

FoEE Biotech Mailout

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INSIDE THIS ISSUE:

P3: Doctors urge halt to GM crop trials

P4: Austrian study shows legal measures against GM contamination are feasible

P5: Croatian government presents new GMO laws

P6: Morphogenics: - a step too far ?

P7: Food crops contaminated by bio-pharmaceuticals

EU MINISTERS AGREE ON LABELLING OF GM FOOD

On 28 November 2002, the Council of EU Agricultural Ministers reached a political agreement on the Regulation concerning genetically modified food/ feed (COM (2001) 425). On 9 December, the Council of EU Environment Ministers reached a similar agreement on the Regulation concerning the traceability and labelling of GMOs and the traceability of food and feed products derived from GMOs (COM (2001) 182).

On most points (e.g. tolerance level for unauthorised GM materials) the decision by the Environment Ministers follows the agreement reached by the Agricultural Ministers. On the point of traceability (the documentation that operators are required to deliver when they want to place GMOs on the market) it were only the Environment Ministers who had to take a decision.

In the agreement finally reached in both Councils the Ministers have taken a position that compromises between the original Commissions proposals and the position taken by the European Parliament (EP) in first reading. This means that there is still considerable room for improvements when the Parliament votes upon the Ministers compromise in second reading. This second reading is expected to take place in March 2003.

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The Ministers decision includes the following essentials:

1. Origin labelling

There is agreement among all the institutions on the new labelling scheme which is based on traceability rather than detectability: All GM food and feed products, i.e. products containing, consisting of or produced from GMOs have to be labelled irrespective of whether they contain DNA or protein resulting from the genetic modification or not.

Under the existing EU law processed GM feed does not have to be labelled at all. Processed food only has to be labelled if the presence of GM material is higher than 1% and only if DNA or protein resulting from the modification can be detected in the food product. Highly refined oils therefore do not have to be labelled according to the current rules.

2. Tolerance level for unauthorised GM materials

The Council decided to set a transitional threshold of **0.5%** for unauthorised GM materials which are present in conventional food or feed due to technically unavoidable or

accidental circumstances. The threshold shall expire after three years. The threshold applies only to those GMOs and GM ingredients which have received a positive opinion from the Scientific Committee before the date of application of the Regulation and which have not been denied authorisation in the meanwhile. The regulation shall apply 6 months after its publication.

In 1st reading, Parliament called for a deletion of the proposed threshold (amendments 25, 74, 122).

3 . Labelling threshold (Art. 13/ 16 GM food/ feed)

The Council agreed on a labelling threshold of **0.9%** for the adventitious/technically unavoidable presence of GMOs or GM ingredients in food or feed products. Lower thresholds may be established in comitology for *food* containing or consisting of live GMOs or in order to take into account advances in science and technology.

The Commission's original proposal did not specify any maximum labelling threshold.

Parliament had proposed to set a maximum threshold of 0.5% which should only apply to processed GMOs, i.e. not to live GMOs. Parliament had also proposed to "define appropriate steps" producers not using GMOs should take in order to avoid contamination, and to lay down appropriate measures to ensure that the utmost care is taken to avoid contamination. Finally, Parliament proposed to require the regulatory committee to set a lower threshold as and when advances in science and technology allow (amendments 164, 161).

4. Measures to avoid the unintentional presence (EP amendments 14, 43, 88)

Council and the Commission

continue to ignore EP amendments concerning the measures necessary to avoid the unintentional presence of GM food/ or feed in other products. EP amendments 14, 43, 88 require the notifier to propose and the Authority to establish effective measures to prevent the unintended presence of the GM feed or GM feed in other products.

5. Sectoral legislation (Art. 5.4; 17.4 & Art. 6.5; 19.4 GM food/ feed)

The Council agreed to establish the GM food/feed regulation as "sectoral legislation". This means that in future companies will be able to receive a permit for the cultivation, food and feed use of GMOs under the GM food/feed regulation. GMOs to be used as seed and food and/or feed will therefore be excluded from the scope of Part C of Directive 2001/18/EC. However, in order to avoid that food experts have to assess environmental effects of GMOs, the compromise requires the European Food Safety Authority (EFSA) to ask a competent authority of a Member State to carry out an environmental risk assessment whenever an application involves GMOs to be used as seed or propagating material.

