German Federal Office of
Consumer Protection and
Food Safety

# Annual report of the work of the Central Committee on Biological Safety in the year 2009

(**BVL 93/2010/4**)

20th report after the Genetic Engineering Act came into force

The report of the work of the Central Committee on Biological Safety in the year 2009 will be announced in the following.

Berlin, March 2, 2010

German Federal Office
of Consumer Protection and Food Safety
On behalf of

Dr. Inge K r u c z e k

# Index



**Abbreviations**

| | |
|---|---|
| BfN | Federal Office for Nature Conservation |
| BfR | Federal Institute for Risk Assessment |
| BMELV | Federal Ministry for Food, Agriculture and Consumer Protection |
| BVL | Federal Office for Consumer Protection and Food Safety |
| EC | European Community |
| EEC | European Economic Community |
| EFSA | European Food Safety Authority |
| EU | European Union |
| FLI | Friedrich Loeffler Institute, Federal Research Institute for Animal Health |
| GenTG | Genetic Engineering Act |
| GenTSV | Genetic Engineering Safety Regulations |
| GMO | genetically modified organism |
| JKI | Julius Kühn Institute |
| PEI | Paul Ehrlich Institute |
| RKI | Robert Koch Institute |
| ZKBS | Central Committee on Biological Safety |

Technical abbreviations are explained in the text.

# 1 Introduction

## 1.1 Background to the ZKBS

The Central Committee on Biological Safety (ZKBS) is an expert committee comprising twenty members and twenty deputy members. The members are experts from various specialist fields and their deputies are experts from the same specialist background. The ZKBS examines and evaluates questions relevant to safety in genetic engineering according to the regulations of the Genetic Engineering Act (GenTG) and advises the Federal Government and Federal States (Bundesländer). The ZKBS provides position statements for the appropriate authorities, particularly on safety or containment level assignment for genetic engineering operations, required safety measures in genetic engineering facilities and possible risks associated with release or placing on the market of genetically modified organisms (GMO). In its recommendations it takes into account international developments in the area of genetic engineering safety. The members of the ZKBS and their deputies perform their activities voluntarily.

The ZKBS is based at the Federal Office for Consumer Protection and Food Safety (BVL), which belongs to the operating area of the Federal Ministry for Food, Agriculture and Consumer Protection (BMELV). The members of the ZKBS and their deputies are appointed for the duration of three years by the BMELV in agreement with the Federal Ministries for Education and Research, of Economics and Technology, for Employment and Social Services, for Health as well as for the Environment, Nature Conservation and Reactor Safety.

The ZKBS has a chairperson, supported by two vice-chairpersons, and reaches its decisions either at a general meeting or by a written procedure. The members of the ZKBS and their deputies are sworn to secrecy. The meetings are not public, but the ZKBS publishes general position statements and reports on its work to the public each year.

## 1.2 Development of genetic engineering in Germany and other member states of the European Union

Legal development

The work of the ZKBS is based on the Genetic Engineering Act (GenTG), passed in 1990, and has been revised many times since then. The Act for reforming the Genetic Engineering Laws from April 1, 2008 came into force on April 5, 2008. The ZKBS was extended therewith by experts in the specialist fields of agriculture, nature conservation, plant protection and toxicology.

Genetic engineering operations and genetic engineering facilities

The term “genetic engineering operations” primarily covers the creation and handling of GMOs. Depending on the required safety, i.e. containment level, genetic engineering operations must be registered or approved by the appropriate state authorities and carried out in a genetic engineering facility, which also has to be registered or approved depending on the required containment level. Genetic engineering facilities can be a laboratory, a production plant, a greenhouse or facilities for keeping animals.

Participation of the ZKBS in such notification or approval procedures has changed since the Genetic Engineering Act (GenTG) came into force in 1990. Initially, the ZKBS provided a

position statement on all genetic engineering operations that were submitted for registration or approval. Since the amendment of the GenTG at the end of 1993, only genetic engineering operations at containment level 3 and 4 and such genetic engineering operations at containment level 2 that cannot be compared to other operations the ZKBS has previously provided a position statement for are to be examined and evaluated by the ZKBS.

Since the GenTG came into force in 1990, 1651 applications for containment level assignment of genetic engineering operations and evaluation of the required technical safety measures have been submitted to the ZKBS. 42 applications were submitted in the year of this report and the ZKBS provided 37 position statements; at the end of the year three applications were still under review. Two of them were completed in 2010, one application was withdrawn, one application is suspended. Additionally, the BVL has been informed by state authorities about 368 position statements on genetic engineering operations in the year of this report. Table 1 lists the position statements from 2009 based on their containment level.

