

Health Security in the EU

New Regulation on serious cross-border threats to health

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for Health

COVID-19 lessons learned and looking
ahead to ensure a stronger EU Health
Security Framework



European Health Union

➤ Regulation on serious cross-border threats to health

- Political agreement between the co-legislators reached **on 23 June 2022**
- Vote in the European Parliament on **4 October 2022**
- Approval by the Council on **24 October 2022**

ENTRY INTO FORCE expected in **January 2023**

➤ New mandate of key EU agencies

- European Centre for Diseases Prevention and Control (ECDC) – adoption 24 Oct 2022
- European Medicines Agency (EMA) - 1 March 2022

➤ Emergency Framework Regulation - adoption 24 Oct 2022



Véronique Trillet-Lenoir

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👏 Nous l'avons fait !

Le Parlement européen vient d'adopter l'accord interinstitutionnel établissant un Plan européen d'urgence sanitaire.

Nous réitérons aujourd'hui notre vol... Zobrazit další

Zobrazit překlad



SCBTH Regulation – Chapter I

General provisions (Articles 1-4)

General provisions

- **Subject matter and the scope of the Regulation** – new elements: a network of EU reference laboratories, a network for substances of human origin, an advisory committee for recognition of public health emergency at Union level

- The **Health Security Committee:**

- Two-tier structure (senior level and technical level)
- Adoption of opinions, guidance and communications and recommendations on surveillance and adoption of working programme



SCBTH Regulation – Chapter II

Prevention, preparedness and response planning (Articles 5-12)

Prevention, preparedness and response planning

- **EU health crisis and pandemic preparedness plan**
- Comprehensive and transparent framework for **reporting on and assessments of preparedness and response planning**
- Regular public health and cross-sector **stress tests and exercises** carried out with Member States
- Targeted **training and knowledge exchange** activities for healthcare and public health staff
- A **reinforced joint procurement**



SCBTH Regulation – Chapter III

Epidemiological surveillance, EU reference laboratories and ad hoc monitoring (Articles 13-17)

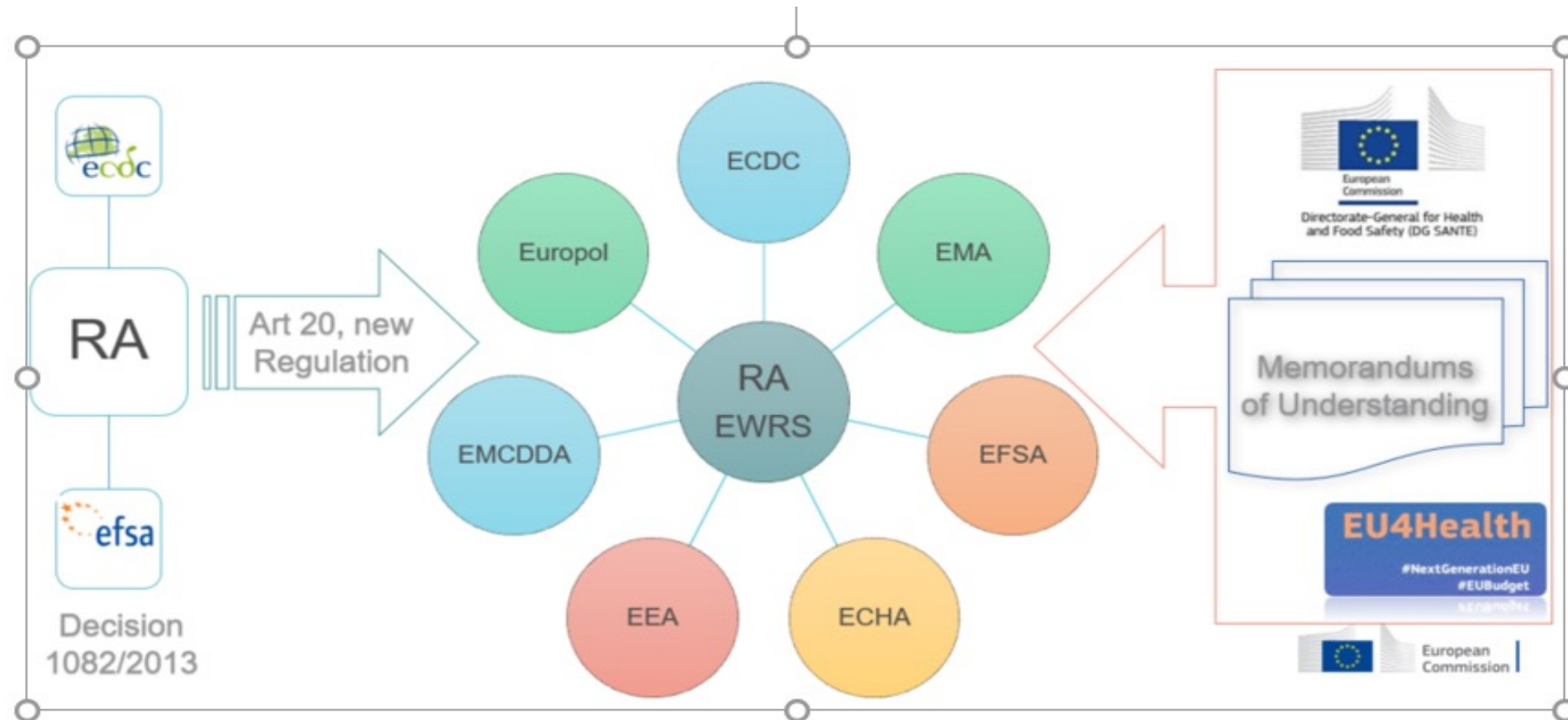
Epidemiological surveillance, new networks

- A new **high performing epidemiological surveillance system at the EU level**
- Strengthened **access of ECDC to health data for research and epidemiological aspects**, in the context of the future systems (eg. European Health Data Space)
- Reporting requirements on health system capacity; surveillance linked to other available information sources and data
- Creation of new networks:
 - **EU reference laboratories network**
 - EU network on **use of substances of human origin & communicable diseases**

SCBTH Regulation – Chapter IV

Early warning and response and risk assessment (Articles 18-22)

- Notifications including on urgent need or shortage of medical countermeasures
- A new risk assessment framework for all hazards,
 - Agencies involved, including: ECDC, EFSA, ECHA, EEA, EMCDDA, Europol, EMA



SCBTH Regulation – Chapter V

Public health emergency at Union level (Articles 23-25)



Coordinated response at EU level

- **Recommendations on response measures**
- **Adoption of opinions and guidance**, including on specific response measures by the Health Security Committee, Commission Recommendation on response measures
- **EU recognition of an emergency situation** and advice on response measures, supported by an independent (multidisciplinary) Advisory Committee
- EU emergency situation triggering **increased coordination and allow for the development, stockpiling and procurement of crisis relevant products**

SCBTH Regulation – Chapter VI

Final provisions (Articles 26-35)

- **December 2024** first evaluation of the implementation of the Regulation including:
 - Assessment of the operation of EWRS
 - Coordination of the response within the HSC
 - Implementation of this Regulation by Health Emergency Preparedness and Response Authority (HERA)

SCBTH Regulation – implementation

- **Focus for 2023:**
 - **Union prevention, preparedness and response plan**
 - **Reporting on preparedness**
 - **Setting-up standard operating procedures between the EU Agencies to work on risk assessment**
 - **New developments for EWRS**
 - **Supporting actions for setting-up the EU Reference Laboratory network**

Thank you

More information:

https://ec.europa.eu/info/strategy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en