

# FoEE Biotech Mailout

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## *GM OILSEED RAPE IS "A HIGH RISK CROP", SAYS EEA*

It's official. According to the European Union's own agency mandated to advise the Community and Member States on environmental protection, genetically modified (GM) crops - in particular oilseed rape - are "high risk crops for pollen mediated gene flow from crop to crop and from crop to wild relatives".

In mid-March, the European Environment Agency (EEA) published a report entitled "Genetically modified organisms (GMOs): The significance of gene flow through pollen transfer" [1]. The background to this report is that it consists of a review and interpretation of published literature and recent/current research from the EEA and from the European Science Foundation (ESF). The ESF is the European association of research funding agencies, national research organisations and academies of science and letters from 24 European countries. Its purpose is described as "to stimulate, develop and support research at a European level". In 1999, the ESF established a 5-year research programme on "Assessing the Impact of GM Plants". As far as the EEA is concerned, in 2000 it started a special project for the European Parliament on the dissemination of research results from technologies characterised by scientific complexity and uncertainty - such as GMOs and chemicals - and the use of such results by the public and their political representatives, including the use of the Precautionary Principle. The report in question is the first one published by this project.

The EEA's report examines the significance of pollen mediated gene flow in six types of crops for which genetically modified varieties exist that are either available for commercial release in the European Union or under development. These are: oilseed rape, sugar beet, potatoes, maize, wheat and barley. There is also a small section devoted to genetically modified fruit varieties such as apples, plums and vines.

The report's findings confirm existing concerns about cross-pollination, gene transfer, gene stacking, multiple tolerance to herbicides, creation of 'superweeds', etc. They are particularly significant with regard to two plants that have many wild relatives in Europe: oilseed rape and beet. In this regard, it should be recalled that the French government first introduced a national moratorium on the commercial cultivation of GM oilseed rape and beet in 1998, specifically for the reasons that are highlighted in the EEA report. In its announcement of 30<sup>th</sup> July

1998, the French government said that: (*free translation*) "Considering the uncertainties linked to the dispersal into the environment of transgenes from plants which, like oilseed rape, present the risk of crossing with other species, it has been decided to apply a two-year moratorium on authorisations for placing on the market of each GMO variety of such plants". In the eyes of many observers, that far-sighted precaution was the precursor of the wider EU 'de facto' moratorium on GMO approvals which is still in place today.

### THE EEA'S FINDINGS GM oilseed rape

According to the EEA, oilseed rape (OSR) "can be described as a high risk crop for pollen mediated gene flow from crop to crop and from crop to wild relatives". Low levels of gene flow will occur at long distances and genetic isolation will be difficult to maintain. This is particularly true for male-sterile OSR, says the EEA, since this will outcross with fully fertile GM OSR at higher frequencies and greater distances than traditional varieties. Referring to the fact that gene-stacking (resulting in double or triple-tolerance to different herbicides) has already been observed in OSR (*see paragraph below "English Nature's concerns"*), the EEA predicts that "plants carrying multiple resistances will become common once oilseed rape is widely commercialised. Volunteers may become more difficult to control with herbicide treatments in certain situations".

Regarding the risk of gene transfer to wild relatives (of which rape has many - turnip, radish, mustard, etc.), the EEA says: "The risk of hybridisation between oilseed rape and some wild relatives - particularly *Brassica rapa*, *Brassica juncea*, *Brassica ad-*

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*pressa*, *Brassica oleracea*, *Raphanus raphanistrum*, etc. - is high". "Introgression of transgenes into some of these species is likely to occur". "The creation of a herbicide-tolerant, competent weed is possible".

The EEA's report concludes that, that under current farm practices, local contamination between crops of oilseed rape is inevitable. While pollen is important in the spatial development of transgenes, says the EEA, seed is also very important because of its longevity which can provide sources of GM plants for many years after a GM crop has been grown.

It is also interesting to note that the EEA comments on other types of genetic modification of OSR, apart from herbicide-tolerance. In this respect the EEA states that: "Predictions currently made by researchers are that oilseed rape plants modified with other transgenic traits yet to be approved for wider (*e.g. market*) release in oilseed rape, such as pest or disease resistance, may be more persistent or invasive".

#### **Commercialisation in the EU**

Oilseed rape was one of the first GM crops to gain approval in the European Union for market release. All the varieties that have already been approved under the Deliberate Release Directive (90/220/EC repealed by 2001/18/EC) are herbicide-tolerant (to Glufosinate) and most are male sterile:

- Plant Genetic Systems \* glufosinate-tolerant male sterile oilseed rape (C/UK/94/M1/1)
- Plant Genetic Systems glufosinate-tolerant male sterile oilseed rape (C/F/95/05/01/A)
- Plant Genetic Systems glufosinate-tolerant male sterile oilseed rape (C/F/95/05/01/B) - same as precedent but with a different transformation event.
- AgrEvo\* glufosinate-tolerant oilseed rape (C/UK/95/M5/1)

Furthermore, there are another three authorisations in the pipeline that could receive the go-ahead if the current 'de facto' moratorium is lifted:

- AgrEvo glufosinate-tolerant OSR (C/DE/96/5)
- PGS glufosinate-tolerant male sterile OSR ((C/BE/96/01)
- AgrEvo glufosinate-tolerant OSR (C/DE/98/6)

(\* now part of Aventis Crop Science, which is in the process of being acquired by Bayer.)

