



# EU Early warning and response system (EWRS)

2<sup>nd</sup> workshop of the Belgian branch of PREZODE, PREZODE pillar 3

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# European Health Union – Serious cross-border threats to health (SCBTH) Regulation 2371/2022/EU

- Strengthen the EU's health security framework – **Regulation on serious cross-border threats to health**
- Reinforce the crisis preparedness and response, including the new mandate of key EU agencies,
  - European Centre for Diseases Prevention and Control (ECDC) and
  - European Medicines Agency (EMA)
- **Reinforce surveillance:**
  - surveillance system at EU level, using Artificial intelligence (AI) & other advanced technological means



# Epidemiological surveillance (Articles 13 -14)

- **Epidemiological surveillance network** (Art. 5 of ECDC new mandate)
- Information to be communicated on **agreed indicators and standards**
  - List of notifiable diseases & case definitions
- **Strengthen the data collection and sharing capacity** of MS
- ECDC to **monitor and evaluate surveillance activities &** report HSC

## EpiPulse – EU Platform for surveillance

ECDC shall ensure **continued development of the digital platform**

- **integrated and interoperable surveillance system** (real-time surveillance)
- The platform shall:
  - Enable **automated collection of surveillance and laboratory data** (non-personal health data)
  - Allow for the **computerised handling and exchange of information, data and documents**

REGULATION (EU) 2022/2370 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control (ECDC)

# Art 14 – Digital Platform for Surveillance support to Member States

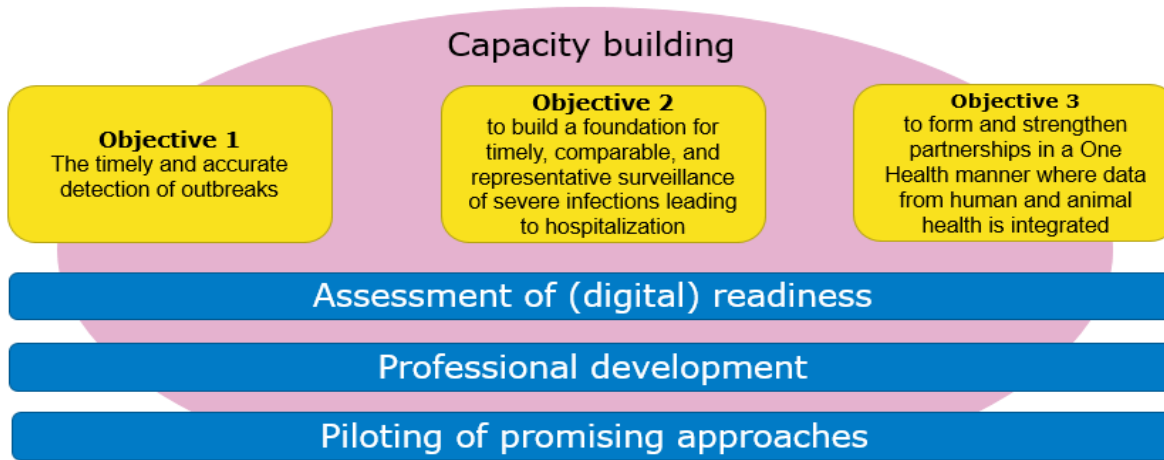
1. JA “Union and National Capacity Building for Integrated Surveillance (UNITED4SURVEILLANCE)”
  - AWP 2021, 7.8 Mio EUR Contribution, Jan 2023 to Dec 2025,
  - Participating countries: 23 EU MS & Norway

Nominations of competent authorities Jun 2023, invitation for submission Oct 2023, signature 2024, duration 2024-2028

1. **Direct grants to Member States’ authorities: improving and strengthening national surveillance systems**
  - AWP 2023, 97 Mio EUR Contribution, single or multi-beneficiary grants,
  - Infrastructure development, capacity building, train-the-trainers (legal aspects, data protection), pilot implementation (incl. test and improvement)
  - Preparatory work: Gaps analysis on laboratory-based reporting and on national surveillance systems, cooperation WHO Hub for Pandemic and Epidemic Intelligence

# UNITED4Surveillance – Union and National Capacity Building 4 IntegraTED Surveillance,

## One Health (NL –RIVM & NO – NHI)



- Detection emerging zoonotic pathogens (integration human-animal-environmental data),
- Foodborne (Salmonella and STEC), Zoonotic influenza (Swine and Avian flu) and Vector borne (West Nile, TBEC and Chikungunya)

