



The EU health security framework on serious cross-border health threats

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DG SANTE C3 – Crisis management and preparedness in health

Best practices in implementing the International Health Regulations (IHR)

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The EU health security framework

1998

- **Decision 2119/98/EC of the European Parliament and of the Council set up a network for the epidemiological surveillance of communicable diseases**

2001

- **EU Health Security Committee (informal) - Anthrax in US**

2005

- **European Centre for Disease Prevention and Control**

2005

- **International Health Regulations (IHR) - All-inclusive threats approach; core capacities – entered into force in 2007**

2009

- **Lisbon Treaty – Article 168 – Monitoring, early warning of and combating serious cross-border threats to health**

2013

- **Decision 1082/2013/EU of the European Parliament and of the Council on serious cross-border threats to health**



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Decision 1082/2013/EU on serious cross-border threats to health

- **Public health emergencies at EU level are managed under the health security framework of Decision 1082/2013/EU**
- **Provides for a comprehensive and coordinated approach for preparedness, early warning, risk assessment and crisis response**
- **Supports Member States to fight cross-border health threats such as communicable diseases, but also chemical, environmental and unknown threats**

Origins of threats



Biological¹



Chemical



Environmental



Unknown



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Structures and mechanisms

Network for
epidemiologic
surveillance

EWRS – alert
system

Health
Security
Committee,
and working
groups

Capacity
building and
technical
assistance
through
Health
Programme

Commission
internal
mechanisms
for crisis
coordination
and response

Epidemiological surveillance

- **Communicable diseases are permanently monitored** by the European Centre for Disease Prevention and Control (ECDC)
- **Network for the epidemiological surveillance** of communicable diseases and of related special health issues:
 - Brings into **permanent communication** the Commission, the ECDC and national competent authorities.
 - MS to communicate **comparable and compatible data** on **47 notifiable diseases** and special health issues (AMR/Healthcare Associated Infections) using EU case definitions
- **New implementing act to be adopted** - will include new (re)emerging diseases, and revised case definitions for several communicable diseases and related special health issues.



Early Warning and Response System (EWRS)

- **Enables the Commission and the national competent authorities to be in permanent communication** for the purposes of: a) alerting; b) assessing public health risks; and c) determining the measures that may be required to protect public health
- **Rapid alert system for notifying alerts in relation to serious cross-border threats to health** that are unusual or unexpected for the given place and time, or cause significant morbidity or mortality, or it grows rapidly in scale; or exceed national response capacity; it affects more than one MS; and require coordinated response at Union level
- **Notification within 24 hours** from when MS became aware of the threat
- **Link to the International Health Regulations notification**



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Examples of serious cross-border threats

Biological threats

- **Communicable diseases**
- **Antimicrobial resistance and healthcare-associated infections related to communicable diseases**
- **Biotoxins or other harmful biological agents not related to communicable diseases**

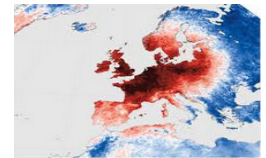
• *Including alerts on chikungunya, malaria, dengue, measles, hepatitis A, drug-resistant Tuberculosis, Salmonellosis, botulism, influenza, yellow and lassa fever, meningitis, Legionellosis, poliomyelitis, cholera, histamine poisoning, etc; including major outbreaks e.g., Ebola, MERS CoV, poliomyelitis, Zika*



Chemical and environmental threats

- Heat wave (2003)

70,000 excess deaths in 12 MS hospitalization and intensive care of elderly



- Volcanic ash clouds (2010)

Risk of exposure affecting persons with respiratory diseases; interruption of transport etc.



