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Food Security, Sustainable Agriculture and Forestry, Marine, Maritime and Inland Water Research and the Bioeconomy

Call

H2020-FNR-2020: Food and Natural Resources

Topic name

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FuturEnzyme:

Technologies of the Future for Low-Cost Enzymes for Environment-Friendly Products

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ETHICS - NEC - REQUIREMENT NO. 3

D9.3

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Document information sheet

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ETHICS - NEC - REQUIREMENT NO. 3. Accomplishment of ethics related to non-european countries.

1. Introduction

This deliverable consists in the description and demonstration of the accomplishment of ethics related to non-european countries. As stated in article 34 of the Grant Agreement about Ethics and research integrity, FuturEnzyme partners are committed to perform their activities related to this project following ethical principles and the corresponding international, EU and national laws, always respecting the fundamental principle of research integrity.

Two non-EU country, Switzerland and United Kingdom (UK), are involved in research related activities. Materials sent or received in the frame of FuturEnzyme are for non-commercial/research purposes; they are not liable to custom duties and can be sent by postal or courier services. In the current project, we will not transfer any goods that are banned or restricted by Swiss or UK customs (e.g., narcotics, protected animals and plants, and weapons). Transfer fees will be covered by the involved partners, upon agreement. Copies of import/export authorisations, as required by national/EU legislation will be kept on file and submitted to the Agency upon request.

The project plans also to collect samples from non-european countries. As example, current sampling by partner CNR is being done in subglacial Antarctic lakes; in particular, from Lake Enigma, an Antarctic Treaty area beyond of Italian Jurisdiction. Therefore, benefit-sharing concerns do not apply.

No endangered species and/or protected areas are going to be collected and therefore the risks in regard to this point do not apply.

The Consortium will ensure that the research conducted outside the EU is legal in at least one EU Member State.

Currently, no benefit-sharing arrangements with non-european countries has been made. But, in positive case in the future, detailed information to demonstrate that fair benefit-sharing arrangements with stakeholders from low and lower-middle income countries are ensured will be submitted as a deliverable.

2. Materials imported/exported from the EU

The following materials are susceptible to be transferred along the project:

2.1. Enzymes

As part of the project's working flow, a number of enzymes (pure or semi-pure) will be transferred from partners to FHNW and Inofea (Switzerland). The enzymes transferred will be only those which show the most promising characteristics for the objective of the project, and the aim for the Switzerland partners is to immobilise them with their shielding technology in order to improve the enzymes' performance in the real-life products (cosmetics, detergent, textile treatment). The materials to send are not corrosive, toxic, explosive, radioactive or pathogenic and are non-hazardous for human, animals or environment. This is stated, and will be stated, in all pro-forma invoices by partners sending the materials. These documents will be kept by partners and will be made available to the EU when requested.

2.2. Environmental samples

Samples from different types of environments can be collected in order to search for enzymes of interest for the project by different partners, one of them from UK (Bangor). When this activity is performed, all

documents and permissions are in order with the Nagoya Protocol and the specific country regulation (see D9.4). In general, Bangor will perform the analysis of the samples they collect by their own, so no need for material transfer to EU countries is expected in this regard. In case this fact may change, the samples to be sent will be not corrosive, toxic, explosive, radioactive or pathogenic and is non-hazardous for human, animals or environment. In addition to that, CNR will collect samples from non-european countries such as subglacial Antarctic lakes, in particular, from Lake Enigma, an Antarctic Treaty area beyond of Italian Jurisdiction.

In case further sampling is performed and new environmental samples are taken, all documents and permissions will be collected and will be made available to the EU upon request.

2.3. Microbial cultures

Bangor (UK) might find useful to send a microbial culture/s to other partner/s (such as CSIC -Spain-, UDUS -Germany-, IST-ID -Portugal-, etc.) derived from the environmental samples, for them to perform further analysis. In this case, the microbial culture/s will be not toxic, or pathogenic and non-hazardous for human, animals or environment. This is stated, and will be stated, in all pro-forma invoices by partners sending the materials. These documents will be kept by partners and will be made available to the EU when requested.

2.4. DNA

If DNA samples are obtained by Bangor that can be of interest to be expressed for enzyme analysis, they can be sent to other partners (such as CSIC -Spain-, UDUS -Germany-, etc.). In this case, the material will be not toxic, or pathogenic and non-hazardous for human, animals or environment. This is stated, and will be stated, in all pro-forma invoices by partners sending the materials. These documents will be kept by partners and will be made available to the EU when requested.

2.5. Chemicals and non-biological products

The following materials have already been sent (08.09.2021) to the now non-EU partner Bangor by partner CSIC: Evonik's hyaluronic acid Hyacare (0.5 g), Evonik's hyaluronic acid Hyacare 50 (0.5 g), Rhodamine B (Sigma, Ref.: 83690, 1 g), gum arabic (Sigma, Ref.: G9752, 40 g), palm oil (Sigma Ref.:70905, 30 g), coconut oil (Sigma, Ref.: C1758, 10 g), olive oil (Sigma, Ref.: O1514, 30 g), calcium caseinate agar (Sigma, Ref.: 21065, 40 g), Henkel's detergent with enzyme (160 mL), Henkel's detergent without enzyme (160 mL), and Scholler's swatches (fabric). These materials are safe, no toxic and no dangerous, are not subjected to pharmaceutical control and they are not going to be used in animal feeding; they do not have commercial value and are for research purposes. This is stated, and will be stated, in all pro-forma invoices by partners sending the materials. These documents will be kept by partners and will be made available to the EU when requested.

The sample materials detailed above have also been shared within the members that belong to EU countries and in all cases all pro-forma invoices by partners sending the materials have been prepared and are available to the EU; the pro-forma invoices detailed that the materials are safe, no toxic and no dangerous, are not subjected to pharmaceutical control and they are not going to be used in animal feeding; they do not have commercial value and are for research purposes.

The following materials have also been sent to partners, including the now non-EU partner Bangor by partner Henkel.

Material	Sent by Henkel	Received by partners
1x Canister detergent_A gel without enzymes. 2.5 % gap to be filled with enzymes/water	August, 2021	August-september 2021
2x Bottles detergent_A gel including all enzymes. no gap	August, 2021	August-september 2021

It is worth mentioning that Henkel in all cases shared with partners a detailed information of the description of the content and the documentation for safety & handling. This information is available to EU upon request.

3. Import/export authorisations (required by national/EU legislation)

Copies of import/export authorisations, as required by national/EU legislation, and pro-forma invoices detailing that the materials are safe, no toxic and no dangerous, are not subjected to pharmaceutical control and they are not going to be used in animal feeding, are and will be compiled and is and will be made available to EU upon request.

4. Ethics on activities undertaken in non-EU countries

Ethics issues in EU and non-EU countries will be ensured through the partners' Ethics Committees detailed in **Table 1**, Section 5.

5. 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
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HENKEL	-	https://www.henkel.com/sustainability/positions/white-biotechnology
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