

Special Report

Dealing with serious cross-border threats to health in the EU: important steps taken but more needs to be done



EUROPEAN
COURT
OF AUDITORS

EUROPEAN COURT OF AUDITORS
12, rue Alcide De Gasperi
1615 Luxembourg
LUXEMBOURG

Tel. +352 4398-1

Enquiries: eca.europa.eu/en/Pages/ContactForm.aspx

Website: eca.europa.eu

Twitter: @EJAuditors

More information on the European Union is available on the internet (<http://europa.eu>).

Luxembourg: Publications Office of the European Union, 2016

Print	ISBN 978-92-872-6122-9	ISSN 1831-0834	doi:10.2865/11880	QJ-AB-16-028-EN-C
PDF	ISBN 978-92-872-6162-5	ISSN 1977-5679	doi:10.2865/517	QJ-AB-16-028-EN-N
EPUB	ISBN 978-92-872-6164-9	ISSN 1977-5679	doi:10.2865/066600	QJ-AB-16-028-EN-E

© European Union, 2016

Reproduction is authorised provided the source is acknowledged.

Special Report**Dealing with serious cross-border threats to health in the EU: important steps taken but more needs to be done**

(pursuant to Article 287(4), second subparagraph, TFEU)

The ECA's special reports set out the results of its performance and compliance audits of specific budgetary areas or management topics. The ECA selects and designs these audit tasks to be of maximum impact by considering the risks to performance or compliance, the level of income or spending involved, forthcoming developments and political and public interest.

This performance audit was produced by Audit Chamber I — headed by ECA Member Phil Wynn Owen — which specialises in sustainable use of natural resources. The audit was led by ECA Member Janusz Wojciechowski, supported by Kinga Wiśniewska-Danek, head of private office; Katarzyna Radecka-Moroz, private office attaché; Colm Friel, principal manager; Stefan den Engelsen, head of task, and Joanna Kokot, deputy head of task. The audit team consisted of Aris Konstantinidis, Jurgen Manjé, Roberto Resegotti and Frédéric Soblet. Language support was provided by Madis Rausi.



From left to right: C. Friel, A. Konstantinidis, K. Radecka-Moroz, S. den Engelsen, J. Wojciechowski, J. Manjé, J. Kokot, R. Resegotti, F. Soblet.

Paragraph

Abbreviations

I - X **Executive summary**

1 - 12 **Introduction**

1 - 2 **Serious cross-border threats to health**

3 - 12 **The EU framework for dealing with serious cross-border threats to health**

13 - 20 **Audit scope and approach**

21 - 111 **Audit observations**

21 - 55 **The decision on serious cross-border threats to health introduced certain innovations for EU health security, but their implementation and development were hampered by delays and strategic and operational challenges remain**

56 - 77 **The important role of existing systems and procedures for early warning and response and epidemiological surveillance is widely recognised but there are certain upgrades to be made**

78 - 94 **The performance of the health programme as regards protecting citizens from health threats showed weaknesses**

95 - 111 **There are gaps in the Commission's internal coordination in terms of health security activities and public health crisis management**

112 - 121 **Conclusions and recommendations**

Annex I — Preparedness and response planning in the international context

Annex II — Description of main roles and responsibilities in the EU framework for protecting citizens against serious cross-border threats to health

Annex III — Overview of audited co-funded actions

Reply of the Commission

AMR: antimicrobial resistance

Chafea: Consumer, Health, Agriculture and Food Executive Agency

DG ECHO: Directorate-General for European Civil Protection and Humanitarian Aid Operations

DG HOME: Directorate-General for Migration and Home Affairs

DG RTD: Directorate-General for Research and Innovation

EEA: European Economic Area

ECDC: European Centre for Disease Prevention and Control

ERCC: Emergency Response Coordination Centre

ERCEA: European Research Council Executive Agency

EWRS: early warning and response system

FP7: seventh framework programme for research

HEOF: Health Emergency Operations Facility

HSC: Health Security Committee

IHR: International Health Regulations (see *Annex I*)

MERS: Middle East respiratory syndrome

PHEIC: Public Health Emergency of International Concern

REA: Research Executive Agency

SARS: severe acute respiratory syndrome

SCHER: Scientific Committee on Health, Environmental and Emerging Risks

SOP: standard operating procedure

STAR: strategic assessment and response

TESSy: The European Surveillance System

TFEU: Treaty on the Functioning of the European Union

WHO: World Health Organisation

I

In the previous decades, various events posing serious threats to health and life have led to increased attention for health security at the international and EU levels. Threats to public health can emerge from a range of different origins. In addition to their health impact, they can cause very significant economic costs, in particular when an emergency lasts for a long time and disrupts travel and trade, and public life in general. Past events have also showed that serious health threats are often cross-border problems, and may require a multi-sectoral and multilateral response.

II

The Treaty on the Functioning of the European Union (TFEU) states that a high level of human health protection shall be ensured and that Union action shall cover the monitoring, early warning of and combating of serious cross-border threats to health. It specifies that EU action in the area of health is designed to support and complement actions of the Member States, which have the main responsibility for health policy. The Commission's role in health policy therefore consists mainly of providing support and taking complementary action.

III

The European Union identified serious cross-border threats to health as an area where Member States can act more effectively together. It therefore developed coordination mechanisms to enable the Union to deal with such threats. A key milestone in building a stronger EU health security framework was the adoption in 2013 of a decision on serious cross-border threats to health, introducing important innovations as regards, for example, the coordination of preparedness planning and the strengthening of the role of the Health Security Committee (HSC). The EU health and research framework programmes also support activities in the field of health security.

IV

Implementing the decision on serious cross-border threats to health and the related framework is complex in view of the competences of the EU and the Member States, and the fact that serious threats keep emerging. We therefore assessed whether the EU framework for protecting citizens from serious-cross-border threats to health was adequately implemented. Under this main question we examined:

- (1) whether the innovations introduced by the decision are effectively implemented;
- (2) whether the existing systems for early warning and response and epidemiological surveillance are adequately managed and implemented;
- (3) whether the EU health programmes are making effective contributions to protecting citizens from threats to health;
- (4) whether the Commission's internal coordination in terms of health security funding and public health crisis management is adequate.

V

We concluded that Decision No 1082/2013/EU¹ on serious cross-border threats to health represents an important step for dealing better with such threats in the EU. However, significant weaknesses at Member State and Commission level affect the implementation of the decision and the related EU framework. While the nature and scale of future threats is unknown and may evolve, more needs to be done to address these weaknesses for the Union to take full benefit from the established mechanisms.

VI

As regards the innovations introduced by the decision on serious cross-border threats to health, we found that their implementation and development were hampered by delays, potentially reducing their effective functioning. The coordination of preparedness planning was initiated but the relevant procedures need to be more robust and better defined to deliver clear-cut results. The Member States have shown insufficient responsiveness to speed up the joint procurement of pandemic influenza vaccine, and there is not yet an EU mechanism to address urgent needs for medical countermeasures within the framework of the decision. The work and role of the HSC have proven to be very important, but it is facing strategic and operational challenges which need to be tackled, including in relation to the coordination of response rules.

VII

As regards the effective implementation of the existing systems for early warning and response and epidemiological surveillance, we found overall that these systems have been operational for years and that their important role at EU level is widely recognised by stakeholders. However, there is scope for making certain upgrades to the Early Warning Response System (EWRS) and related procedures.

VIII

We concluded that the performance of the health programme as regards protecting citizens from health threats showed weaknesses. Most of the audited health threat actions from the second health programme (2008-2013), despite performing well in terms of producing the agreed deliverables, showed a lack of sustainable results, limiting their contribution towards achieving the objective of protecting citizens from threats to health. We also found weaknesses in measuring the indicator for the health threats objective under the third health programme (2014-2020) and a relatively low level of spending in 2014-2016.

IX

Finally, the audit revealed that a number of gaps existed in relation to the Commission's internal coordination of health security activities across different services and programmes. We also found that more work needs to be done to make agreements for cooperation between Commission crisis management structures fully operational, and that DG Health and Food Safety's management of its Health Emergencies Operations Facility showed weaknesses that might hamper its performance.

¹ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

X

The Court makes a number of recommendations to address these observations:

- (i) In order to speed up the development and implementation of the innovations introduced by the decision on serious cross-border threats to health, the Court makes recommendations covering a strategic HSC roadmap for the implementation of Decision No 1082/2013/EU; the performance monitoring of this policy area by the Commission; the working methods of the HSC; and the joint procurement of medical countermeasures (see detailed **Recommendation 1** (a) to (d), following paragraph 118).
- (ii) In order to further upgrade the EWRS and develop more integrated solutions for related risk management procedures, the Court makes recommendations on the development of the EWRS (see detailed **Recommendation 2** (a) and (b), following paragraph 119).
- (iii) In order to address the main weaknesses identified in the performance of the health programme for actions addressing health threats, the Court makes recommendations on improving the sustainability of results from co-funded actions and the relevant performance measurement methodology (see detailed **Recommendation 3** (a) to (c), following paragraph 120).
- (iv) In order to bridge the gaps in the Commission's internal coordination of activities relevant to health security and public health crisis management, and to improve the design of its Health Emergencies Operations Facility, the Court makes specific recommendations on a more structured coordination approach between services for health security activities, operationalising existing crisis management agreements and specific improvements for the Health Emergencies Operations Facility (see detailed **Recommendation 4** (a) to (c), following paragraph 121).

Serious cross-border threats to health

01

In the previous decades, deadly events such as the 2003 severe acute respiratory syndrome (SARS) epidemic, the worldwide H1N1 pandemic of 2009 and the 2011 E. coli outbreak in Germany have led to increased attention being given at international and EU levels to health security. More recently, the worst Ebola outbreak ever in west Africa showed the serious implications for health and other sectors, not only in the affected regions, but also in countries across the world receiving travellers and patients from those regions. The outbreak clearly demonstrated the challenges which arise when a public health emergency is of a serious and cross-border nature (see **Box 1**).

Box 1

The Ebola outbreak of 2014-2016

In March 2014 Guinea notified to WHO an outbreak of Ebola virus disease. On 8 August 2014, the Director-General of WHO declared the Ebola outbreak in west Africa a public health emergency of international concern (PHEIC — see **Annex I** for a description). This outbreak hit three countries directly (i.e. Guinea, Sierra Leone and Liberia) and was the worst ever epidemic of the disease with potentially more than 28 000 cases and 11 000² deaths, including hundreds of healthcare workers.

The epidemic evolved into a public health, humanitarian and socioeconomic crisis with an unprecedented impact in affected countries³. It posed multi-sectoral challenges for the response action stretching far beyond the public health and healthcare sectors, involving a multitude of actors. Seven other countries (i.e. including Italy, Spain and the United Kingdom) later reported imported cases of Ebola⁴. This mainly concerned health-care or aid workers returning or evacuated to their home country after having contracted the disease. The presence of many such foreign workers on the ground, including from Europe, posed additional challenges, in particular for organising medical evacuation and ensuring preparedness of healthcare facilities for treating cases of Ebola in European countries. The PHEIC for Ebola was terminated by the WHO Director-General on 29 March 2016.

2 WHO Ebola Situation Report of 30 March 2016.

3 Council Conclusions on lessons learned for Public Health from the Ebola outbreak in west Africa — Health Security in the European Union (2015/C 421/04) of 17 December 2015.

4 WHO Ebola Situation Report of 30 March 2016.

02

Serious cross-border threats to health are life-threatening or otherwise serious hazards to health of biological, chemical, environmental or unknown origin which may spread across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection⁵ (see **Box 2** for examples of such threats). In addition to the human and health-related costs, serious threats to public health have the potential to cause very significant economic costs, in particular when the outbreak lasts for a longer period of time and disrupts travel and trade, and potentially public life in general. These types of threats usually strike unexpectedly and might evolve rapidly into complex, large-scale emergencies. Health security policy and actions are therefore designed to protect citizens from such threats and avoid or mitigate severe impacts on society and the economy⁶.

5 Decision No 1082/2013/EU.

6 See in particular considerations 1 to 3 of Decision No 1082/2013/EU.

Box 2

Examples of serious cross-border threats to health

In October 2010, a **major chemical incident** occurred when liquid waste spilled from a caustic water reservoir of an alumina plant in Hungary. A wave of the sludge hit nearby localities causing deaths and injuries, with many people being treated for chemical burns. The toxic sludge eventually reached the **Danube River** prompting downstream countries to develop emergency response plans. Hungary also called upon the EU Civil Protection Mechanism for urgent international assistance.

The 2011 **E.coli outbreak** made 3 910 people ill and caused 46 deaths within 2 months. It led to overflowing intensive care units in Germany, shortages of medical equipment, extreme pressure on laboratory capacity and a lack of public confidence in health measures. This epidemic had a major impact on the agriculture sector in the EU. Losses for economic operators were estimated at hundreds of millions of euros, and compensation and aid schemes were put in place by the EU⁷.

Surveillance data show that **antimicrobial resistance** (AMR) is a growing public health problem in European hospitals and communities, mainly linked to the inappropriate use of antibiotics⁸. AMR threatens the effective prevention and treatment of an ever-increasing range of infections caused by bacteria, parasites, viruses and fungi⁹. According to WHO, AMR is an increasingly serious **threat to global public health that requires action across all government sectors and society** as new resistance mechanisms emerge and spread globally.

7 SEC(2011) 1519 final of 8 December 2011 'Impact Assessment accompanying the document Decision of the European Parliament and of the Council on serious cross-border threats to health'.

8 ECDC Factsheet for the general public on antimicrobial resistance (<http://ecdc.europa.eu>).

9 WHO Factsheet No 194 on antimicrobial resistance, updated April 2015.

The EU framework for dealing with serious cross-border threats to health

EU public health strategy

03

The Treaty on the Functioning of the European Union (TFEU) includes provisions on health and provides¹⁰, among other things, that a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities and that Union action shall cover the monitoring, early warning of and combating serious cross-border threats to health. It also specifies that EU action in the area of public health is designed to support and complement actions of the Member States, which hold the main responsibility for health policy¹¹. The Commission's role in health policy therefore mainly consists of providing support and taking complementary action where needed.

04

One of the three objectives of the EU health strategy for 2008-2013¹² was to protect people from health threats¹³. According to the Commission's 2011 mid-term evaluation of the health strategy, the objectives and principles of the health strategy were consistent with Europe 2020, by promoting health as an integral part of the smart and inclusive growth objectives. It therefore remained valid towards 2020. Other relevant Commission publications on EU health security¹⁴ and the wider area of internal security¹⁵ referred to the fact that these health threats are often cross-border problems with an international impact. According to these strategies, Member States cannot effectively respond to such threats alone, providing a basis for Union action in this field.

Mechanisms and tools for EU-wide coordination and international cooperation

05

The Council of Health Ministers had already established in 2001 an informal Health Security Committee (HSC), as one of the mechanisms to coordinate Member State actions in response to health security issues. At that time, the main EU legislation to protect citizens from health threats concerned communicable diseases. Decision No 2119/98/EC¹⁶ set up a network for the epidemiological surveillance and control of communicable diseases in the Community, including an early warning and response system (EWRS). In 2004, the European Centre for Disease Prevention and Control (ECDC), an independent European agency¹⁷, was founded. It started working in 2005 and took on the hosting and coordination of the epidemiological surveillance network and the EWRS.

10 See Article 168(1) of the Treaty on the Functioning of the European Union.

11 Also see Chapter 1 of the white paper 'Together for Health: A Strategic Approach for the EU 2008-2013', COM(2007) 630 final of 23 December 2007.

12 COM(2007) 630 final.

13 The other two are fostering good health in an ageing Europe, and supporting dynamic health systems and new technologies.

14 'Health Security in the European Union and internationally', SEC(2009) 1622 final of 23 November 2009.

15 'EU's Internal Security Strategy in Action: Five steps towards a more secure Europe', COM(2010) 673 final of 22 October 2010.

16 Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community (OJ L 268, 3.10.1998, p. 1).

17 Article 1, paragraph 1 of Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control (ECDC founding regulation) (OJ L 142, 30.4.2004, p. 1).

06

At international level, the Commission collaborates with the Global Health Security Initiative¹⁸ and WHO. WHO coordinates the implementation of the International Health Regulations 2005 (see **Annex I** for more detailed information on the International Health Regulations (IHR)), a legally binding treaty in force since 2007, adopted in the context of the growth in international travel and trade, and the emergence and re-emergence of international disease threats and other public health risks (see **Table 1** for an overview of major threats since the adoption of the IHR). All EU Member States are State Parties to the IHR and need to develop, strengthen and maintain core public health capacities for surveillance and response. They also report to WHO on IHR implementation.

18 This G7 initiative was launched in November 2001 by Canada, the EU, France, Germany, Italy, Japan, Mexico, the United Kingdom and the United States. WHO serves as an expert adviser to the GHSI and the Commission participates in the GHSI as the EU's representative.

Table 1

Major disease outbreaks since the entry into force of the IHR 2005

Year	Major disease outbreaks	Health impact	PHEIC declaration by WHO
2009	H1N1 influenza pandemic (or 'swine flu')	18 449 deaths in more than 214 countries and territories or communities (as per 1 August 2010).	April 2009
2012	Middle East respiratory syndrome coronavirus (MERS-CoV)	1 769 confirmed cases in 27 different countries and 630 deaths reported since September 2012.	N.A.
2013	Avian influenza H7N9 in human beings	Case fatality rate approximately 25 %. Previous cases of other subgroups of H7 avian influenza reported in multiple countries in earlier years.	N.A.
2014	Resurgence of polio after it had nearly been eradicated	In 1988 there were 350 000 cases in 125 countries; in 2015 74 cases in 2 countries.	May 2014
2014	Ebola outbreak in west Africa	More than 28 000 cases confirmed in Guinea, Liberia and Sierra Leone and more than 11 000 deaths.	August 2014
2016	Zika virus outbreak	As of June 2016: 61 countries reporting ongoing mosquito-borne transmission.	February 2016

Source: WHO Fact Sheets and thematic websites on the relevant diseases as per July 2016.

