

FoEE Biotech Mailout

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EP ENVIRONMENT COMMITTEE STRENGTHENS COMMISSION PROPOSALS TO LABEL GM FOOD

On 4th June, the European Parliament's Environment Committee backed calls for a substantial strengthening of European Commission proposals on the traceability and labelling of genetically modified (GM) food and animal feed, and products derived therefrom. An amendment extending labelling to meat, eggs and dairy products derived from animals fed on GM feed was also adopted. MEPs also lowered from 1% to 0.5% the threshold beyond which the accidental contamination of produce by GMOs must be labelled, and demanded a ban on products containing GM ingredients not authorised in the EU. It is expected that the full assembly of the European Parliament will decide upon the Environment Committee's proposals in the first week of July.

Although several amendments were adopted that extend the scope of the European Commissions proposals, the Environment Committee endorsed in majority the main principle underlying the Commission's proposal, which is labelling based on traceability.

In the two proposals from the Commission (*Traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms COM(2001) 182 final*) and *Genetically modified food and feed COM(2001) 425 final*) the traceability principle is laid down in several articles. For example, the Commission defines the traceability principle in the explanatory memorandum to proposal COM(2001) 182 (final) as follows: "Traceability in the context of this proposal can be defined as the ability to trace GMOs and products produced from GMOs at all stages of the placing on the market throughout the production and distribution chains facilitating quality control and also the possibility to withdraw products". To make the traceability principle work, the Commission intends to introduce several traceability and labelling requirements for GMO producers. Operators will be obliged to label pre-packaged products and to transmit information to receiving operators about the unique code(s) of the GMO(s) in case the product contains or consists of GMOs (Article 4.2 of the proposal COM(2001) 182 (final)). In case food products are produced from GMOs, the operators should indicate to receiving producers that the products is produced from GMOs, but are not required to give the unique codes of the GMOs. Also no operator-to-operator labelling is required when the products are produced from GMOs.



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(Article 5). On the other hand, the Commission does propose labelling of these products when they reach the consumer.

The traceability principle is at the heart of the discussions in the European Parliament. A majority of Green, Socialist and Liberal MEPs seems to realise that applying the traceability principle to GMOs is an essential element to secure the freedom of choice for consumers. Also the majority of the MEPs is aware of the fact that traceability is needed to intervene effectively in case unexpected environmental or health problems show up once a GMO has been released into the environment or put on the market. However, the majority in the Parliament for a traceability system is tight. The Conservative Party (EVP-ED), which is the largest party in the Parliament, is opposed to labelling based on the traceability system. They tabled several amendments in the Environment Committee that aim at restricting labelling to only those products in which transgenic DNA or protein can be found through chemical tests. If adopted, these amendments would mean that the majority of the 30,000 food products that can contain GM soya- or maize-derived ingredients would escape from mandatory labelling. For example, no oils made from GM maize would have to be labelled. Basically it would mean a continuation of the present situation in which consumers have no choice and only a tiny minority of GM-foods have to be labelled.

Although the Conservative amendments were rejected by the Environment Committee, this might change when the full assembly of the European Parliament votes on the labelling and traceability proposals. Parliamentarians like Jules Maaten of the

ELDR (Liberals) and David Bowe of the PSE (Socialists) support the Conservative position. However, even if the majority of the full assembly would vote in favour of the Conservative amendments, the case for a better labelling system of GM food and feed is not completely lost. After the vote in the European Parliament, the Council of Ministers will also take a decision on the Commission's proposal and this decision could change the position taken by the full assembly of the EP.

FOE'S POSITION

Friends of the Earth's view is that the Commission's proposal for traceability (and especially the consumer labelling) is a positive development and that the Commission has already undertaken many steps in the right direction. However, the traceability and labelling requirements still should be improved substantially. Mandatory operator-to-operator labelling should also be introduced for food products produced from GMOs and the operators should be obliged to transfer the unique codes for these products as well. Moreover, mandatory labelling should also be introduced for animal products (like milk, eggs and meat) derived from animals fed with GM feed, as the EP's Environment Committee has demanded. Furthermore, Friends of the Earth supports the position of the Environment Committee that there should be no threshold (meaning exemption from the labelling obligation) for the adventitious presence of unauthorised GMOs in food and feed-products. Such a threshold is justifiable for authorised GMOs, but should be set at the lowest level possible and not, as the Environment Committee has proposed, at a level of 0.5 %.

AVENTIS GM MAIZE

Scientist admits research was flawed

Aventis' T25 genetically modified maize was first authorised for deliberate release in the EU (against Directive 90/220/EEC) in spring 1998 - one of the last GMOs to be approved before the current 'de facto' moratorium came into effect. T25 is engineered to be tolerant of the herbicide glufosinate ammonium ('Basta', etc.) and the authorisation covers all uses including cultivation. However, the approval process for T25 has always had a 'nasty smell' about it. As Friends of the Earth has been pointing out for more than one year, the authorisation of T25 was fundamentally flawed, consisting of a catalogue of errors and circumstances that should have meant the maize should never have been commercialised. This article reiterates those facts and discusses startling new admissions made in April 2002 by a senior scientist that safety research presented at the time of T25's approval was not good enough.

