



D1.24 — Ethical Legal and Societal Aspects Report

WP1 — Project Management



The PathoCERT project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 883484.

Document Information

GRANT AGREEMENT NUMBER	883484	ACRONYM	PathoCERT
FULL TITLE	Pathogen Contamination Emergency Response Technologies		
START DATE	1 st September 2020	DURATION	36 months
PROJECT URL	www.pathocert.eu		
DELIVERABLE	D1.24 – Ethical Legal and Societal Aspects Report		
WORK PACKAGE	WP1 – Project Management		
DATE OF DELIVERY	CONTRACTUAL	30/11/2021	ACTUAL 19/01/2022
NATURE	Report	DISSEMINATION LEVEL	Public
LEAD BENEFICIARY	UCY		
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ABSTRACT	This deliverable is a report on the Ethics Legal and Societal Aspects of the PathoCERT project. It includes an analysis of the ethical guidelines, legal directives, and societal impact of the PathoCERT activities.		

Document History

VERSION	ISSUE DATE	STAGE	DESCRIPTION	CONTRIBUTOR
1	14/12/2021	Draft	Initial draft	Dimitrios Kouzapas, Demetris Eliades
2.	7/1/2022	Review	Draft Submission	George Milis
3.	19/1/2022	Final	Final check	Demetris Eliades

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Executive Summary

This deliverable is a report on the Ethics, Legal and Societal Aspects of the PathoCERT project. It includes an analysis on the PathoCERT activities with regards to:

- The ethical guidelines for the interaction with individuals and the usage of data collected from individuals;
- The legal directives for the use of pathogens, the use of Unmanned Aerial Systems (UAS), misuse of research results, and personal data; and
- The societal impact of the PathoCERT activities.

In addition, the document reports on the work of the Ethics Advisory Board of the PathoCERT project.

1 Introduction

This Deliverable describes the ethical, legal, and societal aspects of the activities of the PathoCERT project. These activities are mainly concerned with the requirements of:

- WP3 (Communities of Practice) that requires the interaction with stakeholders and volunteers to gather information for the further development of the PathoCERT technology
- WP8 (Pilot studies) that requires the participation of First Responders and other stakeholders in pilot exercises for the validation of the PathoCERT technologies
- WP4 (Pathogen detection) and WP5 (Situation awareness) that develop technologies that may be subject to ethical, legal, and societal guidelines.

Following the project goals, PathoCERT involves among others:

- human participants in social sciences research (WP3),
- collection of certain personal data, which are relevant to the social study, the evaluation of the effectiveness of the communication activities, as well as the training organized by PathoCERT (WP3, WP8),
- collaboration with Non-EU Countries (South Korea).

PathoCERT gives particular attention to ethics aspects, carefully examining the relevant EU legislation to address possible ethics aspects, covering also the recommendations given to the project through the Ethics Summary Report and incorporated in its description of work. More specifically, PathoCERT confirms the understanding and implementation of the:

- Data Protection Directive (95/46/EC) and the Regulation (EU) 2016/679 (EU General Data Protection Regulation)
- Article 29 Data Protection Working Party Opinions
- Article 5(3) of the ePrivacy Directive (2002/58/EC)

For the avoidance of doubts, it is clarified that PathoCERT

- **does not** involve research with human embryos and fetuses, human cells and tissues, or animals,
- **does not** involve and does not require the collection of sensitive personal data,
- **does not** involve research with elements which can cause harm to the environment,
- **does not** involve dual-use research; it focuses exclusively on civil applications,
- **does not** have a potential for misuse of data and material for unethical purposes,
- **does not** involve children or people from disadvantaged groups as this would not add value to the research results,
- confirms that the research conducted in non-EU countries is legal in the EU Member States from which partners are coming from.

This deliverable is segmented as follows: In Section 2, issues related to the Ethics are identified and analyzed. Section 3, provides an analysis on the Legal aspects, whereas section 4 presents and analyses the Societal Aspects of the PathoCERT project.

2 Ethics

This Section analyzes the ethical implication of the activities of the PathoCERT project. The main ethical issues which are related to PathoCERT, are linked with the involvement of humans. Specifically, the PathoCERT project requires interaction with relevant stakeholders and volunteers implement the requirements of Work Packages 3 (CoPs) and 8 (Pilots). It is important to note that there will be no physical interventions on the study participants.

Regarding the procedures for protecting the Data collected and generated as part of PathoCERT, a detailed “Data Management Plan” has been prepared (D1.23) and a Data Protection Officer has been appointed (D9.3 H - Requirement No. 3).

2.1 Communities of Practice

As part of the activities of WP3, six local and one European Communities of Practices (CoPs) (Task 3.2: The Communities of Practices) are being formed. These CoP engage First Responders, Water organisations, and other expert stakeholders and they gather information from their participants for the purposes of developing and validating the PathoCERT technologies in a structured way. The participant provide an informed consent that the information provided will be used only for the purposes of the PathoCERT project.

