

Republic of Slovenia
Ministry of Agriculture and the Environment

BIOSAFETY FRAMEWORK AND PUBLIC PARTICIPATION - SLOVENIA -

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Environment Directorate,
Ministry of Agriculture and the Environment (MAE)

International Seminar

*“Experience sharing in public education and awareness on biosafety issues”
1 October 2013, Minsk, Belarus*

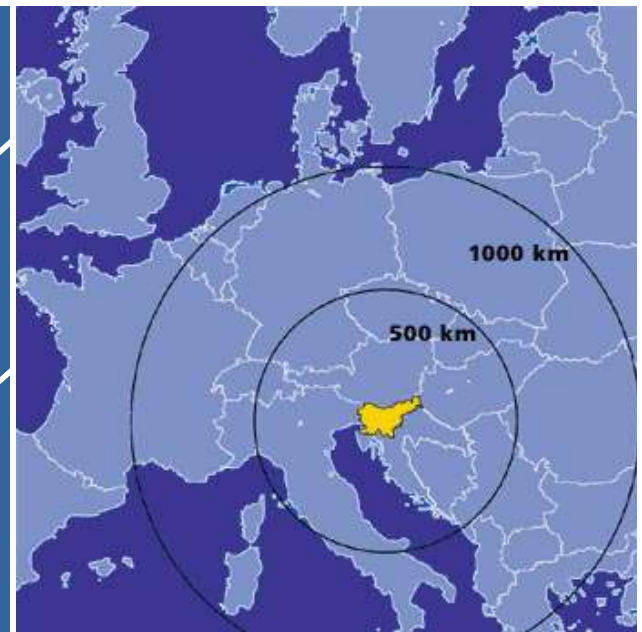
PUBLIC PARTICIPATION

INTRODUCTION INTO SLOVENIAN BIOSAFETY FRAMEWORK

PUBLIC PARTICIPATION IN DECISION MAKING PROCES IN SLOVENIA

- **ELECTRONIC INFORMATION TOOL**
- **PUBLIC HEARING**

CONCLUSIONS



area: 20,273 km²
land borders: 1,382 km
coastal border: 46.6 km
population: 2,039,399
capital: Ljubljana

**I FEEL
SLOVENIA**

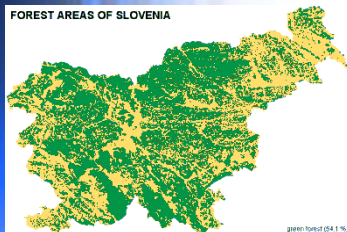
GMO REGULATORY FRAMEWORK



CARTAGENA PROTOCOL ON BIOSAFETY



DIRECTIVE 2009/41/EC
DIRECTIVE 2001/18/ES
Regulation (EC) 1829/2003
Regulation (EC) 1830/2003
Regulation (EC) 65/2004
Regulation (EC) 1946/2003



Act on Management of GMOs (MGMOs Act)

Co-existence Act

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 (CU) of GMOs
 - Deliberate release (DR) 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 Agriculture and the Environment (MAE) for the Contained use systems (in cases of vertebrate consultation with the Administration of RS for Food Safety, Veterinary and Plant Protection), Deliberate release and Placing of GMOs on the market (in co-decision with MH)