Decision No 1082/2013/EU on serious cross-border threats to health

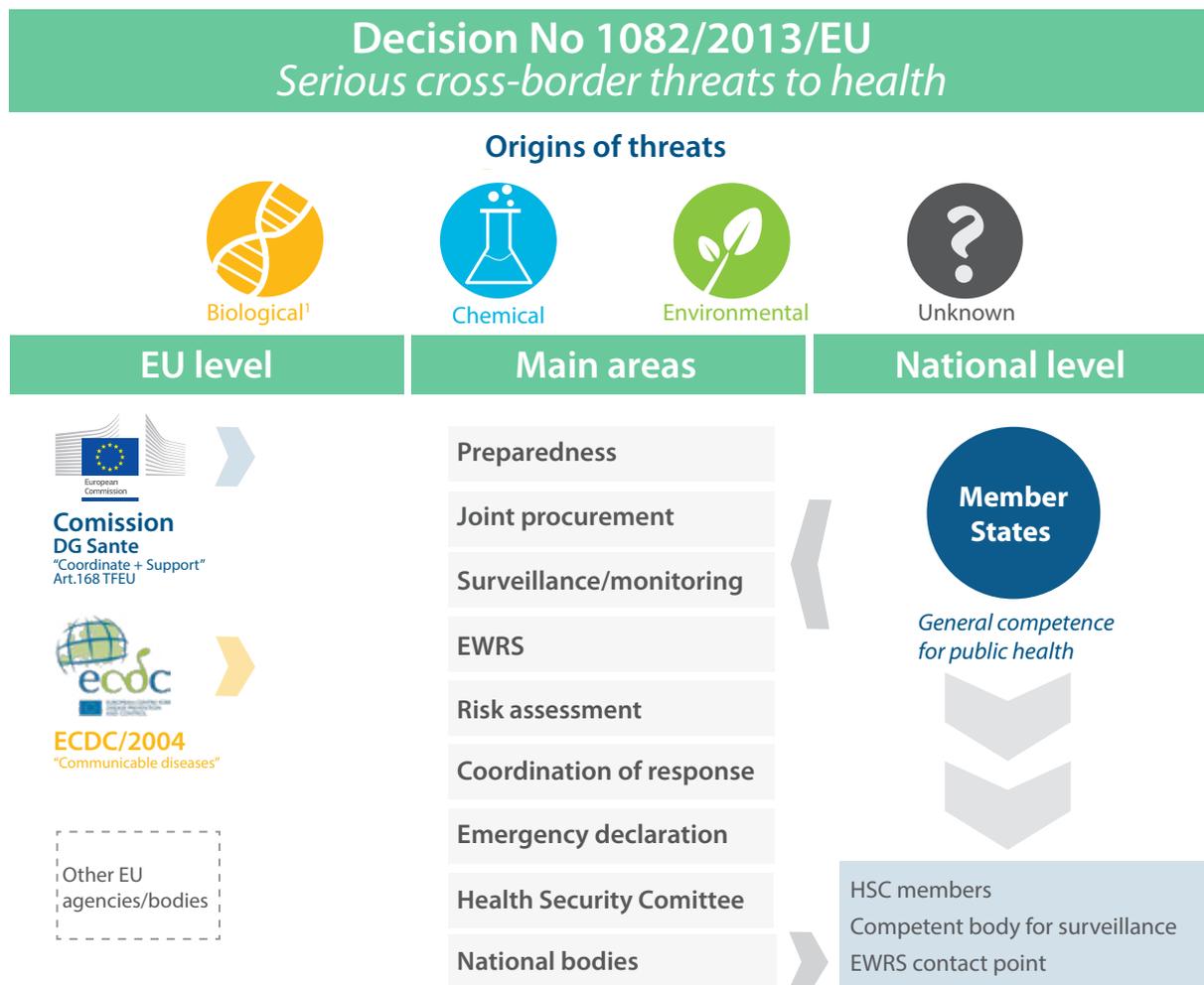
19 Decision No 1082/2013/EU.

07

In an effort to coordinate Member State actions relevant to health security in the Union, Decision No 1082/2013/EU on serious cross-border threats to health¹⁹ was adopted. It introduces the concept of an ‘all hazards approach’ (i.e. similar to the IHR) in the European legislation and puts certain obligations on the Member States and the Commission for cooperation and coordination in specific areas (see **Figure 1**).

Figure 1

Main areas of Decision No 1082/2013/EU on serious cross-border threats to health



¹ Biological threats can be communicable diseases, antimicrobial resistance and special health issues, and biotoxines

Introduction

08

The decision should enable the EU to better address risks related to serious cross-border threats to health. Its innovations in EU legislation include the formalisation and strengthening of the role of the HSC and rules on response coordination; extension of the EU legal framework to also cover threats other than communicable diseases (notably chemical and environmental threats and threats from unknown origin, but also antimicrobial resistance and bio-toxins); consultation on and coordination of preparedness planning; and a new legal basis for the already existing Early Warning and Response System and epidemiological surveillance network.

09

Another innovation of the decision is the joint procurement of medical countermeasures (e.g. vaccinations), which provides that if a Joint Procurement Agreement (JPA) is signed²⁰, specific joint procurements of medical countermeasures can be organised. The decision also provides that the Commission may declare an EU emergency situation (see **Annex I**).

Main roles and responsibilities in implementing the EU framework

10

As stated in paragraph 3, the main responsibility for health policy lies with the Member States. Additionally, the decision on serious cross-border threats to health puts a number of specific obligations on Member States for the areas described in paragraphs 7 to 9, including to nominate certain bodies and representatives for EU-level coordination structures. The Commission (i.e. in particular DG Health and Food Safety) is responsible for the implementation and development of the relevant parts of the EU health strategy and policy. It also has specific responsibilities under the decision, including providing the secretariat and presidency of the HSC, and operates its Health Emergency Operations Facility. The European Centre for Disease Control and Prevention operates the network for epidemiological surveillance of communicable diseases and the Early Warning and Response System (for a more detailed description of these responsibilities, see **Annex II**).

²⁰ The Joint Procurement Agreement was initially signed by 15 Member States in June 2014 and entered into force on 5 July 2014. As per May 2016, 24 EU Member States had signed this agreement.

EU co-funded actions in the area of threats to public health

EU health programmes

11

The EU's health strategy is supported by multiannual health programmes. The second programme ran from 2008 to 2013²¹. The third programme is being implemented in the period 2014 to 2020²². The Consumer, Health, Agriculture and Food Executive Agency (Chafea) is largely responsible for the management of the health programme. Objective 2 of the 2014-2020 health programme, which is relevant to our audit, is aligned with the activities and definitions of the decision on serious cross-border threats to health. **Table 2** provides an overview of the relevant objectives and spending or budget.

- 21 Established by Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13) (OJ L 301, 20.11.2007, p. 3).
- 22 Established by Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC (OJ L 86, 21.3.2014, p. 1).

Table 2

Health programme objectives relevant to this audit¹

	Second health programme 2008-2013	Third health programme 2014-2020
Total operational budget for the period	247 million euro	405 million euro
Number of main objectives	3	4
Sub-actions/priorities	19	23
Relevant strand for this audit	1: Improve citizens' health security 1.1: Protect citizens against health threats	2: In order to protect Union citizens from serious cross-border health threats: identify and develop coherent approaches and promote their implementation for better preparedness and coordination in health emergencies.
Spending/budget for this strand	32 million euro for Action 1.1 (approximately 13 %)	Estimated 12 million euro based on the 2013 multi-annual planning for 2014-2016 (approximately 3 %).

1 In relation to the figures presented in **Table 2** it should be noted that these are not entirely comparable between the programming periods due to different sub-priorities and a shift of certain activities from the health programme to ECDC, which has a considerable annual budget of approximately 55 million euro.

Source: ECA, based on information provided by the Commission.

Other EU funding for health security

12

Other EU funds, in particular the research framework programmes (FP7 in 2007-2013 and Horizon 2020 for 2014-2020), also provide funding for actions related to health security. The thematic areas 'Health' and 'Security' under the FP7 cooperation programme invested more than 7 billion euro²³. DG Research and Innovation and DG Migration and Home Affairs are the directorates-general in charge of this thematic areas. The new Horizon 2020 programme also addresses health and security research²⁴. It is estimated²⁵ that during 2014-2020 the EU will invest some 9.1 billion euro in these areas. For health this includes the objective of enhancing the ability to monitor health and to prevent, detect, treat and manage disease. Grants awarded under these programmes might therefore be directly relevant to health security policy and dealing with serious cross-border threats to health²⁶.

23 See FP7 budget execution figures for 2007-2013 on https://ec.europa.eu/research/fp7/index_en.cfm?pg=budget

24 Under Societal Challenges 1 'Health, demographic change and wellbeing' and 7 'Secure societies'.

25 See Factsheet on Horizon 2020 budget of 25 November 2013.

26 For example projects covering topics such as Ebola, AMR and communicable diseases, and also preparedness.

13

In defining the audit scope and objectives, we considered the EU framework for protecting citizens from serious cross-border threats to health to consist mainly of Decision No 1082/2013/EU on serious cross-border threats to health and the EU resources made available to support its implementation. Overall, this framework fits into the wider context of the EU health strategy.

14

The audit work addressed the following main audit question:

Is the EU framework for protecting citizens from serious cross-border threats to health adequately implemented?

Under this main question we examined:

- (i) whether the innovations introduced by the decision are effectively implemented;
- (ii) whether the existing systems for early warning and response and epidemiological surveillance are adequately managed and implemented;
- (iii) whether the EU health programmes are making effective contributions to protecting citizens from threats to health; and
- (iv) whether the Commission's internal coordination in terms of health security funding and public health crisis management is adequate.

15

The scope of the audit is closely aligned with the various areas of the decision on serious cross-border threats to health (also see **Figure 1** above). Sub-question 1 covered the innovations introduced in EU legislation by the decision (e.g. coordination of preparedness planning, joint procurement and the strengthened role of the HSC, see paragraphs 7 to 9), and sub-question 2 covered the systems that already existed previously (i.e. for epidemiological surveillance and early warning and response).

16

The audit scope also included an assessment of the management of EU resources made available to contribute to protecting citizens from health threats. Under sub-question 3 we assessed relevant actions and projects by DG Health and Food Safety and Chafea for the 2008-2013 and, to a certain extent, 2014-2020 programming periods.

Audit scope and approach

17

Under sub-question 4 we assessed general performance and coordination activities, notably at the level of DG Health and Food Safety's Crisis Management and Preparedness in Health Unit and ECDC's relevant operational units. We also looked into DG Health and Food Safety's coordination with other Commission services, especially in relation to research programmes with health security objectives, as well as to crisis management structures.

18

The Court does not have the mandate to examine the implementation of the WHO IHR by the Member States or the general implementation of preparedness plans at national level. This was therefore not part of the audit scope. However, certain IHR concepts were considered during the audit. As regards our audit work on the coordination of crisis management structures the audit scope did not include a full assessment of their functioning across multiple directorates-general or as part of the EU response to the Ebola outbreak²⁷.

19

Questions 1 to 4 were addressed at the level of the Commission (i.e. DG Health and Food Safety, and for questions 3 and 4 information visits were also made to DG Migration and Home Affairs, DG Research and Innovation, the Research Executive Agency (REA) and the European Research Council Executive Agency (ERCEA)) and ECDC, and discussed during information visits to four Member States²⁸. In addition to interviews during the site visits, we conducted an information visit to WHO Europe, performed a desk review of 20 health programme actions²⁹ (see **Annex III** for an overview of these) and the objectives of ten FP7 projects (see **Annex III**) and consulted Commission progress and implementation reports, as well as documents relating to the work of the HSC.

20

The materiality and potential impact relevant to the implementation and management of the areas included in the audit scope should mainly be judged by the potential costs and consequences of not dealing with cross-border public health threats in the most effective way. Emergency situations typically require the immediate availability of significant (financial) resources for response actions, and all the more so if the early response is slower or less effective than required. In addition, damaging impacts are not restricted to human health, but also potentially extend to many sectors of the wider economy, as described in paragraphs 1 and 2. Given the unpredictable nature and scale of future public health emergencies it is not possible to quantify such damages and impacts up front.

- 27 In this context we also refer to another performance audit by the Court on Commission crisis management in the external domain, including a case study of the Ebola crisis.
- 28 Information visits were made to Estonia, Italy, the Netherlands and the United Kingdom. We selected these countries based on geographical spread and risk factors such as travel, trade and external borders.
- 29 Representing approximately 56 % (i.e. 18 million euro) of the health threats funding under the second health programme. We also visited the main coordinators of seven projects on the spot.

The decision on serious cross-border threats to health introduced certain innovations for EU health security, but their implementation and development were hampered by delays, and strategic and operational challenges remain

21

We examined whether the innovations introduced by the decision on serious cross-border threats to health, as described in paragraphs 7 to 9 and **Figure 1**, were effectively implemented. Overall we found that the implementation and development of these innovations were hampered by delays, and that strategic and operational challenges remain. In the following paragraphs we report on insufficiently clear-cut results from the preparedness planning consultation and coordination and the weak measurement of performance for these activities. We also report on ECDC's role in generic preparedness, which is not sufficiently formalised, the slow progress in joint procurement of medical countermeasures and the absence of an EU mechanism to address urgent needs for medical countermeasures within the framework of the decision on serious cross-border threats to health. Finally, we report on operational and strategic challenges for the Health Security Committee and difficulties in applying the coordination of response rules.

Insufficient clear-cut results from the preparedness planning consultation and coordination

22

Member States and the Commission should consult each other within the HSC with a view to coordinating their efforts to develop, strengthen and maintain their capacities for the monitoring, early warning and assessment of, and response to, serious cross-border threats to health³⁰. That consultation should be aimed at sharing best practices and experience in preparedness and response planning, promoting the interoperability of national preparedness planning and addressing the need for different sectors (e.g. health, civil protection, transport, border control) to work together in preparedness and response planning at Union level. It should also support the implementation of core capacity requirements for surveillance and response as referred to in the IHR (see **Annex I**).

23

Member States should submit to the Commission by 7 November 2014, and every 3 years thereafter, an update on the latest situation with regard to their national preparedness and response planning for the main areas described above. To ensure compatibility and relevance of the information to the objectives, the submission of this information is based on a template adopted by the Commission.

30 Article 4 of Decision No 1082/2013/EU.

Audit observations

24

The Commission, in consultation with the Member States, adopted the template for providing the preparedness information in July 2014, only 4 months before the deadline for completion of the questionnaire by the Member States, during the Ebola crisis. Nine Member States submitted their replies on time through an electronic survey. A further 17 Member States submitted their replies late, mostly in 2015, after the Commission had reminded them several times. The Commission worked with ECDC and WHO Europe to compile a progress report on preparedness and response planning based on the Member State replies, which was put to the HSC in June and November 2015. Despite the delays in submitting the replies, this initiated the required exchange of information on preparedness and response planning.

25

However, most of the information included in this report, apart from some geographical maps sourced from WHO reports³¹, is anonymised and aggregated. It therefore does not show members of the HSC which country provided which information, suggestions for improvements or best practices, or examples, to allow for efficient and transparent exchanges of views, despite the confidential character of the HSC and the report itself. Neither the decision on serious cross-border threats to health nor the template for the questionnaire require Member States to provide supporting evidence such as implementation or action plans, national manuals or actual preparedness plans.

26

The legislation does not provide the Commission with the mandate to collect or verify such information, for example during country visits. The information included in the progress report on relevant aspects of preparedness is solely based on self-assessments by the Member States and does not contain supporting evidence. Although this does not mean that the reported information is inaccurate, the consequence is that strengths and weaknesses identified in the report and presented to the HSC are not based on data that was externally verified or reviewed. Such reviewing and increased transparency, while not foreseen by the legislation, are likely to contribute to a higher level of confidence in relation to preparedness for serious cross-border health threats (see **Box 3** on weaknesses in self-assessment in relation to IHR implementation), and would allow for better targeting of actions needed to address weaknesses.

31 WHO (2014), Summary of State Parties 2013 report on IHR core capacity implementation, Regional Profiles; http://www.who.int/ihr/publications/WHO_HSE_GCR_2014.10/en/

Box 3

International developments concerning preparedness: weaknesses in self-assessment of IHR implementation

Weaknesses inherent in self-assessments on IHR core capacity implementation have been signalled by WHO and its expert panels. The Ebola Interim Assessment Panel wrote in July 2015 that it considered it to be unacceptable that only voluntary self-assessment is required for the measurement of IHR core capacities. It referred to encouraging efforts, both within WHO and through initiatives such as the Global Health Security Agenda (see *Annex I* describing other initiatives addressing the need to enhance preparedness planning and increase transparency), **to promote evaluation frameworks, external monitoring and transparency about core capacities** and underlined that regional political agencies, such as the European Union can support this work.

The 69th World Health Assembly (23 to 28 May 2016) considered the report of the Review Committee on the role of the IHR in the Ebola outbreak and response and arrived at a similar conclusion. The Review Committee identified a lack of implementation of the IHR as contributing to the escalation of the Ebola outbreak. The approaches proposed by the Review Committee to strengthen implementation of the IHR include **recognition of external assessment of country core capacities** as a best practice.

