

Biotech Mailout

Information from the Biotechnology Programme of Friends of the Earth Europe

April 2004



**Friends of
the Earth
Europe**

HEINRICH
BÖLL
FOUNDATION

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Seeds of deception

EU Moratorium on GMOs may soon be lifted

But many hurdles for GMOs remain

It looks almost certain that Europe will soon approve the first new Genetically Modified (GM) food in over five years. The European Commission intends to force new GM foods into Europe by approving the import of a type of maize called Bt11 made by Syngenta. This is despite huge public opposition, almost total market rejection and scientific disagreement over its safety.

EU member states disagree on approvals of GMOs

To try and relieve the pressure stemming from the WTO dispute, the European Commission is trying to force through the commercial approvals (i.e. the approval to market, but not to grow) for the import of the GM maize called Bt11 (made by Syngenta) and the GM maize called NK603 (made by Monsanto)¹.

Many EU countries oppose their approval and there is no political or scientific agreement over their safety. If no consensus can be reached when EU states vote (through a "qualified majority"), the Commission has the power to make the decision. The Commission has stated that it will approve these GMOs if member states cannot reach consensus. In other words, regardless of the scientific disagreements over their safety the Commission will approve them on political grounds.

Concerns over the safety of GM foods

There remain serious differences of opinion in Europe over the safety of GM foods and crops. Scientists and Governments cannot agree over

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the long-term effects of either eating or growing GM crops. However some research has started to highlight that there may be problems. Research in the UK using human volunteers discovered that gut microflora had absorbed the GM DNA after just one meal².

This was unexpected and raises concerns about those crops that currently contain antibiotic resistant genes and whether this resistance will be spread to humans. In March 2004 the British Medical Association (BMA), which represents the majority of UK doctors, reiterated its call for more research, stating that there is "a lack of evidence-based research with regard to medium and long-term effects on health and the environment"³. (See for more information the statement by the BMA on page 6 of this Biotech Mailout)

Consumers don't want GMOs

The European public is largely against the approval of GM foods or crops. Any breaking of the moratorium will therefore be against the will of the people. Official opinion polls published by the European Commission show that 94.6% of EU citizens want the right to choose, 85.9% want to know more before eating GMOs, and 70.9% simply do not want GM food.⁴

The market has responded to the public's concerns and most large food manufacturers and retailers in Europe have removed GM ingredients from their products. This is the real moratorium and no matter how many GM foods the EU approves, the market remains virtually zero.

Lost Exports

The refusal of European consumers to eat GM foods has had a dramatic effect on GM exporting

countries that have seen their exports crash. For example, the export of maize from the US to Europe has declined from 3.3 million tonnes in 1995 to just 25,000 tonnes in 2002. Similarly Canada has lost all of its oilseed rape (canola) market to Europe since they introduced GM crops (worth an estimated \$300 million)⁶.

Companies in retreat

Over recent months the biotechnology industry has started to retreat from Europe. Not only are they testing less crops but they are also withdrawing future GM seed varieties. For example in the UK the industry has reduced the number of applications for GM seed varieties from over 50 down to just two⁶. In addition, in October 2003 Monsanto closed its wheat development centre in Europe, citing "*our lack of success in hybrids means this is no longer a good strategic fit for Monsanto*".⁷ Earlier this year Bayer reportedly sacked many of its GM managers in Europe and in March withdrew Chardon LL from the UK (its only commercial crop in that country) stating that it was "*economically non-viable*".⁸

Support for a GM Free Europe

The number of regions in the EU that want to ban the growing of GM crops is continually growing. In France over 1000 town mayors support GM free zones and in the UK over 44 regions have called for special protection in their areas. More than 500 cities in Italy have also taken a position against the use of GMOs in agriculture. As the number of GM free zones increases the likelihood of GM crops being grown in Europe on a large scale, diminishes.⁹

GMOs in the pipeline

Bt11

Bt 11 maize is made by the Swiss company Syngenta. It is very likely to be the first GM food to be approved after the more than five-year-old moratorium. On 28 January 2004 the European Commission gave the go-ahead for this sweet corn that has been genetically engineered to produce its own insecticide. The next step is that the Agricultural Ministers will vote on the Commission's decision to approve Bt11.

