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Call
H2020-FNR-2020: Food and Natural Resources
Topic name
FNR-16-2020: ENZYMES FOR MORE ENVIRONMENT-FRIENDLY CONSUMER PRODUCTS

FuturEnzyme:
Technologies of the Future for Low-Cost Enzymes for Environment-Friendly Products
Final ID: 101000327

26/11/2021

ETHICS - H - REQUIREMENT NO. 1

D9.1

MANUEL FERRER
CSIC
Marie Curie n2, 28049 Cantoblanco, Madrid, Spain

Document information sheet

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Authors:	CSIC (Manuel Ferrer, Patricia Molina), ITB (Ilaria Re, Sara Daniotti)
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Type	Ethics
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Contact details:	Manuel Ferrer, mferrer@icp.csic.es

Summary

ETHICS - H - REQUIREMENT NO. 1 Report containing the procedures and criteria for recruiting and processing informed consent of the research participants (including consent forms in English)

1. General Ethics Considerations

The purpose of this deliverable is to ensure that FuturEnzyme project activities are conducted in compliance with fundamental ethical principles and data protection regulation, providing information on criteria to recruit research participants and the informed consent procedures to be implemented for the participations of humans and in regard to data collection and processing.

As complementary action, a public event "European Green Deal aligned to Rights, Ethics and Equality" will be organised by FuturEnzyme to reinforce the project's compromise with a society where ethics as well as gender equality, and rights whatever race, ethnic, and cultural and educational backgrounds are defended and integrated, that are priority EU's objectives.

In addition, activities or results from FuturEnzyme will not raise security issues nor 'EU-classified information' as background or results will be involved.

FuturEnzyme involves human participants in several activities as volunteers for social and human sciences research. All of them are able to give informed consent. The research does not include adults with cognitive disabilities, children (with the exception of specific teaching activities for pupils, see below) or any other persons unable to give informed consent. Vulnerable individuals or groups are not involved in the project activities nor patients or healthy volunteers for medical studies. Moreover, FuturEnzyme research activities do not involve physical intervention on the study participants, including invasive techniques (e.g. collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, …) and the collection of biological samples.

By contrast, the research involves the collection and processing of personal data, defined as "any information that could, in any way, lead to the specific identification of one unique person, such as name, address, mails, …". However, these activities do not collect or process sensitive personal data such as health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction. More details on compliance with GDPR and national regulation on personal data protection are included in D9.2.

High ethical standards provide guidelines for every project partner about how to manage ethics and data issues associated with the involvement of human participants and, at the same time, also increase the quality of the research, avoiding errors and bias when conducting research studies, and its social impact, supporting the social uptake of the new products resulting from a scientific research. The most salient ethical values implicated by the use of human participants in research are beneficence (doing good), non-maleficence (preventing or mitigating harm), fidelity and trust within the fiduciary researcher/participant relationship, personal dignity, and autonomy[1]. FuturEnzyme activities will strictly comply with these principles and relevant European and national standards and guidelines on ethics as defined by the following paragraphs.

1.1. Relevant European and national standards and guidelines on ethics

The ethical standards and guidelines of Horizon 2020 are rigorously applied, regardless the country in which the research is conducted. The project addresses the ethical issues and requirements outlined in **Article 34 of the Model Grant Agreement[2]**, which oblige all projects funded under Horizon 2020 to carry out their actions in compliance with:

[1] Kapp M.B. Ethical and legal issues in research involving human subjects: do you want a piece of me? J. Clin. Pathol. 2006; 59(4): 335-339

[2] https://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/amga/h2020-amga_en.pdf

a) Ethical principles (including the highest standards of research integrity as set out, for instance, in the European Code of Conduct for Research Integrity and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct)

b) Applicable international, EU and national law

In particular, according to the **European Code of Conduct for Research Integrity**[3], all project researchers respect the following essential principles:

- *Reliability* in ensuring the quality of research, reflected in the design, the methodology, the analysis and the use of resources.

- *Honesty* in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair, full and unbiased way.

- *Respect* for colleagues, research participants, society, ecosystems, cultural heritage and the environment.

