



REPUBLIC OF SLOVENIA
MINISTRY OF THE ENVIRONMENT AND SPATIAL PLANNING

BIOSAFETY FRAMEWORK AND MONITORING IN SLOVENIA

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Ministry of the Environment and Spatial Planning

ROUND TABLE

«ENHANCING THE CEE COLLABORATION AND KNOW-HOW TRANSFER
IN BIOTECHNOLOGY AND BIOSECURITY»

18-20 September 2019, Minsk, Belarus



✓ RESPONSIBLE MINISTRIES FOR GMOs:



- **Ministry of the Environment and Spatial Planning (MESP)** - (contained use, deliberate release and placing GMOs on the market);



- **Ministry of Agriculture, Forestry and Food (MAFF)** – (coexistence and cultivation);
 - The Administration of Republic Slovenia for Food Safety, Veterinary and Plant Protection (AFSVPP) – (GM Food/Feed/Seed/Processing)



- **Ministry of Health (MH)** – (medicines);

✓ LEGISLATIVE FRAMEWORK:



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RESPONSIBLE MINISTRY



SCBD
→

**Cartagena Protocol on Biosafety
Supplementary Protocol**



MESP



EU



**DIREKTIVA 2009/41/EC
DIREKTIVA 2001/18/EC**

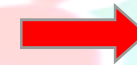
Regulation (EC) 1829/2003

Regulation (EC) 1830/2003

Regulation 1946/2003 (MESP)

Environmental Liability Directive

**(ELD) – The Environmental
Protection Act (SI)**



**MESP
MAFF - AFSVPP**



DG SANCO

DG ENVI

DG AGRI



MESP

Implementation / monitoring

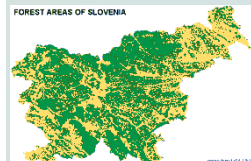


SLOVENIA



**MESP - D ENVI
Biotechnology**

**MANAGEMENT OF GENETICALLY
MODIFIED ORGANISMS Act (MGMOs Act)**



Coexistence Act (Article 26.a)

MAFF

Restriction or Prohibition of the Cultivation of Genetically Modified Plants Act (Article 26.b) (implementation / monitoring)

DIRECTIVE 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory [Article 26.a (amendment), 26.b (cultivation) (phase 1 and 2) and 26.c (transitional measures)]

implementation

✓ LEGISLATIVE FRAMEWORK:



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The Management of Genetically Modified Organisms Act (MGMO Act) adopted in July 2002, amended in 2004, 2010 and 2012

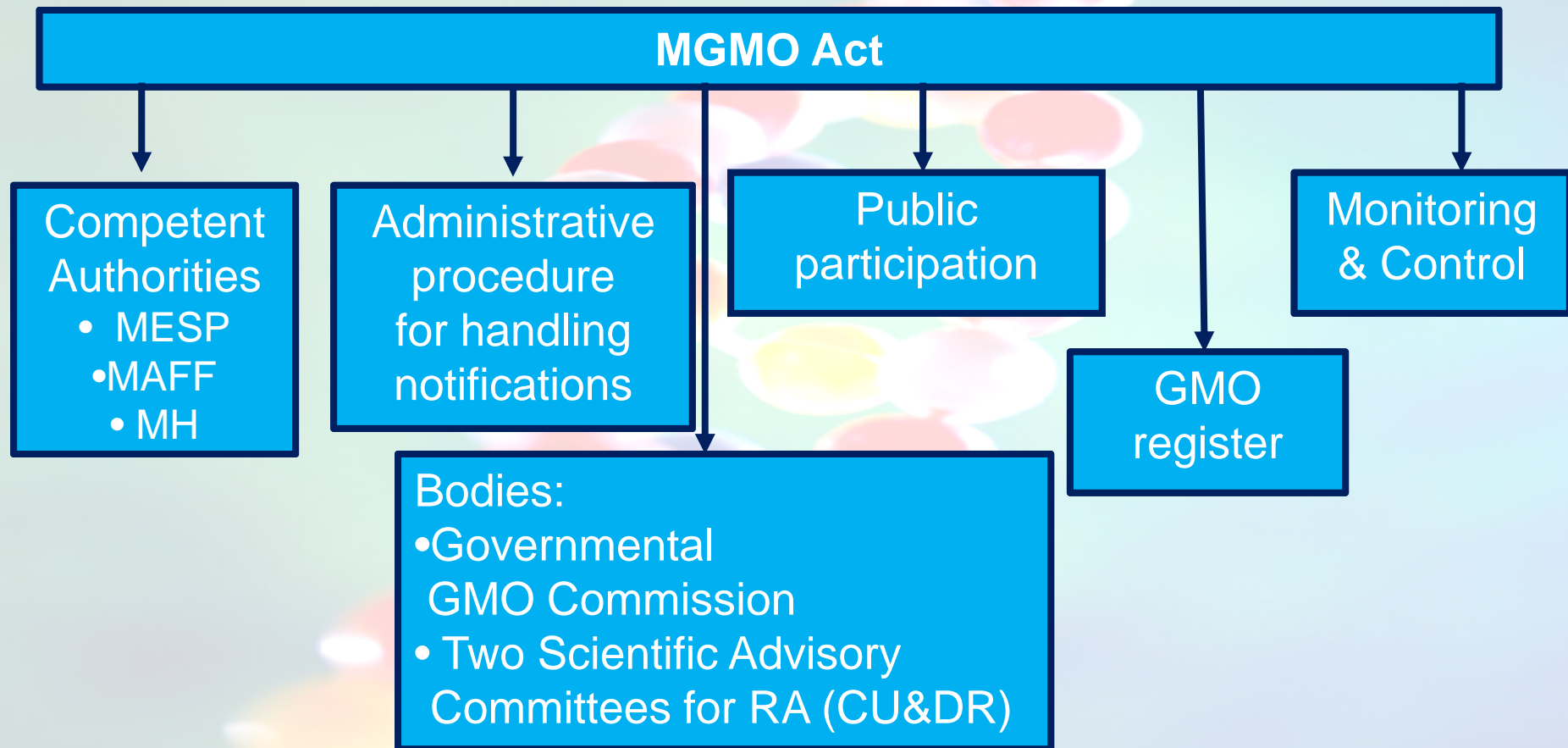
- provides a **horizontal type of legislation** on the use of all GMOs (GMMs, GM plants and GM animals) and their products, and **intermediates** other existing legislation in the areas of agriculture and health care
- Act regulates:
 - contained use (CU) of GMOs
 - deliberate release (DR) of GMOs into the environment
 - placing GMOs on the market
 - importing and exporting GMOs or products containing GMOs
- 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 cases of vertebrate consultation with the Administration of RS for Food Safety, Veterinary and Plant Protection), Deliberate release (in co-decision with MAFF) and Placing of GMOs on the market (in co-decision with MSFF and MH)

