German Federal Office
of Consumer Protection
and Food Safety

Annual report of the work of the Central Committee on Biological Safety in the year 2007

(BVL 64/2008/4)

16th report after the Genetic Engineering Act came into force

March 4, 2008

The report on activities of the Central Committee on Biological Safety in 2007 will be announced in the following.

Berlin, April 5, 2008

German Federal Office
of Consumer Protection and Food Safety

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Abbreviations

AAV	Adeno-associated virus
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 Safedy
EFSA	European Food Safety Authority
EEC	European Economic Community
EC	European Community
EHEC	enterohemorrhagic *Escherichia coli*
EU	European Union
FLI	Friedrich Löffler Institute, Federal Research Institute for Animal Health
GenTG	Genetic Engineering Act
GenTSV	Genetic Engineering Safety Regulations
GMO	genetically modified organism
HIV	Human immunodeficiency virus
JKI	Julius Kühn Institute, Federal Research Centre for Cultivated Plants
RKI	Robert Koch Institute
VIGS	virus-induced gene silencing
VSV	Vesicular stomatitis virus
ZKBS	Central Commission on Biological Safety

1 Introduction

1.1 Background to the ZKBS

The Central Committee on Biological Safety (ZKBS) is an expert committee comprising sixteen members and sixteen 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). It 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, 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 December 21, 2004 came into force on February 4, 2005. Essential changes also affected the structure of the ZKBS, resulting in the ZKBS being divided into two committees: one committee for genetic engineering operations in genetic engineering facilities, which continues to comprise sixteen members; and another committee for release and placing on the market, which comprises twelve members. These new arrangements have not yet been completed. The third Act to change the Genetic Engineering Laws was passed on March 17, 2006. It was stipulated in the transition regulations (§ 41) that until the two committees are formed the relevant tasks should be taken on by a special committee that corresponds to the previous structure of the ZKBS.

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. Further genetic engineering operations at containment level 1 can then be carried out without further registration, as long as the operating facility is already registered. 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 where the ZKBS has previously provided a position statement are to be examined and evaluated by the ZKBS.

Since the GenTG came into force in 1990, 1590 applications for containment level assignment of genetic engineering operations and evaluation of the required technical safety measures have been submitted to the ZKBS. 31 applications were submitted in the year of this report, and the ZKBS provided 25 position statements; at the end of the year 6 applications were still under review and were completed in 2008. Since 1992, the BVL has been informed by state authorities about 8175 position statements on genetic engineering operations, 462 of these in the year of this report. Table 1 lists the position statements from 2007 based on their containment level.

Table 1: Safety evaluated genetic engineering operations in Germany in 2007 (as of December 2007).

Position statement provided by	Containment level	Number
State Authority	S1	167
State Authority	S2	295
ZKBS	S1	1
ZKBS	S2	10
ZKBS	S3	13
ZKBS	S4	1

In Germany, a total of 5700 genetic engineering facilities have operating approval (as of December 2007). The BVL was informed by the relevant state authorities about 255 new genetic engineering facilities going into operation in 2007. 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 2007).

Operator	Containment level	Number
Public	S1	3323
Public	S2	1142
Public	S3	70
Public	S4	1
Private	S1	864
Private	S2	176
Private	S3	13

Further information about genetic engineering operations and genetic engineering facilities as well as about 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.

Exchange of experiences with the Committees on Biological Safety of other member states of the European Union

In June 2007, a meeting took place of the ZKBS with other European Committees on Biological Safety as well as with representatives of their respective secretariats on "Contained Use". Primary subjects were the proceedings of the committees and the basis of risk assessment of genetic engineering operations involving viruses and microorganisms. Examples of naturally occurring recombination of genetic material, new techniques for the modification of genetic material as well as a vector-recipient system called in Germany biological safety measure were discussed with respect to possible exemptions from the scope of the European Directive 98/81/EC of October 26, 1998 amending Directive 90/219/EEC on the contained use of genetically modified microorganisms.

In addition, several options for the communication of expertise on biological safety were discussed.

Deliberate Release

The term "deliberate release" means any intentional introduction of a GMO into the environment, if approval for placing this GMO on the market with the intention of releasing it later into the environment has not yet been granted. According to the Genetic Engineering Act, one must apply for approval for every intended release. This is then granted if according to current knowledge the planned release will present no hazard, or no preventable hazard in relation to the purpose of the release, to humans and the environment.

