

Biotechnology Legislation in Central & Eastern Europe

- *Hungary pioneers biotechnology legislation in Central Europe*
- *Bulgaria establishes gene regulatory body*
- *Russian law regulating genetic engineering activity*
- *The key role of international organisations*

The economies in transition of Central and Eastern Europe (CEE) are supported by a relatively strong scientific and technological base and possess a critical mass of skilled human resources in the biological sciences. Given appropriate and timely support from the international community they are poised to make rapid advances with regard to the development of biotechnology. However, the regulatory environment which existed in the region until recently was not conducive to investment and did not ensure the safe development, application and transfer of biotechnology. In addition the drastic decline in financial resources of a number of CEE countries combined with the formidable legislative programmes confronting countries in transition has meant that the drafting of biotechnology legislation has not been at the forefront of government agendas. However, there is now a strong international impetus towards regulatory harmonisation to avoid non-tariff trade barriers to the import of biotechnology products. As a result the CEE countries have come under increasing pressure from international organisations such as the OECD to implement biotechnology legislation in harmony with that adopted at both regional and global levels.

The aim of this briefing paper is to provide critical analysis of the key biotechnology legislation which has been adopted within the CEE countries. A comprehensive review of draft legislation in preparation is made (see Table 1). It is demonstrated that Hungary, Poland and the Czech Republic are making strenuous efforts to harmonise their legislation in line with Western European regulation of biotechnology. Details are also provided of Bulgaria's regulation of genetically modified higher plants and the possible use of this legislation as a model for other countries in the region. The impact of Russia's new genetic engineering law on international companies wishing to export biotechnology products or conduct genetic research on Russian territory is described. The key role played by international organisations in assisting CEE countries to formulate national laws regulating genetic engineering activity and ensuring harmonisation with existing legislation is described. It is hoped that this

briefing paper will be a useful reference source for both scientists and representatives of companies concerned with the practical application of CEE biotechnology regulations, and government departments and international bodies interested in the wider policy issues.

Regulations covering genetic engineering activity in Central Europe

At present the bulk of the countries of Central and Eastern Europe do not have laws or regulations which deal specifically with the use of biotechnology (see Table 1). A range of other laws such as those concerned with environmental protection or food safety may cover some aspects of genetic engineering activity. As discussed earlier, the drastic decline in financial resources of a number of CEE countries combined with the formidable legislative programmes confronting countries in transition has meant that the enactment of biotechnology legislation has not been at the forefront of government agendas. However, the desire to stimulate collaboration with Western institutes and companies, combined with pressure from domestic scientific and industrial groups, has now led virtually all these countries to prepare draft regulations covering biotechnology.

The three Central European countries which have made most progress with regard to enacting their own legislation specifically regulating genetic engineering activity are the OECD member states of Hungary, Poland and the Czech Republic. Hungary has now emerged as the lead nation in this regard, its Parliament having adopted a Gene Technology Law, "Act XXVII of 1998 on Biotechnology Activities", on the 16 March 1998, which entered into force on the 1 January 1999 (see Table 2). Hungary's pioneering role within Central Europe perhaps reflects its leading position in the region with regard to the development and production of biopharmaceutical products and which led to it being formerly known as the drugstore of the Eastern bloc. Today there are approximately 100 drug manufacturers whose combined output represents an estimated 4.2 per cent of Hungary's GDP. Increasingly such industrial companies can be expected to become engaged

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The Task Group gratefully acknowledges the continuing support and funding of the European Commission, Research Directorate-General, for this and other issues.



Briefing paper

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June 1999

Table 1: Regulation of Biotechnology in Central & Eastern Europe

- Hungary becomes first Central European country to adopt legislation to regulate genetic engineering activity. Its Gene Technology Law entered into force on the 1 January 1999 with the concomitant establishment of an advisory body (the Gene Technology Committee).
- Czech Republic establishes Advisory Committee for Transgenic Plants (1990). Law on seeds, seedlings and cultivars regulates the use of transgenic seeds (1996). Draft law on GMOs has been submitted by the Czech Ministry of the Environment to the Cabinet for approval.
- Poland establishes a Committee of Experts for Genetically Modified Organisms (July 1996). A draft "Gene Law" has been submitted to the government and awaits approval and ratification by Parliament (November 1997). A new "Environmental Law" regulating labelling, trade and introduction into the environment of GMOs is adopted and expected to come into force soon.
- Bulgaria adopts regulation covering deliberate release of genetically modified higher plants. Establishes the first gene regulatory body in Central & Eastern Europe (August 1996).
- Slovenia establishes Commission for Supervision of Manipulation with Genetic Engineering Techniques in Research and Production (June 1994). Draft law on genetically modified organisms circulated to key ministries and institutions (June 1995).
- Russian Federation adopts law on regulation of genetic engineering activity (June 1996). Establishes Commission on Problems in Genetic Engineering Activity to implement law (April 1997).
- Other CEE countries lag behind with regard to biotechnology regulations.

in the development of new products via genetic engineering techniques and to begin production of GMOs. In addition there is a strong research base in genetic engineering with work under way in a number of institutions including the Biotechnology Centre of Szeged and the Gödöllő Agricultural Biotechnology Centre.