✓ LEGISLATIVE FRAMEWORK:



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Administrative system

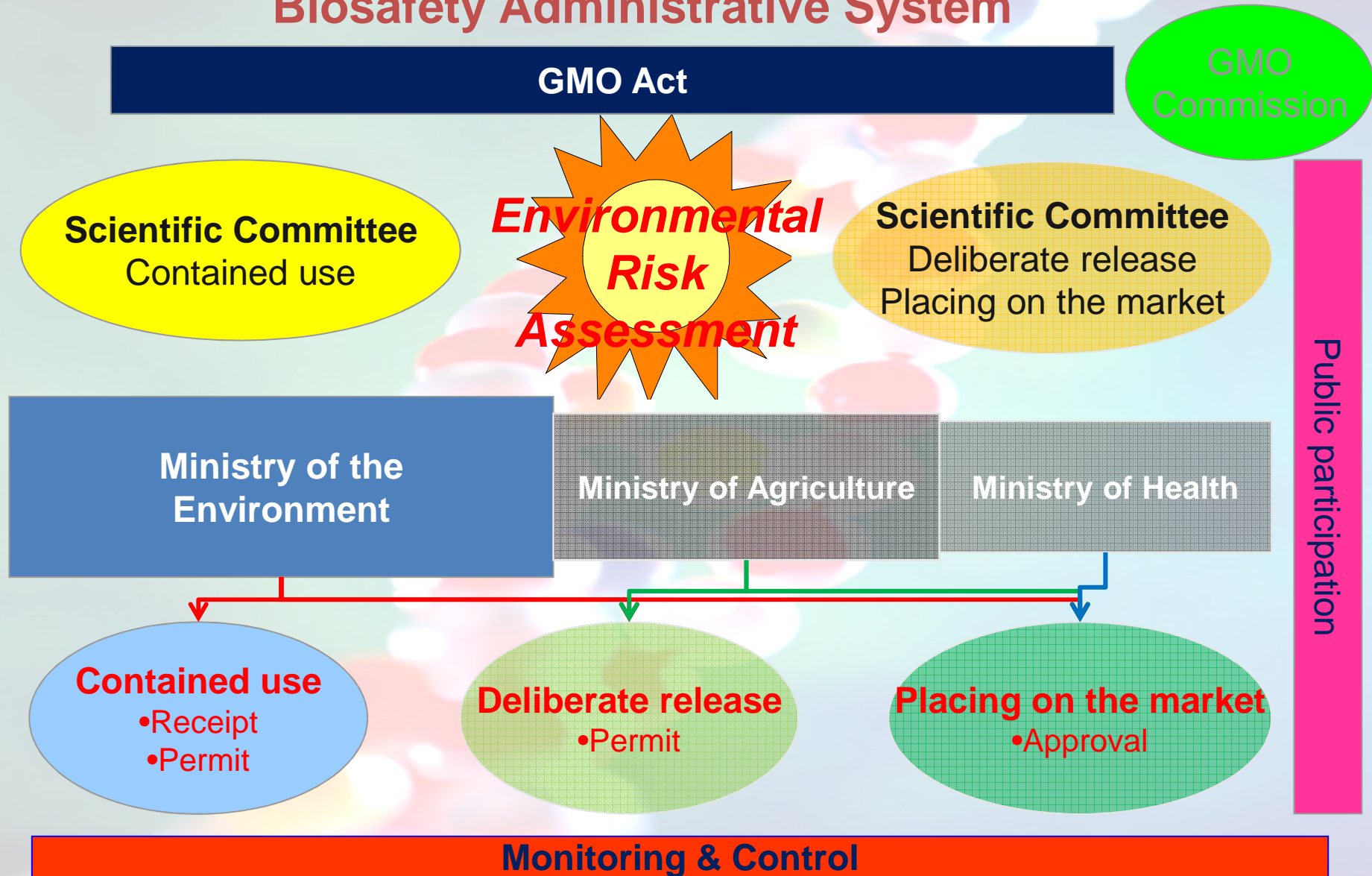


✓ LEGISLATIVE FRAMEWORK:



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Biosafety Administrative System



✓ LEGISLATIVE FRAMEWORK:



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Slovenian Scientific Advisory Committee on the Contained Use of GMOs

- **Appointed by the Slovenian Government**
