

IHR Legal Analysis: Standardized Checklist and Reporting Template

Incorporating the 2024 Amendments

2025

Introduction

For a country to respond effectively to public health events and emergencies, it must have both the legal authority to take decisive action and the flexibility to adapt to rapidly evolving situations. Legal preparedness is a cornerstone of national health security—not only during crises, when urgent measures such as isolation, lockdowns, or mass vaccination campaigns may be necessary, but also during non-emergency periods, when laws and regulations underpin the systems that enable timely surveillance, effective preparedness, and resilient health systems.

The World Health Organization (WHO) International Health Regulations (IHR) (2005) underscore the importance of comprehensive legal frameworks in supporting a country's ability to prevent, detect, prepare and respond to public health threats. This legal foundation is assessed as part of the Joint External Evaluation (JEE), a voluntary, collaborative process that evaluates national capacities across 19 technical areas. Among these, the “Legal Instruments” technical area and associated indicators specifically examine whether legal instruments are in place at national and subnational levels to support IHR compliance.

Despite its importance, legal preparedness often remains a critical gap in national health systems. Legal frameworks may be outdated, fragmented, or misaligned with public health objectives, limiting a country's ability to mount a coordinated response or meet its international obligations under the IHR. Addressing these gaps will improve a country's JEE scores and also bolster the country's long-term preparedness and resilience.

This Checklist and Template Report has been designed to support countries in reviewing and strengthening their national legal frameworks in alignment with IHR requirements and JEE indicators. It offers a structured, practical tool to:

- Identify existing laws relevant to public health preparedness and response;
- Assess legal gaps and inconsistencies;
- Promote alignment with international standards; and
- Support evidence-based legal reforms.

By using this checklist and report template, IHR States Parties can advance both legal preparedness and epidemic readiness, ensuring that the legal foundation for public health action is robust, current, and fit for purpose.

Methodology

The Checklist and Template Report was developed by the RTSL Public Health Legal Team, drawing on extensive experience supporting the national implementation of the International Health Regulations (IHR) across multiple African States Parties. This tool is intended to assist countries in systematically assessing their national legal frameworks for alignment with the IHR, including the 2024 amendments for those States Parties that have not formally rejected them, in accordance with the procedures outlined under Article 59 of the IHR.

The development process began with a comprehensive provision-by-provision analysis of the IHR, as well as related international and regional legal instruments relevant to public health emergency preparedness and response. This analysis was used to distill the core legal obligations and responsibilities of States Parties, with a focus on identifying areas where national legal systems must enable or support specific public health actions under the IHR.

To ensure usability and relevance for national authorities, RTSL translated these obligations into clear, actionable assessment questions. These questions are organized according to the structure similar to the **JEE** tool. This alignment with the JEE facilitates the tool's use in national IHR implementation efforts and

supports countries in tracking progress toward **JEE indicators** and **WHO Benchmarks for Strengthening Health Emergency Capacities**.

Importantly, the tool integrates considerations from the **IHR 2024 amendments**, including expanded provisions on equity, access to medical countermeasures, and National IHR Authorities. By incorporating these updates, the checklist enables States Parties that have not rejected the amendments to assess their legal preparedness in line with the most current international standards. Questions related to the 2024 IHR Amendments are indicated in **Green**.

The RTSL team collaborated closely with partners throughout this process. We gratefully acknowledge the partnership of Health Ethics and Law Consulting, led by Professor Cheluchi Onyemelukwe, whose insights were instrumental in conceptualizing the checklist. We also thank Paul Dossou Banka, Dereje Moges, and Janet Sallah Njie for their expert contributions and thoughtful discussions, which enriched the development of the tool.

An earlier version of the checklist and report template was **piloted in Cameroon, Côte d'Ivoire, Chad, and South Africa**, in partnership with national stakeholders. Feedback from these experiences - particularly from legal, health, and emergency management professionals - was invaluable in refining the checklist's structure, content, and usability. We extend our sincere thanks to all those who participated in these pilot processes and shared their comments and experiences.

The resulting tool is a practical, field-tested resource that supports legal preparedness as a core component of national and global health security. By enabling countries to systematically identify strengths and gaps in their existing legal frameworks, the tool facilitates improved alignment with the IHR, including the 2024 amendments where applicable. States Parties that utilize the checklist and validate the resulting legal analysis through a participatory, multi-stakeholder process can expect to demonstrate the capacities required to achieve Level 2 under JEE Indicator P1.1 Legal Instruments.

How to use the Checklist and Template Report

The **RTSL Checklist and Template Report** is designed to provide a structured methodology for assessing national legal instruments related to the IHR. It helps identify both strengths and gaps in the existing legal framework, with the aim of informing future legal reforms and strengthening IHR implementation. Assessing legal instruments is an essential step in a legal reform process. In providing a detailed framework to conduct such assessments, the RTSL Checklist and Template Report complement existing WHO guidance on national legislation to support the implementation of the IHR (2005), including the recently published [IHR \(2005\) National Legislation Toolkit Series](#) and the [WHO-IPU Handbook for Parliamentarians – Strengthening health security preparedness: The International Health Regulations \(2005\)](#).

This tool serves as a **comprehensive resource** for both conducting legal analyses and drafting assessment reports for State Parties. Users are encouraged to follow the structure of the template, which aligns with the **JEE technical areas**, ensuring that all relevant domains of IHR implementation are systematically addressed.

By offering a standardized report format and suggested draft language for each section, the tool allows users to incorporate **country-specific information** and tailor the content to their national context. The process begins with adapting the **Introduction section**, where users should provide:

- A country profile
- The rationale for the legal assessment
- The methodology applied

The following section focuses on describing the **public health powers** within the State Party.

Once these initial sections are complete, users should **collect all relevant legal instruments currently in force** within the State Party. These legal instruments should then be **mapped against the thematic areas** identified in the RTSL Checklist.

The next step involves **analyzing the collected legal instruments** using the checklist's subsequent sections. The **report template plays a central role** in ensuring consistency and coherence across assessments by thematic area. By adhering to this standardized format, assessors can present findings in a clear, structured manner, allowing readers to easily navigate and understand the results.

For **each thematic area**, users are expected to:

- Identify the relevant laws and regulations
- Analyze these legal instruments based on the assessment questions, and
- Identify strengths and gaps and formulate recommendations to improve alignment with IHR requirements

After the legal analysis is completed, it is strongly recommended to hold a validation meeting to review and endorse the findings and recommendations. This meeting ensures the accuracy, credibility, and representativeness of the legal assessment. Ideally, the same stakeholders involved in the assessment process should participate in the validation phase, together with the political decision-makers from the relevant domains.

During the meeting, the team should present the key findings from the desk review and assessment process. Stakeholders are encouraged to provide feedback, raise concerns, and engage in discussions to resolve any discrepancies. A consensus should be reached before finalizing the report to ensure broad stakeholder agreement on both the findings and the recommendations.

The success of a legal assessment depends on both the thoroughness of the analysis and the quality and feasibility of the recommendations. Given that legal assessments often serve as a precursor to legal reform and surveillance strengthening, early involvement of political leaders and key decision-makers is essential. Engaging these stakeholders from the outset helps build ownership, ensures alignment with national priorities, and increases the likelihood of successful implementation and follow-up actions.

RTSL checklist and template report for IHR (2005) legal analysis

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Introduction

[This introduction must be adapted to the country's context. The text proposals below are intended solely to assist those responsible for the evaluation in drafting the final report.]

Epidemics, health emergencies and weak health systems not only cost lives but pose some of today's greatest risks to the global economy and security. Preventing health events and emergencies is an essential interest for the international community. The World Health Organization (WHO) defines health security as "the activities required, both proactive and reactive, to minimize the danger and impact of acute public health events that endanger people's health across geographical regions and international boundaries."

In recognition of the shared interest in health security, the World Health Assembly adopted the International Health Regulations (IHR), a binding legal instrument which provides a global legal framework aimed at preventing the international spread of diseases, enhancing preparedness, and strengthening national health systems. As WHO Member State, [State Party Name] is obligated to implement the IHR, ensuring its capacity to respond to public health threats. This requires robust legal systems capable of preventing, preparing for and responding to public health risks and events.