The vote is expected on 26 or 27 April 2004 in Luxembourg. If the Ministers do not reach a qualified majority in favour or against the approval, it is up to the Commission to decide. In that case the Commission needs to take another formal decision before the maize is approved. According to a Commission spokeswoman this will happen "in a matter of weeks". In the past, member states did not manage to reach an agreement over the safety of Bt 11. During a vote by an expert committee last November 2003 only 6 out of 15 EU member states supported the maize. Several member states raised serious questions over the safety of Bt 11, such as questions over whether the toxin produced by the corn will cause allergies.

For more details about Bt 11, see the Biotech Mailout of December 2003:

(<http://www.foeeurope.org/GMOs/publications>),

or go to the pending approval section on the website of Friends of the Earth Europe:

<http://www.foeeurope.org/GMOs/pending/index.htm>

NK603

The second GM food in the pipeline is Monsanto's NK603, which is also a type of maize. NK 603 has been genetically engineered to resist Monsanto's herbicide Roundup, in order to boost sales of that herbicide. The Commission has submitted its positive decision on NK603 to the Council of Ministers on 29 March 2004.

This means that the Ministers have some time until 29 June 2004 to approve or reject Monsanto's maize by a qualified majority. Like Bt 11, NK 603 is surrounded by controversy. On 18 February 2004 an expert committee of the EU member states failed to reach agreement over the safety of the maize. One of the problems identified by the member states was that required studies into the effects on subsequent generations, cumulative toxic effects and the effects on the health of sensitive consumers were not done.

For more details on NK 603 and the lack of safety testing, see page 4 of this Biotech Mailout.

REFERENCES

1. Source: 'European Commission regrets US decision', European Commission Press Release dated 13 May 2003.
2. Critiques of these and other GMOs can be found at:
<http://www.foeeurope.org/GMOs/pending/index.htm>
3. <http://www.bma.org.uk/ap.nsf/Content/GMFoods>
4. <http://www.bma.org.uk/ap.nsf/Content/GMFoods>
5. <http://europa.eu.int/comm/research/press/2001/pr0612en-report.pdf>
6. <http://www.defra.gov.uk/plant/pvs/pubreg/preg01.htm>
7. <http://www.guardian.co.uk/gmdebate/Story/0,2763,1064024,00.html>
8. <http://www.bcsbioscience.co.uk/>
9. For more information see <http://www.gmofree-europe.org>

Why the EU member states should not follow EFSA's opinion on Monsanto's GM maize

On 29 March 2004 the European Commission announced that it wants to approve Monsanto's Genetically Modified maize NK603. The Commission's decision was based on a positive opinion of the European Food Safety Authority (EFSA). Soon, ministers from all EU member states will have to vote on this maize. This article argues that ministers should not rely on the opinion of EFSA and should reject Monsanto's NK603 maize.

EFSA ignored risk assessment rules

EFSA's positive opinion on Monsanto's NK 603 maize is not based on a rigorous and independent safety testing; but relies on outdated scientific dogmas and information delivered by the notifier. Moreover, the authority did not take into account the Commission decision 2002/623/EC of 24 July 2002; which describes guidance for risk assessment of GMO's. According to this decision the overall uncertainty, assumptions and extrapolations made at various levels, as well as known limits of mitigation for each identified risk, have to be described in the risk assessment. EFSA has not followed this guidance and did not even mention the word "uncertainty".

Additionally the assessment of the long term effect and its effects on subsequent generations is required under Regulation (EC) No 178/2002

Article 14. However there has been no assessment of such effects. There are several uncertainties in the risk assessment of NK603 but EFSA has denied any risks by assumption-based reasoning (see details below). This clearly shows that EFSA disregards the precautionary principle as laid down in EU-directive 2001/18/EC.

Outdated models of risk assessment

In vitro (chemical test tube) digestion studies with the CP4 EPSPS protein of NK603 have been undertaken by Monsanto to prove the rapid degradation of the protein. However, in vitro digestion studies are questioned by several scientists, and have recently been proved to produce wrong results. The Bt-toxin is degraded in, in vitro within a few seconds to several minutes. In contrast feeding studies on real animals have shown that the Bt protein is astonishingly stable in the digestion system and could be detected in the whole gastro intestinal tract of pigs (CHOWDHURY et al., 2003). If the Bt protein survives in the gastro intestinal tract it can cause all kinds of chronic effects, such as distortion of the immune system.

EFSA ignored new scientific evidence

EFSA did not apparently undertake research of literature, to identify independent scientific studies, not financed or undertaken by Monsanto. How inadequate this is, is shown by

the case of Round up Ready Soybeans. In this case Monsanto and EFSA concluded a history of safe use on the basis of very limited studies by the company, whereas independent studies have found changes of nuclei of liver cells after 8 months of feeding tests with rats (MALATESTA et al. 2002). The consequences of these phenomena are unclear. Changes of nuclei are an indication for precancerous status of cells (Backman, 2000 5701 /id).

