



REGULATORY WATCH - MICROALGAE PROJECT

Call for tender

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1. GENERAL INFORMATION

1.1 MAGNIFICENT project

MAGNIFICENT (Microalgae As a Green source for Nutritional Ingredients for Food/Feed and Ingredients for Cosmetics by cost-Effective New Technologies) is a collaborative project funded by the Bio-Based Industries (BBI) Joint Undertaking (JU) which is a public-private partnership between the EU and the Bio-based Industries Consortium.

Today there are only market opportunities for high value applications due to production costs, which are still too high to make microalgae a competitive feedstock for commodities. There is presently a large production capacity for a limited number of microalgae strains in Europe. However, the number of concrete products and market applications is still limited. The enlargement of current market applications for high-value microalgae ingredients will lead to new business opportunities, industrialize the technology and provide the knowledge and experience required to enter the medium- low value market within 5-10 years.

MAGNIFICENT will expand the range of commercial products and their market volume substantially and in a sustainable manner. The overall objective of the project is to develop and validate a sustainable and economically feasible new value chain based on cultivation and processing, with the aim to transform microalgae biomass into valuable ingredients for food, aquafeed and cosmetics applications. Development and validation of new product formulations of microalgae are included in the project.

To achieve this, optimization will be done: 1) Upstream, cultivation related processes via adaptation and selection of algae varieties, improvement of growing conditions and target product concentration in the cell and 2) downstream process steps (separation, extraction, purification) in order to achieve the overall aim to maximize the production of compounds of interest (phospholipids rich in omega-3 fatty acids EPA and DHA and fucoxanthin as main molecules). The work will be supported by chain evaluation, market assessment, socio-economic impact assessment and LCA. Specific attention will be paid to the requirements of the existing EU regulatory framework.

For more information, please go to: <u>http://cordis.europa.eu/project/rcn/210295_en.html</u>

1.2 MAGNIFICENT consortium and Erdyn's role

The MAGNIFICENT consortium has 16 partners from 7 EU countries incl. 10 SME's, 3 LE's, 1 University and 2 RTO's, and comprises commercial partners in the entire value chain and the 3 target markets. The total budget of the project is 5,9 M \in .

Erdyn is a leading French SME in the field of innovation consulting. Erdyn is an expert in innovation strategy and marketing, scientific and technical studies and innovation processes.

Erdyn oversees the regulatory, market and competition aspects of the MAGNIFICENT project.



Erdyn will coordinate this call for tender and also the relationship with the subcontractor during the regulatory watch

1.3 Context of the regulatory watch

One of the main objectives of the MAGNIFICENT project is to develop high value ingredients and other end products with applications in the food, (aqua)feed and cosmetics sectors. Thus, the MAGNIFICENT consortium will work on chemical characterization, functionality testing, development of product prototypes.

In order to meet the end-market requirements, regulatory aspects related to microalgae products in the targeted sectors must be assessed to ensure that safety and quality of the products are in line with EU legislation.

In the first place, an assessment of the existing regulations must be performed and then periodic updates of the regulatory watch must be provided to the partners of the consortium during the project duration. This will help them draw a perimeter for their development work.



2. OBJECTIVE AND SCOPE OF THE TENDER

2.1 Objective of the tender

The tenderer will be expected to study relevant EU legislation for the application of algae products in food, aquafeed and cosmetics sectors in order to ensure that safety and quality of the products developed within the MAGNIFICENT project are in line with EU legislation and thus proven to meet end-market requirements.

2.2 Expected service

2.2.1 Required information

i. EU regulation related to the use of microalgae based products in the targeted end-markets

The service provider is expected to assess EU authorizations and restrictions related to the production of products made from microalgae in the food, aquafeed and cosmetics sectors. Special attention should be given to the regulations regarding the use of the three strains of microalgae exploited in the MAGNIFICENT project:

- Nannochloropsis oceanica;
- Phaeodactylum tricornutum;
- Isochrysis galbana.

ii. Technical requirements and associated regulations

The service provider is expected to assess technical requirements associated to EU regulation related to the products developed within the MAGNIFICENT products.

