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Organization



International Food Safety Authorities Network (INFOSAN)

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INFOSAN Information Note No. 4/2007 - IHR(2005)

The identification, assessment and management of food safety events under the International Health Regulations (2005)

SUMMARY NOTES

- The scope of the International Health Regulations (2005) (IHR(2005)), which enter into force on 15 June 2007, includes food contamination and foodborne disease events.
- The National IHR Focal Point and the INFOSAN Emergency Contact Point have critical roles in the identification, assessment and management of food safety-related public health events that may have international implications. It is therefore critical that the two parties work in close collaboration.
- Certain animal health events with potential public health implications are also included in the scope of the IHR(2005). Therefore collaboration between the National Veterinary Authority and the National IHR Focal Point is also important.
- World Health Organization (WHO) will manage food safety events in support of countries under IHR(2005)¹, utilizing INFOSAN², as appropriate. This process includes collaboration with many different parties, which varies depending on the event.
- Minimizing the effect of food safety-related public health events requires a multi sectoral approach.

Introduction

The IHR(2005)¹ are an international legal instrument which is legally binding on all WHO Member States who have not rejected them (or, subject to the procedure foreseen in the IHR(2005), who have made reservations) and on all Non-Member States of the WHO that have agreed to be bound by them³. The IHR(2005) will enter into force on 15 June 2007⁴ and will replace the current IHR(1969)⁴.

The purpose and scope of the IHR(2005) 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. The IHR(2005) also established a single code of legal procedures and requirements for routine public health measures at international airports and ports and some ground crossings. Within the very wide scope of IHR(2005), certain food safety events, including both food contamination and foodborne disease events with international implications, will require action under the legal provisions included in the IHR(2005).

This INFOSAN Information Note explains the interface between the IHR(2005) and INFOSAN, key obligations of countries and the WHO under the IHR(2005) as they apply to food safety events.

This INFOSAN Information Note is not a complete summary of the IHR(2005) and therefore it should be read in conjunction with the IHR(2005), which are available at: http://www.who.int/csr/ihr/IHRWHA58_3-en.pdf

¹ Frequently asked questions about the IHR(2005) are available at: <http://www.who.int/csr/ihr/howtheywork/faq/en> and provide a useful summary.

² For more information on INFOSAN see - http://www.who.int/foodsafety/fs_management/infosan/en

³ States who are bound by the IHR(2005) are referred to as State Parties in IHR(2005). However, for the purposes of this Information Note, 'countries' has been used to mean State Parties.

⁴ See <http://www.who.int/csr/ihr/ihr1969.pdf> for more information on IHR (1969).

National IHR Focal Point and WHO IHR contact point

Effective communication between WHO and countries is central to the rapid management of a possible public health emergency of international concern. The IHR(2005) require that notification and reporting by countries, as well as other urgent IHR communications, generally be transmitted through National IHR Focal Points^{5,6} (for countries) and IHR Contact Points⁷ (for WHO), which must be available at all times for these communications. The primary functions for National IHR Focal Points include sending these urgent communications to WHO IHR Contact Points, and disseminating information to, and consolidating input from, relevant administrative sectors of the country, such as those responsible for surveillance and reporting, points of entry (e.g. airports, ports), public health services, clinics, and hospitals. These sectors or agencies should include those responsible for agriculture, food safety and foodborne disease notification.

The Role of INFOSAN under IHR(2005)

Since 2004, INFOSAN, a voluntary network, has managed food safety events with international implications. INFOSAN Emergency Contact Points⁸, designated by the country, have had the responsibility of informing the INFOSAN Secretariat at WHO of relevant events as well as ensuring that their country is aware of alerts sent through INFOSAN to allow appropriate action to occur. It is important that the National IHR Focal Point and the INFOSAN Emergency Contact Point work in close collaboration to ensure national and international public health security and the fulfilment of the requirements under the IHR(2005), including the detection, assessment, notification, reporting, consultation and dissemination processes discussed in this Information Note. INFOSAN recommends that these collaborative agreements be documented.

