

Regulations relating to the collection and processing of personal health data in the Surveillance System for Communicable Diseases (MSIS) and in the Tuberculosis Register and relating to the notification of communicable diseases (the MSIS and Tuberculosis Register Regulations)

Laid down by Royal Decree of 20 June 2003 in pursuance of Act No. 24 of 18 May 2001 relating to personal health data filing systems and the processing of personal health data, sections 6, 8 - fourth paragraph cf. third paragraph, 9 - second paragraph, 16 - fourth paragraph, 17 - third paragraph, 22 - fifth paragraph and 27 - second paragraph, Act No. 64 of 2 July 1999 relating to healthcare personnel etc., section 37, and Act 55 of 5 August 1994 relating to protection from communicable diseases, section 2-3, fourth paragraph. Cf. Protocol 31, Article 16, of the EEA Agreement (Decision No. 2119/98/EC). Submitted by the Ministry of Health.

Chapter 1 General provisions

Section 1-1 (Establishment of the Surveillance System for Communicable Diseases (MSIS) and the Central Tuberculosis Register etc.)

These Regulations provide for the establishment of a national Surveillance System for Communicable Diseases (MSIS) and a Central Tuberculosis Register of such diseases in humans. The Regulations lay down rules for the collection and processing of personal health data in the Registers.

The collection and processing of personal health data in the Registers may be done manually and by electronic means.

These Regulations also provide rules regarding the notification of communicable diseases.

Section 1-2 (Content of the MSIS Register and the Tuberculosis Register)

The MSIS Register shall contain data relating to identifiable persons in Norway who have been infected by diseases that are classified as Group A diseases, ref. third and sixth paragraph below, and de-identified data relating to persons who have been infected by diseases which are classified as Group B or Group C diseases, ref. fourth to sixth paragraph below.

The Tuberculosis Register shall contain data relating to identifiable persons in Norway who have been infected by tuberculosis, persons who are receiving treatment for tuberculosis or persons who are discovered to be tuberculin converters by tuberculin testing in the 10th grade of lower secondary school, ref. Section 5-4 of the Regulations relating to Tuberculosis Control.

Communicable diseases in Group A are diseases where it is necessary to monitor the situation and register detailed information about each case with reference to disease control and international commitments, ref. Section 2-7. These are diseases that are preventable through the Child Vaccination Programme, food-borne diseases, diseases that can be transmitted by animals (zoonoses), virus hepatitis, imported diseases, serious systemic diseases, diseases caused by certain resistant bacteria and serious environmental diseases.

Communicable diseases in Group B are the sexually transmittable diseases gonorrhoea, HIV infection and syphilis.

Group C diseases are diseases from the categories in Group A or B where it is necessary to monitor the situation but where it is not necessary to register detailed information about individual cases.

The Ministry issues more detailed rules about which diseases belong to Group A, B or C.

Section 1-3 (Purpose of the Registers)

The MSIS shall contribute to the surveillance of communicable diseases in humans in Norway through the continuous, systematic collection, analysis, interpretation and reporting of data relating to occurrences of communicable diseases and thereby provide a basis on which to:

1. describe the occurrence of communicable diseases over time and by geographic and demographic conditions,
2. discover and help to contain outbreaks of communicable diseases,
3. give advice to the general public, healthcare personnel and public administration bodies about disease control measures
4. evaluate the effects of disease control measures
5. conduct, promote and provide a basis for research into the spreading and causes of communicable diseases.

In addition to purposes stated in the first paragraph, the Tuberculosis Register shall provide the basis on which to evaluate the effects of treatment measures and assure the quality of these measures.

In addition to the purposes stated above, data in the Registers may be processed for the management, planning and quality assurance of the public health service and public health administration, as well as for the preparation of statistics and for research.

Section 1-4 (*Prohibition against use*)

The data in the Registers may not be used for purposes which are incompatible with the purposes stated in Section 1-3.

Data relating to individual persons which is arrived at through the processing of personal health data pursuant to these Regulations may not be used for insurance purposes even with the consent of the data subject.

Section 1-5 (*Data controller*)

The Norwegian Institute of Public Health is the data controller for the collection and processing of personal health data in the MSIS and Tuberculosis Registers.

Section 1-6 (*Data processor*)

The Norwegian Institute of Public Health may enter into a written agreement with a data processor on the collection and processing of personal health data in the Registers, including monitoring and research, ref. Section 1-3, the operation and quality assurance of the Registers, and disclosure of data to users.

Section 1-7 (*Data in the MSIS Register on cases of Group A and B communicable diseases and data in the Tuberculosis Register*)

The MSIS Register may without consent contain data as stated the third paragraph below relating to persons who have or have had a communicable disease in Group A and Group B, ref. Section 1-2.

The Tuberculosis Register may without consent contain data as stated in the third paragraph below relating to persons who have or have had tuberculosis, persons who are receiving prophylactic treatment for tuberculosis or persons who are discovered to be tuberculin converters by tuberculin testing in the 10th grade of lower secondary school, ref. Section 5-4 of the Regulations relating to the Control of Tuberculosis.

The Registers may contain the following data insofar as this is necessary to achieve the purpose of the Registers:

1. personal data:
 - 1.1 for persons with communicable diseases in Group A: name, personal identity number or other unique identification for persons without a Norwegian identity number, marital

- status and occupation. For persons with communicable diseases in Group B: month and year of birth, sex.
- 1.2 for communicable diseases in Group A: home address, for communicable diseases in Group B: municipality of residence.
 - 1.3 country of birth, parents' country of birth, date of arrival in Norway and reason for staying in Norway,
 - 1.4 for communicable diseases in Group A: name of workplace, school or day nursery to which the patient is attached.
2. administrative data:
 - 2.1 institution/enterprise where medical assistance is available and is provided,
 - 2.2 name and address of the physician responsible for treatment, general practitioner or reporting physician
 - 2.3 hospitalisation, date of admission, date of discharge
 3. medical data:
 - 3.1 relating to diagnosis and basis for diagnosis
 - 3.2 relating to the infectious agent, including resistance
 - 3.3 relating to predisposing and prophylactic factors
 - 3.4 the Tuberculosis Register may also contain data about the course of the disease and treatment of tuberculosis
 4. epidemiological data:
 - 4.1 relating to infectious conditions and infection tracing
 - 4.2 relating to notification

Section 1-8 (*Data in the MSIS Register relating to cases of communicable diseases in Group C*)

The MSIS Register may without consent contain the following data relating to persons who have or have had a communicable disease in Group C, ref. Section 1-2 insofar as this is necessary to achieve the purpose of the Register.

1. personal data:
 - 1.1 year of birth
 - 1.2 sex
 - 1.3 municipality of residence
2. administrative data:
 - 2.1 institution/enterprise where medical assistance is available and is provided
 - 2.2 laboratory where the diagnosis was made
3. medical data:
 - 3.1 localisation of the infectious disease
 - 3.2 basis for the diagnosis

Section 1-9 (*Data relating to cause of death*)

The Registers may contain person-identifiable and de-identified data in accordance with Sections 1-7 and 1-8 relating to cause of death and date of death for everyone who is registered in the Registers.

Section 1-10 (*Coding and classification of data in the Registers, documentation requirements*)

The Norwegian Institute of Public Health shall be able to document which classification or coding system has been used for each entry made in the Registers.

The Ministry may issue further provisions determining which national or international coding systems and classifications are to be used when recording data in the Registers.

Chapter 2 Reporting personal health data to the Registers, quality control etc.

Section 2-1 (Duty of medical practitioners to report)

Medical practitioners who discover or suspect a communicable disease in Group A or B shall without regard to their duty of confidentiality report in writing such data as is listed in Section 1-7, ref. Section 2-2, to the Norwegian Institute of Public Health and to the municipal medical officer in the municipality where the infected person lives. If the infected person is staying in a municipality in which he/she is not resident, a report shall also be sent to the municipal medical officer in the municipality where the infected person is staying. In the case of tuberculosis, a report shall also be sent to the Tuberculosis Coordinator. The report shall be sent on the same day as the disease is discovered or suspected. A copy of the report shall be kept in the patient's medical file.

Medical practitioners who are appointed by the Norwegian Institute of Public Health and who discover a communicable disease in Group C shall without regard to their duty of confidentiality report in writing such data as is listed in Section 1-8 to the Institute of Public Health. Collective reports shall be sent for periods of time defined by the Institute of Public Health.

Section 2-2 (Reporting form, requirements regarding form of reporting)

Such data as listed in Section 2-1 shall be reported on a form or in other manner determined by the Ministry.

The Ministry may issue instructions regarding the use of specific classification systems and coding systems for the registration of the data and issue instructions regarding the use of standardized reporting formats for the transmission of the data.

Section 2-3 (Laboratories' duty to report)

When a laboratory result indicates that a patient has a communicable disease in Group A, the laboratory shall send a report the same day to the Norwegian Institute of Public Health in the form of a copy of the reply form to the requisitioning medical practitioner or in some other manner which includes the same data as the reply form. On the same day, the laboratory shall send a reporting form as mentioned in Section 2-2 to the requisitioning medical practitioner. In the case of tuberculosis, a report shall be also be sent to the Tuberculosis Coordinator.

When a laboratory result indicates that a patient has a communicable disease in Group B, the laboratory shall send a report the same day to the Institute of Public Health in the form of the laboratory's copy of the reporting form as mentioned in Section 2-2. On the same day, the laboratory shall send the other copies of the reporting form to the requisitioning practitioner.