27

Some Member States, despite their involvement in developing the template, found it difficult in practice to reply to the preparedness questionnaire and therefore had some reservations about findings in the progress report. In addition, the technical implementation of the questionnaire through the online survey showed weaknesses limiting the data quality for certain questions. This was in part due to the fact that ECDC was not involved sufficiently early by DG Health and Food Safety in the IT preparations for using the online survey tool.

28

As regards any potential EU criteria for preparedness and response planning, on top of the basic criteria in the decision³², the Commission, in its 2011 Impact Assessment³³, referred to the availability of extensive guidance on generic preparedness planning³⁴ for all types of health threats, and the fact that there was no mechanism in place to ensure its implementation in all Member States. We found that this guidance was not given any status under the framework of the decision on serious cross-border threats to health and that awareness about its content is generally low, despite significant efforts made by the Commission and several Member States to produce the comprehensive, updated version of 2011 and the translations available on the Commission’s website. If the guide is not used by the Member States, or kept up to date, this significant investment of resources is potentially lost.

32 Article 4 of Decision No 1082/2013/EU.

33 Page 17 of SEC(2011) 1519 final of 8 December 2011.

34 ‘Strategy for Generic Preparedness Planning, Technical guidance on generic preparedness planning for public health emergencies’ (Update 2011).

Audit observations

29

Overall we found that the consultation between Member States and the Commission on preparedness and response planning has been initiated as required. However, the procedures for obtaining and exchanging relevant information with a view to better coordinating efforts in relation to preparedness are not yet sufficiently robust and have not yet delivered clear-cut results.

Weak measurement of performance in preparedness coordination

30

The Commission should measure the effectiveness of Union policies and programmes. This also applies to the EU policy objectives of the decision on serious cross-border threats to health, and in particular the efforts made under Article 4 on preparedness and response planning referred to above. SMART³⁵ objectives and indicators therefore need to be defined, in close contact with the Member States, and a methodology to enable a clear progress measurement and evaluation. Member States in turn need to demonstrate their progress.

31

DG Health and Food Safety's objectives for health in the current programming period (2014-2020) include a specific objective related to the protection of citizens from serious cross-border health threats: to identify and develop coherent approaches and promote their implementation for better preparedness and coordination in health emergencies. The related specific result indicator is: 'Number of Member States integrating the developed common approaches in the design of their preparedness plans [...]'³⁶.

32

For this specific objective and indicator, the Commission, in its management plans for 2014 and 2015, set the targets at four Member States integrating the developed common approaches in the design of their preparedness plans by 2015, 14 by 2017 and all Member States by 2020. However, the objective and indicator are not included as such in the decision, meaning that Member States are not bound by them. It also does not provide criteria on what constitute integrated common approaches in the design of preparedness plans, which, according to the objective would still have to be identified and developed. We found that when the Commission set the indicator targets, neither was this concept of common approaches further developed by the Commission in agreement with the Member States, nor was there a clear and agreed approach to measuring progress.

35 Specific, measurable, achievable, relevant and time-bound.

36 The same objective and indicator are also provided in Articles 2 and 3 of Regulation (EU) No 282/2014 to measure the performance of the relevant spending under this objective.

Audit observations

33

Early in 2016, the Commission refined its methodology to measure the progress under the specific indicator and requested ECDC to perform further analysis on the data received from Member States. ECDC was asked to measure the number of Member States that had in place the elements of IHR core capacity implementation, interoperability arrangements between sectors and business continuity plans. ECDC concluded that 16 Member States declared that they had these elements in place and that the indicator for 2015 was therefore ahead of target (i.e. 14 by 2017). However, as illustrated in paragraph 32, we could not confirm that this methodology was discussed with and endorsed by the HSC.

34

We were therefore unable to conclude what the reported progress means in terms of performance and whether all definitions and concepts of the objectives, indicators and targets are supported by the Member States. This is especially important as the effective coordination of preparedness and response planning for serious cross-border threats largely depends on them³⁷, and requires stakeholders to work towards the same objectives.

ECDC's role in relation to generic preparedness is insufficiently formalised

35

ECDC has a mandate to support Member States and the Commission in preparedness activities. ECDC's mandate was traditionally for disease prevention and control and has not been formally updated since its establishment, despite important health security developments, in particular the entry into force of the IHR and the adoption of the decision on serious cross-border threats to health. We therefore examined whether it was sufficiently clear between the Commission and ECDC, as well as *vis-à-vis* ECDC's stakeholders, to what extent ECDC can provide expertise in the area of generic preparedness and how it should plan its activities and resources for this purpose.

36

ECDC's founding regulation states that it can provide scientific and technical expertise to the Member States, the Commission and other Community agencies in the development, regular review and updating of preparedness plans, and also in the development of intervention strategies in the fields within its mission (i.e. protection from infectious diseases and threats of unknown origin). The decision on serious cross-border threats to health specifically attributes tasks to ECDC for epidemiological surveillance and early warning and response, but not for support on preparedness planning.

³⁷ As acknowledged by DG Health and Food Safety in its Annual Activity Report 2015, where it reports on progress for this specific objective and indicator.

Audit observations

37

Following the adoption of the decision on serious cross-border threats to health, ECDC has been working on new tasks³⁸, especially in the area of generic preparedness, addressing the need for the EU to have an all-hazards approach. However, we found that ECDC's role and responsibilities in relation to generic preparedness were not formally defined and agreed, either through updates of the relevant legislation or, for example, in a written agreement between the Commission and ECDC, endorsed by ECDC's stakeholders. If there is insufficient formal clarity on ECDC's role in these activities and how they fit its mission, the organisation may not be able to properly prepare itself for such tasks in the long term, nor to respond effectively to requests for assistance. The risk stemming from this situation has already materialised in relation to joint work done by ECDC and WHO on a guide for influenza pandemic plan revision, as illustrated below.

38

After the pandemic influenza of 2009 one of the Council's main recommendations was the adoption of guidance on preparedness plans³⁹. Countries across Europe started revising their pandemic plans based on the lessons learned. ECDC and WHO Europe made a substantial effort in organising workshops and review work. They published a joint document in 2012 listing the outcomes of this exercise⁴⁰. Subsequently, they worked on a 'Guide for influenza pandemic plan revision'⁴¹. The drafted guide was addressed to all 53 countries in the WHO European region and was developed by experts in pandemic preparedness planning from various countries and organisations.

39

However, the Commission put on hold the publication of the guide by ECDC in March 2014, invoking doubts as regards ECDC's mandate to issue this type of guidance directly to the Member States and concluding that the HSC is the appropriate and mandated body to discuss matters of preparedness. At the time of the audit (2 years later) the timelines for discussion of the guide by the HSC (or its preparedness working group) and its publication were not known. Not publishing and promoting this guide would constitute a lost investment in terms of the resources and efforts engaged for its production and means that EU Member States and WHO Europe countries had no access to it even when efforts were made at national level to update pandemic preparedness plans.

38 One of these tasks was the assistance provided by ECDC to the Commission in aggregating the data submitted by Member States under Article 4 of Decision No 1082/2013/EU and reporting to the HSC.

39 Council conclusions on Pandemic (H1N1) 2009 – a strategic approach, paragraph 11, p. 2.

40 Key changes to pandemic plans by Member States of the WHO European Region based on lessons learnt from the 2009 pandemic, WHO Regional Office for Europe and ECDC, 2012.

41 Guide for influenza pandemic plan revision — Applying the lessons learned from the pandemic H1N1(2009): A guide for the Member States of the WHO European Region, European Union and European Economic Area, draft of 2014.

Audit observations

Insufficient Member State responsiveness to speed up the joint procurement of pandemic influenza vaccine and absence of an EU mechanism to address urgent needs for medical countermeasures within the framework of the decision on serious cross-border threats to health

40

Following the H1N1 influenza pandemic crisis in 2009, the Council⁴² invited the Commission to report on and develop, as soon as possible and no later than December 2010, a mechanism for joint procurement of vaccines and antiviral medication. Already in 2011, the Commission had invited Member States to provide needs analyses in relation to such a joint procurement procedure. However, it was not until 2013, through the adoption of the decision on serious cross-border threats to health, that there was an EU legal basis for the joint procurement of medical countermeasures. The Commission adopted the Joint Procurement Agreement on 10 April 2014. Countries which have signed the Joint Procurement Agreement can participate in specific joint procurement procedures for medical countermeasures, which require a minimum of four Member States.

41

In February 2016, the Commission successfully finalised and published the specifications for the joint procurement of personal protective equipment, initiated in the wake of the Ebola crisis. In addition, several other specific joint procurement procedures have been started. However, preparation of the specific joint procurement procedure for pandemic influenza vaccine, initially requested by the Council in 2010, was still ongoing. Despite various requests sent by the Commission only five Member State needs assessments had been received by April 2016. Future progress depends on the Member States' commitment to these procedures. The Commission reported in its Annual Activity Reports for 2014 and 2015 that the targets for joint procurement of pandemic influenza vaccine had not been met.

42

An emergency instrument to address urgent needs of medical countermeasures would require less complexity and provide higher speed and greater flexibility than the joint procurement agreement provides. Following a case of diphtheria in Spain in 2015, when the treating hospital struggled to get antitoxin in Europe⁴³, the HSC and the Commission decided to look into potential solutions to address such cases in the future. The HSC agreed to task its preparedness working group with the development of standard operating procedures for a rapid and consistent Union response in such emergencies. In January 2016, the Commission requested Member States to nominate participants in the HSC preparedness group on a standard operating procedure for exchanging medical countermeasures. However, during the audit we could not obtain evidence that the relevant procedure had been agreed or that specific work had been initiated (also see paragraphs 46 and 47).

42 Council conclusions of 13 September 2010 on lessons learned from the A/H1N1 pandemic — health security in the European Union.

43 See ECDC Rapid Risk Assessment 'A case of diphtheria in Spain' of 15 June 2015: 'The detection, management and public health response to the first case of diphtheria in Spain in nearly 30 years has highlighted challenges for preparedness against diphtheria in the European Union.'

Audit observations

43

Overall, as regards the implementation of the joint procurement provisions, we found that progress in organising the joint procurement of pandemic influenza vaccine, initiated after the 2009 H1N1 pandemic, had been slow by the time of our audit due to low Member State responsiveness and that there is no mechanism at EU level to address urgent needs for medical countermeasures, potentially reducing the EU's preparedness for pandemic influenza.

Strategic and operational challenges for the formalised Health Security Committee

44

The decision on serious cross-border threats to health establishes the HSC, composed of representatives from the Member States, and chaired by the Commission (see **Annex II** for a more detailed description of its role and responsibilities).

45

All Member States have nominated their members of the HSC. Plenary meetings took place once in 2014 and three times in 2015, as well as a large number of audioconferences, in particular in relation to the evolving Ebola crisis (see **Box 4**).

Box 4

The Health Security Committee and the Ebola outbreak

Discussions about Ebola started in the HSC in March 2014, after the initial notification of the outbreak by Guinea to WHO and the issuance of a rapid risk assessment by ECDC. According to this rapid risk assessment, the risk of transmission to the EU was low, although certain situations could justify measures in the EU, such as tourists returning from Guinea visiting family and friends or exposed persons seeking medical attention in the EU.

The Ebola outbreak was declared a PHEIC by WHO on 8 August 2014. A week earlier, the Commission had called an HSC audioconference meeting in view of the quickly deteriorating circumstances in the affected countries. Many different Commission services, ECDC, WHO and the Member States attended. The objective was to exchange information and coordinate actions on measures being taken and planned, to identify additional actions to strengthen preparedness and to consider assistance to affected countries. Options for the medical evacuation of EU/EEA citizens working in them were also discussed. DG Health and Food Safety, with assistance from ECDC, had drafted a questionnaire on Ebola preparedness (i.e. to obtain an overview of laboratories capacities, hospital facilities for Ebola, suitable transport), which was sent out to the Member States and answered by most of them. After the declaration of the PHEIC by WHO, the frequency of HSC meetings dedicated to Ebola increased significantly (almost weekly until January 2015). Only from February 2015, did operational topics return to the HSC agenda, such as joint procurement and the working groups.

Audit observations

46

At the time of our audit, the terms of reference had been drafted for four working groups under the HSC: a permanent working group on preparedness, a permanent communicators' network, an ad hoc working group on newly arrived migrants and communicable diseases, and an ad hoc working group on combating antimicrobial resistance (AMR) (see **Box 2**). However, the HSC only formally established the communicators' network and preparedness working group. Based on their terms of reference, these working groups were to prepare an annual work plan, including performance indicators for evaluation, to be submitted and approved by the HSC, to ensure a structured way of working on these topics. We found that at the end of the audit (March 2016) no annual work plans with the indicators required under the working groups' terms of reference had been submitted for approval to the HSC. This means that the work done by these working groups is not implemented in accordance with the terms of reference and that their performance is not measured appropriately.

47

Participation in the HSC working groups is voluntary. At the end of our audit, all Member States had nominated their participants in the communicators' network. The Commission had also sent the request to nominate participants to the preparedness working group (also see paragraph 42 above), but by March 2016 only nine EU Member States had done so. The participation of a large number of Member States is important to ensure that outputs of the working groups are later supported and taken forward by the HSC.

48

We found that when the HSC was still informal and mandated by the terms of reference issued by the Council (i.e. until 2013), it had work programmes with annual objectives and reporting, as well as documented action plans with progress reporting. The status and mandate of the current HSC are different under the decision on serious cross-border threats to health. However, we did not find evidence in the HSC documents or at the Commission that the HSC currently executes its tasks on the basis of an agreed strategic planning or up-to-date roadmap identifying relevant longer-term strategic topics. During the course of the audit, Member State representatives also expressed some concern over the nature of the HSC audioconferences, perceived by some to be too focused on technical rather than strategic discussions.

Audit observations

49

Overall, the work of the HSC, in particular in response to the Ebola crisis, has been very important and has initiated the development of collaborative mechanisms, such as for the use of laboratories and for medical evacuation that could be sustained or reactivated for future crises⁴⁴. The HSC became a main platform where representatives from relevant Commission services and Member States joined forces and started exchanging information, including with WHO. This further demonstrates the great relevance and importance of the HSC, which was also acknowledged by the Council in its conclusions on the lessons learned for public health from the Ebola outbreak in west Africa⁴⁵.

50

However, our evidence also shows that from the moment when Ebola was declared a public health emergency of international concern by WHO, for approximately 6 months, most HSC work and its audioconferences focused on the response to the Ebola crisis — which was a low-risk health threat for the EU⁴⁶. As a result, other HSC activities in relation to the strategic development and implementation of the framework of the decision on serious cross-border threats to health were not at the top of the agenda during this period.

51

The high incidence of major health events in recent years, such as Middle East respiratory syndrome (MERS) Corona virus, Ebola and Zika and the absence of strategic planning for the HSC, explain to a certain extent why HSC meetings have often been of a technical, response-oriented nature, rather than strategic. In addition, we identified slow progress on the working groups which should perform or support the HSC's technical work.

52

The Commission itself can also still improve how it produces relevant mappings or reports on activities that take place in other Commission services, agencies and programmes in this context (also see paragraphs 96 to 102). These factors combined indicate that there is still scope for enhancing the HSC's strategic work. This is important as the HSC now has a strong mandate, in particular in terms of coordinating, in liaison with the Commission, the preparedness and response planning of the Member States (see paragraph 44) and thereby ensuring the highest possible level of protection against health threats in the EU.

44 Without prejudice to the audit findings the Court might raise as a result of its ongoing performance audit of Chamber III on crisis management structures, which also deals with the EU response to the Ebola outbreak.

45 Council conclusions on 'Lessons learned for Public Health from the Ebola outbreak in west Africa — Health Security in the European Union', (2015/C 421/04) of 17 December 2015.

46 See ECDC's Rapid Risk Assessment 'Outbreak of Ebola virus disease in west Africa', fourth update, 3 September 2014, which stated that the risk of Ebola spreading from a patient who arrives in the EU as a result of a planned medical evacuation was considered extremely low.

Applying 'coordination of response' rules is difficult in practice

53

The introduction of the decision on serious cross-border threats to health states that although the Member States have a responsibility to manage public health crises at national level, measures taken by individual Member States could damage the interests of other Member States if they are inconsistent with one another or based on diverging risk assessments. Therefore, Member States, when intending to adopt public health measures to combat a serious cross-border threat to health, should⁴⁷ first inform and consult the other Member States and the Commission on those measures. If the need to protect public health is so urgent that the immediate adoption of the measures is necessary they may inform the other Member States and the Commission after the adoption.

54

Experience during the Ebola crisis showed that this requirement to inform other Member States (i.e. through the HSC) before taking measures at national level is challenging. Some Member States decided to diverge from ECDC and WHO risk assessments and implemented entry screening of travellers at airports receiving flights from west Africa. In their subsequent risk assessments, ECDC and WHO continuously did not recommend entry screening measures, pointing at the cost implications, poor results and existence of effective exit screening in the affected countries⁴⁸. The Commission invited EU health ministers to a high-level Ebola coordination meeting on 16 October 2014 where possible entry measures at EU borders were also discussed. One of the outcomes was for the Commission and WHO to organise an audit on exit screening for Ebola in the affected countries in west Africa. The audit concluded that the exit screening processes were well implemented and that the procedures were very likely to catch persons with signs and symptoms of Ebola.