While the requirements of the IHR(2005) state that communication between WHO and countries must occur through the National IHR Focal Points and the IHR Contact Points, this does not preclude technical discussions between country food safety officials and WHO's programme on food safety, including INFOSAN with regard to food safety events. There will be some food safety events which may not require notification or reporting under IHR(2005), but call for action under INFOSAN. The INFOSAN Users Guide⁹ outlines the criteria used to determine if action is required by INFOSAN.

Notification and reporting

One of the primary obligations for countries under IHR(2005) is to detect¹⁰ and assess events occurring within their territories by following the Decision Instrument and additional provisions provided in Annex 2 (see appendix one of this note) of the IHR(2005), and then to notify¹¹ WHO of all such 'events which may constitute a public health emergency of international concern', within 24 hours of assessment, through their National IHR Focal Point.

Some events relating to food safety will meet the criteria of the Decision Instrument and require notification to WHO under the IHR(2005). Such food safety events may relate to any of the three hazards which can occur in food¹²; chemical, physical (sometimes known as foreign matter) and microbiological. Case studies applying the Decision Instrument to food safety events are provided on page four.

Notification is the beginning of the assessment dialogue involving the country and WHO to determine the nature of the event and the appropriate response. The notification of an event must occur through the National IHR Focal Point.

In addition to notification, the IHR(2005) specifically allow for countries to initiate 'consultations'¹³ with WHO in respect to events where mandatory notification does not apply at that time, in particular where

⁵ National IHR Focal Points are national centres to be designated or established by each country, See Article 4.1 and 4.2

⁶ Guidance on the designation, establishment and operation of National IHR Focal Points is available at <http://www.who.int/csr/ihr/nfp/en>.

⁷ See IHR(2005) Article 4.3

⁸ Some countries have not yet designated an INFOSAN Emergency Contact Point. In these cases the INFOSAN Focal Point will be used (see the INFOSAN Users Guide for the Focal Points terms of reference). Where a country is not a member of INFOSAN, the National IHR Focal Point should work with the national authority responsible for food safety to identify a contact person.

⁹ See http://www.who.int/foodsafety/publications/fs_management/INFOSAN_User_Guide_Final.pdf

¹⁰ See IHR(2005) Article 5.1 and Annex 1A

¹¹ See IHR(2005) Article 6 and Annex 2

¹² Codex Alimentarius. Recommended International Code of Practice General Principles of Food Hygiene CAC/RCP 1-1969, Rev. 4-20031, see: http://www.codexalimentarius.net/download/standards/23/cxp_001e.pdf

¹³ See IHR(2005) Article 8

insufficient information is made available to complete the Decision Instrument. Countries must also report¹⁴ to WHO evidence of public health risks occurring outside the country's territory; including imported or exported human cases, or contaminated goods including foodstuffs.

Animal Health surveillance systems are also critical sources of information to consider in the context of IHR(2005). Animal disease outbreaks with a zoonotic potential should feed into the human disease surveillance and investigation process. It is anticipated that the National IHR Focal Point, would consult with the responsible Agricultural and Food Safety (where applicable) Authorities (including the national World Organisation for Animal Health (OIE) Delegate or the national Chief Veterinary Officer) in the determination process whether the event requires notification under IHR(2005). Separately note that for countries that are members of OIE, the Veterinary Authority¹⁵ is required to report diseases and exceptional epidemiological events, including emerging diseases or pathogens having epidemiological significance to other countries to the OIE¹⁶. For animal disease outbreaks with a zoonotic potential, WHO receives this information through the Food and Agriculture Organization of the United Nations (FAO)/OIE/WHO Global Early Warning System for Major Animal Diseases, including Zoonoses (GLEWS)¹⁷. In the situation where a relevant event has not been notified under the IHR(2005), WHO will assess the GLEWS information for relevance to the IHR(2005). If an event reported through this mechanism should be notified under the IHR(2005), a WHO IHR contact point will collaborate with the country National IHR Focal Point following the verification process (see section below on Surveillance and Verification).