The above-mentioned products, and the end-market they are developed for, are listed in the following table. The assessment provided must include, but it is not limited to the compounds listed in the column "Example" in the following table.

Products	Examples	Food	Aquafeed	Cosmetics
Antioxidants	Fucoxanthin and other carotenoids	х		x
Colorants	Carotenoids, phycobiliproteins and chlorophylls	х		х
Antimicrobials	Polyol compounds, preservatives	х	х	
Bioactive peptides	Food spoilage related microorganisms, antioxidants, bio- preservatives	х	x	х
Lipids	Phospho-glycolipids enriched oils (with EPA/DHA)	х	x	х
Polysaccharides	1-3 β-Glucans, 1-6 β-Glucans	х	х	x
Functional proteins	/	х		Х



Definition of the technical requirements related to quality and safety to commercialize microalgae products are expected regarding:

- composition:
 - maximum amount of the microalgae product in the formulation;
 - undesirable and authorized substances and their maximum amount in the formulation;
 - authorized and restricted additives and their concentration in the formulation;
 - compulsory declarations;
- production process:
 - authorized and restricted extraction process, such as supercritical CO₂ process;
 - authorized and restricted solvents;
 - authorizations and restrictions regarding the use of GMO strains;
 - ...
- other relevant information.

For these two parts (i. and ii.), information have to be displayed by application and if relevant by couple product/application.

2.2.2 Organization of the study

The expected service will be divided into two steps as follows.

- **Step 1**: assessment on regulation and caution points linked with the use of microalgae in the targeted markets (process parameters, impurities...) and assessment regarding our algae strains in food
- **Step 2**: quarterly update of regulation from December 2017 to November 2020. For each new regulation, update report must include the required information listed in 2.2.1.



3. TENDERING RULES AND PROCEDURES

3.1 Criteria for the tenders: content, language and contact information

Tenders must be in English.

All supporting documents required in 3.2 must be in English, or in French.

Tenderer must provide all the information requested by Erdyn.

Tenderer must provide contact information (name, email, phone number) for the person who can be contacted about the tender during the evaluation of the tenders and at the end of the tendering competition when the service provider will be selected.

Tenderer must also provide contact information (name, email, phone number) for the person who is authorized to conclude a service contract.

3.2 Content of the tender

Alternative or partial offers are not accepted.

All documentation related to service provisioning have to be in English.

The tenderer shall describe the following items (3.2.1 to 3.2.5).

3.2.1 Description of the service provider

Participation in this call for tender procedure is open on the same terms to all legal persons and public entities of a European Union Member State.

In order to ascertain the eligibility of tenderers, they must indicate in their tenders the country in which they have their registered office or in which they are domiciled. They must also submit the evidence required under their national law or other, equivalent proof enabling Erdyn to check where they come from.

Consortium

Consortium of legal persons and public entities may submit a tender. In that case, a natural or legal person or a public entity of the consortium must be appointed agent of the consortium.

The contract will be concluded between Erdyn and the agent of the consortium.

Subcontracting

Subcontracting is permitted.

The tender shall give details, as far as possible, of that part of the contract which the tenderer proposes to subcontract and the identity of the subcontractors.

Selection criteria

The tenderer must provide a proof of at least one of the following conditions:



- be enrolled in a relevant professional or trade register, except for international organizations;

- for public entities, a copy of the resolution, law, decree, decision or any other official document establishing the organization as a public body.

In the case of a consortium, each member must provide proof of authorization to perform the contract.

In the case of subcontracting, proof of authorization to perform the contract must be provided for each subcontractor.