**Table 1** Safety evaluated genetic engineering operations in Germany in 2009 (as of December 2009)

| Position statement provided by | Containment level | Number |
|---|---|---|
| State Authority | S1 | 195 |
| State Authority | S2 | 335 |
| ZKBS | S1 | 2 |
| ZKBS | S2 | 11 |
| ZKBS | S3 | 24 |
| ZKBS | S4 | 0 |

In Germany, a total of 6019 genetic engineering facilities have operating approval (as of December 2009). The BVL was informed by the relevant state authorities about 272 new genetic engineering facilities going into operation in 2009. Table 2 lists the genetic engineering facilities according to the kind of operator and level of safety measures for the facilities.

**Table 2** Genetic engineering facilities in Germany (as of December 2009)

| Operator | Containment level | Number |
|---|---|---|
| Public | S1 | 3579 |
| Public | S2 | 1247 |
| Public | S3 | 88 |
| Public | S4 | 4 |
| Private | S1 | 911 |
| Private | S2 | 178 |
| Private | S3 | 12 |

Further information on genetic engineering operations and genetic engineering facilities as well as on organisms, cell lines and vectors used in genetic engineering operations is provided on the BVL website: http://www.bvl.bund.de.

It is not possible to compare genetic engineering operations or genetic engineering facilities with other EU member states, since no information is available.

Deliberate release

Shall GMOs during an experiment be introduced into the environment for a limited period of time and in a limited area it is a matter of “deliberate release”. According to the GenTG one must apply for approval for every intended release which can be granted if the planned release will present no hazard to humans and the environment. In case there already exists an approval for placing on the market for the GMO which shall be introduced into the environment, a separate approval is not required.

Since April 01, 2004 the BVL has been responsible as the overall Federal Authority for approving the release of GMOs in Germany. The BVL reaches its decisions in conjunction with the Federal Office for Nature Conservation (BfN), the Federal Institute for Risk Assessment (BfR) and the Robert Koch Institute (RKI). The ZKBS, the Julius Kühn Institute (JKI) and the relevant authorities in the Federal States involved provide position statements on the planned release. In the case of release of genetically modified vertebrates or genetically modified microorganisms that are to be used with vertebrates, the Friedrich Loeffler Institute (FLI) is also involved. Other EU member states are informed about the release application and can take a position on it.

In 2009, five new applications were filed with the BVL, however, a decision was not reached for any of them by the end of the year. In 2009, seven approvals relating to applications submitted in the previous year were granted. In addition there were seven subsequent notifications for further locations of approved releases in 2009. Figure 1 summarises the annual number of approvals for release since the Genetic Engineering Act came into force in 1990. Subsequent notifications of further locations on approved releases according to the simplified procedure (decision of the EU Commission from November 4, 1994 on stipulating simplified processes for the intentional release of genetically modified plants according to Article 6 Paragraph 5 of the Directive 90/220/EWG of the council, 94/730/EC) are not taken into account. The decrease in the frequency of approvals after 1999 corresponds to a decrease in applications for approval. For the year under report, the demolition of eleven deliberate release areas out of 36 deliberate releases of genetically modified plants in Germany was reported to the BVL.