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 Biological Federal Institute for Agriculture and Forestry (BBA, since January 01, 2008: Julius Kühn Institute) 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 Löffler Institute (FLI) is also involved. Other EU member states are informed about the release application and can take a position on it.

Since the Genetic Engineering Act came into force, 195 applications for approval of a release have been made in Germany (as of December 2007). In 2007, nine new applications were submitted to the BVL, and three applications were approved in the same year. In total, ten new approvals were granted in 2007, seven approvals relating to applications made in the previous year. 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/EEC 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.

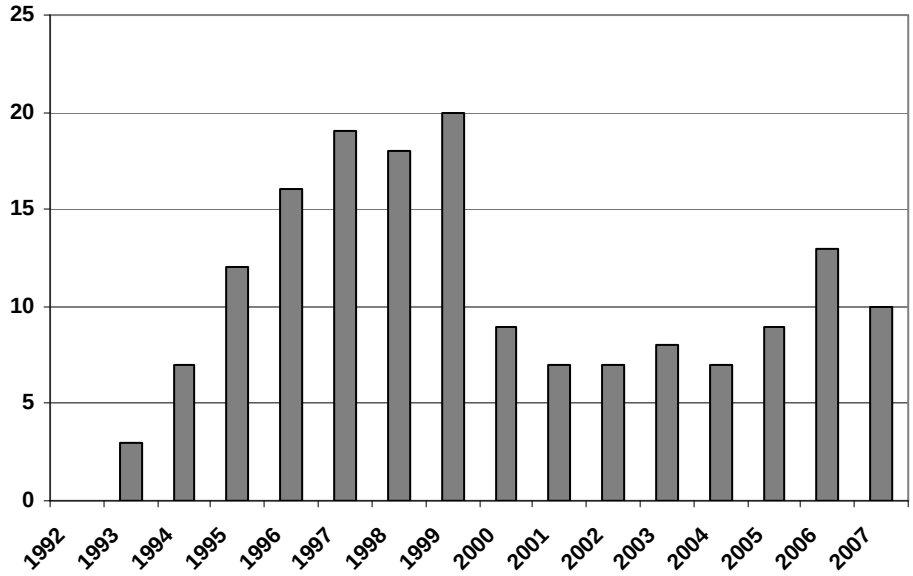

Figure 1: Number of approved releases in Germany since the GenTG came into force in 1990 (as of December 2007).

Figure 2 shows the annual number of notifications of further locations on approved releases according to the simplified procedure.