Microbiological laboratories which have been appointed by the Norwegian Institute of Public Health and which discover a communicable disease in Group C, shall without regard to their duty of confidentiality report information as listed in Section 1-8 to the Institute of Public Health. Collective reports shall be sent for the periods of time defined by the Institute of Public Health.

Section 2-4 (Reference laboratories)

If it is necessary to confirm a laboratory test which indicates a reportable communicable disease, or if supplementary tests are necessary to characterize an infectious agent which has caused such a disease, the laboratory, ref. Section 2-3, shall also send the infectious agent or test material to a laboratory that has been given such a reference function by the Ministry for a reference test.

Any reference laboratory that confirms, disproves or supplements a finding made by another laboratory is responsible for seeing that routines exist to ensure compliance with the obligation to report to the Norwegian Institute of Public Health, regardless of whether the requisitioning laboratory has or may have sent in a report.

The Ministry issues more detailed provisions regarding the diseases for which infectious agents or test material must be submitted.

Section 2-5 (The duty of the enterprise)

Healthcare institutions, out-patients clinics, health centres, microbiological laboratories, clinical chemical laboratories, pathological laboratories or other enterprises that are responsible for recording data that are to be reported to the MSIS and Tuberculosis Registers, ref. sections 1-7 and 1-8, have a responsibility to ensure that the obligations stated in sections 2-1 to 2-4 are fulfilled and that routines exist to ensure such fulfilment, ref. sections 5-2 and 5-3 of the present Regulations.

Section 2-6 (Recipient's responsibility for quality control)

The Norwegian Institute of Public Health shall make sure that the personal health data that is collected and processed in the Registers is correct, relevant and necessary for the purposes for which it is collected, ref. Section 1-3.

As part of the quality control process, the Norwegian Institute of Public Health may establish contact with the medical practitioner who has diagnosed or treated the patient or with the patient's general practitioner. As part of the quality control process, the data may be aligned with data in the Central Population Register, the Causes of Death Register and the National Hospital Pharmacy's list of patients who have been prescribed medicines against tuberculosis.

If it is necessary in order to achieve a quick containment of an outbreak of a communicable disease, the Norwegian Institute of Public Health or the municipal medical officer may also establish contact with the patient or the patient's parents or other persons with parental responsibility. They may not request more information than is required to register the data stated in Sections 1-7 and 1-8 for the disease in question.

If the reporting form contains insufficient data, the sender of the form shall be notified, ref. Section 9, second paragraph, second sentence, of the Personal Health Data Filing Systems Act. If the form still contains insufficient data, the County Health Board shall be notified.

Section 2-7 (Reports from the Registers)

The Norwegian Institute of Public Health shall arrange for regular reports on the incidence of communicable diseases, ref. Section 1-3, by publishing weekly and yearly reports of the incidence of communicable diseases in each municipality. Data that can be related to individuals shall not be published.

The Norwegian Institute of Public Health shall be responsible for reporting the incidence of communicable diseases in Norway to the World Health Organization and the European Commission, ref. Decision No. 2119/98/EC. This data shall be de-identified.

Chapter 3 Notification of communicable diseases

Section 3-1 (Notification of communicable diseases)

Notification of a communicable disease shall be given in addition to the written report, ref. Chapter 2. Notification shall be given of communicable diseases in Groups A and B, ref. Section 1-2, in cases where notification is necessary to ensure that control measures can be implemented

without delay in order to prevent further cases. The notification may contain the data stated in Section 1-7.

The Ministry will issue further details regarding which communicable diseases in Groups A and B are to be notified.

Section 3-2 (Duty of healthcare personnel to give notification)

Any medical practitioner, nurse, midwife or public health nurse who suspects or detects a case of a communicable disease, ref. Section 3-1 second paragraph, shall notify the municipal medical officer. If it is not possible to notify the municipal medical officer, the Norwegian Institute of Public Health shall be notified.

The municipal medical officer shall notify the County Governor and the Institute of Public Health.

Unless suspicion can quickly be dispelled, the Institute of Public Health shall notify the Directorate for Health and Social Welfare of these same cases.

Section 3-3 (Notification of an outbreak of a communicable disease)

Medical practitioners who suspect or detect an outbreak outside a healthcare institution of communicable diseases which are to be reported to the Registers, outbreaks of other particularly serious diseases, outbreaks which are suspected of having a connection with food or particularly widespread outbreaks shall notify the municipal medical officer.

Unless suspicion can quickly be dispelled, the municipal medical officer shall notify the County Governor and the Institute of Public Health.

The Institute of Public Health shall notify the Directorate for Health and Social Welfare of these same outbreaks, if they are serious.

Section 3-4 (Notification of outbreaks of communicable diseases in healthcare institutions)

Suspected or detected outbreaks of communicable diseases in hospitals or other institutions which are subject to Section 1-2 of the Act relating to specialist health services etc. shall be notified immediately to the County Governor and to the Norwegian Institute of Public Health, with a copy to the regional health authority's resource centre for hospital hygiene. The Institute of Public Health shall notify the Directorate for Health and Social Welfare of the same outbreaks, if they are serious.

Suspected or established outbreaks of communicable diseases in municipal healthcare institutions shall be notified to the municipal medical officer and County Governor. Unless suspicion can be quickly dispelled, the municipal medical officer shall notify the Institute of Public Health. The Institute of Public Health shall notify the Directorate for Health and Social Welfare of the same outbreaks, if they are serious.

Section 3-5 (Notification of deliberate spreading of infection)

Any medical practitioner who suspects or detects cases of communicable diseases that may have been caused by the deliberate spreading of infection shall notify the municipal medical officer, the County Governor and the Norwegian Institute of Public Health. The Institute of Public Health shall notify the Directorate for Health and Social Welfare of these same cases.

Section 3-6 (Notification of infection from equipment etc.)

Any medical practitioner who suspects or detects cases of communicable diseases that may have been caused by infection from medical equipment, cosmetics, pharmaceuticals, blood, blood products, tissue or organs shall notify the County Governor and the Norwegian Institute of

Public Health. The Institute of Public Health shall notify the Directorate for Health and Social Welfare of these same cases.

Section 3-7 (*Notification of infection from a blood donor*)

Laboratories and medical practitioners who, in the course of their work, find that a blood donor is infected by a communicable disease that can be transmitted by blood or blood products shall notify the blood bank where the infected donor has donated blood. The notification shall contain the name, identity number, address of the donor and the disease that has been discovered. The blood bank shall notify the County Governor, the Norwegian Medicines Agency, the Norwegian Institute of Public Health and the Directorate for Health and Social Welfare, but without giving any personal data.

Section 3-8 (*Notification of infection from a healthcare institution*)

If an attending medical practitioner in a healthcare institution discovers that a patient transferred from another healthcare institution has a communicable disease, he/she shall notify a medical practitioner at the other institution, if this is required for reasons of disease control.

Section 3-9 (*Notification of infection from food*)

Municipal medical officers who receive information about a suspected or detected communicable disease that may have been transmitted by food shall notify the local food control authority. The notification shall contain information about the assumed disease, the assumed date of infection, the patient's age and municipality of residence and, if possible, which foodstuff is suspected and where it was available.

Section 3-10 (*Notification of infection from animals*)

Municipal medical officers who receive information about a suspected or detected communicable disease that may be due to infection from an animal shall notify the regional veterinary officer. The notification shall contain information about the assumed disease, the estimated date of infection, the patient's age and municipality of residence and, if possible, which animal is suspected and its location.

Chapter 4 Processing personal health data in the Registers

Section 4-1 (*Alignment of data for the production of statistics*)

Data in the MSIS Register and the Tuberculosis Register may be aligned (combined) with each other and with data in the Medical Birth Register, Causes of Death Register, Cancer Register and the System for Vaccination Control (Norw. acronym: SYSVAK), provided that this is done by the data controller for one of these registers or by an enterprise chosen by the Ministry and the result of the alignment appears in an anonymized form.

The data controller shall normally execute enquiries for statistical data as stated in the first paragraph from public administration bodies and researchers within sixty days from receipt of the order. If special circumstances make it impossible to execute the enquiry within this time limit, execution may be postponed until it is possible to carry it out. The data controller shall then give a provisional reply containing information as to whether the enquiry can be effected, the reason for the delay and probable date for effectuation of the order.

Personal health data received for the production of statistics pursuant to the first paragraph shall be erased as soon as the production of statistics has been carried out satisfactorily.

Section 4-2 (*Alignment of data in the Registers with data in other filing systems for research purposes, etc.*)

The Norwegian Institute of Public Health may align data in the MSIS Register and the Tuberculosis Register with each other and with data in the health data filing systems mentioned in Section 4-1, first paragraph, for explicitly stated purposes included in the purposes of the Registers, ref. Section 1-3 of these Regulations, provided that there is no objection from an ethical point of view and the data processor (researcher) is only going to process de-identified data.

Aligned personal health data may not be stored until names, dates of birth and identity numbers have been erased or encrypted. Data directly identifying an individual (name and personal identity number) which are received for processing shall be erased as soon as the alignment (combination) has been carried out satisfactorily.

All data that is included in the processing as mentioned in the first and second paragraph shall be erased on completion of the project.

Section 4-3 (*Disclosure of aligned data files for research etc.*)

Upon application de-identified data as stated in Section 4-2, first paragraph, shall be made available to and disclosed for research, or for any other expressly stated purpose that is consistent with the purposes of the Registers, ref. Section 1-3 of these Regulations, provided that:

- the recipient is only going to process de-identified data
- there is no objection from an ethical point of view to the processing of the data
- the data is aligned and prepared by the data controller for one of the Registers whose data is being processed, or in an enterprise chosen by the Ministry.

Section 4-2 of these Regulations applies correspondingly.