Effects of RNA/DNA to human health

John S. MATTICK Director of Institute of Molecular Bioscience, University Queensland (Australia) (see GIBBS 2003): "The failure to recognise the importance of RNA produced by non coding regions of DNA (introns, RNA genes, pseudogenes etc.) may well go down as one of the biggest mistakes in the history of risk assessment of transgenic plants."

To make a protein, the DNA uses its unique genetic code to write a prescription for its chief assistant, RNA. The role of RNA has long been underestimated in science and the risk assessment of transgenic plants. Proteins have been the main research in nutrition science. For a long time the dogma had been that food DNA is fully degraded in the organisms. But this dogma has been proved wrong. For example: research from EINSPIER et al. (2001) shows that parts of genes from maize genome are found in blood lymphocytes of cows when fed with maize.

Lymphocytes play a key function in the immune system (natural killer cells) of mammals. DNA/RNA from food/feed seems to have a bigger role in the immune system than previously thought. EFSA did not address any effects of

NK603 associated with the immune system, derived from interaction of proteins, DNA or RNA-family (riboswitches, microRNA, intergenic DNA).

Conclusion

In general, the application by Monsanto and the corresponding opinions by EFSA are of a questionable scientific standard. The general approach is that of 'no evidence equating with no harm'. This approach has been widely rejected as being inappropriate to the risk assessment of GMOs. For example, the USA's National Academy of Science commenting on the use of the phrase by regulators in the USA, the Academy emphasised how little it told people (NAS 2002): "The term 'no evidence' can mean either that no one has looked for evidence or that the evidence provides contrary evidence. Lack of evidence is not typically useful in making regulatory decisions about risk" (p10).

Furthermore EFSA has provided a very limited range of references. The assessment of toxicity of the whole food of NK603 maize is based on one single test. Neither this test, nor assumptions made interpreting the observed differences are cited by any reference.

It seems that EFSA's aim was to submit a positive opinion in any case. EFSA disregarded uncertainties and denied chronic risk without any testing. EFSA has missed science and instead argued like industry. It is up to the Ministers to ask EFSA clearly how chronic toxic effects - whether by proteins, RNA or other elements - are addressed in the risk assessment of NK603. It is not the job of EFSA to deny chronic risk but to assess them.

British doctors: lack of research on safety of GMOs

In March 2004 the British Medical Association (BMA) published its second interim statement on genetically modified foods and health. The BMA unites 80% of British doctors and is officially recognised by the UK government. The association has continually raised concerns over GM foods for many years. For example, it produced an interim report in 1999 on the health implications of GM food crops.

In June 2003 the BMA organised a round table meeting of experts and have recently reviewed the emerging evidence. Here are the most important passages from the recent BMA interim statement that are the results of these activities:

The need for further research

A great deal of research, of varying quality, has been conducted since 1999 in the arena of genetic modification of food. However, many unanswered questions still remain, particularly with regard to the potential long-term impact of GM foods on human health and on the environment. The few robust studies that have looked for health effects have been short-term and specific. There is a lack of evidence-based research with regard to medium and long-term effects on health and the environment.

The BMA has identified several areas where we believe more research is needed:

Allergens:

While we are not aware of any evidence that existing GM foods cause allergic reactions, it remains possible that any new food products could elicit new allergies.

Nutritional status:

GM foods could conceivably have different effects on those of poor nutritional status and/or those belonging to 'vulnerable groups' (notably the foetus, infants, children, pregnant and lactating women, the elderly and those with chronic disease) when compared with healthy individuals.

Genetic transfer:

While gene transfer has been observed in the gastrointestinal tract of some mammals and birds, there is still great uncertainty as to the extent and the consequences of this transfer. (...) Research is needed to assess whether transfer of DNA from GM food is more likely to occur as it contains additional material used to assist insertion of the GM DNA in the first place.

Environmental impact:

Major concerns still surround the use of herbicides with GM crops and their effect on the environment. Recent UK Farm Scale Evaluations of GM herbicide-tolerant crops (GMHT) indicate that if GMHT beet and spring oilseed rape were

introduced and managed as they were in the trial, a significant reduction would be expected in weed biomass and weed seed return. This would result in fewer nectar resources for pollinators and fewer weed seed resources for granivorous birds. (...)

