



D10.3. Ethics principles



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Deliverable Information Sheet

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¹ Type [1] R=Document, report; DEM=Demonstrator, pilot, prototype; DEC=website, patent filings, videos, etc.; OTHER=other_
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Revisions

1/4/2025	Version 1.0
31/4/2025	Version 1.1

List of Acronyms

AI	Artificial Intelligence
DPO	Data Protection Officer
ETS	Emissions Trading System
EU	European Union
GDPR	General Data Protection Regulation
GMO	Genetically Modified Organism
NIR	Near-Infrared
REACH	Resilient Agricultural IrrigationN systems for water Scarcity in Europe
S-LCA	Social Life Cycle Assessment
WP	Work Package

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Keywords list

- RAINS (Resilient Agricultural IrrigationN systems for water Scarcity in Europe)
- Ethics Principles
- Personal Data
- Data Minimization

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1. Executive summary

The objective of RAINS is to contribute to making EU agriculture more resilient to water scarcity through the demonstration of innovative and optimised irrigation practices and technologies that will increase the efficiency of water and nutrient management and reduce the impact of extreme events. To that aim, RAINS will demonstrate 10 innovative solutions to improve water and nutrient management at 5 demo-farm systems replicated in Greece and Spain, where distinct agricultural practices are being applied (agroecology, organic production, conventional, intensive and urban agriculture), covering small and large scale and including both experimental and commercial farms. RAINS project methodology will comply with the “not significant harm principle” (Regulation (EU) No 2020/852), having a positive impact or no impact on the EU taxonomy

RAINS will carry out co-creation, knowledge transfer and policy focused sessions, engaging end users and quadruple helix agricultural stakeholders, to support the uptake of optimised and sustainable irrigation and fertilization solutions in practice and contribute to efficient water management and sustainable agricultural systems in the EU. Thus, RAINS will involve the collection of personal data, primarily during the workshops planned in the project (co-creation, identification of barriers, knowledge transfer and sharing, policy). It's important to note that our data collection practices will be confined to the essential minimum required.

RAINS involves the use of Artificial Intelligence (AI) algorithms in the Optifangs-IA v1.0 system, one of the proposed smart solutions. The AI algorithms component will help to model soil and sludge behaviour and support decision-making. The fingerprint of a specific sludge is taken using NIR, obtaining an accurate estimate of the agronomic efficiency and environmental composition of the material, which is used to model (using IA) the behaviour of the sludge under different proposed and validated conditions of dosage, receiving soil and water management.

This deliverable identifies the activities within the RAINS project that raised ethical concerns, in the current reporting period, related to the involvement of Human participants, Human, Personal Data, Environment Health and Safety and Artificial Intelligence

Human participants, not part of the participants' staff, are being involved in the project through RAINS workshops for co-creation and Social Life Cycle Assessment (S-LCA). During project activities involving stakeholders and citizens, RAINS will ensure the compliance of ethics requirements related to the participation of humans in the project activities.

RAINS personal data from participants are being processed to comply with current national and EU legislation such as Article 2(a) EU General Data Protection Regulation 2016/679 (GDPR), Directive 2002/58/EC and the Charter of Fundamental Rights of the EU (2000/c 364/01).

2. Objective of the Deliverable 10.3. Ethics Principles

The main objective of this deliverable is to report the ethical aspects of the tasks carried out in the RAINS project.

The main ethical issues discussed in this deliverable are: Personal Data, Environment, Health and Safety and the use of Artificial Intelligence (AI).

The present deliverable tackles the compliance of ethics requirements related to the participation of humans in the project activities, meaning, according to the Guidance on ethics self-assessment of the Horizon programme, “any research involving work with humans beings (‘research or study participants’), regardless of its nature or topic”, including personal data, observations, tracking or the secondary use of information provided for other purposes, e.g. other research projects, social media sites, etc².

This document outlines the ethical procedures, data protection measures, and informed consent protocols implemented in the project to ensure compliance with Horizon Europe ethical requirements, the General Data Protection Regulation (GDPR) (EU) 2016/679, and relevant national laws.

² European Commission and Directorate-General for Research & Innovation, “Horizon 2020 programme - Guidance How to complete your ethics self-assessment V6.1,” 2019. [Online]. Available: http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf.

