CHALLENGE #8

GENETIC MODIFICATION

The geneology of an issue

1.0 Introduction[1]

An issue is a 'fiercely mounting matter, consisting of disputes that are subject to discussion and awaiting settlement' (Schoonman, in Van Tulder with van der Zwart, 2006:157). Issues can arise within every part or sector of a country or corporation, but are usually the result of a dispute between two different groups of stakeholders.

This paper identifies the major controversies surrounding the issue of genetic modification in three ways: by looking at the life-cycle of the technology, by considering how that creates specific issues in general, and finally how these issues are interpreted and approached differently around the world, thus leading to controversies not only between ethicists, scientists and managers, but also between policy makers. In this paper in particular the debate on genetically modified crops is the leading issue that has resulted in considerable controversy within and between the European Union and the United States. Using the issue life-cycle (Van Tulder with van der Zwart, 2006), the development of this debate is described. In the sections 1.4 to 1.6 the development of the issue in different parts of the world is described. First of all the GM debate in the United States is set forth. It is this country where modern biotechnology started and nowadays it is the main cultivator of GM crops. In section 1.5 the EU view and policy on genetic engineering is described, followed by the worldwide development (section 1.6).

Before proceeding to the growth of the GM issue, first the history of biotechnology is sketched, in order to understand what the technology of genetic engineering is exactly

[1] This issue dossier was written by Eva Oskam. It applies the 'issue life cycle' method that has been elaborated in chapter 9 of the IB-SM book (on issue management) in shows how various 'regimes' go through the life cycle at a different pace, which explain for the fact that they also might be considered 'rival' (as explained in chapter 13 of the book). Last updated: January 2008.

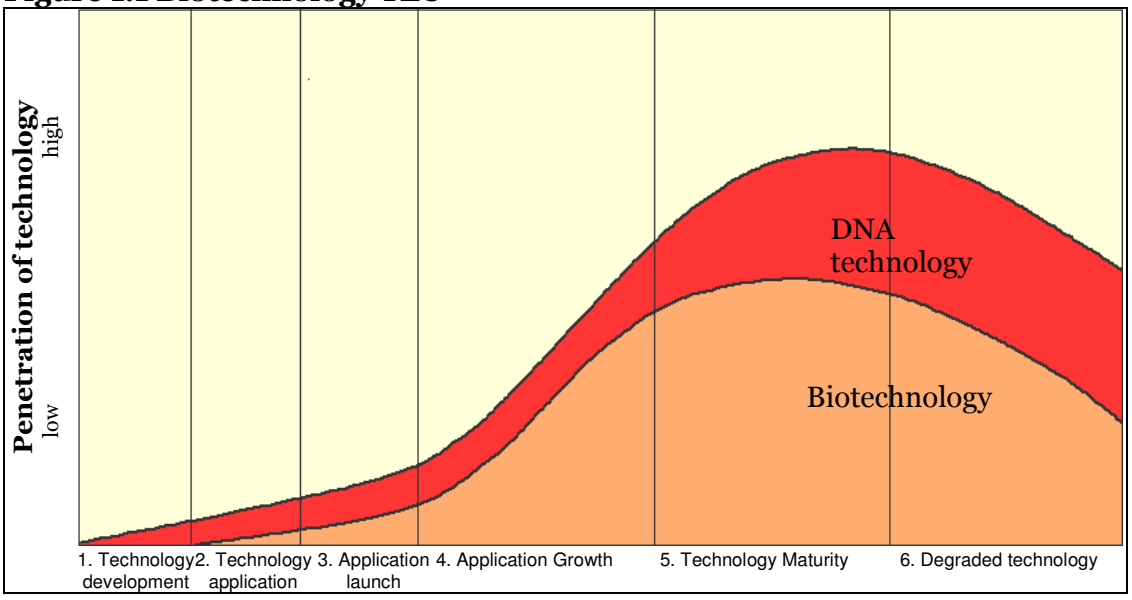
and what have been the key points in the development and application (diffusion) of the technology. In the next two sections the technology life-cycle (section 1.1) and its application to modern biotechnology (section 1.2), will deal with these questions.

1.1 TECHNOLOGY LIFE-CYCLE

The technology life-cycle (TLC)is as a model in which the phases of market penetration of a technology are portrayed. Figure 1.1 shows the entire TLC for biotechnology and DNA technology. This TLC, however, is also applied to most other technology areas such as information technology, new materials or – at the moment – nanotechnology and the like.

