



Guiding principles

**For response to public health threats
related to communicable diseases
and diseases of unknown origin,
at EU level**

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Glossary

EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
ELDSNet	European Legionnaires' Disease Surveillance Network
EMA	European Medicines Agency
EPIS	Epidemic Intelligence Information System
EU	European Union
EWGLINET	European Working Group for Legionella Infections Network
EWRS	Early Warning Response System
FWD	Food- and Waterborne Diseases and Zoonoses
INFOSAN	International Food Safety Authorities Network
IHR	International Health Regulations
MS	EU Member State
OAT	Outbreak Assistance Team
RASFF	Rapid Alert System for Food and Feed
SANCO C3	SANCO – Directorate General for Health and Consumer Protection, of the European Commission C3 - Unit for health threats under Public Health and Risk Assessments
TESSy	The European Surveillance System
WHO	World Health Organization

Introduction

The Parliament and Council Regulation 851/2004 establishing a European Centre for Disease Prevention and Control (ECDC) called for an effective response to disease outbreaks through a coherent approach among Member States and input from experienced public health experts, coordinated at Community level. The core mandate of ECDC is “to identify, assess and communicate current and emerging threats to human health from communicable diseases.” (Article 3.1).

In April 2006, a first consultation was called among the Member States (MS) in order to define the role of ECDC in outbreak investigation and response in various contexts, including multi-MS outbreaks and outbreaks outside the European Union (EU). One of the conclusions of this consultation was the need to develop guiding principles on the role of ECDC in supporting outbreak response, considering the particularities of different transmission modes or pathogens.

It was decided that the development of such guiding principles would involve two stages: 1) the first would focus on a generic framework for outbreak response, providing the basis for the development of any other response guiding principles, focusing on specific diseases; 2) in a second stage, a series of disease-specific principles would be developed, addressing the particularities for the response to that disease.

Hence, the current document will function as a dynamic reference, distinguishing a first generic part that is applicable independent from the pathogen causing the event, and a second part that addresses disease-specific particularities to be considered in the response to the event.

Objective and context of this document

The objective of this document is to provide an established series of steps at the EU level on the response and actions undertaken in case a communicable disease related public health alert threatening the EU has been identified and needs to be further investigated. The document is targeted as information to the main stakeholders as identified in this document. It clarifies the procedures undertaken by ECDC in response to the threat, carried out in collaboration and agreement with main stakeholders. The context of the document is defined by health threats of European importance putting at risk EU MS, or those outside the EU borders but potentially affecting the European Community, and specifically addresses the added value that ECDC can bring in such situations.

Regarding the disease-specific guiding principles, food- and water-borne diseases and zoonoses and travel-associated Legionnaires' disease are addressed as the first applications of the generic framework. These two groups were chosen as they represent the most frequent type of threats ECDC has been dealing with.

PART I: Generic framework for the response to public health threats at EU level

1. Objective

The purpose of the generic framework for threat response is to ensure that public health alerts caused by communicable diseases and threatening the EU are investigated and controlled in an effective and coordinated manner. While the frontline response to these events is ensured by the MS, ECDC can provide an added value with regards to supporting the risk assessment component of European level response activities. The generic framework provides the guiding principles for action for ECDC and key stakeholders involved in response activities at European level.

Therefore, the target audience of this document is mainly the ECDC competent bodies¹ for response in the EU MS, the European Commission and ECDC, and any other stakeholders that take on an active role in response activities following a public health threat event with an EU dimension (see point 2. EU stakeholders for response).

In this document, we describe how the response to health threats consists of all activities implemented by stakeholders for containment and mitigation of the threat. Therefore, response activities encompass risk assessment activities – such as investigating the threat to identify options for control, risk management, consisting of the implementation of control measures, and risk communication. Response starts with the recognition by one EU MS that an event may represent a threat to one or more MS and the issue of a message on the early warning and response system (EWRS). While the ECDC mandate covers only risk assessment, risk management is the prerogative of MS, supported by the coordination of the European Commission. Upon request, ECDC can have an advisory and supporting role in risk management.

A schematic overview of the response steps is given in Annex 1.

2. EU stakeholders for response

The ECDC Founding Regulation mandates ECDC to ensure comprehensive, coherent and complementary actions with those of key stakeholders at European level.

The main actors involved in response to public health events with infectious disease dimension within the EU are the following:

- **Member States**

As the essential players within the Community network for the epidemiological surveillance and control of communicable diseases, the MS have the primary responsibility for response to communicable disease outbreaks within their national boundaries. When MS assessment shows a potential risk for spread in the EU, they should inform each other through the EWRS in order to allow for the coordination of public health measures. In an outbreak situation, a distinction is made between the MS that are directly affected by the outbreak or those at immediate risk for exposure, and the MS for which no immediate risk is identified but who are also interested in the progress of the response to the outbreak.

- **European Commission – SANCO C3**

The European Commission has a mandate for risk management, i.e. the coordination of the implementation of control measures in response to an outbreak situation of European importance. It also provides for the coordination of the whole Community network for epidemiological surveillance and control of communicable diseases in collaboration with the MS. Through the appropriate communication channels (e.g. EWRS) it ensures e.g. the implementation of control measures, as well as a regular flow of information among MS.

