



Plant Biotechnology in Slovakia and the legislation framework

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EuropaBio workshop on Biotechnology

In the last three decades genetically modified organisms got to the centre of attention of scientists as well as producers, businessmen, politicians and non-governmental organizations. Divergent opinions and standpoints were confronted during this time, but research is going on and also the practical use of new findings.

In Slovakia the biotechnology is being developed with different intensity for more than 20 years, sporadically supported by the government via concentrated effort and financing.

The attention is given to the pharmaceutical use of biotechnology, plant biotechnology, biotechnology in animal production, then to the ethical and sociological aspects of biotechnology, as well as to legislations and risk assessments and to the public perception.

As me and my institute (Institute of Plant Genetics and Biotechnology) are involved mainly in field of plant biotechnology, I will try to give an overview of the developments in this area in accordance with your interests.

1. What is the potential for plant biotechnology research and innovation in the Slovak Republic and where are the key regulation clusters?

One of the clusters dealing with biotechnology mainly directed towards protection and improvement of human health is concentrated in Bratislava. Plant biotechnology is only weakly represented in this cluster. There are some first attempts for plant transformation going on at the **Virological institute** (SAS) aiming on plum virus resistance and at the **Chemical institute** (SAS) aiming on production of secondary metabolites in tree tissue cultures with only small personal capacities (2 scientists each institute). The biotechnology research and innovation in Bratislava is mainly oriented towards production of recombinant diagnostics of the IV. and V. generation, then to production of biomedical preparations for human and veterinary medicine (recombinant vaccines, DNA vaccines, recombinant hormones and biologically active peptides), all on microbiological basis. The use of plants in this program is foreseen in near future. The institutes involved in biomedical research are: the **Institute of Molecular Biology, Institute of Virology, Institute of Neuroimmunology** and the **Institute of Heart Research**, all belonging to the Slovak Academy of Sciences.

The potential of researchers active in biotechnology for protection and improvement of human health is quite big (it represents about 30 researchers, some technicians and about 15 PhD students).

The scientific potential for investigations in field of plant biotechnology within Slovakia is concentrated mainly in Nitra, particularly at the **Institute of Plant Genetics and Biotechnology of the Slovak Academy of Sciences (IPGB SAS)**.

At the IPGB SAS there are projects in progress that aim on:

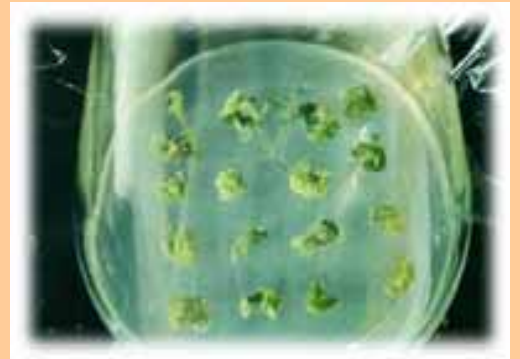
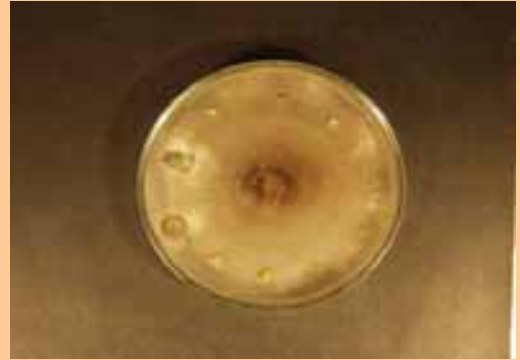
- isolation and analysis of promoters active in the peel of potato tubers with aim to obtain a stable resistance against fungi diseases caused by *Rhizoctonia solani* in Slovak potato cultivars. The specific promoter can induce local production of antifungal proteins and so to prevent the fungi adaptation to the introduced antifungal proteins



- screening of the constitutive and inducible expression of glucanase and chitinase to several fungi diseases as the antifungal synergistic effect of the introduced genes can be different depending on the attacking fungi

- elimination of antibiotic selection markers from the transformed plants and use of Cre/lox recombinant system (cruciferin from seeds finds the locs in the DNA). The use of Cre/lox system in transformations will enable to enhance the biosafety of the risk plants with potential outcrossing

- research on stability and reproducibility of plant transformation. MAR elements (short DNA sections) are used for this purpose



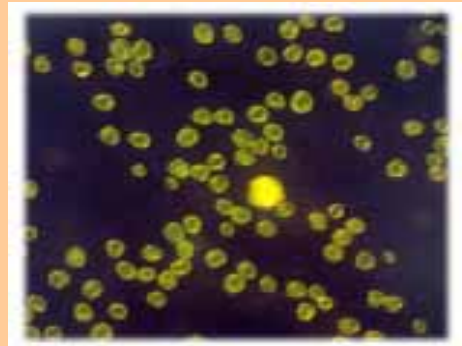
- introduction of chitinase and glucanase genes into the flax genome with aim to improve the flax resistance against fungi pathogen *Fusarium oxysporum f. sp.lini*. The disarmed *Agrobacterium tumefaciens* strain and the plasmid pIL09 is used for this particular purpose