- **9 members and 9 deputies**

- **Expertise:**
 - Microbiology, Genetics, Medicine,
 - Biochemistry, Molecular biology,
 - Pharmacy, Biotechnology and
 - Health protection at work,
 - Toxicology, Ecology

✓ LEGISLATIVE FRAMEWORK:



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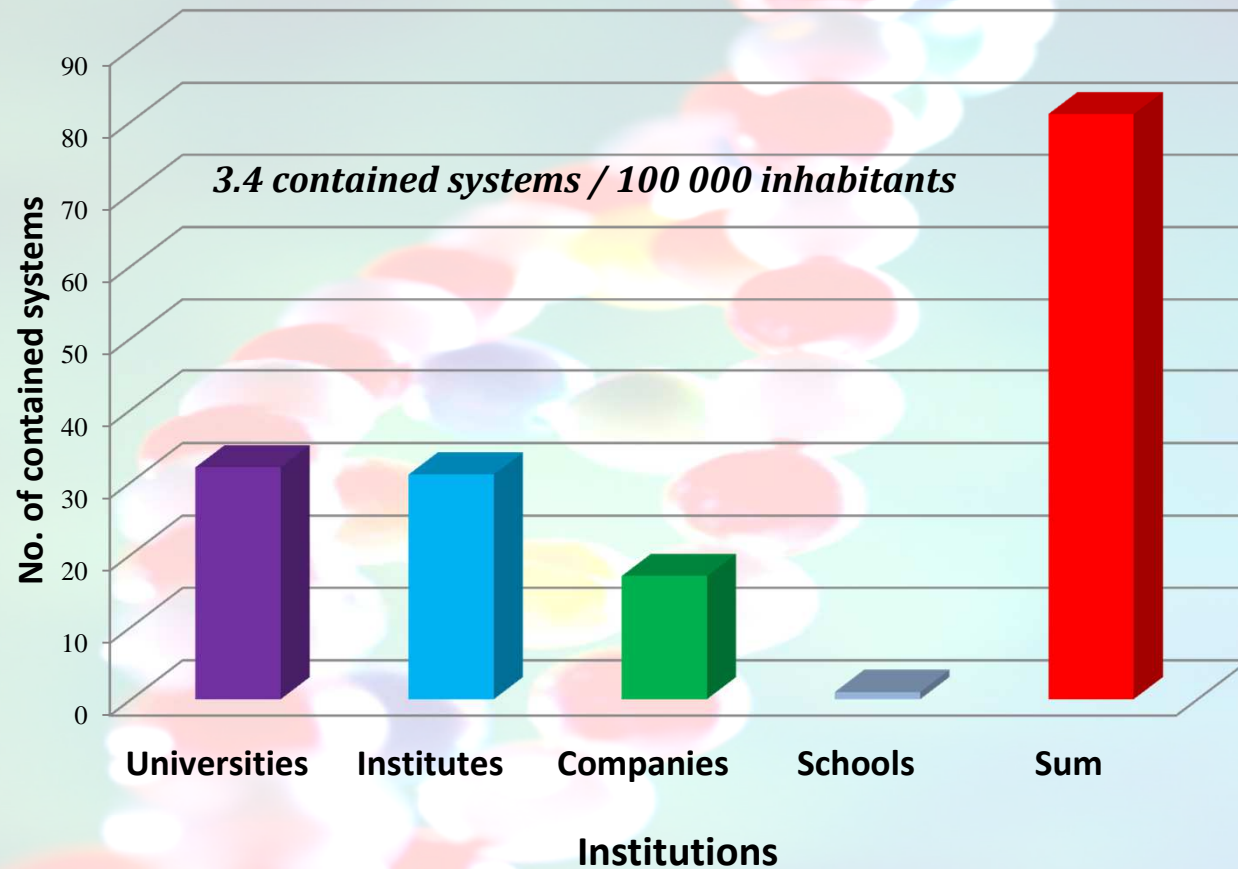
Slovenian Scientific Advisory Committee on the Deliberate Release of GMOs into the Environment and Placing on the market

