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EUROPEAN COMMISSION'S INITIATIVE TO END THE GMO MORATORIUM

For many weeks this summer, it had been rumoured that the European Commissioners would hold an 'orientation debate' on how to go forward with the approval of GMOs, currently blocked since the last authorisations in spring 1998. Although this meeting had been anticipated in May and in June, it finally took place on Wednesday 12th July when the College of Commissioners met to debate a communication prepared by Consumer Affairs Commissioner David Byrne and Environment Commissioner Margot Wallström. What followed was a press conference by the two Commissioners on 13th July on what is optimistically referred to in the media release as "Commission takes initiative to restore confidence in GMO approval process".

The details of the Commission's initiative

In fact this initiative is nothing less than a strategy to break the current de facto moratorium and to move forward as soon as possible with new GMO approvals. The Commission proposes to wait for the results of the forthcoming conciliation procedure between the European Parliament and the Council, and then to enter into "gentlemen's

agreements" with the biotech industry under which the companies would undertake to comply to the rules of the new directive, even though it is not yet in force. The idea is not entirely new since it was already suggested for the last three applications submitted to the Regulatory Committee under Directive 90/220/EEC. That meeting in March, in fact, failed to approve any of the three applications concerned: two herbicide-tolerant oilseed rapes from AgrEvo/Plant Genetic Systems and a herbicide-tolerant fodder beet from Monsanto/DL-Trifolium/Danisco.

In its official document entitled "GMOs Issues Paper - Strategy on Possible Ways Forward", dated 12th July, the Commission states that it has "a responsibility to ensure that legislation is properly enforced" and proposes three options concerning future GMO approvals:

- 1) enforcement of the existing directive 90/220/EEC as it currently stands,
- 2) waiting until the revised directive is transposed by Member States,
- 3) an interim, pro-active approach aimed at relaunching the authorisation of GMOs.

The Commission rejects option number 1) on the basis that it would trigger public resentment and "never be understood

It actually appeared as if the Commission would push the initiative of "gentlemen's agreements" before the conciliation procedure was even completed



Friends of the Earth

in the European Parliament or Member States". Regarding option number 2), the Commission feels that this would meet the demands of "public opinion, certain Member States and the European Parliament". Despite that democratic advantage, however, the Commission rejects this option on the grounds that it would be too lengthy (Member States would not transpose the directive into national law until 2002) and that there is no 'legal basis' for the current standstill in the authorisation procedure. It also fears the consequences under the WTO.

Option number 3), under which "notifying companies voluntarily provide commitments in line with the new requirements as part of their applications for authorisation" is the alternative favoured by the Commission. These voluntary commitments by the biotech industry would "subsequently become legally binding" it promises. The option will be accompanied by additional measures, says the Commission, including a working document which it will produce by autumn 2000 setting out its approach to update other legislation in accordance with the new 90/220, e.g. novel food, novel seeds, and to fill in existing gaps, e.g. novel feed (not before time since the original proposal dates from 1997). The Commission further promises to accelerate work in the areas of environmental liability, monitoring of possible long-term effects of GMOs on biodiversity, etc.

Why wait for conciliation?

Up until the press conference given by Commissioners Byrne and Wallström on 13th July, it actually appeared as if the Commission was planning to push the initiative of "gentlemen's agreements" before the Parliament's and Council's conciliation procedure was even completed. In a draft communication from the Commission dated 24th May

(*"Communication to the Commission for an orientation debate on a strategy on possible ways forward for GMO authorisations and related issues, ENV/SANCO Rev 12/24.05.2000/03.33.05.061*), the proposed 'pro-active approach' makes no specific reference to waiting until the conciliation procedure has been concluded. "The progress made towards final adoption of the revised Directive will be an important consideration in this context", it states. "However, if the pro-active approach has not succeeded by the time that the new regulatory framework is adopted, it will be necessary to reconsider the strategy".

Moreover, the official document released by the Commission on July 12th (*Document of the services for the Commission orientation debate, 12.7.2000 GMOs Issues Paper – Strategy on Possible Ways Forward*) does not refer to the outcome of the conciliation procedure either: "We would call at the same time (as launching discussions with the Member States and the notifying companies)" on the Council and Parliament to start the conciliation procedure as scheduled on 19th September" it says. The Greens in the European Parliament underlined the fact the Commission seemed ready to ignore the conciliation process in their media release of 12th July. However, during repeated questioning by journalists during the press conference on 13th July, Mr. Byrne and Mrs. Wallström were at

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pains to state that the Commission would not act until the conciliation procedure is finished. Whether that was indeed the original intention remains an open question.

