efsa
European Food Safety Authority

European Food Safety Authority ORIGINAL

GRANT AGREEMENT

AGREEMENT NUMBER – GP/EFSA/CONTAM/2013/04-GA1

Following the Call for proposals **GP/EFSA/CONTAM/2013/04** published on the 1st July 2013.

The European Food Safety Authority (hereinafter "the Authority"), established by Regulation (EC) No 178/2002[1] of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as last amended, with offices on Via Carlo Magno 1A, I-43126 Parma (Italy), represented by Mr Bernhard Url, Acting Executive Director,

of the one part,

and

Istituto Superiore di Sanità (ISS),
Viale Regina Elena, 299
00161 Rome
Italy

VAT number: 03657731000

hereinafter called "the co-ordinator", represented for the purposes of signature of the agreement by Dr. Fabrizio Oleari, legal representative,

and the following "co-beneficiaries":

- Partner n.1: Università Cattolica del Sacro cuore – UCSC
  Largo Agostino Gemelli, 1
  20123 Milan
  Italy
  VAT number: 02133120150

represented for the purposes of signature of the agreement by Dr. Fabrizio Oleari, legal representative of the co-ordinator, following the power of attorney in Annex VII.

[1] OJ L 31 of 01.02.2002

And

Partner n.2: Norvegian Institute of Public Health (NIPH)
Lovisenberggata 8
P.O.BOX 4404 Nydalen
N-0403 Oslo
Norway
VAT number: NO983744516MVA

represented for the purposes of signature of the agreement by Dr. Fabrizio Oleari, legal representative of the co-ordinator, following the power of attorney in Annex VIII.

And

Partner n.3: Norwegian Veterinary Institute (NVI)
Ullevålsveien, 68
0106 Oslo
Norway
VAT number: NO970955423

represented for the purposes of signature of the agreement by Dr. Fabrizio Oleari, legal representative of the co-ordinator, following the power of attorney in Annex VIII.

And

Partner n.4: University of Hull (UHULL)
Cottingham Road
HU6 7RX Hull
United Kingdom
VAT number: GB 162378304

represented for the purposes of signature of the agreement by Professor John Hay, legal representative.

hereinafter referred to collectively as “the beneficiaries”, and individually as “beneficiary” for the purposes of this Agreement where a provision applies without distinction between the coordinator or another beneficiary,

of the other part,

HAVE AGREED

the **Special Conditions, General Conditions** and **Annexes** below:

Annex I Call for proposals (including the rules on eligibility of costs)

Annex II Description of the project as presented in the application form submitted and approved by the Authority

Annex III Approved estimated budget of the project (comprising a consolidated version together with a breakdown of costs and incomes between each beneficiary)

Annex IV Financial statements and supporting financial documents

Annex V Monthly timesheet template

Annex VI Declaration on honour concerning Quality Assurance

Annex VII Partnership statement

Annex VIII Powers of attorney, for the co-beneficiaries

which form an integral part of this agreement, hereinafter referred to as ("the agreement").

The terms set out in the Special Conditions shall take precedence over those in the other parts of the agreement.

The terms of the General Conditions shall take precedence over those in the Annexes.

I – SPECIAL CONDITIONS

ARTICLE I.1 – PURPOSE OF THE GRANT

I.1.1 The Authority has decided to award a grant, under the terms and conditions set out in the Special Conditions, the General Conditions and the Annexes to the agreement, which the beneficiaries hereby declare that they have taken note of and accept, for the project entitled “Experimental study of deoxynivalenol biomarkers in urine” (hereinafter referred as "the project").

I.1.2 The beneficiaries accept the grant and undertake to do everything in their power to carry out the project as described in Annex II, acting on their own responsibility.

ARTICLE I.2 – ENTRY INTO FORCE OF THE AGREEMENT AND DURATION

I.2.1 The agreement shall enter into force on the date when the last party signs.

I.2.2 The project shall run for 12 months from the kick off meeting following the entry into force of the grant agreement. The above period shall be determined on the basis of calendar days.

ARTICLE I.3 – BREAKDOWN OF COSTS – FINANCING THE PROJECT

I.3.1 The total cost of the project is estimated at EUR **363.626,53** as shown in the approved estimated budget in Annex III. The approved estimated budget gives a detailed breakdown of the costs that are eligible for the Authority funding, those that are ineligible, under the terms of Article II.19, of any other costs that the project may entail, and of all incomes, so that incomes and costs balance.

I.3.2 The total eligible costs of the project for which the Authority grant is awarded are estimated at EUR **363.626,53** as shown in the approved estimated budget in Annex III.

Indirect costs are eligible for flat-rate funding of 10% of the total direct eligible costs, subject to the conditions laid down in Article II.19.3.

I.3.3 The Authority shall contribute a maximum of EUR **244.762,04** which is maximum ceiling of grant which can be obtained for this project from the Authority. The amount of the Authority grant is further limited to 90 % of the actually incurred eligible costs. The final amount of the grant shall be determined as specified in Article II.24, without prejudice to Article II.26.

For this project, the Authority does not finance the entire costs of it. The amounts and sources of co-financing other than from the Authority funds are set out in the approved estimated budget referred to in paragraph 1.

I.3.4 The co-ordinator may, in agreement with the co-beneficiaries, when carrying out the project, adjust the approved estimated budget by transfers between headings of eligible costs, provided that this adjustment of expenditure does not affect implementation of the project.

ARTICLE I.4 – PAYMENT ARRANGEMENTS

I.4.1 Pre-financing:

Within 30 days of the date when the last of the parties signs the agreement a pre-financing payment of EUR 97.904,82 shall be made to the co-ordinator representing 40 % of the amount specified in Article I.3.3.

I.4.2 Interim payment: NA

I.4.3 Payment of the balance

In order for the request for final payment to be admissible, it shall be submitted together with the written final report and accompanied by the final financial statement of costs actually incurred and incomes, using the form in Annex IV to be certified by the most senior accounting officer of the co-ordinator.

The Authority shall have 90 days to approve or reject written final report or to request additional supporting documents or information under the procedure laid down in Articles II.22.2 and II.23.4 and to make the payment. The Authority may suspend the period for payment in accordance with the procedure in Article II.23.5. In that case, the co-ordinator shall have 30 days to submit the additional information, supporting documents or a new written final report.

ARTICLE I.5 – SUBMISSION OF REPORTS AND OTHER DOCUMENTS

I.5.1 The provisions relating to the submission of the written reports are contained in Annex I.

ARTICLE I.6 – BANK ACCOUNT

I.6.1 All payments shall be made to the co-ordinator's bank account denominated in euros, as indicated below:

Name of bank: TESORERIA CENTRALE DELLO STATO – BANCA D'ITALIA
Address of branch: Via Dei Mille, 52 – 00185 ROMA - ITALIA
Precise denomination of the account holder: ISTITUTO SUPERIORE DI SANITA'
Full account number (including bank codes): 22349
IBAN account code: IT65 U 01000 03245 350200022349

I.6.2 Within 30 days of the day on which the bank account under I.6.1 has been credited, the co-ordinator shall transfer to the co-beneficiaries the amounts

corresponding to his participation in the project in accordance with his pro rata share of the estimated eligible costs as defined in the breakdown in Annex III when pre-financing payments are made, and their share of validated eligible costs actually incurred when other payments are made.

ARTICLE I.7 – GENERAL ADMINISTRATIVE PROVISIONS AND DATA CONTROLLER

I.7.1 Data controller

The entity acting as a data controller according to Article II.6 shall be François Monnart.

I.7.2. Any communication in connection with the agreement shall be in writing, indicating the reference number of the agreement, and shall be sent to the following addresses:

For the Authority:

European Food Safety Authority - EFSA
RASA – P&M Team
To the attention of Erika Cavalli
Via Carlo Magno 1/A
I – 43126 Parma

Ordinary mail shall be considered to have been received by the Authority on the date on which it is formally registered by EFSA unit responsible referred to above.

For the co-ordinator:
Prof Dr Carlo Brera
Istituto Superiore di Sanità (ISS),
Viale Regina Elena, 299
00161 Rome Italy
Carlo.brera@iss.it

ARTICLE I.8 – LAW APPLICABLE AND COMPETENT COURT

The grant agreement is governed by the terms of the agreement, the Union law, complemented, where necessary, by the national substantive law of Italy.

Any dispute between the parties in relation to the interpretation, application or validity of the grant agreement which cannot be settled amicably shall be brought before the General Court of the European Union.

ACTICLE I.9 – PROTECTION OF PERSONAL DATA

Refer to Article II. 6 under the General Conditions

ARTICLE I.10 – OTHER SPECIAL CONDITIONS

I.10.1. The co-ordinator shall submit the payment request, submitted in accordance with Article I.4, in euro.

The exchange rate to be used by the co-ordinator for conversion into EURO is the average of the monthly rates established by the European Commission and published on its website (http://ec.europa.eu/budget/inforeuro/index.cfm?fuseaction=home&Language=en) for the months covered by the declared reporting period for which the financial statements of costs actually incurred is being submitted.

I.10.2. In addition to the obligations stipulated in other provisions of this agreement as regards the eligibility of cost, the co-ordinator shall use the monthly timesheet, of which the template is attached as Annex V to this agreement. This is template must be used to record the type and amount of activities performed under the project and will serve as supporting document when verifying the eligibility of the staff costs. Non compliance with the obligation to fill out this timesheet shall be basis to consider the staff costs as ineligible.