The potential to create 'super weeds' also gives rise to concern. Canadian farmers found that their fields filled with stray GM crop plants known

as 'volunteers' were resistant, not only to the substance against which the main crop was engineered, but to the other two herbicides used as well. It is possible that such 'volunteers' could turn into ineradicable weeds.

Access to the full interim statement of the BMA can be obtained via:

<http://www.bma.org.uk/ap.nsf/Content/GMFoods>

German draft biotech law offers no guarantees

On 11 February 2004 the German government adopted the draft of a new biotech law aimed at the transposition of 2001/18/EG into German law. The draft is a compromise within the (biotech-critical) Green- (pro-biotech-) Socialist-Coalition. Prior to its final adoption it has to be passed by the Bundestag - the parliament and the Bundesrat, the conservative and liberal dominated second legislative chamber.

What this means is that a conciliation procedure is required, which is expected after the parliamentary summer break. Whether there will be improvements or a watering down depends on the public pressure environmental groups, farmers and consumers' organisations will exert on the big coalition of very GMO-friendly politicians. The present version does not guarantee the protection of GMO-free agriculture and food production. The most critical points are:

Coexistence rules only announced'

The draft only announces that there will be coexistence rules and refers to an outstanding regulation no one has seen till now. It formulates general guidelines according to the cause principle: measures securing GMO-free agriculture and food production have to be taken by the GMO-users. Therefore those who are placing GMOs on the market - biotech companies, GMO-seed and feed dealers and farmers who grow GMOs have to take care not to contaminate the GMO-free production.

Access to public registers to be limited²

Only general information shall be accessible to the public: the name of the GMO, its traits, name and postal code of the community where it is grown and the dimension of the area. People who want to know where exactly a GMO-field is will have to prove a "justified interest".

A "justified interest" per definitionem can only cover a specific group: neighbouring farmers and landowners. But even if the authorities accept a "justified interest" it is not sure if one will receive the information. GMO-growers can make a special application for exclusion of information - they can demand a so called "protection interest" which remains undefined. At any rate: there is no obligation foreseen for GMO-farmers to inform their neighbours. This means the non-GMO growers have to investigate the location of GMO-fields and this information - if available - probably will not be free of charge.

Liability problem not solved³

The draft defines GMO-contamination as "essential reduction of value". Therefore the polluted farmers who either cannot sell their harvests or can sell it only with a GMO-label can claim financial compensation. If it is not possible to identify who caused the contamination, all farmers in the area, who have grown that detected GMO, are liable for the economic damage of the non GMO-farmer.

- 1. Article 16c
- 2. Article 16a
- 3. Article 36a

Sounds good in theory but is complicated in practise: the contaminated farmer has to carry the burden of proof. He has to do the testing and pay for it, he has to investigate - with the help of the public register - who has caused the contamination and he has to pay for the trial. It is likely that he will suffer problems with his image - which can cost him his economic existence; it is open whether he will be compensated because it is possible that he has to go through all the courts. Last but not least he will experience a lot of stress with his neighbours.

Due to the fact that there are many open questions and the unfavourable political situation BUND (Friends of the Earth Germany) supports GMO-free regions: For more (German) information see the website:

<http://www.faire-nachbarschaft.de>

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New Swiss GM legislation stricter than EU law

On 1 January 2004 a new law on Genetically Modified Organisms (GMOs) entered into force in Switzerland. The law is based on the precautionary and the 'polluter pays' principle (Article 1) and aims to protect health and security of human beings, animals and the environment. It also aims to permanently maintain biological diversity and fertility of the soil and to allow freedom of choice for consumers.

On several aspects the law is stricter than current EU legislation:

- Liability: Contrary to EU law the Swiss law clearly states that anyone who causes measures to be taken under the provisions of the law shall bear the costs (Article 2.2.) and that these measures include "necessary and reasonable measures that are taken to restore destroyed or damaged items of the environment" (Article 31).

In the EU liability for damage caused by Genetically Modified Organisms (GMOs) is much more limited. For example, liability for damage to the environment is restricted to areas with a special protection status, which means that only 10 -15% of the EU's territory is covered. Moreover, the EU Environmental Liability Directive contains a so-called "state-of-the art-defence", which means that a GMO operator is not liable for any damage that could not be foreseen according to the available scientific knowledge at the time of the approval. In contrast the Swiss law states in Article 30.4 that the person responsible for obtaining authorisation "shall also be liable for all

defects that could not be foreseen according to scientific and technical knowledge at the time of the placing on the market."