- *Accountability* for the research form idea to publication, for its management and organization, for training, supervision, and mentoring and for its wider impacts.

Furthermore, according to **article 19 of the H2020 Regulation EU 1291/2013**[4] FuturEnzyme research and innovation activities complies with "ethical principles and relevant national, Union and international legislation, including the **Chapter of Fundamental Rights of the European Union**[5] and the **European Convention on Human Rights**[6] and its Supplementary Protocols", paying particular attention to "the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection".

Other guidance documents related to ethics that should be followed by H2020 funded projects are the "Ethics for researchers – Facilitating Research Excellence in FP7"[7], describing the most important aspects of research ethics and indicating the main points of attention for the Ethics Review procedure, and the "European Textbook on research in Europe"[8] , designed for the training of researchers and research ethics committee members throughout Europe and beyond.

1.2. National legislation and regulations at partners' organization

Spain

- National Statement of Research Integrity, 2 December 2015 by the CSIC, the Conference of Rectors of Spanish Universities (CRUE) and the Confederation of Spanish Scientific Societies
- Law 14/2007 on Biomedical Research (Ley de Investigación Biomédica, LIB)
- Law 14/2011 on Science, Technology and Innovation, BOE n.131, adopted 2-06-2011
- CSIC Code of Good Scientific Practices, 2011

Italy

- Guidelines for Research Integrity, CNR 2019
- Ethical Charter on Social Sciences and Humanities Research, CNR, adopted 16-03-2017

[3] https://www.allea.org/wp-content/uploads/2017/05/ALLEA-European-Code-of-Conduct-for-Research-Integrity-2017.pdf
[4] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:347:0104:0173:EN:PDF
[5] https://www.europarl.europa.eu/charter/pdf/text_en.pdf
[6] https://www.echr.coe.int/documents/convention_eng.pdf
[7] https://ec.europa.eu/research/participants/data/ref/fp7/89888/ethics-for-researchers_en.pdf
[8] https://op.europa.eu/it/publication-detail/-/publication/12567a07-6beb-4998-95cd-8bca103fcf43/language-pt

- Informed Consent in Scientific Research: Ethical Toolkit, approved 23-11-2017

UK

- Code of Practice for Research, UK Research Integrity Office: it is an essential reference tool to support researchers and research organisations in the conduct of research of the highest quality and standards.

Germany

- Code of Deontology (“Arztliche Berufsordnung”)
- The National Council for Ethics ("Deutscher Ethikrat"), as established by legislation of the "Deutscher Bundestag" on April 26, 2007 which may give recommendations which are not binding. http://www.eurecnet.org/information/germany.html
- Central Ethics Committee of the German Medical Association which gives opinions on general ethical issues.

Portugal

- DRE_National legislation_Life Sciences_Portugal -> Law 24/2009 regulating the Juridical Regime of the National Council for ethics in Life Sciences (in Portuguese)
- Legislation CNECV-Life Sciences_Portugal (the translation of Law 24/2009 to English taken from the oficial website)
- Regulation Ethics Committee-Instituto Superior Técnico

Switzerland

- Code of conduct, INOFEA

Austria

- Anti-bribery and anti-corruption declaration; Corporate human rights declaration anti-slavery charter; Corporate social responsibility charta; EUCODIS
- Chemikaliengesetz 1996 (law for chemical sunstances) http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011071
- Giftverordnung 2000 (law for toxic substances) http://www.ris.bka.gv.at/GeltendeFassung.
- ArbeitnehmerInnenschutzgesetz (law for employee protection) http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10008910; Angestelltengesetz (AngG) https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10008069
- VbA (Verordnung biologische Arbeitsstoffe) (biological material regulation) http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10009126

2. Activities that involve human participants

FuturEnzyme aims at developing a high-tech platform to generate new enzymes from 9 classes with enhanced performances for processes and products with markedly reduced environmental impacts. By taking into account market needs, the project also aims at producing three real-life and solutions-oriented products in the detergent, textile and cosmetic sectors.

To evaluate the efficacy and usability of these new products, humans will be involved in FuturEnzyme project as (1) testers for the in vivo efficacy of cosmetic products, (2) respondents in an online survey, (3) participants to final product testing activities, (4) participants in demonstration events.

