



EU ENLARGEMENT –

THE INTRODUCTION OF GMOS
BY THE BACK DOOR OF EU ACCESSION?

A report prepared for ANPED,
The Northern Alliance for Sustainability
& Friends of the Earth Europe

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The Northern Alliance for Sustainability (ANPED)

ANPED is a network of non-government organisations (NGOs) whose mission is to change unsustainable consumption and production patterns with an emphasis on the North. ANPED's role is to build sustainable societies by empowering grassroots organisations through sharing information and skills, common campaigns, publications and participation in international governmental conferences.

ANPED networks groups working on Genetic Engineering, Local Agenda 21, Corporate Accountability and Environmental Justice. We are a democratic network of NGOs and voluntary organisations, with most of our members in Central and Eastern Europe (CEE) and the Newly Independent States (NIS). Membership is open to any such organisation sharing our aims.

ANPED's work on Genetic Engineering of Food and Agriculture in CEE and NIS started in 1996. Since late 1999, ANPED has been mapping the level of commercialisation of GMOs and regulatory oversight of GMOs in specific CEE countries. To date, we have been published:

- ANPED-Green Action: "*Genetically Engineered Food and Crops in Croatia: A Threat to Sustainable Agriculture*", published in Zagreb, February 2000
- ANPED-EcoSouthWest: "*Bulgaria: The European Corporate Playground for Genetically Engineered Food and Agriculture*", published in Sofia, May 2000
- ANPED-MURE: "*What's for dinner Mum? Genetically Engineered Food and Crops in Poland*", published in Warsaw, May 2000
- ANPED-SEU: "*Genetically Engineered Food and Crops in Russia*", Moscow, November 2000
- ANPED-Umanotera: "*Slovenia - A GMO-free Zone; The Only Way to Protect Biodiversity and ensure Organic Agriculture can Thrive*", Ljubljana, June 2001
- ANPED-Green Network of Vojvodina, Serbia: "*Biosafety Policy and Practice in Yugoslavia*", April 2002
- ANPED-Bioterra-Ecosens: "*Romania: The Dumping Ground for Genetically Crops - A Threat to Romania's Agriculture, Biodiversity and EU Accession*", Bucharest, May 2003

ANPED's GMO programme now includes groups from over 10 countries in the CEE-NIS region working together to raise public awareness of genetically engineered (GE) food. Since many of these NGOs are from EU candidate countries, in 2000, ANPED commissioned research into the implications of GMO policy in Eastern Europe for EU accession. The resulting report: "*EU Enlargement and GMOs - Chasing a Moving Target*" was released in Brussels together with Friends of the Earth, in December 2000. The report is available in 8 Eastern European languages.

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Friends of the Earth is the largest grassroots environmental network in the world, campaigning to protect the environment and create sustainable societies. Friends of the Earth Europe (FoEE) unites more than 30 national member organisations with thousands of local groups.

FOEE has been working on the GMO issue in Europe since 1996, both on the national level in more than 20 European countries and on the EU level from its Brussels office.

The overall goal of the FoEE's European and global GMO campaign is to protect the environment from the (unknown) adverse effects of GMOs, to protect consumers from potential health risks resulting from GMOs and to secure consumer choice whether to eat GMOs or not.

In Europe, FoEE is campaigning and lobbying for stricter legislation on GMOs. To date, this has resulted in several EU Regulations and EU Directives that set rules aimed at protecting the environment and the consumer from the (potential) adverse effects of GMOs.

FoEE's particular concerns regarding environmental impacts of GMOs are:

- The impact of using broad spectrum, total herbicides, such as glyphosate and glufosinate, associated with GM herbicide-tolerant crops.
- The long-term impact of insect-resistant (Bt) crops on beneficial and benign insects and on associated species.
- The impact of out-crossing of transgenic plants and of gene transfer from genetically modified organisms to other organisms.
- The lack of internationally-agreed risk assessment parameters.
- The need for effective, long-term monitoring of both field trials and market releases of genetically modified crops.
- The need for proper risk-benefit analyses of GM crops.
- The unknown interactions of genes in GM plants, resulting in changes of plant biochemistry with potentially damaging effects on ecosystems.
- Contamination of seeds and of conventional and organic crops by GMOs.

FoEE's concerns about potential health and consumer impacts of eating GMOs include:

- The possible long-term effects of genetically modified food and feed on both humans and animals, and the absence of appropriate long-term feeding studies in this regard.
- The absence of consumer certainty about whether or not a food or food ingredient contains, consists of, or is produced from GMOs, and the exemptions in legislation that create loopholes under which GMOs escape labelling.
- The lack of clarity about food that may have been derived through genetic engineering processes or by using genetically modified organisms.
- The possibility of transfer of antibiotic resistance through the feed and food chain resulting from marker genes used in GM crops.
- The potential health risks resulting from unexpected gene interactions, leading to unknown biochemical pathways and products.

For more information: www.foeeurope.org

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Abstract

In June 2004, 10 new Member States are due to join the European Union (EU), eight of which are in Central and Eastern Europe (CEE).¹ By this time, all EU legislation pertaining to genetically modified organisms (GMOs) used in food and agriculture will need to have been transposed and implemented.

This report provides an overview of the main laws of the European Union (EU) pertaining to genetically modified organisms (GMOs), used in food and agriculture. The fast speed of commercialisation of genetically modified seeds and food and the unforeseen consumer rejection of GM food in the EU, has resulted in continuous revisions of existing EU laws and a plethora of proposed new legislation. Despite the dynamic nature of EU policy on GMOs, one thing is clear: the EU is moving towards more transparent and increasingly restrictive laws regulating GMOs.

Given that EU laws on GMOs lack any provisions for EU enlargement, this report attempts to address the following questions:

- What are the implications of EU enlargement on agriculture and food policy in Accession countries?
- What are the implications of EU enlargement on GMO policy and legislation in the EU?

EU enlargement poses potential threats of weakening GMO policy both in EU and in accession countries. The EU could use the accession process for weakening its policy on GMOs. For example, GMOs that have not been approved in the EU, but are found in accession countries could receive post factum approval. From the other side, the European Commission may attempt to weaken any provisions in the laws of the new members that go further than those in the EU. There is already a case in Hungary, when in harmonising with the EU's revised deliberate release directive 2001/18, Hungary extended the period of validity of product approvals from 5 to 10 years.

Chapter 3 examines the difficulties for Accession countries in attempting to harmonise their legislation with the EU's moving targets. It explores the legal status of GMOs after Accession, using different scenarios e.g. GMOs approved or not approved in the EU against GMOs not approved in Central-Eastern Europe (CEE), or approved using EU-compatible or non-EU-compatible legislation. The legal status of specific GMOs after accession will have profound implications on whether they can be marketed throughout the new EU, given the constraints of maintaining the internal market. This could have severe consequences for the functioning of the EU's single market and for Eastern European agriculture.

From the findings of this report, we recommend that the EU should advise applicant countries to refrain from commercially releasing GMOs into the environment, prior to accession. In the case of GMOs, which already have EU approval, candidate countries should be promised automatic "Article 23 procedures" when they accede. This means that EU-approved GMOs may not receive approval on accession, simply by default, but could undergo a renewed approval process, since no risk assessment has been conducted for the ecosystems of the territories of the new Member States. Slovenia's GMO law provides such a safeguard clause, which enables EU-approved GMOs to be re-assessed vis a vis potential national biodiversity impacts. For GMOs with no EU approval, accession countries should be urged to refrain from approving any non-EU-approved GM products.

Given the de facto moratorium on new approvals of GMOs, the uncertain status of the 18 GMOs already approved and pending legislation on traceability/labelling, Novel Food/Feed, Seeds and liability, we urge Accession countries to adopt as a minimum, the same policies

¹ The 8 CEE accession countries are: Poland, Hungary, Czech Republic, Slovakia, Slovenia, Lithuania, Latvia and Estonia

and legislation as the EU. This means refraining from authorising any commercial releases of GMOs prior to accession and preventing imports of GM agricultural commodities and food. Exports of GMOs or their products from CEE to the EU prior to accession are likely to be rejected, either due to their illegal status in the EU or because of consumer rejection.

The absence of GMO-monitoring of imports of agricultural commodities from GM crop-growing countries, such as US, Canada, Romania and Argentina, means that GMOs which have not been approved in the EU may be present on the market of some CEE countries. On accession, these GM products will need to be taken off the market at high cost. For this reason, Accession countries need to monitor imports of agricultural commodities, especially from GM crop-growing countries and build institutional and technical capacity to identify GMO contamination of crops, food and seeds being imported. This will enable GM commodities that have no EU approval to be rejected; for those with EU approval, it will enable appropriate labelling to be enforced.

The report ends with recommendations to the EU and to the governments and NGOs of CEE Accession countries. NGOs need to highlight releases of GMOs that may be taking place without proper monitoring and to warn about the implications of these releases for EU accession. Since EU GMO legislation provides just minimum standards, provisions in the GMO laws of accession countries that go further than the EU or that close current gaps in EU legislation e.g. on liability, should not be harmonised 'down' to EU standards.

Until legislation in CEE accession countries is fully harmonised and implemented according to EU policy, no GMO should be authorised for commercialisation in any pre-accession country.

Introduction

The development of agricultural biotechnology and the commercialisation of its products are moving ahead at an unprecedented speed. The result is that government policy and legislation lags behind every new development. In the case of the EU, the introduction of GM foods has largely failed due to consumer opposition and the subsequent response of the market. Earlier food scandals in Europe had already sensitised consumers and food producers to issues of food safety. Most large European food producers and retailers have eliminated GM ingredients in their foods.

As a reaction to the market rejection of GM foods, the EU and Member States are becoming increasingly restrictive in their policies on GM food and agriculture. Existing legislation is being revised and new regulations are in the process of being adopted to address legal gaps on GM food and animal feed, GM seeds and liability.

All eight of the EU accession countries of Central-Eastern Europe (CEE) have now transposed all but the most recent EU GMO legislation; **the challenge now is to implement their provisions**. The situation is very diverse between countries in the region, with Hungary having a relatively well-controlled and transparent regulatory system. In Poland, Slovenia and Lithuania, State GMO-testing laboratories are only belatedly being established to enable implementation of GMO laws. In Bulgaria and Romania, that are scheduled to join the EU only in 2007, there is little to no government control on releases of GMOs.

This report was commissioned to examine what impacts accession of CEE countries to the EU will have on GMO products. Chapter 1 provides an overview of the existing provisions on GMOs in the laws in CEE countries and describes the implementation problems that many of these countries face. In Chapters 2 and 3 the report aims to explain how the EU works and what policies it follows in the area of agricultural biotechnology; Chapter 4 investigates the possible implications of the current permissive practices on GMOs in some CEE countries once they become members of the EU.

The report attempts to answer the questions:

- How does the principle of the single market work in this field once new countries join?
- What might be the consequences for CEE of releasing GMOs, which have not been approved under EU laws?
- Does the EU have a plan for how to “de-contaminate” areas in CEE countries where GMOs that are not allowed in the EU have been released?
- How to treat progressive provisions in the GMO laws of CEE that provide greater protection for the consumer and the environment than the EU law?