Lack of food safety data, shabby scientific studies

During the latter part of 2000, FoE in England launched a campaign to prevent Aventis T25 being grown in the UK by preventing it from being added to the national seed listing (under the seed name ChardonLL.

The admission that decisions were made based on inconclusive evidence submitted by the company and dismissed by other scientists as 'a waste of time' is deeply disturbing

The opposition to seed listing involved a Public Hearing lasting several weeks at which Aventis refused to give evidence (see *Mailout Volume 6, Issue 8, 15.12.2000*). Several distinguished scientists spoke at the Public Hearing as expert witnesses for FoE:

- Professor Bob Orskov, OBE, Director of the International Feed Resource Unit and a leading expert on ruminant nutrition, said: "The scientific case put forward for this GM maize is not adequate. "If the GM maize was approved for commercial growing in the UK, then people would be justified in turning their back on consuming milk derived from it... As a scientist I wouldn't drink milk from cows fed on GM maize with the present state of knowledge". "Chemical analyses of the kind reported cannot identify potential problems. We need to carry out proper, long-term tests both on the effects of the maize silage for the microbes in the stomach of the ruminants which digest the feed and on the host animals. This has not been done".
- Dr. Vyvyan Howard, Head of the Foetal and Infant Toxicopathology Group at Liverpool University, dismissed Aventis' claims that safety tests were not needed because Chardon LL is not "materially different" from conventional varieties. "My interpretation is that this GM maize has not been tested thoroughly", he said. "They have taken a protein from another plant and fed it to rats. I do not feel this can be used as a basis for making judgements about the safety of this maize with respect to cattle".
- Two scientists working at Bristol University for the Ministry of

"It wasn't really a good enough experiment to base a student project on, let alone a marketing consent for a GM product ..."

Agriculture, Fisheries and Food (MAFF, since replaced by DEFRA), Dr. Stephen Kestin and Dr. Toby Knowles, were requested by FoE to conduct a peer review of T25 feeding studies with chickens, which Aventis used as part of their data to obtain authorisation. Drs. Kestin and Knowles reported that the research was "inadequate" and "not of a standard that would be acceptable for publication in a scientific journal". They expressed concern about suspicious higher mortality among chickens fed with T25 during the study, which according to them contained major flaws. "It's astonishing that this study has not been assessed and found wanting by the government and that it's down to Friends of the Earth to have it properly reviewed", said Dr. Kestin.

The Public Hearing in the UK was indefinitely postponed in November 2000, at the government's request, and reconvened in April 2002 (see *following article*).

Questionable animal feeding tests, significant compositional differences

In spring 2001, FoE groups throughout the European Union combined forces to try to get the authorisation of T25 revoked (see *Mailout Volume 7, Issue 3, 1.06.2001*). To substantiate its opposition, FoE published a catalogue of evidence (1), including the scientific opinions mentioned

above, demonstrating that the approval process for T25 had been fundamentally flawed. This included:

- Although the maize intended for cattle feed, it had never actually been tested on cows. The only studies conducted by Aventis and presented as part of the authorisation dossier referred to chickens and rats which have completely different digestive systems. A UK expert committee on animal feed set up in the wake of the 'Mad Cow' crisis to advise on animal feed issues, criticised the safety evidence presented by Aventis and demanded testing on cattle. Their advice was ignored.
- Significant compositional differences between T25 and conventional maize were discovered: levels of amino acid, fatty acid, fat, carbohydrate, protein and fibre content of T25 were significantly different from those of non-GM maize.
- The only experiment using whole T25 maize kernels which showed suspicious circumstances was not investigated further, i.e. the 1996 feeding study with chickens.

Chair of GMO Advisory Committee admits T25 research was inconclusive

The relaunch of the Public Hearing on the seed listing of Aventis T25 (Chardon LL) has thrust the fiasco of T25's authorisation into the spotlight once more. On 27th April, BBC radio broadcast an interview (2) "Concern over safety of GM crops" during which they questioned a number of relevant people, including Drs. Kestin and Knowles (mentioned above), and Professor (now Lord) Alan Gray, a senior scientist who chairs the UK's Advisory Committee on Releases to the Environment (ACRE). Drs. Kestin and

Knowles reiterated their criticism of the research submitted by Aventis: "It wasn't really a good enough experiment to base a student project on, let alone a marketing consent for a GM product ...it does surprise me that we've got so far down the line of licensing the GM crops apparently based on very weak and rather thin science". "It is an extremely poor design and a relatively inexperienced researcher would have a chance of spotting the flaws in it". "There's no information, no useful information at all in the study ... it was a waste of time".

