application of GMOs in agriculture as a significant environmental problem. Many consumers seem unafraid of health risks from GMO products and most European consumers did not actively avoid GMO products while shopping. The 2010 "Eurobarometer" survey, [23] which assesses public attitudes about biotech and the life sciences in Europe, found that "cisgenics, GM crops produced by adding only genes from the same species or from plants that are crossable by conventional breeding," evokes a different reaction than transgenic methods, where "genes are taken from other species or bacteria that are taxonomically very different from the gene recipient and transferred into plants." [24] A 2007 survey by the Food Standards Australia and New Zealand found that in Australia where labeling is mandatory, [25] 27% of Australians looked at the label to see if it contained GM material when purchasing a grocery product for the first time. [26]

A 2013 poll by the New York Times showed that 93% of Americans wanted GMO labeling. [27]

Protests

In 1983, a biotech company, Advanced Genetic Sciences (AGS) applied for U.S. government authorization to perform field tests with the ice-minus strain of P. syringae, but environmental groups and protestors delayed the field tests for four years with legal challenges. [28] In 1987, the ice-minus strain of P. syringae became the first genetically modified organism (GMO) to be released into the environment [29] when a strawberry field in California was sprayed with the ice-minus strain of P. syringae. The results were promising, showing lowered frost damage to the treated plants. Dr. Lindow also conducted an experiment on a crop of potato seedlings sprayed with ice-minus P. syringae. He was successful in protecting the potato crop from frost damage with a strain of ice-minus P. syringae. [30] Both test fields were attacked by activist groups the night before the tests occurred.



Anti-GMO and Anti-Monsanto protests in Washington, D.C.

Concern about gene flow drives some protesters. In May 2012, a group called "Take the Flour Back" led by Gerald Miles protested against plans by a group from Rothamsted Experimental Station, based in Harpenden, Hertfordshire, England, to stage an experimental trial to use genetically modified wheat to repel aphids. [31] The researchers, led by John Pickett, wrote a letter to the group "Take the Flour Back" in early May 2012, asking them to call off their protest, aimed for 27 May 2012. [32] One of the members of Take the Flour Back, Lucy Harrap, said that the group was concerned about spread of the crops into nature, and cited examples of outcomes in the United States and Canada. [33] Rothamsted Research and Sense About Science ran question and answer sessions with scientists about issues of contamination. [34]

Within the UK and many other European countries many trial crops have been destroyed by protesters: for public research experiments alone, 80 acts of destruction have been compiled. [35]

On May 25, 2013, the March Against Monsanto movement held rallies in protest against companies like Monsanto and the genetically modified food they produce without labeling it as such; the organizers said that rallies were planned in 52 countries and 436 cities. [36] According to the Associated Press, rallies took place in Buenos Aires and other cities in Argentina, and in Portland, Oregon police estimate 6,000 protesters attended. [7] According to the LA Times, hundreds marched in Los Angeles. [37] According to CTV, hundreds of people marched in Kitchener, Ontario. [38] Estimates of the number of participants ranged from 200,000 [38] to two million people. [39][40]

Scientific publishing

Scientific publishing on the safety and effects of GMOs intended for public is controversial because of the public attention on issues around GMOs and the possible policy implications of scientific findings. [41] One of the first incidents occurred in 1999, when *Nature* published a paper on potential toxic effects of Bt maize in butterflies. The paper produced a public uproar and demonstrations against Bt maize; however by 2001 several follow-up studies had proven that "the most common types of Bt maize pollen are not toxic to monarch larvae in concentrations the insects would encounter in the fields." [41] After that event, "some scientists were dismayed that a single paper with preliminary data gave so much ammunition to anti-GMO activists and caused an expensive diversion of resources to calm the scare. [41] This has led such scientists to patrol the scientific literature and react strongly, both publicly and privately, to discredit conclusions they view as flawed, in order to prevent flawed conclusions from again causing public outcry and regulatory action. [41] A 2013 Scientific American article noted that GM-supportive scientists are often overly dismissive in their rejections of counterclaims and concerns about the scientific consensus that currently marketed food from GM crops are safe. [42]

The value of current independent studies is considered by some to be problematic because, due to restrictive end-user agreements, independent researchers sometimes cannot obtain GM plants for study. Cornell University's Elson Shields, the spokesperson for a group of scientists who oppose this practice, submitted a statement to the United States Environmental Protection Agency protesting that "as a result of restrictive access, no truly independent research can be legally conducted on many critical questions regarding the technology". [43] Scientific American noted that several studies that were initially approved by seed companies were later blocked from publication when they returned "unflattering" results. While recognising that seed companies' intellectual property rights need to be protected, Scientific American calls the practice dangerous and has called for the restrictions on research in the end-user agreements to be lifted immediately and for the EPA to require, as a condition of approval, that independent researchers have unfettered access to GM products for testing. [44] In February 2009, the American Seed Trade Association agreed that they "would allow researchers greater freedom to study the effects of GM food crops." This agreement left many scientists optimistic about the future, but there is little optimism as to whether this agreement has the ability to "alter what has been a research environment rife with obstruction and suspicion."

Health

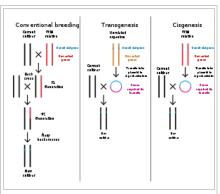
Governments worldwide assess and manage the risks associated with the release of genetically modified organisms and the marketing of genetically modified food. There are differences in the risk assessment of GM food, and therefore in the regulation of GMOs, between countries. Some of the most marked differences occur between the USA and Europe. Crops not intended for food use are generally not reviewed by authorities responsible for food safety. [46] Food derived from GMOs is not tested in humans before it is marketed as it is not a single chemical, nor is it intended to be ingested in specific doses and times, which makes it difficult to design meaningful clinical studies. [47] Regulators examine the genetic modification, its protein products, and any intended changes that those proteins make to the food. [48] Regulators also check to see whether the food derived from a GMO is "substantially equivalent" to its non-GM-derived counterpart, which provides a way to detect any negative non-intended consequences of the genetic engineering. [47] If the newly incorporated protein is not similar to that of other proteins found in food or if anomalies arise in the substantial equivalence comparison, further toxicological testing is required.[47]

There is broad scientific consensus that food on the market derived from GM crops pose no greater risk than conventional food. $^{[1][4][49][5][50][51]}$ No reports of ill effects have been documented in the human population from GM food. [4][5][6] In 2012, the American Association for the Advancement of Science stated "Foods containing ingredients from genetically modified (GM) crops pose no greater risk than the same foods made from crops modified by conventional plant breeding techniques."[1] The American Medical Association, the National Academies of Sciences and the Royal Society of Medicine have stated that no adverse health effects on the human population related to GM food have been reported and/or substantiated in peer-reviewed literature to date. [4][5][6] A 2004 report by Working Group 1 of the ENTRANSFOOD project, a group of scientists funded by the European Commission to identify prerequisites for introducing agricultural biotechnology products in a way that is largely acceptable to European society, [52] concluded that "the combination of existing test methods provides a sound test-regime to assess the safety of GM crops." [53] In 2010, the European Commission Directorate-General for Research and Innovation reported that "The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research, and involving more than 500

The World Health Organization. the American Medical Association, the U.S. National Academy of Sciences, the British Royal Society, and every other respected organization that has examined the evidence has come to the same conclusion: consuming foods containing ingredients derived from GM crops is no riskier than consuming the same foods containing ingredients from crop plants modified by conventional plant improvement techniques.

