DELIVERABLE

– D7.1 Ethics principles –

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Table of Contents

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1. Introduction

The MoeBIOS project aims to revolutionize waste management by developing circular value chains for bioplastics. This project involves a systemic innovation that addresses various stages of the value chain, from waste collection to product upcycling. Given the project's potential impact on the environment, economy, and society, it is crucial to ensure ethical compliance throughout its implementation.

During the preparation of this proposal, an Ethics Self-assessment was performed with the completion of the Horizon Europe's Ethical Issues Table, and this project does not involve ethics issues except for **the survey activities to be carried out** to gain insight on consumers and stakeholders' perspective and the handling of personal data (WP4, WP6).

2. Ethics self-assessment

In the proposal preparation phase, we will perform a self-assessment which includes the following:

2.1. Ethical dimension of the objectives, methodology and likely impact

HUMAN CELLS:

Potential use of human cells is considered in different studies using human cell lines, as mentioned in ST5.2.1. Human collection samples are not foreseen.

MoeBIOS will make use of commercial human cells for the development of methodologies that will allow the study of the human health effects produced by the materials developed within the Project.

All the experimental systems, test items and chemicals that enter the cell culture laboratory are considered as potentially toxic so all the precautions to ensure safety of the research staff and of the environment are taken by all the institutions using human cells. For that, biosafety procedures and Biosafety Cabinets Class II will be used.

Moreover, specific SOPS are in place for the reception, registry, handling, storage, and disposal of the human cell lines. All personnel in the laboratory for cell cultures is trained on these general guidelines. Upon reception, all the cell lines are registered with the following information: Identification of the cell line, origin, person, and date of reception. All the cell lines are tested for Mycoplasmas upon arrival and if contaminated they are disposed of. A certificate of analysis is always asked from the provider.

Research staff is instructed to all use protective equipment (e.g., Biosafety Cabinets Class II, ultraviolet standardization processes) and personal protection gear (e.g., gloves, glasses, protective mask).

Disposal of human cell lines: The experimental systems developed (commercial human cell line), remains of the experimental system of human origin as well as all the material that has been in contact with it are

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inactivated by addition of bleach or sterilised by autoclaving. All the materials collected in plastic jars (never glass) and they are disposed of as type II sanitary waste by an authorized manager.

All the activities to be performed within the MoeBIOS project will be done in confined laboratories, no impact to the environment is expected.

ANIMALS

In ST5.2.1, studies with a model organism (invertebrates) are foreseen: *daphnia magna*. Although invertebrates are categorized by the Directive 2010/63 as 'lower' animals, the project will consider potential impact of the activities on the animals, and their used will be relied, as much as possible, following non-animal methods available, as it stated in ST5.1.1. Other organisms, non-animal, as algae *Selenastrum capricornutum,* are also envisaged.

ENVIRONMENT, HEALTH AND SAFETY:

The initial approach of the project does not negatively impact the environment neither health nor safety of the human participants.

2.2. Compliance with ethical principles and relevant legislations

HUMAN CELLS:

Within MoeBIOS several different types of human cells will be used for the development of in vitro models. The cell types that will be used are all commercial cell lines, are fully anonymized and were produced following the strictest ethical guidelines. Certificates of origin and all other required information will be asked from the provider (e.g. consent of the donor) and will be presented in the corresponding deliverables.

For the ethic compliance, national and EU legislation, will be considered:

- Declaration of Helsinki 1964 (version 2013).
- EU Directive on the Protection of Data: 95/46/EC.
- The Charter of Fundamental Rights of the European Union.
- EC Directive 86/609/EEC; ETS 123, 2010/63/CE.
- Declaration of Helsinki of the WMA (DoH2008).
- ETS N. 164 of 04/04/1997. Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine.
- 13ETS N. 168 of 12/01/1998. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings.

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All cell lines used within MoeBIOS are certified "free of pathogens" and all of them are considered to pose no (bio-safety level 1 (BSL1)) or moderate (BSL 2) potential of hazard. In MoeBIOS, no biological materials with BSL higher that 2 will be used.

We hereby confirm that all research staff involved in the handling and disposal of biological materials will or has already received training to comply with the standard guidelines for working with BSL 2 agents (as defined by WHO).

The following ethical issues associated to use of human cells/tissues will also be considered in the project:

Principles of Bioethics:

- Autonomy: one should respect the right of individuals to make their own decisions
- Nonmaleficence: one should avoid causing harm
- Beneficence: one should take positive steps to help others
- Justice: benefits and risks should be fairly balanced

ANIMALS:

The use of ANIMALS (*Daphnia magna*) was chosen following the "replacement" principle of Directive 2010/63, using for that non-vertebrate animals.

ENVIRONMENT, HEALTH AND SAFETY:

Regarding ENVIRONMENT, HEALTH AND SAFETY, safety checks and procedures implemented by the different laboratory partners will be followed to reduce potential risks of the activities on the project teams and staff.