Moving from the general sketch of the technology life-cycle to the exact phases for modern biotechnology, requires that we try to establish the most important dates for this cycle. This is not always an easy task, because competing claims often lead to different time-frames. For intellectual property rights, for instance, the timing of an innovation can be highly disputed. This section, however, identifies those dates that are relatively undisputed and generally accepted as the benchmarks of biotechnology. Table 1.1 summarizes these benchmarks at two levels: (1) the more fundamental research (scientific development) and (2) applied research highlights (genetic engineering or modern biotechnology).

Figure 1.1 Biotechnology TLC



The life-cycle for modern biotechnology started in 1953, the year of the discovery of the genetic characteristics of DNA. The knowledge that an organism's traits are stored in DNA-strands, which are inheritable, opened up a wide range of future applications and possibilities. One of the applications of this technology was genetic engineering, also known as modern biotechnology. In modern biotechnology, parts of the DNA of one

organism are inserted into another organism in order to manipulate its characteristics. The start of the specific modern biotechnology cycle can be traced back to the year 1973. Twenty years after the start of DNA research, the break through in biotechnology was accomplished. For the first time researchers integrated an isolated part of DNA into another organism. (Van Tulder and Junne, 1988:12) Soon the world realized the possibilities of this technology for food and feed crops. The possibility to change a crop's traits opened up possibilities for enhanced nutritional value, extended shelf life, a better flavour and so on for a wide variety of crops. In the years after, much was invested into these areas of research, with a focus on those crops that were either easiest to manipulate or had the highest potential gains, the "selection environment".

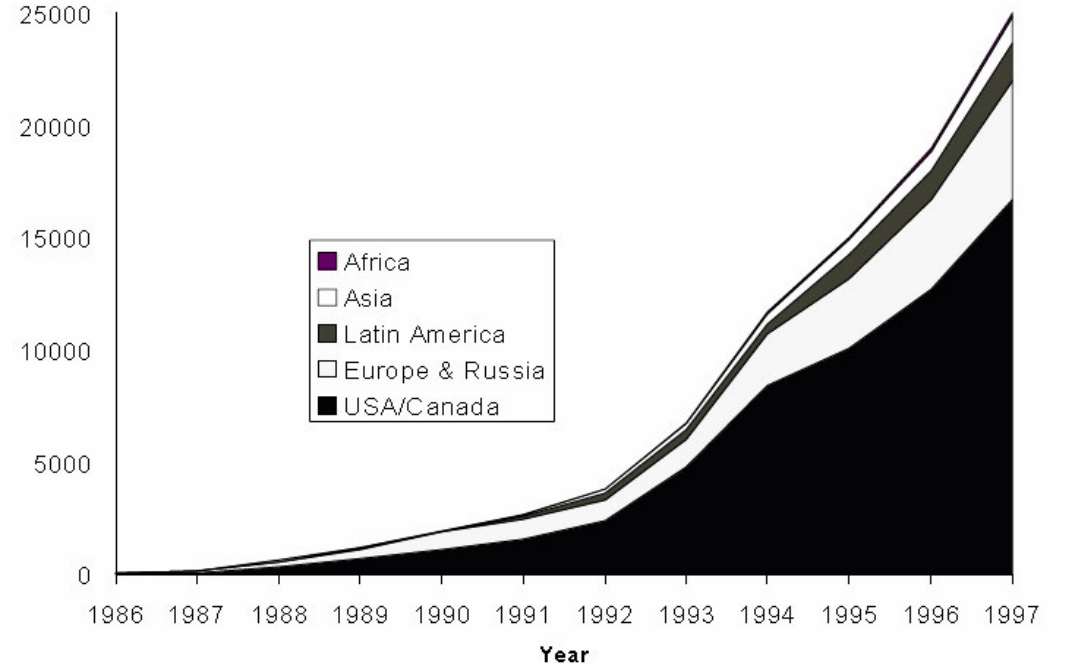
Table 1.1 The chronology of scientific and genetic engineering developments