American Association for the Advancement of Science^[1]

independent research groups, is that biotechnology, and in particular GMOs, are not per se more risky than e.g. conventional plant breeding technologies."[50]



Comparison of conventional plant breeding with transgenic and cisgenic genetic modification.

genetically modified products.^[56]

There is a view from many of the scientists and regulators who support GM food that there is a continuing need for improved testing technologies and protocols to identify and manage risk better. [5] A consensus document released by the OECD in 2010 says that molecular characterisation by itself is not the best way to predict the safety of GM plants, but can focus the other safety assessment procedures. They also suggest that new technologies will develop that will aid in the "food, feed and environmental risk/safety assessments. " $^{[54]}$ While generally transgenic and cisgenic organisms are treated similarly when assessed, in 2012 the European Food Safety Authority (EFSA) Panel on Genetically Modified Organisms (GMO) has said that "novel hazards" could be associated with transgenic crops that will not be present in cisgenic ones. $^{[55]}$ Advocacy groups such as Greenpeace, World Wildlife Fund, Organic Consumers Association, and Center for Food Safety have concerns that potential risks to health and the environment relating to GM have not yet been adequately investigated. In Japan, the Consumers Union of Japan say that truly independent research in these areas is systematically blocked by the GM corporations which own the GM seeds and reference materials. Independence in research has been

studied by a 2011 analysis into conflicts of interest which found a significant correlation between author affiliation to industry and study outcome in scientific work published on health risks or nutritional assessment studies of

Substantial equivalence

The starting point for the safety assessment of genetically engineered food products by regulatory bodies is to assess if the food is "substantially equivalent" to their counterparts, which themselves are the products of genetic manipulation via traditional methods of cross-breeding and hybridization. [57] The application of substantial equivalence has been criticized. In 1999, Andrew Chesson of the University of Aberdeen warned that substantial

equivalence testing "could be flawed in some cases" and that some current safety tests could allow harmful substances to enter the human food chain. [58] The same year Erik Millstone, Eric Brunner and Sue Mayer argued in a commentary in *Nature* that the substantial equivalence standard was pseudo-scientific and was the product of politics and business lobbying—they claimed it was created primarily to reassure consumers and to aid biotechnology companies in avoiding the time and cost of more rigorous safety testing. They suggested that all GM foods should have extensive biological, toxicological and immunological tests and that the concept of substantial equivalence should be abandoned. [59] This commentary was criticized for providing a misleading presentation of history, [60] for distorting existing data and applying bad logic. [61] Retired scientist Harry Kuiper said it presented an oversimplified version of safety assessments and that equivalence testing involves more than chemical tests and may include toxicity testing. [62][63] An opinion piece in the *Los Angeles Times* in 2001 by Barbara Keler and Marc Lappe supported legislation in the US Congress to set aside the substantial equivalence standard and instead mandate that safety studies be performed. [64]

Kuiper examined this process further in a 2002 review published in the journal *Toxicology*. It stated that substantial equivalence does not measure risks, but instead identifies differences between existing products and new foods, which might pose dangers to health. If differences do exist, identifying these differences is a starting point for a full safety assessment, rather than an end point. If all concluded that "The concept of substantial equivalence is an adequate tool in order to identify safety issues related to genetically modified products that have a traditional counterpart". The review also noted difficulties in applying this standard in practice, including the fact that traditional foods contain many chemicals that have toxic or carcinogenic effects and that our existing diets therefore have not been proven to be safe. This lack of knowledge on unmodified food poses a problem, as GM foods may have differences in anti-nutrients and natural toxins that have never been identified in the original plant, raising the possibility that harmful changes could be missed. The possibility also exists that positive modifications may be missed. For example, corn damaged by insects often contains high levels of fumonisins, carcinogenic toxins made by fungi that are carried on the backs of insects and that grow in the wounds of the damaged corn. Studies show that most Bt corn has lower levels of fumonisins than conventional corn damaged by insects. Regulators are aware of these issues and workshops and consultations organized by the OECD, WHO, and FAO have worked to acquire data and develop standards for conventional foods, for use in assessing substantial equivalence. StallerI

A survey of publications describing comparisons between the intrinsic qualities of GM and non-GM reference crop lines (comparing genomes, proteomes, and metabolomes of the plants themselves, not the plants' effects on an organism eating them) indicates that transgenic modification of crops has less impact on gene expression or on protein and metabolite levels than the variability generated by conventional breeding. [68]

In a 2013 review published in the *Journal of Agricultural and Food Chemistry*, Rod A. Herman (Dow AgroSciences) and William D. Price (retired from FDA) argue that transgenesis is less disruptive of composition compared with traditional breeding techniques which routinely involve genetic mutations, deletions, insertions, and rearrangements. The FDA found all of the 148 transgenic events that they evaluated to be substantially equivalent to their conventional counterparts, as have the Japanese regulators for 189 submissions including combined-trait products. This equivalence is confirmed by over 80 peer-reviewed publications. Hence, the authors argue, compositional equivalence studies uniquely required for GM crops may no longer be justified on the basis of scientific uncertainty. [69]

Allergenicity

One of the well-known risks of genetically modifying a plant or animal that is used for food, is that the modification may introduce an allergen. Testing for such allergens is part of the R&D process when developing GMOs that are intended for food, and passing those tests is part of the regulatory requirements. Some environmental organizations, such as the European Green Party and Greenpeace, emphasize this risk.^[70] A 2005 review in the journal *Allergy* of the results from allergen testing of current GM foods stated that "no biotech proteins in foods have been documented to cause allergic reactions". Regulatory authorities require that new GM foods be tested for allergenicity before they are marketed. [72]

GMOs' proponents note that because of the safety testing requirements imposed on GM foods, the risk of introducing a plant variety with a new allergen or toxin using genetic modification is much smaller than using traditional breeding processes. Transgenic genetic engineering can have less impact on the expression of genomes or on protein and metabolite levels than conventional breeding or plant (non-directed) mutagenesis. [73] Toxicologists note that "conventional food is not risk-free; allergies occur with many known and even new conventional foods. For example, the kiwi fruit was introduced into the U.S. and the European markets in the 1960s with no known human allergies; however, today there are people allergic to this fruit."[74]

Genetic modification can also be used to remove allergens from foods, potentially reducing the risk of food allergies. $^{[75]}$ A hypo-allergenic strain of soybean was tested in 2003 and shown to lack the major allergen that is

found in the beans.^[76] A similar approach has been tried in ryegrass, which produces pollen that is a major cause of hay fever: here a fertile GM grass was produced that lacked the main pollen allergen, demonstrating that the production of hypoallergenic grass is also possible.^[77]

The development of GM products which have been found to cause allergic reactions have been halted by the companies developing them before they were brought to market. In the early 1990s, Pioneer Hi-Bred attempted to improve the nutrition content of soybeans intended for animal feed by adding a gene from the Brazil nut. Because they knew that people have allergies to nuts, Pioneer ran both in vitro tests for allergy, in which they tested whether serum from people with nut allergies reacted to the transgenic soy; they also did skin prick tests with protein from the transgenic soy. The tests showed that the transgenic soy was allergenic. Pioneer Hi-Bred therefore discontinued further development. In 2005, a pest-resistant field pea developed by the Australian Commonwealth Scientific and Industrial Research Organisation for use as a pasture crop was shown to cause an allergic reaction in mice. Work on this variety was immediately halted. These cases of products that failed safety testing have been viewed as evidence that genetic modification can produce unexpected and dangerous changes in foods, and as evidence that the current tests are effective at identifying safety problems before foods come on the market. In the early 1990s, Pioneer Hi-Bred attempted to improve the Brazil nut. Because

During the Starlink corn recalls in 2000, a variety of genetically modified maize containing the Bacillus thuringiensis (Bt) protein Cry9C, was found contaminating corn products in U.S. supermarkets and restaurants. It was also found in Japan and South Korea. [82]:20-21 Starlink corn had only been approved for animal feed as the Cry9C protein lasts longer in the digestive system than other Bt proteins raising concerns about its potential allergenicity. [83]:3 In 2000, Taco Bell-branded taco shells sold in supermarkets were found to contain Starlink, resulting in a recall of those products, and eventually led to over 300 other products being recalled. [84][85][86] Sales of StarLink seed were discontinued and the registration for the Starlink varieties was voluntarily withdrawn by Aventis in October 2000. [87] Aid sent by the UN and the US to Central African nations was also found to be contaminated with StarLink corn and the aid was rejected. The US corn supply has been monitored for Starlink Bt proteins since 2001 and no positive samples have been found since 2004. [88] In response, GeneWatch UK and Greenpeace International set up the GM Contamination Register in 2005. [89] During the recall, the US Centers for Disease Control evaluated reports of allergic reactions to StarLink corn, and determined that no allergic reactions to the corn had occurred. [90][91]

Horizontal gene transfer from plants to animals

One concern raised has been the possibility of a horizontal gene transfer from plants used as feed to animals that are used for food, or from plants as used as food, to humans.

The risk of horizontal gene transfer between plants and animals is very low and in most cases with GM crops this is expected to be lower than background rates. $^{[92]}$ Two studies on the possible effects of giving genetically modified feed to animals found no residues of recombinant DNA or novel proteins in any organ or tissue samples obtained from animals fed with GMP plants. $^{[93][94]}$ Studies have found DNA from the M13 virus, Green fluorescent protein, and Rubisco genes in the blood and tissue of animals, $^{[95][96]}$ and in 2012, a paper suggested that a specific microRNA from rice could be found at very low quantities in human and animal serum. $^{[97]}$ Studies from groups at Harvard $^{[98]}$ and Johns Hopkins, $^{[99]}$ however, found no or negligible transfer of plant microRNAs into the blood of humans or any of three model organisms.