For all these activities, the partners involved will take care of requirements for data security, confidentiality, anonymity, and transparency. Participation of human subjects will be 100% voluntary.

2.1. Online survey

Partner involved: ITB

ITB will produce a customer survey based on a Multi-Choice Experiment model, with at least 10.000 people interviewed across Europe, to understand and analyse how consumers react to these new enzymes as well as the new products and if they are willing to appreciate and buy the more sustainable enzyme-based products rather than the alternative standard product on the market. The purpose of the activity is to assess consumers' preferences and assess their willingness to pay for a more sustainable product.

The survey management will be entrusted to Qualtrics which is an ISO 27001 certified and FedRAMP authorised company. They will manage Personal Data following their Privacy Statement, updated on June 3, 2020, which is compliant with the GDPR (for more information see D9.2).

2.2. Product testing

Partners involved: Altroconsumo (subcontracted by ITB)

The product testing will be performed by Altroconsumo, the Italian Consumer Organization, with consolidated experience in tests and investigations on products and services. The purpose of this activity is to evaluate the consumers' experience and impressions in using the new enzyme-based products developed during the project and, therefore, assess the usability of the products in the new world.

Altroconsumo will select 100 consumers from their database and perform a product testing which means that participants will receive a sample of the final products and test them. Altroconsumo's experts will create a set of questions/tests/proofs to be also submitted to the consumers. The audience will be involved in, i.e., interviews, focus groups, surveys (live or online) to ascertain consumer reactions to the project's products. Altroconsumo product test with customers will involve personal data collection which will be performed according to the GDPR rules and ethical principles (for more information see D9.2).

2.3. Efficacy testing

Partner involved: Evonik

Evonik will analyse in vivo efficacy properties of enzyme-based cosmetic products. The properties analysed include transepidermal waterloss, skin hydration, overall skin elasticity and wrinkle depth/skin surface replica.

As already stated in the Grant Agreement, these tests cannot be considered as clinical studies, in the meaning of the term used for pharma applications. Therefore, WHO or ICMJE approval is not applicable. All tests are performed in a way that no pain or harm can occur, simply because the technology of the tests is in a way of measure with a device that operates only in the surface on the skin. The procedures and measures to analyse in vivo efficacy properties of cosmetic, that prove all tests are performed in a way that no pain or harm can occur can be found in Annex 2.

During this activity, no personal or health data will be collected from participants; all applicants will remain anonymous.

2.4. Demonstration events and teaching activities

Partner involved: CSIC

FuturEnzyme will also consider demonstration events with product prototypes during science festivals and teaching activities with Master students, PhD students, school pupils or general audience to implement the communication and dissemination of the project.

As already stated in the Grant Agreement, these activities are regulated by an Agreement signed between the Community of Madrid (General Directorate of Education) and the CSIC, guaranteeing that activities follow ethical principles and that no personal data is collected or shared during the events or during any teaching activity. A copy of these Agreements (nr. 2020020077, 2020020076, 2012020149) can be seen in the links below:

https://boe.es/boe/dias/2021/10/18/pdfs/BOE-A-2021-16961.pdf

https://www.boe.es/boe/dias/2021/10/19/pdfs/BOE-A-2021-17038.pdf

Moreover, these events and teaching activities do not represent a risk for the attendees since there is no direct contact between the participants and the products.

3. Advisory Board and Panels of Stakeholders, Policymakers and Consumers

The project will create a wider network of relevant organizations, platforms and influential individuals based on their experience in the field, establishing an Advisory Board and Panels of Stakeholders, Policymakers and Consumers. These panels will organize periodical meetings where experts can express their opinion on the progress of the project. These activities will be fundamental to strengthen the societal impact of FuturEnzyme activities and products. The project may collect and process personal data from these established panels, mainly contact information to easily communicate with relevant individuals and organizations asking their feedbacks on project activities. Any information that could, in any way, lead to the specific identification of one unique person, such as name, address, mails, etc., from relevant organizations, platforms and influential individuals will not be made public without their prior consent. During the process of identification of such persons no activities will consider collection or processing sensitive personal data such as health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction on compliance with GDPR and national regulation on personal data protection.