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 permissions

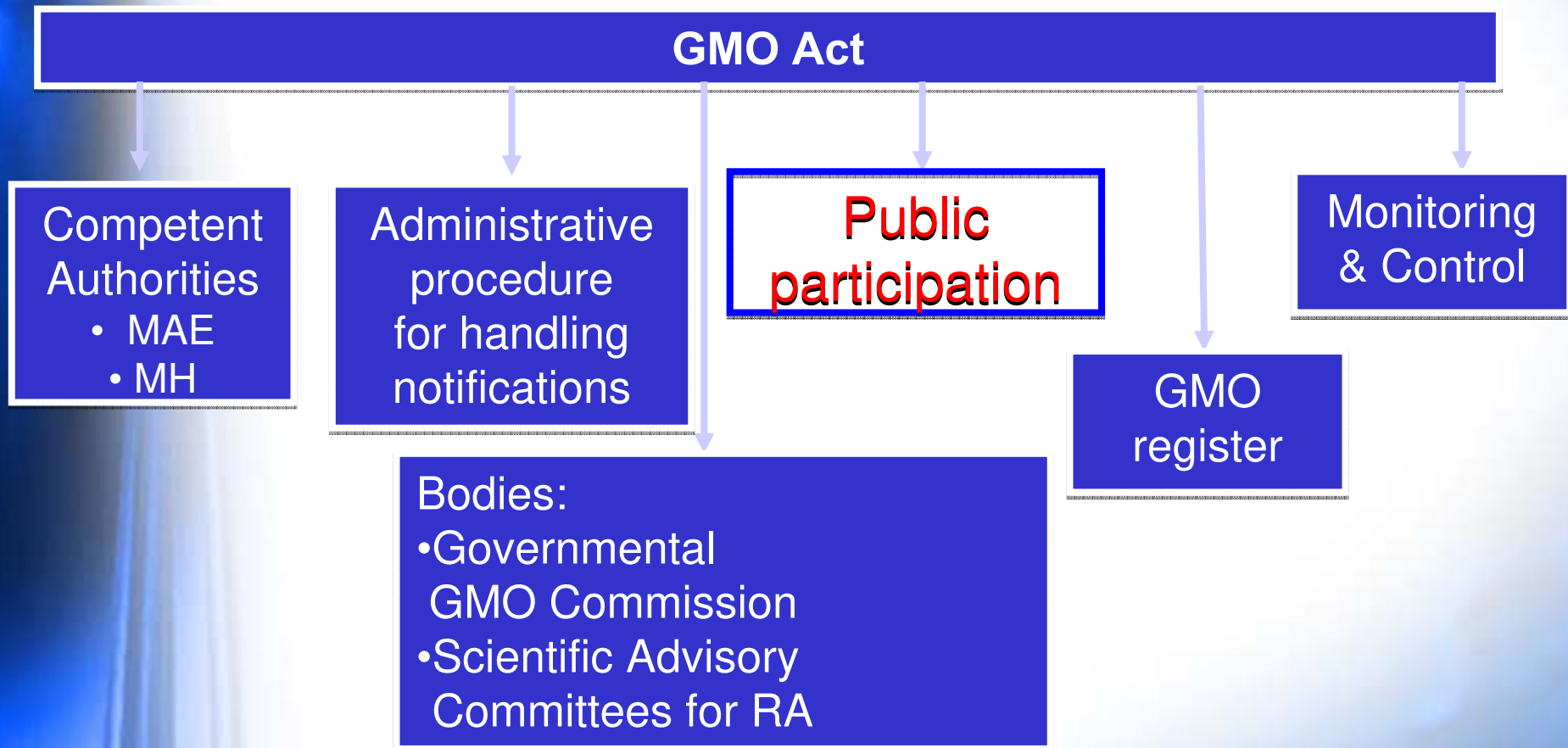
Art. 12.1 - information to the public:

- data on contained use, deliberate release and placing on the market, and data on procedures and activities of ministry 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 (17) of:
 - science (social, humanist, natural, medical and veterinary);
 - scientific advisory 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 Advisory Committees (CU&DR)

- two scientific advisory committees nominated to provide professional assistance to ministries (CU&DR) and inspectors
- provide public with the opinion 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 on class 3 and 4 contained use and deliberate release

- In procedure for issuing a permit public has right to:
 - notification, including risk assessment,
 - opinion of the committee
 - public hearing
- Decision of the Ministry shall include a standpoint to the opinions and comments of the general public

GMO Register

- components:
 - records, receipts and permits or approvals for
 - premises
 - contained use of GMOs
 - deliberate release of GMOs 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 CA 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 advisory committees
- GMO register was built gradually (paper version, electronic version)

Biosafety information system

GenMOP

- Upgrade -

Notifiers

GenMOP - 1.0.2.0 (20.8.2010)

Domov Sistem Evidenca Interni register Poročila Spletni register

Aktivnosti

Iskanje:

Prijaviteljev:	17 / 17	1VR:	2VR:	3VR:	4VR:
Sistemov:	55 / 55	50	5	0	0
Del:	61 / 61	50	11	0	0