#### **GM beet**

"Sugar beet can be described as a medium to high risk crop for pollen mediated gene flow from crop to crop (especially seed crops) and from crop to wild relatives" according to the EEA's report. The history of hybridisation and introgression between cultivated beet and wild relatives suggests that, if grown on a commercial scale, escape of transgenes from the crop is likely and, even without hybridisation, the transgene may be able to persist in weed beets derived from 'bolters' or volunteers which produce GM seeds. "Hybridisation between bolting GM beet and weed beet could lead to the transfer of GM traits, in which case GM weed beet may become more difficult to control with chemical treatments", says the EEA.

"The current recommended isolation distance for GM beet seed production of 1000 metres may not guarantee the prevention of seed contamination in the long term".

Like Brassicas, the beet family (*Beta*) is very vast with many cultivated and wild varieties (among them sugar beet, spinach beet, seakale, Swiss chard, beetroot, mangles, sea beet, wild beet, etc.). With regard to GM beet's ability to transfer genes to wild relatives, for example *Beta vulgaris* ssp *maritima* (sea beet) and *Beta macrocarpa* (annual wild beet), the EEA's report notes that seed production areas in Europe are particularly at risk. "GM beet seed of varieties containing fitness genes that could affect the ecology or genetic diversity of wild beet should be produced in selected areas away from the coast in southern Europe and in areas where inland wild beets are absent". Indirect gene flow is also important, says the report, since beet seed persists in the soil for a considerable length of time.

The EEA report makes an interesting point with regard to consumer implications of gene flow in beet. In the event that GM weed beet is harvested with conventional sugar beet, the refined sugar produced therefrom contains neither nucleic acid nor protein from the source plant, and there is no analytical way of detecting whether it is derived from a GM or non-GM crop. The consumer's right to know is therefore compromised, says the EEA, and can only be guaranteed by a traceability system.

#### **Commercialisation in the EU**

So far no GM beet has been authorised for market release in the European Union. There is, however, one application in the pipeline for a fodder beet produced by DLF Trifo-

lium/Monsanto/Danisco (C/DK/97/01) which is tolerant to glyphosate (Roundup).

#### **GM maize**

The EEA report says that: "maize can be described as a medium to high risk crop for pollen mediated gene flow from crop to crop, but low risk for gene flow to wild species". Because maize has no wild relatives in Europe, this aspect of gene transfer is obviously not comparable to that of oilseed rape and beet. However, with regard to gene flow between GM maize and conventional maize, the report finds that: "The levels of cross-pollination recorded between different maize varieties up to 800 metres show it is possible that pollen released from GM maize plants would cross-pollinate non-GM maize plants up to and beyond their recommended isolation distances". Furthermore, "small quantities of pollen are likely to travel much further under suitable atmospheric conditions", and "GM maize presents a medium to high risk for the inclusion of pollen in honey".

#### **ENGLISH NATURE'S CONCERNS**

The EEA's report highlights concerns that were raised just a few weeks ago by another official agency, the UK's English Nature, an organisation set up by the government to advise on nature conservation. In a press release on 5<sup>th</sup> February 2002, English Nature reported that an extensive study it had commissioned on GM oilseed rape in Canada confirmed

cross pollination, gene stacking and multiple tolerance to herbicides. As a result, English Nature said that the UK SCIMAC's\* code "is probably inadequate to prevent gene stacking happening in Britain if these crops were commercialised. The consequences for farmers could be that volunteer crops would be harder to control and they might have to use different and more environmentally damaging herbicides to control them".

(\* The UK organisation Supply Chain Initiative on Modified Agricultural Crops that issues guidelines to the government on issues related to herbicide-tolerant crops.)

The study commissioned by English Nature, "Gene-stacking in herbicide-tolerant oilseed rape: lessons from the North American experience" [2] is based on research in Canada into the development of GM oilseed rape volunteers which are triple tolerant to three different herbicides. This raises concerns that more toxic products have to be used to control them. According to English Nature, "attempts to eliminate GM volunteers with multiple herbicide tolerance in 'weedy' crops like oilseed rape could lead to more intensive herbicide use in field margins and uncropped habitats which can be important for wildlife".

English Nature is also worried about the European Commission's proposal to set thresholds of up to 0.7% for the contamination of conventional seed by seeds of GM varieties. English Nature says that if such proposals were adopted "it might be a recipe for gene stacking because the GM plants for a seed batch could be made up of several varieties that would inevitably hybridise, giving 'volunteer' plants next season with multiple GM trait".