- Red Aluminium sludge spill in Hungary and in Danube (2010)

8 deaths, 130 cases of burn injuries, cross border impact on the environment



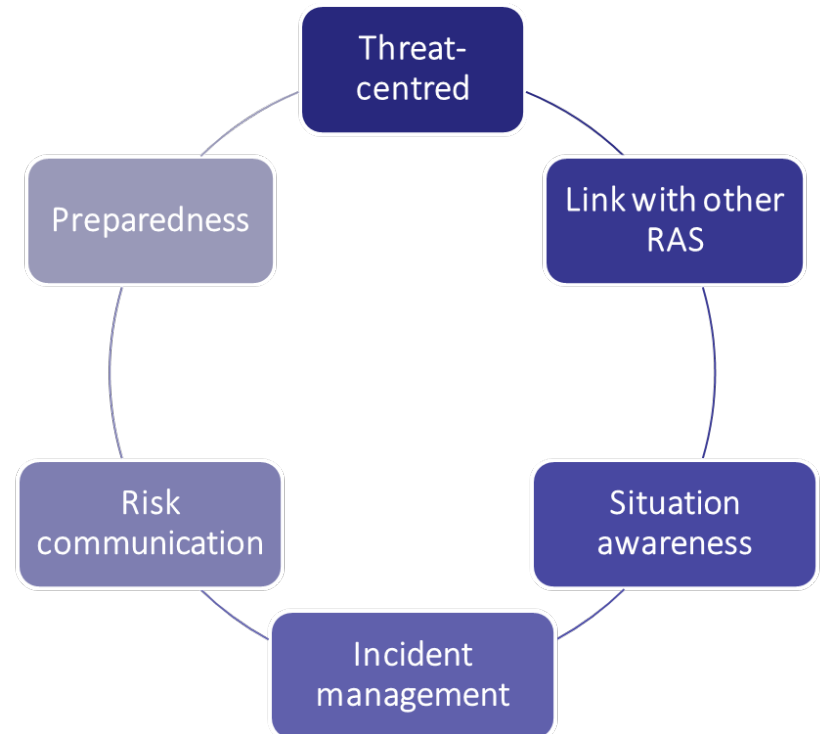
• Other alerts:

- Food poisoning linked to malathion
- Chemical explosion in China

EWRS update

The remodelled EWRS will include modules to:

- Support efficiently the **detection and management of serious cross-border threats to health**;
- **Link to other EU rapid alert systems (RAS)**;
- Provide access to **contextual information** allowing an informed assessment and coordination of response;
- Ensure appropriate **flexibility** through a modular architecture to adjust to future changes





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Risk Assessment

For the coordination of response the Commission, where necessary, makes available to the Member States risk assessment **of the potential severity of the threat**, including possible **public health measures**



Communicable diseases

Food safety

e.g. Chemical threats



NATIONAL COMPETENT AUTHORITIES

Health and Food Safety

RAPID RISK ASSESSMENT

Outbreak of plague in Madagascar, 2017

9 October 2017

Main conclusions and options for response

Since 23 August 2017 Madagascar has been experiencing an outbreak of plague, and as of 3 October 2017, 194 cases and 39 deaths (case fatality rate 20.1%) have been reported. Of these cases, 124 cases are pneumonic plague including 23 deaths, 69 are bubonic plague, including nine deaths, one is a septicemic plague and one is an undetermined plague case. The cases are from 20 central, eastern and northern districts in Madagascar.

RAPID RISK ASSESSMENT

Risk related to the use of 'do-it-yourself' CRISPR-associated gene engineering kit contaminated with pathogenic bacteria

2 May 2017

Conclusions

On 24 March 2017, the German authorities reported the contamination of a 'do-it-yourself' bacterial gene engineering (CRISPR) kit produced in the US. The kit was contaminated with pathogenic bacteria (risk group 2), including some bacteria that are multi-drug-resistant and ESBL-producing. The kits are sold online and target non-professional users. The kit was declared by the producer to contain a harmless 'non-hazardous and non-pathogenic' laboratory strain of *E. coli* and to be safe for home use.