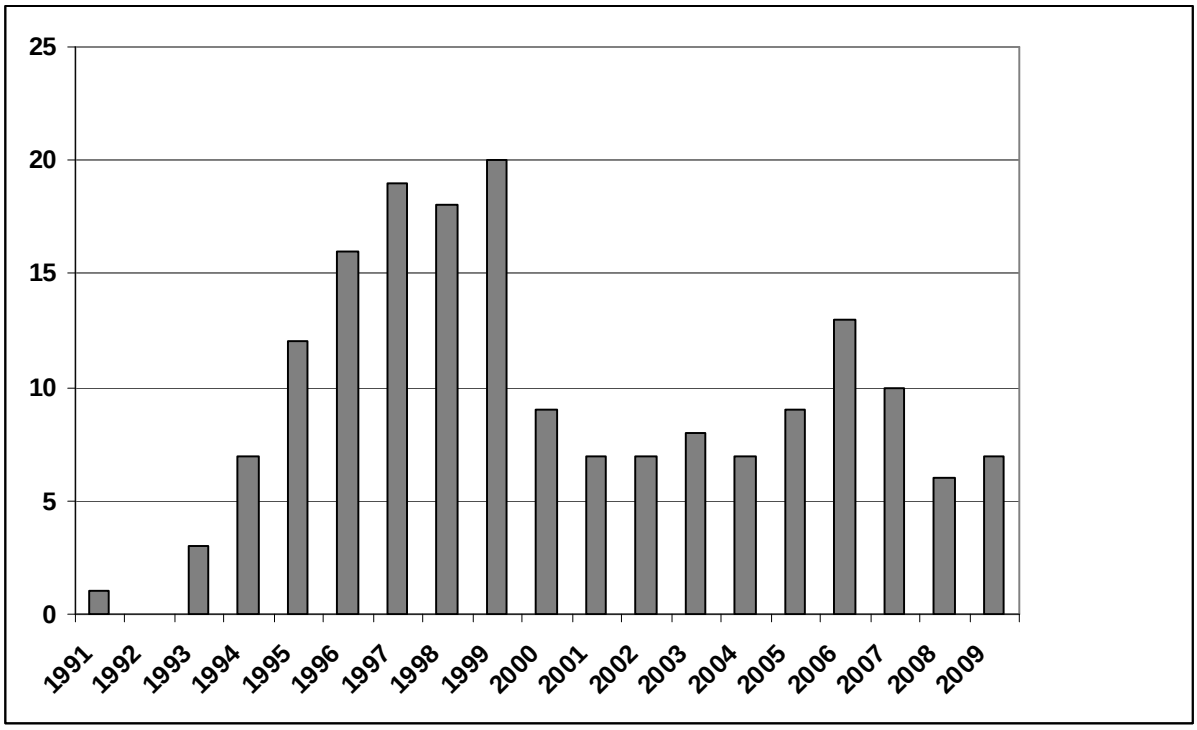


**Figure 1** Number of approved releases in Germany since the GenTG came into force in 1990 (as of December 2009)

A comparison of the registered applications from various member states of the EU is given in Table 3, showing the following selected years: the current report year of 2009, the previous years 2008, 2007, 2006 and 2005 and the year 1999, when the highest number of applications was submitted and approved in Germany.

**Table 3** Applications for approval of deliberate release of genetically modified crops by the member states of the EU (as of December 2009).

| State | 1999 | 2005 | 2006 | 2007 | 2008 | 2009 |
|---|---|---|---|---|---|---|
| Belgium | 8 | - | - | - | 1 | 2 |
| Czech Republic | | 2 | 5 | 5 | 3 | 7 |
| Denmark | 4 | 1 | 2 | 5 | 2 | 4 |
| Finland | 3 | 1 | - | - | 1 | 2 |
| France | 60 | 22 | 17 | 16 | - | 1 |
| Germany | 22 | 9 | 13 | 9 | 6 | 5 |
| Great Britain | 11 | - | 1 | 2 | 1 | 1 |
| Greece | 6 | - | - | - | - | - |
| Hungary | | 10 | 7 | 9 | 3 | - |
| Iceland | - | - | - | - | - | 1 |
| Ireland | - | - | 1 | - | - | - |
| Italy | 47 | 1 | - | - | - | - |
| Lithuania | | - | | 2 | - | - |
| Poland | | 3 | 3 | - | 3 | 1 |
| Portugal | 1 | 3 | 5 | 1 | 2 | 1 |
| Rumania | | | | 14 | 9 | 21 |
| Slovakia | | - | - | - | 4 | 2 |
| Spain | 56 | 20 | 41 | 45 | 45 | 64 |
| Sweden | 16 | 8 | 6 | 4 | 4 | 4 |
| The Netherlands | 19 | 3 | 8 | 5 | 2 | 1 |

The table shows that the number of applications for approval of deliberate release of genetically modified crops has decreased since 1999 not only in Germany, but generally in the EU (except for Spain). This conclusion cannot be drawn for Poland, the Czech Republic, Hungary, Bulgaria, Rumania and Slovakia, since they joined the EU only in 2004 (Rumania only in 2007) and no information is available for the period before.

Since the GenTG came into force, a total of 2543 applications for the release of genetically modified plants have been submitted within the EU. No information has been submitted by the EU member states not included in Table 3.

