

**Act on the Reform of the Communicable Diseases Law
(Communicable Diseases Law Reform Act)
*Gesetz zur Neuordnung seuchenrechtlicher Vorschriften -
(Seuchenrechtsneuordnungsgesetz - SeuchRNeuG)***

of 20 July 2000

The following Act has been adopted by the Bundestag with the consent of the Bundesrat:

Article 1

**Act on the Prevention and Control of Infectious Diseases in Man
(Protection against Infection Act)
*Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten
beim Menschen
(Infektionsschutzgesetz - IfSG)***

Table of Contents

Chapter One - General provisions

- Section 1 Purpose of the Act
- Section 2 Definition of terms
- Section 3 Prevention through information

Chapter Two - Co-ordination and early detection

- Section 4 Tasks of the Robert Koch Institute
- Section 5 Mutual information procedure for the Federal and Laender authorities

Chapter Three - Notification system

- Section 6 Notifiable diseases
- Section 7 Notifiable evidence of pathogens
- Section 8 Persons obliged to notify
- Section 9 Notification on a named-patient basis
- Section 10 Notification on a non-named patient basis
- Section 11 Communications by the health office and the competent Land authority
- Section 12 Notification to the World Health Organization and the European Network
- Section 13 Sentinel surveys
- Section 14 Identification of diseases to be monitored via sentinel surveys
- Section 15 Adaptation of the obligation to notify to the epidemiological situation

Chapter Four - Prevention of communicable diseases

- Section 16 General measures to be taken by the competent authority
- Section 17 Special measures to be taken by the competent authority, ordinances issued by the Laender
- Section 18 Decontamination, disinfestation and control of vertebrate vectors of pathogens, ordered by an authority, costs
- Section 19 Tasks of the health office in special cases
- Section 20 Vaccination and other measures of specific prophylaxis
- Section 21 Vaccines
- Section 22 Vaccination card
- Section 23 Nosocomial infections, resistances

Chapter Five - Control of communicable diseases

- Section 24 Treatment of communicable diseases
- Section 25 Investigations, duties of the health office to inform in respect of blood, organ or tissue donors
- Section 26 Implementation
- Section 27 Participation of the physician in charge of treatment
- Section 28 Protective measures
- Section 29 Observation
- Section 30 Quarantine
- Section 31 Prohibition of professional activities

Section 32 Issue of Ordinances

Chapter Six - Additional provisions for schools and other community facilities

Section 33 Community facilities

Section 34 Health requirements, duties to co-operate, tasks of the health office

Section 35 Instruction of persons caring for children and young persons

Section 36 Compliance with infection control hygiene

Chapter Seven - Water

Section 37 Quality of water for human use and water for swimming and bathing pools, monitoring

Section 38 Issue of ordinances

Section 39 Analyses, measures taken by the competent authorities

Section 40 Tasks of the Federal Environmental Agency

Section 41 Sewage

Chapter Eight - Health requirements for food-handlers

Section 42 Prohibitions with respect to engaging in or employing another to engage in food-handling activities

Section 43 Instruction, certificate by the health office

Chapter Nine - Activities involving pathogens

Section 44 Requirement to obtain an authorization for activities involving pathogens

Section 45 Exceptions

Section 46 Activities under supervision

Section 47 Grounds for refusal, prerequisites for granting an authorization

Section 48 Revocation and withdrawal

Section 49 Obligation to notify

Section 50 Notice of change

Section 51 Supervision

Section 52 Supply

Section 53 Requirements for premises and installations, precaution against risk

Chapter Ten - Competent authority

Section 54 Notification of the authority

Chapter Eleven - Approximation to Community law

Section 55 Approximation to Community law

Chapter Twelve - Compensation in special cases

Section 56 Compensation

Section 57 Relation to social insurance schemes and employment promotion

Section 58 Reimbursement of expenses

Section 59 Special provision for germ carriers

Section 60 Pension in the case of vaccine injuries and health impairments due to other measures of specific prophylaxis

Section 61 Recognition of health impairment

Section 62 Therapy

Section 63 Concurrence of claims, application of provisions of the Federal War Victims' Compensation Act, transitory regulations for the reimbursement procedure to the health insurance funds

Section 64 Competent authority for pensions

Section 65 Compensation for official measures

Section 66 Entity liable to pay

Section 67 Attachment

Section 68 Recourse to the courts

Chapter Thirteen - Costs

Section 69 Costs

Chapter Fourteen - Special Provisions

Section 70 Tasks of the Bundeswehr and the health office

Section 71 Tasks under the Seamen's Law

Section 72 Tasks of the Federal Railway Agency

Chapter Fifteen - Penal Provisions and Provisions on Administrative Fines

Section 73 Provisions on administrative fines

Section 74 Penal provisions

Section 75 Additional penal provisions

Section 76 Confiscation

Chapter Sixteen - Transitory provisions

Section 77 Transitory provisions

Article 5

Entry into force, repeal

Chapter One

General provisions

Section 1

Purpose of the Act

(1) It is the purpose of this Act to prevent communicable diseases in human beings, to detect infections at an early point in time and to prevent their spread.

(2) The participation of and co-operation between authorities at the Federal, Laender and local levels, physicians, veterinary surgeons, hospitals, scientific establishments well as any other parties involved that is necessary for the above purpose shall correspond to the current state of medical and epidemiological science and technology and shall be supported. The individual responsibility of the bodies responsible for and persons in charge of community facilities, food-handling establishments, health facilities and the personal responsibility of each individual in preventing communicable diseases shall be clearly explained and encouraged.

Section 2

Definition of terms

For the purposes of the Act,

1. **pathogen**
is an agent capable of replication (virus, bacterium, fungus, parasite) or any other transmissible biological agent capable of causing an infection or communicable disease in human beings,
2. **infection**
is the entry of a pathogen and its subsequent development or replication in the human body,
3. **communicable disease**
is a disease caused by pathogens or the toxins they produce that are communicated to humans directly or indirectly,
4. **ill**
is a person who suffers from a communicable disease,

5. suspected of being ill
is a person who shows symptoms suggestive of the presence of a specific communicable disease,
6. germ carrier
is a person who excretes pathogens and can thus be a source of infection for the general public without being ill or suspected of being ill,
7. suspected of being contagious
is a person who can be assumed to be infected with pathogens without being ill, suspected of being ill or a germ carrier
8. nosocomial infection
is an infection with topical or systemic symptoms of infection in response to the presence of agents or their toxins that is temporally related to a inpatient or outpatient medical measure, unless it is a pre-existing infection,
9. immunisation
is the administration of a vaccine designed to afford protection against a communicable disease,
10. other measure of specific prophylaxis
is the administration of antibodies (passive immunoprophylaxis) or administration of medication (chemoprophylaxis) to afford protection against the spread of certain communicable diseases,
11. vaccine injury
are the health-related and economic consequences of a health impairment due to vaccination the degree of which exceeds that of a normal post-vaccinal reaction; a vaccine injury is also present if agents capable of replication were used for vaccination and persons other than the person vaccinated were injured,

12. pest
is an animal by which pathogens may be transmitted to humans,
13. sentinel survey
an epidemiological method of ascertaining by means of sample surveys the incidence of certain communicable diseases and the immunity to certain communicable diseases among defined subsets of the population,
14. health office
the authority designated under Laender law to implement this Act and which employs a Public Health Officer.

Section 3

Prevention through education

Providing the general public with information and education about the risks of communicable diseases and the possibilities of preventing them is a public function. Particularly the authorities responsible under Laender law have to provide information about possibilities of community and individual protection against infection as well as about counselling, care and treatment services.

Chapter Two

Co-ordination and early detection

Section 4

Tasks of the Robert Koch Institute

(1) Within the framework of this Act, the Robert Koch Institute has the task of developing concepts for the prevention of communicable diseases as well as for the early detection of infections and the prevention of their spread. This includes the development and conduct of epidemiological and laboratory analyses as well as research into the causes, the diagnosis and prevention of communicable diseases. In the field of zoonoses and food-borne infections, the Federal Institute for Health Protection of Consumers and Veterinary Medicine (*Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin*) shall be involved. At the request of the supreme health authority of a Land, the Robert Koch Institute advises the competent authorities on measures for the prevention and detection of serious communicable diseases and the prevention of their spread and advises the supreme health authorities on

measures involving more than one Land. It collaborates with the respective competent Federal authorities, the competent Laender authorities, the national reference centres, other scientific establishments and professional societies as well as foreign and international organisations and authorities and executes co-ordinating functions within the framework of the European network for the epidemiological surveillance and control of communicable diseases.

(2) The Robert Koch Institute

1. draws up in consultation with the respective competent federal authorities guidelines, recommendations, leaflets and other information on the prevention and detection of communicable diseases and the prevention of their spread as a measure of preventive health protection addressed at technical circles,
2. shall prepare and update according to the respective epidemiological requirements
 - a) criteria (case definitions) for the reporting of a case of illness or death and means of detecting pathogens,
 - b) shall stipulate the nosocomial infections and pathogens with special resistances and multiple resistances that are to be recorded pursuant to section 23 paragraph 1,

and publish them in form of a list in the Federal Health Gazette (*Bundesgesundheitsblatt*),

3. compiles the notifications made under this Act to evaluate them under epidemiological aspects,
4. makes the compilations and the results of the epidemiological evaluations available to the competent Federal authorities, the medical service of the *Bundeswehr* (Federal Armed Forces), the supreme health authorities of the Laender, the health offices, medical associations of the Laender, the central associations of the health insurance funds, the Federal Association of panel doctors (*Kassenärztliche Bundesvereinigung*), the central office for health and safety at work of the German professional associations (*Berufsgenossenschaftliche Zentrale für Sicherheit und Gesundheit - BGZ*) and the German Hospital Federation (*Deutsche Krankenhausgesellschaft*) and publishes them on a periodic basis,

5. may carry out sentinel surveys as specified in sections 13 and 14 to fulfil the tasks under this Act.

Section 5

Mutual information procedure for the Federal and Laender authorities

The Federal Government, by means of a general administrative regulation with the consent of the Bundesrat, draws up a plan for the mutual information of the Federal and Laender authorities in epidemiologically significant cases in order to

1. prevent the importation into the Federal Republic of Germany of dangerous communicable diseases or to prevent their spread,
2. initiate the necessary measures wherever a spatial or temporal cluster of a dangerous communicable disease or cases of dangerous illness occurs that may be due to pathogens and is likely to spread beyond one Land.

The administrative regulation may also regulate the co-operation between the Federal and Laender authorities involved and other entities involved.

Chapter Three

Notification system

Section 6

Notifiable diseases

(1) The following shall be notified on a named-patient basis:

1. suspect cases, clinical cases of and deaths from
 - a) botulism
 - b) cholera
 - c) diphtheria
 - d) human spongiform encephalopathy, other than familial hereditary forms
 - e) acute infective hepatitis
 - f) enteropathic hemolytic uremic syndrome (HUS)
 - g) viral hemorrhagic fever

- h) measles
- i) meningococcal meningitis or sepsis
- j) anthrax
- k) poliomyelitis (to be suspected in every case of acute flaccid paralysis unless trauma-induced)
- l) plague
- m) rabies
- n) abdominal typhus/ paratyphoid fever

as well as clinical cases and deaths from tuberculosis requiring treatment even in the absence of bacteriological evidence,

2. suspect cases and clinical cases of a food-borne infection or acute infectious gastro-enteritis, if
 - a) the person affected exercises an activity within the meaning of section 42 paragraph 1,
 - b) two or more similar cases occur which are likely or assumed to be epidemiologically linked,
3. the suspicion of a health impairment the degree of which exceeds that of a normal post-vaccinal reaction,
4. the injury caused to a person by an animal suffering from or suspected of suffering from or suspected of being infected with rabies as well as any contact with such an animal or animal carcass,
5. where not already notifiable under numbers 1 to 4, the occurrence of
 - a) a dangerous disease or
 - b) two or more similar cases that are likely or assumed to be epidemiologically linked,

if this suggests a grave danger for the general public and may be due to pathogens other than those mentioned in section 7.

Notifications pursuant to sentence 1 shall be made according to section 8 paragraph 1 nos. 1, 3 to 8, section 9 paragraph 1, 2, 3 sentence 1 or 3 or paragraph 4.

(2) In addition to the notification under paragraph 1 no. 1, the health office shall be informed wherever persons suffering from pulmonary tuberculosis requiring treatment refuse or discontinue such treatment. The notification pursuant to sentence 1 shall be made according to section 8 paragraph 1 no. 1, section 9 paragraphs 1 and 3 sentence 1 or 3.

(3) The health office shall be immediately notified on a non-named patient basis of any cluster of nosocomial infections which are likely or assumed to be epidemiologically linked as constituting an outbreak. Notifications pursuant to sentence 1 shall be made according to section 8 paragraph 1 nos. 1, 3 and 5, section 10 paragraph 1 sentence 3, paragraphs 3 and 4 sentence 3.

Section 7

Notifiable evidence of pathogens

(1) Any direct or indirect evidence of the following pathogens shall be notified on a named-patient basis, if the evidence suggests an acute infection:

1. Adenoviruses; only direct evidence from conjunctival smears is notifiable
2. Bacillus anthracis
3. Borrelia recurrentis
4. Brucella sp.
5. Campylobacter sp., enteropathogenic
6. Chlamydia psittaci
7. Clostridium botulinum or evidence of toxins
8. Corynebacterium diphtheriae, toxin-producing
9. Coxiella burnetii
10. Cryptosporidium parvum
11. Ebola virus
12. a) Escherichia coli, enterohemorrhagic strains (EHEC)
b) Escherichia coli, other enteropathogenic strains
13. Francisella tularensis
14. SSME virus
15. Yellow fever virus
16. Giardia lamblia
17. Haemophilus influenzae; only direct evidence obtained from liquor or blood is notifiable
18. Hanta viruses

19. Hepatitis A virus
20. Hepatitis B virus
21. Hepatitis C virus; all types of evidence are notifiable unless chronic infection is known to be present
22. Hepatitis D virus
23. Hepatitis E virus
24. Influenza viruses; only direct evidence is notifiable
25. Lassa virus
26. Legionella sp.
27. Leptospira interrogans
28. Listeria monocytogenes; only direct evidence obtained from blood, liquor or from other normally sterile sites as well as from smears taken from new-borns is notifiable
29. Marburg virus
30. Measles virus
31. Mycobacterium leprae
32. Mycobacterium tuberculosis/africanum, mycobacterium bovis; notifiable is the direct evidence of pathogens and subsequently the result of resistance determination; initially also evidence of acid-fast bacilli in the sputum
33. Neisseria meningitidis; also direct evidence from liquor, blood, hemorrhagic infiltrations of the skin or from other normally sterile sites is notifiable
34. Norwalk-like virus; only direct evidence from stool is notifiable
35. Polio virus
35. Rabies virus
36. Rickettsia prowazekii
38. Rotavirus
39. Salmonella paratyphi; all types of direct evidence are notifiable
40. Salmonella typhi; all types of direct evidence are notifiable
41. Salmonella, others
42. Shigella sp.
43. Trichinella spiralis
44. Vibrio cholerae 01 and 0139
45. Yersinia enterocolitica, enteropathogenic
46. Yersinia pestis
47. Other agents of hemorrhagic fevers.

