

## **LEGISLATIVE FRAMEWORKS AND ADDITIONAL LEGAL MECHANISMS NEEDED FOR IHR IMPLEMENTATION**

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### **1.1 Provide a written list and description of stakeholders at the national level in your country relevant to IHR (2005) implementation (approximately 500–750 words)**

Taiwan Centers for Disease Control (TCDC), on behalf of the Republic of China (Taiwan), is the National IHR Focal Point (NFP) designated through a national authorized designation process of the Cabinet in 2006. The designation process and thereupon the linking intended to function within or using the operational structures of the authorized body made TCDC legitimate and empowered to carry out the full scale presentation of the mandatory and optional functions, which included the surveillance arm, the decision-making platform, and the response arm. Moreover, TCDC serves as the coordination center for points of entry.

To implement the International Health Regulations (2005) (IHR(2005)), four legislative frameworks have been aligned with the Regulations thereafter. The four legislations concerned are the Communicable Disease Control Act, the Food Sanitation Governing Act, the Disaster Prevention and Protection Act, and the Nuclear Emergency Response Act. The legal and governmental mandates and instruments have thus been established. The main stakeholders relevant to IHR(2005) implementation at the national level are listed and described as follows.

For the events of biological/infectious nature, Ministry of Health is defined as the competent authority under the Communicable Disease Control Act, with TCDC serving as the general staff. The infrastructures and mechanisms

required are established according to the Act. When indicated, Ministry of Health shall activate the Central Epidemic Command Center with the Premier or a designated equivalent as the Commander General to chair the Center.

Besides, Ministry of Health is defined as the competent authority under the Food Sanitation Governing Act for the events of food-borne nature, with Food and Drug Administration assuming the general staff and TCDC serving as a collaborating staff. When indicated, Ministry of Health shall activate the National Health Command Center.

For the events of chemical nature, Environmental Protection Administration is defined as the competent authority under the Disaster Prevention and Protection Act. According to the degree of possible impact of the chemical accident, the competent authority shall activate the Central Disaster Prevention and Protection Council when indicated.

For the events of nuclear nature, Atomic Energy Council is defined as the competent authority under the Nuclear Emergency Response Act. Likewise, according to the degree of possible impact of the nuclear accident, the competent authority shall activate the National Nuclear Emergency Response Center and the Radiation Monitoring and Dose Assessment Center when indicated.

Under the four legislations mentioned in the preceding paragraph, the authorities relevant to IHR(2005) implementation at the national level further include Council of Agriculture, Ministry of Transportation and Communications, Coast Guard Administration, Ministry of the Interior, Ministry of Economic Affairs, Fair Trade Commission, Council for Economic Planning and Development, Ministry of Justice, Government Information Office, National Communications Commission, Ministry of Education, Central Personnel Administration, Council of Labor Affairs, Veterans Affairs Commission, Ministry of National Defense, Mainland Affairs Council, Ministry of Foreign Affairs, Ministry of Finance, Directorate-General of Budget, Accounting and Statistics, and Financial Supervisory Commission.

All of the stakeholders listed above have local counterparts which are subordinate to or coordinated at the 25 local governments (intermediate level). Specific core capacities are thus practiced at the community level and primary public health response level, the intermediate level, and the national level for surveillance and response. The levels of involvement are defined in the four legislations mentioned above and relevant legal, administrative, or other governmental instruments, which includes legally-binding ones, legally non-binding ones, and other instruments that applicable in all relevant sectors and at all levels. The contingency plans are also important templates for the involvements of the stakeholders to be further defined, and the involvements shall be subject to change to cope with the real situation.

As to non-governmental actors, nationally or locally, relevant stakeholders are invited, recruited, and updated according to the legislations and as required. Policy orientation and alliance building are important instruments. The profiles include health care systems (e.g., public or private, totally 21 medical centers, 493 regional hospitals, and 19792 primary health care units), professional societies (such as Taiwan Medical Association, 25 local Medical associations, The Infectious Diseases Society of Taiwan, Nosocomial infection Control Society of Taiwan, a series of professional associations and subspecialist societies, and, of course, those of chemical, radio-nuclear, zoonotic, food-safety, transportation, and other professional fields), community leaders (such as community councils, occupational organizations, public interests associations, etc.), industrious sectors (such as The Chinese National Federation of Industries, The General Chamber of Commerce of the Republic of China, etc.), and non-governmental organizations (including The Red Cross Society of The Republic of China, Tzu Chi Foundation, DDM Social Welfare and Charity Foundation, and a variety of non-governmental organizations non-governmental organizations), etc.