55

In its 2015 implementation report⁴⁹ the Commission therefore stated that a major conclusion from the Ebola outbreak was that there was scope for improving the implementation of the provisions which require Member States to coordinate national responses. If information on national public health measures which Member States are considering taking or have taken is not adequately shared with other Member States at an early stage, this could impact other Member States. Examples include duplications of checks and tracing of people that have already been checked on their first entry to the EU, requiring additional efforts and resources from other Member States or increased media pressure on public health authorities to explain why certain Member States follow WHO or ECDC scientific advice and others do not.

47 According to Article 11 of Decision No 1082/2013/EU.

48 ECDC's Rapid Risk Assessment 'Outbreak of Ebola virus disease in west Africa', fourth update, 3 September 2014, or ECDC's Technical Report 'Infection prevention and control measures for Ebola virus disease — entry and exit screening measures', 12 October 2014.

49 Report on the implementation of Decision No 1082/2013/EU, COM(2015) 617 final of 7 December 2015.

Audit observations

The important role of existing systems and procedures for early warning and response and epidemiological surveillance is widely recognised but there are certain upgrades to be made

56

We examined whether the existing systems for early warning and response and epidemiological surveillance, for which the decision on serious cross-border health threats provides the legal basis (also see **Figure 1**), are adequately managed and implemented. Overall, we found that these existing systems have been operational for years and that their important role at EU level is widely recognised by stakeholders, but that certain upgrades were needed to procedures and systems. In the following paragraphs we report on the need for further enhancements of the EWRS and interfacing with other alert systems and the fact that the updated EU-level approach to early warning and response for serious chemical and environmental threats is not yet tested. Finally, further work is required on the EU system for epidemiological surveillance for optimising data comparability and quality.

Despite extensive use and wide appreciation of the EWRS, further enhancements are needed, including for the interfaces with other alert systems

57

The decision on serious cross-border threats to health provides the legal basis for the EWRS for notifying at Union level alerts in relation to serious cross-border threats to health. The EWRS should enable the Commission and the competent authorities responsible at national level to be in permanent communication for the purposes of issuing alerts, assessing public health risks and determining the measures that may be required to protect public health. ECDC should support and assist the Commission by operating the EWRS and by ensuring with the Member States the capacity to respond in a coordinated manner. ECDC should analyse the content of messages received by it via the EWRS and should provide information, expertise, advice and risk assessment.

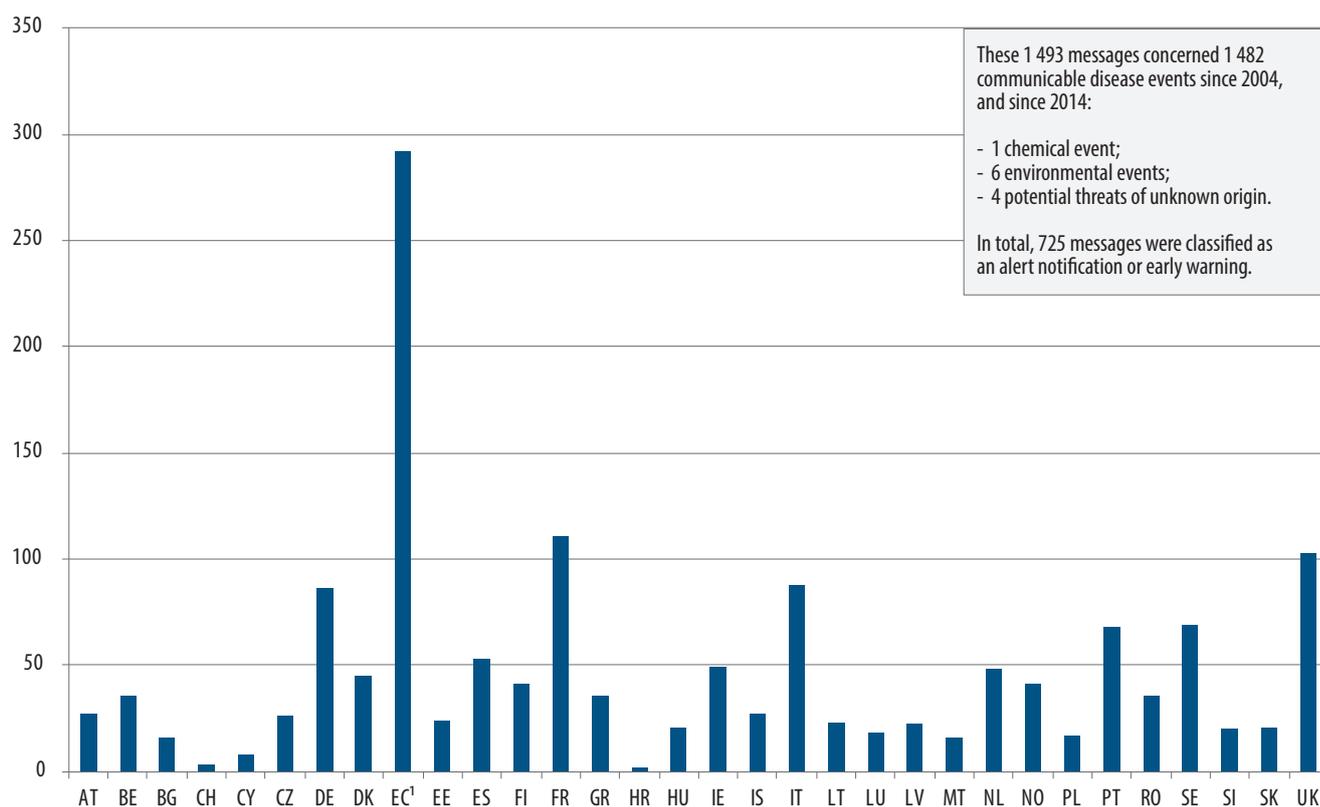
58

The Commission and ECDC should also take action to ensure that the EWRS is efficiently linked with other Community alert systems (e.g. animal health, food and feed and civil protection). Based on these standards, we have made a general assessment of the EWRS's adequate functioning and management.

59

Following the adoption of the decision, the EWRS has been modified to include changes, such as the addition of new data fields for threats other than communicable diseases and the integration of the definitions on alert notification. We found that the EWRS is widely used by the relevant Member State authorities and the Commission. Since 2004, 1 493 messages have been initiated in the EWRS by the Member States and the Commission (see **Figure 2**). However, despite updates and upgrades over time, we found that it has inherent system limitations due to the outdated system design, which does not allow for the integration of the latest IT tools, social media connections or full mobile device compatibility.

Figure 2 Messages initiated in the EWRS (2004-2015)



These 1 493 messages concerned 1 482 communicable disease events since 2004, and since 2014:

- 1 chemical event;
- 6 environmental events;
- 4 potential threats of unknown origin.

In total, 725 messages were classified as an alert notification or early warning.

1 EC is European Commission

Source: ECA, based on EWRS data provided by ECDC in October 2015.

Audit observations

60

The latest ECDC external evaluation report⁵⁰, referring to the 2008-2012 time-frame, identified a broadly positive rating of the EWRS technical design and user-friendliness, but also noted that the performance of the EWRS during crises had been poor, stating that the system had easily overloaded in the past and that there appeared to be room to review the EWRS to enable it to better support health emergency situations.

61

There is currently no dedicated situational awareness platform or tool at EU level for maintaining a real-time overview of national public health measures taken for dealing with a serious cross-border health threat. Either the EWRS is used for such purposes or emails are exchanged, for example between HSC members and the Commission. There is scope to develop such functionality, for example in a dedicated tool or an integrated function in an enhanced version of the EWRS.

62

An EWRS Committee existed until 2012. This Committee dealt with technical aspects of health crises while the informal Health Security Committee was more strategically oriented at that time⁵¹. Our findings suggest that there is still a need to perform such technical preparatory work in the current framework (also see paragraph 51 on the HSC above). Options for organising a group to review public health risk assessments and to explore policy options had also been discussed between the Commission and ECDC at the time of our audit (March 2016). Setting up such a group was deemed necessary to avoid overwhelming the HSC, but no practical arrangements had been proposed or agreed.

63

An EWRS user group or similar body to support and facilitate the work of the EWRS user community for functional and procedural aspects of the system's daily use and potential requests for changes and upgrades, as well as training, did not exist at the time of the audit. However, similar activities took place in the EWRS Committee until 2012 and Member State representatives for the EWRS identified a continuing need to regularly discuss these issues.

50 The second independent evaluation of the ECDC in accordance with its founding regulation (Regulation (EC) No 851/2004), Final Report of 8 October 2014.

51 For most Member States, the HSC member and the EWRS contact point are not the same person. The general distinction is between senior policy staff from health ministries that are delegated to the HSC and senior technical staff from national public health agencies appointed as EWRS contacts, although other configurations exist.

Audit observations

64

In its 2015 implementation report⁵², the Commission stated that it was considering a further upgrade of the EWRS that would in the medium term allow more user-friendly functions to be developed as soon as the proposal for a full reshape (i.e. modernisation) of the EWRS IT tool had been agreed with the stakeholders and ECDC. However, we could not obtain any specific Commission evidence of progress in this context at the time of the audit.

65

Already in 2011, the Commission⁵³ identified agencies and rapid alert systems at EU level⁵⁴ that should be linked to the EWRS. The list included comments on each alert system justifying the need to ensure that alert notifications under the EWRS are linked with them. It identified objectives and gaps to be closed in relation to this interfacing. We examined progress made on this interfacing since 2011 and found that at the time of our audit (March 2016) there was still a list⁵⁵ of alert and information systems to be progressively linked with the EWRS.

66

The issue of linking alert systems is important, as different EU alert systems (e.g. Europhyt for plant health or RAPEX for dangerous non-food products) managed by different Commission services may also have different contact points in Member States, making appropriate channelling of communication at national and EU levels essential.

67

According to the Commission⁵⁶, full completion of the (procedural and technical) interfacing activities might not be achieved until there is more clarity on the scope and impact of the 'full reshape' of the EWRS IT tool as described in the previous paragraphs. In the meantime, effective procedures still need to be in place to avoid any overlap or duplication of activities and to ensure effective early response to alerts for different threats.

52 COM(2015) 617 final.

53 'Structure for preparedness and response to cross-border health threats' annexed to impact assessment SEC(2011) 1519 final.

54 For example alert systems for non-food dangerous products, for animal health and food safety.

55 Annex to the Draft Implementing Act under Article 8 of Decision No 1082/2013/EU, not yet adopted at the time of the audit.

56 COM(2015) 617 final.

Audit observations

68

Overall, we found that the EWRS has been operational for many years and that its important role at EU level is widely recognised by stakeholders, including EWRS users consulted during our audit. However, the Commission and ECDC had not yet taken substantial action to further enhance the EWRS and develop integrated solutions for situational awareness and incident management for serious cross-border threats to health. In addition, the procedural or technical interfacing with other rapid alert systems at Union level was not yet completed.

The updated EU level approach to early warning and response for serious chemical and environmental threats is not yet tested

69

If a threat is raised in accordance with the alert notification rules of the decision on serious cross-border threats to health, the Commission should make available to the national competent authorities and to the Health Security Committee, through the EWRS, a risk assessment of the potential severity of the threat to public health, including possible public health measures⁵⁷. ECDC should prepare such a risk assessment if the threat concerns a communicable disease, AMR or related special health issues, or is of unknown origin. The European Food Safety Authority and other Union agencies can also be requested by the Commission to provide the risk assessment if appropriate. Where the risk assessment needed is totally or partially outside the mandates of the Union agencies, and it is considered necessary for the coordination of the response at Union level, the Commission should provide an ad hoc risk assessment. We examined how this would work in practice.

70

For chemical and environmental threats, the decision gives full discretion to the Commission to source a rapid risk assessment from any appropriate source. At the time of the audit, rapid risk assessments for chemical threats were sourced from an EU co-funded project. The project developed a comprehensive toolkit to deal with such threats, but came to an end in March 2016. In order to fulfil its legal obligation to provide rapid risk assessments for these threats after that date, the Commission developed a standard operating procedure with its Scientific Committee⁵⁸, which took over some, but not all, of the project's outputs to provide the required capacity.

57 Article 10 of Decision No 1082/2013/EU on public health risk assessments.

58 When preparing its policy and proposals relating to consumer safety, public health and the environment, the Commission relies on independent Scientific Committees to provide it with sound scientific advice. The Scientific Committees can call on additional expertise from scientific advisers and a database of experts. One of three committees launched in 2009 was the Scientific Committee on Health and Environmental Risks (SCHER). It was replaced by the new SCHEER Committee in 2016.

Audit observations

71

The frequency of serious cross-border chemical incidents is generally low, but their nature entails that there may be a requirement to deliver rapid risk assessments in timeframes as short as 12-36 hours, and out of office hours. The Scientific Committee did not provide its scientific advice on such a basis before.

72

An exercise held by the same project in 2016 further illustrated the added value of the components of its toolkit for dealing with chemical threats. It showed that once all experts in the Scientific Committee's Working Group on rapid risk assessment for chemical threats was recruited (the call for experts closed on 9 May 2016), a significant training and exercise effort would most likely be required until this mechanism reached optimal effectiveness to deliver rapid risk assessments of the required quality and within the required timeframes. In addition we found that the hosting of the IT tool⁵⁹ developed by the project, for monitoring potential serious chemical incidents before alerting them to the EWRS, had indeed been taken over from the project by the Commission. However, only 14 Member States had registered users at the time of our audit, meaning that there is no full and consistent EU coverage for this type of threat reporting. The Commission did not provide clear evidence of how the platform would be moderated and maintained, or how training and promotion of its use would be organised.

73

The standard operating procedure for rapid risk assessments to be performed by the Scientific Committee only referred to chemical incidents and did not mention environmental threats. We did not identify any other standard operating procedure at the level of the Commission for obtaining rapid risk assessments for serious cross-border environmental threats. Overall there was little EU-level experience in responding to serious cross-border chemical or environmental threats, and the relevant updated monitoring and early response arrangements for such threats were yet to be tested.

⁵⁹ Rapid Alert System for chemical threats: RASCHEM.

Audit observations

The EU system for epidemiological surveillance generally works well, but some further work is required to optimise data comparability and quality

74

The Commission should⁶⁰ establish and update procedures for the operation of the epidemiological surveillance network as developed in application of specific provisions in the ECDC founding regulation. In addition, when reporting information on epidemiological surveillance, the national competent authorities should, where available, use the case definitions⁶¹ adopted in accordance with the decision for each communicable disease and related special health issue included in an EU list of diseases. The Commission adopts case definitions to ensure data comparability and compatibility at Union level. ECDC hosts and operates the epidemiological surveillance platform TESSy to which Member States upload their surveillance data. Improving the quality of surveillance data collected at a European level constitutes one of ECDC's objectives in its long-term surveillance strategy for 2014-2020. ECDC's strategic multiannual programme⁶² also states that data quality and comparability across Member States can be increased.

75

ECDC and surveillance experts in the Member States have collaborated to develop surveillance standards in order to streamline EU surveillance and to improve data quality. ECDC considers Member States' compliance with reporting requirements to be overall satisfactory. However, data quality (completeness and representativeness) is often problematic. ECDC has conducted specific data quality assessments on three⁶³ diseases to assess quality indicators such as completeness, precision and validity. These assessments have identified multiple shortcomings for these criteria.

76

A project run by ECDC since 2009 devoted to improving the quality of data collected by the national surveillance systems was planned to finish in 2011, but was still ongoing at the end of 2015. Finally, according to ECDC, one of the factors contributing to the data quality issues is the fact that Member States often choose to use other case definitions than the EU case definitions established by a 2012 Commission implementing decision⁶⁴.

77

Overall, we therefore found that ECDC's efforts to address issues in epidemiological surveillance data reporting have not yet been fully effective to ensure optimal data comparability and quality. Member States could also still improve in this area by consistently using EU-level case definitions and optimising their data delivery to ECDC.

60 Chapter III of Decision No 1082/2013/EU.

61 A case definition is a set of commonly agreed criteria that have to be fulfilled in order to accurately identify cases of a targeted serious cross-border threat to health.

62 ECDC Chapter 9.1 Surveillance 'Context and future outlook'.

63 ECDC collects, analyses and disseminates surveillance data on 53 communicable diseases and related special health issues from all 28 European Union (EU) Member States and two of the three remaining European Economic Area (EEA) countries (Iceland and Norway) (<http://ecdc.europa.eu/en/activities/surveillance/Pages/index.aspx>).

64 Commission Implementing Decision 2012/506/EU of 8 August 2012 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community Network under Decision No 2119/98/EC of the European Parliament and of the Council (OJ L 262, 27.9.2012, p. 1).

The performance of the health programme as regards protecting citizens from health threats showed weaknesses

78

We examined whether the EU health programmes are making effective contributions to protecting citizens from threats to health. This included a detailed examination of the management by the Consumer, Health, Agriculture and Food Executive Agency (Chafea) and performance of 20 actions (see *Annex III* for an overview) funded under the health threats objective of the second health programme (see paragraph 11), including visits to coordinating beneficiaries of seven projects. We also audited the progress of the health threats objective under the current third health programme in terms of relevant actions formulated in the annual work plans and the related performance measuring by the Commission. Overall, we found that the performance of the health programmes, as regards protecting citizens from (serious cross-border) health threats, showed weaknesses. In the following paragraphs we report on the lack of sustainable results for health threat actions under the second health programme (2008-2013) and weaknesses in measuring the indicator for the health threat objective under the third health programme. For the 2014-2016 period we also found a relatively low level of spending on health threat actions, considering the importance and ambition of the relevant objective and available resources.

