

## **Development of Laws and Regulations on Communicable Diseases Control in Taiwan**

The Regulations Governing the Control of Communicable Diseases, in 35 articles, was promulgated by the Nationalist government on 6 December 1944 on mainland China. The set of regulations has been, since its promulgation, amended twice to meet the changing society, the need for more intensified control of communicable diseases, and the improvement in livelihood. The first amendment of Article 31 and Article 32 was made on 28 December 1948 and the second amendment of 40 articles in total was made on 19 January 1983. In the early stage, 12 communicable diseases namely, cholera, dysentery bacillary and amoebic, typhoid and paratyphoid, smallpox, meningococcal meningitis, diphtheria, scarlet fever, plague, typhus fever, and relapsing fever were classified as notifiable. When the Second World War ended, Taiwan was in a devastating state. The healthcare infrastructures, among others, had been seriously damaged quarantine services stood at a standstill and sanitary conditions were generally poor. Active communication between Taiwan and the mainland China then had brought about to Taiwan outbreaks of some notifiable communicable diseases such as smallpox, cholera, plague, dysentery bacillary and amoebic, typhoid and paratyphoid, meningococcal meningitis, diphtheria, and scarlet fever. To prevent the spread of the notifiable diseases, the health authorities had taken active preventive measures, and required all public and private health and medical care institutions to function strictly in accordance with the Regulations Governing the Control of Communicable Diseases, and all counties and cities to closely follow these diseases. In case of any infection, immediate and effective control measures were taken to interrupt the

transmission. Through these measures, many communicable diseases had been brought under effective control gradually.

Therefore, after several outbreaks of rabies in the later, for its effective control, the government decided on 20 August 1952 to add rabies to the list of notifiable diseases. There were then 13 notifiable diseases in total. When the World Health Organization announced the global eradication of smallpox, smallpox was removed from the list of notifiable diseases. While yellow fever was still prevalent in the Central and South America and Africa where Taiwan people visited relatively frequently, it was made notifiable. Thus, the amended Regulations Governing the Control of Communicable Diseases promulgated by the President of the Republic of China, Taiwan on 19 January 1983 had 13 notifiable diseases. To realize the control of communicable diseases, a set of implementation rules on the Regulations Governing the Control of Communicable Diseases, iii 12 articles, was formulated and announced by the Department of Health on 9 September 1985.

During this period, because of the effective promotion of various preventive measures, the active participation of health and medical care institutions at all levels, the improvement in general livelihood and environmental sanitation, the availability of public utilities such as safe water supply, and the national immunization programs, many communicable diseases had been either completely eradicated or brought under control. No cases of plague since 1948, smallpox since 1955, and rabies since 1959, for instance, have been reported. For the control of malaria, Taiwan Provincial Malaria Research ( TAMRI ) was established in 1948 to combat the epidemic. In December 1965, the World Health Organization officially declared that Taiwan was free of malaria. Quarantine services had also been strengthened to prevent the entry of diseases. Plans had also been formulated for the control of other reportable diseases, endemic diseases and chronic diseases. A sound foundation for the effective control of communicable diseases in Taiwan had thus been laid.

Along with the rapid social and economic development, improvement in living standards and environmental sanitation, universal availability of safe drinking water, advancement in medical technology, diagnostic techniques and therapeutic methods, national coverage of immunization, improvement in antibiotics, chemical therapy, immunology and vaccines, effective interruption of communicable diseases, effective treatment of wastes and waste water, and strengthening of disease control organization and manpower, several communicable diseases have either been eradicated (smallpox for instance) , or brought under effective control ( Japanese encephalitis, hepatitis B, and poliomyelitis, for instance) . However, disease control is facing new challenges of some emerging infectious diseases such as AIDS, and re-emerging diseases such as dengue fever, for which no vaccines are available yet. At present, their control can only be realized through intensive health education, health promotion, environmental sanitation, and effective disease control measures, then sparing no efforts. To provide legal basis for the control of AIDS, the Department of Health formulated the AIDS Prevention and Control Act. This Act was promulgated by the President of the Republic of China, Taiwan on 17 December 1990. AIDS was then made notifiable, and the number of notifiable diseases had increased to 14.