¹ The ECDC Competent Bodies have been defined by the Management Board of December 2007: http://ecdc.europa.eu/en/About_us/Organisation/Competent_bodies/Default.aspx

The Commission, through implementing measures, establishes (1) the list of diseases to be covered by epidemiological surveillance within the Community network as well as (2) criteria for selection of these diseases, and (3) case definitions. It also determines (4) the nature and type of data and information to be collected and transmitted by public health authorities and other structures designed by them as well as (5) ways in which such data are to be made comparable and compatible, (6) epidemiological and microbiological surveillance methods, (7) guidelines on information and guides to good practice for public, and (8) the appropriate technical means and procedures by which the data will be disseminated and analysed at the Community level.

- **European Centre for Disease Prevention and Control (ECDC)**
ECDC is mandated to provide scientific and technical expertise at EU level within risk assessment and can provide, upon request, technical support to the European Commission and MS in their tasks of threat management. The scientific and technical expertise may be also requested by a third country, including the EU candidate countries, or by international organisations such as the World Health Organization (WHO).
- **European and international networks**
European-funded networks (e.g. dedicated surveillance networks) or projects, as well as international networks (e.g. Global Health Security Action Groups), may play a role in the outbreak response, depending on the cause of the outbreak.
- **European agencies**
Depending on the focus of the outbreak response, other European agencies (e.g. EFSA, EMA) may be involved in the response activities.
- **International Organisations – World Health Organization**
ECDC primarily channels contacts with WHO through the regional office for Europe (WHO/EUR). The context of the outbreak will determine the nature of the collaboration between the two agencies:
 - For outbreaks affecting only EU MS, WHO is kept informed at each step of the response;
 - For outbreaks affecting EU MS and involving at least one non-EU MS, WHO plays a central role in ensuring optimal coordination with these third countries.

The revised international health regulations [IHR(2005)] play an important role in the MS and ECDC's preparedness and response for outbreaks with an international dimension.

3. Trigger for an EU response

EU Member States are routinely assessing communicable disease events occurring within their country for potential public health threats requiring response measures. Each of these threats is also assessed by the MS against the notification criteria of the Early Warning and Response System (EWRS) (Decision 2119/98/EC and 2000/57/EC¹) to identify potential risk of spread to other EU MS.

According to Article 1 and Annex 1 of Decision 2000/57/EC the events to be reported within the early warning and response system are:

- Outbreaks of communicable diseases extending to more than one MS;
- Spatial or temporal clustering of cases of diseases of a similar type, if pathogenic agents are a possible cause and there is a risk of propagation between MS;
- Spatial or temporal clustering of cases of disease of a similar type outside the EU, if pathogenic agents are possible cause and there is a risk of propagation to the EU;

¹ http://ec.europa.eu/health/ph_threats/com/early_warning_en.htm

- The appearance or resurgence of a communicable disease or an infectious agent which may require timely coordinated EU action to contain it;
- Manifestation of a disease or an occurrence that creates a potential for a public health emergency of international concern as defined by the new International Health Regulations (2005) and related measures to be notified to the World Health Organization under the International Health Regulations (2005).

The procedures for the exchange of information indicating an event are described in annex II, section 1 (related to EWRS notification level 1). The procedures for an event with the potential to become a public health threat (level 2), or when an event is definitely a public health threat (level 3), are described in annex II of Decision 2119/98/EC, in section 2 and 3, respectively. The procedures to be followed for information to be provided to the general public and the concerned professions are described in annex II, section 4. A list of operative criteria for the identification and reporting of events within the EWRS of the Community Network for the surveillance and control of communicable diseases, have been agreed upon in annex I of decision 2000/57/EC.

Level 1 EWRS messages are considered individually on whether or not a European level threat assessment is relevant. In contrast, level 2 and level 3 EWRS messages, indicating a potential or definite threat to the EU on the basis of the issuing MS threat assessment, are automatically regarded as a trigger for an EU coordinated response, and should therefore result in:

- Other MS to carry out a preliminary threat assessment at national level;
- ECDC to issue an assessment of the extent of the risk for the EU population;
- EC to coordinate the implementation of threats/risk management of the event at Community level, including coordination of public health measures.

Alternatively, if ECDC is aware of an event in the EU or outside the EU which could be relevant for, or have an impact on EU level, it will contact the concerned Member State(s) and the European Commission in order to ensure a message is posted through the EWRS¹.

4. Initial threat assessment for the EU

Following the notification of an EWRS early warning message of level 2 or level 3, ECDC activates an internal response team which liaises with EU stakeholders to complete the initial threat assessment for the EU. In particular, the concerned MS is informed from the start that a threat assessment will be prepared, and is involved in its finalisation. The objective of this initial threat assessment is to gain a perspective of the extent of the risk at European level posed by the notified event.

The initial threat assessment for the EU is a short document (2 pages maximum), to be delivered to the Commission within an agreed delay, and providing the main background elements (e.g. descriptive epidemiology) and the extent of the risk for the EU. A structure of the initial threat assessment document is provided in annex 3, page 13.