The data controller shall disclose or transmit necessary and relevant data to the person responsible for the project in question within sixty days from date on which the application is received. The legal basis for processing the data shall be given in the application, ref. first paragraph.

If special circumstances make it impossible to effect the enquiry within the given time limit, effectuation may be postponed until it is possible to carry it out. The data controller shall then give a provisional reply containing information as to whether the enquiry can be effected, the reason for the delay and probable date for effectuation of the order.

All data that is included in the processing under the first and second paragraph shall be erased on completion of the project.

Section 4-4 (*Duty to disclose non-aligned data for research etc.*)

Upon request from public administration bodies and researchers the Norwegian Institute of Public Health shall disclose statistical data from the MSIS Register and the Tuberculosis Register within thirty days from the date on which the request is received.

Upon application the Norwegian Institute of Public Health shall disclose de-identified data from the Registers provided that:

- the data is to be used for an expressly stated purpose included in the Registers' purposes,
- the recipient is only going to process de-identified data and
- there is no objection from an ethical point of view to the processing of the data

The Norwegian Institute of Public Health shall disclose or transmit necessary and relevant data to the person responsible for the given project within thirty days from date on which the application is received. The legal basis for processing the data shall be given in the application, ref. first paragraph.

Section 4-3, fourth and fifth paragraph, shall apply correspondingly.

Section 4-5 (Disclosure and other processing of data in the Registers)

Unless otherwise provided for in these Regulations, data relating to an identifiable person in the MSIS and Tuberculosis Registers may only be processed (aligned, disclosed, etc.) with the permission of the Data Inspectorate and in compliance with the general rules for confidentiality.

The Directorate for Public Health and Social Affairs shall reply to enquiries regarding disclosure of data relating to identifiable persons for use in explicitly stated research projects within thirty days from the date on which the enquiry is received. If special circumstances make it impossible to effect the enquiry within the given time limit, the reply may be postponed until it is possible to reply. The Directorate shall then give a provisional reply containing information as to whether the enquiry can be effected, the reason for the delay and probable date for when a reply can be given.

Section 4-6 (Information strategy targeting user groups)

In order to promote the use of the Registers and to build up information and knowledge, ref. Section 1-3 of the Regulations, the Norwegian Institute of Public Health shall have an active information strategy and information plan targeting the public health administration, the health service and other public administration bodies, such as scientists carrying out medical research, healthcare research and social research.

Section 4-7 (Costs)

The Norwegian Institute of Public Health may charge a fee for processing and preparation of data as stipulated in Sections 4-1 to 4-5. The fees shall not exceed the actual costs of such processing and preparation of the data.

Section 4-8 (Records of disclosures)

The Norwegian Institute of Public Health shall keep records of who receives data from the Registers and the legal basis for the disclosures. These records shall be stored for at least five years after disclosure of the data.

Chapter 5 Duty of confidentiality, data security and internal control

Section 5-1 (Duty of confidentiality)

Any person processing personal health data pursuant to these Regulations has a duty of confidentiality as stipulated in Sections 13 to 13e of the Public Administration Act and as stipulated in the Healthcare Personnel Act.

The duty of confidentiality as stated in the first paragraph also applies to the patient's place of birth, date of birth, personal identity number, pseudonym, nationality, marital status, occupation, place of residence and place of work.

Data may only be given to other public administration bodies pursuant to Section 13b, fifth and sixth paragraphs, when this is necessary to facilitate the performance of tasks pursuant to these Regulations or to prevent significant danger to life or serious damage to a person's health.

Section 5-2 (Data security)

The Norwegian Institute of Public Health and the data processor shall, with the help of planned and systematic measures, guarantee satisfactory data security as regards confidentiality, integrity, quality and accessibility in connection with the processing of personal health data in

accordance with these Regulations, ref. Section 16 et seq. of the Personal Health Data Filing Systems Act.

When the processing of personal health data takes place wholly or partly by electronic means, the provisions on data security in Sections 2-1 to 2-16 in the Personal Data Regulations shall apply.

Section 5-3 (*Duty to establish internal controls*)

The Norwegian Institute of Public Health shall establish internal control routines as laid down in Section 17 of the Personal Health Data Filing Systems Act. The systematic measures shall be adapted to the nature, activities and size of the enterprise to the extent necessary to comply with the requirements given in or in pursuance of the Personal Health Data Filing Systems Act, with particular attention to provisions issued in pursuance of Section 16 of the same Act.

Data processors who process personal health data on behalf of the Institute of Public Health shall process the data in accordance with routines established by the Institute of Public Health.

Section 5-4 (*Content of internal controls*)

Internal controls require the data controller to be familiar with the current rules regarding the processing of personal health data, to have adequate, up-to-date documentation for the implementation of the routines, and to have this documentation available for whoever it may concern.

Internal controls shall include:

1. an overview of the way in which the enterprise is organized
2. an overview of responsibilities and authority
3. an overview of the requirements laid down in and issued in pursuance of the Personal Health Data Filing Systems Act that apply to the enterprise
4. routines followed by the enterprise in order to ensure compliance with the requirements, including routines for:
 - 4.1. fulfilment of requirements that data identifying an individual may only be processed when this is necessary to promote the purpose of the data processing, and in keeping with current provisions regarding the duty of confidentiality, ref. Sections 11 and 15 of the Personal Health Data Filing Systems Act
 - 4.2. documentation and quality control of personal health data, ref. Sections 1-10 and 2-6 of these Regulations
 - 4.3. fulfilment of requests for data and right of access, ref. Sections 21 to 25 of the Personal Health Data Filing Systems Act, and Section 6-2 of these Regulations,
 - 4.4. the way in which the enterprise complies with the provisions regarding access to person health data filing systems, ref. Sections 4-1, 4-3, 4-4 and 4-5,
 - 4.5. compliance with the rules regarding duty to report to the Data Inspectorate, ref. Section 29 of the Personal Health Data Filing Systems Act
5. routines followed by the enterprise in the event of non-conformance and information about who is responsible
6. routines followed by the enterprise in order to prevent the recurrence of non-conformance and information about who is responsible
7. routines for the way in which the enterprise systematically and regularly reviews its internal controls to check that the activities and their results conform with the system established by the enterprise and whether this leads to compliance with the Personal Health Data Filing Systems Act

8. routines for the way in which the enterprise ensures that all relevant and only current routines are used, and
9. routines for the way in which the enterprise ensures that its employees have sufficient knowledge and skills to comply with the requirements laid down in these Regulations.

Written documentation shall at a minimum include documentation of the routines listed in the first paragraph, items 1 to 8. The supervisory authorities may issue instructions regarding additional documentation, if this is deemed necessary. Under special circumstances the supervisory authorities may grant dispensation from all or parts of this chapter.

Chapter 6 The right of the data subject to information and access

Section 6-1 (The reporting medical practitioner's duty to inform)

When a medical practitioner who has a duty to report in accordance with Section 2-1, first paragraph, reports a communicable disease in Group A or B, the medical practitioner shall inform the person concerned about where the reports are being sent and what they are to be used for. The medical practitioner should endeavour to obtain the assistance of the patient to make sure that the data in the reporting form is as correct as possible.

Section 6-2 (The right of the data subject to information and access)

Data subjects have the right to information about the Registers and access to the processing of personal health data about themselves, as laid down in Sections 22 to 25 in the Personal Health Data Filing Systems Act.

Access to personal health data about oneself, ref. Section 22, second paragraph, of the Personal Health Data Filing Systems Act, should preferably be arranged by the medical practitioner and the healthcare institution that have most recently treated the data subject. The personal health data must be given in a comprehensible form.

Section 6-3 (Information and access when the data subject is under age)

Parents and other persons with parental responsibility have right of access pursuant to rules corresponding to those laid down in Section 3-4 of the Patients' Rights Act.

Section 6-4 (Time limit for replying to enquiries about access)

Requests for access pursuant to Section 6-2 shall be answered without undue delay and no later than thirty days from the date on which the request is received, ref. Section 19 of the Personal Health Data Filing Systems Act.

If special circumstances make it impossible to reply to the enquiry within thirty days, the reply may be postponed until it is possible to reply. The data controller shall then give a provisional reply containing information about the reason for the delay and a probable date for when a reply can be given.

Chapter 7 Storage of personal health data in the Registers

Section 7-1 (Storage of personal health data)

Unless otherwise provided for in these Regulations or in Section 26 or Section 28 of the Personal Health Data Filing Systems Act, data in the MSIS and Tuberculosis Registers shall be stored indefinitely.

Chapter 8 Penalties

Section 8-1 (*Penalties*)

Any person who wilfully or through gross negligence contravenes the provisions laid down in Sections 2-1, 2-3, 2-4, 2-5 and Sections 5-2 and 5-4 of these Regulations shall be liable to fines or imprisonment for a term not exceeding one year or both.

Anyone participating in such an offence shall be liable to similar penalties.

Chapter 9 Final provisions

Section 9-1 (*Entry into force*)

These Regulations shall enter into force on 1 July 2003. Regulations No. 1224 of 30 December 1994 relating to the reporting and notification of communicable diseases by medical practitioners and other healthcare personnel shall be repealed on the same date.

Comments to the individual chapters and sections in the Regulations

The comments are guidelines which explain in more detail the content of the different provisions in the Regulations. The comments are not binding in themselves. The Regulations and the guidelines should be read together in order to obtain the best possible understanding of the provisions in the Regulations.

To Section 1-1 Establishment of the MSIS and the Central Tuberculosis Register

The Regulations concern reporting systems for communicable diseases and tuberculosis in humans, and not in animals.