Placing on the market

"Placing on the market" of GMOs or products containing GMOs refers to each kind of propagation like giving away or selling, unless they are not intended to be used for a genetic engineering operation in a genetic engineering installation or for an approved deliberate release. Placing GMOs on the market requires approval. Since an approval for placing a GMO on the market is met through an EU-wide procedure, it applies to all member states of the EU. The BVL is the competent German authority, and in conjunction with the BfN, BfR and RKI, provides position statements on applications for placing GMOs on the market. Before this, however, the ZKBS presents position statements to the BVL on applications made in Germany

for approval of placing on the market according to the Directive 2001/18/EC, previously 90/220/EEC. The JKI also provides the BVL with a position statement, and in the case of genetically modified vertebrates or genetically modified microorganisms that are to be used with vertebrates, also the FLI and Paul Ehrlich Institute (PEI).

In the EU-wide processes it is distinguished whether the GMO may be used as feed or food [since 1997 regulation (EC) No. 258/97 for food, since 2004 regulation (EC) No. 1829/2003 for food and feed] or not. Products derived from GMOs that are not used as feed or food and that do not contain organisms capable of replicating (e.g. clothing made of cotton) require no approval for placing on the market. Table 4 lists those GMOs that have been approved for placing on the market in the EU according to the Directive 90/220/EEC and/or the Directive 2001/18/EC for the year under report.

**Table 4** GMOs approved by the EU for placing on the market in the year 2009

| Product | Genetic modification | Purpose |
|---|---|---|
| Cotton MON1445 | herbicide resistance | FF |
| Cotton MON531 | insect resistance | FF |
| Cotton MON531xMON1445 | herbicide and insect resistance | FF |
| Cotton MON15985 | insect resistance | FF |
| Cotton MON15985xMON1445 | herbicide and insect resistance | FF |
| Cotton LLCotton25 | herbicide resistance | FF |
| Carnation Moonlite | modified flower colour | IP |
| Carnation Moonshadow 1 | modified flower colour | C |
| Carnation Moondust | modified flower colour | IP |
| Maize MIR604 | insect resistance | IP, FF |
| Maize 59122xMON88o17 | herbicide and insect resistance | IP, FF |
| Maize MON88017 | herbicide and insect resistance | IP, FF |
| Maize MON89034 | insect resistance | IP, FF |
| Maize 59122 “Herculex“ | herbicide and insect resistance | IP, FF |
| Maize 1507xNK603 | herbicide and insect resistance | IP, FF |
| Maize NK602xMON810 | herbicide and insect resistance | FF |
| Maize T25 | herbicide resistance | IP, FF |
| Maize MON810 | insect resistance | IP, FF, C* |
| Maize MON863 | insect resistance | IP, FF |
| Maize 1507 | herbicide and insect resistance | FF |
| Maize GA21 | herbicide resistance | IP, FF |
| Maize Bt11 | insect resistance | FF |
| Maize MON863xMON810 | insect resistance | FF |
| Maize MON863xNK603 | herbicide and insect resistance | FF |
| Maize NK603 | herbicide resistance | FF |
| Canola GT 73 | herbicide resistance | IP, FF |
| Canola T54 | herbicide resistance | FF |
| Canola MS8xRF3 | herbicide resistance, male sterility | IP, FF |
| Soy MON40-3-2 | herbicide resistance | FF |
| Soy A2704-12 | herbicide resistance | IP, FF |
| Soy MON89788 | herbicide resistance | IP, FF |

| | | |
|---|---|---|
| Sugar beet H7-1 | herbicide resistance | FF |

Abbreviations:
- IP: import as replication-competent GMO and processing
- FF: feed and food
- C: cultivation in the EU
- C*: cultivation ban on MON810 in Germany based on the suspension of the approval for placing on the market according to § 20 Para. 2 GenTG

In contrast to release experiments limited to a particular location and time, the agricultural cultivation of genetically modified plants is not limited to a particular location or experimental year. Cultivation of genetically modified plants can only take place if placing genetically modified seeds on the market for the purpose of introducing them into the environment has been approved. Approval for placing on the market is initially limited to ten years.

Since 2004, strict rules apply in the EU for the approval and labeling of genetically modified food and feed. The newly established European Food Safety Authority, EFSA, is responsible for the scientific evaluation. Genetically modified food and feed that were placed on the market in the EU before 2004 are permitted to remain on the market for a transitional period of time. Subsequently, reapplication for their placing on the market must be made. In addition, a standardized certification process for each GMO must be available.

