Template for INFOSAN/IHR Communication:

national protocol for information sharing with national and international partners during food safety events and outbreaks of foodborne illness
How to use this document

The following text can serve as a starting point for the development of a national protocol for information sharing among various stakeholders involved in food safety emergency response in your State Party. This includes members of the International Food Safety Authorities Network (INFOSAN), the International Health Regulations (IHR 2005) National Focal Point (NFP), and other stakeholders as appropriate. The final document, when adapted to your national context, should provide a clear guidance about the procedures for communication between domestic authorities, as well as the World Health Organization (WHO), including the INFOSAN Secretariat.

The red text below should be edited to reflect your national context. The black text may also need revision, but is written in a generic way that may hold true for many State Parties. Should you require assistance with the adaptation of this template in your State Party, please contact the INFOSAN Secretariat (infosan@who.int).
Preamble

The global nature and growing complexity of the food chain means that risks posed by unsafe foods have the potential to quickly evolve from a local problem to an international incident in a short period of time. Collaborating with international agencies thus becomes increasingly important, to ensure the rapid and accurate transfer of information to food safety and public health partners globally.

Objective

The objective of this protocol is to outline the roles, responsibilities, reporting mechanisms and requirements for each of the national partners during a food safety / foodborne illness event with international implications. It describes how information is shared by national partners in <<State Party X>> with international partners, including foreign food safety authorities, the International Food Safety Authorities Network (INFOSAN) and the World Health Organization (WHO) International Health Regulations (IHR) Contact Point.

Roles and Responsibilities

INFOSAN: The International Food Safety Authorities Network (INFOSAN) is a joint FAO/WHO entity which assists Member States in managing food safety risks and in ensuring rapid sharing of information during food safety emergencies. The aim is to stop the spread of contaminated food from one State Party to another. INFOSAN also facilitates the sharing of experiences and tested solutions at the national level and between State Parties in order to optimize future interventions to protect the health of consumers. National authorities of 190 Member States are part of this network. The INFOSAN Emergency Contact Point (ECP) is responsible for reporting urgent food safety events and responding to verification requests from the INFOSAN Secretariat. INFOSAN Focal Points (FP) work with the INFOSAN ECP on food safety events, share information and disseminate information from INFOSAN as appropriate. The INFOSAN ECP for <<State Party X>> is located in the <<Ministry X, Agency X, Department X, etc.>>. Focal Points have been designated from <<Ministry Y, Agency Y, Department Y, etc.>> and <<Ministry Z, Agency Z, Department Z, etc.>>. Appendix 1 provides the contact details for the INFOSAN ECP and FPs in <<State Party X>>. Appendix 2 outlines the roles and responsibilities of ECP and FPs within INFOSAN.
IHR: The International Health Regulations (IHR 2005) are an international legal instrument that is binding on 196 States Parties across the globe, including all Member States of the WHO. The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade. Pursuant to the IHR, each State Party must establish or designate a National IHR Focal Point (NFP). The NFP is the national centre or office which is accessible at all times for IHR related communications with WHO IHR Contact Point and all relevant sectors of the State Party’s administration. The IHR NFP for <<State Party X>> is located at <<Ministry X, Agency X, Department X, etc.>>. <<Insert contact details of NFP>>

<<Insert main functions of the agency where the ECP is designated as they relate to food safety>>

For example: The National Food Safety Authority delivers all national inspection and enforcement services related to food in the State Party. Legislation covers all stages of the food continuum ensuring risks to food safety are mitigated. The National Food Safety Authority’s contribution to the investigation and control of foodborne illness outbreaks includes food safety investigation, testing and recall activities, as well as regulatory compliance and enforcement activities. The food safety investigations provide the basis for the assessment of risk and the development of appropriate risk management strategies to control affected products. The INFOSAN ECP is stationed here.

<<Insert main functions of the agencies where a FP is designated as they relate to food safety>>

For example: The Department of Health is the national department responsible for helping all citizens maintain and improve their health. With respect to food safety, the Department of Health’s primary responsibilities include setting standards and regulations, and conducting, upon request, health risk assessments on food-related hazards for the National Food Safety Authority or other stakeholders (e.g. sub-national governments). An INFOSAN FP is stationed here.