The interview is shocking in that Lord Gray, who was a member of ACRE when the committee approved T25 in July 1996, now admits on public radio that the research on T25 should have been re-analysed and that safety tests weren't good enough. Lord Gray told the BBC that ACRE originally looked at a summary of the chicken study "that is all we saw, we saw a summary", and only saw the full chicken study later. After seeing the whole thing, Lord Gray admits: **"the problem with the study is that its size and the way it was analysed doesn't enable us to draw any conclusions ... We're unable to say one way or the other whether the study tells us that it is or its different in the way it impacts on the chickens"**. Later in the interview, however, Lord Gray became confused as to whether ACRE had actually seen the whole chicken study or not before it approved T25.

Interviewer: In July 96 you gave the original marketing consent. Had you seen the chicken study before you did that?

Lord Gray: I don't recall to be honest. I mean if you ask ...when did the chicken, I'm not sure when the chicken

study actually appeared, but I ...

Interviewer: I think, I think it appeared in July 1996.

Lord Gray: Yeah well in, I mean, I, whether we actually saw that you will need to remind me. And I will need to consult the dossier whether we actually saw that, whether that was part of our original risk assessment. But certainly we have seen it subsequently.

Questioned by the interviewer about the higher mortality rate of the chickens fed with T25 - 8% compared to a usual mortality rate among broiler chickens of 3.8% - Lord Gray's initial response is that the mortality rate is within the range of those traditionally found in broiler feeding studies. However, he then appears not to disagree with the Bristol University scientists' interpretation of the data, i.e. that the results should have prompted a larger or re-designed trial. Later on he states that "We think the experiment should be re-analysed again".

On the issue of whether T25 should be tested on cattle, Lord Gray passed the buck to the Advisory Committee on Animal Feeds which, according to him, "saw nothing in the tests that had been done which would raise any alarm in feeding these products to animals". During the interview, he mentions the fact that cattle feeding studies have since been carried out at the University of Reading but admits under duress from the interviewer that he is uncertain if cattle feeding studies were available to ACRE when it approved T25 in July 1996.

"the problem with the study is that its size and the way it was analysed doesn't enable us to draw any conclusions ... "

The interviewer then tackled Lord Gray on whether, as now Chairman of ACRE, he is the appropriate person to oversee a review of the authorisation of T25, bearing in mind that he was on the committee when it granted the original approval.

Interviewer: Even though you've also said earlier in the interview that it, is a pretty useless study you're happy with being presented data about the safety of this product on the basis of what you yourself described as a fairly useless study?

Lord Gray: I didn't say it was useless, I said it, its ... power to tell us anything about the impact on mortality of feeding with the two different types was, not good.

Conclusions

The admission by the chair of a government agency responsible for approving market release of GMOs that decisions were made based on inconclusive evidence submitted by the company, and dismissed by other scientists as "a waste of time" is deeply disturbing, to put it mildly. How can a sceptic public possibly have any confidence in an authorisation process which is clearly so deeply flawed? And how many skeletons are there in other cupboards, which have not yet come to light where biotech companies may have presented insufficient data in order to persuade the authorities to license authorise GM products?

The fact that T25 was ever granted market authorisation on the basis of such flimsy data, and that the European Commission has declined to initiate an investigation, despite being presented with all the data, is extremely unsatisfactory. In 2001, FoE wrote to Margot Wallström, EU Environment Commissioner, whose Directorate was responsible for

overseeing the EU authorisation of Aventis T25, presenting all the considerable counter evidence surrounding its approval. When the Commission in due course replied, all it would say was that the procedures relative to the authorisation had been followed correctly - therefore, no problem. It did, however, leave open a small window of opportunity by suggesting that the issue could be raised with the French competent authority, since France was the notifying country which initiated the approval process. If the Commission will not act and continues to wash its hands of this whole affair, it will take political pressure from the Member States to get the T25 approval revoked, or at least re-examined. In this respect, more than one EU Member State has used emergency procedures in European legislation to prohibit T25 on their territory. Austria and Wales (via the UK government) have invoked

Article 16 of Directive 90/220/EEC against T25. And in August 2000, the Italian government announced that it was banning four GM maize varieties, including T25, because it disagreed with their approval under the simplified 'substantial equivalence' rules of the EU's Novel Food Regulation (EC 258/97). Despite the fact that the EU's Scientific Committee on Food disagreed with the Italian objection, and threats by the Commission that the ban is therefore "illegal", it has declined to take any action against Italy to get the ban

That T25 was ever granted authorisation, and that the European Commission has declined to initiate an investigation, despite being presented with all the data, is extremely unsatisfactory

lifted. A negative aspect of the proposed new Traceability/Labeling and GM Food/Feed Regulations (see *article on page 1 of this Mailout*) is that they will undermine the Member States' possibilities to invoke emergency clauses concerning GMOs and thus effectively outlaw national bans.

The T25 experience should be a salutary lesson in how easily biotech companies may get their products to the market, via a regulatory system that allowed inconclusive research to serve as a basis for approval ... and how difficult it is to overturn such approvals once they have been granted.