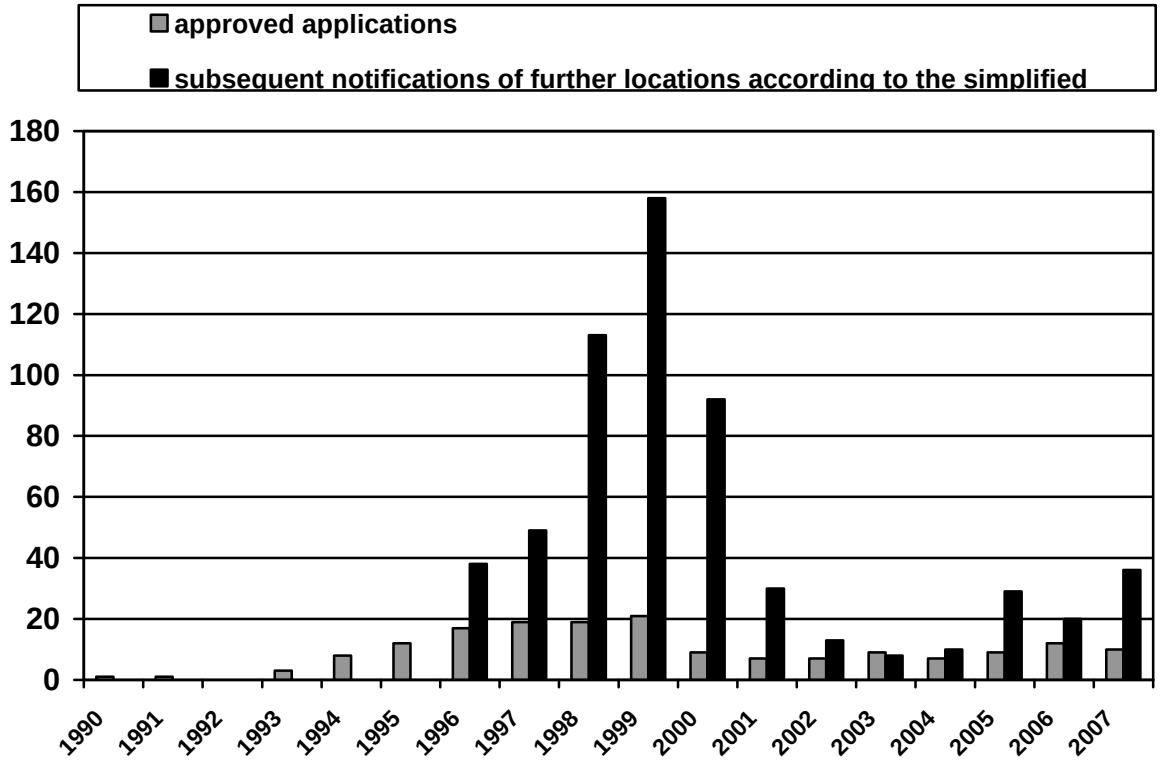

Figure 2: Number of approved deliberate releases and subsequent notifications of further locations according to the simplified procedure in Germany since the GenTG came into force in 1990 (as of December 2007).

For the year under report, the demolition of seven deliberate release areas for genetically modified crops in Germany was reported to the BVL:

May 2007	a deliberate release field destroyed by fuel oils in Bavaria, on which genetically modified potatoes had been cultivated and on which follow-up examinations were to be conducted
June 2007	a deliberate release field in Hesse with genetically modified barley
June 2007	a deliberate release field in North Rhine-Westphalia with genetically modified maize
July 2007	a deliberate release field in Mecklenburg-Western Pomerania with genetically modified maize
July 2007	a deliberate release field in Saxony with genetically modified maize
July 2007	a deliberate release field in Baden-Wuerttemberg with genetically modified maize
August 2007	a deliberate release field in Saxony with genetically modified maize

Due to this, the deliberate release experiments could not be analysed any longer.

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 2007, the previous years 2006, 2005 and 2004 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 in the years 1999, 2004, 2005, 2006 and 2007 (as of December 2007).

State	1999	2004	2005	2006	2007
Belgium	8	-	-	-	-
Czech Republic	-	-	2	5	5
Denmark	4	-	1	2	5
Finland	3	1	1	-	-
France	60	10	22	17	16
Germany	22	9	9	13	9
Great-Britain	11	1	-	1	2
Greece	6	-	-	-	-
Hungary	-	-	10	7	9
Ireland	-	-	-	1	-
Italy	47	3	1	-	-
Lithuania	-	-	-	-	2
Poland	-	-	3	3	-
Portugal	1	-	3	5	1
Rumania	-	-	-	-	14
Slovakia	-	-	-	-	-
Spain	56	18	20	41	45
Sweden	16	8	8	6	4
The Netherlands	19	5	3	8	5

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 Genetic Engineering Act came into force, a total of 2385 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

The term “placing on the market” of GMOs or products containing GMOs applies to making these products available to third parties. Placing of GMOs on the market requires approval. Since the decision to place a GMO on the market is made through an EU-wide approval procedure, it applies to all member states of the EU. All the relevant authorities of all EU member countries are involved in the approval process. 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 the BVL with position statements 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.

In the EU-wide processes it is distinguished whether the GMO may be used as feed or food [since 1997 regulation (EG) no. 258/97 for food, since 2004 regulation (EG) 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.

Table 4: GMOs approved by the EU (as of 2007).

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
Carnation Moonlite	modified flower colour	IP
Carnation Moonshadow 1	modified flower colour	C
Carnation Moonshadow 2	increased shelf life	C
Carnation Moondust	modified flower colour	IP
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
Maize 1507	herbicide and insect resistance	FF
Maize GA21	herbicide resistance	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
Soy MON40-3-2	herbicide resistance	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

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 of 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 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/

Advising the Federal Government

In December 2007, the ZKBS and the Federal Minister for Food, Agriculture and Consumer Protection, Horst Seehofer, met. The main focus of the discussion was on the position of the ZKBS regarding political advice to the Federal Ministry of Food, Agriculture and Consumer Protection, and a new structure in the European process for GMO approval, after which decisions should be reached on a scientific basis. The Federal Minister promised a closer cooperation between the Ministry and the ZKBS.

