

Republic of Slovenia Ministry of the Environment and Spatial Planning

BIOSAFETY FRAMEWORK IN SLOVENIA - PUBLIC PARTCIPATION-

Martin Batič and Ruth Rupreht

Biotechnology Division, Environment Directorate, Ministry of the Environment and Spatial Planning (MESP)

Joint Aarhus Convention/Cartagena Protocol on Biosafety workshop on public awareness, assess to information and public participation regarding LMOs/GMOs 8-9 October 2010, Nagoya, Japan

PUBLIC PARTICIPATION

INTRODUCTION INTO SLOVENIAN BIOSAFETY FRAMEWORK

PUBLIC PARTICIPATION IN DECISION MAKING PROCES IN SLOVENIA



- ELECTRONIC INFORMATION TOOL
- PUBLIC HEARING

CONCLUSIONS

GMO Act "horizontal legislation"

The Management of Genetically Modified Organisms Act adopted in July 2002, amended in 2004 and 2010

- provides a horizontal type of legislation on the use of all GMOs (GMMs, GM plants and GM animals) and their products, and intermediates other existing legislation in the areas of agriculture and health care
- Act regulates:
 - Contained use of GMOs
 - Deliberate release of GMOs into the environment
 - Placing on the market
 - Export and transit of GMOs and products
- The Act includes provisions of the
 - Directive 2009/41/EC,
 - Directive 2001/18/EC and
 - some provisions from Cartagena Protocol on Biosafety
- provides a responsibility of the Ministry of the Environment and Spatial Planning (MESP) for the CU Systems (in co-decision with MAFF only in the cases of vertebrate), Deliberate release and Placing GMOs on the market (in co-decision with MAFF)

GMO Act "horizontal legislation"

Public principle

Art. 3.10 - public has the right:

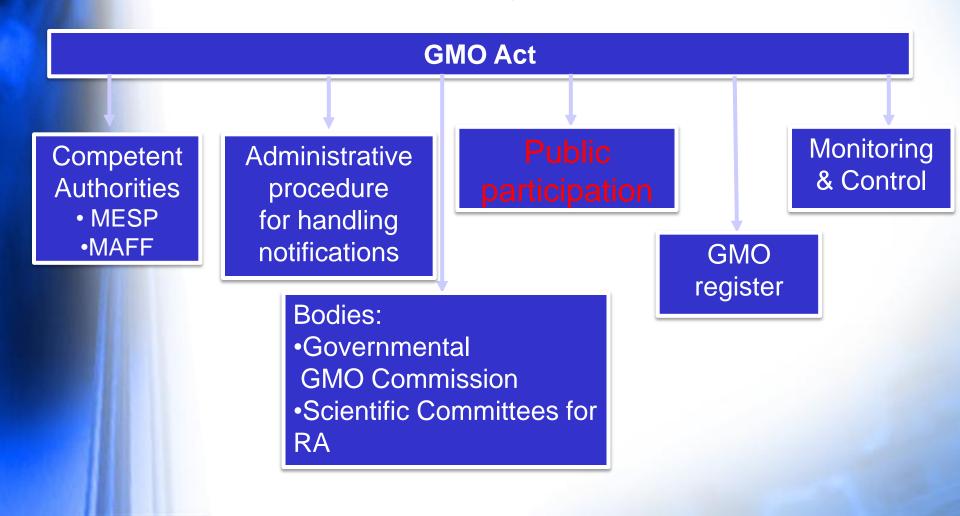
- to be informed about GMO management
- to be involved in the procedure of issuing permission

Art. 12.1 - information to the public:

data on contained use, deliberate release and placing on the market, and data on procedures and activities of ministries responsible for GMO management, shall be public

GMO Act "horizontal legislation"

Administrative system



Commission for GMO management

- Nominated by the Government of RS
- Consists of representatives of:
 - science (social, humanist, natural, medical and veterinary);
 - scientific committees (CU, DR);
 - of non-governmental organisations (NGOs);
 - Chamber of Commerce and Industry;
 - Chamber of Agriculture and Forestry.
- Shall be independent and sovereign, its work shall be public

Scientific Committees (CU&DR)