As a mechanism for ensuring accountability, states are required to submit annual reports on their domestic IHR implementation to the World Health Assembly. In addition, they may voluntarily undertake a Joint External Evaluation (JEE), which assesses progress with IHR capacities. One indicator of prevention under this tool is in the technical area "Legal Instruments", which require a state to conduct a legal mapping of relevant legal instruments to progress past the "no capacity" score.

This report aims to provide guidance for a comprehensive assessment of a country's health security legislation and its compliance with the IHR (2005). It sets out a mapping exercise to assess the powers of the state government to enact laws to ensure compliance with the IHR (2005), and the extent to which it has exercised those powers in enacting legislation.

Those responsible for the analysis are also invited to adapt the introduction to present the country profile and ground the analysis into the national context, including by:

- Providing the country's health security profile
- Explaining the health system, its national and subnational components
- Describing the landscape of ministries, agencies and departments with health security related mandates

Finally, the methodology for the legal analysis should be presented:

- What methodology was used to collect information for this report?
- Have previous data sets such as JEEs or Global Health Security Agenda (GHSA) mappings been considered?
- How were relevant legal instruments identified?
- What legal instruments were included in the analysis? Were soft-law instruments also included?

Public Health Powers in [State Party Name]

Understanding the division of powers within the country is a prerequisite to comprehensively assess national legal instruments. In this first section, we suggest identifying and explaining the relevant constitutional provisions to the readers, including by answering the following questions:

- Under the Constitution, which bodies (legislative, judicial, or executive) hold legal authority for public health decisions?
- What is the division of public health authority between the national vs the subnational level?
- Which part of the government has the power to declare a state of emergency?
- Are there extraordinary measures that can be taken during a state of emergency?
- Does the Constitution provide for the limitation or restriction of rights on the protection of public health? Are there non-derogable rights?
- Are there Constitutional provisions relevant to public health (i.e. rights to health, data privacy, or healthy environment)? If so, are these judicially enforceable?
- Are international agreements such as the IHR self-executing under the Constitution, or are additional steps needed for the IHR to become legally binding at national level?

Mapping of IHR (2005) Legal Instruments in [State Party Name]

S/No	Title of the legal instrument	Relevance to the IHR (2005)	Corresponding Thematic Area

Legal Assessment of IHR related legal instruments in [State Party Name]

1. IHR (2005) Related Definitions

Although it is not a requirement under the IHR (2005), adopting clear and near-identical definitions to those provided in the IHR (2005) would greatly facilitate the effective implementation of the regulations during public health events and emergencies within the state. This approach would eliminate any ambiguities surrounding the legal requirements for the application of health measures and ensure consistency in response activities across all states.

Assessors should assess relevant legal instruments against the questions below. They should provide a detailed analysis of how the above-mentioned instruments comply with the IHR (2005) obligations outlined below, highlight the strengths, gaps, and provide recommendations to fill these ones.

Definition	Is the definition aligned with the IHR (2005)	Comments (May include the definition (if any) under national legislation and potential conflicts with the IHR definition)
Deratting: A procedure whereby health measures are taken to control or kill rodent vectors of human disease present in baggage, cargo, containers, conveyances, facilities, goods and postal parcels at the point of entry		
Disease: An illness or medical condition, irrespective of origin or source that presents or could present significant harm to humans		
Event: A manifestation of a disease or an occurrence that creates the potential for disease		
Health Measures: Procedures applied to prevent the spread of disease or contamination; a health measure does not include law enforcement or security measures		
Ill Person: Individual suffering from or affected with a physical ailment that may pose a public health risk		
Infection: Entry and development or multiplication of an infectious agent in the body of humans and animals that may constitute a public health risk		
Inspection: The examination, by the competent authority or under its supervision, of areas, baggage, containers, conveyances, facilities, goods or postal parcels, including relevant data and documentation, to determine if a public health risk exists		

Isolation: Separation of ill or contaminated persons or affected baggage, containers, conveyances, goods or postal parcels from others in such a manner as to prevent the spread of infection or contamination		
Pandemic emergency: A public health emergency of international concern that is caused by a communicable disease and: (i) has, or is at high risk of having, wide geographical spread to and within multiple States; and (ii) is exceeding, or is at high risk of exceeding, the capacity of health systems to respond in those States; and (iii) is causing, or is at high risk of causing, substantial social and/or economic disruption, including disruption to international traffic and trade; and (iv) requires rapid, equitable and enhanced coordinated international action, with whole-of-government and whole-of-society approaches.		
Point of entry: A passage designated under the IHR (2005) for international entry or exit of travellers, baggage, cargo, containers, conveyances, goods and postal parcels as well as agencies and areas providing services to them on entry or exit		
Public Health Emergency of International Concern: An extraordinary event which is determined, as provided in these [International Health] Regulations: (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response		
Public Health Observation: Monitoring of the health status of a traveller over time to determine the risk of disease transmission		
Public Health Risk: Likelihood of an event that may affect the health of human populations adversely, with an emphasis on one which may spread internationally or may present a severe and direct danger		
Quarantine: Restriction of activities and/or separation from others of suspect persons who are not ill or of suspect baggage, containers, conveyances or goods in such a manner as to prevent the possible spread of infection or contamination		

Relevant health products: Health products needed to respond to public health emergencies of international concern, including pandemic emergencies, which may include medicines, vaccines, diagnostics, medical devices, vector control products, personal protective equipment, decontamination products, assistive products, antidotes, cell- and gene-based therapies, and other health technologies		
Reservoir: Animal, plant, or substance in which an infectious agent usually lives and whose presence may constitute a public health risk		
Surveillance: A systematic ongoing collection, collation and analysis of data for public health purposes and the timely dissemination of public health information for assessment and public health response as necessary		
Suspect: Persons, baggage, cargo, containers, conveyances, goods or postal parcels considered by a State Party as having been exposed, or possibly exposed, to public health risk and that could be a possible source of spread of disease		
Vector: Insect or other animals which usually transports an infectious agent that constitutes a public health risk		

Strengths, Gaps and Recommendations

In framing gaps, we suggest using the table above to identify any terms that have not been defined by national legal frameworks and whether these terms are used in the course of public health security activities. Where important terms have not been defined, we suggest identifying the gap and recommending the appropriate definition.

2. Financing

The JEE technical area on financing assesses the existence of adequate funding for IHR (2005) implementation and response to public health emergencies through the national budget or other mechanisms. It evaluates whether State Parties have access to financial resources for the routine implementation of IHR (2005) capacities and financial resources that can be accessed on time and distributed for readiness and response to public health emergencies.

Assessors should assess relevant legal instruments against the questions below. They should provide a detailed analysis on how the above-mentioned instruments comply with the IHR (2005) obligations outlined below, highlight the strengths, gaps, and provide recommendations to fill these.

Assessment Questions

ASSESSMENT QUESTION	NATIONAL LEGAL INSTRUMENT REFERENCE	COMMENTARY
Do legal instruments explicitly mandate the allocation of financial resources for IHR implementation?		
Do legal instruments mandate allocation of financial resources for public health emergency response?		
Do legal instruments require the integration of health security financing into the national budget planning process?		
Do legal instruments provide for multi-sectoral financing across all relevant ministries, departments, and agencies responsible for IHR implementation?		
Do legal instruments allocate domestic funding to health security activities (e.g., surveillance, vaccination, maintenance or strengthening of core capacities, etc.)? Are the allocations reviewed annually, and is budget execution monitored?		

Do legal instruments authorize the development of guidance and disbursement procedures for health security funds? Are these procedures available and used by health security ministries, departments, and agencies?		
Do legal instruments provide for circumstances where a declaration of an emergency can allow for executive, rather than legislative, release of funds?		
Do legal instruments establish special accounts or funds that can be mobilized to respond to public health events?		
Does it suspend other bureaucratic procedures that may hinder rapid mobilization?		
Are there provisions to ensure coordination between ministries (e.g., health, finance, interior/security) in accessing emergency financing?		

Strengths, Gaps and Recommendations

Assessors are invited to summarize the identified gaps and strengths in the national legal framework. Identifying these gaps and strengths will help develop recommendations for improvement around this specific thematic area. In framing this sections, we recommend considering the extent to which the legal framework ensures that authorities at all levels have sufficient financial resources to implement their obligations under the IHR (2005). Where financial resources cannot be accessed or distributed in a timely manner, we suggest identifying the gap and recommending the appropriate legal remedy.

