

# FoEE Biotech Mailout

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## ***NO LIABILITY FOR GMOs*** ***The Commission fails to deliver***

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On 23rd January 2002, the European Commission finally delivered its long-awaited Proposal for an EU Directive on Environmental Liability. 'Long-awaited' since legislation to ensure the principle of 'The Polluter Pays' has been promised and under discussion for several years. As soon as it was published, the Proposal was strongly criticised by environmental NGOs who consider it a watered-down and weak piece of legislation which will invariably let polluters avoid liability and restoration of damage (*see joint NGO press release: [http://www.foeeurope.org/press/24.01.02\\_The\\_European.htm](http://www.foeeurope.org/press/24.01.02_The_European.htm)*).

As far as genetically modified organisms (GMOs) are concerned, the Proposal completely fails to provide an adequate legal framework under which the biotech industry could be held liable for damage caused by GMOs. In this respect, the Commission has reneged on its promise to the European Parliament and to EU citizens at the time of the revision of the Deliberate Release Directive (2001/18/EC repealing 90/220/EEC).

### THE OVERALL SHORTCOMINGS OF THE PROPOSAL

In general, the Proposal has been criticised for its very restrictive definition of biodiversity, the exemptions under which polluters could escape liability, and the procedure under which action against polluters can be taken.

The proposed Directive does not put forward a regime for civil liability under which personal injury and damage to goods or property - so-called traditional damage - are covered. Instead it is based on the concept of fault-based liability for damage to very narrowly defined biodiversity. It explicitly excludes economic damage in, for example, the case of an organic farmer whose crops might be contaminated by GMOs on the basis that this is traditional rather than environmental damage and is therefore covered by national law (although GMOs are approved at EU level and although it is entirely unclear to what extent national legislation would cover such damage).

### BIODIVERSITY

One could have expected that an EU Directive on Environmental Liability would seek to protect nature and the countryside from polluting activities in the broadest sense. However, the Commission has chosen to limit damage to biodiversity

by restricting its definition (Article 2.2) to apply only to sites and species covered by the EU's Habitats Directive (92/43/EEC) and the Birds Directive (79/409/EEC), as well as places and/or species which are protected under national legislation of EU Member States. The latter category which would include, for example, National Parks, was only added quite recently after pressure from environmental NGOs and was not included in earlier draft proposals. The bottom line therefore is that, under this narrow definition of biodiversity, the Directive will only apply to about 13% of the EU's territory, and will be an irrelevancy to the remaining 87% although events and activities may take place in that unprotected countryside which could have damaging or irreversible effects on the biodiversity therein.

The Commission's excuse for not using the broader definition of biodiversity given in the Convention on Biological Diversity (to which the EU and all its Member States are signatories) is given in an EC News Release (*"Frequently asked questions on environmental liability proposal, 24.01.2002"*). The CBD's definition of biodiversity goes beyond habitats and species and includes the notion of variability which implies, according to the Commission, that "it could be argued that damage to biological diversity would encompass injury to 'variability among living organisms'. Such an approach raises the delicate question of how such a damage would be quantified and what would be the threshold of damage entailing liability".

#### ENVIRONMENTAL DAMAGE

Article 2.19 defines 'environmental damage' as damage to biodiversity, water and land but, in the latter category, only land damage "that creates serious potential or actual

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harm to public health as a result of soil and subsoil contamination". This wording is quite bizarre on two counts. First, harm to public health is akin to personal injury and could therefore be considered 'traditional damage' which is not, as the Commission itself states, the focus of this directive. Secondly, soil contamination could clearly cause long-term damage to biodiversity. In the case of GMOs, for example, leakage of Bt toxin from GM crops into the ground has been observed giving rise to questions about unknown effects on soil micro-organisms and future impacts on biodiversity.

#### DANGEROUS ACTIVITIES

At least GMOs and GMMOs (genetically modified micro-organisms) are classified in Annex I as "risky or potentially risky" activities and therefore fall within the scope of the Directive (Article 3.1), as do other potentially dangerous operations such as air emissions, discharge of dangerous substances, hazardous waste, plant protection and biocidal products, and so on.

