

# Training on working with genetically modified organisms (GMOs) at Jožef Stefan Institute

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Biosafety Officer

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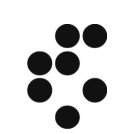
# Working with GMOs

Regulation on working with GMOs:

- [Management of Genetically Modified Organisms \(GMO\) Law \(ZRGSO\)](#) regulates the handling of GMOs and determines measures to prevent and reduce possible adverse effects on the environment, in particular regarding the preservation of biodiversity, and on human health, which could occur when working with GMOs in enclosed systems, deliberate release of GMOs into the environment or placing products on the market (Official Gazette of the Republic of Slovenia, No. 23/05 – official revised text, 21/10 and 90/12 – ZdZPVHVVR)

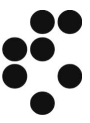
Subordinate regulations:

- [Rulebook on Risk Assessment for Contained Use of Genetically Modified Organisms](#) (Ur.l.RS 45/2004)
- [Rulebook on the Content of Enclosed System Registration and Registration of Contained Use of Genetically Modified Organisms](#) (Ur.l.RS 65/2004)
- [Rulebook on Contingency Plan in the Event of an Accident During the Contained Use of GMOs](#) (Ur.l.RS 69/2005)
- [Rulebook on the Register of Genetically Modified Organisms](#) (Ur.l.RS 79/2006)
- [Regulation on the Criteria for Classification of Contained Use of GMOs in a Biosafety Class and on Containment and Other Security Measures for Each Biosafety Class](#) (Ur.l.RS 71/2011)
- [Regulation on the Protection of Workers From Risks Related to Exposure to Biological Agents at the Workplace](#) (Ur.l.RS 168/2020)



# Working with GMOs – Terms 1/3

- **A GENETICALLY MODIFIED ORGANISM (GMO)** is an organism that is not human, or a microorganism whose genetic material is altered by processes that alter the genetic material differently than occurs under natural conditions through crossing or natural recombination..
- **ENCLOSED SYSTEM** is a laboratory or production facility or other **enclosed space where GMOs are handled.**
- **CONTAINED USE OF GMOs** includes **work in an enclosed system** where the organism is genetically modified, GMOs are **grown, propagated, stored, transported, destroyed, disposed of, or otherwise used**, and for which **containment measures are implemented.**
- **CONTAINMENT MEASURE** means physical containment, or a combination of physical containment and chemical or biological restraint, or any other specific measure or combination of measures, including the use of good laboratory and production practices for the contained use of GMOs, to **limit the contact of the GMOs with the environment and the public and to eliminate or reduce the possibility of reproduction of GMOs or transfer of modified genetic material outside the contained system.**



# Working with GMOs – Terms 2/3

- **The RISK ASSESSMENT is the identification and assessment of risks** that may arise from working with GMOs in an enclosed system, or from the deliberate release of GMOs into the environment or the placing of products on the market **on a case-by-case basis**.
- **The RISK is the likelihood** that handling GMOs will have direct or indirect, immediate or long-term, or long-term cumulative **impact on the environment or human health**, particularly with respect to the conservation of biodiversity, the preservation of indigenous plant varieties and animal breeds, soil fertility, the food chain, or human and animal health.

**RISK LEVEL** is based on the assessment of the **LIKELIHOOD OF A HAZARD** and **ITS CONSEQUENCES** according to the **risk assessment matrix**:

CONSEQUENCE OF HAZARD	LIKELIHOOD OF A HAZARD			
	HIGH	MEDIUM	LOW	NEGLIGIBLE
SEVERE	HIGH	HIGH	MEDIUM	NEGLIGIBLE
MODEST	HIGH	MEDIUM	MEDIUM/LOW	NEGLIGIBLE
MINOR	MEDIUM/LOW	LOW	LOW	NEGLIGIBLE
NEGLIGIBLE	NEGLIGIBLE	NEGLIGIBLE	NEGLIGIBLE	NEGLIGIBLE



