

This project has received funding from the Bio Based Industries Joint Undertaking (BBI-JU) under grant agreement No 887474. The JU receives support from the European Union's Horizon 2020 research and innovation programme and the Bio Based Industries Consortium.



# Consortium

SO : stratégique orientation

NENU2PHAR est un projet financé sur la ligne BBI2019.SO3.R8 – Develop sustainable bio-based materials for high-volume consumer products, [Développer des matériaux durables d'origine biologique pour des produits de consommation à haut volume]

NENU2PHAR rassemble 17 partenaires européens

Financement EU+ BBI: 5 M€

Budget : 6.4 M€

Coordinateur:



RTOs & academic

Cluster

SMEs

Large companies



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# OBJECTIFS



Obj6. Sensibiliser davantage les parties prenantes et les consommateurs



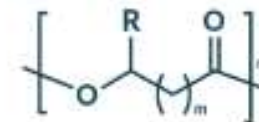
Obj5. Démontrer l'économie circulaire de la chaîne de valeur de nenu2PHAr et sa durabilité



Obj4. Développer des produits éco-conçus à base de PHA pour des produits de consommation à haut volume



Obj1. Développement d'une nouvelle bio-ressource de polymère PHA compétitive

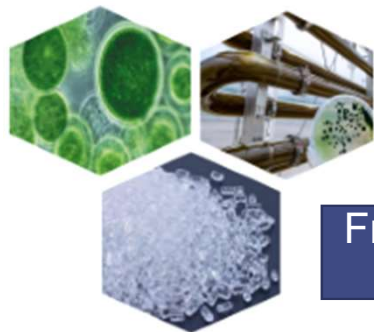


Obj2. Formuler et fonctionnaliser des mélanges-mâtres et des mélanges de polymères pour approvisionner les fabricants de produits plastiques.



Obj3. Identifier les process permettant aux matériaux PHA d'atteindre des propriétés fonctionnelles définies supérieures à celles des matériaux fossiles.

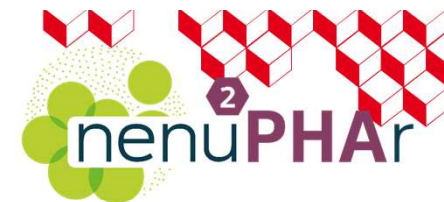
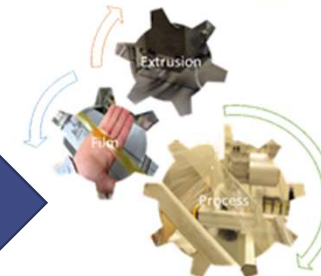
# Applications



From Biomass  
feedstock



To Bioplastic



Packaging  
alimentaire



Packaging  
cosmetique



Filament pour  
impression  
3D



Plastique pour  
dispositifs  
medicaux



Films  
agricoles



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# Montage du projet NENU2PHAR



1° tentative

2° tentative

2017 BBI- R6

2018 BBI-R10

2019, BBI-R8

**BBI 2017.R6 – Competitive biodegradable, compostable and/or recyclable bio-based plastics for sustainable end-of life phase**

**ESR: 5//4//4 (13)**

*The lack of significant consortium own contribution does not provide sufficient assurance that the impact of the action will be maximised.*

**BBI 2018. SO3.R10 – Develop bio-based packaging products that are biodegradable/ compostable and/or recyclable**

**ESR: 5//4.5//4.5 (14)**

*However, the management of background and foreground IPR, including patents, is not described in sufficient detail.*

*The significant own contribution of the consortium will greatly maximize the impact of the action. → IKOP : 15%*

*However not all the critical risks have been identified*

**BBI2019.SO3.R8 – Develop sustainable bio-based materials for high-volume consumer products**

**ESR: 5//4.5//5 (14.5)**

*Pre- and co- normative research TRLs well described and realistic Interdisciplinary approaches The significant consortium own-contribution will greatly maximize the impact of the action. → IKOP: 22%*