Of particular concern is that the antibiotic resistance gene commonly used as a genetic marker in transgenic crops could be transferred to harmful bacteria, creating superbugs that are resistant to multiple antibiotics. [100][101]:250 In 2004 a study involving human volunteers was conducted to see if the transgene from GM soy would transfer to the bacteria that naturally lives in the human gut. As of 2012 it is the only human feeding study conducted with genetically modified food. The transgene was only detected in three volunteers, part of seven who had previously had their large intestines removed for medical reasons. As this gene transfer did not increase after the consumption of GM soy, the researchers concluded that gene transfer did not occur during the experiment. In volunteers with complete digestive tracts, the transgene did not survive passage through intact gastrointestinal tract. [102] The antibiotic genes used in genetic engineering are already found in many natural pathogens, [103] commonly used during animal husbandry [103] and not widely prescribed. [104]

Animal feeding studies

A 2012 review of more than 24 long-term animal feeding studies conducted by public research laboratories, concluded that none of these studies discovered any safety problem linked to long-term consumption of GM food. [105] A 2009 review by Javier Magaña-Gómez found that although most studies concluded that GM foods do not differ in nutrition or cause any detectable toxic effects in animals, some studies did report adverse changes at a cellular level

caused by some GM foods, concluding that "More scientific effort and investigation is needed to ensure that consumption of GM foods is not likely to provoke any form of health problem". [106] A review published in 2009 by Dona and Arvanitoyannis concluded that "results of most studies with GM foods indicate that they may cause some common toxic effects such as hepatic, pancreatic, renal, or reproductive effects and may alter the hematological, biochemical, and immunologic parameters". [107][108] However responses to this review in 2009 and 2010 note that the Dona and Arvanitoyannis concentrated on articles with an anti-GM bias that have been refuted by scientists in peer-reviewed articles elsewhere - for example the 35S promoter, stability of transgenes, antibiotic marker genes and the claims for toxic effects of GM foods. [109][110][111] Gerhard Flachowsky concluded in a 2005 review that the current GM food with only a single gene modification are similar in nutrition and safety to non-GM foods, but noted that food with multiple gene modifications would be more difficult to test, and would require further animal studies. [93] A 2004 review of animal feeding trials by Aumaitre et al. found no differences among animals eating genetically modified plants. [112]

In 2007, José L. Domingo searched the Pubmed database using 12 search terms and concluded that the "number of references" on the safety of GM/transgenic crops was "surprisingly limited" and questioned whether the safety of genetically modified food has been demonstrated; the review also remarked that its conclusions were in agreement with three earlier reviews. [113] In contrast, Philippe Vain found 692 research studies in 2007 that focused on GM crop and food safety and identified a strong increase in the publication of such articles in recent years. [114][115] Vain commented that the multidisciplinarian nature of GM research complicates the retrieval of GM studies and requires using many search terms (he used more than 300) and multiple databases. Domingo again reviewed the literature in 2011 and said that although there had been a substantial increase in the number of studies since 2006, most were conducted by the biotechnology companies responsible for commercialising the plants. [116]

Human studies and obstacles

While some groups and individuals have called for more human testing of GM food, [117] there are several obstacles to such studies. Both the US General Accounting Office (in a review of FDA procedures requested by Congress) and the FAO/WHO have confirmed that long term studies of the effect of GM food on humans are not feasible, for reasons including: there is no plausible hypothesis to test; very little is known about the potential long-term effects of any foods; identification of such effects is further confounded by the great variability in the way people react to foods; and epidemiological studies are not likely to differentiate the health effects of GM foods from the many undesirable effects of conventional foods. [118][119] Additionally, there are strong ethics that guide the conduct of research on human subjects, which mandate that the intervention being tested must have a potential benefit for the human subjects, such as treatment for a disease or nutritional benefit (ruling out toxicity testing on humans). [120] In this context, scientists and regulators discussing clinical studies of GM food have written that the "ethical and technical constraints of conducting human trials, and the necessity of doing so, is a subject that requires considerable attention." [121] Golden rice has been tested in humans to see if the rice provides a nutritional benefit, namely, increased levels of Vitamin A. [122][123][124]

Controversial studies

There have been some published studies that have suggested negative impacts from eating GM food. The first such peer reviewed paper to be published was in 1999 and covered research conducted by Arpad Pusztai in 1998. Pusztai had fed rats GM potatoes transformed with the Galanthus nivalis agglutinin (GNA) gene from the Galanthus (snowdrop) plant, allowing the GNA lectin protein to be synthesised. Lectin is known to be toxic, especially to gut epithelium, and while some companies were considering making GM crops expressing lectin, GNA was an unlikely candidate. On June 22, 1998 a short interview was shown on Granada Television's current affairs programme World in Action, with Pusztai saying that rats fed the potatoes had stunted growth and a repressed immune system. A media frenzy resulted and Pusztai was suspended from the Rowett Institute with misconduct procedures used to seize his data and ban him from speaking publicly. The Rowett Institute and the Royal Society reviewed Pusztai's work and concluded that the data did not support his conclusions. When his work was eventually published in *The Lancet* it reported significant differences in the thickness of the gut epithelium of rats fed genetically modified potatoes (compared to those fed the control diet), but no differences in growth or immune system function were suggested. The published paper was criticised on the grounds that the unmodified potatoes were not a fair control diet, and that any rats fed only on potatoes will suffer from a protein deficiency. The published paper was criticised on the grounds that the unmodified potatoes were not a fair control diet, and that any rats fed only on potatoes will suffer from a protein deficiency. Pusztai responded to these criticisms by stating that all the diets had the same protein and energy content and that the food intake of all rats was the same.

A 2011 study, the first to evaluate the correlation between maternal and fetal exposure to Bt toxin produced in genetically modified maize and to determine exposure levels of the pesticides and their metabolites, reported the presence of pesticides associated with GM foods in both non-pregnant women and pregnant women and their

fetuses. [135][136] The paper and the media reports around it were criticized for overstating the results. [137][138] FSANZ took the unusual step of posting a direct response, saying that the suitability of the ELISA assay method for detecting the Cry1Ab protein was not validated and that there was no evidence that that GM food was the source of the protein. They also suggested that even if the protein was detected it was more likely to come from conventional or organic sources. [139]

In 2007, 2009, and 2011 Gilles-Eric Seralini published re-analysis studies that used data from Monsanto rat feeding experiments for three GM maize varieties (insect resistant MON 863 and MON 810, and the glyphosate resistance NK603). He concluded that they had actually caused liver, kidney, and heart damage in the rats. [140][141][142] The European Food Safety Authority (EFSA) reviewed the data and concluded that the small differences were all within the normal range for control rats. [143] The EFSA review also stated that the statistical methods used were incorrect. [144][145][146] The EFSA conclusions were supported by Food Standards Australia New Zealand (FSANZ), [147][148][149] a panel of toxicologists funded by Monsanto [150] and the French High Council of Biotechnologies Scientific Committee (HCB). [151]

In 2012 the Séralini lab published a paper that looked at the long term effects of feeding rats various levels of GM roundup resistance maize, maize spiked with the roundup chemical and a mixture of the two. $^{[152]}$ The paper concluded that rats fed GM maize had an increased incidence of cancer. $^{[152]}$ Once published, there was widespread criticism of the study. Séralini held a press conference just before the paper was released; he allowed reporters access to the paper before his press conference only if they signed a confidentiality agreement under which they could not get other scientists' responses to the paper. $^{[153]}$ This method of announcing the research met with strong criticism from scientists and some journalists as it excluded critical commentary in the breaking stories. $^{[154][155]}$ $^{[156][157]}$ Many claimed that Séralini's conclusions were impossible to justify given the statistical power of the study and that Sprague-Dawley rats were not appropriate for a lifetime study (as opposed to a shorter toxicity study) because these rats have a high tendency to get cancer over their lifespan (one study found over 80% got cancer under normal conditions). $^{[158][159][160][161]}$ For a similar study the Organisation for Economic Co-operation and Development guidelines recommend using 65 rats per experiment, not 10. $^{[160][161][162]}$ Questions were also raised about the statistical method chosen to analyse the data $^{[163]}$ and the lack of data regarding the amount of food fed to the rats and their growth rates. $^{[164][165]}$ Other criticisms included the lack of a dose-response relationship (females fed three times the dose showed a decreased number of tumours) $^{[166]}$ and no identifiable mechanism for the increase in tumours. $^{[167]}$ Six French national academies of science issued an unprecedented joint statement condemning the study and the journal that published it. $^{[168]}$ Food and Chemical Toxicology published 17 letters to the editor that expressed strong criticism of