#### EXEMPTIONS

Under the exemptions given in Article 9.1, the Commission effectively precludes liability for any operators responsible for "(c) a specific emission or event explicitly authorised in applicable laws and regulations or in the permit or authorisation delivered to the operator", and "(d) emissions or activities which were not considered harmful according to

the state of scientific and technical knowledge at the time the emission release or the activity took place". This concession to industry is justified by the Commission as a measure that "safeguards incentives for innovation". In its News Release, the Commission goes further to explain that "when a release of the GMO has been specifically authorised or when it was not possible for foresee the damaging effect of the GMO on the basis of the best science, there would be no strict liability". Failure to exempt damage caused by events which were not considered harmful according to the state of scientific and technical knowledge at the time, says the Commission, "would have unduly stifled technological development in the EU". Whose 'best science' would be considered valid under Art. 9.1 (d) is not specified. Bearing in mind past examples of environmental problems which resulted from substances or activities not being "considered harmful according to the state of scientific and technical knowledge at the time" – DDT, asbestos and so on – this loophole is considered unacceptable by many observers.

The exemptions in Article 9.1 effectively let off the hook any company which could claim that its GMO was authorised under the Deliberate Release Directive, the Novel Food Regulation or other EU legislation, as well as those which might argue that an - as yet - unauthorised GMO is not "considered harmful" if, for example, it has received a positive opinion from the EU's Scientific Committee, or even if the company itself claims that its own scientific knowledge does not point to harmful effects. The only way, therefore, a company could be held liable for damage caused by a GMO would be if the GMO was not authorised, had

not been positively assessed by the EU's Scientific Committee and the company itself could not demonstrate to the satisfaction of the authorities that 'best science' did not foresee damaging effects – yet there was clearly damage to biodiversity in the very restrictive sense of the definition given in the Proposal. Only in the case that a GMO user does not follow the instructions of the GMO producer can the user be held liable.

#### TIMEFRAME AND RETROACTIVITY

Another area of concern is the time-frame proposed by the Commission in Article 12 "Limitation period for recovery". Competent authorities are able to initiate recovery proceedings against the operator who has caused the damage or imminent threat of damage only for a very limited time period of five years. In the case of GMOs, critics will find this a ridiculously short space of time since environmental damage is not always immediately apparent and the longer-term impacts are only just beginning to be understood. Furthermore, the Proposal explicitly excludes activities that have been carried out before the Directive enters into force (Article 19). Since it is likely that the legislation will not be transposed in Member States before 2004-2005, it means that all GMOs already on the market or which may come onto the market before 2004-2005 are excluded. This in addition to the fact that under the exemptions described above, they are likely to be exempt from liability anyway.

#### WHO CAN ACT?

The Proposal places full responsibility for initiating measures against those who cause environmental damage in the hands of the national competent authorities and excludes persons or NGOs from initiating legal action against the polluter. Ac-

ording to the Commission, third parties shall only be entitled to "submit to the competent authority any observations relating to any instances of environmental damage" and "shall be entitled to request that the CA take action" (Article 14.1). It therefore places the Competent Authorities in the position of being both 'prosecutor' and 'authoriser' in some cases, since the CA may have been responsible for granting the operator a permit for the activity in the first place. The only recourse left to third parties such as NGOs is to initiate a judicial review if they deem that the Competent Authority has failed to act appropriately.

#### WHO PAYS?

No compulsory insurance schemes or compensation funds are foreseen in the Proposal (Article 16). In the case of so-called 'orphan damage' where the polluter cannot be identified or is insolvent and cannot pay for reparation of damage, the Proposal suggests that Member States envisage the possibility of 'safety nets' in order to pay for restoration, and that the Member States decide for themselves how these are financed. Clearly such 'safety nets', if they are established in some Member States, will most likely be financed by the tax payer.

#### NATIONAL LAWS

The Proposal does not exclude the possibility that Member States can take more stringent measures than those set out by the Commission

(Article 18). Given the very weak provisions for environmental liability in the Commission's text, and given the lack of national legal frameworks to cover economic loss or damage to human health, Member States may feel an urgency to enact such measures. It is clear that under the Defective Products Directive (85/374/EEC as amended by Directive 1999/34/EC) financial losses a farmer suffers due to the contamination of the seeds he bought would not be considered as damage. Damage to, or destruction of, any item of property other than the defective product itself, requires, - according to that Directive - that the item of property is "(a) of a type ordinarily intended for private use or consumption, and (b) was used by the injured person mainly for his own private use or consumption".

Recent information indicates that at least one Member State, the United Kingdom, is indeed considering national legislation to cover the economic loss for organic farmers whose harvest may have been contaminated with GMOs. On the other hand, it was the UK that, at the time of the adoption of the revised Deliberate Release Directive 2001/18/EC, submitted a minutes statement emphasising that the term liability used in Recital 16 of the Directive "refers only to environmental liability in relation to activities within the scope of this directive".