In the meantime, there had been some drastic changes in government policies. People were allowed to travel abroad for tourism, to visit their relatives on mainland China, and alien workers were brought in. These new changes had posed a challenge to disease control in Taiwan. At the same time, the control of several major communicable diseases was not regulated by laws and regulations. Without legal basis, their control, which was regulated by administrative orders only, was difficult. In this connection, the Department of Health called several meetings in 1990 of representatives of various government organizations, experts and scholars, and representatives of medical organizations and societies concerned to recommend suggestions for the amendment of the Regulations Governing the Control of Communicable diseases. The draft amendment was submitted to the Executive Yuan on 28 February 1991 for review and approval, and subsequently approved by the Executive Yuan on 13 June at its 2235<sup>th</sup> meeting. The amendment was later submitted on 26 June to the Legislative Yuan for review and approval. It passed the first reading in 1992.

During this time, there had been several drastic changes domestically and internationally. More alien workers from the southeast Asian countries had been brought in exchanges between the two sides of the Strait had become more frequent overseas tourism was a boom and trade and commercial activities had become more globalized. Diseases would spread freely irrespective of boundaries, and disease control had become more complex. In the meantime, there were in Taiwan the unfortunate incidents of soft turtles contaminated by *Vibrio cholerae* O-139 and outbreaks of enterovirus 71 infection, both being pathogenic agents of the emerging infectious diseases. The sharing of responsibilities between the central and the local governments was not clearly specified, and the existing regulations were inadequate to meet the purpose of disease control. For these reasons, the Department of Health withdrew the amended Act the Control of Communicable Diseases submitted earlier to the Legislative Yuan for review and approval. The Regulations was given an overall review along the line of structural reorganization, strengthening of disease surveillance system, and sharing of responsibilities between the central and the local governments in disease control. Local authorities were, upon legal rights and responsibility and under the supervision of the national authorities, authorized to take adequate preventive measures. The national authorities would formulate national disease control policies and plans, supervise and technically assist local governments, and when necessary, directly command local authorities in the control of communicable diseases. At time of major disease outbreaks, a joint disease control command center would be created for more coordinated actions and to mobilize all manpower and resources of governments at all levels for the timely control of diseases. The set of Regulations Governing the Control of Communicable Diseases was then re-amended. The amended Regulations was legislated and promulgated by the President of the Republic of China, Taiwan on 23 June 1999 as the Law of the Control of Communicable Diseases. The Law contains 47 articles.

When Act the Control of Communicable Diseases was re-amended, factors considered at the time of the amendment included the higher general educational level and better knowledge of healthcare of the public, better awareness of the importance of personal hygiene, more concerns of the media

on disease outbreaks, improvement in the transportation and communication, and closer contacts between people because of improved transportation and thus increased opportunities for disease transmission. With the improvement in transportation, the world has become smaller, and the effects of quarantine have diminished. Air and sea quarantine can no longer effectively prevent the entry of communicable diseases. An infected person entering the country during his/her incubation period will develop symptoms only a few days or even longer after entry, therefore, there are no such effective quarantine measures that can prevent the entry of diseases. Early detection and early treatment are essential to disease control. When the front-line quarantine services cannot entirely keep diseases away, the second-line disease surveillance system must be established for better disease reporting to control diseases at their early stage.

On the other hand, the self-governing of local government, and the downsizing of the Provincial government has placed more and heavier responsibilities on local governments in general, and the local healthcare organizations as well. The central and the local health authorities must also face the issue of cross-county and cross-regional control of communicable diseases. The existing systems do not contain mechanisms to manage such issue.

Under those circumstances, disease control strategies must be amended and adjusted, and changed its foundation. The existing disease control measures cannot meet the demands, and the relevant regulations must be changed totally. The classification of diseases for control purpose by their severity currently in practice is outdated. The new practice requires that diseases be classified by “difference in control measures” such as reporting time, urgency, and requirement for isolation, into four categories. Furthermore, the emphasis of reason and purpose of people would like to be adapted to, disease control should be an all-out effort, the responsibilities of all level governments, and the public, the communities, and the medical care and disease-control networks should all be involved.

