



Brussels, 7.12.2015
COM(2015) 617 final

**REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND
THE COUNCIL**

**Report on the implementation of 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**

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1. Executive summary

This report is intended to inform the European Parliament and the Council about the implementation of Decision 1082/2013/EU on serious cross-border threats to health, adopted on 22 October 2013¹. This obligation is stipulated in Article 19 of Decision 1082/2013/EU, which provides that the report is to be submitted by 7 November 2015, and every three years thereafter. The report is in particular to include an assessment of the operation of the Early Warning and Response System (EWRS) and of the epidemiological surveillance network, as well as information on how the established mechanisms and structures complement other alert systems at Union level while not duplicating them.

Decision 1082/2013/EU, in force since 6 November 2013, has improved health security in the European Union and the protection of the Union's citizens from communicable diseases, and other biological, chemical and environmental events.

The preparedness of Member States as well as the mechanisms to notify an alert, assess the risk and manage a cross-border threat through the coordination of response at EU level has been systematically tested during health events of comparatively low and medium severity for the EU. However, the biggest challenge has been the recent Ebola epidemic.

In all cases, the established mechanisms and structures, namely the EWRS, the epidemiological surveillance network, the European Centre for Disease Prevention and Control (ECDC), and the Health Security Committee (HSC) have proven to operate effectively and up to the quality level required in case of a serious cross-border threat to health. Apart from the standard day-to-day functioning of these structures, they have operated successfully during the Ebola outbreak, the Middle East Respiratory Syndrome caused by coronavirus (MERS CoV) and the poliomyelitis threat.

The EWRS has been instrumental to notify alerts as well as measures undertaken by the Member States. The selective exchange functionality was crucial for the transmission of personal data to support the medical evacuation of Ebola patients from the affected countries into the EU.

ECDC has been established by Regulation (EC) No 851/2004² as an independent EU agency responsible for, among others, providing timely risk assessment of a public health threat caused by communicable diseases, including options for possible public health measures.

These systems have shown to complement other EU rapid alert systems which cover other areas (e.g. food, animal health, etc.) but may have a severe impact on public health without duplicating them. Complementarity has been ensured by upgrading the EWRS informatics tool to allow access to the information for users responsible for other sectors and by creating operational arrangements in order to share the notifications circulated through the EWRS with Commission services responsible for food safety, animal health, medical devices and medicines, and other sectors potentially impacted by serious cross-border threats to health. Further details and examples are given later in the report.

In accordance with Article 4(2) of Decision 1082/2013/EU, most Member States have provided the Commission with an update on their preparedness and response planning at national level. Based on the information so far received, the Commission in collaboration with ECDC and the WHO Regional Office for Europe (WHO EURO) compiled a synthesis progress report with the purpose of initiating discussion in the HSC.

¹ OJ L 293, 5.11.2013, p. 1.

² 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 (OJ L 142, 30.4.2004, p. 1).

As the competence to take public health measures on serious cross-border threats lies with the Member States, Decision 1082/2013/EU obliges them to inform of such measures with a view to enhancing coordination among themselves in liaison with the Commission. During the Ebola outbreak, Member States exchanged information and discussed their response to the outbreak in the HSC. An important measure successfully carried out during the outbreak has been the medical evacuation to the EU of health workers infected or suspected to be infected with the Ebola virus. In addition, measures were put in place to facilitate entry screening of travellers coming to the EU from the Ebola-affected countries.

Furthermore, while the overall communication in the HSC has been reasonably effective, there have been some important lessons learned from the process. During the peak of the Ebola outbreak there was a strong focus on the exchange of information while the impetus to discuss and coordinate response was less considerable. A major conclusion from the Ebola outbreak is that there is scope for improving the implementation of provisions whereby Member States are to co-ordinate their national responses.

2. The implementation activities and their key achievements

2.1. Health Security Committee

The HSC was set up in 2001 at the request of EU Health Ministers as an informal advisory group on health security at European level. Decision 1082/2013/EU formalised the establishment and strengthened the role of the Committee.