The draft initial threat assessment is shared with the directly concerned ECDC Competent Bodies for Response; if considered relevant, it is shared with all MS and/or with the ECDC Advisory Forum. Finally, the threat assessment is communicated to the European Commission (SANCO C3 duty officer) which posts it to the EWRS.

¹ In case of an emergency situation, the consultations foreseen with different ECDC partners may be abandoned.

5. EU threat action plan

Following the circulation of the ECDC initial threat assessment through the EWRS, the Commission may call a EWRS teleconference to assess the need for coordinated measures in the EU and to prepare a MS, ECDC and EC joint plan of action for response to the public health alert, therefore covering risk assessment and risk management issues.

To ensure a coordinated approach, a European ad hoc response team is created, with participation of the main stakeholders (with as a minimum: affected MS, ECDC, SANCO C3) (see annex 1). Meetings will often consist of a teleconference with one or more of the following objectives:

- Update on the status of the outbreak investigation – to include epidemiological and microbiological perspective as needed, as well as veterinary and environmental elements;
- Specific attention may be given to the case definition in use, protocols in place for patient management, diagnostics and contact tracing, identification of the population at risk, and measures to prevent new cases;
- Update on the actions taken by all actors – the need for an outbreak assistance team (OAT) can be considered;
- Consideration of when, how and by whom information about the event should be made public. Consideration of media/public opinion risks associated with the event and development of appropriate media messages and/or defensive lines;
- Decision on who takes the lead for the follow-up of the continuous risk assessment related to the outbreak – the coordination role is assigned on a case by case basis, and may be undertaken by e.g., the index country or ECDC;
- The coordination of the actual management of the outbreak is always ensured by the Commission.

The minutes of such meetings as well as the final action plan are shared with all stakeholders through EWRS.

Through a consultative process the affected MS, the Commission, and ECDC agree on the exact extent of ECDC's involvement in supporting response activities, as foreseen in the European level plan of action.

6. Monitoring the EU action plan

As long as the threat is ongoing, ECDC ensures a continuous monitoring of the risk on a European level related to the event, by a constant gathering of updated information through its epidemic intelligence channels, in order to adapt its threat assessment conclusions accordingly.

A loop of monitoring and assessing (see annex 2) is undertaken by the European ad hoc response team in order to provide timely updated threat assessments to the Commission and to MS to support response activities. Reports and information from outbreak assistance teams should also feed back to the ad hoc response team to assist in this task.

Finally, the Commission ensures the monitoring of the public health measures implemented by the MS, in order to coordinate the measures on a European level.

7. Closure of the threat and follow-up

The objective of formally closing the event is to ensure that the health threat is officially declared to be over, and that lessons for improvement on response activities, best practices for prevention and control, and the appropriate follow-up actions are identified. With reference to decision 2000/57/EC, only level 2 and 3 events are to be deactivated through the EWRS, by the Member State who issued the initial EWRS message.

When considered useful, the lessons learnt are documented and shared with all involved actors. At national level, MS may wish to produce the lessons learnt related to this event, including those

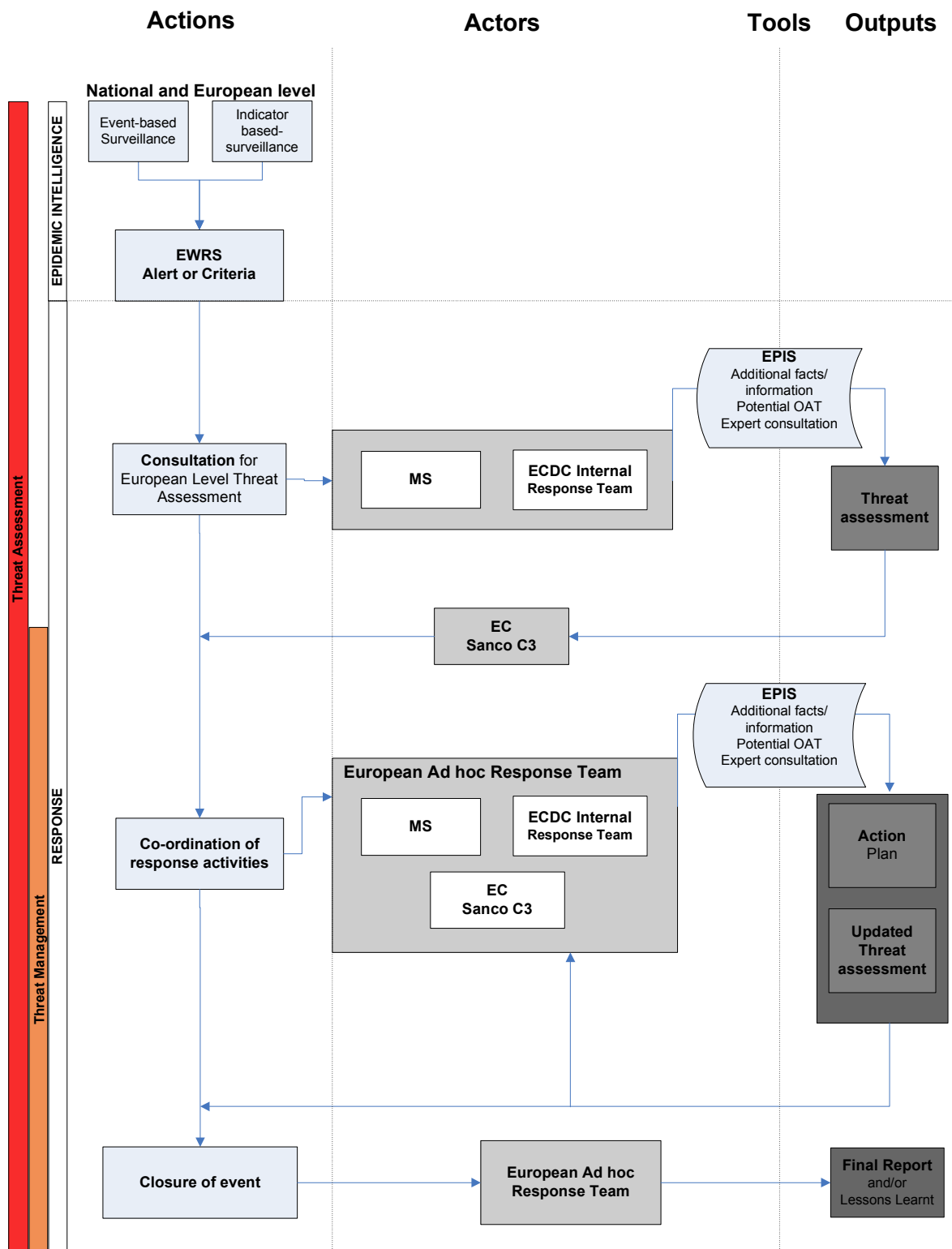
related to the international collaboration aspects. ECDC, in collaboration with the European ad hoc response team, will perform the development of lessons learnt at EU level. Within ECDC, this lessons-learned report can serve for further related activities, such as the building of an “outbreak surveillance database” for long term follow-up of outbreaks and clusters, or training etc. This internal lessons learnt report will be prepared in consultation with the concerned MS and the Commission, and may be shared with other MS upon agreement with the MS directly involved.