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3. IHR Coordination and Responsible Authorities

The approach promoted by the IHR, which calls for considering all diseases regardless of their origin or source, requires the establishment of multisectoral/multidisciplinary approaches through national partnerships that allow efficient and alert response systems for effective implementation of the IHR. It requires setting up a national multisectoral coordination mechanism and designating responsible authorities within the jurisdiction of the State Party. Legal frameworks should require timely and accurate reporting of notifiable diseases, including the reporting of any events of potential public health significance according to WHO requirements and consistent relay of information to the Food and Agricultural Organisation of the United Nations (FAO) and the World Organisation for Animal Health (WOAH).

The 2024 Amendments to the IHR (2005) introduced a requirement to designate or establish a National IHR Authority – an entity responsible for the coordination of the implementation of the Regulations within the jurisdiction of the State Party. States Parties that have not rejected or made reservations to the 2022 and 2024 amendments will be bound by them on 19 September 2025. They are encouraged to consider the questions in green below.

Assessors should assess relevant legal instruments against the questions below. They should provide a detailed analysis on how the above-mentioned instruments comply with the IHR (2005) obligations outlined below, highlight the strengths, gaps, and provide recommendations to fill these ones.

Assessment Question

ASSESSMENT QUESTION	NATIONAL LEGAL INSTRUMENT REFERENCE	COMMENTARY
Do legal instruments establish or designate a multisectoral coordination mechanism for IHR (2005) implementation and governance?		
Are roles and responsibilities of different sectors clearly defined in law for IHR implementation and coordination?		
Do legal instruments require multisectoral coordination mechanisms to be implemented at national, intermediate, and local levels?		
Does the law require that these coordination mechanisms are regularly exercised, evaluated, and updated based on simulation exercises, after-action reviews (AARs), or intra-action reviews (IARs)?		

Do legal instruments mandate the adoption of clear protocols for information-sharing between national public health authorities?		
Do legal instruments mandate the adoption of clear guidelines or protocols for interagency information and data-sharing?		
Do legal instruments establish or designate an NFP?		
Do legal instruments empower the NFP to share with WHO public health information hailing from the State's surveillance system of events which may constitute a Public Health Emergency of International Concern (PHEIC), evidence of a public health risk identified outside the State's territory that might cause international disease spread, information required to verify information about such events, or health measures taken in responses to those events?		
Do legal instruments require the NFP to remain accessible at all times for communications with WHO?		
Do legal instruments require the NFP to disseminate information to, and consolidate input from, relevant sectors, including those responsible for surveillance and reporting, points of entry, and other health services?		

Do legal instruments require the NFP to assess all detected events by using the decision instrument annexed to the IHR? In case of urgent events, is there a requirement that the assessment of reports from the national surveillance system must occur within 48 hours?		
Do legal instruments require the NFP to notify—within 24h—WHO about all events which may constitute a PHEIC within its territory and any health measure implemented in response?		
Is the NFP legally empowered to access all relevant health and non-health sector information required to assess and notify events?		
Do legal instruments establish or designate the National IHR Authority within the State Party?		
Do legal instruments empower the National IHR Authority to coordinate authorities responsible for the implementation of the Regulations in all relevant sectors and at all levels of governance?		
Do legal instruments enable the National IHR Authority to advise on, monitor and evaluate the implementation of the IHR in all relevant sectors?		

Do legal instruments allow the National IHR Authority to interact directly with Office of the Head of State and/or the Office of the Prime Minister, the Cabinet Ministers, and/or other institutional bodies with decision-making authority on IHR related matters?		
Do legal instruments authorize the National IHR Authority to communicate directly with WHO and the Health Assembly on the implementation of the IHR?		
Are the necessary operational and administrative arrangements in place to ensure effective functioning of the National IHR Authority?		

Strengths, Gaps and Recommendations

Assessors are invited to summarize the identified gaps and strengths in the national legal framework. Identifying these gaps and strengths will help develop recommendations for improvement around this specific thematic area.

Determining essential gaps in the legal framework requires a comprehensive analysis of the results of the initial assessment. In framing these gaps, we suggest reflecting on whether the legal framework establishes the relevant authorities and clearly defines mechanisms for multisectoral coordination at national, intermediate and local levels of governance. Where the framework fails to establish guidelines and protocols for collaboration and coordination, we suggest identifying the gap and recommending an appropriate legislative remedy.

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4. Antimicrobial Resistance

Legal instruments should aim to increase awareness of Antimicrobial Resistance (AMR) risks and how to respond to them; strengthen surveillance and laboratory capacity; enhance infection prevention and control activities; ensure uninterrupted access to essential antimicrobials of assured quality; regulate and promote the appropriate use of antimicrobials in human medicine, veterinary medicine, food production and other fields as appropriate; and support initiatives to foster the development and appropriate use of new antimicrobial agents, vaccines and diagnostic tools.

Assessors should assess relevant legal instruments against the questions below. They should provide a detailed analysis on how the above-mentioned instruments comply with the IHR (2005) obligations outlined below, highlight the strengths, gaps, and provide recommendations to fill these ones.

Assessment Question

ASSESSMENT QUESTION	NATIONAL LEGAL INSTRUMENT REFERENCE	COMMENTARY
Do legal instruments establish a national regulatory agency and authority?		
Do legal instruments establish a multisectoral committee or governance system to regulate AMR across sectors?		
Do legal instruments require the development and implementation of a national AMR action plan?		
Do legal instruments require the establishment of a national AMR surveillance system?		
Do legal instruments regulate AMR use in humans and animals?		
Does the national regulatory framework incorporate international standards on the responsible use of antimicrobials (e.g., WOA Codes, Codex)?		
Do legal instruments impose labelling requirements or advertising/promotion restrictions to limit AMR spread?		
Do legal instruments establish authority to regulate substandard/counterfeit medicines?		

Do legal instruments regulate human medicines?		
Do legal instruments regulate veterinary medicines?		
Do legal instruments address AMR guidance in health facilities?		

Strengths, Gaps and Recommendations

Assessors are invited to summarize the identified gaps and strengths in the national legal framework. Identifying these gaps and strengths will help develop recommendations for improvement around this specific thematic area.

Determining essential gaps in the legal framework requires a comprehensive analysis of the results of the initial assessment. In framing gaps, we suggest considering whether the legal framework sufficiently regulates the use of antimicrobials in humans and animals. Where the framework fails to provide clear guidance on when and how antimicrobials should be used, we suggest identifying the gap and recommending an appropriate legislative remedy.

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5. Zoonotic diseases

Legal instruments should support functional multisectoral, multidisciplinary mechanisms, policies, systems and practices to minimize the transmission of zoonotic diseases from animals to human populations.

Assessors should assess relevant legal instruments against the questions below. They should provide a detailed analysis on how the above-mentioned instruments comply with the IHR (2005) obligations outlined below, highlight the strengths, gaps, and provide recommendations to fill these ones.

Assessment Question

ASSESSMENT QUESTION	NATIONAL LEGAL INSTRUMENT REFERENCE	COMMENTARY
Do legal instruments establish an agency with authority for veterinary medicine or the prevention and response to zoonotic diseases?		
Do legal instruments regulate abattoirs, as well as animal husbandry and aquaculture? Do legal instruments provide for the registration and inspection of such facilities?		
Do legal instruments regulate zoonotic feed and medicine?		
Do legal instruments regulate cross-border animal transport or trade?		
Do legal instruments provide a list of public health events to be reported including zoonotic diseases?		
Do legal instruments require maintenance and periodic review of the national list of priority zoonotic diseases?		
Do legal instruments provide for the systematic and timely collection and collation of zoonotic disease data?		
Do legal instruments provide for a competent authority for zoonotic disease surveillance?		
Do legal instruments provide for utilization of the community for zoonotic disease surveillance?		

Do legal instruments provide for collaborations between animal and human health surveillance authorities and laboratories?		
Do legal instruments specify collaboration and sharing of information between national and lower-level authorities on zoonotic disease surveillance?		
Do legal instruments provide for the collaboration between human and animal health sectors in response to zoonotic disease events?		
Does the instrument specify collaboration between surveillance authorities regarding potential zoonotic risks and urgent zoonotic events?		
Do legal instruments establish focal point(s) which are responsible for animal health (including wildlife) for coordination with the public health authorities and/or IHR (2005) NFP?		