**Hybridisation between GM beet and wild beet "could lead to the transfer of GM traits, in which case GM weed beet may become more difficult to control with chemical treatments".**

## THE AGENCIES' RECOMMENDATIONS

Both the EEA and English Nature clearly express their concerns about cross-pollination and gene stacking in GM crops. Both agencies recommend that isolation distances between GM and non-GM plants will have to be increased. For English Nature, as far as oilseed rape is concerned, separation distances would have to be increased up to 400 metres or more. Post-harvest cultivation would need to be monitored in order to minimise 'volunteer' populations, and attention paid to preventing 'volunteers' establishing themselves on uncultivated land and methods of control that would not harm biodiversity. In case of gene stacking between glyphosate and glufosinate-tolerant plants, the likely result would be increased use of the weed killer paraquat which can have a negative impact on wildlife such as hares.

The European Environmental Agency says that current isolation distances should be reviewed for some crops in order to reduce levels of gene flow, especially for seed crops. Male-sterile GM plants which are particularly likely to outcross with neighbouring crops may require even greater separation distances.

Another measure to consider, says the EEA, are 'gene flow barriers' which could reduce cross-pollination levels. These might take the form of physical barriers such as isolation zones (land left barren or planted with a non-insect pollinated crop), or barrier crops (a border of non-GM plants of the same type which 'absorbs' the pollen and is then destroyed). A further option put forward by the EEA is biological barriers, i.e. constructing GM plants to improve biosafety by avoiding or minimising certain gene sequences.

Such measures could include production of seeds without fertilisation, self-fertilisation, pollination incompatibility and seed abortion, inhibition of plant flowering, male sterility, and seed sterility. Some of these suggestions are themselves controversial, e.g. seed sterility since it precludes the possibility of farmers to save seed. Others may lead to even more questions about the long-term impact on biodiversity.

### Where do we go from here ...?

As the EEA states in its summary of its Report, this project is in support of the EEA's duty to "assist the Commission in the diffusion of information on the results of relevant environment research". As such, one assumes that the European Commission and other decision-making bodies will not overlook the serious concerns highlighted in the report, and will take the necessary steps to avoid the risks becoming reality.

Environmental groups have been warning about these consequences of GM crops for many years. Those cautions initially fell on deaf ears, particularly from proponents of GM crops. On the contrary, the biotech industry and its supporters always claimed that GM crops are 'environmentally-friendly' because herbicide-tolerant crops supposedly need less chemicals. Remarkably they pursue that argument, despite the fact that the evidence shows gene flow and triple-tolerant oilseed rape in Canada after just a few years of commercial cultivation.

**If cross pollination and gene flow from GM crops is allowed to happen in the EU, consumer and farmer choice would become a thing of the past.**

The question now is whether co-existence of GM and non-GM crops possible? If GM crop approvals are re-started in the EU, major decisions will have to be taken on how to keep GM and non-GM crops separate in order to maintain farmer and consumer choice. Discussions are therefore underway on separation distances around GM fields, zoning agricultural areas into GM and non-GM, banning certain types of GM crops in some countries, and (as mentioned above) developing new GM plants with modified fertility/sterility traits.

The EEA report, and the one from English Nature, underlines the fact that the European Union is approaching a crucial crossroads on the issue of GM crops. Does European farming go down the GMO route or not? Systems that would be needed to ensure that GM and non-GM plants could grow alongside each other - separation distances, physical and biological barriers, and further genetic modification to interfere with plant fertility - appear to be either impractical or undesirable. At the same time, the logistic, bureaucratic and legal situation is far from clear and would need to be resolved before any widespread cultivation of GM crops is allowed. One thing, however, seems clear - the findings in these reports confirm the huge problems that cross-pollination and gene flow from crop to crop will cause. If that is allowed to happen without appropriate measures being taken before GM crops gain a foothold in the EU, consumer and farmer choice would become a thing of the past.

[1] ([http://reports.eea.eu.int/environmental\\_issue\\_report\\_2002\\_28/en](http://reports.eea.eu.int/environmental_issue_report_2002_28/en))

[2] (<http://www.english-nature.org.uk/news/story.asp?ID=335>)

# ***RISK ASSESSMENT AND MONITORING OF GMOs***

## ***More questions than answers***

The European Commission is currently drafting two guidance notes on risk assessment and monitoring of deliberate releases of GMOs into the environment. The notes will provide guidance for the competent authorities in the Member States and the biotech industry of how to conduct environmental risk assessment and environmental monitoring of releases of GMOs into the environment under Directive 2001/18/EC. A meeting on 27<sup>th</sup> March organised by DG-Environment showed there is a high level of disagreement among stakeholders, especially concerning monitoring.

The Commission is under considerable time pressure to complete the guidance notes for risk assessment and monitoring of GMOs as, according to Directive 2001/18/EC, the guidance notes shall be completed by 17<sup>th</sup> October 2002 when it comes into force.