3. Ethical and legal aspects

Most of the ethical issues raised by the project are mentioned in the Grant Agreement in Part A, and the consortium is aware of them. These issues include the following points: Personal Data, Health and Safety of terrestrial and marine plants and microorganisms and the use of AI.

3.1. Humans

According to the Guidance on ethics self-assessment of Horizon programme [1], the compliance of ethics requirements related to the participation of humans in the project activities, meaning, “any research involving work with humans beings (‘research or study participants’), includes research that involves human participants, their personal data, observations, tracking, or the secondary use of information collected for other purposes (e.g., other research projects, social media).

Human participants, not part of the participants' staff, are being involved in the project through RAINS workshops and co-creation, and they will have frequent interactions with the RAINS consortium to ensure that the project objectives are achieved.

Within the RAINS project, activities that involve humans are those that imply their participation under the frame of stakeholder engagement and social impact assessment. These activities are listed as follows:

- WP4: Task 4.1 with the preliminary environmental impact of the RAINS solutions; Task 4.2. with the preliminary environment safety RAINS solutions
- WP5: Task 5.1. Evaluation of the environmental socio-economic and health impact of RAINS (s-LCA)
- WP8: Task 8.2. Stakeholder database update
- WP9: Task 9.2. Stakeholder database update

Table 1 shows the ethical issues regarding the activities with human participation in the project, as stated in the Grant Agreement.

Table 1: Ethical issues regarding the activities with human participation in the project.

2. Humans	
Does this activity involve human participants?	Yes
Are they volunteers for non-medical studies (e.g. social or human sciences research)?	No
Are they healthy volunteers for medical studies?	No
Are they patients for medical studies?	No
Are they potentially vulnerable individuals or groups?	No
Are they children/minors?	No
Are there other persons unable to give informed consent?	No
Does this activity involve interventions (physical also including imaging technology, behavioural treatments, etc.) on the study participants?	No
Does this activity involve conducting a clinical study as defined by the Clinical Trial Regulation (EU 536/2014)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)	No

At all times, RAINS is ensuring the compliance with current EU General Data Protection Regulation (GDPR)³

3.2. Personal Data.

RAINS personal data from participants are being processed to comply with current national and EU legislation such as Article 2(a) EU General Data Protection Regulation 2016/679 (GDPR), Directive 2002/58/EC and the Charter of Fundamental Rights of the EU (2000/c 364/01).

The RAINS partners adopt the following fundamental ethics principles which will be followed in the course of the project:

- **Legality.** All RAINS partners must comply with the General Data Protection Regulation (GDPR) 2016/679 when collecting and/or processing personal data and they are expected to conduct the project actions according to these principles.
- **Privacy and personal data protection.** Individual research subjects have an absolute right to privacy and to the protection of their own personal data. Data that human subjects give to a research collection will be treated such that it is not accessible to anyone other than the individual and the researchers involved.
- **Informed consent.** Individual research subjects will be fully informed about all aspects of the research in which they are being asked to participate, including the future use of the data they might provide (see Data Management Plan). Individual participants will not contribute without their knowledge and consent. Individual participants will have the right to withdraw at any time. No vulnerable individuals (i.e. children and elderly people) will participate in the RAINS project. But in case of strictly necessary, the acquisition of the consent of the legal representatives (and assent, when applicable) will be required.
- **Anonymization.** Anonymization is an irreversible procedure after which the data subject cannot be identifiable by the data anymore⁴. Anonymization will be used when possible, when the identity of the person is not relevant for the purposes of the task. This will be obtained by means of substitution of the name with a numerical identifier. Anonymization measures will be taken when processing the data. All primary research will be conducted under the conditions of non-attributability of information to protect the anonymity of the participant.
- **Data minimization.** The personal data to be collected and processed will be minimal, relevant and limited to the purposes of the project, both from the point of view of communication, registration and for research activities. This principle of minimization does not only apply to collection, but also to the extent to which they may be accessed, further processed and/or shared, the purposes for which they are used, and the period for which they are kept.
- **Security.** The data must be collected and processed in a manner that the data are protected against unauthorised or unlawful processing, accidental loss, destruction or damage, using appropriate technical or organizational measures. Files containing personal data are confidential and will only be shared between partners who need them for the purposes of the project tasks. The sharing of these files will use suitable and safe repositories, organized on a case-by-case basis by their administrator (coordinator, WP leaders)

³ The European Parliament and the Council, "Regulation 2016/679 of 27 April 2016 on the protection of natural persons with regard to processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)," Off. J. Eur. Union, 2016

⁴ E. Commission, "Ethics and data protection," 2018. [Online]. Available: https://ec.europa.eu/info/sites/default/files/5_h2020_ethics_and_data_protection_0.pdf

according to their particular needs. The administrator will grant access to these files by password. This is in general applicable to any kind of personal data which needs to be stored.