Involved stakeholders might decide to recommend on post-outbreak studies to refine the scientific knowledge and information. Any of the involved actors (including ECDC) may decide to provide public communications with relation to the international public health event. This may be in form of reports, scientific publications, website communications, training materials, etc. All publicly available communication is coordinated with all stakeholders beforehand.

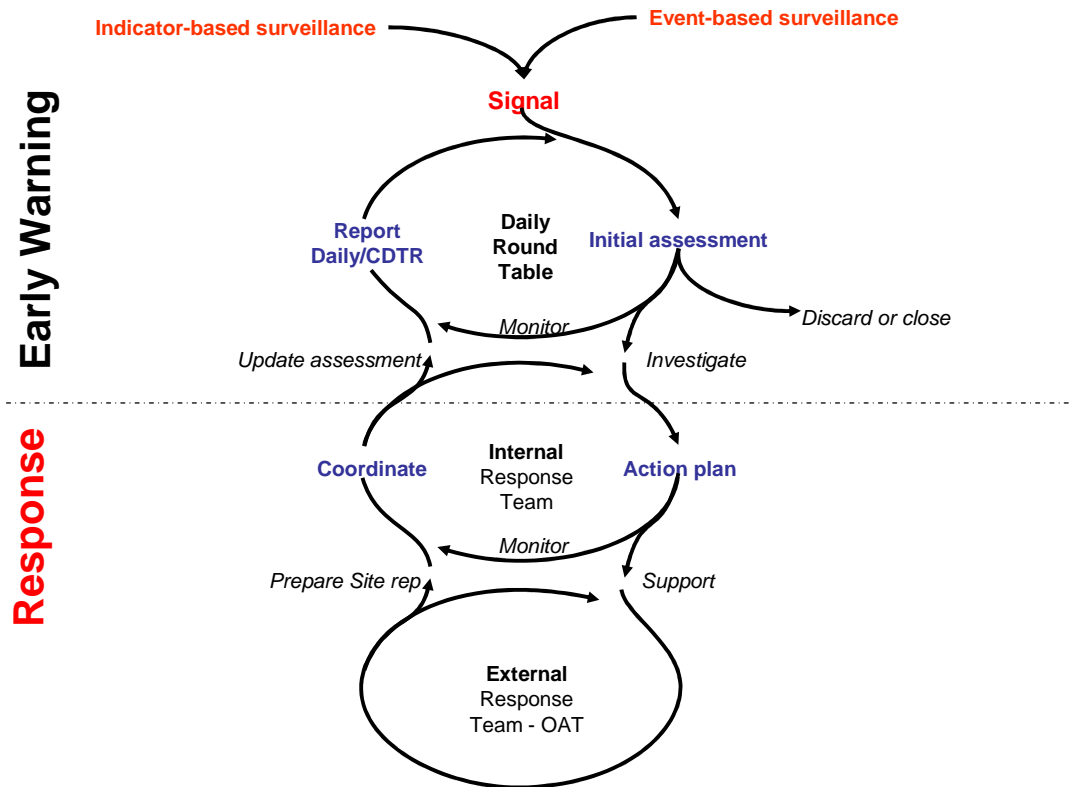
8. Communication

For the duration of the response activities, internal and external communication needs to be ensured. Within the European ad hoc response team, regular situation updates need to be provided, in particular when the threat assessment is updated during the response activities. In addition, adequate and timely communication with the general public is ensured. Such communication is coordinated with the Member States and with the European Commission, according to the applied standard operating procedures. In particular, the link between ECDC, the Competent Bodies for Response and the Competent Bodies for Health Communication, when planning publications on threat assessments, needs to be ensured.