The procedure and templates for Informed Consents have been released in the internal deliverable D9.1 “H - Requirement No. 1”. Additional templates and guidelines have been prepared by the CSCP to support the CoP organizers.

2.2 Societal engagement and gender issues study

As part of the activities of WP3, a social study is being conducted (subtask T3.3.3) by the University of Cyprus, in Cyprus, on the impact of water and/or pathogen-related emergency situations (e.g., flooding, water contaminations and pandemics) and the use of technologies for responding to such emergencies. The social study will collect data through from individuals participating on a volunteering basis, through structured interviews.

The study has been approved by the [Cyprus National Bioethical Committee](#), and additional details can be found in the internal deliverable D9.2 “H - Requirement No. 2”. The relevant informed consent has also been approved by the CNBC.

As a note, the social study does not involve vulnerable individuals or groups, children/minors, or patients.

2.3 Pilot Exercises

As part of WP8, 5 pilot exercises will be conducted for the purposes of validating and extracting conclusions on the PathoCERT technologies, that are under development. For the purposes of Task 8.1-Horizontal Preparation the feedback from the CoPs will be collected in order to prepare the scenario and the requirements of the pilot exercises. Moreover, First Responders, water utilities and organisation responsible for crisis management, and other experts will participate in the exercises. The exercises will be organized as part of the First Responders/Water Operators routine training, with professional staff. The pilots will constitute an extension to the Communities of Practice, which are already covered by Informed Consents.

2.4 Technological Aspects

Ethical aspects are considered in the development of all PathoCERT technologies. Specifically, the following technologies have been identified whose ethical issues have been identified and addressed from their design. These include:

1. The mobile application for PathoTeSTICK. This device will be used by professionals and will record the location and contaminant concentrations before communicating them to the PathoCERT cloud. The professionals will sign an Informed Consent before using the mobile application.
2. The wearable devices for PathoVIEW. These devices (mobile app, smartphone etc.) will be used by professionals, and share information related to the position of the FR and their exposure to possible contamination events. The professionals will sign an Informed Consent before using these devices application.
3. The PathoDRONE will be equipped with a camera which will be used for path planning and water sampling only.
4. The PathoTWEET technology is recording in real-time anonymized social media “tweets” using certain keywords, using open-source information.
5. The PathoCAM technology will be used for analyzing the colour of water and will not be used for tracking humans.

3 Legal

This section provides information about the legal aspects of the PathoCERT project activities and in particular with regards to:

- the use of pathogens
- the use of Unmanned Aerial Systems
- the potential of misusing research results
- the personal data
- importing/exporting any material – including data – from/to non-EU countries into EU

3.1 Use of pathogens

Specific pathogens will be studied in a laboratory environment for the testing of certain PathoCERT technologies. Copies of relevant certifications/accreditations for all the laboratories (e.g., ISO/IEC 17025, ISO/IEC 17020, ISO 14001, ISO 9001,) are collected and kept on file (see Deliverable D9.5). It is important to note that **no pathogens will be released into the environment for the purposes of the pilots. All analysis will be conducted in controlled laboratory conditions or in simulation using the tools from WP7.** For further clarifications and copies of the certificates and accreditations see Deliverable D9.5.

3.2 Use of Unmanned Aircraft Systems

The relevant legislation for the use of UAS, is the [*Commission Implementing Regulation \(EU\) 2019/947*](#) which defines the requirements for drone capabilities for achieving maximal safety. The European Union Aviation Safety Agency have also published a [document](#) that covers the Commission Implementing Regulation (EU) 2019/947, the related acceptable means of compliance (AMC) and guidance material (GM), as well as the Commission Delegated Regulation (EU) 2019/945 on unmanned aircraft systems (UAS) and on third-country operators of UAS.

In Deliverable D9.5, we list the relevant legislation, the licenses for operating UAS ([Drone Pilot Sites – Scenarios – Operator Certificates](#)), and the pilot names for the UAS are listed.

3.3 Misuse of research results

Misuse of research results is a subject that is thoroughly analysed in Deliverable D9.7. In particular D9.7 deals with:

- providing a full risk assessment to identify, evaluate, mitigate, and treat risks including a procedure to ensure responsible reporting for evaluating and reporting risks for potential misuse
- procedures to raise awareness among partner institutions related to misuse of research findings and how to identify risks

3.4 Personal data

The processing of the personal data collected by the PathoCERT project is in full compliance with the EU General Data Protection Regulation (GDPR).

PathoCERT will collect certain personal data that are necessary to implement the requirements of Task 3.3 - Societal Engagement and Gender Issues, the evaluation of the effectiveness of the communication activities, as well as implement the trainings organized by PathoCERT,

Deliverable D9.3 details the procedure for processing personal data and in particular it is concerned with:

- Appointing a **Data Protection Officer** (DPO) by the host institutions involved in activities where personal data is collected and processed and making available his/her contact details to all data subjects involved in the research. In case there is no obligation for a DPO, a Data Privacy Policy should be in place.
- Describing the compliance of PathoCERT partners to GDPR
- Describing of the technical and organisational measures that are being implemented to safeguard the rights and freedoms of the data subjects/research participants.
- Describing of the security measures that are being implemented to prevent unauthorised access to personal data or the equipment used for the processing.
- Confirming that in case personal data are transferred from the EU to a non-EU country or international organisation, that such transfers are in accordance with Chapter V of the GDPR 2016/679.
- Confirming that in case personal data are transferred from a non-EU country to the EU (or another third state), that such transfers comply with the laws of the country in which the data was collected.