- Appointed by the Slovenian Government
- 13 members and 13 deputies
- **Expertise:**
 - Genetics, Biology, Agriculture, Veterinary, Biochemistry and Molecular biology, Microbiology, Medicine, Toxicology, Alergology, Food, Plant protection, Animal nutrition, Ecology

✓ LEGISLATIVE FRAMEWORK – contained use



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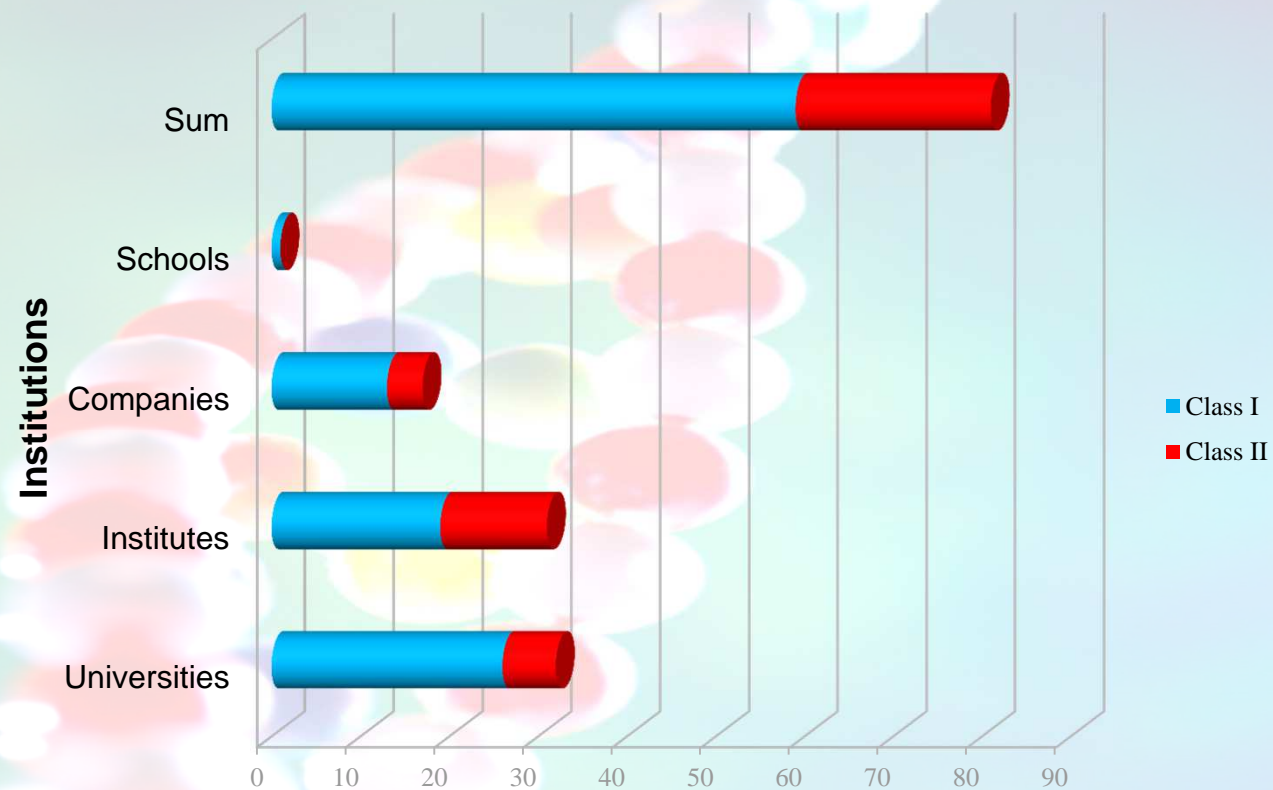


Graph: Number of systems in which contained use of GMOs is acknowledged in Slovenia in 2018

✓ LEGISLATIVE FRAMEWORK – contained use



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No. of contained systems according to containment level

Graph: Number of GMO contained systems and containment level in Slovenia by institution type