Annex I.1. Steps in response to a public health threat at EU level



Annex I.2. Early warning and response loop



Annex I.3. Structure of a threat impact assessment

ECDC Threat Impact Assessment

<Title describing the event>

Source and date of request

Public health issue

<Summary of the public health issue to be assessed, such as exposure to co-travellers, risk for further local transmission...>

Consulted experts

<List of the experts who were contacted in relation with the threat impact assessment>

Disease background information

<Useful background information on the disease or condition implicated in the threat, and which may provide insight on understanding the rationale for the threat impact assessment>

Event background information

<Summary of the event information>

ECDC rapid scientific advice

<Conclusion of the rapid scientific advice, if requested in the context of this assessment>

ECDC initial threat assessment for the EU

<ECDC assessment of the impact of the threat at EU level>

Conclusions

<List of conclusions resulting from this threat impact assessment>

Contact

support@ecdc.europa.eu

References

<List of useful documents or web site where additional information and evidence can be found >

PART II: Food and Waterborne Disease threats at EU level

1. Objective

The objective of this section is to provide guiding principles for ECDC and for the collaboration with other stakeholders in response activities at the EU level following a Food and Waterborne Disease and Zoonosis (FWD) threat.

While the main principles for response are described in Part I of this document, the current chapter (Part II) is a complement to the generic framework. It provides the specificities of response to a FWD health threat, and does not repeat the general principles. Therefore, in case of a FWD health threat, both documents need to be considered.

2. Specific FWD stakeholders and network arrangements

• The Food- and Waterborne Diseases and Zoonoses (FWD) Network

The ECDC coordinated FWD network is a platform for the voluntary sharing of specific epidemiology and laboratory information as urgent inquiries on suspected clusters or outbreaks of food- or water-borne disease and zoonoses, principally among MS, and some non-EU partners. This network uses the Epidemic Intelligence Information System (EPIS) as its communication tool.

FWD network members include all EU and EFTA/EEA MS, EC, and contact points from the following countries: Japan, Canada, Australia, South Africa, Switzerland, Turkey and New Zealand. WHO is maintained informed by either ECDC or MS if events have potential implications outside the EU.

This network is a continuation of the former Dedicated Surveillance Network 'Enter-net' that was transferred to ECDC in October 2007. Since then, the function of the urgent inquiries is done by ECDC. Any FWD can be notified through the FWD network, although special attention has been paid to *Salmonella* and verocytotoxigenic *E.coli* (VTEC) pathogens.

▪ Other stakeholders in the EU Member States and EFTA/EEA countries

Other stakeholders to be included in the response activities may include:

- Regional and national environmental and/or food authorities who are responsible for investigating outbreaks and investigating premises;
- Regional and national veterinary authorities concerned with zoonoses due to animal exposure.

▪ European organisations and other international networks

Rapid Alert System for Food and Feed (RASFF)

The European Commission coordinates the Rapid Alert System for Food and Feed (RASFF). This is a tool for rapid information exchange between food and feed central competent authorities in the MS in case a risk for human health has been identified in food or feed. It is regulated by EU legislation¹.

European Food Safety Authority (EFSA)

The European Food Safety Authority (EFSA) provides EU risk assessment regarding food and feed safety. It provides also with independent scientific advice and communication on existing and emerging risks in food and feed products.

¹ http://eur-lex.europa.eu/pri/en/oj/dat/2002/l_031/l_03120020201en00010024.pdf

International Food Safety Authorities Network (INFOSAN)

INFOSAN is an International Food Safety Authorities Network co-ordinated by the World Health Organization (WHO)¹, which functions as an information network for the dissemination of important data about food safety issues. INFOSAN Emergency is specifically dedicated to food borne disease outbreaks or food contamination events which may result in a Public Health Event of International Concern under IHR.

PulseNet USA (CDC,US) , PulseNet International (CDC,US) and PulseNet Europe²

The different PulseNet networks have the objective of linking up food, human and animal laboratories with a focus on molecular surveillance, especially in sharing information on pulsed-field gel electrophoresis (PFGE) patterns of major food borne pathogens like *Salmonella* and verocytotoxigenic *E. coli*.

3. Trigger for an EU response

EWRS message

If a EWRS message is posted by a MS, the generic response framework is applied.

Epidemic intelligence information fulfilling EWRS criteria

- Information shared in EPIS by the FWD network does not automatically trigger a EWRS message. If information in EPIS fulfils EWRS criteria and no EWRS has been issued, then ECDC will review the threat and consider the need for a EWRS with affected MS. ECDC may also undertake an initial threat assessment as part of its mandate and share this with the affected MS.
- EWRS criteria are systematically considered when ECDC receives epidemic intelligence information on a FWD threat. If EWRS criteria are met, the MS where the threat originates from is contacted for review and consideration of EWRS notification.