- <u>provide public with the opinion</u> of the committee in a procedure for issuing a permit
 - for contained use class 3 and 4,
 - for deliberate release
 - for placing on the market
- the committees shall issue annual reports on their work, which should be accessible to the general public

General public – contained use and deliberate release

Consultation of and information to the public class 3 and 4 and deliberate release

- In procedure for issuing a permit public is provided with perusal of:
 - notification, including risk assessment,
 - opinion of the committee
 - public hearing
- Reasoning of the Ministry shall include a standpoint to the opinions and comments of the general public

Register GMO

- components:
 - records, receipts and permits or approvals for
 - premises
 - contained use
 - deliberate release including field trials
 - placing on the market of GMOs and products
- register is publicly available
- confidential data are not part of the register
- The GMO register shall be kept by the ministry as a public document.
- Anyone shall have the right to peruse the data from the GMO register and request and obtain an extract from the GMO register against payment of the costs, which may not exceed the material costs of communicating the data.

Biosafety information system

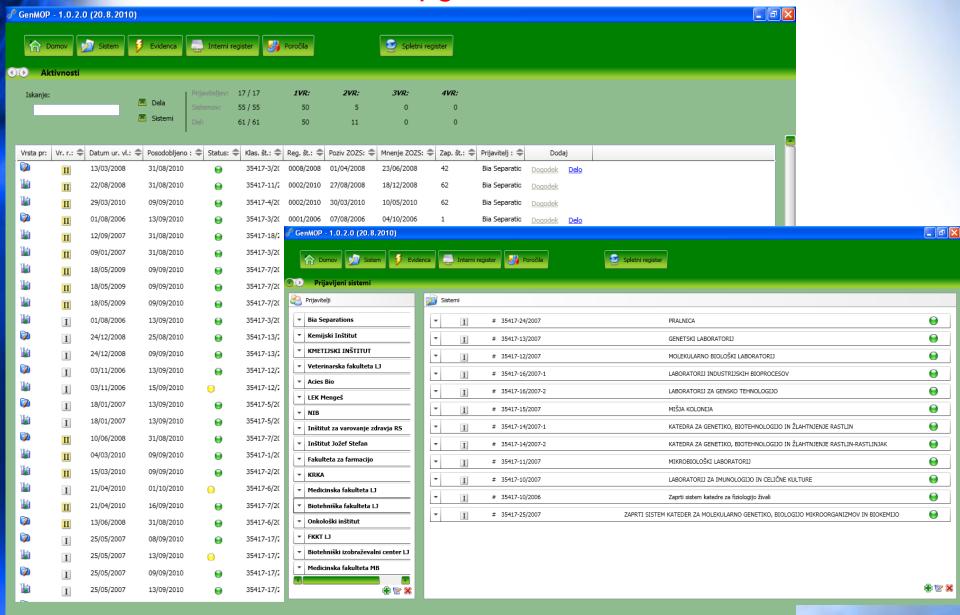
- Simplify the notification procedure and to support the subsequent administrative and decision making procedures
- Support the work of scientific committees
- GMO register was built gradually (paper vesion, electronic version)

Biosafety information system

GenMOP

- Upgrade -

Notifiers





















Biosafety information system

Electronic access to biosafety information

Slovenian BCH (www.biotechnology-gmo.gov.si)



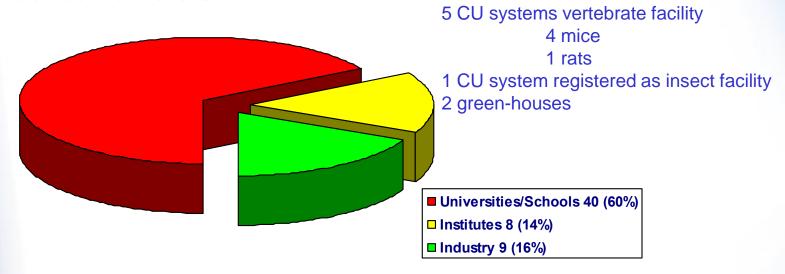
Homepage of the Ministry of the Environment and Spatial Planning

(www.sigov.si/mop)