Surveillance and Verification

WHO is mandated under the IHR(2005) to continue to carry out its surveillance activities taking into consideration information from sources other than notifications, assess events for international significance and to seek verification from the countries involved of unofficial reports or communications (e.g. the media) of potential events within their territories which may constitute a public health emergency of international concern. Countries must respond to WHO with an initial reply or acknowledgement within 24 hours and the public health information on the status of the event. Verification becomes the starting point for collaborative risk assessment¹⁸ and response.

During the past year, WHO through INFOSAN undertook verification processes on a global basis, on average, ten times per month.

¹⁴ See IHR(2005) Article 9

¹⁵ Veterinary Authority means the governmental [Veterinary Service](#) having authority in the whole country for implementing the animal health measures and international veterinary certification process which the OIE recommends, and supervising or auditing their application (OIE Terrestrial Animal Health Code)

¹⁶ The conditions for notification are described in the respective chapters on notification and epidemiological information of the Terrestrial Animal Health Code (chapter 1.1.2) and the Aquatic Animal Health Code (chapter 1.2.1). The OIE disseminates the information to Veterinary authorities and to the public through its web site and distribution lists.

¹⁷ Further information on GLEWS is available at: <http://www.who.int/zoonoses/outbreaks/en/> and http://www.oie.int/eng/OIE/accords/GLEWS_Tripartite-Finalversion010206.pdf

¹⁸ Risk assessment as described by the IHR(2005), in the area of food safety, is what is sometimes referred to as 'risk profiling' and 'rapid risk assessment' for emergency food safety events. See the FAO/WHO publication 'Food safety risk analysis. A guide for national food safety authorities.' 2006 at <http://www.who.int/foodsafety/publications/micro/riskanalysis06/en>

Examples of the Decision Instrument applied to food safety events:

Case one: *E. coli* O157:H7 in Spinach (This case study occurred in 2006 and is summarized in an INFOSAN Note¹⁹).

In September 2006, the United States of America experienced an *E. coli* O157:H7 outbreak involving fresh, bagged spinach with reported 205 cases of illness including 104 hospitalizations, 31 cases of kidney failure and 3 deaths. Under the IHR(2005) Decision Instrument (see appendix one), the presence of at least two of the four criteria means that the event needs to be notified:

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

- Yes. The event is caused by a pathogen which causes serious disease and death.

2. *Is the event unusual or unexpected?*

- No. Event is caused by a known agent from a likely common source outbreak.
- Evolution of cases is not more serious than expected.
- Presence of Enterohaemorrhagic *E. coli* in produce is a known problem.

3. *Is there a significant risk of international spread?*

- Yes. The national authority responsible for food safety confirmed that export of the affected product occurred.
- National authority responsible for food safety confirmed that many people cross the border daily from two neighbouring countries and may have been exposed to the contaminated food.

4. *Is there significant risk of international travel or trade restrictions?*

- Yes. Similar events have resulted in National Authorities in importing countries putting in place international trade restrictions.

Three of the four criteria have been met. Therefore based on the above information, this event would have required notification under the IHR(2005).

Case Two: High Pesticide Residue Levels in Rice

Through food surveillance systems, the presence of mevinphos, an organophosphorus pesticide, was identified by an importing country. The country recalled the rice from the market although no associated human cases were reported. Under the IHR(2005) Decision Instrument (see appendix one), the presence of at least two of the four criteria means that the event needs to be notified:

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

- Yes. When undertaking an exposure assessment, it was estimated that the Acute Reference Dose for mevinphos in the contaminated rice was exceeded by a factor of 20 times for adults and 30 times for children. The adverse health effects of organophosphorus pesticides includes mild and reversible symptoms at low doses, like headache and nausea, but with higher doses, can progress to diarrhoea, vomiting, fatigue and difficulty breathing. This indicates that serious public health consequences were possible.

2. *Is the event unusual or unexpected?*

- Yes. The pesticide is not approved for use during primary production and was unexpected. Furthermore, the level detected in the rice was unusual in that it greatly exceeded the level permitted for similar organophosphorus pesticides.

3. *Is there a significant risk of international spread?*

- Yes. Contamination was identified in an importing country. The exporting National Authority responsible for food safety could not confirm that export of the affected product to other countries had not occurred.

