



**State-approved, MPG In-service Training Course in accordance with
§ 15 Para. 4 Sentence 1 GenTSV (Genetic engineering safety regulations)
MPI of Biochemistry Martinsried, 10. and 11.12.2020**

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Day 1 (Thursday, December 10, 2020)

8:15 -8:30 **Dr. Ralf Tatzel**
(MPI of Biochemistry Martinsried, course instructor)

Welcome address, organization

Regulations pertaining to safety precautions for genetic engineering facilities and release of genetically modified organisms into the environment, as well as occupational health and safety

8:30 – 09:30 **Prof. Dr. Joachim Knoche**
(University of Munich)

Introduction to genetic engineering laws
- Important legal terms,
- Hierarchy, categorization, evaluation and interpretation of the legal provisions

1. International regulations on the utilisation of genetic engineering with particular regard to EU guidelines
2. Genetic engineering laws I:
 - General regulations
 - Genetic engineering operations in genetic engineering facilities
 - Release of genetically modified organisms into the environment
 - Common regulations
 - Regulations on liabilities, penalties and fines
3. Genetic engineering laws II:
 - Regulations on genetic engineering proceedings
4. Genetic engineering laws III:
 - Regulations on genetic engineering hearings
5. Genetic engineering laws IV:
 - ZKBS regulations (Federal Consumer and Food Safety Ministry)

09:30-09:40 **Break**

09:40 – 10:40 **Maureen Storm**
(Bavarian State Ministry of the Environment and Consumer Protection)

Genetic engineering laws V:

- Genetic engineering safety regulations

10:40 – 11:00 **Break**



- 11:00 – 12:00 **Dr. Isabel Müller**
(District Government of Upper Bavaria)
1. Genetic engineering laws VI:
 - genetic engineering documentation regulations
 2. Genetic engineering laws VII
 - Genetic engineering emergency regulations
 3. Information on the practical execution of genetic engineering laws during relevant procedures
 - Application, application forms
 - Instructions from the government's regulatory authority
- 12:00-12:10 **Break**
- 12:10 – 13:10 **Dr. Ingrid Korsa**
(District Government of Upper Bavaria)
1. Regulations pertaining to epidemics:
 - Infection Safety Act
 - Animal health law and regulations concerning importation of animal epidemic agents
 - Laws related to plant protection including regulations on importation of plants
 2. Further legal regulations:

Animal protection laws; animal by-products disposal act; plant protection laws; application of plant protection regulation, laws on plant protection agents, embryo protection, laws pertaining to chemicals, as well as regulations on hazardous substances, radiation protection laws, building laws, laws on occupational safety, federal laws on emission protection, as well as 4 regulations on emission protection; federal laws on soil protection, as well as regulations on soil protection and waste deposit, laws on water supplies, as well as regulations on sewage water; laws on recycling management; laws pertaining to the control of weapons of war, etc.
 3. Transportation of biological substances:

Rules and regulations on the transportation of biological substances by road (GGVS), rail (GGVE), sea (GGVBinSch, GGVSee) and air (IATA)
 4. Interconnections with regard to genetic engineering laws:
 - Impact of concentration etc.
- 13:10 – 14:10 **Lunch break**
- 14:10 – 15:10 **Dr. Karin Lanzl**
(Bavarian State Ministry of the Environment and Consumer Protection)
- Structure of the occupational safety systems
Public occupational safety regulations
Government safety organisations data sheets and technical standards
Regulations related to biological substances
- 15:10 – 15:30 **Break**

Potential risks from organisms in genetic engineering operations with particular regard to microbiology

15:30 – 18:00 **Dr. Birgit Schöning**
(Federal office of Consumer Protection and Food Safety, Berlin)

ca. 16:45-17:00 break

Safety aspects with regard to the handling of organisms in genetic engineering

- Theoretical fundamentals of risk assessment
- Potential risks, especially from spender and recipient organisms in various cloning and expression systems (viral expression systems, procaryotical systems, yeast and other lower eukaryotes, plant systems, insects and invertebrates, vertebrates, especially mammals, cell systems)
- Stability of genetic characteristics, gene transfer
- Pathology and epidemiology of microbial infections
- Immunology, prophylaxis and therapy of microbial infections

