Impact of EU and national regulatory framework upon biotech research in the Czech Republic

Jarka OVESNÁ

Crop Research Institute

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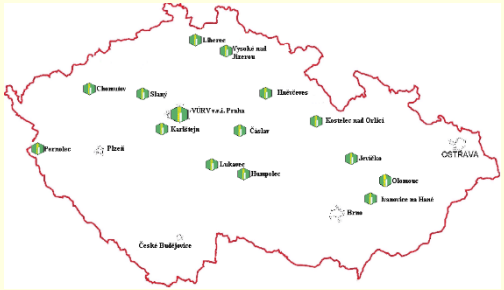
Crop Research Institute



Enhance knowledge for sustainable agriculture

Organization structure of CRI

THREE RESEARCH DIVISIONS:

- ❑ Division of Crop Management Systems
- ❑ Division of Crop Genetics and Breeding
- ❑ Division Crop Protection and Plant Health

25 research teams

EXPEREMTAL SUPPORT

- ❑ Division of Experimental stations

7 experimental stations

RESEARCH SUPPORT

- ❖ Project and human resource team
- ❖ Economy team
- ❖ Property management team
- ❖ Technical Services team

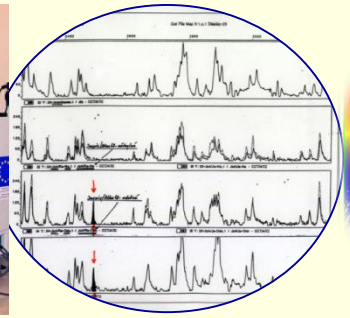
Advisory bodies, NRL

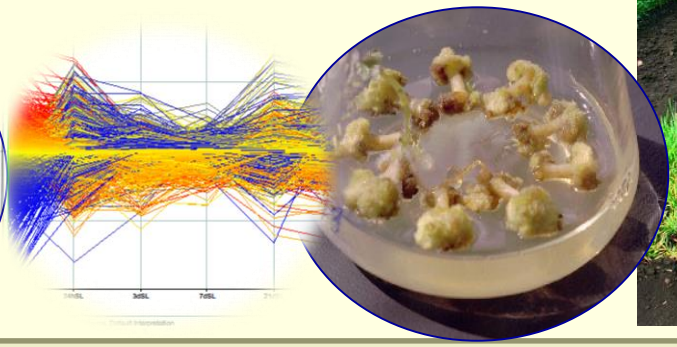
Division of Crop Genetics and Breeding

Research theme: Genetics, Plant Breeding and quality of plant products

Eight Research Teams:

- ❑ Gene Bank
- ❑ Physiology and Cryobiology of Plants
- ❑ Quality of Plant Products
- ❑ Plant Stress Biology and Biotechnology
- ❑ Plant Genetics and Breeding Methods
- ❑ Molecular Genetics
- ❑ Genetic Resources of Vegetables and Specialty Crops
- ❑ Phytochemistry





Engagement in Biotech

Research (breeding, DH production, transformation, field testing – vegetable, major crops, trees)

Advisory body of the Ministry of Agriculture for **GM Food and Feed** (1829/2003)

Member of Commisssion for GMO at Ministry of Agricultury (**cultivation**) Act. On agriculture 252/1997

Collaboration with the Ministry of the Environment (Czech Commission for GMOs) 2001/18

NRL GMO (882/2004)

Czech Technology Platform of Plant Biotechnologies – Plants for Future

Basic Legal Frameworks

Act No. 78/2004 Coll., on the use of GMOs and genetic products as amended by Act No. 346/2005 Coll., Act No. 124/2008 Coll., Act No. 227/2009 Coll., Act No. 281/2009 Coll., Act No. 18/2012 Coll. Trasposition of directive 2001/18

Regulation (EC) 1829/2003 on genetically modified food and feed

Regulation (EC) 1830/2003 concerning the traceabilityand labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms

Act No. 252/1997 Coll., on Agriculture, as amended by 62/2000 Coll., Act No. 307/2000 Coll.,……., Act No. 26/2017 Coll., Act No. 104/2017 Coll., Act No. 183/2017 Coll. , Act No. 299/2017 Coll., 208/2019

