Biotech Mailout

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Friends of the Earth Europe

The genetic contamination of organic agriculture in Europe

On 21st December 2005, the European Commission presented a new draft EU Regulation for organic production and the labelling of organic products. In the accompanying press release, it announced that "P*roducts containing* GMO*s will not be able to be labelled as organic, except those containing up to* 0.9 *percent of* GMO *content through accidental contamination*."[1] This is the first time that the Commission has made their interpretation of the law so clear and it is likely to cause an outcry over the coming months.

According to Commission officials, the 0.9% contamination threshold of organics is already European law and the new proposed Regulation simply clarifies the situation. Officials claim that the 0.9% contamination threshold became law when the GM Food and Feed Regulation 1829/2003 came into force in 2003, claiming that the threshold for general contamination is applicable to both organic and non-organic products.[2]

Although the Commission gave the contamination threshold high priority in their press release, the draft Regulation does not mention it all except in its Explanatory Memorandum, where it states:

"I*n order to maintain consumer confidence, the use of* GMO*s and of products produced from or by* GMO*s should continue to be prohibited in organic farming, as it is the case in the current* Regulation. D*espite this, in cases where products have been accidentally contaminated by* GMO*s, the current organic rules do not prohibit the simultaneous labelling as organic and* GMO. A*s announced in the* EAP*, the proposal prohibits the use of the term 'organic' for* GMO *labelled products.* F*inally, the labelling thresholds for organic and non-organic produce should be identical, unless detailed rules foresee specific thresholds for example possibly for organic seeds*".

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The decision not to include anything specifically in the draft Regulation has apparently been made by their lawyers, who instructed the Commission not to repeat existing EU legislation in the new proposal, i.e. 1829/2003.

This position will have taken many by surprise, but the Commission's position is not new. In its co-existence recommendations of July 2003, it stated that: "F*uture labelling thresholds covering both food and feed are established in the* Regulation on GM F*ood and Feed*. T*hese labelling thresholds would apply to conventional and organic farming alike… The organic farming regulation does allow for the setting of a specific threshold for the unavoidable presence of* GMOs, *but no threshold has been set*. I*n the absence of such a specific threshold, the general thresholds apply*".[3]

Is the Commission correct?

There are different interpretations of EU law that question whether the Commission is right to say that the thresholds set in 1829/2003 are also applicable to organic products. A legal opinion commissioned by NGOs in the UK in January 2005 arrived at a different result. It concluded that: "W*e are firmly of the view, therefore, that the* O*rganic* R*egulation provides that, in order to be labelled or referred to as organic, a product must not contain* GMOs *or* GM *derivatives in whatever quantity.* I*t does not therefore permit of any threshold content* (*irrespective of whether or not such content is adventitious or technically unavoidable*)".[4]

There is therefore an urgent need to clarify the legal situation with regard to the Commission's position.

Setting contamination thresholds

Article 13 of the previous Organic Regulation 2092/91 (as amended) allows for thresholds to be set for unavoidable contamination:
"A*rticle* 13 - T*he following may be adopted in accordance with the procedure laid down in* Article 14:
… *implementation measures according to scientific evidence or technical progress to apply the prohibition on the use of* GMOs *and* GMOs *derivatives with regard, in particular, to a de minimis threshold for unavoidable contamination which shall not be exceeded*".

This clause appears to be excluded in the new draft Regulation, with the Commission deciding instead that the 0.9% already applies. Has their interpretation of the law taken away the right of Member States to decide the level of contamination? This is likely to be debated during the Austrian presidency.

Will consumers buy it?

There has been an extraordinary boom in organic shopping over the past 5 years. This has been partly down to the long list of food scares and the public's distrust of industrial farming. The threat of genetic modification has no doubt contributed to this attitude of consumers. The question is: would the public be so keen to spend more money on organic foods if they knew that they could contain GMOs (even if it were only a small amount caused accidentally)? The answer is almost certainly "no". The public is currently prepared to pay more for organic foods precisely because they do not contain residues of industrial farming, in particularly GMOs. If the contamination threshold is allowed, then this could mark the end of the organic boom.

Are thresholds sustainable?

Contamination is the Achilles heel of the GM industry. With their current products they cannot avoid it and the only way for them to achieve commercial success is when a certain amount of contamination in all foods is allowed. However, it is well-recognised that if commercial growing of

GM crops increases then the thresholds for food will have to be revised upwards. For example, back in 2001, the Scientific Committee on Plants was asked to give an opinion on the Commission's proposal for seed thresholds, which were set to meet the then 1% threshold in food (this threshold was lowered to 0.9% at a later date). The Committee concluded, however that: "*Achieving the* 0.3% *and the* 0.5% *thresholds will become increasingly difficult as* GM *crop production increases in* Europe. I*n due course the* 1% *threshold set by the Commission may have to be revised*".[5]

Therefore, if GM crops were to be grown on a larger scale, the threshold for organic production would also have to be increased. The current proposal is the thin end of the wedge. Accepting 0.9% contamination now may mean accepting a higher threshold when, or if, GM crops are planted over a larger area.