Date	Scientific Developments	Genetic Engineering
1950s	**1953** Structure of DNA published **1957** Central paradigm postulated (DNA makes RNA makes protein)	
1960s	**1966** Genetic code deciphered	
1970s	**1970** Reverse transcriptase discovered in viruses (RNA makes DNA) **1977** Introns discovered – genes are not continuous in higher organisms but interdispersed with non-coding sequences.	**1973** Recombinant DNA technology – plant cloning
1980s	Techniques of "DNA fingerprinting" introduced to courtrooms.	**1983** First genetically modified plant – tobacco **1986** First field trials of GE crop-tobacco **1985** First release of GE organisms (bacteria)
1990s	**1990-1996** Interfering RNA discovered in several organisms – previously unrecognised properties of RNA now recognised as important. **1995** First full DNA sequence of an organism, a bacterium, published. **1996** Sequencing of the genomes of ancient organisms leads to a new kingdom in the classification of life, the Archaea	**1990** First genetically modified cereal **1994** The first GE food, Flavr Savr, the GE tomato produced by Calgene is approved by FDA. **1994** Roundup Ready soya approved for commercial planting. **1996** Roundup Ready soya and Bt maize commercially grown for the first time in US.
2000s	**2000** Sequence of first plant genome published, *Arabidopsis thaliana*. This is still the only plant genome whose sequence has been made public, although GE companies are thought to have privately sequenced several of the major crops. **2001** Draft sequence of the human genome published with far fewer genes than expected. This radically alters the understanding of how genes must function – a paradigm shift. The Central Dogma is now viewed as over-simplified – genes are subject to a control network. **2002** Landmark publication demonstrating a complex regulatory network of DNA functions in yeast, a simple, but multicellular, organism. **2002** small interfering RNAs named as a scientific highlight of the year. New insights into gene silencing and regulation of gene function.	**2004** First new approval of GM crops in EU

Source: based on Greenpeace, 2003 with additions by the author

Within ten years the first successful genetic modification of a crop was an established fact. In 1983, scientists created a tobacco variety resistant to herbicide, which three years later was the first GE crop to be released into the environment for field tests (James, 1996:7). In 1992, China was the first country to grow this crop commercially. Since then the range of genetically modified crops was extended to tomatoes, soya, maize, papaya, canola, potato. Figure 1.2 shows the growth in field tests of genetically modified crops. The slope of the total amount of tests indicates the transition from technology application to application launch, and even to application growth. After the first successful field tests in the early nineties it only took a couple of years until GM crops were introduced commercially in most developed countries. In May 1994, biotech company Calgene received approval to sell the GM FlavrSavr tomato on the US market. Within two years GM maize, cotton and soya varieties got commercial approval in most western countries too.
From the year 1996 onwards the dissemination of modern biotechnology took up a tremendous pace. Most of the new GM crops have become "zero tillage" and herbicide tolerant, which makes them very popular among farmers. From 1998 onwards the biotechnology line flattens. Biotechnology companies slow down their investments in GM research and the dissemination of products stalls. To what extent this development is caused by the ban on GM products in EU supermarkets, and the hesitation of developing countries to adopt the technology will be discussed in the next sections.

Figure 1.2 GM Crop Field Trial Sites Worldwide by Region, 1986-1997



Source: James (1998)

1.4 UNITED STATES' GM ISSUE LIFE-CYCLE

In 1986 the Co-ordinated Framework for Regulation of Biotechnology (CFR) specified the Animal and Plant Health Inspection Service (APHIS) of the United States Department of

Agriculture (USDA), the Environmental Protection Agency and the Food and Drug Agency (FDA) as the primary governmental agencies for regulating modern biotechnology in USA.
In that same year the 'Co-ordinated Framework for the Regulation of Biotechnology' was initiated which is still in use today (MacKenzie, 2000). According to this framework regulatory assessments had to be science, risk and case based. A crucial decision in this CFR was that no new and specific biotechnology regulation system was necessary.
The at-that-time-current laws, the Federal Plant Pest Act, the Federal Plant Quarantine Act and the Federal Insecticide, Fungicide and Rodenticide Act, provided adequate statutory authority for biotechnology regulation (MacKenzie, 2000). This decision implies that in USA the regulation focuses primarily on the characteristics of the product, rather than the way in which the product is produced. This product-based assessment is a major difference with the philosophy of regulation in, for example, the EU, which is process based. This process–product difference of philosophy has sparked considerable controversy over recent years.
This approach led the FDA, the agency responsible for determining food and feed safety, to develop an approach that substantially differs from the EU view on modern biotechnology. The FDA follows a decision tree safety assessment approach, based on the 'substantial equivalence' principle (FDA, 1992). If a product has similar health and nutritional characteristics as a similar product with an established history of safe use, a product is considered safe. In the case of genetically engineered crops these characteristics do not differ, hence all crops are easily accepted.
The rate of acceptance of GM crops in the United States is high. Since the introduction of the first U.S. commercially planted GM crop in 1994, the acreage planted with these crops has grown to almost 50 million hectares in 2005 (see table 1.2). For the main GM crops grown in the U.S. (soya, maize, cotton, and canola) the GM acreage accounted for about 60% of the total US acreage. (James, 2006)