Notifications pursuant to sentence 1 shall be made according to section 8 paragraph 1 nos. 2, 3, 4 and paragraph 4, section 9 paragraphs 1, 2, 3 sentence 1 or 3.

(2) Pathogens other than those stipulated in this regulation shall be notified on a named-patient basis if their spatial and temporal cluster suggests the presence of a grave danger for the public. Notifications pursuant to sentence 1 shall be made according to section 8 paragraph 1 nos. 2, 3 and paragraph 4, section 9 paragraphs 2, 3 sentence 1 or 3.

(3) Direct or indirect evidence of the following pathogens shall be notified on a non-named-patient basis:

1. Treponema pallidum
2. HIV
3. Echinococcus sp.
4. Plasmodium sp.
5. Rubella virus; only congenital infections are notifiable
6. Toxoplasma gondii; only congenital infections are notifiable.

Notifications pursuant to sentence 1 shall be made according to section 8 paragraph 1 nos. 2, 3 and paragraph 4, section 9 paragraphs 2, 3 sentence 1 or 3.

Section 8

Persons obliged to notify

(1) The following persons shall be obliged to notify:

1. in the case of section 6 the physician who has established the finding; in hospitals or other facilities providing in-patient care, the person responsible for notification shall be the chief physician in addition to the physician who has established the finding, in hospitals with several independent departments, the chief physician in the department, and in hospitals which have no chief physician, the attending physician,
2. in the case of section 7 the heads of medical control laboratories (*Medizinaluntersuchungsämter*) and other private or official laboratories including hospital laboratories,
3. in the case of sections 6 and 7 the heads of facilities for pathological and anatomical diagnosis if the finding is certain or highly likely to suggest the presence of a notifiable disease or infection by a notifiable pathogen,

4. in the case of section 6 paragraph 1 no. 4 and in the case of section 7 paragraph 1 no. 36 for animals with which human beings had contact, also the veterinary surgeon,
5. in the case of section 6 paragraph 1 nos. 1, 2 and 5 and paragraph 3 members of any paramedical profession the exercise or use of professional title of which requires a state-regulated training or recognition,
6. in the case of section 6 paragraph 1 nos. 1, 2 and 5 the responsible pilot of an aircraft or the captain of a sea-going vessel,
7. in the case of section 6 paragraph 1 nos. 1, 2 and 5 the heads of nursing facilities, prisons, residential institutions, camps or similar facilities,
8. in the case of section 6 paragraph 1 the alternative medical practitioner.

(2) The obligation to notify shall not apply to personnel of the emergency medical service if the patient was taken to a physician-directed facility without delay. The obligation to notify shall apply to the persons stipulated in paragraph 1 nos. 5 to 7 only if a physician was not called in.

(3) The obligation to notify does not apply if the person obliged to notify has evidence before him/her that the notification has already been made and data other than those already notified were not recorded. Sentence 1 shall also apply to cases of illness already notified as suspect cases.

(4) Paragraph 1 no. 2 shall apply *mutatis mutandis* to persons who have the test for the detection of pathogens performed outside the territory covered by this Act.

(5) The person obliged to notify shall inform the health office immediately if a suspect case notified is not confirmed.

Section 9
Notification on a named-patient basis

(1) Notification on a named-patient basis by one of the persons mentioned in section 8 paragraph 1 nos. 1, 4 to 8 must contain the following information:

1. surname, forename of the patient
2. sex
3. day, month and year of birth
4. address of the main residence and, if not identical: address of the current abode
5. activity in facilities within the meaning of section 36 paragraph 1 or 2; activity within the meaning of section 42 paragraph 1 in case of acute gastro-enteritis, acute viral hepatitis, abdominal typhus/paratyphoid fever and cholera
6. cared for in a community facility pursuant to section 33
7. diagnosis or suspected diagnosis
8. date of clinical presentation or date of diagnosis, if applicable date of death
9. likely source of infection
10. country in which the infection was presumably acquired; for tuberculosis country of birth and nationality
11. name, address and telephone number of the laboratory charged with diagnosing the pathogen
12. referral to a hospital or admission to a hospital or other institution providing in-patient care and discharge from the institution, if known to the person obliged to notify
13. any blood, organ or tissue donation within the preceding six months
14. name, address and telephone number of the notifier
15. for a notification pursuant to section 6 paragraph 1 no. 3 the information specified in section 22 paragraph 2.

For the persons mentioned in section 8 paragraph 1 nos. 4 to 8, the obligation to notify is limited to the information available to them.

(2) Notification on a named-patient basis by a person mentioned in section 8 paragraph 1 nos. 2 and 3 shall contain the following information:

1. surname, forename of the patient
2. sex, if known
3. day, month and year of birth, if known

4. address of the main residence and, if not identical: address of the current abode, if known
5. type of investigational material
6. date of receipt of the investigational material
7. method of detection
8. examination finding
9. name, address and telephone number of the submitting physician or hospital
10. name, address and telephone number of the notifier.

When testing for the presence of hepatitis C, the submitting physician shall advise the person obliged to notify as to whether he/she knows the patient to be suffering from chronic hepatitis C.

(3) Notification on a named-patient basis shall be made immediately to the health office responsible for the abode of the affected person, in the case of paragraph 2 the health office responsible for the submitting physician, not later than 24 hours after the detection of the case. Notification may not be delayed because of the absence of individual pieces of information. These shall be immediately supplied or corrected as they become available. Should the main residence or the habitual abode of the person affected lie in the jurisdiction of another health office, the health office notified shall immediately inform the health office responsible either for the person's main residence or, if the person has several places of residence, his/her habitual abode.

(4) The responsible pilot of an aircraft or the captain of a sea-going vessel shall notify the airport or port physician of the national places of destination and departure of any notifiable diseases detected on the way. The physicians in charge there shall pass the notification on to the health office responsible for the airport or port concerned.

(5) The health office may process and use the personal data notified only for the purpose of executing its functions under this Act. Personal data shall be deleted, once their existence is no longer required for the health office to execute the functions within its remit; however, data pursuant to section 7 para 1 no. 21 shall be deleted after three years at the latest.

Section 10

Notification on a non-named-patient basis

(1) Notification on a non-named-patient basis under section 7 paragraph 3 shall contain the following information:

1. in the case of section 7 paragraph 3 no. 2 a case-based coding pursuant to paragraph 2
2. sex
3. month and year of birth
4. the first three numbers of the postal code of the main residence
5. examination finding
6. month and year of diagnosis
7. type of investigational material
8. method of detection
9. likely route of infection, likely risk of infection
10. country in which the infection was probably acquired
11. name, address and telephone number of the notifier
12. for malaria information relating to the exposure prophylaxis and chemoprophylaxis.

The physician submitting the investigational material shall support the person obliged to notify particularly with respect to the information stipulated in numbers 9, 10 and 12. Notification on a non-named-patient basis pursuant to section 6 paragraph 3 shall contain the information stipulated in numbers 5, 9 and 11 as well as the name and address of the institution concerned.

(2) The case-based coding consists of the third letter of the forename combined with the number of letters of the forename and the third letter of the first surname combined with the number of letters of the first surname. In case of double-barrelled names only the first part of the name is considered; umlauts are given as two letters. Name adjuncts are not considered.

(3) For the persons mentioned in section 8 paragraph 1 nos. 3 and 5, the scope of the notification is limited to the information already available to them.

(4) Notification on a non-named-patient basis pursuant to section 7 paragraph 3 must be made to the Robert Koch Institute within two weeks. A formsheet prepared by the Robert Koch Institute or a suitable data carrier shall be used for this purpose. Section 9 paragraph 3

sentences 1 to 3 shall apply *mutatis mutandis* to notifications on a non-named-patient basis pursuant to section 6 paragraph 3.

(5) Information pursuant to paragraph 2 and the information about the month of birth may be processed and used by the Robert Koch Institute only to check if several notifications refer to the same person. It shall be deleted as soon as the resultant restriction to the checks pursuant to sentence 1 is no longer likely to cause a not insignificant distortion of the epidemiological evaluation to be obtained from the notifications, but after ten years at the latest.

Section 11

Communications by the health office and the competent Land authority

(1) Any cases of illness and death as well as evidence of pathogens notified on a named-patient basis to the health office responsible for the patient's main residence are compiled to establish a diagnosis based on the case definitions published pursuant to section 4 paragraph 2 no. 2 letter a and communicated weekly, not later than on the third working day of the following week, to the competent Land authority and from the latter to the Robert Koch Institute within the space of one week, including none other than the following information:

1. sex
2. month and year of birth
3. competent health office
4. date of clinical presentation or date of diagnosis, if applicable date of death and, if possible, point in time or time window of infection
5. type of diagnosis
6. likely route of infection, likely risk of infection, belonging or not to a cluster of cases
7. country, if the infection is likely to have been acquired abroad
8. for tuberculosis country of birth and nationality
9. hospitalisation.

For communications from the competent authorities of the Laender to the Robert Koch Institute the latter determines the formsheets, the data carriers, the format of the data carriers and the individual data sets. Sentences 1 and 2 also apply to corrections and supplementations of previous communications.

(2) Any suspicion of a health impairment the degree of which exceeds that of a normal post-vaccinal reaction notified to the health office pursuant to section 6 paragraph 1 no. 3 and

notification to the latter that a pharmaceutical product is suspected to be the source of the infection shall be immediately communicated by the health office to the competent Land authority and the higher federal authority responsible in this case pursuant to section 77 of the Drug Law. The communication shall contain all necessary information that can be established, such as name of the product, name or firm of the pharmaceutical entrepreneur and the batch number, for vaccinations additionally the date of vaccination and onset of illness. The patient notified shall be exclusively referred to by his/her date of birth, sex and the first letter of his/her first forename and the first letter of his/her first surname. The competent higher federal authority shall make the communications available to the Robert Koch Institute for epidemiological evaluation within the space of one week. This shall not affect paragraph 1.

(3) The competent authority communicates to the Robert Koch Institute via the competent Land authority the information prescribed in Article 4 of Decision no. 2119/98/EC of the European Parliament and the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community (OJ EC no. L 268/1). Paragraph 1 sentence 2 and section 12 paragraph 1 sentence 3 shall apply *mutatis mutandis*.

Section 12

Notifications to the World Health Organisation and the European Network

(1) The health office shall immediately notify the appearance of cholera, diphtheria, typhoid fever, yellow fever, viral hemorrhagic fever, plague, poliomyelitis, relapsing fever as well as cases of influenza virus evidence to the competent supreme health authority of the Land and the latter shall immediately notify the Robert Koch Institute. The Robert Koch Institute shall transmit the notification to the World Health Organisation in accordance with the international obligations. The health office may not transmit the following within the framework of this regulation:

1. surname, forename
2. information relating to the date of birth
3. any information relating to the main residence or abode of the person affected
4. name of the notifier.

(2) The Robert Koch Institute shall immediately communicate the information stipulated in section 11 paragraph 3 to the Commission of the European Union and the competent authorities of the Member States.

(3) The Laender inform the Federal Ministry for Health about any facts that are subject to the obligation to provide information as stipulated in Article 6 of Decision no. 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community (OJ EC no. L 268/1).

Section 13

Sentinel surveys

(1) The Robert Koch Institute may, in co-operation with selected facilities for disease prevention or health care, co-ordinate and carry out surveys on persons who avail themselves of the services of these institutions independently of the survey to establish:

1. the spread of communicable diseases, if these diseases have a major significance for public health and the diseases cannot be recorded through notification of individual cases owing to their incidence or for other reasons,
2. the number of persons who are not immune to certain pathogens if this is necessary to assess the risk that these pathogens pose to the general population.

The surveys can also be done by means of anonymous unlinked testing of residual blood samples or other suitable material. If personal data are used that have already been obtained in the course of check-ups or treatments, they shall be anonymised. No data that allow identification of the persons involved in the testing may be recorded in these surveys.

(2) The physicians who voluntarily participate in a sentinel survey pursuant to paragraph 1, the responsible medical directors of hospitals or other medical facilities inclusive of the laboratories report to the Robert Koch Institute on a formsheet or other suitable data carrier prepared by the latter their observations and findings according to the stipulations pursuant to section 14 and communicate, at the same time, any information about the total number and statistical composition of the persons cared for over the same period of time that is required for evaluation.

(3) The authorities of the Laender responsible in each case shall be involved in the sentinel surveys.

Section 14

Identification of the diseases to be monitored by means of sentinel surveys

The Federal Ministry for Health establishes on a case-by-case basis, in consultation with the supreme health authorities of the Laender responsible, which diseases and pathogens will be monitored by surveys pursuant to section 13. The supreme health authorities of the Laender may carry out additional sentinel surveys.

Section 15

Adaptation of the obligation to notify to the epidemiological situation

(1) The Federal Ministry for Health shall be empowered to terminate, restrict or extend the obligation to notify the diseases specified in section 6 or the pathogens specified in section 7 to include other communicable diseases or pathogens, in so far as permissible or required according to the epidemiological situation, by issuing an ordinance having the force of law (hereinafter referred to as ordinance) with the consent of the Bundesrat.

(2) In urgent cases, the ordinance can be issued without the consent of the Bundesrat. An ordinance issued on the basis of sentence 1 shall cease to be in force one year after its entry into force; its period of validity may be extended with the consent of the Bundesrat.

(3) As long as the Federal Ministry for Health does not avail itself of the powers conferred upon it under paragraph 1, the Laender governments shall be empowered to issue an ordinance under paragraph 1 in so far as the obligation to notify under this Act is not restricted or terminated thereby. They may delegate the power to act to other authorities by means of an ordinance.

Chapter Four

Prevention of communicable diseases

Section 16

General measures of the competent authority

(1) If circumstances are observed which could lead to the outbreak of a communicable disease or if it can be assumed that such circumstances exist, the competent authority shall take the measures necessary to avert the danger which these circumstances pose to the individual or the public at large. The personal data collected in the course of these measures may only be processed and used for the purposes of this Act.