The Commission seems to have realised that without a proper framework for monitoring and risk assessment of GMOs there will be little chance of lifting the moratorium. In 1998, five EU Member States - Denmark, Greece, France, Italy and Luxembourg - called, in a joint declaration, for the suspension of new GMO marketing authorisations. This declaration forms the basis of the European 'de facto' moratorium on GMOs. An important consideration of the five countries was that there is "a need for a tighter, more transparent framework, in particular for risk assessment, having regard to the specifics of European ecosystems, monitoring and labelling (...)".

Under the current GMO legislation in the EU (90/220/EEC) there are already provisions for the environmental risk assessment of GMOs. However, the Directive contains many loopholes and does not foresee any programme for the monitoring of the potential adverse effects of GMOs on the environment and human health.

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One of the advantages of the new Directive 2001/18/EC, which will replace Directive 90/220/EEC as of 17<sup>th</sup> October 2002, is that it acknowledges the necessity of such monitoring. However, before a monitoring framework can be put into practice, a lot of difficulties have still to be overcome. The competent authorities hardly have any experience in environmental monitoring of GMOs and consequently there are many unresolved questions. An important discussion is still going on about, for example, against which baseline (desired state of the environment) environmental effects of GMOs will be measured. There is no clear definition of this baseline. Some policy-makers argue that the baseline should be the present state of the environment, whereas others argue that transgenic plants should be subject to national laws concerning nature protection.

The following issues, among others, are still controversial among stakeholders:

- What effects on the environment will have to be risk assessed and monitored? The Commission has not yet presented a list of possible adverse effects to be assessed and monitored. While representatives of the biotech industry present at the aforementioned hearing want the scope of risk assessment and monitoring limited to a very restricted number of parameters and wish to see, for example, the possible effects of GMOs on bacteria in the soil excluded from the monitoring programmes, environmental organisations believe that, in principle, all known parameters should be assessed and monitored. While industry does not want to monitor the amount of pesticides used on GM crops compared to the amount used on conventional crops, environmental NGOs like Friends of the Earth argue that such effects should definitely be monitored, since they may clearly imply an environmental risk. Besides, if the biotech industry is convinced about the claimed beneficial effects of GMOs (like reduced use of pesticide) it should expect that such effects are verified.
- Another issue that raises many questions is the area to be monitored. Industry argues that monitoring should be restricted to the fields where GMOs are actually grown, whereas NGOs want a much bigger area to be monitored. According to them, the

size of the area to be monitored should depend on the capacity of a certain GM crop to spread its pollen and seeds (see article on page 1 of this Mailout concerning the recent report by the European Environmental Agency on gene flow). Behind the controversy over the size of the area to be monitored is a much bigger and more fundamental issue. Industry argues that gene flow in itself does not necessarily pose an environmental risk and therefore does not have to be monitored. Environmental NGOs, however, point to the fact that many of the environmental risks of gene flow are still unknown. Therefore the Precautionary Principle should be applied. Consumer organisations are worried that gene flow could greatly reduce the freedom of choice, since conventional crops could get contaminated with GMOs. If there are no adequate monitoring provisions, this contamination could pass unnoticed, which from the standpoint of freedom of choice is of course unacceptable.

- The European Commission still has to establish who is going to conduct risk assessment and monitoring. While Article 20 of the Directive unambiguously requires the notifier to "ensure that monitoring and reporting on it are carried out according to the conditions specified in the consent" following every placing on the market of a GMO as or in a product, neither the Directive nor the draft Guidance notes define whether the actual work shall be carried out by the notifier or by independent scientists. For obvious reasons, Friends of the Earth prefers the last option although the notifier should cover the costs of the post-marketing monitoring. In the past, data provided by in-

dustry have often been shown to be biased. Therefore the research data in risk assessment and monitoring programmes should be peer-reviewed. The Commission seems to be heading in the same direction. In the guidance note on environmental risk assessment it is stated that "Member States and the Commission should ensure that systematic and independent research on the potential risks involved in the deliberate release or the placing on the market of GMOs is conducted". However, the notes do not specify how independence of research should be ensured.

- From the guidance notes it is still unclear who is going to bear the costs of environmental risk assessment and monitoring. Industry seems to want to avoid the costs of so-called general surveillance programmes. These programmes, mentioned in Annex VII of Directive 2001/18, are focused on indirect, delayed and unanticipated effects of the introduction of GMOs into the environment, which are not necessarily mentioned in the environmental risk assessment.
- Also unclear is how long monitoring programmes have to stay in place. Industry argues that monitoring should stop as soon as GMOs are taken off the market. Environmental NGOs however, are of the opinion that these programmes should continue as long

as adverse environmental effects can occur. Obviously these effects could take place long after the GMO in question is taken off the market. This applies in particular to organisms such as trees. The Commission seems to agree with this point of view, since the draft note says that: "The monitoring plan could extend the period of the consent". However, no further guidance is given.