## Outbreak detection (DE – RKI & DK –SSI)

- Improving laboratory based reporting & outbreak and signal detection

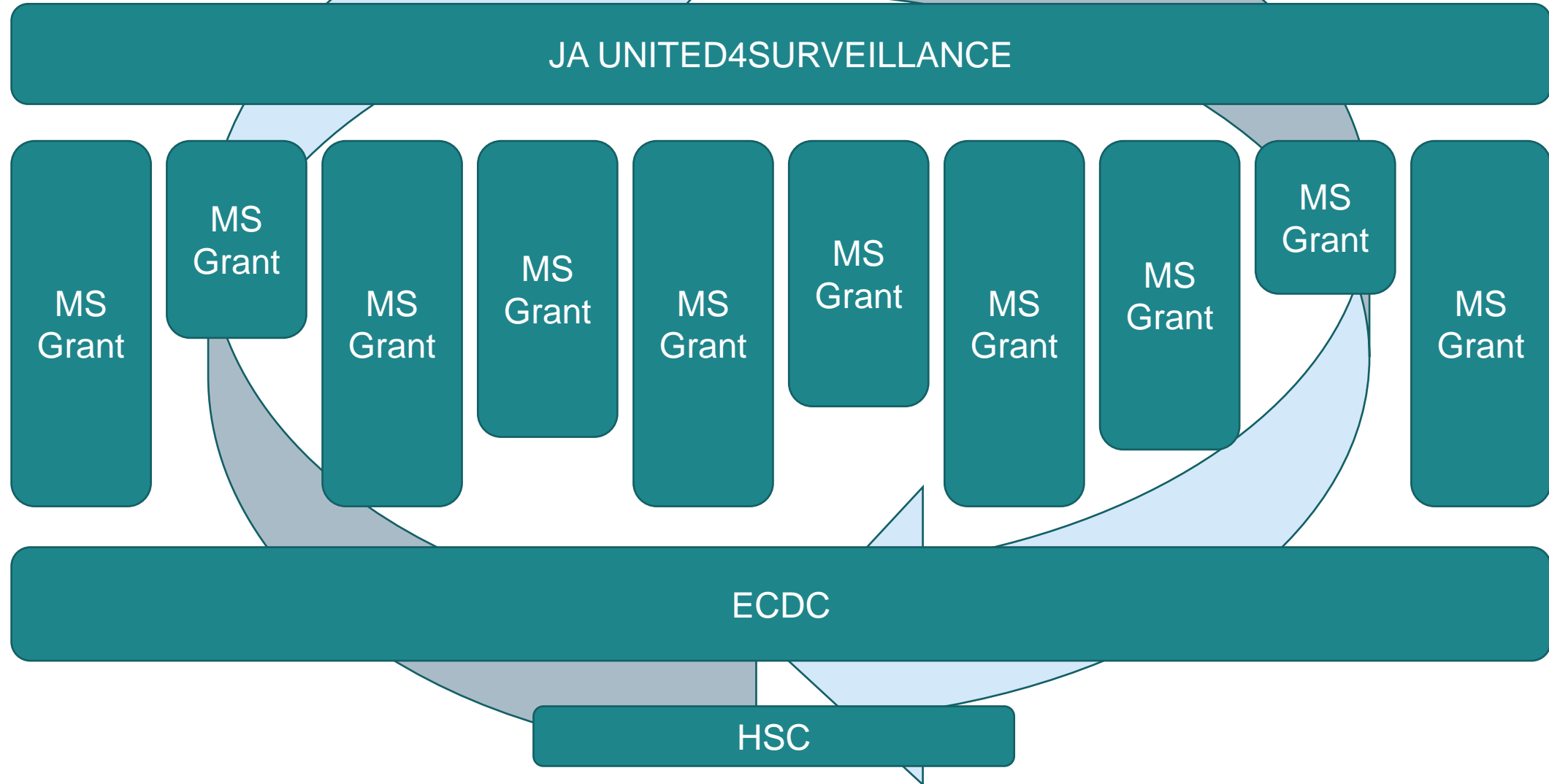
## Hospital surveillance severe infectious diseases (FI – THL)

- Integrated clinical and laboratory data, including AMR

- **Expected results: Roadmap for a decentralized integrated surveillance system for effective infectious disease surveillance and crisis response**