ARTICLE I.11 – OTHER PROVISIONS

With reference to article II.4, the co-ordinator shall provide individual declarations of interest for new members in the project team or for those project team members whose interests declared on the occasion of signature of the grant agreement have substantially changed during the implementation of the grant agreement.

ARTICLE I.12 – ROLE OF THE BENEFICIARIES

I.12.1 The co-ordinator shall:

a) have full responsibility for ensuring that the project is implemented in accordance with the agreement;

b) be the intermediary for all communication between the co-beneficiaries and the Authority in accordance with Article I.7. Any claims that the Authority might have in respect of the agreement shall be addressed to, and answered by, the co-ordinator, save where specifically stated otherwise in the agreement;

c) be responsible for supplying all documents and information to the Authority which may be required under the agreement, in particular in relation to the requests for payment. The co-ordinator shall not delegate any part of this task to the co-beneficiaries or to any other party. Where information from the co-beneficiaries is required, the co-ordinator shall be responsible for obtaining and verifying this information and for passing it on to the Authority;

d) inform the co-beneficiaries of any event of which the co-ordinator is aware that is liable to substantially affect the implementation of the project;

e) establish the payment requests on behalf of the beneficiaries, detailing the exact share and amount assigned to each beneficiary, in accordance with the

agreement, the estimated eligible costs as foreseen in Annex III, and the actual costs incurred. All payments by the Authority are made to the bank account referred to in paragraph 1 of Article I.6;

g) where designated the sole recipient of payments on behalf of all of the beneficiaries, ensure that all the appropriate payments are made to the co-beneficiaries without unjustified delay in accordance with paragraph 3 of Article I.6 and shall inform the Authority of the distribution of the Authority's financial contribution between the co-beneficiaries and of the date of transfer;

h) be responsible, in the event of audits, checks or evaluations, as described in Article II.26, for providing all the necessary documents, including the accounts of the co-beneficiaries, the original accounting documents and signed copies of sub-contracts, if any have been concluded by the beneficiaries in accordance with Articles II.9 and II.10.

I.12.2 The co-beneficiaries shall:

a) agree upon appropriate arrangements between themselves and the co-ordinator for the proper performance of the project in respect of the requirements set out in the partnership statement annexed to the Agreement (Annex VII). The beneficiaries are deemed to have concluded this internal co-operation partnership statement annexed to the proposal regarding their internal operation and co-ordination. The partnership statement shall include all aspects necessary for the management and the implementation of the project, as it is reflected in detail in the proposal itself and in the approved estimated budget. The partnership statement, the proposal and the approved estimated budget are binding as regards the repartition of the tasks and the financial aspects. All modifications have to be requested to the Authority in writing and approved in advance by the Authority, except the transfers between headings of eligible costs in the approved estimated budget. In the latter case, the Authority's project officer needs only to be informed and to confirm that any adjustment of expenditure does not affect implementation of the project.

b) forward to the co-ordinator the data needed to draw up the reports, financial statements and other documents provided for in the agreement including its Annexes;

c) ensure that all information to be provided to EFSA is sent via the co-ordinator, save where the agreement specifically stipulates otherwise;

d) inform the co-ordinator immediately of any event liable to substantially affect or delay the implementation of the project of which they are aware;

e) inform the co-ordinator of transfers between items of eligible costs;

f) provide the co-ordinator with all the necessary documents in the event of audits, checks of evaluations, as described in Article II.26.

ARTICLE I.13 –SETTLEMENT OF DISPUTES WITH A NON EU BENEFICIARY

By derogation from Article II.18.2, where the beneficiary is legally established in a country other than a Member State of the European Union (the 'non EU beneficiary'), the Authority and/or the non EU beneficiary may bring before the Italian Courts any dispute between the Authority and the non EU beneficiary concerning the interpretation, application or validity of the Agreement, if such dispute cannot be settled amicably. In such case where one party (i.e. the Authority or the non EU beneficiary) has brought proceedings before the Italian Courts concerning the interpretation, application or validity of the Agreement, the other party may not bring a claim arising from the interpretation, application or validity of the Agreement in any other court than the Italian Courts already seized.

II – GENERAL CONDITIONS

PART A – LEGAL AND ADMINISTRATIVE PROVISIONS

ARTICLE II.1 – GENERAL OBLIGATIONS OF THE BENEFICIARIES

The beneficiaries shall:

(a) be responsible for carrying out the project in accordance with the terms and conditions of the Agreement;

(b) be responsible for complying with any legal obligations incumbent on it;

(c) inform the Authority immediately of any change likely to affect or delay the implementation of the project of which the beneficiaries are aware;

(d) inform the Authority immediately of any change in its legal, financial, technical, organisational or ownership situation and of any change in its name, address or legal representative;

ARTICLE II.2 – COMMUNICATIONS BETWEEN THE PARTIES

II.2.1 Form and means of communications

Any communication relating to the Agreement or to its implementation shall be made in writing (in paper or electronic form), shall bear the number of the Agreement and shall be made using the communication details identified in Article I.7.

Electronic communications shall be confirmed by an original signed paper version of that communication if requested by any of the parties provided that this request is submitted without unjustified delay. The sender shall send the original signed paper version without unjustified delay.

Formal notifications shall be made by registered mail with return receipt or equivalent, or by equivalent electronic means.

II.2.2 Date of communications

Any communication is deemed to have been made when it is received by the receiving party, unless the agreement refers to the date when the communication was sent.

Electronic communication is deemed to have been received by the receiving party on the day of successful dispatch of that communication, provided that it is sent to the addressees listed in Article I.7. Dispatch shall be deemed unsuccessful if the sending party receives a message of non-delivery. In this case, the sending party shall immediately send again such communication to any of the other addresses listed in Article I.7. In case of unsuccessful dispatch, the sending party shall not be held in breach of its obligation to send such communication within a specified deadline.

Mail sent to the Authority using the postal services is considered to have been received by the Authority on the date on which it is registered by the department identified in Article I.7.

Formal notifications made by registered mail with return receipt or equivalent, or by equivalent electronic means, shall be considered to have been received by the receiving party on the date of receipt indicated on the return receipt or equivalent.

ARTICLE II.3 – LIABILITY FOR DAMAGES

II.3.1 The Authority shall not be held liable for any damage caused or sustained by the beneficiaries, including any damage caused to third parties as a consequence of or during the implementation of the project.

II.3.2 Except in cases of force majeure, the beneficiaries shall compensate the Authority for any damage sustained by it as a result of the implementation of the project or because the project was not implemented or implemented poorly, partially or late.

ARTICLE II.4 - CONFLICT OF INTERESTS

II.4.1 The beneficiaries shall take all necessary measures to prevent any situation where the impartial and objective implementation of the Agreement is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ("conflict of interests").

II.4.2 Any situation constituting or likely to lead to a conflict of interests during the implementation of the Agreement shall be notified to the Authority, in writing, without delay. The beneficiaries shall immediately take all the necessary steps to rectify this situation. The Authority reserves the right to verify that the measures taken are appropriate and may require additional measures to be taken within a specified deadline.

ARTICLE II.5 – CONFIDENTIALITY

II.5.1 The Authority and the beneficiaries shall preserve the confidentiality of any information and documents, in any form, which are disclosed in writing or orally in relation to the implementation of the Agreement and which are explicitly indicated in writing as confidential.

II.5.2 The beneficiaries shall not use confidential information and documents for any reason other than fulfilling its obligations under the Agreement, unless otherwise agreed with the Authority in writing.

II.5.3 The Authority and the beneficiaries shall be bound by the obligations referred to in Articles II.5.1 and II.5.2 during the implementation of the Agreement and for a period of five years starting from the payment of the balance, unless:

(a) the concerned party agrees to release the other party from the confidentiality obligations earlier;

(b) the confidential information becomes public through other means than in breach of the confidentiality obligation through disclosure by the party bound by that obligation;

(c) the disclosure of the confidential information is required by law.

ARTICLE II.6 – PROCESSING OF PERSONAL DATA

II.6.1 Processing of personal data by the Authority

Any personal data included in the Agreement shall be processed by the Authority pursuant to Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

Such data shall be processed by the data controller identified in Article I.7 solely for the purposes of the implementation, management and monitoring of the Agreement, without prejudice to possible transmission to the bodies charged with the monitoring or inspection tasks in application of Union law.

The beneficiaries shall have the right of access to his/her personal data and the right to rectify any such data. Should the beneficiaries have any queries concerning the processing of his/her personal data, he/she shall address them to the data controller, identified in Article I.7.

The beneficiaries shall have the right of recourse at any time to the European Data Protection Supervisor.

II.6.2 Processing of personal data by the beneficiaries

Where the Agreement requires the processing of personal data by the beneficiaries, the beneficiaries may act only under the supervision of the data controller identified in Article I.7, in particular with regard to the purpose of the processing, the categories of data which may be processed, the recipients of the data and the means by which the data subject may exercise his or her rights.

The access to data that the beneficiaries grant to its personnel shall be limited to the extent strictly necessary for the implementation, management and monitoring of the Agreement.

The beneficiaries undertake to adopt appropriate technical and organisational security measures having regard to the risks inherent in the processing and to the nature of the personal data concerned, in order to:

(a) prevent any unauthorised person from gaining access to computer systems processing personal data, and especially:

  (i) unauthorised reading, copying, alteration or removal of storage media;

  (ii) unauthorised data input as well as any unauthorised disclosure, alteration or erasure of stored personal data;

  (iii) unauthorised persons from using data-processing systems by means of data transmission facilities;

(b) ensure that authorised users of a data-processing system can access only the personal data to which their access right refers;

(c) record which personal data have been communicated, when and to whom;

(d) ensure that personal data being processed on behalf of third parties can be processed only in the manner prescribed by the Authority;

(e) ensure that, during communication of personal data and transport of storage media, the data cannot be read, copied or erased without authorisation;

(f) design its organisational structure in such a way that it meets data protection requirements.