- According to Article 4.2 of Directive 2001/18/EC, antibiotic-resistant markers in GMOs that may have adverse effects on human health and the environment have to be phased out by 31<sup>st</sup> December 2004 in the case of GMOs placed on the market, and by 31<sup>st</sup> December 2008 in the case of GMOs authorised for non-commercial or test purposes. However, the guidance notes do not go into any details how this phasing out is going to be organised and on the basis of which criteria.
- In the draft guidance notes the Commission mentions management strategies for GMOs that have been identified as a risk factor to the environment. However, concrete measures to evade these risks are still lacking. For example, the guidance note does not address measures such as isolation distances between GM crops and conventional crops.

It is safe to conclude that the Commission still has to make up its mind about many issues concerning the environmental risk assessment and monitoring of GMOs. Given the many unresolved questions, it can be seriously doubted whether the Commission will reach its goal to complete the Guidance Notes by 17<sup>th</sup> October.

**Given the many unresolved questions, it can be seriously doubted whether the Commission will complete the Guidance Notes by 17th October.**

# GMO TRIALS IN THE UK

The biotech industry has struggled to comply with the scientific requirements set down for the controversial farm scale trials in the UK. The scientific committee overseeing the trials has repeatedly requested industry to find new farms to take part, and also to grow the trials in areas representative of conventional farming. However, for maize in particular, industry failed to get any trials in the top maize growing counties in the south-west of the country where up to 43% of England's maize is grown. Instead they had to rely mostly on farmers in other areas who had previously participated in the trials programme.

## New test sites announced

On 14<sup>th</sup> March, the government announced the location of the latest round of GM trials. In England, there are a total of 35 maize sites, along with 18 beet and 24 oilseed rape sites. Some have already been withdrawn due to local opposition. For the location of the test sites in England, see: <http://www.foe.co.uk/pubsinfo/infoteam/pressrel/2002/20020314155908.html>

This is the last year of the UK farm scale trials and government ministers have already started to distance themselves from the results and have even argued for bigger separation distances. Margaret Beckett, Secretary of State for Environment, Food and Rural Affairs, stated that "the separation distances for the FSEs [farm scale evaluations] have been set to ensure that cross-pollination is a maximum of 1%. However, there is a case for separation distances to be greater so as to ensure a maximum of, for example, 0.1% cross-pollination". To achieve this, FoE

estimates that separation distances should be at least 5 Kms. (See the government's response to the Agriculture and Environment Biotechnology Commission's report "Crops on Trial" - [www.aebc.gov.uk](http://www.aebc.gov.uk))

## Wales stays GM-free

Despite fears that some trials would be located there, Wales has remained GM-free despite the fact that one farmer wanted to grow GM Chardon LL maize (a line of Aventis T25). The news was hailed as a victory for the National Assembly, which has consistently opposed the planting of GM seeds. Rural Affairs Minister Carwyn Jones said: "The decision on the trial sites was made on purely scientific grounds but reflects the Welsh Assembly's policy of taking a restrictive approach to the use of GM crops in Wales". "This decision is to be welcomed and I am sure those communities and interest groups who have shared my concerns over the possible implications of the planting of GM crops for organic and conventional produce will share my satisfaction" (*Western Mail and Echo*). Mr. Jones confirmed that discussions with the European Commission were proceeding. Wales had been threatened with a massive fine, running to hundreds of millions of pounds if it refused to allow GM crops to be planted. Last year, Wales (via the UK government) filed an Article 16 notification restricting the marketing of Aventis T25 in Wales. The National Assembly said that growing GM maize would be a risk to the environment for growing organic and non-GM maize (see *FoEE Biotech Mailout Volume 7 Issue 6, page 6, 1.12.2001*).

Jill Evans, MEP (Plaid Cymru/Party of Wales) said: "Following last year's protests in Pembrokeshire and Flintshire, I hope that the government has finally realised that Wales will not tolerate being a GM crop guinea pig again" (*Liverpool Daily Post & Mail*). She claimed that the organic farming organisation, the Soil Association, had shown more than 100 organic farms could be at risk of contamination from the current round of GM crop test sites for oil seed rape, sugar beet and fodder beet, in England.

## Anger in Scotland

There was anger, however, in Scotland, at the announcement of more GM trials. Scottish Environment Minister Ross Finnie said that GM oilseed rape crops would be planted this spring at three new sites. This is on top of twelve other Scottish sites that have already been cultivated with GM oilseed rape as part of the UK's farm-scale evaluation programme.

The decision was greeted with protests from the Green Party which called for the trials not to go ahead until local communities had been properly consulted. An anti-GM petition signed by 4,000 people protesting about one site at Munloch was recently handed in to Members of the Scottish Parliament.

FoE Scotland's Chief Executive, Kevin Dunion, said: "We know that these new trials will be deeply unpopular with local communities who have raised a number of important issues in recent weeks". He added that the latest decision followed a warning by a leading health consultant, Charles Sanders, who said a gamble was being taken with public health because of the "irreversible" release of genetic organisms into the environment.