*Stakeholder knowledge is appropriately incorporated in the proposal and industry participation adds value*

*Workplan is constructively aligned with the objectives of the project, well scheduled, and supported by relevant and specific deliverables, milestones and means of verification.*

*The risk management and mitigation measures are outlined in a credible way, including some realistic acknowledgements of technical risks*

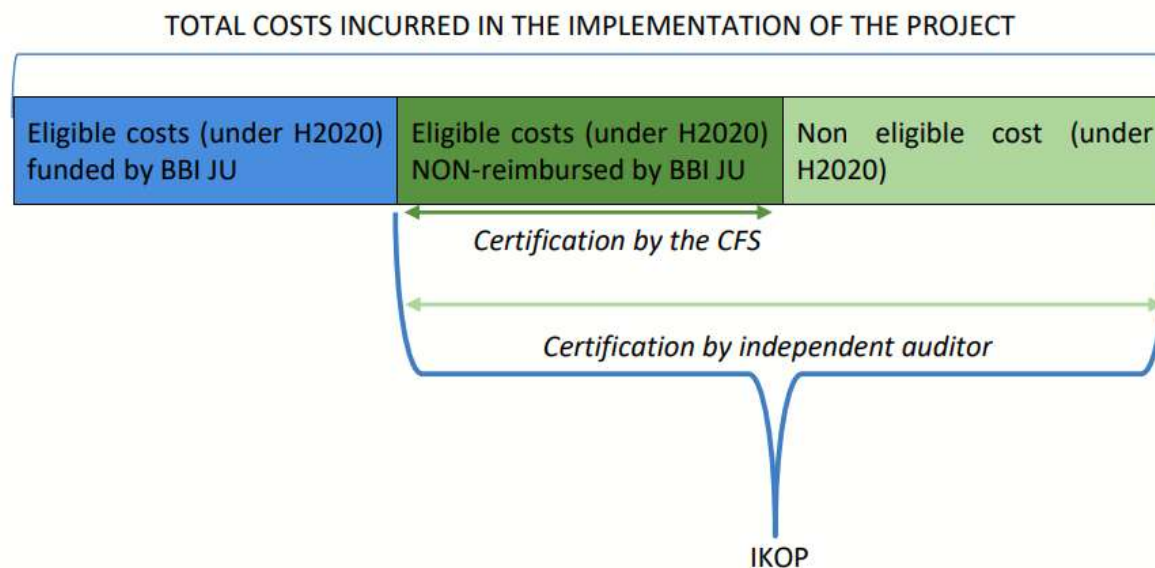
IKOP : 1%



# Les IKOP

L'IKOP est défini comme les coûts encourus par **les membres (privés)** pour la mise en œuvre des actions indirectes moins la contribution de l'EC ou toute autre contribution de l'Union en remboursement de ces coûts.

Les IKOP contribuent à la part de co-financement industriel dans le partenariat public-privé.





# Différences entre BBI-JU et CBE-JU et Horizon Europe

BBI-JU (H2020)	CBE-JU (HORIZON EUROPE)
RIA: les grands groupes ne sont pas financés. → l'ensemble de leurs coûts apparaissent sous forme d'IKOP. Viser 15% IKOP, → Si les grands groupes ne sont pas suffisants, les autres partenaires doivent aussi participer aux IKOP.	RIA: toutes les typologies de partenaires sont financés à 100%, mais IKOP bien venu.
IA, flagship: profits organisation (70%) comme dans H2020	IA, flagship: profits organisation (60%) → 40% du budget =40% IKOP
Cible de 20% d'IKOP par projet.	<b>Cible de 15% (IA)-20%(Flagship) d'IKOP par projet</b>
4% de contribution pour fonctionnement du BBI-JU collecté auprès de l'ensemble des membres du consortium.	8% ( 2x 4%) de contribution pour fonctionnement du CBE-JU collecté auprès des membres industriels du BIC participants au projet.
Evaluation: niveau seuil : Excellence : 3 Impact : 4 Implementation : 3	Evaluation: niveau seuil : Excellence : 3 Impact : 4 Implementation : 3