✓ LEGISLATIVE FRAMEWORK – deliberate release and cultivation of GMOs



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❖ NO DELIBERATE RELEASE OF GM PLANTS



❖ NO CULTIVATION OF GM PLANTS



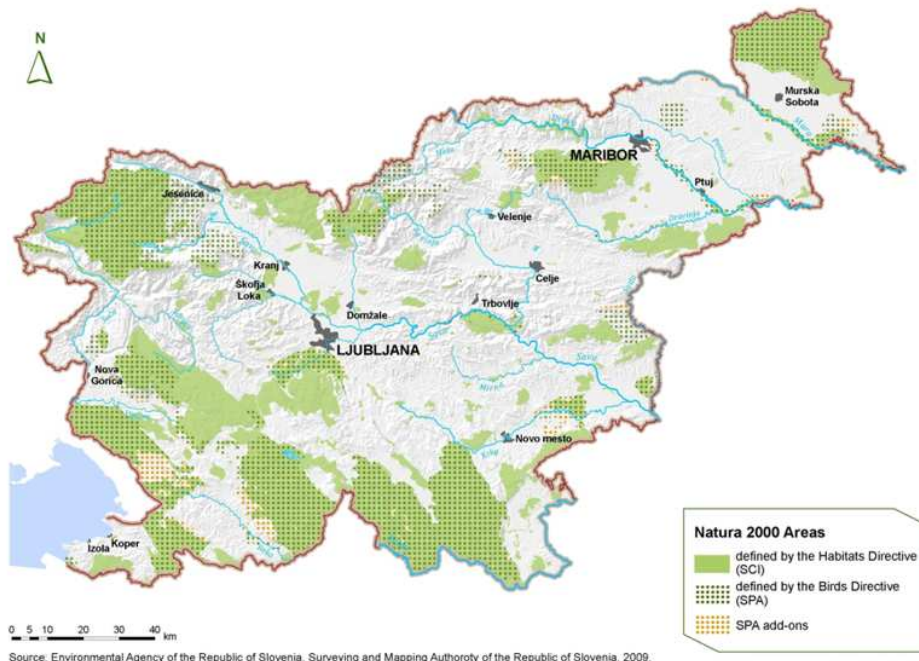
✓ LEGISLATIVE FRAMEWORK – deliberate release and cultivation of GMOs



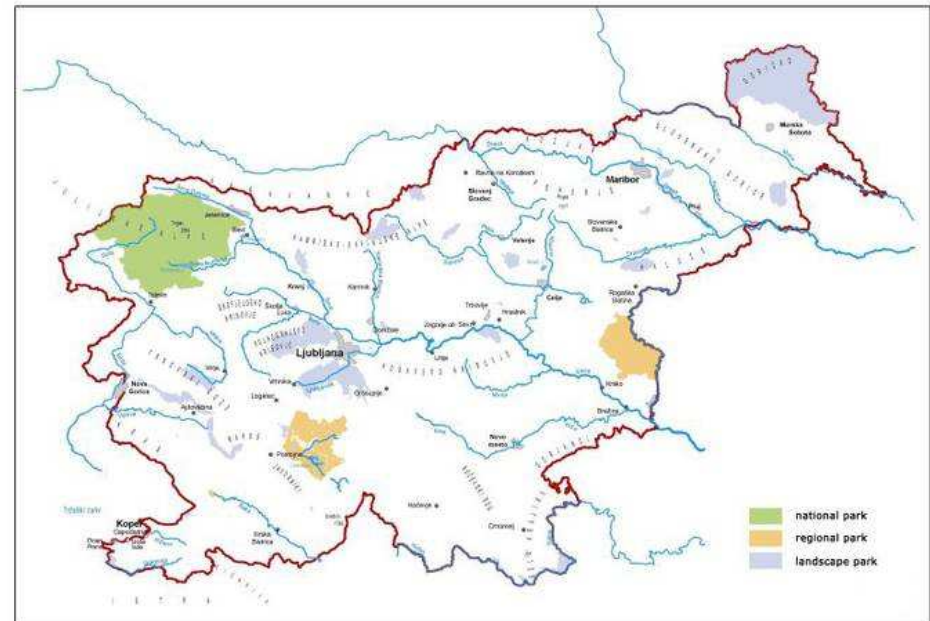
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✓ ENVIRONMENT (protection of the environment and biodiversity)

- ❖ One of the highest percentage of protected areas in EU - almost 39% of the Natura 2000 sites and more than 11% of protected areas (parks, reserves, etc.);
- ❖ Cultivation of GMOs in protected areas is limited to some extent (in favour of sustainable farming which maintains and preserves the biodiversity of flora and fauna and the environment)



Source: Environmental Agency of the Republic of Slovenia, Surveying and Mapping Authority of the Republic of Slovenia, 2009.