Environment

Genetically modified crops are planted in fields much like regular crops. There they interact directly with organisms that feed on the crops, and indirectly with other organisms in the wider food chain. The pollen from the plants behaves like the pollen of any other crop. This has led to concerns about effects of genetically-engineered crops on non-target species, and about gene flow to other plants, animals and bacteria. Some supporters of GM crops see these crops as providing benefits to the environment through a reduction in the use of pesticides [179][180] and a reduction in greenhouse gas emissions. [181] However, recent research shows that the spread of glyphosate-resistant weeds in herbicide-resistant weed management systems has brought about substantial increases in the number and volume of herbicides applied. A 2012 study on pesticide use in the U.S. over the 16-year period, 1996–2011, shows that herbicide-resistant crop technology has led to a 239 million kilogram (527 million pound) increase in herbicide use in the United States between 1996 and 2011, while Bt crops have reduced insecticide applications by 56 million kilograms (123 million pounds). Overall, pesticide use increased by an estimated 183 million kgs (404 million pounds), or about 7%, largely due to the replacement of older persistent pesticides by glyphosate. [182] As more resistant weeds continue to emerge, some farmers are finding the need to return to the practice of yearly plowing as part of their strategy for weed control. [183]

Non target organisms

One of the major uses of GM crops is in insect pest control though the expression of the cry (crystal delta-endotoxins) and Vip (vegetative insecticidal proteins) genes from Bacillus thuringiensis (Bt). There are concerns that these toxins could target predatory and other beneficial or harmless insects as well as the targeted pest insect. The proteins produced by Bt have been used as organic sprays for insect control in France since 1938 and the USA since 1958 with no ill effects on the environment reported. [184] While cyt proteins are toxic towards the insect orders Coleoptera

(beetles) and Diptera (flies), cry proteins selectively target Lepidopterans (moths and butterflies). As a toxic mechanism, cry proteins bind to specific receptors on the membranes of mid-gut (epithelial) cells resulting in rupture of those cells. Any organism that lacks the appropriate receptors in its gut cannot be affected by the cry protein, and therefore Bt. [185][186] Regulatory agencies assess the potential for the transgenic plant to impact non target organisms before approving their commercial release. [187][188]

In 1999 a paper was published in *Nature* showing that in a lab environment pollen from Bt maize dusted onto milkweed could harm the monarch butterfly. A collaborative research exercise was carried out over the next two years by several groups of scientists in the US and Canada, looking at the effects of Bt pollen in both the field and the laboratory. This resulted in a risk assessment that concluded that any risk posed by the corn to butterfly populations under real-world conditions was negligible. A 2002 review of the scientific literature concluded that "the commercial large-scale cultivation of current Bt-maize hybrids did not pose a significant risk to the monarch population" and noted that despite large-scale planting of GM crops, the butterfly's population is increasing. [191]

An analysis of laboratory settings found that Bt toxins can affect nontarget organisms, usually organisms closely related to the intended targets. Typically, exposure occurs through the consumption of plant parts, such as pollen or plant debris, or through Bt ingestion by their predatory food choices. The methodology used by Lövei et al. has been called into question by a group of academic scientists who wrote "We are deeply concerned about the inappropriate methods used in their paper, the lack of ecological context, and the authors' advocacy of how laboratory studies on non-target arthropods should be conducted and interpreted". [193]

Biodiversity

There are concerns that the genetic diversity of various crops will decrease (as the development of GM varieties will lead to less cultivars being used overall) or that they will indirectly affect the diversity of other organisms. Also, there are concerns that the widespread use of GM crops designed to resist agrochemicals, leads to increased use of those agrochemicals, which in turn causes damage to the environment and to biodiversity.

Studies comparing the genetic diversity of cotton have found that in the USA the diversity has either increased or stayed the same, while in India it has reduced. This has been put down to the larger number of breeding varieties the technology was used on in the USA compared to India. [194] A review of the effects of Bt crops on soil ecosystems found that in general they "appear to have no consistent, significant, and long-term effects on the microbiota and their activities in soil". [195] The diversity and number of weed populations has been shown to decrease in farm-scale trials in the UK and Denmark when comparing herbicide resistant crops to their conventional counterparts. [196][197] The UK trial suggested that the diversity of birds could be impacted by the decrease in weed seeds available for feeding. [198] Published data from farms involved in the trials showed that seed eating birds were more abundant on conventional maize after the application of the herbicide, but that there were no significant differences in any other crop or prior to herbicide treatment. [199] A 2012 study found a correlation between the reduction of milkweed in farms that grew glyphosate-resistant crops and the decline in adult monarch butterfly populations in Mexico. [200] The New York Times reported that the study "raises the somewhat radical notion that perhaps weeds on farms should be protected. [201]

A scientific study published in 2005 designed to "simulate the impact of a direct overspray on a wetland" with four different agrochemicals (carbaryl (Sevin), malathion, 2,4-Dichlorophenoxyacetic acid, and glyphosate in a Roundup formulation) by creating artificial ecosystems in tanks and then applying "each chemical at the manufacturer's maximum recommended application rates", found that "species richness was reduced by 15% with Sevin, 30% with malathion, and 22% with Roundup, whereas 2,4-D had no effect". [202] The study has been used by environmental groups to argue that use of agrochemicals causes unintended harm to the environment and to biodiversity. [203]

Emergence of secondary pests

Several studies have documented surges in secondary pests (which are not affected by Bt toxins) within a few years of adoption of Bt cotton. In China, the main problem has been with mirids, [204][205] which have in some cases "completely eroded all benefits from Bt cotton cultivation". [206] A 2009 study in China concluded that the increase in secondary pests depended on local temperature and rainfall conditions and occurred in half the villages studied. The increase in insecticide use for the control of these secondary insects was far smaller than the reduction in total insecticide use due to Bt cotton adoption. [207] Another study published in 2011 was based on a survey of 1,000 randomly selected farm households in five provinces in China and found that the reduction in pesticide use in Bt cotton cultivars is significantly lower than that reported in research elsewhere, consistent with the hypothesis suggested by recent studies that more pesticide sprayings are needed over time to control emerging secondary pests, such as aphids, spider mites, and lygus bugs. [208] Similar problems have been reported in India, with both

mealy bugs^{[209][210]} and aphids.^[211]

Gene flow

Genes from a genetically modified organism may pass to another organism just like an endogenous gene. The process is known as outcrossing and can occur in any new open-pollinated crop variety, with newly introduced traits potentially crossing into neighboring crop plants of the same or sometimes closely related species. There are concerns that the spread of genes from modified organisms to unmodified relatives could produce species of weeds resistant to herbicides [212]:99[179][213] that could contaminate nearby non-genetically modified crops or organic crops, [214] or could disrupt the ecosystem, [215][216] This is primarily a concern if the transgenic organism has a significant survival capacity and can increase in frequency and persist in natural populations. [217] This process, whereby genes are transferred from GMOs to wild organisms, is different from the development of so-called "superweeds" or "superbugs" that develop resistance to pesticides under natural selection.

In most countries environmental studies are required prior to the approval of a GM plant for commercial purposes, and a monitoring plan must be presented to identify potential gene flow effects which have not been anticipated prior to the approval.

In 2004, Charles Chilcutt and Bruce Tabashnik published a communicated paper in Proceedings of the National Academy of Sciences of the United States of America describing findings of Bt protein in kernels of the refuge (a non-genetically modified food crop planted alongside a genetically modified one to prevent or slow the development of predators resistant to its modified properties by purposely encouraging the mating of species across said crops), and raised concerns about gene flow from Bt to unmodified corn varieties. [218]

In 2007, the U.S. Department of Agriculture fined Scotts Miracle-Gro \$500,000 when modified genetic material from creeping bentgrass, a new golf-course grass Scotts had been testing, was found within close relatives of the same genus $(Agrostis)^{[219]}$ as well as in native grasses up to 21 km (13 mi) away from the test sites, released when freshly cut grass was blown by the wind. [220]

In 2009 the government of Mexico created a regulatory pathway for approval of genetically modified maize, [221] but because Mexico is the center of diversity for maize, concerns have been raised about the effect that genetically modified maize could have on local strains. [222][223] A 2001 report in *Nature* presented evidence that Bt maize was cross-breeding with unmodified maize in Mexico, [224] although the data in this paper was later described as originating from an artifact and *Nature* stated that "the evidence available is not sufficient to justify the publication of the original paper". A subsequent large-scale study, in 2005, failed to find any evidence of contamination in Oaxaca. However, other authors have stated that they also found evidence of cross-breeding between natural maize and transgenic maize. [227]

In 2005, scientists at the UK Centre for Ecology and Hydrology reported the first evidence of horizontal gene transfer of pesticide resistance to weeds, in a few plants from a single season; they found no evidence that any of the hybrids had survived in subsequent seasons. [228]