- **Transparency and integrity.** RAINS treats societal concerns seriously, maintaining awareness of the public and its concerns, reacting to the public. Personal Data collected in RAINS will never be used for third-party purposes.

It has been appointed a Data Protection Officer (DPO) for RAINS project, being a member of the Coordinator partner SAV:

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The project DPO will be involved in all the stages of the project and together with the coordinators will provide advice to the rest of the partners on data privacy issues.

In addition, SAV has the support of a specialized company on personal data protection (Asocia2 Consultores, <https://www.asocia2consultores.es/>) which will be contacted if required to provide advice on these matters.

Besides the project DPO, each partner must appoint their own DPO according to the conditions established in Article 37 of GDPR. It is required that the partner has their own data protection policy compliant with GDPR and the corresponding national legislation.

Table 2 shows the ethical issues regarding the processing of private data in the project, as stated in the Grant Agreement.

Table 2. Ethical issues related to the processing of personal data in the project.

4. Personal Data	
Does this activity involve processing of personal data?	Yes
Does it involve the processing of special categories of personal data (e.g.: genetic, biometric and health data, sexual lifestyle, ethnicity, political opinion, religious or philosophical beliefs)?	No
Does it involve profiling, systematic monitoring of individuals, or processing of large scale of special categories of data or intrusive methods of data processing (such as, surveillance, geolocation tracking etc.)?	No
Does this activity involve further processing of previously collected personal data (including use of preexisting data sets or sources, merging existing data sets)?	No
Is it planned to export personal data from the EU to non-EU countries?	No
Is it planned to import personal data from non-EU countries into the EU or from a non-EU country to another non-EU country?	No
Does this activity involve the processing of personal data related to criminal convictions or offences?	No

3.3. Environment, health and safety

The RAINS project follows the Precautionary Principle to avoid irreversible harm to soils, water, and ecosystems in all research and field applications. This approach ensures that scientific and agricultural innovations do not compromise environmental integrity, even in the face of uncertainty. This includes the EU Habitats Directive 92/43, the EU Wild Birds Directive 79/409, EU Wild Fauna Protection Regulation 338/97, the EU GMO Directive 2009/41 and the Cartagena Protocol on Biosafety.

The project will assess potential risks to the environment and avoid or minimise the risks. In relation to issues related to health and safety, the partners will establish and follow a set of safety checks and procedures to avoid harm to soils, water, and ecosystems.

The RAINS project will implement a rigorous and systematic approach to risk assessment and mitigation. This involves:

- **Comprehensive Environmental Impact Assessments:** Before any field trials or large-scale applications, thorough assessments will be conducted to identify potential risks to soils, water bodies (including groundwater and surface water), air quality, biodiversity, and overall ecosystem health. These assessments will consider both direct and indirect, short-term and long-term impacts.
- **Proactive Risk Avoidance and Minimization Strategies:** RAINS will prioritize strategies to avoid these risks altogether. If avoidance is not feasible, robust mitigation measures will be developed and implemented to minimize the likelihood and severity of any adverse environmental effects. This includes adopting best available techniques and practices in agricultural and research methodologies.
- **Development and Adherence to Stringent Safety Protocols:** In all project activities, particularly those involving field work and the handling of biological or chemical materials, partners will collaboratively establish and strictly adhere to a comprehensive set of safety checks and procedures. These protocols will be designed to prevent any accidental or intentional harm to soils, water resources, and ecosystems. This will include guidelines on the safe storage, handling, and disposal of materials, as well as emergency response plans.
- **Continuous Monitoring and Evaluation:** The project will incorporate ongoing monitoring of key environmental indicators to detect any unforeseen impacts and to evaluate the effectiveness of implemented mitigation measures. Findings from this monitoring will be used to adapt and improve project protocols as needed, ensuring continuous environmental improvement.