http://www.mop.gov.si/en/areas_of_work/nature/nature_parks_of_slovenia/

✓ LEGISLATIVE FRAMEWORK – monitoring & control



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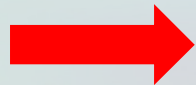
MGMO Act – Art 55. Inspection supervision

Performed by

- Inspectorate of the Republic of Slovenia for Environment and Spatial Planning;
- The Administration of Republic Slovenia for Food Safety, Veterinary and Plant Protection (AFSVPP);
- Financial Administration (Customs)



<https://bch.cbd.int/protocol/>



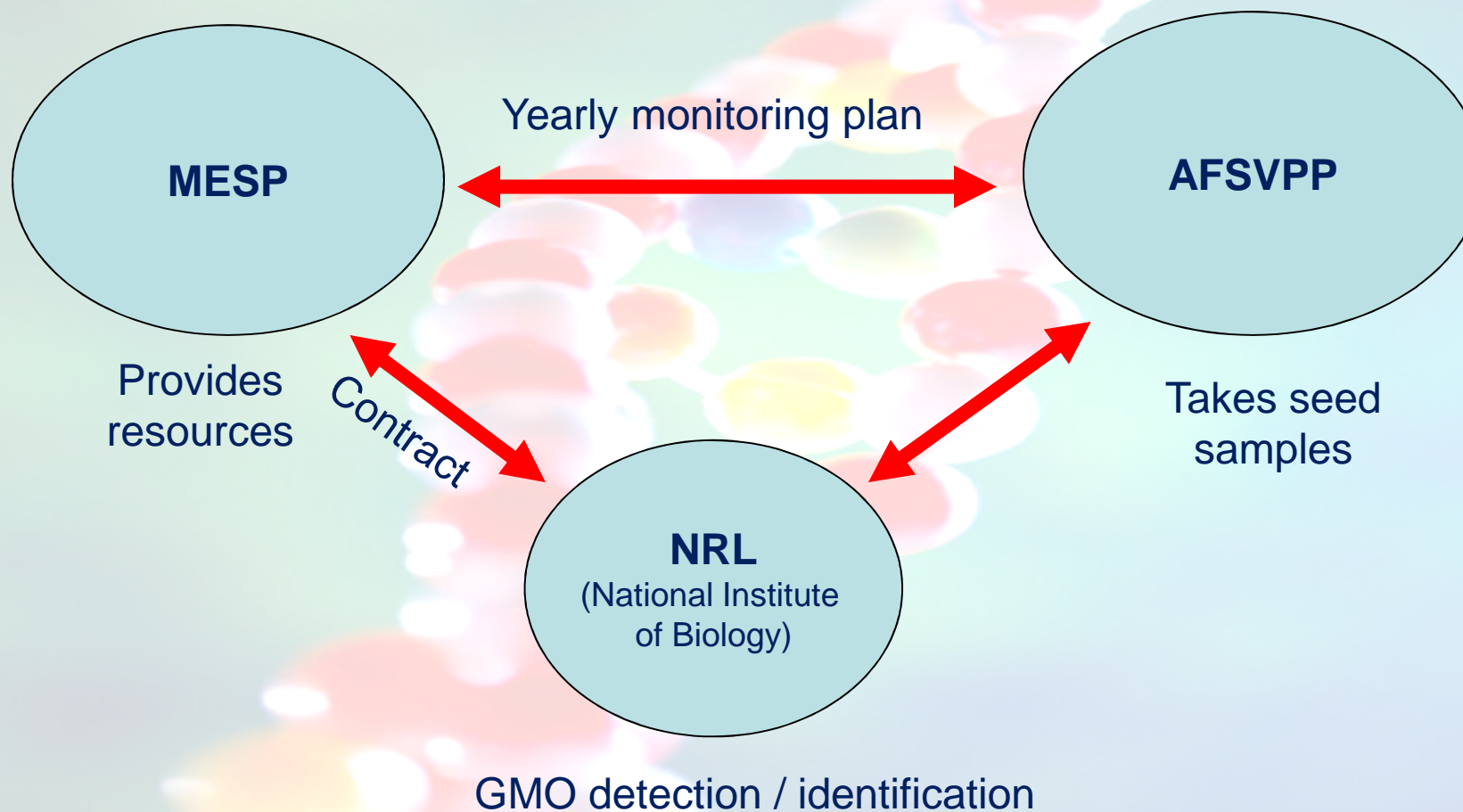
each in line with their respective competence

✓ LEGISLATIVE FRAMEWORK – monitoring & control



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Seeds



✓ **LEGISLATIVE FRAMEWORK** – monitoring

NATIONAL REFERENCE LABORATORY (NRL) - GENETICALLY MODIFIED ORGANISMS -

National Institute of Biology (NIB)