#### GMOs - THE COMMISSION LETS CITIZENS DOWN

Throughout the revision of the deliberate release directive (90/220/EEC repealed by 2001/18/EC), the biotech industry lobbied intensively against the inclusion of liability. Indeed, it was one of the key amendments that companies did not want the European Parliament to adopt. To quote EuropaBio's circular to

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MEPs at the time: "It should be clearly understood that a sector-specific liability regime will discriminate against the already highly regulated use of this beneficial technology, and will severely restrict or even STOP its further use in Europe". Furthermore, the Commission itself argued energetically against liability being mentioned in the revised Directive, promising repeatedly that the issue would be dealt with by the forthcoming Environmental Liability Directive.

Despite that, the European Parliament came very close to adopting an amendment that would have ensured strict liability for GMO producers. The amendment\* was adopted by the EP's Environment Committee and, in April 2000, came very close to being adopted by the full Assembly. However, the amendment was lost in rather bizarre circumstances that caused many MEPs

to leave the Plenary in protest at the unforeseen arrival of the Austrian President (*see Biotech Mailout Volume 6, Issue 3, 30.04.2000*). At that time, Environment Commissioner Margot Wallström did not conceal her relief that the Parliament had not, in the end, adopted the liability amendment. To quote the Commission press release: "The Commission welcomes the fact that the Parliament chose to refrain from introducing rules on environmental liability, which are specific to GMOs. **The Commission indeed believes that a horizontal approach to liability is the most efficient way to guarantee a comprehensive responsibility regime for environmental damage. This will provide clarity for complainants and prevent loopholes**".

Many will now question that statement. With the Proposal for a Directive on Environmental Liability finally on the table, observers may reach the conclusion that Mrs. Wallström's promises have not been fulfilled and that the Commission has undeniably failed to table legislation that goes anywhere near covering the problem of liability for damage caused by GMOs. In the interests of environment and society, they can only hope that the elected representatives will succeed where the civil servants have failed and that the European Parliament will significantly amend the Proposal to turn it into something more meaningful.

*(\*Those legally responsible for deliberate releases of genetically modified organisms shall have strict civil liability for any damage to human health and the environment caused by the releases in question. Before the activities begin, they shall take out sufficient liability insurance to cover such losses as might be occasioned thereby.)*

## **AMERICAN FARMERS WARN OF GMO CONTAMINATION**

American farmers visited Europe during January this year to tell firsthand about their experiences of GMO contamination, liability and patent infringement when conventional farmers' fields are polluted by GM crops. After a tour of several Central and Eastern European countries (Slovenia, Croatia, Bulgaria and Poland), the farmers visited Brussels and Paris where they participated in public hearings and several meetings with European policy-makers and stakeholders.

Percy Schmeiser from Saskatoon, Canada, is probably the best known victim of GMO contamination. In

1998, Monsanto's Roundup Ready oilseed rape was discovered on his land, although Schmeiser claims never to have knowingly planted RR rape and explains that the seed must have originated through GM contamination from neighbouring farms. Monsanto nevertheless sued Schmeiser for patent infringement. Although Schmeiser maintained that the contamination was involuntary on his part, Justice William McKay of the Federal Court of Canada said that how the GM seed had arrived on his land – blown by the wind, cross pollination, whatever – and whether or not Schmeiser intentionally infringed Monsanto's patent, was

not at issue. The judge said that: "*intention is immaterial, for infringement occurs when the essence of an invention is taken*", regardless of the intention of the infringer." Consequently, the judge said that a: "*farmer whose field contains seed or plants originating from seed spilled into them or blown as seed from swaths from a neighbour's land or even from germination by pollen carried into his fields from elsewhere by insects, birds or by the wind, may own the seeds or plants on his land even if he did not set about planting them. He does not, however, own the right to the use of the patented gene, or the seed or plant containing the patented gene or cell*".

## FARMERS LOSE RIGHTS TO SAVE AND REPLANT SEED

The ruling, in effect, means that farmers whose crops have been contaminated by patented GM seed forfeit the right to their harvest and to save seed for replanting. Although one would expect that conventional or organic farmers whose harvest has been contaminated by GMOs could claim compensation at least for any financial loss they suffer, the legal situation is quite different in European, US or Canadian law. Not only might those farmers face considerable difficulties if they try to sue the biotech companies that are ultimately responsible, but it also appears that the companies can prevent farmers from replanting seeds which have been contaminated by GM crops on the basis of their GM seed patents.