Unintentional presence or acceptable contamination?

The 0.9% threshold defined in Regulation 1829/2003 has been set only for the adventitious or technically unavoidable presence of GMOs. However, these terms have never been legally defined and this has led to various interpretations. For DG Agriculture, the threshold is seen as a permitted contamination threshold which farming has to meet in order to avoid the products being labelled as containing GMOs. This has become the clear position of the Commission. Under these interpretations, the 0.9% threshold for organics could therefore become more the norm then the exception.

Can organics and GMOs co-exist?

The debate over organic thresholds is likely to run into the simultaneous debate over coexistence. What level of protection is needed to ensure that organic production can continue without being threatened by contamination? The 2002 Joint Research Centre report on coexistence concluded that "*a* 0.1% *limit will be extremely difficult to meet for any farm-crop combination in the scenarios considered* (10% *and* 50% GMO*s in the region*), *even with significant changes in farming practices*".[6] This begs the question of whether GM crops should be grown at all if protecting other forms of agriculture will be "extremely difficult".

What next?

The proposal will be debated at the May Agriculture Council, and a decision is expected in June. A heated debate is, however, already brewing with a number of governments saying that the contamination is unacceptable.

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2 Personal communication with the Commission, January 2005.

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4 K.P.E.Lasok QC and Rebecca Haynes, "In the matter of co-existence, traceability and labelling of GMOs", 21st January 2005. http://www.foeeurope.org/GMOs/gmofree/Coexistence_Lasok_Advice.pdf

5 Opinion of the Scientific Committee on Plants concerning the adventitious presence of GM seeds in conventional seeds. (Opinion adopted by the Committee on 7th March 2001.)

6 Scenarios for co-existence of genetically modified, conventional and organic crops in European agriculture, a synthesis report prepared by Anne-Katrin Bock, Karine Lheureux, Monique Libeau-Dulos, Hans Nilsagård, Emilio Rodriguez-Cerezo (IPTS - JRC) in May 2002. www.jrc.cec.eu.int

Germany shifts biotech policy

Since November 2005, Germany has a new government, a grand coalition between the Conservatives and the Social Democrats, and a new coalition contract which announces a major shift in Germanys former biotech policy. The current German biotech law - in force since February 2005 and part of the implementation of the Deliberate Release Directive 2001/18 - will be amended. The aim of this amendment is to support the research and use of agro-biotechnology in Germany. It states that: "*The biotech law shall set the framework for further development and use of biotechnology in all areas of life and economy*".

Two concrete points are mentioned: To make the definitions of deliberate release and placing on the market more precise, and to pave the way for a compensation fund financed by all economic protagonists (which means GMO farmers and the seed industry). The compensation fund shall replace the current liability regime (see Biotech Mailout December 2004).

Definitions of deliberate release and placing on the market

The powerful German pro-GMO scientific community is pushing to delete the zero tolerance for genetic pollution caused by deliberate releases. Non-approved GMOs from field trials shall be legally permitted in small, undefined amounts in the harvest of neighbouring fields and, subsequently, in the conventional food and feed chain - of course without labelling. Last year, after a lot of pressure, the former German Consumer Protection and Agriculture Minister, Renate Künast (Greens), asked the EU Commission whether that point of view was in accordance with EU law. The answer from the Commission was that it is not. Currently, the new government is asking the same question again and obviously hopes for another, more positive, answer.

Compensation fund

The most controversial part of the biotech law in force is liability. This compensation scheme for economic damage means that all neighbouring farmers who might have caused cross-contamination are responsible for polluted harvests. If there are several GMO growers in a specific area and it cannot be determined exactly which one caused the damage, the non-GMO grower is free to decide which neighbour to claim compensation from. This legal construction will be replaced by a compensation fund. According to the coalition contract, the government will pave the way for a compensation fund financed by GMO farmers and the seed industry. The compensation fund shall grant compensation for non-GMO growers if it cannot be determined exactly which GMO grower caused the damage. In the long-term, the government is striving for an insurance-based solution.