- <https://united4surveillance.eu/project/>

# Joint Action complemented with MS grants



# Surveillance within EU funding programmes

## EU4Health (SANTE B.2/ECDC)

**United4Surveillance**  
7.0 M EUR

**Direct Grants surveillance**  
97.3 M EUR

**EWRS**  
2.0 M EUR

**EU ref labs**  
12.4 M EUR

**JA AMR**  
50.0 M EUR

**Prep action EURLs**  
0.4 M EUR

**PostCOVID Surveillance**  
lessons learned

## EU4Health (Other DGs/SANTE Units)

**Direct Grants One Health  
Surveillance** - 20.0 M EUR

**DURABLE – HERA lab  
network** - 25.0 M EUR

**HERA IT system (threat  
detection and MCMS)**

**JA wastewater surveillance**

**Wastewater infrastructure  
+ Cap Building grants**

## Other examples

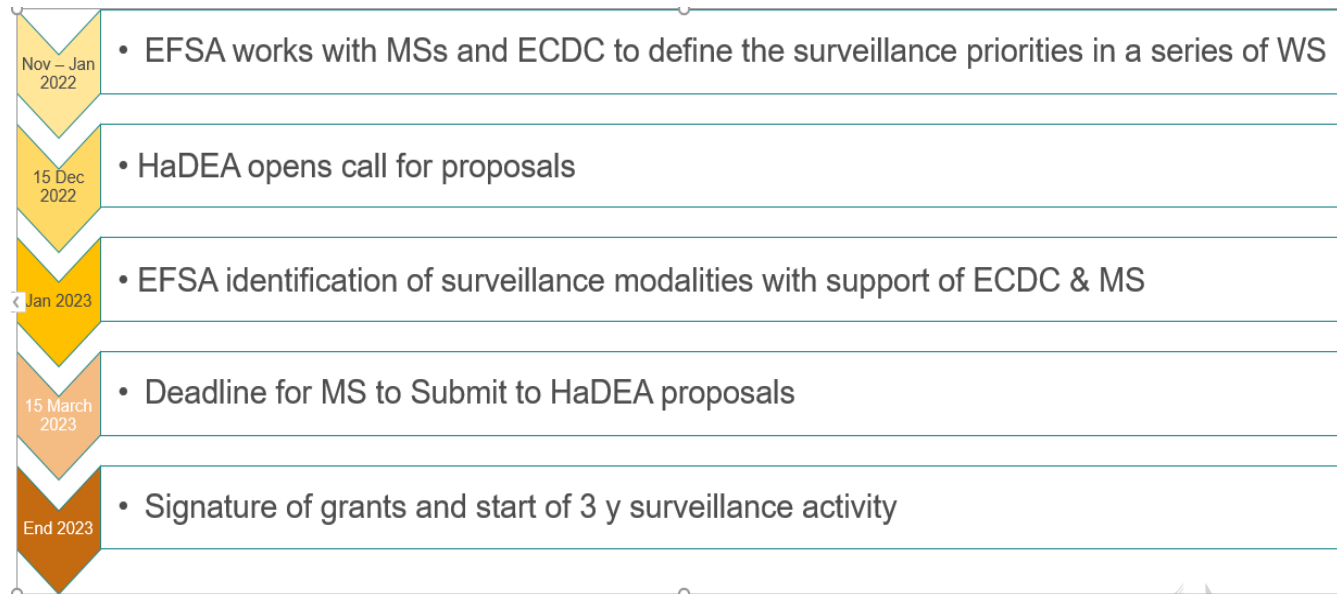
**BE READY**  
H2020

**PREZODE**  
International

**EU Partnership on  
Animal Health & Welfare**

# One Health Surveillance in Animals for cross-border pathogens (AWP 2022) – EC funding 20M - 36 Months (**under preparation**)

**Objectives:** Setting up a coordinated surveillance system under **One Health approach for cross-border pathogens - scaling up animal and environmental surveillance system**