- introduction of additional CAD gene (T - CAD 19) into the flax genome with aim to alter the flax fiber quality. Enzyme CAD (cinamylalcohol dehydrogenase) catalyses the last step of lignin synthesis - the monolignans

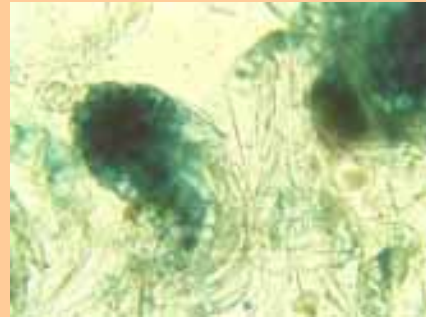
- research exploiting the plant cell totipotency and the somatic embryogenesis. Genes promoting the plant growth hormone synthesis are used in flax



- development of reliable protocols for somatic and gametic embryogenesis in some crop plants (maize, wheat, barley, potato, flax) and some woody plants (oak, fir, pinus). The cytological, morphological and molecular aspects are followed and a stress is put on the identification of morphological and/or molecular markers for this unique developmental pathway



- improvement of production and quality of fruit trees via application of innovative biotechnological approaches
- establishment of stable transformed lines of some conifers (*Pinus nigra*, *Abies alba*) via particle bombardment (incorporation of NPT II and GUS reporter genes)
- improvement of selected *Amaranthus* cultivars by means of mutation induction and biotechnological approaches



The research potential at the mentioned institute (IPGB SAS, Nitra) is represented by 3 leading scientists (2 of them with the highest possible qualification DrSc), 16 scientists with PhD qualification, 4 postdoctorals and 11 PhD students. This is a very strong personnel background that together with well established infrastructure secures promotion and development in the plant biotechnology research at this institute.

Our colleagues are also involved in the gradual and postgradual education procedure in field of plant biotechnology at both universities in Nitra. Two colleagues are also teaching and reading plant biotechnology abroad (Agricultural University in Timisoara, Romania).

Besides our institute there in Nitra is located the **Slovak Agricultural University** and the **University of the Constantine the Philosopher**, where the plant biotechnology field is supervised by the scientists from our institute and is being gradually developed.



The next centre where the field of plant biotechnology is developed is in Piestany - the **Institute of Plant Production**. This institute belongs to the Ministry of Agriculture of the Slovak Republic. The research is oriented towards:

- seeking, identification and characterization of donors (genotypes) with economically significant traits in crop plants
- introduction of tissue culture phenomena into plant breeding procedure (micropropagation, thermotherapy, somaclonal variability, haploidy etc.)
- molecular assisted plant breeding
- genetic modification of plants (*Medicago*, *Humulus*)
- identification of GMOs in plants and in products prepared from plants
- application of protein and DNA analysis in plant breeding, management of a seed gene bank

At the Institute of Plant Production there are 8 scientists and 20 technicians involved in this research area and the institute has a RT (real-time) PCR.



The third centre is located in east Slovakia in Kosice at the **Pavol Jozef Safarik University**. The main topic is focused on physiological, genetical, molecular biological and cryobiological studies of selected medicinal plant species (*Hypericum perforatum* and *Taxus baccata*) and is aimed at productivity increasing of secondary metabolites with pharmaceutical activities by cell and tissue cultures. A special attention is given to the study of expression of a gene encoding for *Hyp 1* protein, which is the crucial enzyme in hypericin pathway.

Research in *Taxus baccata* provides an opportunity for increasing the content of paclitaxel, an anticancer drug via application of biotechnological approaches. The research potential in this group comprises one full professor, 3 postdocs, 4 researchers and 3 PhD students.

There is another small laboratory with 2-3 people working mainly on tree tissue culture in Zvolen (**Technical University**)





What concerns private companies dealing with plant biotechnology, to my knowledge there are only 2 of them, predominantly oriented towards micropropagation of ornamental plants (**Arbor** in Senec - 30 km east from Bratislava and the **UNIS** company located in Piestany). **Arboretum**, located in Mlynany, also produces sempervirent trees via tissue culture.

IPGB SAS prepared a proposal for creation of a **Biotech-park** in Nitra area. The project was delivered to the Agency for Regional Development.



2. Which regulatory framework is in place to deal with biotech policy, particularly concerning GMOs and pharmaceutical legislation?