3.5 Import/export any material –including data– from/to non-EU countries into EU

The PathoCERT project involves two partners from South Korea: 1) Sundosoft and 2) Korean Institute of Technology and Sciences. The two partners are mainly involved in the activities of WP3 and in the activities of WP7. This implies information gathering activities, technology development and in-the-field demonstrations.

Regarding personal data exchange with non-EU partners, appropriate measures are being taken, in consultation with the project Ethics Advisor and project's Security Board, as well as, with all of the involved national competent authorities, as to avoid any exchange (import or export) of personal data. In case data will be exchanged for research purposes they will be fully anonymised, ensuring that no option is left for the identification of any individual involved in the studies whatsoever. For more information on data exchange see Section 4 - EU and non-EU exchange of personal data in Deliverable D9.3.

During the pilot tests and field validations, it may become necessary to exchange certain technology (software and/or hardware) developed by the S. Korea partners. In such cases, the project will initiate the relevant procedures as described in WP9, to receive required clearance from involved competent authorities in EU and the third country.

Copies of any import/export authorisations, as required by national/EU legislation, will be kept on file and confirmation will be submitted with WP9 reports, and in particular D9.4 that requires to submit copies of import/export authorisations, as required by national/EU legislation, and D9.6 that requires consultation with a national export control authority to clarify the need for export control licenses and relevant authorisations compliant with Reg. 428/2009. In case activities undertaken in non-EU countries raise ethics issues, the beneficiaries will ensure that the research conducted outside the EU, and in particular in South Korea, is legal in at least one EU Member State.

4 Societal

PathoCERT addresses societal threats covering the whole range of risk uncertainties, covering terrorist attacks and accidents, to natural occurring events. All segments of the society, and the society as a whole, can benefit from the outputs of PathoCERT. Moreover, the activities of are in line with sustainable development standards and good governance. PathoCERT will not have a negative impact to the society, to the rights and values enshrined in the Treaties (e.g., freedom of association, freedom of expression, protection of personal dignity, privacy and data protection), and will not impact disproportionately upon specific groups or unduly apply any discrimination against them.

PathoCERT supports Article 37 of the EUCFR which calls for EU policies in relation to environmental protection are effectively implemented, by promoting standards and by offering certifying training to water operators in security and water safety.

4.1 PathoCERT Technologies

PathoCERT addresses the water pathogen contamination challenge, which can affect all members of the society, and in its more extreme cases, can cause serious harm to First Responders and the public in general, to the economy and to the environment. The integrated output of PathoCERT will be a prototype system comprised of a set of decision support tools, guides, knowledge bases, procedures, recommendations to standards, new networks of experts and compliance with risk standards, as well as training material, to cover the spectrum of contamination risk management.

The PathoCERT technologies under development, includes technologies for monitoring, sampling and information exchange on the field. Moreover, there are being technologies developed for the supporting of the decision-making procedure for crisis management and for performing forensics analysis that will help investigation and enforce accountability.

PathoCERT technologies adopt a human-in-the-loop approach where information gathered during an emergency is always evaluated and decisions are made by relevant stakeholders (first responders or human experts). No technologies will be developed following human-out-of-the-loop or human-behind-the-loop schemes.

4.2 Societal Engagement and Gender Issues

The main objectives of the social research carried out under the Subtask 3.2.2 of WP3 are to assess the impact of an emergency on the society and to propose ways to strengthen the resilience of society and to enhance recoverability.

4.2.1 Justification of the social study

It is known that emotions affect social and political behavior, often in unexpected ways. Research has linked emotions to different types of social and political behavior.

Emergency situations are sources of strong emotions within the public. The pandemic outbreak of COVID-19, although a very recent phenomenon, has highlighted the link between emotions and social behavior. Many people report very intense negative emotions, such as anxiety, fear and anger all over the world, that affect the way people behave in public spaces, express themselves in social networks, such as Facebook, Twitter, or interact with public services and First Responders. It has been observed that strong negative emotions have interacted powerfully with

the social and political behavior of the citizens (e.g., conspiracy theories). Large segments of the population, even people with higher education degrees, are vulnerable to misinformation and conspiracy theories, which erode public trust.

The Societal Engagement and Gender Issues study will investigate the above issues using the experience of the COVID-19 pandemic crisis and link the results to the cases of water emergency and the use of technology during water emergencies.

4.2.2 Approvals and other ethical issues

As discussed in the Ethics section, more details about the Methodology and the relevant approvals can be found in Deliverable 9.2.