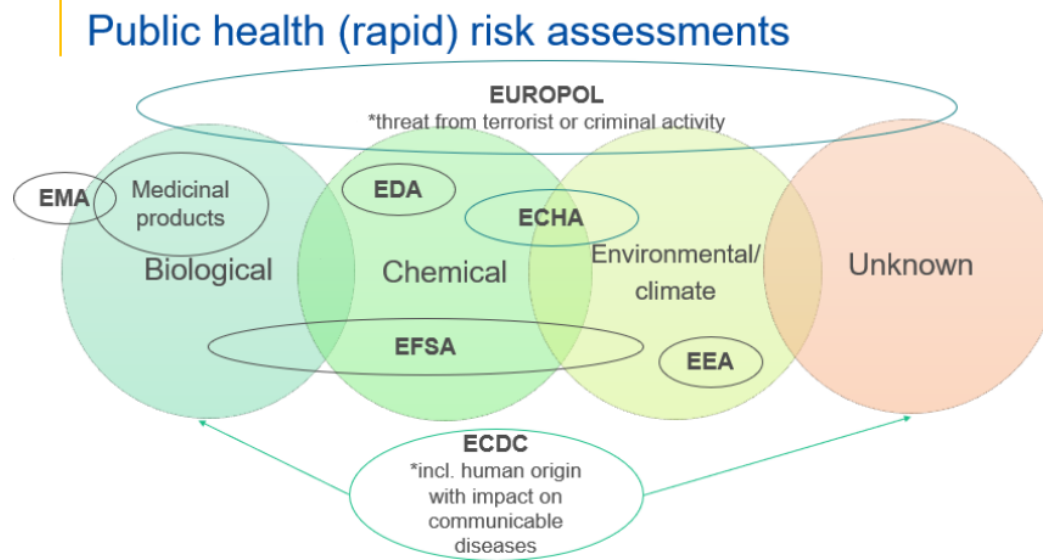


- Systematic collection & assessment of data by EFSA, with ECDC
- Exchange of knowledge, threats reporting, joint undertaking of risk assessment
- Surveillance system for emerging and re-emerging zoonotic pathogens in animals and the environment
- Capacity building based on identified surveillance priorities and risks identified by EFSA/ ECDC assessments
- Piloting diagnostic procedures, data collection and sharing data with EFSA, national assessment across in One Health Approach & capacity building)



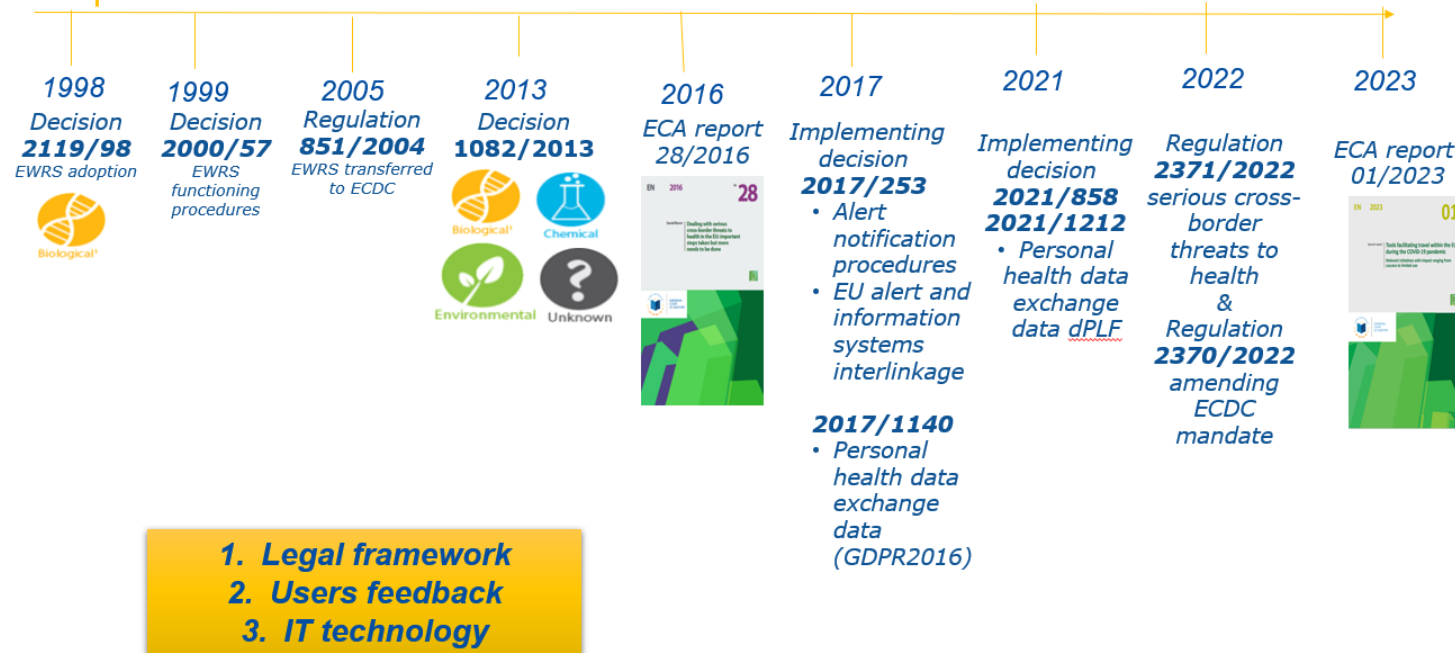
# Early warning and response, including risk assessment (articles 18 – 20)