Following the designation of representatives by Member States, the full composition of the HSC has been achieved by June 2014. The Rules of Procedure adopted on 26 June 2015 provided that they would be reviewed within six months in the light of the two draft Implementing Decisions to be adopted under Article 8 and 11 of Decision 1082/2013/EU. The HSC is chaired by a representative of the Commission, which also provides the secretariat, and meets in plenary in Luxembourg on average twice a year (once in 2014 and three times in 2015) and on an ad hoc basis through audio-meetings. Ad hoc audio-meetings are called by the Commission or by initiative of the HSC to discuss EU coordination of measures to respond to serious cross-border threats to health.

At the plenary meeting on 27 February 2015, the HSC agreed to set up a permanent Communicators' network and a permanent working group on preparedness.

Following nominations from interested Member States, a group of representatives from the Member States was set up in April 2015 which discussed the draft Terms of Reference for each working group during dedicated audio-conferences in May 2015.

2.2. Preparedness and response planning

Article 4(2) of Decision 1082/2013/EU requires Member States to provide the Commission, by 7 November 2014 and three years thereafter, with an update on the latest situation on their preparedness and response planning at national level. The information to be provided is to cover the implementation of the International Health Regulations (IHR)³, interoperability between the health sector and other sectors, and business continuity plans. In addition, according to Article 4(3) Member States are to inform the Commission in a timely manner when substantially revising national preparedness planning. The Commission set up a dedicated 'EUSurvey' website to allow for secure, user friendly and coherent reporting by means of a template laid down in Commission Implementing Decision 2014/504/EU⁴. As of

³ <http://www.who.int/ihr/en/>

⁴ Commission Implementing Decision 2014/504/EU of 25 July 2014 implementing Decision No 1082/2013/EU of the European Parliament and of the Council with regard to the template for providing the information on

23 October 2015, 26 EU Member States and 1 EEA country⁵ representing 86% of the combined EEA population, provided the requested information by use of the website. Member States who have so far not provided the requested information have been reminded to do so.

Based on the received information, in accordance with Article 4(5) of Decision 1082/2013/EU, the Commission transmitted a synthesis progress report to the HSC with the purpose of initiating discussion. The structure of that document follows the structure of the template annexed to Commission Implementing Decision 2014/504/EU. The information transmitted to HSC presents only aggregated data.

The information provided revealed a number of strengths and weaknesses. As regards the strengths, the majority of the respondents indicated that they have implemented the IHR core capacities and that they involved other sectors in the preparedness and response planning activities covering a wide range of serious cross-border threats to health. Standard Operating Procedures (SOPs) are in place for the coordination between the health sector and a number of other sectors considered critical for addressing serious cross-border threats to health. Most respondents replied that they tested the interoperability of sectors.

As regards weaknesses, a number of respondents indicated incomplete implementation of the IHR core capacities. Preparedness and response planning activities involving other sectors was inconsistently reported to cover other communicable diseases apart from threats of foodborne, zoonotic and waterborne origin, or antimicrobial resistance. A number of respondents reported that sectors have been identified as critical for addressing serious cross-border threats to health without appropriate coordination arrangements including Standard Operating Procedures in place for the collaboration of these critical sectors with the health sector. A number of respondents reported that national business continuity plans are not in place although some indicated efforts to create them, or that the existence of national business continuity plans is “not known”. Business continuity plans for the Points of Entry as referred to in the IHR were not consistently reported to be in place.

The discussion in the HSC on the information under Article 4(5) of Decision 1082/2013/EU on 25 June 2015 concluded that the work to address the gaps identified in the report will be followed up by the working group on preparedness and response planning.

In their replies to the survey Member States proposed actions that the Commission, the EU agencies or Member States should take to ensure that the IHR core capacities are maintained and strengthened in the future including regular follow-up with all Member States, training and exercises, sharing experiences, guidelines and procedures, and technical support and expertise with preparedness and response planning.