# Working with GMOs – Terms 3/3

- An **ACCIDENT** is an extraordinary event or series of events that result in an **unexpected release of GMOs into the environment** during contained use of GMOs that **may pose an immediate or subsequent risk to the environment or human health.**
- A **EXTRAORDINARY EVENT** is an uncontrollable event or series of events when working with GMOs (**1st or 2nd biosafety level**) in a contained system, where:
  - There was **no release of GMOs into the environment or threat to human life or health**, and the **applicant can independently take appropriate action** in accordance with the contingency plan.
  - There was a release of GMOs into the environment, but it does not pose a threat to human life or health or to the quality of the environment, and the applicant can take appropriate action on its own according to the contingency plan.



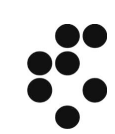
# Working with GMOs – biosafety levels 1/2

**BIOSAFETY LEVEL 1** – *recipient organism, parental organism, source organism, vector, insert and newly created GMOs* do not cause diseases or changes in healthy humans, animals, or plants, including allergic and toxic effects; do not cause adverse effects on the environment; and do not threaten biodiversity or the natural balance;

**BIOSAFETY LEVEL 2** – ... can cause diseases in humans, animals or plants and threaten their health, but effective disease prevention or treatment is available; in the event of an accidental release, any adverse effects on the environment are correctable;

**BIOSAFETY LEVEL 3** - ... can cause severe diseases in humans, animals, or plants and poses a major risk to their health; effective prevention or treatment is usually difficult to access or unavailable; in the event of an accidental release, adverse effects are observed that pose a moderate risk to the environment.

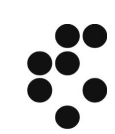
**BIOSAFETY LEVEL 4** – ... frequently causes fatal disease or death in humans, animals, or plants and poses a very high risk to their health; effective prevention or treatment is not available; adverse effects in the environment are irreversible.



# Working with GMOs – biosafety levels 2/2

**The biosafety level of GMOs** is determined on a case-by-case basis and based on the biosafety levels of:

- **Recipient organism** is a cell or organism, that receives the genetic material from the source organism or environment, replicates it, and can express and pass on information to progeny.
- **Parental organism** is the recipient organism prior to genetic modification.
- **Source organism** is the organism from which the genetic material is obtained for transfer into the recipient organism.
- **Vector** is a carrier of the genetic material or relevant cellular components from the source organisms to the recipient organism.
- **Insert** is the genetic material integrated into the vector and transferred to the recipient organism.



# Documents for contained use of GMOs 1/3

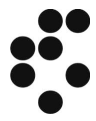
## RISK ASSESSMENT

- [Rulebook on Risk Assessment for Contained Use of Genetically Modified Organisms](#) (Ur.l.RS 45/2004)
- Prepared prior to commencement of work
- Updated annually
- Also for work with non-GMOs in the contained system! [Regulation on.... Biological Agents at the Workplace](#) (Ur.l.RS 168/2020)

## WRITTEN INSTRUCTIONS FOR WORKING WITH GMOs

- [Article 17. Regulation on criteria...\(Ur.l.RS 71/11\)](#)
- all persons working in the contained system informed
- Includes mainly:
  - description of measures to prevent hazards to the health of personnel,
  - description of procedures and activities related to waste management, wastewater discharge, cleaning and disinfection of premises and other procedures to be carried out in accordance with the plan of containment measures,
  - description of measures to be taken in the event of errors at work, extraordinary events or accidents.