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Coordination of responses

- **MS to consult each other within the Health Security Committee (HSC) and in liaison with the Commission to coordinate:**
 - **national responses** to serious cross-border threat to health
 - **risk and crisis communication**, to the public and to healthcare professionals.
- MS to inform about their **intention to adopt measures** unless so urgent that immediate adoption is necessary.
- MS may request **assistance** from other MS **through the Civil Protection Mechanism** if threat overwhelms national capacity

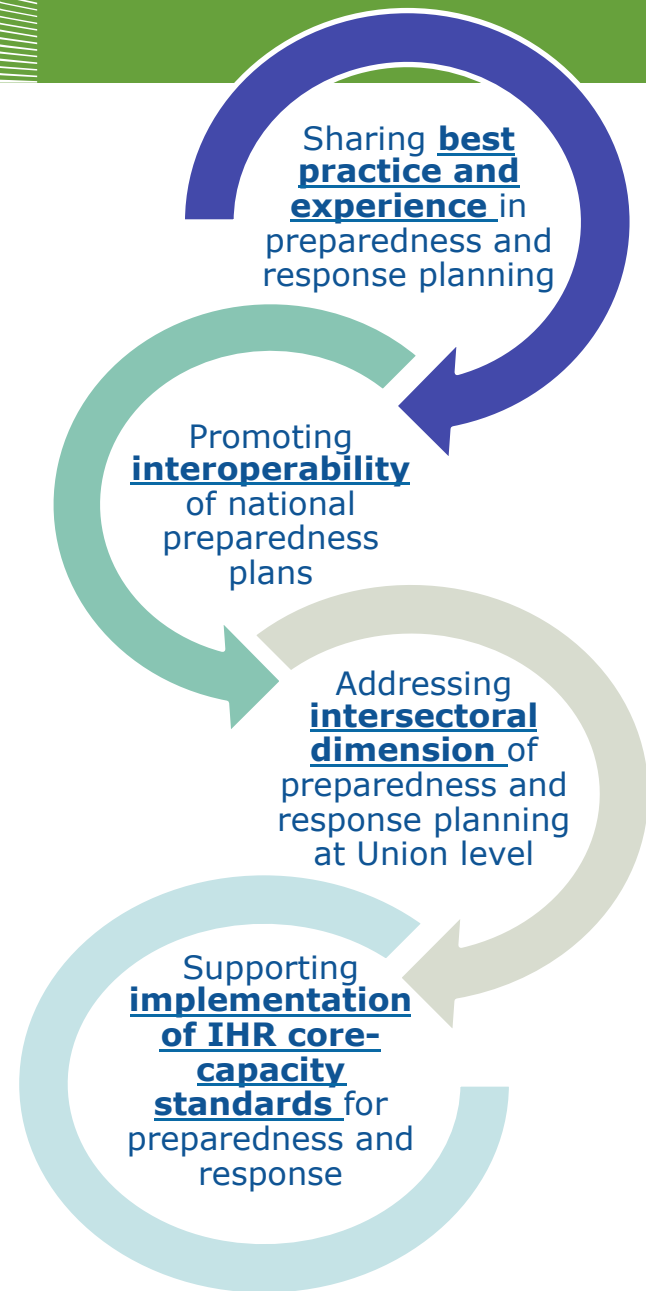


- **Existed as informal group established on the basis of 2001 Council Conclusions on bioterrorism**
- **Consists of MS representatives, with candidate countries as observers, ECDC and WHO, plus other bodies when relevant - chaired by the Commission**
- **Permanent working groups** on preparedness and communication, ad-hoc working groups

Preparedness

Article 4 - aims at ensuring **adequate coordination** between MS for a **consistent level of preparedness** and **interoperability** between national preparedness and response plans.

MS and the Commission shall consult each other within the HSC **to coordinate efforts** to develop, strengthen and maintain their **capacities for effective monitoring, early warning and assessment of and response** to serious cross-border threats to health aiming at:





Capacity building and technical assistance

Commission supports MS to improve preparedness and response capacity through the **Health Programme**:

- **Organisation of exercises, workshops and trainings**
 - *Inter-sectoral table-top exercise on hybrid threats, 30-31 January*
 - *Workshops on preparedness and IHR implementation, 1st workshop, 25-27 April*
 - *Inter-sectoral table-top exercise on business continuity planning during a pandemic, Q3 2018*
 - *Training on best practices regarding entry and exit screening (Q3 2018)*
- **Co-financing Joint Actions (JA)**
 - *JA on preparedness and action at points of entry*
 - *JA on vaccination*
 - *JA on efficient response to highly dangerous and emerging pathogens at EU level EMERGE*
 - *JA on preparedness and IHR implementation, including laboratory strengthening*