The new Hungarian Law regulating genetic engineering activities is modelled on European Commission Directives 90/219 and 90/220. It requires laboratories where work involves the utilisation of modern gene technology to be pre-approved and all work with GMOs to be subject to risk analysis. Companies or organisations utilising such technologies will be subject to the same liability rules as are enforced for hazardous industries. Registration of all GMOs will be required and all food containing genetically modified components will have to be labelled. The Law also provides for public access to information with regard to the release and commercialisation of genetically modified organisms and lists of

laboratories engaged in genetic modification. In addition the advisory body which has been established, the Committee for Evaluating Biotechnology Procedures, includes not only representatives of the Academy of Sciences and industry, but also elected representatives of public interest groups concerned with protection of public health and the environment⁽¹⁾.

The Czech government has also been quick to recognise that within the country there is widespread research activity with genetically modified microorganisms. Many laboratories and institutes utilise bacteria for gene cloning and for the construction of gene libraries. Bacteria are used for human gene therapy at the Institute of Haematology and Blood Transfusion. The University of South Bohemia utilises *Agrobacterium tumefaciens* for genetic engineering of plants. At least two institutions, the Institute of Chemical Technology and the Academy of Sciences of the Czech Republic's Institute of Microbiology are engaged in direct research on genetically modified strains of bacteria for bioremediation of soil and water purification. Charles University Faculty of Sciences' Department of Genetics and Microbiology has constructed genetically modified yeasts and used baculovirus as a model for production of engineered peptides. Research on genetically engineered plants is also performed at the University of South Bohemia (Cesk Budejovice), the Academy of Sciences' Institute of Experimental Botany (Prague), the Academy of Sciences' Institute of Biophysics (Brno) and the Research Institute of Crop Production (Prague-Ruzyně). Research is also under way at a number of centres on transgenic animals including frogs, mice and poultry.

As early as 1990 the Czech Advisory Committee for Transgenic Plants (CACTP) was established on a voluntary basis and comprises biologists working in the fields of transgenic plants, molecular biology and agricultural science. Until a law covering GMOs is passed the Czech Ministry of Environment has consulted with the Czech Advisory Committee for Transgenic Plants (CACTP) with regard to all applications from companies for field experiments using transgenic plants. In principle the evaluation procedure follows the 90/219/EEC and 90/220/EEC Directives. Since its formation CACTP has reviewed 14 experiments involving potato, oilseed rape, tobacco, sugar beet and *Lotus corniculatus* in small field trials. The introduced genes include natural pTi and pRi T-DNA genes, kanamycin-resistance nptII and hygromycin-resistance hptII selectable genes, the b-glucuronidase (GUS) reporter gene and the *Bacillus thuringiensis* delta-endotoxin gene. In 1996 the Czech Republic also passed a law "On seeds, seedlings and cultivars" which regulated the use of transgenic seeds.

With a view to implementing regulations specifically directed towards GMOs scientists within the Czech Republic have striven to raise awareness among key decision-makers and in industry of the issues surrounding biotechnology. The civil association Biotrend (which comprises molecular biologists from Czech universities and the Czech Academy of Sciences), for example, has organised courses

Table 2: Key Features of Hungary's Biotechnology Law

- Laboratories which are engaged in genetic engineering experiments have to be accredited.
- Genetic modification of natural organisms is subjected to risk analysis and may be carried out only by persons who have received a licence to do so.
- Requires the registration of all GMOs and all food containing genetically modified components will have to be labelled by the beginning of July 1999.
- Establishes a new Committee for Evaluating Biotechnology Procedures as an advisory body.
- Companies or organisations utilising genetic engineering technologies will be subject to the same liability rules as are enforced for hazardous industries.
- Annual reports to be published in the official journal of the Academy of Sciences.

for civil servants and the regional authorities, exchanged information with the media, disseminated professional information to government bodies and legislators and established contacts with international organisations in the field. Biotrend has also published a "White Book" on the application of genetically modified organisms in agriculture and the food industry, run a specialised course for Ministry employees, set up a course for environmentalists belonging to NGOs, and organised seminars for Senate and Parliament.