ARTICLE II.7 – VISIBILITY OF THE AUTHORITY FUNDING

II.7.1 Information on Authority funding and use of EFSA emblem

Unless the Authority requests or agrees otherwise, any communication or publication related to the project, made by the beneficiaries, including at conferences, seminars or in any information or promotional materials (such as brochures, leaflets, posters, presentations, etc.), shall indicate that the project has received funding from EFSA and shall display the EFSA emblem.

When displayed in association with another logo, the EFSA emblem must have appropriate prominence.

The obligation to display the EFSA emblem does not confer to the beneficiaries a right of exclusive use. The beneficiaries shall not appropriate the EFSA emblem or any similar trademark or logo, either by registration or by any other means.

For the purposes of the first, second and third subparagraphs and under the conditions specified therein, the beneficiaries are exempted from the obligation to obtain prior permission from the Authority to use the EFSA emblem.

II.7.2 Disclaimers excluding Authority responsibility

Any communication or publication related to the project, made by the beneficiaries in any form and using any means, shall indicate that it reflects only the author's view and that the Authority is not responsible for any use that may be made of the information it contains.

ARTICLE II.8 – PRE-EXISTING RIGHTS AND OWNERSHIP AND USE OF THE RESULTS (INCLUDING INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS)

II.8.1 Ownership/use of the results

II.8.1.1 Ownership of the results of the project, including industrial and intellectual property rights, and of the reports and other documents relating to it shall be vested in the beneficiaries.

II.8.1.2 Without prejudice to paragraph 1, the beneficiaries grant the Authority the right to make exclusive use of the results of the project, including the reports submitted by the beneficiaries, for a period of three years.

II.8.1.3 In compliance with paragraph 2 the beneficiaries can not make any use of the results of the project for the period of three years foreseen in paragraph 2 including the prohibition to divulge or disclose the results of the project.

II.8.2 Pre-existing industrial and intellectual property rights

Where industrial and intellectual property rights, including rights of third parties, exist prior to the conclusion of the Agreement, the co-ordinator shall establish a list which shall specify all rights of ownership and use of the pre-existing industrial and intellectual property rights and disclose it to the Authority at the latest before the commencement of implementation.

The beneficiaries shall ensure that them or their affiliated entities have all the rights to use any pre-existing industrial and intellectual property rights during the implementation of the Agreement.

II.8.3 Rights of use of the results and of pre-existing rights by the Authority

Without prejudice to Articles II.1, II.3 and II.8.1, the beneficiaries grant the Authority the right to use the results of the project for the following purposes:

(a) use for its own purposes, and in particular, making available to persons working for the Authority, other Union institutions, agencies and bodies and to Member States' institutions, as well as, copying and reproducing in whole or in part and in unlimited number of copies;

(b) distribution to the public, and in particular, publication in hard copies and in electronic or digital format, publication on the internet, including on the Europa website, as a downloadable or non-downloadable file, broadcasting by any kind of technique of transmission, public display or presentation, communication

through press information services, inclusion in widely accessible databases or indexes;

(c) translation;

(d) giving access upon individual requests without the right to reproduce or exploit, as provided for by Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Authority documents;

(e) storage in paper, electronic or other format;

(f) archiving in line with the document management rules applicable to the Authority;

(g) rights to authorise or sub-licence the modes of exploitation set out in points (b) and (c) to third parties.

Additional rights of use for the Authority may be provided for in the Special Conditions.

The co-ordinator and co-beneficiaries shall warrant that the Authority has the right to use any pre-existing industrial and intellectual property rights, which have been included in the results of the project. Unless specified otherwise in the Special Conditions, those pre-existing rights shall be used for the same purposes and under the same conditions applicable to the rights of use of the results of the project.

Information about the copyright owner shall be inserted when the result is divulged by the Authority. The copyright information shall read: "© – year – name of the copyright owner. All rights reserved. Licenced to the EFSA under conditions".

ARTICLE II.9 – AWARD OF CONTRACTS NECESSARY FOR THE IMPLEMENTATION OF THE PROJECT

II.9.1 Where the implementation of the project requires the procurement of goods, works or services, the beneficiaries shall award the contract to the tender offering best value for money or, as appropriate, to the tender offering the lowest price. In doing so, it shall avoid any conflict of interests.

Beneficiaries acting in their capacity of contracting authority within the meaning of Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts or contracting entity within the meaning of Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors shall abide by the applicable national public procurement rules.

II.9.2 The beneficiaries shall retain sole responsibility for carrying out the project and for compliance with the provisions of the Agreement. The beneficiaries shall

ensure that any procurement contract contains provisions stipulating that the contractor has no rights vis-à-vis the Authority under the Agreement.

II.9.3 The beneficiaries shall ensure that the conditions applicable to it under Articles II.3, II.4, II.5, II.8 and II.26 are also applicable to the contractor.

ARTICLE II.10 – SUBCONTRACTING OF TASKS FORMING PART OF THE PROJECT

II.10.1 A "subcontract" is a procurement contract within the meaning of Article II.9, which covers the implementation by a third party of tasks forming part of the project as described in Annex I.

II.10.2 The beneficiaries may subcontract tasks forming part of the project, provided that, in addition to the conditions specified in Article II.9 and the Special Conditions, the following conditions are complied with:

(a) subcontracting respects the eligibility of implementation contracts/subcontracting conditions as indicated in Annex I of this Grant Agreement;

(b) recourse to subcontracting is justified having regard to the nature of the project and what is necessary for its implementation;

(c) the estimated costs of the subcontracting are clearly identifiable in the estimated budget set out in Annex III;

(d) any recourse to subcontracting, if not provided for in Annex I, is communicated by the beneficiaries and approved by the Authority without prejudice to Article II.12.2;

(e) the beneficiaries ensure that the conditions applicable to it under Article II.7 are also applicable to the subcontractor.

ARTICLE II.11 - FINANCIAL SUPPORT TO THIRD PARTIES

II.11.1 Where the implementation of the project requires giving financial support to third parties, the beneficiaries shall give such financial support in accordance with the conditions specified in Annex I, which shall at least contain:

(a) the maximum amount of financial support, which shall not exceed EUR 60 000 for each third party except where the financial support is the primary aim of the project as specified in Annex I;

(b) the criteria for determining the exact amount of the financial support;

(c) the different types of activity that may receive financial support, on the basis of a fixed list;

(d) the definition of the persons or categories of persons which may receive financial support;

(e) the criteria for giving the financial support.

II.11.2 By way of derogation from Article II.11.1, in case the financial support takes the form of a prize, the beneficiaries shall give such financial support in accordance with the conditions specified in Annex I, which shall at least contain:

(a) the conditions for participation;

(b) the award criteria;

(c) the amount of the prize;

(d) the payment arrangements.

II.11.3 The beneficiaries shall ensure that the conditions applicable to it under Articles II.3, II.4, II.5, II.7, II.8 and II.26 are also applicable to the third parties receiving financial support.

ARTICLE II.12 – AMENDMENTS TO THE AGREEMENT

II.12.1 Any amendment to the Agreement shall be made in writing.

II.12.2 An amendment may not have the purpose or the effect of making changes to the Agreement which would call into question the decision awarding the grant or be contrary to the equal treatment of applicants.

II.12.3 Any request for amendment shall be duly justified and shall be sent to the other party in due time before it is due to take effect, and in any case one month before the end of the period set out in Article I.2.2, except in cases duly substantiated by the party requesting the amendment and accepted by the other party.

II.12.4 In case of an operating grant the period set out in Article I.2.2 shall not be extended via amendments.

II.12.5 Amendments shall enter into force on the date on which the last party signs or on the date of approval of the request for amendment.

Amendments shall take effect on a date agreed by the parties or, in the absence of such an agreed date, on the date on which the amendment enters into force.

ARTICLE II.13 – ASSIGNMENT OF CLAIMS FOR PAYMENTS TO THIRD PARTIES

II.13.1 Claims for payments of the co-ordinator against the Authority may not be assigned to third parties, except in duly justified cases where the situation warrants it.

The assignment shall only be enforceable against the Authority if it has accepted the assignment on the basis of a written and reasoned request to that effect made by the co-ordinator. In the absence of such acceptance, or in the event of failure to observe the terms thereof, the assignment shall have no effect on the Authority.

II.13.2 In no circumstances shall such an assignment release the co-ordinator from its obligations towards the Authority.

ARTICLE II.14 – FORCE MAJEURE

II.14.1 "*Force majeure*" shall mean any unforeseeable exceptional situation or event beyond the parties' control, which prevents either of them from fulfilling any of their obligations under the Agreement, which was not attributable to error or negligence on their part or on the part of subcontractors, affiliated entities or third parties involved in the implementation and which proves to be inevitable in spite of exercising all due diligence. Any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure, as well as labour disputes, strikes or financial difficulties cannot be invoked as *force majeure*.

II.14.2 A party faced with *force majeure* shall formally notify the other party without delay, stating the nature, likely duration and foreseeable effects.

II.14.3 The parties shall take the necessary measures to limit any damage due to *force majeure.* They shall do their best to resume the implementation of the project as soon as possible.

II.14.4 The party faced with *force majeure* shall not be held to be in breach of its obligations under the Agreement if it has been prevented from fulfilling them by *force majeure*.