4. Details on procedures and criteria that will be used to identify/recruit research participants

In the recruitment process of research participants for the above-mentioned activities, FuturEnzyme will follow some general ethical principles of freedom, human dignity, non-discrimination, fairness, transparency, respect, anonymity and voluntariness. Potential participants will receive adequate information about the purpose, modalities, possible risks and benefits of the study before participating in the study in order to be able to make a choice about whether or not to share their personal data. Their engagement will be 100% voluntary; therefore, potential participants will not be pressured, cajoled, coerced into taking part in the project activities. They will be free to choose whether to begin the study or, if they have already started, complete it. Furthermore, the project is committed to avoid any form of discrimination: persons of both genders, regardless their racial, ethnic, cultural and educational backgrounds, will be involved in the project activities.

5. Details on the informed consent procedures that will be implemented for the participation of humans for the consumer survey

As defined by art. 4 of the GDPR[9], consent means "any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her".

The consent procedures for recruiting human participants for the above-mentioned activities will follow European and national guidelines and the standard practices within the research organizations.

Informed consent procedures are considered a fundamental part of the work process, assessment and intervention with the participants. The informed consent document (see Annex 1) is designed to be clear and straightforward, aiming at providing the subjects all the information they need to decide whether or not to participate in the study. To ensure that participants fully understand the implications of being involved in the research, the content of the consent form should be translated in many languages as necessary for the project.

The informed consent form implemented for the activities of this project will include the following information: (1) Brief introduction to the project; (2) Purpose of the study; (3) Participant involvement; (4) Kind of information collected; (5) Risks/benefits; (6) Confidentiality; (7) Rights of data subject; (8) Contact information. The form does not require the collection of sensitive data (such as age, health, sexual orientation, ethnicity, political opinion, religious or philosophical conviction).

Selected participants for the survey will receive via e-mail an invitation to participate in the survey and asked if they would be interested in participating in the project. This invitation will be sent by members of ITB or its specific collaborator, Altroconsumo. If they agree, the respondents will have access to the survey simply by clicking to a link contained in the e-mail in which the duration of the survey shall be explicitly mentioned. Before the beginning of the actual survey they will be asked for their consent. Qualtrics allows you to upload the informed consent form which can be easily downloaded by the selected subjects. After they read it, they can virtually sign the form giving their consent and then they will be sent to the rest of the survey. The selected subjects can also freely decide not to participate in the project or to withdraw from the survey at any time without any consequences; in these cases, their survey session will end.

6. Contacts for Ethics Committees of the partners

Table 1. Contact/link of the responsible of the Ethics Committee from the institutions conforming FuturEnzyme.

PARTNER	NAME	EMAIL
CSIC	D. Lluís Montoliu José	montoliu@cnb.csic.es; comitedeetica@csic.es
BSC	Simona Giardina[1]	simona.giardina@bsc.es
BANGOR	Gwenan Hine	gwenan.hine@bangor.ac.uk
UHAM	-	https://www.inf.uni-hamburg.de/en/home/ethics.html
UDUS	Prof. Dr. med. Thomas Hohlfeld	ethikkommission@med.uni-duesseldorf.de
IST-ID	-	comissaoetica@tecnico.ulisboa.pt
CNR	Dr. Cinzia Caporale	cnr.ethics@cnr.it
ITB	Lanfranco Masotti	presidenza@italbiotec.it
FHNW	Karin Hiltwein	Karin.hiltwein@fhnw.ch

[9] https://gdpr-info.eu/art-4-gdpr/

CLIB	Dennis Herzberg	herzberg@clib-cluster.de
INOFEA	Anne Timm	anne.timm@inofea.com
BIOC_CHEM	Fabrizio Beltrametti	fbeltrametti@bioc-chemsolutions.com
SCHOELLER	Eveline Scheidegger	eveline_scheidegger@schoeller-textiles.com
HENKEL	-	https://www.henkel.com/sustainability/positions/white-biotechnology
EVONIK	-	compliance-officer@evonik.com
EUCODIS	Jan Modregger	modregger@eucodis.com

[1]Secretary of the BSC Internal Board of Revision of projects, in collaboration with BSC experts and legal and DPO departments.