3. Ethical Governance

We have established an ethical governance system to develop a code of ethics and creating channels for ethical issues to be reported. The Euro-funding, EUPB, EROSKI and ITENE will oversee all the procedures with ethical issues and make sure that the compliance with the recommendations, policies and procedures.

4. Data protection and privacy policy

The project is required to implement robust measures to protect personal data and ensure privacy, following the General Data Protection Regulation (GDPR). This includes transparent data handling, obtaining informed consent, and minimizing data retention periods (Art. 15 GA).

▪ **Ethical data collection and protection**: Details on recruitment, inclusion and exclusion criteria, informed consent procedures and unexpected findings policy will be prepared prior to the development survey related

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tasks. They will be compliant with applicable international, EU and national law and will allow the results to be published more easily in refereed journals. They will clarify the ethical implications of the chosen methodologies.

▪ **Ethical data collection and protection**: All personal data collected in the MAA approach or in the end user acceptance studies will be manged following ethical principles & informed consent, in compliance with the General Data Protection Regulation (Regulation (EU) 2016/ 679) and other applicable EU regulations (the Regulation (EU) 2016/679, Directive 2002/58/EC, the Charter of Fundamental Rights of the EU (2000/c 364/01)).

5. Ethical considerations for MoeBIOS project participation in Surveys

The survey activities to be carried out during MoeBIOS must comply with the following recommendations:

5.1. Informed consent

Informed consent will be obtained from all participants prior to their participation in the survey. Participants will be provided with clear and comprehensive information about the survey's scientific purpose, procedures, potential risks, and anticipated benefits. This information will be presented in a language and format that is easily understandable and accessible to all participants, regardless of their literacy level or any disabilities. Consent will be documented electronically, using a secure and confidential system. Participants of a survey will have the opportunity to ask questions and seek clarification before providing their consent.

5.2. Confidentiality and anonymity

Participants' data will be handled with the utmost confidentiality. All data will be stored securely using encryption and strong password protection as overseen in the Data Management Plan, DMP (D7.1). Access to the data will be restricted to authorized personnel only, and measures will be taken to prevent unauthorized disclosure. To ensure anonymity, personal identifiers will be removed from the data before analysis, if applicable. Participants will be informed about these confidentiality measures at the beginning of their involvement to foster trust and transparency.

5.3. Data protection and privacy

To ensure compliance with relevant data protection laws, such as the GDPR, we will only collect data that is strictly necessary to achieve the research objectives. This minimization of data collection will help protect the privacy of participants. Data will be retained for the period specified in the DMP after the research is concluded, and then securely disposed of to prevent unauthorized access or misuse.

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5.4. Voluntary participation and right to withdraw

Participants should be free to choose whether or not to participate in the survey, without any pressure or coercion. Additionally, they should have the right to withdraw from the survey at any time, even after they have begun. This ensures that participants are involved in the research voluntarily and have control over their involvement.

5.5. Avoidance of harm

To minimize potential risks to participants, such as emotional distress from sensitive questions, we will clearly communicate the survey's purpose, offer participants the option to skip or decline questions, and provide information about support resources. This ensures that participants' well-being is prioritized throughout the survey process.

5.6. Transparency and honesty

To maintain ethical standards, it is essential to provide participants with accurate and transparent information about the survey. This includes clearly communicating the purpose of the study, the expected duration, and the potential benefits and risks involved. Additionally, if any form of deception is used in the survey, a debriefing process must be in place to inform participants about the true nature of the study afterward. This debriefing should address any misconceptions or concerns participants may have and provide an opportunity for them to ask questions. By ensuring transparency and conducting a thorough debriefing, researchers can maintain trust with participants and ensure that the survey is conducted ethically.

6. Ethical procedures, review and approval

6.1. Submission of survey proposal

The document, which will be submitted to the coordinator for review, must be prepared and submitted no later than 60 days before the planned start of the survey. This submission timeline is critical to allow sufficient time for a thorough ethical review and any necessary revisions. The document must strictly follow the structure and content requirements detailed in ANNEX 1 to ensure that all relevant ethical considerations are addressed comprehensively.

Each section outlined in ANNEX 1 is essential for the ethical evaluation of the survey. Therefore, the survey design and associated documentation must include all these sections. If a particular section is determined to be inapplicable to the study, it is mandatory to provide a clear and detailed explanation justifying its exclusion. This rationale should demonstrate that the omission does not compromise the ethical integrity of the research or the protection of participants' rights and welfare.

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Additionally, the document should clearly articulate how the survey will comply with ethical standards, including informed consent, confidentiality, data protection, and the minimization of potential harm to participants. The ITENE and EURO-FUNDING will evaluate the document to ensure that the survey is ethically sound, and their feedback may necessitate adjustments to the survey design or methodology.

It is essential that the document is comprehensive, well-organized, and thoroughly addresses all ethical concerns, as this will facilitate a smoother review process and contribute to the timely approval of the survey.

