CP-g-23-18 Direct grants to Member States' authorities: to enhance, extend and consolidate wastewater surveillance for public health (HERA)

POLICY CONTEXT

HERA is responsible for the assessment of health threats and intelligence gathering in the area of medical countermeasures⁴⁷. In order to do this, HERA will have dedicated capacities for horizon scanning, foresight, data analysis and market intelligence and will strengthen genome sequencing and environmental surveillance including wastewaters surveillance working closely with Member States, other Commission services and agencies.

Wastewater surveillance and the related epidemiological assessment emerged during the COVID-19 pandemic⁴⁸ as a tool to ensure timely and relevant intelligence gathering independent of behaviour (e.g. preparedness to test) and interventions (e.g. the quantitative assessment of virus particles in sewage revealed trends and its strong correlation with clinical cases⁴⁹). This action will build on the activities started as part of the HERA incubator and the Commission Recommendation to support a consistent approach to the use of wastewater monitoring to track SARS-CoV-2 and its variants⁵⁰ and supported Member States with EUR 23⁵¹ million funding (implemented through DG ENV) to accelerate the deployment of wastewater surveillance for COVID-19. In addition, DG JRC has initiated, stimulated and coordinated the authorities' network (national and international level including stakeholders), the development of a dashboard for exchanging of relevant information (DEEP) and organised the testing of samples from super-sites (used to compare and assess wastewaters of residential population vs. transportation hubs) in Lisbon, Madrid, Nicosia, Amsterdam, Frankfurt and Prague.

Since its roll-out, this joint effort has not only detected the emergence of the delta and omicron variants, but has provided additional insights and understanding how SARS-CoV-2 variants move across borders. Therefore, extending the support programmes set up under the HERA Incubator is essential to strengthen not only the detection and identification of SARS-CoV-2 variants in the Union but to also build on preparedness to other serious cross-border health threats such as those identified by HERA in its health threat prioritisation.

The award of a direct grant as referred to in Article 13(5) of Regulation (EU) 2021/522 is duly justified because this action can be best carried out by the Member States' authorities (namely

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Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority 2021/C 393 I/02.

In line with research findings such as from the Horizon 2020 project VEO.

As reported by several authorities dealing with wastewaters and based on public information available for instance Correlation between Clinical and Wastewater SARS-CoV-2 Genomic Surveillance, Oregon, USA (cdc.gov).

⁵⁰ C(2021) 1925 final.

The HERA, an initiative to better respond to variants of concern, included EUR 20 million from the Emergency Support Instrument (ESI) (direct grants to 26 of 27 Member States, leveraged by at least EUR 33.4 million from Member States) and EUR 3 million from NEAR for neighbouring countries.

public health authorities and those dealing with environmental surveillance) as they have the required legal and technical competences and responsibilities to implement the Union policies at national level.

This joint action supports the policy priority to strengthen the capability of the Union for prevention of, preparedness for, and rapid response to, serious cross-border threats to health particularly through supporting data gathering, information exchange and surveillance, as well as Health in all policies. It implements the EU4Health Programme's general objective of protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States to cope with serious cross-border threats to health (Article 3, point (b) of Regulation (EU) 2021/522) through the specific objectives defined in Article 4, points (a) and (b), of Regulation (EU) 2021/522.

OBJECTIVES, SCOPE, ACTIVITIES

Regular surveillance of wastewaters in combination with other indicators for the management of the COVID-19 pandemic can facilitate decision making as it allows among others things to follow-up any resurgences and emerging trends, as well as the reach of a peak wave, to confirm and complement the trends information coming from the lab-based positive cases, which is especially important in low-testing periods. As a consequence, wastewater surveillance has been included more systematically in the national surveillance strategies for the prevention and control of the COVID-19 pandemic. However, the level of maturity of the detection of the SARS-CoV-2 and its variants in sewage varies among Member States.

The main focus of this joint action is to support activities, to enhance and/or improve national public health wastewater surveillance capacities (including the EU outermost regions⁵²) by strengthening knowledge exchange and sharing best practices. The activities of this joint action will target and bring together Member States' authorities such as public health ministries, health institutes and/or laboratories or other relevant structures at national, regional and/or local level and take into account evidence from relevant research. They should facilitate the integration and complementarity of wastewater surveillance with other surveillance systems with a clear public health perspective to strengthen preparedness and response to cross border health threats.