A study published in 2010 by scientists at the University of Arkansas, North Dakota State University, California State University and the US Environmental Protection Agency showed that about 83 percent of wild or weedy canola tested contained genetically modified herbicide resistance genes. [229][230][231] According to the researchers, the lack of reports in the US suggests inadequate oversight and monitoring protocols are in place in the US. [232] The development of weeds resistant to glyphosate, the most commonly applied herbicide, could mean that farmers must return to more labour intensive methods to control weeds, use more dangerous herbicides or till the soil (so increasing then risk of erosion). [233] A 2010 report by the National Academy of Sciences stated that the advent of glyphosate-herbicide resistant weeds could cause the genetically engineered crops to lose their effectiveness unless farmers also use other established weed management strategies. [234][235]

One means that has been explored to avoid environmental contamination is Genetic use restriction technology, also dubbed 'Terminator'. $^{[236]}$ This uncommercialized technology would allow the production of crops with sterile seeds, which would prevent the escape of genetically modified traits. Groups concerned with control of the food supply had expressed concern that the technology would be used to limit access to viable seeds. $^{[237]}$ Another similar hypothetical trait-specific technology known as 'Traitor' or 'T-GURT', requires application of a chemical to genetically modified crops to reactivate engineered traits. $^{[236][238]}$ These technologies have also caused controversy, as there are fears the technology itself, and the patents on them, would allow companies to further control the market for seeds. $^{[239]}$

Coexistence of organic and GM crops

Main article: Co-existence of genetically modified and conventional crops and derived food and feed

In the US there is no legislation governing the co-existence of neighboring farms growing organic and GM crops; instead the US relies on a "complex but relaxed" combination of three federal agencies (FDA, EPA, and USDA/APHIS) and the common law tort system, governed by state law, to manage risks of co-existence. [240]:44 In the face of continuing concerns about the economic losses that might be suffered by organic farmers by unintended intermixing, the Secretary of Agriculture convened an Advisory Committee on Biotechnology and 21st Century Agriculture (AC21) to study the issue and make recommendations as to whether to address these concerns and if so, how, economic losses to farmers caused by unintended presence of genetically engineered materials, as well as how such mechanisms might work. The members of AC21 include representatives of the biotechnology industry, the organic food industry, farming communities, the seed industry, food manufacturers, State government, consumer and community development groups, the medical profession, and academic researchers. The AC21 recommended that a study should be conducted to answer the question of whether and to what extent there are any economic losses to US organic farmers; recommended that if the losses are serious, that a crop insurance program for organic farmers be put in place, and that an education program should be undertaken to ensure that organic farmers are putting appropriate contracts in place for their crops and that neighboring GM crop farmers are taking appropriate containment measures. Overall the report supported a diverse agriculture system in which many different farming systems could co-exist. [241][242]

Some countries - notably the European Union - have implemented regulations specifically governing co-existence and traceability. Traceability has become commonplace in the food and feed supply chains of most countries in the world, but the traceability of GMOs is made more challenging by the addition of very strict legal thresholds for unwanted mixing. Within the European Union, since 2001, conventional and organic food and feedstuffs can contain up to 0.9% of authorised GM material without being labelled $\mathrm{GM}^{[243]}$ (any trace of non-authorised GM products and would cause shipments to be rejected. To be able to monitor and enforce compliance with co-existence regulations, authorities require the ability to trace, detect and identify GMOs, and the several countries and interested parties created a non-governmental organization, Co-Extra, to develop such methods. [245]

Escape of GM crops

Related to gene flow, but separate, is the issue of GM crops escaping field tests, or GM crops that are approved for a given purpose, escaping into supply chains for other purposes. This is of great concern to farmers whose crop is exported to countries that have not approved harvests from GM crops. [246]:275

In 1999 scientists in Thailand claimed they discovered glyphosate-resistant genetically modified wheat that was not yet approved for release in a grain shipment from the Pacific Northwest of the United States, even though transgenic wheat had never been approved for sale and was only ever grown in test plots. No one could explain how the transgenic wheat got into the food supply.^[247]

In 2000, Aventis StarLink corn, which had been approved only as animal feed due to concerns about possible allergic reactions in humans, was found contaminating corn products in U.S. supermarkets and restaurants. This corn became the subject of a widely publicized recall, which started when Taco Bell-branded taco shells sold in supermarkets were found to contain the corn, resulting in sales of StarLink seed being discontinued. [84][85] The registration for the Starlink varieties was voluntarily withdrawn by Aventis in October 2000, though no allergic reactions to the corn were ever reported. [87]

In another example, American exports of rice to Europe were interrupted in 2006 when the U.S. crop was contaminated with rice containing the LibertyLink modification, which had not been approved for release. ^[248] An investigation by the USDA's Animal and Plant Health Inspection Service (APHIS) was unable to determine the cause of the contamination. ^[249]

In May 2013, glyphosate-resistant genetically modified wheat that was not yet approved for release (but which had been approved for human consumption)^[250] was discovered in a farm in Oregon, growing as a weed or "volunteer plant" in a field that had been planted with winter wheat. The GM wheat was developed by Monsanto, and was a strain that was field-tested from 1998 to 2005 and was in the regulatory approval process before Monsanto withdrew it based on concern that importers would avoid the crop. The discovery threatened US wheat exports which totaled \$8.1 billion in 2012. [251] Japan, South Korea, and Taiwan suspended purchases of winter wheat and concerns were raised by advocates for organic food. [252][253][254] As of August 30, 2013, while the source of the GM wheat remained unknown, Japan, South Korea and Taiwan had all resumed placing orders, and the disruption of the export market was minimal. [255][256]

Chemical use

Herbicides

The development of glyphosate-resistant (Roundup Ready) plants has changed the herbicide use profile away from the use of more environmentally persistant herbicides with higher toxicity, such as atrazine, metribuzin, and alachlor, and has reduced the dangers of herbicide runoff into drinking water. [257][258] However, a study published in Environmental Sciences Europe by Chuck Benbrook [259] concluded that the spread of glyphosate-resistant weeds in herbicide-resistant weed management systems has increased herbicides applied. [259][260]

Pesticides

One of the major environmental benefits from using GM crops is the reduction in the use of pesticides. Insectresistant Bt-expressing crops will reduce the number of pest insects feeding on these plants without the farmers having to apply as much insecticides. [261][262] A study published by the UK consultancy PG Economics, concluded that globally pesticide spraying was reduced by 286,000 tons in 2006, decreasing the environmental impact of herbicides and pesticides by 15%. [263] A survey of small Indian farms between 2002 and 2008 concluded that Bt cotton adoption has led to higher yields and lower pesticide use. [264] One study concluded insecticide use on cotton and corn during the years 1996 to 2005 fell by 35.6 million kg of insecticide active ingredient, which is roughly equal to the amount of pesticide applied to arable crops in the EU in one year. [265] A study on the effects of using Bt cotton in six northern provinces of China from 1990 to 2010 concluded that Bt cotton halved the use of pesticides and doubled the level of ladybirds, lacewings and spiders, with the environmental benefits extended to neighbouring crops of maize, peanuts and soybeans. [266][267]

Resistant insect pests

Resistance evolves naturally after a population has been subjected to intense selection pressure in the form of repeated use of a single herbicide or insecticide. [268] In November 2009, Monsanto scientists found the pink bollworm had become resistant to the first generation Bt cotton in parts of Gujarat, India—that generation expresses one Bt gene, Cry1Ac. This was the first instance of Bt resistance confirmed by Monsanto anywhere in the world. [269][270] Bollworm resistance to first generation Bt cotton has also been identified in Australia, China, Spain, and the United States. [271] The strategy to delay the emergence of Bt resistant pests has been to have non-GM refuges within the GM crops to dilute any resistant genes that may arise or more recently to develop GM crops that have multiple Bt genes that target different receptors within the insect. [272] In 2012, a Florida field trial demonstrated that army worms were able to eat pesticide-containing GM corn produced by Dupont-Dow without any ill effects, meaning they had become resistant to it; armyworm resistance was first discovered in Puerto Rico in 2006, prompting Dow and DuPont to voluntarily stop selling the product on the island, [273] The European corn borer, one of the primary insects Bt is meant to target, has been shown to be capable of developing resistance to the Bt protein. [274]

Economics

The economic value derived from growing genetically modified food has been a major selling point for the technology. One of the key reasons for the widespread adoption is the perceived economic benefit the technology brings to farmers, including those in developing nations. [275][276][277] A 2010 study by US scientists, found that the economic benefit of Bt corn to farmers in five mid-west states was \$6.9 billion over the previous 14 years. They were surprised that the majority (\$4.3 billion) of the benefit accrued to non-Bt corn. This was speculated to be because the European Corn Borers that attack the Bt corn die and there are fewer left to attack the non-GM corn nearby. [278][279] Agriculture economists have calculated that "world surplus [increased by] \$240.3 million for 1996. Of this total, the largest share (59%) went to U.S. farmers. The gene developer, Monsanto, received the next largest share (21%), followed by U.S. consumers (9%), the rest of the world (6%), and the germplasm supplier, Delta and Pine Land Company (5%). "[280] A comprehensive 2012 study by PG Economics, a UK company, concluded that GM crops increased farm incomes worldwide by \$14 billion in 2010, with over half this total going to farmers in developing countries. [181]

Claims of major benefits to farmers, including poor farmers in developing countries, have been challenged by opponents. The task of isolating impacts of the technology is complicated by the prevalence of biased observers, and by the rarity of controlled comparisons (such as identical seeds, differing only in the presence or absence of the Bt trait, being grown in identical situations). The main Bt crop being grown by small farmers in developing countries is cotton, and a 2006 exhaustive review of findings on Bt cotton by agricultural economists concluded, "the overall balance sheet, though promising, is mixed. Economic returns are highly variable over years, farm type, and geographical location". [281] Mark Lynas, an environmental activist, believes that an outright rejection of the technology is "illogical and potentially harmful to the interests of poorer peoples and the environment".