# Autres différences par rapport à H2020 ou HORIZON Europe



Contribution aux KPIs du BBI/ CBE: 1 Livrable obligatoire / an

KPI	Cible BBI 2024	RIA	DEMO	Flag
1. Nombre de nouvelles interconnexions intersectorielles dans les projets de l'entreprise commune BBI → >=1	36	10	4	5
2. Nombre de nouvelles chaînes de valeur biosourcées créées/réalisées grâce aux projets de l'EC BBI → >=1	10	10	4	6
4. Nombre de nouveaux composants de base biosourcés développés (TRL 3), validés (TRL 4-5) ou démontrés (TRL 6-7) dans le cadre de projets de l'EC BBI	5	0	1	3
5. Nombre de nouveaux matériaux biosourcés développés (TRL3), validés (TRL 4-5) ou démontrés (TRL 6-7-8) dans le cadre de projets de l'EC BBI → >=2	50	11	0	6
6. Nombre de nouveaux produits de consommation biosourcés ou d'applications biosourcées démontrés (TRL 6-7-8) grâce aux projets de l'EC BBI	30	0	6	7
7. Nombre de conventions de subvention signées entre l'entreprise commune BBI et les consortiums de projets Flagship	5	0	0	3-5
8. Progression de TRL : technologies validées et améliorées qui comblent des lacunes dans les chaînes de valeur et permettent de créer de nouveaux composants chimiques, de nouveaux matériaux, de nouveaux produits de consommation ou de nouvelles applications. → >=1	20	10	0	0

**Questionnaire on KPIs and impacts for BBI JU projects:**  
Please fill in the questionnaire indicating the expected impacts by the end of the project or by 2024 (the earliest). For projects that will be finished by September 2021, please indicate actual impacts by the end of your project.  
Please fill in the grey cells when applicable

**Scientific and socio-economic impact**

Please select with an "x" the impacts addressed in your project. For the selected aspects, provide an explanation and quantitative estimations, if available. Provide a brief explanation. Indicate quantitative estimates, if relevant and available.

Science and innovation	Provide a brief explanation	Indicate quantitative estimates, if relevant and available
Knowledge creation/ scientific breakthrough	x Demonstration of starch from microalgae as new bio material / Demonstration of PHA as biosourced polymer for high-volume consumer plastic products	
Contribution to KET, eg. Biotechnology	x Photobioreactor for polysaccharides production, bacterial fermentation reactor	
Increased cooperation across regions and countries	x collaboration between France (CEA, UBS, ELIXANCE, Belgium (CELABOR) and Portugal (BIOFINNO) to produce biopolymer.	
Scientific community/network building	x Scientific publications and communications in progress	
Creation of spin offs and start-ups		
New patents and IP rights		
Increase academia - industry cooperation		
<b>Markets and impact on industry</b>	<b>Scientific and socio-economic impact</b>	
Technology transfer		
Increase competitiveness (European comp)		
Creation of new markets		
Reduce dependence on imports of fossil		
Reduce dependence on imports of renewable		
Investments in facilities and equipment		
Expansion of production capacity		
Other (specify)		
<b>New jobs</b>	<b>KPI 5: New bio-based materials</b>	
In rural regions		
In coastal regions		
In the product development and engineering		
Other (specify)		
<b>Growth of incomes of primary produce</b>	<b>Number of new bio-based materials: Number</b>	
General		
KPI 1		
KPI 2		
KPI 3		
KPI 4		
KPI 5		
KPI 6		
KPI 7		
KPI 8		
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KPI 100		