The seed industry is currently bombarding the responsible Agriculture and Consumers Protection Ministry - now led by the conservative Christian Social Union's Horst Seehofer - with legal expert opinions to show why the government cannot force them to pay into the fund. The umbrella organisation of German insurance companies once again stated that it sees no way to insure economic damage caused by GMOs. The result is a brand new political constellation.

The Agriculture Minister and the powerful mainstream farmers association (Deutscher Bauernverband), both of which are very much in favour of GMOs, are extremely annoyed with Monsanto for not being prepared to pay into a fund. But the biotech industry is afraid of a precedent. In Germany, the powerful Federal Association of German Industry (Bundesverband der Deutschen Industrie BDI) is afraid that other polluting industries, such as the chemical industry, could be forced to pay for pollution from not clearly defined origins, and world-wide it would be a real challenge for biotech industry to explain why they pay compensation to German farmers but not to Canadian, US, Indian etc farmers.

The first negotiations between the government, seed industry, and the German farmers association are over and a new round started in January 2006, together with insurance companies. Press reports suggest that industry has proposed to "initially" finance a liability fund.[1] The question remains: what happens if there are no results? For the government it is clear - all economic damage suffered by non-GMO farmers shall be compensated (at least, in theory - at the moment, it is completely unclear how and whether the fund will work). So far, there has been no mention of the taxpayer having to pay. Questions to the EU Commission and negotiations have taken place behind closed doors.

Seehofer attacks organics and praises GMOs

In one of his first public announcements, the new Minister, Horst Seehofer (who, until 1998, was Health Minister under Helmut Kohl and already responsible for GMOs) promoted the virtues of GMO crops and attacked organic farming. The Social Democratic coalition partners immediately counter-attacked Seehofer and made objections in the media, stating that the Precautionary Principle, freedom of choice for consumers and farmers, and coexistence between all kinds of agriculture are part of the coalition contract. Therefore Seehofer's point of view is not secured through the coalition contract. Whether there is a serious disagreement or not is an open question at the moment. But at their party convention in November, the Social Democrats made clear that the Precautionary Principle to protect the public, and environment and consumer interests are much more important than economic interests, and that they will defend GMO- free agriculture and food production.

According to press reports, the German cabinet approved minor changes at the beginning of February, and are talking of a two way process. Because Germany has not yet fully implemented Directive 2001/18, the likely scenario is that the government and parliament agree to implement part II very soon (drafted under Künast but refused for ideological reasons through the former opposition which had the necessary blocking majority in the responsible second chamber of parliament, the Bundesrat) and take its time to change part I. The Commission has set a time limit until the end of March, after that Germany has to pay for non implementation.

In the meantime, Seehofer has given the green light to the first three types of GM maize ever listed on the German seed register. Since mid-December, Monsanto's YieldGard (Dc 3421 YG) and Pioneer Hi-Breed's (PR39V17 and PR38F71) Mon 810 seeds are authorised for general use and sale to German farmers. This means that 2006 will be the first year of commercial GMO growing in Germany but likely under the old law.

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Monsanto plans to dominate Europe

In November 2005, Monsanto announced to its investors that it aims to genetically modify all of Europe's maize over the next 4 years.[1] In addition, it is aiming to introduce 400,000 hectares of its GM soya beans.

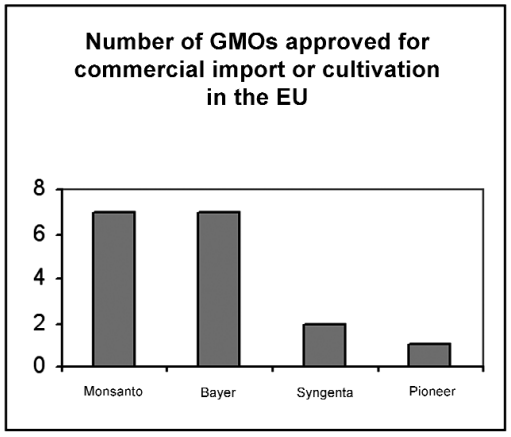
Monsanto currently has permission to grow only one type of insect-resistant maize in the EU. So how realistic are Monsanto's plans and should they be taken seriously, or laughed at? This article is an edited excerpt from a new report by Friends of the Earth International (www.foei.org) that looks at how Monsanto and its trade bodies have, over the past 10 years, consistently worked to weaken European laws to protect consumers, the environment and farmers, and the fact that, despite overwhelming public rejection in Europe, Monsanto and the biotech industry have an unacceptable influence over many parts of European food, research and agriculture policy.