Legal Enforcement of "Gentlemen's Agreements"

There is a clear discrepancy between the above two documents concerning whether voluntary "gentlemen's agreements" with the biotech industry would be legally binding. Whereas the document issued on 12th July says that "Such commitments would subsequently become legally binding as part of the authorisation granted", the draft Communication of 24th May says completely the opposite! "Whilst this option may reduce potential delays in authorisation, such commitments would not be legally binding and total reliance would have to be placed on notifiers in meeting the new obligations", it says.

This is particularly worrying for environmental and consumer organisations who have little faith in voluntary agreements, particularly where industry is involved. As one observer put it: "If I had to enter into a gentlemen's agreement with anyone about anything, multinational biotech companies would certainly not be at the top of my list".

Opponents also feel that the Commission's 'pro-active initiative' to speed up GMO approvals is clearly breaking all the barriers in that it is the only incidence of its kind where the Commission has tried to enact 'law' which is not even in place yet, which has not received its third reading in the European Parliament, and which is not transposed into Member States' legislation. Questioned during the press conference as to whether this would not be a precedent in the EU, Commissioner Byrne replied: "You couldn't generally have a situation where you could put such a practice in operation to the world at large - it depends on the unique nature of this legislation". NGOs are asking themselves exactly what the so-called "unique nature of this legislation" really is. The answer to the question seems clear: the Commission is being squeezed by the United States, amid threats of legal action under

the WTO, and the biotech companies.

The lack of liability

Throughout the revision of Directive 90/220/EEC, there has been a continuous debate about the issue of the lack of liability for biotech companies in case damage to human health or the environment. Despite the fact that the European Parliament adopted one of the weaker amendments in its second reading (i.e. that the Commission should bring forward its proposal for a directive on environmental liability by 2001), the controversy continues to grow. It has been fuelled even more during recent weeks by the contamination of seed by GMOs: GM-contaminated rape seed in France, Germany, Sweden and the UK, GM-contaminated maize in France and GM-contaminated cotton in Greece.

Yet the Commission still continues to ignore this problem, or at least tackle it head-on. During the July 13th press conference, Commissioners Byrne and Wallström were questioned several times about liability and never managed to come up with a satisfactory answer: the revised 90/220 "is without prejudice to liability law in the Member States" (DB); "Member States can use their own national legislation" (MW); "we will present a proposal next year" (MW); "the new directive (*on environmental liability*) will cover damage to biodiversity" (MW), "most of the MEPs and some of the Member States are worried about liability but we can say we have that on track and will present a proposal as soon as we are ready; until then Member States must use national legislation" (MW), etc.

What these statements ignore, however, is that Member States do not have national legislation to deal with liability concerning GMOs. If some Member States are worried about liability, as Mrs.

The Commissioners were questioned several times about liability and never managed to come up with a satisfactory answer

Wallström states, it is because they don't know which legal foot they have to stand on. The recent cases of GM-contaminated seed clearly prove that. There is no legislation on thresholds of seed contamination by GMOs. The very reason that the French government ultimately decided not to order the destruction of the GM-contaminated maize (*see separate article in this Mailout*) was because it was being threatened with legal action by the French maize producers association (AGPM) and feared that it lacked a clear legal basis to have the maize dug up.

There are a number of reasons to fear that the proposal for a Directive on Environmental Liability (when it finally comes, and bearing in mind that legislation would probably not be transposed into Member States national laws until at least 2005!) will focus, as Mrs. Wallström said, on damage to biodiversity (and perhaps even specifically to Natura 2000 sites). Such scope is clearly much too narrow to ensure effective liability for those who cause damage to the environment, and specifically for companies which produce GMOs. Furthermore, the White Paper produced by the Commission in February 2000 proposes strict liability for damage caused by "dangerous activity". How would such a definition apply in the case of GMO? Would the farmer (unknowingly) planting GM-contaminated seed be considered to have carried out a "dangerous activity"? Who would be liable: the farmer, the landowner, the seed importer/distributor, the company producing the GMO? Although Advanta, as a goodwill gesture, offered to compensate farmers who had to dig up GM-contaminated oilseed rape, they explicitly denied responsibility.