Parliament had rejected this approach and proposed that in line with Art. 12.3 of Directive 2001/18/EC the GM food/feed regulation should not become sectoral legislation (EP amendments 33, 79, 120). Art. 12.3 of Directive 2001/18/EC requires the adoption of a regulation ensuring that "sectoral legislation" is equivalent to Directive 2001/18/EC before "sectoral legislation" may replace part C of Directive 2001/18/EC. Until such regulation exists no product may be marketed without having first been approved against 2001/18/EC.

6. Traceability of GMOs to be used as food and feed (Art. 4.2 Traceability/labelling)

In the draft Regulation concerning traceability and labelling the European Commission had proposed an obligation for operators to transmit the unique code(s) assigned to GMOs to the operator receiving the product. This measure would make it much easier to « follow » a GMO once it is on the market, to assess its environmental and health impact and to organise recalls in case of adverse effects. However, the Commission made one important exception : if the product is only to be used as food or feed, the unique codes may be replaced by a declaration by the operator that the product shall only be used as food or feed, or for processing, together with the unique codes for the GMOs that the product « may contain ». In first reading, the Parliament deleted this exception, considering that « transparency » should be « ensured » (amendment 16). The Council's now proposes that –in case of products to be used directly as food or feed, as well as for processing– "operators may replace written information with a declaration of use accompanied by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture".

7. Authorisation procedure (Art. 6 - 8 GM food/ feed)

The Council agreed on a centralised authorisation procedure which will give EFSA and the Commission a central role. However, while the Commission had proposed that applications should be directly sent to the EFSA/ Commission, the Council agreed that they should be sent to the national competent authority which should then carry out the risk assessment. However, the Commission, and not the competent authority, shall produce the draft decision which will then be dealt with by comitology. In other words: the competent authorities become the mail boxes of the EFSA.

(continue reading on page 3)

Roadmap

The Council's common position shall be formally adopted before the end of December. It could then be transmitted to Parliament at the earliest on 13 January 2003, the first day of the first January plenary.

Parliament then has to complete the second reading within three months which may be extended by one month if the Council agrees. The common position will be referred to the responsible Environmental Committee and to the committees asked for their opinion at first reading (AGRI, JURI).

In the second reading amendments to the common position shall be admissible only if they seek:

- (a) to restore wholly or partly the position adopted by Parliament in its first reading; or
- (b) to reach a compromise between the Council and Parliament; or
- (c) to amend a part of the text of a common position which was not included in - or differs in content from - the proposal submitted in first reading and which does not amount to a substantial change within the meaning of Rule 71; or
- (d) to take account of a new fact or legal situation which has arisen since the first reading.

The President's discretion to declare an amendment admissible or inadmissible cannot be questioned. An amendment shall be adopted only if it secures the votes of a majority of the component Members of Parliament (314 votes). If the Council rejects any of the amendments adopted by Parliament with at least 314 votes, a conciliation procedure and a third reading follow. In the third reading Parliament votes yes or no.

DOCTORS URGE HALT TO GM CROP TRIALS

Senior doctors have demanded an immediate halt to genetically modified crop trials. The British Medical Association (BMA) has warned that insufficient care is being taken to protect public health and that there has been a lack of public consultation about crop trials despite the steady increase in the number of them.

The call for a halt on any further planning of GM crops until trials can be assessed for ecological and health impact was made in a submission to the Scottish Parliament's health committee which was conducting an inquiry into GM crops on 20 November.

The BMA - that has a membership of over 120,000 representing more than 80% of British doctors - originally set out its case against the further planting of commercially produced GM crops in 1999, but its latest demands are made with the benefit of more information.

“ There has not yet been a robust and thorough search into the potentially harmful effects of GM foodstuffs on human health. “

The BMA was asked by the health committee if it believed the Scottish Executive should prevent GM crop trials from continuing on the grounds that the policy is against "the precautionary principle to allow them to continue". The BMA responded: "Yes. As with scientific matters, it can be difficult and timeconsuming to demonstrate safety to an acceptable standard. Safety is a relative matter and is generally based on the results of a robust and thorough search for possible harm. There has not yet been a robust and thorough search

into the potentially harmful effects of GM foodstuffs on human health. On the basis of the precautionary principle, farm-scale trials should not be allowed to continue."