As far as we are aware, these questions have never been examined in detail before. But, at least awareness seems to be growing within the Commission that certain problems do exist. During a European Parliamentary session held 24 October 2000, the Commission acknowledged that there are problems in CEE countries concerning the release of EU-unapproved GMOs and that they have insufficient information about what is going on.²

A March 2001 Resolution by the European Parliament on the Future of the Biotechnology Industry (2000/2100(INI)) acknowledges EU concerns when it: *"Urges the Commission to make an assessment of the biotechnology industry in applicant countries and of the adequacy of their regulatory arrangements;"* (Para. 49)

² Oral questions and answers to the Commissioner for the Environment and Commissioner for Public Health during a hearing of the EP's Environment Committee in Strasbourg

This report focuses solely on legislative issues related to accession scenarios in agricultural biotechnology, and does not examine legislation related to other applications of GMOs, e.g. in pharmaceutical production or health care.

The findings are based on a review of existing EU legislation, interviews with EU officials, experts in national competent authorities, Members of the European Parliament and lawyers working on these issues.

EU legislation on GMOs, first formulated in the late 1980s, was not designed with accession in mind. In fact, the EU legislative framework has even proved to be unworkable within the EU, for which it was designed. However, from the provisions enshrined in the legislation, especially the need for environmental risk assessments to be undertaken for each and every GMO under the EU's comitology procedures, certain scenarios can be deduced for the moment of accession. It must be noted that exact rules under which CEE countries will accede have yet to be established and the issue of GMO approvals remains for the most part an open question. The opinions expressed in Chapter 4 of this report are not legal fact, but an interpretation of legislation that lacks any provisions for enlargement of the EU.

This report is aimed at NGOs and decision-makers in Central and Eastern European Accession countries, as well as officials and politicians in Brussels. We hope the recommendations in this report help inform your policies and legislative efforts, in this complex and fast-changing field.

CHAPTER 1: GMO laws of CEE accession countries

All CEE accession countries now have GMO legislation that attempts to harmonise with EU laws on deliberate release of GMOs and GM food authorisation and labelling. In some cases, accession countries are ahead of Member States in transposing Community legislation. Slovenia, Slovakia and Hungary have already transposed the revised directive on deliberate release 2001/18, ahead of most Member States.³

Many accession countries have provisions in their GMO laws that address gaps in EU laws or go further than EU legislation:

- Article 10 of **Hungary's** 1/1999 regulation on GMOs allows for the creation of "genetic protective zones" taking into account "*flowering-biological features of the GM and the affected plant species, the environmental and climate relations, the other features of the GM and the affected plant species and environmental- and nature protection.*"
- **Poland's** GMO law passed in 2001 allows for assurance bonds to be deposited by the applicant, in cases of particular environmental concerns, before a permit for releasing GMOs or their placing on the market is granted. Art. 25 states that the insurance would be used against any claims of negative environmental impacts, and could take the form of a deposit, a bank guarantee or an insurance policy. This provision, if applied, provides a mechanism for implementing the precautionary principle.
- Article 62 (4) of **Slovenia's** 2002 GMO law provides a safeguard clause, based on Art. 23 of the EU's 2001/18, which means that Slovenia does not need to automatically authorise all GMOs already approved in the EU. (For list of EU approved GMOs, see Annex A) Where there are concerns about potential biodiversity or other impacts, the Environment Ministry can re-assess the risk of releasing the GMO into Slovenia's ecosystems.
- Article 6 of the **Slovak** GMO law, which entered into force in April 2002, contains emergency planning provisions on liability which require the elimination of damages and provision of compensation.

Will the European Commission allow CEE accession countries to retain provisions that go further than EU legislation or address gaps in EU law?

1.1. Rights to Information and Public Participation on GMOs in CEE accession countries

Citizens of most CEE accession countries have stronger public participation rights on GMOs than those in EU Member States, but the public seldom exercises their rights.

In 1998, the Århus Convention on Public Participation⁴ was signed by EU Member States, the EU Community and all EU candidate countries, with the exception of Slovakia, which has still not signed. To date, Hungary, Romania, Poland, Latvia, Lithuania and Estonia have ratified the Convention, but of the 15 EU Member States, only Belgium, Denmark, France and Italy have ratified. The Århus Convention gives the public rights to information on the deliberate release of GMOs.

Access to Information on GMOs

The rights of citizens in EU candidate countries look better on paper than in practice. Information on field trials is published on the web in Hungary and Poland, although information on the location of the trials is withheld. In Lithuania, Slovakia and Slovenia, there are no field trials of GM crops.

³ To date, only Denmark, Sweden and UK have enacted this directive.

⁴ UNECE Convention on Access to Information, Public Participation and Access to Justice in Environmental Matters, signed in Århus, Denmark, June 1998

All accession countries have harmonised their legislation on GM food labelling with EU law and require consumer information on GMOs in food, where the GMO content is above the 1% threshold. However, in most accession countries, GM food labelling is erratic. Where there is GM labelling, it is due more to the efforts of the market players (food processors, retailers) than to government agencies, which in many countries still lack the laboratory capacity to enforce food authorisation and labelling requirements.

Current EU labelling requirements are inadequate and are being improved to ensure process-based (instead of the current product-based) labelling and to provide for the authorisation and labelling of GM animal feed.

Public Participation on GMOs

The Århus Convention is weak on public participation in decision-making on GMOs. During the First Meeting of the Parties to the Convention,⁵ the Polish government delegate stated that in transposing the Convention into national law, Poland was guided "*by the rule that the Århus Convention is 'a floor, not a ceiling'. For example: the requirements for public participation based on Article 6 of the Convention, apply in Poland not only to the procedures related to development consents and integrated pollution permits for specific projects listed in the annex I to the Convention, but also to various decisions concerning GMOs.*"

Lithuania is currently preparing a regulation on access to information and public participation on GMOs, to address the democratic deficiencies in the Århus Convention.

In many EU candidate countries, NGOs are represented on the national biosafety or genotech commissions, which evaluate applications for deliberate release of GMOs and advise the competent authorities. In Hungary, the 17-member Genetech Commission includes 4 NGO representatives. In Poland, the 19-member Biosafety Commission includes 3 NGO delegates. The Czech Biosafety Commission includes one NGO representative. In Slovenia, however, NGOs representatives are not included in the scientific committees that comment on the applications.

1.2. The Implementation Deficit

"It isn't enough to have the laws on your books, you have to implement them".

Environment Commissioner Wallström⁶

Most CEE accession countries still lack the institutional capacity to enable implementation of GMO legislation. Without laboratories to undertake GMO testing and in the absence of border controls to check imports or routine GMO monitoring programmes to monitor seed and food on the market, there are no means to check compliance with GMO regulations. These implementation deficits open the way for transnational GM seed and food producers and traders to import products that they are unable to sell on the EU market.

Slovenia passed a GMO law in 2002, but it is not yet in force. A GMO testing laboratory has been established at the National Institute of Biology but is not yet accredited. A second laboratory at the Agricultural Institute is in the process of accreditation for GMO seed testing. To date, no authorisations have been given for imports of GMOs. However, this does not mean that there are no GMOs on the Slovene market.

In 2002, the Slovene Consumer Association (ZPS) published results of GMO testing of food in Slovenia. This revealed that 8 out of 20 food tested contained GMOs. In two of the products, both of Slovene origin, the GMO contamination was above 1%. In response to the demands of NGOs, the Government is currently in the process of undertaking a comprehensive monitoring programme to establish the scale of GMO contamination of seed,

⁵ First MOP to Århus Convention took place in Lucca, Italy, 21-23 October 2002

⁶ "*Eastern States pressured to apply EU green laws*", Environment Daily 1367, 21 January 2003

feed and food in Slovenia. The source of the GMO contamination may be imports of contaminated maize seed and soybeans for planting from the USA, Canada and Romania. Official statistics show that imports from these countries are increasing and up to November 2002, over 18% of maize seeds were imported from these countries.

In October 2001, prior to any authorisations for putting GMOs on the market, the **Polish food authority GISPAR**⁷ published the results of their inspection programme to check compliance with Polish labelling requirements, including of GMOs. The authority inspected 32'000 tons of food and feed, potentially containing GMOs, sampled from 58 producers and 79 wholesalers and supermarkets over the period from June 2000 to June 2001. The inspection revealed four companies using bulk GE soya, but only one had a permit to import and use GE soya. The inspectors did not find a single consignment of commodity maize labelled as GE. The GISPAR report concludes that there is no institutional capacity to enforce the law and no implementing regulations. *"And until we have these regulations, everything can be bought and sold without fear of prosecution."* In early 2002, Poland authorised the import of Monsanto's herbicide tolerant soybeans and Monsanto's Bt maize (MON 810) for use as animal feed, despite the absence of any capacity to monitor these imports. Poland is only now setting up a State laboratory capable of testing for GMOs with the financial and technical assistance of the EU's PHARE programme and the UNEP-GEF biosafety capacity-building programme. There is no routine GMO monitoring programme for seeds, food and feed on the Polish market.

In Estonia, in 2001 the Phytosanitary Inspectorate tested 120 products for GMOs and found 9 products containing GMOs, including soy sauce and sausage. However, a GMO-testing laboratory to serve all three Baltic States is only now being established in Lithuania with support from the EU PHARE's 'Twinning Programme'.

The situation with GMO monitoring is better in the **Czech Republic and Hungary**, which both have GMO testing laboratories. Testing of 20 products on the Czech market by Greenpeace in early 2002 revealed no GMO contamination. Hungary now has 3 state-owned laboratories and is setting up a fourth laboratory to test food and feed for GMOs. There is a routine GMO monitoring programme for maize hybrid seeds, parent lines and commercial seeds. Hungary is a centre of maize and rape seed breeding; hybrid maize seed is exported to the EU and CEFTA⁸ countries. Moreover, EU countries are increasingly looking to Hungary as a source of GMO-free maize for food and animal feed. Today, 60% of Hungary's food exports are to the EU.

GMO-contamination from historical field trials?

Prior to the adoption of comprehensive GMO laws, several CEE accession countries had field trials of GM crops, in the absence of any transparent authorisation procedures or regulatory oversight. Thus, it is unclear if the biosafety control measures employed during the trials were adequate to ensure no GMO-contamination or what was the fate of the harvest from the trials.

In **Hungary**, field trials of GE potatoes, tobacco, maize, tomatoes, oilseed rape and alfalfa were taking place already in 1996, in the absence of a GMO law.