- (1) www.foe.co.uk/resource/evidence/analysis_chicken_study.pdf
- (2) http://news.bbc.co.uk/1/hi/english/sci/tech/newsid_1954000/1954408.stm

UK SEED LISTING RECONVENES

The public hearings into the proposed National Seed Listing of ChardonLL, a T25 maize from Aventis, have concluded in the UK. The original hearing was suspended in November 2000 after it was discovered that only one year's testing data was available instead of the legally-required two. More testing has been done in the meantime. In addition, the Minimum Characteristics Directive (72/180) was amended (now called 2002/8) after Friends of the Earth submitted that the criteria used to test ChardonLL was different to the legal requirements.

The Hearings have now ended but not without controversy. Aventis had already refused to submit evidence during the hearings. But

when it came to the final summing-up they produced a whole series of new evidence – most of it unsupported, badly referenced or simply untrue. They then instructed their lawyer not to be cross-examined on any of this evidence. Whilst the hearing Chairman, Alan Alesbury QC, was clearly irate, he was legally unable to summon Aventis or their legal team to take the stand and be cross-examined. The Chairman will now have to report to UK Ministers and somehow explain how some of the evidence is unsupported.

In another twist, Friends of the Earth received a leaked document from the UK Government which explained how they will be urgently amending the legislation to prevent

GMO objections at any future seed listing. The document outlined recommendations to bring in legal changes as soon as possible after the ChardonLL case and before the next GMO seed, Sheridan (also from Aventis). In what will be an embarrassment for the Government, a substantial amount of the document dealt with "presentation" and how the Government can spin the announcement into a positive story as "Any proposal to remove GM safety issues from the scope of National List representations and hearings will be criticised because it will seem we are trying to silence GM objections"!!! (The leaked document is available at: http://www.foe.co.uk/resource/leaked_documents/gm_draft_submission.pdf)

EU's JOINT RESEARCH CENTRE SAYS GMOs WILL MEAN FINANCIAL LOSSES FOR FARMERS

In May, the Joint Research Centre (JRC) - an official agency of the European Union based in Italy - published a lengthy report dealing with the consequences of large scale introduction of GM crops in the EU. The report, "Scenarios for co-existence of genetically modified, conventional and organic crops in European agriculture", is based on expert opinions and on computer simulations. It presents data on genetic contamination and analyses financial losses in cases of such contamination. The study was done on three crops for which GM varieties are available (oilseed rape for seed production, maize for feed production and potatoes for human consumption) and for several farm types (both organic and conventional) that were defined to cover the variability present in EU farming infrastructure. For all crop-farm combinations, a hypothetical share of GM crops of 10% or 50% in the region was considered.

The main conclusion that can be drawn from the report is that GM contamination of conventional and organic crops is inevitable as a result of the introduction of GM varieties. The report also makes it very clear that the introduction of GM crops into the EU would lead to a substantial cost increase for both conventional and organic farmers.

In the report the researchers investigate the possibility to maintain a threshold near the analytical limit (<0,1%) for GM contamination in organic crops. Such a threshold reflects the situation in organic farming

where the use of GM varieties is not allowed (Council Regulation (EC) 1804/1999). The report concludes that a "0.1% limit will be extremely difficult to meet for any farm-crop combination in the scenario's considered". **This means that if, for example, the proportion of GM crops in any EU region would be 10%, organic farming, according to the current EU's legal standards, would be made impossible!**

The report also considers the possibilities to maintain a 0.3% threshold for GM contamination of conventional seed and a 1% threshold for GM contamination of conventional food/feed. These figures were chosen by the researchers because the European Commission is currently proposing a threshold of 0.3% GM contamination for seeds and a threshold of 1% GM contamination for food/feed, meaning that if contamination by GMOs were below these thresholds, conventional seed, food and feed would not have to be labelled as being derived from GMO (see article on page 9 of this Mailout).

But even these high thresholds as proposed by the European Commission are very difficult to meet when GM crops are introduced. In the words of the JRC report: "Co-existence of GM and non-GM crops in a region (with 10% or 50% GMO share) might technically be possible but economically difficult because of the costs and complexities of changes associated". Compliance with the 0.3% and 1% thresholds through changes in farming practices and introduction of a monitoring system, as well as likely insurance re-

quirements, may result in additional costs of 1%-10 % of current production price for the farm-crops combinations studied (in the 50 % scenario). In the case of organic oilseed rape, the cost increase would be as high as 41%. In all cases, monitoring activities account for a large part of the additional costs.

Increased costs and liability

The researchers allocate the increased cost resulting from the introduction of GM crops to farmers growing conventional or organic crops and not to GMO producers or farmers growing GM crops! This reflects the current situation in which there is no legal obligation for commercial GM crop production to introduce measures to minimise adventitious presence of GM crops in non-GM crops. Obviously this is a very unjust situation. GMO producers cause a substantial cost increase but conventional and organic farmers (and probably consumers and taxpayers as well) have to pay for it! Therefore the JRC report underlines once more the need for comprehensive liability legislation covering economic and ecological damage caused by GMO producers. Until now the EU has failed to deliver such legislation (see *Biotech Mailout Volume 8, Issue 2, February 2002*). Also, the report makes it very clear that the threshold for GMO contamination currently proposed by the European Commission would have huge financial implications.