4. *Is there significant risk of international travel or trade restrictions?*

- Yes. Similar events have resulted in National Authorities in importing countries putting in place international trade restrictions.

All four criteria have been met. Therefore based on the above information, this event would have required notification under the IHR(2005).

Note: If the Acute Reference Dose had not been exceeded, this issue would not constitute a serious public health risk and would not result in notification under the IHR(2005). It is recognized that long-term exposure to levels above the Acceptable Daily Intake can lead to chronic disease and are important public health issues. However disease caused by chronic exposure are generally not included within the scope of IHR(2005).

International and National Response

International Response

After the assessment of public health information gained through surveillance activities, notification, consultation, other reports and verification processes, WHO is mandated to disseminate relevant information to National IHR Focal Points, including information necessary to enable countries to respond to a public health risk^{20,21}.

¹⁹ INFOSAN Note No 1/2007. *Escherichia coli* O157:H7 outbreak in spinach, see http://www.who.int/foodsafety/fs_management/infosan_archives/en

²⁰ Public health risk is defined in the Regulations as 'a likelihood of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger.'

During the past year, WHO through INFOSAN disseminated information on international food safety events, on average, 1.25 times per month.

The different provisions of the IHR(2005) relating to the identification and management of public health risks and events have application across a wide range of situations, the vast majority of which will never be determined to constitute a public health emergency of international concern (PHEIC)^{22,23}.

National Response

The approach the IHR(2005) is for early detection and efficient communication in respect of public health events so that a timely assessment can be made regarding necessary response measures. The IHR(2005) require countries to develop and maintain their own response capacities²⁴ and in addition, places obligations upon WHO to provide support to national response activities when required to do so. The nature of such support will vary considerably depending on a wide range of factors including the existing capacity of the national agencies, the level of international threat and the availability of expertise and resources. Additional technical and operational assistance to support national authorities may be coordinated through the Global Outbreak Alert and Response Network (GOARN) mechanism. GOARN is a technical collaboration of existing institutions and networks that pool human and technical resources to support the rapid identification, confirmation and response to outbreaks of international importance²⁵.

The IHR(2005) calls upon WHO to work with its sister organizations, including FAO and OIE. FAO has an ongoing technical assistance programme to build capacity in the field of food safety and quality at national and regional level. FAO has also strengthened its capacity to react to emergency situations and support response at national and regional levels through the establishment of the Crisis Management Centre (CMC).

Point of entry (obligations/rights)

The IHR(2005) contain provisions relating to public health measures applied during the international movement of persons, goods and conveyances. These measures are often applied at international ports, airports or ground border posts (referred to as 'points of entry'). Many of these provisions have the potential for application in the context of food safety.

Further guidance

FAO and WHO are developing food safety emergency response guidelines. Training courses on food safety emergency response are also been planned and will be announced on the INFOSAN web site and relevant WHO Regional Office web sites. A bibliography of documents aiding implementation of the IHR(2005) is being developed and will appear on WHO's International Health Regulations web site: <http://www.who.int/csr/ihr/en/>. This bibliography includes relevant food safety publications.