In Poland, in 1999, there were field trials of 12 varieties of GM crops, including spring and winter oilseed rape and sugar and fodder beet. Recent research shows that pollen from male-sterile oilseed rape was pollinating 5% of flower buds up to 4000 metres away.⁹ Since,

⁷ Główny Inspektorat Skupu i Przetwórstwa Artykułów Rolnych - Chief Inspectorate for Collecting and Processing Crops

⁸ Central European Free Trade Area includes the countries of the former Eastern Bloc

⁹ Simpson, E.C., Norris, C.E., Law, J.R., Thomas, J.E. & Sweet, J.B. (1999) *"Gene flow in genetically modified herbicide tolerant oilseed rape (Brassica napus) in the UK"*, 1999 BCPB Symposium

Polish biosafety measures for field trials require a buffer zone of just 400m for rape, the harvests of neighbouring farmers are highly likely have been contaminated by GM pollen - **potentially creating GM varieties of rape that have not been approved in the EU**. In 2000, 9 permits were granted for field trials of 6 varieties of herbicide tolerant (HT) sugar beet, one HT variety of maize and 2 varieties of GM potatoes.

Bulgaria and Romania

These countries are due to join the EU only in 2007. However, the commercialisation of GM crops and lack of regulatory oversight present grave obstacles to EU accession. If unapproved by the time of their accession, how will these GMOs be taken off the market? How will GM soybeans, which are being saved by Romanian farmers, be cleansed of GMO contamination?

- **Commercial cultivation of GM maize in Bulgaria:** Monsanto's Roundup Ready maize and 4 GM varieties of Pioneer's maize were already advertised in the 2000 Seed Catalogues and available to Bulgarian farmers from local seed distributors. None of the Pioneer maize varieties have been authorised for cultivation in or import to the EU.
- **50-75% of soybeans grown in Romania are Monsanto's GM herbicide tolerant varieties:** some 50,000-75,000 ha. The EU currently allows only the import and processing of this GM soybean variety.
- **Monsanto's GE Bt potatoes are listed in the 2002 Romanian Seed Catalogue:** In addition, Monsanto has allowed the use of its Bt gene construct, which confers resistance to the Colorado beetle, to be inserted into local potato varieties in Bulgaria, Romania, Ukraine and Russia. In Romania, this research and development is being funded by a World Bank loan. The *Bt* potato has not been approved for cultivation or putting on the market in the EU. In March 2001, Monsanto announced that it will stop selling the *Bt* potato in North America.
- **Romania is cited as the source of GMO-contamination of soybeans in Vojvodina, Serbia:** Serb officials and the company Sojaprotein in Bečej have found that soybeans grown in Vojvodina are contaminated by Monsanto's GM herbicide tolerant soybeans which they claim is caused by smuggling of the latter from Romania. Vojvodina is a centre of seed breeding of soybeans, maize and sugar beet; thus, Yugoslav policy is not to allow the cultivation of GM crops.

Does the European Commission have a plan for how to de-contaminate accession countries that have been cultivating GMOs that are unapproved in the EU?

Clearly, there are more questions regarding GMOs and accession than there are answers. Moreover, the EU is still resolving several outstanding issues, such as on co-existence between GMOs and non-GM or organic agriculture, and drafting legislation to fill policy gaps e.g. regulations on Traceability and Labelling and Novel Food and Feed and a directive on liability. A draft Regulation concerning the transboundary movement of GMOs, to enable the EU to implement the Cartagena Protocol on Biosafety, is currently in the co-decision process. This regulation is likely to go further than the requirements of the Biosafety Protocol. The Czech Republic and Slovenia, meanwhile, have already transposed the minimum requirements of the Protocol – do they now need to amend national legislation to harmonise up to the EU regulation?

CHAPTER 2: THE EUROPEAN UNION

2.1. Essentials about the European Union

The European Union (EU, sometimes also called EC – European Communities) is a supranational body currently comprising 15 individual and sovereign Member States.¹⁰ This “club” of countries has decided to co-ordinate wide areas of their policies with each other, and in particular to maintain a single market - often referred to as the European Common Market. In order to do so, they have signed international treaties between themselves; currently in place is the **Treaty of Nice**, signed in December 2000, also referred to as “the Treaty”.

All EU legislation is created through approval by the Governments of the Member States (**The European Council of Ministers**,¹¹ also referred to as The Council) and the directly elected **European Parliament (EP)**. EU law overrides national laws; only where there is no EU legislation do national laws apply. **The European Commission** oversees the implementation of EU law and in certain areas also has an administrative role. The Commission works somewhat like a European government, with a President at its head and 20 Commissioners, each holding specific portfolios.

There are three forms of EU legislation: Directives, Regulations and Decisions:

“**Directives**” are framework laws, which normally give minimum or maximum standards; they only give “directions”. Each Member State is required to transform an EU directive into national law, usually within 2 years.¹² Within the framework of a directive, each Member State is free as to how exactly the national law looks like, but it must not hamper the functioning of the single market.

A directive can be distinguished by the numbering: first, the year in which it was passed at EU level, then the respective number; e.g. “deliberate release” Directive 2001/18/EC.

“**Regulations**” are EU laws that directly apply in all Member States from the moment that they are adopted. They become national law word-for-word, immediately and automatically, without the national parliament’s involvement.

Their numbering is the reverse to that of a directive: first the number, then the year; e.g. Novel Food Regulation 258/97/EC.

“**Decisions**” are similar to regulations, but may apply not to all Member States, but to one or more. The de facto moratorium on new approvals of GMOs is an example of a Decision.

Green and White Papers

In important political questions the Commission can publish so-called Green or White Papers, in which it outlines its policy and recommends actions to be taken to address a certain area. First, Green Papers invite the public (including the European Parliament) for comments, which are then more or less incorporated into the White Paper, which outlines the Commission’s position on the issues discussed.

In 1999, the Commission published its **White Paper on Food Security**, which proposed the establishment of an European Food Safety Authority. In 2000, the Commission published a long awaited **White Paper on Environmental Liability**, which includes references to GMOs.

¹⁰ Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Portugal, Spain, Sweden, The Netherlands, United Kingdom.

¹¹ Not to be confused with the “Council of Europe” which is based in Strasbourg and is an assembly of parliamentarians from most countries of geographical Europe

¹² This is done by the national governments and/or parliaments

This was followed up in January 2002 with a Proposal for a Directive on Environmental Liability.

Law-making process

Because of the special nature of the EU, the law-making process is very complicated and lengthy. The European Commission is the only one, of the three EU bodies, that has the right to propose a new directive or regulation. This draft then goes to the European Parliament and the Council of Ministers for adoption. In the field of agricultural biotechnology, the focus of this report, most legislation needs the approval of both the EP and the Council (i.e. the Governments of all Member States) in order to be adopted (“**Co-decision Procedure**”). It often takes many years for the two bodies to agree on a common text and to adopt it. Once a directive is adopted at the EU level, it then takes another year or two to be transformed into national law. So, from the time of a published Commission proposal, it can easily take 4 - 5 years for the new directive to become effective.

There are some separate pieces of legislation, like **Commission Decisions/Regulations**, which the Commission can adopt on its own, and **Council Regulations/Directives**, which are adopted only by the Council upon a proposal by the Commission. These laws take a much shorter time to be passed.

Internal market

One of the main principles of the EU is that it is an internal market with no borders between Member States. This means any product sold in one country can also be sold anywhere else in the EU (the principle of “**free movement of goods**”, as enshrined in the Treaty¹³).

2.2. Accession to the European Union

Any country can in principle become a member of the EU. Accession needs to be approved by all existing members and the applicant country’s government and parliament (and often requires a referendum). By becoming a member, the applicant country signs onto the Treaties that form the Union. From the moment of accession, the new Member State accepts all previous EU legislation (the so-called “**Acquis communautaire**”). From that moment on, all EU Regulations automatically become law in the new Member State, and all EU Directives will already have had to be transposed into national legislation.

Pre-accession negotiations between the EU and countries wanting to become members focus on the terms under which the applicants will adopt, implement and enforce the *acquis*, and, notably, the granting of possible transitional arrangements which must be limited in scope and duration. In certain cases, derogation is also possible. Under similar arrangements in previous accession negotiations, new Member States have been able to phase in their compliance with certain laws and rules by a date agreed during the negotiations. However, **in the case of GMOs none of the applicant countries has applied for such transitional arrangements. They would also seem highly unlikely to be granted by the EU.**¹⁴ Any such exemption would lead to major problems with the internal market, which stipulates the free movement of goods within the EU.

¹³ Treaty of Amsterdam, Part 3, Title 1, Articles 23-31

¹⁴ Interviews with Commission officials

CHAPTER 3: EU's GMO POLICY

3.1. General EU policy on genetically modified organisms (GMOs)

The main competence in the field of GMOs at the EU level lies with the Commissioner for Environment and increasingly with the Commissioner for Health and Consumer Protection.

EU legislation on agricultural GMOs was originally addressed by one directive (90/220/EC). However, the speed at which this new technology has been brought to the market, before considering all the implications of using GMOs in the agricultural system and the food chain, has led to a proliferation of legislation dealing with GMOs, either exclusively or as part of a general framework. These include the revised directive on Deliberate release 18/2001/EC and new regulations still in co-decision on Traceability/ Labelling and Novel Food and Feed, as well as other new legislative measures currently pending.

The EU's legal structure dealing with GMOs is a patchwork of both horizontal and vertical legislation,¹⁵ constantly under review, revision and expansion. It is such a volatile and constantly changing picture that even experts have difficulties following the various processes. This unworkable mess is one of the main reasons for the self-imposed de facto moratorium on approvals of releases of new GMOs.

According to the European Commission, the GMO legislation is "*designed to protect its citizen's health and the environment while simultaneously creating a unified market for biotechnology*".¹⁶

“Guilty until proven innocent”

In general the EU has adopted a policy, which requires any new GMO to be individually approved by the Commission and the Member States. Without such specific approval, GMOs are banned within the territory of the EU; they are neither allowed to be grown, sold, nor imported without such approval. The aim of the approval process is to conduct an environmental risk assessment to establish the safety of the products prior to their release into the environment and food chain.

This process of approval is lengthy and complicated, involving many steps on both the national and EU level. However, the two key principles applied are: approval **“case by case”** and **“based on sound science”**. The “precautionary principle”, although mentioned in the legislation, has so far played only a minor role.

Apart from the use of GMOs in 'contained use',¹⁷ there are two principal steps for releasing GMOs “into the environment”.¹⁸

¹⁵ “Horizontal legislation” comprehensively covers general principles, e.g. directive 2001/18/EC which requires risk assessments, traceability, labeling etc. for all GMOs; “Vertical legislation” is more sectoral, and relates to specific products, e.g. the Novel Food Regulation. On liability, horizontal legislation would cover liability for all hazardous activities and products, whereas vertical legislation would address liability issues separately for each hazardous activity e.g. nuclear power, biotechnology, hazardous chemicals

¹⁶ “Questions and Answers on the regulation of GMOs in the EU”, MEMO/02/160 - REV. Brussels, 4 March 2003

¹⁷ 'Contained use' of GMOs means the use of GM micro-organisms (GMMOs) in laboratories for research purposes, and commercial uses of GMMOs for the production of pharmaceuticals, enzymes and other biochemicals.