# Documents for contained use of GMOs 2/3

## PLAN OF CONTAINMENT MEASURES

- [Article 16 of the Regulation on criteria... \(Ur.l.RS 71/11\)](#)
- designate the person responsible for the maintenance and control of the implementation
- copy of the plan available to anyone working with GMOs
- must be kept in written and electronic form throughout the duration of the work with GMOs and for 10 years after its completion

## RECORD OF CONTROL OVER THE IMPLEMENTATION OF CONTAINMENT MEASURES IN CONTAINED SYSTEMS

- the implementation of containment measures is reviewed at least once a year by the Biosafety Officer

**OPERATING LOG** (book of numbered pages) - may be a combination of a laboratory record book and a waste management log (traceability must be assured)

- [Article 19. of the Regulation on the criteria...\(Ur.l.RS 71/11\)](#)
- designate the person responsible for management and storage (throughout the duration of the work with GMOs)
- Includes:
  - basic information about GMOs and procedures for working with them,
  - data on waste and wastewater management,
  - information about possible work errors.



# Documents for contained use of GMOs 3/3

## **CONTINGENCY PLAN FOR ACCIDENTS**

- [Rulebook on Contingency Plan in the Event of an Accident During the Contained Use of GMOs \(Ur.l. RS 69/2005\)](#)

## **CONTINGENCY PLAN FOR EXTRAORDINARY EVENTS**

- Article 11b. in 11c. [GMO Management Law \(Ur.l.RS 23/05 UPB, 21/10 in 90/12 – ZdZPVHVVR\)](#)

## **RECORD OF EXTRAORDINARY EVENTS AND ACCIDENTS**

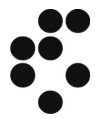
- Report extraordinary events (e.g. culture spill of > 20 mL) and accidents to the Biosafety Officer!

## **LIST OF PERSONNEL** managed by the project manager ([Article 24 Regulation on the criteria...](#))

- Anyone working in contained systems for contained use of GMOs signs a statement that they are aware of the hazards and procedures involved in working with GMOs

## **REPORT ON GMO WORK on the previous calendar year ( to be submitted to the Ministry of the environment by March 31)**

- [Article 20 Regulation on the criteria...](#)



# Responsible persons

## **PERSON RESPONSIBLE FOR BIOSECURITY, BIOSAFETY OFFICER (dr. Jerica Sabotič, dr. Aleksandra Usenik)**

[Article 22. Regulations on the criteria... Ur.I.RS 71/11](#)

- monitoring developments in the field of work with GMOs and briefing the applicant and staff on these developments;
- informing the applicant and advising on new findings and information that may affect the level of risk or the classification of work with GMOs in the biosafety class;
- advise and assist in the preparation of risk assessments for the proposed work with GMOs;
- provide opinions and proposals on containment measures and participate in the development of the plan for containment measures;
- regular monitoring of the implementation of containment measures and equipment;
- preparation of written instructions for work with GMOs (Article 17 Regulation on the Criteria...);
- regular education and training of the personnel working in the contained system;
- preparation of annual reports (Article 20 Regulation on the criteria);
- informing the public about the work with GMOs;
- cooperation with the person responsible for control and safety, and
- other tasks related to ensuring biological safety within the scope of the applicant's authority.

The applicant shall enable the Biosafety Officer to perform these tasks in a professional and independent manner and ensure access to all necessary data.

## **PERSON RESPONSIBLE FOR CONTROL AND SAFETY, HEALTH AND SAFETY ENGINEERS (mag. Bojan Huzjan, Ana Marija Horvat, Erika Potrč Hribar)** [Article 21. Regulations on the criteria... Ur.I.RS 71/11](#)

- participation in the introduction of general security measures and control of their implementation;
- participation in the introduction of the principles of good working, laboratory or production practice and control of their application;
- participation in the development of contingency plans for extraordinary events and accidents and regular review of their adequacy;
- Instructing personnel in general safety measures and in contingency plans for extraordinary events and accidents;
- providing measures for the safety of personnel working with GMOs and for the prevention of health risks;
- informing the applicant and the competent authorities in case of emergencies and accidents, and
- other tasks related to control and safety in accordance with the applicant's authority.