4. Initial threat assessment for the EU

For a FWD threat, ECDC's internal response team is composed, at a minimum, of a person from PRU (co-ordinating) and a representative from the FWD programme. In order to ensure a maximum of information available, the team liaises with:

- **FWD experts** – based on identified needs, MS experts involved in identified threats and disease-specific experts can be invited to participate in an ad hoc forum within EPIS, dedicated to the threat in question.
- **Affected MS** – EU MS reporting the FWD threat or having associated cases, or with the evidenced threat of exposure to suspected contaminated vehicle or product. Contacts are undertaken with the MS FWD contact points and Response Competent Bodies if an EWRS has been issued. The Response Competent Bodies also assist in providing working links with national food and veterinary authorities. EWRS contact points and the Commission are also associated in that activity.
- **RASFF, EC Directorate General for Health and Consumer Protection** – RASFF may be contacted to request information concerning implicated or contaminated food/feed products
- **WHO** – in case the FWD threat originates from, or a suspect product is exported from or to a non-EU country, the WHO contact persons ensure the link with the national authorities of affected non- EU countries. MS may also consider, under an EWRS message, to inform WHO under IHR criteria.

¹ http://www.who.int/foodsafety/fs_management/infosan/en/

² <http://www.pulsenet-europe.org/>

- **European Food Safety Authority** – technical input on regulations or food safety requirements may be requested from EFSA under the initial threat assessment.

5. EU threat action plan

Following the initial threat assessment, the European ad hoc response team is established. This includes the ECDC internal response team, appropriate FWD contacts, and other stakeholders as needed by the European ad hoc team.

If a EWRS teleconference is called to assess the need for coordinated measures in the EU a joint plan of action for response to the FWD threat will be prepared. Experts from the FWD network may be asked to participate as technical experts, although their country may not be affected.

In addition to those listed in the generic framework (section 3), the following specific information or response actions should be considered for the action plan:

- information on outbreak investigations underway for the FWD threat, including epidemiological study and preliminary hypotheses as well as diagnostics undertaken, including typing of human, food, animal or environmental strains, in particular molecular typing results;
- assess the need to request and share additional typing information among the FWD network to assist in identifying the extent of cluster/outbreaks in Europe and among other appropriate networks to identify links to a potential food/animal exposure;
- assess the need for expert assistance in undertaking outbreak investigation, environmental investigation, sharing of laboratory diagnostics or advice on control measures;
- implemented control measures against the implicated food or product or water distribution or production source by the affected MS;
- indicate whether a RASFF alert has been issued on the implicated product, including whether implicated product has been exported to another country and/or been removed from the market;
- information about the event – awareness of whether the event has been brought to the attention of the public, and if brands or company names are known to the public;

Minutes of these meetings are prepared by the ECDC internal response team and shared with all meeting participants.

6. Monitoring the EU action plan

In its continuous monitoring of the risk on a European level related to the event, regular contact is maintained with the FWD network in affected countries and other implicated contact points, in order to adapt the threat assessment conclusions accordingly. As appropriate, information and updates are also shared with MS, the Commission and WHO.

The FWD network and FWD programme continues to inform the European ad hoc response team on further related notifications or updates on the outbreaks, in a timely manner.