Since 1995 under the terms of a TEMPUS Project Charles University's Institute of Biotechnology has been taking measures to ensure that suitably trained personnel will be available for the regulation of GMO work. This has involved experts from universities in the Czech Republic, the UK, the Netherlands, Spain and Portugal. Another TEMPUS Project was initiated in 1998 at the Institute of Chemical Technology which focuses on the provision of courses on safety regulations in biotechnology for civil servants. Other developments include the establishment of a Bioethics Committee as part of the Government Commission for Research and Development and the design of a system of public information concerning GMOs with the aim of managing public perception of risks associated with biotechnology. All this activity means that among the CEE countries the Czech Republic now has in place one of the most developed infrastructures with regard to the drafting and implementation of regulations governing genetic engineering activity.

Since becoming a member of the OECD in 1996 it was agreed that specific regulations covering work with GMOs should be introduced within two years. The Czech Ministry of the Environment was designated by the government as the responsible authority for this legislation. A working group of experts was established at Charles University's Institute of Biotechnology to prepare the technical basis for the legislation. The draft law on GMOs which has been prepared is based mainly on European Commission Directives 90/219 and 90/220 but takes a

Table 3: The Role of Bulgaria's Gene Release Body

- Approves licenses for the release of genetically modified higher plants (GMPs).
- Maintains registers of research and commercial releases of GMPs in Bulgaria.
- Evaluates environmental hazard assessments posed by the release of GMPs.
- Evaluates the efficacy of proposed safety measures associated with the release of GMPs.
- Ensures compliance with the regulations governing the release of GMPs.
- Possesses powers to destroy GMPs or undertake other measures where violation of terms of a licence has occurred.
- Submits an annual report on GMP releases to the Ministry of Agriculture and Food-Processing Industry.

different approach with regard to some points. The Czech Cabinet approved the draft law on the 7 April 1999.

A number of other Central European countries are currently attempting to push through GMO legislation. Under the auspices of the Ministry of Agriculture in co-operation with the State Committee for Scientific Research, the Ministry of Environmental Protection and the Ministry of Health, Poland for example, established a Committee of Experts for Genetically Modified Organisms in July 1996. The aims of the Committee are to draw up legal regulations and to evaluate applications concerning the release of GMOs. In February 1997 procedures for applications concerning the introduction of GMOs to the environment were established. This was quickly followed by Poland's first field trials of three transgenic plants (potato, corn and beet) in 1997. By 1998 more than twenty such experiments were underway, all requiring permission from the Minister of Agriculture and under the strict supervision of relevant experts. In November 1997 a team of experts submitted a draft "Gene Law" to the government based on EC Directives 90/219 and 90/220, which now awaits approval and ratification by Parliament. A new Environmental Law which regulates labelling, trade and introduction into the environment of GMOs was also adopted in January 1999. The Ministry of the Environment, in conjunction with the Ministries of Health and Agriculture, is responsible for enforcement of the new regulations. These will not come into force until after a period of consultation and discussion with relevant ministries, NGOs etc. In a similar way in Slovenia in June 1994 the Ministry of Science & Technology established the Commission for Supervision of Manipulation with Genetic Engineering Techniques in Research & Production. In June 1995 the Commission, which was charged with preparing a programme dealing with the ethical and legal aspects of GMOs, submitted for expert assessment a draft Law of Genetically Modified Organisms to all other ministries and institutions dealing with GMOs.

The remaining Central European countries appear to be lagging behind with regard to the drafting and adoption of regulations governing genetic engineering activity. Romania, for example, has launched two ambitious programmes, the National Applied Biotechnology Programme co-ordinated by the Ministry of Research & Technology's Romanian Biotechnology Agency (ARBA) and the National Advanced Biotechnology programme co-ordinated by the Romanian Academy's Advanced Biotechnology Commission. In addition the Ministry of Industry has established the "Biotechnos" Biotechnological Research Centre with branches in several towns. However, despite all this activity Romania has no special scientific advisory body on biosafety and relies on existing labour regulations and legislation to regulate genetic engineering activity. Similar lags are evident in Croatia and Slovakia.