Strengths, Gaps and Recommendations

Assessors are invited to summarize the identified gaps and strengths in the national legal framework. Identifying these gaps and strengths will help develop recommendations for improvement around this specific thematic area.

Determining essential gaps in the legal framework requires a comprehensive analysis of the results of the initial assessment. In framing gaps, we suggest reflecting whether the existing legal framework clearly outlines the scope, obligations and procedures for zoonotic disease surveillance. Where the legal framework fails to do so, we suggest identifying the gap and recommending an appropriate legislative remedy.

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6. Food safety

Legal frameworks, including monitoring and enforcement, are a prerequisite for functional systems responsible for surveillance and response to foodborne diseases and food contamination risks or events with effective communication and collaboration among all the sectors responsible for food safety.

Assessors should assess relevant legal instruments against the questions below. They should provide a detailed analysis on how the above-mentioned instruments comply with the IHR (2005) obligations outlined below, highlight the strengths, gaps, and provide recommendations to fill these ones.

Assessment Question

ASSESSMENT QUESTION	NATIONAL LEGAL INSTRUMENT REFERENCE	COMMENTARY
Do legal instruments provide a list of public health events to be reported including foodborne diseases?		
Do legal instruments provide for risk-based food inspection services?		
Do legal instruments provide for procedures on how epidemiological data related to food contamination are systematically collected and analyzed?		
Do legal instruments require a surveillance system (indicator-based or event-based) for detecting foodborne diseases and contamination events?		
Do legal instruments provide for a competent authority for foodborne diseases surveillance?		
Do legal instruments require the development and maintenance of a national food safety emergency response plan?		
Do legal instruments establish procedures that guarantee access to laboratory capacity to confirm priority food safety events of national concern?		

Do legal instruments specify collaboration and sharing of information between national and lower-level authorities on foodborne disease surveillance?		
Do legal instruments mandate the timely and systematic information exchange between food safety authorities, public health surveillance units and other relevant sectors regarding food safety events?		
Do legal instruments establish a central coordination mechanism for food safety emergencies, involving all relevant sectors (e.g., public health, veterinary services, agriculture, food inspection, customs, quarantine, national security, tourism, environmental services)?		
Do legal instruments outline the responsibilities of these sectors in emergency response? If not, are there clear terms of reference jointly agreed by all sectors?		
Is the coordination mechanism required to function at both national and intermediate levels?		

Strengths, Gaps and Recommendations

Assessors are invited to summarize the identified gaps and strengths in the national legal framework. Identifying these gaps and strengths will help develop recommendations for improvement around this specific thematic area.

Determining essential gaps in the legal framework requires a comprehensive analysis of the results of the initial assessment. In framing gaps, we suggest reflecting on whether the legal framework establishes a system empowered to detect, prevent and respond to food safety events with effective collaboration and coordination among all the sectors responsible for food safety. Where the law does not mandate and empower sectors to act in a manner essential to achieve this, we suggest identifying the gap and recommending an appropriate legislative remedy.

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7. Biosafety and Biosecurity

Country-specific biosafety and biosecurity legislation supports several elements of a whole-of-government multisectoral national biosafety and biosecurity system. These may identify handling biological agents, regulation of facilities, and mandated risk management training, regulation of safe transfer, laboratory licensing, and pathogen control measures.

Assessors should assess relevant legal instruments against the questions below. They should provide a detailed analysis on how the above-mentioned instruments comply with the IHR (2005) obligations outlined below, highlight the strengths, gaps, and provide recommendations to fill these ones.

Assessment Question

ASSESSMENT QUESTION	NATIONAL LEGAL INSTRUMENT REFERENCE	COMMENTARY
Do legal instruments regulate biosafety and biosecurity? In all sectors (health, agriculture, academia, research, etc.)?		
Do legal instruments establish or designate a responsible entity to:		
Conduct biological risk evaluation of biological agents and toxins?		
License and inspect laboratories for the handling of controlled biological agents and toxins ¹ ?		
Regulate national and international transfer of controlled biological agents and toxins?		
Regulate transportation of controlled biological agents and toxins?		

¹ In most cases, only biological agents and toxins that pose a severe threat to public health, safety, and national security will be subject to enhanced biosafety and biosecurity measures. The responsible authority generally establishes and maintains a list of such agents and toxins, as well as the measures applicable to their development, possession, use, storage, or transfer.

Is risk management training mandatory for individuals or laboratories handling dangerous pathogens?		
Is there regulation of labs that can produce or use biological agents and toxins?		
Do legal instruments prohibit misuse of biological agents and toxins?		
Do legal instruments provide an oversight and monitoring mechanism for biosafety and biosecurity, including the safe and secure use, storage, disposal and containment of biological agents found in laboratories, record-keeping, and a minimal number of holdings across the country, and involving research, diagnostic and biotechnology facilities within all sectors?		
Do legal instruments provide for oversight, enforcement and attribution for biosafety and biosecurity legislation, regulations and/or guidelines?		
Is there a comprehensive national biosafety and biosecurity regulatory framework being enacted?		
Does the instrument provide for a list of controlled biological agents and toxins?		
Do legal instruments provide for a list of controlled equipment and technology?		
Do legal instruments provide for the licensing of activities involving controlled biological agents and toxins?		

Do legal instruments require laboratories to comply with applicable national and international biosafety and biosecurity standards?		
Do legal instruments specify safe storage and secured transport of dangerous pathogens?		
Do legal instruments specify the obligation of private medical facilities in the handling of infectious substances?		

Strengths, Gaps and Recommendations

Assessors are invited to summarize the identified gaps and strengths in the national legal framework. Identifying these gaps and strengths will help develop recommendations for improvement around this specific thematic area.

Determining essential gaps in the legal framework requires a comprehensive analysis of the results of the initial assessment. In framing gaps, we suggest reflecting on whether framework establishes a mechanism which ensures safety in handling dangerous substances and prevents biosecurity events. Where the legal framework fails to do so, we suggest identifying the gap and recommending an appropriate legislative remedy.

- [...]

8. Immunization

A successful national vaccine delivery system capable of responding to new disease threats requires legal backing for regulation of vaccine quality, quantity, and to impose vaccine requirements for the population.

Assessors should assess relevant legal instruments against the questions below. They should provide a detailed analysis on how the above-mentioned instruments comply with the IHR (2005) obligations outlined below, highlight the strengths, gaps, and provide recommendations to fill these ones.

Assessment Question

ASSESSMENT QUESTION	NATIONAL LEGAL INSTRUMENT REFERENCE	COMMENTARY
Is there legal authority to regulate routine vaccination?		
Is there legal authority to require vaccination, with exceptions?		
Does a National Regulatory Authority have the ability to regulate vaccine quality?		
Is there legal authority to make provisions for the storage/administration of vaccines? For management of a vaccine stockpile?		
Do legal instruments require any measures to be taken to ensure equitable access to vaccines?		
Are there provisions for liability protection or compensation?		
Do legal instruments specify competent authorities for vaccinations specified under IHR (2005)?		
Do legal instruments mandate vaccination for specific diseases and populations?		
Do legal instruments authorize mandatory vaccination for any		

specific diseases or during a public health emergency?		
Do legal instruments permit exceptions from vaccination based on health and religion?		
Do legal instruments designate or authorize the designation of vaccination centers in the State?		
Do legal instruments specify immunization against zoonotic diseases?		
Do legal instruments identify funding sources for vaccination?		
Do legal instruments maintain international supply chains for relevant vaccines and medical countermeasures?		
Do legal instruments facilitate research, development and equitable access to health products for responding to a public health emergency of international concern or a pandemic emergency?		

Strengths, Gaps and Recommendations

Assessors are invited to summarize the identified gaps and strengths in the national legal framework. Identifying these gaps and strengths will help develop recommendations for improvement around this specific thematic area. In framing gaps, we suggest reflecting whether the existing legal framework authorizes and enables the appropriate agency to determine necessary vaccines and ensure all individuals have access to them. Where it fails to do so, we suggest identifying the gap and recommending an appropriate legislative remedy.

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10. National laboratory system

This technical area aims for surveillance with a national laboratory system, including all relevant sectors, particularly human and animal health, and effective modern point-of-care and laboratory-based diagnostics. Legal instruments can regulate the standards for facilities, operations, coordination, and reporting from these labs.