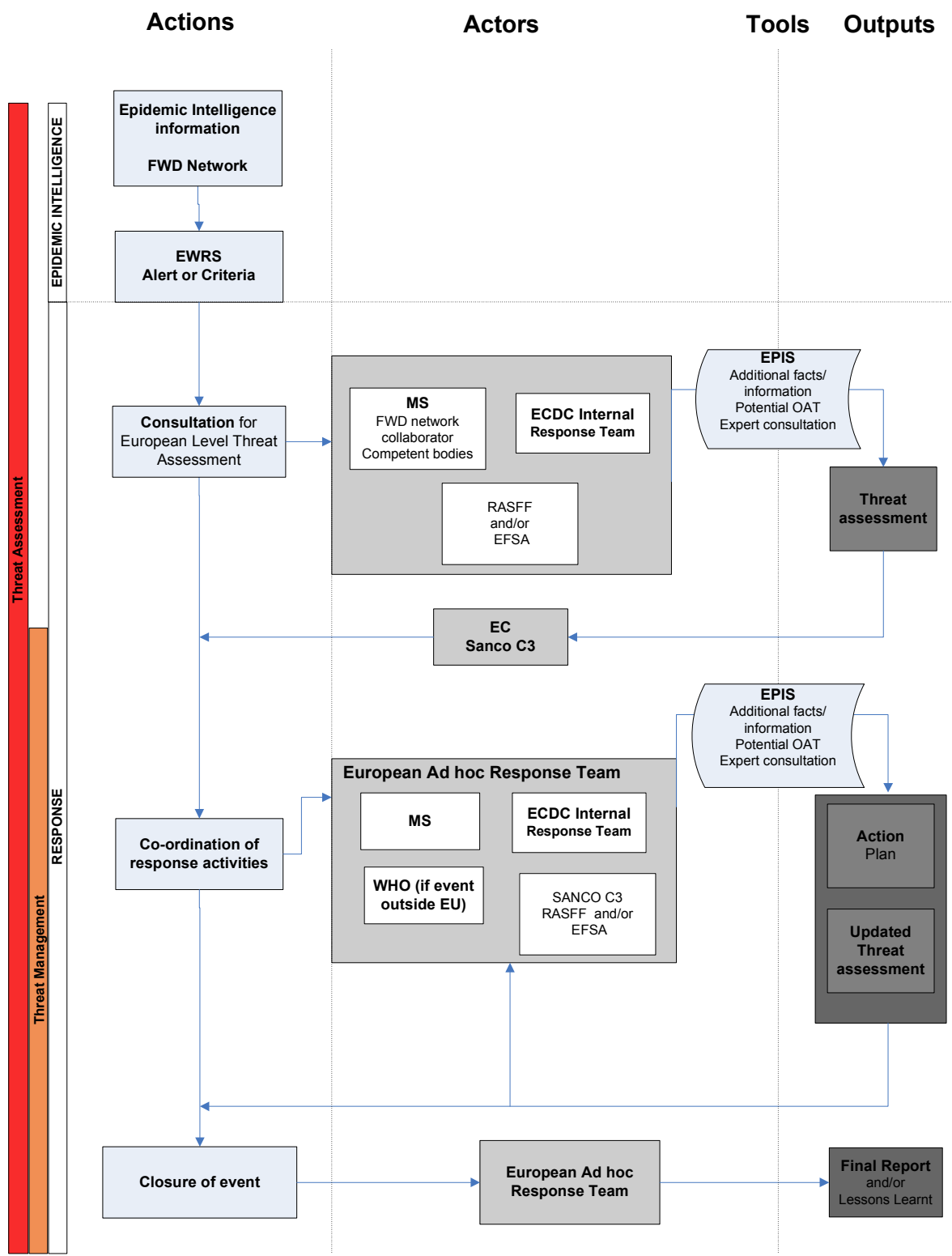
7. Closure of the threat and follow-up

At the EU level, the decision of closing the event is taken by either the Member State who issued the initial EWRS message in closing the threat in the EWRS system, or if the event originated from epidemic intelligence information to ECDC, the decision of closure of the threat is taken by the Commission on the basis of the ECDC assessment done by the European ad hoc response team.

8. Communication

Information to the public on ECDC web site is co-ordinated with the affected MS, through the health communication unit and ECDC internal response team. Affected MS may want to communicate the event through appropriate channels, e.g. Eurosurveillance or any other scientific journal and thus, ECDC shall take this into account in the potential communication to the public. ECDC will act in close collaboration with MS and the Commission to promote the necessary coherence in the risk communication process.

Annex II.1. Steps in response at EU level to a FWD threat



PART III: Travel-Associated Legionnaires' disease threats at EU level

1. Objective

The objective of this section is to provide the guiding principles for ECDC and for the collaboration with stakeholders in response activities at the EU level following a Travel-Associated Legionnaires' Disease (TALD) threat. Other Legionnaires' disease threat events in the EU could include a community outbreak in a MS (e.g. by a cooling tower source) in which EU citizens from other MS visiting the affected area may have been at risk. In such cases, a EWRS message maybe considered by the MS and response would be initiated as under the generic framework (Part I). A notification of travel-associated legionellosis cases is likely to be issued through the "European Legionnaires' Disease Surveillance Network" (ELDSNet), for which coordination has been transferred to ECDC in April 2010. The network has a key role to assist in the assessment and investigation of the event.

While the main principles of response are described in Part I of this document, the current chapter under Part II is a complement to the generic framework. It provides the specificities proper to the response to a TALD health threat, and does not repeat the general principles. Therefore, in case of a TALD health threat, both documents need to be considered.

2. Stakeholders and specific network arrangements

- **ELDSNet**

The previous ECDC funded EWGLINET network (as of 1 April 2010 ELDSNet, and from this point onwards called as such) carries out the epidemiological surveillance and coordinated response for TALD cases in the EU. ELDSNet operates according to guidelines that apply to all EU MS participating in the scheme¹.

The network contributes to the identification of TALD clusters in the EU/EEA as well as in non-EU/EEA countries, through the reporting of single TALD cases by the MS to The European Surveillance System (TESSy) held at ECDC. A TALD cluster is defined as two or more cases who stayed at or visited the same accommodation site in the two to ten days before onset of illness and whose onset is within the same two-year period. Notifications of identified clusters are then reported back to MS network members.

According to the standard operating procedures of the European Guidelines, the country where the TALD cluster is related to is asked to undertake an accommodation site risk assessment by their appropriate authorities to assess any current risk to guests.

Results by investigating authorities are coordinated by the ELDSNet network member and communicated to ECDC through risk assessment Forms A and B, under the agreed actions of the network.

If the forms are not suitably completed or returned, ongoing risk for exposure to *Legionella* at the implicated accommodation site is considered not known and the name of the accommodation site published on the ECDC/ELDSNet public website.