# ***GM FOOD/FEED REGULATION***

## ***EP Agriculture Committee***

The vote on 20<sup>th</sup> March of the European Parliament's Agriculture and Rural Development Committee on the Opinion of MEP Danielle Auroi (Greens, France) concerning the draft Regulation on GM Food/Feed (COM(2001) 425) was disappointing. None of the amendments proposed by rapporteur Auroi were adopted. While the Socialists supported almost all her amendments, the European People's Party (Conservatives/Christian Democrats) and the Liberals rejected them. The main points of the vote are described below.

### **Labelling**

The Committee adopted some amendments that limit mandatory labelling of GM food and feed to those products in which either DNA or protein can be identified. This approach, of course, undermines the whole traceability scheme proposed by the Commission with the aim of facilitating labelling of products produced from GMOs in which no DNA or proteins are present.

Processing aids and food produced

from animals fed with GMOs shall be explicitly excluded from labelling which could, however, be interpreted to mean that they should not be exempted from the mandatory pre-marketing authorisation procedure, as the Commission proposes.

### **Thresholds**

The threshold of 1% remains unchanged. The proposal to have a tolerance level of 5% for feed was rejected. One moderate improvement is that unauthorised GMOs may only be present in conventional products if the European Food Safety Authority has concluded that the GMO is "safe".

### **"Adventitious" and "Technically unavoidable"**

Two of the amendments adopted call for a detailed definition of what is meant by "adventitious" or "technically unavoidable". While this is positive in principle, the problem is that all the measures listed in the amendments adopted are ones that would have to be taken by those who do not use GMOs. What is

needed is the definition of measures which users of GMOs have to take in order to avoid contamination of other conventional or organic products. Amendments reflecting this demand, however, were rejected.

### **Amendment of Directive 2001/18/EC**

The Committee voted in favour of a deletion of Article 42 of the GM Food/Feed proposal which includes the amendment of Directive 2001/18/EC. However, it is obviously the EPP's intention to move Article 42 to the parallel proposal on Traceability/Labelling of GMOs (COM(2001) 182), as was also proposed by Council Working Group.

The vote in the Agriculture and Rural Development Committee on the Opinion of rapporteur Redondo Jiminéz (EPP, Spain) on the Traceability/Labelling proposal was postponed until 15/16th April.

The most recent schedule for debate/amendment of the two proposals in the EP is shown below.

<b>EP Committee</b>	<b>ITRE</b>	<b>JURI</b>	<b>AGRI</b>	<b>ENVI</b>
Proposal:	Traceability	Food/Feed	Both	<b>Both</b>
Rapporteur	Seppänen	Gebhardt	Auroi Redondo*	<b>Scheele Trakatellis</b>
Exchange of view without report	-	21 March	-	<b>19 February</b>
Draft reports ready for translation:	30 November	26 March	31 January	<b>28 February</b>
Discussion of draft report:	18 December	tba	19 February	<b>16/17 April</b>
Deadline for amendments:	10 January	tba	27 February	<b>24 April</b>
Discussion of amendments				<b>22/23 May</b>
Vote in committee	24 January	tba	19 March	<b>3/4 June</b>
Vote in Plenary				<b>July</b>
ITRE = Industry, External Trade, Research and Energy				
JURI = Legal Affairs and Internal Market				
AGRI = Agriculture and Rural Development				
ENVI = Environment, Public Health and Consumer Policy				
		* postponed to 15/16 April		(tba = to be announced)

# ***DUTCH GOVERNMENT REFUSES PERMISSION FOR MONSANTO'S POTATO***

Recently the Dutch Ministry of Environment rejected an application by Monsanto to conduct field trials in The Netherlands with a genetically modified potato, *Solanum tuberosum* L. The Monsanto potato is resistant to the Colorado beetle. Monsanto wanted to grow the potato in the municipalities of Ede, Wageningen and Noordoostpolder.

The reasons of the Dutch Ministry for the refusal are twofold:

- Monsanto has not been able to prove that the GM potato plants do not contain the antibiotic-resistant marker *spc/str*. This marker was used during the process of modification in the laboratory. Under Dutch law that came into force at the beginning of 2002, the only two genes that may contain antibiotic-resistant markers are *npt II* and *hpt*.

- Monsanto did not sufficiently specify the location where it intends to grow the GM potatoes. According to the Dutch Environment Ministry, this is contradictory to a verdict by the Dutch Council of State. In November 2000, in a case initiated by Greenpeace and some private individuals, the Council of State (a higher Dutch Court of Law) ruled that the location of GM field trials should be precisely indicated in the application in order to give local farmers and other interest groups the opportunity to appeal against the trials.

Besides rejecting permission for the Monsanto potato, the Dutch Environment Ministry also refused 14 other applications by different companies for cultivation of several GM crops (including rape seed and sugar beet). However, three applications

were granted, one of them being permission for Advanta Seeds to grow genetically engineered oilseed rape in the municipality of Reimerswaal in the South of The Netherlands.

It is still unclear if Monsanto and the other the companies involved are going to appeal against the decision of the Dutch Environmental Ministry. Also there is the possibility that environmental NGOs or local interest groups will appeal against the three authorisations that were granted.