ARTICLE II.15 – SUSPENSION OF THE IMPLEMENTATION OF THE PROJECT

II.15.1 Suspension of the implementation by the beneficiaries

The beneficiaries may suspend the implementation of the project or any part thereof if exceptional circumstances make such implementation impossible or excessively difficult, in particular in the event of *force majeure*. The co-ordinator shall inform the Authority without delay, giving all the necessary reasons and details and the foreseeable date of resumption.

Unless the Agreement is terminated in accordance with Article II.16.1 or points (b) or (c) of Article II.16.2.1, the co-ordinator shall, once the circumstances allow resuming

the implementation of the project, inform the Authority immediately and present a request for amendment of the Agreement as provided for in Article II.15.3.

II.15.2 Suspension of the implementation by the Authority

II.15.2.1 The Authority may suspend the implementation of the project or any part thereof:

(a) if the Authority has evidence that the beneficiary have committed substantial errors, irregularities or fraud in the award procedure or in the implementation of the Agreement or if the beneficiary/beneficiaries fail to comply with its obligations under the Agreement;

(b) if the Authority has evidence that the beneficiary have committed systemic or recurrent errors, irregularities, fraud or breach of obligations under other grants funded by the Union or the European Atomic Energy Community which were awarded to the beneficiary/beneficiaries under similar conditions, provided that those errors, irregularities, fraud or breach of obligations have a material impact on this grant; or

(c) if the Authority suspects substantial errors, irregularities, fraud or breach of obligations committed by the beneficiary in the award procedure or in the implementation of the Agreement and needs to verify whether they have actually occurred.

II.15.2.2 Before suspending the implementation the Authority shall formally notify the co-ordinator and where applicable the co-beneficiaries/ies of its/their intention to suspend, specifying the reasons thereof, and, in the cases referred to in points (a) and (b) of Article II.15.2.1, the necessary conditions for resuming the implementation. The co-ordinator and where applicable co-beneficiaries/ies shall be invited to submit observations within 30 calendar days from receipt of this notification.

If, after examination of the observations submitted by the co-ordinator and co-beneficiaries, the Authority decides to stop the suspension procedure, it shall formally notify the co-ordinator and where applicable the co-beneficiaries/ies thereof.

If no observations have been submitted or if, despite the observations submitted by the co-ordinator and where applicable by the co-beneficiaries/ies, the Authority decides to pursue the suspension procedure, it may suspend the implementation by formally notifying the co-ordinator thereof, specifying the reasons for the suspension and, in the cases referred to in points (a) and (b) of Article II.15.2.1, the definitive conditions for resuming the implementation or, in the case referred to in

point (c) of Article II.15.2.1, the indicative date of completion of the necessary verification.

The suspension shall take effect on the day of the receipt of the notification by the co-ordinator or on a later date, where the notification so provides.

In order to resume the implementation, the co-ordinator and co-beneficiaries shall endeavour to meet the notified conditions as soon as possible and shall inform the Authority of any progress made in this respect.

Unless the Agreement is terminated in accordance with Article II.16.1 or points (b), (h) or (i) of Article II.16.2.1, the Authority shall, as soon as it considers that the conditions for resuming the implementation have been met or the necessary verification, including on-the-spot checks, has been carried out, formally notify the co-ordinator thereof and invite the co-ordinator to present a request for amendment of the Agreement as provided for in Article II.15.3.

II.15.3 Effects of the suspension

If the implementation of the project can be resumed and the Agreement is not terminated, an amendment to the Agreement shall be made in accordance with Article II.12 in order to establish the date on which the project shall be resumed, to extend the duration of the project and to make any other modifications that may be necessary to adapt the project to the new implementing conditions.

The suspension is deemed lifted as from the date of resumption of the project agreed by the parties in accordance with the first subparagraph. Such a date may be before the date on which the amendment enters into force.

Any costs incurred by the beneficiaries, during the period of suspension, for the implementation of the suspended project or the suspended part thereof, shall not be reimbursed or covered by the grant.

The right of the Authority to suspend the implementation is without prejudice to its right to terminate the Agreement in accordance with Article II.16.2 and its right to reduce the grant or recover amounts unduly paid in accordance with Articles II.24.4 and II.25.

Neither party shall be entitled to claim compensation on account of a suspension by the other party.

ARTICLE II.16 – TERMINATION OF THE AGREEMENT

II.16.1 Termination of the Agreement by the beneficiaries

In duly justified cases the co-ordinator and co-beneficiaries may terminate the Agreement by having the co-ordinator formally notifying the Authority thereof, stating

clearly the reasons and specifying the date on which the termination shall take effect. The notification shall be sent before the termination is due to take effect.

If no reasons are given or if the Authority considers that the reasons exposed cannot justify the termination, it shall formally notify the co-ordinator, specifying the grounds thereof, and the Agreement shall be deemed to have been terminated improperly, with the consequences set out in the third subparagraph of Article II.16.3.

II.16.2 Termination of the Agreement by the Authority

II.16.2.1 The Authority may decide to terminate the Agreement in the following circumstances:

(a) if a change to the beneficiary's legal, financial, technical, organisational or ownership situation is likely to affect the implementation of the Agreement substantially or calls into question the decision to award the grant;

(b) if the beneficiary does not implement the project as specified in Annex I or fails to comply with another substantial obligation incumbent on it under the terms of the Agreement;

(c) in the event of *force majeure*, notified in accordance with Article II.14, or in the event of suspension by the beneficiary as a result of exceptional circumstances, notified in accordance with Article II.15, where resuming the implementation is impossible or where the necessary modifications to the Agreement would call into question the decision awarding the grant or would result in unequal treatment of applicants;

(d) if the beneficiary is declared bankrupt, is being wound up, is having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, is the subject of any other similar proceedings concerning those matters, or is in an analogous situation arising from a similar procedure provided for in national legislation or regulations;

(e) if the beneficiary or any related person, as defined in the second subparagraph, have been found guilty of professional misconduct proven by any means;

(f) if the beneficiary is not in compliance with its obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which it is established or in which the project is implemented;

(g) if the Authority has evidence that the beneficiary or any related person, as defined in the second subparagraph, have committed fraud, corruption, or are involved in a criminal organisation, money

laundering or any other illegal activity detrimental to the Union's financial interests;

(h) if the Authority has evidence that the beneficiary or any related person, as defined in the second subparagraph, have committed substantial errors, irregularities or fraud in the award procedure or in the implementation of the Agreement, including in the event of submission of false information or failure to submit required information in order to obtain the grant provided for in the Agreement; or

(i) if the Authority has evidence that the beneficiary has committed systemic or recurrent errors, irregularities, fraud or breach of obligations under other grants funded by the Union or the European Atomic Energy Community which were awarded to the beneficiary under similar conditions, provided that those errors, irregularities, fraud or breach of obligations have a material impact on this grant.

For the purposes of points (e), (g) and (h) "any related person" shall mean any natural person which has the power to represent the beneficiary or to take decisions on its behalf.

II.16.2.2 Before terminating the Agreement, the Authority shall formally notify the co-ordinator of its intention to terminate, specifying the reasons thereof and inviting the co-ordinator, within 45 calendar days from receipt of the notification, to submit observations and, in the case of point (b) of Article II.16.2.1, to inform the Authority about the measures taken to ensure that it continues to fulfil its obligations under the Agreement.

If, after examination of the observations submitted by the co-ordinator, the Authority decides to stop the termination procedure, it shall formally notify the co-ordinator thereof.

If no observations have been submitted or if, despite the observations submitted by the co-ordinator, the Authority decides to pursue the termination procedure, it may terminate the Agreement by formally notifying the co-ordinator thereof, specifying the reasons for the termination.

In the cases referred to in points (a), (b), (d) and (f) of Article II.16.2.1, the formal notification shall specify the date on which the termination takes effect. In the cases referred to in points (c), (e), (g), (h) and (i) of Article II.16.2.1, the termination shall take effect on the day following the date on which the formal notification was received by the co-ordinator.

II.16.3 Effects of termination

Where the Agreement is terminated, payments by the Authority shall be limited to the amount determined in accordance with Article II.24 on the basis of the eligible costs incurred by the beneficiaries and the actual level of implementation of the project on

the date when the termination takes effect. Costs relating to current commitments, which are not due for execution until after the termination, shall not be taken into account. The co-ordinator shall have 60 days from the date when the termination of the Agreement takes effect, as provided for in Articles II.16.1 and II.16.2.2, to produce a request for payment of the balance in accordance with Article II.22.2. If no request for payment of the balance is received within this time limit, the Authority shall not reimburse or cover any costs which are not included in a financial statement approved by it or which are not justified in a technical report approved by it. In accordance with Article II.25, the Authority shall recover any amount already paid, if its use is not substantiated by the technical reports and, where applicable, by the financial statements approved by the Authority.

Where the Authority, in accordance with point (b) of Article II.16.2.1, is terminating the Agreement on the grounds that the co-ordinator has failed to produce the request for payment and, after a reminder, has still not complied with this obligation within the deadline set out in Article II.22.3, the first subparagraph shall apply, subject to the following:

(a) there shall be no additional time period from the date when the termination of the Agreement takes effect for the co-ordinator to produce a request for payment of the balance in accordance with Article II.22.2; and

(b) the Authority shall not reimburse or cover any costs incurred by the beneficiaries up to the date of termination or up to the end of the period set out in Article I.2.2, whichever is the earlier, which are not included in a financial statement approved by it or which are not justified in a technical report approved by it.