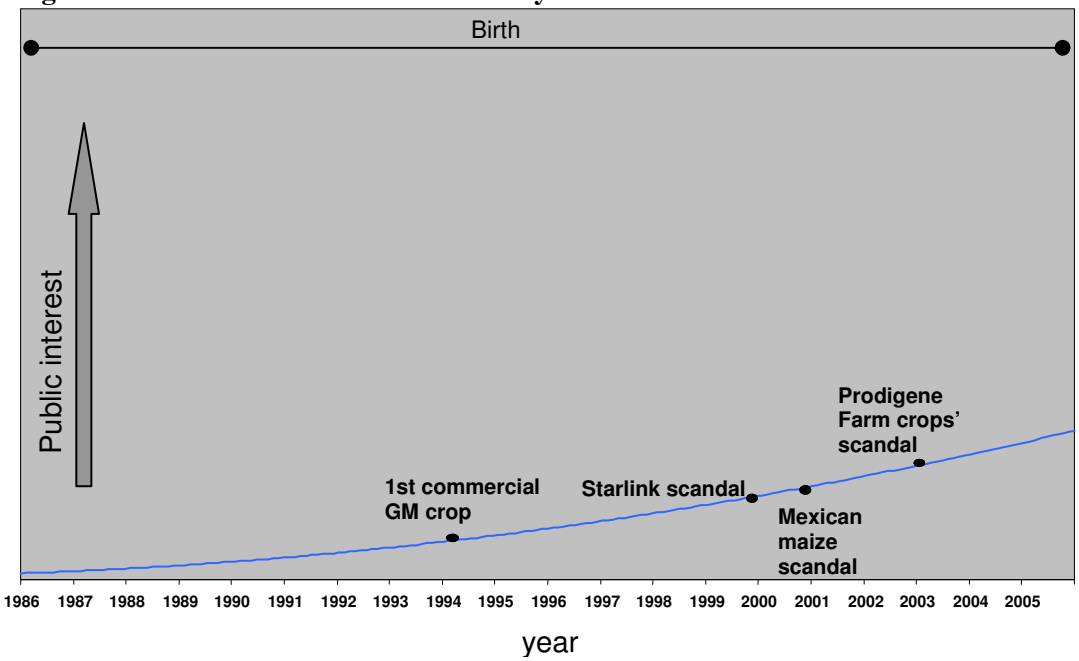
Table 1.2 GM Acreage in the United States 1996-2005 (mha)

Year	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
Hectares	1.5	8.1	20.5	28.7	30.3	35.7	39.0	42.8	47.6	49.8

Source: James (2006)

The U.S. system does not create much room for technological and/or even ethical controversy over genetic modification as a technological trajectory. However since 2000 the United States, Canada and Mexico (constituting the North American Free Trade Agreement) also experienced some GM scandals. It started with the Starlink scandal. This so-called maize variety is meant for animal feed production. In 2000 it turned out that part of the US maize production was contaminated with this variety due to crosspollination and was even sold for human consumption in some supermarkets. Due to this event NGO Friends of the Earth International (FOEI) started a campaign against the most visible supermarket in this scandal: Kraft Foods (for the campaign website see www.krafty.org).

Figure 1.3 United States GMO issue life-cycle



Also in 2000, Roundup Ready soya was found to have unintended additional fragments of the genetic insert. This problem was followed in 2001 by the Mexican maize scandal. The presence of transgenes in traditional races of maize was revealed, which was thought to have originated in maize exports from US. In the same year Roundup Ready Soya was found to have a region of unidentified DNA at one end of the genetic insert. In 2002 legal action was taken by organic farmers in Saskatchewan against GE companies – it is no longer possible to grow uncontaminated oilseed rape in Canada. In 2002, the US faced the Prodigene Farm crops' scandal. Millions of dollars worth of soya were destroyed in the US, because it may be contaminated with GE maize to produce drugs. These developments have certainly raised some public concern on the issue in the North American region – in a more widespread manner than before. They might have started up a modest of the issue-life-cycle in GMO, but certainly not resulted in widespread growth – let alone a clear development – of the issue life-cycle in the United States. See also the U.S. issue Life-cycle in figure 1.4. The protests by FOEI against Kraft Foods have come on a deadlock; after six years of campaigning Kraft hasn't changed its U.S. product range to GM free yet. And also the US government doesn't feel any need to change its policy towards GM crops; right now companies are still free to choose whether or not they want to label their product as Genetically Modified whilst for organic companies to label their product as "GM-free" the regulations are numerous and very strict.

