

ROADMAP

Roadmaps aim to inform citizens and stakeholders about the Commission's work in order to allow them to provide feedback and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have.

TITLE OF THE INITIATIVE	Protecting citizens against health threats
LEAD DG – RESPONSIBLE UNIT	DG RTD – UNIT E3 – CO-LEAD DG SANTE – PA01 - UNIT C3
LIKELY TYPE OF INITIATIVE	Communication from the Commission
INDICATIVE PLANNING	<i>Adoption expected Q2- 2018</i>
ADDITIONAL INFORMATION	-

This Roadmap is provided for information purposes only and its content might change. It does not prejudice the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the Roadmap, including its timing, are subject to change.

A. Context, Problem definition and Subsidiarity Check

Context

In a globalised world, infectious diseases can move quickly across borders, carried by humans, animals, food, plants or water. The recent outbreaks of Severe Acute Respiratory Syndrome (SARS), Middle East Respiratory Syndrome coronavirus (MERS-coV), Ebola and Zika virus have shown how vulnerable and poorly prepared the world was to respond effectively. Effective preparedness and response measures are essential to address outbreaks of infectious diseases, which often have a dramatic socio-economic impact, cost lives, threaten global security and affect food safety and food security. Concerns have been raised at multiple levels: President Juncker called for "a Europe that protects, empowers and defends", including health security; G7 and [G20](#)¹ have agreed to strengthen global health security and public health emergency preparedness and response. This Communication will address these calls by outlining a comprehensive preparedness and response strategy for the EU and its Member States, with relevant actions, including research and innovation, taking a One Health approach linking human and animal health, and enhancing the EU's role as a partner for global health security.

Problem the initiative aims to tackle

Ebola and Zika viruses have been known for decades, but the recent epidemics confirmed that the pattern has changed, the threat has increased and that a delayed or inadequate response may cause considerable social and economic impacts, in addition to the expected health impacts. The Ebola outbreak killed over 11,000 people and the economic cost of the outbreak is estimated at least at EUR 5.4 billion. In Europe, influenza kills up to 70,000 people each year while some strains present a pandemic threat that could appear anytime. Outbreaks of infectious diseases continue and will continue to spread and strike more widely due to increased mobility and trade, urbanisation, climate and environmental changes if effective measures to ensure preparedness at national and Union level and successful response are not taken. In fact, outbreaks will happen more frequently. The spread of zoonotic infections, from animals to humans and vice versa, or transmitted through food, is of particular concern.

Previous outbreaks have taught significant lessons on the nature of the threat, the gaps in our preparedness and the bottlenecks for an effective response. To counter these threats, new, comprehensive approaches to preparedness, surveillance and response, using modern and innovative technologies and new research to allow better surveillance and earlier detection, and new and innovative therapeutic and prophylactic countermeasures are indispensable.

Basis for EU intervention (legal basis and subsidiarity check)

Infectious diseases are cross border health threats challenges requiring a coordinated effort across the EU and its Member States and with global partners. Such coordination of effort can only take place at EU level. Avian flu, Ebola, Zika and other infectious diseases are examples of major health scourges as referred to in [Article 168 TFEU](#), which give the EU the overall competence to support, coordinate or supplement the actions of the

¹G20 Leaders' Declaration - Shaping an interconnected world -Hamburg, 7/8 July 2017
http://www.consilium.europa.eu/media/23955/g20-hamburg-leaders_communicu%C3%A9.pdf

Member States for promoting research into their causes, their transmission and their prevention, as well as monitoring, early warning and combating serious cross-border threats to health. The [European Consensus on Development](#) "Our World, Our Dignity, Our Future" also makes this commitment to take action to address global health threats explicit.

The added value of action at Union level is also recognized in the [EU Decision 1082/2013/EU on serious cross-border threats to health, which provides for supporting the implementation of core capacity requirements of the International Health Regulations](#); and Regulation (EU) 2016/429 on transmissible animal diseases and Regulation (EC) No 178/2002 on food and feed.

B. What does the initiative aim to achieve and how

This Communication aims to strengthen the EU framework for more effective and comprehensive crisis preparedness and management, including preparedness research, and streamline and strengthen capacities and structures to protect European citizens from the threat of infectious diseases using a One Health approach by bringing together expertise in public health, animal health, food safety, bio-safety, environment, research and innovation. The EU's resilience in the face of these threats depends on two mutually reinforcing and complementary capacities: the EU capacity for public health, food safety and animal health preparedness and response to those threats, and the EU capacity for targeted and coordinated research and innovation to deliver effectively and timely with successful therapeutic and prophylactic countermeasures including new medicines; both these capacities are further enhanced by global coordination and collaboration.