In 1962, the Central Tuberculosis Register was established at the National Mass Radiography Service, later called the National Health Screening Service. In 1974, *Meldesystem for infeksjonssykdommer* (MSIS) – the Surveillance System for Infectious Diseases – was established at the National Institute of Public Health. Rules for the Registers were laid down in Regulations dated 20 October 1996 relating to the control of tuberculosis and Regulations dated 30 December 1994 relating to reporting and notification of communicable diseases by medical practitioners and other healthcare personnel.

The purpose of Act No. 24 of 18 May 2001 relating to personal health data filing systems and processing of personal health data (the Personal Health Data Filing Systems Act) is to provide a legal basis for data and information processing of personal health data in the public health administration and in the health service. Section 8, third paragraph, of the Act stipulates that personal data may be processed without the consent of the data subject provided that this is necessary to achieve the purposes of such Registers as the MSIS Register and the Central Tuberculosis Register. The responsibility for data control rests with the Norwegian Institute of Public Health. The Norwegian name of the MSIS Register has now been changed to *Meldesystemet for smittsomme sykdommer* – Surveillance System for Communicable Diseases (the acronym remains the same) and this is the name that is used in regulations and comments to them.

The Regulations contain rules for the collection and processing of the personal health data in the Registers. It is stated in Section 1-1, second paragraph, that the collection and processing of personal health data may take place manually or by electronic means. The use of electronic means is conditional on adequate data security in connection with the use of these means. Adequate data security means safeguarding integrity, confidentiality, accessibility and quality. The requirement of confidentiality means that it must be possible to comply with the provisions relating to duty of confidentiality. Duty of confidentiality does not only mean a passive duty to keep quiet; it also means an active duty to prevent unauthorized persons from gaining access to confidential information. If the provisions relating to confidentiality cannot be complied with when using electronic means, then these means cannot be used.

To Section 1-2 Content of the MSIS and Tuberculosis Registers

This section gives the content of the Registers. The MSIS Register may contain information about persons in Norway who are infected with specific communicable diseases. The diseases are classified in groups. Diseases in Group A are diseases that, according to the Regulations, must be reported giving the patient's full identity. For the sake of disease control and international commitments, these diseases must be closely monitored. Diseases in Group B are diseases that, according to the Regulations, must be reported giving de-identified information, but with one report per patient. It is believed that a duty to report the patient by name could

discourage people who may be infected with these diseases from undergoing a medical examination. Gonorrhoea, HIV infection and syphilis are among the diseases in Group B. The diseases in Group C are diseases that normally have to be reported in summarized tables giving the number of cases. These are diseases which do not require close surveillance for the sake of disease control.

The Tuberculosis Register may contain person-identifiable information about persons in Norway who have tuberculosis, persons who are receiving prophylactic treatment against tuberculosis or persons who are discovered to be tuberculin converters through tuberculin testing in the 10th grade of lower secondary school, ref. Section 1-7 of the Regulations.

As of 1 July 2003, the following diseases must be reported:

Diseases in Group A

Diseases that are preventable through the Child Vaccination Programme:

Diphtheria
 Rubella
 Measles
 Mumps
 Poliomyelitis
 Systemic *Haemophilus influenzae* diseases
 Tetanus
 Tuberculosis
 Pertussis

Viral hepatitis:

Hepatitis A
 Hepatitis B
 Hepatitis C

Food and water-borne diseases:

Botulism
 Campylobacteriosis
 E. coli enteritis
 Giardiasis
 Listeriosis
 Salmonellosis
 Yersiniosis

Zoonoses:

Anthrax
 Brucellosis
 Echinococcosis
 Lyme borreliosis
 Nephropathia epidemica
 Rabies
 Trichinosis
 Tularemia

Serious imported diseases:

Cholera
 Haemorrhagic fever
 Leprosy
 Malaria
 Plague
 Recurrent fever
 Shigellosis
 Typhus fever
 Yellow fever

Serious environmental diseases:

Atypical mycobacterial infections
 Legionellosis

Serious systemic diseases:

AIDS
 Encephalitis
 Paratyphoid fever
 Prion diseases
 Serious acute respiratory syndrome (SARS)
 Smallpox
 Systemic Group A streptococcal disease
 Systemic Group B streptococcal disease
 Systemic meningococcal disease
 Systemic pneumococcal disease
 Typhoid fever

Carrier state of or infections with:

Meticillin-resistant yellow staphylococci
 Penicillin-resistant pneumococci
 Vancomycin-resistant enterococci

Diseases in Group B

These diseases are laid down in Section 1-2, fourth paragraph, of the Regulations and are:

Gonorrhoea
 HIV infection
 Syphilis

Diseases in Group C

Genital chlamydial infection
 Influenza-like diseases

The situation regarding communicable diseases can change quickly. New diseases can appear in Groups A, B and C, while other diseases can lose their significance. It may be necessary to change the list of reportable diseases quickly and the Ministry is authorized by Section 1-2, sixth paragraph, to issue further provisions regarding which communicable diseases belong to the different categories or groups of diseases.

Registered data relating to cases of a disease play a useful role in the practical work of controlling the disease and this is an important element in considering whether a disease in Group A, B or C should be reportable. Certain diseases will be reportable, even if they do not normally occur in Norway, because Norway is bound by international reporting commitments, ref. for example Decision 2119/98/EC. The Norwegian Institute of Public Health provides guidance on case definitions, i.e. which clinical, microbiological and epidemiological criteria must be met before a given disease can be regarded as diagnosed. Such definitions are important with a view to comparing their occurrence over time and with other countries. It is natural to use adapted versions of the definitions used in the EU, see Decision 2119/98/EC. The definitions may be changed as new methods of diagnosis come into use.

To Section 1-3 Purpose of the Registers

The MSIS Register is both a health data filing system for keeping track of and doing research into communicable diseases and a tool in the practical work of controlling disease. Speedy reports to the MSIS Register and early use of the data are therefore important. Good surveillance is characterized by data leading to action. The Tuberculosis Register must also evaluate the effect of treatment measures, among other things in order to improve them. This section of the Regulations aims to cover the purposes that can be seen today from the current regulations governing the reporting and notification of communicable diseases by medical practitioners and other healthcare personnel, and the reason for monitoring tuberculosis, on which the Regulations relating to the control of tuberculosis are based.

The third paragraph states other purposes for which the data in the Registers can be used, with particular reference to measures which strengthen the health service and public health administration. Even when data in the Registers are used for statistical and research purposes that are not stated in the first paragraph, the overriding requirement is that they be used to advance health-related purposes.

To Section 1-4 Prohibition against use

This section prohibits the use of the data in the Registers for certain purposes.

It is stated in the first paragraph that the data in the Registers may not be used for purposes that are incompatible with the purpose of the Registers as stated in Section 1-3. This provision follows naturally from Section 11, third paragraph, of the Personal Health Data Filing Systems Act. The question of whether the use of the data is incompatible with the purposes stated in Section 1-3 must be decided specifically.

The second paragraph establishes that data relating to individual persons, which emerge as a result of the processing of personal health data in the MSIS and Tuberculosis Registers, may not be used for insurance purposes, even with the consent of the data subject. This prohibition is important in order to maintain people's trust in the Registers. By imposing an absolute ban on the use of the data for insurance purposes, we can avoid a situation where an insurance company puts pressure on the data subject to request access to the Registers in order to be able to give information to the company as the basis for an insurance contract.

To Section 1-5 Data controller

This section establishes that the Norwegian Institute of Public Health is the data controller for the collection and processing of data in the Registers. This assignment of responsibility

safeguards the need for collective, overall management of Norway's central epidemiological Registers.

To Section 1-6 Data processor

According to this section, the Norwegian Institute of Public Health may enter into a written agreement with a data processor on the collection and processing of personal health data in the Registers.

In Section 2 (9) of the Personal Health Data Filing Systems Act, 'data processor' is defined as the person who processes personal health data on behalf of the controller. It follows from Section 18 of the Act that a data processor may only process the data in the manner agreed upon in writing with the data controller. Without such an agreement, the data may not be handed over another person for storage or processing.

It follows from Section 29 and 30 of the Act that the Data Inspectorate must be informed of the name and address of any data processor and of who has the day-to-day responsibility for fulfilling the data controller's duties as laid down in the Regulations.

To Section 1-7 Data in the MSIS and Tuberculosis Registers relating to cases of Group A and Group B communicable diseases

It follows from Section 8, third paragraph, of the Personal Health Data Filing Systems Act that the MSIS and Tuberculosis Registers may contain personal data without the consent of the data subject insofar as this is necessary to achieve the purpose of the Registers. Section 1-7 of the Regulations specifies which kinds of information may be recorded and processed in the MSIS and Tuberculosis Registers without the consent either of the data subject or of his/her next of kin.

Item 1 in the third paragraph in this section lists the personal data which must be recorded, including name and personal identity number. For persons with no Norwegian identity number, the Registers can contain some other identification, such as a passport number.

Item 2 deals with the administrative data, such as data relating to the enterprise where medical assistance is provided, name of medical practitioners, etc.

Item 3 lists the medical data. The medical data is important to ensure the correct classification of the case, to evaluate the certainty of the diagnosis and to evaluate the consequences of the disease. As regards the diagnosis and the basis for the diagnosis, it is relevant to record data relating to the reason for visiting the health service, time and course of symptoms, diagnosis and treatment, localization of the disease, the examinations leading to the diagnosis, name and classification of the infectious agent and its properties (such as resistance to anti-microbial agents) and factors in the patient such as susceptibility to or protection against the disease, including exposure to possible sources of infection. In the case of tuberculosis, the result of the tuberculin test must be included under the basis for the diagnosis. The Tuberculosis Register may also contain data relating to the course of the disease and treatment for tuberculosis.