Specific suggestions for actions that the European Commission and EU agencies could take include strengthening the capacity of and cooperation between EU agencies, supporting global initiatives towards better cooperation and coordination, including Joint Action type funding in Health Programmes and developing mechanisms for coordinated funding, supporting country twinning activities, country-specific assessment of preparedness and networking between countries and joint meetings, and conducting cross-border exercises. Further suggested actions include facilitating in-country networking of stakeholders, conducting in-country exercises and implementing a shared IT-platform to facilitate information flow among stakeholders.

preparedness and response planning in relation to serious cross-border threats to health (OJ L 223, 29.7.2014, p. 25).

⁵ Decision 1082/2013/EU has been incorporated into the EEA Agreement by means of the EEA Joint Committee Decision 073/2015 - paragraph 1 of Article 16 of Protocol 31 to the EEA Agreement.

Dedicated 'EUSurveys' on the preparedness to detect, identify, confirm and manage patients with suspect or confirmed Ebola Virus Disease, MERS-coronavirus patients and cases of new avian influenza strains have been carried out at the occasion of the EU coordination and management of specific events, which has shown a good level of preparedness of Member States.

2.3. Joint procurement of medical countermeasures

Article 5 of Decision 1082/2013/EU lays down a new mechanism for Member States to engage in a joint procurement procedure with the Union institutions with a view to enabling the advance purchase of medical countermeasures for serious cross-border threats to health. For the implementation of this joint procurement, the Commission developed a framework agreement laying down common rules for practical organisation of joint procurement procedures – the Joint Procurement Agreement.

On 20 June 2014, the Joint Procurement Agreement was signed between 14 Member States and the Commission. Since then, additional 8 Member States have signed the agreement⁶. At the time of preparation of this report, the first joint procurement procedure has been launched to commonly procure personal protective equipment needed to treat patients with infectious diseases with potentially severe consequences. Furthermore, preparatory work for the joint procurement of pandemic vaccines is on-going.

Overall - with the Joint Procurement Agreement in place and the first joint procurement procedures under way– the implementation of Article 5 of Decision 1082/2013/EU has progressed well.

2.4. Epidemiological surveillance

Building on the framework set up by Decision No 2119/98/EC⁷, Article 6 of Decision 1082/2013/EU provides a legal basis for a network between the Commission, ECDC and Member States' competent authorities for the epidemiological surveillance of communicable diseases and of related special health issues. The network is to be operated and coordinated by ECDC.

The adoption of Decision 1082/2013/EU gave new impetus to the EU/EEA surveillance activities coordinated by ECDC.

ECDC has continued to coordinate EU/EEA surveillance through meetings and bilateral communications with National Focal Points for Surveillance and Disease Group-specific National Focal Points. Technical consultations took place on special topics such as automatic reporting to the European Surveillance System (TESSy)⁸, EU/EEA surveillance standards, and EU/EEA molecular clusters. Weekly videoconferences were held between ECDC and the Commission. Cross-cutting issues were discussed at meetings between ECDC, the Commission and the Member States. EU candidate and potential candidate countries have been increasingly engaged by sharing of standards, testing of TESSy reporting and participating in relevant meetings.

⁶ The list of the Member States that signed the Joint Procurement Agreement can be found at: http://wcmcom-ec-europa-eu-wip.wcm3vue.cec.eu.int:8080/health/preparedness_response/joint_procurement/jpa_signature_en.htm

⁷ 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). This decision was repealed by Decision 1082/2013/EU.

⁸ TESSy is the technical platform for EU/EEA communicable disease surveillance, i.e. web-based data submission, data storage and dissemination and is a password-protected, fully anonymised database hosted by ECDC.

Stronger data feedback and dissemination channels were established through the Atlas of Infectious Diseases, the further extension of the Epidemic Intelligence Information System (EPIS)⁹ and its integration with molecular surveillance for Food- and Waterborne Diseases. Cross-sectorial reports, such as the one on antimicrobial consumption and resistance in humans and animals were published in addition to more traditional disease-specific surveillance reports and the cross-cutting annual epidemiological report¹⁰. Monitoring of reports on threats to public health in news and social media was carried out using the MedISys¹¹ system.