The 145 page report is available on the Internet in PDF format at: <http://www.jrc.cec.eu.int/GECrops/>

GMO MORATORIUM NEWS

Swiss committee votes for ten-year moratorium on cultivation Austrian Parliament demands prolongation of EU moratorium

Swiss committee approves ten-year moratorium

At the end of May, Switzerland's Committee on Science, Education and Culture, part of the National Council (CSEC-CN), approved a ten-year moratorium on the cultivation of genetically modified plants. The vote was close - 13 in favour and 12 against. The decision was welcomed by the Working Group on Genetic Engineering (Groupe de Travail sur le Génie Génétique (GTG) and partner associations who described it as a minimal compromise that would allow Swiss agriculture to maintain a favourable market position and to apply the Precautionary Principle in the fields of both environment and human health. The decision should also encourage scientists to conduct research targeted at the prevention of risk. Swiss farmers should be able to produce natural food products which are guaranteed free of genetic modification, thus responding to the demands of the majority of consumers in both Switzerland and the European Union.

The decision for a moratorium adopted by the majority of the CSEC-CN is a positive response to both public concern and the unanimous opinion of the farming community. The Committee took into account potential risks linked to transgenic plants, and encouraged researchers to continue work on risk prevention. A ten-year moratorium would give Swiss agriculture the time to evolve further towards a system that both respects the environment and meets the demands of consumers, without giving in to

pressure from agro-industry. Consumers would therefore be assured of their freedom to choose products which have not been genetically modified.

The GTG and partner associations are urging the National Council to uphold the decision which they consider would fill gaps currently existing in the national genetic engineering law by inclusion of the Precautionary Principle. Organisations working in the areas of consumer affairs, environment, nature and animal protection, medicine, cooperation and development, and agriculture have all pledged to put all their efforts into supporting a moratorium.

A Swiss moratorium would send a powerful message to the European Union which is itself also calling increasingly for the application of the Precautionary Principle as far as genetic engineering in agriculture is concerned. A recent study issued in the EU (see JRC article on page 7 of *this Mailout*) has clearly shown that for small areas of cultivation, as exist in Switzerland, the release of GM plants would make it impossible to guarantee crops free of GMOs.

The Swiss National Council will vote in September whether to uphold the Committee's decision.

Austrian parliament votes to prolong EU moratorium

On 23rd May, the Austrian National Parliament voted (unanimously) in favour of prolonging the 'de facto' EU moratorium on GMO approvals. In a resolution, the Parliament

('Nationalrat') urged the government of Austria to "plead with all its force for a prolonging of the moratorium". The Parliament pointed to the fact that the moratorium was installed in 1999 because EU Member States were concerned about the lack of labelling and traceability legislation for GMOs. As long as such legislation is not in place, lifting the moratorium would be premature, according to the Austrian Parliamentarians.

Apparently the Austrian Parliament realises that it might still take some time before traceability and labelling legislation comes into effect in the EU. Maybe the Parliament even considers the possibility that full traceability and labelling will never be realised (see article on page 1 of *this Mailout*). The Austrian resolution once again emphasises the fact that failure of the European Parliament and the Council to adopt strict labelling and traceability legislation for GMOs, could easily lead to a continuation of the EU-wide moratorium.

Interestingly, the Austrian Parliament's statement refers not only to traceability and labelling but also to liability. It calls on the government to solve the liability problem before the autumn of 2002, thereby indicating that the lack of liability legislation for GMO covering adventitious contamination is another reason to uphold the moratorium.

The full statement of the Austrian Parliament (available in German only) is available at: www.parlinkom.gv.at

BELGIAN ENVIRONMENT MINISTER REFUSES TWO GMO FIELD TRIALS

On 29th April, Environment Minister Magda Aelvoet announced that she would not give permission for new field trials involving GM oilseed rape in Belgium. An application to conduct such trials from the biotech company Aventis was turned down by the Minister Aelvoet, who also refused an application for GM apple trees.

Oilseed rape

In the case of the GM oilseed rape, the Belgian Minister backed up her decision by referring to the Precautionary Principle. Aelvoet also referred to two recent reports, one of which was published earlier this year by the Belgian SBB - Sectie Bioveiligheid en Biotechnologie (Department of Biosafety and Biotechnology). The SBB is an institute attached to the Scientific Institute for Public Health in Belgium and has the authority to evaluate applications for GMO field trials. The other report, "Genetically modified organisms (GMOs): The significance of gene flow through pollen transfer" (see *Mailout Volume 8, issue 2, 1.04.2002*), was released two months ago by the European Environmental Agency (EEA). The EEA report was written as part of a special project for the European Parliament, started in 2000, on the dissemination of research results from technologies characterised by scientific complexity and uncertainty.