Item 4 refers to epidemiological data. Epidemiological data are particularly important in the practical work of disease control. Data relating to assumed sources of infection, means of infection, places of infection and times of infection can be of direct use in containing outbreaks of communicable diseases. Information as to whether contacts have been traced is also necessary. In the case of contact tracing for tuberculosis, a special reporting form must be filled

in giving the names of contacts who have been referred to a specialist, along with the results of the examination. A special form has also been issued for reporting the overall result of contact tracing, ref. Section 5-3 of the Regulations relating to the control of tuberculosis. A similar system is not planned for other diseases. Information that the notification requirement in Chapter 3 has been fulfilled must be reported to the Register, but the notification system as such is not included in the Register.

The other information that is to be reported and the way in which this is to be done can be seen from the reporting form issued by the Ministry of Health, ref. Section 2-2.

To Section 1-8 Data in the MSIS Register relating to cases of communicable disease in Group C

Data relating to these diseases will normally be reported in summarized tables distributed by age, sex and municipality of residence.

To Section 1-9 Data relating to cause of death

This section establishes that the Registers may, without the consent of the data subject, contain personal data and de-identified data, see Sections 1-7 and 1-8, relating to cause of death for everyone who is registered in the Registers.

To Section 1-10 Coding and classification of the data in the Registers, requirements regarding documentation

This provision deals with coding and classification of data in the Registers and sets requirements for documentation.

It is stipulated in the first paragraph that the Norwegian Institute of Public Health must be able to document which coding systems and classifications have been used for each registration in the Registers. The intention of this provision is to facilitate access to the data in the Registers. The data that is submitted to the Registers is recorded there in coded form. To ensure that the contents of the Register and the medical data are accessible by and comprehensible to the persons who are going to use them in specific research projects etc., the users must know what the different codes mean, i.e. the coded information must be translated into the Norwegian language or medical terminology.

To Section 2-1 Duty of medical practitioners to report

The duty to report as laid down in the Regulations applies to every medical practitioner. Reports must be made on forms or other manner as determined by the Ministry.

A report of a communicable disease in Group A or B must be sent the same day as the disease is discovered or suspected. The report must be sent to the Norwegian Institute of Public Health. The report must also be sent to the municipal medical officer, in practice in the form of a copy or carbon copy of the report. This means that the municipal medical officers have a central place in the reporting system. They must use the reports, among other things, to keep informed at all times of the infection/epidemiological situation in the municipality, ref. Section 7-2 of the Communicable Diseases Control Act. The reports are part of a treatment-oriented health data registration system, ref. Section 6 of the Personal Health Data Filing Systems Act, and are absolutely necessary to enable the municipal medical officer to carry out his duties as laid down, for example, in Section 4-1, fifth paragraph, of the Communicable Diseases Control Act. In the case of tuberculosis, the report must also be sent to the Tuberculosis Coordinator, ref.

Regulations relating to the Control of Tuberculosis. The report is also a necessary tool which enables the Coordinator to carry out his duties, ref. Section 4-4 of the Tuberculosis Control Regulations. As regards the storing of personal health data in treatment-oriented health data filing systems by the municipal medical officer and the Tuberculosis Coordinator, the provisions in the Act relating to Healthcare and the Regulations relating to patients' medical records apply.

Collective reports are submitted of communicable diseases in Group C, normally in the form of summary tables listing the number of cases. These reports shall be sent in at the intervals defined by the Norwegian Institute of Public Health. For influenza, the interval may be a week; for genital chlamydia, perhaps a year. The Norwegian Institute of Public Health informs the persons who are to give notification about these intervals and about the reporting method.

To Section 2-2 Reporting form – requirements regarding form of reporting

The Ministry determines which forms are to be used. Different forms must be used for Groups A, B and C, because of the variation in the scope of the information to be reported. For some diseases, such as tuberculosis, other forms are also necessary in order to obtain information, for example, about the result of treatment, ref. Section 1-7. The Ministry may decide that the reports are to be submitted in some other manner, such as by electronic transmission.

It is stated in the second paragraph that the Ministry can set requirements regarding the use of specific classifications and coding systems for the registration of the information, and require that standard reporting/messaging formats are used to submit the information. The requirement of a specific messaging format is particularly relevant in the case of electronic messaging and will also be relevant in the case of electronic reporting by the medical microbiological laboratories.

To Section 2-3 Duty of laboratories to report

The laboratories have a duty to report under the Regulations, ref. Sections 2-3, 2-4 and 2-5.

Group A diseases are reported giving the name and personal identity number. Stocks of blank, unnumbered reporting forms are kept by the medical microbiological laboratories and the hospital departments and doctor's surgeries which frequently diagnose reportable diseases without laboratory tests. The laboratory sends a blank form to the doctor with a reply form (test result) which indicates that the patient has a reportable disease. It should be clear from the reply form that the patient has a reportable disease. The doctor fills in the blank reporting form, if appropriate in cooperation along with the patient, and sends it to the Norwegian Institute of Public Health. The laboratory has already sent a copy of the reply form direct to the Institute. The reports may also be sent electronically, ref. Section 2-2.

Reports of tuberculosis must be sent in the same way as reports of Group A diseases, but the report must also be sent to the Tuberculosis Coordinator, ref. Section 5-5 of Regulations relating to the control of tuberculosis. Finds of acid-fast rods, cultivation, determination of species and sensitivity test results must be reported. All suspected isolations of the *Mycobacterium tuberculosis* complex must be sent to the Institute of Public Health.

Group B diseases, including HIV infection, are reported giving de-identified data. Blank, numbered reporting forms are stored by the medicinal microbiological laboratories. The serial number is printed on the copy that is sent direct to the Institute of Public Health and on the copy that sent to the medical practitioner's for completion, preferably in cooperation with the patient,

and forwarding to the Institute of Public Health. The two copies can be aligned in the database without using person-identifiable data. A report from a medical practitioner is also necessary, because the medical practitioner can obtain the necessary epidemiological data (place of infection, method of infection, etc.) from the patient. The medical-microbiological laboratories will not normally have this information.

Group C diseases are reported by the laboratories with few data about each case. As a rule, summarised tables giving the number of diagnosed cases distributed by sex and age group will be sufficient.

To Section 2-4 Reference laboratories

In the case of many infectious agents, it will be relevant to refer the sample to another laboratory for more thorough testing, so that a diagnosis can be made with certainty or for further characterization of the infectious agent. Such characterization, where relevant using gene technology methods, is a useful tool in revealing whether cases are related and are part of an outbreak. Section 4-5 of the Regulations relating to the control of tuberculosis states that the reference laboratory services for tuberculosis will be performed by the Norwegian Institute of Public Health.

The Ministry allocates any reference functions to laboratories. Reference laboratories have the same duty to report to the Institute of Public Health as other laboratories. The primary laboratory has a duty to report in the normal way, even if the sample has been referred to a reference laboratory.

To Section 2-5 The enterprises' duty to report

It follows from this section that healthcare institutions, outpatients clinics, medical centres, microbiological laboratories, clinical chemical laboratories, pathological laboratories or other enterprises that are responsible for data that is to be registered and reported as laid down in Sections 2-1 to 2-4 have a responsibility to see that these obligations are met and that routines exist to ensure this. In practice, the reporting form will be filled in either electronically or on paper by healthcare personnel, as part of the documentation required under Section 39 of the Healthcare Personnel Act. The enterprise in which the health personnel in question are employed must make sure that the forms are forwarded to the Norwegian Institute of Public Health. Electronic transfer of data is conditional on adequate information security, for example by the encryption of personal designations (name and personal identity number) and other personal health data during the transfer.

To Section 2-6 The recipient's responsibility for quality control

The first paragraph in this section stipulates that the Norwegian Institute of Public Health, as data controller for the filing systems, must make sure that the personal health data registered in the filing systems are correct, relevant and necessary for the purposes for which they have been collected, ref. Section 1-3.

The second paragraph in this section deals with alignment with other registers, etc. Quality control must be carried out regularly with the Central Population Register and the Causes of Death Register to ensure, among other things, that the data subjects have the correct personal identity numbers and that deaths are discovered. Medicines for the treatment of tuberculosis are only dispensed by the pharmacy at the National Hospital. This means that the pharmacy's register of prescription copies is a valuable source for quality control of the surveillance of

tuberculosis. If medicine is prescribed for a patient who has not been reported as having tuberculosis, the Institute of Public Health can take the matter up with the medical practitioner who issued the prescription.

The third paragraph of this section deals, among other things, with the patient. On the outbreak of a communicable disease, it may be necessary to interview the patients in detail about what they have been exposed to (for example in the way of foodstuffs) during the period prior to the disease, i.e. information about the method of infection and predisposal factors, ref. Section 1-7. Normally, contact will be made with the patient by the municipal medical officer or the Norwegian Institute of Public Health via the medical practitioner who has reported the disease. However, in exceptional cases, when necessary for the sake of disease control, the municipal medical officer or the Institute may have to establish contact with the patient quickly in order to obtain information which can help to reveal the reasons for an outbreak of a communicable disease.

The fourth paragraph in this section states that if the reporting form does not contain sufficient data, the sender must be notified. This is an amplification of Section 9, second paragraph, second sentence, of the Personal Health Data Filing Systems Act. A form that has not been completed will also contain insufficient data. If this situation continues, the County Health Board must be notified. If repeated (at least two) reminders have to be sent, this will constitute 'insufficient data'.