Other supporting measures should also be considered. The strengthening of laboratories and their authorization and contract, regulations governing designation of hospitals for the isolation treatment of communicable diseases,

conditions and standards of isolation wards, the level of hospitals for patient isolation, diseases requiring isolation, flexible or strict isolation of patients, mandatory isolation and the responsibilities of the government, and reimbursement by the National Health Insurance, are some of the issues that should be considered. It should also be clearly specified that, iii disease control, the role of the central government is to provide technical assistance, and that the local government should strictly implement disease control measures according to regulations. Other issues such as how to disseminate the concept of disease control, and how disease control responsibilities are shared by the Center for Disease Control of the Department of Health and local healthcare authorities should also be carefully studied.

The major points of amendment of the Act include the increase of the number of notifiable diseases from 13 to 38 more considerations on the rights of the people and more administrative power for the government disease control agencies. Some special features are

1. Some emerging infectious diseases are made notifiable. 38 communicable diseases are classified by difference in control measures into four categories (Article 3 of the amended Act)

1) Category 1 ( diseases to be reported immediately and placed under mandatory isolation) : cholera, plague, yellow fever, rabies, and Ebola hemorrhagic fever

2) Category 2 : in sub-categories A and B

Sub-category A (mandatory isolation, to be reported within 24 hours)  
typhus fever, diphtheria, meningococcal meningitis, typhoid, paratyphoid, anthrax

Sub-category B ( recommended isolation, to be reported within 24 hours ) : poliomyelitis, dysentery bacillary, and open pulmonary tuberculosis (may be reported within one week)

3) Category 3 : in sub-categories A and B (to be reported within 24 hours /one week, no mandatory isolation for treatment required)

Sub-category A (to be reported within 24 hours) : dengue fever, malaria, measles, acute viral hepatitis A, Enterohemorrhagic E. coli infection, Enterovirus complicated severe case

Sub-category B (to be reported in one week) : tuberculosis (except open pulmonary tuberculosis) , Japanese encephalitis, leprosy, rubella, congenital rubella syndrome, pertussis, scarlet fever, tetanus, scrub typhus, acute viral hepatitis ( except hepatitis A ) , mumps, chickenpox, legionnaire, Hib, syphilis, gonorrhea, influenza;

4) Category 4 : other communicable diseases or new infectious diseases that may be designated by the central competent authorities at times when the need for their control by this Law arises.

2 .Provisions for relief measures and compensation, and protection of the privacy of patients have been added to protect the rights of the people.

1) Relief for victims of immunization: Channels for relief of victims of complications or significant side reactions of immunization are made available (Article 18 of the amended Act)

2) Local governments are authorized to compensate for food items, animals, or remains of animals to be burned, buried or handled in other ways required by law (Article 22 of the amended Act)

3) To protect the privacy of patients of communicable diseases, their names and information related to their medical records obtained through professional practice should not be leaked out without reasons (Article 31 of the amended Act)

4) Losses of private medical care institutions and their employees incurred by required participation in disease control should be compensated adequately (Article 15 of the amended Act)

5) Mandatory autopsy is required of persons die of infectious or suspected infectious diseases. Their funeral costs should be compensated (Article 39 of the amended Act)

3 .Rights and responsibilities of the central and the local governments are specified. Disease control agencies are given more administrative powers aid responsibilities.

- 1) The rights and responsibilities of the central aid the local governments are specified. Functions of each competent authority at all levels are clearly indicated Article 4 of the amended Act)
- 2) The public, the communities, physicians, and medical care institutions are required to cooperate in the control of communicable diseases (Article 5 of the amended Act)
- 3) A sound disease control command system will be established to strengthen the disease control system ( Articles 9 through 12 of the amended Act)
- 4) The central competent authority shall designate certain hospitals to set up isolation wards, aid decide 011 the standard operational procedure (Article 15 of the amended Act)
- 5) More files for violations of regulations are added. The amount of fines is raised (Articles 40 through 43 of the amended Act)