1.5 EUROPEAN UNIONS' GM ISSUE LIFE-CYCLE

Public concern on GM technologies in Europe can be traced back to the introduction to the market of the first commercial GM crop in 1994 (see the EU issue life-cycle in figure 1.5). This crop was allowed to be sold according to the EU biotechnology directive from 1990. This directive on how to handle GMOs followed the existing national approaches by countries such as

Germany and Denmark. Here GMOs were managed according to the characteristics of the GM process. This represented a typical and unique European approach, especially compared to the United States' product-based. (Shaffer and Pollack, 2004:17)
In 1994 the Flavr tomato was planted in the United States, but it made it first to the market in the United Kingdom. In this country, supermarkets Safeway and Sainsbury started selling tomato paste from GM tomatoes in 1995, and the product was very popular. Due to a delayed ripening period the paste was substantially cheaper and by 1999 it even had a 60 percent market share. (GeoPie, 2006). Even though the tomato paste itself was popular, the GM tomatoes have never been grown in the EU. So far the only commercially grown GM crop in the EU is maize. However, compared to the United States, the market share is still very small. In 2005 only Spain, France, Portugal, Germany and the Czech Republic grew the 1997 BT maize variety, with a total acreage of 55000 hectares or a 0.5 percent market share.
It seems that in the early nineties the European public was enthusiastic to embrace the GM technology, yet table 1.3 displays a different picture.

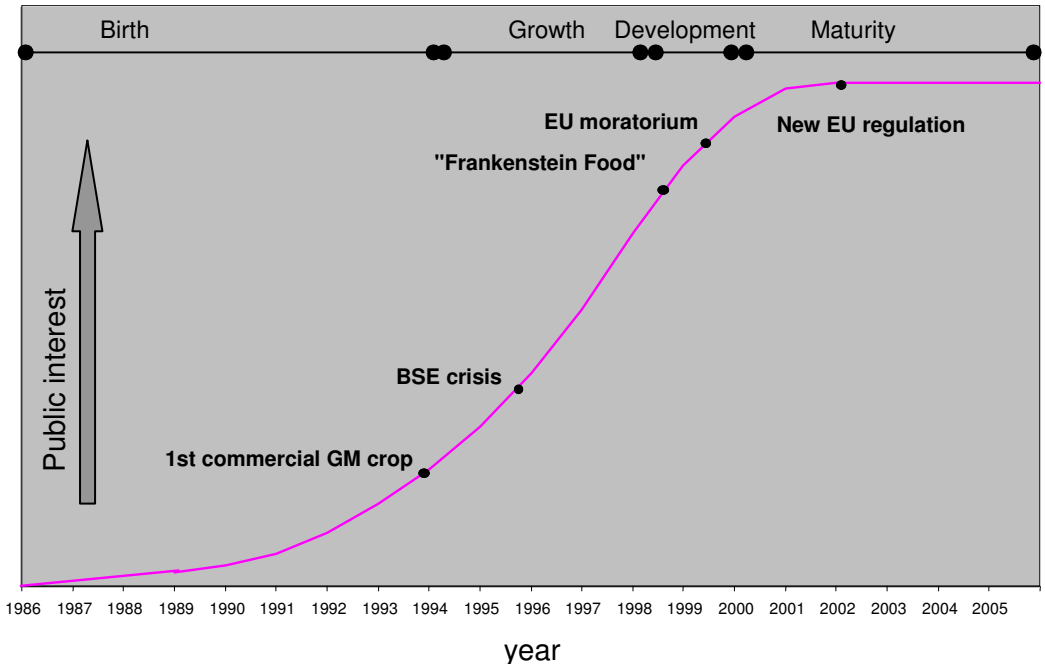
Table 1.3 Index of biotechnology optimism 1991-2005 for EU-15

Index score	1991	1993	1996	1999	2002	2005
Spain	82	78	67	61	71	75
Sweden			42		61	73
Portugal	50	77	67	50	57	71
Italy	65	65	54	21	43	65
Denmark	26	28	17	-1	23	56
Luxembourg	47	37	30	25	29	55
Ireland	68	54	40	16	26	53
United Kingdom	53	47	26	5	17	50
France	56	45	46	25	39	49
Netherlands	38	20	29	39	39	47
Belgium	53	42	44	29	40	46
Finland			24	13	31	36
Germany	42	17	17	23	24	33
Austria			-11	2	25	22
Greece	70	47	22	-33	12	19

Source: Gaskell et al, 2006

Already in 1991 there was a difference between countries in their attitude towards GMOs. However the real structural concern did not start until 1996. That year was a dramatic year for many European farmers; it was the year of the Bovine spongiform (BSE) syndrome outbreak. Thousands of cows got sick of the BSE, also known as the mad cow disease, and had to be killed. However, besides the farmers the European citizens were affected by the issue. For months the media wrote about new outbreaks of the disease, human beings being infected, and the governments seemed unable to stop it. It turned out to be a big blow for the public trust in their governments; It made one wonder to what extent the governments were able to guarantee their food safety.