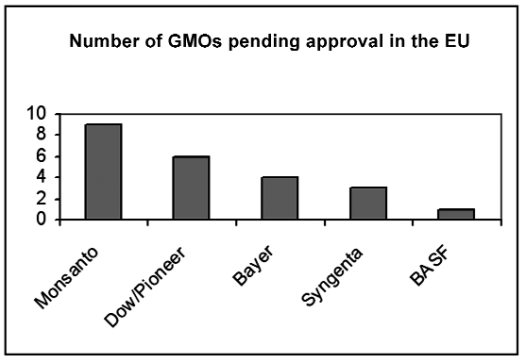
Monsanto in Europe

Europe's market leader

Despite its public image, Monsanto remains the leading applicant for GM foods and crops in Europe. The following graphs show how many products are so far permitted and how many applications are waiting in the pipeline.[2]

All of the food or feed crops approved so far, or pending approval, are genetically engineered either to tolerate broad-spectrum herbicides or insect attack. These products offer little, if any, benefit to either European farmers or the environment and no consumer benefit whatsoever. The GMO industry in Europe claims that genetic modification is: "*a tool for plant breeders developed over the past 30 years… It enables new crop varieties to be produced with desirable traits not achievable using longer-established methods*".[3] Despite the hype from the industry about its potential, it is remarkable that they can only bring two traits to the European market despite 30 years research.





Monsanto's influence

The impact of Monsanto's lobbying in Europe can be seen not from their public image but

from the success they have in influencing decision-makers. Despite overwhelming public objection, some national governments and the European Commission continue to support and push for GM foods and crops. This is no coincidence and shows the real impacts of industry lobbying.

The lobby groups

On GMOs, Monsanto works mainly in two European lobby groups - the European Association for Bioindustries (Europabio) and the European Seeds Association (ESA).

Europabio is the main lobby group for the GMO industry in Europe. As well as Monsanto, its other members include Bayer, Syngenta and Dow Chemicals. Although Europe has some of the most comprehensive GMO legislation in the world, the work of Europabio and its members has resulted in weaker standards than those demanded by the public. For example, during the debate over GMO labelling legislation, Europabio lobbied against a labelling threshold of 0.5% that was proposed by the European Parliament's Environment Committee. It argued that: "*Setting the labelling threshold at this level will prevent the use of innovative and beneficial biotechnology in food production in Europe*".[4] Its lobbying was successful and the labelling threshold was set at 0.9%, thereby allowing for a higher level of contamination of food.

Another contentious issue is liability. The industry continues to fight against a strict liability regime in Europe for GMOs. This becomes a key issue considering the lack of knowledge of the long-term effects of GMOs combined with the poor quality research submitted by industry. Europabio uses a wide range of arguments to attempt to avoid liability. During negotiations for EU-wide environmental liability legislation, Europabio argued against strict GMO liability, stating that: "*This would only result in more years of lost opportunity and outright disinvestment in European biotechnology. Protect the Environment - Don't Stigmatise* GMOs!".[5]

Europabio is now pushing the European institutions into supporting GMOs for the sake of "*growth, competitiveness and jobs*". In their current lobbying exercise, they even claim that GM crops will be good for the environment. One of their newest lobbying publications claims that: "*Today, agricultural biotechnology can help European farmers to grow crops more efficiently while providing sustainable options that can improve farmland, wildlife and diversity*".[6] The reality is vastly different. The most comprehensive environmental trials of GM crops ever done in the world were conducted in the UK over a four-year period, between 1999 and 2003.[7] Farmers grew GM crops alongside conventional crops and scientists examined the different impacts on wildlife on both crops. The GM crops were grown following agronomic guidance from the GMO industry. Of the four different GM crops tested, three were shown to have damaging effects on wildlife. Furthermore, follow-up research suggests that these effects are likely to persist for many years. Despite such comprehensive research and such clear results, the GMO industry chooses to ignore such inconvenient data.

Monsanto's other vehicle is the European Seeds Association. One of the most contentious GMO issues in Europe is the contamination of conventional seeds by GMOs. The ESA had, for a long time, lobbied for weak standards that would lead to widespread contamination of both agriculture

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and the environment. Within the current debate, the ESA reacted strongly to proposals from the Environment and Agriculture Commissions of the EU to put in place a threshold for maize seed contamination of 0.3%. ESA lobbies that the threshold for maize should be 0.5%, arguing that the 0.3% is: "*economically unsustainable and poses unnecessary additional costs on seed producers, farmers and consumers in the* EU".[8] GM Maize is the only crop grown commercially in Europe and any measures to reduce contamination are likely to have a big impact on the GMO industry, Monsanto in particular. The ESA also lobbied against a lower labelling threshold in food and "deplored" proposals for EU-wide co-existence measures.[9] In order to protect consumer and farmer choice for GMO-free food and farming, no GMO contamination should be allowed in seeds.