It adds: "Scientists, farmers and politicians need to re-establish public trust. Further research is required into the health and environmental effects of GMOs before they can be permitted to be freely cultivated. This may be executed in such a way as not to expose the population to possibly irreversible environmental risk, which may, in turn, have as yet unquantified public health implications."

More specifically, the BMA refers in its document to worries about the issue of antibiotic resistance. Antibiotic resistance "markers" help identify GM plants and there is evidence that these genes may be transferred to non-GM plants and "possibly into pathogenic organisms causing human disease", it warns.

Also the doctors point at the "potential effects of allergenicity on human health from genetically modified products."

Underlining the responsibility of the parliament and the Executive to protect the nation's health, the BMA says it is disappointed that, to date, the Executive has decided not to include health monitoring of local populations as part of the farm-scale evaluation programme.

Sources: The Scotsman/ Submission of the British Medical Association to the Health and Community Care Committee. This submission is available from the website of Friends of the Earth Europe:
www.foeeurope/GMOs/index.htm
 (see section: what's wrong with gmo?)

PROTECTING AGRICULTURE AGAINST GMO POLLUTION

Austrian study shows legal measures are feasible

The EU moratorium blocking new approvals of genetically modified (GM) crops could be over before the end of 2003. From then onward, there is a realistic possibility that countries belonging to the European Union will be overrun with genetically modified crops. Already 22 pending applications for different types of genetically modified oilseed rape, maize, sugar beet and radish are on waiting list to be approved for commercialisation. If these crops were to get the green light from the European Union, they could be grown throughout the EU without further limitations.

Without adequate protective measures (which are not yet foreseen by the EU or by most of its Member States), transgenes will spread unhindered through pollen transfer and other mechanisms and will contaminate conventional and organic agriculture. It is therefore urgently required to find ways to bring the contradictory EU policy – on the one hand, allowing genetically modified crops and, on the other, wanting to promote organic agriculture and the protection of nature through the creation of "Natura 2000" areas - into line with targets for protection of the environment.

To contribute to this objective, last year Global 2000 (Friends of the Earth Austria) commissioned a study about possible legal measures to fight genetic contamination. Explaining the goal of the study, Global 2000's GMO expert Daniel Hausknost said: "There is a huge

need for action, for political and legal measures, to protect organic agriculture and conventional GM-free agriculture against complete genetic contamination. These measures need to be implemented before the first fields will be affected". The completed study, carried out by the University of Linz¹, and entitled "Possible legal measures to protect organic agriculture and conventional GM free agriculture in Austria against contamination and pollution by GMOs taking into account EU law and the WTO Treaty" was published in October 2002.

Key results of the study:

- **Organic agriculture must remain free of genetically modified organisms.** This is prescribed in the EU "Bio" Regulation 1804/99, although the regulation foresees no legal measures to achieve this target. Without specific protective measures, however, GM-free organic agriculture cannot be guaranteed, if one assumes a spread of GM agriculture in the future. This problem will affect Austria in particular given that it has a high density of organic farms.
- **"Protective zones" surrounding fields in which organic crops are grown are feasible and legally possible.** The model proposed by Global 2000 to install around each organic field a protective zones with a radius of 4 kilometres seems to be compatible with EU law and the WTO Treaty. On the basis of a study² conducted by the EU's European Environment Agency, a GM-free zone with a radius of at least 4 kilometres needs

to be specified bearing in mind the Austrian law that prescribes zero tolerance for genetic contamination of seeds.

- **A Regulation to install protective zones is also useful and legally possible for Natura 2000 areas.** This should be a zone with a radius of 4 kilometres starting from the outside borders of the Natura 2000 areas.
- **A strengthening of liability legislation for GM producers that bring GM products into circulation would be in accordance with the Precautionary Principle and the principle that 'the polluter pays'.** A method of securing financial redress (e.g. in the form of a compensation fund) in case of genetic contamination should be considered.
- **There are ways of protecting organic agriculture and GM-free conventional agriculture through the distribution of subsidies.** Subsidies meant for environmental-friendly agriculture could be given only to farmers who do not grow GMOs.