## **PROJECT MANAGER (head of department or lab with the contained system for contained use of GMO) and his deputy**

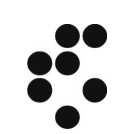
[Article 24. Regulations on criteria... Ur.I.RS 71/11](#)

plans, directs and supervises the work with GMOs throughout the duration of the project and is responsible in particular for:

- preparing and managing the documentation for the work with GMOs,
- directing and supervising the activities related to the work with GMOs,
- keeping a list of the personnel working with GMOs,
- contributing to the preparation of the written instructions for the work with GMOs (Article 17) and instructing personnel on these instructions, and
- Contributing to the preparation of the annual reports (Article 20)

The project manager is **required to inform the Biosafety Officer of any changes in the work with GMOs** that he/she manages, as well as of any new information or data that could affect the level of risk.

The project manager or his deputy **must be present at all times during work with the GMO.**



# Responsibilities of all persons working with GMOs

- Familiarization with the documents (updated once a year)
- Training on how to work with GMOs (1x per year)
- Train new workers with the procedures – they must be included in the list of personnel!
- Prepare risk assessments for new GMOs (& non-GMOs)
- Implement containment measures (appropriate use of gloves!)
- Proper handling of waste (mandatory to keep records in the operating logbook)
- Know how to use the equipment correctly and how to identify anomalies
- Reporting of extraordinary event to the project manager and the Biosafety Officer (mandatory records)
- Reporting of the accident to the project manager and the Biosafety Officer (mandatory records)
- Application of the contained system and work with GMOs to the Ministry prior to the start of the work!



# Containment measures for working with GMOs

- Be familiar with the "Containment Plan" document
- Be familiar with the documents „Contingency Plan for extraordinary event, accident“
- Suitable work areas
- Adhere to the principles of good laboratory practice
- Adhere to the principles of good microbiological practice
- Use procedures to avoid the formation of bioaerosols
- Eating and storing food and drink and smoking are prohibited
- Mandatory use of laboratory coats and other required protective equipment
- Frequent hand washing, mandatory after contact with GMOs
- Availability of appropriate disinfectants
- Use closed containers for GMO transfer
- One glove rule to be used during GMO transfer
- Appropriate inactivation of GMOs is mandatory