A modernized legal system for disease control alone cannot meet the needs of the changing society. For more effective and coordinated operation, the Department of Health established the Center for Disease Control on 1 July 1999 by consolidating the existing Bureau of Communicable Disease Control, the National Quarantine Service and the National Institute of Preventive Medicine, all of the Department, to solve, once and for all, the structural and system-wide problems associated with the long-existing disease control system, and to upgrade the standard of disease control by more effective promotion and implementation of disease control measures. The Center has, since its inauguration, made considerable efforts in either amending or formulating regulations, 11 sets in total (see Appendix) , relevant to the Law of Control of Communicable Diseases. Each set of regulations and guidelines and the process of amendment or formulation or promulgation are summarized as follows



## 1 .Amendment of the Enforcement Regulations of the Regulations Governing the Control of Communicable Diseases

The set of Implementation Regulations was announced for implementation by the Department of Health on 7 March 2000 under the new title of the Enforcement Regulations of the control of Communicable Diseases. Some major points in the amendment are (1) the legal basis of the Enforcement Regulations previously was Article 39 of the Control of Communicable Diseases Act, is now Article 46 of the Law of the Control of Communicable Diseases (2) the scope of communicable disease control and definitions (3) bases for the recognition of matters concerning the Law of the Control of Communicable Diseases and their implementation principles and (4) items and levels of costs for the mandatory isolation of patients of various communicable diseases, and assistance by the competent authorities to families of patients under mandatory isolation.

## 2. Formulation of Regulations Governing Surveillance and Alarm System of Communicable Diseases

For the effective operation of various reporting systems and the timely detection of communicable diseases for early warning, the Center for Disease Control has been, in accordance with Article 9 of the Law of the Control of Communicable Diseases, in the process of formulating this set of Regulations and submitted to Committee on Legal Affair of Department of Health for review and approval.

## 3. Formulation of the Regulations Governing Designation of Hospitals for the Isolation Treatment of Communicable Diseases

For the effective isolation of sources of communicable diseases and control the diseases, the Center for Disease Control has been, in accordance with Article 15 of the Law of the Control of Communicable Diseases, in the process of formulating this set of Regulations and submitted to Committee on Legal Affair of Department of Health for review and approval.

## 4. Formulation of Regulations Governing Operational Procedures and Compensations for the Public Spaces and Manpower of Private Hospitals Requisitioned at Time of Disease Outbreaks

The Regulations was announced for implementation by the Department of Health on 27 June 2000. Some major points in the guidelines are (1) for preventing the communicable diseases, the local government should classify and record the private hospitals, public spaces and healthcare manpower (2) at the times of diseases outbreak, the local governments should requisite the private hospitals, public spaces and healthcare manpower through the lists while the shortage of the assigned medical institutes and manpower, and set up the temporarily communicable disease hospitals to help control the diseases.

5 .Formulation of Regulations Governing Review of Immunization Records and Make-up Immunization for Children of Primary Schools and Pre-school Educational Institutions

To improve immunization coverage, the Center for Disease Control has, acting on Article 17 of the Law of the Control of Communicable Diseases, formulated this set of guidelines for review by organizations concerned.

6 .Formulation of Regulations Governing Management of the Incomes and Expenditures and the Utilization of the Relief Funds for the Victims of Immunization

To meet the principles of relief and to compensate victims of immunization, the Center for Disease Control has been, acting on Article 18 of the Law of the Control of Communicable Diseases, in the process of formulating this set of guidelines and submitted to Department of Health for review and approval.

7 .Formulation of Regulations Governing Compensation of Vectors of Communicable Diseases Processed According to Regulations

The Regulations were announced for implementation by the Department of Health on 27 June 2000. Some major points in the guidelines are (1) the definition of Vectors of Communicable Diseases (2) for controlling the communicable diseases, the food items of vectors of communicable diseases, animals, or remains of animals to be burned, buried or handled in other ways required by law are authorized to compensate.