Assessors should assess relevant legal instruments against the questions below. They should provide a detailed analysis on how the above-mentioned instruments comply with the IHR (2005) obligations outlined below, highlight the strengths, gaps, and provide recommendations to fill these ones.

Assessment Question

ASSESSMENT QUESTION	NATIONAL LEGAL INSTRUMENT REFERENCE	COMMENTARY
Is there a designated government agency for the national public health laboratory system?		
Do legal instruments establish standards for laboratory operation and licensing?		
Do legal instruments provide for laboratory inspection and sample sharing, and regulate transfer of agents between labs?		
Do legal instruments provide for the standard for operation of laboratories?		
Do legal instruments provide for laboratory certification?		
Do legal instruments provide the procedure to maintain certification?		
Do legal instruments provide for the inspection of laboratories?		
Do legal instruments authorize the closure of the laboratory facility for inability to meet minimum standards?		

Do legal instruments specify different types of tests that laboratories can carry out?		
Do legal instruments recognize requirements set by relevant professional bodies for certification of laboratory technicians who work with zoonotic diseases?		
Do legal instruments authorize the establishment of animal health laboratories?		
Do legal instruments specify the procedure for sharing laboratory reports and specimens with competent public health authorities at the national level?		
Do legal instruments set minimum education and training requirements for laboratory staff?		
Do legal instruments establish the scope of practice for laboratory staff?		
Do legal instruments provide for the handling and processing of health data?		
Do legal instruments provide information sharing between local public laboratories, regional public health laboratories and national laboratories?		
Do legal instruments authorize the development of agreements between neighboring States?		
Do legal instruments specify the collaboration with national laboratories (including reference laboratories)?		

Strengths, Gaps and Recommendations

Assessors are invited to summarize the identified gaps and strengths in the national legal framework. Identifying these gaps and strengths will help develop recommendations for improvement around this specific thematic area.

The IHR requires that laboratory systems be capable of analysis and diagnostics in a manner that facilitates timely detection of public health events. Doing so requires laboratory systems to be governed by a robust legal framework which outlines mechanisms and protocols for their operation, reporting and collaboration. Where the legal framework fails to meet these criteria, we suggest identifying the gap and recommending an appropriate legislative remedy.

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11. Surveillance

Detection and reporting of public health events are critical to ensuring that potential outbreaks are identified and contained before they become widespread. The IHR (2005) provides a framework for the detection and reporting of public health events at the national and international levels. It requires countries to develop and maintain surveillance and response systems that can detect and report public health events in a timely and effective manner.

At the national level, the IHR 2005 requires countries to designate national focal points for communication with the WHO, establish and maintain national public health surveillance systems, and develop and maintain capacity for laboratory testing of potential public health events. Member States are also required to report certain events to the WHO within 24 hours of detection.

At the subnational level, the detection and reporting of public health events are equally important. Subnational authorities are often the first to detect and respond to potential outbreaks, and they play a critical role in implementing national surveillance and response systems.

Assessors should assess relevant legal instruments against the questions below. They should provide a detailed analysis on how the above-mentioned instruments comply with the IHR (2005) obligations outlined below, highlight the strengths, gaps, and provide recommendations to fill these ones.

Assessment Question

ASSESSMENT QUESTION	NATIONAL LEGAL INSTRUMENT REFERENCE	COMMENTARY
Do legal instruments establish a surveillance system for public health events?		
Do legal instruments designate surveillance authority for public health events in the State?		
Do legal instruments support capacity for consistent collection of public health data, or designate a government agency for surveillance activities?		
Do legal instruments require the sharing of surveillance reports with surveillance authority at the national level?		
Do legal instruments designate a single entity to coordinate surveillance, aggregate information collected across sectors (human, animal & food), and coordinate the		

sharing of that information across sectors?		
Do legal instruments designate a single entity to coordinate surveillance between national, intermediary, and local levels?		
Do legal instruments contain mandatory requirements for national disease reporting, including enforcement/incentive mechanisms for reporting mandates?		
Do legal instruments address the sharing of health information without consent, or require specific data reporting processes to protect privacy?		
Do legal instruments provide diagnostic capacity for detection and identification?		
Do legal instruments provide analysis capacity for epidemiologic investigation?		
Do legal instruments include or link to case definitions for specific diseases?		
Do legal instruments provide for indicator and event-based surveillance?		
Do legal instruments provide for a list of public health events to be reported?		
Do legal instruments state the nature of public health information being reported?		
Do legal instruments provide for a duty to report public health events for community health workers?		
Is there a specific timeframe for reporting public health events?		

Do legal instruments provide for the designation of surveillance focal points at all levels of governance and outline reporting lines toward the IHR national focal point?		
Do legal instruments provide for sanctions for the failure to report public health events?		
Is there any law codifying the IDSR System?		
Are there guidelines and standard operating procedures for an integrated disease surveillance and response system in the State?		
Is there a protocol for the dissemination of information to and from IHR NFP?		
Are relevant sectors able to transmit inputs to IHR NFP?		

Strengths, Gaps and Recommendations

Assessors are invited to summarize the identified gaps and strengths in the national legal framework. Identifying these gaps and strengths will help develop recommendations for improvement around this specific thematic area.

. In framing gaps, we suggest reflecting whether the existing legal framework clearly outlines the obligations and responsibilities at each stage of disease surveillance. Where the legal framework fails to do so, we suggest identifying the gap and recommending an appropriate legislative remedy.

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12. Human Resources

A skilled and multisectoral health workforce is critical to effective health security, enabling countries to prevent, detect, and respond to public health threats in line with IHR (2005) requirements. Legal instruments must regulate workforce education, licensing, deployment, and surge capacity to ensure sustained readiness and intersectoral coordination. Without robust legal frameworks, health systems risk fragmentation and delays during emergencies, undermining health resilience.

Assessors should assess relevant legal instruments against the questions below. They should provide a detailed analysis on how the above-mentioned instruments comply with the IHR (2005) obligations outlined below, highlight the strengths, gaps, and provide recommendations to fill these ones.

Assessment Question

ASSESSMENT QUESTION	NATIONAL LEGAL INSTRUMENT REFERENCE	COMMENTARY
Do legal instruments address educational mandates for workforce development for health professionals and/or provide educational standards for the health professional?		
Do legal instruments address licensing standards for health professionals?		
Do legal instruments address scope of practice for health/public health professionals?		
Do legal instruments address provisions for foreign medical personnel (visa waivers, management of licenses, and liability considerations) with respect to an emergency?		
Do legal instruments address special hazard pay and other benefits for emergency responders?		
Is there a legally established national surge workforce strategy or contingency plan for public health emergencies?		

Do legal instruments address the application of instruments regulating federal civil service in an emergency?		
Do legal instruments allow for the secondment of non-governmental staff in government health agencies?		
Do legal instruments authorize the government to develop mutual agreements with other countries in the context of disasters or public health emergencies?		

Strengths, Gaps and Recommendations

Assessors are invited to summarize the identified gaps and strengths in the national legal framework. Identifying these gaps and strengths will help develop recommendations for improvement around this specific thematic area.

In framing gaps, we suggest reflecting whether the existing legal framework ensures that health facilities are equipped with adequate and equipped human resources, with the capacity to sustain emergencies. Where the legal framework fails to do so, we suggest identifying the gap and recommending an appropriate legislative remedy.

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13. Health Emergency Management

This capacity focuses on management of health emergencies and systems for enabling countries to be prepared and operationally ready for response to any public health event, including emergencies, as per the all-hazard requirement of IHR. Ensuring risk-based plans for emergency preparedness, readiness and response, robust emergency management structures and mobilization of resources during an emergency is critical for a timely response to public health emergencies.

Assessors should assess relevant legal instruments against the questions below. They should provide a detailed analysis on how the above-mentioned instruments comply with the IHR (2005) obligations outlined below, highlight the strengths, gaps, and provide recommendations to fill these ones.

Assessment Question

ASSESSMENT QUESTION	NATIONAL LEGAL INSTRUMENT REFERENCE	COMMENTARY
Do legal instruments authorize a public health emergency operations center (PHEOC)?		
Do legal instruments provide a procedure for the activation of the PHEOC?		
Do legal instruments designate a focal point for activation?		
Do legal instruments establish the accountability/reporting mechanism for the PHEOC?		
Do legal instruments specify functions and powers of the PHEOC?		
Do legal instruments establish the leadership and organizational structure of the PHEOC?		
Do legal instruments specify core PHEOC officers and their functions?		
Do legal instruments specify coordination of response between different levels of government (state or local)?		
Do legal instruments specify collaboration with different levels of government (state or local)?		