# Attendus & impacts, ambitions pour NENU2PHAR



## Environnement



- Augmenter la durabilité environnementale des matériaux PHA
- Augmenter l'efficacité globale des ressources

## Économique



- Soutenir la mise en œuvre de l'économie circulaire
- Favoriser l'adoption future par le marché des matériaux biosourcés dans le domaine des produits de consommation à haut volume
- Renforcer les capacités de production de bioplastiques en Europe

## Social



- Sensibiliser davantage le public à la fin de vie des plastiques
- Augmenter les revenus et les opportunités commerciales pour les parties prenantes (y compris les producteurs primaires) dans les secteurs biosourcés

# 1° deliverable: Legal, regulatory framework, REACH and policies for plastic products & processes



## Roadmap 1: FOOD CONTACT (ii)

Flexible transparent film packaging | Thermofomed food plastic tray | Stand up pouch (for dry food) | Plastic cup, container for comports

## Roadmap 2: COSMETICS (ii)

Roll on bottle: ball dozes and applicator

## Roadmap 2: COSMETICS (i)

Roll on bottle: ball dozes and applicator

### Regulation (EC) 1223/2009

**Cosmetic Products:** Rules to be complied with any cosmetic product made available on the market, in order to ensure the functioning of the internal market and a high level of protection of human health.

#### Article 3 - Safety

A cosmetic product made available on the market shall be **safe for human health** when used under normal or reasonably foreseeable conditions of use, taking account the following:

- (a) presentation including conformity with Directive 87/357/EEC;
- (b) labelling;
- (c) instructions for use and disposal;
- (d) any other indication or information provided by the responsible person (Art. 4).

#### Article 8 - Good manufacturing practice

1. The manufacture of cosmetic products shall comply with good manufacturing practice to ensuring the above objectives.
2. Compliance with GMP shall be presumed where the manufacture is relevant harmonised standards.

#### Article 19 - Labelling

- Reference to attached information
- Period after opening
- Date of durability

### ANNEX I - COSMETIC PRODUCT SAFETY REPORT (CPSR)

The cosmetic product safety report shall contain:

4. Impurities, traces, information about the packaging material. (i) The purity of the substances and mixtures; (ii) in the case of traces of prohibited substances, evidence for their technical unavoidability; (iii) the relevant characteristics of packaging material, in particular purity and stability.

### Commission Implementing Decision 2013/674/EU

#### Guidelines on Annex I

3.4. Impurities, traces, information about the packaging material

- 3.4.1. Purity of substances/mixtures: Include data on the purity of raw materials and identification of the toxicologically relevant unintended substances in the CPSR for product safety assessment.
- 3.4.2. Evidence of the technical unavoidability of traces of prohibited substances: Traces generated by the degradation of substances within the final product, by preservation or transport problems, or by the interaction of raw materials should be avoided through GMP, or re-formulation.
- 3.4.3. The relevant characteristics of packaging material:

Reference to Regulation (EC) No 1935/2004 could be useful. Materials that have been developed for food packaging have often already been tested, so relevant information on stability and migration may be available. Additional testing may not be required. However, more evaluation may be needed for new or novel packaging.

Safety of the finished product can be affected by: (i) interaction between the cosmetic product and the packaging material; (ii) barrier properties of the packaging material; (iii) substance migration from/to the packaging material.

The information on relevant characteristics of the packaging materials in direct contact with the product should allow an Estimation of potential risks through packaging relevant characteristics: (i) composition of the packaging material, including technical substances such as additives; (ii) technically unavoidable impurities; (iii) possible migration from the packaging.