- Dispersal of GMOs in the environment: Under EU law, once a GMO has received an authorisation, there are no further restrictions on its dissemination, unless a Member State takes measures to avoid the unintended presence of GMOs in other products, this is according to Article 26a of Directive 2001/18 (the so called "co-existence article"). However, Member States are not obliged to take such co-existence measures, since the Directive only says that the Member States may take measures.

In contrast, the Swiss law states that Genetically Modified Organisms (GMOs) destined for use in the environment may only be placed on the market if it has been shown - by contained use experiments or experimental releases - that they do "not disperse in the environment" (Article 3). Also, GMOs may only be released for experimental purposes if "according to scientific knowledge a dispersal of these organisms or their transgenic properties can be excluded."

Friends of the Earth believes that the new Swiss law clearly demonstrates that it is possible to considerably improve the EU's regulatory framework on GMOs, notably in the areas of liability and the prevention of genetic pollution. For the full text of the Swiss law (in German only), see: <http://www.admin.ch/ch/d/ff/2003/2778.pdf>

UK ministers to promote biotech industry in the EU

Leaked minutes of a top-level meeting of UK Ministers reveal that the British Government is to embark on a strategy to promote the biotechnology industry in Europe. Key to its tactics will be to ensure that ethical issues of healthcare products are dealt with by national governments and not by the EU.

The minutes recorded that the EU was slipping behind the US due in part "to a comparatively cumbersome regulatory regime and the EU's treatment of ethical issues." Furthermore, the Ministers stated that "careful handling of healthcare and ethics was needed, as raising such issues in the EU could be counterproductive...At a Government level, the UK had few supporters on key issues such as clinical trials, stem cells and tissues. Germany would not be an ally, and many MEPs were opposed. The UK had more in common with scientific and patient organisations than member states."

The minutes also make it clear that they do not foresee European enlargement to be a positive move in this area, "...it was important to avoid extending EU competence on ethical issues, particularly given that the prevailing mood was likely to become more hostile following enlargement on 1 May".

De-regulating pharmaceuticals

The UK Government ministers made it clear that they favour less regulations for the pharmaceuti-

cal industry in biotechnology and seem prepared to work with the industry lobby groups. Their minutes stated that, "finance and industry ministries might work together to promote a lighter regulatory framework for the pharmaceutical industry. The European Medicine Authority might be receptive to such suggestions, although enlargement would mean slow progress."

Lobbying Heads of States

The UK's Science Minister Lord Sainsbury, who is one of Labours biggest financial donors and before becoming a Minister invested heavily in the biotechnology industry, will be key to the strategy. The minutes state that he will be personally lobbying Tony Blair. One of their tasks will apparently be to steer Heads of Governments away from the views of their Health Ministers. "Health Ministers were focused more on reducing drug costs than taking a strategic view of the pharmaceutical industry. A steer in the opposite direction from Heads of Governments might pay dividends. The UK could push for language in the European Council conclusions, perhaps with the ground prepared through the forthcoming trilateral with France and Germany."

Informing the public

Many supporters of biotechnology burnt their fingers over the introduction, and subsequent rejection, by the public over GM foods. With other forms of biotechnology the UK should "make better use of existing EU structures, lobby MEPs

more effectively and make early progress on informing public perception of biotechnology, which would be an uphill task... Making the public aware of clearly beneficial aspects of biotechnology, such as biopharmaceuticals, could be a useful way of creating a rational environment

for debate on the more controversial aspects." You have been warned!

See the full text of the leaked minutes on: <http://www.foeeurope.org/GMOs/Index.htm>

Biosafety Protocol - a good first step

During the last week of February 2004 the First Meeting of the Parties (MOPI) to the Cartagena Protocol on Biosafety took place in Kuala Lumpur, Malaysia. The UN agreement on Genetically Modified Organisms (GMOs) was adopted in January 2000, and entered into force on 11 September 2003. Currently, 87 countries - mainly developing countries - are parties to the Treaty.

During the meeting in Kuala Lumpur key decisions were made in the following areas:

1. Liability

Significant progress was made towards elaborating an international liability and redress regime for damage from transboundary movements of GMOs. The MOP 1 adopted a decision to create an "Ad hoc Working Group of Experts" in order to propose rules and procedures in the field of liability and redress, which shall be completed by 2007.

The terms of reference

During the negotiations of the Biosafety Protocol

between 1996 and 2000, the majority of Developing Countries constantly expressed their desire to have strong provisions on liability and redress within the Cartagena Protocol. At the end of the negotiations and for the sake of compromise they had to agree on an enabling clause, Article 27, which would not establish liability rules for GMO damage, but would enable a process to build such rules.