¹⁸ as regulated in Directive 2001/18/EC, which revised the former Directive 90/220/EC

Field trials, i.e. the growing of GMOs on a small area for scientific research in order to find out whether the GMO can be considered “safe”. This is done on a purely national level, i.e. the national “**competent authority**” (in most Member States this is the Ministry of Environment) approves and oversees such field trials. Other Member States and the Commission need only to be informed. No explanation need be provided on the reasons for rejecting applications for undertaking field trials. In principle, this means that any Member State or accession country can ban field trials.

Commercialisation or marketing authorisation, i.e. the putting on the market of a GMO (both seeds and food) needs to undergo authorisation on the European level. To enable the functioning of the single internal market, any product that can be sold in one country can also be sold in all other Member States. Therefore, a “European authorisation” is needed. A country that wants a GMO to be commercialised has to apply for a European authorisation, after it has conducted national field trials.

All applications for commercialisation have to undergo the scrutiny of several scientific committees. Any EU-wide marketing approval needs to be evaluated by the Competent Authorities (and their respective Scientific Committees) of all Member States, plus those of the European Commission. This is known as the “**comitology procedure**”. Authorisation is given only after all other Member States and the Commission have reached a positive agreement by voting on each proposal.¹⁹

These authorisation principles basically apply in all areas and are enshrined in all the respective legislation.

The EU’s first attempts at legislation on GMOs

The EU introduced its first general legislation dealing with GMOs in 1990 (Directives 90/219/EC²⁰ on “contained use” of GMOs and 90/220/EC on “deliberate release”²¹), followed in 1997 by a special law on GM foods (“Novel Foods”, 258/97/EC). However, already in 1996, when the first GMO crops were to be granted marketing authorisation, it became clear that the laws were highly inappropriate and unworkable.

Since then, the two original directives have undergone a lengthy revision process, which was only completed in early 2001. Apart from updating these basic directives, there is a lengthy list of upcoming changes or additions to the EU’s GMO laws pending. As GMOs move into the agricultural sector and the food chain, the EU has realised that its whole legal system needs a complete overhaul; provisions on how to deal with genetically modified seeds, trees, vines and other agricultural products need to be included in respective legislation. In general, the requirement for risk assessments to be conducted in accordance with Directive 2001/18/EC is being introduced into all product-specific legislation.

The Commission’s **White Paper on Food Safety**,²² published in 1999, is a signpost about where EU legislation is headed. There, the Commission lists more than 80 action points on legislation that still need revising or need to be created in the first place, many of which include provisions on GMOs. In general, they include:

- New legal framework for food safety

¹⁹ In addition to this GM approval, other, separate authorizations might be needed prior to actual marketing, such as under the seed variety legislation, or the legislation on the marketing of forestry products etc

²⁰ now amended: 98/81/EC

²¹ now amended: 2001/18/EC

²² White Paper on Food Safety - COM(1999)719fin. Can be downloaded from the Commission’s webpage at: http://www.europa.eu.int/comm/dgs/health_consumer/library/pub/pub06_en.pdf

- Legal provisions for traceability and labelling
- Legal provisions on GM Food and Feed
- A revision of the Seeds Marketing Directive
- New legal framework to deal with GM seeds
- The establishment of a European Food Safety Authority.

It will be many years before this major project is completed, but work is already underway. Regulations on traceability and labelling and Novel Food and Feed are likely to be approved by the end of 2003. In July 2002, the Commission presented a second draft Directive addressing the issue of GM seed in seed lots of non-GM seed varieties. The European Food Safety Authority is being established: the current debate concerns its location: Finland and Italy. Under normal circumstances, it takes 2-4 years for a new piece of legislation to evolve from the draft to the actual law, but experience in the field of GMO policy has shown that this can sometimes be a much longer process.

Even without these forthcoming legal changes, we have already seen a significant shift in EU policy over the past 7 years: the original Directive 90/220/EC was first strengthened (labelling requirements were added) by a Commission decision in 1997. The revised directive 2001/18/EC provides for transparency and stricter rules (see 2.2). Some highly controversial policy decisions, however, still remain to be taken, such as the question of liability, thresholds of permissible contamination by GMOs in food, animal feed and seeds, co-existence (of non-GM and organic agriculture) and GMO-free zones.

National bans

Despite the general rule that marketing approvals are always valid throughout the internal market, there are **safety clauses** in each piece of legislation, to allow for temporary national bans of approved products. These safety clauses go back to a principle enshrined in the Treaties²³ that allows for such bans, if there is a perceived threat to the environment (this must be argued on the basis of new scientific findings).

In Directive 2001/18/EC, this safety clause is enshrined in **Article 23**. If a Member State invokes Article 23, the GMO is banned in its territory and a renewed "comitology procedure" is initiated, during which all other Member States and the Commission review the new scientific evidence presented by the Member State wanting to ban the GMO. According to the law, this process should be completed within 3 months. However, over the past few years five Member States²⁴ have invoked Article 23 in the case of 8 GMOs, and none of these national bans have been overturned so far. Some of them have already been in place for years.

In the Novel Food Regulation, which deals with GM foods, **Article 12** provides for such national bans. In August 2000, Italy made use of this provision to ban any food product containing any of 4 GM maize ingredients. In October, other Member States defended this Italian ban against the wishes of the Commission, who wanted to overturn it. However, in March 2003, the Court of justice overruled the Italian ban as illegal.²⁵

The Moratorium

By 1999, the system of approving GMOs had proved to be totally inadequate and was disintegrating. Blocked approval processes, existing approvals being overturned by courts, a number of national bans of already approved products, confusion about the legal frameworks in transition and the acknowledgement that the present system was inadequate to protect the environment and the consumer from the potential adverse effects of GMOs, led to an

²³ Treaty of Amsterdam, Article 95 (4) and (5)

²⁴ Austria, France, Greece, Luxembourg and Germany

²⁵ "*Italian GM maize prohibition put in doubt*" ENDS Daily No. 1404, 13 March 2003 at: <http://www.environmentdaily.com/articles/index.cfm?action=article&ref=14041>

unprecedented move by EU governments. In June 1999 the Environment Council in Luxembourg adopted a **de facto moratorium** on new releases of GMOs.²⁶

There are no sound legal provisions in place in the Treaty for such moratoria. Thus, the “de facto Moratorium on GMOs” is based on the fact that a sufficient number of EU Member States have not processed the applications or have decided to vote against any approval, to prevent any positive vote in the comitology procedures (blocking minority). The declared time-frame is for the Moratorium to stay in place until the legal frameworks have been clarified. Efforts by the Commission to lift this de facto moratorium have so far failed due to the resistance of Member States on at least two occasions. (See Annexes B and C)

Liability

One of the sticking points in all debates and also concerning the moratorium, is the question of liability. Existing EU legislation on product liability does not cover environmental damage. Due to the highly unpredictable and irreversible consequences of releasing GMOs into the environment, there have always been strong calls for a liability regime to be in place before any more GMOs are approved for release. The European Parliament tried unsuccessfully to introduce a liability clause into the revised deliberate release directive.

The Commission has always favoured a more general (horizontal) approach and in January 2001 presented a long-awaited White Paper on Environmental Liability,²⁷ which includes a chapter on GMOs. There is pressure from some Member States for the de facto Moratorium to stay in place until the question of liability has been resolved (see Annex C). In January 2002, the European finally tabled a very weak proposal for an EU Directive on Environmental Liability. (See 3.2.2 Other Proposed Legislation)

3.2. Specific EU legislation on GMOs

This section lists only the most important pieces of EU legislation, relating to agricultural biotechnology. This list is neither comprehensive nor can it be expected to be up-to-date for long, as several laws are currently under revision.²⁸

3.2.1. Existing and pending legislation

Directive 2001/18/EC on the deliberate release of GMOs into the environment (formerly directive 90/220/EC)

This is the “mother-directive” of all EU laws on GMOs. It is a classic horizontal legislation, everything that is not regulated in other legislation (see below) falls under this directive. GMOs regulated under other legislation also have to undergo an environmental risk assessment in accordance with this directive.

There are essentially 2 parts to this directive: Part B deals with experimental “field trials”; Part C lays down procedures for EU-wide commercialisation (marketing approval).

The original directive 90/220/EC was revised in a 6-year process with highly controversial debates in the Parliament and in Member States. The new directive was adopted at the EU-level in spring 2001 and should have been transformed into national law by all Member States by 17 October 2002. However, by April 2003, only three Member States: Denmark, Sweden and UK had enacted the Directive. In April 2003, the European Commission

²⁶ In fact no GMO has been given marketing authorisation since April 1998.

²⁷ The White Paper on Environmental Liability, COM(2000)66fin, had been promised by the Commission for the past 10 years, but was constantly delayed due to resistance by industry. One of the reasons it has now finally been published is an attempt to try to take the steam out of calls for liability clauses to be put into GMO legislation.

²⁸ See also “White Paper on Food Safety”

threatened the other 12 Member States with court action if they fail to implement the new rules within the next two months.²⁹

The revised Directive sets higher safety standards to protect the environment and human health, is based on a broader risk assessment approach and introduces new concepts of traceability and monitoring which might help to identify and remedy adverse effects of GMOs at an earlier stage. On the other hand, the revision streamlines administrative procedures, fails to completely ban the use of antibiotic resistant marker genes, postpones liability and the problem of GMO contamination thresholds. (For details, see Annex D)

Regulation 258/97/EC on novel foods and novel food ingredients (“Novel Foods” Regulation)

This regulation deals specifically with GM foods. It is modelled on the approval systems contained in Directive 2001/18/EC.

Although adopted in 1997, only a year later it was amended by an addition: Council Regulation 1139/98, on labelling of 2 specific products (Monsanto RR soybeans and Bt 176 maize). This in turn was amended two years later by Commission Regulation 49/2000, to establish a 1% threshold of permissible GMO contamination of food, for labelling purposes. Later that year, Commission Regulation 50/2000 was introduced to close yet another important loophole in the Novel Food Regulation to address “*the labelling of food stuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms*”.

A major problem of the Novel Food legislation is that it allows for **fast-track approval** (without risk assessment) for GM foods which are deemed to be “substantially equivalent” to non-GM food. In October 2000, several EU Member States challenged this principle, when they defended a national ban imposed by Italy under Article 12 against the Commission’s proposal to lift this ban.

In response to the demands of six Member States³⁰ who announced in February 2001 (see Annex C) that they would not agree to any new GMO approvals until: (1) GM products can be traced back to their source and (2) all GMO-derived products are labelled, the European Commission adopted proposals to address these issues. In July 2001, the Commission presented proposals for new **EU Regulations for Traceability/Labeling of GMOs (COM(2001)182) and Novel Food/Feed (COM(2001)425)**.

Positive aspects of the proposed legislation include:

- The EU will have a **traceability system** that ensures GMOs can be identified throughout the food and feed chain, from 'farm to fork'.
- **GM animal feed will need to be authorised and labelled.**
- All food derived from GMOs will need to be labelled, regardless of whether or not the finished product contains traces of foreign DNA/foreign protein. This includes all products consisting or containing GMOs, food and ingredients, including additives and flavouring, as well as feed materials and feed additives produced from GMOs. This moves the EU's GM labelling regime from one based on product-labelling to one based on **process-labelling**.
- The simplified notification procedure based on 'substantial equivalence' of GM and non-GM will be abolished.