ANNEX 1

Preliminary Draft Template

CONSENT FORM FOR PROJECTS PARTICIPANTS

TITLE OF THE PROJECT: FuturEnzyme – Technologies of the Future for Low-Cost Enzymes for Environment-Friendly Products.

DURATION OF THE PROJECT: 01/06/2021 -31/05/2025

SPONSOR: This project has received funding from the European Union's Horizon 2020 research and innovation programme under Grant Agreement no 101000327

RESEARCHER: to be filled depending on the activity *(beneficiary responsible of the project activity)*

CONTACT DETAILS: to be filled depending on the activity

DATE: to be filled depending on the activity

Information about the project

FuturEnzyme is a research initiative funded by the European Commission under Horizon2020: The EU Framework Programme for Research and Innovation (Grant Agreement no. 101000327). The project is coordinated by CSIC (Consejo Superior de Investigaciones Científicas, Spain) and involves 16 project partners from seven different countries to ensure that the research aims are achieved. In particular, the entities in charge of conducting activities involving human participants and in charge of collecting their voluntary participation and data are:

1. Consejo Superior de Investigaciones Cientificas (CSIC), Spain
2. Evonik Operations GmbH (EVO), Germany
3. Consorzio Italbiotec (ITB), Italy

ITB has also a specific collaborator, Altroconsumo, one of the main Italian Consumer Organization, which is involved as well in collection data for the project purposes.

Purpose of the study

In a world facing major environmental threats, Europe stands by its commitments from the Paris Climate Conference (COP21) and has agreed concrete measures in the European Green Deal: become the world's

first climate-neutral continent by 2050 while improving economic competitiveness. In this context, enzymes undoubtedly have a central role as green catalysts operating efficiently at low energy needs and enabling novel functionalities. By tackling current technological limitations, FuturEnzyme will strive to develop new enzymes with enhanced performances for processes and products with markedly reduced environmental impacts. Using an innovative yet pragmatic and solution-oriented strategy, the enzymes developed will be used to improve real-life consumer products focusing on 3 market segments: textiles, detergents, and cosmetics. FuturEnzyme will therefore produce new products with lower environmental impact (energy, CO_2, water, toxicity) of production processes, and/or with reduced environmental footprint during their use or end-of-life, while creating advantageous characteristics.

To better fulfil the objectives of the project, some research activities involve humans' participation.

This section will also define the purpose of the specific activity in which the research participant will take part as defined by the paragraph "activities that involve human participants".

Participant involvement

If you agree to participate in this study, you will be asked to *… (to be completed depending on the specific activities)* as part of the activities carried out by Work Package X of the project. This activity will last for approximately XX. *More information about the involvement of the research participant -> details on what the participants will be asked to do.*

Participation in this study is completely voluntary. You are under no pressure to participate in the study. If you choose not to participate in the study, you are free to do so at any time without any negative consequences. Any information collected to that time will be destroyed if you do not wish of us to use the information.

Type of information collected

Different accordingly to the specific activities (to be defined).

Risks/benefits

Since confidentiality is being provided, no risks are foreseen in relation to data protection. *Different accordingly to the specific activity (to be defined).*

Privacy and confidentiality

We assure full compliance with European and national ethical principles and legislation on data protection, including GDPR regulation (n. 2016/679). Therefore, all information collected on you as a participant and the acquired data are strictly confidential. The data will be used for research purpose only and they will be handled with appropriate security measures to ensure full protection of personal data and their correct and lawful management. All information collected will be kept in institutional servers (where available) or in password-protected electronic files on the hard disk of their secured computers with access protection. Data collected will be retained for 5 years after the completing of the activity. All your personal information that will no longer be used for project purpose (e.g. full name and contact details) will be immediately destroyed after the activity is completed. In addition, at your written request, your data can be erased at any time without any negative consequences to you. Other personal data useful for statistical analysis or for research purpose will be made anonymous as soon as possible or, at least, pseudonymised. At the end of the project, if data has been accurately anonymized, the analysis results may be subject to scientific publication on open access journals or repository.