2 Structure of the ZKBS

The ZKBS brings together experts from various specialist fields. The specialist fields represented are defined in the Genetic Engineering Act (GenTG) and must be covered by the structure of the ZKBS. This makes it possible to institutionalise 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.

Table 5: Specialist areas and members of the ZKBS (as of December 2007).

Specialist area	Member	Representative member
Microbiology	Prof. Dr. Regine Hakenbeck TU Kaiserslautern	Prof. Dr. Klaus Lingelbach University of Marburg
Cell biology	Prof. Dr. Bernd Gänsbacher TU München	Prof. Dr. Achim Leutz Max Delbrück Center for Molecular Medicine, Berlin-Buch
Virology	Prof. Dr. Dr. h.c. Herbert Pfister University of Köln	Prof. Dr. Edgar Maiß University of Hannover
Virology	Prof. Dr. Angelika Vallbracht University of Bremen	Prof. Dr. Klaus Überla University of Bochum
Genetics	Prof. Dr. Jürgen Wienands University of Göttingen	Prof. Dr. Gerhard Wenzel TU München
Genetics	Prof. Dr. Alfred Pühler University of Bielefeld	Prof. Dr. Uwe Sonnewald University of Erlangen-Nürnberg
Hygiene	Prof. Dr. Uwe Groß University of Göttingen	Prof. Dr. Dr. Andreas Podbielski University of Rostock
Ecology	Prof. Dr. Marcus Koch University of Heidelberg	Prof. Dr. Stefan Vidal University of Göttingen
Ecology	Prof. Dr. Wolfgang Dott RWTH Aachen	Prof. Dr. François Buscot Helmholtz Center for Environmental Research GmbH, Halle
Technical safety	Dr. Jürgen Wahl Roche-Diagnostics GmbH, Penzberg	Dr. Uwe Bücheler Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach a.d. Riß
Trade unions	Prof. Dr. Dr. h.c. Wilfried Wackernagel University of Oldenburg	Dr. Manfred Keilert, Berlin
Business	Dr. Siegfried Throm Association of Research-based Pharmaceutical Companies, Berlin	Dr. Anja Matzk KWS SAAT AG, Einbeck
Employment protection	Frank Gerschke State Authority for Employment Protection, Potsdam	Dr. Hans-Josef Riegel Professional Trade Union of the Chemical Industry, Köln
Research-funding organisations	Dr. Ingrid Ohlert DFG, Bonn	Prof. Dr. Elisabeth Knust Max Planck Institute for Molecular Cell Biology and Genetics, Dresden
Environmental protection	Dr. Gerd Neemann BLaU Environmental Studies Göttingen	Prof. Dr. Thomas Eikmann University of Gießen
Consumer protection	Sigrid Lewe-Esch Working Group of Protestant Housekeeping Managers of the German Protestant Women's Federation e.V., Duisburg	Jutta Jaksche Federation of German Consumer Organisations e.V., Berlin

Prof. Dr. Dr. h.c. Herbert Pfister was elected chairperson of the ZKBS in July 2007. Vice-chairpersons are Prof. Dr. Angelika Vallbracht and Prof. Dr. Alfred Pühler.

In 2007, the members Prof. Dr. Klaus-Peter Schaal (hygiene), who had been chairperson until July 2007, Prof. Dr. Bernd Müller-Röber (research-funding organisations) and Prof. Wolfgang Dott (ecology) stepped down. New appointments were Prof. Dr. Regine Hakenbeck (microbiology), Prof. Dr. Achim Leutz (cell biology), Prof. Dr. Dr. Andreas Podbielski (hygiene), Prof. Dr. François Buscot (ecology) and Prof. Dr. Elisabeth Knust (research-funding organisations).

The structure of the ZKBS presented here corresponds to the previously valid version of the GenTG. When the Act for reforming the Genetic Engineering Laws came into force on February 4, 2005, the ZKBS was divided into two committees, but this new arrangement has not yet been completed. In the structure given here, as in the past, the ZKBS has taken into account the functions of both new committees yet to be established.