Industrial agriculture

GM crops play a key role in contemporary large scale agriculture, which involves monoculture, use of herbicides and pesticides, use of equipment that requires large amounts of fossil fuels, and irrigation. Opponents of GM food like Jonathan Latham of the Bioscience Research Center and Vandana Shiva often discuss the paradigm of industrial agriculture and GM crops at the same time and instead argue for an agriculture that works with the environment instead of controlling it. [283][284][285][286][287]:527

Proponents of modern agriculture, including GM crops, tout the low prices and wide array of choices the system has produced, and claim that technology must be applied to agriculture if we are to feed a growing world population. [288][289][290][291]

Impoverished nations

The effect that genetically modified food may have on developing nations is debated. There is agreement that there is a food supply issue, $^{[292][293][294]}$ although there is disagreement on the best ways to solve this. Some scientists suggest that a second Green Revolution with increased use of GM crops is needed to meet the demand for food in the developing world. $^{[295][296]:12}$ Others say that there is more than enough food in the world and that the hunger crisis is caused by problems in food distribution and politics, not production. $^{[297][298]}$ The potential for genetically modified food to help impoverished nations was recognised by the International Assessment of Agricultural Science and Technology for Development, but as of 2008 they found no conclusive evidence that they have offered a solution. $^{[299]}$

Additionally, those who argue against the adoption of food from GM crops in human diet say that the reason the world has so many people is due to the second green revolution, where unsustainable agricultural practices have left us with more mouths to feed than the planet can safely and ecologically sustain. [300]:73 Even if GM crops are successful in feeding the current population using transgenic methods, the world will undergo another population explosion which will require even more drastic agricultural interventions, and with the coming crisis in oil shortages, there will not be enough fuel to make fertilizers, pesticides, or to drive the tractors, combines, transports, factories and distribution centres that modern agricultural methods have required. [301]

Constraints to the deployment of this technology to impoverished nations are the lack of easy access, expense of modern agricultural equipment, and that certain aspects of the system revolving around intellectual property rights are unfair to "undeveloped countries". Consultative Group on International Agricultural Research (CGIAR), an aid and research organization, was praised by the World Bank for its efforts but suggested they shift to genetics research and productivity enhancement. This plan has several obstacles such as patents, commercial licenses, and the difficulty that third world countries have in accessing the international collection of genetic resources and other intellectual property rights that would educate them about modern technology. The International Treaty on Plant Genetic Resources for Food and Agriculture has attempted to remedy this problem, but results have been inconsistent. As a result, "orphan crops", such as teff, millets, cowpeas, and indigenous plants, which are important in these countries receive little investment. [302]

Yield

There is also debate over whether the use of genetically modified crops increases or decreases yield. The currently commercialised varieties have traits that reduce yield loss from insect pressure or weed interference. [303][304] There are however crops and animals being developed with traits aimed at directly increasing the yield, [305] with the closest to commercialisation being salmon with an added growth hormone gene. [306]

A 2010 article supported by CropLife International summarised the results of 49 peer reviewed studies on GM crops worldwide. On average, farmers in developed countries experienced increase in yield of 6% and in underdeveloped countries of 29%. Tillage was decreased by 25–58% on herbicide resistant soybeans, insecticide applications on Bt crops were reduced by 14–76% and 72% of farmers worldwide experienced positive economic results. Another yield gain can be seen with the planting of glyphosate-resistant crops. It allowed farmers to plant rows closer together as they did not have to control post-emergent weeds with mechanical tillage.

Critics of genetic engineered crops disagree that they result in increased yield. In 2009 the Union of Concerned Scientists, a group opposed to genetic engineering and cloning of food animals, summarized peer-reviewed studies on the yield contribution of genetic engineered crops—soybeans and maize in the United States. [310] The report concluded that in the United States, other agricultural methods have made a greater contribution to national crop yield increases in recent years than genetic engineering. Such critics also point to a study published in Nature Biotechnology by University of Wisconsin researchers that concluded that the introduction of Roundup Ready crops as well as the Bt trait for corn rootworm actually lowered yields. [311][312]

Market dynamics

The seed industry is dominated by several seed and biotechnology firms. Firms have engaged in vertical integration, causing structural changes in the seed industry. [313][314] It is reported that in 2011, 73% of the global market is controlled by 10 companies. [315]

In 2001, the USDA published an article showing that the concentration of market power in the seed industry has led to economies of scale that facilitated market efficiency because production costs have decreased, however, the move by some companies to divest their seed operations calls into question the long-term viability of these conglomerates. [316] Two economists, guest speakers on the AgBio Forum [317] cite that the huge market power possessed by the small number of biotechnology companies in crop biotechnology could be beneficial in raising welfare despite the pricing strategies they practice because "even though price discrimination is often considered to be an unwanted market distortion, it may increase total welfare by increasing total output and by making goods available to markets where they would not appear otherwise." [318]

Market power gives seed and biotechnology firms the ability to set or influence price, dictate terms, and act as a barrier to entry into the industry. It also gives firms the bargaining power over governments in policy making. [319][320] In March 2010, the US Justice Department and the U.S. Department of Agriculture held a meeting in Ankeny, Iowa to look at the competitive dynamics in the seed industry. Christine Varney, who heads the antitrust division in the Justice Department, said that her team was investigating whether biotech-seed patents are being abused to extend or maintain companies' dominance in the industry. A key issue is how Monsanto sells and licenses its patented trait that allows farmers to kill weeds with Roundup herbicide while leaving crops unharmed the gene was in 93 percent of U.S. soybeans grown in 2009. [322] About 250 family farmers, consumers and other critics of corporate agriculture held a town meeting prior to the governmental meeting to protest Monsanto for what they see as manipulation of the market by buying up independent seed companies, patenting the seeds and then raising seed prices. [321]

Intellectual property

Traditionally, farmers in all nations saved their own seed from year to year. However since the early 1900s hybrid crops have been widely used in the developed world and seeds to grow these crops must be purchased each year from seed producers. The offspring of the hybrid corn, while still viable, lose the beneficial traits of the parents, resulting in the loss of hybrid vigor. In these cases, the use of hybrid plants has been the primary reason for growers not saving seed, not intellectual property issues. However, for non-hybrid biotech crops, such as transgenic soybeans, seed companies use intellectual property law and tangible property common law, each expressed in contracts, to forbid farmers from saving seed. For example, Monsanto's typical bailment license (covering transfer of the seeds themselves) forbids saving seeds, and also requires that purchasers sign a separate patent license agreement. [324][325][326]

Corporations say that they need product control in order to prevent seed piracy, to fulfill financial obligations to shareholders, and to invest in further GM development. DuPont spent approximately half its \$2 billion R&D budget on agriculture in 2011^[327] while Monsanto spends 9-10% of their sales in their research and development effort every year. [328]

Detractors such as Greenpeace say that patent rights give corporations a dangerous amount of control over their product. $^{[329]}$ Others claim that "patenting seeds gives companies excessive power over something that is vital for everyone. $^{[330]}$ Regarding the issues of intellectual property and patent law, an international report from the year 2000 states: "If the rights to these tools are strongly and universally enforced - and not extensively licensed or provided pro bono in the developing world - then the potential applications of GM technologies described previously are unlikely to benefit the less developed nations of the world for a long time (i.e. until after the restrictions conveyed by these rights have expired). $^{[331]}$