Rights of the data subject

According to Regulation n. 2016/679 (General Data Protection Regulation), you, as a research participant, have the right:

- To withdraw consent or discontinue participation at any time without penalty or loss benefits to which you are otherwise entitled.
- To access to your personal data
- To review, rectify or erase inaccurate or incomplete personal data
- To be forgotten, which means that in any moment, you have the right to ask to delete your personal data
- To data portability on request
- To lodge a complaint with supervisory authority

Contact information

If you have any questions, concerns or complaints about this study, its procedures or its risks and benefits or if you wish to learn more about this project, or if you wish to opt-out from the study or make use of any other rights recognized by R(EU) 679/2016, please contact

- Manuel Ferrer (mferrer@icp.csic.es) Consejo Superior de Investigaciones Cientificas (CSIC), Spain
- Moniec van Logchem (moniec.van-logchem@evonik.com), Evonik Operations GmbH (EVO), Germany
- Sara Daniotti, (sara.daniotti@italbiotec.it) Consorzio Italbiotec (ITB), Italy.

Consent

This consent form is compliant with the relevant national, European and international data protection laws and regulations. Specifically, this consent form complies with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation).

- ☐ I have read and understood all the information above
- ☐ I accept to participate in FuturEnzyme activity
- ☐ I have voluntary decided to participate in this research. I have been informed that I may withdraw at any stage of the project without being penalised or disadvantaged in any way.
- ☐ I authorised the entity XXX and the designated partners of FuturEnzyme project to use my data for scientific purposes. The data will remain confidential and no identity information will be given.

Name and surname of the participant

……..

Participant's Signature

……..

Place and date

……

Name and surname of the Researcher

……

Researcher's Signature

……

Place and date

……

Preliminary Draft Template

PARTICIPANT INFORMATION SHEET TEMPLATE

TITLE OF THE PROJECT: FuturEnzyme – Technologies of the Future for Low-Cost Enzymes for Environment-Friendly Products.

DURATION OF THE PROJECT: 01/06/2021 - 31/05/2025

SPONSOR: This project has received funding from the European Union's Horizon 2020 research and innovation programme under Grant Agreement no 101000327

RESEARCHER:

to be filled depending on the activity *(beneficiary responsible of the project activity)*

CONTACT DETAILS: to be filled depending on the activity

DATE: to be filled depending on the activity

Invitation paragraph

You have been selected to participate in some activities within the EU funded project FuturEnzyme. We hope to be able to count on you to achieve the objective to which we have committed. Before making a decision on whether you want to participate or not, please read this document carefully. Please feel free to

ask any questions to ensure that you fully understand the purpose and the proceedings of this study, including risks and benefits.

We assure full compliance with European and national ethical principles and legislation on data protection, including GDPR regulation (n. 2016/679).

What is the purpose of the study?

This study for which you have been selected is part of the FuturEnzyme research project which aims to produce new enzyme-based products with lower environmental impact (energy, CO2, water, toxicity) of production processes, and/or with reduced environmental footprint during their use or end-of-life focusing on 3 market segments: textiles, detergents, and cosmetics.

Specifically, you will be asked to participate in …. *Define the background and the purpose of the specific activity.*

Do I have to take part?

Your participation in this research activity is completely voluntary, therefore you are under no pressure to participate in the research. If you decide to take part in the study, you can withdraw at any time without any negative consequences to you. Before making a decision, if you have any questions or want clarification regarding this activity or your participation, you are free to contact the researcher. Contact details are provided in the last section of this document.

If you decide to take part, you can proceed to fill out the informed consent form. *Complete with details of the activity:*

(a) You can access the survey with the link XXXXX. The survey will take around XXX

(b) You can respond to the invitation to attend the workshop via the link XXXX. The workshop will be held online/in XXX and will take place on XXX (date) from XXX to XXX.

(c) You will then receive in XXX months the product samples to proceed with the testing and the associated questionnaire to be completed with your experience and impressions of the products.

(d) You can confirm your participation with the link XXXX and then you will receive via e-mail detailed information on the efficacy testing procedures (i.e. where and when the study will take place)

What are the risks and benefits of taking part in this research?