Vrsta pr:	Vr. r.:	Datum ur. vl.:	Posodobljeno:	Status:	Klas. št.:	Reg. št.:	Poziv ZOZS:	Mnenje ZOZS:	Zap. št.:	Prijavitelj:	Dodaj
	II	13/03/2008	31/08/2010		35417-3/20	0008/2008	01/04/2008	23/06/2008	42	Bia Separatic	Dogodek Delo
	II	22/08/2008	31/08/2010		35417-11/2	0002/2010	27/08/2008	18/12/2008	62	Bia Separatic	Dogodek
	II	29/03/2010	09/09/2010		35417-4/20	0002/2010	30/03/2010	10/05/2010	62	Bia Separatic	Dogodek
	II	01/08/2006	13/09/2010		35417-3/20	0001/2006	07/08/2006	04/10/2006	1	Bia Separatic	Dogodek Delo
	II	12/09/2007	31/08/2010		35417-18/2						
	II	09/01/2007	31/08/2010		35417-3/20						
	II	18/05/2009	09/09/2010		35417-7/20						
	II	18/05/2009	09/09/2010		35417-7/20						
	II	18/05/2009	09/09/2010		35417-7/20						
	I	01/08/2006	13/09/2010		35417-3/20						
	I	24/12/2008	25/08/2010		35417-13/2						
	I	24/12/2008	09/09/2010		35417-13/2						
	I	03/11/2006	13/09/2010		35417-12/2						
	I	03/11/2006	15/09/2010		35417-12/2						
	I	18/01/2007	13/09/2010		35417-5/20						
	I	18/01/2007	13/09/2010		35417-5/20						
	II	10/06/2008	31/08/2010		35417-7/20						
	II	04/03/2010	09/09/2010		35417-1/20						
	II	15/03/2010	09/09/2010		35417-2/20						
	I	21/04/2010	01/10/2010		35417-6/20						
	II	21/04/2010	16/09/2010		35417-7/20						
	II	13/06/2008	31/08/2010		35417-6/20						
	I	25/05/2007	08/09/2010		35417-17/2						
	I	25/05/2007	13/09/2010		35417-17/2						
	I	25/05/2007	09/09/2010		35417-17/2						
	I	25/05/2007	13/09/2010		35417-17/2						

GenMOP - 1.0.2.0 (20.8.2010)

Domov Sistem Evidenca Interni register Poročila Spletni register

Prijavljeni sistemi

Prijavitelji	Sistemi
Bia Separations	I # 35417-24/2007 PRALNICA
Kemijski Inštitut	I # 35417-13/2007 GENETSKI LABORATORIJ
KMETIJSKI INŠTITUT	I # 35417-12/2007 MOLEKULARNO BILOŠKI LABORATORIJ
Veterinarska fakulteta LJ	I # 35417-16/2007-1 LABORATORIJ INDUSTRIJSKIH BIOPROCESOV
Acies Bio	I # 35417-16/2007-2 LABORATORIJ ZA GENSKO TEHNOLOGIJO
LEK Mengeš	I # 35417-15/2007 MIŠJA KOLONIJA
NIB	I # 35417-14/2007-1 KATEDRA ZA GENETIKO, BIOTEHNOLOGIJO IN ŽLAHTNENJE RASTLIN
Inštitut za varovanje zdravja RS	I # 35417-14/2007-2 KATEDRA ZA GENETIKO, BIOTEHNOLOGIJO IN ŽLAHTNENJE RASTLIN-RASTLINJAK
Inštitut Jožef Stefan	I # 35417-11/2007 MIKROBIOLOŠKI LABORATORIJ
Fakulteta za farmacijo	I # 35417-10/2007 LABORATORIJ ZA IMUNOLOGIJO IN CELIČNE KULTURE
KRKA	I # 35417-10/2006 Zaprti sistem katedre za fiziologijo živali
Medicinska fakulteta LJ	I # 35417-25/2007 ZAPRTI SISTEM KATEDER ZA MOLEKULARNO GENETIKO, BIOLOGIJO MIKROORGANIZMOV IN BIOKEMIJO
Biotehniška fakulteta LJ	
Onkološki inštitut	
FKKT LJ	
Biotehniški izobraževalni center LJ	
Medicinska fakulteta MB	

start > Fw: Consulta... ISBV, BCH, Regi... KEM.INŠ(35417... predloge Microsoft Power... GenMOP - 1.0.2... SL 09:57

Biosafety information system

Electronic access to biosafety information

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

We have established Slovene biosafety portal where public may find:

- Basic information on GMOs,
- Biosafety system and
- GMO Registry of Slovenia.