Further information about the approved and submitted applications for GMOs in the EU is provided on the following websites:

http://www.bvl.bund.de

http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

http://www.transgen.de/zulassung/gvo/

# 2 Structure of the ZKBS

The ZKBS brings together experts from various specialist fields. The specialist fields represented are defined in the GenTG and must be covered by the structure of the ZKBS. This makes it possible to institutionalize and access a broad range of factual knowledge for the tasks performed by the ZKBS as defined by the GenTG, namely the evaluation of microorganisms as donor and recipient organisms in genetic engineering operations, containment assignment for genetic engineering operations, the evaluation of technical safety measures in genetic engineering facilities as well as the evaluation of release and placing on the market of GMOs. The members of the ZKBS are listed in table 5.

The composition of the ZKBS depicted in table 5 corresponds to the GenTG.

**Table 5** Specialist areas and members of the ZKBS (as of December 2009)

| Specialist area | Member | Representative member |
|---|---|---|
| | **Experts according to § 4 Para. 1 No. 1 GenTG** | |
| **Microbiology** | Prof. Dr. Regine Hakenbeck<br>University of Kaiserslautern | Prof. Dr. Klaus Lingelbach<br>University of Marburg |
| **Cell biology** | Prof. Dr. Bernd Gänsbacher<br>Technische Universität Muenchen | tba |
| **Virology** | Prof. Dr. Dr. h.c. Herbert Pfister<br>University of Cologne | Prof. Dr. Edgar Maiß<br>University of Hannover |
| **Virology** | Prof. Dr. Angelika Vallbracht<br>University of Bremen | Prof. Dr. Klaus Überla<br>University of Bochum |
| **Genetics** | Prof. Dr. Jürgen Wienands<br>University of Göttingen | tba |
| **Genetics** | Prof. Dr. Alfred Pühler<br>University of Bielefeld | Prof. Dr. Uwe Sonnewald<br>University of Erlangen-Nürnberg |
| **Hygiene** | Prof. Dr. Uwe Groß<br>University of Göttingen | Prof. Dr. Dr. Andreas Podbielski<br>University of Rostock |
| **Ecology** | Prof. Dr. François Buscot<br>Helmholtz Center for Environmental Research GmbH, Halle | Dr. Walter Durka<br>Helmholtz Center for Environmental Research GmbH, Halle |
| **Ecology** | Prof. Dr. Stefan Vidal<br>University of Göttingen | tba |
| **Plant breeding** | Dr. Patrick Schweizer<br>Leibniz Institute of Plant Genetics and Crop Plant Research (IPK), Gatersleben | Prof. Dr. Chris-Carolin Schön<br>Technische Universität Muenchen, Freising |
| **Technical safety** | Dr. Uwe Bücheler<br>Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach a.d. Riß | Dr. Sven Deutschmann<br>Roche-Diagnostics GmbH, Penzberg |
| **Toxicology** | Prof. Dr. Doris Marko<br>University of Vienna | Prof. Dr. Pablo Steinberg<br>University of Veterinary Medicine Hannover |
| | **Specialists according to § 4 Para. 1 Nr. 2 GenTG** | |
| **Employment protection** | Frank Gerschke<br>State Authority for Employment Protection, Potsdam | Dr. Hans-Josef Riegel<br>Berufsgenossenschaft Rohstoffe und chemische Industrie (BG RCI) Cologne |
| **Trade unions** | Prof. Dr. Dr. h.c.<br>Wilfried Wackernagel<br>University of Oldenburg | Dr. Manfred Keilert,<br>Berlin |
| **Agriculture** | Prof. Dr.<br>Norbert Lütke Entrup<br>South Westphalia University of Applied Sciences, Soest | tba |

| | | |
|---|---|---|
| **Nature conservation** | tba | tba |
| **Research-funding organisations** | Dr. Ingrid Ohlert<br>Deutsche Forschungsgemeinschaft (DFG), Bonn | tba |
| **Environmental protection** | Dr. Gerd Neemann<br>BLaU Environmental Studies Göttingen | Prof. Dr. Thomas Eikmann<br>University of Gießen |
| **Consumer protection** | Sigrid Lewe-Esch<br>Working Group of Protestant Housekeeping Managers of the German Protestant Women's Federation e.V., Duisburg | Jutta Jaksche<br>Federation of German Consumer Organisations e.V., Berlin |
| **Economy** | Dr. Siegfried Throm<br>Association of Research-based Pharmaceutical Companies, Berlin | Dr. Anja Matzk<br>KWS SAAT AG, Einbeck |

Abbreviation: tba: to be assigned

Since July 2007, Prof. Dr. Dr. h.c. Herbert Pfister is the chairperson of the ZKBS. Vice-chairpersons are Prof. Dr. Angelika Vallbracht and Prof. Dr. Uwe Groß (December 2009).