In addition to the first and second subparagraphs, where the Agreement is terminated improperly by the co-ordinator or by a co-beneficiaries within the meaning of Article II.16.1, or where the Agreement is terminated by the Authority on the grounds set out in points (b), (e), (g), (h) and (i) of Article II.16.2.1, the Authority may also reduce the grant or recover amounts unduly paid in accordance with Articles II.24.4 and II.25, in proportion to the gravity of the failings in question and after allowing the co-ordinator and where relevant the co-beneficiaries to submit its observations.

Neither party shall be entitled to claim compensation on account of a termination by the other party.

ARTICLE II.17 – ADMINISTRATIVE AND FINANCIAL PENALTIES

II.17.1 By virtue of Articles 109 and 131(4) Regulation (EU, EURATOM) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and with due regard to the principle of proportionality, if the co-ordinator/co-beneficiaries has committed substantial errors, irregularities or fraud, has made false declarations in supplying required information or has failed to supply such information at the moment of the submission of the application or during the implementation of the grant, or has been found in serious breach of its obligations under the Agreement, it shall be liable to:

(a) administrative penalties consisting of exclusion from all contracts and grants financed by the Union budget for a maximum of five years from the date on which the infringement is established and confirmed following a contradictory procedure with the co-ordinator/co-beneficiaries; and/or

(b) financial penalties of 2% to 10% of the maximum amount of the grant set out in Article I.3.

In the event of another infringement within five years following the establishment of the first infringement, the period of exclusion under point (a) may be extended to 10 years and the range of the rate referred to in point (b) may be increased to 4% to 20%.

II.17.2 The Authority shall formally notify the co-ordinator and where applicable also the co-beneficiaries of any decision to apply such penalties.

The Authority is entitled to publish such decision under the conditions and within the limits specified in Article 109(3) of Regulation (EU, EURATOM) No 966/2012.

A project may be brought against such decision before the General Court of the European Union, pursuant to Article 263 Treaty on the Functioning of the European Union ("TFEU").

ARTICLE II.18 – APPLICABLE LAW, SETTLEMENT OF DISPUTES AND ENFORCEABLE DECISION

II.18.1 The Agreement is governed by the applicable Union law complemented, where necessary, by the law of Italy.

II.18.2 Pursuant to Article 272 TFEU, the General Court or, on appeal, the Court of Justice of the European Union, shall have sole jurisdiction to hear any dispute between the Authority and the beneficiaries concerning the interpretation, application or validity of this Agreement, if such dispute cannot be settled amicably.

II.18.3 By virtue of Article 299 TFEU, for the purposes of recoveries within the meaning of Articles II.25 or financial penalties, the Authority may adopt an enforceable decision to impose pecuniary obligations on persons other than States. A project may be brought against such decision before the General Court of the European Union pursuant to Article 263 TFEU.

PART B – FINANCIAL PROVISIONS

ARTICLE II.19 – ELIGIBLE COSTS

II.19.1 Conditions for the eligibility of costs

"Eligible costs" of the project are costs actually incurred by the beneficiaries which meet the following criteria:

(a) they are incurred in the period set out in Article I.2.2, with the exception of costs relating to the request for payment of the balance and the corresponding supporting documents referred to in Article II.22.2;

(b) they are indicated in the estimated budget set out in Annex III;

(c) they are incurred in connection with the project as described in Annex I and are necessary for its implementation;

(d) they are identifiable and verifiable, in particular being recorded in the accounting records of the beneficiary and determined according to the applicable accounting standards of the country where the beneficiary is established and with the usual cost accounting practices of the beneficiary;

(e) they comply with the requirements of applicable tax and social legislation; and

(f) they are reasonable, justified, and comply with the principle of sound financial management, in particular regarding economy and efficiency.

II.19.2 Eligible direct costs

"Direct costs" of the project are those specific costs which are directly linked to the implementation of the project and can therefore be attributed directly to it. They may not include any indirect costs.

To be eligible, direct costs shall comply with the conditions of eligibility set out in Article II.19.1.

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In particular, the following categories of costs are eligible direct costs, provided that they satisfy the conditions of eligibility set out in Article II.19.1 as well as the following conditions:

(a) the costs of staff working under an employment contract with the beneficiary and assigned to the project, comprising actual salaries plus social security contributions and other statutory costs included in the remuneration, provided that these costs are in line with the beneficiary's usual policy on remuneration; Those costs may include additional remuneration, including payments on the basis of supplementary contracts regardless of their nature, provided that it is paid in a consistent manner whenever the same kind of work or expertise is

required and independently from the source of funding used; including costs of the personnel of national administrations to the extent that they relate to the cost of activities which the relevant public authority would not carry out if the project concerned were not undertaken;

(b) costs of travel and related subsistence allowances, provided that these costs are in line with the beneficiary's usual practices on travel and do not exceed the scales approved annually by the European Commission;

(c) the purchase cost of equipment (new or second-hand), provided that it is written off linearly in accordance with the tax and accounting rules applicable to the beneficiary and generally accepted for items of the same kind. Only the portion of the equipment's depreciation corresponding to the duration of the project and the rate of actual use for the purposes of the project may be taken into account by the Authority, except where the nature and/or the context of its use justifies different treatment by the Authority;

(d) costs of consumables and supplies, provided that they are purchased in accordance with Article II.9 and are directly assigned to the project;

(e) costs arising directly from requirements imposed by the Agreement (dissemination of information, specific evaluation of the project, audits, translations, reproduction), including the costs of requested financial guarantees, provided that the corresponding services are purchased in accordance with Article II.9; Such costs may also include specific costs incurred by the co-ordinator for fulfilling his responsibilities in his capability of the body responsible for the overall management of the project and the co-ordination of the beneficiaries.

(f) costs entailed by subcontracts within the meaning of Article II.10, provided that the conditions laid down in that Article are met; including costs entailed by implementation contracts awarded by the beneficiaries for the purposes of carrying out the action/project, provided that the conditions laid down in the grant agreement or grant decision are met;

(g) value added tax ("VAT") where it is not recoverable under the applicable national VAT legislation and is paid by a beneficiary other than a non-taxable person as defined in the first subparagraph of Article 13(1) of Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax; unless specified otherwise in the Agreement;

(h) costs relating to external audits where required in support of the requests for payments;

II.19.3 Eligible indirect costs

"Indirect costs" of the project are those costs which are not specific costs directly linked to the implementation of the project and can therefore not be attributed directly to it. They may not include any costs identifiable or declared as eligible direct costs.

To be eligible, indirect costs shall represent a fair apportionment of the overall overheads of the beneficiary and shall comply with the conditions of eligibility set out in Article II.19.1.

Unless otherwise specified in the Article I.3, eligible indirect costs shall be declared on the basis of a flat rate of 10% of the total eligible direct costs.

II.19.4 Ineligible costs

In addition to any other costs which do not fulfill the conditions set out in Article II.19.1, the following costs shall not be considered eligible:

(a) return on capital;

(b) debt and debt service charges;

(c) provisions for losses or debts;

(d) interest owed;

(e) doubtful debts;

(f) exchange losses;

(g) costs of transfers from the Authority charged by the bank of a beneficiary;

(h) costs declared by the beneficiary in the framework of another project receiving a grant financed from the Union budget (including grants awarded by a Member State and financed from the Union budget and grants awarded by other bodies than the Authority for the purpose of implementing the Union budget); in particular, indirect costs shall not be eligible under a grant for a project awarded to the beneficiary when it already receives an operating grant financed from the Union budget during the period in question;

(i) contributions in kind from third parties;

(j) excessive or reckless expenditure;

(k) recoverable VAT.

ARTICLE II.20 – IDENTIFIABILITY AND VERIFIABILITY OF THE AMOUNTS DECLARED

II.20.1 Reimbursement of actual costs

Where, in accordance with Article I.3, the grant takes the form of the reimbursement of actual costs, the beneficiary must declare as eligible costs the costs it actually incurred for the project.

If requested to do so in the context of the checks or audits described in Article II.26, the beneficiary must be able to provide adequate supporting documents to prove the costs declared, such as contracts, invoices and accounting records. In addition, the beneficiary's usual accounting and internal control procedures must permit direct reconciliation of the amounts declared with the amounts recorded in its accounting statements as well as with the amounts indicated in the supporting documents.

ARTICLE II.21 – BUDGET TRANSFERS

Without prejudice to Article II.10 and provided that the project is implemented as described in Annex I, the beneficiary is allowed to adjust the estimated budget set out in Annex III, by transfers between the different budget categories, without this adjustment being considered as an amendment of the Agreement within the meaning of Article II.12. However the Authority's project officer needs to informed in order to confirm that this adjustment of expenditure does not affect implementation of the project.

ARTICLE II.22 – TECHNICAL AND FINANCIAL REPORTING – REQUESTS FOR PAYMENT AND SUPPORTING DOCUMENTS

II.22.1 Requests for further pre-financing payments and supporting documents

Where, in accordance with Article I.4, the pre-financing shall be paid in several instalments and where Article I.4 provides for a further pre-financing payment subject to having used all or part of the previous instalment, the beneficiary may submit a request for a further pre-financing payment once the percentage of the previous instalment specified in Article I.4 has been used.

Where, in accordance with Article I.4, the pre-financing shall be paid in several instalments and where Article I.4 provides for a further pre-financing payment at the end of a reporting period, the co-ordinator shall submit a request for a further pre-financing payment within 60 days following the end of each reporting period for which a new pre-financing payment is due.

In both cases, the request shall be accompanied by the following documents:

(a) a progress report on implementation of the project ("technical report on progress");

(b) a statement on the amount of the previous pre-financing instalment used to cover costs of the project ("statement on the use of the previous pre-financing instalment"), and

(c) where required by Article I.4, a financial guarantee.