To Section 2-7 Reports from the Registers

A core function of the Registers is to give regular feedback about the infection epidemiological situation. This is important, as it enables the disease control authorities at local and central level to initiate the necessary measures. The Norwegian Institute of Public Health provides weekly surveys in MSIS reports. In time, this form of publishing can be replaced by equally frequently updated surveys on the Internet, distributed by municipality.

The Institute of Public Health has been appointed as point of contact for reports to the World Health Organization and the European Commission, ref. Decision No. 2119/98/EC. These reports are sent in the form of summaries without personal identification for use in compiling surveillance data in Europe. Norwegian reports pursuant to the Zoonoses Directive (92/117/EEC), which is referred to in Decision No. 2119/98/EC, are the responsibility of the Ministry of Agriculture.

To Chapter 3 Notification of communicable diseases

'Notification' is understood to mean a message dispatched immediately about certain individual cases or outbreaks of a communicable diseases in such a way that the notifier can immediately reassure himself that the recipient has received the notification.

Individual cases of certain diseases and certain types of outbreaks of communicable diseases are notifiable. 'Outbreak' means either more cases than expected of a particular disease within an area during a given period or two or more cases with an assumed common source. It follows from this that individual cases of a disease that is not normally expected to occur in Norway are regarded as notifiable outbreaks.

Notification is intended to help to ensure that:

- individual cases or outbreaks can quickly be seen in a larger context so that major outbreaks are discovered early and disease control measures can be initiated
- the notifier is given assistance in handling the situation, if necessary on the spot
- the authorities which are responsible for handling the situation are brought in
- the scope of the outbreak in Norway can be established
- foreign authorities are informed through Norway's participation in international early warning systems

A 24-hour notification centre has been set up at the Norwegian Institute of Public Health (Smittevernvakta tel. 22 04 23 48). Personal data must not be sent by fax or by e-mail. The Institute of Public Health will prepare a form to help persons notifying outbreaks of communicable diseases.

On receipt of such notifications, the Institute of Public Health will provide expert assistance in investigating and dealing with incidents, ref. Section 7-9 of the Communicable Diseases Control Act. The Institute will also arrange for any notification to the Directorate for Health and Social Welfare and to any international early warning systems under the World Health Organization or European Commission.

Section 3-1 Notification of communicable diseases

Notification of individual cases or outbreaks is given in addition to reports to the MSIS and Tuberculosis Registry, ref. Chapter 1 and 2, but the notification is not included in the Registers.

Notifications of individual cases of communicable diseases or of outbreaks of diseases that have to be reported to the Registers, ref. Section 1-2, may contain the data listed in Section 1-7. Notifications of other outbreaks to the municipal medical officer may contain person-identifiable data, but these data must not be included in notifications to the Institute of Public Health. Notifications to the Institute may contain the same type of data as Group B diseases, i.e. non-person-identifiable data.

It is the responsibility of the Ministry to determine pursuant to the second paragraph which diseases in Groups A and B, ref. Section 1-2, have to be notified.

The following diseases are notifiable as of 1 July 2003:

Anthrax
 Botulism
 Cholera
 Diphtheria
 Rubella
 Haemorrhagic fever
 Legionellosis
 Measles
 Meningococcal disease
 Plague
 Poliomyelitis
 Rabies
 Serious acute respiratory syndrome – SARS
 Smallpox

Spotted fever
Trichinosis

To Section 3-2 Duty of healthcare personnel to give notification

As previously, nurses, midwives or public health nurses have a duty to notify suspected or established cases of communicable diseases. This section also establishes the medical practitioners' duty to give notification, and this replaces the duty the municipal medical officer previously had to give a verbal report of suspected or established cases of specific communicable diseases.

To Section 3-3 Notification of outbreaks of communicable diseases

Four types of outbreaks must be notified to the municipal medical officer and then to the County Governor and the Norwegian Institute of Public Health:

- outbreaks of the diseases that are reportable to the MSIS Register, ref. Section 1-2
- outbreaks of particularly serious diseases (other than those that are covered by the MSIS Register), i.e. diseases with a high mortality rate, serious clinical picture or high complication rate
- outbreaks that are suspected of being food-borne
- particularly wide-spread outbreaks

The last three categories also apply to outbreaks of communicable diseases that do not have to be reported to the MSIS.

It is the task of the Norwegian Institute of Public Health, in collaboration with the municipal medical officer, to evaluate the seriousness of the outbreak as regards, among other things, mortality, morbidity and risk of spreading. The Institute of Public Health shall notify the Directorate of Health and Social Welfare of serious outbreaks.

To Section 3-4 Notification of outbreaks of communicable diseases in healthcare institutions

This section deals with outbreaks of communicable diseases in healthcare institutions and refers to the relevant provision in Regulations No. 699 of 5 July 1996 regarding disease control in healthcare institutions – hospital infections. However, Section 3-4, second paragraph, extends the scope of the duty to notify, since it includes all municipal healthcare institutions, not only nursing homes or other forms of residential round-the-clock nursing care.

Outbreaks in healthcare institutions are understood to be either the occurrence of noticeably more cases of a communicable disease than expected in the institution or parts of it within a given period of time, or two or more cases of a communicable diseases with a suspected common source. Suspected outbreaks must be notified as early as possible. The purpose of early notification is, among other things, to bring to light outbreaks that affect several institutions, to enable the healthcare institution to receive advice and assistance, to prepare a national overview of the scope of the outbreak in healthcare institutions and to gain experience of the factors that make healthcare institutions susceptible to outbreaks.

Healthcare institutions must establish routines which ensure compliance with the duty to notify. In the specialist health service, notification can be done by, for example, the medical practitioner who is responsible for coordinating communicable disease control in the institution, ref. Section 2-3 of the Regulations regarding communicable disease control in healthcare institutions – hospital infections, or by other hospital hygiene personnel.

The Norwegian Institute of Public Health must assess the seriousness of the outbreak as regards mortality, morbidity, risk of spreading, etc. and notify the Directorate for Health and Social Welfare of serious outbreaks.

In addition to the notification mentioned here, healthcare institutions have a duty to notify the County Health Boards in writing of outbreaks that have led to or could have led to considerable personal injury to a patient as result of the provision of health services, ref. Section 3-3 of the Act relating to Specialist Health Services.

To Section 3-5 Notification of deliberate spreading of infection

Unless the spreading is announced by the perpetrator, the deliberate spreading of infectious agents for the purpose of terrorism (bioterrorism) or for other purposes will not be discovered until people become sick. The discovery will be made by general practitioners, by emergency clinics or at hospitals. The patients may have sought help in different places. It is therefore vital for early tracing to see the connection between these cases.

Early tracing is important in order to 1) be able to give the correct treatment to the diagnosed patients, 2) to be able supervise the diagnosis of other persons who are being evaluated for unusual symptoms and 3) be able to find persons who have been exposed and are in the incubation stage, and offer them treatment which will prevent the disease from breaking out.

A good notification system depends on medical practitioners who are alert. Indications that an infectious disease is due to deliberate spreading may be:

- the disease or infectious agent is unusual in the place it occurs
- the infectious agent has unusual characteristics, e.g. resistance pattern and genetic pattern
- a particular infectious agent gives an unusual clinical picture, e.g. a higher morbidity or mortality rate
- the cases have an unusual distribution over time, place and persons, e.g. are only found in persons who have spent time out of doors.

The deliberate spreading of infectious agents is not necessarily limited to infectious agents that are normally associated with biological weapons.

To Section 3-6 Notification of infection from equipment etc.

We have seen examples of large numbers of people being infected by medical equipment, cosmetics, pharmaceuticals, blood, blood products, tissue and organs before the situation has been discovered. If these products are contaminated at the time of production, they can potentially spread infection to thousands of people. It is therefore important that the slightest suspicion is followed up by notification to a central body, which can see suspicions from several sources in a larger context. The duty to notify is therefore not intended to apply to situations where equipment is contaminated during use, for example, where a thermometer is contaminated by a patient during use and the infection is passed to the next patient. These are matters for the individual practitioner's surgery or healthcare institution and notification to a central body is not necessary.

To Section 3-7 Notification of possible infection from blood donor

Medical practitioners who find that a patient has a disease which can be transmitted in blood or blood products must, as part of personal disease control guidance, ref. Section 2-1 of the

Communicable Diseases Control Act, explain to the patient that he or she may not donate blood. Blood donors are also asked before they give blood if they have diseases that can be transmitted in blood. As an extra precaution, the laboratories and medical practitioners themselves must also notify the blood bank in question. Such notification has significance not only for the patient's future possibility of donating blood but also for an evaluation of previous blood donations. On receipt of such notification, the blood bank must, among other things, notify the Norwegian Medicines Agency and it must also consider whether the patient may previously have donated infected blood. If this is the case, the blood bank must initiate the necessary measures.

To Section 3-8 Notification of possible infection from healthcare institution

Patients are sometimes transferred from one healthcare institution to another while they are in the incubation phase or an asymptomatic phase of a communicable disease. The first healthcare institution will therefore not know about the infection and can therefore not initiate any disease control measures. This can have undesirable consequences for some conditions, such as an infection with meticillin-resistant yellow staphylococci (MRSA). Attending physicians who discover a communicable disease in a recently transferred patient must therefore consider whether the infection can have taken place in the first healthcare institution and whether disease-control reasons make it advisable to notify this institution.

To Section 3-9 Notification of possible infection from food

Municipal medical officers will be notified of possible food-borne outbreaks as laid down in Section 3-3 of the Regulations, and will get to know of such outbreaks in other ways. It is important for containment of the outbreaks that the municipal medical officer notifies and cooperates with the local food safety authority. The food safety authority can, for example, inspect the conditions in which production, preparation and presentation of food take place and also take samples for infectious agents. Furthermore, it may be relevant to interview the patients in more detail about what and where they have eaten. The municipal medical officer may not give person-identifiable data to the food control authority without the patient's consent.