Bulgaria establishes first gene regulatory body in Central Europe

Bulgaria has pioneered research into genetically modified higher plants within Central Europe. Its Institute of Genetic Engineering (IGE, Kostinbrod) is one of the region's leading plant biotechnology centres. As early as 1991 Bulgarian tobacco varieties, transformed with the gene that encodes the nucleocapsid protein of the tomato spotted-wilt virus gene, were subject to research field trials in Gotze Delchev by IGE. In addition IGE has been responsible for releases of alfalfa transformed with kanamycin-resistance genes at Pleven and of tobacco resistant to bacterial wild-fire disease (*Pseudomonas syringae* pv. *Tabaci*). The work with transgenic tobaccos is part of IGE's commercial research contract with the Bulgartabac holding company. It is anticipated that the seeds from the transgenic tobacco will be tested at experimental stations across Bulgaria subsequently leading to the commercialisation of the genetically modified species.

The advanced nature of the plant biotechnology research underway in Bulgaria and the reluctance of Western companies to collaborate with the country's institutes until regulations had come into force, led Bulgaria in August 1996 to adopt a regulation covering the "deliberate release into the environment of genetically modified higher plants obtained by recombinant DNA technology". Given that there had been no releases of genetically modified animals or microorganisms in Bulgaria, and in the light of the problems the Russian Federation had recently experienced with its more broad-ranging set of GMO regulations, the government decided initially to focus its attention on plant-only rules. Following the model of the regulatory structure set out in the European Commission's "deliberate release" directive (90/220), the core of the Bulgarian regulation is the legal requirement that deliberate releases of genetically modified higher plants (GMPs) may only be carried out by persons who have received a licence to do so. Penalties for those who infringe the terms of the licence or release GMPs without a licence include fines and confiscation of the plants⁽²⁾. A key feature of the Bulgarian GMP regulation was the establishment of Central Europe's first gene regulatory body - the Council for the Safe Use

Table 4: Key Features of the Russian Genetic Engineering Legislation

- Principal objective is to promote development of genetic engineering activity whilst simultaneously protecting human health and preventing damage to the environment.
- Biotechnological products should be subject to regular national laws governing health and safety.
- The law does not regulate the application of genetic engineering techniques to human beings or human cells or tissues. This area will be subject to regulation by a separate law or set of laws.
- Companies or individuals engaged in genetic engineering activity shall be required at the request of interested entities or persons to furnish information on the level of risk of genetic engineering activity and on safety precautions to be taken in its regard.
- Remains unclear what specific procedures a foreign company or institution will have to adhere to either with regard to exporting biotechnology products to the Russian Federation or engaging in genetic engineering research within Russian facilities.

of Genetically Modified Higher Plants under the Ministry of Agriculture & Food-Processing Industry (Table 3).

Bulgaria's gene release regulation provides a solid system by which Western companies can conduct field trials or sell their GMPs in Bulgaria. It does include ambiguities with regard to the requirements for licences for commercial sales of GMPs and it does not set out any criteria for determining whether an application should be approved or not. However, for Western companies seeking to collaborate with Bulgarian research centres the existence of a legal framework is more important than its specific content. In addition the Bulgarian regulation, which creates a relatively simple system for granting licences, may serve as a useful model for other Central and East European countries considering similar laws. The plant regulations are regarded within Bulgaria as the prelude towards the adoption of a complete set of GMO regulations by the Bulgarian National Assembly.

Russian Federation pioneers biotechnology legislation in Eastern Europe

In terms of bulk output the Russian Federation possesses the most significant biotechnology industry in Central and Eastern Europe today. Its industrial base for the production of traditional fermentation products such as single cell protein, antibiotics, microbial pesticides etc is enormous. However, historically the country has lagged behind the advances made by Western countries in the development and application of modern genetic engineering techniques. This situation is slowly beginning to change and a significant number of research centres have now become engaged in the development of new vaccine and therapeutic

preparations (including a recombinant hepatitis B vaccine and recombinant interleukin-2) based on the latest genetic engineering technologies. There has also been an enormous growth in the number of small entrepreneurial companies attempting to commercialise genetically engineered products within the Russian Federation. Some indication of the importance attached to biotechnology by the Russian government is indicated by the fact that of seventeen scientific areas selected for priority state funding by the Russian Ministry of Science, five are in the biosciences (including recombinant vaccines, biotechnology based on bio-engineering and immune-correction technologies). However, until recently there has been no single legal act referring specifically to biotechnology and genetic engineering and recourse was made to guidelines issued by various government departments⁽³⁾.

Russia's new law was adopted by the Duma as a Federal Act of the Russian Federation on State Regulation of Genetic Engineering Activity in June 1996⁽⁴⁾. It establishes a regulatory system similar to those already in place in the West, and is the most over-arching legislation regulating biotechnology in Central and Eastern Europe today. The law which was ratified by President Yeltsin, is strikingly similar to European legislation in this area and establishes fundamental standards regarding the safe conduct of genetic engineering (see Table 4). One of the key features of the Russian legislation is that it does not establish a separate regime of regulation but rather makes provision that biotechnological products should be subject to regular national laws governing health and safety. Overall, therefore, the Genetic Engineering Act has resulted in the creation of a framework which appears to be generally favourable to genetic engineering activity and biotechnology and one which might be expected to encourage Western biopharmaceutical, agroindustrial etc companies to create, develop and market their products in the Russian Federation.