Conclusions

- The Commission is not taking this initiative at the request of Member States. On the contrary, at least half of them are happy to continue with the current de facto moratorium. Instead the Commission's action seems to be principally a result of continuous pressure from the biotech companies, as well as threats of action under the WTO from the United States. The draft communication from the Commission makes clear reference to possible legal action by both industry and the US.
- The Commission is proposing this action when the outcome of the conciliation procedure between the Parliament and the Council is still unclear. Many EU Member States, under the current Presidency of France, are continuing to press for better provision for liability, traceability and labelling. These questions will not be resolved simply by the revision of 90/220.
- This is a completely new way of doing business because no-one remembers a previous case where the Commission has proposed to pre-empt legislation by doing deals with industry before the legislation has completed its passage through the EU institutions, let alone been transposed into national law at Member State level.
- The notion of "gentlemen's agreements" with industry is highly contentious and not likely to gain support from the public, the European Parliament or a number of Member States. Furthermore, the issue of whether voluntary commitments under such "gentlemen's agreements" would be legally binding on the

EU ENVIRONMENT MINISTERS DISCUSS GMO APPROVALS

Right after the initiative from the European Commission to unblock GMO approvals (*see previous article in this Mailout*), the EU's Environment Ministers met in informal session in France on 14th & 15th July under the Presidency of Dominique Voynet. A part of this meeting was devoted to GMOs and the revision of Directive 90/220/EEC, for which the European Parliament's rapporteur David Bowe (PES, UK) was invited.

At the meeting, Environment Commissioner Margot Wallström explained the "gentlemen's agreement" initiative presented by herself and Consumer Affairs Commissioner David Byrne on 13th July. According to information received by Friends of the Earth, the first official notice the Member States had received about this initiative was a letter from Mrs. Wallström to Environment Ministers forwarded on 12th July, the Commission having declined to provide them with the most recent draft communication.

Six Member States now effectively support a moratorium

The discussions between Ministers revealed that the Council is very split on the issue of GMO approvals generally and on the Commission's initiative in particular. Those countries who indicated their support for the proposal of "gentlemen's agreements" with industry were Finland, Ireland, Netherlands, Portugal, Spain, Sweden, and the UK.

On the other hand, the five countries which have been maintaining the de facto moratorium since June 1999 – Denmark, France, Greece, Italy and Luxembourg – are supporting the position that the revision of 90/220 will not solve all the

problems, and that progress has to be made on traceability and liability before any further GMO authorisations are granted. The five are now supported in this view by Germany, which is a new approach for the Berlin government but which is explained by the fact that the German authorities have recently entered into an agreement with industry for a three-year voluntary moratorium on commercial releases of GMOs. The five's position is also

A total of six EU Member States (including three of the 'big four') now support a moratorium position, with the further backing of two smaller countries

supported to a lesser extent by Austria and Belgium.

This is a significant development since it means that a total of six EU Member States (including three of the 'big four') now support a moratorium position, with the further backing of two smaller countries. Unless the Commission can revise its proposal, or put pressure on the Member States to accept it, it seems highly unlikely that it will gain the necessary support.

Other results of the meeting

Labelling

During the meeting, all the Environment Ministers insisted on the necessity to implement measures which allow reliable labelling of GM products, from seeds to final consumer products. It is encouraging that all Member States seem to continue to support labelling, despite increasingly loud noises from the United States that such labelling is discrimination against their products and therefore a trade barrier. Very recent reports indicate

that the row is hotting up with the Guardian newspaper quoting a pro-biotech Senator as saying that the two trading blocs are "on collision course" over GM labelling.

Traceability & liability

Ministers also all agreed on the need for a legally binding framework ensuring the traceability of GM products. In this respect, the Commission undertook to make proposals by this autumn. The traceability factor, championed by France is seen not only as the only way to ensure free choice for consumers, but also as the means of establishing future liability of GMO producers. From that point of view, the Presidency concludes that the EU must embark without delay on the development of a legal framework which will enable those responsible to be made liable for damage to the environment caused by GMOs.

The French Presidency concludes that the adoption of necessary decisions on labelling, traceability and liability is indispensable in parallel with the revision of Directive 90/220. The EU will only have a satisfactory legal framework when decisions have been made on the entirety of these issues, it says.

GMO-free zones

At least three Member States - France, Greece and Italy - are promoting the possibility of GMO-free zones. These countries feel the need to preserve some parts of the EU from any cultivation of GMOs in order to protect the heritage and biodiversity of European agriculture. In this regard, Ministers from countries which favour the concept of GMO-free zones feel that no new authorisations should be granted until the adoption of a comprehensive legal framework.