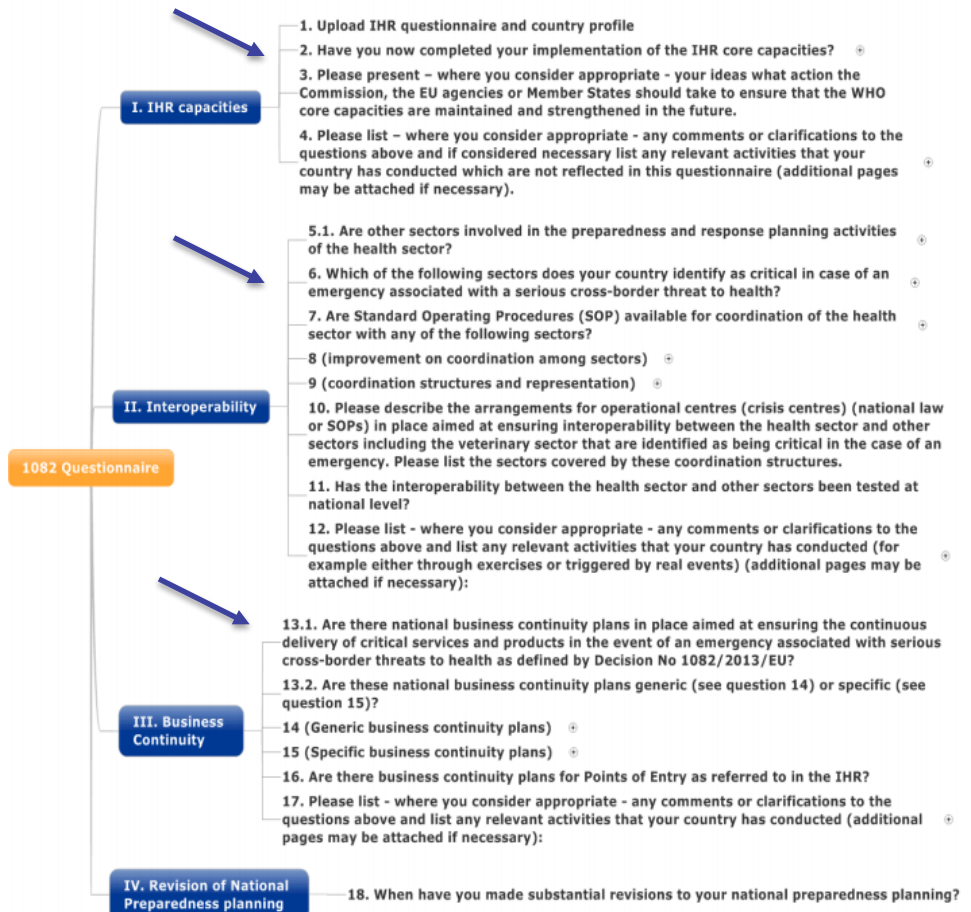


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Reporting on Preparedness and Response Planning

