



# 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



Biological<sup>1</sup>



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**

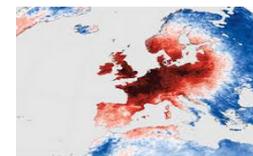
• *Including alerts on chikungunya, malaria, dengue, measles, hepatitis A, drug-resistant Tuberculosis, Salmonellosis, botulism, influenza, yellow and lassa fever, meningitis, Legionellosis, poliomyelitis, cholera, histamine poisoning, etc; including major outbreaks e.g., Ebola, MERS CoV, poliomyelitis,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



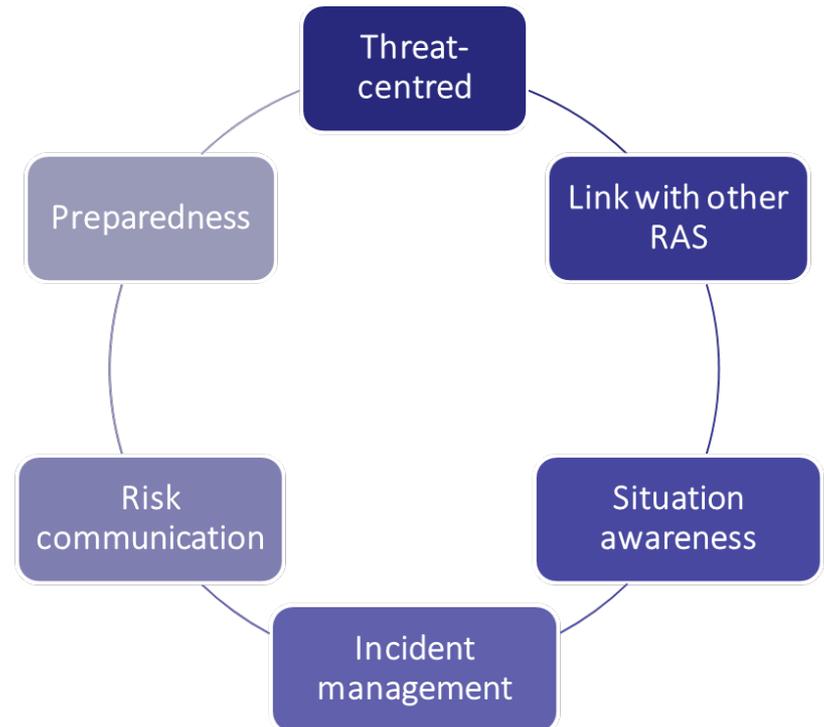
### • Other alerts:

- 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 33 deaths (case fatality rate 15.5%) have been reported. Of these cases, 124 cases are pneumonic plague including 23 deaths, 49 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