National reference laboratory & *nominated state representatives in ENGL*

Diagnosis and detection of GMOs in seed, plants, food and feed samples

Method development and validation in accordance with ISO/IEC 17025 and ENGL guidelines

Training, consulting and technical auditing

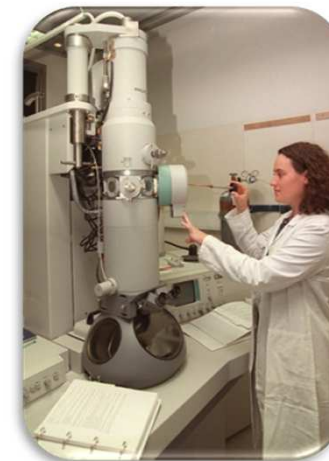


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NATIONAL INSTITUTE OF **BIOLGY**

✓ **LEGISLATIVE FRAMEWORK – monitoring**

NRL - METHODS USED -

- ❑ 82 methods accredited for GMOs
- ❑ Pentaplex method for screening
- ❑ Mostly qPCR methods
- ❑ 4 dPCR (among first ones for accreditation for dPCR methods in GMO detection)



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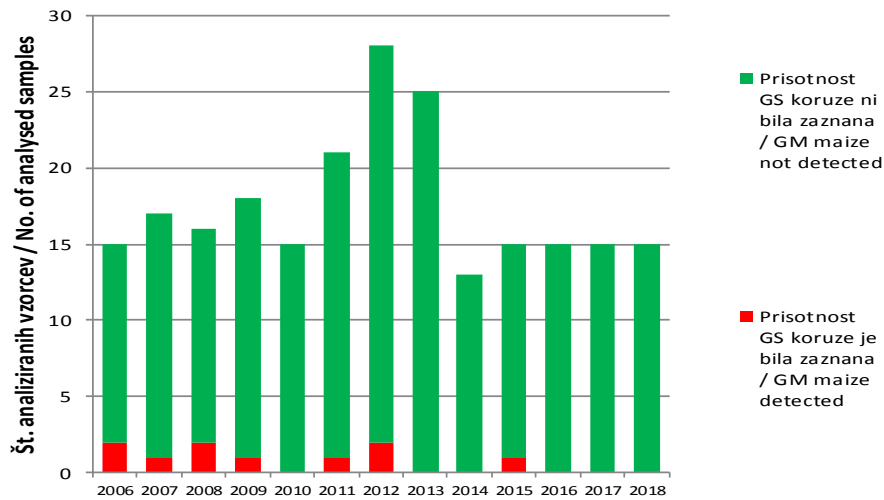
✓ LEGISLATIVE FRAMEWORK – monitoring & control



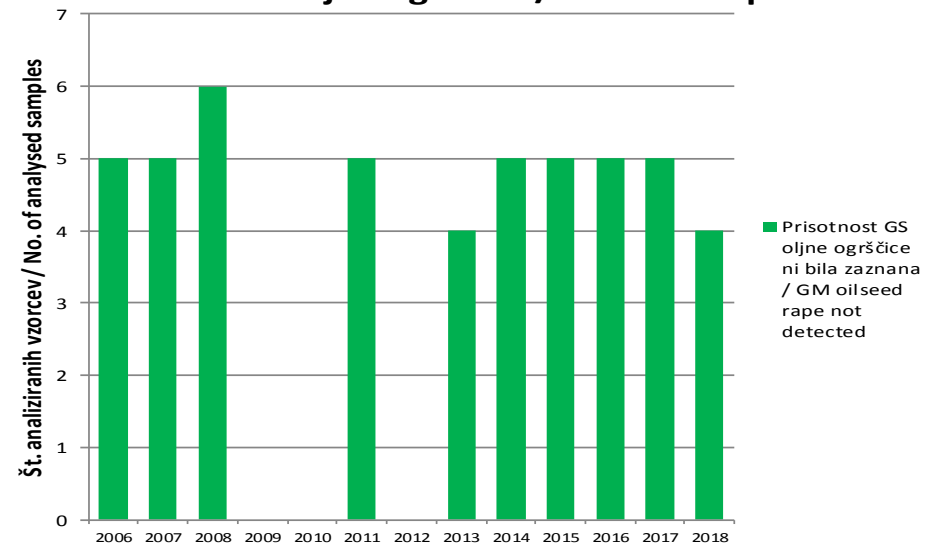
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GMO content in seed samples (2006 – 2018)