There is a regulatory framework to deal with GMOs, the **Act No 151/2002** on use of genetic technologies and genetically modified organisms known as “**Act on GMOs**” that came into force as of 1st April 2002 and the Implementing regulation No 252/2002 Coll. of the Act on GMOs as of June 1st, 2002. Both documents were prepared by the Ministry of the Environment of the Slovak Republic – a competent authority on biosafety. In accordance with the mentioned act some related acts were amended: the **Act on seeds, Act on food, Act on feed, Act on public health** etc.

A Biosafety Department and a Biosafety Inspection Department were established within the Ministry of the Environment of the Slovak Republic and currently they are in the process of development and organizational strengthening. An advisory body - the Slovak Biosafety Committee - has been established in accordance with the Act on GMOs. Members of the Slovak Biosafety Committee are representatives from Ministry of Agriculture, Health and Education Ministries, from the Slovak Academy of Sciences and from business sector as well.

The basis for creation of our regulatory framework was the EU Directive on dealing with GMOs and the so called Cartagena protocol (Protocol on Biological Safety).

The law has 41 paragraphs in 6 parts. The 1st part is defining the basic terms and definitions, the 2nd part is on use of GMOs in closed environments, the 3rd part is on release into free environment, the 4th is on competence of the regulatory body - the Ministry of the Environment and the 2 Committees, the 5th is on the procedure for release of the products containing GMOs, and the last part contains the transient regulations which will come into life after Slovakia will join EU.

The Biosafety Department does not yet have too much experience on dealing with requests for release; so far it was only one request on release of Bt maize to the market. On the other hand, there were 25 project leaders trained and a publication on risk assessment methods was prepared.

3. What innovation policy in biotech does the Slovak Republic pursue? Is there a national biotech strategy?

This very moment there is no general innovation policy on biotechnology in the Slovak Republic. In years 1997- 1999 a **National Biotechnological Program** was in life. It covered the field of the human health and welfare, agrobiotechnology and food, education and public perception. After this time there was no particular support for biotech development on the national level.

From the last year on a state program for research and development "**Quality of Life - health, food and education**" is going on and within this, some biotechnology activities could be developed and supported (plant biotechnology and some therapeutics as well).

A virtual **Centre of Excellence for Biotechnology** (BITCET) has been created last year, that associates excellent laboratories within the Slovak Academy of Sciences and universities. Our institute is also a part of this association. The activities within the centre are oriented towards the functional genomics, proteomics, cell engineering and bioinformatics. This centre will get also an extra financial support to develop its activities and to improve the technical side of the biotech research and buy some new instruments (for microchips, microarrays).



4. *How far does Slovak Republic take part in European efforts to encourage research and innovation in the biotechnology field, particularly the European Life Science action plan?*

According to my knowledge, Slovak scientists are not aware of the **European Life Science action plan**. I think it was not adequately advertised and there are no links to this action plan.

On the other side, the Slovak Republic takes part in several European programs that encourage research and innovation in the biotechnology field. First of all, it is the **5. and 6. Framework program** coordinated by the EU. This is true, more in the medical science; plant science is not very well supported under the 6. Framework Program. Projects in the field of plant biotechnology are more successful in the **Maria Curie Network** and in other fellowship programs.



There are also some other European activities that Slovak scientists entered massively, like the **COST** program previously coordinated by EU and currently under gestation of the ESF.

They are:

COST 836 aiming towards integrated research in berries

COST 837 aiming to bioremediation

COST 840 aiming to bioencapsulation innovations and technologies

COST 843 aiming to plant quality enhancement by tissue culture

COST 844 aiming to apoptosis and programmed cell death and applications in agriculture and biotechnology

COST 847 aiming to textile quality and biotechnology

COST 851 aiming to gametic cells and molecular breeding for crop improvement

I am personally also a member of the **Technical Committee for the COST domain in Agriculture, Biotechnology and Food.**

Our institute is also involved in a special scientific program under ESF: Assessing the Impacts of Genetically Modified Plants. I also work in the Steering Committee of this program.

The Institute of Plant Genetics and Biotechnology is the initiator of the biannual international event – **Symposium on Recent Advances in Plant Biotechnology** - that became a perfect forum for exchange of knowledge, experience in the field of plant biotechnology and for establishment of new cooperations.

First symposium was organized in 1995 in Nitra, later alternatively organized with the Czech partner, Institute of Plant Molecular Biology, in Ceske Budejovice. The 5th Symposium of this series was organized in High Tatras (Slovakia) last year, and the next one is in preparation.



Slovak scientists are also organized in the Biotechnological Society that became a member of the **European Biotechnological Federation** in 1999.

Our Institute has also well established contacts to **FAO** in Rome with the Biotechnology Department and Department for Genetic Resources.

This is a complete review of all activities going on in the Slovak Republic in the field of Plant Biotechnology. As you can see, the potential is quite high with a very good scientific background and experience, but the practical side – the application of results is nearly totally lacking in Slovakia.