Basic Legal Frameworks – division of responsibility

Ministry of the ENVIRONMENT

- Contained use (Plants, microbial cultures, animals)
- Medical products
- Released in the environment for experimental purposes
- Assessment of cultivation dossiers 1828/2003
- Environmetal controls

Ministry of AGRICULTURE

- GM food and feed
- Assessment of cultivation dossiers
- Coexistence rules
- Cultivation
- Food Feed controls
- Coexistence rules controls
- SC FFGMO

http:

GMO cultivation

Allowed in the Czech Republic of those approved in EU (MON810)

Corn MON 810 cultivated since 2002 with the peak in 2008 (2nd producer in EU), decline down to zero in 2018 (socio – economy)

- Variety accesibility and productivity
- Pest occurence
- Legal status of GMO and obligations – co-existence
- Transboundary co-existence (2017)
- Demands of market

Amflora potatoes cultivated on 150 ha in 2010 for industrialal starch production, approval withdrawn, monitoring of cultivation area for subsequent 5 years

Coexistence rules

Co-existence between conventional, ecological and biotech agriculture aiming on socio-economic factors not products safety

2003, the Commission adopted a Recommendation on guidelines for the development of national strategies and best practices

The **Czech Republic established** the rules for coexistence for GMO cultivation **in 2005** with several obligation how to separate the production chains

§ duty to inform neighbors
§ duty to inform the State Intervention Fund
§ abide buffer zones
§ allow compliance checks
§ keep documentation for 5 years
§ label products with the GMO code

Community guidelines for crop-specific coexistence measures beeing develooed **since 2006**.

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Commertial sector? GM cultivation stopped. GM free ?

The **applied plant sector** (plant breeders) expected impatiently the European Court decission, to avoid useless investment into technology that would fit under the EU GMO regulative framework. As for genome editing applications, they are willing to pay for patent rights, just to speed up the selection and breeding process. They have several projects in their mind, but…. The techniques fall under GMO regulation

Meantime several workplaces investigated structure and function of plant genome including crop species and phenotypic associations, isolated genes and use GM technologies to verify their function.

On other workplaces tissue cultures and transformation protocols were optimized for several crop species. Breeder would like to improve several trait and speed up the breeding process aiming to

- better adaptability
- **improvement abiotic/biotic stress tolerance/resistance**
- improvement of nutrition uptake and utilization
- manipulating end use quality

New breeding techniques, namely **genome editing may facilitate** the process.

Impact upon plant GMO (GMP) developement

- Persisting high **interest of researchers** in GMP development gene function testing, practical application
- No interest of privat companies to invest into GMP development
- No interest of grant agencies to support GMP development
- International projects – focused on products safety
- Basic research of gene function (contained use, greenhouses) supported

National Center of Competence - Biotech Center for Plant genotyping

NCK

Národní Centrum Kompetence
Biotechnologické centrum
pro genotypování rostlin

- Consortium of Research Institutes and Commertial Companies focused on cereals, grasses, potatoe, pea, cherries
- Genetic resources including cultivars tested for specific traits
- Genotyping done by NGS – DART, whole genome NGS, genome reduction NGS
- Expected application in plant breeding MAS, genome editing ?