- Homepage of the Ministry of Agriculture and the Environment (<http://www.mko.gov.si/en/>)

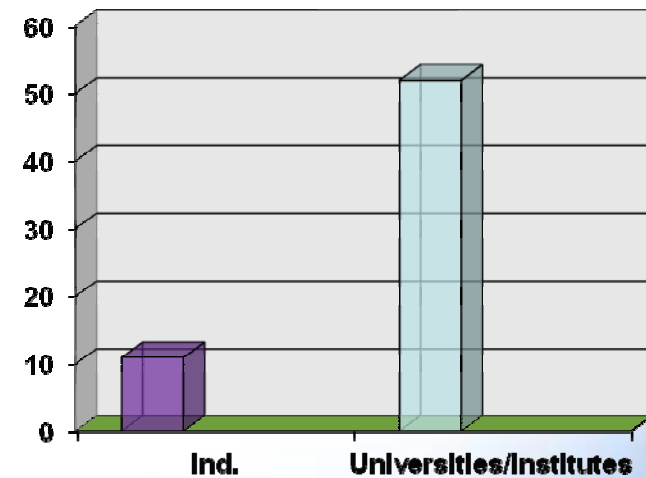
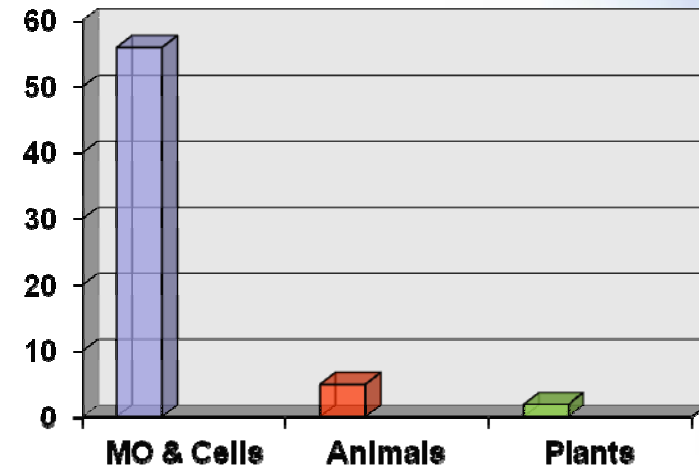
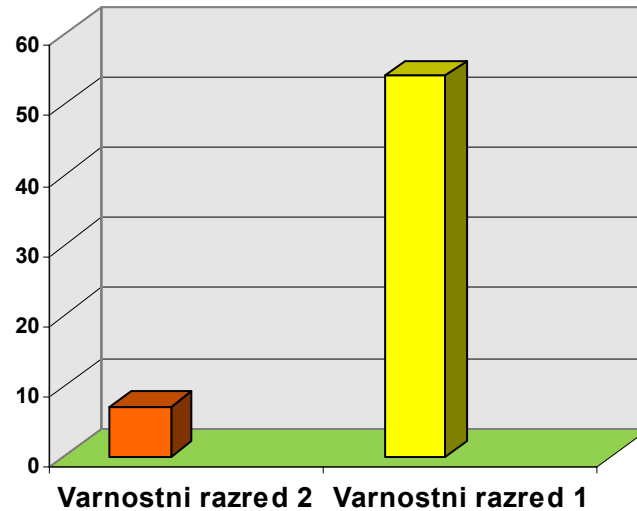
The screenshot shows the Slovene Biosafety Portal in a Windows Internet Explorer browser. The page features a blue header with the title "Slovene Biosafety Portal" and a navigation menu. Below the header, there is a "Welcome to the Slovenian Biosafety Portal" section with a photograph of a person in a lab coat. The page also includes a "News" section with two articles: "Scientific opinion on 'Séralin et al., Long term toxicity of a Roundup-tolerant genetically modified maize'" and "Scientific opinion on the web initiative for ban of GMOs in Slovenia".