Studies on interactions/suitability: **NO standard procedures for cosmetic products**

## Roadmap 3: 3D PRINTING

3D Printing Filament

## Roadmap 5: AGRO-TEXTILE (i)

Agro-textile tips for woven groundcovers (Industrial and consumer market)

## Roadmap 5: AGRO-TEXTILE (ii)

Agro-textile tips for woven groundcovers (Industrial and consumer market)

### REGULATION (EC) 1107/2009

#### ANNEX II: Procedure and criteria for the approval of active substances, safeners and synergists

##### Relevant Requirements for Impact on Human Health

- Fate and behaviour in the environment - An active substance, safener or synergist shall only be approved where it is not considered to be POP, PBT and/or vPvB. It shall only be approved if:
- the risk assessment demonstrates risks to be acceptable in accordance with Art. 29(6) under realistic proposed conditions;
  - on the basis of the assessment of Community/internationally agreed test guidelines, it is not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant.

<p><b>Persistent organic pollutant (POP)</b></p> <p>bioaccumulation = bioconcentration factor in aquatic species is &gt; 5,000 in the partition coefficient = octanol/water log K<sub>ow</sub> is &gt; 5, or evidence that substance causes other concerns for concern, such as high bioaccumulation in other target species, high toxicity or ecotoxicity</p> <p><b>Potential for long-range environmental transport:</b></p> <ul style="list-style-type: none"> <li>- measured levels in locations distant from the released sources are of potential concern;</li> <li>- monitoring data show that long-range environmental transport of the substance may have occurred via air, water or migratory species;</li> <li>- environmental fate properties and/or model results demonstrate that the substance has a potential for long-range environmental transport through air, water or migratory species, with the potential for transfer to a receiving environment in locations distant from the sources of its release. For a substance that migrates significantly through the air, its DT50 in air &gt; 2 days.</li> </ul>	<p><b>Persistent, bioaccumulative and toxic (PBT)</b></p> <p>Persistence = half-life &gt; 60 days in marine water, &gt; 40 days in fresh or estuarine water, &gt; 180 days in marine sediment &gt; 100 days in fresh or estuarine water sediment, or &gt; 120 days in soil</p> <p>bioaccumulation = bioconcentration factor &gt; 2,000 (based on measured data on bioconcentration in target species)</p> <p><b>Toxicity</b></p> <ul style="list-style-type: none"> <li>- the long-term no-observed effect concentration for marine or freshwater organisms is &lt; 0.01 mg/l;</li> <li>- the substance is classified as carcinogenic (category 1A or 1B), mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2) (Regulation (EC) No 1272/2008); or</li> <li>- other evidence of chronic toxicity, as identified by the classifications STOT</li> </ul>
<p><b>Very persistent &amp; very bioaccumulative substance (vPvB)</b></p> <p>Persistence = half-life &gt; 60 days in marine water, fresh or estuarine water, &gt; 180 days in marine sediment, &gt; 100 days in fresh or estuarine water sediment, or &gt; 180 days in soil</p> <p>Bioaccumulation = Bioconcentration = bioconcentration factor &gt; 2,000.</p>	

## Roadmap 4: MEDICAL DEVICES (i)

Implantable medical devices, sutured meshes / sutures

## Roadmap 4: MEDICAL DEVICES (ii)

Implantable medical devices, sutured meshes / sutures

## Roadmap 4: MEDICAL DEVICES (iii)

Implantable medical devices, sutured meshes / sutures

## Roadmap 4: MEDICAL DEVICES (iv)

Implantable medical devices, sutured meshes / sutures

### REGULATION (EU) 2017/745

#### ANNEX I > CHAPTER II > Requirements regarding Design and Manufacture

**Substances:** Reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device. **Special attention shall be given to nanomaterials.**

Devices that are invasive and come into direct contact with the human body shall only contain the following substances in a concentration that is above 0,1 % weight by weight (w/w) where justified (Sec. 10.4.2):

- (a) substances which are carcinogenic, mutagenic or toxic to reproduction (CMR), [cat. 1A or 1B, Annex VI-Part 3 Regulation (EC) No 1272/2008]
- (b) substances having endocrine-disrupting properties (Art. 59 of Regulation (EC) No 1907/2006 or Art. 5(3) of Regulation (EU) No 528/2012

Devices composed of substances intended to be introduced into the human body, and that are absorbed by or locally dispersed in the human body shall comply, where applicable and in a manner limited to the aspects not covered by this Regulation, with the relevant requirements laid down in Annex II to Directive 2001/83/EC.