For example: The National Public Health Authority promotes and protects the health of all citizens. Among its activities is the coordination of responses to national outbreaks of foodborne illness. An INFOSAN FP is stationed here. This agency is also where the IHR NFP is stationed. <<explain the different units, functions, etc.>>
Reporting mechanisms and requirements

Verification requests
When necessary, the INFOSAN Secretariat at WHO may request the INFOSAN ECP to validate or verify information regarding an event. Similarly, the WHO IHR Contact Point may request verification of information from the IHR NFP (under IHR article 10). When this occurs, the receiving State Party will engage with the relevant national authorities, as appropriate, and in relation to their respective mandates while respecting the 24-hour timeline to provide available public health information as required by Article 10 of the IHR.

Reporting of issues to international partners
The mechanism by which <<State Party X>> reports an event is dependent upon its nature. Figure 1 provides a flow diagram to assist in determining whether reporting should occur via the INFOSAN and/or IHR network.

Reports to INFOSAN
The INFOSAN ECP at <<Agency X>> will notify the INFOSAN Secretariat at WHO of significant food safety events and certain food product recalls as outlined in Appendix 3. In all instances, when information shared with INFOSAN contains information on actual human illness, officials from the <<Public Health Authority>> will be copied on the notification. The INFOSAN Secretariat may subsequently determine that an alert needs to be posted on both the INFOSAN Community Website and/or the WHO Event Information Site for IHR NFPs. In such situations, the INFOSAN Secretariat will share the draft alert with the ECP in <<State Party X>>, who will consult with other FPs in <<Agency Y, Z, etc.>> if the alert contains details on actual human illness. If there is additional public health information that should be reported (and not contained in the INFOSAN alert), this should be reported to WHO separately through one of the IHR communication mechanisms (notification, consultation, other reports) described below.
Figure 1: Decision trees for determining whether to report via INFOSAN and/or IHR

A. National Food Recall in <<State Party X>>

1. Does the issue meet the National Food Safety Authority’s criteria (Appendix 3) for reporting to INFOSAN Secretariat?
   - Yes: Emergency Contact Point copies INFOSAN FPs and IHR NFP on INFOSAN notification (Appendix 4)
   - No: INFOSAN Secretariat determines if an Alert needs to be posted on INFOSAN Community Website and/or WHO Event Information Site for IHR National Focal Points and shares the draft alert with <<State Party X>> for review before posting

2. Is there human illness in <<State Party X>>?
   - Yes: Emergency Contact Point sends notification to INFOSAN Secretariat
   - No: Not necessary to report to INFOSAN Secretariat

B. Human foodborne disease cases in <<State Party X>>

1. Is the event a potential PHEIC, a case of Hepatitis A or Cholera in a non-citizen diagnosed in <<State Party X>>, or illnesses in citizens acquired while travelling abroad?
   - Yes: No further action
   - No: Not necessary to report to IHR NFP

2. Is there imported or exported food (into/out of <<State Party X>>) involved?
   - Yes: Infographic continues
   - No: INFOSAN NFP as per usual national process

3. Has INFOSAN already been notified or has an INFOSAN Alert already been posted?
   - Yes: Infographic continues
   - No: <<Agency X>> notifies IHR NFP as per usual national process

4. Is there additional public health information (not contained in the notification or alert) that still needs to be reported?
   - Yes: <<INFOSAN FP in Agency X>> informs <<INFOSAN ECP in Agency Y>> and/or allows for review draft IHR notification (if needed)
   - No: No further action
Communication with WHO (under the IHR)

There are numerous types of reports which are required to be sent to WHO by the IHR NFP under the IHR (2005); however, for the purposes of this protocol, the following types of notification and information sharing are most likely to occur:

- In <<State Party X>>, all events of potential international public health concern have to be assessed for potential notification within 48 hours of the State Party becoming aware of it at the national level. Under Article 6 of the IHR, notifications must occur within 24 hours of assessment by the State Party using the decision instrument provided in Annex 2 of the Regulations. Appendix 5 contains the Annex 2 decision instrument and examples for its application. Information shared with the WHO may include public health information such as case definitions, laboratory results, source and type of risk, numbers of cases and deaths, conditions affecting the spread of the disease and the health measures employed in response to the event and when necessary, the difficulties faced and support needed in responding to the potential public health emergency of international concern. Please refer to Appendix 6 for a template for the notification of events.