- **EU Member States, EFTA/EEA countries and candidate countries**

Within MS or other collaborating countries, in addition to the nominated ELDSNet microbiology and epidemiology country collaborators, stakeholders include the local or national environmental authorities who are responsible for investigating environmental risk for *Legionella* infection.

¹ The European Guidelines for Control and Prevention of Travel Associated Legionnaires' disease (2002).

- **Third countries**

In some occasions, especially if the cluster/outbreak occurs outside the EU and there is no national collaborator in ELDSNet, Ministries of Health in the respective countries may be stakeholders during the investigation and control activities. They are informed through collaboration with WHO.

- **International and other organisations**

WHO

WHO is informed of clusters detected through the ELDSNet concerning accommodation sites located outside the EU or EFTA/EEA countries. Under the guidelines, WHO then informs the national authorities of the country related to the detected cluster.

Tour operators

ELDSNet shares TALD cluster notifications with tour operators when:

- there is a cluster of 3 or more cases with onset within three months, therefore presenting a continuing risk of exposure;
- the cluster notification involves a site outside of ELDSNet member network or if the ELDSNet collaborator is not officially using the European guidelines.

3. Trigger for an EU response

EWRS message

If a EWRS message is posted by a MS, the generic response framework is applied.

Epidemic intelligence information fulfilling EWRS criteria

The issuing of a TALD cluster does not automatically trigger a response and a EWRS message. A message in EWRS by a MS concerning a TALD cluster remains the decision of the MS under its reporting requirements.

From a European response perspective, upon the identification of TALD clusters, ECDC applies the following criteria:

- If the number of Legionnaires' disease cases associated with the same accommodation site, suggests 1) a rapidly evolving problem and 2) that there is an ongoing risk for the guests, the added value for an EU level response is considered. In general, a rapid evolving situation can be considered to correspond to three or more cases with dates of onset within a time span of three months associated to the same accommodation site.

4. Initial threat assessment for the EU

For TALD clusters, ECDC's internal response team liaises with:

- **Affected MS** – EU MS and EEA/EFTA countries reporting the *Legionella* cases through the ELDSNet MS network. If an EWRS is issued, contacts will be made with the Response Competent Bodies or specific EWRS contact point and the MS ELDSNet country collaborator; EWRS contact points and the Commission are also associated in that activity.
- **Tour operators** – those who have guests at the implicated accommodation site may be able to provide more detailed information on the local risk assessment and on the measures implemented. Contact with the tour operators generally goes through the affected MS Competent Bodies but can also occur directly as an established stakeholder registered with ELDSNet;
- **WHO** – in case the TALD cases are reported from a country outside the network, links with the national authorities can be established through WHO.

The threat assessment may be shared with parts of the ELDSNet group before circulating through the EWRS.

5. EU threat action plan

If a EWRS teleconference is called to assess the need for coordinated measures in the EU and to prepare a joint plan of action for response to the public health alert, members of the ELDSNet network will be called upon to join, as well as potential other technical experts.

The European ad hoc response team includes appropriate ELDSNet members of the affected MS.

In addition to those listed in the generic framework, the following specific information or response actions should be considered during response team meetings or teleconferences:

- local risk assessments undertaken for *Legionella* bacteria, completion of Form A and Form B under the ELDSNet scheme for TALD clusters;
- implemented control measures against *Legionella*;
- the need for expert assistance in undertaking site risk assessment or outbreak investigation, with particular attention to the environmental investigation;
- diagnostics undertaken, including samples taken for culture or any other laboratory methods (e.g. urine antigen test, serology or PCR) of any human or environmental specimens to identify *Legionella* species, sero-group and even strain;
- consider the need for informing previous, current and future guests, identified to have been or who may be at risk from the implicated *Legionella* source;¹
- information about the event – whether an implicated accommodation site name is in the public media, or whether the site name will be published on the ECDC/ELDSNet website (when European Guidelines criteria met).

Minutes of these meetings are prepared by the ECDC internal response team and will be shared with the European ad hoc response team and any other meeting participants.

6. Monitoring the EU action plan

In its continuous monitoring of the risk on a European level related to the event, regular discussion is maintained within the European ad hoc response team, in order to adapt the threat assessment conclusions accordingly. As appropriate, information and updates (cluster notification updates) are also shared with the ELDSNet members, the MS, the Commission, and WHO and major stakeholders such as tour operators.

Further related notifications or updates on the TALD cluster alert continue to be monitored by ECDC, and communicated as needed in a timely manner.

7. Closure of the threat and follow-up

The decision of closing the event is taken by the Commission on the basis of ECDC assessment done by the European ad hoc response team or, in the event of a EWRS, through the MS issuing the EWRS via closing the EWRS in the notification system.

8. Communication

Situation updates and information to the public are coordinated at ECDC through ELDSNet with the affected MS. ECDC will act in close collaboration with MS and the Commission to promote the necessary coherence in the risk communication process.

¹ Meeting report: ECDC Consultation on Response to Travel Associated Legionnaires' Disease cluster alerts, Stockholm, 26 October 2007.

Annex III.1. Steps in response at EU level to a TALD threat