(2) In the cases specified in paragraph 1, the officers of the competent authority and of the health office are entitled to enter upon land, rooms, facilities and installations as well as means of transport of all types, and to inspect books or other documents and to prepare copies, photocopies or excerpts from them as well as to examine these and other objects and to demand or take samples for testing in order to carry out investigations and to supervise the implementation of the stipulated measures. The person who possesses actual power over said land, rooms, facilities, installations and means of transport as well as other objects, shall be obliged to allow the officers of the competent authorities and the health office access to the same. Persons in a position to provide information on the circumstances specified in paragraph 1, shall be obliged to furnish the requisite information particularly about the establishment and the details of its operation inclusive of its control and submit relevant documents inclusive of technical plans that reflect the actual situation. The obligated party can refuse to answer certain questions if he/she has reason to fear that answering them could expose him/her or one of the relatives specified in Section 383 paragraph 1 nos. 1 to 3 of the German Code of Civil Procedure (*Zivilprozeßordnung*) to the danger of prosecution under criminal law or a lawsuit according to the Act on Administrative Offences (*Gesetz über Ordnungswidrigkeiten*); this provision shall apply accordingly to the submission of documents.

(3) Where the ascertainment of the epidemiological situation so requires, the competent authority can order the handing over of investigation materials specified in paragraph 2 for the purpose of examination and safekeep to institutes of the public health service or other institutions to be determined by the Land.

(4) The basic constitutional right to the inviolability of the home (Article 13 paragraph 1 of the Basic Law) shall be limited in respect of paragraphs 2 and 3.

(5) In cases where the person affected by the measures stipulated in paragraphs 1 and 2 has no legal capacity or restricted legal capacity, the person responsible for the care of the former's person shall ensure the fulfilment of the obligations specified. The same obligations are to be fulfilled by the person having the care of one who is affected by the measures stipulated in paragraphs 1 and 2 in so far as the care of the person of the affected person falls within the scope of his/her duties.

(6) The order that the measures specified in paragraph 1 are to be taken shall be given by the competent authority at the proposal of the health office. Should the competent authority be unable to obtain a proposal from the health office on time, it shall immediately inform the health office of the measures implemented.

(7) In case of imminent danger, the health office itself may order that the measures be implemented. It shall inform the competent authority immediately thereof. The latter can modify or revoke the order. Should the order not be revoked within the space of two working days after the competent authority is informed, it shall be considered as an order made by the competent authority.

(8) Objections and actions to rescind measures taken under paragraphs 1 to 3 have no suspensory effect.

Section 17

Special measures by the competent authority, ordinances issued by the Laender

(1) Where articles have been or can be assumed to have been contaminated by pathogens capable of causing a communicable disease subject to notification, thus giving reason to fear that the disease will spread, the competent authority shall take the measures necessary to avert the danger thus posed. Where other measures do not suffice, the destruction of such articles may be ordered. Their destruction may also be ordered if other measures are too expensive when compared with the value of said objects unless the person having an interest in or actual control of them makes an objection and assumes the higher costs. Should objects need to be decontaminated, rid of pests or destroyed, their use and the use of the rooms and land in which or on which they are located may be prohibited until the measure has been executed.

(2) When pests are detected and there are grounds for believing that there is a danger of pathogens being spread by them, the competent authority shall direct that the necessary

measures be taken for their control. The control of pests comprises measures to prevent the appearance, reproduction and spread of pests and measures for exterminating the same.

(3) Should the implementation of a measure under paragraphs 1 and 2 require special expert knowledge, the competent authority can order the obligated person to commission suitable experts to do the job. The competent authority itself can commission suitable experts to do the job if necessary to ensure the effective control of the communicable disease and if the obligated person cannot implement these measures or does not comply with an order as provided for in sentence 1 or if the person's history suggests that he/she will not comply with an order pursuant to sentence 1 on time. The person having an interest in or actual control of the objects shall have to acquiesce to the implementation of the measures.

(4) If the conditions specified in section 16 and paragraph 1 exist, the Laender governments shall be empowered to issue, by means of an ordinance, corresponding orders and prohibitions designed to prevent communicable diseases. They may delegate the power to act to other authorities by means of an ordinance.

(5) The governments of the Laender may issue ordinances on the detection and control of pests, head lice and sarcoptic mites in order to prevent and control the spread of communicable diseases. They may delegate the power to act to other authorities by means of an ordinance. The ordinances can stipulate provisions governing, in particular,

1. the obligation of the persons who own, are entitled to use, have actual control of or are responsible for the maintenance of articles,
 - a) to detect any infestation with pests or have it detected and to notify the competent authority,
 - b) to control pests or have them controlled,
2. the powers and obligation of the local authorities or associations of local authorities to detect and to control pests, in human beings as well, and to ascertain the results of the control operations,
3. detection and control, in particular regarding
 - a) the type and scope of the control measures,
 - b) the use of expert personnel,
 - c) the admissible pesticides and control procedures,

- d) the minimisation of residues and the disposal of pesticides, and
 - e) the obligation to notify the competent authority of the conclusion and results of the control measures and to have the results thereof ascertained by expert personnel,
4. the obligation to co-operate and the obligation to tolerate within the meaning of section 16 paragraph 2, incumbent upon the persons specified in number 1.

(6) Section 16 paragraphs 5 to 8 shall apply *mutatis mutandis*.

(7) The basic constitutional rights: the right to personal freedom (Article 2 paragraph 2 sentence 2 of the Basic Law), the right to freedom of movement (Article 11 paragraph 1 of the Basic Law), the right to freedom of assembly (Article 8 of the Basic Law) and the inviolability of the home (Article 13 paragraph 1 of the Basic Law) shall be limited within the framework of paragraphs 1 to 5.

Section 18

Decontamination, disinfestation and control of vertebrate vectors of pathogens, ordered by an authority, costs

(1) For the protection of human beings from communicable diseases, only those agents and procedures that have been published by the competent higher federal authority in a list in the Federal Health Gazette (*Bundesgesundheitsblatt*) may be employed for decontamination (disinfection), disinfestation (control of invertebrates) and measures to control vertebrates susceptible to spread pathogens that are ordered by an authority. The agents and procedures will only be included in the list if they are sufficiently effective and have no unreasonable effects on health and the environment.

(2) The higher federal authority responsible for publishing the list is, in the case of

1. agents and procedures for decontamination, the Robert Koch Institute that examines the effectiveness of agents in agreement with the
 - a) Federal Institute for Drugs and Medical Devices that examines the effects on human health and the
 - b) Federal Environmental Agency that examines the effects on the environment,

2. agents and procedures for disinfestation and decontamination and for the control of vertebrates the Federal Institute for Health Protection of Consumers and Veterinary Medicine that examines their effectiveness, except for the examinations assigned to the Federal Environmental Agency, and the effects on human health, except for the examination assigned to the Federal Institute for Drugs and Medical Devices, in agreement with the
 - a) Federal Institute for Drugs and Medical Devices that examines their effects on human health, where it is responsible for the marketing authorization pursuant to section 77 paragraph 1 of the Drug Law, and the
 - b) Federal Environmental Agency that examines the effectiveness of agents and procedures for disinfestation and the control of rats and mice and the effects on the environment; examinations to determine the effectiveness shall be done in the pests concerned including, in the case of parasitic non-vertebrates, their animal hosts, unless the agents or procedures have been equivalently examined and authorized under the Crop Protection Act (*Gesetz zum Schutz der Kulturpflanzen*) according to the extermination principle.

The examinations can be done by means of tests performed by the competent federal authority itself or on the basis of expert opinions drafted on behalf of the competent federal authority. If the agents contain compounds that are contained in plant protection agents authorized for use or undergoing authorization procedure, the list will be published in consultation with the Federal Biological Agency for Agriculture and Forestry (*Biologische Bundesanstalt für Land- und Forstwirtschaft*).

(3) The Robert Koch Institute and the Federal Institute for Health Protection of Consumers and Veterinary Medicine charge expenses (fees and outlays) for administrative services pursuant to paragraphs 1 and 2.

(4) The Federal Minister for Health shall be empowered to stipulate by means of an ordinance, in agreement with the Federal Minister of Environment, Nature Protection and Nuclear Safety and without the consent of the Bundesrat, the items of the administrative services that are subject to the payment of a fee pursuant to paragraphs 1 and 2 and to provide for fixed rates or guideline rates.

(5) The Federal Minister for Health shall be empowered to stipulate by means of an ordinance in agreement with the Federal Minister for the Environment, Nature Conservation and Nuclear Safety and without the consent of the Bundesrat, the details of the listing procedure.

Section 19

Tasks of the health office in special cases

(1) The health office offers counselling and testing in respect of sexually transmitted diseases and tuberculosis or ensures the provision of such services in co-operation with other medical establishments. The foregoing shall also be offered on an outreach basis to persons whose life circumstances expose them to an increased risk of infecting themselves or others and can in individual instances comprise out-patient treatment by a physician of the health office, if this is necessary to prevent the spread of sexually transmitted diseases and tuberculosis. Services offered in respect of sexually transmitted diseases can be utilised anonymously, unless this jeopardises the assertion of claims to cost reimbursement under paragraph 2.

(2) The costs of examination and treatment are borne:

1. by the health insurance funds according to part five of chapter three of the Social Code (*Sozialgesetzbuch*) Book V, if the person is a member of a health insurance fund pursuant to section 4 of the Social Code Book V,
2. otherwise from public funds, if the person is unable to bear the expenses of examination or treatment himself/herself; means-testing need not be done if the inability is evident or if there is a risk that recourse to other parties liable to pay would render the implementation of testing or treatment more difficult.

If it is not known, at the time of testing or establishment of the need for treatment, which entity will bear the costs, these will be provisionally defrayed from public funds. The entity responsible for meeting the costs thus incurred is obliged to refund them.

Section 20

Vaccination and other measures of specific prophylaxis

(1) The competent higher federal authority, the supreme health authorities of the Laender and the entities charged by them as well as the health offices inform the general public about the importance of vaccinations and other measures of specific prophylaxis against communicable diseases.

(2) A Standing Vaccination Commission shall be established at the Robert Koch Institute. The Commission adopts Rules of Procedure that are subject to the consent of the Federal Ministry for Health. The Commission issues recommendations on the conduct of vaccinations and other measures for the specific prophylaxis of communicable diseases and develops criteria for the distinction between a normal post-vaccinal reaction and a health impairment the degree of which exceeds that of a normal post-vaccinal reaction. The members of the Commission are appointed by the Federal Ministry for Health, in consultation with the supreme health authorities of the Laender. Representatives of the Federal Ministry for Health, the supreme health authorities of the Laender, the Robert Koch Institute and the Paul Ehrlich Institute shall attend the sessions in an advisory capacity. The sessions may also be attended by representatives from other federal authorities. The recommendations of the Commission shall be passed on by the Robert Koch Institute to the supreme health authorities of the Laender and subsequently published.

(3) The supreme health authorities of the Laender shall issue public recommendations for vaccinations or other measures of specific prophylaxis drafted on the basis of the respective recommendations of the Standing Vaccination Commission.

(4) The Federal Ministry for Health shall be empowered, after hearing the Standing Vaccination Commission and the central associations of the health insurance funds to determine by means of an ordinance without the consent of the Bundesrat that the costs for certain vaccinations are to be borne by the health insurance funds pursuant to section 3 chapter 3 of the Social Code Book V if the person is insured with a health insurance fund pursuant to section 4 of the Social Code Book V. The ordinance can also incorporate regulations on the recording and transmission of anonymised data about vaccinations performed.

(5) The supreme health authorities of the Laender can determine that the health offices conduct vaccinations or other measures of specific prophylaxis against certain communicable diseases free of charge.

(6) The Federal Ministry for Health shall be empowered to determine by means of an ordinance with the consent of the Bundesrat that those segments of the population which are at risk have to undergo the vaccinations or other measures of specific prophylaxis if a communicable disease occurs that takes a severe clinical course or can be expected to take on the proportions of an epidemic. The basic constitutional right to physical integrity (Article 2 paragraph 2 sentence 1 of the Basic Law) can be restricted in this respect. Any person required to undergo a vaccination under this ordinance who cannot be vaccinated without endangering his/her life or health and produces a medical certificate to that effect shall be exempted from the obligation to be vaccinated; this also applies to other measures of specific prophylaxis. Section 15 paragraph 2 shall apply *mutatis mutandis*.

(7) Where the Federal Ministry for Health does not avail itself of the powers conferred upon it by paragraph 6, the governments of the Laender shall be empowered to issue an ordinance pursuant to paragraph 6. The governments of the Laender may delegate the power to act to the supreme health authorities of the Land by means of an ordinance. The basic constitutional right to physical integrity (Article 2 paragraph 2 sentence 1 of the Basic Law) can be limited in this respect.

Section 21

Vaccines

In the case of a vaccination stipulated by law, one required under the provisions of this Act, a vaccination recommended to the general public by the supreme health authority of the Land or a vaccination pursuant to section 17 paragraph 4 of the Act on Soldiers (*Soldatengesetz*), vaccines containing micro-organisms which can be excreted by the vaccinated person and taken up by others, may be employed. The basic constitutional right to physical integrity (Article 2 paragraph 2 sentence 1 of the Basic Law) shall be limited in this respect.

Section 22

Vaccination card

(1) The vaccinating physician shall enter each vaccination immediately into a vaccination card pursuant to paragraph 2 or, should the latter not be presented, shall issue a certificate of vaccination. The vaccinating physician shall enter the contents of the certificate of vaccination into the vaccination card upon request. In his absence, the health office shall make the entry pursuant to sentence 2.

(2) The vaccination card or the vaccination certificate shall contain the following information on each vaccination:

1. date of vaccination
2. name and batch number of the vaccine
3. name of the disease vaccinated against
4. name and address of the vaccinating physician and
5. signature of the vaccinating physician or confirmation of the entry by the health office.

(3) The vaccination card shall contain, in an appropriate form, information on the proper conduct in the event of an unusual post-vaccinal reaction and on the claims that may arise from sections 60 to 64 if a vaccine injury were to occur, as well as the authorities at whose offices these claims can be put forward.

Section 23

Nosocomial infections, resistances

(1) Heads of hospitals and institutions for outpatient surgery are obliged to continuously record and evaluate in a separate document the nosocomial infections and the appearance of pathogens with special resistances and multiple resistances stipulated by the Robert Koch Institute pursuant to section 4 paragraph 2 no. 2 letter b. The records pursuant to sentence 1 shall be kept for ten years. The competent health office shall be given permission to inspect the records on request.

(2) A Commission for Hospital Hygiene and Infection Prevention shall be set up at the Robert Koch Institute. The Commission adopts Rules of Procedure that are subject to the consent of the Federal Ministry for Health. The Commission drafts recommendations on the prevention of nosocomial infections and on operational and organisational as well as construc

tional and functional measures to ensure hygiene in hospitals and other medical facilities. The recommendations of the Commission shall be published by the Robert Koch Institute. The members of the Commission are appointed by the Federal Ministry for Health in consultation with the supreme health authorities of the Laender. Representatives of the Federal Ministry for Health, the supreme health authorities of the Laender and the Robert Koch Institute shall attend the session in an advisory capacity.