However, both the Traceability/Labeling and Novel Food/Feed proposals **allow for up to 1% 'adventitious contamination' ('technically unavoidable') by unauthorised GMOs with**

²⁹ "EU 12 face Court action over GM crops" at:

www.lifesciencesnetwork.com/newsdetail.asp?newsID=3748

³⁰ The six MS are: Austria, Denmark, France, Greece, Italy and Luxembourg

NO LABELLING. Moreover, the proposals still exclude the labelling of enzymes, pharmaceuticals and non-food GMOs, such as cotton and tobacco, as well as animal products (e.g. meat, dairy) from animals fed on GMO feed.

In July 2002, the European Parliament strengthened the Commission proposals by voting that foods or feeds that are contaminated with GMOs up to a level of 0,5% would not have to be labelled, whereas the Commission had proposed a 1% threshold. The EP also rejected the Commission's proposal to allow GMOs that have not been approved in the EU to be used in food and feed up to a level of 1%. In November 2002, the European Council of Ministers decided that the threshold should be set at 0.9% for authorised GMOs and at 0.5% for unauthorised GMOs, for a transition period of three years. The common position of the Council will be considered and amended during the second reading in European Parliament in July 2003.

The new regulations on traceability/labelling and Novel Food/Feed are likely to be adopted by the end of 2003. However, there are still disagreements with regard to the level of genetic contamination to be allowed in food and animal feed. Some countries advocate a 0,5% threshold; others want up to 1%. Another point of dispute concerns traces of unauthorised GMOs in food and feed. The European Parliament is against allowing traces of unauthorised GMOs, whereas in the Council there seems to be a qualified majority that is willing to allow unauthorised GMOs for a transition period of three years.

Directive 98/95/EC on the marketing of seeds

Legislation governing seeds has had to be revised to take into consideration GMOs:

1. By amending the Seeds Marketing Directive
2. By adopting a new GM Seed Directive (in process)

Directive 98/95/EC updates the rules governing the marketing of seeds. The marketing of seeds within the EU is only possible if a seed receives the status of a "variety" and is registered in a national catalogue. This is also true for GM seeds. However, this directive now establishes that GM seeds will have to undergo a risk assessment, in accordance to 2001/18/EC. It also states clearly that the public must be informed about the use of GM seeds. Directive 98/95/EC, Article 18 reads: "*The published note shall clearly indicate those [seed] varieties which have been genetically modified.*"

However, the European Commission recognises that there are still policy gaps and problems specific to GM seeds that have not been addressed by directive 98/95/EC. In January 2001 the Commission's DG-Sanco produced an internal working paper entitled: "*Adventitious presence of GM seeds in seed of conventional plant varieties*", as a precursor to a future Proposal for an EU legislation, dubbed "Novel Seed". The Commission proposed that only seed contamination by GE varieties, approved by the EU for cultivation, would be tolerated at all. It recommended thresholds of 0,7% for field peas and soya, 0,5% for self-pollinating crops like maize and beet and 0,3% for cross-pollinating crops, for approved varieties, and zero contamination for non-approved varieties. The proposal would also forbid farmers from growing plants for seed on land used for GE crop cultivation within the previous 2-5 years (depending on crop-type) instead of the one year at present. The Paper also proposed doubling the separation distances when non-GE varieties are being grown for seed near their GE counterparts.³¹

In early July 2002, the European Commission presented a revised draft of the "Novel Seed" **Directive (SANCO/1542/02 - July 2002) that aims to establish conditions and**

³¹ More information see DG Health and Food Safety websites:
http://europa.eu.int/comm/food/fs/biotech/biotech_index_en.html and
http://europa.eu.int/comm/food/fs/rc/scsp/rap19_en.html

requirements concerning the presence of GM seed in seed lots of non-GM seed varieties. Compared to the original proposal, some remarkable changes have been introduced to weaken the draft directive:

- The Commission has reduced the required isolation distances between plots where seeds are produced and possible sources of genetic contamination (like cross-pollinating GM crops).
- Provisions that would have required seed producers to keep a plot of land free of GM crops for a number of years (depending on crop type) before growing conventional seeds are missing in the Commission's second draft.
- The Commission has dropped the idea of banning the marketing of seeds with the "adventitious" or "technically unavoidable" presence of GMOs above a certain threshold. Instead, these seeds would now have to be labelled, but could still be sold.

The proposed "Novel Seed" directive does not fall under the responsibility of the European Parliament or the EU's Council of Ministers. Instead, it is being dealt with under the 'comitology' rules, whose procedures are both non-transparent and undemocratic. Yet, decisions currently being considered under these comitology rules could undermine and conflict with parallel decisions yet to emerge from the European Council concerning traceability/labelling and authorisation procedures for Novel Food/Feed. All the political groups in the Parliament agree that no contamination thresholds for seeds should be adopted under comitology rules until the above two Regulations, which include contamination thresholds for food and feed, have been agreed by the EP and the Council.

In October 2002, a delegation representing over 300 European environmental, farming and consumer organisations handed a petition to EU Agriculture Commissioner Franz Fischler and EU Consumer Affairs Commissioner David Byrne, demanding that the future EU Seed Directive guarantees seed purity, instead of tolerating GM contamination. The groups warned that if the Commission's current proposals are accepted - allowing between 0,3-0,7% presence of GM seed in conventional seed without labelling - it would result in the unwanted and uncontrolled widespread dissemination of GM crops in Europe.³²

The directive on GM contamination of conventional seeds is currently awaiting comitology decision. There is a "gentlemen's agreement" between European Parliament, Council and the Commission that the directive will be adopted only after the Regulations on novel food/feed and traceability/labelling have been finalised.

Directive 98/81/EC on contained use of GM Micro-organisms (GMMOs)

This is the revised Directive 90/219/EC, the original sister-directive of 90/220/EC (now 2001/18/EC). It deals only with the use of GM micro-organisms in "contained" circumstances, i.e. laboratories and commercial use of GMMOs in the production of pharmaceuticals and other biochemicals.

Biosafety Protocol

The EU and its Member States have signed the Biosafety Protocol to the Convention on Biodiversity, the so-called "Cartagena Protocol". This international law establishes rules on the transboundary trade of GMOs, especially the need for prior informed consent, i.e. the need for explicit permission from an importing country before any imports can actually take place. It also gives importing governments the possibility to ban the import of specific GMOs on the basis of health and environmental risks, even in the absence of scientific certainty. In this way, the Protocol enables importers to invoke the precautionary principle. The Protocol will enter into force, once 50 countries have ratified, probably sometime in 2003.

In October 2002, the Council of Environment Ministers reached a political agreement on a Regulation concerning the transboundary movement of GMOs. The Regulation - which

³² The petition and related information is at: www.saveourseeds.org

imposes rules for the export of GMOs from the EU - was proposed by the European Commission in February 2002 (COM(2002)85) and will implement the Cartagena Protocol on Biosafety.

The main issues agreed by the Council were:

- No export of GMOs without the explicit consent of the country of import
- No unintentional transboundary movements
- The exporter is responsible for notification
- The export of GM pharmaceuticals should be in line with international agreements
- Exporters should respect countries of import in the case of GMO food and feed import
- No EU authorisation as export requirement, which means that GMOs which have not been approved in the EU could be exported
- Labelling of GMOs destined for food and feed to be decided later.

Although the Council's text still contains loopholes, the Environment Ministers have substantially improved the Commission's proposal for export rules governing GMOs. Indeed the current proposals go further than the requirements of the Cartagena Protocol, which sets only minimum standards. Hopefully, the European Parliament and the Council will again strengthen this Regulation before it enters into force.

This regulation is currently awaiting a second reading in the European Parliament.

Århus Convention

In June 1998, the EU and member states, as well as all the governments of Accession countries signed the Århus Convention on public participation.³³ The 'access to information' pillar of this Convention guarantees citizens the right to information about "releases of GMOs into the environment". So far, 23 countries have ratified the Convention; only four Member States³⁴ have ratified this Convention, whereas of the 10 accession countries, six have ratified. The Convention entered into force into force 30 October 2001.³⁵

A Taskforce, that includes NGOs, has been meeting since 2000 to examine the ambiguities and shortcomings of the Convention, with regards to public participation in decision-making on GMOs. During the First Meeting of the Parties, which took place in Italy in October 2002, a set of non-binding guidelines on public participation in decision-making on GMOs was adopted by the Parties. NGOs are calling for the Convention to ensure legally-binding rights of the public to participate in decision-making on GMOs.

3.2.2. Other Proposed Legislation

Legislation currently being formulated includes:

- **The Commission's proposal for a directive amending directive 68/193/EC on the marketing of material for vegetative propagation of the GM vines** is currently heavily debated in the EP (368L0193-Proposed Amendment)
- **Proposal for a Directive on Environmental Liability**

In January 2002, the European Commission finally delivered its long-awaited Proposal for an EU Directive on Environmental Liability (COM(2002)17). As soon as it was published, the

³³ UNECE Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters

³⁴ The four EU parties to the Århus Convention are Belgium, Denmark, France and Italy.

³⁵ More information: www.unece.org/env/pp/ctreaty

Proposal was strongly criticised by environmental NGOs who believe that it will let polluters avoid liability and restoration of damage.³⁶

With respect to GMOs, 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 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 draft Directive fails to provide a regime for civil liability under which personal injury and damage to goods or property - so-called traditional damage - are covered. Instead, for many activities that are potentially dangerous to the environment, like oil pollution and nuclear radiation, there is only fault-based and not strict liability. Moreover, damage to biodiversity is very narrowly defined - applying only to sites and species covered by the EU's Habitats Directive (92/43/EEC), the Birds Directive (79/409/EEC) and sites/species protected by national legislation of EU Member States. As such, the proposed Directive would only apply to some 13% of the EU's territory.

The proposed Directive allows for two defences:

- Article 9.1. (c) precludes liability for a company whose GMOs cause damage, if the company has a permit to undertake these releases;
- Article 9.1 (d) allows the company to avoid liability if at the time of releasing the authorised GMOs, the state of scientific and technical knowledge could not have foreseen environmental damage. **This directly contradicts the precautionary principle.**

In its News Release, the Commission explains that "*when a release of the GMO has been specifically authorised or when it was not possible to foresee the damaging effect of the GMO on the basis of the best science, there would be no strict liability*". However, the key problem of GMOs is that they behave unpredictably, so environmental damage could occur as a result of GMOs that were considered 'safe' at the time of release.

Economic damage is explicitly excluded from the proposed Directive. So, in the case of an organic farmer whose crops are contaminated by GMOs and who is thus unable to sell his produce as organic, he would be unable to seek compensation under this proposed directive because his damage is economic and hence traditional, rather than environmental.