The development of a system for liability and redress is foreseen in the Protocol and has to be established within four years after the first MOP. Weak terms of reference would have prevented the creation of a strong liability regime. After an initial round of country views on the topic of Liability and Redress, a draft terms of reference for the Working Group on liability and redress was circulated to all delegations. The first draft had a very vague wording, and failed to guarantee a clear mandate and outcome for the Working Group. This was underlined by several delegations at the meeting such as Ethiopia, Colombia, Mexico, Malaysia, among others.

Securing a strong mandate

After a round of views on the draft terms of reference presented by the Chairman, it was decided to create a small group of "Friends of the Chair" composed of the EU, Ethiopia, Malaysia, Colombia and Cameroon. The EU did not oppose the principle of elaborating a liability regime under the Protocol, but showed a preference towards having a text with vague wording and without concrete and clear commitments.

Despite this developing countries, led by Ethiopia, Malaysia and Colombia, made it very clear that they wanted a strong and clear mandate that would allow the Working group to complete its work by 2007. Those countries reminded the EU delegates that from the very beginning of the negotiations of the Biosafety Protocol Southern countries always advocated for a legally binding international regime on liability and redress, but for the sake of compromise they had to accept the enabling provision of Article 27 of the Protocol, which would not create a regime, but simply enable a process to further elaborate such regime.

By making clear that Southern countries did not want more delays on this topic the Working Group ended by having a clear mandate to work on the appropriate liability process and rules. The text adopted was very clear: "The Ad Hoc Group on Liability and Redress shall complete its work in 2007 in order to enable the Conference of the Parties serving as the meeting of the Parties to the Protocol to fulfil the requirements under Article 27 of the Protocol". During the adoption of this text, the US had strong objections, but as a non-Party their demands were not taken into consideration by the chair.

2. Systems of identification for GMOs

Under the Biosafety Protocol, Living Modified Organisms (LMOs) which are intended for intentional introduction into the environment have to be clearly identified as LMOs, for example seeds. On the other hand GM commodities or Living Modified Organisms for Food, Feed and Processing (LMOs-FFP in the terminology of the CPB) will only have to be identified as "may contain" LMOs. During the MOP 1 the most difficult issue to negotiate among delegations was LMOs-FFP.

LMOs-FFP

GM commodities or LMOs-FFP constitute more than 90% of Genetically Modified products traded today. It is therefore not surprising that GM producing countries oppose strict systems of identification and labelling, and why the discussion on identification was one of the most contentious issues at MOP

In preparatory meetings and other technical meetings on these issues, no agreement was reached on the detailed requirements of the documentation accompanying LMOs-FFP. The MOP1 had to decide on the detailed requirements of the documentation accompanying LMOs intended for direct use as food or feed, or food processing, including specification of their identity and any unique identification, no later than two years after the date of entry into force of the Protocol.

In the end - after heated discussions - a decision was adopted that affirms that all LMOs-FFP should be clearly identified as may contain LMOs. It should also be stated that they are not intended for deliberate introduction into the environment. In the documentation the common,

scientific and commercial name of the LMO, the transformation event, or its unique identifier. It should be noted that these measures were adopted only on an interim basis. An expert group was created to elaborate detailed requirements on LMOs-FFP and will report to Parties by 2005. One important implication of this decision is that national legislation can require that documentation accompanying LMOs-FFP can be identified as such with no ambiguity.

3. Compliance

Compliance was one of the priorities for EU countries, which wanted a strong compliance mechanisms in order to make Parties comply with their obligations under the Protocol. A compliance Committee was finally established, with 15 persons that will serve on their individual capacity. The Committee will meet twice a year and some of the countries that will have representatives will be Malaysia, Colombia, Mexico, Ethiopia, Mali, Hungary, Norway, Switzerland. It will have a non-confrontational nature, and will provide advice to Parties in order to comply, and if necessary will make recommendations. Once a Party complains, the accused Party would have between three to six months to respond.

Bilateral agreements undermine meeting

During the MOP 1 bilateral agreements between major GMO producers and third countries was the subject of heated polemic. Mexico a party to the Protocol signed an agreement with US and Canada on the topic of LMOs-FFP, which was strongly criticised by Non Governmental Organisations. An important issue in this debate was the thresholds for unintentional presence of GMOs.