Three Italian regions - Marche, Tuscany and Lazio - have already declared themselves GMO-free zones and banned the cultivation of

FRANCE BACKS DOWN ON CONTAMINATED MAIZE

As reported in the last FoEE Biotech Mailout (*Volume 6, Issue 4, 15th June 2000*), more than 4,000 hectares of farmland in south-western France was planted this spring with maize seed contaminated by GM varieties.

Initial results of analyses revealed that the contamination was due to three different varieties of GM maize:

- Bt 176 (Novartis : insect-resistant, herbicide-tolerant (to glufosinate) antibiotic-resistant marker gene conferring resistance to ampicillin) (*)
- Bt 11 (Novartis : insect-resistant, herbicide-tolerant (to glufosinate) (**)

and a third unidentified variety.

Further testing revealed the third variety to be:

- MON 810 (Monsanto : insect-resistant) (*)

(*) authorised for cultivation in the European Union,
(**) authorised for import and processing in the EU but **not** for cultivation

The contaminated seed was imported into France from the United States by the company Golden Harvest.

The initial reaction of the French authorities was to announce investigations to identify exactly where the seed had been planted, with the possibility that Ministers might order its destruction at a later stage. It was then announced on 10th July that the unauthorised variety, Bt 11, 'only' accounted for a maximum of 1,000 hectares of the land sown with contaminated seed, and that the level of contamination was low (<1%). There was a silent

sight of relief in some quarters when the third variety was eventually identified as MON 810 since it is authorised for cultivation in the EU. Nevertheless, a majority of government ministers, including the Environment Minister Dominique Voynet, were strongly in favour of ordering that the maize be destroyed. They were opposed, however, by the powerful maize-producers group, AGPM, which threatened legal action.

In the end, the government unfortunately backed down, citing a lack of legal basis as the reason why they could not force the maize to be destroyed even though most Ministers would have favoured this action. The European Union has not set a threshold for GMO-contamination of seeds and the government feared that it would lose court action brought by AGPM. But Agriculture Minister Jean Glavany said that European law will have to be changed to ad-

ADVANTA SAYS OILSEED RAPE

The seed company Advanta, at the heart of the controversy over the GMO-contaminated oilseed rape, has said that separation distances between its crops and fields of GM rape in Canada were 4,000 metres. This is considerably more than the 800 - 1400 metres first reported when the contamination came to light in May this year. The revelation came in evidence presented to a UK parliament agriculture select committee on 18th July.

The voluntary code of practice established last year by the British government with the biotech industry foresees separation distances of only 50 metres between conventional crops and field trials of GM

oilseed rape and maize (200 metres in the case of seed production). Environment Minister Michael Meacher has already admitted that this may be insufficient and has promised a review of so-called buffer zones. An announcement is expected on 3rd August.

Separation distances between GM and non-GM crops are not specified in EU legislation regulating GMOs and the width of buffer zones to prevent GMO pollution is left up to the discretion of the Member States.

Advanta also called on the UK government to introduce thresholds for contamination of seeds by GMO

material. According to Advanta, which is calling for a 1% threshold, levels of GM impurities will occur "now that various parts of the world have accepted the value and safety of GMOs". No legislation currently exists in the European Union for GM contamination of seed but the European Commission is believed to be considering a proposal for 0.5% threshold.

It was this very lack of a legal basis concerning seed contamination that detracted the French government from ordering the destruction of GM-contaminated maize seed earlier this month (*see article above*).

MORE "FUNNY" HONEY"

As already reported in the last issue (*Volume 6, Issue 4, 15th June 2000*) pollen from genetically modified (GM) crops is being picked up by bees and contaminating honey throughout Europe. As a result of this genetic pollution, honey is losing its status as a natural, healthy food.

In the UK, Friends of the Earth has called for an immediate ban on the outdoor field trials of genetically modified oilseed rape and maize after shop-bought honey was found to contain GM pollen. The honey was purchased in an area where GM crops were grown during 1999, and sent for independent analysis to the Austrian Federal Laboratory in Vienna. (1)

Two samples - one from a jar of honey and one honeycomb - were found to contain "*genetically modified components*" from the biotech company Aventis (formerly AgrEvo) which tests its GM crops in the UK and is taking part in the UK government's farm-scale trials programme. Last year Friends of the Earth discovered GM oilseed rape pollen in bee-hives over two and a half miles from the nearest GM trial site.