Another concern is the timeframe proposed by the Commission for initiating recovery or compensation proceedings against the operator who has caused environmental damage, which is limited to five years (Art. 12). In the case of damage to biodiversity by GMOs, environmental damage is not always immediately apparent. Furthermore, the Proposal excludes activities that have undertaken before the Directive enters into force (Art. 9) Since the Liability Directive is unlikely to be transposed by Member States before 2004-2005, all GMOs already on the market or which may be placed on the market before this time, are excluded. During a Council meeting of Environmental Ministers in March 2002, eight Member States³⁷ stated that GMOs pose particular problems to the environment, which are not covered in the draft Directive. Several countries called for traditional damage (e.g. damage or loss of income for farmers due to GMO contamination) to be included. Some Member States do not want licences to exempt operators from liability, and some argued in favour of mandatory financial security for companies. In general, most Member States seem to believe that the draft Directive undermines the Polluter Pays Principle (not only for GMOs).

The draft Liability Directive is awaiting its first reading in the European Parliament.

³⁶ See joint NGO press release: http://www.foeeurope.org/press/24.01.02_The_European.htm

³⁷ Austria, Finland, Portugal, Luxembourg, Sweden, France, Belgium and Germany

- **3.2.3. Co-existence**

Co-existence is the term being used to describe the ability to grow genetically modified (GM) crops alongside non-GM ones. If the area under GM crops in the EU is increased due to commercial cultivation, there will be major impacts on the way we farm, what we choose to eat and the environment.

In March 2003, Agriculture Commissioner Franz Fischler presented the Commission with a Communication on co-existence, which stated that legislative action at the Community level “*should be avoided*”. Fischler also argued that the burden of taking co-existence measures should fall on those benefiting from a particular form of cultivation. In other words, organic and non-GM farmers should pay the costs of staying GM-free. This goes against the ‘polluter pays’ principle and is therefore unacceptable.

Fischler’s Communication triggered numerous responses, revealing his position as highly controversial. During a high-level meeting in Brussels in April 2003, eight EU Member States argued that the proposals for Regulations on labelling and traceability, that are currently pending their second reading, “*do not deliver an adequate answer to the specific legal, economic and political problems relating to co-existing*”. They stated that additional legislation was needed to solve the problem of co-existence (often also described as GM contamination). In her comments on who should pay the costs of co-existence, Germany’s Agricultural Minister Künast told the German newspaper, Der Spiegel that “*those who want to produce without GMOs in the future should under no circumstance be confronted with extra costs*”. The issue of co-existence is also becoming more prominent in the European Parliament. MEPs have called on the European Commission to present “new, more ambitious proposals” and have tabled several amendments relating to co-existence to the Novel Food/Feed and Traceability/Labelling Regulations that are due for second reading in July 2002.

Thus, there is increasing pressure on the European Commission to present draft legislation that addresses the question of co-existence and in particular the following issues:

- **How to avoid the unwanted and uncontrolled dissemination of genetically modified organisms (both authorised and unauthorised) in the environment?** Directive 2001/18 certainly does not cover all the environmental risks resulting from GMOs, not even for those GMOs that have been authorised.
- **How to ensure the right of farmers and consumers to produce and consume food without genetically modified organisms?** Labelling and traceability regulations are necessary, but insufficient to ensure freedom of choice. Without a sufficient supply of non-GM food, feed and seeds, these rules become meaningless.
- **How to ensure that GM polluters will be held liable?** Crops that are contaminated by GMOs from neighbouring fields may lead to economic losses for non-GM farmers, because their crops cannot be sold at the premium price offered for non-GM products. The current proposals for an EU Liability Directive do not cover such damage.
- **Who is going to pay the costs of co-existence?** The answer provided in Fischler’s Communication is very unsatisfactory and violates the polluter pays principle. Hence, the Commission should present a proposal that puts the burden of applying measures to avoid genetic contamination of the environment, food and farming onto GM producers and GM operators.

It could well be that the commercialisation of GMOs in the EU is only expanded once these issues are addressed. Many problems relating to co-existence have yet to be resolved. It therefore makes sense to keep the de facto EU moratorium in place, until legally binding measures are in place to ensure the protection of the environment, organic and conventional farms from genetic contamination.

CHAPTER 4: What does EU Accession mean for GMO policy in CEE?

This chapter examines what will happen at the moment of accession, when CEE countries join the EU. What will be the legal status of GMOs that have been put on the market either in the old EU or on the market of a pre-accession country, after the two markets merge to create one single market?

This question has not been examined before. There are no provisions within EU legislation dealing with GMOs on how to deal with new Member States joining the single market. Hence, the findings below are not legal fact, but interpretations of existing legislation combined with the general principles of EU accession.

4.1. Chasing Moving Targets: Implementing legislation in transition

As discussed in Chapter 3, EU legislation and policies in the area of GMOs are currently undergoing substantive changes and a large number of laws are being amended, changed, updated or newly created. For accession countries, this could mean that they will have to transpose legislation that only comes into force a very short time prior to their accession.

Several pieces of legislation will still be in the process of being amended within the EU at the time of accession in June 2004. This leads to a situation where the accession country is required to adopt EU legislation that is already considered to be insufficient.

4.2. The Internal Market

The EU is an internal market: this means any product sold in one country can also be sold anywhere else in the EU (EU principle of “Free movement of goods”). In consequence, products need EU-wide approval before being commercialised. In the case of GMOs, this process involves all 15 Member States and the Commission. During that process each Member State can make a case against commercialisation of a certain GMO, based on a threat to the environment or public health.

How does the principle of the internal market work when new members join?

Unless agreed otherwise in the accession treaties, products that are allowed on the EU market will automatically also be allowed on the markets of new Member States. However, products on pre-accession markets with no EU authorisation will not automatically be allowed on the EU internal market. Products that have been approved in pre-accession countries according to EU-compatible law will gain EU-wide approval.

However, in the case of GMOs that have been released into the environment, this principle might not be so easy to apply. GMOs with EU-wide approval for commercial releases have not undergone an environmental risk assessment for ecosystems of new Member States. Since EU-wide approval is only given if the GMO is considered safe in all perceivable circumstances, it must be argued that EU approval must not automatically include new Member States. Instead a new approval process must be initiated.

Even GMOs approved within the EU and the pre-accession country might need to undergo a renewed application process under the EU’s “comitology procedures”.

These “**comitology procedures**” are designed for administrative approval of certain products within the internal market. They ensure that before a product is granted marketing authorisation within the EU, all Member States and the European Commission have had a chance to scientifically evaluate the environmental and health risks associated with the

product. This is done by the scientific committees of the Commission and the national “competent authorities”.³⁸

In the case of the deliberate release Directive 2001/18/EC, this procedure is also referred to as “**Article 30 Committee**”.³⁹ The Committee is made up of representatives (“competent authorities”) of all Member States and the European Commission. GMOs can only gain authorisation for deliberate release into the environment and marketing if they have been approved through the “Article 30” Procedures of Directive 2001/18/EC, or the equivalent procedures in related legislation (e.g. Novel Food). In essence, this means a vote on each and every application.

Since the “Article 30 Committee” will not have been able to conduct risk assessments for the deliberate release of GMOs in pre-accession countries, EU authorisations cannot be extended to the territories of new Member States by default, irrespective of whether the GMOs were approved in pre-accession countries or not. Arguably, a new approval procedure must be initiated for all GMOs (at least for the new territories).

A look at the problem by GMO categories

Notwithstanding any specific agreements to be negotiated in the Accession Treaties, the following scenarios prevail in the different categories of GMOs and products thereof.

4.2.1 Field trials – Directive 2001/18/EC Part B

Field trials are a national matter, but regulated under EU legislation. Field trials conducted in an applicant country in accordance with EU legislation may be allowed to continue, but those conducted under different (or no) laws would have to be terminated after accession.

However, many of the applicant countries do not have the scientific institutions in place necessary to advise the competent authorities according to EU legislation. Therefore, the case can be made that even where the actual legislation has been made compatible with EU law, the field trials themselves would not be seen as EU-compatible, because the necessary monitoring cannot be conducted in EU-compatible ways.

Applications for EU-wide commercialisation of GMOs based on field trials that are not compatible with EU law, or that lack the necessary monitoring, will not be able to be processed under EU law after accession.

Example: a new GMO has been tested in field trials in Hungary prior to accession. If these field trials were not conducted in accordance with EU legislation, then they will have to be terminated as of the date of accession. If they are being conducted according to EU legislation, including the necessary scientific monitoring, then they could be allowed to continue even after accession.

4.2.2. GMOs released into the environment – Directive 2001/18/EC Part C

Commercial releases of GMOs onto the EU market need approval under the “comitology procedures”. A number of different scenarios exist and are investigated below.

³⁸ In most Member States, “competent authorities” are situated in the national Environment Ministry. This makes sense, since the “deliberate release of GMOs into the environment” at the EU level lies within the competence of the Commissioner of Environment; and it will also be the Environment Ministry that has the best competence in evaluating “environmental risks”.

³⁹ Formerly Article 21 Committee of Directive 90/220/EC.

EU not approved	EU approved	CEE not approved	CCE approved (under EU-compatible law)	CEE approved (under laws not EU-compatible)	EU Status after Accession
X		X			Not approved
X			X		Not approved
X				X	Not approved
	X	X			New approval needed for new MS
	X		X		New approval needed??
	X			X	New approval needed

1) Any GMO product that does not have EU approval but has been put on the market in any of the pre-accession countries, will be illegal within the EU from the moment of accession, including the territory of the new Member State.

This situation also prevails, if the GMO was authorised in a pre-accession country under legislation compatible with EU legislation. The product does not have approval within the EU and hence, also not in the new Member State. At the moment of accession, the national authorisation would cease and the GMO would have to be taken off the market.

The new Member State could apply for EU-wide authorisation after accession, provided the experimental field trials were conducted in accordance with Part B of Directive 2001/18/EC.

2) GMOs that have EU approval but have not been released into the environment of the pre-accession country, have to undergo a renewed approval process.

In principle, a new Member State accepts all existing EU law and decisions that have been made to date. This means that products on the market within the “old” EU are automatically allowed on the new part of the internal market as well.

However, given the special nature of GMOs, the “comitology procedures” under which they are authorised and the “precautionary principle”, it is clear that the deliberate release of GMOs cannot be accepted in new Member States simply by default. No risk assessment has been conducted for the ecosystems of the territories of the new Member States. Therefore, a new approval process must be undertaken under Part C of the Directive (with special emphasis given to the new Member States) before any of the GMOs approved within the old EU can also be released in the new Member State.

In legal terms this would amount to an automatic “Article 23” procedure for all new Member States. Until the comitology procedures have been completed, the GMOs would remain banned in the new Member States.

The same situation prevails for GMOs that have been authorised in pre-accession countries under legislation not compatible with EU legislation.