Monsanto's plans for Europe

Despite the clear opposition to GM foods and crops in Europe, Monsanto still attempts to persuade its investors that it will succeed in the European market. At its recent Investor Day, one of Monsanto's Vice Presidents made an extraordinary presentation, outlining ambitious plans for expanding Monsanto's global "genetic footprint" in Europe over the next five years.[10]

In other words, the company sees itself targeting the maize production of the whole of the European continent over the next four years. They also predict an annual increase in seed ownership on the European and African continents over a similar period, pointing out that they have increased seed ownership on the two continents by 4% over the past two years alone.

Barriers to Monsanto's expansion plans

European public opinion

Public opinion in Europe remains steadily opposed to GM foods. European polls show that 70% of the public do not want to eat GM foods and around 95% demand labelling in order to make a choice.[11] Some major European food retailers were the first to introduce and market GM foods. The first food product, a GM tomato purée, arrived on the shelves of the UK retailers Sainsbury's and Safeways in 1996. By 1999, however, they were no longer to be found. Public disquiet forced all the major manufacturers and retailers to remove GM ingredients, and in particular Monsanto's GM soya, from their foods. This position has not weakened and the market for GM foods in Europe remains dead ever since.

Table 1: Market Potential for Biotech Traits Highlights Continued Growth Opportunity

	Soybeans	Corn		
	Roundup Ready	Roundup Ready	Yieldguard borer	Yieldguard rootworm
Europe	1m acres (0.4m Ha)	24m acres (9.7m Ha)	8 m acres (3.2m Ha)	5 m acres (2m Ha)

Table 2: Global Breeding Programs Should Fuel Future Market Share Growth in Seed in Europe-Africa

2003	2004	2005
10%	12%	14%

National bans

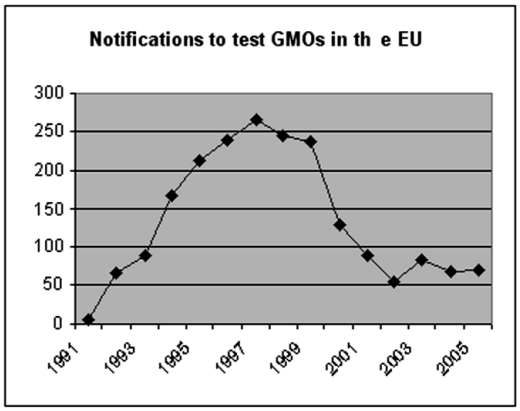
A growing number of EU countries have banned the import or cultivation of some GM products as outlined in the table below.

In June 2005, the Environment Ministers of all EU Member States voted on a proposal from the European Commission to lift these bans. The proposal was comprehensively defeated and the bans remain in place. This was the first time that the EU members have defeated the Commission on the issue of GM crops.[12]

Company	GMO	Banned in:
Syngenta	Bt176 maize	Austria, Germany, Luxembourg
Bayer	Topas oilseed rape	France, Greece
Bayer	MS1xRf1 oilseed rape	France
Bayer	T25 maize	Austria
Monsanto	MON810 maize	Austria, Greece, Poland, Hungary
Monsanto	GT73 oilseed rape	Austria

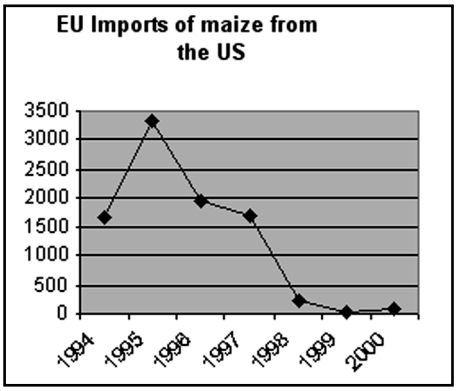
Test site applications plummet

In recent years, the number of applications to test GM crops in Europe has dramatically reduced. In 1997, the industry made over 260 notifications to test GM crops but, following public opposition, this has now withered to around 60 or 70 a year.[13] This is thought to have a major impact on future developments of GM crops in Europe.