Monsanto has a strong patent portfolio on its GM seed, and obligates farmers who choose to buy their seeds to sign a license agreement, agreeing that they cannot save seed from their crop to plant in successive years and can use the seed only to grow a crop that they will sell to elevators or end users. [100]:213[332]:156 Monsanto has filed patent infringement suits against 145 farmers, but has proceeded to trial with only 11. [333] Although in some of those 11 cases, a defense of unintentional contamination by gene flow was used, Monsanto won all 11 cases. [333] Monsanto Canada's Director of Public Affairs has stated that "It is not, nor has it ever been Monsanto Canada's policy to enforce its patent on Roundup Ready crops when they are present on a farmer's field by accident...Only when there has been a knowing and deliberate violation of its patent rights will Monsanto act. [334]

One example of such litigation is the Monsanto v. Schmeiser case. [335] This case is widely misunderstood: "The fear

about a company claiming ownership of a farmer's crop based on the inadvertent presence of GM pollen grain or seed is...widespread and ...unfounded."[336] In 1997, Percy Schmeiser, a canola breeder and grower in Bruno, Saskatchewan, discovered that a section of one of his fields contained canola that was resistant to herbicide Roundup by spraying it with Roundup, leaving only the resistant plants. He had not purchased roundup-resistant canola; it was apparently sown from seed blown onto his land from neighboring fields. He later harvested and saved the seed from this area, and replanted the saved seed in 1998. During the 1998 growing season, Monsanto approached Schmeiser and asked him to take a license to the patent covering the transgenic seed he had planted; Schmeiser refused, claiming that he owned the physical seeds he had harvested in 1997 and had the right to do with them as he wished. Monsanto sued Schmeiser for patent infringement and prevailed in the initial case. Schmeiser appealed and lost, and appealed again to the Canadian Supreme Court, which in 2004 ruled 5 to 4 in Monsanto's favor.

Regulation

Main article: Regulation of the release of genetically modified organisms

Labeling

While some groups advocate the complete prohibition of GMOs, others call for mandatory labeling of genetically modified food or other products, while others call for no labeling of GM food. [337]

The European Union, Australia, [338] New Zealand, [338] China, India [339] and other countries require GMO labeling, while others make GMO labeling voluntary or have plans to introduce labeling. [340][341][342]

Biotechnology labelling is not required in the United States, although there have been numerous efforts to pass labeling laws. [343] One of the first efforts was on the 2002 Oregon Ballot, which failed to pass by a ratio of 7 to 3. Eighteen state legislatures that debated GM labeling legislation in early 2012 [344] and Vermont's House Agriculture Committee drafted and passed a bill requiring labeling in April 2012, but it was introduced too late in the legislative season to be passed into law during 2012. [345] In 2012, the U.S. state of California voted against Proposition 37, which would have required the labelling of genetically modified food. [346][347] In 2013, the legislature of Connecticut passed a law requiring GM food labeling, the first such law to be passed in the United States; Governor Dannel Malloy has said he will sign the bill into law. [348]

Washington Initiative 522 would require labeling of genetically engineered foods in the state of Washington and will be voted on in the November 5, 2013 general election. [349]

The American Medical Association (AMA)^[4] and the American Association for the Advancement of Science^[1] oppose mandatory labeling of GM food because there is no scientific evidence of harm. The AMA believes that even voluntary labeling is misleading unless accompanied by focused consumer education. The AAAS argues that mandatory labeling "can only serve to mislead and falsely alarm consumers".

[Labeling] efforts are not driven by evidence that GM foods are actually dangerous. Indeed, the science is quite clear: crop improvement by the modern molecular techniques of biotechnology is safe. Rather, these initiatives are driven by a variety of factors, ranging from the persistent perception that such foods are somehow "unnatural" and potentially dangerous to the desire to gain competitive advantage by legislating attachment of a label meant to alarm. Another misconception used as a rationale for labeling is that GM crops are untested. [1]

A 2007 study on the effect of labeling laws found that once labeling went into effect, few products contained genetically modified ingredients. Businesses stopped carrying products with GM food. The study also found that costs are higher in food-exporting countries than in food-importing countries. Food exporting countries such as the U.S., Argentina, and Canada have adopted voluntary labeling approaches while countries that have adopted mandatory labeling are generally importers of genetically modified food. [350]

A website posted by P. Bryne of the Colorado State University Extension, provides a concise list of pros and cons of labeling food derived from GMOs, with further detail. [351] The list of pros and cons is reproduced here with modifications:

Pros and Cons of Mandatory Labeling

There are several arguments put forward in favor of and against mandatory labeling of GM foods. Those arguments are summarized below.

Pro-mandatory labeling Arguments

■ Consumers have a right to know what's in their food, especially concerning products for which health and

- environmental concerns have been raised.^[352]
- Proponents of mandatory labeling in the US argue that Europe, Japan, India and China require mandatory labeling and that a majority of Americans support mandatory labeling. [353]

Anti-mandatory labeling Arguments

- Labels on food made with genetically modified ingredients imply a warning about health effects, whereas no significant differences between conventional foods and GM foods have been detected. If a nutritional or allergenic difference were found in a GM food, current FDA regulations require a label to that effect.
- Labeling of GM food, to fulfill the desires of some consumers, would impose a cost on all consumers. Experience with mandatory labeling in the European Union, Japan, and New Zealand has not resulted in consumer choice. Rather, retailers have eliminated GM products from their shelves due to perceived consumer aversion to GM products. [354]
- The Right to know approach (as opposed to the need to know approach) is too open ended and potentially unbounded, because it can be invoked for virtually anything. [355]
- Consumers who want to buy non-GM food already have an option: to purchase certified organic foods that are labelled "100% Organic," which by definition cannot be produced with non-organic ingredients. [356][357]
- Segregation, identity preservation and systematic testing are costly activities. The providers of the non-GM product have the best incentives to undertake such activities effectively. Therefore, voluntary labelling of the non-GM attribute is preferable from an economics perspective. [355]

Objectivity of regulatory bodies

Groups opposing the release of genetically modified organisms or their use as food have questioned whether regulatory authorities in various countries are too close to companies that seek approval for their products, or have received bribes from such companies.

Critics in the US have protested in regards to the appointment of pro GM lobbyists to senior positions in the FDA. Michael R. Taylor, a former Monsanto lobbyist, was appointed as a senior adviser to the FDA on food safety in 1991. Following his tenure at the FDA, Taylor became a vice-president of Monsanto. On 7 July 2009, Taylor returned to government as Senior Advisor to the Commissioner of the US Food and Drug Administration for the Obama administration. [358]

The Canadian Biotechnology Advisory Committee that reviewed Canada's regulations in 2003 was accused by environmental and citizen groups of not representing the full spectrum of public interests and for being too closely aligned to industry groups. [359]

Most of the Chinese National Biosafety Committee are involved in biotechnology leading to criticisms that they do not represent a wide enough range of public concerns. $^{[360]}$

In 2001, when the Starlink corn recall became public, the Environmental Protection Agency was criticized for being slow to react by Joseph Mendelson III of the Center for Food Safety. [361] He also criticized the EPA and Aventis CropScience for statements at the time of the recall, that indicated they did not anticipate that such a thing would happen. [361]

Litigation and disputes over regulation

In the US

Four federal district court suits have been brought against Animal and Plant Health Inspection Service (APHIS), the agency within USDA that regulates genetically modified plants. Two involved field trials (herbicide-tolerant turfgrass in Oregon; pharmaceutical-producing corn and sugar in Hawaii) and two the deregulation of GM alfalfa. [362] and GM sugar beet. [363] Initially APHIS lost all four cases, with the judges ruling they failed to diligently follow the guidelines set out in the National Environmental Policy Act. However, the Supreme Court overturned the nationwide ban on GM alfalfa [364] and an appeal court allowed the partial deregulation of GM sugar beet crops. [365] After APHIS prepared Environmental Impact Statements for both alfalfa and sugar beet they were deregulated again. [366][367]

Trade disputes over EU regulation

See also: Regulation of the release of genetic modified organisms#Europe

GM food and GM crops have been the subject of international trade disputes. Such a dispute arose between the US and Europe in the early 2000s. Until the 1990s, Europe's regulation was less strict than in the United States. [368] In

1998, the use of MON810, a Bt expressing maize conferring resistance to the European corn borer, was approved for commercial cultivation in Europe. However, in the 1990s, a series of unrelated food crises created consumer apprehension about food safety in general and eroded public trust in government oversight of the food industry most importantly, the infection of cows with bovine spongiform encephalopathy and the mishandling of food safety by European authorities. [369] In 1998, a *de facto* moratorium led to the suspension of approvals of new genetically modified organisms (GMO) in the European Union pending the adoption of revised rules to govern the approval, marketing and labelling of biotech products.