Lack of sustainable results for health threat actions under the second EU health programme

79

The second health programme should⁶⁵ complement, support and add value to the policies of the Member States by protecting and promoting human health and safety and improving public health. The programme has three objectives, one of which is to improve citizens' health security. Under this objective, the action covered in the scope of this audit is Action 1.1: Protect citizens against health threats.

80

The EU financial regulation requires the budget to be implemented in compliance with the principles of sound financial management (i.e. economy, efficiency and effectiveness). The principle of effectiveness requires attaining the specific objectives set and achieving the intended results. The Commission and Chafea need to ensure that the co-funded actions contribute to achieving the objectives of the health programme. We also consider that results delivered by the funded actions, provided that they are of sufficient quality, should be sustained and promoted after the actions finish, in order to ensure that there is an impact and added value from them.

65 Article 2(1) of Decision No 1350/2007/EC.

Audit observations

81

Most of the 14 projects⁶⁶ in our sample of 20 actions performed well in terms of producing the agreed deliverables (except for two, which were rated by Chafea as 'fair' and failed to produce some of the required deliverables, or to the required quality). However, we found that many deliverables, even if very practical or ready for use (e.g. toolkits, protocols, guides) were not being used after the projects had finished, or no clear demonstration could be provided of how the deliverables influenced policymaking at national or EU levels. For nine out of the 12 completed actions audited we identified significant issues concerning the lack of sustainability of results, which in many cases were also identified in Chafea's own internal assessment notes prepared at the end of these projects (see **Box 5** for examples).

82

In addition, we found that Chafea and/or the Commission give very limited technical feedback on the content of project deliverables and policy relevance when the projects finish. This was also confirmed by the beneficiaries that we visited on the spot. When they finish, Chafea assesses projects' potential for the broader policy context and the relevance of the action for DG Health and Food Safety's policy. However, we found that DG Health and Food Safety, despite having access to these Chafea files, does not systematically review the information included in them to assess which role it can play in taking results marked as relevant for its policies further at EU level or enabling a stronger or wider EU impact⁶⁷. During our visits to project coordinators we discussed their concerns that despite significant dissemination activities required under the grant agreement, they find it challenging to reach specific target audiences, in particular EU-level and national level policymakers.

66 The sample included 14 projects, one joint action and five procurement actions (see **Annex III**).

67 The Court has already recommended that the Commission evaluate projects *ex post* in order to improve the design of forthcoming projects by applying lessons learnt: see Recommendation 2 of Special Report 2/2009 on the first health programme (2003-2007).

Box 5

Examples of audited projects and issues found

Our audit work for one project in the sample showed that part of the project **results could not be sustained** because the network of specialists using the developed IT platform largely ceased to function after the project ended. We also audited a project with extensive research components, which proved to be overly complex and costly. The **main objective of this project was not achieved**. This was in part due to the fact that lessons from the project's predecessor were not duly taken into account and ambitions were therefore set too high. In a third project for screening of a specific disease in certain populations we found that the project was very successful at delivering the required high-quality outputs, but its **outputs were not updated further after the project finished, nor widely used**. The contributions of these projects to the health programme's health threats objective would therefore rapidly decrease with time.

83

The *ex post* evaluation of the health programme⁶⁸ listed similar issues saying that even though a considerable effort was made during the second half of the programme to enhance dissemination, there remained room for improvement in terms of raising awareness among relevant stakeholders of the results⁶⁹ of co-funded actions, in order to maximise their uptake and impact⁷⁰. In addition, the evaluation report identified that if policy links are absent, it is difficult to overcome barriers for EU-wide implementation of results. According to the same report, not all co-funded actions were particularly effective when it came to achieving tangible and useful results and impacts. While joint actions (see **Box 6**) typically achieve a tangible impact, the report said, projects relatively often fail to see their results taken forward and put into practice. Among other reasons this was due to insufficient attention being paid to key barriers to implementation and engagement of relevant enablers⁷¹.

84

As regards the five procurement items (see *Annex III*) that we audited at DG Health and Food Safety and Chafea, we also identified a limited uptake of outputs and evaluation of results. Recommendations from final activity and evaluation reports for exercises and workshops/trainings were generally not integrated in action plans whose implementation could be monitored⁷². Two exercises (held in 2011 and 2014) included in our sample of five procurement items covered chemical threats and identified many similar and also some identical issues and recommendations.

68 *Ex post* evaluation of the health programme (2008-2013), 2016.

69 The text in this paragraph is paraphrased from the *ex post* evaluation report. The use of the terms 'results' and 'impacts' here is therefore not necessarily aligned with the Court's methodology.

70 Executive summary of the *ex post* evaluation of the health programme (2008-2013), 2016.

71 Conclusions of the *ex post* evaluation of the health programme (2008-2013), 2016.

72 This also concerned four studies procured under a 2012 framework contract for which we found that DG Health and Food Safety had no structured approach for collecting and documenting the recommendations, identifying relevant actions and monitoring implementation progress. These studies had also not been disseminated to the HSC at the time of the audit (October 2015).

Box 6

Joint actions under the health programme

The EU health programme includes an innovative, promising funding instrument called '**Joint Actions**'. These are generally co-financed by competent authorities responsible for health in the Member States. Joint actions' proposals should provide a genuine **European dimension**. On average, joint actions have included 25 partners⁷³. The fact that joint actions involve or get support from national competent authorities for public health should allow for a better uptake of results and policy impact. However, given their significant size, they take more time to prepare and also require political backing and national co-funding. This means that, despite their potential for increasing the EU-wide take up of outputs produced with health programme funding, there cannot be too many subsequent joint actions in one policy area.

73 Chafea publication on joint actions under the third health programme (2014-2020).

Audit observations

85

Two actions implemented under administrative arrangements with the Joint Research Centre were discontinued after 1 year and 6 years respectively. When the first action for an epidemiological modelling network was discontinued, the Commission did not make an assessment of the action results and did not document its considerations to close the action. The second action continued for 6 years, from 2005 until 2011. It concerned an information exchange platform for public health situations. It was developed at the request of Member States based on discussions within the HSC, but was discontinued in 2012, when the Commission decided to close all existing IT systems that were not integrated in any legal base.

86

Notwithstanding the issues presented above, there is evidently high added value in the audited projects in terms of EU-wide networking and capacity building⁷⁴. All project grants are implemented by consortia of partners, and although the geographical spread in this part of the health programme is not yet optimal and there is a certain concentration of activities with a limited number of national agencies, much experience has been gained. However, the Commission does not take sufficient structured action, in collaboration with its partners, agencies and committees, to optimise the policy feedback loop. This is an issue, in particular because the health programme is a policy driven programme.

87

We found that in the third health programme (2014-2020) (also see paragraphs 89 to 94 below), there was a shift from projects to procurement⁷⁵. This is a different funding mechanism putting the ownership of the outputs with the Commission. However, as already mentioned in the Ex-post evaluation of the second health programme, there is a risk that excessive reliance on service contracts would be detrimental to health programme inclusiveness (in terms of types and geographic spread of beneficiaries). Our audit work for the second health programme showed (see paragraph 84) that also in the area of procurement, Chafea and the Commission could have performed better in ensuring sustainable results.

88

Overall, the sustainability of results is not ensured for most of the audited actions under the health threats action of the second health programme, limiting their contribution towards achieving the objective of protecting citizens from threats to health. The Commission could take more effective action to help beneficiaries in overcoming barriers for targeted dissemination and assessing and promoting the policy relevance of completed actions.

74 As already recognised by the Court in paragraph 88 of its Special Report 2/2009 on the first health programme (2003-2007).

75 There have been no calls for projects in 2014, 2015 and 2016 for the health threats objective.

Weaknesses in measuring the indicator for the health threats objective under the third EU health programme (2014-2020) and a relatively low level of spending in 2014-2016

89

The third health programme for Union action in the field of health (2014-2020)⁷⁶ covers four specific objectives and indicators, one of which (i.e. Objective 2) addresses serious cross-border threats to health: 'In order to protect Union citizens from serious cross-border health threats: identify and develop coherent approaches and promote their implementation for better preparedness and coordination in health emergencies'. The objective should be measured through the increase in the number of Member States integrating coherent approaches in the design of their preparedness plans (also see paragraphs 30 to 34). Thus the funded actions should contribute to achieving this specific objective, and methodologies should be in place to effectively measure the progress through the specific indicator.

90

The financial envelope for the implementation of the 2014-2020 programme is 449 million euro. The criteria for establishing annual work programmes⁷⁷ say that there should be a balanced distribution of budgetary resources between the different objectives of the programme.

91

We analysed the Commission's internal multiannual planning established in 2013, and a draft 2016 update⁷⁸ which we received during the audit. For Objective 2 activities were initially planned for three out of the four underlying thematic priorities. The budget overview showed that the expected overall amount for the period 2014-2020 for Objective 2, covering all different funding mechanisms, would be 12 069 000 euro, or 3 %⁷⁹ of the total programme amount across all four objectives.

92

Even if the details and potential adjustments of the 2016 review of the indicative multiannual planning and the potential changes for Objective 2 were not yet available at the time of our audit, the evidence showed that fewer actions had been included in the annual work programmes for 2014 and 2015 than were initially planned⁸⁰. Consequently, the programme was not on track to spend the forecast 3 % of the total available resources on Objective 2 by 2020. This casts doubt over whether the relatively low level of spending for this objective is sufficient to achieve this important and ambitious objective, and does not achieve a balanced distribution of budgetary resources between the objectives⁸¹.

- 76 Regulation (EU) No 282/2014.
- 77 Annex II to Regulation (EU) No 282/2014.
- 78 The full 2016 update was still ongoing at the time.
- 79 In an updated version of this mapping the figures had been increased to a total forecast amount of 14 685 000 euro for Objective 2 representing 3.63 % of the total health programme for 2014-2020.
- 80 No calls for projects were launched under this objective in 2014, 2015 or 2016.
- 81 According to the forecasts, Objective 3 would take 52.5 %, and Objectives 1 and 4 approximately 20 % of the budgetary resources for the programme.

Audit observations

93

We also examined whether there was a clear methodology for measuring the specific indicator associated with Objective 2 (see paragraph 89). Similar to our observation in paragraphs 30 to 34, we could not identify such a methodology. Chafea collects certain information on the implementation of the health programme, in collaboration with the national focal points of the health programme in the Member States, but not with the specific aim of quantifying the progress under this indicator on the basis of projects' results and outcomes. Although the results of the few actions funded until now under Objective 2 of the third health programme were not assessed in this audit, we find that there is no clear methodology to measure the progress under the relevant specific indicator from the funded actions.

94

Overall, the measuring of the indicator for the third health programme's objective to protect citizens from serious cross-border threats to health showed weaknesses and there was a relatively low level of spending for this objective in 2014-2016, in any case much lower than for the other main objectives of the programme. This raises concerns over whether a sufficient number of policy-relevant actions to achieve some balance between the objectives, and make a real impact for serious cross-border threats to health, can be funded by 2020.

There are gaps in the Commission's internal coordination in terms of health security activities and public health crisis management

95

We examined whether the Commission's internal coordination in terms of health security funding and public health crisis management is adequate. Overall the audit revealed that a number of gaps exist in this internal coordination. The coordination between Commission services for health security funding from different EU programmes does not fully ensure the achievement of synergies. More progress is needed in operationalising the cooperation between Commission crisis management structures and we found weaknesses in the Commission's management of its Health Emergencies Operations Facility.

Coordination between Commission services for health security funding from different EU programmes does not fully ensure synergies

96

In order to ensure that health security objectives of the health programmes are achieved in the most efficient way, the work of relevant services at the Commission and its agencies should be effectively coordinated. In implementing the EU budget, the European Commission needs to ensure sound financial management and that the use of EU resources achieves EU added value. The Commission should also, in cooperation with the Member States, ensure overall consistency and complementarity between the programme and other policies, instruments and actions of the Union, including those of the agencies⁸².

97

We analysed a sample of 10 projects funded under the seventh research framework programme (FP7), representing a total level of EU co-funding of approximately 50.8 million euro. We selected projects with a potential relevance to DG Health and Food Safety's policy area of health security based on an analysis of their objectives, originating from different strands of the FP7 programme (see paragraph 12) and managed by different Commission services or agencies. We reviewed the objectives and scope of the projects, and their complementarity to the relevant health threats objectives of the health programme⁸³.

98

DG Health and Food Safety is generally involved in all formal coordination structures and procedures for FP7 and for Horizon 2020, including inter-service consultations for the work plans of Horizon 2020 and for relevant grant award decisions. DG Research and Innovation participates in DG Health and Food Safety consultation procedures for the health programme and the wider policy area and is involved in the evaluation of proposals submitted under the health programme. DG Research and Innovation is also on the ECDC management board.

82 See Article 12 of Regulation (EU) No 282/2014 establishing the third health programme.

83 We tested to what extent the relevant policy unit in DG Health and Food Safety coordinated its involvement in or informed itself on relevant research-funded actions. During visits to DG Migration and Home Affairs, DG Research and Innovation, the Research Executive Agency and the European Research Council, we discussed coordination structures in place and tested the relevance of these projects for DG Health and Food Safety.

Audit observations

99

We found that despite the scientific character of FP7 health and security projects, six projects we reviewed showed clear links with certain projects that we examined under the EU health programme. These often focused on preparedness and aimed to produce tangible, policy-relevant outputs. One potential reason is that two of the reviewed projects are so-called coordination and support actions (CSAs). These are actions that do not cover the research itself, but rather coordination and networking, dissemination and use of knowledge, or studies or expert groups assisting the implementation of the programme.

100

The other Commission services interviewed indicated that upon request from policy DGs they can perform analyses of their project portfolios, but DG Health and Food Safety had not requested this for the health threats area.

101

The Commission experience of these research programmes, in particular the security strand of FP7⁸⁴, shows that there is a need to better involve end-users to ensure a better take-up of results, similar to the issues we found in relation to the health programme (paragraphs 79 to 88 above). DG Migration and Home Affairs took the initiative to develop a 'Community of Users for Disaster Risk and Crisis Management', which provides a forum for information exchanges between users and other stakeholders. The forum should also facilitate synergies by performing regular surveys of projects from different calls, and by organising ad hoc meetings for exchanging views between policymakers and stakeholders to discuss synergies. A comprehensive mapping of EU-supported actions as part of the community of users is a promising initiative that could potentially be developed for other policy or thematic areas.

102

Projects operating in the same thematic area might be funded from different EU programmes. High volumes of EU funding from different thematic programmes and the involvement of a range of Commission services in their management, requires complex networking between Commission services, national policy makers, end-users and other stakeholders. The risk of overlaps, though minor, persists, and opportunities for achieving more synergies remain. In this context, there is scope for better policy-oriented and structured coordination, in particular for health security policy and related actions. We found that DG Health and Food Safety could do more structured work to facilitate this type of coordination and to allow it to better steer policy feedback and dissemination of relevant results to its own stakeholder group and the HSC.

84 Interim Evaluation of FP7 Security Research, Executive Summary, January 2011.

More progress needed in operationalising cooperation between Commission crisis management structures

103

A memorandum of understanding signed in May 2013 by DG Health and Food Safety, DG Migration and Home Affairs and DG European Civil Protection and Humanitarian Aid Operations covers the coordination of their respective crisis management structures⁸⁵. This coordination should encompass cross cutting activities on serious cross-border threats to health in all areas where joint efforts would be of mutual advantage. This includes training and exercises on preparedness, risk assessment and the provision of mutual support during the response phase and when drawing lessons learned after crises. Secured communication channels between the respective crisis centres are also foreseen.

104

The memorandum of understanding was put in place to increase the EU's capacity to respond to major multi-sector emergencies. However, we found that at the time of the audit, standard operating procedures to implement the agreement were still being developed. Although DG Migration and Home Affairs, DG European Civil Protection and Humanitarian Aid Operations and DG Health and Food Safety have been active in preparing, planning, conducting and utilising the outcomes of a series of joint exercises, we could not obtain evidence at DG Health and Food Safety that there had been systematic joint training sessions, workshops or regular meetings involving key crisis management staff operating the crisis management facilities of DG Health and Food Safety, DG Migration and Home Affairs and DG European Civil Protection and Humanitarian Aid Operations as planned in the agreement. The lack of progress on these issues was to a large extent due to the evolving Ebola crisis, when it was difficult to organise development work.

105

The report on the 2015 Ebola lessons learned conference⁸⁶ includes recommendations for actions regarding crisis management at EU level. It stated that cooperation between public health and development aid partners and other key actors at various levels should be enhanced to better coordinate and integrate public health considerations in resilience building and response to emergencies. To this end, common response plans and further joint training, exercises, exchange of best practices and cross-sectoral guidelines should be pursued. According to the report, the Commission's Emergency Response Coordination Centre should be further developed as an information exchange and coordination platform at EU level for public health crises originating from outside the EU, in close cooperation with the Health Security Committee. Although it was mostly addressed to DG European Civil Protection and Humanitarian Aid Operations which operates the Emergency Response Coordination Centre (ERCC), we did not find, at the time of the audit, a specific action plan for DG Health and Food Safety's involvement in the follow-up of these recommendations.

85 I.e. HEOF (Health Emergency Operations Facility)
— DG Health and Food Safety, STAR (Strategic Assessment and Response)
— DG Migration and Home Affairs and ERCC (Emergency and Response Coordination Centre) — DG European Civil Protection and Humanitarian Aid Operations.

86 Summary report on the conference 'Lessons learned for public health from Ebola outbreak in west Africa — how to improve preparedness and response in the EU for future outbreaks', Mondorf les Bains (Luxembourg), 12-14 October 2015, p. 23.