II.22.2 Requests for interim payments or for payment of the balance and supporting documents

The co-ordinator shall submit a request for an interim payment or for payment of the balance within 60 days following the end of each reporting period for which, in accordance with Article I.4, an interim payment or the payment of the balance is due.

This request shall be accompanied by the following documents:

(a) an interim report ("interim technical report") or, for the payment of the balance, a final report on implementation of the project ("final technical report); the interim or final technical report must contain the information needed to justify the eligible costs declared, as well as information on subcontracting as referred to in Article II.10.2(d);

(b) an interim financial statement ("interim financial statement") or, for the payment of the balance, a final financial statement ("final financial statement"); the interim or final financial statements must include a breakdown of the amounts claimed by the co-ordinator; it must be drawn up in accordance with the structure of the estimated budget and detail the amounts for each of the forms of grant set out in Article I.3 for the reporting period concerned;

(c) only for the payment of the balance, a summary financial statement ("summary financial statement"); this statement must include a breakdown of the amounts declared or requested by the co-ordinator, aggregating the financial statements already submitted previously and indicating the receipts referred to in Article II.24.3.2 for the co-ordinator;

(d) a certificate on the financial statements and underlying accounts ("certificate on the financial statements") where the following conditions are met:

(i) in case of a grant for an action, where such a certificate is required by Article I.4 or where both the total contribution in the form of reimbursement of actual costs as referred to in Article I.3 is at least EUR 750 000 and the co-ordinator requests a reimbursement in that form of at least EUR 325 000 (when adding all previous reimbursements in that form for which a certificate on the financial statements has not been submitted),

This certificate shall be produced by an approved auditor or, in case of public bodies, by a competent and independent public officer and drawn up. It shall certify that the costs declared in the interim or final financial statement by the co-ordinator for the categories of costs reimbursed in accordance with Article I.3 are real, accurately recorded and eligible in accordance with the Agreement. In

addition, for the payment of the balance, it shall certify that all the receipts referred to in Article II.24.3.2 have been declared; and

(e) where required by Article I.4, an operational verification report ("operational verification report"), produced by an independent third party approved by the Authority.

This report shall state that the actual implementation of the project as described in the interim or final report complies with the conditions set out in the Agreement.

The co-ordinator shall certify that the information provided in the request for interim payment or for payment of the balance is full, reliable and true. It shall also certify that the costs incurred can be considered eligible in accordance with the Agreement and that the request for payment is substantiated by adequate supporting documents that can be produced in the context of the checks or audits described in Article II.26. In addition, for the payment of the balance, it shall certify that all the receipts referred to in Article II.24.3.2 have been declared.

II.22.3 Non-submission of documents

Where the co-ordinator has failed to submit a request for interim payment or payment of the balance accompanied by the documents referred to above within 60 days following the end of the corresponding reporting period and where the co-ordinator still fails to submit such a request within 60 days following a written reminder sent by the Authority, the Authority reserves the right to terminate the Agreement in accordance with Article II.16.2.1(b), with the effects described in the second and the third subparagraphs of Article II.16.3.

II.22.4 Currency for requests for payment and financial statements and conversion into euro

Requests for payment and financial statements shall be drafted in euro in line with the provisions under Article I.10.

ARTICLE II.23 – PAYMENTS AND PAYMENT ARRANGEMENTS

II.23.1 Pre-financing

The pre-financing is intended to provide the co-ordinator with a float.

Without prejudice to Articles II.23.5 and II.23.6, where Article I.4 provides for a pre-financing payment upon entry into force of the Agreement, the Authority shall pay to the co-ordinator within 30 days following that date or, where required by Article I.4 , following receipt of the financial guarantee.

Where payment of pre-financing is conditional on receipt of a financial guarantee, the financial guarantee shall fulfill the following conditions:

(a) it is provided by a bank or an approved financial institution or, at the request of the co-ordinator and acceptance by the Authority, by a third party;

(b) the guarantor stands as first-call guarantor and does not require the Authority to have recourse against the principal debtor (i.e. the co-ordinator); and

(c) it provides that it remains in force until the pre-financing is cleared against interim payments or payment of the balance by the Authority and, in case the payment of the balance is made in the form of a debit note, three months after the debit note is notified to the co-ordinator. The Authority shall release the guarantee within the following month.

II.23.2 Further pre-financing payments

Without prejudice to Articles II.23.5 and II.23.6, on receipt of the documents referred to in Article II.22.1, the Authority shall pay to the co-ordinator the new pre-financing instalment within 60 days.

Where the statement on the use of the previous pre-financing instalment submitted in accordance with Article II.22.1 shows that less than 70% of the previous pre-financing instalment paid has been used to cover costs of the project, the amount of the new pre-financing to be paid shall be reduced by the difference between the 70% threshold and the amount used.

II.23.3 Interim payments

Interim payments are intended to reimburse or cover the eligible costs incurred for the implementation of the project during the corresponding reporting periods.

Without prejudice to Articles II.23.5 and II.23.6, on receipt of the documents referred to in Article II.22.2, the Authority shall pay to the co-ordinator the amount due as interim payment within the time limit specified in Article I.4.

This amount shall be determined following approval of the request for interim payment and of the accompanying documents and in accordance with the fourth, fifth and sixth subparagraphs. Approval of the request for interim payment and of the accompanying documents shall not imply recognition of the regularity or of the authenticity, completeness and correctness of the declarations and information it contains.

Without prejudice to any ceiling set out in Article I.4. and to Articles II.23.5 and II.23.6, the amount due as interim payment shall be determined as follows:

(a) where, in accordance with Article I.3, the grant takes the form of the reimbursement of eligible costs, the amount obtained by application of the reimbursement rate specified in that Article to the eligible costs of the project approved by the Authority for the concerned reporting period and the corresponding categories of costs, for the co-ordinator;

Where Article I.4 requires that the interim payment clears all or part of the pre-financing paid to the co-ordinator, the amount of pre-financing to be cleared shall be

deducted from the amount due as interim payment, as determined in accordance with the fourth and fifth subparagraphs.

II.23.4 Payment of the balance

The payment of the balance, which may not be repeated, is intended to reimburse or cover after the end of period set out in Article I.2 the remaining part of the eligible costs incurred by the co-ordinator for its implementation. Where the total amount of earlier payments is greater than the final amount of the grant determined in accordance with Article II.24, the payment of the balance may take the form of a recovery as provided for by Article II.25.

Without prejudice to Articles II.23.5 and II.23.6, on receipt of the documents referred to in Article II.22.2, the Authority shall pay the amount due as the balance within the time limit specified in Article I.4.

This amount shall be determined following approval of the request for payment of the balance and of the accompanying documents and in accordance with the fourth subparagraph. Approval of the request for payment of the balance and of the accompanying documents shall not imply recognition of the regularity or of the authenticity, completeness and correctness of the declarations and information it contains.

The amount due as the balance shall be determined by deducting, from the final amount of the grant determined in accordance with Article II.24, the total amount of pre-financing and interim payments already made.

II.23.5 Suspension of the time limit for payment

The Authority may suspend the time limit for payment specified in Article I.4 at any time by formally notifying the co-ordinator that its request for payment cannot be met, either because it does not comply with the provisions of the Agreement, or because the appropriate supporting documents have not been produced, or because there is doubt about the eligibility of the costs declared in the financial statement.

The co-ordinator shall be notified as soon as possible of any such suspension, together with the reasons thereof.

Suspension shall take effect on the date when notification is sent by the Authority. The remaining payment period shall start to run again from the date on which the requested information or revised documents are received or the necessary further verification, including on-the-spot checks, is carried out. Where the suspension exceeds two months, the co-ordinator may request a decision by the Authority on whether the suspension is to be continued.

Where the time limit for payment has been suspended following the rejection of one of the technical reports or financial statements provided for by Article II.22 and the new report or statement submitted is also rejected, the Authority reserves the right to terminate the Agreement in accordance with Article II.16.2.1(b), with the effects described in Article II.16.3.

II.23.6 Suspension of payments

The Authority may, at any time during the implementation of the Agreement, suspend the pre-financing payments, interim payments or payment of the balance:

(a) if the Authority has evidence that the beneficiary has committed substantial errors, irregularities or fraud in the award procedure or in the implementation of the grant, or if the beneficiary fails to comply with its obligations under the Agreement;

(b) if the Authority has evidence that the beneficiary has committed systemic or recurrent errors, irregularities, fraud or breach of obligations under other grants funded by the Union or by the European Atomic Energy Community which were awarded to the beneficiary under similar conditions, provided that those errors, irregularities, fraud or breach of obligations have a material impact on this grant; or

(c) if the Authority suspects substantial errors, irregularities, fraud or breach of obligations committed by the beneficiary in the award procedure or in the implementation of the Agreement and needs to verify whether they have actually occurred.

Before suspending payments, the Authority shall formally notify the co-ordinator of its intention to suspend payments, specifying the reasons thereof and, in the cases referred to in points (a) and (b) of the first subparagraph, the necessary conditions for resuming payments. The beneficiary shall be invited to make any observations within 30 calendar days from receipt of this notification.

If, after examination of the observations submitted by the beneficiary, the Authority decides to stop the procedure of payment suspension, the Authority shall formally notify the co-ordinator thereof.

If no observations have been submitted or if, despite the observations submitted by the beneficiary, the Authority decides to pursue the procedure of payment suspension, it may suspend payments by formally notifying the co-ordinator, specifying the reasons for the suspension and, in the cases referred to in points (a) and (b) of the first subparagraph, the definitive conditions for resuming payments or, in the case referred to in point (c) of the first subparagraph, the indicative date of completion of the necessary verification.