3 Advisory activities of the ZKBS in 2007

3.1 Working methods

In 2007, eight 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

In the year of this report two new working groups were set up. The first working group evaluated the actuality and accuracy of a ZKBS position statement from 1996, regarding the biological safety of antibiotic resistance genes in genetically modified plants. This working group comprised ZKBS representatives from the specialist areas of micro-biology, the union representative in the ZKBS, who is an expert in genetics, and representatives from the secretary of the ZKBS.

The second working group dealed with the risk assessment of highly pathogenic avian influenza viruses of subtypes H5, H7 and their derivative laboratory strains. This working group included the ZKBS experts for virology, the union representative in the ZKBS, who is an expert in genetics, as well as external experts from FLI, RKI, a few universities and representatives from the secretary of the ZKBS.

The 2006 founded working group, which was primarily concerned with the evaluation of safety measures corresponding the planning of new genetic engineering facilities at the RKI, held one meeting during the year under review. In addition this working group included experts of the ZKBS, regarding the experts for technical safety, employment safety, ecology and virology, representatives of the federal authority and the ZKBS secretary. Furthermore, 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.

The detailed examinations and discussions of the working groups are presented to the entire ZKBS and are integrated into a position statement of the ZKBS for the appropriate competent authority.

3.3 Advising the Federal Government

The ZKBS provided a position statement to the BMELV concerning the blueprint of the fourth amending law on the genetic engineering law.

3.4 Advising competent authorities of the Bundesländer within the scope of administrative assistance

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

- Classifying microorganisms that are to be used as donor or recipient organisms in genetic engineering operations (see Table 5)
- Risk assessment of replication defective Vesicular stomatitis virus pseudo-type particles
- Biological safety of genetically engineered maize MON810
- Safety evaluation of genetically modified Baculoviruses
- Evaluation of genetic engineering work with defective Lentivirus-like particles
- Differentiation between production area and laboratory as well as mapping of genetic engineering work
- Safety evaluation of genetic engineering work with a Newcastle disease virus vector vaccine against avian influenza viruses
- Downgrading of recombinant Human respiratory syncytial virus and Murine pneumonia virus
- Risk assessment of the vector pJET1 as a component of the Bluegene kit
- Risk assessment of genetic engineering work with TGFβ influenced signal transduction pathways / genes
- Risk assessment of cell line WPMY1
- Contamination of cell cultures with Squirrel Monkey retrovirus

3.5 Risk assessment of donor or recipient organisms

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 of the Genetic Engineering Safety Regulations (GenTSV):

Table 6: Newly classified assigned microorganisms.

Organism	Risk group
Viruses	
Cytomegalovirus (HCMV) strains AD169 and Towne	1
Marek´s disease virus (MDV BAC20 and MDV CVI988 BAC)	2
Rabies virus vaccine strain SAD B19	2
Salem virus	2
Squirrel monkey retrovirus	2
Torque teno Virus	2

Chikungunya virus	3**
Highly pathogenic Avian influenza virus, strain A/Vietnam/1203/04	3
Bacteria	
Clostridium orbiscindens (DSM 6740)	1
Eubacterium ramulus (DSM 15684)	1
Kluyvera cryocrescens	2
Mycobacterium smegmatis laboratory strain mc^2155	2
Mycobacterium tuberculosis H37Rv ΔnarG (GMO)	3
Fungi	
Alternaria alternata	1
Asteriochloris spec.	1
Dendryphiella arenaria	1
Trebouxia arboricola	1
Trebouxia simplex	1
Xanthoria parietina	1
Alternaria alternata pathovar *malus* (*Alternaria mali*)	2
Candida albicans strain HLC84	2
Plasmopara halstedii (syn. *Plasmopara helianti*)	2
Parasites	
Eimeria nieschulzi	2
Cell lines	
CR (embryonic duck cell line)	1

3.6 Containment level assignment for genetic engineering operations

In 2007, the ZKBS provided 23 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

Genetic engineering operations to establish a packing system for alpha virus based vaccines

Containment level 2

Genetic engineering operations

- to produce AAV2 vectors with genes of prion proteins and neurotrophic factors
- to produce genetically modified *Eimeria nieschulzi* oocystes
- to transfer a GFP gene into avirulent strains of *Bacillus anthracis*
- to generate cytotoxic AAV vectors