No markets

The GMO industry in Europe, in its attempts to persuade us that we need GMOs, claims that: "*Agricultural subsidies are under pressure, European farmers continue to leave their land because they cannot make a living, other countries agricultural economies are experiencing rapid export growth and the economic and environment needs of rural development are increasing. It is necessary to adopt the modern technologies that the rest of the world has to face these challenges*".[14] It is highly questionable whether farmers in other countries are really experiencing "rapid export growth" as stated. The introduction of GMOs in North and South America has had a major effect on their agriculture trade with Europe. Countries such as Canada have lost virtually all of their export market of oilseed rape to Europe (replaced by Poland) since introducing GM oilseed rape. Similarly, the United States has lost its exports of maize (replaced by Argentina) over the same time period.[15]



GM-Free Europe

In 2004, the European Commission commercialised Monsanto's MON810 seeds, making them available to farmers across the whole of the EU.[16] Instead of allowing Monsanto to increase its "genetic footprint" in Europe, this decision has

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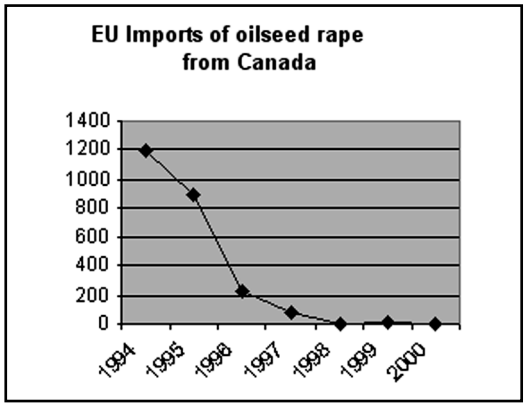

generated a new movement against the cultivation of Monsanto's GM crops. Not only have a number of countries introduced bans on either the GMO itself or the Monsanto seeds (see National Bans above), but a growing number of political regions and local governments have also declared themselves GM-Free. This dramatic development has ensured that in some countries, such as Greece or Poland, virtually every region has declared itself GM-free. There are currently 172 European regions and 4500 local government and smaller areas declaring themselves GM-free.[17]

Conclusion

Probably nowhere on Earth has seen more protests against the introduction of GM crops than Europe. The public is solidly against eating GM foods and a remarkable political movement against their cultivation is rapidly growing. Although Monsanto continues to believe it has a future in Europe, its prospects continue to look poor. No markets, more national bans and growing evidence of environmental damage ensure that one of the world's biggest markets will remain a disaster zone for Monsanto.

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Proposal for Hungarian Coexistence Legislation

On 9th November 2005, the Hungarian government passed the draft amendment of the Act on Gene Technologies (1998/XVII) incorporating a new chapter with coexistence rules. This move was preceded by a lengthy preparation process which goes back to late 2004. As a first step, the Ministry of Agriculture convened a special working group, composed of fellow state agencies, expert organisations such as the Chamber of Agriculture, the Seed Council and the Association of Plant Breeders, research institutions, organic growers, and also a representative of environmental NGOs.

During the first half of the year, the working group met every month, and its members were free to express their position and opinions, both in writing and in person. It soon became apparent during the debates that most participants - including those representing agriculture organisations - were in favour of strong coexistence rules and would rather keep GMOs out of the country. Not even the ministry itself leaned towards GMOs. Pressure came from an unexpected direction: the Minister for the Economy who, after his visit to the US, tried to convince his colleagues that biotechnology is the future of agriculture. Fortunately, agriculture officials did not bow to this pressure - at least until now - and thus, there was the opportunity to create good legislation.

The final version of a GMO law, now adopted by the government, while having some shortcomings, contains fairly strict and wide-ranging provisions. The core of the coexistence regulation itself is a two-step approval process. Farmers wishing to plant GMOs must have a diploma proving that they have the necessary knowledge to do so, and request permission from the competent authority for each planting. After receiving the request, the authority must seek the opinion of the Ministry of Environment and, based on that opinion, issue a preliminary approval which still does not entitle the farmer to start planting. In order to do that, he/she must obtain the agreement of all land owners and users within the isolation zone. In their declaration, neighbours must also undertake not to plant any sexually compatible varieties and can be prosecuted if they fail to fulfil this commitment. (Given the way land is distributed in Hungary, according to the ministry's calculations, in the case of a 6 hectare plot this may mean as many as 57 agreements!) If one neighbour refuses to make this declaration, the permit cannot be granted. Illegal activities or breaching the permit conditions can result in fines.

Permits will be valid for one planting season and the information will be made public by the competent authority. Even after planting, the farmer is obliged to keep GMO seeds and crops separately and to observe precautionary measures. The law would also oblige seed traders to check whether their buyers have planting permits, to keep records of their sales of GMO seeds, and to report them to the authority annually.