In addition to receiving a hefty fine for patent infringement, Schmeiser was also forced to hand over to Monsanto his profits on the crop as well as his oilseed rape seed and plants. His case raises a number of questions:

- why should farmers face financial penalties for GM contamination,
- why should farmers be forced to accept GM contamination of their seed,
- why may GM contamination lead to patent infringement by those whose crops have been contaminated, and
- why should conventional farmers have to cover the costs of coping with gene flow that is unwanted, involuntary, or unavoidable?

Schmeiser has incurred considerable financial hardship rather than agree to an out-of-court deal with Monsanto that would require him never to talk publicly about the case again.

**“By all standards of reasonable justice, you would have expected that someone whose conventional crops have been contaminated to be compensated, not the other way around”**

He has appealed the original court decision and the case is expected to come up again in the Federal Court this summer, with the likelihood that it will go to the Supreme Court. For more information, see: <http://www.percyschmeiser.com>

### ECONOMIC LOSS

Tom and Gail Wiley are also victims of economic loss due to GM contamination. On their mixed farm in North Dakota, the Wileys raise beef cattle and grow a variety of cereals: wheat, maize and soya. They do not grow GM crops but, last year, their conventional soya bean crop was polluted by GM soya. Because of its high protein content, good colour and size, Wiley had secured a contract to sell his soya overseas and was ready to transport his crop to a plant where the beans would be put in sealed containers destined for Japan. However, prior to shipment, tests showed that Wiley's soya was contaminated up to 1.37% with GM soya and he consequently lost the contract. The difference between the “identity preserved” contract for Japan and selling the soya on the open market cost Wiley about \$10,000. He did not know where the contamination had come from, although several neighbouring farmers were growing GM soya. But, as he said, it was impossible for him to know if pollen had been brought in on a north wind from “X” or a south wind from “Y”, and the

Wileys did not want litigation to spoil good relations with their neighbours.

### ‘BAN GM OR REAP WHAT YOU SOW’

During their visit to Brussels and Paris, Schmeiser and Wiley participated in public hearings at the European Parliament and the French Assemblée Nationale, hosted by Green Group/European Free Alliance politicians. They are both convinced that there is no such thing as containment of GM crops and that co-existence of GM and non-GM is impossible. In just a few years that GMOs have been commercially cultivated in North America, contamination of conventional and organic farming is widespread. Schmeiser said that it is already virtually impossible to find non-GM rape seed in Western Canada, whereas Wiley indicated that this is the last year that his North Dakota agricultural university can guarantee being able to provide seed for non-GM soya.

### THE LIABILITY ISSUE

The American farmers' situation again highlights the problem of liability when conventional or organic crops are contaminated by GMOs. Speaking at the public debate in the European Parliament on 21<sup>st</sup> January, Jill Evans MEP (Plaid Cymru/The Party of Wales) said that the farmers' experiences reinforced the need for a proper liability regime for GMOs in the European Union. “By all standards of reasonable justice, you would have expected that someone whose conventional crops have been contaminated to be compensated, not the other way around”, she said. “We'll have to have a proper liability scheme; to have proposals from the European Commission that doesn't include economic damage caused by GM contamination doesn't make sense”.

# SCIENTISTS DEMAND BETTER SAFETY TESTS ON GM FOOD

Two scientific bodies in two EU Member States have recommended better evaluation in order to assess the safety of GM foods.

## AFSSA

The French Food Safety Agency – AFSSA (Agence Française pour la Sécurité Sanitaire des Aliments) says that more testing is needed to evaluate the long-term health risks of GM food. In its opinion published on 30<sup>th</sup> January for the French government, AFSSA concludes:

- Risk evaluation and the concept of substantial equivalent should not exclude the evaluation of GM products from full safety testing. Proposed regulations which would end the simplified procedure for approval based on substantial equivalence are therefore justified.
- AFSSA believes that, in addition to information usually provided in product applications, more data should be provided about transgene sequences and where the junction is made with the genome of the host species, in order to check the identity of the inserted gene and to know its position and environment. New techniques currently under development to analyse the expression of the gene could be used to detect possible changes resulting from the integration of the transgene.
- It is essential that precautions are taken to minimise the risks of allergies to transgenic products.
- Since the only information available concerns toxicity testing at

high dosage, AFSSA considers that low dose testing over long periods should be required on laboratory animals. Only these kinds of studies will reveal the potential effects of prolonged exposure on vital systems, especially the immune, hormonal and reproductive systems.