Example: a product that has EU-wide approval but has so far not been approved in Poland. During the EU approval process the specific nature of Polish ecosystems was not taken into account when conducting the environmental risk assessment. It could be the case, that a certain GMO has gained approval only with certain limitations attached to it, prohibiting for example the growing of it in certain parts of the Union (e.g. the Massurian Lake district) due to very different ecosystems.

3) GMOs that have EU approval and have been approved in pre-accession countries under laws compatible with EU legislation, should also have to undergo a renewed approval process.

This is the most tricky case, as it is easy to argue that those GMOs which have gained approval in both the old EU and a pre-accession country under similar rules, must surely be considered approved also within the enlarged EU.

However, a different, legalistic argument could be made: under the “comitology procedures”. EU-wide marketing authorisation is granted only after all Member States and the Commission have had a chance to evaluate all aspects of the application, including different ecosystems within Europe. This system is a bit like saying “15 pairs of eyes see more than one pair of eyes”.

A GMO that had gained market approval from the authorities of a pre-accession country was only evaluated by “one pair of eyes”. Even if the same GMO had received marketing approval within the old EU, it was not evaluated either by the competent authorities of the old EU Member States and the new Member States or the Scientific Committees of the Commission on how it would perform when released into the possibly very different environments of the accession countries. Therefore, it can be argued that after (or prior to) accession, the product would have to undergo a renewed approval process with special emphasis given to the newly acquired ecosystems. Again, this could be termed as an automatic Article 23 procedure.

Besides this legalistic perspective, it should also be noted that most of the applicant countries do not yet have the necessary scientific institutions in place or competent authorities that function to the level that is reached in the Member States of the old EU. For example, in some cases the scientists in the competent authorities have close links to the applicants. Therefore, even if an authorisation in a pre-accession country was granted based on EU-compatible law, it seems a sensible measure (precautionary principle) to review the authorisation process under the EU’s “comitology procedure” and extend the EU-wide authorisation only after all the other Member States and the Commission have had a chance to evaluate it.

4.2.3. Processed Food/Imports – Novel Food Regulation

Products that have received permits from the EU under the Novel Food Regulation would in principle gain automatic permits for new Member States.

However, a distinction must be made between processed food no longer “*capable of replication or transferring genetic material*”, and products that are intended for growing within the EU or that could reproduce “accidentally” (e.g. whole maize kernels in animal feed). Under the Novel Food Regulation, the latter can gain authorisation only if an environmental risk assessment has been conducted in accordance with Directive 2001/18/EC on “deliberate release”, in which case the same situation as described under 3.2.2. applies.

Example 1: Corn flakes made from GM maize in the USA have an import permit under the Novel Food Regulation. From the moment of accession, the product will also be allowed on the market of the new Member State, irrespective of whether it was already allowed there or

not prior to accession. Since processed food is not considered to pose a threat to the environment and health risks should be the same for Belgians as for Slovenians, the case can be made that an EU-wide Novel Food authorisation is also valid for new Member States. (If the new Member State objects, it could file a temporary restriction or suspension under Art. 12 of Novel Food – but this needs to be based on new scientific information.)

Example 2: a GM potato, intended for growing in Europe, has been given authorisation under the Novel Food Regulation. This authorisation also contains an environmental assessment in accordance with Directive 2001/18/EC, under which all Member States would have had the chance to review the product. As of accession, the product would only be allowed to be sold as a processed product no longer "*capable of replication or transferring genetic material*". This means that it would not be allowed to be grown in the new Member State, until a renewed authorisation process was positively completed, although its import in processed food e.g. frozen chips or crisps, would be allowed.

4.2.4. Labelling

The EU's various labelling regimes immediately apply to all products and GMOs that have been approved for the markets of new Member States. Any products on the market found without the necessary labels would infringe EU law.

CHAPTER 5: RECOMMENDATIONS

5.1. Recommendations to the EU

There is currently little information about the situation of GMO releases in most accession countries, particularly for imports of agricultural commodities, including seeds imported from GMO crop-growing countries. Only Hungary and the Czech Republic have established certified State laboratories capable of testing GMOs, and even in these countries, there is no routine GMO monitoring of food and feed on the market. Only Hungary undertakes routine monitoring of seeds for GMOs.

Elsewhere, laboratories for GMO testing, which would enable implementation of GMO authorisation and labelling laws, are only now being established. Despite the lack of institutional capacity, in early 2002 Poland already approved the import of Monsanto's herbicide tolerant soybeans and insect resistant (Bt) maize. In Slovenia, Slovakia and Lithuania, no authorisations have been granted for releasing GMOs, but GMO testing by a Slovene NGO has found GMOs on the market.

In Romania and Bulgaria that are due to join the EU in 2007, GM crops are already being commercially cultivated for several years, some of which are not approved for cultivation or placing on the market in the EU. Moreover, there are insufficient controls in place to deal biosafety issues; Bulgaria still have no comprehensive GMO law.

Given the dangers and the irreversibility of releasing GMOs into the environment, it is in the self-interest of the EU to prevent any such illegal or insufficiently monitored releases into the environment of a future part of the Union. Whilst it is true that accession countries are sovereign states and that the EU has no right to dictate to them, the Union could still highlight potential problems to the officials of applicant countries. Especially in the light of the legal situation, as outlined in Chapter 4, it seems sensible to advise applicant countries to refrain from commercially releasing GMOs into the environment prior to accession:

- In the case of GMOs that already have EU approval, applicant countries should be promised an automatic "Article 23 procedure" to be conducted when they accede. Until the EU-approved GMOs are re-assessed for the potential impacts on the environment of accession countries, there should be a moratorium on all GMO approvals.
- As to GMOs with no EU approval, accession countries should be strongly advised to refrain from approving any such products.
- Accession country officials should be invited to participate in the EU legislative process e.g. in the development of Regulations on Traceability/ Labelling and Novel Food/Feed and Directive on Environmental Liability, since on accession they will need to transpose their requirements into national law.
- The EU should ensure that EU-approved GMOs do not contaminate other products.

As a first step, the European Commission and the Member States must be made aware of the problem. NGOs should then push the Commission to act accordingly.

Given consumer opposition to GM food, it would not be politically wise for the EU to be seen to allow new non-EU approved GMOs to be released into the environment simply "by default" when new Member States join.

5.2. Recommendations to CEE Accession Candidates

"The unfortunate fact is that nearly all candidate countries are behind schedule" --

Ms Margot Wallström, EU Environment Commissioner addressing the sixth regular meeting of accession country Ministers of Environment, Brussels, 9 October 2000⁴⁰

1. Given the fact that applicant countries need to adopt the same policies and legislation as the EU, the authorities of CEE accession countries should be advised to abstain from authorising any commercial releases of GMOs into the environment prior to accession and to prevent (illegal) imports or releases for the following reasons:

- there is currently a de facto moratorium in place within the EU on new GMO approvals;
- the status of many of the 18 GMOs that have been approved within the EU is unclear, given that national bans have been imposed on 8 of these GMOs by 5 different Member States (under Art 16 of Directive 90/220/EEC, now Article 23 of Directive 2001/18/EC) and these bans are still awaiting final evaluation, which could lead to a withdrawal of the EU authorisation;⁴¹
- at the moment of accession, GMOs approved in a pre-accession country will either have to be taken off the market or undergo a renewed approval process under the EU's "comitology rules";
- exports of GMOs or products thereof from CEE to the EU prior to accession are likely to be hampered, because these GMOs are either not authorised within the EU or the markets reject them due to consumer demands for GMO-free products;
- imports of agricultural commodities especially from North America, Argentina and other GM crop-growing countries might be legal in some CEE countries prior to accession but might be illegal within the EU's common market and will have to be taken off the market at high cost after accession.

2. Accession countries need to **anticipate outcomes of the revision of existing legislation** and follow closely pending legislative proposals, so as not to constantly lag behind EU legislation – which is a difficult process, given the constantly changing EU legislation. Special emphasis should be given to capacity building of the national "competent authorities" to establish the necessary scientific expertise in dealing with these matters. For example, accession countries should already be preparing for the implementation of the Regulations on Traceability/ Labelling and Novel Food/Feed in 2004, by requiring authorisation and labelling all food and feed containing GMOs or their derivatives.

3. Accession countries need to **monitor imports** of agricultural commodities especially from North America, Argentina, Romania and other GM crop-growing countries and **build institutional and technical capacity to identify GMO contamination of crops, foods and seeds** being imported. This will enable GM commodities that have no EU approval to be rejected; for those that have EU approval, it will enable appropriate labelling to be enforced. Until national GMO-testing laboratories are certified and operational, accession countries should use the facilities of the EU's Joint Research Centre.

4. In transposing the provisions of Directive 2001/18/EC, accession countries should ensure their implementation by providing systems to enable **traceability**, to enforce authorisation and labelling requirements, also for seeds. Directive 2001/18/EC requires the **labelling of all live GMOs**. According to this Directive, accession countries need to

⁴⁰ "Commission warns accession countries over EIA", ENDS Daily, 9 October 2000

⁴¹ Although a total withdrawal is not envisaged in the legislation, should a majority of Member States (MS) conclude that an individual national ban is justified in one MS due to risks to public health or the environment, it is hard to argue against the withdrawal of the authorisation also in all other MS.

establish **public registers** with locations of existing field trials and any future commercial releases.

5. Where there are still **gaps in EU GMO legislation** e.g. liability, co-existence, seed contamination, accession countries should address these deficiencies in national GMO laws. The GMO laws of some accession countries e.g. Slovakia and Poland, already provide for **liability**, but these provisions should be made more concrete. On **GMO contamination of conventional seed** varieties, EU accession countries should use the Austrian Seed Law as a model and support Austria in keeping its seed law.

5.3. Recommendations to NGOs in CEE countries

- NGOs in accession countries need to raise awareness about the fact that GMOs are being released into the environment without routine GMO-monitoring programmes in place to check compliance with legislative requirements. In the absence of Government GMO-monitoring, NGOs should undertake random testing of seeds, food and feed and use any positive results to **alert the public to the lack of implementation capacity**.
- NGOs need to highlight the fact that the EU's legal framework on GMOs is both much more restrictive and more transparent than those in place in most CEE countries.
- NGOs need to point to the fact that the EU is currently implementing a self-imposed **de facto Moratorium** on new approvals of GMOs, which is expected to be in place until the confusing rules within the EU have been tightened.
- NGOs need to highlight that the internal EU policies on GMOs are currently undergoing substantial revisions, and the trend is towards more restrictive legislation.
- NGOs need to **defend provisions in national GMO laws** that go further than those in the EU (e.g. on public participation) or that fill gaps in EU GMO policy e.g. liability, seed contamination.
- NGOs can publicise several cases within the EU where illegal GMOs have already had to be destroyed or taken off the market at great expense, and that such measures will have to be taken in accession countries as well, if illegal releases of GMOs are not prevented.
- NGOs need to demand that GMOs on the markets of accession countries will have to undergo renewed EU authorisation approval or be withdrawn on accession.
- NGOs can show that exports of GMOs to EU markets are de facto impossible because of either legal bans or market rejection.⁴²
- NGOs can demonstrate that despite the EU's initial opposition to transparency, consumer demands for "right to know" have led to mandatory labelling regimes in all areas, and this in turn has given consumers the power to reject GM products.
- NGOs can show that consumer choice and opposition to GMOs has led to the fact that the EU is largely GMO-free. There is no substantial commercial growing of GM crops in Europe's fields and most major supermarkets have banned GM products from their shelves; as a prime example, Austria can arguably be called "100% GM-free",

⁴² Market rejection means that food processors, such as Unilever and Nestle, and retailers, like supermarket chains, operating in the EU will not buy agricultural commodities or processed foods which are GMOs or products thereof, because of their corporate GM-free policies

- NGOs can point to the fact that consumer opposition to GM food in some parts of the EU has moved on to animal feed.
- NGOs must demand that measures are put in place to **ensure co-existence of GM crops with non-GM and organic crops**. If co-existence is shown to be impossible, NGOs should demand that no GMOs are authorised for commercial cultivation.