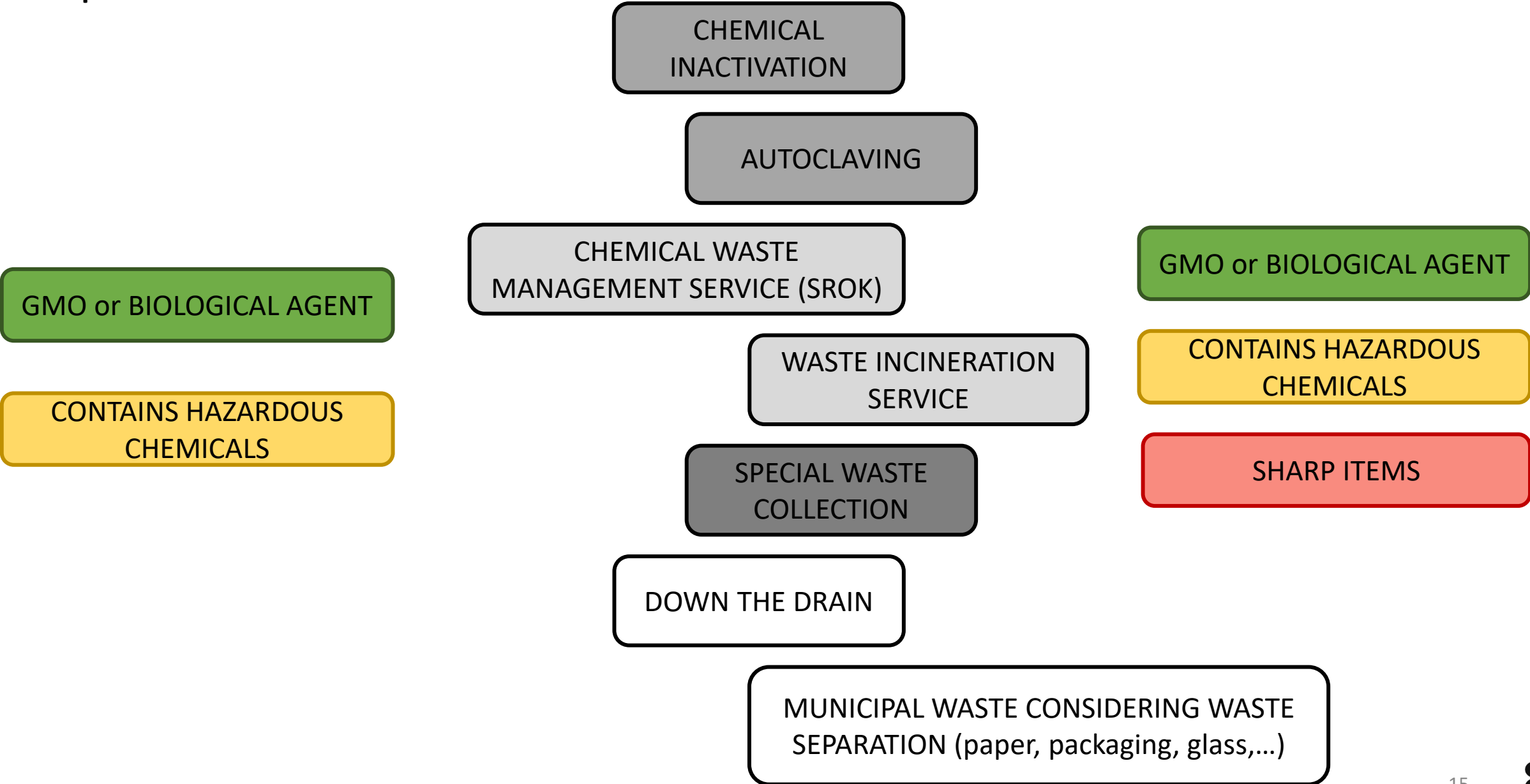


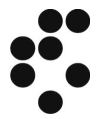
# GMO inactivation - waste management

- Be familiar and understand the relevant guidance document with written instructions for the laboratory or enclosed system.
- Guarantee traceability! Waste is always properly labelled and recorded in the appropriate logbooks.
- Ensure safety! Comply with the rules on waste handling and follow the one glove rule for GMO and GMO waste transfer.

# Liquid waste

# Solid waste





# GMO Management Law - control

- ❖ Law passed on January 26, 2005 and in force since March 15, 2005
- ❖ Changes introduced on 30 March 2010 (effective from 16 June 2010)


**Inspection supervision** is carried out by the Inspectorate of the Republic of Slovenia for Agriculture, Forestry, Food and Environment:

- Regularly every 2 years
- Additionally in case of an extraordinary event or accident

**The inspector may order the following measures:**

- 1. Prohibits work with GMOs** in a contained system
- 2. Orders a temporary suspension of work** with GMOs
- 3. Orders the elimination of detected irregularities** within a certain period of time
- 4. Orders additional measures to eliminate or reduce the consequences of adverse effects** that could arise or have arisen from the handling of GMOs
- 5. Proposes to remove the contained system** from the register of GMOs
- 6. Orders the destruction of GMOs**





# GMO Management Law – penal provisions 1/2

A fine of between € 12,500 and € 250,000 € shall be imposed on a **legal entity** if:

1. in the event of an accident, **fails to take the measures provided for in the contingency plan** or **fails to notify the authority** responsible for notification without delay (Article 11.a)

2., 3. **does not have** and does not act in accordance with a **contingency plan**,

4. when working with GMOs in contained systems, **does not provide for the prescribed containment and safety measures** and does not comply with the prescribed requirements depending on the biosafety class,