The International Grain Trade Council (IGTC) proposed - at MOP 1 - a tolerance level of 5% for the unintentional presence of GMOs in a non-GMO shipment. The IGTC was of the view that a 95% non-GMO purity level should be adopted by the MOP as a temporary measure, allowing shipments containing up to 5 % GMOs on unintentional shipments be exempted from identification requirements under the Protocol.

In a recent trilateral agreement between Mexico, Canada and the US it is establish a 5% threshold for intentional contamination. If it achieves the minimum of 95% of GMO content it can be defined as non GMO shipment. Moreover under this agreement any level of contamination by LMOs that are unintentional in a non-LMO shipment should not be considered as a trigger for the "may contain" required documentation.

So only intentional shipments will trigger contamination requirements. Such proposals were unacceptable for Friends of the Earth, since it would legalise genetic contamination, and would not guarantee consumers freedom of choice. GMOs could spread in the environment and the foodchain, without being traceable.

Although so far Mexico is the only Party to the Protocol that has signed a (trilateral) agreement with the US (and Canada), the US strategy of settling bilateral agreements sets serious concerns on the future shape of the international policy on biosafety. The US is not a party to the Protocol, but exercises a great influence in this process.

The arrangement of bilateral agreements seriously hampers the multilateral efforts made

so far in forums such as the Biosafety Protocol. This constitutes a clear attempt to water down the Protocol and impose weaker standards on biosafety.

Friends of the Earth condemned this attitude from GM producing countries, and called on the first day of the negotiations on all Parties of the Protocol and countries that wish to adequately protect their environment and human health from

the potential risks of GMOs, not to accept those type of agreements.

Friends of the Earth is happy the attempts by the US government and others to undermine the Biosafety Protocol have not been successful and welcomes the results of Kuala Lumpur as an important step forward for protecting consumers, farmers and the environment from the dangers of GMOs.

Bayer's GM rice: is it safe?

Introduction

In September 2003 German genetech giant Bayer sent in an application to the European Commission for the commercialisation of Genetically Modified (GM) rice LL62. The application is for use of the rice as food and animal feed only. Under Directive 2001/118/EC, any application to import or cultivate GM crops is initially assessed by the government it was originally sent to - in this case, the UK. In January 2004 the UK competent authority published a positive risk assessment for the rice, as far as the use for animal feed is concerned. However, recently it became apparent and was confirmed by a Commission spokesman, that - following the positive assessment by the UK authorities - nine EU Member States (Austria, Belgium, Denmark, France, Germany, Italy, the Netherlands, Sweden and Spain) have objected to Bayer CropScience's request to import a genetically-modified variety of rice into the EU. Friends of the Earth considers this yet another troubling case in which the member states disagree over the safety of a GMO.

Presently, it is still unclear on what grounds the

member states have objected. Most of the objections are still confidential and/or could not be obtained before the deadline of this Biotech Mailout. However, Friends of the Earth Europe, in cooperation with Dr Suman Sahai from Genecampaign India, have presented a detailed analysis of Bayer's application¹ before the member states tabled their objections. The findings indeed raise concerns. Bayer and the UK authorities have both failed to look at independent scientific evidence concerning potential negative impacts of the rice on the environment. They have also not conducted any further investigation following irregularities that were found by Bayer itself, such as an increase of the existing allergic potential of rice.

Food safety concerns

Friends of the Earth believes that there are several serious concerns about the safety of LLrice62 for use in human food:

- Changes were observed in known compositional compounds of rice, including a substantial increase in the amount of existing allergenic compounds (compounds responsible for allergic reactions to rice), but no further research was

conducted.²

- One of the feeding studies conducted by Bayer was judged by the UK authorities to be of "limited capacity" to identify adverse effects, while in another a difference in response (increased weight gain) was observed for consumption of the GM rice.

- Long term studies to examine potential for more serious health effects were not carried out.

Environmental concerns

Bayer's application is for import of the GM rice but not cultivation. Rice is grown in 5 southern EU member states - Italy, Spain, Greece, Portugal and France. Although gene flow to crop rice or weedy red rice is possible in such areas,³⁴⁵ Bayer have said in its application that it considered this risk to be only 'theoretical'. According to Bayer, LLRICE62 is not intended to be grown in Europe. However, nowhere in its application has Bayer provided data to show that grains will not be imported into regions where rice is grown and that it cannot escape.

Bayer did not provide any information on the proportion of imported rice that may contain viable rice and whether or where spillages of imported rice have occurred in the past. Spillages of GM rice could lead to all kind of problems for rice farmers in Southern Europe, such as difficulties in selling conventional rice that has been contaminated by Bayer's GM rice.