Detailed rules and isolation zones are not included in the law itself but will be regulated by a lower

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level Decree that has not yet been passed. It seems likely that the distances will be defined as twice the ones for seed production - e.g. 400 metres for maize, although the authority can also demand bigger separation zones as well. The weakest points of the legislation are liability and compensation since the proposal does not create any special mechanism, despite it being repeatedly demanded mainly by organic farmers. In its present form, the text only contains a reference to the Civil Code's provisions on hazardous facilities - thus, in case of contamination conventional farmers could only seek compensation in the court which tends to be a lengthy and expensive process. Officials argued that the establishment of a fund or obligation to take out insurance would cause serious legal problems under the Hungarian system. Nevertheless, even in the absence of any liability and compensation provisions, the Hungarian coexistence legislation, if adopted in its present form, will probably be among the more restrictive in Europe.

The legislative process continues now in Brussels, as the draft was submitted for notification which may take 3 months (and be prolonged by a further 3 in the event many comments are received). As general elections in Hungary are scheduled for next April/May, if the notification process is not finalised by very early 2006, Parliament will not be able to pass the law until after the summer holidays, potentially leaving farmers without protection for another year. Environmental and other interest groups are therefore hoping for a speedy and smooth notification process.

New GMO Law in Bulgaria

In spring 2005, the Bulgarian parliament adopted a new law on genetically modified organisms which came into force on 1st June 2005. The law concerns the use of GMOs under controlled conditions and the release into the environment. It was adopted by the parliament after long discussions among politicians, representatives of environmental NGOs and scientists. Thanks to the efforts of the AGROLINK Association and Za Zemiata (For the Earth), together with many other environmental NGOs, parliamentarians, political parties, scientists and citizens, the previous, very liberal draft of the law was quite radically amended.

The law which has now been adopted is mainly in line with EU legislation and in some parts even sets stricter conditions - changes that have been made possible by the pressure of environmental NGOs and civil society. The new law prohibits several important crops from being released into the environment in Bulgaria: tobacco, oil-yielding rose, grape vines, all vegetables and fruits, cotton and wheat. However, the door is open for the most common GM crops such as maize, soya and oilseed rape. Furthermore, the law falls short on several important issues - for instance, it does not deal with labelling requirements of processed GM products in order to provide consumer information.

Nevertheless, the environmental NGOs appreciate very much parliament's decision to safeguard protected areas in the National Ecological Network and their 30-kilometre surrounding belt, as well as organic farms and adjacent fields

against GM crops. In addition, the ban on the release of GMOs containing antibiotic-resistant marker genes is welcomed.

Activities for the first GM-free region in Bulgaria

The AGROLINK Association together with Za Zemiata and many other environmental NGOs are continuing their campaign for a GM-free Bulgaria. It is planned to declare parts of the Rhodope Mountains (Southern Bulgaria) a GM-free region in 2006, as a pilot GM-free zone in Bulgaria. This action will include an awareness-raising campaign with farmers, local authorities and the general public in this region. The project for "GM-free Rhodope" is financially supported by the Grassroots Foundation - Germany.

Currently, one of the major tasks is to ensure that the new GMO law is being implemented and to provide public information, as well as to monitor and influence further developments at the legislative level.

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Could GM foods cause allergies?

New research raises serious concerns about allergenicity testing of GM foods.

Scientists in Australia halted a ten year research project into a genetically modified pea after mice exposed to the pea developed an immune response, with allergic-type reactions.[1] The GM pea contained a protein naturally found in beans which protects them from pea weevils, and not previously associated with allergic reactions.

But when the gene producing the protein was transferred to peas, subtle changes were seen in the protein produced, and mice exposed to the pea suffered swelling and asthmatic-type reactions.

The research also demonstrated that when the mice were fed a common food allergen (egg white protein) at the same time as the GM peas, they developed an immune response to the egg white protein too, indicating that the new protein was priming the mice to react to other foods.

Inadequate testing

The findings have been spun by the biotech industry as a demonstration of the effectiveness of the regulatory system, as the effects were picked up prior to commercialisation.[2] But the reality is rather more sobering.

Friends of the Earth reviewed the testing carried out on currently approved GM foods in the EU, and examined the current guidance for allergenicity testing.[3] No currently approved GM

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foods in the EU have had sufficient testing to identify the kind of effect seen in the GM peas, and current allergenicity testing guidelines are not sufficient to pick up such effects in future approvals.

In almost all cases, the conclusions of 'no significant allergenic risk' were based on tests that would not have identified the immune effects found in the transgenic pea. These include comparisons to known allergens, digestibility studies and history of safe use.

The problem is not just that the testing was very basic - the methods themselves have also been criticised, for example:

- In most cases the tested protein was not produced by the GM plant, but was a 'surrogate' protein produced by GM bacteria. But the proteins may not behave in the same way.[4]
- Digestibility studies may not be adequate to assess allergenic potential,[5] and industry procedures may not use accurate simulations.[6]
- Only the proteins the plant was expected to produce were tested, not the whole plant, ignoring the possibility of unintended effects of the genetic modification process.