Figure 1.4 European Union GMO issue life-cycle



The point of growth of the GM issue can be traced back to an article by Prince Charles on June 6th 1998. In the Daily Telegraph article he stated that "I happen to believe that this kind of genetic modification takes mankind into realms that belong to God, and to God alone". Then he continuous to explain how GM crops could possible harm nature and mankind, and why traditional breeding is as good an option to fight the hunger problem in the world as genetic modification (The Prince of Wales, 1998) Besides that, he was the first to address GMOs as "Frankenstein food", hereby giving the issue a popular name that is even used nowadays (Van Tulder with van der Zwart, 2006). The action by such a highly respected public figure triggered the interest of the British public for the GM issue that so far did not really seem to care. Although they had been warning for the effects of GMOs before that time, NGOs such as Greenpeace and Friend of the Earth could really pick up the issue. They started big public campaigns that were sometimes rather violent: many harvests were destroyed, supermarkets attacked.
Under pressure of consumer boycotts (of the threat of it), many large European retailers therefore decided to stop buying or selling GM foods. Major importers of soybeans, such as Unilever, stopped buying any U.S. soybeans, as the country was not able to segregate GM and non-GM crops (Ansell et al., 2000). Monsanto at that point started a campaign to promote GM products, but the campaign backfired. Instead of assuring the public of the safety of the products, it only made consumers aware of the genetically engineered components an increased their anxiety (Vogel, 2001).

Even though consumers were becoming more and more negative, the European Commission continued to allow the sale of new GM crops. Early 1997 BT maize was allowed onto the EU market. However, at that point all (14) EU member governments, except France, opposed the

decision. Due to the European decision making system, a crop could only be denied to the market if there was a unanimous veto.
As the crops could not be stopped on an EU level many governments decided to prohibit the crops from entering their country with national laws. The EU Directive 90/220 permitted a country to prohibit an approved GM variety in its territory if it had "justifiable reasons to consider that [the] product… constitutes a risk to human health or the environment" (European Parliament, 2001).
Then in June 1999, the governments of Denmark, France, Germany, Italy and Luxembourg announced the need for a moratorium. In their point of view the EU needed special GMO laws that ensured rules for labelling and traceability, and as long as that wasn't in place they would "take steps to have any new authorizations for growing and placing [of GMOs and GMO-derived products] on the market suspended" (Council of Ministers, 1999). Most of the other EU countries declared to take a precautionary approach and also not authorize "the placing on the market of any GMOs until it is demonstrated that there is no adverse effect on the environment and human health".

The combination of this "de facto" moratorium on GM crops, but also the supermarkets' changing stance towards biotechnology forced the EU commission to revise its policy. On February 2, 2000 the EU commission therefore issued the Precautionary Principle (Commission of the European Communities, 2000). This principle enabled the EU commission to take measures in case where the public might suffer severe harm and there is no scientific consensus. Or as summarized by Von Schomber (2006)

> "Where, following an assessment of available scientific information, there are reasonable grounds for concern for the possibility of adverse effects but scientific uncertainty persists, provisional risk management measures based on a broad cost/benefit analysis whereby priority will be given to human health and the environment, necessary to ensure the chosen high level of protection in the Community and proportionate to this level of protection, may be adopted, pending further scientific information for a more comprehensive risk assessment, without having to wait until the reality and seriousness of those adverse effects become fully apparent".

In March 2001 the European parliament came up with a new GM field trial law, followed by a GM Labelling and Traceability law in 2003, which went into force in April 2004 (European Parliament, 2003). These laws have opened the EU market again for new GM varieties. However so far only a handful of requests have been approved and they all concern the import of GM crops grown abroad. At this moment, the EU council discordant about allowing the first "live" GM crop into the EU since 1998; GM opponents are already preparing for a new round of GM controversy.

1.6 GLOBAL ISSUE DEVELOPMENT

North America and Europe have paved the way for the development and environmental release of GM crops. They have also defined the general framework for a regulatory system. The 1989 framework of the National Research Council (NRC) in USA was an early attempt to regulate the

application of GM technology in the field and still offers a good overview of concerns and regulatory issues (NRC, 1989). The 1993 OECD guidelines for industrial applications of GM organisms (OECD, 1993 a,b) resulted in an extended framework for evaluating the environmental impact of GM organisms and safety assessments for application of GM in food and feed. More recently, the Cartagena protocol on Biosafety helps to provide a more general framework for implementation in individual countries (SCBD, 2000).