The full text of the study by the University of Linz can be downloaded from the website of Global 2000: www.global2000.at (in German only).

¹ Authors are Prof.Dr. Ferdinand Kerschner and Univ. Ass. Dr. Erika Wagner from the Institute of Environmental Law of the Johannes-Kepler-University.

² The significance of gene flow through pollen transfer. http://reports.eea.eu.int/environmental_issue_report_2002_28/en

CROATIAN GOVERNMENT PRESENTS NEW GMO LAWS

Over the last year the Government of Croatia has been under heavy pressure from the US government not to adopt a law that would ban genetically modified organisms (GMOs). In November 2001 the first evidence appeared that the country on the Balkans –that wants to be as restrictive as possible on GMOs to protect its unique biodiversity and hence tourism- is being bullied by the US government. In a leaked memo of 28 th November 2001 addressed to the Ministry of Environment by the US Embassy in Zagreb, obtained by Green Action (Friends of the Earth Croatia), the US tries to put trade before environmental protection stating “if such a ban is implemented, the US government must consider its rights under WTO.” The US memo to Croatia also tries to discourage other countries from adopting legal frameworks on GMOs similar to the European Union. The Embassy “suggests caution in implementing EU biotech directives, which require substantial infrastructure and institutional capacity to carry out.”

As a result of the US threats the Government of Croatia has made considerable changes in its draft legislation on GMOs, but its critical attitude has nevertheless remained. The idea of an outright ban has been dropped: in October the Croatian Government decided not to present the draft law that would ban GMOs to the Parliament. Although the Government has not explicitly said so, the main reason for this step appears to be the risks that Croatia would have to face

countermeasures (e.g. fines on Croatian export products to the US) following a WTO case.

Croatia, however, has not given up the battle and has now put on the table three draft laws aimed at regulating the release of GMOs into the environment and food chain. The regulations should ensure protection of nature and human health against the risks of GMOs and guarantee consumers choice through labelling of genetically modified food products.

Protecting nature

On 2nd December, during a Round Table meeting organised by Friends of the Earth Croatia, the new draft laws were presented by several Croatian government officials. Miss Radovic from the Ministry of Environment explained that the new draft law with regard to nature protection has been derived (but not copied) from existing and draft EU legislation, thus neglecting the US advice not to adopt legal frameworks similar to the EU. She also stressed that the new regulations were in compliance with the Biosafety Protocol, that has been ratified by Croatia in May 2002. The new draft law on the protection of nature includes a strict risk assessment of GMOs. Miss Radovic stressed that there would be no releases in those cases “ where risk assessment has shown that a certain GMO can spread in the environment.” She also emphasised that Croatia still has the right to refuse GMOs on a case-to-case ba-

sis. Contrary to an outright ban, such approach would not be in conflict with WTO- rules.

In addition to risk assessment of GMOs on a case-to-case basis the draft law also contains provisions that grant the public at large access to information about releases of GMOs into the environment.. Moreover, the public will be given the opportunity to be consulted during the risk assessment process.

“ Croatia still has the right to refuse GMOs on a case-to-case-basis”

Health concerns

After the presentation by Miss Radovic Miss Volar - Pantic from the Ministry of Agriculture presented a draft law that regulates the authorisation of genetically modified food and other novel foods. A third law prescribing mandatory labelling of food derived from GMOs was drafted by the Ministry of Health, but not presented during the Round Table. According to Miss Volar-Pantic the food acts have been drafted for three basic reasons:

- Protection of health
- Protection of the interest of consumers (notably freedom of choice)
- Protection of the position of Croatia in the international market

She stressed that under the new laws - if adopted by Parliament – no genetically modified (GM) food would be put on the market without permit. Also all GM food would have to be labelled. Volar-Pantic emphasised that under

the draft laws “the competent authority can temporarily ban a food product if there is a risk to human health.”

Immediately after the presentation of the new proposals by the government Green Action expressed a series of concerns. According to Green Action President Jagoda Munic the current draft laws are “closer to US law than to EU law”. She stressed that amendments are needed to make the law workable and to prevent that Croatia would become the dumpingground for GM products that have been rejected in the EU. The key points of criticism brought forward by Munic are:

n There is no clear definition of food products that would have to be labelled.