**1.2 Research and develop a written report that identifies national legislation in your own country relevant to IHR (2005) implementation and discuss any additional provisions that might be necessary for**

## **effective implementation (approximately 1,000 words)**

### **Identify national legislation relevant to IHR(2005) implementation**

Briefly, the term "legislation" for purposes of this exercise means the range of legal, administrative or other governmental instruments which may be available for States Parties to implement the IHR. They include legally-binding instruments (e.g. state constitutions, laws, acts, decrees, orders, regulations, ordinances), legally non-binding instruments (e.g. guidelines, standards, operating rules, or other non-binding administrative procedures or rules), and other types of instruments (e.g. protocols, resolutions, and inter-sectoral or inter-ministerial agreements). This encompasses legislation in all sectors (e.g. health, agriculture, transportation, environment, ports and airports), and at all applicable governmental levels (e.g. national, regional, provincial, and local), including ports and airports.

As the Cabinet designated Taiwan Centers for Disease Control (TCDC) as the National IHR Focal Point (NFP) through a national authorized process in 2006, the designation document therefore serves as the first legislation in line with IHR(2005) implementation. To further identify the national legislation relevant to IHR(2005) implementation, the four platforms/networks will be again used as the four approaches, each of which serves as an entity that the pertinent legislations shall be applied to. However, the importance of the Constitution, the Civil Code, the Cabinet Act, the Local Government Act, the legislations concerning the organization, funding, personnel, professionalism, and techniques, and the contingency plans (as one kind of administrative document) will not be stressed here.

For the events of biological/infectious nature, besides the Communicable Disease Control Act, the legislations include the Enforcement Regulations Governing the Central Epidemics Command Center, the Regulations Governing the Implementation of the Epidemiological Surveillance and Alert System for Communicable Diseases, the Regulations Governing Laboratory Testing for Communicable Diseases and Management of Laboratory Testing

Institutions, the Regulations Governing Management of Infectious Biological Materials and Collection of Specimens from Patients of Communicable Diseases, the Implementation Regulations Governing Disease Control Materials and Establishment of Resources, the Regulations Governing Operation of the Communicable Disease Control Medical Network, the Regulations Governing Inspection of the Implementation of Infection Control Measures in Medical Care Institutions, the Regulations Governing the Operational Procedures and Compensation for Designation and Expropriation for the Establishment of Quarantine and Isolation Site and Requisition of Related Personnel, the Regulations Governing Compensation for the Handling of Vectors of Communicable Diseases, the Regulations Governing Immunization Operation, Examination of Children's Immunization Record and Catch-up Immunization, the Standards for Subsidies for Funeral Costs of Human Remains Subject to Autopsy, the Statute for Prevention and Control of Infectious Animal Disease, Rules of Meat Inspection, etc.

For the events of chemical nature, besides the Disaster Prevention and Protection Act, the legislations include the Toxic Chemical Substances Control Act, the Toxic Chemical Substances Hazard Prevention and Response Plan Regulations, and the Toxic Chemical Substances Transportation Management Regulations. The related guidelines, standards, operating rules, or other non-binding administrative procedures, and contingency plans are under review and revision, covering notification system, response organization, and methods of external aid, issuance of alarms, emergency response for accidents within the handling site, rescue of personnel and isolation of areas where accidents have occurred, hazard prevention and response procedures, preparedness of prevention and rescue equipment, accident prevention and response training, exercises, education and awareness, appropriation of accident prevention and rescue funds, handling of remaining toxic chemical substances after an accident, etc.

For the events of nuclear nature, besides the Nuclear Emergency Response Act, the legislations further include the Atomic Energy Law, the Nuclear Damage Compensation Law, the Ionizing Radiation Protection Act, the

Nuclear Materials and Radioactive Waste Management Act, the Nuclear Reactor Facilities Regulation Act, the Regulations for the Review and Approval of Applications for Construction License of Nuclear Source Material and Nuclear Fuel Production and Storage Facilities, the Regulations for the Review and Approval of Applications for Decommissioning Permit of Nuclear Reactor Facilities, the Regulations for the Nuclear Source Materials Operational Safety Management, the Regulations for the Nuclear Fuels Operational Safety Management, the Regulations on Treatment and Storage of Radioactive Waste and Safety Management of the Facilities, the Radioactive Substance Transportation Regulations, the Administrative Regulations for Waste Generated from Naturally Occurring Radioactive Materials, the Radioactive Workplace Management and Surveillance Guideline, the Radio-nuclear Protection Safety Standard, etc.

For the events of food-safety nature, the Food Sanitation Governing Act dominates on the platform/network. However, as food-safety events could involve biological/infectious, chemical, radio-nuclear and zoonotic approaches, the pertinent legislations identified in the previous paragraphs shall be applied to the events of food-safety nature. On the other hand, related guidelines, standards, operating rules, or other non-binding administrative procedures and contingency plans are under review and revision to enhance the capacity of the food-safety platform/network.