According to a press release issued by the Belgian Minister, the SBB report confirms, in the case of GM-oilseed rape field trials, that "in spite of strong precautionary measures which the Belgian authorities have put in place, not all dispersal of

transgenic material can be prevented". The Minister also quoted from the EEA report, saying that pollen from GM rape can be transferred as far as 4 kilometres by bees and can survive for several days.

Companies must be liable

In her press statement Minister Aelvoet says that the "long-term effects on the ecosystem and on biodiversity of the dispersal of transgenic material have not been researched thoroughly until now". According to the Minister, just a few transgenic oilseed rape plants will suffice to form a reservoir from which the spread of transgenic material into the environment can take place. Taking into account the irreversible character of such spread and the uncertainties surrounding the exact effects, the Minister prefers to apply the Precautionary Principle. However, concerning applications for field trials of other crops, Aelvoet did allow the testing of transgenic maize by Aventis, but only on condition that the tests take place in greenhouses. The Minister also gave the green light for field trials of transgenic sugar beet and chicory, provided that flowering of the plants is prevented.

Another new element of the Belgian policy is that there is more public in-

formation available. Since Aelvoet is in office, all mayors of the municipalities where field trials are taking place receive a letter indicating the exact location of the trials.

The Minister has also added to the conditions under which field trials are allowed that the company which introduces GMOs into the environment bears "full civil liability for possible damage to human and animal health and the environment".

Tighter rules in future

Aelvoet announced in the same press statement that she is working on tighter rules for future applications. The Minister regrets that currently there is "no assessment of the scientific usefulness" of GMO field trials". She also expressed the view that the consequences of GMO field trials for farmers and bee-keepers should be better investigated in the future. She announced that, from now on, more research data should be available before an application will be taken into consideration. "This is the last time that GMO field trials are approved on a narrow basis", the Minister said. Aelvoet intends to expand Belgium's "Bioveiligheidsraad" (Biosafety Council) to include ecologists and economists in order to make a better assessment of the risks of GMO field trials possible in the future.

For more information see:
<www.biosafety.ihe.be>

"long-term effects on the ecosystem and on biodiversity of the dispersal of transgenic material have not been researched thoroughly"

NO SEEDS SAFE FROM GM CONTAMINATION?

As previously reported in the FoEE Biotech Mailout, the European Commission plans to introduce tolerance levels for GMO contamination of conventional seeds and propagating material. The Commission's draft Directive proposes that seeds contaminated with GMOs can be marketed without any labelling provided that contamination does not exceed 0.3, 0.5 or 0.7 % depending on the plant species.

According to the report on the 7-8th May 2000 meeting of the EU's Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry (1), the Commission intends to hold an indicative vote at the beginning of July and, followed by a notification to the World Trade Organisation, with a subsequent vote in September. The proposed Commission Directive will be adopted under the EU's comitology procedure, i.e. through a regulatory committee and, if that fails to reach agreement, through the Council. The European Parliament will not be involved in the procedure.

An unacceptable process

This procedure is unacceptable for at least two reasons:

1. It is clearly unacceptable that the Commission should make decisions about seed contamination by GMOs before the European Parliament has debated and voted on the proposed EU Regulations on Traceability/ Labelling and GM Food/Feed which also deal with contamination levels, but in finished products such as food and feed. For

“It’s a hell of a thing to say that the way we win is don’t give the consumer a choice, but that might be it”

the Commission to take action to set thresholds for seed contamination beforehand is clearly a case of 'cart before horse', since such decisions would preempt the Parliament's later decisions on food/feed.

2. Any moves to legalise GMO contamination of seed will clearly undermine both organic and conventional farming and could be the beginning of the end for non-GM agriculture. This, of course, is exactly what the biotech industry wants and the Commission is playing into its hands by setting tolerance levels. As mentioned in FoEE Biotech Mailout Volume 7, Issue 1, 1.02.2001, by allowing threshold limits, GMO contamination becomes possible and even inevitable for everything - seeds, food and feed. GM-free plants and thus GM-free food/feed will become a relic of the past. Once seed contamination by GMOs is legalised, all the biotech industry has to do is sit back and wait for it to happen.

It is not only worried consumer and environmental groups, and the general public who fear their freedom of choice is threatened, who say this. The biotech industry itself actually

admits it, as borne out by a recent quote from Dale Adolphe in the publication "Western Producer", 4th April 2002: "The total acreage devoted to GM crops around the world is expanding. That may be what eventually brings the debate to an end. It's a hell of a thing to say that the way we win is don't give the consumer a choice, but that might be it". Dale Adolphe was previously President of the pro-GM Canola (oilseed rape) Council of Canada and now heads the Canadian Seed Growers Association.

Save our Seeds

Environmental NGOs in Germany have started a campaign, aimed at EU Commissioners Byrne, Fischler and Wallström. The campaign - "Save our Seeds" - calls for a halt to the uncontrolled spread of GMOs through seed contamination. A petition urges the Commissioners to ensure that the proposed Directive on seed purity does not allow for contamination of non-GM crops by GMOs.