- For unusual or unexpected public health events within <<State Party X>>, irrespective of origin or source, as defined under Article 7 of the IHR, the relevant health programme area should consider keeping WHO informed to allow for rapid assessment and early warning of an event that has the potential to become an international concern.

- Furthermore, through the NFP, States Parties must, as far as is practicable, inform WHO within 24 hours of receipt of evidence of public health risks identified outside their territories that may cause international disease spread, as manifested by exported or imported human cases, vectors that may carry infection or contamination, or contaminated goods (Article 9.2).

- In the case of events occurring within its territory not requiring notification as provided in Article 6, the State Party may keep WHO advised thereof and consult with WHO on appropriate health measures (Article 8 Consultation).

- In addition to notifications under Article 6, consultations under Article 8, and information sharing under Articles 7 and 9, the NFP may also send bilateral information sharing notices to other State Parties under Article 44 of the IHR.

- Under the Article 10 of the IHR, WHO may request verification from a State Party of reports from sources other than official notifications or consultations of events which may constitute a PHEIC allegedly occurring in the State’s territory. [For example, if WHO received a report from State Party X or a media report of a significant public health event in State Party Y, WHO could request further information, or a verification of the event, from State Party Y.] The State Party, via the NFP, is required to verify and provide:
  - within 24 hours, an initial reply to, or acknowledgement of, the request from WHO
  - within 24 hours, available public health information on the status of events referred to in WHO’s request; and
  - information to WHO in the context of an assessment under Article 6, including relevant information as described in that Article.

In all instances, when information shared with the IHR NFP contains information on a food safety investigation, the <<INFOSAN ECP at the National Food Safety Authority>> will be made aware and given the opportunity to comment and correct, if necessary.
Coordination

To streamline the reporting process among national stakeholders, the <<INFOSAN ECP at the National Food Safety Authority>> and the <<INFOSAN FP at the Department of Health>> will liaise with the <<INFOSAN FP at the Public Health Authority>> for matters related to food safety, and that in turn, <<INFOSAN FP at the Public Health Authority>> will be responsible for liaising with the national IHR NFP <<by contacting the 24/7 single window account at the Department of Health>>.

Accuracy Control

Unless otherwise stated in existing procedures or guidelines, any response to verification requests, reports to the INFOSAN Secretariat, and other reports to WHO will require accuracy check from <<State Party X>>; for instance, under IHR communication process before posting on the Event Information Site (EIS). Verification request under IHR should be replied within 24 hours as required in Article 10 (Please see Report to WHO under IHR)

<<may need to refer to other internal guidance relevant to specific State Party’s operating procedures>>
Appendix 1: Contact details for the INFOSAN ECP and FPs in <<State Party X>>

<< TO BE INSERTED >>
**Appendix 2: Overview of INFOSAN Roles and Responsibilities**

INFOSAN seeks to reflect the multidisciplinary nature of food safety and promote intersectoral collaboration by requesting the designation of Focal Points in each of the respective national authorities with a stake in food safety, and a single Emergency Contact Point in the national authority with the responsibility for coordinating national food safety emergencies.

Countries choosing to be members of INFOSAN are committed to sharing information between their respective food safety authorities and other INFOSAN members.

In some countries, an INFOSAN Emergency Contact Point or INFOSAN Focal Point may have the dual role of being their country’s International Health Regulations (IHR) National Focal Point (NFP), in countries where this is not the case, it is important for the INFOSAN Emergency Contact Point and the IHR NFP to liaise with each other to ensure that food safety events that also constitute Public Health Emergencies of International Concern (PHEIC) are reported through the appropriate channels as required by the International Health Regulations (2005) (http://www.who.int/ihr/en/).
Appendix 3: **<<National Food Safety Authority’s>> Process for Proactive Reporting of Food Recalls to International Partners including INFOSAN**

**Purpose**
This appendix outlines the **<<National Food Safety Authority’s>>** process for sharing information on national food recalls with international partners, including the International Food Safety Authorities Network (INFOSAN).