The discovery of honey containing GM pollen confirms FoE's warnings that GM crops threaten the livelihoods of neighbouring farmers and bee-keepers. Despite this, farmers planting GM crops are under no obligation to consult neighbouring farmers and bee-

keepers about the trials, and the Bee Farmers Association of the UK (which represents 350 commercial bee farmers throughout the country) was not consulted about the siting or potential impact of GM sites. The British bee-keeping industry is taking steps to try to protect its honey from GMO pollution and has advised its members to move hives at least 6 miles from the nearest GM trial site. However, if GM crops get full commercial approval in future, the location of the GM sites will not have to be made public and bee-keepers won't be able to move their hives.

The UK's bee-keeping industry produces an estimated £10 million worth of honey annually - but the value of pollination of fruit and other crops is twenty times more valuable. By forcing beekeepers to pull out of areas near GM test sites, the biotech industry is also causing damage to fruit and vegetable farmers. In addition to producing honey, professional bee-keepers provide a vital pollination service for the fruit industry, both for top fruit (apples, pears, plums and cherries) and soft fruit (strawberries and raspberries). This is an important source of income for bee-keepers who transport their hives to particular sites on request. The value of the service to fruit growers is put at £200 million per annum. Loss of bees from an area because of the presence of a GM test site could have serious consequences for local fruit growers. The question of liability for any GM pollution of honey has not been resolved. Beekeepers are not compensated for the extra work and expense of moving their hives, or for the loss of any contracts.

In light of the irrefutable evidence that GM crops can contaminate honey, Friends of the Earth is demanding that the government takes immediate action to protect this multi-million pound industry from the GM threat. "Honey is seen as a



pure and natural product", said FoE's senior food campaigner Pete Riley. "The public has already made it clear that they do not want GM food - they won't be happy if the Government allows GMOs to threaten their honey. Friends of the Earth welcomes the swift action taken by the bee-keeping industry in protecting our food from GMOs. Taking these steps should ensure that UK honey will be GM-free. However, if GM crops are given commercial approval, GM pollen will inevitably undermine the purity of British honey."

Bee-keeper Roger Holdy is moving his hives away from a GM oilseed rape farm-scale trial in Gloucestershire to avoid GM pollen affecting his honey. "A GM trial site has been given the go-ahead very close to my hives, yet I wasn't even consulted", he said. "Now I have to go to the expense and trouble of moving my hives to ensure that my honey will not contain GMOs. I'm prepared to do this to keep my honey pure but I am angry that the Government has let this situation happen".

(1) *Friends of the Earth purchased jars of honey and honeycombs from near a GM trial site in November 1999 and February 2000. Samples were selected with the aid of a pollen expert (to ensure that the samples contained pollen) and 2 batches of honey - (eight jars of honey and one honeycomb) - were sent to the Austrian Federal Laboratory in Vienna for DNA scanning. Two of these samples were found to be positive for GM herbicide resistant genes. A copy of the report is available on request to Dr Andreas Heissenberger.*

As a result of GMO pollution, honey is losing its status as a healthy, natural food

GM CONTAMINATED COTTON IN GREECE

Greece is one of the ten top cotton producing countries in the world, and the largest cotton producer in Europe. Some 400,000 hectares are planted each year and cotton farmers are highly subsidised by the European Union. Much of the cotton is exported to neighbouring countries and further afield. Cotton seed is processed for use in both food and animal feed, as well as industrial applications.

An ecological disaster is happening in the cotton-growing lowlands of Greece, according to Nea Ecologia (Friends of the Earth Greece). This is a result of thousands of tons of cotton seed imported from the United States which is contaminated with illegal genetically modified varieties. Although the Greek government has finally this month ordered for the cotton to be destroyed, the decision has come too late to prevent genetic pollution on a grand scale according to Nea Ecologia.

In spring this year, it was rumoured that cotton seed imported into Greece from the United States was contaminated with illegal genetically modified (GM) varieties. No GM types of cotton have been authorised by the European Union either for cultivation or for import. But two kinds are in the pipeline for approval against the EU's directive 90/220/EEC regulating the deliberate release into the environment of genetically modified organisms (GMOs). These are both produced by Monsanto:

- One has been genetically modified to be herbicide-tolerant of Monsanto's RoundUp (glyphosate).
- The other is insect-resistant (Bt) and carries two 'marker genes' conferring resistance to

the antibiotics kanomycin and spectinomycin.