Chapter Five

Control of communicable diseases

Section 24

Treatment of communicable diseases

The treatment of persons suffering from or suspected of suffering from one of the communicable diseases specified in section 6 paragraph 1 sentence 1 nos. 1, 2 and 5 or section 34 paragraph 1 or infected by a pathogen specified in section 7 shall be permitted, within the framework of the professional exercise of medicine, only to physicians. Sentence 1 shall apply *mutatis mutandis* to sexually transmitted diseases and diseases and pathogens which are also subject to compulsory notification by an ordinance pursuant to section 15 paragraph 1. The direct and indirect evidence of a pathogen for the detection of an infection or communicable disease shall also be considered treatment within the meaning of sentences 1 and 2; section 46 shall apply *mutatis mutandis*.

Section 25

Investigations, duties of the health office to inform about blood, organ or tissue donors

(1) Should it occur that or should there be reason to assume that a person is ill, suspected of being ill, suspected of being contagious, is a germ carrier, or that a deceased person had been ill, suspected of being ill or a germ carrier, the competent health office shall carry out the necessary investigations, especially with regard to the type, cause, source of infection and spread of the disease.

(2) Should it occur that or should there be reason to assume that a person suffering from a notifiable disease or infected with a notifiable pathogen or that a deceased person who had been suffering from a notifiable disease or infected with a notifiable pathogen, donated his/her blood or any organ or tissue after the presumed date of infection, the competent health office shall, if the disease or infection in question can be transmitted through blood, blood

products, tissues or organs, immediately inform the competent authorities about the result or suspicion. In doing so, it shall report the facts that have come to its knowledge. For donors of organs which are subject to allocation (section 9 sentence 2 of the Transplantation Act), the health office shall also inform the co-ordinating agency established or appointed pursuant to section 11 of the Transplantation Act, for other organ or tissue donors pursuant to sections 3, 4 or 8 of the Transplantation Act the transplantation centre in which the organ was or is to be transplanted, as stipulated in sentences 1 and 2.

Section 26

Implementation

(1) Section 16 paragraphs 2, 3, 5 and 8 shall apply *mutatis mutandis* to the conduct of the investigations under section 25 paragraph 1.

(2) The persons named in section 25 paragraph 1 can be summoned by the health office. They can be obligated by the health office to undergo investigations and have samples of body material taken, they shall particularly acquiesce to having the necessary external examinations, X-rays, tuberculin tests, withdrawal of blood samples, taking of swabs from the skin and mucous membranes, performed by the officers of the health office and shall furnish the necessary investigational material on request. Invasive interventions that exceed the scope of the foregoing and interventions that require general anaesthesia, may only be carried out by physicians and with the consent of the person concerned. Section 16 paragraph 5 only applies *mutatis mutandis* if the person concerned is unable to give his/her consent. The personal data recorded in the course of these investigations may only be processed and used for the purposes of this Act.

(3) The physicians of the health office and its medical officers shall be permitted by the person having custody and control of the bodies of the deceased persons mentioned in section 25 to examine the latter. The competent authority may issue an order requiring the persons having custody and control to allow an autopsy if the health office considers this to be necessary.

(4) The basic constitutional rights to physical integrity (Article 2 paragraph 2 sentence 1 of the Basic Law), to personal freedom (Article 2 paragraph 2 sentence 2 of the Basic Law) and to the inviolability of the home (Article 13 paragraph 1 of the Basic Law) shall be limited in this respect.

Section 27

Participation of the physician in charge of treatment

The physician in charge of treatment is entitled to be present during the investigations provided for in section 26 as well as during the autopsy.

Section 28

Protective measures

(1) If persons are diagnosed as being ill, are suspected of being ill or contagious, are diagnosed as germ carriers, or should it occur that a deceased person had been ill, suspected of being ill or had been a germ carrier, the competent authority shall order the implementation of the necessary protective measures, in particular those specified in sections 29 to 31 in so far as and as long as such action is necessary to prevent the spread of communicable diseases. If the conditions stipulated in sentence 1 are fulfilled, the competent authority shall be entitled to restrict or prohibit events or other gatherings of large numbers of people and may close public bathing establishments or community facilities as specified in section 33 or parts of them; it may also force persons not to leave the place they are in or not to enter places specified by it until the necessary protective measures have been taken. A person may not be forced to submit to curative treatment. The basic constitutional rights: the right to personal freedom (Article 2 paragraph 2 sentence 2 of the Basic Law), the right to freedom of assembly (Article 8 of the Basic Law) and the inviolability of the home (Article 13 paragraph 1 of the Basic Law) shall be limited in this respect.

(2) Section 16 paragraphs 5 to 8 shall apply in respect of the measures provided for in paragraph 1 and section 16 paragraph 2 shall apply *mutatis mutandis* with regard to their supervision.

Section 29

Observation

(1) Persons who are ill, suspected of being ill, suspected of being contagious and germ carriers may be placed under observation.

(2) Persons placed under observation pursuant to paragraph 1, shall permit the officers of the health office to perform such investigations as are deemed necessary and shall comply with the instructions of the health office. Section 26 paragraph 2 shall apply *mutatis mutandis*. Furthermore, persons as specified in sentence 1 shall also be bound to permit the officers of

the health office to enter their homes for the purpose of interrogation or investigation, to furnish them with information bearing on all the circumstances surrounding their state of health and, in cases of a change of main residence or habitual abode they shall immediately notify the hitherto competent health office thereof. This obligation to notify shall also apply to changes occurring with respect to an activity in the food sector within the meaning of section 42 paragraph 1 sentence 1 or in facilities as specified in section 36 paragraph 1 as well as with respect to a change of community facility within the meaning of section 33. Section 16 paragraph 2 sentence 4 shall apply *mutatis mutandis*. The basic constitutional rights: the right to physical integrity (Article 2 paragraph 2 sentence 1 of the Basic Law), the right to personal freedom (Article 2 paragraph 2 sentence 2 of the Basic Law) and the inviolability of the home (Article 13 paragraph 1 of the Basic Law) shall be limited in this respect.

Section 30

Quarantine

(1) The competent authority shall order that persons suffering from or suspected of being infected with pneumonic plague or a haemorrhagic fever that can be transmitted from person to person are forthwith isolated in a hospital or an establishment equipped to handle these diseases. In respect of other persons who are ill or suspected of being ill, suspected of being contagious, and germ carriers, it may order that they are isolated in an appropriate hospital or by any other means considered appropriate; however, this only applies to germ carriers if they do not, are unable or unlikely to comply with the other protective measures and thus pose a danger to their environment.

(2) Should the person concerned fail to comply with the order regarding his/her isolation or if his/her behaviour hitherto gives reason to assume that he/she will not adequately comply with such orders, he/she shall be forcibly isolated by means of placement in a closed hospital or in a closed ward of a hospital. Persons suspected of being contagious and germ carriers may also be isolated in another suitable closed establishment. The basic constitutional right to personal freedom (Article 2 paragraph 2 sentence 2 of the Basic Law) can be limited in this respect. The Law of 29 June 1956 on Legal Procedures in Cases of Deprivation of Liberty (*Gesetz über das gerichtliche Verfahren bei Freiheitsentziehungen*) of 29 June 1956, in the consolidated version published in the Federal Law Gazette Part III, classification no. 316-1, last amended by Article 2 of the Law of 26 August 1998 (BGBl. I p. 2461) shall apply *mutatis mutandis*.

(3) The isolated person shall comply with the instructions issued by the hospital or other isolation establishment and shall acquiesce to those measures which are necessary to ensure the proper functioning of the establishment or to achieve the purpose for which he/she was hospitalized. In particular, objects which might directly or indirectly facilitate his/her escape may be removed from the person's possession and stored elsewhere until his/her discharge. Packages or written messages arriving for or despatched by the person affected may be opened and confiscated in his/her presence in so far as this is necessary to achieve the purpose for which he/she was hospitalized. The personal data recorded in the context of isolation and the information obtained through packages and written messages may only be processed and utilised for the purposes of this Act. Mail from the courts, public authorities, legal representatives, lawyers, notaries or pastors may neither be opened nor confiscated; mail sent to such places or persons may only be opened and confiscated if necessary for purposes of disinfection. The basic constitutional rights: the right to physical integrity (Article 2 paragraph 2 sentence 1 of the Basic Law), the right to personal freedom (Article 2 paragraph 2 sentence 2 of the Basic Law) and the basic right to privacy of letters, posts and telecommunications (Article 10 of the Basic Law) shall be restricted in this respect.

(4) The physician in charge of treatment and the persons responsible for the patient's care shall have free access to the person in isolation. The pastor or **notaries** must be allowed access to the patient by the physician in charge of treatment; the latter may allow other persons access provided that they observe the necessary rules of conduct.

(5) The entities in charge of the establishment shall ensure that the personnel deployed as well as any other persons at risk of exposure receive the necessary immunization or a specific prophylaxis.

(6) The Laender authorities shall see to it that the necessary premises, installations and means of transport pursuant to paragraph 1 sentence 1 are available.

(7) The competent local authorities shall ensure that the necessary premises, installations and means of transport pursuant to paragraph 1 sentence 2 and paragraph 2 as well as the personnel required to implement the isolation measures outside the person's home, are available. The premises and installations required for isolation pursuant to paragraph 2 shall be provided and maintained by the government of the respective Land, if necessary.

Section 31

Prohibition of professional activities

The competent authority may totally or partially prohibit persons who are ill, suspected of being ill, suspected of being contagious and germ carriers from exercising certain professional activities. Sentence 1 shall also apply to other persons who carry pathogens in or on them in such a manner that a risk of transmitting them is present in an individual instance.

Section 32

Issue of ordinances

The governments of the Laender shall be empowered to issue orders and prohibitions for the control of communicable diseases also by means of ordinances if circumstances exist which are relevant for the implementation of measures under sections 28 to 31. The governments of the Laender may delegate the power to act to other bodies by means of an ordinance. The basic constitutional rights: the right to personal freedom (Article 2 paragraph 2 sentence 2 of the Basic Law), the right to freedom of movement (Article 11 paragraph 1 of the Basic Law), the right to freedom of assembly (Article 8 of the Basic Law), the inviolability of the home (Article 13 paragraph 1 of the Basic Law) and the right to privacy of letters, posts and telecommunications (Article 10 of the Basic Law) may be restricted in this respect.

Chapter Six

Additional provisions for schools and other community facilities

Section 33

Community facilities

Community facilities within the meaning of this Act are facilities in which predominantly infants, children and young people are cared for, particularly day nurseries, kindergartens, infant day-care centres, day-care centres for school-age children, schools or other educational facilities, homes, holiday camps and similar facilities.

Section 34

Health requirements, duties to co-operate, tasks of the health office

(1) Persons who are suffering from or are suspected of suffering from

1. cholera
2. diphtheria
3. enteritis caused by enterohaemolytic E. coli (EHEC)
4. viral haemorrhagic fever
5. haemophilus influenzae type b-meningitis
6. *impetigo contagiosa* (contagious ringworm)
7. whooping cough
8. contagious tuberculosis
9. measles
10. meningococcal infection
11. mumps
12. paratyphoid fever
13. plague
14. poliomyelitis
15. scabies
16. scarlet fever or other infections caused by *streptococcus pyogenes*
17. shigellosis
18. abdominal typhus
19. viral hepatitis A or E
20. chicken pox

or are lice-infested, may not exercise any teaching, educational, caring, supervisory or other activities in the community facilities mentioned in section 33, which bring them into contact with the persons taken care of there, until medical opinion rules out all danger of an onward spread of the disease or lice infestation by such persons. Sentence 1 applies *mutatis mutandis* to the persons taken care of there with the understanding that they may not enter the premises used for the purposes of the community facility, may not use installations of the community facility and may not attend functions of the community facility. Sentence 2 also applies to children under the age of six who are suffering from or suspected of suffering from infectious gastro-enteritis.

(2) Carriers of

1. vibrio cholerae 01 and 0139
2. corynebacterium diphtheriae, toxin-producing
3. salmonella typhi
4. salmonella paratyphi
5. shigella sp.
6. enterohaemolytic E. coli (EHEC)

may enter premises used for the purposes of the community facility, use installations of the community facility and attend functions of the community facility only with the permission of the health office and on condition that the precautions imposed on the carrier and the community facility are taken.

(3) Paragraph 1 sentences 1 and 2 apply *mutatis mutandis* to persons who are household contacts of any individual whom medical opinion deems to be a case or suspect case of

1. cholera
2. diphtheria
3. enteritis caused by enterohaemolytic E. coli (EHEC)
4. viral haemorrhagic fever
5. haemophilus influenzae type b-meningitis
6. contagious tuberculosis
7. measles
8. meningococcal infection
9. mumps
10. paratyphoid fever
11. plague
12. poliomyelitis
13. shigellosis
14. abdominal typhus
15. viral hepatitis A or E.

(4) If the persons obligated under paragraphs 1 to 3 are incapacitated or partially incapacitated, the person who is responsible for the care and custody of said persons shall ensure that the obligations laid down in paragraphs 1 to 3 regarding their person are observed. The same obligation is incumbent on the person having the care of an obligated person within the

meaning of paragraphs 1 to 3 in so far as the care of the person of the latter falls within the scope of his/her duties.

(5) If one of the conditions specified in paragraph 1, 2 or 3 occurs in the persons specified in paragraph 1, the latter or in the cases of paragraph 4 the person in charge of the community facility shall immediately make a notification to that effect. The management of the community facility shall instruct each person as he/she is received in the community facility or the persons who have the care and custody of them about the obligations stipulated in sentence 1.

(6) If facts become known that suggest the presence of a condition specified in paragraph 1, 2 or 3, the management of the community facility shall immediately inform the competent health authority and furnish data on the disease and the persons involved. This shall also apply where two or more similar, severe cases of illness occur if these are suspected to be due to pathogens. An obligation to inform does not exist if the management can produce documentation proving that the circumstances have already been notified by another person mentioned in section 8.

(7) The competent authority may, in agreement with the health office, permit exceptions from the prohibition pursuant to paragraph 1, also in conjunction with paragraph 3, for the facilities mentioned in section 33 if measures have been or are being implemented which are able to prevent a transmission of the diseases listed or the lice infestation.

(8) The health office can order vis-à-vis the management of the community facility that the appearance or the suspected appearance of a disease be made public without reference to the person in the community facility.