**Background**
The **<<National Food Safety Authority’s>>** has a **<<Protocol for Sharing of Information during Food Safety Investigations and Recalls ---this is an example from Canada, posted online>>** which provides an understanding of the type of information that can be shared by the **<<National Food Safety Authority>>** with other government departments, other State Parties, third parties and the public during food safety investigations and recalls. It also describes how information is shared and outlines the type of information that the **<<National Food Safety Authority>>** is obligated to protect.

As per this protocol, when the **<<National Food Safety Authority>>** determines that a food product that poses a risk has been exported, information relating to the nature of the problem as well as names of receiving consignees is shared with the government of the receiving State Party. Similarly, if the food in question had been imported into **<<State Party X>>**, investigation findings will be shared with the government of the originating State Party. In both instances, the information exchange enables the foreign State Party in question to take any follow up action it deems necessary.

**Notification to INFOSAN**
The **<<INFOSAN ECP at the National Food Safety Authority>>** will notify the INFOSAN Secretariat via e-mail of all recalls of food products that entered international trade (that are likely to result in serious adverse health consequences) as per the guidance in section 5.4 of the INFOSAN Members’ Guide.

**Notification to Implicated State Parties**
The **<<INFOSAN ECP at the National Food Safety Authority>>** will notify implicated State Parties¹ (both importing and exporting) of all recalls in the following manner:

- The **<<INFOSAN ECP at the National Food Safety Authority>>** will notify INFOSAN member State Parties through their INFOSAN Emergency Contact Point.

**Recall Details**
The template, Notification of a National Food Recall (Appendix 4), will be used by the **<<INFOSAN ECP at the National Food Safety Authority>>** to capture all of the relevant information relating to the recalled product(s). This will be sent to the appropriate recipients via e-mail (flagged as “high priority”).

¹ Implicated State Parties are those who have either received the affected product from **<<State Party X>>**, or are the State Parties where the recalled product originated.
### Appendix 4: Template - Notification of a National Food Recall in <<State Party X>>

<table>
<thead>
<tr>
<th>RECALL INFORMATION</th>
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<tbody>
<tr>
<td>Reason for Recall</td>
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<tr>
<td>Recall Level</td>
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<td>Recall #</td>
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<td>Date of Notification</td>
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<tr>
<td>Trigger</td>
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<tr>
<td>Illness Reported</td>
<td>Yes or No</td>
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<td>Communication Undertaken</td>
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| <<State Party X>> EXPORTER INFORMATION |  |  |  |
|----------------------------------------|-----------------|----------------|
| Exporter |  |  |  |
| Domestic or Foreign Manufacturer |  |  |  |
| Receiving State Parties |  |  |  |
| Receiving Consignee Information | Yes – see attached list / No – to follow |  |  |

| IMPORTER INFORMATION |  |  |  |
|----------------------|-----------------|----------------|
| State Party of Origin of Product |  |  |  |
| Exporter to <<State Party X>> |  |  |  |

<table>
<thead>
<tr>
<th>PRODUCT INFORMATION</th>
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<tbody>
<tr>
<td>Label Attached</td>
<td>Yes or No</td>
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<tr>
<td>Other Relevant Details</td>
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<th>Brand</th>
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Appendix 5: IHR Annex 2 Decision Instrument

DEcision instrument for the assessment and notification of events that may constitute a public health emergency of international concern

Events detected by national surveillance system (see Annex 1)

A case of the following diseases is unusual or unexpected and may have serious public health impact, and thus shall be notified:\(^1\): - Smallpox - Poliomyelitis due to wild-type poliovirus - Human influenza caused by a new subtype - Severe acute respiratory syndrome (SARS).