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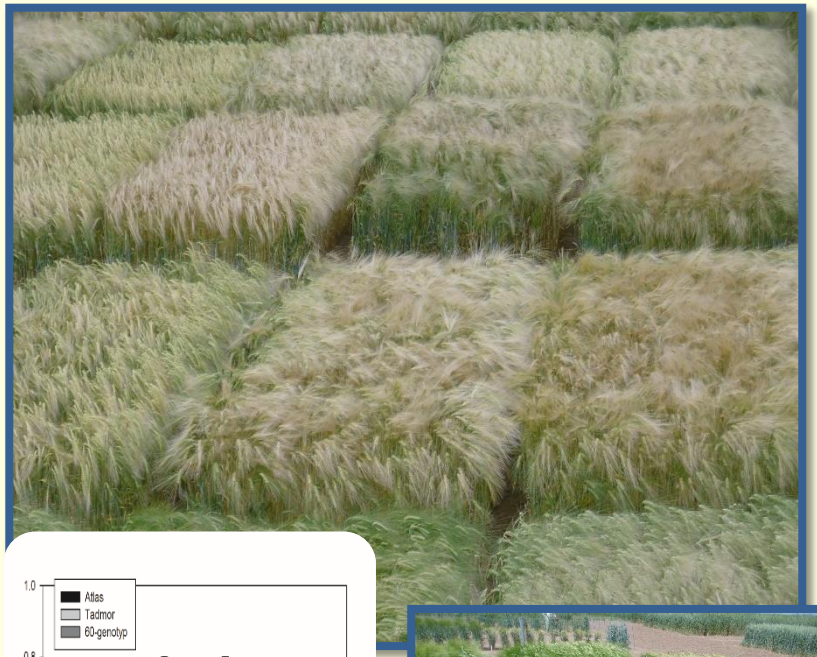
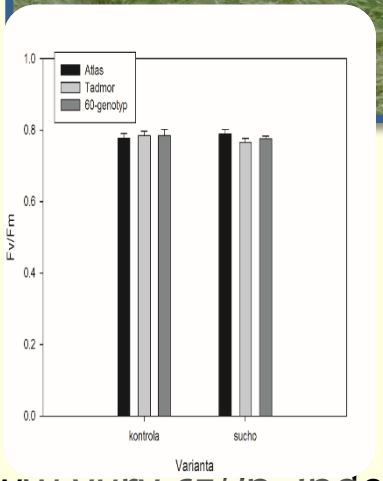
Testing 380 barley GRs in field and lab





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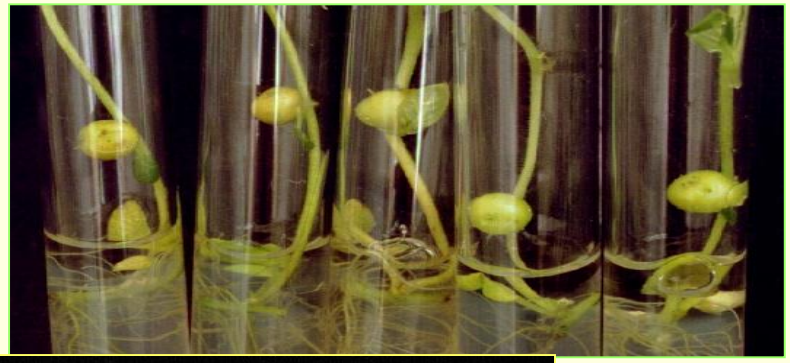
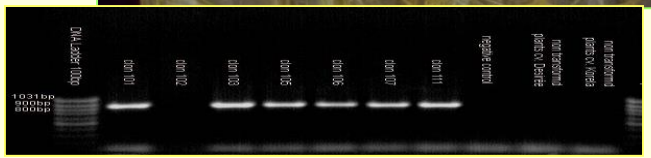
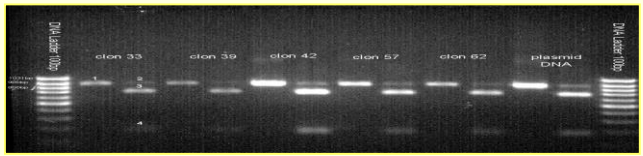
Tissue cultures (improvement, efficiency, CRISPr/Cas transformation protocols)