The approval of GM crops in the US in the mid-1990s precipitated strong public concern in Europe and led to a dramatic decrease in US exports to the EU. "Prior to 1997, corn exports to Europe represented about 4% of total U.S. corn exports, generating about \$300 million in sales. Starting in 1997, however, the U.S. largely stopped shipping bulk commodity corn to the EU because such shipments typically commingled corn from many farms, including genetically modified varieties not approved by the EU. The change was dramatic. For example, before 1997, the U.S. sold about 1.75 million tons of corn annually to Spain and Portugal, the two largest importers of U.S. corn in the EU. But in the 1998–99 crop year, Spain bought less than a tenth of the previous year's amount and Portugal bought none at all." [369]

In May 2003, the United States and twelve other countries filed a formal complaint with the World Trade Organization that the European Union was violating international trade agreements, in blocking imports of U.S. farm products through its long-standing ban on genetically modified food. The countries argued that the EU's regulatory process was far too slow and its standards were unreasonable given the overwhelming body of scientific evidence showing that the crops were safe. The case was also lobbied by U.S. biotechnology giant Monsanto and France's Aventis, as well as by US agricultural groups such as the National Corn Growers Association. In response, in June 2003, the European Parliament ratified a U.N. biosafety protocol regulating international trade in genetically modified food, and in July agreed to new regulations requiring labeling and traceability, as well as an opt-out provision for individual countries. Following this, the approval of new GMOs began again in May 2004. While a number of other GMOs have been approved since then, approvals remain controversial and various countries have utilized the opt-out provisions. In 2006, the WTO ruled that the pre-2004 restrictions had been violations, [370][371] although the ruling had little immediate effect since the moratorium had already been lifted.

In late 2007, the U.S. ambassador to France recommended "moving to retaliation" to cause "some pain" against France and the European Union in an attempt to fight the French ban and changes in European policy toward genetically modified crops, according to a U.S. government diplomatic cable obtained by WikiLeaks. [372][373]

African controversies

In 2002, Zambia refused emergency food aid from developed countries, fearing that the food is unsafe. During a conference in the Ethiopian capital of Addis Ababa, Kingsley Amoako, Executive Secretary of the United Nations Economic Commission for Africa (UNECA), encouraged African nations to accept genetically modified food and expressed dissatisfaction in the public's negative opinion of biotechnology. [374] Studies for Uganda show that transgenic bananas have a high potential to reduce rural poverty but that urban consumers with a relatively higher income may reject the introduction. [375][376]

Indian controversies

Controversies over GM crops and GM food in India have recapitulated many of the issues discussed in this article, but have unique aspects as well. In India, GM cotton yields in Maharashtra, Karnataka, and Tamil Nadu had an average 42% increase in yield with GM cotton in 2002, the first year of commercial GM cotton planting. However, there was a severe drought in Andhra Pradesh that year and the parental cotton plant used in the genetic engineered variant was not well suited to extreme drought, so Andhra Pradesh saw no increase in yield. Drought resistant variants were developed and, with the substantially reduced losses to insect predation, by 2011 88% of Indian cotton was GM. Though disputed the economic and environmental benefits of GM cotton in India to the individual farmer have been documented. A long-term study (2002 through 2008) on the economic impacts of Bt cotton in India, published in the journal PNAS in 2012, showed that Bt cotton increased yields, profits, and living standards of smallholder farmers. However, recently cotton bollworm has been developing resistance to Bt cotton and the Indian Agriculture Ministry linked farmers' suicides in India to the declining performance of Bt cotton for the first time. Consequently, in 2012 the state of Maharashtra banned Bt cotton and ordered a socio-economic study of its use by independent institutes. Indian regulators cleared the Bt brinjal, a genetically modified eggplant, for commercialisation in October 2009. Following opposition from some scientists, farmers and environmental groups, a moratorium was imposed on its release in February 2010 "for as long as it is needed to establish public trust and confidence".

On 1 January 2013, a new law came into effect that required all packaged foods containing any genetically modified organisms to be labeled as such. The Legal Metrology (Packaged Commodities) Rules, 2011 states that "every package containing the genetically modified food shall bear at the top of its principal display panel the letters GM." The rules apply to 19 products including biscuits, breads, cereals and pulses, and a few others. [387] The law faced criticism from consumer rights activists as well as from the packaged food industry; both sides had major concerns that no logistical framework or regulations had been established to guide implementation and enforcement of the law [339][387]

See also

- Alter-globalization
- Environmental impact of agriculture
- Food sovereignty
- Genetic Roulette The Gamble of Our Lives
- Ice-minus bacteria
- Nayakrishi
- The Non-GMO Project

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External links

Pros and cons of GM food.

- TechCast Article Series, Whitney Tull, "Why Do People Fear or Accept Genetically Modified Foods?" (http://www.techcast.org/Upload/PDFs/060705165246TC%20GMF.pdf)
- Genetic Imperialism? (http://hdl.handle.net/10822/552560) from the Dean Peter Krogh Foreign Affairs Digital Archives (https://repository.library.georgetown.edu/handle/10822/552494)
- ORNL.gov (http://www.ornl.gov/sci/techresources/Human Genome/elsi/gmfood.shtml)
- Website Citizens To Label GMO Food (http://www.gmofoodlabel.org/) Information on GMO food labeling.
- FAO Agriculture Department (http://www.fao.org/ag/) and its SOFA report on Agricultural Biotechnology (http://www.fao.org/docrep/006/y5160e/y5160e00.HTM) addressing GM food safety
- GMO Compass (http://www.gmo-compass.org/) Information on the use of genetic engineering in the agri-food industry. Authorization database with all GM plants in the EU.
- GMO Safety (http://www.gmo-safety.eu/en/) Information about research projects on the biological safety of genetically modified plants.
- Database detailing all currently accepted GM crops (http://cera-gmc.org/index.php?action=gm_crop_database& mode=Synopsis)
- New Scientist article on GMO foods (http://www.newscientist.com/channel/life/gm-food/dn9921)
- The FDA List of Completed Consultations on Bioengineered Foods (http://www.cfsan.fda.gov /~lrd/biocon.html#list)
- Coextra research project on coexistence and tracebility of GM and non-GM supply chains (http://www.coextra.eu/)
- STEPS Centre Biotechnology Research Archive (http://www.steps-centre.org/ourresearch/gm.html)
- Controlling Our Food (http://video.google.com/videoplay?docid=6262083407501596844) a documentary film by

Marie-Monique Robin

- bEcon Economics literature about the impacts of genetically engineered (GE) crops in developing economies (http://www.mendeley.com/groups/1296883/becon)
- Plant Transformation Lab (http://www.oardc.ohio-state.edu/plantranslab/Default.htm)
- GMO Compass Information on genetically modified organisms (http://www.gmo-compass.org/) Authorization database with all GM plants in the EU.
- Co-Extra (http://www.coextra.eu) EU funded research project on co-existence and traceability of GM and non-GM crops. Development of new GMO detection methods.
- "GM Crops and Foods" conference (http://www.akademie-fresenius.de/1824) International conference on authorisation, co-existence and economic impacts 20 and 21 November 2006 (Germany)
- European biotechnology regulations (http://ec.europa.eu/food/food/biotechnology/index en.htm)
- International Council for Science (http://www.icsu.org/2 resourcecentre/Resource.php4?rub=8&id=40)
- [7] (http://civileats.com/2009/11/06/europe-moves-to-allow-import-of-three-varieties-of-genetically-modified-corn/) Civil Eats Europe Moves to Allow Import of Three Varieties of Genetically Modified Corn, Risking Contamination
- bEcon Economics literature about the impacts of genetically engineered (GE) crops in developing economies (http://www.mendeley.com/groups/1296883/becon)

Opponents

- Soil Association (http://92.52.112.178/web/sa/saweb.nsf/GetInvolved/geneng.html)
- Center for Food Safety (http://www.centerforfoodsafety.org/geneticall7.cfm)
- Greenpeace (http://www.greenpeace.org/usa/campaigns/genetic-engineering/ge-reports)
- Sierra Club (http://www.sierraclub.org/biotech/)

Advocates

- Council for Biotechnology Information (http://www.whybiotech.com/)
- AgBioWorld (http://www.agbioworld.org/)
- BioTech Now (http://biotech-now.org/)

Governmental

- German Federal Ministry of Education and Research (http://www.gmo-safety.eu/en/)
- UK Food Standards Agency (http://www.food.gov.uk/gmfoods/)
- European Food Safety Authority (http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812 1178621456978.htm)
- Government of Canada BioPortal (http://www.bioportal.gc.ca/english/BioPortalHome.asp?x=1)

Medical and scientific

- NIH National Library of Medicine (http://www.nlm.nih.gov/medlineplus/ency/article/002432.htm)
- Royal Society (http://royalsociety.org/landing.asp?id=1216)

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