The Cartagena protocol is the first legally binding international protocol for governing biosafety and GMOs. Even though negotiations for the protocol started as early as 1995, it wasn't until September 2003 before the protocol entered into force. This is primarily due to the difficulties all parties involved in the protocol encountered during the negotiations. Especially the grain-exporting countries feared that a strong protocol would act as a license to block GM crops. It was during these negotiations that the EU had already started to postpone decisions on new GM applications, and some of its member states enforced a moratorium.

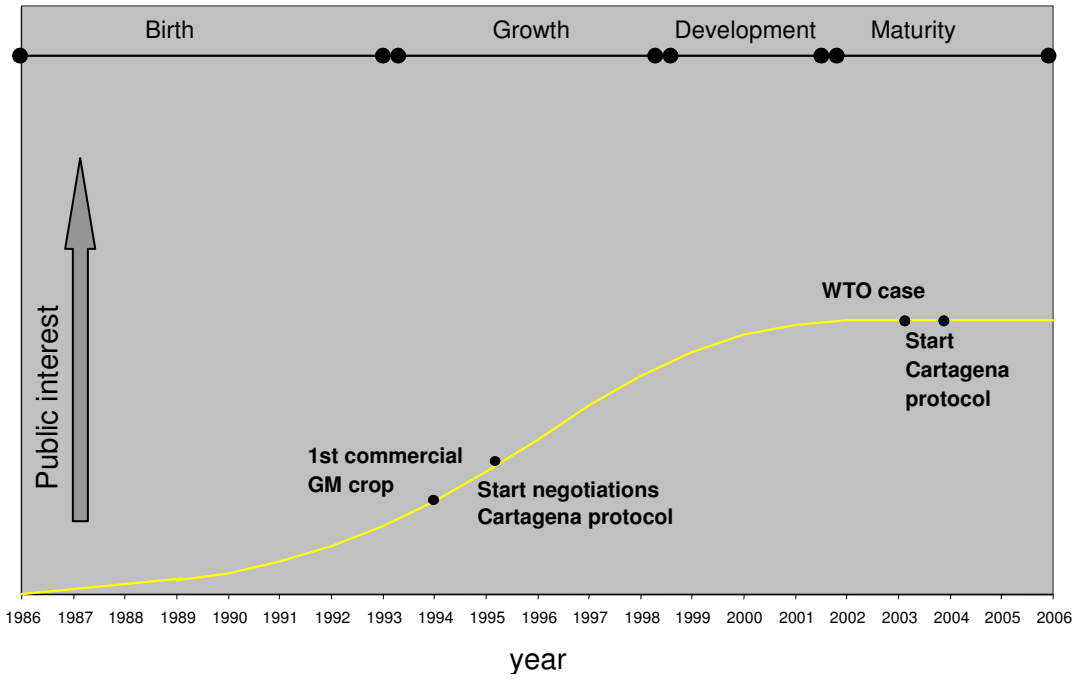
The most debated part of the Biosafety protocol is the Precautionary principle, which allows countries to take measures if it is scientifically unsure what the risks of a new GM technology or variety encompass. The difficulty here lies in the challenge to prove the GM variety is safe, especially when opponents are questioning long-term effects. The protocol entered into force in 2003, but the EU by that time already blocked new GM crops based on the precautionary principle. Fearing that other countries might use the Cartagena protocol in a similar manner, the main grain exporting countries United States (backed up by Argentina and Canada) therefore filed a complaint to the WTO half a year before the protocol entered into force.

Three-and-a–half year's later, in November 2006, the WTO finally ruled in this complicated case. It decided that the European Union broke trade rules with the GM block, and that by not approving GM products between 1998 and 2004, the EU was applying an effective moratorium, which constituted "undue delay" and violated trade rules. However, since the new EU directives from 2001 and 2002, formally the EU doesn't block GMOs anymore, and the WTO therefore didn't force the EU to change its current policy.

During the negotiations on the Cartagena protocol and the WTO case, most of the developed countries have picked sides in the GM debate. Outside the EU almost all countries seem to support genetic modification, except for Japan. In 2001 the country, which is the world's largest importer of agricultural products, put a ban on many GM products as the producers were unable to prove there safety.

The developing world however appears to be divided in its attitude towards GMOs.