- **Notifications for all hazards, including on urgent need or shortage of medical countermeasures**, requests and offers for cross-border emergency assistance
- A **new risk assessment framework for all hazards**, including rapid and appropriate recommendation for response measures that Member States should implement (**Interagency risk assessment**)
  - Agencies involved, including: **ECDC, EFSA, ECHA, EEA, EMCDDA, Europol, EMA**



# EU Early warning and response system (EWRS)

## EWRS: rationale



# Early Warning and Response System (EWRS)

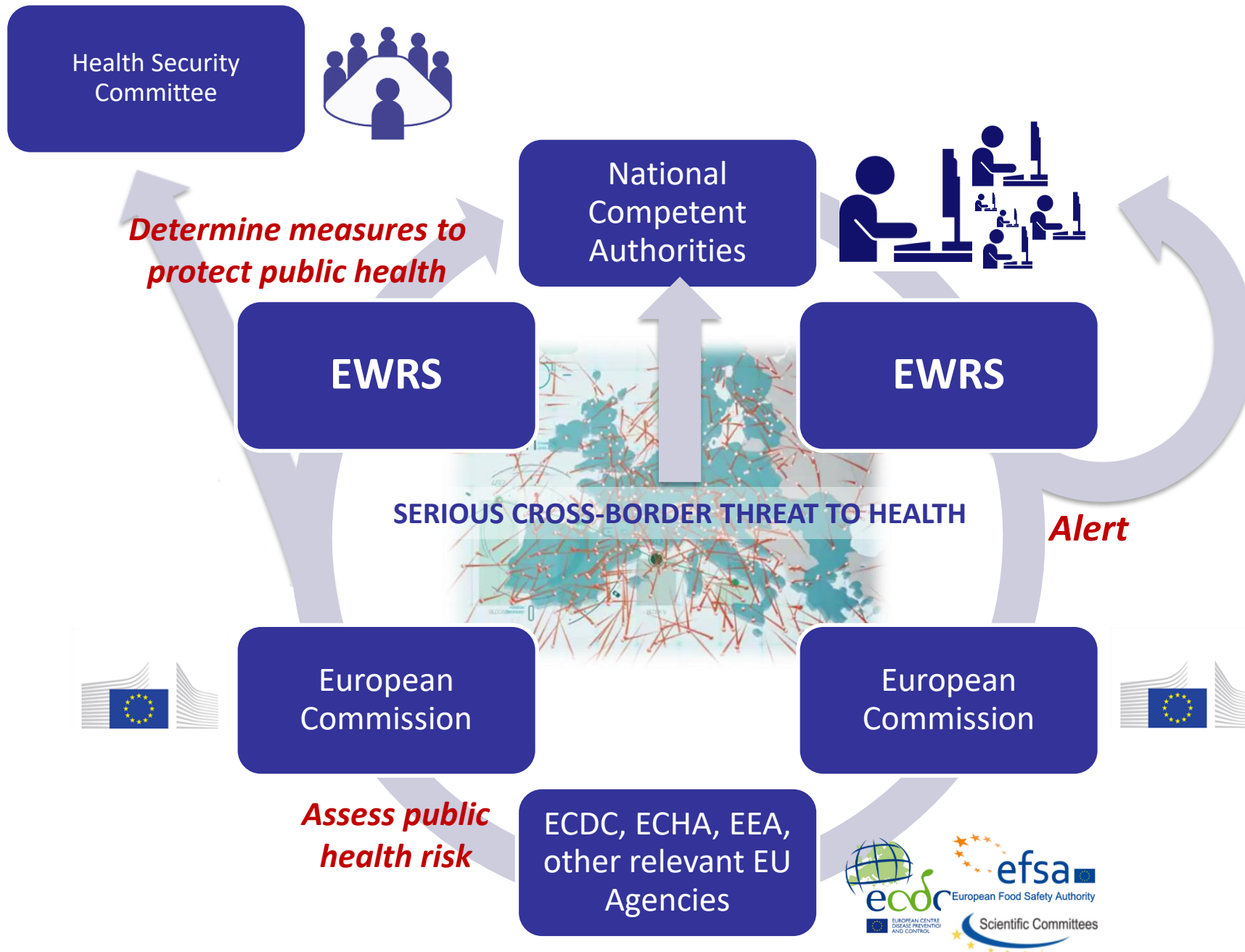
EWRS is a rapid alert system to notify alerts at Union level in relation to Serious Cross-border Threats to Health (SCBTH - **Article 18 of 2371/2022/EU**)