The petition also states that the costs arising from the obligation to keep seeds GM-free should be borne by GMO producers or by those who grow GMOs, and not by consumers or farmers. Currently the petition (which Friends of the Earth has co-signed) is circulating in several European countries to be signed by as many organisations and individuals as possible. If you want to sign up, go to: www.saveourseeds.org.

(1) <http://europa.eu.int/comm/food/fs/rc/scsp/rap31_en.pdf>

BIOSAFETY NEGOTIATIONS - NO SUBSTANTIAL PROGRESS

The third meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) to the Convention on Biological Diversity took place on 22nd-26th April in The Hague. As of April 2002, the Protocol has been ratified by 17 countries but will only enter into force when 50 countries have done so. The progress on the status of ratification announced by the Secretariat indicates that the Protocol would enter into force before the end of this year. If that were the case, the first meeting of the Parties (MOP) could take place within a year.

Topics discussed during the ICCP included liability and redress; compliance; the provisions on documentation for living modified organisms (LMOs) for food feed or processing; monitoring and reporting; information sharing and other issues related to the implementation of the Protocol. In general, no substantial progress was made, taking into account the attitude of several countries, including the US and Australia, which delayed decisions on key provisions of the agenda like identification of LMOs, and liability and redress. Those issues were the most contentious at the meeting.

Liability and redress

The discussions on liability and redress focused on establishment of draft terms of reference for an open-ended ad hoc working group which would make recommendations on the elements of a liability and redress regime for damage resulting from the transboundary movement of LMOs. The discussion on the elements to be considered by the working group were blocked since several countries, namely the US, Australia and Argentina, wanted more discussion on whether the working group on liability should be established or not, and asked for more information about this issue. Paradoxically, the Secretariat had already provided comprehensive documentation on the topic beforehand.

LMOs-FFP

Documentation for living modified organisms for food, feed or processing (LMOs-FFP), contained use and intentional introduction (Article 18.2 (a) of the Protocol) requires that documentation should identify that shipments of LMOs-FFP "may contain" LMOs, and a decision on detailed requirements concerning LMOs-FFP should be taken no later than two years after the Protocol

enters into force. Parties need that information to monitor imports and it is an important element of a traceability system. The deadline of two years was welcomed by the same countries that blocked progress on liability to delay progress on this issue, since they obviously want to postpone decisions until the deadline expires.

NGOs were very critical of the lack of substantial progress and strongly condemned the obstructionist tactics of the delegations mentioned above. On liability and redress in particular, the NGO Caucus deeply regretted that the delegations at ICCP 3 did not agree on terms of reference for the establishment of an open ended ad hoc working group and called for the establishment, in the meantime, of an adequate retroactive compensation fund that would be maintained by the exporters and producers. As far as the identification of LMOs is concerned, the NGO Caucus called for a meaningful system of unique identifiers for all LMOs based on reliable and precise detection methods for event-specific molecular characterisation data such as PCR. Finally, the NGOs reiterated their demand for an immediate moratorium on releases of Living Modified Organisms until a biosafety regime is in place and, in addition, called for a ban on imports of LMOs in centres of origin in light of the recent cases of the contamination of maize in Mexico.

TRANSBOUNDARY MOVEMENTS OF GMOs

On 18th February, the European Commission presented a Proposal for a Regulation of the European Parliament and the Council on the transboundary movements of GMOs (COM(2002) 85) which aims to implement the Cartagena Protocol on

Biosafety which was signed by the European Union and its Member States on 24th May 2000. According to the Protocol: "nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the con-

servation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objectives and the provisions of this Protocol and is in accordance with that Party's other obligations under in-

ternational law” Art. 2(4). The Regulation, however, fails to fully implement the minimum obligations of the Protocol, and also fails to address export of certain product categories such as GM food/feed, although these product categories are subject to strict authorisation procedures under EU law.

Scope

The Regulation covers “export and unintentional transboundary movement of all GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health”, but would not cover “pharmaceuticals for human use”. Article 2 allows for GMOs to be excluded from the scope of the Protocol following a decision of the Meeting of the Parties. In contrast, the Protocol covers “transboundary movement, transit, handling and use of all living modified organisms”.

Comparison with Art. 4 of the Protocol

The Protocol defines both export and import as “transboundary movement”. As import of GMOs is already covered by EU legislation, the Regulation should only address “export”. Since the EU's definition of a GMO is broader than the Protocol's definition of LMO, and since the introduction of a new category of “LMOs” would be confusing, the term “GMO” would be more appropriate. “Handling and use” of GMOs within the Union is already covered by EU legislation. However, Art. 2 of the Regulation does not cover transit. While transit through the territory of the Union is regulated by EU law, the Protocol (Art. 6) and the Regulation (Art. 7) also address transit through the territory of other parties. “Transit through the territory of Parties that have taken the decision to regulate transit of GMOs through their territory”

should be added to the scope of the Regulation.