➔ 5. **uses a contained system** for the contained use of GMOs without a certificate of registration of the contained system in the GMO Register,

➔ 6. **carries out work with GMOs of the first biosafety class** in a contained system **without a certificate of registration of the contained system** in the GMO Register,

➔ 7. carries out work with GMOs of the second biosafety class without registration or starts work before the expiry of the statutory period or without the approval of the Ministry or in violation of the decision on the prohibition of work (Article 21, paragraphs 1, 3 and 4),

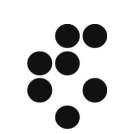
➔ 8. **carries out work with GMOs of the third or fourth biosafety class without authorization** or in violation of (Article 22, paragraph 1)

➔ 9. Works **to obtain genetically modified vertebrates or work with them without authorization** or in violation of the authorization (Article 23, paragraph 1),

10., 11. does not take into account the additional requirements of the Ministry (temporary ban on work until regulated) – Article 24

12. acts in violation of the provisions of Article 25 = new information that significantly affects the level of risk or the classification of work in the biosafety class – need for a new application (2nd biosafety class),

- A fine of between € 1,250 and € 10,000 € is imposed on the **responsible person of a legal entity** (= director)
- A fine of 2,100 to 3,800 € is imposed on an **individual** for a misdemeanor if the acts of items 5., 6., 7, 8., 9. are committed

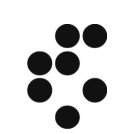


# GMO Management Law – penal provisions 2/2

A **legal entity** shall be fined from € 12,500 to €41,700 for a misdemeanor if:

1. **fails to inform the Ministry of the cessation of work with GMOs** (Article 15a),
2. **fails to keep the risk assessment** until the end of the work with the GMO or fails to inform the Ministry about the additions to the assessment if the work is of the second, third or fourth biosafety class (Article 16, paragraphs 5 and 6)
3. **Does not provide for the preparation of a contingency plan for accidents** or does not inform the relevant ministries and the relevant service of the local community about this plan or its amendments (Article 17),
4. **fails to submit the risk assessment for work with GMOs** in a contained system to the ministry upon its request (Article 20, paragraph 2)

A fine of € 1,250 to € 10,000 is also imposed on the **responsible person of a legal entity** (= director)



# Contained systems for contained use of GMOs at Jožef Stefan Institute

## **BIOSAFETY LEVEL 1**

- IJS-B1 (B1)
- IJS-B2 (B2)
- IJS-B3 (B3)
- IJS-BH (B1)
- IJS-J10BC (B2, B3)
- K9-BiomatLab (K9)
- O2-ZS5-RBC-MIC (O2)

## **BIOSAFETY LEVEL 2**

- IJS-B202 (B1)
- IJS-B12 (B1) – application in process
- IJS-B411 (B3)
- IJS-F5-LBF (F5)
- IJS-F5-BioFotonika (F5)

<https://www.ijs.si/ijsw>

# Znotraj inštituta Varnost in zdravje pri delu Genesko spremenjeni organizmi

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Direktorjeva pisarna

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Stiki z javnostjo  
Tiskane Novice IJS

## VARNOST IN ZDRAVJE PRI DELU (VZD)

### POVEZAVE

- Zakonodaja in dokumenti (Ministrstvo za delo, družino socialne zadeve in enake možnosti - MDDSZ)
- Inšpektorat RS za delo
- Urad RS za kemikalije
- Zbornica varnosti in zdravja pri delu

### IZOBRAŽEVANJE VZD

- Osnove VZD VPP (PDF)
  - Osnove VZD VPP ENGLISH - The Basis of Health and Safety at Work and Fire Protection (PDF)
- Varno delo s slikovnim zaslonom (PDF)
- Varno delo v laboratoriju (PDF)
  - Varno delo v laboratoriju ENGLISH - Safe Working Practices in the Laboratory (PDF)
- Umetna optična sevanja (PDF)
- Navodila za varno delo - uporaba zaščitnih rokavic (PDF)
- Navodila za varno delo - premeščanje bremen (PDF)
- Varno delo na višini (PDF)