The screenshot shows the homepage of the Ministry of Agriculture and the Environment in a Windows Internet Explorer browser. The page features a blue header with the title "REPUBLIC OF SLOVENIA MINISTRY OF AGRICULTURE AND THE ENVIRONMENT". Below the header, there is a "BIOTECHNOLOGY" section with a large image of a DNA double helix. The page also includes a "NEWS" section with an article titled "A Genetically Modified Organism (GMO) is an organism that was changed using methods of modern biotechnology".

Contained Use systems in Slovenia

64 contained use systems in Slovenia

- 8 BS class II
- 54 BS class I



2 notifications of the BS class II CU system rejected
2 notifications of the work with GMOs in BS2 CU systems in the procedure
6 institutions more expected to notify BS2 CU systems

GMO Register

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

Register GMO - Facilities



Register GMO-Use

Klasif. oznak.	Zap. števil.	Reg. števil.	Firma	Naslov	Naziv zap. sist.	Var. Razred	delo z GSO
35417-3/2008	42 0008/2008	BIA SEPARATIONS D.O.O.	TESLOVA ULICA 30,	BIASEP BSL2/2	VR 2	Delo z GSO	
35417-3/2006	1 0001/2006	BIA SEPARATION D.O.O.	TESLOVA ULICA 30,	BIASEP BSL2	VR 2	Delo z GSO	
35417-13/2008	51 0002/2009	Kemijski inštitut	Hajdrihova 19, p. p.	Kemijski inštitut L11/L12a	VR 1	Delo z GSO	
35417-12/2006	9 0002/2007	Kemijski inštitut	Hajdrihova 19, p. p.	Kemijski inštitut	VR 1	Delo z GSO	
35417-5/2007	16 0009/2007	Kemijski inštitut	Hajdrihova 19, p. p.	Kemijski inštitut	VR 1	Delo z GSO	
35417-7/2008	48 0014/2008	Kemijski inštitut	Hajdrihova 19, p. p.	L12	VR 2	Delo z GSO	
35417-6/2008	49 0015/2008	Kemijski inštitut	Hajdrihova 19, p. p.	L11	VR 2	Delo z GSO	
35417-17/2007-	26 0019/2007	KMETIJSKI INŠTITUT SLOVENIJE	HACQUETOVA 17, 1	KMETIJSKI INŠTITUT SLOVENIJE, G-LAB	VR 1	Delo z GSO	
35417-17/2007-	52 0003/2009	KMETIJSKI INŠTITUT SLOVENIJE	HACQUETOVA 17, 1	KMETIJSKI INŠTITUT SLOVENIJE, SKI ANIČE GSO, mlečno vzrejo VR 1	VR 1	Delo z GSO	
35417-2/2006	2 0002/2006	Veterinarska fakulteta	Gerbičeva ulica 6				
35417-26/2007	38 0004/2008	UNIVERZA V LJUBLJANI, VETERIN	GERBIČEVA ULIC				
35417-5/2009	59 0010/2009	UNIVERZA V LJUBLJANI, VETERIN	GERBIČEVA ULIC				
35417-6/2009	57 0008/2009	ACIES BIO, biotehnološke razisk	Železna cesta 18				
35417-21/2007	34 0027/2007	Lek farmacevtska družba d.d.	Verovškova 57,				
35417-14/2006	4 0004/2006	Lek farmacevtska družba d.d.	Verovškova 57,				
35417-17/2006	7 0007/2006	Lek farmacevtska družba d.d.	Verovškova 57,				
35417-13/2006	8 0001/2007	Lek farmacevtska družba d.d.	Verovškova 57,				
35417-10/2008	47 0013/2008	Lek farmacevtska družba d.d.	Verovškova 57,				
35417-9/2008	46 0012/2008	Lek farmacevtska družba d.d.	Verovškova 57,				
35417-15/2006	5 0005/2006	Lek farmacevtska družba d.d.	Verovškova 57, 1				
35417-16/2006	6 0006/2006	Lek farmacevtska družba d.d.	Verovškova 57, 1				
35417-19/2007	40 0006/2008	NACIONALNI INŠTITUT ZA BIOL	VEČNA POT 111,				
35417-18/2006	18 0011/2007	Nacionalni inštitut za biologijo	Večna pot 111 11				