Tenderers must have sufficient economic and financial capacity to enable them to perform the contract in compliance with the contractual provisions. Financial and economic capacity will be assessed based on the information included in, the following documents, to be provided by the tenderer:

- appropriate statements from banks or evidence of professional risk indemnity insurance;

- the presentation of balance sheets or extracts from balance sheets for at least the last two years for which accounts have been closed, where publication of the balance sheet is required under the company law of the country in which the economic operator is established;

- statement of overall turnover and turnover concerning the works, supplies or services covered by the contract during a period which may be no more than the last three financial years;

In the case of a consortium, each member must provide the above-mentioned documents.

In the case of subcontracting, above-mentioned documents must be provided for each subcontractor.

Exclusion criteria

Erdyn shall not award a contract for a given procurement procedure to a legal person, or a public entity, or a member of a consortium, or a subcontractor, who:

a) is in an exclusion situation established in accordance with Article 106 of the Financial Regulation¹;

b) has misrepresented the information required as a condition for participating in the procedure or has failed to supply that information;

Should a tenderer give fraudulent information in their tender, that in the magnitude and essence can be judged to be more than a simple error or single mistake, will the tenderer be disqualified from the tendering process.

Erdyn retains the right to require any document allowing to complete missing information about the tenderer.

¹ The full texts of Articles 106 of the Financial Regulation on exclusion criteria and their application are available in the Official Journal of the European Union, N° L-286 published on 30th October 2015, pages 1-29.



3.2.2 Methodology, action plan and deliverables

Methodology and action plan

The tender describes the general methodology that will be employed in order to perform the regulatory watch. The information about the methodology include, but is not limited to:

- the methodology employed to make the requests for the regulatory watch;
- the possible databases that will be employed to monitor the relevant regulations;
- the number and the perimeter of the requests that will be made in these databases;
- the number of new regulations that is expected every three month.

The tender also contains a detailed action plan associated with a timetable and a staff efforts distribution amongst the project team.

The expected timetable is expected as follows.

Service provider delivers a regulatory watch update report every three month from 2017.12.10 to the 2020.11.10 (included) at the latest by the 10 th of the month	
Service provider delivers first regulatory watch report latest by	2017.11.22
Contract with the Service provider signed, 'Start date'	2017.10.10

'End date'

2020.11.10

The contract that is signed between the customer and the service provider is valid for the period between 'Start date' and 'End date' (inclusive) or until the final deliveries have been accepted by the customer.

Deliverables

The tender includes a detailed description of the content of the deliverables for step 1 and step 2 of the regulatory watch.

In order to ensure the greatest readability of the deliverables for the entire MAGNIFICENT consortium, the service provider separates in two distinct parts:

- regulations specifically related to each end-market (food, aquafeed, cosmetics);
- specific regulations related to one or several products that are developed within the project. In this part, the service provider also indicates the relevant end-market(s).

Meetings

Kick-off meeting and end of step 1 meetings at Erdyn's office in Paris (France) have to be included in the tender.

If judged relevant, these meetings could be replaced by phone meetings.



3.2.3 Project team and references

The project team must be identified by listing each person individually. A brief description (ca. 5 lines) of each person is needed. What would be the role of the person in the project team and what would be the expertise she/he provides? Erdyn reserves the right to request each person's CV, when contract preparation starts with the selected tenderer.

If subcontractors are used in the team, their technical capacity and professional ability must be identified the same way as others.

The tenderer must have experience of provisioning of similar type of service where new technologies and processes have been developed in the field of microalgae processes or bioprocesses in general and with final applications in the food, aquafeed and/or cosmetics industries.

One such reference must be introduced and well documented. The reference must have a European scope, where the products would be delivered in multi-national scale, for example EU wide. The description of the reference must include at least the following:

- what was the perimeter of the regulatory watch;

- what were the final applications;
- what was the approach taken to monitor the regulations that enters the scope;
- what type(s) of new regulations were identified;
- what was the duration of the watch;
- what was the budget of the project;
- what were the final outcomes/deliverables from the project.

Lack of reference will lead to disqualification from the tendering process.