For devices manufactured using non-stable biological substances other than human and animal origin, the processing, preservation, testing and handling of those substances shall be carried out so as to provide safety for patients. In particular, safety with regard to viruses and other transmissible agents shall be addressed by appropriate methods of sourcing and by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

### DIRECTIVE 2001/83/EC

#### ANNEX I > Analytical, Pharmacovigilance and Clinical Standards and Protocols in respect of the Testing of Medicinal Products > MODULE 4: NON-CLINICAL REPORTS

The pharmacological and toxicological tests must show the potential toxicity of the product and any dangerous or undesirable toxic effects that may occur under the proposed conditions of use in human beings; these should be evaluated in relation to the pathological condition concerned;

**Pharmacokinetics** means the study of the fate of the active substance, and its metabolites, within the organism, and covers the study of the absorption, distribution, metabolism (bio-transformation) and excretion of these substances.

#### Single-dose Toxicity (single administration)

Repeat-dose Toxicity (repeated administration: Effect of dosage)

Generally, 2 tests (short-term (2-4 weeks) and long term (duration depending on conditions of clinical use))

Genotoxicity Study of mutagenic and cytotoxic potential reveals the changes which a substance may cause in the genetic material of individuals or cells. They present a serious hazard to health (including mutations leading to cancer). These studies are obligatory for any new substance.

Carcinogenicity: Tests to reveal carcinogenic effects. What normally be required for any medicinal product where repeated doses are to be administered (period of products 10, and recommended for some medicinal products if there is a concern about their carcinogenic potential).

Reproductive and developmental toxicity Studies the effect on adult male or female reproductive function, studies of the toxic and teratogenic effects at all stages of development from conception to sexual maturity as well as infant effects, when the medicinal product under investigation has been administered to the female during pregnancy. Omission of these tests must be adequately justified.

Local tolerance Determine whether medicinal products are tolerated at sites in the body, which may come into contact with the medicinal product as a result of the administration in clinical use. The tests are optional.

# Pre- & Co normative research



This project has received funding from the European Union's Horizon 2020 Research and Innovation programme under the grant agreement No 887474 (NENU2PHAR) This output reflects only the author's view and the European Union cannot be held responsible for any use that may be made of the information contained therein.





## Communication, dissemination

Lien vers le site projet

<https://nenu2phar.eu/>

<https://nenu2phar.eu/news-and-events/>



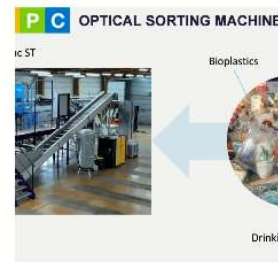
27 / 02 / 2023

**THE NENU2PHAR  
PROJECT ORGANISES ITS  
FIRST EXTERNAL EVENT  
ON APRIL 4TH AND 5TH  
2023**



07 / 02 / 2023

**DISCOVER THE  
EURONEWS REPORT ON  
MICROALGAE AND THE  
NENU2PHAR PROJECT**



02 / 02 / 2023

**SUCCESS STORY #5 - IPC**



01 / 02 / 2023

**SURVEY ON INDUSTRY  
AND CONSUMER VIEWS  
ON BIOBASED PLASTIC  
PRODUCTS**



13 / 01 / 2023

**FOCUS ON PAST EVENTS**



16 / 11 / 2022

**SUCCESS STORY #4 -  
ITENE**



## Quelques éléments d'aide CBE (Info day CBE, avril 2023)

- [How to write a good proposal](#)
- [Specific requirements](#)
- [Call rules conditions](#)