To Section 3-10 Notification of possible infection from animals

The district veterinary officer may initiate measures, including destroying animals, in order to prevent infection of humans by zoonoses (diseases that can be transmitted from animals to humans). The municipal medical officer and the district veterinary officer may work together to investigate the circumstances under which infection occurred. The municipal medical officer may not give person-identifiable data to the district veterinary officer without the patient's consent.

To Section 4-1 Alignment of data for the production of statistics

This section provides the legal basis for the preparation of statistics. The production of statistics must be carried out by the data controller for one of the registers mentioned in the first paragraph or by an institution as determined by the Ministry. The data controller for the registers mentioned is the Norwegian Institute of Public Health and the institution is the Cancer Registry.

An alignment of data pursuant to Section 4-1 or production of statistics implies that it is statistics or tabled data that have been requested. The request may be from a municipality, a regional municipality or a region that is going to use the data for planning purposes, or they may be requested by a research scientist. Whether the tabled data or statistics have been sufficiently anonymized must be determined in each individual case. When publishing tables at local and

regional level, the practice has been to base them on four or five units. This means that material containing fewer than four or five persons will not be aligned.

The second paragraph sets a time limit for how quickly an order for statistical data has to be effectuated. This provision is a follow-up of official report NOU 1997:26 on access to personal health data filing systems. It is the Ministry's wish that data in central personal health data filing systems be used more actively for planning purposes.

The third paragraph establishes that personal health data that is received for the production of statistics pursuant to the first paragraph must be deleted as soon as the alignment has been successfully completed. This provision follows naturally from Section 27, first paragraph, which stipulates that personal health data must not be stored for longer than is necessary to achieve the purpose for which the personal health data is being processed.

To Section 4-2 Alignment of data from the Registers with data from other registers for research purposes, etc.

This section provides rules for in-house research on aligned personal health data in the two Registers, i.e. in cases where data in the Registers are aligned with each other or with data in other central personal health data filing systems which are mentioned in the preceding section. The legal basis for disclosure of personal health data from these personal health data filing systems to the MSIS Register and/or the Tuberculosis Register for alignment purposes is Section 14, first sentence, ref. Section 12, second sentence, of the Personal Health Data Filing Systems Act.

A licence from the Data Inspectorate is not required to process data pursuant to this section, but a report must be sent to the Inspectorate, ref. Section 29 of the Personal Health Data Filing Systems Act.

The first paragraph sets three conditions that must be fulfilled before processing (alignment, combination and preparation) of data for use in a specific research project can take place pursuant to this section.

One of the conditions is that the project must have an expressly stated purpose which is consistent with the purpose of the Register, ref. Section 1-3.

The second condition is that the data processor (researcher, person responsible for the project, etc.) must only process or do research on de-identified data. The data controller for the Register must carry out and be responsible for the actual process of aligning and of assuring the quality of and preparing the data. The data will not be de-identified until this process has been carried out. It must be carried out in close cooperation with the aligner/quality controller and research scientist.

The third condition is that the alignment must be regarded as ethically unobjectionable. 'Unobjectionable' may, for example, refer to whether the research project is considered to be justified and acceptable. It is the responsibility of the data controller for the Registry to see that there is no objection to the processing of the data.

In the second paragraph, first sentence, it is stated that aligned personal health data may not be stored until names, dates of birth and personal identity numbers have been deleted or encrypted.

This provision prohibits the data controller from storing combined data by name and date of birth. In the second paragraph, second sentence, it is stated that directly identifiable data, i.e. names and personal identity numbers that are received for processing, must be deleted as soon as the alignment has been successfully completed. This provision will prevent the storage of copies of directly identifiable personal health data outside the Register's database.

In the third paragraph, it is stated that all data that is processed in accordance with the first and second paragraphs must be deleted on completion of the project. The requirement regarding deletion of all data that can directly and indirectly identify a specific person refers both to the de-identified data which the researcher or any other person has processed, ref. first paragraph, and to any encrypted personal health data, ref. second paragraph.

To Section 4-3 Disclosure of aligned data files for research etc.

The first paragraph gives external research scientists and any other persons who have tasks in the health services and public health administration access to aligned and prepared de-identified data from several central personal health data filing systems, provided that the data is to be used for an expressly stated purpose consistent with the purpose of the Register, ref. Section 1-3 of the Regulations. Personal health data filing systems which may be aligned for this purpose are listed in Section 4-1 of the Regulations. This provision is a follow-up to official report NOU 1997:26 on access to personal health data filing systems and it allows for greater access to data in the Registers.

There are three cumulative conditions that must be fulfilled before alignment and disclosure of data for an expressly stated purpose can take place.

Firstly, the recipient must only process de-identified data. De-identified data are defined as personal health data from which names, personal identity numbers and other unique personal data have been removed, so that the data can no longer be related to an individual, and where identity can only be recovered by alignment with the same data that was previously removed. Fulfilment of this condition presumes that the recipient (for example the researcher) who is going to process the data does not possess his/her own information or data about individuals that is to be combined with and processed along with the disclosed data.

The alignment/preparation body will carry out the actual process of aligning and quality-assuring the data. Only after that process has been completed will the data will be de-identified. The process must take place in close cooperation between the aligner/quality controller and the researcher. The data must not be disclosed to external researchers until they have been sufficiently de-identified. Whether the data has been de-identified or not, must be assessed specifically in relation to each particular project.

The recipient of the de-identified data must send a report to the Data Inspectorate in accordance with Section 29 of the Personal Health Data Filing Systems Act.

If the recipient has his/her own data and asks to have data from one or more of the said personal health data filing systems aligned with data (identities) the recipient him/herself possesses, Section 4-5 of the Regulations applies.

Disclosure of de-identified data to researchers, or other persons entitled to receive them – in the way de-identified data are defined in the Personal Health Data Filing Systems Act – is not

deemed to conflict with the provisions regarding duty of confidentiality in the Act relating to Healthcare Personnel or the Public Administration Act. It is therefore not necessary to apply for dispensation from the duty of confidentiality. The de-identified data will not be anonymous because it will be possible to trace back the data, i.e. the alignment/preparation body will be able to trace back the data. It must not be possible for the recipient to trace it back.

If it is a question of a research project where the need for data is great and requires the use of many variables, including information about gender, month of birth, year etc. and the data can be traced back to a specific individual, Section 4-3 will not be the correct legal basis. In such cases, Section 4-5 will be the correct legal basis.

The second condition is that the processing of the data must be ethically unobjectionable. 'Unobjectionable' refers among other things to whether the research project is justified and acceptable. It is the person responsible for the project who is responsible for seeing that there is no objection to the processing and use of the data. If the Regional Committee of Medical Research Ethics reviews a project positively, the data controller cannot refuse to disclose de-identified data on the grounds that the project is not acceptable or justified.

The third condition is that the alignment and preparation of the data must be done by the data controller for one of the Registers whose data is being processed (aligned). Any enterprise which the Ministry chooses to align and prepare data for external researchers will be data processor for the Norwegian Institute of Public Health and an agreement must be reached in writing in accordance with Section 18 of the Personal Health Data Filing Systems Act, cf. Section 1-6 of the Regulations.

The second paragraph refers to Section 4-2, second paragraph, of the Regulations. It follows from this provision that the enterprise must not store the aligned personal health data until names, dates of birth and personal identity numbers have been erased or encrypted. It must also erase directly identifiable personal health data (name and personal identity number) which are received for processing immediately the alignment has been satisfactorily carried out.

The third paragraph stipulates that the data controller must disclose or transfer the necessary and relevant data to the person responsible for the project within sixty days from receipt of the application. The legal basis for the given processing of the data must be stated in the application, as mentioned in the first paragraph. If the Ministry determines that a particular enterprise is to align and prepare research data for external recipients, deadlines and procedures for how this is to take place must be laid down in a written agreement between the Norwegian Institute of Public Health and the enterprise in question, to ensure that the deadline of sixty days is complied with.

Compliance with the sixty-day deadline depends on the submission of a precisely worded application. The Ministry is aware that applications for research data can be incomplete and that it takes several rounds to achieve an application that is sufficiently detailed to allow data to be disclosed. In the latter cases, it may be difficult to deliver data within a sixty-day time limit and disclosure may be postponed until it is possible to fulfil this requirement. This follows from the fourth paragraph. The data controller must then give the applicant a provisional answer stating the reason for the delay. If an incomplete application is the reason why it is difficult to provide the data, this should be remedied through communication, advice and guidance on the part of the Registry. Special and temporary circumstances must exist at the Registry before it can plead

postponement of disclosure pursuant to the fourth paragraph. A longer administrative period than sixty days must not become the norm. However, the demand for compliance with the deadline must not be met at the expense of quality.

To Section 4-4 Duty to disclose non-aligned data for research etc.

This provision regulates the access to non-combined/aligned data from the MSIS and Tuberculosis Register. The projects which make use of non-aligned data, are regulated in the same way as projects which make use of aligned/combined data. Use of this section presumes that the external recipient does not have any data of its own that can be combined with the disclosed data.

To Section 4-5 Disclosure and other processing of data in the Registers

This section regulates disclosure and other processing of data in the Register(s) which is not covered by the above sections. The first paragraph requires that such processing is permitted by the Data Inspectorate and takes place in accordance with the general rules regarding duty of confidentiality, i.e. the rules relating to duty of confidentiality in the Public Administration Act and the Act relating to Healthcare Personnel, ref. Section 5-1 of the Regulations.