The suspension of payments shall take effect on the date when the notification is sent by the Authority.

In order to resume payments, the beneficiary shall endeavour to meet the notified conditions as soon as possible and shall inform the Authority of any progress made in this respect.

The Authority shall, as soon as it considers that the conditions for resuming payments have been met or the necessary verification, including on-the-spot checks, has been carried out, formally notify the co-ordinator thereof.

During the period of suspension of payments and without prejudice to the right to suspend the implementation in accordance with Article II.15.1 or to terminate the Agreement in accordance with Article II.16.1, the beneficiary is not entitled to submit any requests for payments and supporting documents referred to in Article II.22.

The corresponding requests for payments and supporting documents may be submitted as soon as possible after resumption of payments or may be included in the first request for payment due following resumption of payments in accordance with the schedule laid down in Article I.4.

II.23.7 Notification of amounts due

The Authority shall formally notify the amounts due, specifying whether it is a further pre-financing payment, an interim payment or the payment of the balance. In the case of payment of the balance, it shall also specify the final amount of the grant determined in accordance with Article II.24.

II.23.8 Interest on late payment

On expiry of the time limits for payment specified in Articles I.4., II.23.1 and II.23.2, and without prejudice to Articles II.23.5 and II.23.6, the co-ordinator is entitled to interest on late payment at the rate applied by the European Central Bank for its main refinancing operations in euros ("the reference rate"), plus three and a half points. The reference rate shall be the rate in force on the first day of the month in which the time limit for payment expires, as published in the C series of the *Official Journal of the European Union*.

The first subparagraph shall not apply where the beneficiary is a Member State of the Union, including regional and local government authorities and other public bodies acting in the name and on behalf of the Member State for the purpose of this Agreement.

The suspension of the time limit for payment in accordance with Articles II.23.5 or of payment by the Authority in accordance with Article II.23.6 may not be considered as late payment.

Interest on late payment shall cover the period running from the day following the due date for payment, up to and including the date of actual payment as established in Article II.23.10. The interest payable shall not be considered for the purposes of determining the final amount of grant within the meaning of Article II.24.3.

By way of derogation from the first subparagraph, when the calculated interest is lower than or equal to EUR 200, it shall be paid to the co-ordinator only upon request submitted within two months of receiving late payment.

II.23.9 Currency for payments

Payments by the Authority shall be made in euro.

II.23.10 Date of payment

Payments by the Authority shall be deemed to be effected on the date when they are debited to the Authority's account.

II.23.11 Costs of payment transfers

Costs of the payment transfers shall be borne in the following way:

(a) costs of transfer charged by the bank of the Authority shall be borne by the Authority;

(b) costs of transfer charged by the bank of the co-ordinator shall be borne by the co-ordinator;

(c) all costs of repeated transfers caused by one of the parties shall be borne by the party which caused the repetition of the transfer.

ARTICLE II.24 – DETERMINING THE FINAL AMOUNT OF THE GRANT

II.24.1 Calculation of the final amount

Without prejudice to Articles II.24.2, II.24.3 and II.24.4, the final amount of the grant shall be determined as follows:

(a) where, in accordance with Article I.3, the grant takes the form of the reimbursement of eligible costs, the amount obtained by application of the reimbursement rate specified in that Article to the eligible costs of the project approved by the Authority for the corresponding categories of costs, for the beneficiary;

II.24.2 Maximum amount

The total amount paid to the co-ordinator by the Authority may in no circumstances exceed the maximum amount specified in Article I.3.

Where the amount determined in accordance with Article II.24.1 exceeds this maximum amount, the final amount of the grant shall be limited to the maximum amount specified in Article I.3.

II.24.3 No-profit rule and taking into account of receipts

II.24.3.1 The grant may not produce a profit for the beneficiary, unless specified otherwise in the Special Conditions. "Profit" shall mean a surplus of the receipts over the eligible costs of the project.

II.24.3.2 The receipts to be taken into account are the receipts established, generated or confirmed on the date on which the request for payment of the balance is drawn up by the beneficiary, which fall within one of the following two categories:

(a) income generated by the project; or
(b) financial contributions specifically assigned by the donors to the financing of the eligible costs of the project reimbursed by the Authority in accordance with Article I.3.

II.24.3.3 The following shall not be considered as a receipt to be taken into account for the purpose of verifying whether the grant produces a profit for the beneficiary:

(a) financial contributions referred to in point (b) of Article II.24.3.2, which may be used by the beneficiary to cover costs other than the eligible costs under the Agreement;
(b) financial contributions referred to in point (b) of Article II.24.3.2, the unused part of which is not due to the donor at the end of the period set out in Article I.2;

II.24.3.4 The eligible costs to be taken into account are the eligible costs approved by the Authority for the categories of costs reimbursed in accordance with I.3.

II.24.3.5 Where the final amount of the grant determined in accordance with Articles II.24.1 and II.24.2 would result in a profit for the beneficiary, the profit shall be deducted in proportion to the final rate of reimbursement of the actual eligible costs of the project approved by the Authority for the categories of costs referred to in Article I.3. This final rate shall be calculated on the basis of the final amount of the grant in the form referred to in Article I.3, as determined in accordance with Articles II.24.1 and II.24.2.

II.24.4 Reduction for poor, partial or late implementation

If the project is not implemented or is implemented poorly, partially or late, the Authority may reduce the grant initially provided for, in line with the actual implementation of the project according to the terms laid down in the Agreement.

ARTICLE II.25 – RECOVERY

II.25.1 Financial responsibility

Where an amount is to be recovered under the terms of the Agreement, the co-ordinator shall repay the Authority the amount in question. The co-ordinator shall be responsible for the repayment of any amount unduly paid by the Authority.

II.25.2 Recovery procedure

Before recovery, the Authority shall formally notify the co-ordinator of its intention to recover the amount unduly paid, specifying the amount due and the reasons for recovery and inviting the co-ordinator to make any observations within a specified period.

If no observations have been submitted or if, despite the observations submitted by the co-ordinator, the Authority decides to pursue the recovery procedure, the Authority may confirm recovery by formally notifying to the co-ordinator a debit note ("debit note"), specifying the terms and the date for payment.

If payment has not been made by the date specified in the debit note, the Authority shall recover the amount due:

(a) by offsetting it against any amounts owed to the co-ordinator by the Union or the European Atomic Energy Community (Euratom) ("offsetting"); in exceptional circumstances, justified by the necessity to safeguard the financial interests of the Union, the Authority may recover by offsetting before the due date; the co-ordinator's prior consent shall not be required; an action may be brought against such offsetting before the General Court of the European Union pursuant to Article 263 TFEU;

(b) by drawing on the financial guarantee where provided for in accordance with Article I.4 ("drawing on the financial guarantee");

(c) by taking legal action in accordance with Article II.18.2 or with the Special Conditions or by adopting an enforceable decision in accordance with Article II.18.3.

II.25.3 Interest on late payment

If payment has not been made by the date set out in the debit note, the amount due shall bear interest at the rate established in Article II.23.8. Interest on late payment shall cover the period running from the day following the due date for payment, up to and including the date when the Authority actually receives payment in full of the outstanding amount.

Any partial payment shall first be appropriated against charges and interest on late payment and then against the principal.

II.25.4 Bank charges

Bank charges incurred in connection with the recovery of the sums owed to the Authority shall be borne by the co-ordinator except where Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC applies.

ARTICLE II.26 – CHECKS, AUDITS AND EVALUATION

II.26.1 Technical and financial checks or audits and interim and final evaluations

The Authority may carry out technical and financial checks and audits in relation to the use of the grant. It may also check the statutory records of the beneficiary for the purpose of periodic assessments of actual costs.

Information and documents provided in the framework of checks or audits shall be treated on a confidential basis.

In addition, the Authority may carry out interim or final evaluation of the impact of the project measured against the objective of the Authority's objectives concerned.

Checks, audits or evaluations made by the Authority may be carried out either directly by its own staff or by any other outside body authorised to do so on its behalf.

Such checks, audits or evaluations may be initiated during the implementation of the Agreement and for a period of five years starting from the date of payment of the balance. This period shall be limited to three years in case the maximum amount specified in Article I.3 is not more than EUR 60 000.

The check, audit or evaluation procedure shall be deemed to be initiated on the date of receipt of the letter of the Authority announcing it.

II.26.2 Duty to keep documents

The beneficiary shall keep all original documents, especially accounting and tax records, stored on any appropriate medium, including digitalised originals when they are authorised by its national law and under the conditions laid down therein, for a period of five years starting from the date of payment of the balance.

This period shall be limited to three years if the maximum amount specified in Article I.3 is not more than EUR 60 000.

The periods set out in the first and second subparagraphs shall be longer if there are on-going audits, appeals, litigation or pursuit of claims concerning the grant, including in the case referred to in Article II.26.7. In such cases, the beneficiary shall keep the documents until such audits, appeals, litigation or pursuit of claims are closed.

II.26.3 Obligation to provide information

The beneficiary shall provide any information, including information in electronic format, requested by the Authority, or by any other outside body authorised by it, in the context of checks, audits or evaluations as referred to in Article II.26.1

In case the beneficiary does not comply with the obligation set out in the first subparagraph, the Authority may consider:

(a) any cost insufficiently substantiated by information provided by the beneficiary as ineligible.