6.2. Review and evaluation

The ITENE and EURO-FUNDING will evaluate the proposal in terms of the following aspects:

1. **Necessity of the survey:** The survey must be planned in the Annex 1 of the Grant Agreement. If it now a planned survey, its necessity must be fully justified in the objectives section of the documentation.
2. **Survey design:** the population (size, inclusion/exclusion methods), survey type, questions and length must be clearly justified.
3. **Ethical considerations:** The survey must comply with all the ethical considerations stated in section 4.
4. **Data collection and further analysis:** including the appropriateness of the data analysis plan, and the reporting and dissemination.
5. **Plan post project use**, including data use and storage period.

The ITENE and EURO-FUNDING will take the decision 30 days prior to the survey and officially notified by e-mail. This decision can be

- **Approval**: The proposal is approved as submitted.
- **Modification**: it requires changes to the proposal to address ethical concerns.
- **Rejection**: The proposal is rejected, and the researcher may need to revise and resubmit.

In the case modifications are proposed, a new submission will be done before 10 natural days after the official notification. The final decision will be taken 5 natural days prior of the beginning of the survey.

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7. ANNEX 1: Survey document guideline

1. Survey objectives

- **Purpose**: Define the primary goals of the survey. What information do you aim to gather, and why is it important?
- **Research questions**: List the specific research questions the survey seeks to answer.

2. Target Population and Sampling

- **Population Definition**: Clearly define the population that the survey will target. Include demographic characteristics such as age, gender, occupation, location, etc.
- **Sampling Method**: Describe the sampling method to be used (e.g., random sampling, stratified sampling, convenience sampling) and justify the choice.
- **Sample Size**: Determine the sample size required to achieve statistically significant results.

3. Survey Design

- **Survey Type**: Specify whether the survey will be conducted online, via phone, face-to-face, or through another method.
- **Questionnaire Development**: Outline the process for developing the questionnaire, including:
    - Types of questions (open-ended, closed-ended, Likert scale, etc.)
    - Question wording and order
    - Pre-testing or piloting the questionnaire to identify any issues
- **Survey Length**: Estimate the time required to complete the survey and ensure it is reasonable for participants.

4. Ethical Considerations:

4.1 Informed Consent

- **Process**: Describe how informed consent will be obtained from participants. Include details on:
    - Information provided to participants about the survey's purpose, procedures, risks, and benefits
    - How consent will be documented (written, verbal, or electronic)

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- **Accessibility**: Ensure that the consent process is understandable and accessible to all participants, considering language, literacy, and any disabilities.

4.2 Confidentiality and Anonymity

- **Data Handling**: Explain how participants' data will be handled to ensure confidentiality. Include information on:
    - Secure storage of data (e.g., encryption, password protection)
    - Who will have access to the data
    - Procedures for anonymizing data, if applicable
- **Communication**: Clearly communicate confidentiality measures to participants.

4.3 Data Protection and Privacy

- **Compliance**: Outline how the survey will comply with relevant data protection laws (e.g., GDPR).
- **Minimization**: Ensure that only the data necessary for the research objectives is collected.
- **Data Retention**: Specify how long data will be retained and the process for secure disposal of data after the retention period.

4.4 Voluntary Participation and Right to Withdraw

- **Voluntary Participation**: Confirm that participation is entirely voluntary, and no undue pressure or coercion will be applied.
- **Right to Withdraw**: Explain how participants can withdraw from the survey at any stage and how their data will be handled if they choose to withdraw.

4.5 Avoidance of Harm

- **Risk Assessment**: Identify any potential risks to participants (e.g., emotional distress from sensitive questions) and outline steps to minimize these risks.
- **Support Resources**: Provide participants with information on support resources (e.g., counselling services) if the survey involves potentially distressing topics.

4.6 Transparency and Honesty

- **Survey Information**: Ensure that all information provided to participants is accurate and transparent.

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- **Debriefing**: If any form of deception is used in the survey, describe the debriefing process that will be employed to inform participants about the true nature of the study afterward.

5. Data Collection Plan

- **Timeline**: Outline the timeline for data collection, including start and end dates.
- **Survey Administration**: Describe how the survey will be administered, including procedures for recruiting participants and distributing the survey.
- **Monitoring**: Detail how the data collection process will be monitored to ensure ethical standards are maintained.

6. Data Analysis Plan

- **Analysis Methods**: Describe the statistical or qualitative methods that will be used to analyse the survey data.
- **Bias and Fairness**: Outline steps to minimize bias in the analysis process and ensure that the results are reported fairly and accurately.

7. Reporting and Dissemination

- **Report Preparation**: Explain how the findings will be compiled into a report, including how ethical considerations will be addressed in the reporting.
- **Dissemination**: Describe how and to whom the survey results will be disseminated, ensuring that this is done in a way that protects participants' identities and respects their contributions.
- **Feedback to Participants**: Outline any plans to provide feedback to participants on the survey results.

8. Post-Survey Considerations

- **Data Retention and Archiving**: Detail plans for the secure retention and potential archiving of data, ensuring that ethical standards are maintained.

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