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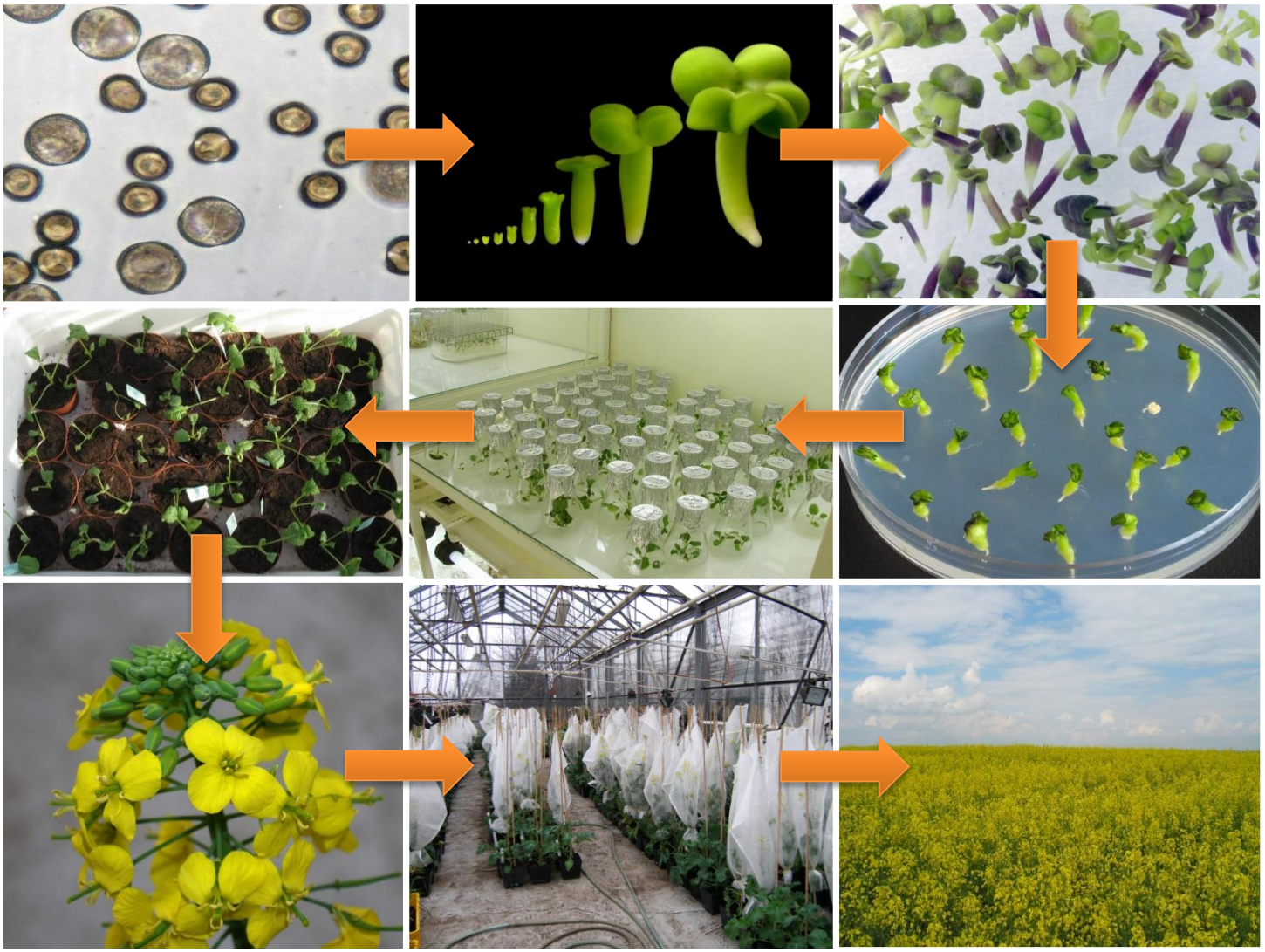
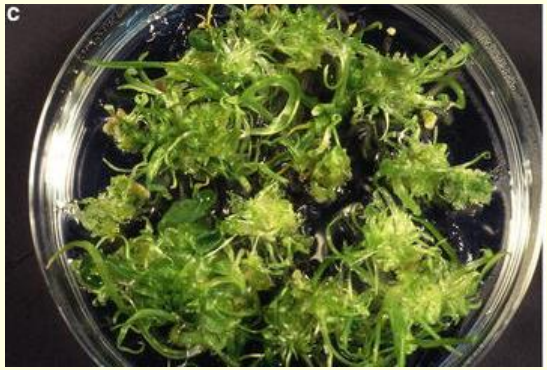
Tissue cultures rapeseed (DH, biotech)



Genome editing in barley

BARLEY GENOME EDITING USING CRISPR/CAS – (2017 – 2019 CZECH SCIENCE FOUNDATION)

Drought is a major stress factor, which has begun to negatively influence the production of high-yield cereals in recent years. The stable gene transformation method of barley has been used for genome editing by the CRISPR-Cas system of four genes with a possible link to increased tolerance to drought or yield. Since the integration of T-DNA responsible for the induction of deletion is independent of the target sequence, segregation of foreign DNA components from the transformed genome results in the non-GMO plant being obtained.