Do legal instruments specify information sharing between different levels of government (state or local)?		
Do legal instruments specify the funding mechanism for the PHEOC?		
Are there legal and regulatory processes to allow for		
Rapid national or cross-border deployment and receipt of public health, medical personnel and logistics and supplies during emergencies?		
Visa waivers for medical personnel?		
Product authorization for Medical Counter Measures (MCMs)?		
Management of licenses to practice for foreign assistance workers?		
Liability protections for medical personnel deployed to the country?		
International travel of persons in life-threatening or humanitarian situations?		
Does the country have a plan in place that identifies procedures and decision-making related to sending and receiving medical countermeasures during a public health emergency which addresses regulatory concerns of requesting/accepting and receiving drugs or devices from an international source?		
Do legal instruments provide for the implementation of preliminary control measures by community health workers?		
Do legal instruments provide for the implementation of preliminary control measures by primary health care professionals (private and public)?		

Do legal instruments support preliminary control measures implemented at the local/ primary public health response level?		
Do legal instruments provide for the implementation of additional control measures implemented at the state level?		
Do legal instruments authorize the government to designate health care centres to treat affected individuals?		
Do legal instruments provide authority to restrict the movement of individuals?		
Do legal instruments specify the procedure for restricting the movement of individuals?		
Do legal instruments authorize the government to ban mass gatherings in the State?		
Do legal instruments specify the procedure for issuing a ban on mass gatherings in the State?		
Do legal instruments authorize the State to close public or private places?		
Do legal instruments specify the procedure to close public or private places?		
Do legal instruments provide authority to quarantine individuals?		
Do legal instruments specify the procedure to quarantine individuals?		
Do legal instruments authorize the State to designate facilities for quarantine persons suspected of being infected with an infectious disease in collaboration with national public health authorities?		

Do legal instruments provide authority to isolate individuals?		
Do legal instruments specify the procedure to isolate individuals?		
Do legal instruments authorize the State to designate facilities to isolate persons with infectious diseases in collaboration with national public health authorities?		
Do legal instruments specify the requirement for quarantine facilities?		
Do legal instruments specify collaboration between State Ministries of Health and Agriculture during public health events?		
Do legal instruments specify sharing of information across sectors?		
Do legal instruments specify the focal point in each of the relevant ministries (Ministry of Health, Agriculture and Environment)?		
Do legal instruments provide for animal quarantine and/or isolation?		
Do legal instruments specify coordination between laboratories and medical facilities during public health responses?		
Do legal instruments specify the obligation to report to a higher level and/or NCDC the public health measures implemented?		
Do legal instruments specify how the States authorities can avail themselves of NCDC's guidance, technical and logistic support?		
Do legal instruments designate specific law enforcement agencies for public health emergencies?		
Do legal instruments authorize collaboration between law		

enforcement agencies and public health authorities to conduct a criminal investigation into bioterrorism?		
Do legal instruments require reporting of suspected or confirmed chemical, biological or radiological events to national law enforcement agents?		
Do legal instruments specify sharing of information between law enforcement and public health agencies?		

Strengths, Gaps and Recommendations

Assessors are invited to summarize the identified gaps and strengths in the national legal framework. Identifying these gaps and strengths will help develop recommendations for improvement around this specific thematic area.

In framing the gaps and recommendations, assessors may consider whether the legal framework enhances the state's capability to effectively manage health emergencies. This could include reflecting on how it creates and upholds standards, procedural clarity, communication, and collaboration during public health emergencies. Where legal frameworks do not mandate timely action or specify protocols for public health responses, we suggest identifying the gap and recommending an appropriate legislative remedy.

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14. Linking public health and security authorities

Public health events can occur naturally or deliberately. In both situations, coordination between public health and security authorities will strengthen the country's ability to conduct a rapid, multisectoral response for any event of suspected or confirmed deliberate origin, including the capacity to link public health and law enforcement, and to provide timely international assistance. The desired impact includes development and implementation of legislation, an MoU or other similar framework outlining roles, responsibilities and best practices for sharing relevant information between and among appropriate human and animal health, law enforcement and defense personnel.

Assessors should assess relevant legal instruments against the questions below. They should provide a detailed analysis on how the above-mentioned instruments comply with the IHR (2005) obligations outlined below, highlight the strengths, gaps, and provide recommendations to fill these ones.

Assessment Question

ASSESSMENT QUESTION	NATIONAL LEGAL INSTRUMENT REFERENCE	COMMENTARY
Is there a MoU or other agreement between public health and security authority entities at the national level?		
Does the military or law enforcement have designated entities responsible for public health emergency response alongside public health officials?		
Do legal instruments allow the government to detain/quarantine an individual who presents a public health risk, including through law enforcement?		
Do legal instruments require that reports be regularly shared between public health and any security authorities within the country?		
Is there legal authority for a response across multiple sectors in the case of a biological event of suspected or confirmed deliberate origin?		

Do legal instruments provide for management of international assistance in the event of an emergency?

Strengths, Gaps and Recommendations

Assessors are invited to summarize the identified gaps and strengths in the national legal framework. Identifying these gaps and strengths will help develop recommendations for improvement around this specific thematic area.

In framing gaps, we suggest considering the role security authorities play during public health events and whether this involvement is regulated by the legal framework in a manner that ensures timely assistance. Where the legal framework fails to do so, we suggest identifying the gap and recommending an appropriate legislative remedy.

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15. Health services provision

This indicator relates to legal backing for the establishment of resilient health systems that can deliver emergency related clinical care, and optimal utilization of health services while ensuring continuity of health systems functions including delivery of essential health services in emergencies.

Assessors should assess relevant legal instruments against the questions below. They should provide a detailed analysis on how the above-mentioned instruments comply with the IHR (2005) obligations outlined below, highlight the strengths, gaps, and provide recommendations to fill these ones.

Assessment Question

ASSESSMENT QUESTION	NATIONAL LEGAL INSTRUMENT REFERENCE	COMMENTARY
Is there legislation or regulation concerning an integrated/aligned mechanism to ensure health system data (e.g., surveillance, service delivery, service utilization) are streamlined, high quality and are reported from the community and facility to the national level, to inform effective policy and decision-making?		
Is there legislation or regulation concerning the timeline for reporting health system data, particularly for reportable events?		
Is there legislation or regulation concerning the timeline within which action should be taken?		
Is there legislation or regulation on implementation of control measures in response to an emergency, including communications, response plans, essential service provision, etc.?		
Is there a legal framework for the national health system, including accreditation of health systems? Is there a legal framework for the regulation and accreditation of different cadres of health workers?		

Strengths, Gaps and Recommendations

Assessors are invited to summarize the identified gaps and strengths in the national legal framework. Identifying these gaps and strengths will help develop recommendations for improvement around this specific thematic area. Where the legal framework fails to support a resilient health system, we suggest identifying the gap and recommending an appropriate legislative remedy.

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16. Infection prevention and control

This indicator relates to strong, effective infection prevention and control (IPC) programmes that enable safe health care and essential services delivery, and prevention and control of health care acquired infections (HCAIs). National IPC legal frameworks capture areas such as accountability mechanisms and resources required for implementation, leadership structure, monitoring and evaluation.

Assessors should assess relevant legal instruments against the questions below. They should provide a detailed analysis on how the above-mentioned instruments comply with the IHR (2005) obligations outlined below, highlight the strengths, gaps, and provide recommendations to fill these ones.

Assessment Question

ASSESSMENT QUESTION	NATIONAL LEGAL INSTRUMENT REFERENCE	COMMENTARY
Is there a legal framework for IPC in the country?		
If so, does it cover:		
<ul style="list-style-type: none"> Health and safety legislation 		
<ul style="list-style-type: none"> Surveillance of Healthcare Associated Infections (HAIs) at the facility level 		
<ul style="list-style-type: none"> Required curricula for education, training, pre-service competencies and continuing professional development 		
<ul style="list-style-type: none"> Water management, hygiene, and sanitation 		
Does the legal framework provide for the inclusion of IPC in AMR Frameworks?		
Do legal instruments mandate the development and implementation of a national IPC operational plan?		