#### 8. Amendment of the Guidelines on the Quarantine Rules and Costs at International Ports of Entry:

To effectively prevent the entry and exit of communicable diseases, the Center for Disease Control has been, acting on Article 27 of the Law of the Control of Communicable Diseases and in coordination with the Law on Administrative Procedures, in the process of amending this set of guidelines.

#### 9. Formulation of Regulations Governing Examination or Screening of the Risk Groups and Specific Target Groups of Communicable Diseases

For better control and to prevent the spread of communicable diseases, the Center for Disease Control has, acting on Article 37 of the Law on the Control of Communicable Diseases, drafted a set of guidelines. Meetings of medical experts and representatives of organizations concerned will be called soon to review this set of guidelines.

#### 10. Formulation of the Standards of Compensation for Funeral Costs of Deceased Patients of Communicable Diseases or Suspected Communicable Diseases Undergoing Anatomy

The standards was announced by the Department of Health on 27 June 2000. Some major points in the standards are (1) the necessary conditions and standards of compensation; (2) the payment and application.

#### 11. Formulation of Regulations Governing Incentive Measures for Communicable Disease Control

To encourage the public and organizations concerned for active participation in disease control, the Center for Disease Control has been, in accordance with Article 45 of the Law of the Control of Communicable Diseases, in the process of formulating this set of Regulations and submitted to Committee on Legal Affairs of Department of Health for review and approval.

The Department of Health has been, for the effective implementation of disease control measures to protect the health of the people, and to meet the increasing complexity of disease control, based on the principles of forward-looking, innovation, effectiveness and comprehensiveness, active in

developing the above-mentioned regulations and guidelines. The purposes are to strengthen laws and regulations on disease control, to establish the Center for Disease Control, and to intensify the functions of the Bureau of Chronic Disease Control, to eventually set up a solid and modern disease control system for more effective control of diseases to create a high-quality living environment and thus to upgrade the quality of life. It is hoped that through this comprehensive disease control system that the final goal of health for all can be attained.

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### **References**

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- 3.Department of Health. Laws and Regulations on Medical Affairs (in Chinese) , December 1997.
- 4.Department of Health. Health Reports (in Chinese) , vol. 9, No. 3, June 1999.
- 5 .Department of Health. Public Health in the Taiwan Area, Republic of China (in Chinese and English) ,December 1999.

## Appendix : Regulations and Guidelines Relevant to the Law on the Control of Communicable Diseases

The Enforcement	Legal Basis	Amend/Formulate	Expected Date of Completion
Implementation Regulations of the Regulations Governing the Control of Communicable Diseases	Article 46	Amend	Announced on 7 March 2000 under the title of the Enforcement Regulations of the Law on the Control of Communicable Diseases
Regulations Governing Surveillance and Alarm System of Communicable Diseases	Article 9	Formulate	30 September 2000
Regulations Governing Designation of Hospitals for the Isolation Treatment of Communicable Diseases	Article 15	Formulate	30 September 2000
Regulations Governing Operational Procedures and Compensation for the Public Spaces and Manpower of Private Hospitals Requisitioned at Time of Disease Outbreaks	Article 15	Formulate	Announced on 27 June 2000
Regulations Governing Review of Immunization Records and Make-up Immunization of Children of Primary Schools and Pre-school Educational Institutions	Article 17	Formulate	30 September 2000
Regulations Governing Management of the Incomes and Expenditures and the Utilization of Relief Funds for the Victims of Immunization	Article 18	Formulate	30 September 2000
Regulations Governing Compensation of Vectors of Communicable Diseases Processed According to Regulations	Article 22	Formulate	Announced on 27 June 2000
Guidelines on the Quarantine Rules and Costs at International Ports of Entry	Article 27	Amend	30 September 2000
Regulations Governing Screening of Risk Groups and Specific Target Groups of Communicable Diseases	Article 37	Formulate	30 September 2000
Standards of Compensation for Funeral Costs of Deceased Patients of Communicable Diseases of Suspected Communicable Diseases Undergoing Anatomy	Article 39	Formulate	Announced on 27 June 2000
Regulations Governing Incentive Measures for Communicable Disease Control	Article 45	Formulate	30 September 2000