### Nevarne snovi

- Označevanje nevarnih kemikalij - plakat (PDF)
- Označevanje nevarnih snovi in zmesi - plakat (PDF) (PDF)
- CLP - plakat maj 2015 (PDF)
- Pravila za rokovanje s plinskimi jeklenkami (PDF)
- Moj kemijski vodnik - Priporočila (PDF)
- Moj kemijski vodnik - Kontrolnik (PDF)

### GENESKO SPREMENJENI ORGANIZMI (GSO)

- Izobraževanje o delu z GSO (PDF)
  - Training on Working with Genetically Modified Organisms (GMOs) (PDF)
- Test za izobraževanje za delo z GSO (PDF)
  - Training on Working with Genetically Modified Organisms (GMOs) - Test (PDF)

### Zakonodaja s področja genesko spremenjenih organizmov (GSO)

- Zakon o ravnanju z genesko spremenjenimi organizmi (GSO) (Ur. l. RS 23/2005 in Ur. l. RS 21/2010)
- Pravilnik o oceni tveganja za delo z genesko spremenjenimi organizmi v zaprtem sistemu (Ur. l. RS 45/2004)
- Pravilnik o vsebini prijave zaprtega sistema in prijave dela z genesko spremenjenimi organizmi v zaprtem sistemu (Ur. l. RS 65/2004)
- Pravilnik o načrtu ukrepov za primer nesreče pri delu z genesko spremenjenimi organizmi v zaprtem sistemu (Ur. l. RS 69/2005)
- Pravilnik o registru genesko spremenjenih organizmov (Ur. l. RS 79/2006)
- Uredba o merilih za uvrstitev dela z genesko spremenjenimi organizmi v zaprtem sistemu v varnostni razred in o zadrževalnih ter drugih varnostnih ukrepih za posamezen varnostni razred (Ur. l. RS 71/2011)
- Pravilnik o varovanju delavcev pred tveganji zaradi izpostavljenosti biološkim dejavnikom pri delu (Ur. l. RS 4/2002 in 39/2005)

## VARNOST, NUJNI PRIMERI

- poklicni **gasilci, reševalna postaja**, center za obveščanje: 112; **policija**: 113
- dežurni **gasilec** in glavni vratar na Jamovi: (01) 477-3200, na Reaktorskem centru: (01) 588-5212
- **varnostni inženir** mag. Bojan Huzjan: (01) 588-5227, 041 596-045, Ana Marija Horvat, dipl. var. inž.: (01) 477-3104, 031 268 675 in Erika Potrc Hribar, dipl. var. inž.: (01) 477-3104, 041 926 581 - Varnost in zdravje pri delu
- koordinator splošne varnosti IJS Jože Matko: (01) 477-3785, (01) 477-3200, (01) 588-5212, (01) 562-6032, 041 695-863
- Služba za varstvo pred ionizirajočim sevanjem SVPIS, vodja mag. Matjaž Stepišnik: (01) 588-5254, 031 378-356
- reaktorski center - **operaterji reaktorja - vodje izmen**: Anže Jazbec, univ. dipl. fiz.: (01) 588-5228, 031 360-358; Marko Rosman, elektrotehnik - elektronik: (01) 588-5345, 041 521-712; Sebastjan Rupnik, dipl. inž. fiz.: (01) 588-5414, 040 577-257
- Služba za ravnanje z odpadnimi kemikalijami SROK
- **ekološki laboratorij** z mobilno enoto ELME (vodja dr. Matej Lipoglavšek), klicati center za obveščanje: 112 in zahtevati vodjo ELME na pager št. 132-33-23
- Uprava RS za **jedrsko varnost** (URSJV) - dežurni **radiološki monitoring**: 041 982-713