(9) If persons cared for in a community facility carry pathogens in them or on them in such a way that there is a danger of spreading them in the individual instance, the competent authority may order the necessary protective measures.

(10) The health offices and the community facilities mentioned in section 33 shall inform the persons cared for there or the persons having the care and custody of them about the importance of a complete and age-appropriate vaccine protection that is sufficient according to the recommendations of the Standing Vaccination Commission and about the prevention of communicable diseases.

(11) As children are first enrolled in the first grade of a general school, the health office or the physician commissioned by it shall ascertain their vaccination status and transmit the aggregated data obtained that have been anonymised, to the Robert Koch Institute via the supreme health authority of the Land.

Section 35

Instruction of persons caring for children and young persons

Persons who exercise any teaching, educational, caring, supervisory or other regular activities in the community facilities mentioned in section 33 and have contact with the persons taken care of there, must be instructed by their employer about the health requirements and obligations to co-operate under section 34 before they first take up their duties and subsequently at a maximum interval of two years. The instruction shall be the subject of a record that shall be kept by the employer for a period of 3 years. Sentences 1 and 2 shall apply *mutatis mutandis* to civil service employers.

Section 36

Compliance with infection control hygiene

(1) The community facilities mentioned in section 33 as well as hospitals, preventive or rehabilitative health care facilities, institutions for outpatient surgery, dialysis facilities, day hospitals, maternity hospitals, institutions pursuant to section 1 paragraphs 1, 1a of the Act on Residential Accommodation (*Heimgesetz*), similar therapeutic, care or treatment facilities as well as shelters for the homeless, community facilities for asylum-seekers, repatriates and refugees as well as other mass accommodation and prisons shall lay down in hygiene plans internal protocols on infection control hygiene. The foregoing entities are subject to the monitoring of infection control hygiene by the health office.

(2) Practices of dental surgeons and physicians as well as the practices of other paramedical professions in which invasive interventions are performed as well as other facilities and professions which involve manipulations of the human body in the course of which pathogens can be transmitted via blood, may be monitored by the health office in terms of infection control hygiene.

(3) Section 16 paragraph 2 shall apply *mutatis mutandis* to the implementation of the monitoring.

(4) Persons who are to be accepted into homes for the elderly, residential homes for the elderly, nursing homes or similar establishments according to section 1 paragraph 1 of the Act on Residential Accommodation or into a community facility for homeless persons, refugees, asylum-seekers or into an initial reception centre of the Federal Government for repatriates must submit a medical certificate to the management of the facility, before or immediately after their acceptance, stating that they present no signs of contagious pulmonary tuberculosis. To gain admission to a community facility for refugees or asylum-seekers or to an initial reception centre of the Federal Government for repatriates, the certificate for persons aged 15 years or over must be based on an X-ray of the lung made in the territory covered by this Act; if they are admitted for the first time, the findings may not be older than 6 months, for repeated admissions 12 months. Pregnant women shall be exempted from taking the X-ray examination; instead, they shall present a medical certificate stating that, on the strength of the other findings, there is no reason to fear the existence of contagious pulmonary tuberculosis. Section 34 paragraph 4 shall apply *mutatis mutandis*. Sentence 1 does not apply to persons who are admitted for less than 3 days to a community shelter for homeless persons. Persons who, pursuant to sentence 1, have to present a medical certificate, are obliged to acquiesce to the examinations necessary for issuing the certificate pursuant to sentences 1 and 2. Persons received into a prison are obliged to acquiesce to a medical examination for communicable diseases including an X-ray of the lung.

(5) The basic rights to the inviolability of the home (Article 13 paragraph 1 of the Basic Law) and to physical integrity (Article 2 paragraph 2 sentence 1 of the Basic Law) shall be limited in this respect.

Chapter Seven

Water

Section 37

Quality of water for human use as well as of swimming and bathing pool water, monitoring

(1) Water for human use must be of such quality that there is no reason to fear any damage to human health, particularly through pathogens, being involved in its consumption or use.

(2) Water used in swimming or bathing pools in business establishments or public baths as well as in other facilities for not exclusively private use must be of such quality that there is no reason to fear any damage to human health, particularly through pathogens, being involved in its consumption or use.

(3) Water catchment installations and water supply plants and swimming or bathing pools, including their water treatment installations, shall be subject to monitoring by the health office in respect of the requirements stipulated in paragraphs 1 and 2. With regard to the implementation of monitoring, section 16 paragraph 2 shall apply *mutatis mutandis*. The basic constitutional right to the inviolability of the home (Article 13 paragraph 1 of the Basic Law) shall be limited in this respect.

Section 38

Issue of ordinances

(1) The Federal Ministry for Health shall determine by an ordinance with the consent of the Bundesrat

1. which requirements shall be fulfilled by the water for human use in order to comply with the provisions contained in section 37 paragraph 1,
2. that and in what way water catchment installations and water supply plants and the water must be monitored in terms of hygiene,
3. which duties to act, to omit, to co-operate and to acquiesce are incumbent on the operator or owner, if not identical, of a water catchment installation or water supply plant or of

swimming and bathing pools within the meaning of nos. 1 and 2, which water analyses he/she shall perform or have performed and at what intervals such analyses are to take place,

4. the requirements regarding the use of substances and materials for the treatment and distribution of water for human use, in so far as these are not subject to the provisions of the Law on Foods and Commodities,
5. in which cases the water for human use that does not comply with the requirements of no. 1 or 4, may not be supplied or only supplied subject to restrictions or may not be made available to others or only made available subject to restrictions,
6. that and in what way the population is to be informed about the quality of the water for human use and any measures that need to be taken, if necessary,
7. that and in what way data relating to the production and quality of water for human use including personal data, in so far as these are necessary for the ascertainment and monitoring of the water quality and water supply, are to be transmitted and
8. the requirements for the laboratories that analyse water for human use.

The ordinance may also incorporate regulations on the requirements for the water catchment installations and water supply plants. The ordinance requires agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, in so far as it refers to water catchment installations.

(2) The Federal Ministry for Health shall determine by an ordinance with the consent of the Bundesrat,

1. which requirements shall be fulfilled by the water specified in section 37 paragraph 2 in order to comply with the provisions contained in section 37 paragraph 2,
2. that and in what way swimming and bathing pools and the water must be monitored in terms of hygiene,
3. which duties to act, to omit, to co-operate and to acquiesce are incumbent on the operator or owner, if not identical, of a water catchment installation or water supply plant or of swimming and bathing pools, within the meaning of nos. 1 and 2, which water analyses

he/she shall perform or have performed and at what intervals such analyses are to take place,

4. in which cases water specified in section 37 paragraph 2 that does not comply with the requirements of no. 1, may not be made available to others and
5. that only such substances and procedures as have been published by the Federal Environmental Agency in a list may be used for the treatment of swimming or bathing pool water.

The substances and procedures for the treatment of water for swimming or bathing pools will only be included in the list under no. 5 if the Federal Environmental Agency has found them to comply with the state of the art; the Federal Environmental Agency may charge expenses (fees and outlays) for administrative services specified in the first half of this sentence. The ordinance pursuant to sentence 1 may also contain regulations on the requirements for other water in business establishments, public baths as well as in other facilities for not exclusively private use that is made available for swimming or bathing and its monitoring in so far as this is necessary for the protection of human health. Sentence 3 does not apply to waters within the meaning of Council Directive 76/160/EEC of 8 December 1975 concerning the quality of bathing water (OJ EC no. L31 of 5 February 1976, p. 1).

(3) The Federal Ministry for the Environment, Nature Conservation and Nuclear Safety shall be empowered to stipulate by means of an ordinance without the consent of the Bundesrat, the acts subject to the payment of a fee for tasks executed by the Federal Environmental Agency as stipulated in paragraph 2 sentence 1 no. 5 and sentence 2, and to provide for fixed rates or guideline rates.

Section 39

Analyses, measures taken by the competent authorities

(1) The operator or owner, if not identical, of a water-catchment installation or water supply plant or of a swimming or bathing pool shall be bound to assume the costs for performing the analyses incumbent on him/her by virtue of ordinances provided for in section 38 paragraph 1 or 2, or for having the same performed. He/she shall also bear the expenses (fees and outlays) of the water analyses which the competent authority performs or commissions by virtue of the ordinance provided for in section 38 paragraph 1 or 2.

(2) The competent authority shall take such measures as are necessary to:

1. ensure compliance with the provisions contained in section 37 paragraphs 1 and 2 and the ordinances provided for under section 38 paragraphs 1 and 2,
2. avert any danger to human health that could be posed by water for human use within the meaning of section 37 paragraph 1 as well as water for and in swimming or bathing pools within the meaning of section 37 paragraph 2, especially with a view to preventing the appearance or the spread of communicable diseases.

Section 16 paragraphs 6 to 8, shall apply *mutatis mutandis*.

Section 40

Tasks of the Federal Environmental Agency

Within the framework of this Act, the Federal Environmental Agency has the task of developing concepts for the prevention, detection and prevention of the spread of water-borne diseases. To execute these tasks, advisory expert commissions may be set up at the Federal Environmental Agency that can issue recommendations for the protection of human health as regards the requirements for the quality of water as specified in section 37 paragraphs 1 and 2 and the measures necessary to achieve it. The members of this commission are appointed by the Federal Ministry for Health in consultation with the supreme Land authorities responsible in each case. Representatives of the Federal Ministry for Health, the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety shall attend the sessions in an advisory capacity. Additional representatives of federal and Laender authorities may attend the sessions as well.

Section 41

Sewage

(1) Those obliged to dispose of sewage have to see to it that the sewage is disposed of in a way that does not give rise to any hazards to human health due to pathogens. Facilities for the disposal of sewage mentioned in sentence 1 are subject to the monitoring of infection control hygiene by the competent authority. The operators of facilities under sentence 2 are under the obligation to grant the officers of the health office access to their land, rooms, facilities and installations and to furnish information upon request in so far as this is necessary for monitor

ing purposes. The basic constitutional right to the inviolability of the home (Article 13 paragraph 1 of the Basic Law) shall be limited in this respect. Section 16 paragraphs 1 to 3 apply.

(2) The governments of the Laender shall be empowered to issue an ordinance on sewage to enact orders and prohibitions designed to prevent communicable diseases. The governments of the Laender may delegate the power to act to other authorities by means of an ordinance. The basic constitutional right to the inviolability of the home (Article 13 paragraph 1 of the Basic Law) may be limited in this respect.

Chapter Eight

Health requirements for food-handlers

Section 42

Prohibitions with respect to engaging in or employing another to engage in food-handling activities

(1) Persons who are

1. suffering or suspected of suffering from abdominal typhus, paratyphoid fever, cholera, shigellosis, salmonellosis, any other infectious enteritis or viral hepatitis A or E,
2. suffering from infected wounds or skin diseases, the pathogens of which can be transmitted via foodstuffs,
3. excreting shigellae, salmonellae, enterohaemolytic *Escherichia coli* or cholera vibriones

may not be engaged or employed in

- a) the manufacture, processing or marketing of the foodstuffs specified in paragraph 2 if in the process they come into contact with said foodstuffs or
- b) in kitchens of restaurants or other institutional caterers.

Sentence 1 shall apply *mutatis mutandis* to persons who come into contact with commodities used for the activities mentioned there, in a way that involves a risk of transmission of pathogens to the foodstuffs within the meaning of paragraph 2. Sentences 1 and 2 shall not apply to private households.

(2) Foodstuffs within the meaning of paragraph 1 are

1. meat, poultry meat and products of the foregoing
2. milk and milk products
3. fish, crustaceans, shellfish or molluscs and products of the foregoing
4. egg products
5. foods for infants and young children
6. ice cream and semi-finished ice cream products
7. bakery products which contain fillings or toppings which are not thoroughly baked or heated
8. delicatessen salads, raw vegetable salads and potato salads, marinades, mayonnaise, other emulsified sauces, baking yeast.

(3) Persons who come into contact with the foodstuffs specified in paragraph 2 or with commodities within the meaning of paragraph 1 sentence 2 in an official capacity or even within the framework of a vocational training relationship, are prohibited from engaging in their activities if they are suffering from or suspected of suffering from one of the diseases specified in paragraph 1 no. 1, are suffering from one of the diseases specified in paragraph 1 no. 2, or excrete any of the pathogens specified in paragraph 1 no. 3.

(4) The health office may permit exceptions from the prohibitions under this provision if measures are implemented that are capable of preventing a transmission of the diseases and pathogens specified.

(5) The Federal Minister for Health shall be empowered to restrict the list of diseases specified in paragraph 1 nos. 1 and 2, the list of pathogens contained in paragraph 1 no. 3 and the list of foods contained in paragraph 2 by means of an ordinance with the consent of the Bundesrat if epidemiological findings so allow and may extend it if this is necessary to protect human health from the danger posed by pathogens. In urgent cases, the ordinance may be issued without the consent of the Bundesrat to ensure the protection of the population. An ordinance issued on the basis of sentence 2 shall cease to be in force one year after its entry into force; its period of validity may be extended with the consent of the Bundesrat.

Section 43

Instruction, certificate by the health office

(1) Persons may engage in the activities specified in section 42 paragraph 1 for the first time and may be employed to pursue these activities for the first time only if a certificate from the health office or a physician commissioned by the health office of not more than three months standing proves that they

1. have been instructed about the prohibitions to engage in activities mentioned in section 42 paragraph 1 and the obligations pursuant to paragraphs 2, 4 and 5 in an oral and written form by the health office or by a physician commissioned by the health office and
2. have declared in writing after the instruction within the meaning of no. 1 that they are not aware of any facts that would prohibit them to engage in such activities.

If there are indications suggesting that impediments pursuant to section 42 paragraph 1 exist with respect to any person, the certificate may only be issued after a medical certificate proves that the impediments do not or no longer exist.

(2) If impediments pursuant to section 42 paragraph 1 arise after the persons have taken up their activities, they are obliged to immediately inform their employer thereof.

(3) If indications or facts come to the knowledge of the employer that constitute grounds for a prohibition pursuant to section 42 paragraph 1, the employer shall immediately initiate the measures necessary to prevent the further spread of the pathogens.

(4) The employer shall instruct persons who exercise any activity specified in section 42 paragraph 1 sentence 1 or 2 about the prohibitions specified in section 42 paragraph 1 and about the obligation pursuant to paragraph 2 after they have taken up their activity and subsequently every year. Attendance at the instruction shall be documented. Sentences 1 and 2 apply *mutatis mutandis* to civil service employers.

(5) The certificate pursuant to paragraph 1 and the latest documentation of instruction pursuant to paragraph 4 shall be kept with the employer. The employer shall keep the documentary evidence pursuant to sentence 1 and, if he/she exercises an activity pursuant to section 42 paragraph 1 himself, the certificate pursuant to paragraph 1 sentence 1 that concerns him/her, available at the site and present it on request to the competent authority and its officers. Where activities are exercised at various locations it shall suffice to present an authenticated copy.