Field trials

Potatoes (sweetening, disease resistence/tolerance)

Flax (herbicide tolerance, bioremediace)

Pea (herbicide tolerance)

Barley (phytase)

Plum (disease resistance)

Soya (commercial)

Corn (commercial)

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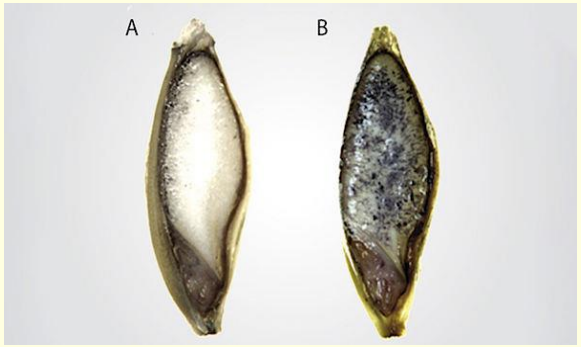
Successfull stories

Scientist from Center Hana Region developed transgenic barley that expressed peptide named katelicidin that is a part of human immune systém and served as natural antibiotics. Aurthors belived that a new technology - example of molecular farming - has been developed that allow for sufficient production of instable peptide and contribute to substantial drop of the peptide price



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Succesfull stories plum

Figure 1. Plantation of HoneySweet trees in Czech Re
public (Orig. J. Polák)

Honey Sweet transgenic plum resistant to PPV (plum pox virus has been tested since 2002 showing stable degree of tolerance. PPV cause serious damage upon stony fruit.

Nowadays consortium was established that aims to commercialize the GM plum EU

Animals - BIOCEV
Czech Center for Phenogenomics

Genetically modified mouse models have become a key tool in basic and biomedical research. The ability to engineer the mouse genome has greatly transformed biomedical research in the last decade. Crucial for this technology is the ability to control the expression of genes of interest. It is possible to increase or decrease gene expression, or eliminate the expression of a gene completely. include **pronuclear microinjection of DNA** constructs into mouse zygotes for the production of **transgenic founders**; microinjection of targeted ES cell lines into morulas (8-stage cell embryo) to produce chimeric mice; mouse archiving (cryopreservation of embryos and sperm); and recovery of live mice

Animals

TARGETED GENE MODIFICATION FOR GROWTH AND RESISTANCE TO NEW RETROVIR TYPES IN FOWLS, CZECH SCIENCE FOUNDATION 2015 - 2019

Bird leukosis viruses causes a wide range of tumors in domestic poultry. In the case of resistant species (quail, pheasant, plowshares and other pigeons) there is always a deletion or substitution of critical W38. Therefore, development of permanent line of chicken with W38 deletion by homologous recombination of CRISPR/Cas9n. Has a hge prospect.

DEVELOPMENT OF TRANSGENIC TECHNOLOGIES IN DOMESTIC COURSE AND THEIR BIOTECHNOLOGICAL USES National Agency for Agricultural research 2018 - 2021

The project aim to 1) Generate expression vectors with directional expression of recombinant proteins in egg yolk 2) Create vectors for CRISPR/Cas editing of chicken receptor *Tva* 3) Derivatize and subsequently transfect PGC cell lines from selected breeds of chicken-formed vectors. 4) Create two transgenic lines of domestic transplantation of modified PGC cells

What will be the next ?

Medical oriented biotech sector will be **developing fast** and get financial support

Animal models have commercialized already

Animal for pharmaceutical poduction have a **great prospect**

Development of GM based products for food uses are not financially supported by grant agencies

Private sector will not invest into this risky sector

Changes in legislation is demanded and at the moment is supported by Czech CC

WILL SOCIO-ECONOMY RESEARCH HELP TO CHANGE PUBLIC PERCEPTION ?

Thank You for your attention