3.2.4 Risk analysis

Tenderers must provide a description of risks that the service provider may face and of measures that will be taken to mitigate these risks.

3.2.5 Pricing and invoicing

The tenderer must tender one fixed price fee for the entire advisory service. The price must be given in EUROs excluding the VAT.

Firm, inclusive and non-revisable price must be quoted.

The tendered price must be divided and correspond to the distribution of effort, and external expenses in the action plan.

The tendered price must include all expenses such as, but not limited to, personnel, travel, travelling time, copies and materials, translations, use of equipment and software, insurances, licenses and other fees needed to perform the services. The service provider may not present any other fees than the agreed fixed fee, unless Erdyn have requested additional services in writing.

The price for step1 and step 2 must be given distinctly.



Invoicing takes place at two instalments for step 1 and three instalments for step 2:

- Step 1:
 - 1st (30%) once the contract has been signed (Oct 2017);
 - 2nd (70%) once the first report (Nov 2017) has been accepted by the customer;
- Step 2:
 - 1st (30%) once the twelfth update report (Nov 2018) has been accepted by the customer;
 - 2nd (40 %) once the twenty-fourth update report (Nov 2019) has been accepted by the customer;
 - 3rd (30%) once the last update report (Nov 2020) has been accepted by the customer.

3.3 Execution and timetable of the procurement

The procurement timetable is defined as follows.

Activity	Schedule
Tenders sent to selected organizations	2017.09.15
Deadline for the tenders to arrive	2017.10.04
Service Provider selected	2017.10.06
Contract with the Service provider signed, 'Start date'	2017.10.10

3.4 Validity of the tender

The tender shall be binding and valid until 15th of November 2020.

3.5 Submission of tenders

The tenders shall be submitted by email to the following email address:

maud.huche@erdyn.fr

The email subject shall clearly be marked as tender for this procurement with the following text:

'Tender Erdyn, REGULATORY WATCH - MICROALGAE PROJECT'

The tender has to be received no later than 2017.10.04 4pm French time.

The tenders will be received and accepted up to the deadline given above. Each tender email will be opened at the time of arrival as to verify that it has been correctly received and the documents can be opened.

Tenders received after the deadline will not be considered.

The tenders will not be returned.



Questions or queries for additional information can be sent by email to: Mrs. Maud Huché, Senior consultant – industry and sustainable development maud.huche@erdyn.fr

3.6 Subcontractor selection

The tenderer is requested to provide all the relevant information for the customer to be able to evaluate the tender against the evaluation criteria.

The tender shall include all information asked for in this call for tender in order to evaluate and compare tenders duly and equally.

In principle tendering means acceptance of all terms and conditions of the invitation to tender.

Tenderer will not be auditioned.

Erdyn retains the right to ask any questions to the tenderer to clarify possible misunderstanding on the tender.

The comparison criteria are listed below. They are all evaluated separately and finally the weighted scores are added. The tender with the highest total score is the winner of this competitive bidding.

Should the result indicate equal points for tenders at this stage the tender with the higher score for pricing (lowest price) will be the winner.

Comparison Criteria	Weight
Criterion A: experience, technical capacity and professional ability	
This criterion includes sub-categories score on a scale 1-5:	
- technical capability, history and reputation of the service provider	
- quality of the reference(s)	30%
 experience and depth of the project team. The total points from criterion A is the average of scores in sub-categories multiplied with the weight of criteria A. 	
Criterion B: credibility and quality of the plan	
This criterion includes sub-categories score on a scale 1-5:	
- familiarity of the service provider with the end-markets;	
- perimeter of the regulatory watch;	50%
- clarity and relevance of the method;	50/0
The total points from criterion B is the average of scores in sub-categories multiplied with the weight of criteria B.	
Criteria C: Price: (lowest price/tendered price) *100	20%



3.7 Other

The tenderer as well as Erdyn are responsible for their own expenses what comes to the participation of the tendering process and selection of the advisory service. A tenderer does not have a right to get compensation for the participation to the tendering process.