(6) If the persons obligated under paragraph 1 sentence 1 no. 2 and paragraph 2 are incapacitated or partially incapacitated, the person who is responsible for the care and custody of said persons shall ensure that the foregoing obligations are observed. The same obligation is also incumbent on the person having the care of this person in so far as the care of the person of the latter falls within the scope of his/her duties. The obligations under this provision that are incumbent on the employer apply *mutatis mutandis* to persons who exercise the activities specified in section 42 paragraph 1 on a self-employed basis.

(7) The Federal Ministry for Health shall be empowered to determine by an ordinance with the consent of the Bundesrat that examinations and further requirements be introduced or requirements restricted, if legal instruments of the European Community so require.

Chapter Nine

Activities involving pathogens

Section 44

Requirement to obtain an authorization for activities involving pathogens

Any person who wishes to import or export pathogens to and from the territory covered by this Act, store, supply or work with them there requires an authorization to do so from the competent authority.

Section 45

Exceptions

(1) An authorization pursuant to section 44 shall not be required by persons who are licensed to exercise the profession of physician, dental surgeon or veterinary surgeon in their own practice, for microbiological tests for the purpose of exploratory medical or veterinary diagnosis using cultural methods that are restricted to the primary culturing and subsequent sub-culturing for the purpose of resistance determination and who employ methods that are not geared to detecting specific pathogens that are subject to notification, in so far as the examinations are performed for the direct treatment of their own patients for their own practice.

(2) An authorization pursuant to section 44 is not required for

1. sterility tests, colony counts and other activities involved in microbiological quality assurance in the manufacture, testing and control of the trade in

- a) pharmaceutical products,
 - b) medical devices,
2. sterility tests, colony counts and other activities involved in microbiological quality assurance in so far as these are not performed for the detection of specific pathogens and, for that purpose, involve operations targeted at the concentration or replication of specific pathogens.

(3) The competent authority shall exempt persons from the obligation to obtain an authorization under section 44 for other activities of microbiological quality assurance that are limited to the primary culturing in selective media if the persons have acquired the expertise necessary to exercise the activity intended through at least two years of activity in the field of microbiological quality assurance or through a state-regulated training.

(4) The competent authority shall prohibit activities within the meaning of paragraphs 1, 2 and 3 if a person engaged in such work has proven to be unreliable with reference to those activities which do require an authorisation as specified in paragraphs 1, 2 or 3.

Section 46

Work under supervision

A person who works under the supervision of someone who either has an authorization, or requires no authorization pursuant to section 45, shall require no authorization under section 44.

Section 47

Grounds for refusal, prerequisites for granting an authorization

(1) The authorization shall be refused if the applicant

1. does not possess the necessary expert knowledge or
2. has proven to be unreliable with respect to the very activities for the exercise of which he/she now seeks an authorization.

(2) Proof of the necessary expert knowledge is furnished through

1. completion of studies of human, dental or veterinary medicine, pharmacy or completion of natural scientific studies at a technical college or university with microbiological subjects and
2. at least two years of full-time activity involving pathogens under the supervision of a person who holds an authorization for work involving pathogens.

The competent authority shall also recognize as proof of expert knowledge under number 2 another full-time activity of at least two year's duration in the field of bacteriology, mycology, parasitology or virology, if the applicant has acquired an equivalent expert knowledge in the course of this activity.

(3) The authorization shall be restricted to certain activities and certain pathogens and shall be subject to certain obligations in so far as this is necessary to prevent communicable diseases. The competent authority can grant persons who have completed natural scientific studies at a technical college or university without microbiological subjects or engineering studies at a technical college or university including microbiological subjects or who meet only part of the requirements pursuant to paragraph 2 no. 2, an authorization pursuant to sentence 1 if the applicant has acquired an expert knowledge adequate for his/her limited field of activities.

(4) In the case of applicants who are neither licensed to practise as nor installed as physicians, dental surgeons or veterinary surgeons, the authorization may not cover the direct or indirect detection of a pathogen for diagnosing an infection or communicable disease. Sentence 1 does not apply to applicants who perform activities on behalf of a physician, dental

surgeon or veterinary surgeon, or carry out examinations in hospitals for the immediate treatment of patients of this hospital.

Section 48

Revocation and withdrawal

The authorization pursuant to section 44 may be revoked or withdrawn for reasons other than those specified in the provisions of the Administrative Procedure Act (*Verwaltungsverfahrensgesetz*) if a ground for refusal exists pursuant to section 47 paragraph 1.

Section 49

Obligation to notify

(1) Any person who wishes to engage in the activities within the meaning of section 44 for the first time shall notify this to the competent authority pursuant to sentence 2 at least 30 days in advance. The notification pursuant to sentence 1 shall comprise:

1. an authenticated copy of the authorisation unless the authorisation was issued by the authority pursuant to sentence 1, or information on the exemption from authorisation within the meaning of section 45,
2. information on the kind and scope of the intended activities as well as disposal measures,
3. information on the condition of the premises and installations.

If the information has already been given in another procedure regulated under federal law, reference may be made to the documentation submitted in the course of this procedure. The obligation to notify does not apply to persons who work on the basis of section 46.

(2) With the consent of the competent authorities, the activities within the meaning of section 44 can be commenced before the stipulated period has expired.

(3) The competent authority shall prohibit activities if it is to be feared that they will pose a danger to public health, particularly because

1. the premises or installations are not appropriate for the type and scope of the activities or

2. the prerequisites for a safe disposal are not fulfilled.

Section 50

Notice of change

Any person who exercises an activity mentioned in section 44 shall notify the competent authority forthwith of any substantial modification to the relevant premises or installations, the disposal measures and type and scope of the activity. The same goes for changes with regard to the termination or resumption of the activity. Section 49 paragraph 1 sentence 3 shall apply *mutatis mutandis*. The obligation to notify does not apply to persons working on the basis of section 46.

Section 51

Supervision

All persons engaged in the activities specified in section 44 are subject to supervision by the competent authority. In this respect, they shall be bound to allow the competent authority, or such persons as are entrusted by the latter with this task, to enter upon their land, and they shall provide access to rooms, facilities, installations, books and other documents and allow these to be inspected and the necessary examinations to be conducted. The basic constitutional right to the inviolability of the home (Article 13 paragraph 1 of the Basic Law) shall be limited in this respect.

Section 52

Supply

Pathogens as well as material containing pathogens, may only be supplied to persons who hold an authorization, work under the supervision of a person holding an authorisation or do not require an authorisation pursuant to section 45 paragraph 2 no. 1. Sentence 1 does not apply to official medical or veterinary laboratories.

Section 53

Requirements for premises and installations, precaution against risk

(1) The Federal Ministry for Health shall be empowered, in agreement with the Federal Ministry of Labour and Social Affairs, to issue provisions governing

1. the requirements for the condition of the premises and installations as well as

2. the precautionary measures to be taken with activities pursuant to section 44,

by means of an ordinance with the consent of the Bundesrat in so far as this is necessary for the protection of the population from communicable diseases.

(2) For the purpose of supervising the activities, the ordinance issued pursuant to paragraph 1 may also contain the stipulation that inventories are to be kept of specific types of work and reports on the work carried out be submitted to the competent authority and that certain observations are to be reported to the health office in so far as this is necessary for the prevention or control of communicable diseases.

Chapter Ten

Competent authority

Section 54

Appointment of the authority

(1) The governments of the Laender determine, in the absence of a regulation under Laender law, by means of an ordinance, which entities are competent authorities within the meaning of this Act. In addition, they may also determine therein that either all of the tasks or individual tasks assigned under this Act to the supreme health authority of the Land or the supreme Land authority responsible for the pension scheme for war victims are executed by a Land authority subordinate to the foregoing authorities and that the supreme Land authorities forgo their right to reserve consent under this Act.

Chapter Eleven

Approximation to Community law

Section 55

Approximation to Community law

(1) Ordinances under this Act may also be issued for the purpose of harmonising the legal provisions of the Member States of the European Union, in so far as this is necessary for the implementation of regulations or the implementation of directives or decisions of the Council of the European Union or the Commission of the European Communities that concern the subjects covered by this Act.

Chapter Twelve

Compensation in special cases

Section 56

Compensation

(1) Any germ carrier or any person who is suspected of being contagious or is suspected of being ill or is otherwise a carrier of pathogens and is, within the meaning of section 31 sentence 2, subject or subjected to prohibitions affecting the pursuit of the occupation engaged in up to that date on the basis of the provisions contained in the present Law and consequently suffers a loss of earnings, shall receive pecuniary compensation. The same shall apply to persons who have been or are isolated because they are carriers or suspected of being contagious, however, this only applies to germ carriers if they cannot comply with any other protective measures.

(2) The compensation payable is calculated according to the loss of earnings. For the first six weeks, compensation payments will fully cover the earnings lost. From the beginning of the seventh week onwards, compensation shall be equivalent to the sickness benefit specified in section 47 paragraph 1 of the Social Code Book V in so far as the amount of earnings lost does not exceed the yearly remuneration limit which determines whether or not employees have to belong to the statutory health insurance scheme.

(3) Lost earnings is defined as the remuneration (section 14 of the Social Code Book IV) due to the employee according to the regular working hours applying in his/her case after deduction of taxes and contributions to the social insurance scheme and employment promotion or corresponding sums disbursed to secure an adequate amount of social security (net remuneration). In addition to this amount, the employee shall receive the short-time pay or winter bad weather benefit and the additional winter allowance to supplement winter bad weather benefit to which the employee would have been entitled if he/she had not been prevented from working on the grounds contained in paragraph 1. Should a part of the employee's previous remuneration payments after having ceased to pursue the forbidden occupation or in case of isolation still be outstanding, the lost earnings shall constitute the difference between the net remuneration, mentioned in sentence 1, and the net remuneration received from his or her previous employment in the calendar month following the cessation of the prohibited occupation or the isolation. Sentences 1 and 3 shall apply *mutatis mutandis* to persons doing homework or self-employed persons on condition that in the case of homeworkers the average

monthly remuneration for the year prior to cessation of the prohibited occupation or isolation and in the case of self-employed persons one-twelfth of the last annual income (section 15 of the Social Code Book IV) from the activity liable to compensation shall underlie the calculation of lost earnings.

(4) Where the existence of persons entitled to compensation is placed in jeopardy, they may be reimbursed to an adequate degree by the competent authority, upon request, for the additional expenditure incurred in the periods during which there is a loss of earnings. Self-employed persons whose business or practice has to close for the duration of a measure implemented under paragraph 1 shall, upon request, be granted adequate indemnification by the competent authority for continuing operating costs which are not covered, in addition to compensation under paragraphs 2 and 3.

(5) In the case of employees, the employer shall pay the compensation instead of the competent authority for the duration of the period of employment, but a maximum of six weeks. The sums paid shall be reimbursed to the employer, upon request, by the competent authority. Otherwise, compensation shall be granted by the competent authority upon request.

(6) In the case of employees, the time of payment of the amounts due as compensation shall depend on the time at which the remuneration from the occupation engaged in previously were due. In the case of other persons entitled to compensation, compensation shall be paid on the first day of each month for the preceding month.

(7) Should the person entitled to compensation become unfit for work, the claim to compensation for the same amount to which he/she was entitled at the time of disablement shall remain valid. Claims to which the person entitled to compensation pursuant to paragraph 1 sentence 2 is entitled by reason of the loss of earnings due to incapacity to work on the basis of other legal provisions or a private insurance policy shall, in this respect, pass on to the Land liable to pay the compensation.

(8) The following shall be deducted from the compensation:

1. allowances from the person's employer in so far as these exceed the real earnings lost when combined with the compensation,
2. net remuneration and income pursuant to paragraph 3 from an occupation which is pursued as a substitute for the prohibited occupation in so far as it exceeds the real earnings lost when combined with the compensation,

3. the amounts which the person entitled to compensation wilfully fails to earn by neglecting to pursue an activity other than the prohibited activity in so far as they exceed the real earnings lost when combined with the compensation,
4. the amount of unemployment benefit or unemployment assistance which would have had to be paid to the person entitled to compensation without applying the provisions governing the suspension of the entitlement to unemployment benefit throughout the period of disqualification or default according to current versions of the Social Code Book III and section 66 of the Social Code Book I.

In so far as the prerequisites for a deduction according to both numbers 3 and 4 are met, the higher amount shall be deducted.

(9) The claim to compensation shall be transferred to the Federal Institute of Labour in so far as the person entitled to compensation also has to be granted unemployment benefit, short-time work pay or winter bad weather benefit for the same timespan, and to the Federal Government if he/she is to be granted unemployment assistance for the same timespan. The Federal Institute of Labour is entitled and obliged to assert the claim on behalf of the Federal Government in court.

(10) A claim to indemnification for earnings lost by the person entitled to compensation owing to a prohibition preventing said person from pursuing his/her gainful employment or owing to the isolation measure, and which is founded on other statutory provisions, shall be transferred to the Land liable to grant the compensation in so far as said Land is liable to grant benefits to the person entitled to compensation under the present Act.

(11) The requests for compensation as provided for in paragraph 5, shall be made to the competent authority within three months following the cessation of the prohibited activity or after termination of the period of isolation. Employees shall enclose, with the request, a certificate from the employer, persons engaged in home-work shall enclose a certificate from their contract-giver stating the amounts earned by them in the relevant period and the statutory deductions according to paragraph 3, and self-employed persons shall enclose a certificate from the inland revenue office stating their last income from work as proven to the office. Has such an income not yet been proven, or should a difference according to paragraph 3 have to be calculated, the competent authority can request the submission of one or more additional supporting documents.

(12) The competent authority shall, upon request, make an advance payment amounting to the anticipated reimbursement to the employer and shall make an advance payment amounting to the anticipated compensation to persons engaged in home-work and self-employed persons.

Section 57

Relation to the social insurance schemes and employment promotion

(1) Persons entitled to compensation according to section 56 paragraph 1 shall continue to enjoy compulsory insurance coverage in the statutory pension scheme. The contributions shall be calculated on the basis of

1. in the case of a compensation pursuant to section 56 paragraph 2 sentence 2, the remuneration underlying the compensation for lost earnings pursuant to section 56 paragraph 3 prior to the deduction of taxes and shares in the contributions to the social insurance or corresponding sums disbursed to secure social security,
2. in the case of a compensation pursuant to section 56 paragraph 2 sentence 3, 80 per cent of the remuneration or income underlying this compensation.