Audit observations

106

The memorandum of understanding between the three DGs referred to above is an important step in increasing preparedness at EU level for serious cross-border threats to health and other major multi-sector emergencies. However, our audit work at DG Health and Food Safety showed that more progress is needed to implement this memorandum, notwithstanding the extensive cooperation between DG Health and Food Safety and DG European Civil Protection and Humanitarian Aid Operations during the Ebola outbreak.

Weaknesses found in the Commission's management of its Health Emergencies Operations Facility

107

DG Health and Food Safety operates a Health Emergencies Operations Facility which can be activated at different alert levels⁸⁷ in times of a health crisis. We considered that such a facility requires a structured approach to post-event evaluation. Emergency management plans need to be updated in accordance with the recommendations made in a post-event evaluation. Examples of such arrangements can also be found in ECDC's public health emergency plan and its standard operating procedures⁸⁸.

108

In order to effectively fulfil their role in crisis management and coordination structures, relevant staff members should keep their knowledge of their potential role and systems up to date by participating in training programmes. The relevant organisation needs to monitor its staff's knowledge and awareness of their potential role, for example by monitoring their effective training participation. Clear and adequate arrangements need to be in place to ensure that an organisation with crisis coordination or management responsibilities can sustain its activities at a heightened state of alert for a prolonged period of time, and staff needs in this respect should be duly taken into account.

109

The Health Emergencies Operations Facility is based on a DG Health and Food Safety manual⁸⁹. This manual had been updated and simplified following the lessons learned from the 2009 H1N1 crisis. Nonetheless, we found a number of significant weaknesses in the Commission's management of the Health Emergencies Operations Facility. The content of the manual was not up to date at the time of the audit. It was insufficiently clear which parts of the specific recommendations from the major 2014 Quicksilver Exercise⁹⁰ had been taken up to improve its design. In addition, the Commission had not performed an internal evaluation of the functioning of the Health Emergencies Operations Facility during the Ebola crisis and the guide was therefore not updated accordingly.

- 87 I.e. green (normal duty), orange (medium or major events) and red (acute crisis).
- 88 ECDC PHE Evaluation SOP: Processes of activation of a level 1 or 2 due to a threat or a simulation exercise should be evaluated and lessons learned incorporated into the management of the updated PHE plan.
- 89 Health Emergency Operations Facility for a coordinated management of public health emergency at EU level — Revised practical guidance for HEOF members (April 2015).
- 90 Quicksilver Exercise: 'Command Post Exercise on serious cross-border threats to health falling under the chemical and environmental categories', Final Report.

110

We further found that there had not been any continuous training of relevant staff to ensure that they can take up their roles in the Health Emergencies Operations Facility at any given time, in particular when staff members are not part of the Crisis Management and Preparedness Unit but could be called for duty if the highest alert level is raised. Concerning staffing during periods of increased alert, we found that only regular compensation arrangements within the flexitime regime were in place, which are not adequate to address the challenges faced by DG Health and Food Safety in coordinating the management of public health emergencies at EU level, in particular when the emergency lasts for a long period of time and staff work in shifts without opportunities for taking compensatory leave.

111

We also found that the Health Emergencies Operations Facility had not been 'peer reviewed' by any other institution or agency, and that no specific exchanges of experiences or best practices in relation to the design and operation of their respective emergency management plans had been carried out between ECDC and DG Health and Food Safety.

Conclusions and recommendations

112

The entry into force of Decision No 1082/2013/EU on serious cross-border threats to health contributes to building and strengthening a comprehensive EU framework for health security, and for enabling the Union to protect its citizens from such threats. Developing and implementing this decision and related EU-level health security actions, including funding programmes, is a complex matter due to the multitude of actors and complex structures in place within countries and in the international context (see **Annexes I and II**), as well as from a legal perspective. The Member States have the main responsibility for health policy (see paragraph 3), and EU action in this area is only designed to complement and support Member States' activities. The Commission's role and responsibility therefore consist mostly of providing support and taking complementary action where needed.

113

To add to the complexity, a relatively high frequency of serious emergencies requires almost constant attention. There have been several such emergencies since the adoption of the decision and new threats could materialise quickly, including a major pandemic influenza hitting the EU. This means that there is an almost continuous need for Member States, the various relevant Commission services and international organisations to be engaged in response actions while still continuing substantial remaining work on preparedness.

114

Against this challenging background, the existence of the decision in itself, and measures and programmes to support its implementation, is not enough to ensure optimal protection of citizens from serious cross-border threats to health in the EU. Moreover, the decision is an EU law whose rules need to be applied effectively and consistently by all involved to ensure that its objectives can be met. We therefore assessed whether the EU framework for protecting citizens from serious-cross-border threats to health was adequately implemented. In doing so, we focused on the effective implementation of the innovative and previously existing areas of the decision (paragraphs 7 to 9). We also addressed the questions whether the EU health programmes were making effective contributions to protecting citizens from threats to health and whether the Commission's internal coordination in terms of health security funding and public health crisis management was adequate (paragraphs 15 and 17).

Conclusions and recommendations

115

Our overall conclusion is that Decision No 1082/2013/EU on serious cross-border threats to health represents an important step for dealing better with such threats in the EU. However, significant weaknesses at the level of the Member States and the Commission affect the implementation of the decision and the related EU framework. While the nature and scale of future threats is unknown and may evolve, more needs to be done to address these weaknesses and allow the Union to take full benefit from its established mechanisms.

116

We found that the implementation and development of the innovations introduced by the decision on serious cross-border threats to health (paragraph 21) since its entry into force in December 2013 were hampered by delays, potentially reducing their effective functioning. The consultation between Member States and the Commission on preparedness and response planning for serious cross-border threats to health has been initiated as required. However, the procedures for obtaining and exchanging relevant information with a view to better coordinating efforts in relation to preparedness are not yet sufficiently robust and have not yet delivered clear-cut results (paragraphs 22 to 29). As regards the Commission's measurement of performance for the implementation of the cross-border health threats policy area, we found that key elements of the Commission's specific objective and indicator are not clearly defined and agreed with the Member States, to ensure that all stakeholders work towards the same objectives (paragraphs 30 to 34).

117

We further found that: ECDC's role in relation to generic preparedness is insufficiently formalised, which may limit its capacity to properly plan its related tasks in the long term or respond effectively to assistance requests (paragraphs 35 to 39); Member States have shown insufficient responsiveness to speed up the joint procurement of pandemic influenza vaccine (paragraphs 40 to 43); and the EU does not have a mechanism to address urgent needs for medical countermeasures within the framework of the decision on serious cross-border threats to health (paragraph 42). Finally, the work and role of the HSC have proven to be very important, but it is facing some strategic and operational challenges which need to be tackled to enable it to make full use of its strong mandate (paragraphs 44 to 52) and thereby ensure the highest possible level of protection against health threats in the EU; this also relates to ensuring that the decision's coordination of response rules can be applied effectively (paragraphs 53 to 55).

Conclusions and recommendations

118

It is necessary to speed up the development and implementation of the innovations introduced by the decision, and tackle the remaining operational and strategic challenges for the HSC. This requires a better common understanding between Member States and the Commission of the objectives and joint priorities for the enhanced coordination and information exchange efforts under the decision, in particular in the areas of preparedness planning, joint procurement and organising the work of the HSC in the long term. For preparedness and response planning, an additional challenge is to consider the developments occurring in the wider international context as outlined in **Box 3** and **Annex I**.

Recommendation 1

In order to speed up the development and implementation of the innovations introduced by the decision on serious cross-border threats to health, and tackle the remaining operational and strategic challenges for the HSC:

- (a) The **Commission should propose to the HSC that it develop** a strategic HSC roadmap for the implementation and development of the decision. While the decision does not require the setting of targets and indicators, this roadmap should reflect joint priorities, in particular on the coordination of preparedness planning, to facilitate a common understanding of how to achieve more clear-cut results towards 2020. Work in this area should take account of the international initiatives in this domain which in particular call for peer review or external assessment mechanisms to be applied. If possible, this work should also take account of preparedness guidance already developed at EU level.
- (b) The **Commission** should ensure that lessons learned from the first reporting cycle on preparedness planning are applied for the next round of reporting in 2017 and improve its performance reporting for the implementation of the decision towards 2020. It should ensure that reported progress is accurate and based on methodologies agreed with the Member States where relevant.
- (c) The **Commission, in cooperation with the Member States**, should identify how to best make use of the HSC working groups and ensure that their work is well structured around technical issues and serves as an input to the HSC. Working groups already established need to apply their terms of reference from 2017 and deliver results, based on annual work plans and clearly identified objectives. This also applies to the HSC preparedness working group and its work to develop an EU mechanism to address urgent needs for medical countermeasures.
- (d) The **Commission and the Member States** need to ensure that the work on the joint procurement of pandemic influenza vaccine accelerates and delivers results as soon as possible.

Conclusions and recommendations

119

As regards the effective implementation of the existing systems for early warning and response and epidemiological surveillance (paragraph 56), for which the decision on serious cross-border threats to health provides the legal basis, we found overall that these systems have been operational for years and that their important role at EU level is widely recognised by stakeholders. However, for early warning and response we found that there is scope for making upgrades to the EWRS, including to related procedures and processes for situational awareness and incident management and the organisation of the EWRS user community (paragraphs 57 to 68). In addition, the updated EU-level approach to early warning and response for serious chemical and environmental threats was not yet tested (paragraphs 69 to 73). Finally, the epidemiological surveillance system generally works well, but further work by ECDC and the Member States is required to ensure maximum comparability and quality of surveillance data (paragraphs 74 to 77).

Recommendation 2

In order to further upgrade the EWRS and develop more integrated solutions for related risk management procedures, **the Commission, in cooperation with the Member States and ECDC**, should:

- (a) examine and propose in 2017 options for modernising and enhancing the EWRS. This should include integrated or complementary options for EU-level situational awareness and incident management for serious cross-border threats to health;
- (b) obtain regular feedback from users on integrated solutions for risk management and the operation and development of the EWRS.

120

As regards the health programme objectives to protect citizens from (serious cross-border) threats to health (paragraph 78), we found that its performance showed weaknesses. Most of the audited health threat actions from the second health programme (2008-2013), despite performing well in terms of producing the agreed deliverables, showed a lack of sustainable results (paragraphs 79 to 88), limiting their contribution towards achieving the objective of protecting citizens from threats to health. Although this is not a new observation, it underlines that the Commission needs to do more, in consultation with its stakeholders, to improve performance on this issue. In addition, we found weaknesses in measuring the indicator for the health threats objective under the third health programme as well as a relatively low level of spending for this particular objective in 2014-2016, suggesting that it is difficult to fund a sufficient number of policy relevant actions under this objective to ensure that a real impact is made towards 2020 in achieving the objective (paragraphs 89 to 94).

Conclusions and recommendations

Recommendation 3

In order to address the main weaknesses identified in the performance of the health programme for actions addressing health threats, **the Commission** should:

- (a) examine and propose options in 2017 for ensuring a greater sustainability of results for health threat-related actions funded under the health programme towards 2020. These should include stronger needs and policy relevance identifications when programming actions, but also a more collaborative analysis between DG Health and Food Safety and Chafea of the policy relevance of ongoing and recently completed actions with a view to identifying options to promote the uptake of good-quality results (also see Recommendation 4);
- (b) define and agree, in consultation with the Member States, a clear methodology for collecting performance information needed to report progress towards 2020 under the specific indicator for health threats in the third health programme (also see Recommendation 1).
- (c) clearly identify in 2017, for the remaining years of the health programme until 2020, which priorities under the objective to protect citizens from serious cross-border threats to health provide opportunities for funding policy-relevant actions towards 2020 (see Recommendation 3(a)).

121

Finally, the audit revealed that, despite a wide array of coordination mechanisms, a number of gaps exist in relation to the Commission's internal coordination of health security activities across different services and programmes to ensure that full use is made of potential synergies. In a context of high volumes of EU funding from different thematic programmes and a range of Commission services being involved in their implementation, requiring complex networking between Commission services, national policymakers, end-users and other stakeholders, there is scope for better policy-oriented and structured coordination (paragraphs 96 to 102). We also found that more work needs to be done to make existing agreements for cooperation between Commission crisis management structures fully operational (paragraphs 103 to 106), and that DG Health and Food Safety's management of its Health Emergencies Operations Facility showed weaknesses that might hamper its performance when dealing with future health crises in the EU (paragraphs 107 to 111).

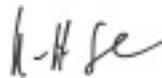
Recommendation 4

In order to bridge the gaps in the Commission's internal coordination in terms of activities relevant to health security and public health crisis management, and to improve the design of its Health Emergencies Operations Facility:

- (a) **the Commission** should define from 2017 a more structured, detailed approach for coordination between DG Health and Food Safety and other Commission services which perform activities relevant to health security, including a mapping of past, ongoing and planned activities. This should allow for the identification of potential synergies and enhance cooperation on common issues such as the limited uptake of outputs for EU co-funded actions and enabling stakeholders to better target policymakers;
- (b) **the Commission** should take immediate action to operationalise the memorandum of understanding for crisis management structures between DG Health and Food Safety, DG Migration and Home Affairs and DG European Civil Protection and Humanitarian Aid Operations; this includes organising joint lessons learned activities and mutual training on policy areas and systems, as well as putting in place standard operating procedures;
- (c) **the Commission** should without delay review its Health Emergencies Operational Facility and ensure that: it is updated in line with lessons learned from the Ebola crisis and major EU-level exercises; a continuous monitored training plan is in place for all relevant staff potentially involved in its operations; and, if possible, exchange views with ECDC and DG European Civil Protection and Humanitarian Aid Operations, in particular on the design of their respective crisis management manuals or structures.

This Report was adopted by Chamber I, headed by Mr Phil WYNN OWEN, Member of the Court of Auditors, in Luxembourg at its meeting of 5 October 2016.

For the Court of Auditors



Klaus-Heiner LEHNE
President

Preparedness and response planning in the international context

International Health Regulations 2005 (IHR 2005)

1. The 1969 WHO International Health Regulations were fully revised and replaced by the IHR (2005), which entered into force in 2007. The IHR objective is 'to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade'¹. The IHR 2005 requires State Parties to report to WHO any event that may constitute a public health emergency of international concern, independently of its origin, and to develop, strengthen and maintain core public health capacities for surveillance and response by using existing national resources, such as the national plans for influenza pandemic preparedness. The IHR are also designed to reduce the risk of disease spread at international airports, ports and ground crossings and require the establishment of national and WHO IHR focal points for urgent communication.
2. The IHR (2005) do not include any enforcement mechanism for States which fail to comply with its provisions. WHO monitors the implementation of the IHR, and issues and updates relevant guidelines. Its expert panels and review committees also review IHR effectiveness in emergency situations, as was done, for example, after the Ebola outbreak (see **Box 3** in the report for more information on this).

Public Health Emergencies of International Concern (PHEIC)

3. Under the IHR, a public health emergency of international concern refers to an extraordinary public health event which constitutes a public health risk to other States through the international spread of disease and potentially requires a coordinated international response. The PHEIC is declared by the director-general of WHO based on a recommendation from the Emergency Committee. If a PHEIC is declared, WHO is required to deliver a 'real time' response to the emergency. The Director-General of WHO, assisted by the Emergency Committee, will develop and recommend the critical health measures for implementation by State Parties.

The IHR and the EU

4. All EU Member States are State Parties to WHO and report to WHO, for example through questionnaires and self-assessments, on their IHR implementation. The EU itself is not a WHO member, and therefore is not a party to the IHR. However, the IHR recognises the potential role of the EU as a 'regional economic integration organization' and states that, 'without prejudice to their obligations under these Regulations, States Parties that are members of a regional economic integration organization shall apply in their mutual relations the common rules in force in that regional economic integration organization'. The Commission and ECDC coordinate their activities with WHO at policy² and technical level, including information sharing for risk communication and read access to certain alert systems (such as the WHO Event Information System and the EU's EWRS). Decision No 1082/2013/EU also introduced the innovation of a public health emergency declaration by the Commission, but it is significantly different from a PHEIC declaration by the Director-General of WHO (see **Box A**).

1 International Health Regulations (2005), Second Edition, World Health Organisation 2008.

2 See for example the 2010 Joint Declaration ('Moscow Declaration') outlining cooperation between WHO and the Commission, as well as relevant updates on DG Health and Food Safety's public website. An administrative agreements is also in place between ECDC and WHO.²www

Box A — Public health emergency declaration in the EU

As explained above, the term Public Health Emergency of International Concern is defined in the International Health Regulations as ‘an extraordinary event which is determined, as provided in these Regulations: to constitute a public health risk to other States through the international spread of disease; and to potentially require a coordinated international response’. The responsibility of determining whether an event is within this category lies with the WHO Director-General and requires the convening of a committee of experts — the IHR Emergency Committee.

One of the innovations of Decision No 1082/2013/EU is that the Commission can now also declare a situation of public health emergency for the EU. In accordance with Article 12, the Commission may recognise a situation of public health emergency in relation to: (a) epidemics of human influenza considered to have pandemic potential, where the Director-General of WHO has been informed and has not yet adopted a decision declaring a situation of pandemic influenza in accordance with the applicable rules of WHO; or (b) cases other than that referred to in point (a) where the Director-General of WHO has been informed and has not yet adopted a decision declaring a public health emergency of international concern in accordance with the IHR, and where:

- (i) the serious cross-border threat to health in question endangers public health at the Union level;
- (ii) medical needs are unmet in relation to that threat, which means that no satisfactory method of diagnosis, prevention or treatment is authorised in the Union or, despite the existence of such a method, the authorisation of a medicinal product would nonetheless be of major therapeutic advantage to those affected’.