Data comparability across countries and data quality have remained top priorities for ECDC and have continued to be fostered through agreed reporting protocols, common meta-datasets, meticulous data validation, and proactive feedback during network meetings. New initiatives have included the systematic data quality assessment and feedback through indicators published in a restricted version of the Atlas, a progressive reduction of variables to be reported to TESSy, and the pilot collection of detailed information on Member State surveillance systems.

The Annex to Commission Decision 2000/96/EC¹² lays down the criteria for selection of communicable diseases and related special health issues to be covered by epidemiological surveillance within the epidemiological surveillance network. The Decision as amended currently provides for the list of 47 diseases and two special health issues, and Commission Decision 2002/253/EC¹³ as amended lays down specific case definitions for those diseases and special health issues.

ECDC has been enforcing the use of EU case definitions by rejecting non-compliant data or excluding them from analysis and reporting.

2.5. Early warning and response

Article 8 of Decision 1082/2013/EU extends the scope of the EWRS established by Decision No 2119/98/EC beyond communicable diseases, to notifications in relation to all serious cross-border threats to health within the scope of the former Decision. The EWRS is to enable the Commission and the competent national authorities in the Member States to be in permanent communication in order to alert, assess public health risks and determine the measures that may be required to protect public health.

For that purpose, the existing IT tool of the EWRS was expanded to include threats of biological, chemical, environmental and unknown origin. The new version of this IT tool was put in place on 4 February 2015. Criteria to check whether an event matches the definition of a 'serious cross-border threat to health' were included in the reporting algorithm and a specific functionality to report 'information messages' was added as well as the functionality to report an event under the IHR provisions. The 'selective exchange' functionality has been maintained without modifications as it was in the IT application established by Decision No 2119/98/EC.

⁹ EPIS is a web-based communication platform that allows nominated public health experts to exchange technical information to assess whether current and emerging public health threats have a potential impact in the European Union (EU). It aims to ensure transparent and timely information sharing among the participating public health authorities in order to detect public health threats at an early stage and facilitate their reporting under Decision 1082/2013/EU and the coordination of response activities.

¹⁰ <http://ecdc.europa.eu/en/publications/Pages/Publications.aspx>

¹¹ <http://medisys.newsbrief.eu/>

¹² Commission Decision 2000/96/EC of 22 December 1999 on the communicable diseases to be progressively covered by the Community network under Decision No 2119/98/EC of the European Parliament and of the Council (OJ L 28, 3.2.2000, p. 50).

¹³ Commission Decision 2002/253/EC of 19 March 2002 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 86, 3.4.2002, p. 44).

As the EWRS system involves the processing of sensitive data, such as health data, the new tool has been developed taking due account of the provisions of Regulation (EC) No 45/2001¹⁴ and Directive 95/46/EC¹⁵. A number of recommendations based on the results of 'stress tests' carried out in 2013 by the Commission have been taken into account, including a strict 'user-access' policy. Since August 2015, the EWRS access is granted through the European Commission Authentication Service (ECAS) via personalised e-mail and passwords, although some Member States expressed preference for access through 'generic mailboxes'.

In order to avoid duplication and to ensure that alert notifications under the EWRS are linked with other rapid alert systems at Union level the new EWRS allows access to other Commission services and EU bodies responsible for risk management and risk assessment in areas not specifically covered by the Public Health Directorate of the Directorate General for Health and Food Safety of the Commission. These areas include food safety, substances of human origin, animal health, medicines and medical devices, biologicals other than communicable diseases (e.g. plant toxins), chemicals, environmental threats, health security and nuclear and radiological threats. The links allow the flow of information between the Commission services responsible for the above mentioned areas and the Member States health authorities responsible for the EWRS. The Commission is considering a further upgrade of the application that will in the medium term allow more user friendly functions to be developed as soon as the proposal for a full re-shape of the EWRS IT tool has been agreed with the stakeholders and the ECDC.

2.6. Alert notification and public health risk assessment

Article 9 of Decision 1082/2013/EU obliges national competent authorities and the Commission to notify an alert in the EWRS where the emergence or development of a serious cross-border threat to health fulfils certain criteria.