Do legal instruments provide for an IPC committee or an authority empowered to oversee the implementation of an IPC operational plan?		
Do legal instruments regulate:		
<ul style="list-style-type: none"> Provision and prioritisation of PPE and immunization for healthcare personnel 		
<ul style="list-style-type: none"> Legal protection and support, including hazard pay and occupational health protection, for frontline workers during a health emergency 		
<ul style="list-style-type: none"> Requirements for accreditation of health facilities 		
<ul style="list-style-type: none"> Infrastructure and build environment alterations 		
<ul style="list-style-type: none"> IPC supply chain procurement, including personal protective equipment 		
<ul style="list-style-type: none"> IPC supply dissemination and transportation during public health emergencies 		

Strengths, Gaps and Recommendations

Assessors are invited to summarize the identified gaps and strengths in the national legal framework. Identifying these gaps and strengths will help develop recommendations for improvement around this specific thematic area.

In framing gaps, we suggest considering whether the legal framework establishes an effective IPC programme which enables healthcare personnel to act in a manner which prevents health care associated infections. The system should establish clear roles and responsibilities of relevant authorities and be

supported at all levels. Where the legal framework fails to do so, we suggest identifying the gap and recommending an appropriate legislative remedy.

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17. Risk communication and community engagement (RCCE)

Effective risk communication mitigates the potential negative impact of health hazards before, during and after public health emergencies or unusual events. Relevant legislation or regulation would ensure: (1) Formal government RCCE plans, arrangements and systems, including coordination mechanisms are in place. (2) Evidence that public communication, including relevant aspects of infodemics management operates efficiently and effectively; and risk communication units systematically engage populations at the community level during emergencies. (3) Existence of formal infodemic management plans as well as arrangements and systems to gather information on perceptions, risky behaviours and misinformation to analyse public concerns and fears.

Assessors should assess relevant legal instruments against the questions below. They should provide a detailed analysis on how the above-mentioned instruments comply with the IHR (2005) obligations outlined below, highlight the strengths, gaps, and provide recommendations to fill these ones.

Assessment Question

ASSESSMENT QUESTION	NATIONAL LEGAL INSTRUMENT REFERENCE	COMMENTARY
Do legal instruments provide a mandate to combat misinformation or disinformation about health in the country?		
Is there a legal authority for infodemic management (e.g., surveillance of misinformation, coordination of responses)?		
Do legal instruments require or enable the collection and analysis of community perceptions, risky behaviours, and rumours?		
Are social listening systems or behavioural insight tools established in law or official regulation?		
Do legal instruments authorize communication with the public?		
Do legal instruments require consultation and inputs gathering from the communities		
Do legal instruments designate authority that receives and shares		

information with the public during public health events?		
Do legal instruments specify sharing of information in local languages to the public?		
Do legal instruments specify a communication mechanism involving the private sector?		
Do legal instruments specify a focal point at the community level for the exchange of information?		

Strengths, Gaps and Recommendations

Assessors are invited to summarize the identified gaps and strengths in the national legal framework. Identifying these gaps and strengths will help develop recommendations for improvement around this specific thematic area.

In framing gaps, we suggest considering whether the legal framework establishes clear protocols and mechanisms to ensure risk communication is systematic, accurate and effectively engages populations at the community level during emergencies. Where the legal framework fails to do so, we suggest identifying the gap and recommending an appropriate legislative remedy.

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18: Points of entry and border health

The IHR (2005) focuses on controlling outbreaks at the source as well as preventing the spread of communicable diseases across borders. Borders and crossing points are gateways for disease transmission, making their management a critical aspect of global health security.

Under the IHR (2005), a point of entry (PoE) refers to a passage for international entry or exit of travelers, baggage, cargo, containers, conveyances, goods, and postal parcels, as well as agencies and areas that provide services to them upon entry or exit. State Parties are required to designate airports, ports, and ground crossings that shall develop core capacities.

Assessors should assess relevant legal instruments against the questions below. They should provide a detailed analysis on how the above-mentioned instruments comply with the IHR (2005) obligations outlined below, highlight the strengths, gaps, and provide recommendations to fill these ones.

Assessment Questions

ASSESSMENT QUESTION	NATIONAL LEGAL INSTRUMENT REFERENCE	COMMENTARY
Do legal instruments designate points of entry and provide for the development and maintenance of related IHR capacities?		
Do legal instruments designate competent authorities at designated points of entry?		
Do legal instruments contain obligations to monitor baggage, cargo, containers, conveyances, goods, postal parcels and human remains departing and arriving from affected areas, so they are free of sources of infection or contamination?		
Do legal instruments contain obligations to supervise derating, disinfection, disinsection, or decontamination of any baggage, cargo, containers, conveyances, goods, postal parcels and human remains, especially for affected conveyances using a technique with adequate level of control as determined by WHO or the competent authority?		
Do legal instruments contain obligations to ensure sanitary condition of facilities used by travelers at points of entry and supervise sanitary measures?		

Do legal instruments contain obligations to advise conveyance operators of applied control measures and provide written information on methods employed?		
Do legal instruments contain obligations to supervise removal and safe disposal of any contaminated water or food, human or animal dejecta, wastewater and any other contaminated matter from a conveyance?		
Do legal instruments contain obligations to monitor and control ship discharge of sewage, refuse, ballast water and other potentially disease-causing matter which might contaminate waters of a port or waterway?		
Do legal instruments contain obligations to supervise service providers at points of entry including inspections and medical examinations as necessary?		
Do legal instruments contain obligations to create contingency arrangements to deal with an unexpected public health event?		
Do legal instruments contain obligations to communicate with National IHR Focal Point on relevant public health measures implemented?		
Do legal instruments contain obligations to ensure conveyance operators permanently keep conveyances free of sources of infection or contamination, and otherwise comply with, and inform travelers of, the health measures recommended by WHO and adopted by the State Party?		
Do legal instruments contain obligations to inform the point of entry at destination of a suspect traveler placed under public health observation who was allowed to continue an international voyage,		

as he or she did not pose an imminent public health risk?		
Do legal instruments contain obligations to ensure the Maritime Declaration of Health conforms with Annex 8 of IHR and inform shipping operators or their agents of the maritime declaration of health requirements in place?		
Do legal instruments ensure Ship Sanitation Control Certificates and Exemption Certificates conform with Annex 3 of IHR?		
Do legal instruments require to send to WHO, and regularly update, a list of ports authorized to offer the issuance of Ship Sanitation Control Certificates, issuance of Ship Sanitation Control Exemption Certificates only, services referred to in Annexes 1 and 3?		
Do legal instruments ensure open communication channels between the points of entry and the NFP?		
Do adequate legislation and/or policies exist for the provision of health services for ill travelers and in response to public health events at PoEs in the country?		
Do legal instruments provide for applying recommended measures to derat, disinfect, decontaminate baggage, containers, goods, parcels and cargo?		
Do legal instruments require that measures applied to cargo, containers or conveyances, the parts treated, the methods employed, and the reasons for their application be indicated in writing?		
Do legal instruments affect personnel attending to affected travelers?		

Do legal instruments provide for authority to quarantine or isolate travelers?		
Do legal instruments require travelers to be vaccinated against specific diseases in line with the IHR requirements		
Do legal instruments ensure any person employed at a point of entry where WHO has determined a risk of yellow fever transmission and every member of crew of conveyance using such point of entry possesses a valid certificate of yellow fever vaccination?		
Do legal instruments require no other health documents than those provided for under the IHR or in recommendations issued by WHO, unless the traveler is applying for temporary or permanent residence, or document requirements concerning the public health status of goods or cargo in international trade pursuant to applicable international agreements?		
Do legal instruments provide for authority relating to plant or animal quarantine and isolation?		
Do legal instruments require adopting health measures that would achieve the desired public health objective while protecting travelers' rights and avoiding unnecessary interference with international traffic and trade?		

Strengths, Gaps and Recommendations

Assessors are invited to summarize the identified gaps and strengths in the national legal framework. Identifying these gaps and strengths will help develop recommendations for improvement around this specific thematic area.

In framing gaps, we suggest considering whether there is a structured framework for coordination and cooperation which enables actors to improve readiness and response capacity at critical entry points. Where the legal framework fails to support such collaboration, we suggest identifying the gap and recommending an appropriate legislative remedy.