CU systems in Slovenia

Licence holders 57



57 license holders, registered systems

53 biosafety class I

4 biosafety class II,

2 notifications of the BS class II CU system rejected

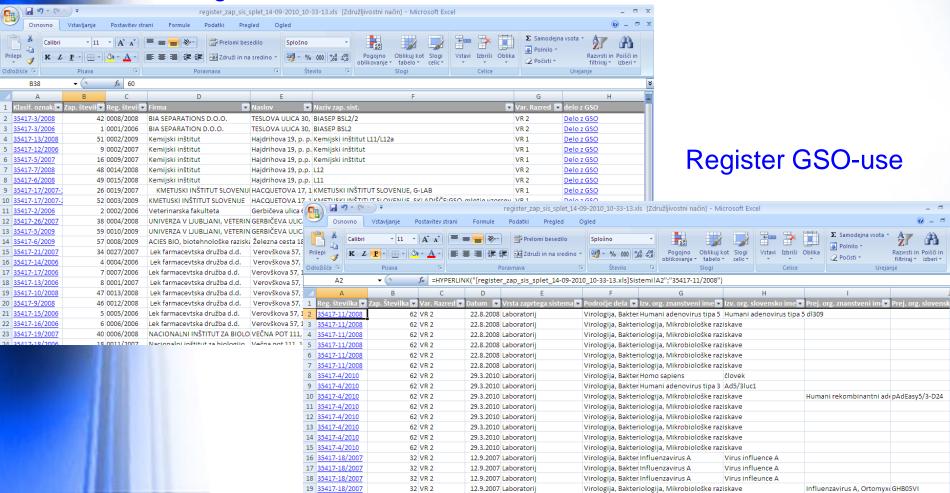
4 notifications of the work with GMOs in BS2 CU systems in the procedure

12 institutions more expected to notify BS2 CU systems

Register GMO

- public document
- anyone shall have the right to use the data from the GMO register

Register GMO - Facilities





Deliberate release in Slovenia - PABLIC PARTICIPATION -

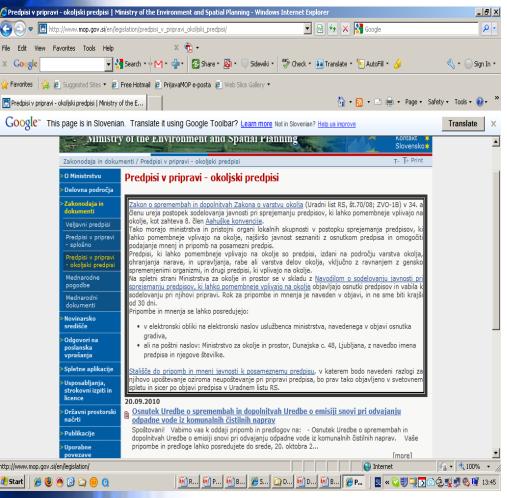
In 2009/10 - case of gene therapy of cannine patients

Public access to information: National

- available in paper and electronic version included :
 - notification (technical documentation (SNIF (lenguage SI/EN) including risk assessment),
 - scientific opinion of the Committee
- deadline to give opinions and comments was announced
- opinions and comments could be sent electronically, mailed or given verbally with written statements
 Public hearing:
 - Information on the date, place and time of hearing was announced in the newspaper and on the ministry webpage

EU (SNIF (EN) - http://gmoinfo.jrc.ec.europa.eu/)

SI



nvironmental Protection Legislation

Aarhus Convention (Art.8)

Opinions and comments:

- electronically
- mailed





Deliberate releases and placing on the EU market of Genetically Modified Organisms - GMO Register

Notification report

General information

Notification Number B/SI/09/01

Member State Slovenia

Date of Acknowledgement 04/03/2009

Title of the Project

Intratumoral application of naked DNA, encoding gene for human interleukin 12, followed by electrically-assisted gene transfer into tumor cells of canine patients

Proposed period of release:

01/11/2009 to 01/10/2012

Name of the Institute(s) or Company(ies)