Following protests from environmental organisations, the Greek government finally set about testing some 3,000 samples from the 14,000 tons of suspect seed that was planted this spring. Only two companies, including Spyros Spyrou SA, the biggest seedmerchants in south-east Europe, agreed to give seed samples for analysis. The Ministry of Agriculture is still refusing to reveal the names of the companies which refused to have samples tested.

Analyses revealed that the seed was indeed contaminated with a GM variety and the Ministry of Agriculture finally decided that all suspect cotton should be dug up and destroyed.

The decision came too late, however, to prevent genetic pollution on a wide scale, according to Nea Ecologia. By the time the government made its decision in July, the cotton was already in flower. "The bees have already been transfer-

ring genetic pollution to all cotton crops for a month now", said Vangelis Stogiannis, President of Nea Ecologia. To prove the point, Nea Ecologia and other environmentalists occupied the town hall of Trikala, centre of the main cotton-growing area in Greece, and presented the mayor with a glass beehive full of bees and armfuls of flowering cotton. Nea Ecologia asked him to send them to the Environment Ministry so that officials there would realise when cotton plants actually come into flower, and when it would be useful to decide to destroy them (i.e. not wait until pollination has already started).

The Greek government has announced that all farmers affected by having to dig up the cotton fields will be compensated. No information is available at this stage as to whether the seed companies and importers involved will pay up, or whether the European Commission will still pay out subsidies to the farmers. Although the Agriculture Ministry has tried to play down the problem, the Deputy Environment Minister has called for



Vangelis Stogiannis, President of FoE Greece, presents a beehive and flowering cotton plants to the mayor of Trikala

DIRECTIVE 90/220/EEC - THE

As mentioned elsewhere in this Mailout, the conciliation procedure between the Council and the European Parliament concerning the revision of Directive 90/220/EEC is scheduled to start around 19th September. While the official process is not yet underway, some details have already emerged as to where the different parties are coming from as they approach these negotiations.

The Parliament adopted 29 out of a possible 52 amendments during its second reading on 12th April this year. As reported in Mailout Volume 6, Issue 3 of 30th April, the Commission has already rejected more than half of the amendments favoured by the Parliament (5, 6, 10, 16, 20, 21, 22, 23, 25, 26, 27, 28, 31, 32, 34 and 39). It has now produced a working document proposing possible alternatives to those that it "accepts in principle" (1, 3, 4, 8, 24, 35, 36, 38 and 48). In an Opinion of the Commission dated 16.05.2000, it explains its reasons for accepting, accepting in principle or rejecting the Parliament's amendments.

There has already been a meeting

of the Parliamentary delegation on 4th July to discuss the EP Rapporteur's informal contacts with the Council Presidency and the Commission. It still seems that the Parliament's Rapporteur David Bowe (PES, UK) wants to press for something stronger on liability with at least some definition of environmental damage. The Commission, on the other hand, in its proposed alternative to Amendments 36 and 46 adopted by the Parliament, proposes to use the recently amended Defective Products Directive (99/34/EC) as a basis. This, of course, would be highly controversial since a GM seed, marketed after having received Part C approval under Directive 90/220/EEC, could not *per se* be considered "defective".

The liability question is very sensitive within the Council delegations and is expected to be the one of the key discussion points during the conciliation process. Interestingly, the EU's Economic and Social Committee has recently produced its comments on the Commission's White Paper on Environmental Liability and has singled GMOs out for particular atten-

tion. In its opinion adopted on 13th July, the Committee stresses that it is vital for a future EU liability regime that the Member States fulfil their obligations in the long term under the Habitats Directive. Also, it feels that **urgent action must be taken to introduce legislation covering liability for damage to the environment and biodiversity caused by genetically-modified organisms** (GMOs). In addition, the Committee points out that for the proposed system to be effective, it requires the active involvement of socio-economic organisations and non-governmental organisations (NGOs).

As far as the Council is concerned, the following amendments adopted by the Parliament are facing problems:

- 6 centralised procedure
- 10, 20 pharmaceuticals for human use
- 16 extension of the 90-day assessment period
- 21 legal basis
- 22, 23 time limit
- 25 differentiated procedures
- 27, 31 comitology/deadlines
- 28 exports/implementation of the Biosafety Protocol.

Some Member States, most notably the UK, are also expressing

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