An event involving the following diseases shall always lead to utilization of the algorithm, because they have demonstrated the ability to cause serious public health impact and to spread rapidly internationally\(^2\): - Cholera - Pneumonic plague - Yellow fever - Viral haemorrhagic fevers (Ebola, Lassa, Marburg) - West Nile fever - Other diseases that are of special national or regional concern, e.g. dengue fever, Rift Valley fever, and meningococcal disease.

\[\text{Is the public health impact of the event serious?}\]

\[\text{Any event of potential international public health concern, including those of unknown causes or sources and those involving other events or diseases than those listed in the box on the left and the box on the right shall lead to utilization of the algorithm.}\]

\[\text{Is the event unusual or unexpected?}\]

\[\text{Is there a significant risk of international spread?}\]

\[\text{Is there a significant risk of international travel or trade restrictions?}\]

\[\text{EVENT SHALL BE NOTIFIED TO WHO UNDER THE INTERNATIONAL HEALTH REGULATIONS}\]

\(^1\) As per WHO case definitions.

\(^2\) The disease list shall be used only for the purposes of these Regulations.
# EXAMPLES FOR THE APPLICATION OF THE DECISION INSTRUMENT FOR THE ASSESSMENT AND NOTIFICATION OF EVENTS THAT MAY CONSTITUTE A PUBLIC HEALTH EMERGENCY OF INTERNATIONAL CONCERN

The examples appearing in this Annex are not binding and are for indicative guidance purposes to assist in the interpretation of the decision instrument criteria.

## DOES THE EVENT MEET AT LEAST TWO OF THE FOLLOWING CRITERIA?

<table>
<thead>
<tr>
<th>1. Is the public health impact of the event serious?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the number of cases and/or number of deaths for this type of event large for the given place, time or population?</td>
</tr>
<tr>
<td>2. Has the event the potential to have a high public health impact?</td>
</tr>
<tr>
<td>The following are examples of circumstances that contribute to high public health impact:</td>
</tr>
<tr>
<td>✓ Event caused by a pathogen with high potential to cause epidemic (infectiousness of the agent, high case fatality, multiple transmission routes or healthy carrier).</td>
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<tr>
<td>✓ Indication of treatment failure (new or emerging antibiotic resistance, vaccine failure, antidote resistance or failure).</td>
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<tr>
<td>✓ Event represents a significant public health risk even if no or very few human cases have yet been identified.</td>
</tr>
<tr>
<td>✓ Cases reported among health staff.</td>
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<tr>
<td>✓ The population at risk is especially vulnerable (refugees, low level of immunization, children, elderly, low immunity, undernourished, etc.).</td>
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<tr>
<td>✓ Concomitant factors that may hinder or delay the public health response (natural catastrophes, armed conflicts, unfavourable weather conditions, multiple foci in the State Party).</td>
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<tr>
<td>✓ Event in an area with high population density.</td>
</tr>
<tr>
<td>✓ Spread of toxic, infectious or otherwise hazardous materials that may be occurring naturally or otherwise that has contaminated or has the potential to contaminate a population and/or a large geographical area.</td>
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</table>

<table>
<thead>
<tr>
<th>3. Is external assistance needed to detect, investigate, respond and control the current event, or prevent new cases?</th>
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</thead>
<tbody>
<tr>
<td>The following are examples of when assistance may be required:</td>
</tr>
<tr>
<td>✓ Inadequate human, financial, material or technical resources – in particular:</td>
</tr>
<tr>
<td>✓ insufficient laboratory or epidemiological capacity to investigate the event (equipment, personnel, financial resources);</td>
</tr>
<tr>
<td>✓ insufficient antidotes, drugs and/or vaccine and/or protective equipment, decontamination equipment, or supportive equipment to cover estimated needs;</td>
</tr>
<tr>
<td>✓ existing surveillance system is inadequate to detect new cases in a timely manner.</td>
</tr>
</tbody>
</table>

**Is the public health impact of the event serious?**

Answer “yes” if you have answered “yes” to questions 1, 2 or 3 above.
II. Is the event unusual or unexpected?