The Federal Land liable to grant compensation shall pay the contributions to the statutory pensions insurance. Where the employer pays the compensation on behalf of the competent authority, sentences 2 and 3 shall apply to him or her accordingly; the competent authority shall, upon request, reimburse the sums disbursed by the employer.

(2) Persons who shall be granted a compensation pursuant to section 56 paragraph 1 sentence 2 shall continue to enjoy compulsory coverage in the statutory health insurance and the statutory long-term care insurance schemes as well as pursuant to the Social Code Book III. Paragraph 1 sentences 2 to 4 shall apply *mutatis mutandis*.

(3) In the statutory accident insurance, the yearly earnings during the periods in which the injured person had been entitled to compensation under section 56 paragraph 1 in the year prior to the occupational accident, shall be calculated on the basis of the remuneration or income from work that corresponds to the person's average remuneration or income during the periods of this time-span in which he/she received remuneration or income, if this procedure is more favourable to the person entitled to compensation. Section 82 paragraph 3 of the Social

Code Book VII shall apply *mutatis mutandis*. The additional expenditure, arising as a result of the implementation of sentence 1, shall be reimbursed to the insurance schemes by the competent authority.

(4) In the health insurance scheme, benefits are calculated according to the level of remuneration paid before the claim to compensation was established.

(5) Periods in which, pursuant to paragraph 1, the person continues to be subject to compulsory insurance pursuant to the Social Code Book III shall not be taken into consideration in establishing the temporal basis for a claim to unemployment benefits pursuant to the Social Code Book III.

Section 58

Reimbursement of expenditure

Persons entitled to compensation within the meaning of section 56 paragraph 1 and who are not subject to compulsory insurance in the statutory health or pension or long-term care insurance schemes are entitled to claim adequate reimbursement of their expenditure for social security from the competent authority. In cases where they are earning net remuneration and income from an occupation which serves as a substitute for the prohibited one, the claim pursuant to sentence 1 shall diminish in the same proportion as this income constitutes of the compensation before deductions.

Section 59

Special provisions for germ carriers

Germ carriers who are entitled to compensation pursuant to section 56, shall be considered physically disabled within the meaning of the Social Code Book III.

Section 60

Pension in the case of vaccine injuries and health impairments due to other measures of specific prophylaxis

(1) Any person who has suffered a health impairment through a vaccination or another measure of specific prophylaxis that was

1. publicly recommended by a competent authority and administered within the sphere of its responsibility
2. prescribed on the basis of the present Act
3. prescribed by law or
4. administered on the basis of ordinances issued in the implementation of international health regulations,

shall receive a pension upon request after the vaccination because of the vaccine injury within the meaning of section 2 no. 11, or following another measure to which the latter applies *mutatis mutandis*, in compensation for the health-related and economic consequences of the impairment, applying *mutatis mutandis* the provisions of the Federal War Victims' Compensation Act (*Bundesversorgungsgesetz*) unless the present Act provides otherwise. Sentence 1 no. 4 shall apply only to persons who were vaccinated for the purpose of re-entering the territory covered by this Act and whose residence or habitual abode is located in this territory or who had only left their residence or habitual abode temporarily for professional reasons or for training purposes, as well as their dependents who live with them in the same household. The persons specified in section 10 of the Social Code Book V shall be considered dependents.

(2) A pension, within the meaning of paragraph 1, shall also be granted to German citizens who suffer a vaccine injury, outside of the territory covered by this Act, through a vaccination which would have been compulsory for a stay on the territory covered by this Act under the provisions of the Vaccination Law of 8 April 1874 in the consolidated version published in the Federal Law Gazette Part III, classification number 2126-5. The pension shall be granted only if the injured person

1. could not have been vaccinated on the territory covered by this Act,
2. was vaccinated by a physician and

3. had been living in the same household with either parent or a person who had care and custody of him/her at the time of the vaccination and if at such time said persons had been residing outside of the territory covered by this Act for professional reasons or for the purpose of vocational training and not only on a temporary basis.

(3) A pension within the meaning of paragraph 1 shall also be granted to persons who suffer a vaccine injury as a result of a smallpox vaccination outside of the territory covered by this Act administered in keeping with the provisions of the Vaccination Law or as the result of a smallpox vaccination which was required by law or the administration of which was ordered on the basis of a law in the territories designated in section 1 paragraph 2 no. 3 of the Federal Act on Expelled Persons (*Bundesvertriebenengesetz*), in the former German Democratic Republic or in East Berlin unless compensation is being awarded on the basis of other legal provisions. Claims under sentence 1 may only be asserted by persons who had taken or take up permanent residence within the limits of the territory covered by this Act

1. as German citizens, by 8 May 1945,
2. as persons entitled under sections 1 to 4 of the Federal Act on Expelled Persons or section 1 of the Refugee Assistance Act (*Flüchtlingshilfegesetz*) in the version published on 15 May 1971 (Federal Law Gazette I, page 681) last amended by Article 24 of the Law of 26 August 1994 (Federal Law Gazette I, page 1014),
3. as spouses or descendents of repatriates within the meaning of section 7 paragraph 2 of the Federal Act on Expelled Persons in the version applying before 1 January 1993,
4. by way of family reunification pursuant to section 94 of the Federal Act on Expelled Persons.

(4) The surviving dependants of an injured person within the meaning of paragraphs 1 to 3 shall be awarded a pension upon request in application *mutatis mutandis* of the provisions contained in the Federal War Victims' Compensation Act.

(5) A vaccine injury within the meaning of section 2 no. 11 shall also be deemed to be present in the case of a health impairment resulting from an accident which meets the prerequisites stipulated in section 1 paragraph 2 letters e or f or section 8a of the Federal War Victims' Compensation Act. Damage to a medical aid worn on the body, spectacles, contact

lenses or dental prostheses resulting from an adverse post-vaccinal reaction within the meaning of paragraph 1 or an accident within the meaning of sentence 1, shall be equivalent to a vaccine injury within the meaning of sentence 1.

(6) Within the framework of pensions pursuant to paragraphs 1 to 5, the provisions of Chapter Two of the Social Code Book X on the protection of social data shall be applied.

Section 61

Recognition of health impairment

The probability of a causal link shall suffice for the recognition of a health impairment as a consequence of an injury within the meaning of section 60 paragraph 1 sentence 1. Should the only reason preventing this probability from being accepted be uncertainty in medical-scientific circles about the cause of the detected condition, the health impairment may be recognized as the consequence of an injury within the meaning of section 60 paragraph 1 sentence 1, with the consent of the supreme Land authority responsible for the pension scheme for war victims. Consent may be given generally. Recognition of a claim pursuant to sentences 1 and 2 and administrative acts based thereon, may be withdrawn with retroactive effect should it be established beyond doubt that the health impairment did not result from a vaccination or another measure of specific prophylaxis; benefits received do not have to be reimbursed.

Section 62

Therapy

Within the framework of his/her treatment, the injured person within the meaning of section 60 paragraphs 1 to 3 shall also be entitled to therapeutic pedagogical treatment as well as physiotherapeutic and kinesiotherapeutic exercises if these constitute a necessary part of the treatment.

Section 63

Concurrence of claims, application of provisions of the Federal War Victims' Compensation Act, transitory regulations for the reimbursement procedure to the health insurance funds

(1) Should claims arising from section 60 collide with claims from an injury within the meaning of section 1 of the Federal War Victims' Compensation Act, or other laws which provide for a corresponding application of the Federal War Victims' Compensation Act, a uniform pension shall be fixed taking into consideration the reduction in the person's working capacity caused by all of the consequences of the injury.

(2) Should a pension claim pursuant to section 60 collide with a claim for compensation on the grounds of breach of official duty through negligence, the existence of the prerequisites stipulated under section 60 shall be without prejudice to the claim arising under Article 839 paragraph 1 of the Civil Code.

(3) Section 4 paragraph 1 no. 2 of the Social Code Book VII shall not apply in the case of vaccine injuries.

(4) Section 81a of the Federal War Victims' Compensation Act shall apply provided that the legal claim for compensation vis-à-vis third parties passes on to the Land obliged to grant the benefits under this Act.

(5) Sections 64 to 64d, 64f and 89 of the Federal War Victims' Compensation Act shall apply *mutatis mutandis* provided that the consent of the Federal Minister of Labour and Social Affairs is replaced by that of the supreme Land authority responsible for the pension scheme for war victims. Consent shall be granted in application *mutatis mutandis* of section 89 paragraph 2 of the Federal War Victims' Compensation Act in agreement with the supreme health authority of the Land.

(6) Section 20 of the Federal War Victims' Compensation Act shall apply provided that the number mentioned in paragraph 1 sentence 3 is replaced by the number of disabled persons and surviving dependents entitled to a pension pursuant to this Act compared to the number in the previous year, that in paragraph 1 sentence 4 the expenditure per pensioner of the health insurance funds as mentioned there is replaced by their national expenditure per member, that paragraph 2 sentence 1 applies to the supreme Land authority responsible for the pension scheme for war victims or an authority determined by it and that in paragraph 3

the number mentioned in sentence 1 is replaced by the figure 1.3 and sentences 2 to 4 do not apply.

(7) Any reimbursements for benefits provided by the health insurance funds prior to 1 January 1998 that have not been made by 1 January 1998 will be settled according to the reimbursement regulations applicable until that date.

(8) For the year 1998, the lump sum pursuant to section 20 of the Federal War Victims' Compensation Act will be assessed as follows: the annual average is calculated on the basis of the total amounts reimbursed by the Land to the health insurance funds pursuant to this Act in the years from 1995 to 1997, minus the amounts reimbursed for benefits in case of need for long-term care pursuant to section 11 paragraph 4 and section 12 paragraph 5 of the Federal War Victims' Compensation Act in the version applicable until 31 March 1995, and minus the amounts reimbursed pursuant to section 19 paragraph 4 of the Federal War Victims' Compensation Act in the version applicable until 31 December 1993.

Section 64

Competent authority for pensions

(1) The pension due according to sections 60 to 63 paragraph 1 shall be paid by the authorities responsible for the implementation of the Federal War Victims' Compensation Act. The local jurisdiction of said authorities shall be determined by means of an ordinance issued by the government of the Land liable to pay the pension (section 66 paragraph 2). The government of the Land shall be authorized to delegate the power to act to other authorities by means of an ordinance.

(2) The Law on Administrative Procedure with regard to the Pension Scheme for War Victims in the version published on 6 May 1976 (Federal Law Gazette I, p. 1169), last amended by the Law of 18 August 1980 (Federal Law Gazette I, p. 1469), with the exception of sections 3 and 4, the provisions of chapters one and three of the Social Code Book X, and the provisions contained in the Social Court Law on Preliminary Proceedings shall apply.

(3) Paragraph 2 shall not apply in so far as the pension comprises the granting of benefits which correspond to those awarded by virtue of war victims' relief pursuant to sections 25 to 27j of the Federal War Victims' Compensation Act.

Section 65

Compensation for official measures

(1) In so far as a measure pursuant to sections 16 and 17 causes the destruction of, damage to or otherwise a reduction in the value of objects or any pecuniary prejudice other than an insignificant one, compensation shall be paid in cash; however, no compensation shall be paid to any person whose objects are contaminated with or suspected of being contaminated with pathogens or pests which are presumed to be carriers of such pathogens. Section 254 of the Civil Code shall apply *mutatis mutandis*.

(2) The amount of compensation payable pursuant to paragraph 1, shall depend on the usual value of the object if the latter is destroyed; if it is damaged or its value otherwise diminished, the compensation payable shall depend on the amount of the reduction in the usual value. Should it prove possible to redress this reduction in value, compensation shall depend on the expenditure needed to achieve this. Compensation may not exceed the usual value which the object would have had, had it not been damaged or its value otherwise reduced. In determining the usual value, the state of the object and all other circumstances which determine the latter's value at the time when the measure was implemented, shall be decisive. Compensation for any other than insignificant pecuniary prejudices may not place the affected person in a better financial position than he/she would be in had the measure not been implemented. Expenditure incurred as a result of the measure shall be reimbursed.

Section 66

Entity liable to pay

(1) Liable to grant compensation pursuant to section 56 is that Land in which the prohibition has been issued, in the cases provided for in section 34 paragraphs 1 to 3 and section 42, the Land in which the prohibited activity was engaged in. Liable to grant compensation pursuant to section 65 is the Land in which the injury has been caused.

(2) A pension due as a result of a vaccine injury pursuant to sections 60 to 63 shall be payable

1. in the cases provided for in section 60 paragraph 1 by the Land in which the injury has been caused,
2. in the cases provided for in section 60 paragraph 2
 - a) by the Land in which the injured person has his/her residence or habitual abode, at the time when the injury occurs, on the territory covered by this Act,

- b) by the Land in which the injured person had his/her last residence or habitual abode if no residence or habitual abode exists on the territory covered by this Act at the time when the injury occurs,
 - c) in the case of injured minors, by the Land in which the parent or the person having the care and custody of the injured minor, with whom the latter lives in a common household, has his/her residence or habitual abode on the territory covered by this Act or, in the event that such a residence or habitual abode does not exist, the Land in which the person had his/her most recent residence or habitual abode, if the prerequisites applicable to residences, contained in letter a or b, are not fulfilled,
3. in the cases provided for in section 60 paragraph 3, by the Land in which the injured person has established or establishes his/her residence or habitual abode for the first time upon the territory covered by this Act.

(3) In the cases provided for in section 63 paragraph 1 the costs generated by the supervision of additional injury, shall be paid by the provider of benefits who is responsible for paying the pension due as a result of the additional injury.

Section 67 **Attachment**

(1) The compensation to be paid pursuant to section 56 paragraph 2 sentences 2 and 3 may be attached according to the currently valid provisions on earned income contained in the Code of Civil Procedure.

(2) The transfer, pledging and attachment of claims under sections 60, 62 and 63 paragraph 1 shall comply with the provisions of the Federal War Victims' Compensation Act.

Section 68

Recourse to the courts

(1) The normal recourse to the courts is possible in the event of disputes over claims to compensation pursuant to sections 56 and 65 and in the case of disputes over claims for reimbursement pursuant to section 56 paragraph 4 sentence 2, section 57 paragraph 1 sentence 2 and paragraph 2 sentence 3 as well as section 58 sentence 1.

(2) Recourse to the courts of social jurisdiction shall be possible for disputes under public law over matters arising from sections 60 to 63 paragraph 1. In so far as the Law on Social Courts contains special provisions governing the pension scheme for war victims, these shall also apply to disputes under sentence 1.

(3) Paragraph 2 shall not apply in so far as a pension is paid according to the provisions relating to war victims' relief pursuant to sections 25 to 27e of the Federal War Victims' Compensation Act. In this respect, recourse to the administrative courts shall be possible.