The assessment of the potential risks to the environment will be achieved in:

- WP4: Task 4.1. Preliminary evaluation of environmental impact of RAINS solutions.
- WP5: Task 5.1. Evaluation of environmental, socio-economic and health impacts of RAINS solutions
- WP6: Task 6.1. Evaluation of safety and environmental, socio-economic and health impacts of RAINS solutions II.

RAINS will be aligned with the following regulations and frameworks promoted by the European Union (EU) aiming at promoting sustainability and its goal of transitioning to a more sustainable economy:

European Green Deal⁵: Launched in December 2019, the European Green Deal is a comprehensive roadmap aimed at making Europe the first climate-neutral continent by 2050. It includes measures to reduce greenhouse gas emissions, promote sustainable industry, and protect biodiversity.

EU Climate Directive⁶: This law sets a legally binding target for the EU to achieve climate neutrality by 2050 and establishes a framework for setting intermediate targets and monitoring progress.

Fit for 55 Package⁷: Introduced in July 2021, this package aims to reduce net greenhouse gas emissions by at least 55% by 2030 compared to 1990 levels. It includes revisions to existing legislation, such as the EU Emissions Trading System (ETS), and introduces new measures in sectors like transport and energy.

EU Taxonomy Regulation⁸: This regulation, which came into effect in July 2021, establishes a classification system for environmentally sustainable economic activities. It aims to guide investments towards sustainable projects and activities.

Circular Economy Action Plan⁹: Part of the European Green Deal, this plan aims to promote sustainable product design, reduce waste, and encourage recycling and reuse of materials. It includes initiatives for various sectors, including textiles, plastics, and electronics.

Biodiversity Strategy for 2030¹⁰: This strategy aims to protect and restore ecosystems and biodiversity in the EU. It includes commitments to increase protected areas and restore degraded ecosystems.

Farm to Fork Strategy¹¹: This strategy aims to make food systems fair, healthy, and environmentally friendly. It includes measures to promote sustainable agriculture, reduce the use of pesticides, and encourage organic farming.

REACH Regulation¹²: The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation aims to protect human health and the environment from the risks posed by chemicals. It requires companies to register chemical substances and assess their safety.

Waste Framework Directive¹³: This directive sets the basic concepts and definitions related to waste management, including recycling and recovery targets, to promote a circular economy.

The RAINS project has established a comprehensive circular economy framework for nutrient management that transforms biowaste streams into high-value fertilizers while reducing dependency on synthetic inputs.

This will offer a multitude of significant benefits across environmental, economic, and societal dimensions:

⁵ https://eur-lex.europa.eu/resource.html?uri=cellar:b828d165-1c22-11ea-8c1f-01aa75ed71a1.0002.02/DOC_1&format=PDF.

⁶ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R1119>

⁷ <https://www.consilium.europa.eu/en/policies/fit-for-55/#:~:text=Fit%20for%2055%20refers%20to,line%20with%20the%202030%20goal>.

⁸ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R0852>

⁹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1583933814386&uri=COM:2020:98:FIN>

¹⁰ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52020DC0380>

¹¹ https://food.ec.europa.eu/document/download/472acca8-7f7b-4171-98b0-ed76720d68d3_en?filename=f2f_action-plan_2020_strategy-info_en.pdf

¹² <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20221217>

¹³ <https://eur-lex.europa.eu/eli/dir/2008/98/oj/eng>

- Environmental Benefits:** Reduced Dependency on Synthetic Fertilizers: Synthetic fertilizers are often produced using energy-intensive processes that rely on fossil fuels, contributing to greenhouse gas emissions. By utilizing biowaste, RAINS lessens the demand for these synthetic inputs, thereby reducing the project's and potentially the agricultural sector's carbon footprint.
- Mitigation of Nutrient Pollution:** Over-application or inefficient use of synthetic fertilizers can lead to nutrient runoff and leaching, polluting water bodies (eutrophication) and harming aquatic ecosystems. The RAINS framework promotes a more controlled and tailored release of nutrients from bio-based fertilizers, minimizing these risks.
- Improved Soil Health:** Bio-based fertilizers derived from organic matter can enhance soil structure, water retention capacity, and microbial biodiversity, leading to healthier and more resilient soils in the long term. This contrasts with some synthetic fertilizers that can degrade soil health over time.
- Waste Reduction and Valorization:** The project will transform biowaste streams such as animal blood from slaughterhouses, which would otherwise be discarded (potentially leading to landfill issues and greenhouse gas emissions from decomposition), into valuable resources. This aligns with the principles of waste hierarchy and resource efficiency.
- Enhanced Biodiversity:** Healthier soils and reduced pollution can create more favorable conditions for a wider range of soil organisms and overall biodiversity in agricultural landscapes and surrounding ecosystems.