– to characterise neurons with recombinant toxins through in vitro and in vivo manipulation of specific receptors
– to produce recombinant vaccine derived Measles virus
– to identify bacterial genes which encode flavinoid catalysing enzymes
– on adenoviral oncolysis

Containment level 3

Genetic engineering operations

– to identify candidates for drugs against the human immunodeficiency virus
– to analyse recombinant Human immunodeficiency virus (HIV) with chemotherapy drug resistances
– on the relevance of anaerobic nitrate reduction for intracellular survival of *Mycobacterium tuberculosis*
– to investigate Chikungunya virus
– to generate genetically modified Lyssaviruses
– to investigate the effect of APOBEC-3G on HIV-1
– to investigate viral non-structural gene derivatives of Bunyaviruses
– to identify HIV envelope epitopes by neutralising antibodies
– to characterise host factors which facilitate host transition of avian influenza A viruses
– to develop a Marek's disease virus derived vaccine against avian influenza
– with recombinant chimeric VSV, Lymphocytic choriomeningitis virus and Vaccinia viruses
– to produce EHEC mutants
– to investigate Shiga-like toxins
– to characterise the impact of genes from *Mycobacterium tuberculosis* and *Mycobacterium bovis* in virulence and latency

Containment level 4

Genetic engineering operations with recombinant filoviruses

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 Genetic Engineering Safety Regulations (GenTSV), the ZKBS thoroughly examined the technical and building safety measures in individual genetic engineering facilities and produced position statements on:

– Building of new genetic engineering facilities with safety measures corresponding to containment level 4
– Building of new genetic engineering facilities with safety measures corresponding to containment level 3

– Building a new genetic engineering laboratory with safety measures corresponding to containment level 3 for work with HIV (reduced safety measures regarding reduced infectivity via air)

3.8 Publication of general position statements

The ZKBS passed the following general position statements, which were published in the Federal Bulletin:

– Position statement of the ZKBS on criteria for assessing and categorising plant viruses, phytopathogenic fungi and phytopathogenic bacteria as donor and recipient organisms in genetic engineering operations
Ref. No. 6790-10-53, April 2007

– General position statement of the ZKBS on frequently carried out genetic engineering operations based on the criteria of comparability: Genetic engineering operations with Sindbis virus and Semliki Forest virus expression systems
Ref. No. 6790-10-50, revised version from September 2007

– General position statement of the ZKBS on safety measures for handling retroviruses of risk group 3**
Ref. No. 6790-10-80 1, revised version from September 2007

– General position statement of the ZKBS on risk assessment of *E. coli* K12 containing the cDNA of a complete retrovirus genome
Ref. No. 6790-10-89, December 2007

– General position statement of the ZKBS on frequently carried out genetic engineering operations based on the criteria of comparability: gene transfer using retroviral vectors
Ref. No. 6790-10-41, October 2007

– Position statement of the ZKBS on risk assessment of highly pathogenic avian influenza virus A strains of subtype H5 and H7 and derived laboratory strains according to § 5 Paragraph 1 of the Genetic Engineering Safety Regulations
Ref. No. 6790-05-02-34, March 2007

– Supplementary position statement of the ZKBS on the biological safety of antibiotic resistance genes in the genome of genetically modified plants
Ref. No. 6790-10-62, June 2007

3.9 Position statements on releases

In 2007, the ZKBS provided position statements for the BVL on the twelve applications for approval of release of GMOs listed in Table 7. The table specifies applicants, plants, major genetic modifications with their expected effects and the time period for the planned release. Eight of these applications were already submitted in 2006, and the four applications listed last in the table were submitted in 2007. All twelve were supported by the ZKBS and approved by the BVL.

3.10 Placing on the market

No position statements are provided on applications for approval of placing on the market since no applications for approval are submitted through Germany according to the directive 2001/18/EC of the EU. However, the ZKBS provided a position statement on the biological safety of maize MON810 on demand of the federal states.

Table 7: Applications for approval of release of genetically modified plants on which the ZKBS provided a position statement in 2007.