From 5 November 2013 until 4 September 2015, a total of 168 messages were posted with 354 comments. Of the remaining messages, 90 were alert notifications and 78 were information messages.

The breakdown of messages by notifying countries or institution was as follows: European Commission 28, France 22, United Kingdom 20, Germany 12, Spain 11, The Netherlands 10, Norway 8, Italy 7, Greece 5, Belgium 4, Bulgaria 4, Austria 3, Czech Republic 3, Denmark 3, Iceland 3, Portugal 3, Sweden 3, Switzerland 3, Ireland 2, Lithuania 2, Malta 2, Slovenia 2, Croatia 1, Cyprus 1, Finland 1, Hungary 1, Latvia 1, Poland 1, Romania 1 and Slovakia 1. 49 alert notifications were related to Ebola Virus Disease, 13 to measles, 9 to influenza, 8 to MERS CoV, Chikungunya, rabies and meningitis, 6 to hepatitis, 5 to salmonellosis, botulism, dengue and West Nile virus, 4 to poliovirus and legionellosis, 3 to anthrax, cholera and diphtheria, 2 to tuberculosis, listeriosis, septicemia, mycobacterium and gastroenteritis, and 1 to each of the following: malaria, shigellosis, Hemolytic Uremic Syndrome (HUS), paratyphoid fever, cryptosporidiosis, leptospirosis, enterovirus, Zikavirus, streptococcus, Severe Acute Respiratory Syndrome (SARS), schistosomiasis, cyclosporiasis, trichinosis, Borna virus, HIV, varicella zoster virus, chickenpox, pertussis, norovirus, hantavirus, and louse borne relapsing fever. Two alert notifications related to threats stemming from chemical agents: food poisoning linked to malathion and the chemical explosion in China. One alert

¹⁴ Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p.1).

¹⁵ Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

notification related to a threat stemming from environmental origin: the volcanic ash cloud in Iceland.

The MERS CoV and Ebola outbreaks have triggered the activation of the orange level of the Health Emergency Operation Facility of the Health Threats Unit of the Directorate General for Health and Food Safety.

According to Article 10 of Decision 1082/2013/EU, the Commission is to make promptly available to the national competent authorities and to the HSC a risk assessment of the potential severity of the threat to public health, including possible public health measures. This provision applies where it is necessary for the coordination of the response at Union level and on the request of the HSC or on the Commission's own initiative. Such risk assessment is to be carried out by the ECDC or – according to the nature of the threat – another Union agency, such as e.g. the European Food Safety Authority (EFSA).

Since November 2013, the ECDC produced rapid risk assessments for 28 events: Ebola, MERS-CoV, polio, avian influenza, salmonella, measles, Zika virus, Chikungunya, legionellosis, schistosomiasis, anthrax, healthcare associated infection with mycobacterium, enterovirus, diphtheria, louse borne relapsing fever, Borna virus, food intoxication due to malathion, chemical explosion in China and the floods in Bosnia Herzegovina, Serbia and Croatia¹⁶.

Rapid risk assessments prepared by the ECDC, as well as their updates when needed, have been very well received by Member States. In addition 'options for actions', which in many cases were included in the risk assessments, have proved useful to discuss within the HSC possible measures at EU level to respond to the events, as it was the case for the main events notified since November 2013, namely MERS CoV, poliomyelitis in vulnerable countries and the Ebola epidemic in West Africa.

2.7. Coordination of response

According to Article 11 of Decision 1082/2013/EU, following an alert in the EWRS, on a request from the Commission or a Member State, Member States are to consult each other within the HSC and in liaison with the Commission with a view to coordinating national responses to a serious cross-border threat to health, as well as risk and crisis communication. The consultation is also to cover national responses to events declared a public health emergency of international concern by the WHO in accordance with the IHR. In addition, the Committee is mandated to reinforce the coordination and sharing of best practice and information on national preparedness activities. The Committee further deliberates on communication messages to health care professionals and the public in order to provide consistent and coherent information adapted to Member States' needs and circumstances.