Impacts in non EU countries

If Bayer's GM rice would be approved for import into the EU, it would be cultivated outside the EU. Dispersal of transgenes into wild rice, non GM rice and traditional varieties of rice would be of particular concern in those areas which are centres of agricultural biodiversity, such as India. The importance of protecting such world resources cannot be over stated; rice gets its resistance to two of Asia's four main rice diseases from a single sample of rice that came from central India.⁶ Dr Suman Sahai from Genecampaign, India commented that "it is particularly ironic that India and other centres of diversity for rice could end up jeopardising their principal food source for producing animal feed for the west."

What's next ?

Many member states have asked Bayer for additional information, and the company now has the opportunity to reply. In the meantime the clock has stopped. When additional information is supplied and circulated to all Member States and the Commission, the clock will re-start and Member States will have a further 45 days to take a final position. If the member states maintain their objections, they can reject the application by a qualified majority. If no qualified majority is reached to either support or reject the rice, the Commission (which has not yet taken a position) decides.

Friends of the Earth will keep a close watch on the further application process and will ensure that all concerns raised will be treated seriously.

¹ See for the full analysis: <http://www.foeeurope.org/GMOs/pending/index.htm>

² *Ibid*, paragraph 3

³ OECD (1999) 'Series on Harmonisation of Regulatory Oversight in Biotechnology No.14. Consensus document on the biology of *Oryza sativa* (rice)' ENV/JM/MONO(99)26

⁴ Messegeur, J. et al (2001) 'Field assessments of gene flow from transgenic to cultivated rice (*Oryza sativa* L.) using a herbicide resistance gene as tracer marker. *Theoretical and Applied Genetics* 103 pp. 1151-1159.

⁵ Zhang, N.; Linscombe, S. & Oard, J. (2003) 'Out-crossing frequency and genetic analysis of hybrids between transgenic glufosinate herbicide-resistant rice and the weed, red rice' *Euphytica* 130 pp. 35-45.

⁶ World Resources Institute <http://www.wri.org/wri/biodiv/agrigene.html>

BOOK REVIEW

SEEDS OF DECEPTION

Very often it has been suggested by representatives of the biotech industry that in the US, Genetically Modified (GM) foods are generally accepted. We are told that there is no safety problem, since millions of Americans are happily eating GM foods for many years and no one, so far, has fallen ill.

The recently published book "*Seeds of Deception*" by Jeffrey M. Smith deals an effective blow to these and other myths about GM foods in the US. In chapters that sometimes read like adventure stories but at the same time are amazingly accurate, Smith convincingly shows that:

- The biotech industry exerts a disproportional political influence on the Federal Drugs and Food Agency (FDA), the government agency responsible for the safety assessment of GM foods.
- Scientists of the FDA who repeatedly warned of the health risks of GM foods, have been neglected and obstructed by the management of the agency. The book describes in detail internal memos by FDA scientists warning of toxins, allergies and new diseases- all ignored by their superiors, including a former attorney for Monsanto.
- The FDA failed to properly investigate a deadly epidemic caused by the genetically engineered food supplement L-tryptophan and neglected the offer by the Japanese company which produced the supplement to further

investigate the causes of the disaster that killed nearly forty people.

One of the interesting things about Smith's book is that it not only describes these and other scandals, but that it also gives guidance on how Americans can avoid GM foods. Since in the United States and Canada GM foods do not have to be labelled this is not an easy task and is even described as "an art and a science". Still Smith manages to show how it can be done, for example by avoiding food that may contain soy or corn altogether.

At the end of his book Smith corrects the often-heard statement that American consumers simply do not care about GM foods. He quotes from several opinion polls showing that 70 to 94% of the US population favour mandatory labelling of GM foods. 58% of Americans said that if GM food were labelled, they would avoid purchasing them. Remarkably, these figures do not differ much from those found in Europe.

Smith's book so far can only be found in bookstores in the US. This is a shame, as this book should be read by anyone who is concerned over the (future) safety of our food. Fortunately, the book can be ordered via this website:

<http://www.seedsofdeception.com>

"Seeds of deception. Exposing Industry and Government lies about the Safety of the genetically engineered foods you're eating."

Author: Jeffrey M. Smith. ISBN: 0-9729665-8-7

Friends of the Earth Europe 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

The Biotech Mailout is printed quarterly and is also available online at www.foeeurope.org/GMOs/index.htm

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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