Newly appointed in the year under report were: Dr. Patrick Schweizer as a representative member for the specialist field of plant breeding, Prof. Dr. Chris-Carolin Schön as the deputy member for this field, Prof. Dr. François Buscot and Prof. Dr. Stefan Vidal as representative members for the specialist field of ecology, Prof. Dr. Doris Marko as a representative member for the specialist field of toxicology, Prof. Dr. Pablo Steinberg as the deputy member for this field, Dr. Uwe Bücheler as a representative member for the specialist field of technical safety, Dr. Sven Deutschmann as the deputy member for this field and Prof. Dr. Norbert Lütke Entrup as a representative member for the specialist field of agriculture. Prof. Dr. Gerhard Wenzel, Dr. Jürgen Wahl, Prof. Dr. Marcus Koch, Prof. Dr. Elisabeth Knust and Prof. Dr. Achim Leutz have resigned.

# 3 Advisory activities of the ZKBS in 2008

## 3.1 Working methods

In 2009, six meetings of the ZKBS took place at the BVL in Berlin. Position statements of the ZKBS were usually adopted at these meetings. In addition, decisions were also made in written procedures if simpler questions not requiring detailed discussions between all the members had been submitted.

## 3.2 Working groups

A working group of the ZKBS has existed for many years to deal with preparing position statements of the ZKBS on applications for deliberate release approvals before these are presented to the plenum for passing a resolution.

No further working groups were established in the year under report.

## 3.3 Advising the Federal Government

The Federal Government did not make demands on an advisory service by the ZKBS in the year under report. Nevertheless, the cultivation ban on the Bt maize MON810 of April 2009 prompted the ZKBS to review its risk assessment of the cultivation of Bt maize MON810 of 2007 and to adopt an actual position statement (see chapter 3.10).

## 3.4 Advising competent authorities of the Bundesländer

Within the scope of administrative assistance, state authorities have asked the ZKBS for position statements on the following themes:

- Risk assessment of the cell line C8166 transduced with lentiviral vectors
- Risk assessment of the expression of conotoxins in *Nicotiana tabacum*
- Risk assessment of the expression of effector genes from enterohemorrhagic *Escherichia coli* in cell lines and in *Saccharomyces cerevisiae*

## 3.5 Risk assessment of donor or recipient organisms

During the first quarter of the year under report the list of organisms which have been assigned to risk groups according to § 5 para. 6 GenTSV was updated and published. This list was lastly updated in 2001. The update of 2009 does not only comprise all newly assigned organisms. Also the classifications according to EU Council Directive 2000/54/EC were rechecked and the viruses HBV, HDV, HGV, SIV and LCMV were assigned to risk groups differing from the Directive. In addition, the taxonomy of the microorganisms was updated.

The following microorganisms used as donor and recipient organisms in genetic engineering operations were assigned to a risk group according to § 5 in conjunction with Appendix 1 GenTSV in 2009:

**Table 6** Newly classified assigned microorganisms (as of December 2009)

| Organism | Risk group |
|---|---|
| **Viruses** | |
| *Laboratory strains of* Lymphocytic Choriomeningitis Virus (LCMV) | 2 |
| *Hepatitis B virus* (HBV) | 2 |
| *Hepatitis D virus* (HDV) | 2 |
| *Hepatitis G virus* (HGV) | 1 |
| Batai virus (BATV) | 2 |
| Inkoo virus (INKV) | 2 |
| Jamestown Canyon virus (JCV) | 2 |
| Ťahyňa virus (TAHV) | 2 |
| *Simbu virus* (SIMV) | 2 |
| Dugbe virus (DUGV) | 3 |
| Erve virus (ERVEV) | 2 |
| *Sandfly fever Naples virus* (SFNV) | 2 |
| *Langat virus* (LGTV) | 2 |
| *Eyach virus* (EYAV) | 2 |
| Tribeč virus (TRBV) | 2 |
| *Ambystoma tigrinum virus* (ATV) | 2 |
| Paramyxoviruses of reptiles (oPMV) | 2 |
| Adenoviruses of reptiles | 2 |
| Reoviruses of reptiles | 2 |
| Iridoviruses of reptiles | 2 |
| Herpesviruses of reptiles | 2 |
| Xenotropic murine leukemia virus related virus (XMRV) | 2 |
| *Modoc virus* (MODV) | 2 |
| *Mason-Pfizer monkey virus* (MPMV) | 2 |
| Nyamanini virus (NYMV) | 2 |
| Midway virus (MIDWV) | 2 |
| *Simian virus* 5 (SV5) | 2 |
| **Bacteria** | |
| *Salmonella* Typhimurium LT2A | 2 |
| **Fungi** | |
| *Pseudozyma tsukubaensis* | 1 |
| *Candida krusei* | 2 |
| *Aspergillus terreus* | 2 |