No tests using blood serum from allergenic patients or relevant animal testing were carried out for any of the GM foods. The 'cross-priming' effects seen in the GM pea research, where mice fed egg white protein and GM peas developed immune responses to the egg white too, were only considered for one approval, and it was not thought necessary to do any further tests. In essence, currently approved GM foods have not had sufficient testing to rule out negative impacts such as the immune responses seen in the transgenic pea.

EFSA's inadequacies

And nor will future GM foods - the current guidelines for allergenicity testing provided by the European Food Safety Authority (EFSA)[7] are simply inadequate for identifying this kind of impact. According to their guidance, if the source of the protein expressed by the GM plant is not considered allergenic, and shows no similarities to known allergens, only very basic testing, along similar lines to that discussed above, is required.

Yet the original guidance produced by the FAO/WHO Expert Consultation[8] was much stronger, requiring tests using blood serum from allergenic patients and animal testing in such cases. EFSA's predecessors[9] also required such testing. But EFSA has weakened the guidelines, and if the transgenic pea was assessed in this way it would probably be approved.

A new moratorium?

Allergic reactions affect only a small proportion of the population, but their consequences can be deadly. Yet current allergenicity testing for GM foods is simply inadequate - guidelines for testing urgently need to be improved.

But it is not a simple matter of repeating the tests used for the GM pea on all other GM foods. There is no validated and widely accepted animal model for allergenicity testing available,[10] and animal models do not reflect all aspects of food allergies in humans.[11] Further research is needed in the whole area of allergenicity - a fact apparently acknowledged by the UK's Food Standards Authority in their recent call for research into state of the art scientific techniques for identification of potential allergens in novel foods.[12]

Until there are validated and accepted methods for detection of potential allergenicity, there should be no further approvals of GM crops and foods, and existing approvals should be suspended.

There is also an urgent need to question the actual need for a new GM crop before testing even begins. The need for a novel product must justify both the ethical issues involved in its testing, as well as the intensive use of resources. Only when this can be justified should the full range of applicable tests be applied.

A full report of the review by Friends of the Earth will be available at www.foeeurope.org/gmos.

References:

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2 See, for example, CSIRO press release at http://www.csiro.au/csiro/content/standard/pssp,,.html

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11 Op cit viii

12 Food Standards Agency (2005). *Research Requirements Document, Issue 20: Requirements for Research and Surveys, December* 2005. http://food.gov.uk/multimedia/pdfs/rrd20.pdf

WTO GMO dispute: interim report leaked

Friends of the Earth has made the full text of the interim report of the WTO dispute on GMOs public. FoEE strongly condemns the WTO's lack of transparency and calls on governments to ensure that complex health and environmental decisions are taken in a transparent manner by bodies qualified to do so.

The report and a Friends of the Earth briefing can be downloaded at:
http://www.foeeurope.org/biteback/index.htm

Background[1]

The Interim report of the WTO panel on the GMO complaint brought by the US, Canada and Argentina against the EU was issued on February 7th[2] 2006.

This is a preliminary report and parties may ask for a review, after which a final report will be issued and made public. Unless a consensus at the WTO's Dispute Settlement Body rejects the final report, it becomes the Body's ruling or recommendation. Both sides can appeal the ruling, which would be heard by members of the standing Appellate Body. The appeal can uphold, modify or reverse the Panel's legal findings and conclusions. The Dispute Settlement Body has to accept or reject the appeals report, and rejection is only possible by consensus.

The losing party will then have to bring its policy into line with the ruling or recommendations. If complying with the recommendation immediately proves impractical, the member is given a "reasonable period of time" to do so. If it fails to act within this period, it has to enter into negotiations with the complaining country (or countries) to determine mutually-acceptable compensation. If after a certain period, no satisfactory compensation is agreed, the complaining side may ask the Dispute Settlement Body for permission to impose limited trade sanctions against the other side.

References:

1 Taken from a Third World Network commentary, February 10th 2006, http://www.twnside.org
2 WTO Case: "European Communities - Measures Affecting the Approval and Marketing of Biotech Products"

Friends of the Earth Europe (FoEE) campaigns for sustainable and fair societies and for the protection of the environment, unites more than 30 national organisations with thousands of local groups and is part of the world's largest grassroots environmental network, Friends of the Earth International. FoEE gratefully acknowledges EU funding support.

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If you wish to feedback on the articles in this edition of the Biotech Mailout or if you wish to receive a copy of the Biotech Mailout by email or in print email us at info@foeeurope.org

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