The system enables the European Commission and the National Competent Authorities in EU/EEA countries to be in permanent communication for the **purposes of preparedness, early warning and response, alerting, assessing public health risks and determining the measures that may be required to protect public health.**

The system is owned and managed by the European Commission (DG SANTE) and the European Centre for Disease Prevention and Control (ECDC) operates the IT platform, since 2005 (**Regulation (EC) 851/2004 - article 8**).

***Commission Implementing Decision (EU) 2017/253 of 13 February 2017 on EWRS and for the information exchange, consultation and coordination of responses***



# EWRS: alert notification



Article 19 of Regulation 2371/2022/EU

**National competent authorities or the Commission shall notify** an alert in the EWRS where the emergence or development of a **SCBTH** fulfils the following **criteria**:

a) It is unusual or unexpected for the given place and time, or it causes significant morbidity or mortality in humans, or it grows rapidly or may grow rapidly in scale, or it exceeds or may exceed national response capacity;

**and**

b) it affects or may affect more than one Member State;

**and**

c) it requires or may require a coordinated response at Union level;

# EWRS: alert notification

## Detailed description

1. Description of the event: time, place, people affected\*
2. Risk assessment
3. Information on public health measures planned or undertaken
4. Risk communication measures
5. Additional relevant information

## Organisation access

Select who should have access to the notification

WHO

EMA

EFSA

ECHA

DG ENVIRONMENT

EMCDDA

# EWRS - Interlinkage with other AISs

(list to be updated in the new Decision 2017/253/EU)

	Alert System	Description	Bio	Chemical	Environm.
1	ADIS	Animal Disease Information System	X		
2	RAB & RATC	Rapid Alert for Blood and for tissues and cells	X		
3	iRASFF	Rapid Alert System for Food and Feed	X	X	
4	Safety Gate	Rapid Alert System for dangerous non-food products	X	X	
5	EpiPulse	European surveillance portal for infectious diseases	X		
6	EUROPHYT	European Notification System for Plant Health Interceptions	X		
7	CECIS	Common Emergency Communication and Information System			X
8	ECURIE	European Community Urgent Radiological Information Exchange		X	X
9	eMARS	Major Accident Reporting System		X	X
10	EWS-NPS	Early Warning System on New Psychoactive Substances (EWS-NPS)		X	
11	ARGUS	Commission's cross sectoral warning system	X	X	X

# EpiPulse vs EWRS



**Main stakeholders:** Public health institutes, ECDC



## EpiPulse

**Case-based data**

**Notify: Individual cases or isolates**

**Event-based data**

**Notify: Outbreaks, clusters**

**Aim: Risk Assessment**

Identification, assessment & communication of the risk

Biological

**Main stakeholders:** Ministries of health, Health Security Committee, European Commission - SANTE B2



## EWRS

### Early Warning and Response System

**Notify: Outbreaks, clusters and data for contact tracing**

All hazards SCBTH

**Aim: Risk Management**

Implementation of the control measures



# Domains cover all infectious diseases

List of EpiPulse Domains	
1. ARHAI	Antimicrobial resistance and healthcare-associated infections
2. EI	Epidemic Intelligence
3. EVD	Emerging and vector borne diseases
4. FWD	Food and waterborne diseases and zoonoses
5. HIV	HIV/AIDS
6. STI	Sexually transmitted infections
7. HEP	Viral hepatitis
8. IRV	Influenza and other respiratory viruses
9. PREP	Preparedness
10. SoHO	Substances of Human Origin
11. ELDSNet	Legionnaires' disease
12. TB	Tuberculosis
13. VPD	Vaccine-preventable Diseases
14. SRV	General Surveillance

# EWRS contact details

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# Thank you!



EU Commission Public Health: <https://ec.europa.eu/health/>

Health Policy Platform: <https://webgate.ec.europa.eu/hpf/>

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