Risk assessment and safety categorization in commercial and research areas with examples from course participants

- Assessment criteria (§ 5 and appendix I GenTSV)
- Classification of bacteria, fungi, viruses and parasites; *Merckblätter der Chemie* (the BG chemistry bulletin) „*Einstufung von biologischen Agenzien*„ (Classification of biological agents); list of risk-evaluated spenders and receivers for genetic engineering operations, in accordance with § 5 paragraph 6 GenTSV (announcement in the *Bundesgesundheitsblatt*)
- Safety categorization of genetic engineering operations (§ 4, 7 and appendix I GenTSV)
- Fundamentals of safety categorization (§ 4 GenTSV)
- Safety categorization of genetic engineering operations involving microorganisms and cell cultures in production areas (§ 7 paragraph 2 GenTSV)
- Safety categorization of genetic engineering operations involving microorganisms and cell cultures in laboratories (§ 7 paragraph 3 GenTSV)
- Safety categorization of genetic engineering operations involving animals and plants (§ 7 paragraph 4 GenTSV)
- Biological safety precautions (§ 6 and appendix II GenTSV)
- Techniques used in compiling, identifying and supervising organisms

Day 2 (Friday, December 11, 2020)

8:15 – 09:15 **Dr. Birgit Schöning**
(Federal office of Consumer Protection and Food Safety, Berlin)

Program continued:

Risk assessment and safety categorization in commercial and research areas with examples from course participants

09:15 – 09:25 **Break**

09:25 - 10:55 **Dr. Werner Schenkel**
(Federal office of Consumer Protection and Food Safety, Berlin)

Environmental considerations in case of accidental or targeted release of genetically modified organisms into the environment

10:55 – 11:15 **Break**



11:15 – 12:00 **Dr. Jörg Reichert**
(Company doctor, MPI Martinsried)
Occupational medicine regulations

12:00 – 12:10 **Break**

12:10 – 13:10 **Dr. Kerstin Nicolaisen**
(District Government of Upper Bavaria)
Organizational measures
- Operating instructions, as well as regulations on access, labelling,
Hygiene plan and emergency plan in genetic engineering operation areas
S1-S3 (Laboratory, animal facility rooms, green house)
- DIN EN 12128 and other DIN EN
- Storage, in-plant transport and destruction of genetic engineering materials
- Topics for instructions

Secure methods of operation, purposive handling of materials
- Fundamentals of good microbiological operations aimed at minimizing
risks
- Typical errors that arise when carrying out routine procedures

13:10 – 14:10 **Lunch break**

Safety precautions for genetic engineering facilities and release of genetically modified organisms into the environment

14:10 – 17:10 **Dr. Bernhard Skrobranek**
(Roche Diagnostics GmbH, Penzberg)

ca. 15:40-16:10 break

Construction and equipping of S1-S4 areas (according to appendix. III-V GenTSV), maintenance
- Containment in accordance with the safety categorization of GenTSV
- Structural prerequisites
- Regulations on access, infiltrating and discharging
- Personal protective equipment
- Indoor air technical facilities (ventilation, filter systems)
- Safety work benches, sterilisers, disinfectors
- Fermenters, centrifuges, homogenisers
- Technical safety measures for sewage water and waste materials
- Specific requirements for the production area
- Supply and discharge, shaft feedthroughs
- Sample drawing, other reconditioning measures

Sterilisation, disinfection, deactivation, disposal of waste
- Fundamentals of sterilisation and disinfection
- Deactivation in terms of § 3 No. 5 GenTSV
- Decontamination
- List of disinfectors and disinfection procedures reviewed and approved by Robert Koch Institute; List of disinfectors of the Association for Applied Hygiene



17:10 – 17:25

Dr. Ralf Tatzel

(MPI of Biochemistry Martinsried)

- Discussion of problems / Final discussion



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