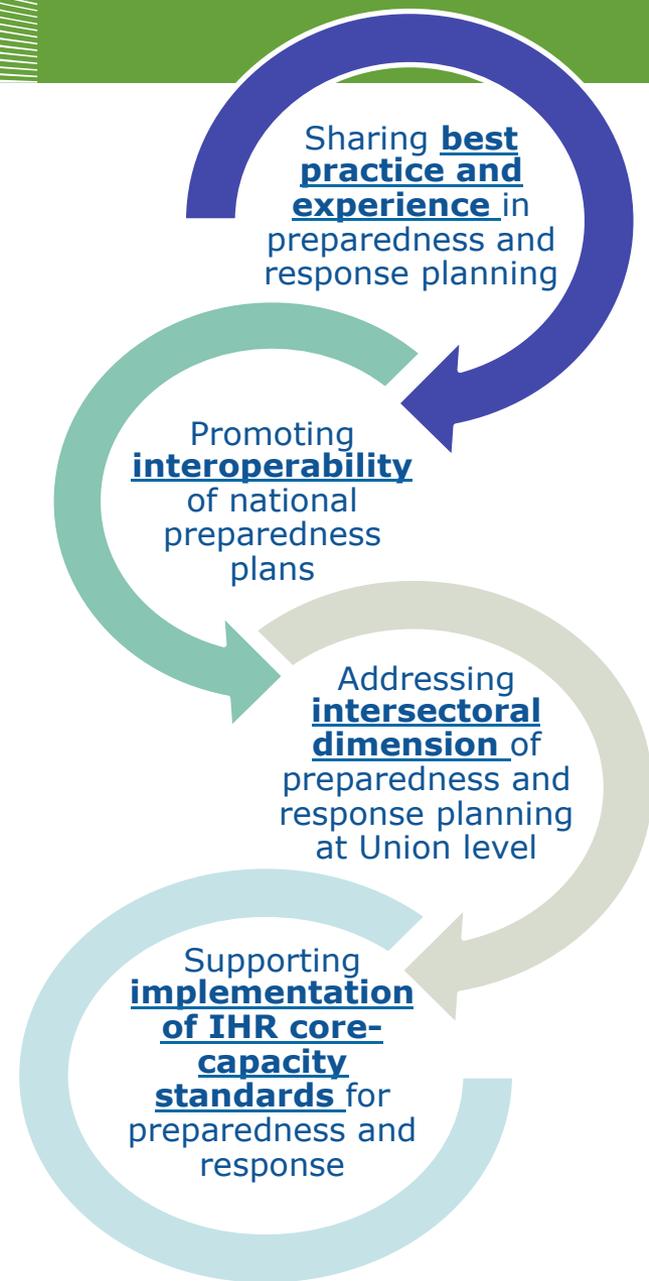


- **Existed as informal group established on the basis of 2001 Council Conclusions on bioterrorism**
- **Consists of MS representatives, with candidate countries as observers, ECDC and WHO, plus other bodies when relevant - chaired by the Commission**
- **Permanent working groups** on preparedness and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

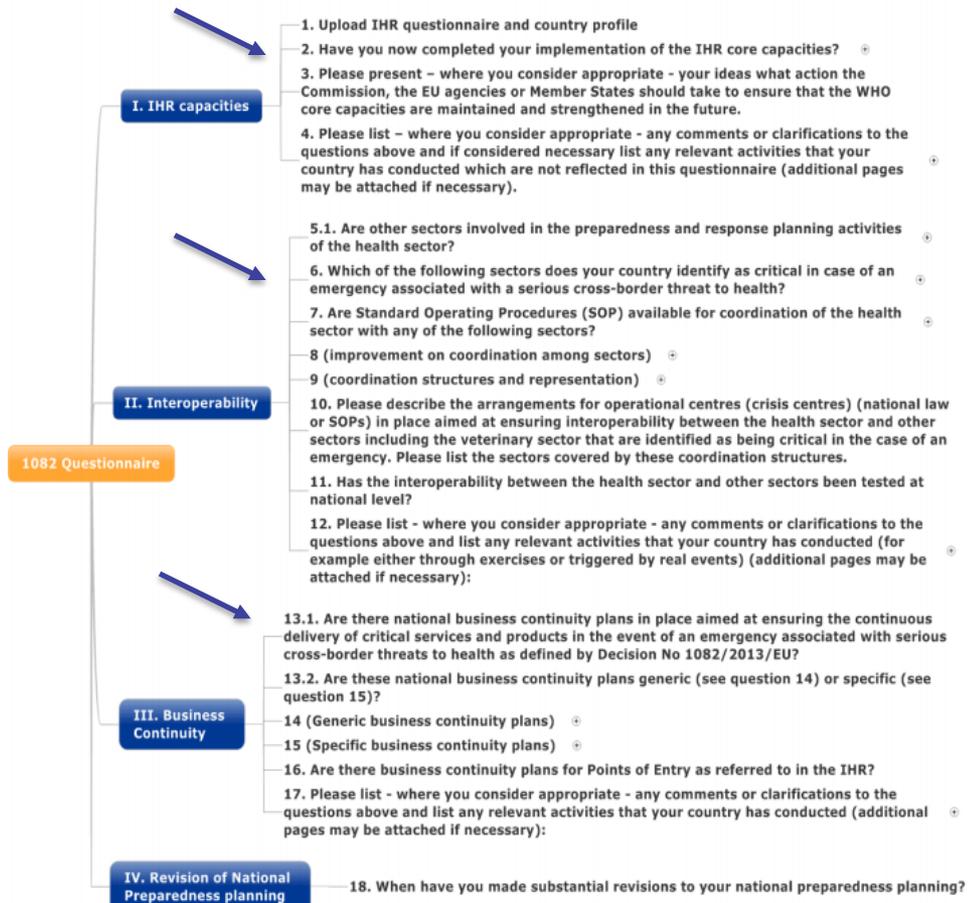


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# Reporting on Preparedness and Response Planning

- 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



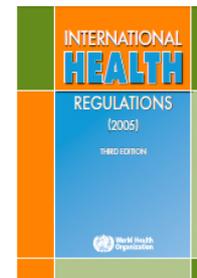
EU Member States



EEA & EFTA



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GHSI: Global Health Security Initiative

Global Health Security Agenda





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# Thank you!

[https://ec.europa.eu/health/preparedness\\_response/overview\\_en](https://ec.europa.eu/health/preparedness_response/overview_en)