In order to comply with the obligation laid down in Article 11(5) of Decision 1082/2013/EU, the Commission is currently preparing an Implementing Decision specifying the necessary procedures for the uniform implementation of the information exchange, consultation and coordination within the HSC.

In the period November 2013 - September 2015, 49 ad hoc audio meetings have been called covering events and issues of cross-border relevance, including polio threats (6 audio-meetings), MERS CoV outbreaks (2), Ebola epidemic in West Africa (30)¹⁷, health related aspects of migration (7), and vaccine shortage, HIV/AIDS, antimicrobial resistance, and the state of implementation of Article 4 of Decision 1082/2013/EU.

¹⁶ Risk assessments and guidance documents are available at: <http://ecdc.europa.eu/en/Pages/home.aspx>

¹⁷ Flash reports from the plenary and audio meetings of the HSC are available at: http://ec.europa.eu/health/ebola/recent_developments_en.htm

For the Ebola outbreak, in view of its multi-sectorial character, in addition to the HSC a series of other tools were activated at the same time, including the Union Civil Protection Mechanism (upon an initial request from the WHO). The cross-sectorial coordination at Union level was also facilitated through the Ebola Task-Force meetings, organised in the Emergency Response Coordination Centre of the Commission. The HSC was useful in contributing to the task-force meetings and in sharing with public health authorities the outcomes of these meetings. This multi-faceted coordination process also supported the setting up and running of the Union medical evacuation system for cases and suspected cases of Ebola Virus Disease to Europe. The Common Emergency Communication and Information System (CECIS) was instrumental in identifying aerial means, while the 'selective exchange' facility of the EWRS allowed the coordination on the provision of suitable hospital treatment capacities. Through this system, so far, a total of 16 persons were evacuated to the EU in 13 flights. The Commission also contributed financially to some of these evacuation operations, with an estimated total of EUR 1,240,000: EUR 740,000 through the Union Civil Protection Mechanism for 6 flights carrying 8 humanitarian workers, and another EUR 500,000 from the humanitarian aid budget for 3 flights with 4 humanitarian workers.

2.8. Emergency situations

Article 12 of Decision 1082/2013/EU enables the Commission to recognise a situation complying with the specified criteria as a public health emergency.

During the reporting period, there was no need to have recourse to this article since the WHO declared the outbreaks of Ebola and Polio Public Health Emergencies of International Concern under the IHR. The two events matched the criteria to be reported as serious cross-border threats to health.

2.9. Designation of national authorities and representatives

Article 15 of Decision 1082/2013/EU requires Member States to designate competent authorities for epidemiological surveillance, for notifying alerts and determining the required measures, and the members of the HSC.

During the reporting period designations were carried out as required by Decision 1082/2013/EU. The Commission, in collaboration with the ECDC provided uniform access to the EWRS to the appointed individuals by means of the ECAS.

3. Conclusions

The recent Ebola epidemic has not only been a devastating crisis for the affected West African countries but also had significant repercussions for Europe. The initial reaction was to protect the EU and only later the attitude changed to recognise that crucial help was needed from Europe and the international community in order to contain/manage the Ebola outbreak at source. A major conclusion from the Ebola outbreak is that there is scope for improving the implementation of provisions whereby Member States are to co-ordinate their national responses.

Ad-hoc consultations within the HSC have proven very useful to share options to plan and implement a coherent EU response to specific threats, although an evidence based evaluation on how the Member States have used the technical guidelines, options for actions, advice to travellers, and other technical documents provided by the Commission is currently lacking. This kind of assessment should be promoted in the future to have an evidence based appreciation of the impact and the use of such materials at national level with a view to identifying possible measures to improve their impact.

The cooperation among the relevant Commission services and the collaboration with the Commission agencies and Member States to implement the framework provided by Decision 1082/2013/EU has worked well during the period. There is currently no need to introduce any changes in this respect.

As regards Article 4 of Decision 1082/2013/EU, the actions proposed by Member States to ensure that the IHR core capacities are maintained and strengthened in the future include regular follow-up with all Member States, training and exercises, sharing experiences, guidelines and procedures, and technical support and expertise with preparedness and response planning.