- In order to discern unexpected or unintentional toxic effects which would not come to light in toxicity testing of the transgenic product in a laboratory animal, AFSSA recommends two additional types of evaluation:
  - toxicity/tolerance studies on laboratory animals of the parts of plants destined to be eaten;
  - studies on tolerance, nutritional equivalence and digestibility on target animals.

Such studies, in order to achieve a probability of 80%, would require testing of seventeen cows for a period of two months, the Agency says.

Regarding the use of antibiotic marker genes, AFSSA considers that their use in GMOs authorised to date presents only a theoretic risk. However, as far as genetically modi-

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fied micro-organisms are concerned, the Agency says that the use of antibiotic markers represents a non-negligible risk of transferring those genes to bacteria present in intestinal flora, and that it would therefore be advisable to be much more restrictive on their use.

A summary and the full text of the AFSSA report is available (in French) on [www.afssa.fr](http://www.afssa.fr)

## THE UK ROYAL SOCIETY

The United Kingdom's Royal Society (an independent, national academy of science) has just published a policy document "Genetically modified plants for food use and human health – an update", focussing on the effects that GM foods might have on human health and the use of the principle of substantial equivalence in GM food safety testing. The Society advises caution particularly in relation to baby foods and allergies, including inhalant allergies. In its recommendations, the Society says:

- Safety assessments should continue to consider potential effects of the transformation process. The phenotypic characteristics to be compared between foods derived from GM plants and their conventional counterparts should be defined. It may not be necessary or feasible to subject all GM foods to the full range of evaluations but those conditions that have to be satisfied should be defined.
- Research should be undertaken to develop modern profiling techniques and to define the 'normal' compositions of conventional plants. The working group welcomes the funding initiatives already put in place by the European Union Framework V programme and the UK's Food Stan-

dards Agency (FSA).

- The biotechnology industry should collaborate with academia and regulators to develop and share suitable reference data sets. This will help ensure that the new technologies are wisely applied and that agreement is reached on the appropriate interpretation of the data that they will generate.
- The UK Government should review the enforcement of the regulations on infant foods and GM foods to ensure these regulations are complementary.
- The European Commission should consider the use of novel and GM foods in infant foods as part of its review of Directive 91/321/EEC that covers infant formulas and follow-on foods;
- The current decision trees used to assess allergy should be expanded to encompass inhalant as well as food allergies.
- In the longer term, should GM foods be re-introduced into the market in the UK, we suggest that the Food Standards Agency considers whether post-marketing surveillance should be part of the overall safety strategy for allergies, especially of high-risk groups such as infants and individuals in 'atopic' families.

The Royal Society's Policy Document can be found on [www.royalsoc.ac.uk](http://www.royalsoc.ac.uk)

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## ***EP INDUSTRY COMMITTEE VOTES ON TRACEABILITY***

On Thursday, 24<sup>th</sup> January 2002, the European Parliament's Committee on Industry, External Trade, Research and Energy (ITRE) voted on its opinion on the Commission's Proposal on traceability of GMOs. The opinion, adopted by 43 votes in favour and 4 votes against (1 abstention), calls for the deletion of Article 5 which addresses the traceability of GM food and feed produced from GMOs. Moreover, ITRE recommends replacing the obligation to trace GMOs by a clause claiming that GMO-free products should be labelled 'GM-free', while all other products should be considered as (potentially) containing GMOs. Another amendment calls for thresholds for the adventitious presence of authorised GM seeds in conventional seeds, in contrast to the Commission's GM Food and Feed Proposal which foresees a threshold only for GMOs intended for direct use as food, feed or for processing, i.e. not for seeds.

The vote mainly showed the Committee's ignorance of the issues at stake. While the Committee recommended watering down the proposed Regulation considerably, the Regulation as amended by the Committee no longer makes any sense whatsoever. Surprisingly, an amendment by John Purvis MEP (PPE, UK) calling for the deletion of exceptions to the traceability scheme was withdrawn at the last minute. Thus, the ITRE Committee's report now recommends having no traceability scheme and that this non-scheme should have several exceptions.....

The Committee ignored the fact that the new Deliberate Release Direc-

**The vote mainly showed the Committee's ignorance of the issues at stake**

tive 2001/18/EC already requires Member States to ensure the traceability of GMOs. If no uniform traceability scheme is agreed on at Community level, Member States would each have to develop their own traceability scheme. The Committee also ignored that it was Parliament itself that once demanded the labelling of animal products derived from animals fed on GMOs and rejected the pertinent amendments. It also ignored the fact that at least six Member States have decided to maintain the GMO moratorium as long as no additional legislation regarding traceability and labelling of GMOs is in place. Thus, the Committee's vote, therefore, resulted in disbelief and exasperation from all sides, including NGOs, industry and the Commission.