Reg. številka	Zap. številka	Var. Razred	Datum	Vrsta zaprtega sistema	Področje dela	Izv. org. znanstveni ime	Izv. org. slovensko ime	Prej. org. znanstveni im	Prej. org. slovensk
35417-11/2008	62 VR 2	22.8.2008	Laboratorij	Virologija, Bakter	Humani adenovirus tipa 5	Humani adenovirus tipa 5 dl309			
35417-11/2008	62 VR 2	22.8.2008	Laboratorij	Virologija, Bakteriologija, Mikrobiološke raziskave					
35417-11/2008	62 VR 2	22.8.2008	Laboratorij	Virologija, Bakteriologija, Mikrobiološke raziskave					
35417-11/2008	62 VR 2	22.8.2008	Laboratorij	Virologija, Bakteriologija, Mikrobiološke raziskave					
35417-11/2008	62 VR 2	22.8.2008	Laboratorij	Virologija, Bakteriologija, Mikrobiološke raziskave					
35417-4/2010	62 VR 2	29.3.2010	Laboratorij	Virologija, Bakter	Homo sapiens	človek			
35417-4/2010	62 VR 2	29.3.2010	Laboratorij	Virologija, Bakter	Humani adenovirus tipa 3	Ad5/3luc1			
35417-4/2010	62 VR 2	29.3.2010	Laboratorij	Virologija, Bakteriologija, Mikrobiološke raziskave			Humani rekombinantni ad	pAdEasy5/3-D24	
35417-4/2010	62 VR 2	29.3.2010	Laboratorij	Virologija, Bakteriologija, Mikrobiološke raziskave					
35417-4/2010	62 VR 2	29.3.2010	Laboratorij	Virologija, Bakteriologija, Mikrobiološke raziskave					
35417-4/2010	62 VR 2	29.3.2010	Laboratorij	Virologija, Bakteriologija, Mikrobiološke raziskave					
35417-4/2010	62 VR 2	29.3.2010	Laboratorij	Virologija, Bakteriologija, Mikrobiološke raziskave					
35417-18/2007	32 VR 2	12.9.2007	Laboratorij	Virologija, Bakter	Influenzavirus A	Virus influenza A			
35417-18/2007	32 VR 2	12.9.2007	Laboratorij	Virologija, Bakter	Influenzavirus A	Virus influenza A			
35417-18/2007	32 VR 2	12.9.2007	Laboratorij	Virologija, Bakter	Influenzavirus A	Virus influenza A			
35417-18/2007	32 VR 2	12.9.2007	Laboratorij	Virologija, Bakteriologija, Mikrobiološke raziskave			Influenzavirus A, Ortomyx	GHB05V1	

Deliberate release in Slovenia

- PUBLIC PARTICIPATION -

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

Public access to information:

National level

- available in paper and electronic version - included :
 - notification (technical documentation (SNIF (language 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 CA webpage

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

SI

EU

The screenshot shows the website of the Ministry of Agriculture and Environment of the Republic of Slovenia. The page is titled 'Zakonodaja in dokumenti' and features a navigation menu with options like 'DELOVNA PODROČJA', 'APLIKACIJE, REGISTRI IN OBRAZCI', 'MEDUSKO SREDIŠČE', 'ZAKONODAJA IN DOKUMENTI', 'O MINISTRSTVU', and 'JAVNE OBJAVE'. The main content area is titled 'ZAKONODAJA IN DOKUMENTI' and contains text about the ministry's commitment to transparency and public access to information. There is a search bar and a list of 'veljavni predpisi' (valid regulations). A sidebar on the left includes a 'Prebrskaj na sonce' (Search on the sun) button and a 'Prebrskaj na sonce' (Search on the sun) button. The bottom of the page has a footer with contact information for the Ministry of Agriculture and Environment.

European Commission
Joint Research Centre
Institute for Health and Consumer Protection

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;

Environmental Protection Legislation Aarhus Convention (Art. 6, 8)

Opinions and comments:

- **electronically**
- **mailed**

Conclusions

- public participation -

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