Article 13 then adds that this recognition of an emergency situation pursuant to Article 12 shall have the sole legal effect of enabling point 2 of Article 2 of Regulation (EC) No 507/2006³ to apply or, where the recognition specifically concerns epidemics of human influenza considered as having a pandemic potential, of enabling Article 21 of Regulation (EC) No 1234/2008⁴ to apply. This means that the purpose of emergency declaration under Article 12 of Decision No 1082/2013/EU is restricted only to a fast track authorisation for pandemic medical countermeasures and operationalising pharmaceutical legislation. Its application is much more limited compared to a declaration of a Public Health Emergency of International Concern by WHO, even though situations could occur where a serious cross-border threat to health, from any potential origin, specifically affects the EU and not necessarily the wider global community for which WHO is responsible. It also means that there is no EU scale of alert levels (e.g. linked to the rules of procedure of the Health Security Committee) triggering response activities and capacities within the remit of the decision or to ensure the triggering of a mechanism for surge capacity or funding.

3 Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 92, 30.3.2006, p. 6).

4 Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, p. 7).

International initiatives on preparedness planning and transparency

5. There are also several other international initiatives addressing the need to enhance preparedness planning and increase transparency. These initiatives mainly include the Global Health Security Agenda⁵ initiative to perform 'peer reviews'⁶ and the G7 and Global Health Security Initiative⁷ support to these activities⁸, as well as ECDC country visits that occur on a voluntary basis and where preparedness is also addressed⁹. The report on the conference¹⁰ 'Lessons learned for public health from the Ebola outbreak in west Africa — how to improve preparedness and response in the EU for future outbreaks', which fed into the Council conclusions of December 2015, included the following recommendation: 'A peer-review mechanism could help Member States to improve their national preparedness plans taking into account past and current initiatives on independent country evaluations on global and regional level.'

5 'The Global Health Security Agenda (GHSa) was launched in February 2014 and is a growing partnership of nearly 50 nations, international organisations, and non-governmental stakeholders to help build countries' capacity to help create a world safe and secure from infectious disease threats and elevate global health security as a national and global priority. GHSa pursues a multilateral and multi-sectoral approach to strengthen both the global capacity and nations' capacity to prevent, detect, and respond to human and animal infectious diseases threats whether naturally occurring or accidentally or deliberately spread.' (<https://ghsagenda.org>).

6 'A self-assessment and an external assessment conducted by a team of experts from other GHSa countries. This peer-to-peer model ensures an objective approach and facilitates cross-border learning. GHSa external assessments should be conducted at least twice for each country, once to establish a baseline measurement and, subsequently, to identify progress made.' EU Member States that have already participated and for which a report has been published are Portugal and the United Kingdom.

7 'The Global Health Security Initiative (GHSI) is an informal, international partnership among like-minded countries to strengthen health preparedness and response globally to threats of biological, chemical, radio-nuclear terrorism (CBRN) and pandemic influenza. This initiative was launched in November 2001 by Canada, the European Union, France, Germany, Italy, Japan, Mexico, the United Kingdom and the United States. The World Health Organisation serves as an expert advisor to the GHSI' (<http://www.ghsi.ca/english/index.asp>).

8 'In order to prevent future outbreaks from becoming large-scale public health emergencies, the G7 leaders have agreed to offer to assist at least 60 countries, including the countries of west Africa, over the next 5 years to implement the IHR, including through the Global Health Security Agenda (GHSa) and its common targets and other multilateral initiatives', Declaration of the G7 Health Ministers, 8 and 9 October 2015, Berlin.

9 ECDC Technical Report, 'Ebola emergency preparedness in EU Member States: conclusions from peer-review visits to Belgium, Portugal and Romania', June 2015.

10 High level conference organised by DG Health and Food Safety on 12 to 14 October 2015 in Mondorf-les-Bains, Luxembourg.

Description of main roles and responsibilities in the EU framework for protecting citizens against serious cross-border threats to health

Member State public health authorities

1. Member State public health authorities are responsible for public health policy at national level, and for dealing with public health threats. Differences in responsibilities for certain aspects of preparedness and response planning and early warning and response might exist between Member States, involving different public authorities, depending on their government organisation, national risks or specific situations. Some Member States may have decentralised parts or most of the public health responsibilities, including those for preparedness and response planning. EU Member States are also members of the WHO Europe Region¹ and have an obligation to implement the International Health Regulations as explained in **Annex I**.
2. Since the adoption of Decision No 1082/2013/EU, Member States also have an obligation to provide certain information on their preparedness and response planning to the Commission. Decision No 1082/2013/EU requires Member States and the Commission to consult each other in the Health Security Committee to develop, strengthen and maintain their capacities for the monitoring, early warning and assessment of, and response to, serious cross-border threats to health. That consultation is aimed at sharing best practice and experience in preparedness and response planning; promoting the interoperability of national preparedness planning; addressing the intersectoral dimension of preparedness and response planning at Union level; and supporting the implementation of core capacity requirements for surveillance and response as referred to in the IHR. Member States also appoint national competent authorities for epidemiological surveillance that are responsible for delivering data to the European surveillance system in accordance with EU rules and guidance, and nominate national EWRS contacts to monitor EWRS and notify alerts, under the rules set out in the decision.

European Commission — DG Health and Food Safety

3. The Commission ensures the secretariat and presidency of the Health Security Committee and coordinates and operates its Health Emergency Operations Facility (HEOF). It also manages relevant IT systems and coordinates with other Commission services and agencies for cross-cutting issues in this policy area, as well as with relevant international organisations, such as WHO. Decision No 1082/2013/EU on serious cross-border threats to health specifically provides that the Commission (i.e. DG Health and Food Safety), in liaison with the Member States, ensures coordination and exchange of information between the mechanisms, structures and activities which are relevant to preparedness and response planning, monitoring, early warning of and combating serious cross-border threats to health. The Commission is also responsible for ensuring that any duplication of activities or conflicting actions is avoided, and that adequate resources are made available for all its required and critical tasks and functions.

¹ Covering a total of 55 countries reporting to the WHO Regional Office Europe in Copenhagen.

European Centre for Disease Control and Prevention (ECDC)

4. ECDC operates and coordinates the network for epidemiological surveillance of communicable diseases and of antimicrobial resistance and healthcare-associated infections related to communicable diseases. It is an EU agency with the mission to identify, assess and communicate current and emerging threats to human health posed by infectious diseases. ECDC also hosts the operation of the Early Warning and Response System (EWRS). EWRS is a web-based system linking the Commission, public health authorities in Member States responsible for measures to control communicable diseases and ECDC. EEA countries (Iceland, Liechtenstein and Norway) are also linked to the system and WHO has read access.
5. Under the decision on serious cross-border threats to health, ECDC is required to provide scientific advice and risk assessments concerning threats that are alerted through the EWRS, in particular for threats of biological or unknown origin. Other EU agencies or bodies (e.g. scientific committees) might be requested by the Commission to provide rapid risk assessments when their expertise is closer linked to the type of threat at hand. When requested, ECDC further assists the Commission and the Member States in implementing Decision No 1082/2013/EU requirements for preparedness planning. The annual budget of ECDC also covers disease programmes; these are vertical programmes for specific diseases, which also have components such as capacity building and risk communication. ECDC can provide outbreak response support to countries or international organisations like WHO, as it did during the Ebola outbreak. It operates an emergency operations centre, based on a public health emergency manual. The current ECDC approach is to target all hazards (i.e. not just threats to health from communicable diseases, but also from other origins), aligned with the objectives of the IHR and Decision No 1082/2013/EU. This is beyond ECDC's previous, traditional mandate that focused on communicable diseases and pandemic preparedness.

Overview of audited co-funded actions

The following table provides a list with key features of the audited actions, co-funded under the health threats objective of the second EU health programme 2008-2013, managed by Chafea or DG Health and Food Safety (for three procurement items).

Ref.	General description	Funding instrument	EU co-funding as per grant agreement (euro)
1	Developing a generic framework for the fast production and evaluation of emergency vaccines	Project	2 116 023
2	Optimising testing and linkage to care for HIV across Europe	Project	1 429 984
3	A network for the control of public health threats and other bio-security risks in the Mediterranean region and Balkans	Project	900 000
4	Screening for Hepatitis B and C among migrants in the European Union	Project	800 000
5	Syndromic surveillance survey, assessment towards guidelines for Europe	Project	798 814
6	Public health adaptation strategies to extreme weather events	Project	750 000
7	Empowering civil society and public health system to fight tuberculosis epidemic among vulnerable groups	Project	750 000
8	Cost-effectiveness assessment of European human influenza pandemic alert and response strategies	Project	700 000
9	A European network on cervical cancer surveillance and control in the new Member States	Project	615 023
10	Promotion of Immunisation for health professionals in Europe	Project	604 000
11	Coordinated action in the aviation sector to control public health threats	Project	598 566
12	Promote vaccinations among migrant populations in Europe	Project	548 680
13	Alerting, Surveillance and Reporting System for Chemical Health Threats, Phase III	Project	497 760
14	European Chemical Emergency Network	Project	447 600
15	Quality assurance exercises and networking on the detection of highly infectious pathogens	Joint action	3 316 326
16	Command post exercise on serious cross-border threats to health falling under the chemical and environmental categories	Procurement/service contract	458 989
17	Organisation of two regional training seminars with Member State public health authorities relating to the implementation of the new decision on serious cross-border threats to health.	Procurement/service contract	249 599
18	Early alerting and reporting system, Hedis, Nemo (monitoring information exchange mechanisms for crisis management)	Procurement/service contract	1 588 500
19	The European reference laboratory system for human pathogens	Procurement/service contract	500 000
20	Organisation of training of staff and conducting exercises at European level as a fundamental element of preparedness	Procurement/service contract	333 646
Total :			18 003 510

The following table provides a list with key features of the reviewed actions, co-funded under the seventh framework programme for research (FP7) 2008-2013.

Ref.	General objective of the selected action	Funded under FP7 programme	Responsible Commission service	EU co-funding (euro)
1	Forecasting epidemic evolution and pandemic simulations	ERC ¹	ERCEA	684 000
2	Platform for emerging and re-emerging infectious disease entities	HEALTH	RTD	11 909 560
3	Infection control in aviation, ranging from effective quarantine to protocols for sanitizing/decontaminating the airliner cabin	PEOPLE	REA	100 000
4	To develop an evidence-based behavioural and communication package for health professionals and agencies throughout Europe in case of major outbreaks	HEALTH	RTD	1 999 607
5	The role of pharmaceutical companies in the formulation and implementation of health security policy	ERC	ERCEA	1 197 694
6	Transform Europe's response to future severe epidemics or pandemics by providing infrastructure, coordination and integration of existing clinical research networks	HEALTH	RTD	23 992 375
7	Create an integrated toolbox to aid transport operators and relevant actors in major transport hubs in the development of their current pandemic and dangerous pathogen preparedness and response plans	SEC ²	HOME	3 142 004
8	Interoperability and preparedness of European health services in relation to deadly threats such as pandemic disease and major terrorism attack	SEC	REA	2 789 940
9	To increase preparedness to large-scale and cross-border disasters amongst communities and societies in Europe.	SEC	REA	999 084
10	To address effectively scientific and societal challenges raised by pandemics and associated crisis management. To develop an integrated, transdisciplinary, strategy.	SiS ³	RTD	3 939 880
Total :				50 754 144

1 European Research Council.

2 Security programme.

3 Science in Societies.

Executive summary

III

The decision on serious cross-border threats to health is based on Article 168 of the Treaty, the public health article.

V

The Commission and Member States are working to put in place the infrastructure required to fully and effectively implement the decision on serious cross-border threats to health. This is a complex matter. While it is acknowledged that there have been delays, for example, in adopting certain implementing acts, these delays are being addressed and did not weaken significantly the effectiveness of the EU response to cross-border health threats. Both Member State and Commission responsibilities are clearly defined in Decision No 1082/2013/EU.

VI

The delays in implementing the decision on serious cross-border threats to health are a reflection of the complexity of the health threats situation or 'complexity of the subject matter'. As set out in the detailed comments below, important progress has been made in preparing the remaining implementing acts and in advancing the work on medical countermeasures. The joint procurement mechanism is now fully established. The Health Security Committee is fully operational; the Commission will discuss the Court's observation with the Member States in the Committee.

VII

The Commission considers that despite technical upgrades of the system over time, it is desirable to modernise the system. The Commission is currently working with ECDC to modernise the EWRS system.

IX

The Commission considers that good coordination is in place between Commission departments dealing with various aspects related to health security and the specific points raised by the Court are being addressed. DG Health and Food Safety took important steps in 2016 to improve the operation of the Health Emergencies Operations Facility (HEOF).

X (i)

The Commission accepts Recommendation 1 and agrees as far as its role in the HSC and in the joint procurement mechanism is concerned. It will discuss these matters in the HSC.

(ii)

The Commission accepts Recommendation 2. The Commission is currently working with ECDC to modernise the EWRS system and will discuss with the Member States how user feedback can enhance the functioning of the system.

Reply of the Commission

(iii)

The Commission accepts Recommendations 3(a) and (c) and partially accepts Recommendation 3(b).

The Commission recognises that sustainability is a pending issue although much has been done in recent years. Continuous improvements are being made especially in the framework of the action plan established by the Commission following the evaluation of the second health programme.

(iv)

The Commission partially accepts Recommendation 4(a) and accepts Recommendations 4(b) and (c). Good cooperation between the respective Commission services is in place and discussions between services are under way to further develop coordination.

The Commission considers that the structure of the HEOF is stable and defines the roles and alert levels. From June 2016, the Commission has developed a continuous training programme to ensure the full operability of the HEOF at any moment.

Audit observations

21

The decision on serious cross-border health threats represents an important step forward in enhancing cooperation of Member States to improve the response to health threats and the protection of EU citizens.

The Commission is aware that certain delays occurred but considers that they have not put into question the effective cooperation of Member States on serious cross-border health threats.

24

As health security preparedness covers sensitive fields, the reporting template was discussed thoroughly with the Member States and a second comitology meeting was necessary to reach an agreement.

25

The report submitted to the HSC did not include individual information from the Member States as health security preparedness covers sensitive fields. The report is based only on Member States' input given that the legislation does not mandate the Commission to verify and check information provided by Member States.

The results of the report were further discussed within the Working Group of the HSC on Preparedness and Response Planning (12 November 2015). At the plenary meeting of the HSC (7 and 8 June 2016) Member States were informed about an updated report reflecting in detail key problems in each Member States.

26

The Commission considers that the progress report provides a comprehensive overview on the state of national preparedness in the EU and delivers clear orientations as to how the gaps and shortcomings can be addressed through an action plan agreed with Member States through endorsement by the HSC. The subgroup on preparedness of the HSC will continue its discussions on how the findings of the report are followed up in combination with the lessons learned from the Ebola outbreak. A first audio meeting of this group took place prior to the HSC in November 2015.

Discussions and work with ECDC and WHO/Europe are ongoing to review the reporting template under Article 4, considering the WHO approach to IHR implementation and the new monitoring and evaluation framework.

Box 3 — International developments concerning preparedness: weaknesses in self-assessment of IHR implementation

This box refers to developments within WHO which are outside the EU legal framework.

27

As explained above, Member States were actively involved in drafting the questions and the comitology procedure reached the required qualified majority.

28

The decision on serious cross-border threats to health does not confer any powers on the Commission to impose a particular generic preparedness structure on Member States. The strategy for generic preparedness planning mentioned by the Court is a technical document which forms part of the background of the ongoing work with Member States on preparedness. Within the Member States, it is particularly up to the HSC members to disseminate the existing guidance.

29

The procedures are complex both from a legal perspective, in view of EU competence in health which is to support, coordinate or supplement actions of the Member States in the area of public health, but also due to the multitude of actors and complex structures in place within countries and in relation to international structures working on these topics.

The Commission considers that the information gathered under the reporting exercise of Article 4 of the decision on serious cross-border threats to health provides a comprehensive review on the state of national preparedness in the EU and provides clear orientations about how the gaps and shortcomings can be addressed. The subgroup on preparedness of the HSC is taking this further.

30

The Commission is working closely with Member States in the HSC and its preparedness working group to develop the structures and arrangements on cooperation on preparedness, including an action plan, cooperation on medical countermeasures and reporting under Article 4 of the decision on serious cross-border threats to health. This will include a discussion on reporting on progress.

31

As the objective and indicator are not included in the decision on serious cross-border threats to health, the Commission has developed other ways of reporting in cooperation with ECDC, as outlined in paragraph 33.

33 ECDC's assessment is based on the responses to the reporting exercise under Article 4 of the decision on serious cross-border threats to health. This is a technical assessment fully in the remit of ECDC.

The Commission is discussing with ECDC the development of suitable indicators to confidently measure progress on preparedness.

The development of new indicators is part of the wider approach of developing country health profiles, in discussion with ECDC, WHO /Euro and Member States in the preparedness working group.

34

As part of the work on preparedness, the Commission will discuss the appropriateness of indicators with the Member States in the HSC. The ECDC report provides a technical overview of the situation, gaps and needs in Member States regarding preparedness and response planning.

37

The Commission considers that day-to-day cooperation on serious health threats, such as the Zika virus outbreak, demonstrates that the division of tasks is understood and that ECDC is able to fully play its role in providing risk assessment information to the HSC. The distinction between risk assessment (ECDC's responsibility) and coordination of risk management (the Commission's responsibility) is set out in the legislation. Specific cases and new tasks, however, often need to be discussed and agreed between the Commission and ECDC on a case-by-case basis. To this end, the monthly coordination meetings between ECDC and the Commission ensure close cooperation and enable ECDC to respond effectively to requests for assistance.