Will all products derived from GMOs be labelled (according to the present EU draft regulation on traceability and labelling (see page. 1-3 of this Mailout)) or will the new Croatian laws only implement mandatory labelling for those products that contain transgenic DNA or pro-

tein (like in the present (and heavily criticised) EU Novel Food Regulation) ? According to Green Action these questions should not be dealt with in a by-law, because that would mean that there will be no debate and vote in Parliament but everything would instead be handled by the Minister.

n The draft laws do not contain any authorisation procedure and labelling requirements for genetically modified animal feed.

n According to Directive 2001/18 the EU will expell genetically modified antibiotic resistance markers in 2004. The Croatian draft laws don't mention those markers.

n The permits that will be issued under the Croatian draft laws are not limited in time, whereas the EU issues permits for a period of ten years.

A hot debate awaiting

With the decision in Parliament ahead Green Action will keep participating in the public debate on GMOs in Croatia

and seek support for improvement of the draft laws. During the Round Table several Members of Parliament already made clear that they are willing to push for amendments. According to Member of Parliament Marijana Petir (from the Peasant Party HSS) Croatia should abide by EU law. She expressed concern about the possibility that some GM ingredients might cause allergies and stressed that her party will fight for the maximum protection of consumers.

Mr. Miroslav Rozic from the Croatian Party of Rights (HSP) added that Croatia's economy should be protected against the risks of GMOs. According to Rozic Croatia will loose competitiveness on the world market if GMOs are produced in the country. He believes that Croatia has more chances when it focuses on the export of organic food.

Croatia looks set for another hot debate on GMOs.

MORPHOGENICS - A STEP TOO FAR?

One could be forgiven for thinking that the world really is going a little mad In November it came to light that cancer-causing cells are being used to genetically engineer new varieties of plants, animals, viruses and bacteria. The company concerned, Morphotek, based in Philadelphia, USA, has patented the technology which can reportedly speed up evolution "1000-fold" by increasing the mutation rate of organisms. Morphotek claims future benefits for drug and agriculture companies and has reportedly been actively seeking potential business customers - notably ag-biotech companies Bayer, Monsanto and Syn-

genta - in a bid to secure a multinational market for this technology.

Cancer-causing cells speed up mutations

In their quest to speed up the creation of new varieties, Morphotek is using a cancer-causing gene to generate mutations in far greater numbers and much more rapidly than would be produced by natural evolutionary processes. What Morphotek has done is to isolate a gene that causes bowel cancer in humans which, using genetic engineering techniques, can be inserted into plants, animals and other organisms. The defective gene, called PMS2-134,

provokes an increased rate of cell mutation in human beings, which can lead to cancer of the colon (large bowel). The gene in effect "switches off" an organism's natural defences to protect itself from abnormal mutation. It is this trait of increased mutation, described as "hypermutable" that Morphotek is using in order to create many more varieties much more quickly than would happen through normal evolution. The company claims that the process "can be used to produce new varieties of plants, mammal, viruses and bacteria".

Among the thousands of mutant off-

spring produced by this procedure, some will simply not survive and most are discarded after screening in order to select just those that are judged to have useful commercial characteristics. In the case of plants, the selected offspring are subsequently bred with conventional varieties in order to produce new plant varieties that exhibit desired characteristics such as, according to Morphotek's claims, higher yields, pest resistance, drought and frost resistance. Morphotek says it can breed out the cancer-causing gene in the final plant varieties, which raises an important question from a European perspective: would such plants be considered a GMO or could they escape having to gain authorisation against EU legislation?

Safety and ethical aspects

Environmental groups including FoE have expressed serious concerns that morphogenics seem to be progressing unchecked in the USA, and have

“ What if a gene got in the food chain? Some people could suffer fatal reactions “.

raised a number of questions regarding the safety and ethical aspects, e.g.:

- How will ethical and moral issues be addressed regarding the use of a human cancer gene in the production of food plants?
- What measures will be taken to prevent plants containing the rogue gene escaping from the laboratory?
- What would happen if the cancer-causing gene failed to be removed from the final crop plant, i.e. the release of plants that have not been back-crossed sufficiently?
- What would be the impact on human health if the gene and the protein it produces enters the food chain?
- Could the gene become established in the wider environment through horizontal gene transfer

via viruses and bacteria, which escape from manufacturing facilities?