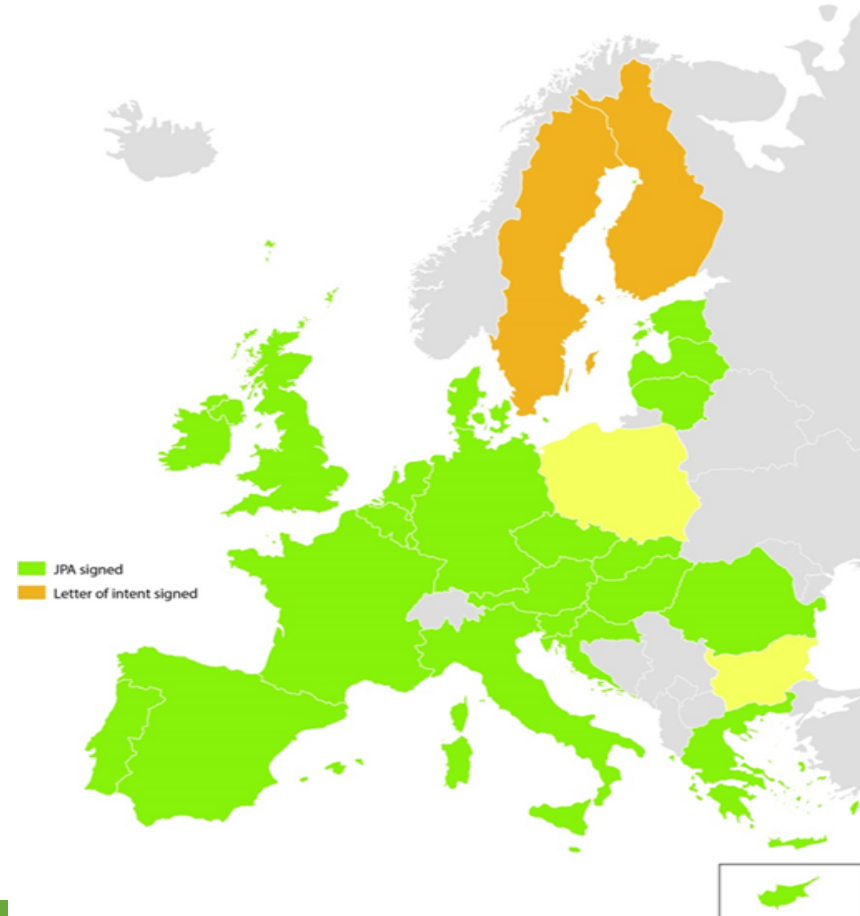
- Article 4 – MS report regularly on the state of play on preparedness and response planning.
- MS when providing information shall use a template adopted in 2014 by Commission Implementing Decision 2014/504/EU to ensure its relevance and comparability.
- Commission prepares report to support discussion in the HSC with a view to coordinate efforts for effective preparedness and response capacities to serious cross-border threats to health.

Structure of the Questionnaire (following template of the Commission implementing decision of 25 July 2014)



Joint procurement of medical countermeasures

- **Joint Procurement Agreement**, adopted in 2014, provides for a **voluntary mechanism** for procuring jointly.
- It is a framework laying down common rules for practical organisation of joint procurement procedures.
- So far **24 MS participate**





Joint procurement of medical countermeasures (Article 5)

- Joint procurement mechanism is well established.
- Procurement procedure for pandemic influenza vaccines involving 18 MS+Commission is underway.
- Procurements for other medical countermeasures (diphtheria anti-toxin, Tuberculin and BCG vaccines) are under preparation.

Rationale:

- **Improving Member States' preparedness to mitigate serious cross-border threats to health**
- **Ensuring equitable access to specific medical countermeasures**
- **Strengthening purchasing power**
- **Ensuring more balanced prices**

Coordination within the Commission

DG SANTE

- Frameworks for food safety and animal health and for pharmaceutical products

DG ECHO

- EU Civil Protection Mechanism, European Medical Corps, European Voluntary Aid Corps

DG HOME

- European Agenda on Security, Security Union; EU CBRN Action Plan

DG GROW-EEAS

- EU Joint Framework on countering hybrid threats

DG RTD

- EU Framework Programme for Research and Innovation Horizon 2020

DG DEVCO

- **Bilateral programmes** - IHR implementation within health systems strengthening and promoting universal health coverage

DG ECHO-JRC

- EU Action Plan on the Sendai Framework for Disaster Risk Reduction 2015-2030

DG EEAS

- Strategy on Foreign and Security Policy



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Coordination under the EU health security framework



EU Member States



EEA & EFTA



Commission européenne



GHSI: Global Health Security Initiative

Global Health Security Agenda



Technical Advisor





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Thank you!

https://ec.europa.eu/health/preparedness_response/overview_en