However, the Act may also represent something of a bureaucratic minefield for international companies wishing to export biotechnology products or conduct genetic research in the Russian Federation. For it remains unclear what specific procedures a foreign company or institution will have to adhere to either with regard to exporting biotechnology products to the Russian Federation or engaging in genetic engineering research within Russian facilities. The August 1998 financial crisis in Russia may also have a detrimental impact on the operation of the new genetic engineering law. When the law was originally passed it was anticipated that the new regulatory system would cost around \$1.6 million to set up and \$200,000 per annum to operate. The Russian government expected that industry would contribute around half the start-up costs and that income from licenses would make it profitable in little more than two years. However, it is likely that in the face of Russia's severe financial crisis anticipated revenues from these sources will have been substantially reduced and insufficient funding may now be available to make the system operate effectively. New Russian legislation requiring the approval and labelling of all food products containing GMOs was expected to come into force soon.

In April 1997 the Russian government approved a resolution for the establishment of a permanently operating Interdepartmental Commission on Problems in Genetic Engineering Activity. The Commission's main task is to ensure the full implementation of Russia's genetic engineering law. It is also charged with a number of other important functions including harmonisation of Russia's biosafety regime with rules being developed by international organisations concerned with genetic engineering regulation. The main criticism which might be levelled with regard to the membership of the Commission concerns its domination by professional bioscientists and government ministers responsible for the industrial application of the new genetic engineering technologies. Presently there are no representatives from NGOs, unofficial pressure groups etc which might give voice to public concerns over new applications of biotechnology.

Other newly independent states in Eastern Europe continue to lag behind the Russian Federation with regard to biotechnology legislation. Lithuania, which has prioritised biotechnology in state scientific programmes, and has established a Biotechnology Advisory Committee, has no specific legislation in place. Similar lags are evident in Belarus, Latvia, Estonia and Ukraine. The latter has a substantive biotechnology capability and possesses a specialised research centre working on GMOs, the Institute of Cellular Biology & Genetic Engineering (Kiev).

The key role played by international organisations

A number of international organisations are playing key roles in assisting the CEE countries to formulate national laws regulating genetic engineering activity and ensuring harmonisation with existing legislation both within the region and in the European Union and North America. One of the principal organisations involved in this area within Central and Eastern Europe is the United Nations Industrial Development Organisation's Biosafety Information Network and Advisory Service (BINAS) which monitors global developments in regulatory issues in biotechnology. At the request of CEE

government authorities in September 1994 BINAS convened an Expert Group Meeting on "Biotechnology Regulation: Towards the Establishment of Intergovernmental Co-operation in Central & Eastern Europe" which had the objective of developing an adequate regulatory capability in the region. At the meeting official representatives from eight countries and other participants recognised that while CEE demand for industrial and environmental biotechnology is likely to increase considerably in the near future, the regulatory environment is not conducive to investment and, in addition, it does not ensure the safe application of biotechnology. In order to overcome the problems of insufficient expertise and a scarcity of national resources the BINAS meeting took the view that the best approach was a regional one and that the emerging biotechnology institutional structures of the CEE countries should access the advanced technical and information capabilities and pool of expertise made available by BINAS and the International Centre for Genetic Engineering and Biotechnology (ICGEB) in Trieste, Italy. In order to achieve the objectives set out in the September 1994 meeting a Task Force of Regulatory Oversight for Central and Eastern Europe was established. However, thus far reports suggest that the Task Force has met with limited success in coordinating the development of regulatory frameworks within the CEE region.

The international organisation which now appears to be playing a lead role in assisting the CEE countries to formulate national laws regulating genetic engineering activity is the United Nations Environment Programme (UNEP)'s Biodiversity Unit which has biotechnology and biosafety as a key part of its remit. What appears to be one of the most important UNEP initiatives resulted from a meeting of representatives of Poland, Slovenia, the Czech Republic and Hungary in Columbia in February 1999. They agreed to the urgent implementation of appropriate biosafety mechanisms and with the aim of securing funding for this work resolved that a proposal would be submitted to UNEP in conjunction with the Global Environmental Fund (GEF) for a project on the "Preparation of a National Biosafety Framework in Central & East European Countries".

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