There is also an important question regarding animal welfare since the use of morphogenics to create thousands of mutated animals, most of which will not survive or simply be 'discarded', raises huge ethical and moral issues.

There is even concern within the biotech industry itself. According to the British "Observer" newspaper (24.11.2002), a senior researcher working for one of Europe's largest biotech corporations, who is a keen supporter of GM technology, said he was completely shocked about Morphotek's plans: "What would happen if an organism containing such a dangerous gene escaped? What if a gene got in the food chain? Some people could suffer fatal reactions".

Welcome to the brave new world
.....

FOOD CROPS CONTAMINATED BY BIO-PHARMACEUTICALS USDA orders crop destruction

It had been described as "an accident waiting to happen". In November, it was confirmed that it had indeed happened - genetically modified plants engineered to produce pharmaceuticals had contaminated other crops grown for food production. The United States Department of Agriculture (USDA) ordered the quarantine of the contaminated plants and subsequently their destruction. One of the most worrying aspects of the story is that this is not

the first time - it has apparently happened before, at least once in 2001.

The company at the centre of this latest food scandal is Prodigene which has conducted a range of open air testing of crops containing pharmaceuticals and industrial products. Prodigene has received 85 permits for outdoor tests which are known to have been carried out in at least 96 locations in the US. The plants in question have been genetically engineered to produce drugs

or chemicals for a variety of applications. In the latest incident, Prodigene failed to properly remove all the maize from a field cultivated last year. Consequently, some seed remained in the ground and germinated this year, thereby contaminating a crop of soya. USDA investigators reportedly warned the company about the problem but no action was taken. Subsequently, when the soya had been harvested and

was at a grain elevator in Nebraska, it was discovered that it had indeed been contaminated by the Prodigene maize. 500,000 tons of soya worth some \$2.7 million were quarantined by the USDA and later ordered to be destroyed.

Drugs in your cornflakes?

The US authorities have been unwilling to reveal exactly what type of bio-pharmaceuticals might be involved in the Prodigene crop contamination case. However, based on research into the company's activities, any of the following might be possible:

- AIDS vaccine gp120 -- a glycoprotein;
- Blood-clotting agent -- Aprotinin;
- Trypsin -- a digestive enzyme that can be used in leather-tanning or to produce insulin;
- Industrial adhesive Laccase -- an enzyme derived from a fungus;

Other "pharmaceutical" GM crops reportedly grown by ProdiGene include experimental oral vaccines for Hepatitis B and for a pig disease, transmissible gastro-enteritis.

A coalition of environmental and consumer groups in the United States is claiming that the US authorities have irresponsibly allowed drugs and industrial chemicals to be engineered into food crops, and food retailers are demanding that the biotech industry "direct its substantial research capabilities into investigating the use of non-food crops for the development of pharmaceuticals" (*Karil Kochenderfer, director of new technologies for the Grocery Manufacturers Association of America, quoted by Associated Press, 15.11.2002*). Even some biotech companies themselves are worried about the massive problems that would result from contamination of food crops by biopharmaceuticals. In October, the industry announced a 'voluntary ban' of growing biopharmaceuticals in food-growing areas such as the American mid-west. According to Andrew Baum, head of the Biotechnology Industry Organisation task force that recommended the ban: "nobody wants pharmaceuticals in their cornflakes".

Regulatory authorities must act

The biotech industry fears the huge potential problems of product recalls, decontamination of sites, compensation to food processors, retailers and customers (this would make the StarLink scandal appear as nothing). But as long as biopharming is allowed to progress unchecked, and biopharmaceutical plants are authorised to be grown in the open air, the Prodigene incident could be the tip of the iceberg. As the pro-biotech journal "Nature Biotechnology" stated, in its June 2002 issue: "current gene-containment strategies cannot work reliably in the field" and "gene flow (like mixing) could result in GM material unintended for human consumption ending up in the human food chain". The fact is that we are no longer talking "could" but "does" and this latest biopharmaceutical incident lends even more weight to the argument that contamination by GMOs is an crucial question that regulatory authorities must urgently address.

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