The amendments recommended by the ITRE Committee are scheduled to be voted on before the beginning of May, as are the amendments submitted in the EP's Agriculture, Legal Affairs, and Environment Committees. The Environment Committee's timetable is currently as follows (for both the Traceability/Labelling and GM Food/Feed proposals):

First exchange of views : 19-20.02.

Discussions of draft reports : 21.03

Deadline for amendments : 26.03

Discussion in committee: 16-17.04

Env committee vote: 23.04

The First Reading in the EP Plenary might take place in May.

# LIFE SCIENCES STRATEGY TO LIFT THE MORATORIUM?

On 23<sup>rd</sup> January, EU Commissioners Busquin (Research) and Likkänen (Enterprise) proudly presented the European Commission's Communication "Life Sciences and Biotechnology - a Strategy for Europe", the follow-up to the consultation document *"Towards a strategic vision of life sciences and biotechnology"* published last September. The Communication proposes a strategy which allows Europe to benefit from the "positive potential of life sciences and biotechnology", ensure proper governance, and meet Europe's global responsibilities.

## IT'S NOT JUST ABOUT GMOs

Since most global biotech companies have given up the idea that one company can operate successfully in all fields of 'life sciences', deciding concentrate on the most profitable applications while spinning off others (in particular agro-food), the Communication appears strangely out-of-date. The Commission's approach also seems counter-productive from its own perspective. While many biotech applications, especially pharmaceuticals, are uncontroversial, the life sciences approach forces the Commission to throw all the different applications into one hat. The Commission itself points out that life sciences "may be applied for a wide range of purposes" and concedes that biotechnology

plays very different roles (with different success) in various economic sectors. In some sectors the European biotech industry is clearly in a leading position. In others, especially agro-food, neither European nor US companies are able to sell their products in the EU simply because consumers do not accept them. The Commission cautiously points out several times that "life sciences and biotechnology" (which, incidentally, are not defined anywhere in the document) does not exclusively mean GMOs and complains that the debate so far has "focused narrowly" on GMOs, pointing out almost self-defensively that there are many biotech applications "far beyond uses such as genetically modified crops". Nobody would deny that, but it remains unclear why, when the problems in various areas are obviously hugely different, all the applications are addressed in one strategy.

## MORATORIUM

Shortly before adopting its Communication, the Commission dropped its plan to lift the moratorium by forcing a decision at the March EU Summit. However, the Communication gives a hint of the Commission's plan to lift the moratorium in October: "(...) a revised framework legislation on GMOs has been adopted and will enter into force in October 2002. The new legislation provides a sound basis to overcome the present standstill in

authorising new products". This statement is factually wrong. Directive 2001/18/EC entered into force on 17<sup>th</sup> April 2001; it is the deadline for implementation that expires on 17<sup>th</sup> October. The Commission also ignores two important points. First, as of 17<sup>th</sup> October all pending marketing applications will be subject to the provisions of the new Directive and therefore might require a new risk assessment. Such assessment could be more difficult than the Commission assumes since it only recently began work on the guidance notes concerning risk assessment principles which have to be completed by 17<sup>th</sup> October. If the Commission and Member States fail to agree on the guidance notes before then, authorisation of new products might be severely affected. Secondly, at least six Member States still insist that no new GMOs should be approved until new traceability and labelling schemes are in place.

## CO-EXISTENCE

The current debate on GMO thresholds has set the Commission thinking about the relationship between thresholds and consumer freedom of choice. The Communication emphasises that "in order full apply the principle of **freedom of choice for economic operators** and to safeguard sustainability and diversity of agriculture in Europe, public authorities in partnership with farmers and other private operators need to develop agronomical and other measures to facilitate the co-existence of different agricultural practices without excluding GM crops". Even more remarkable, Action 17 of the Action Plan annexed to the Communication, states: *"The Commission will take initiative to develop, in partnership with Member States, farmers and other private operators, research and pilot projects to clarify the need, and possible options, for agronomic and other measures to ensure the viability of conventional and organic farming and their sustainable co-existence with genetically modified crops. Moreover, the Commission recognises the importance of safeguarding the existing genetic resources in agriculture. It will launch a new action programme for the conservation, characterisation, collection and utilisation of genetic resources in agriculture in the Community."*

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