| Cell lines | |
|---|---|
| CMMT | 2 |
| sMAGI | 2 |
| AGS | 2 |
| 22Rv1 | 2 |

Risk assessments regarding the organisms listed above can be looked up on the BVL web-site under the heading “Genetic Engineering”, “Central Committee on Biological Safety”, in a list, a database or in short position statements (mainly in German) (http://www.bvl.bund.de/cln_007/nn_491798/DE/06_Gentechnik/093_ZKBS/zkbs_node.html_nnn=true).

### 3.6 Containment level assignment for genetic engineering operations

In 2009, the ZKBS provided 36 position statements on safety and containment level assignment for genetic engineering operations. The evaluated genetic engineering operations addressed the following questions and were assigned as follows:

Containment level 1

- Development of replication defective vectors on the basis of *Tupaia paramyxovirus*
- Analysis of Alzheimer-typical neuropathology in a mouse model

Containment level 2

- Interaction between pneumococcal phages and *Streptococcus pneumoniae*
- Analysis of induced pluripotent stem cells
- Development of lentiviral vectors for somatic gene therapy
- Cloning of the genome of porcine isolates of *Torque teno virus*
- Characterisation of an attenuated *Orf virus* for foreign gene expression
- Production of recombinant Nyamanini und Midway viruses
- Identification of immunologically relevant proteins of *Porcine reproductive and respiratory syndrome virus*
- Analysis of amination and oxidation of alkanes in yeast
- Identification of central virulence genes in *Candida spp*.
- Bioassay for detection of short-chain acetylhomoserine lactones

Containment level 3

- Characterisation of mutants of *Mycobacterium tuberculosis*, *Salmonella* Typhi und *Shigella dysenteriae*

- Construction of a genomic *Hepatitis C virus* replicon
- Analysis of *Human immunodeficiency virus*
- *In vitro* replication of Chronic wasting disease and other prion proteins
- Replication, pathogenesis und immunological control of the *Hepatitis C virus*
- Characterisation of cellular interaction partners of Influenza A viruses
- Analysis of replication and resistance of the *Human immunodeficiency virus*
- Analysis of gene products of Influenza viruses
- Characterisation of recombinant Rabies viruses
- Regulators and virulence factors of enterohemorrhagic *Escherichia coli*
- Characterisation of *Mycobacterium tuberculosis*, *M. africanum* and *M. bovis*
- Characterisation of Env variants of *Human immunodeficiency virus*
- Characterisation of recombinant mycobacteria
- Influence of prion proteins on the release of retroviruses in mammalian cells
- Analysis of viral nonstructural gene derivates of the *Rift Valley fever virus*
- Function of the NS1 protein of avian Influenza viruses in chicken
- Characterisation of Shiga toxin producing *Escherichia coli*
- Relevant host factors for *Mycobacterium tuberculosis* infection
- Characterisation of Iha in enterohemorrhagic *Escherichia coli*
- Salmonella typhi mutant screen
- Analysis of genetically engineered Influenza A viruses
- Evaluation of a vaccine based on a nef-defective hybrid lentivirus
- Significance of the *Hepatitis C virus* membrane anchor
- *In vitro* system for replication and detection of *Hepatitis C virus*

### 3.7 Assessing technical safety measures in genetic engineering facilities

In addition to stipulating the safety measures for the evaluated genetic engineering operations according to the categories in the appendices of the GenTSV, the ZKBS extensively examined the technical and building safety measures in individual genetic engineering facilities and produced position statements with risk assessment of a pipette robot in a containment level 3 facility and with risk evaluation of the exhaust air filtration in an animal level 2 facility. In addition, the ZKBS produced general position statements on safety technical requirements of animal cage change stations in genetic engineering facilities of levels 1 to 4 and on the safety of product protection cabinets for carrying out genetic engineering operations of biosafety level 1, and furthermore they updated the position statement on genetic engineering operations with enterohemorrhagic *Escherichia coli* strains.