Figure 1.5 World GMO issue life-cycle



1.7 CONCLUSION: DEFINING THE TIME-LINE FOR THE CONTROVERSY

This paper has applied the technology- and issue-life-cycle as tools to frame the dynamism of a particular controversy on the development and diffusion of modern biotechnology and GMOs. The result of this effort is that we can show the shape and timing of the issue life-cycle at four levels of analysis (see Figure 1.6):

1. the technology cycle – separated for fundamental and applied (engineering) research
2. the weakly sloped issue life-cycle for the United States, the country were most basic innovations in GMO were pioneered not in the least because the national regulatory and stakeholder environment was more receptive towards these technologies.
3. a much more sharp sloped issue life-cycle in Europe, particularly triggered by sentiments in the civil society and organized NGO, but also facilitated by a different regulatory approach to scientific progress. Whereas in Europe the issue more or less seems to be settled, in the United States there are indications that the issue is growing in importance.
4. an in-between issue life-cycle in the world that has been the result of in particular the controversy between Europe and the United States, and its dispute before the WTO and Cartagena protocol negotiations.

In addition the decisive moments in the GM debate have been distinguished.

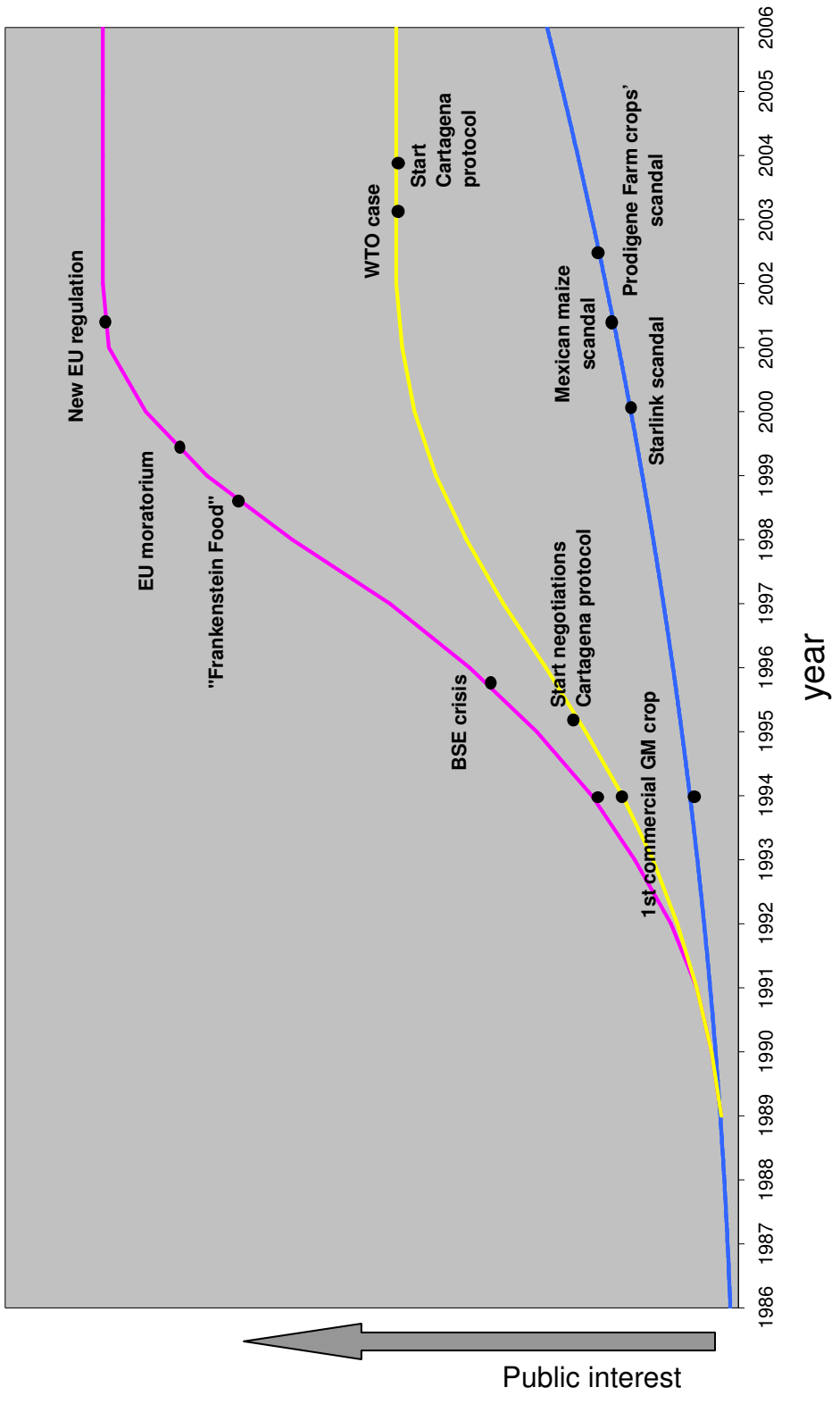


Figure 1.6 Overview GMO issue life-cycle

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