The implementation of this strategy will enhance the EU's role in global health security and contribute to meeting the UN Sustainable Development Goals – including its specific target "*strengthen capacity (...) for early warning, risk reduction and management of national and global health risks*". The proposed Communication will outline a strategy with three pillars:

- 1) Increase the capacity of EU and Member States to efficiently prevent, detect and control infectious disease outbreaks in humans, animals and food through ensuring interoperability of infectious diseases' related datasets, systematic application of big data analytics and artificial intelligence to pathogen genome data enabling better analysis of outbreaks, as well as strengthening the EU reference laboratory networks, in particular those addressing emerging and highly pathogenic agents.
- 2) Strengthen the impact of research and innovation by embedding research gap analysis and priority setting together with the Member States under the Permanent Working Group of the Health Security Committee on Preparedness and Response Planning. In parallel, accelerate the development of innovative medical (therapeutic and prophylactic) countermeasures, including through promoting the use of new technologies and applications and new models of collaboration with the private sector.
- 3) Enhance the EU's role as a partner in global health security, by building stronger capacities and networks, including through support for low and middle-income countries, to allow for a more rapid, integrated and effective global response to outbreaks. This will include support to EU pre-accession and European Neighbourhood Partner countries through a common framework for strengthening national capacities and reinforced cooperation with amongst other stakeholders, the World Health Organisation, the Food and Agriculture Organization, and the World Organisation for Animal Health to make the One Health approach the gold standard for preparedness policy and research prioritization. The EU, with the support of the European Centre for Disease Prevention and Control, should develop a capacity to mobilise EU expertise in field epidemiology and other areas for better and swifter outbreak response in the field. The EU and the European Centre for Disease Prevention and Control will cooperate closely with global partners and Centres for Disease Control, providing a network for sharing of best practices, surveillance information and expertise, supporting IHR implementation through capacity building and peer reviews and follow-up actions, and providing further opportunities for public health outreach and impact.

This strategy is complementary to other ongoing EU policy initiatives such as the 'Action Plan to enhance preparedness against chemical, biological, radiological and nuclear Security Risks', the 'Joint Framework on countering hybrid threats', 'Action Plan on the Sendai Framework for Disaster Risk Reduction', the 'One Health Action Plan against Anti-Microbial Resistance', the Civil Protection Mechanism and the European Medical Corps and the upcoming initiatives on a Communication on the 'Digital Transformation of Health and Care', and a 'Council Recommendation on Strengthening cooperation against vaccine preventable diseases'.

C. Better regulation

Consultation of citizens and stakeholders

The views of many stakeholders on the core topics of the planned Communication were already gathered in previous related consultations and meetings (e.g. in the course of preparing the new Action Plan on Anti-Microbial Resistance; the Meeting of the "One Health Network" in February 2017; the Commission Workshop on Vaccination in May 2017, the open consultation on Strengthening cooperation against vaccine preventable

diseases in December 2017; and regular meetings with Member States and civil society in Commission expert groups on infectious diseases²). The views expressed in these fora will be taken into account in the Communication.

Evidence base and data collection

- [Report on the implementation of Decision No 1082/2013/EU](#).
- [European Court of Auditors' Special Report No 28/2016](#) : "Dealing with serious cross-border threats to health in the EU: important steps taken but more needs to be done" and relevant [recommendations of the European Court of Auditors](#).
- [The synopsis report](#) accompanying the Communication from the Commission to the Council and the European Parliament A European One-Health Action Plan against Antimicrobial Resistance.
- [Communication on the Mid-term Review of the Digital Single Market Strategy](#) and accompanying [Staff Working Document](#) of 10 May 2017; COM(2017)228 final and SWD (2017) 155 final
- The outcome of the ongoing REFIT – 'Fitness Check' of Regulation (EC) No 178/2002 (the General Food Law)

No impact assessment is needed for this initiative. The actions it encompasses are of non-regulatory nature aimed at better enabling the Commission and the Member States to exploit possible synergies between EU and national policies across public health and animal health ongoing initiatives and support national authorities in their efforts to develop and implement coherent measures for research and public health policy decisions.

² Such as regular meetings in the framework of [Global Research Collaboration for Infectious Diseases Preparedness](#), of the [Global Health Policy Forum](#), and of the [Health Security Committee's](#) Working Group on Preparedness and Response Planning.