By establishing this comprehensive circular economy framework for nutrient management, the RAINS project not only addresses the environmental challenges associated with conventional fertilizer use but also unlocks the potential of biowaste as a valuable resource. This innovative approach contributes to a more sustainable, resilient, and economically viable agricultural sector, aligning with the principles of a green and circular economy for the European Union and beyond.

Table 3 shows the ethical issues regarding the environment, health and Safety in the project, as stated in the Grant Agreement.

Table 3. Ethical issues regarding the environment, health and Safety.

7. Environment, Health and Safety  Associated with document Ref. Area(2024)70870	
Does this activity involve the use of substances or processes that may cause harm to the environment, to animals or plants (during the implementation of the activity or further to the use of the results, as a possible impact)?	No
Does this activity deal with endangered fauna and/or flora / protected areas?	No
Does this activity involve the use of substances or processes that may cause harm to humans, including those performing the activity (during the implementation of the activity or further to the use of the results, as a possible impact)?	No

3.4. Artificial Intelligence

RAINS will use a combination of NIR and AI technologies in the Optifangs-IA v1.0 system to estimate sewage sludge agronomic composition and reliability, as well as soil needs, in order to decide the amount of sewage sludge to be applied in specific zones, minimising nutrient dose and water use and loss. The system contributes to the decision-making on real-time sewage sludge application. The AI system to be used is technically robust (the algorithm that adjusts 4 possible models and compares them to determine as the physicochemical behaviour of the sludge in the soil, having two quality control points of the received data), socially robust (it does not cause physical or mental harm), reliable (it considers context and environment in which they operate) and functional as intended. The decision-making process is as conservative as the agrochemical experts indicate in the tolerance of their predictions, in order to return sludge values that never cause significant impact on the lives of the people surrounding the treatment plants.

Table 4 shows the ethical issues regarding the activities with AI involved in the project, as stated in the Grant Agreement.

Table 4. Ethical issues regarding the activities with AI involved in the project.

8. Artificial Intelligence	
Does this activity involve the development, deployment and/or use of Artificial Intelligence- based systems?	Yes

4. Conclusions

Most of the ethical issues raised by the project are mentioned in the Grant Agreement in Part A, and the consortium is aware of them. These issues include the following points: Humans, Personal Data, Environment Health and Safety, and Artificial Intelligence.

Human participants, not part of the participants' staff, are being involved in the project through RAINS co-creation workshops and Social Life Cycle Assessment (S-LCA). During project activities involving stakeholders and citizens, RAINS will ensure the compliance of ethics requirements related to the participation of humans in the project activities. This includes their personal data, observations, tracking, or the secondary use of information collected for other purposes (e.g., other research projects, social media). RAINS will ensure that the methods do not result in discriminatory practices and that participation will be entirely voluntary with a necessary consent.

RAINS personal data from participants are being processed to comply with current national and EU legislation such as Article 2(a) EU General Data Protection Regulation 2016/679 (GDPR), Directive 2002/58/EC and the Charter of Fundamental Rights of the EU (2000/c 364/01).

For the participation of the stakeholder in the co-creation workshops, the consent form is necessary not only to assure participants that their privacy will be respected, but also to allow the project to process and use the input generated. The Deliverable 10.3 will explain the Data Management Plan.

The collected data will be used for research and project purposes only and always while protecting the private data of participants.

The RAINS project follows the Precautionary Principle to avoid irreversible harm to soils, water, and ecosystems in all research and field applications. This approach ensures that scientific and agricultural innovations do not compromise environmental integrity, even in the face of uncertainty.