NGOs must call for clear rules establishing procedures on how to deal with GMOs after accession. No GMO must be authorised in a pre-accession country before such clear rules have been established!

ANNEX A

GMO PRODUCTS APPROVED UNDER DIRECTIVE 90/220/EEC as of May 2000

1. Vaccine against Aujeszky's disease, Vemie Veterinär Chemie GmbH
2. Vaccine against rabies, Rhône-Mérieux
3. Tobacco tolerant to bromoxynil, SEITA
4. Vaccine against Aujeszky's disease (further uses) Vemie, Veterinär Chemie GmbH
5. Male sterile swede rape resistant to glufosinate ammonium (MS1, RF1)
Uses: breeding activities, Plant Genetic Systems
6. Soybeans tolerant to glyphosate Uses: import and processing, Monsanto
7. Male sterile chicory tolerant to glufosinate ammonium Uses: breeding activities, Bejo-Zaden BV
8. Bt-maize tolerant to glufosinate ammonium (Bt-176), Ciba-Geigy
9. Male sterile swede rape tolerant to glufosinate ammonium (MS1, RF1), Plant Genetic Systems
10. Male sterile swede rape tolerant to glufosinate ammonium (MS1, RF2), Plant Genetic Systems
11. Test kit to detect antibiotic residues in milk, Valio Oy
12. Carnation lines with modified flower colour, Florigene
13. Swede rape tolerant to glufosinate ammonium (Topas 19/2) Uses: import and processing, AgrEvo
14. Maize tolerant to glufosinate ammonium (T25), AgrEvo
15. Maize expressing the Bt *cryIA(b)* gene (MON 810), Monsanto
16. Maize tolerant to glufosinate ammonium and expressing the Bt *cryIA(b)* gene (Bt-11)
Uses: import and processing, Novartis (formerly Northrup King)
17. Carnation lines with improved vase life, Florigene
18. Carnation lines with modified flower colour, Florigene

ANNEX B

Excerpts from a press release issued by the European Commission, Brussels, 13 July 2000⁴³

This initiative by the Commission, to “*resume the authorisation process for GMOs in the near future*” has so far failed; the de facto Moratorium remains in place.

“Commission takes initiative to restore confidence in GMO approval process

*The European Commission decided yesterday to propose to Member States a strategy to regain public trust in the approval procedure for Genetically Modified Organisms (GMOs). The objective is to **resume the authorisation process for GMOs** in the near future whilst addressing public concerns on GMOs as well as problems of legal uncertainty for stakeholders. (...)*

The Commission's strategy aims to enable the relaunch of authorisations of GMO products on the basis of a reinforced framework for approvals. It entails the following:(...)

- A comprehensive set of labelling provisions which would cover GMOs and GMO products to be submitted by the Commission by autumn 2000*
- An initiative on a traceability system for GMOs to be submitted by the Commission by autumn 2000*
- Acceleration of work on related issues. This includes environmental liability, the monitoring and study of possible long-term effects on biodiversity; further research; as well as taking into account international developments (i.e. Biosafety Protocol) (...)*

Background

*GMOs and the use of modern biotechnology in food and plants is currently the focus of intense public and political debate. Growing concerns have particularly focused on potential risks to human health and the environment. A **“de facto moratorium”** applied by Member States has implied that no new GM products have received approval under the EU procedure since October 1998. Five Member States have banned already approved GM products, under Art 16 of Directive 90/220. This article enables Member States to ban or restrict use/sale of specific GMO products temporarily, on certain conditions.*

Approvals of GMO products in the EU are based on both general and specific legislation. 18 products have been approved to date under the general Directive (Directive 90/220/CEE), while 14 are pending approval. This Directive is currently under revision. The second reading in the European Parliament was completed in April, and a conciliation procedure between Council and European Parliament is scheduled to be launched on 19 September.

Released on 13/07/2000”

⁴³ Full text can be found at:

http://www.europa.eu.int/comm/dgs/health_consumer/library/press/press62_en.html

ANNEX C

STATEMENT BY SIX MEMBER STATES IN RESPONSE TO AMENDMENT OF DIRECTIVE 90/220/EC⁴⁴, NOT TO LIFT THE EU MORATORIUM

Statement by the Danish, Austrian, Italian, Greek, Luxembourg and French delegations on the occasion of the third reading vote by the council, February 2001

Considering the principles of prevention and precaution,

The governments of the following Member States (Denmark, Austria, Italy, Greece, Luxembourg and France)

- take note of the agreement concluded between the Council and the European Parliament concerning the proposal for the amendment of Directive 90/220/EEC;
- reaffirm the necessity, on one hand, to put in place a more rigorous, more transparent and more complete framework for the assessment and management of risks (taking into account the specificity of European ecosystems), for the monitoring, traceability and labelling of the GMOs and, on the other hand, to generally restore public confidence and that of operators;
- note that the provisions of the Directive 90/220/EEC as amended improve, in a significant but only partial way, the existing system, and underline the essential improvements provided in the fields of transparency, public access to information, biological monitoring of the territory, progressive eradication of resistance markers to antibiotics, legal safety, and ratification of the Cartagena protocol;
- request the Commission to comply with its commitment soon to present thorough legislative proposals for traceability and labelling in the field of the GMOs, for environmental liability and for the ratification of the Cartagena protocol.

Consequently, the above-mentioned delegations

- reaffirm their will, in the framework of the power which has been vested in them, that new authorisations for bringing under cultivation and for the placing of GMOs on the market are suspended until effective arrangements are adopted for the thorough traceability of GMOs enabling reliable labelling of all GMO-derived products to be guaranteed.
- request the Commission to go forward quickly in establishing a system for environmental liability so as to complete the regulatory framework necessary for a development in the field of biotechnologies, as in other environmental fields.

⁴⁴ amended Directive 2001/18/EC

ANNEX D

KEY CHANGES IN THE REVISED DIRECTIVE 2001/18/EC **(formerly Directive 90/220/EC)**

Regulating the deliberate release of genetically modified organisms **into the environment⁴⁵**

The revised directive 2001/18/EC was finally approved by the European Parliament 14 February 2001. Although the revised Directive includes significant improvements compared to the previous one (90/220/EC), it fails to provide adequate provisions to protect consumers and the environment.

Improvements to Directive 90/220/EC

Directive 2001/18/EC includes some major improvements, notably by:

- Making direct reference to the **Precautionary Principle**;
- Requiring **direct and indirect, delayed and immediate adverse effects of GMOs** on the environment or human health to be considered;
- Extending risk assessment to **cumulative, long-term effects on human health and the environment**, including biological diversity and non-agricultural eco-systems (Annex II);
- Requiring Member States to ensure **traceability of GMOs at all stages of the placing on the market**;
- Abolishing the former labelling option of "*may contain GMOs*" in favour of an unambiguous **label stating "*this product contains GMOs*";**
- Requiring **mandatory monitoring of GMOs** released for commercial or any other purposes;
- Requiring **public registers for the locations of GMOs**, whether deliberately released or placed on the market;
- Requiring **product approvals to be given for a maximum period of 10 years**, providing at the same time for a renewal procedure which also applies to approvals given before the entry into force of the Directive, and to pending notifications;
- "Inviting" the Commission to bring forward a **legislative proposal for the implementation of the Cartagena Biosafety Protocol** before July 2001;
- Requiring that **unauthorised releases be terminated**;
- Providing for the right to consult any scientific committee with regard to the **ethical implications of biotechnology**;
- Foreseeing the regulatory procedure for GMO product approvals, thereby giving Member States more influence;
- Allowing **thresholds** to be introduced, but **only for adventitious or technically unavoidable traces of authorised GMOs**;
- Enabling the introduction of national **environmental liability legislation** and stating the need for complementary Community legislation in this field.

Weaknesses of the Revised Directive

The revised Directive:

Fails to immediately ban the use of antibiotic-resistant marker genes (ABRs) and requires instead that only ABRs "*which may have adverse effects*" be phased out by 2004 in the case of 'Part C' releases, and by 2008 in the case of 'Part B' releases;

Does not ban "GMO pollution" from contaminating organic and conventional crops: instead requires that adverse effects of gene transfer be "*accurately assessed on a case-by-case basis*";

⁴⁵ This annex is based on information from Friends of the Earth Europe: FoEE Biotech Mailout, Vol 7, Issue 1, 1 February 2001 and press release "*Should have been better - Europe adopts new GMO directive*", Strasbourg, 14 February 2001

Exempts medicinal substances (for human use) containing or made using GMOs from Part B and C of the Directive, provided certain minimum requirements are met by relevant Community legislation;

Retains the option for Member States to accept **long-term, multi-site notifications**;

Introduces the option to propose **new simplified "differentiated procedures"** for GMO releases and for GMO products; retains the existing simplified procedure (94/730/EC) for plants;

Streamlines and **speeds up the authorisation procedure** in general, by setting shorter deadlines for decision-making;

Requires a **centralised authorisation procedure to be examined in 2003**;

Does not provide for a liability regime addressing damage caused through GM contamination.

In Summary

The revised Directive 2001/18/EC sets higher safety standards to protect the environment and human health, is based on a broader risk assessment approach and introduces new concepts of traceability and monitoring which might help to identify and remedy adverse effects of GMOs at an earlier stage. On the other hand, the revision streamlines administrative procedures, fails to ban the use of antibiotic resistant marker genes, postpones liability and the problem of GMO contamination thresholds.

Outstanding Issues Missing from the Revised Directive

Several Member States have indicated that even with this revised directive 2001/18/EC, they will not relax the current 'de facto' moratorium on GMO approvals. In this regard, the European Commission is working on the following texts on:

- **Traceability**
- **Labelling of GMOs and GMO derivatives**
- **Adventitious contamination of seeds by approved and unapproved GM varieties**
- **Environmental liability**

The majority of Member States is believed to favour new horizontal legislation on traceability and labelling. However, the Commission and Ministers are unlikely to make a decision on traceability before the proposal regarding labelling is on the table. Both proposals are of course, closely interlinked given that one of the goals of traceability is to facilitate comprehensive and consistent labelling.