²¹ See IHR(2005) Article 11.1

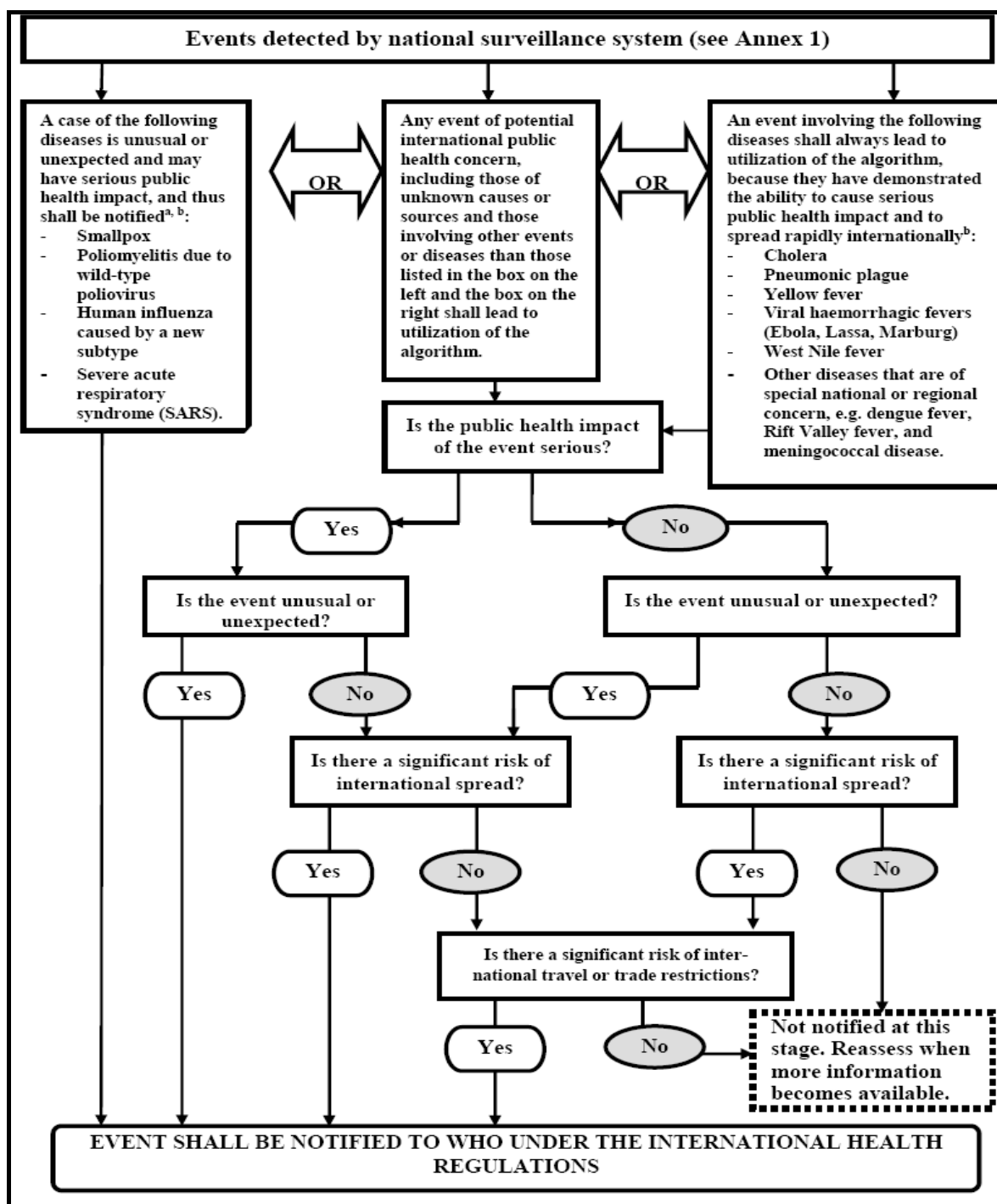
²² PHEIC is defined in the Regulations as 'an extraordinary event which is determined, as provided in [the] Regulations: (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response.'

²³ See IHR(2005) Article 12

²⁴ See IHR(2005) Article 13

²⁵ For more information see <http://www.who.int/csr/outbreaknetwork/en/>⁵

Appendix 1: ANNEX 2 of the IHR(2005) Decision Instrument for the assessment and notification of events that may constitute a public health emergency of international concern.



a As per WHO case definitions.

b The disease list shall be used only for the purposes of these Regulations (IHR(2005)).

INFOSAN serves as a vehicle for food safety authorities and other relevant agencies to exchange food safety information and to improve collaboration among food safety authorities at both the national and international level.

INFOSAN Emergency, embedded in INFOSAN, links official national contact points to address outbreaks and emergencies of international importance and allows for the rapid exchange of information. INFOSAN Emergency is intended to complement and support the existing WHO Global Outbreak Alert and Response Network (GOARN).

INFOSAN is operated/managed by WHO, Geneva. It currently includes 154 Member States.

More information is available at: www.who.int/foodsafety