Biotechnology regulations (cont.)

edited by: Tomasz Twardowsk

As the continuation of our presentations of legislation on biotechnology in Central and Eastern Europe, in this issue of Biotechnologia we are publishing reports describing:

1) Czech Republic,
2) Bulgaria.

Czech Republic

The field is partly covered by the existing legislation, viz. *Environment Act* (Act. No 17/92 Sb), *Environmental Impact Assessment Act.* (Czech National Council Act. No. 244/92 Sb.), *Human Health care Act* (Act. No 86/92 Sb) *Animal Protection Act* and *Plant Variety Act* (under preparation). A Working Group was established at the Charles University which, in co-operation with the Czech Ministry of Environment, is preparing a new law on handling and release of GMO.

The philosophy of the law is to take care of very general issues. Thus the law will cover the following problems:

a) statement that GMOs represent a risk area,

b) requesting from anybody who intends to perform any activity within the risk area prior notification of the Institution described in and obey its rules,

c) establishment of an Institution responsible for protecting people, their property and the environment against any hazards arising from the area specified in a); the Institution's responsibility shall be supported with its power to set rules on activities in the aforementioned area,

d) penalties,

e) detailed regulations to be elaborated.

Since harmonisation with the EU legislation means going over about 500 legal documents, the biosafety law represents a distant horizon. Therefore the above mentioned Group is preparing Guidelines of the Ministry of Environment which should come into force next year.

The Working Group which has been authorised by the Ministry of Schools Sport and Youth and by the Governmental Committee for Science and Te

chnology is mainly working in the following directions:

a) to awaken social awareness at various levels — from the Prime Minister's office to newspapers,

b) to prepare professional background for legislation,

c) to organize training opportunities,

d) to gather international experience and information and to establish connections with international bodies.

Helena Stepankova, Jaroslav Drobnik
Institute of Biotechnology
Charles University
Prague, Czech Republic

The Bulgarian perspective

In 1991, the first genetically modified organisms to be released into the environment of the Balkan peninsula were introduced in the fields of the Tobacco Experimental Station by the researchers of the Institute of Genetic Engineering (IGE) in Kostinbrod. These were Bulgarian tobacco varieties to whom a TSWV coat-protein gene had been transferred in order to make them resistant to this virus. Progenies of these tobacco plants are currently being investigated under strict safety measures and monitoring.

In the field of medicine, three genes have been cloned (Interferon, Calsitonin and Cystis fibrosis), but no release or commercialization has occurred so far.

The first release of GMOs did not attract an adequate degree of official attention due to the numerous thorny problems facing the often changing Bulgarian government. However, thanks to the awareness of the researchers releasing the GMOs, all the necessary precautions have been taken, and the transgenic plants are now grown isolated from other crops.

In 1994, due to the increased concern of the international scientific community, the first attempts have been made to formalize local regulations regarding the deliberate release of GMOs. A Bulgarian Biosafety Committee was created to include representatives of academia and the ministries of agriculture, environment and health. Many organizational problems do not allow yet this committee to function as it might be expected (for instance, the government has again resigned recently). In March 1994, the first meeting of the Biosafety Committee defined the main factors which were seen to influence the formulation and application of national biosafety regulations. These are:

- The geographic situation of Bulgaria requires an intensive exchange of genetic material and information on releases of GMOs with the EU countries.

- Bulgaria possesses sufficient intellectual potential for sound evaluation of the risks related to the deliberate release of GMOs, which enables it to treat work with GMOs as a priority in the field of agricultural and health-care research.
- Official institutions are busy with a wide range of reforms, a situation which involves a danger of bureaucratization of the notification/permission procedures.
- It is very unlikely that the country budget would be able to afford the functioning of a permanent specialized biosafety committee. Therefore, close cooperation and intensive exchange of information and material with the national biosafety committees of the countries of the European Union are vital. This can be achieved via international organizations such as ICGEB, FAO and EC.

As long as national regulations have not been drawn up, IGE will on request, provide information in accordance with Annex IIa of Directive XII of the EEC on any deliberately released higher transgenic plants. IGE will also be using all of its informal power to prevent hazardous of GMOs.

Atanas I. Atanassov
Institute of Genetic Engineering
Plant Biotechnology Research Center
Kostinbrod, Bulgaria