Chapter Thirteen

Costs

Section 69

Costs

(1) The costs for

1. the transmission of notification under sections 6 and 7,
2. the carrying out of surveys pursuant to section 14 sentence 2,
3. the measures pursuant to section 17 paragraph 1, also in conjunction with paragraph 3, in so far as they have been ordered by the competent authority and the need for the measures was not caused wilfully,
4. examination and treatment pursuant to section 19 paragraph 2 no. 2,
5. the measures pursuant to section 20 paragraph 5,
6. the carrying out of investigations pursuant to sections 25 and 30,
7. the carrying out of protective measures pursuant to sections 29 and 30,
8. the X-ray examinations pursuant to section 36 paragraph 4 sentence 2

shall be defrayed by public funds unless third parties are obliged to bear the costs by virtue of other legal regulations or by virtue of a contract. As for the rest, the liability to pay fees and the amount of such fees shall be governed by the law of the respective Land without prejudice to sections 18 and 38.

(2) It shall be within the purview of the Laender to determine who shall have to provide the public funds in question.

Chapter Fourteen

Special provisions

Section 70

Tasks of the Bundeswehr and the health office

(1) In the sphere of responsibility of the German Ministry of Defence, the enforcement of this Act shall be incumbent on the competent agencies of the German Federal Armed Forces (*Bundeswehr*) in so far as it applies to

1. persons accommodated in quarters or other facilities belonging to the German Federal Armed Forces,
2. soldiers who permanently or temporarily live outside of the facilities specified in no. 1,
3. members of the German Federal Armed Forces during transportation, on marches, manoeuvres and exercises,
4. the instruction pursuant to section 43 in the case of persons who engage in one of the activities specified in section 42 in establishments belonging to the German Federal Armed Forces,
5. premises, installations, pieces of equipment and articles of daily use belonging to the German Federal Armed Forces,
6. within the sphere of responsibility of the German Federal Armed the activities involving pathogens.

The obligations to notify pursuant to sections 6 and 7 shall be incumbent on the medical officer of the base.

(2) In the cases specified in paragraph 1 no. 2, the measures to control communicable diseases are to be carried out in consultation with the competent health office.

(3) In the case of civilian employees living outside of the facilities specified in paragraph 1, no. 1, the measures to control communicable diseases are to be taken in consultation with the competent body of the German Federal Armed Forces.

(4) Where there is imminent danger, provisional measures may be undertaken by the health office in the cases specified in paragraph 2 and by the competent body of the German Federal Armed Forces in the cases specified in paragraph 3.

(5) The Federal Government may determine by means of general administrative provisions with the consent of the Bundesrat, to what extent the health offices and the competent bodies of the German Federal Armed Forces shall have to inform each other in the event of the appearance or suspected appearance of a communicable disease and to what extent they shall have to provide mutual support in carrying out investigations.

Section 71

Tasks pursuant to the Seamen's Law

In the case of crew members within the meaning of section 3 of the Seamen's Law (*Seemannsgesetz*) who engage in one of the activities specified in section 42 paragraph 1 sentence 1 or 2 on board merchant vessels, the instructions pursuant to section 43 paragraph 1 shall be incumbent on the physicians empowered pursuant to section 81 paragraph 1 of the Seamen's Law to ascertain a sailor's fitness for sea duty to perform the examinations.

Section 72

Tasks of the Federal Railway Agency

In the domain of the railways of the Federal Government and magnetic levitation systems, the enforcement of this Act with respect to track vehicles as well as fixed installations used exclusively for supplying water to passenger trains shall be incumbent on the Federal Railway Agency (*Eisenbahn-Bundesamt*) in so far as the tasks of the health office and the competent authority pursuant to sections 37 to 39 and 41 are concerned.

Chapter Fifteen

Penal Provisions and Provisions on Administrative Fines

Section 73

Provisions on administrative fines

(1) An administrative offence shall be deemed to be committed by any person who wilfully or negligently:

1. contrary to section 6 paragraph 1 or section 7, each also in conjunction with an ordinance pursuant to section 15 paragraph 1 fails to make a notification or fails to do so correctly, in full or in time,
2. contrary to section 6 paragraph 2, section 34 paragraph 5 sentence 1 or section 43 paragraph 2 fails to make a notification or fails to do so correctly, in full or in time,
3. contrary to section 16 paragraph 2 sentence 2, also in conjunction with section 26 paragraph 1, section 36 paragraph 3 or an ordinance pursuant to section 17 paragraph 4 sentence 1, section 41 paragraph 1 sentence 3, also in conjunction with an ordinance pursuant to paragraph 2 sentence 1, or section 51 sentence 2, fails to allow access to a piece of land, a room, a facility, an installation, a means of transport or another article,
4. contrary to section 16 paragraph 2 sentence 3, also in conjunction with section 26 paragraph 1, section 36 paragraph 3 or an ordinance pursuant to section 17 paragraph 4 sentence 1, section 29 paragraph 2 sentence 3, also in conjunction with an ordinance pursuant to section 32 sentence 1, or section 41 paragraph 1 sentence 3, also in conjunction with an ordinance pursuant to paragraph 2 sentence 1, fails to provide information or fails to do so correctly, in full or in time,
5. contrary to section 16 paragraph 2 sentence 3, also in conjunction with section 26 paragraph 1, section 36 paragraph 3 or an ordinance pursuant to section 17 paragraph 4 sentence 1, fails to submit a document or fails to do so correctly, in full or in time,
6. contravenes an enforceable order pursuant to section 17 paragraph 1, also in conjunction with an ordinance pursuant to paragraph 4 sentence 1, section 17 paragraph 3 sentence 1, section 26 paragraph 2 sentence 1 or 2, also in conjunction with section 29 paragraph 2 sentence 2, the latter also in conjunction with an ordinance pursuant to section 32 sentence 1, section 26 paragraph 3 sentence 2, section 28 paragraph 1 sentence

1, also in conjunction with an ordinance pursuant to section 32 sentence 1 or section 34 paragraph 8 or 9,

7. contrary to section 18 paragraph 1 sentence 1 applies an agent or a procedure,
8. contrary to section 22 paragraph 1 sentence 1 or 2 fails to make an entry or fails to do so correctly, in full or in time or fails to issue a vaccination certificate or fails to do so correctly, in full or in time,
9. contrary to section 23 paragraph 1 sentence 1 or 2 fails to record infections or the appearance of pathogens specified there or fails to do so correctly, in full or in the manner prescribed or fails to keep this record or fails to keep it for not less than ten years,
10. contrary to section 23 paragraph 1 sentence 3 fails to permit an inspection,
11. contrary to section 26 paragraph 3 sentence 1 fails to permit an examination,
12. contrary to section 29 paragraph 2 sentence 3, also in conjunction with an ordinance pursuant to section 32 sentence 1 fails to permit access,
13. contrary to section 29 paragraph 2 sentence 3, also in conjunction with sentence 4 or an ordinance pursuant to section 32 sentence 1, section 49 paragraph 1 sentence 1 or section 50 sentence 1 or 2 fails to make a notification or fails to do so correctly, in full or in time,
14. contrary to section 34 paragraph 1 sentence 1, also in conjunction with sentence 2 or paragraph 3, exercises an activity, enters a room, uses installations or attends functions stipulated in these provisions,
15. enters a room, uses installations or attends functions without a permission pursuant to section 34 paragraph 2,
16. contrary to section 34 paragraph 4 fails to see to it that the obligations stipulated there are complied with,
17. contrary to section 34 paragraph 6 sentence 1, also in conjunction with sentence 2, fails to inform the health office or fails to do so correctly, in full or in time,

18. contrary to section 35 sentence 1 or section 43 paragraph 4 sentence 1 fails to provide an instruction or fails to do so correctly, in full or in time,
19. contrary to section 36 paragraph 4 sentence 6 fails to acquiesce to an examination,
20. contrary to section 43 paragraph 1 sentence 1, also in conjunction with an ordinance pursuant to paragraph 7, employs a person,
21. contrary to section 43 paragraph 5 sentence 2 fails to submit an evidence or a certificate or fails to do so in time,
22. contravenes an enforceable obligation pursuant to section 47 paragraph 3 sentence 1,
23. contrary to section 51 sentence 2 fails to submit a book or other document or fails to do so in time, fails to permit inspection or fails to acquiesce to an examination or
24. contravenes an ordinance pursuant to section 17 paragraph 5 sentence 1, section 20 paragraph 6 sentence 1 or paragraph 7 sentence 1, section 38 paragraph 1 sentence 1 no. 3 or paragraph 2 no. 3 or 5 or section 53 paragraph 1 no. 2 or an enforceable order based on such an ordinance in so far as the ordinance refers to this provision on administrative fines for a specific offence.

(2) The administrative offence can, in the cases stipulated in paragraph 1 nos. 8, 9 and 21, be punished with a fine of up to two thousand five hundred Euro, in the other cases with a fine of up to twenty five thousand Euro.

Section 74
Penal provisions

Any person who wilfully commits one of the acts stipulated in section 73 paragraph 1 nos. 1 to 7, 11 to 20, 22, 23 or 24 and as a result spreads a disease specified in section 6 paragraph 1 no. 1 or a pathogen specified in section 7 shall be punished with imprisonment of up to five years or with a fine.

Section 75
Further penal provisions

(1) Any person who

1. contravenes an enforceable order pursuant to section 28 paragraph 1 sentence 2, section 30 paragraph 1 or section 31, each also in conjunction with an ordinance pursuant to section 32 sentence 1,
2. contrary to section 42 paragraph 1 sentence 1, also in conjunction with sentence 2, each also in conjunction with an ordinance pursuant to section 42 paragraph 5 sentence 1, or section 42 paragraph 3 employs a person or exercises an activity,
3. without a permission pursuant to section 44 moves, exports, stores, supplies or works with pathogens or
4. contrary to section 52 sentence 1 supplies pathogens or material

shall be punished with imprisonment of up to two years or with a fine.

(2) Any person who contravenes an ordinance pursuant to section 38 paragraph 1 sentence 1 no. 5 or paragraph 2 no. 4 or an enforceable order based on such an ordinance in so far as the ordinance refers to this penal provision for a specific offence shall be liable to the same punishment.

(3) Any person who spreads one of the diseases specified in section 6 paragraph 1 no. 1 or one of the pathogens specified in section 7 by committing one of the acts stipulated in paragraph 1 shall face imprisonment of not less than three months to not more than five years unless the act entails a more severe punishment under another provision.

(4) If the offender acts negligently in the cases provided for in paragraph 1 or 2, he or she shall face imprisonment of up to one year or a fine.

(5) Any person who, contrary to section 24 sentence 1, also in conjunction with sentence 2, the latter also in conjunction with an ordinance pursuant to section 15 paragraph 1, treats a person shall face up to one year imprisonment or a fine.

Section 76

Confiscation

Objects to which a criminal offence under section 75 paragraph 1 or 3 refers, can be confiscated.

Chapter Sixteen

Transitory provisions

Section 77

Transitory provisions

(1) The authorization for the work involving pathogens and the trade in them granted under the provisions of the Federal Law on Communicable Diseases is considered as an authorization within the meaning of section 44 in the territory covered by this Act; for legal entities this shall apply for up to five years after the entry into force of this Act provided that the authorization pursuant to section 48 can be revoked or withdrawn if grounds for refusal pursuant to section 47 paragraph 1 no. 2 are present with respect to the persons appointed by law or by-laws as representatives; this provision shall also apply if the holder of the authorization does not assume the management of the activities himself and the person entrusted by him with the management of the activities presents a ground for refusal pursuant to section 47 paragraph 1. The restriction stipulated in section 47 paragraph 4 sentence 1 does not apply to the persons mentioned in section 22 paragraph 4 sentence 2 of the Federal Law on Communicable Diseases if they themselves or the persons entrusted by them with the management of the activities, hold an authorization which is unrestricted in this respect. For persons who have lawfully performed activities specified in section 20 paragraph 1 sentence 1 of the Federal Law on Communicable Diseases prior to the entry into force of this Act, the exemption from the authorization for these works shall continue valid for a period of five years following the entry into force of this Act; section 45 paragraph 4 shall apply *mutatis mutandis*.

(2) A certificate pursuant to section 18 of the Federal Law on Communicable Diseases shall be considered as a certificate pursuant to section 43 paragraph 1.

Article 5

Entry into force, repeal

(1) This Act, with the exception of paragraph 2, shall enter into force on the first day of the sixth calendar month following its publication. At the same time, the following shall be repealed:

1. the Federal Law on Communicable Diseases in the version published on 18 December 1979 (Federal Law Gazette I, p. 2262; 1980 I, p 151), last amended by Article 2 section 37 of this Act,
2. the Act on the Control of Sexually Transmitted Diseases (*Gesetz zur Bekämpfung der Geschlechtskrankheiten*) in the consolidated version published in the Federal Law Gazette Part III, classification no. 2126-4, last amended by Article 10 of the Law of 19 December 1997 (Federal Law Gazette I, p. 3158),
3. the Laboratory Reporting Ordinance (*Laborberichtsverordnung*) of 18 December 1987 (Federal Law Gazette I, p. 2819), last amended by article 7 section 2 of the Law of 24 June 1994 (Federal Law Gazette I, p. 1416),
4. the Ordinance on the extension of the obligation to notify to include human spongiform encephalopathies (*Verordnung über die Ausdehnung der Meldepflicht auf die humanen spongiformen Enzephalopathien*) of 1 July 1994 (Federal Law Gazette I, p. 1455),
5. the First Ordinance on the Implementation of the Act on the Control of Sexually Transmitted Diseases in the consolidated version published in the Federal Law Gazette Part III, classification no. 2126-4-1,
6. the Second Ordinance on the Implementation of the Act on the Control of Sexually Transmitted Diseases in the consolidated version published in the Federal Law Gazette Part III, classification no. 2126-4-2,

7. the Ordinance on the extension of the obligation to notify pursuant to section 3 of the Federal Law on Communicable Diseases to include the enteropathic haemolytic-uraemic syndrome (HUS) and infection with enterohaemorrhagic Escherichia coli (EHEC) of 9 November 1998 (Federal Law Gazette I, p. 3425).

(2) Article 1 sections 37, 38 and article 2 section 37 shall enter into force on the day following publication.

The above Act is herewith signed and will be published in the Federal Republic of Germany.

Berlin, 20 July 2000

The Federal President
Johannes Rau

The Federal Chancellor
Gerhard Schröder

The Federal Minister for Health
Andrea Fischer

The Federal Minister of the Interior
Schily

The Federal Minister of Food, Agriculture and Forestry
Karl-Heinz Funke

The Federal Minister of Defence
Rudolf Scharping

The Federal Minister for the Environment,
Nature Conservation and Nuclear Safety
Jürgen Trittin