The activities to be covered by the joint action would include:

- (a) Definition of wastewater surveillance strategies. This will include for instance:
 - identification of priority pathogens and substances to be monitored (maintaining and extending the current SARS-COV-2 surveillance capacities, including those that were put in place through the emergency funding above mentioned to other priority threats⁵³, including but not limited to Antimicrobial

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In line with COM(2022) 198 final.

Taking into account the HERA priority list of cross border health threats.

Resistance (AMR), vaccine-derived poliovirus variants and emergent pathogens to ensure better preparedness) in line with the HERA threat prioritisation;

- definition of objectives for the different priority threats identified, e.g. detecting emerging threats, monitoring on-going events, assessing trends;
- selection of strategic sampling location, collection, frequency and transportation;
- collection, interpretation and translation of results;
- modelling and integration into existing public health surveillance systems, including clinical surveillance;
- capacity development, exchange of experience, networking and training and development of educational materials for integration into (existing) diverse discipline programmed for target audiences (e.g. engineers, physicians, epidemiologists).
- (b) Definition of technical procedures. This will include for instance:
 - alignment of methods for e.g. detection, normalisation, data visualisation used by Member States to the extent needed;
 - identification and exchange of best practices for various purposes and resource settings;
 - enhancing comparability of data, interoperability of IT platforms, reporting and sharing of data with DEEP;
 - capacity development, exchange of experience, networking and training.
- (c) Establishment of governance framework:
 - EU, European and international coordination;
 - mapping of stakeholders and other actors and subsequent engagement;
 - interaction and coordination with on-going activities at international level including with the WHO⁵⁴;
 - capacity development, exchange of experience, networking and training.
- (d) Communication i.e. to the public, physicians, decision makers, technicians, engineers.
- (e) Sustainability and financial viability of the wastewater surveillance.

The joint action will work in cooperation with HERA and DG JRC as well as with other relevant EU and global bodies e.g. the ECDC, the WHO, the UN Environment Programme (UNEP). Progress of this joint action should also serve to provide support to global actors and low- and middle-income countries that can benefit from the exchange of experience and lessons learned during this exercise. In addition, there will be coordination and duplications should be avoided with the EU sentinel system to be established under the procurement section (see action CP-p-23-20) for instance to submit samples to the system to be established in the context of an emergency.

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Other stakeholders such as ECDC and the HERA laboratory network are expected to be involved for their knowledge and expertise where relevant.

EXPECTED RESULTS AND IMPACTS

This joint action will result in increased surveillance capacities at national and EU level for (pandemic) preparedness and control of infectious diseases and AMR, and a better evidence-based integration of this type of surveillance into other types of routine surveillance by focusing on complementarities that environmental data can bring for instance to clinical surveillance.

Consolidating wastewater-based surveillance systems will add value beyond SARS-CoV-2 monitoring. The already implemented systems will be extended to provide possibilities for monitoring and early warning for future possible outbreaks of other pathogens of concern or the emergence of threats of environmental or chemical origin, whether intentional or not, affecting global security.

The approach could be particularly relevant to monitor pathogens of concern, AMR, and chemical substances such as pharmaceuticals. The monitoring of quantitative and qualitative changes and trends of pathogens/substances concentrations in wastewater can inform preparedness and response measures to certain cross-border health threats.

INDICATIVE TIMETABLE, BUDGET, IMPLEMENTATION AND PROCEDURE TYPE

Call topic/sub-topic	Estimated call publication	Budget
Direct grants - CP-g-23-18	Q1/2023	EUR 15 000 000
Procedure type	Implemented by	Type of applicants targeted
Direct grant to Member States (joint action) in accordance with Article 195, first paragraph, point (c), of Regulation (EU, Euratom) 2018/1046	HaDEA	Member States' authorities

CP-g-23-22 Direct grant to support the Africa Pathogen Genomics Initiative (PGI) (HERA)

POLICY CONTEXT

The Council adopted on 20 May 2021 a decision to support the launch of negotiations for an international treaty on the fight against pandemics within the framework of the WHO. Such a treaty would support international efforts to reinforce global health security, on preparedness