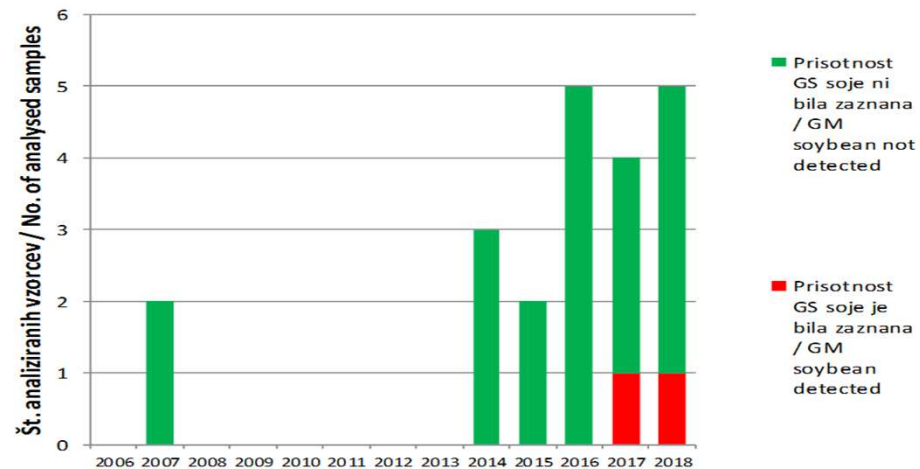
Semena koruze / Maize seeds



Semena oljne ogrščice / Oilseed Rape



Semena soje / Soybean seeds



✓ LEGISLATIVE FRAMEWORK – monitoring & control



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GMO content in seed samples in 2019

15 maize samples – all negative

5 soya samples – one positive (< 0.1 % MON89788 (MON-89788-1))

Oilseed rape samples – in testing



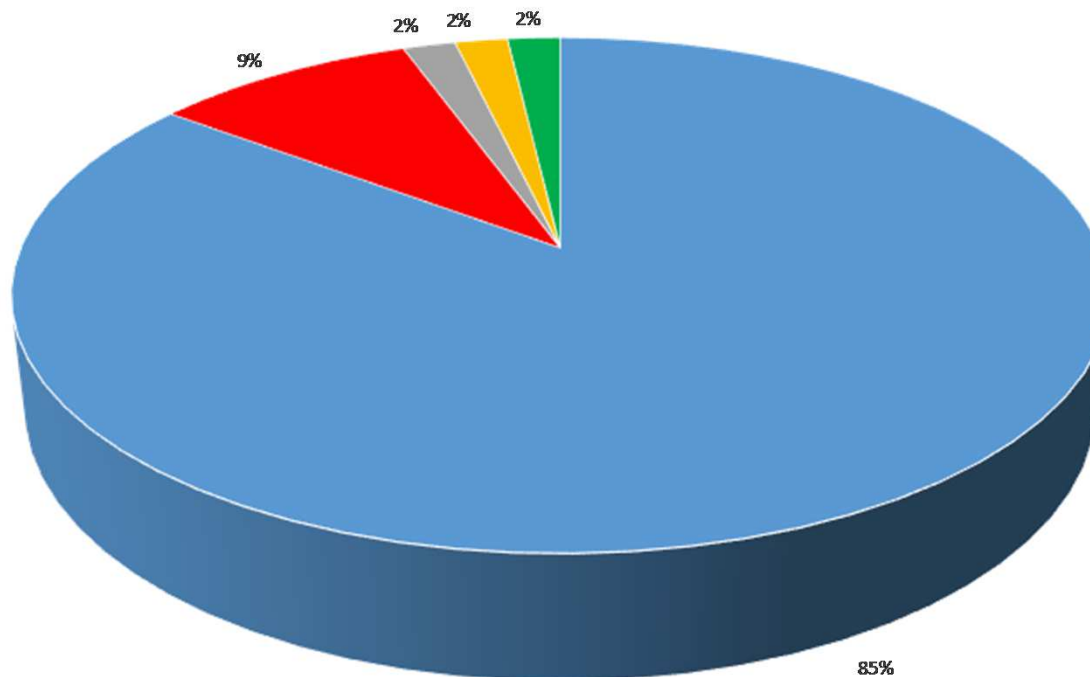
✓ LEGISLATIVE FRAMEWORK – monitoring & control



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Food

GMO content in food samples of plant origin in 2018



N = 54

- ne vsebuje testiranih GSO, neoznačeni vzorci v skladu z zakonodajo
- vsebuje sojo MON40-3-2 (MON-04032-6) pod 0,1%, neoznačeni vzorci v skladu z zakonodajo
- vsebuje soji MON40-3-2 (MON-04032-6), A2704-12 (ACS-GM005-3) pod 0,1%, neoznačeni vzorci v skladu z zakonodajo
- vsebuje soji MON40-3-2 (MON-04032-6), MON89788 (MON-89788-1), pod 0,1%, in sojo A2704-12 (ACS-GM005-3) pod mejo kvantifikacije, ki znaša 0,25%, neoznačeni vzorci v skladu z zakonodajo
- pozitiven na presejalni analizi, vendar ne vsebuje testiranih GSO, neoznačeni vzorci v skladu z zakonodajo



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THANK YOU