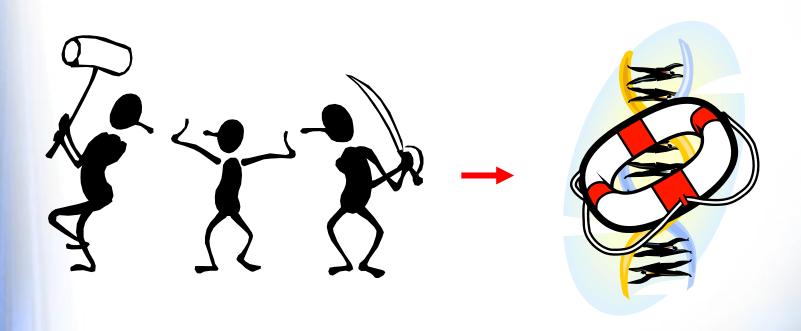
University of Ljubljana, Veterinary faculty, Gerbičeva 60, Ljubljana, Slovenia;

Conclusions

- public participation -

- each existing administrative system is specific and different (communication practices, knowledge, available infrastructure, etc.);
- Building capacity (ongoing need):
 - Resources (human and financial);
 - Knowledge (education and research);
 - Infrastructure (current options, build, update and upgrade)

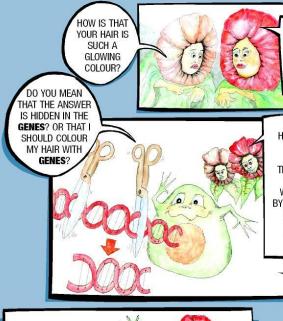
Thank you!



safe use of LMOs/GMOs is in everybody interest -



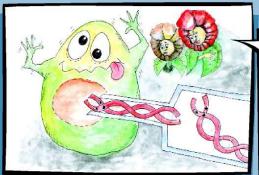
HOW DO WE MAKE A GMO?



THE SECRET OF MY
COLOUR IS NOT
CONCEALED IN A
SHAMPOO, BUT IN THE
GENES WHICH ARE
PRESENT IN MY CELLS.

IT'S HARD FOR ME TO HELP YOU. PERHAPS THE SCIENTISTS IN THE LABORATORY COULD TRY TO MAKE SURE THAT YOUR DESCENDANTS WOULD HAVE RED HAIR, BY EXTRACTING THE GENES FOR THE COLOUR RED FROM MY DNA AND TRANSFERRING THEM INTO YOUR CELLS.

... I'LL SHOW YOU ...



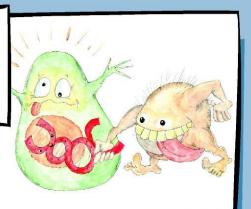
...THE GENES WHICH
DETERMINE THE REDNESS
OF MY HAIR ARE
INTRODUCED INTO
THE GENE GUN AND
IMPLANTED INTO YOUR
CELLS, FROM WHICH NEW
GENETICALLY MODIFIED
PLANTS DEVELOP WHICH
ARE THE SAME AS YOU,
ONLY THEY HAVE
RED FLOWERS.

GLOSSARY OF LESS KNOWN EXPRESSIONS

GENE GUN

Using the gene gun we insert DNA into the cells in such a way that the DNA is affixed to tiny metal parts and fired with great force into the cells.

...IF, HOWEVER, YOU DON'T LIKE GENE GUN METHOD, THE TRANSFER OF GENES CAN BE CARRIED OUT WITH THE AID OF AN AGROBACTERIUM WHICH WILL TRANSMIT THE RED COLOUR GENES INTO YOUR CELLS.



SUPER! THANKS FOR THE RED COLOUR GENES. FROM NOW ON , MY DESCENDANTS WILL ALSO BE GLOWING RED.



GLOSSARY OF LESS KNOWN EXPRESSIONS

GENETICALLY MODIFIED PLANT Genetically modified plants are obtained by first extracting a cell from the mother plant and modifying a specific gene. Then from this cell a new plant is grown which has the modified property which is determined by that gene.

AGROBACTERIUM

is bacterium which, in nature, during the infection of plants transfers part of its genes into the plants' DNA. In preparing GMO plants this bacterial capacity is used and certain bacterial genes are exchanged for those which one wishes to introduce into the plant. Then, of course, the agrobacterium preforms the genetic transfer instead of us.