39

The work on the development of the guide dates from before the adoption of the decision.

Following the adoption of the decision, the Commission has suggested to ECDC that discussions be held with the HSC on the guide and its recommendation. Following further work on the document, a discussion is foreseen in the HSC preparedness working group in autumn 2016.

40

The subsequent steps to develop the joint procurement agreement in the framework of the decision on serious cross-border threats to health were undertaken without undue delay; it has to be considered that individual Member States had to comply with national ratification procedures to sign the agreement, which inevitably takes a certain time.

41

The procurement of influenza pandemic vaccine is an extremely complex matter. Moreover, it proved to be time-consuming to identify and bring together Member States' specific requirements. At the same time, in 2016, significant progress has been made in preparing a joint procurement procedure for pandemic vaccines. In addition to the procedure on pandemic vaccines, four other procurement procedures were under way as of September 2016.

42

The Commission would like to point out that both joint procurement and a more developed procedure on exchanging medical countermeasures have their place in preparedness for serious cross-border health threats. By its nature, any procurement will take time and will require following procedures set out in EU legislation.

With the mandate of the HSC, standard operating procedures are currently being developed with the aim to ensure a rapid and consistent response in future emergencies. The outcome of the discussion will be presented to the HSC in November 2016.

In any case the Civil Protection Mechanism already provides a framework for the exchange of countermeasures.

Reply of the Commission

43

While progress on the joint procurement of influenza vaccines has indeed been slow due to the complexity of the matter, the Commission would point out that 24 Member States have agreed so far to participate in the joint procurement agreement and that a number of joint procurement processes are currently ongoing. Urgent needs for the exchange of medical countermeasures can always be handled through the EWRS (as done e.g. for diphtheria antitoxin in 2016) or in general through the Civil Protection Mechanism.

46

So far, the HSC has decided not to establish a working group on migrants. The need for such a working group will be discussed again in an HSC workshop.

When operational topics returned to the HSC agenda after February 2015, HSC meetings were thematically organised and a detailed roadmap for the HSC is under preparation. The action plan on preparedness will further provide a framework for a work plan of the preparedness working group. In addition, discussions with ECDC are ongoing in order to better coordinate the work of the ECDC Coordination Committee on Preparedness and the preparedness working group under the HSC. Work on establishing work plans has commenced with both the communicators network and the preparedness working group.

47

As of September 2016, 11 Member States, WHO and ECDC participated in the working group on preparedness. The working group is important to prepare documents for the HSC, such as the standing operating procedures on medical countermeasures and the action plan on preparedness, etc. A full participation is less important here as the working group brings together technical experts to prepare proposals for endorsement/acknowledgement by the full HSC.

48

The tasks of the HSC are listed in the decision on cross-border threats to health (Article 17, paragraph 2). HSC meetings were thematically organised and a detailed roadmap for the HSC is under preparation (see paragraph 46). In order to coordinate responses, technical documents, such as risk assessments produced by ECDC and relevant traveller's advice, are discussed during the ad hoc meetings of the HSC. However, in case of technical discussions, relevant ad hoc working groups can be convened based on the decision of the HSC, composed of technical experts from Member States. This was the case during the current Zika outbreak, when the ad hoc working group on the Zika virus outbreak was set up and convened two times.

51

The Commission agrees that when the entry into force of the decision on serious cross-border threats to health coincided with the Ebola crisis, efforts to develop a more structured approach, in particular towards preparedness, were delayed. This work is however now well under way.

52

The Commission considers that the information it provides to the HSC in relation to activities of relevant Commission departments is adequate. Cooperation arrangements between departments are in place. Participation of other services in the HSC meetings is frequent. Additionally, DG Health and Food Safety also participated, for example, in the daily audio conferences of the Ebola task force and in many other interservice groups.

60

The ECDC external evaluation report referred to a period between 2008 and 2012, before the decision on serious cross-border threats to health entered into force and before the corresponding (limited) modifications of the EWRS took place.

63

The Commission agrees that user feedback is essential in the review of the EWRS.

64

The Commission is working with ECDC to reshape the system.

65

The Commission highlights that the list referred to in this paragraph was identified in the impact assessment prepared in advance of the actual decision.

67

The Commission has commenced work with ECDC to reshape the EWRS system.

70

Rules and procedures for dealing with chemical and environmental threats in the framework of the decision on serious cross-border threats to health are the same as for the other threats caused by biological events or communicable diseases. Notification criteria are the same as well as the use of the IT tool designed for this purpose. A specific network for the monitoring and assessment of events due to chemical and environmental threats was co-founded 3 years ago under the health programme. A link with the European Commission Scientific Committee has also been established to ensure that sufficient expertise for risk assessments outside the ECDC mandate can be recruited.

The functioning of the system will be tested in a future exercise.

Reply of the Commission

72

The Commission is moderating and maintaining the system but the intention is to integrate RASCHEM into EWRS. As of September 2016, 18 countries were registered with RASCHEM.

74

The Commission is aware and is working with ECDC to improve the data quality and completeness of the Member State reporting.

77

The Commission is aware and is working together with ECDC to increase the data quality and completeness of the Member States reporting.

78

The Commission notes that the Court has examined activities under the second and third health programmes. The management of the programme has significantly changed between the two programmes. The calls for tender funded from the health programme have actively contributed to improving the cross-border preparation against health threats and most projects delivered results as planned.

The cross-country exercises funded from the health programme have actively contributed to improving the cross-border preparation against health threats.

81

The Commission is well aware that the sustainability of results has not always been satisfactory for some projects co-funded under the second health programme before Decision No 1082/2013/EU came into place. A minimum of sustainability is always ensured through the dissemination of the projects' results and their sustained availability on Chafea's website. Recently improvements have been made: the new database will be launched on Chafea's website in mid November 2016; a new IT platform (providing the possibility to host projects'/joint actions' websites during and after the end of grants) is under development; Chafea has prepared a model dissemination strategy to be provided to project coordinators.

Box 5 — Examples of audited projects and issues found

The Commission is aware that not all projects perform equally and to the highest quality possible. To ensure that each project performs at the highest possible level, Chafea has for several years put measures in place such as providing 'at risk' projects with external expertise and coaching.

The Commission considers that the action plan established by the Commission and Chafea after the *ex post* evaluation of the second health programme will ensure that only actions with a high possibility of contributing to important EU policy initiatives and high EU added value are co-funded in order to minimise the risk of low performance and uptake of the results.

82

Besides the written files, Chafea also informs the Commission in bilateral meetings about important project results. In addition, since mid-2016 Commission staff have had access to the new IT system Chafea uses for project management. This system was not in place for the projects audited.

As already mentioned above (under paragraph 81), Chafea has prepared a model dissemination strategy that will help project coordinators in their work in this field. Chafea engaged recently a full-time dedicated dissemination officer to — inter alia — support health project coordinators in their dissemination tasks.

83

Further to the *ex post* evaluation of the second health programme, the Commission, in collaboration with Chafea, has developed an action plan to implement all recommendations made by the external evaluators. Progress is being made, for example by revamping the public database, defining monitoring indicators and setting up a monitoring system and developing a dissemination strategy.

Box 6 — Joint actions under the health programme

The Commission considers that joint actions are an important instrument to facilitate the cooperation of Member State authorities on specific technical issues, which has proven to be effective in the health threats area. Joint actions are supplemented in particular by activities (e.g. exercises) funded through procurements.

84

The outcomes of exercises and training regularly feed into preparedness work; most recently, the HSC received information on lessons learnt from exercises in its June 2016 meeting.

85

Certain tools developed by the JRC for modelling are still in existence and are being used inter alia by ECDC. Discussions are under way to strengthen cooperation between ECDC and the JRC on the basis of these tools.

86

The Commission considers that actions taken could be more structured. However, there are actions taken such as project coordinators being invited to expert group meetings (such as the EWRS, FLU, GPP, chemical threats) and/or HSC meetings or a workshop in December 2014 on 'How to benefit from European projects: an EU Member State initiative to disseminate the results of the second EU health programme (2008-2013) in the health security area' (<http://ec.europa.eu/chafea/news/news349.html>).

87

The Commission, when using procurement contracts, purchases services for which its follow-up actions depend on the kind of service delivered. Moreover, results of the procured services, mostly available in the form of a report, are published and available for a sufficiently long period.

The Commission takes several actions in order to increase the diversity of contractors such as having framework contracts with reopening of competition.

Reply of the Commission

88

The Commission recognises that sustainability is a pending issue although much has been done in recent years, such as the production of the generic preparedness planning (GPP) brochure (2011)¹, the cluster meeting on vaccination (2012), the High Level Health Programme Conference (2012)² and the Regional Health Security Conference (2014)³. A minimum of sustainability is always ensured through Chafea's website. Continuous improvements are being made (see comment under 81).

89

The action plan developed by the Commission after the evaluation of the second health programme includes the development of new monitoring indicators. These are being used in a new monitoring system which beneficiaries have been including in their periodic reporting since 2016. This monitoring will also help to measure the contributions of co-funded action to the overall third health programme objectives.

91

The Commission highlights that the multiannual planning is an informal and internal process. It is not legally mandatory under the third health programme.

92

Forecasts on budget implementation are only indicative. The priority on risk assessment is, for example, only relevant for emergencies. If no such emergency occurs, the work programme for this priority could be implemented without any spending. Moreover, this does not mean that the budget distribution is unbalanced.

93

The *ex post* evaluation of the second health programme and the Commission's action plan of March 2016 point to the development of a new monitoring system and indicators applicable starting from 2016.

94

The monitoring system and indicators are currently being improved with some new indicators already applicable from 2016.

When the Commission forecasts the budget implementation, achieving a balance between the objectives of the programme is not a goal.

1 http://ec.europa.eu/chafea/publications/publications_for_health_programme.html#

2 http://ec.europa.eu/health/programme/events/ev_20120503_en.htm

3 <http://ec.europa.eu/chafea/news/news349.html>

95

The Commission considers that it has put in place structured cooperation between departments.

101

The Commission considers that a good structured cooperation between departments is already in place. This can always be improved, which may include further mapping of activities. However, this will not in itself address the issues relating to the uptake of research results.

102

The Commission is committed to further develop the good cooperation between departments and considers that there is room for improvement. Thanks to the diverse measures in place, such as the memorandum of understanding with several DGs, and the regular meetings and other ways of exchanging information effectively and efficiently, the cooperation is adequate.

Common Commission reply to paragraphs 103 to 106

During the most recent crises, the Commission considers that the ERCC has demonstrated that it plays an effective role as central convening platform, as entry point for the IPRC and in coordinating the response to disasters outside the Union.

107

Indeed, the lessons learned from the H1N1 outbreak in 2009/2010 led to a substantial simplification of the structure of the HEOF, which has been stable since then. Moreover, major exercises and training lead to an update of the handbook if deemed necessary.

108

The Commission acknowledges that a continuous programme for training and exercises is a good means to keep up and strengthen knowledge that can be recalled easily when the HEOF is activated.

Following the reorganisation of DG Health and Food Safety in early 2016, HEOF training for all staff concerned has been developed and started being delivered. Training sessions are organised at regular intervals.

Staff have been assigned to cover the predefined HEOF roles. This allows better familiarisation and more focused training with regard to the respective roles.

109

The Commission is of the opinion that the HEOF proved to be functional in past crisis situations, considering the limited number of staff operating under the HEOF. The current HEOF structure was defined following the lessons learned from the H1N1 outbreak in 2009/2010. The Commission considers that the structure is stable and defines the roles and alert levels. At the time of the Ebola outbreak, staff concerned in DG Health and Food Safety were well aware of the procedures. More recently, the HEOF operations were reviewed and training provided to staff concerned.

Reply of the Commission

111

The Commission recalls that, given the historical development, emergency response procedures within the Commission are quite diverse and have been set up in different manners and with different staff schemes to meet individual challenges. This also applies to ECDC, which runs, for example, a 24/7 availability roster even during peace time.

Conclusions and recommendations

115

The decision on serious cross-border health threats represents an important step forward in enhancing cooperation of Member States to improve the response to health threats and the protection of EU citizens.

The Commission is aware that certain delays occurred but they have not put into question effective cooperation of Member States on serious cross-border health threats.

116

The Commission recognises certain delays in establishing effective cooperation of Member States on serious cross-border health threats.

The state of national preparedness in the EU and the gaps and shortcomings will be addressed through an action plan agreed with Member States through endorsement by the HSC.

Discussions and work with ECDC and WHO/Europe are ongoing to review the reporting system considering the WHO approach to IHR implementation and the new monitoring and evaluation framework.

117

The Commission considers that ECDC's role is defined in its founding regulation and in the cross-border decision.

Preparations for a joint procurement procedure for pandemic vaccines have been well advanced in 2016. Further joint procurement initiatives are under way.

The civil protection mechanism already provides for the exchange of countermeasures, and a specific SOP for medical countermeasures is being developed.

The HSC proved to be an effective coordination mechanism for Member States.

118

The governing body of the JPA is the JPA Steering Committee.

Recommendation 1

(a)

The Commission accepts the recommendation; it will discuss this recommendation and the potential scope and content of a roadmap with the HSC. Depending on the outcome of the discussion, the Commission will prepare such a document for endorsement by the HSC.

(b)

The Commission accepts this recommendation.

(c)

The Commission accepts this recommendation.

The working groups are important tools for the HSC. They develop results based on specific tasks as an input to the HSC. The Commission does not accept that 2017 should be the end point of their activities, but rather sees preparedness and communication as ongoing tasks where the maintenance of specific working structures would be justified.

(d)

The Commission accepts, as far as its role and responsibilities in the joint procurement mechanism is concerned.

119

The Commission agrees that despite technical upgrades of the system over time, it is desirable to modernise the system. Discussions are ongoing with ECDC.

Recommendation 2

(a)

The Commission accepts this recommendation. The Commission is currently working with ECDC to modernise the EWRS system.

(b)

The Commission accepts this recommendation and will discuss with the Member States how user feedback can enhance the functioning of the system.

120

The Commission recognises that sustainability is a pending issue although much has been done in recent years, such as the production of the generic preparedness planning (GPP) brochure (2011), the cluster meeting on vaccination (2012) and the Regional Health Security Conference (2014). Continuous improvements are being made, most recently the revamping of the public database, the HELI platform, and implementing the new dissemination strategy.

The performance monitoring system is currently being improved with some new indicators already applicable since 2015.

Reply of the Commission

Recommendation 3

(a)

The Commission accepts the recommendation. All aspects are already addressed in the action plan that the Commission drafted in 2016 further to the *ex post* evaluation of the second health programme. DG Health and Food Safety will continue to cooperate with Chafea on the issue of policy relevance of ongoing and recently completed actions.

(b)

The Commission partially accepts the recommendation and will discuss reporting with the Member States in the HSC. An effective implementation of this recommendation depends on the Member States.

(c)

The Commission accepts the recommendation and already addresses it in its multiannual planning exercise for the years 2018-2020, which should be finalised in autumn 2016 to plan the priorities for the third health programme for these years.

Recommendation 4

(a)

The Commission partially accepts this recommendation.

The Commission considers that a good structured cooperation between departments is already in place. This can be improved, which may include further mapping of activities. However, this will not in itself address the issues relating to the uptake of research results.

(b)

The Commission accepts the recommendation to further develop the good cooperation between departments.

(c)

The Commission accepts this recommendation. Following the lessons learned from the H1N1 outbreak in 2009/2010, the HEOF has been significantly simplified and reorganised. The Commission considers that the structure as it stands today is stable and defines the roles and alert levels. From June 2016, a continuous training programme has been developed and training sessions are organised at regular intervals. Still ongoing are discussions on a sustainable long-term solution for compensation of staff who participate in the management of public health emergencies.

After Ebola and in light of needs to address environmental and chemical threats, several exercises were organised identifying further improvement needs. Work with ECDC is under way.

HOW TO OBTAIN EU PUBLICATIONS

Free publications:

- one copy:
via EU Bookshop (<http://bookshop.europa.eu>);
- more than one copy or posters/maps:
from the European Union's representations (http://ec.europa.eu/represent_en.htm);
from the delegations in non-EU countries (http://eeas.europa.eu/delegations/index_en.htm);
by contacting the Europe Direct service (http://europa.eu/europedirect/index_en.htm) or
calling 00 800 6 7 8 9 10 11 (freephone number from anywhere in the EU) (*).

(* The information given is free, as are most calls (though some operators, phone boxes or hotels may charge you).

Priced publications:

- via EU Bookshop (<http://bookshop.europa.eu>).

Event	Date
Adoption of the Audit Planning Memorandum/Start of audit	15.7.2015
Official sending of draft report to Commission (or other auditee)	22.7.2016
Adoption of the final report after the adversarial procedure	5.10.2016
Commission's (or other auditee's) official replies received in all languages	14.11.2016

A key milestone in building a stronger EU health security framework was the adoption in 2013 of a decision on serious cross-border threats to health. The EU health and research framework programmes also support actions related to this framework. The audit found that the decision on serious cross-border threats to health indeed represents an important step for dealing better with such threats in the EU, but that significant weaknesses affect the implementation of the health security framework. More needs to be done to address these weaknesses for the Union to get full benefit from the established mechanisms. The Court therefore makes a number of recommendations mainly aiming at accelerating and strengthening the implementation.



EUROPEAN
COURT
OF AUDITORS



Publications Office