4. *Is the event unusual?*

The following are examples of unusual events:

- The event is caused by an unknown agent or the source, vehicle, route of transmission is unusual or unknown.
- Evolution of cases more severe than expected (including morbidity or case-fatality) or with unusual symptoms.
- Occurrence of the event itself unusual for the area, season or population.

5. *Is the event unexpected from a public health perspective?*

The following are examples of unexpected events:

- Event caused by a disease/agent that had already been eliminated or eradicated from the State Party or not previously reported.

Is the event unusual or unexpected?
Answer “yes” if you have answered “yes” to questions 4 or 5 above.

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III. Is there a significant risk of international spread?

6. *Is there evidence of an epidemiological link to similar events in other States?*

7. *Is there any factor that should alert us to the potential for cross border movement of the agent, vehicle or host?*

The following are examples of circumstances that may predispose to international spread:

- Where there is evidence of local spread, an index case (or other linked cases) with a history within the previous month of:
  - international travel (or time equivalent to the incubation period if the pathogen is known);
  - participation in an international gathering (pilgrimage, sports event, conference, etc.);
  - close contact with an international traveller or a highly mobile population.

- Event caused by an environmental contamination that has the potential to spread across international borders.
- Event in an area of intense international traffic with limited capacity for sanitary control or environmental detection or decontamination.

Is there a significant risk of international spread?
Answer “yes” if you have answered “yes” to questions 6 or 7 above.

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IV. Is there a significant risk of international travel or trade restrictions?

8. *Have similar events in the past resulted in international restriction on trade and/or travel?*

9. *Is the source suspected or known to be a food product, water or any other goods that might be contaminated that has been exported/imported to/from other States?*

10. *Has the event occurred in association with an international gathering or in an area of intense international tourism?*

11. *Has the event caused requests for more information by foreign officials or international media?*

Is there a significant risk of international travel or trade restrictions?
Answer “yes” if you have answered “yes” to questions 8, 9, 10 or 11 above.

States Parties that answer “yes” to the question whether the event meets any two of the four criteria (I-IV) above, shall notify WHO under Article 6 of the International Health Regulations.
Appendix 6: Sample IHR Article 6 notification

FOR OFFICIAL USE ONLY

This communication is for official use only and is not for further distribution. Recipients may distribute it at their discretion, solely for operational purposes, to relevant public health officials in their organization.

Dear WHO IHR Colleagues,

In accordance with the International Health Regulations (IHR) (2005), Article 6 on “Notification”, <<State Party X>>, National IHR Focal Point on behalf of the Government of <<State Party X>> would like to report <insert event overview>.

<Insert event description, where possible including:
- number of cases and deaths
- case definitions
- laboratory results
- source and type of the risk
- conditions affecting the spread of the disease and
- public health measures employed>

(Note: if this information is not yet available, then provide it to WHO as soon as possible in a follow-up / update report)

IHR ASSESSMENT

(Note: If a PHEIC has already been declared by the WHO, then the IHR assessment portion of the template can be omitted unless there is a specific <<State Party X>> rationale for including an IHR assessment.)

Using the IHR (2005) Annex 2 decision instrument, the << Public Health Authority’s>> assessment is as follows:

* Does the event involve smallpox, wild-type poliovirus, human influenza caused by a new sub-type (including H5N1) or SARS? Yes/No

If “YES”, the National IHR Focal Points notifies WHO IHR Contact Point within 24h under Article 6 of the IHR.

1. Is the public health impact of the event serious?
Yes/No. <Include rationale>
2. Is the event unusual or unexpected?
   Yes/No. <Include rationale>

3. Is there a significant risk of international spread?
   Yes/No. <Include rationale>

4. Is there a significant risk of international travel or trade restrictions?
   Yes/No. <Include rationale>

If the answer is “yes” to at least two of the questions above, the National IHR Focal Point notifies WHO IHR Contact point within 24h under Article 6 of the IHR (2005).

The <<Department of Health>> << or other specific agencies>> will continue to monitor the situation for any developments and respond accordingly.

For urgent assistance after hours, please contact <<insert emergency contact details>> either by email at XX@XX, or at the below telephone number.

Regards

IHR NFP Officer

<<Contact Details>>