Since confidentiality is being provided, no risks are foreseen in relation to data protection. *Different accordingly to the specific activity. …*

Will my information be kept confidential?

We assure full compliance with European and national ethical principles and legislation on data protection, including GDPR regulation (n. 2016/679). Therefore, all information collected on you as a participant and the acquired data are strictly confidential. The data will be used for research purpose only and they will be handled with appropriate security measures to ensure full protection of personal data and their correct and lawful management. All information collected will be kept in institutional servers (where available) or in password-protected electronic files on the hard disk of their secured computers with access protection. Data collected will be retained for 5 years after the completing of the activity. All your personal information that will no longer be used for project purpose (e.g. full name and contact details) will be immediately destroyed after the activity is completed. In addition, at your written request, your data can be erased at any time without any negative consequences to you. Other personal data useful for statistical analysis or

for research purpose will be made anonymous as soon as possible or, at least, pseudonymised. At the end of the project, if data has been accurately anonymized, the analysis results may be subject to scientific publication on open access journals or repository.

What will happen to the results of the study?

The results of this study will implement the activity of the Work Programme X "XX" within the research project FuturEnzyme. *In particular, define the main results of the activity.* Due to the relevance of the study, the results of the research aggregating your data and the data of other participants may be published in open access journals. In any case, the data will remain confidential and no identity information will be given.

Contact information

If you have any questions, concerns or complaints about this study, its procedures or its risks and benefits or if you wish to learn more about this project, or if you wish to opt-out from the study or make use of any other rights recognized by R(EU) 679/2016, please contact

- Manuel Ferrer (mferrer@icp.csic.es) Consejo Superior de Investigaciones Científicas (CSIC), Spain
- Moniec van Logchem (moniec.van-logchem@evonik.com), Evonik Operations GmbH (EVO), Germany
- Sara Daniotti, (sara.daniotti@italbiotec.it) Consorzio Italbiotec (ITB), Italy.

ANNEX 2

Moisturization - Corneometer

- Most popular method for determination of skin hydration

- The measuring principle is based on capacitance measurement of a dielectric medium

- Result is given as CU (Corneometer units)

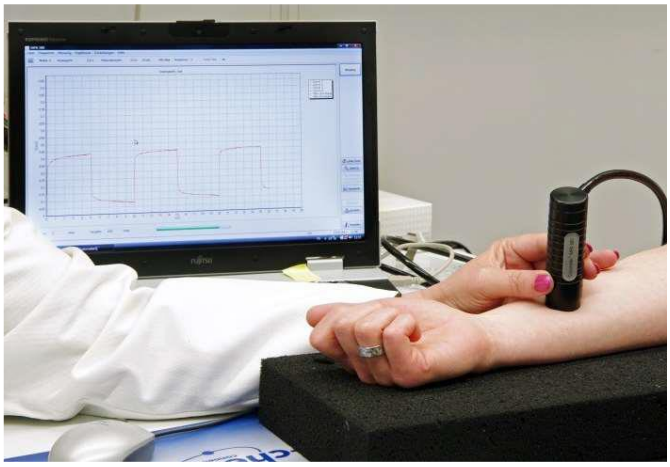
- The higher CU is the better the moisturization of the skin is

Transepidermal water loss (TEWL) - Tewameter

- Determination of transepidermal water loss
- Describes the integrity of the skin lipid barrier
- The relative humidity inside the hollow cylinder is measured and analysed by a microprocessor
- Results are given as g/hm2
- The lower the values are, the stronger the skin lipid barrier is
- Assesses skin barrier repair, barrier recovery

Skin elasticity - Cutometer

- Determination of skin elasticity
- Skin is soaked into the probe by a negative preasure
- Stretching cycle is followed by relaxation cycle
- Depth of impression during stretching cycle and relaxation cycle is measured
- Using the shape of the curve different parameters can be calculated which describe the elasticity state of the skin



Primos Pico - Wrinkle depth/skin surface

- Digital stripe projection
- Contactless method (in contrast to replicas)

- Stripes are projected onto the surface of the measuring object and that projection is recorded at a defined triangulation angle by a CCD camera.

- Measuring field: 40 x 30 mm^2