At present, TCDC serves as the coordination center for points of entry (PoE). The legislations concerned include the Civil Aviation Act, the Regulations of Civil Air Transport Enterprise, the Regulations Governing General Aviation, the Regulations Governing Air freight Forwarder, the Aircraft Flight Operation Regulations, the Regulations Governing the Safe Transport of Dangerous Goods by Air, the Commercial Port Law, the Shipping Law, the Maritime Act, the Law of Ships, the Regulations for Inspection of Ships, the Regulations for Administration Passenger Ship, the Regulations for Equipment of Ships, the Regulations for supervising classification societies, the Regulations Governing Quarantine at Ports, the Regulations of Import Quarantine Operation for Animal Products Transported by Closed Container, the Regulations Governing

Collection of Quarantine Fees at Ports, the Regulations Governing Fees for Animal and Plant Quarantine, the Regulations for the Execution of Monitoring Inspection on Imported Animals, the Rules for Quarantine of Animal/Plant Carried by Passengers and Service Personnel on Vehicles or via Mail, etc.

Because of the roles of the collaborating authorities mentioned on the four platforms/networks in the previous section, the pertinent legislations related to the authorities serving as collaborating stakeholders shall also be applied. For example, they include the Medical Care Act, the Emergency Medical Services Act, the Fire Services Act, the Labor Safety Health Act, the National Health Insurance Act, the Fair Trade Act, etc.

**Discuss additional provisions that might be necessary for effective IHR(2005) implementation**

The core capacity development has been performed before the adoption of the IHR(2005). The competent authority of each platform/network has been responsible for the coordination thereof since the beginning. However, the IHR(2005) does provide the opportunity to further enhance some of the core capacities originally not well developed or appreciated.

As the IHR(2005) are all-hazard-approach, the hazards concerned shall include those of the biological/infectious nature, the chemical nature, the nuclear nature, the zoonotic nature, and the food-safety nature, also taking the nature of unknown into consideration. Not only for ensuring effective implementation of the IHR(2005) but also for coping with the national security and prosperity, the legal, administrative, and other governmental instruments have been under review and revision, as described above, to meet the need of the prospective future.

In terms of the eight core capacities of the IHR(2005) implementation, namely national legislation and policy, coordination, surveillance capacity, response, preparedness, risk communication, laboratory, and human resource for surveillance and response, we are facing a similar situation as WHO. Starting

from the events of the infectious disease hazards, as the all-hazard-approach becomes the prospective paradigm, we shall highly appreciate the experiences of the platforms/networks of zoonotic events, food-safety events, chemical events, and radiological and nuclear events. Additional provisions that might be necessary for effective IHR(2005) implementation could be strategically in line with the all-hazard-approach which actually opens the problem window facing the threats to global health security.

However, before the policy and political windows become even more favorable to further advance in the all-hazard-approach, the core capacity enhancement and collaboration at points of entry (PoE) provides a good platform to recruit and integrate competent and collaborating authorities. After the planning process, the Core Capacity Enhancement and Collaboration at Points of Entry (PoE) Program has been ongoing and defined to meet the goal to develop the IHR(2005) core capacities requirements by 2012. Efforts are addressed not only on the establishment of the effective surveillance and response to public health events at PoE to minimize the risk of international spread of disease through transportation, travel, and trade but also the all-hazard-approach of IHR(2005) implementation.

Since the Cabinet designated TCDC as the National IHR Focal Point through a national authorized process in 2006, TCDC has been serving all the mandatory and optional functions as defined. To further meet the requirements of the all-hazard-approach in the future, the composition of the National IHR Focal Point, nevertheless, deserves a broader consideration. Reorienting the National IHR Focal Point to cope with the scope of all-hazard-approach of IHR(2005) implementation is thus under consideration. In a sense, Ministry of Health, Environmental Protection Administration, Atomic Energy Council could be recruited into the National IHR Focal Point as the core task force. Moreover, Council of Agriculture could be mobilized as another competent authority, and, if indicated, probably also Ministry of Transportation and Communications.

Though properly appropriated from the budgets of the four platforms/networks, the funding of the IHR(2005) implementation has not yet been identified as an



independent entity. Furthermore, In terms of the all-hazard-approach of the IHR(2005) implementation, the resources appropriated/allocated so far, including funding and human resources, will not be commensurate with the need in the future. Paradigm shifting is expecting and resource mobilization will go along with. It is not only a good opportunity to scrutinize the development of the core capacities to meet the IHR(2005) implementation, but also an elegant timing of recruiting required resources to cope with the all-hazard-approach in the future.

The all-hazard-approach provides a heuristic opportunity to tackle the challenges of unfolding public health emergencies and to facilitate the inter-sectoral resource coordination and mobilization. Surveillance arms, decision platforms, and response arms could be more closely integrated horizontally or even reoriented vertically. Opportunities could also come up with even higher profile legislation with funding well specified and human resources well recruited. Common interfaces and commutable instruments could follow to support information sharing, decision making, and response deployment with transparency and efficiency.

To further capacitate the IHR(2005) implementation, an integrated multi-sectoral and multi-disciplinary body addressing IHR requirements on surveillance and response for public health emergencies of national and international concern, rather than the ones on the four platforms/networks, could be in place. To meet the need of resources required for the all-hazard-approach in the future, specified funding and human resources should be legally bounded.