## 3.8 Publication of general position statements

The ZKBS passed a general position statement on the risk evaluation of genetic engineering operations using primary cells of vertebrates. This statement as well as the statement on the safety of product protection cabinets for carrying out genetic engineering operations of bio-safety level 1 were published in the Federal Bulletin.

## 3.9 Position statements on releases

In 2009, the ZKBS provided position statements for the BVL on the seven applications for approval of release of GMOs listed in Table 7. All seven were supported by the ZKBS and approved by the BVL.

## 3.10 Position statements on placing on the market

In 2009, the ZKBS did not provide a position statement on an application for placing on the market of GMOs according to the Directive 2001/18/EC.

However, the ZKBS reviewed its risk assessment of the cultivation of Bt maize MON810 of 2007 and subjected six new studies on the impact of Bt maize on non-target organisms to a detailed assessment.

The scientific assessment of these study results has revealed that none of them confirm potential adverse effects on non-target organisms by MON810 under cultivation conditions. This assessment is presented and explained in detail in the position statement “Statement of the ZKBS on the risk assessment of MON810 – New studies on the environmental impact of MON810” of July 2009.

In addition, the ZKBS has given a comment to a study “Can the cultivation of gene maize MON810 be banned in Germany? A scientific and legal assessment” which was compiled on behalf of the Bund Ökologische Lebensmittelwirtschaft e.V. (BÖLW) and campact e.V.

**Table 7** Applications for approval of release of genetically modified plants on which the ZKBS provided a position statement in 2009.

| **Applicant** | **Plant** | **Major genetically engineered modifications** | **Time period** |
|---|---|---|---|
| BASF Plant Science GmbH, Ludwigshafen | potato | production of amylose-free starch: the potato expresses a fragment of the coding region of a starch synthase gene of potato (*granule bound starch synthase*, GBSS) in *antisense*-orientation | 2009 - 2010 |
| Syngenta Seeds GmbH, Bad Salzuflen | maize | herbicide resistance; the maize expresses an *in vitro* modified variant (*mepsps*) of the endogenous *epsps* gene of maize | 2009 - 2012 |
| University of Rostock | potato | a. production of the antigen VP60: the potato expresses a gene encoding the capsid protein of VP60 of *Rabbit hemorraghic disease virus*, or<br>b. production of a biopolymere (cyanophycin): the potato expresses the *cphA*$_{Te}$ gene encoding a storage protein from the cyanobacterium *Thermosynechococcus elongatus,* or<br>c. production of the non-toxic subunit of the cholera toxin B: the potato expresses a gene encoding the cholera toxin subunit B (*ctxB*) of *Vibrio cholerae.* | 2009 - 2012 |
| Justus-Liebig-University of Gießen | barley | protection against fungal infection: the barley expresses the *cThEn42(GC)* gene of *Trichoderma harzianum* und the *bar* gene of *Streptomyces hygroscopicus,* or<br>expression of a (1,3-1,4)-ß-glucane catabolizing enzyme: the barley expresses a synthetic gene of bacterial origin encoding (1,3-1,4)-ß-glucanase, the *bar* gene of *Streptomyces hygroscopicus* and the *sGFP* gene. | 2009 - 2010 |
| Monsanto Agrar Germany GmbH | maize | protection against damage by insect larvae and herbicide tolerance: the maize expresses a modified Cry1A protein, a variant of the *cry2Ab2* gene and a variant of the c*ry3Bb1* gene, all three genes derive from *Bacillus thuringiensis* subsp. *kurstaki*. In addition, it expresses the *epsps* gene of *Agrobacterium* sp. strain CP4. | 2009 - 2012 |
| University of Rostock | potato | biosafety research, tests on changes in biological parameters such as cold resistance; the potato expresses the *PsbY-cph*A$_{Te}$ gene of the cyanobacterium *Thermosynechococcus elongatus* | 2009 - 2011 |
| University of Rostock | petunia | plasmid transformation as a tool for biological containment: the petunia expresses the *aadA* gene and the *uidA* gene, both genes derive from *E. coli* | 2009 - 2012 |