



State-approved, MPG In-service Online Training Course
-Basic Course-
in Accordance with § 28 GenTSV
MPI of Biochemistry Martinsried

Committee for
Biological Safety

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Thursday and Friday, 28 and 29 November 2024

Day 1 (Thursday, 28.11.2024)

8:15-8:30 **Dr. Ralf Tatzel / Julian Schuster**
(MPI of Biochemistry Martinsried)

Welcome address, organization

Legal Regulations re Safety Measures for Genetic Engineering Facilities (Laboratories, Production, Animal Rooms, Greenhouses) and Releases, as well as Occupational Health and Safety

8:30-9:30 **Dr. Jürgen Mertsching**
(Consulting Mertsching Biosafety)

Introduction to genetic engineering laws

- Important legal terms
- (Administrative act, execution of the administrative act, legal remedies, objections, safety and order, regulatory offences, offence, legal proceedings)
- Hierarchy, categorization, evaluation and interpretation of legal provisions

International regulations on the utilisation of genetic engineering with particular regard to EU guidelines

Law on genetic engineering

- Genetic engineering laws (GenTG)

Further regulations re the genetic engineering laws

- Regulations on genetic engineering proceedings (GenTVfV)
- Regulations on genetic engineering hearings (GenTAnhV)
- ZKBS regulations (ZKBSV)

9:30-9:40 *Break*

9:40-10:40 **Dr. Boris Schneider**
(Bavarian State Ministry of the Environment and Consumer Protection)

Law on genetic engineering

- Genetic Engineering Safety Ordinance (GenTSV)

10:40-11:00 *Break*

11:00-12:00 **Dr. Isabel Müller**
(District Government of Upper Bavaria)

Further regulations re the genetic engineering laws

- Genetic engineering documentation regulations (GenTAufzV)
- Genetic engineering emergency regulations (GenTNotfV)

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)

Legal regulations pertaining to epidemics and animal protection

- German Federal Protection against Infection Act (IfSG) with special regard to the regulations on work with pathogens
- Animal health law (TierGesG)
- Epizootic pathogens ordinance (TierSeuchErV)
- Animal protection laws (TierSchG)

OECD documents, CEN and DIN standards

External transportation of biological substances

- Hazardous goods transportation act (GGBefG); Dangerous goods regulation: road, railway and inland waterway transport (GGVSEB), European agreements concerning the international transport of hazardous goods by road (ADR) or by rail (RID), aviation - IATA regulations

Further legislation and regulations:

- Embryo protection law (ESchG); stem cell law (StZG); GCP regulation; species protection regulations; plant protection law (PflSchG); federal immission control law (BImSchG); radiation protection law (StrlSchG); radiation protection ordinance (StrlSchV); building regulations law, in particular fire protection; laws on the control of weapons of war (KrWaffKontrG) and on the prohibition of bacteriological weapons (see § 11 Abs. 1 Nr. 5 GenTG)

13:10-14:10 **Lunch break**

14:10-15:10 Sibylle Rögner
(District Government of Upper Bavaria – Labour Inspectorate)

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 with Particular Regard to Microorganisms

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

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

- Theoretical fundamentals of risk assessment
- Potential risks, especially from donor and recipient organisms in various cloning and expression systems (viral expression systems, prokaryotic 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

16:30 – 16:50 *Break*



Risk assessment and safety categorization

- Risk assessment of organisms
- Assessment criteria (§ 5 and appendix I GenTSV)
- Classification of viruses, bacteria, parasites; fungi and other eukaryotic protozoa, list of risk-evaluated donor and receiver organisms for genetic engineering operations, in accordance with § 6 GenTSV (announcement in the *Bundesanzeiger*) as well as databases on the website of the ZKBS-*Geschäftsstelle*; technical rules for biological agents with classification criteria or classifications of biological agents (TRBA 450, TRBA 460, TRBA 462, TRBA 464 und TRBA 466)
- Safety categorization of genetic engineering operations (§§ 4, 10, 11 and appendix I GenTSV)
- Fundamentals of safety categorization (§ 4 GenTSV)
- Safety categorization of genetic engineering operations with microorganisms (§ 10 GenTSV)
- Safety categorization of genetic engineering operations involving animals and plants (§ 11 GenTSV)
- Biological safety measures (§ 7 GenTSV)
- General statements of the ZKBS
- Techniques for the detection and identification of organisms

Gene Therapy – clinical studies

Day 2 (Friday, 29.11.2024)

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. Georg Leggewie

(Federal Office of Consumer Protection and Food Safety, Berlin)

Requirements for the release of GMOs

10:55 – 11:15 *Break*

11:15 – 12:00 Dr. Jörg Reichert

(Company Doctor, MPI Martinsried)

Occupational medicine regulations

12:00 - 12:10 *Break*



Safety Measures for Genetic Engineering Facilities and Releases

12:10 - 13:10 Dr. Markus Helfer

(District Government of Upper Bavaria)

Organizational measures

- Access regulations and marking of the work areas
- Operating instructions
- Instruction
- Hygiene plan
- Emergency plan (internal, external)
- Records
- Storage, destruction of genetic engineering material

Special requirements for the keeping of genetically modified animals (rodents, fish, insects, large animals, etc.) and animals to which recombinant, replication-capable or replication-defective microorganisms have been transferred

Special requirements for greenhouses

Secure methods of operation, conscious acting (Principles of good microbiological technique)

- Preventive measures, hazard minimization
- Typical errors in the performance of routine procedures

Sterilization, disinfection, deactivation

- Basics of sterilization and disinfection
- Inactivation within the meaning of § 3 No. 6 GenTSV
- Decontamination
- List of disinfectants and disinfection methods tested and approved by the Robert Koch Institute; disinfectant lists of the Association for Applied Hygiene (VAH) and the German Veterinary Medical Society (DVG)

13:10 – 14:10 *Lunch break*

14:10 – 17:10 Dr. Katrin Singethan

(Bundeswehr Institute of Microbiology, Munich)

Construction and equipment in accordance with Annexes 2-4 GenTSV for the individual safety levels 1 - 4, maintenance and inspection

- Construction requirements
- Indoor air technical facilities (ventilation, filter systems)
- Safety work benches
- Sterilizers, disinfectors
- Fermenters, centrifuges, homogenisers
- Technical safety measures for sewage water and waste materials

15:30 – 15:50 *Break*

- Personal protective equipment
- Special case S3**
- Specific requirements for the production area
- Containment in accordance with the safety levels of the GenTSV
- Entering and exiting via a sluice
- Supply and discharge, shaft feedthroughs
- Sample drawing
- Other reconditioning measures

17:10 – 17:25 Dr. Ralf Tatzel / Julian Schuster

(MPI of Biochemistry Martinsried)

Discussion of problems / Final discussion