Products other than GMOs

Major categories of biotech products regulated (or shortly to be regulated) by EU legislation are not covered by the Regulation, e.g. food/feed produced from but not containing live GMOs. While food produced from GMOs is currently covered by Regulations EC 258/97 and EC 50/2000, the proposed EU Regulation COM(2001) 425 (see *article on page 1 of this Mailout*) will address both GM food/feed. Since one of the main goals of the Protocol is to prevent double standards for products used within/ exported from the EU, the Regulation should also cover food/feed produced from GMOs and should at least require exporters to comply with the laws of Parties of import. The EU would thus acknowledge some responsibility regarding GM food/feed produced within the EU and exported outside the Union. Another option would be that exports should comply with the EU's own food/feed safety standards.

Optional exclusions from scope

The Regulation foresees optional exclusion of certain GMOs from the scope of Section I (Art. 2(3)). Given political reality, a decision of the Meeting of the Parties to exclude certain LMOs from the scope of the AIA procedure cannot be taken against the EU's will. Therefore Art. 2(3) would make it possible for the Commission and Member States to change the Regulation's scope by initiating/approving a decision of the Parties to exclude certain LMOs from the scope of the AIA. In order to prevent changing the scope without the European Parliament's approval, Art. 2(3) should require a Parliament and Council Regulation, in addition to the decision of the meeting of the Parties.

Definitions

Contained Use

The Regulation defines “contained use” (Art. 3(5)), although the term is not used elsewhere. Since the Protocol allows Parties to set their own standards for import of GMOs destined for contained use (Art. 6(2)), the Regulation should require compliance with any rules of Parties of import regarding import of such organisms. In addition, in accordance with Art. 18(3) of the Protocol, the Regulation should require the identification of GMOs destined for contained use.

Food/feed

The definitions of food/feed should be updated to reflect the definitions of “Food” and “Feed” laid down in Regulation (EC) 178/2002 on general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety (Art. 2 and 3(4) respectively).

Export of GMOs for deliberate release

The AIA procedure

Section I of the Regulation is meant to implement the Protocol's AIA (advance informed agreement) procedure but fails to address the principle that GMOs intended for deliberate release should not be exported without the AIA of the Party of import (unless the Party of import has indicated otherwise through its domestic regulatory framework).

GMOs “intended for deliberate release”

GMOs will often not be released immediately after they reach the territory of the Party of import, but might be stored, sometimes crossed with other organisms or propagated under contained use conditions before being released into the environment. The question therefore arises whether those GMOs qualify as be-

ing “intended for deliberate release”. Neither the Protocol nor the Regulation give much guidance on this question. Given the Protocol’s aim to make information available for risk assessment of GMOs released into the environment, the Regulation should clarify that the AIA procedure (Art. 4-6) should apply to all GMOs which “after temporary storage, transportation, cultivation or multiplication, or after use in any other operation, are intended to be released or to lead to a deliberate release of GMOs into the environment”.

Notifier/Exporter

The Regulation requires the exporter to “ensure notification”. Given the definition of “exporter” (Art. 3(14)) and “notifier” (Art. 3(11)), this would mean that either the exporter or a third party (the “notifier” - e.g. the importer) could send the notification to the competent national authority of the Party of import. According to the Regulation, it is the notifier not the exporter who would be responsible for the accuracy of the information in the notification. However, the Protocol does not mention a “notifier” but says the Party of export shall notify or require the exporter “to ensure notification” of the transboundary movement (Art. 8(1)). The exporter is defined as the natural or legal person who arranges for a trans-

boundary movement. The Party of export shall ensure “there is a legal requirement for the accuracy of information provided by the exporter”. The Regulation tries to reinterpret exporter into importer obligations. While it may be acceptable that exporters mandate a representative (e.g. the importer) to take care of “paper work”, the Protocol stipulates that this representative acts on behalf of the exporter who is responsible if the representative acts improperly. The category of “notifier” should therefore be abolished in the Regulation.

Accompanying documentation

The Protocol states that Parties shall take measures to ensure that documentation accompanying “living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter” (Art. 18(2)c). This is not reflected in the Regulation which fails to address the issue of accompanying documentation in sufficient detail (Art. 9).

Export of GMOs for FFP

In accordance with the Protocol (Art. 11), the Regulation foresees a simple information exchange procedure for transboundary movements of GMOs intended for direct use as food, feed or processing (FFP). The Regulation overlooks, however, that the Protocol does not oblige Parties to recognise product authorisations notified under Art. 11 to the Biosafety Clearinghouse but instead allows them to require a separate authorisation procedure under their domestic regulatory framework (Art. 11(4)).

Similarly, the Regulation ignores Art. 11(6) of the Protocol which allows developing countries (and those with economies in transition) to declare that the first import of an FFP-GMO requires their prior informed consent. Although not explicitly required by the Protocol, EU legislation should require exporters to comply with such authorisation requirements where they exist. In addition, in accordance with Art. 18(2)a of the Protocol, exporters should be required to ensure that documentation accompanying FFP-GMOs clearly identifies that they “may contain” living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information.

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