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19. Chemical events

This technical area requires that States Parties have national policies or plans or legislation in place for management of chemical events in order to enable timely detection of and effective response to potential chemical risks and/or events in collaboration with other sectors responsible for chemical safety, industries, transportation and safe disposal.

Assessors should assess relevant legal instruments against the questions below. They should provide a detailed analysis on how the above-mentioned instruments comply with the IHR (2005) obligations outlined below, highlight the strengths, gaps, and provide recommendations to fill these ones.

Assessment Question

ASSESSMENT QUESTION	NATIONAL LEGAL INSTRUMENT REFERENCE	COMMENTARY
Are guidelines or manuals on the surveillance, assessment and management of chemical events, intoxication and poisoning available?		
Is there a national legislation or public health plan on response to chemical events?		
Is there a national coordinating body/committee with regard to the assessment and management of chemicals and chemical events?		
Are local, state and national authorities required to plan for emergency measures to be taken in the event of a chemical event?		
Are there multisectoral/interdisciplinary coordination mechanisms with regard to chemical management?		
Is there national legislation or regulation that governs chemicals and their applications with potential harm to human health and the environment?		
Do national or regional land use plans identify sensitive locations which should be separated from chemical installations?		

Is there a strategic plan to strengthen the assessment and management of chemicals (e.g. a national chemicals profile)?

Strengths, Gaps and Recommendations

Assessors are invited to summarize the identified gaps and strengths in the national legal framework. Identifying these gaps and strengths will help develop recommendations for improvement around this specific thematic area.

In framing gaps, we suggest considering whether the legal framework enables timely detection of and effective response to potential chemical risks. Where it fails to do so, we suggest identifying the gap and recommending an appropriate legislative remedy.

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20. Radiation emergencies

This technical area requires that States Parties have national policies or plans or legislation in place for management of radiological emergencies to enable detection and effective response to potential radiological emergencies and nuclear accidents in a cross-sectoral coordinated manner.

Assessors should assess relevant legal instruments against the questions below. They should provide a detailed analysis on how the above-mentioned instruments comply with the IHR (2005) obligations outlined below, highlight the strengths, gaps, and provide recommendations to fill these ones.

Assessment Question

ASSESSMENT QUESTION	NATIONAL LEGAL INSTRUMENT REFERENCE	COMMENTARY
Are there national policies, strategies or plans available for the detection, assessment, response and recovery after radiation emergencies?		
Is there an authority/institute/agency with primary responsibility for radiation and surveillance/monitoring?		
Is there a policy or strategic plan for ensuring safe use of radiation in the country?		
Is there an emergency response plan for radiological and nuclear emergencies?		
Is there a national coordinating body/committee with regard to radiological and nuclear emergencies?		
Are there multisectoral/interdisciplinary coordination mechanisms with regard to radiation emergency preparedness and response management?		

Strengths, Gaps and Recommendations

Assessors are invited to summarize the identified gaps and strengths in the national legal framework. Identifying these gaps and strengths will help develop recommendations for improvement around this specific thematic area.

In framing gaps, we suggest considering whether the legal framework enables timely detection of and effective response to potential radiation emergencies. Where it fails to do so, we suggest identifying the gap and recommending an appropriate legislative remedy.

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21. Human Rights and Data Privacy

The implementation of the IHR (2005) is cognizant of States' obligation to respect, protect and fulfil human rights. Article 3 of the IHR (2005) requires State Parties to respect the dignity, human rights, and fundamental freedoms of persons, and shall promote equity and solidarity. Article 32 also mandates a non-discriminatory approach to applying health measures.

While implementing health security measures, it is therefore crucial to balance the need for public health protection with the protection of human rights and fundamental freedoms. Failure to do so may result in unintended consequences, including stigma, discrimination, and violation of privacy. It is therefore essential to ensure that the implementation of health measures is grounded in respect for human dignity, non-discrimination, and accountability. The Siracusa Principles on the Limitation and Derogation of Provisions in the International Covenant on Civil and Political Rights provide some guidance to States willing to implement measures infringing on individual rights. These measures may include the State's power to authorize compulsory medical treatment, order isolation and quarantine, physical distancing, or other orders that may restrict individual freedom during a public health emergency.

In addition, the IHR (2005) mandates that information received by a State regarding an individual must be kept confidential and processed fairly, in accordance with national legal instruments. Additionally, the IHR outlines situations where State Parties may disclose and process personal data if it is essential for assessing and managing a public health risk. To comply with the IHR (2005), the processing of personal data must be fair and lawful, and it must be carried out in a manner compatible with the requisite purpose. The processing must also be adequate, relevant, and not excessive, and it should have a limited duration. The accuracy of the data must be ensured, and measures must be taken to protect it from erasure or other breaches.

Assessors should assess relevant legal instruments against the questions below. They should provide a detailed analysis on how the above-mentioned instruments comply with the IHR (2005) obligations outlined below, highlight the strengths, gaps, and provide recommendations to fill these ones.

Assessment Question

ASSESSMENT QUESTION	NATIONAL LEGAL INSTRUMENT REFERENCE	COMMENTARY
Do legal instruments protect human rights and fundamental freedoms during public health surveillance and response activities?		
Do legal instruments provide for transparency in the application of public health measures by State public health authorities?		
Do legal instruments mandate non-discrimination in applying public health measures by State public health authorities within the State?		
Do legal instruments provide against harmful consequences of		

public health surveillance and response activities?		
Do legal instruments provide for the judicial review of public health measures infringing individual rights?		
Do legal instruments specify the procedure for processing personal health data during the application of public health measures?		
Do legal instruments provide for the confidentiality of personal public health data of individuals received by public health authorities?		
Do legal instruments authorize the processing of personal health data when essential for the purposes of assessing and managing a public health event?		
Do legal instruments ensure that personal health data is processed fairly and lawfully?		
Do legal instruments provide for the accuracy of the personal health data of individuals processed, and how inaccurate or incomplete data should be handled?		
Do legal instruments regulate how personal data can be shared?		
Do legal instruments provide that State public health authorities ensure personal health data is relevant, adequate, and not excessive in relation to its processing purpose?		
Do legal instruments provide that State public health authority ensures personal health data is kept accurate, and inaccuracies are erased?		

Do legal instruments provide that State public health authorities must not keep data longer than necessary?		
Do legal instruments provide for the period of time for which data may be kept by the public health authorities?		
Do legal instruments mandate a "whole of society" approach to decision making during public health emergencies, ensuring that civil-society organizations and community are heard and involved in tailoring of public health and social measures to local contexts and needs?		
Do legal instruments prohibit actions that may result in arbitrary deprivation of life, including extrajudicial killings during the enforcement of public health measures?		
Do legal instruments recognize and address the increased risk of domestic violence during public health emergencies (e.g. lockdowns and quarantines)?		
Are there provisions for emergency response mechanisms, including shelters and access to justice for victims of violence during public health emergencies?		
Do the legal instruments provide clear conditions under which individuals may be detained for public health reasons, and do they include judicial review mechanisms?		
Do the legal instruments recognize the increased risk of sexual violence including rape during public health emergencies?		

Do the legal instruments establish reporting, accountability, and victim support mechanisms for survivors of sexual violence during public health emergencies?		
Do legal instruments mandate minimum standards for the humane treatment of individuals in isolation and quarantine centers?		
Are there legal requirements for adequate healthcare, sanitation, food, and general welfare for individuals in isolation or quarantine ?		

Strengths, Gaps and Recommendations

Assessors are invited to summarize the identified gaps and strengths in the national legal framework. Identifying these gaps and strengths will help develop recommendations for improvement around this specific thematic area.

In framing gaps, we suggest reflecting on whether the legal framework incorporates comprehensive human rights protections which address individuals' freedoms, privacy and dignity; establish mechanisms for redress; and ensure accountability and adherence to human rights standards. Where it fails to do so, we suggest identifying the gap and recommending an appropriate legislative remedy.

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Summary of Legal ANALYSIS of IHR related legal instruments in [State Party Name]

At the end of the analysis, it is recommended that assessors provide a summary of the gaps identified and the proposed recommendations.

Creating a strong and comprehensive summary is an important part of the legal analysis process.

The summary will likely be shared with decision makers for validation and decisions on the way forward. As such, it might help guide a legal reform for health security in the State.