Disclosure of data in the Register(s) for research purposes is conditional on a decision by the Directorate for Public Health and Social Welfare that the data may be used for the formulated purpose without regard to duty of confidentiality, and permission from the Data Inspectorate to the recipient to process the data for the given purposes. Research on identifiable human material or identifiable data must also be submitted to a regional committee for medical research ethics for evaluation.

Research projects which involve the alignment of data from the Register(s) with the researchers' own data are also governed by this section.

It follows from the second paragraph, first sentence, that the Directorate for Public Health and Social Welfare shall answer enquiries regarding the disclosure for data identifying specific persons for use in expressly stated research projects within thirty days from the receipt of the enquiry. The deadline of thirty days is deemed to be important with a view to increasing the use of data from the Register(s) in specific research projects.

It is stated in the second sentence that if special circumstances make it impossible to reply to the enquiry within the stated deadline, the reply can be postponed until it is possible to give an answer. The Directorate for Public Health and Social Welfare shall then give a provisional reply stating the reason for the delay and the probable date for when the enquiry can be answered. In such a provisional reply, the Directorate must also inform the enquirer if further information is necessary, if this is required for a positive reply. Special and temporary circumstances must exist at the Registry before it can plead postponement of disclosure pursuant to the fourth paragraph. A longer administrative period than thirty days must not become the norm.

To Section 4-6 Information strategy targeting user groups

This section establishes that the Norwegian Institute of Public Health must have an active information strategy and information plan targeting user groups. The Regulations do not require this plan to be in writing. The point of the provision is to have a consciously open and positive attitude to interacting with different research communities and other user groups. The use of the data in research projects outside the Register(s) and for planning of the health services is an

independent objective. Efficient use of data from the Register(s) can best be achieved by the Institute informing municipal medical officers, health planners, health administrators, researchers, etc. about the ways in which the Register(s) can help to build up and develop knowledge.

To Section 4-7 Costs

This section gives the right to demand payment for services rendered using processed data from the Register(s). The provision does not mean that coverage is to be demanded for the costs of all data disclosures from the Register(s). Costs relating to disclosure of statistics and de-identified data for research purposes should as a general rule be covered by ordinary running expenses. It should be possible to demand payment for major projects. It is stated in the second sentence that payment must not exceed the actual expenses of processing and preparing the data.

To Section 4-8 Record of disclosures

This provision orders the Norwegian Institute of Public Health to keep a record of who receives data from the Register(s) and the legal basis for the disclosures. The Institute has a duty to keep a record of disclosures of personal health data to any aligning body, ref. Sections 4-1 and 4-3, first paragraph, third point, of disclosures of de-identified health data in accordance with Section 4-4 and of other disclosures in accordance with Section 4-5. These records must be kept for at least five years after the disclosures have taken place.

To Section 5-1 Duty of confidentiality

This provision establishes that both the rules in the Public Administration Act and the rules in the Act relating to Healthcare Personnel regarding duty of confidentiality are applicable to personal health data that are processed in accordance with the Regulations. This means among other things that any exemption from the duty of confidentiality must be authorized by both Acts before disclosure of data from the Register(s) can take place.

The duty of confidentiality is not only a passive duty to keep silent; it is also an active duty to prevent unauthorized persons from gaining access to confidential information. Compliance with the statutory duty of confidentiality therefore requires safe handling and storage of personal health data.

To Section 5-2 Information security

The first paragraph refers to Section 16 et seq. of the Personal Health Data Filing Systems Act. This provision instructs the Norwegian Institute of Public Health and the data processor to arrange for adequate information security in connection with the processing of personal health data. This includes the responsibility to ensure that sufficient security expertise is available. In addition to being responsible for security in its own organization, the Institute must assure itself that information security is satisfactory at its communication partners and suppliers. 'Information security' means:

- securing confidentiality, i.e. protecting the data from access by unauthorized persons, including compliance with the rules relating to confidentiality
- securing integrity, i.e. protecting the data from unintentional changes in them
- securing accessibility, i.e. ensuring that sufficient and relevant data are present
- assuring quality, i.e. ensuring that the data are correct.

Planned, systematic measures must be used to achieve adequate information security. This means that recognized techniques and standards for quality control, internal quality control and information security must be applied. Both organizational and technical measures must be established. It must be possible to document the security measures and the information system itself.

The second paragraph applies when personal health data are processed wholly or partially by electronic means. In these cases, Sections 2-1 to 2-16 of the Regulations apply. These provisions are a continuation of the current security requirements.

Wilful or grossly negligent infringement of this section will render the offender liable to prosecution under Section 8-1.

To Section 5-3 Duty to implement internal controls

This section imposes on the Norwegian Institute of Public Health a duty to introduce and carry out internal quality controls in accordance with Section 17 of the Personal Health Data Filing Systems Act. These controls must, according to Section 17, second paragraph, be documented and the documentation must be accessible to employees and the supervisory authorities.

Data processors must process data in accordance with the routines established by the Institute of Public Health.

Wilful or grossly negligent infringement of this section will render the offender liable to prosecution under Section 8-1.

To Section 5-4 Content of internal controls

This section provides rules for the content of internal controls. The wording of this section is modelled on the provision covering internal control in the Personal Data Regulations.

Wilful or grossly negligent contravention of this provision will render the offender liable to prosecution under Section 8-1.

To Section 6-1 The duty of the reporting medical practitioner to inform

It follows from this section that the medical practitioner has a duty to inform the subject of a report who is going to receive the report and what the report is going to be used for. This duty to inform the person concerned also follows from the Healthcare Personnel Act and the Act relating to patient rights.

To Section 6-2 The right of the data subject to information and insight

The first paragraph refers to Sections 22 to 25 in the Personal Health Data Filing Systems Act. These provisions give the data subject the right to information about the personal health data filing systems and the right to insight into the processing of his/her own personal health data.

The provisions in the Personal Health Data Filing Systems Act on the right of the general public to information and the right of anyone who so requests to information (Sections 20 and 21 of the Act) have not been included in the Regulations. Nor have the provisions in the Personal Health Data Filing Systems Act regarding the data controller's duty to inform the data subject (Sections 23 and 24 in the Personal Health Data Filing Systems Act) been included in the Regulations. These are general rules which apply whether they are included in the Regulations or not.

As a general rule, access shall be granted free of charge. There is no right to demand payment for costs, unless this is expressly laid down in the Regulations. This complies with the current legislation. No provision has been made for covering the cost of exercising right of access in the Regulations.

To Section 6-3 Information and access when the data subject is under age

It can be seen from this section that parents or other persons with parental responsibility have right of access according to rules corresponding with those in Section 3-4 of the Patients' Rights Act. It follows from this that, as long as the data subject is under 16 years of age, both the data subject and his/her parents or other persons with parental responsibility are entitled to access. If the data subject is between 12 and 16 years of age, the information must not be given to the parents or other persons with parental responsibility if the data subject does not wish this for reasons that should be respected. It should be taken as the general rule that children between 12 and 16 have no objection to their parents or other persons with parental responsibility being given right of access to information about themselves. However, children between 12 and 16 should be informed that their parents or other persons with parental responsibility are being given access.

Access must take place free of charge, see above under Comment to Section 6-2.

To Section 6-4 Time limit for replying to enquiries about access

This section sets a time limit of thirty days for replies to requests for access.

To Section 7-1 Storing personal health data

It follows from this section that the data in the MSIS and Tuberculosis Registers must be stored indefinitely, unless otherwise provided for in Section 26 or 28 of the Personal Health Data Filing Systems Act.

Section 26 of the Personal Health Data Filing Systems Act concerns rectification of deficient data. This provision gives the data controller a responsibility to correct data which are incorrect or incomplete. This also applies in cases where personal health data processed in accordance with the Regulations have been unrightfully processed. The data controller may make the corrections on his/her own initiative or at the request of the data subject. The data controller must if possible ensure that the error does not have consequences for the data subject. If the personal health data have been disclosed, the data controller must notify the recipients of the disclosed data of this.

Section 28 of the Personal Health Data Filing Systems Act provides rules for the erasure or blocking of personal health data in cases where processing is regarded as disadvantageous to the data subject. This section establishes that the data subject may demand that personal health data processed under the Regulations be erased or blocked if the processing of the data is felt by the data subject to be strongly disadvantageous to him/herself or there are no strong general considerations which warrant processing of the data. Demands for erasure or blocking of such data should be addressed to the data controller responsible for the data. After consulting the Director General of the National Archives of Norway, the Data Inspectorate may decide that the right to erase the data pursuant to the first paragraph may take precedence over the provisions in sections 9 and 18 of Act No. 126 of 4 December 1992 relating to Archives. If the document that

contained the erased data gives a clearly misleading picture after the erasure, the entire document must be erased.

In other respects, the Archives Act and regulations issued in pursuance of this Act will be applicable to the MSIS and Tuberculosis Registers.

To Section 8-1 Penalties

This section grants the right to impose penalties for contravention of the provisions in Sections 2-1, 2-3, 2-4, 2-5 and Sections 5-2 to 5-4.

The Personal Health Data Filing Systems Act also provides for other possible sanctions in the event of contravention of the Act or regulations issued in pursuance of the Act. It opens for the Data Inspectorate to issue orders or impose coercive fines. Furthermore, the data subject may in certain cases demand compensation if personal health data are processed contrary to the Regulations. These provisions are general and they apply whether they are included in the Regulations or not. Reference is made to Sections 32, 33 and 35 of the Act.

To Section 9-1 Entry into force

This section establishes that the Regulations enter into force on 1 July 2003.