The permission for field trials with GM oilseed rape, in particular, is highly controversial from an environmental point of view. This is even more true after the recent publication of report by the European Environmental Agency on the "high risks" GM oilseed rape (*see also the front page of this Mailout*).

## ***LIABILITY FOR GMOs***

### ***Member States critical of Commission's proposal***

As reported in the last FoEE Biotech Mailout (*see Vol. 8 Issue 1, 1.02.2002*), the European Commission has tabled a very weak proposal for an EU Directive on Environmental Liability that would let GMO producers and users off the hook in almost every case. According to various reports, a majority of EU Member States is also critical of the Proposal. At the March Council meeting of Environment Ministers, eight countries - Austria, Finland, Portugal, Luxembourg, Sweden, France, Belgium and Germany - said that GMOs pose particular problems to the environment which are not covered in the draft Directive. Several countries called for traditional damage (e.g. damage or loss of income for organic farmers) to be included. Some Member States do not want licences to exempt operators from liability, and some argued in favour of mandatory financial security for companies. In general, most Member States appear to think that the draft Directive undermines the Polluter Pays principle (not just for GMOs).

According to the media (*Agence Europe*), Environment Commissioner Margot Wallstrom refused "to see in these requests for a stricter scheme a snub for the Commission's proposal, and considered that the criticisms stemmed from misunderstandings, and that more demands were along its own lines. 'The principle of polluter-payer will apply. I am not opposed to a compulsory insurance scheme', she stated.

# ***US EVIDENCE ON GM LABELLING AND TRACEABILITY***

The UK's House of Lords has held an inquiry into the EU proposals for Traceability/ Labelling and GM Food/ Feed. Some of the most interesting evidence came from the US government representatives. They argued that the term "GMO" refers to all breeding methods and therefore all food crops. Peter Kurz, Minister-Counsellor for Agricultural Affairs at the US embassy in London, went further and agreed that bread, cheese and even cider should be labelled as "produced with biotechnology"!

## **US Public concern**

On being asked whether there was much public concern in the US, Kurz

admitted that GMOs were in the US as if "it had come through the back door". In response, one Lord said that if Europe wanted GMOs, then it wanted them through the front door! Kurz also admitted that concern was growing in the US and that they had to rewrite their proposed organic laws due to the 300-400,000 objections to permit GM ingredients.

## **Exports crash**

The US Embassy highlighted the effects their GM policy has had on exports from the US. They said that they are losing \$200 million in maize sales to the EU each year, falling from a peak of 3.5 million tons in 1995 to

just 100,000 tons in 2001.

## **EU Consultative Forum**

The Lords questioned the US representatives on whether they still supported the EU-US Consultative Forum's conclusions on GM (where both parties agreed that it was essential to ensure consumer choice and that consumers should have the right of informed choice). Unfortunately the US government couldn't answer the question - "I do not know if I can specifically comment on that..." - and we'll now have to wait for the final report where they will have submitted a written reply!

# ***THE AARHUS CONVENTION AND GMOs***

## ***Towards legally binding provisions on public participation***

### **The Aarhus Convention: "an ambitious venture in environmental democracy"**

The Aarhus Convention on Access to information, public participation and access to justice entered into force 30 October 2001. Up to now, 19 countries have ratified the Convention, mostly Eastern European and Central Asia countries. Only two of them are Western countries, Italy and Denmark. The Aarhus Convention gives rights to the public, and places obligations on Parties and public authorities concerning access to information and public participation and access to justice. The Convention is an ambitious and significant step in international environmental law. Koffi Annan, Secretary-General

of the United Nations stated: "The Aarhus Convention is the most ambitious venture in environmental democracy undertaken under the auspices of the United Nations".

### **Public participation on GMOs excluded in the Aarhus Convention**

With regard to GMOs, the Aarhus

Convention (AC) has a major shortcoming since it excludes GMOs from the scope of the Convention's provisions on public participation in decision-making. At present, public participation for GMOs is addressed in Article 6.11 of the AC which explicitly excludes GMO activities from the public participation provisions of the AC and defers it to national legislation.

**Article 6.11 of the Aarhus Convention explicitly excludes GMO activities from public participation and defers it to national legislation**

Friends of the Earth, as part of the European ECOForum - the federation of environmental NGOs working on the follow-up of the AC - is involved in preparatory work towards providing the same public participation rights for GMOs as for other types of activities covered by

the AC. Friends of the Earth believes that in order to adequately address the issue of public participation for GMO activities in the AC, an amendment to the Convention is required. The amendment would consist of the deletion of Article 6.11 since it does not impose legally binding obligations on the Parties, and constitutes an arbitrary exclusion. At the same time, GMO activities should be included in the AC Annex that lists the activities that are subject to a process of public participation.