Applicant	Plant	Major genetically engineered modifications	Time period
Pioneer Hi-Breed	Maize	Maize hybrid 59122x1507xNK603; resistance to herbicide and insects; modified copies of genes *cry34Ab1* (14 kDa δ–endotoxin and 44 kDa –endotoxin) of *Bacillus thuringiensis* strain PS149B1, modified copy of phosphinothricin-N-acetyltransferase gene (*pat)* of *Streptomyces viridochromogenes*, *cry1F* of *Bacillus thuringiensis* subsp. *aizawai,* 5-enol-pyruvyl-shikimate-3-phosphate-synthase gene (*cp4 epsps)* of *Agrobacterium* sp. strain CP4	2007 - 2010
Pioneer Hi-Breed	Maize	Maize hybrid 1507xNK603, resistance to herbicide and insects; *cry1F, pat*, *cp4 epsps*	2007 - 2010
Pioneer Hi-Breed	Maize	Maize hybrid, resistance to herbicide; *cp4 epsps*	2007 - 2010
Novoplant GmbH	Pea	Production of scFv antibody against F4 fimbriae; *Pisum sativum* line BA11-2; scFv antibody BA11 of *Mus musculus*	2007
BASF Plant Science GmbH	Potato	Carbohydrate metabolism and resistance to *Phytophthora infestans;* fragment of granule bound starch synthase (*gbss*) of potato, either in antisense orientation or in sense- and antisense orientation, acetohydroxy-acid synthase gene *(ahas)* of *Arabidopsis thaliana* or fragment of the branching enzyme genes 1 and 2 (*be*1 und *be*2) of *Solanum tuberosum*, each in sense snd antisense orientation, *ahas* or two *Phytophthora infestans* resistance genes *Rpi-blb1* and *Rpi-blb2* of wild potato *Solanum bulbocastanum*, *ahas*	2007 - 2011
BASF Plant Science GmbH	Potato	Carbohydrate metabolism; Potato (*Solanum tuberosum*) line EH92-527-1; *npt*II of *Escherichia coli*, fragment of *gbss* in antisense orientation	2007 - 2008
Fraunhofer Gesellschaft zur Förderung der angewandten Forschung e.V.	Maize	Maize hybrid MON 88017 x MON 810; resistance to herbicide and insects; synthetic variant (Cry1A.105) of *cry1A(b)* of *Bacillus thuringiensis* subsp. *kurstaki*, synthetic variant of c*ry3Bb1* of *Bacillus thuringiensis* ssp. *kumamotoensis*, *cp4 epsps ,* gene of glyphosate oxidoreductase of *Ochrobactrum anthropi* sp. strain LBAA.	2007 - 2010
Monsanto Agrar Deutschland GmbH	Maize	Maize hybrid MON89034 x MON88017; resistance to herbicide and insects; *cp4 epsps,* synthetic variant of c*ry3Bb1*, synthetic gene encoding Cry1A.105*, cry2Ab2*	2007 - 2011

Applicant	Plant	Major genetically engineered modifications	Time period
		Maize hybrid MON89034 x NK603, resistance to herbicide and insects; *cry2Ab2*, *cp4 epsps*, synthetic gene encoding Cry1A.105	
Max Planck Institute for Chemical Ecology	Black Nightshade	Reduction of insect resistance; internal gene fragment of proteinase inhibitor 2b (*pin*2b) of *S. nigrum* in antisense orientation, intron 3 of pyruvate-ortho-phosphate-dikinase gene (*pdk* i3) of *Flaveria trinervia* (Asteraceae), internal gene fragment of proteinase inhibitor 2b (*pin*2b) of *S. nigrum* in antisense orientation, hygromycin resistance (*hpt*II) from *E. coli*	2007 - 2009
Max Planck Institute for Chemical Ecology	Black Nightshade	Reduction of insect resistance; internal fragment of prosystemine gene (*nigpro*) of *S. nigrum* in antisense orientation, *pdk* i3, internal fragment of prosystemine gene (*nigpro*) of *S. nigrum* in antisense orientation, *hpt*II	2007 - 2010
Max Planck Institute for Chemical Ecology	Black Nightshade	Reduction of insect resistance; internal gene fragment proteinase inhibitors Pin1 and Pin2b of *S. nigrum* in antisense orientation, *pdk* i3, internal gene fragment proteinase inhibitors Pin1 and Pin2b of *S. nigrum* in antisense orientation, *hpt*II	2007 - 2009
Planta GmbH	Sugar Beets	resistance to herbicide; *cp4 epsps*	2008 - 2011

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