The European Commission, France, Germany and UK oppose legally binding provisions on public participation for GMOs. At two recent meetings of the working group on GMOs (October 2001 and February 2002 in Geneva), the European Commission, France, Germany and UK formed a hard line opposition to amending the Convention and making public participation for GMOs legally binding under the AC. They strongly contested the necessity of establishing legally binding provisions and instead proposed that just voluntary guidelines would be an adequate instrument.

This opposition to legally binding provisions on public participation for GMOs seems contradictory to the European Union's (EU) own legal framework. EU legislation on deliberate releases of GMOs into the environment sets out legally binding provisions for public participation under which, for example, the Member States shall consult the public on proposed deliberate releases. Taking this into account, the need to have legally binding provisions on public participation for GMO activities in the AC cannot be questioned by EU Member States since those provisions already exist in the EU's own legislation. Therefore the question

**The European Commission, France, Germany and the UK formed a hard line opposition to amending the convention and making public participation for GMOs legally binding.**

arises as to how those legally binding provisions should be established in AC?

#### **An unjustified exclusion: why a special status for GMOs?**

Article 6 of the AC requires Parties to guarantee public participation for decision-making on activities with a potential significant environmental impact, which are listed in Annex I of the Convention. The Annex lists activities which present risks for human health and the environment, such as oil and gas refineries, chemical installations, waste installations, industrial plants, dams, pipelines, etc. GMO activities are given a special status since they are explicitly excluded under Article 6.11, and therefore implicitly deemed not to be a potentially dangerous activity.

Is this exclusion justified? Can European Union Member States warrant the exclusion of GMOs from the Annex? Since Annex 1 includes activities that present risks to the environment, the exclusion of GMO activities would only be justified if they did not present similar potential risks to the environment and human health. However, this is certainly not the situation in EU legislation. The EU's Directive on deliberate releases of GMOs into the environment says that the effects of releases on the environment may be irreversible and therefore present potential risks to the environment and human health.

Furthermore, the European Commission's Proposal for a Directive on Environmental Liability includes the deliberate releases of GMOs and contained use of micro-organisms in the list of occupational activities which present a risk for human health and the environment. Therefore EU Member States would not be able to defend the exclusion of GMO activities in the AC.

#### **Guidelines are not enough**

The development of voluntary guidelines on GMOs alone would be an inadequate solution to a major shortcoming in the AC. Unfortunately, the development of such guidelines for GMOs in the field of Access to Information, Public Participation and Access to Justice seems to be the goal of several EU Member States - mainly France, Germany, UK plus the European Commission, which strongly opposes an amendment to the Convention.

Friends of the Earth believes that guidelines are not enough, and that the Convention should be amended, for two reasons. First, the necessity to establish legally binding provisions for public participation on GMOs since voluntary measures would hardly be implemented, particularly in Eastern European and Central Asian countries. Second, the necessity to avoid arbitrary exclusions. GMO-related activities are potentially dangerous for the environment, and, as such, citizens should be granted the same public participation rights as for similarly dangerous activities which are covered by the AC.

Both these reasons are in line with EU legislation on deliberate releases of GMOs into the environment and cannot, as such, be questioned by the European Commission or the Member States.

# ***CURRENT BIOTECH DOSSIERS IN THE EU***

**Genetically modified food and feed (COM(2001) 425): awaiting 1st reading** – see timetable on page 8.

**Traceability of GMOs, GM food and feed (COM(2001) 182): awaiting first reading** – see timetable on page 8.

**Life sciences and biotechnology: a strategy for Europe.**

**Communication (COM(2002) 27): awaiting consultation**

Responsible Committee: ITRE (Industry, External Trade Research and Energy)

Opinion: AGRI (Agriculture and Rural Development), JURI (Legal Affairs and Internal Market), ENVI (Environment, Public Health and Consumer Policy)

**Transboundary movement of genetically modified organisms (COM(2002) 85): awaiting first reading**

Responsible Committee: ENVI – rapporteur SJÖSTEDT (GUE, Sweden)

Opinion: ITRE, AGRI

**Environment: liability with regard to the prevention and remedying of environmental damage (COM(2002) 17): awaiting first reading**

Responsible Committee: JURI – rapporteur MANDERS (ELDR, Netherlands)

Opinion: EMAC (Economic and Monetary Affairs), ENVI

**Patent law: patentability of computer-implemented inventions (COM(2002) 92): awaiting first reading**

Responsible committee: JURI – rapporteur McCARTHY (PSE, UK)

Opinion: ITRE

**6th Research Framework Programme (COM(2001) 94): awaiting second reading**

Responsible Committee: ITRE

**Thresholds for GM contamination of conventional seeds**

**(SANCO/1542/02- January 2002): awaiting comitology decision**

Responsible Regulatory Committee: Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry.

Stakeholder Meeting in April

**DRAFT Guidance Notes for the implementation of Annex II (risk assessment) and Annex VII (post-marketing monitoring) of Directive 2001/18/EC: awaiting comitology decision**

Responsible Committee: to be established under Article 32.2

Stakeholder meeting: 27 March (*see article on page 5 of this Mailout*)

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