II.26.4 On-the-spot visits

During an on-the-spot visit, the beneficiary shall allow Authority staff and outside personnel authorised by the Authority to have access to the sites and premises where the project is or was carried out, and to all the necessary information, including information in electronic format.

It shall ensure that the information is readily available at the moment of the on-the-spot visit and that information requested is handed over in an appropriate form.

In case the beneficiary refuses to provide access to the sites, premises and information in accordance with the first and second subparagraphs, the Authority may consider:

(a) any cost insufficiently substantiated by information provided by the beneficiary as ineligible.

II.26.5 Contradictory audit procedure

On the basis of the findings made during the audit, a provisional report ("draft audit report") shall be drawn up. It shall be sent by the Authority or its authorised representative to the beneficiary, which shall have 30 days from the date of receipt to submit observations. The final report ("final audit report") shall be sent to the beneficiary within 60 days of expiry of the time limit for submission of observations.

II.26.6 Effects of audit findings

On the basis of the final audit findings, the Authority may take the measures which it considers necessary, including recovery of all or part of the payments made by it, in accordance with Article II.25.

In the case of final audit findings made after the payment of the balance, the amount to be recovered shall correspond to the difference between the revised final amount of the grant, determined in accordance with Article II.24, and the total amount paid to the beneficiary under the Agreement for the implementation of the project.

II.26.7 Correction of systemic or recurrent errors, irregularities, fraud or breach of obligations

II.26.7.1 The Authority may take all measures which it considers necessary, including recovery of all or part of the payments made by it under the Agreement, in accordance with Article II.25, where the following conditions are fulfilled:

(a) the beneficiary is found, on the basis of an audit of other grants awarded to it under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant; and

(b) the final audit report containing the findings of the systemic or recurrent errors, irregularities, fraud or breach of obligations is

received by the beneficiary within the period referred to in Article II.26.1.

II.26.7.2 The Authority shall determine the amount to be corrected under the Agreement:

(a) wherever possible and practicable, on the basis of costs unduly declared as eligible under the Agreement.

For that purpose, the beneficiary shall revise the financial statements submitted under the Agreement taking account of the findings and resubmit them to the Authority within 60 days from the date of receipt of the final audit report containing the findings of the systemic or recurrent errors, irregularities, fraud or breach of obligations.

In the case of systemic or recurrent errors, irregularities, fraud or breach of obligations found after the payment of the balance, the amount to be recovered shall correspond to the difference between the revised final amount of the grant, determined in accordance with Article II.24 on the basis of the revised eligible costs declared by the beneficiary and approved by the Authority, and the total amount paid to the beneficiary under the Agreement for the implementation of the project;

(b) where it is not possible or practicable to quantify precisely the amount of ineligible costs under the Agreement, by extrapolating the correction rate applied to the eligible costs for the grants for which the systemic or recurrent errors or irregularities have been found.

The Authority shall formally notify the extrapolation method to be applied to the beneficiary, which shall have 60 days from the date of receipt of the notification to submit observations and to propose a duly substantiated alternative method.

If the Authority accepts the alternative method proposed by the beneficiary, it shall formally notify the beneficiary thereof and determine the revised eligible costs by applying the accepted alternative method.

If no observations have been submitted or if the Authority does not accept the observations or the alternative method proposed by the beneficiary, the Authority shall formally notify the beneficiary thereof and determine the revised eligible costs by applying the extrapolation method initially notified to the beneficiary.

In the case of systemic or recurrent errors, irregularities, fraud or breach of obligations found after the payment of the balance, the amount to be recovered shall correspond to the difference between the revised final amount of the grant, determined in accordance with Article II.24 on the basis of the revised eligible costs after

extrapolation, and the total amount paid to the beneficiary under the Agreement for the implementation of the project; or

(c) where ineligible costs cannot serve as a basis for determining the amount to be corrected, by applying a flat rate correction to maximum amount of the grant specified in Article I.3 or part thereof, having regard to the principle of proportionality.

The Authority shall formally notify the flat rate to be applied to the beneficiary, which shall have 60 days from the date of receipt of the notification to submit observations and to propose a duly substantiated alternative flat rate.

If the Authority accepts the alternative flat rate proposed by the beneficiary, it shall formally notify the beneficiary thereof and correct the grant amount by applying the accepted alternative flat rate.

If no observations have been submitted or if the Authority does not accept the observations or the alternative flat rate proposed by the beneficiary, the Authority shall formally notify the beneficiary thereof and correct the grant amount by applying the flat rate initially notified to the beneficiary.

In the case of systemic or recurrent errors, irregularities, fraud or breach of obligations found after the payment of the balance, the amount to be recovered shall correspond to the difference between the revised final amount of the grant after flat-rate correction and the total amount paid to the beneficiary under the Agreement for the implementation of the project.

II.26.8 Checks and inspections by OLAF

The European Anti-Fraud Office (OLAF) shall have the same rights as the Authority, notably right of access, for the purpose of checks and investigations.

By virtue of Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Authority in order to protect the European Unions' financial interests against fraud and other irregularities and Regulation (EC) No 1073/1999 of the European Parliament and the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF), OLAF may also carry out on-the-spot checks and inspections in accordance with the procedures laid down by Union law for the protection of the financial interests of the Union against fraud and other irregularities.

Where appropriate, OLAF findings may lead to recovery by the Authority.

II.26.9 Checks and audits by the European Court of Auditors

The European Court of Auditors shall have the same rights as the Authority, notably right of access, for the purpose of checks and audits.

European Food Safety Authority
ORIGINAL

SIGNATURES
For the co-ordinator
Istituto Superiore di Sanità

Dr. Fabrizio Oleari

Done at Rome, on 13.12.2013

For the Authority
Acting Director of RASA

Marta Hugas

Done at Parma, on 17/12/13

[redacted]

For the Co-beneficiary 4

University of Hull (UHULL)
Professor John Hay

signature: J. M. Hay

Done at Hull on 9 December 2013

In triplicate in English

Annex I Call for proposals (including the rules on eligibility of costs)

CALL FOR PROPOSALS AND GUIDE FOR APPLICANTS

Call reference: GP/EFSA/CONTAM/2013/04
Call title: Experimental study of deoxynivalenol biomarkers in urine

[OBLIGATORY CONSORTIUM]

Restricted to the list adopted by EFSA Management Board according to article 36 of European Parliament and Council Regulation (EC) No 178/2002

Provide EFSA with feedback:
If, as an economic operator, you considered applying to this call for proposals but finally decided not to do so, your feedback and reasoning for such a decision would be very much appreciated. You should address your feedback to the EFSA contact point indicated in this document. EFSA will process your feedback so as to improve the quality of its future grant calls.

TABLE OF CONTENT:

1. ABOUT THIS CALL FOR PROPOSALS

1.1 LEGAL FRAMEWORK AND APPLICABLE TEXTS

Article 36 of the European Parliament and Council Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety foresees the possibility to financially support a networking of organisations operating in the fields within the EFSA's mission.

On the 19th December 2006 the Management Board, acting on a proposal from the Executive Director, drew up a list of competent organisations designated by the Member States which may assist EFSA, either individually or in networks, with its mission. This list is regularly updated by Management Board.

Article 5 of the Commission Regulation (EC) No 2230/2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the EFSA's mission specifies that the financial support to the networking organisations shall take the form of grants awarded in accordance with the EFSA's financial regulation and implementing rules.

The present Call for proposal and guide for applicants (hereinafter referred to as "the Call") is governed by the Regulation No 966/2012 of the European Parliament and of the Council of 25 October 2012 (OJ L 298, 26.10.2012, p.1) (hereinafter referred to as "EU Financial Regulation") and Commission Delegated Regulation C(2012)7507 on the rules of application of Regulation (EU) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union, adopted on 29 October 2012 (hereinafter referred to as "Rules of Application of EU Financial Regulation").

This call is launched following the 2013 EFSA annual work programme for grants adopted on 14/06/2012 and it is published at EFSA webpage: http://www.efsa.europa.eu/en/art36grants/docs/art36grants2013.pdf.

1.2 CONTEXT AND SCIENTIFIC BACKGROUND OF THE CALL

Deoxynivalenol (DON) is a widespread mycotoxin that is produced by Fusarium spp. and belongs to the group of type B trichothecenes. It contaminates predominantly grains and grain-based products and causes gastro-intestinal problems, immunosuppression and interferences with reproduction and development of humans and animals.
Recent studies have demonstrated that consumption of DON-contaminated grain-based products is associated with the presence of DON and its metabolites (e.g. DON-glucuronide) in human urine. The available data show that the main fraction of this mycotoxin is excreted in the urine. DON is detectable also in serum in high amounts immediately after ingestion, but is rapidly cleared from the blood stream. So far, two major metabolites of DON have been identified in mammals: DON glucuronide (DON-G) and de-epoxy deoxynivalenol, also known as DOM-1. Methods with high sensitivity have been developed and applied for precise quantification of DON and/or its metabolites in urine samples (e.g. Turner et al., 2008)[1]. Hence, DON and its metabolites in urine could serve as appropriate biomarkers of human exposure to this mycotoxin.
Therefore, the present call for proposals aims at the preparation of a study on the concentrations of relevant DON biomarkers in human urine samples collected from different geographic regions in Europe to possibly serve as supporting information to the CONTAM Panel for future risk assessment for DON.

[1]Turner PC, Burley VJ, Rothwell JA, White KLM, Cade JE and Wild CP, 2008. Dietary wheat reduction decreases the level of urinary deoxynivalenol in UK adults. Journal of Exposure Science and Environmental Epidemiology, 18, 392–399

1.3 OBJECTIVES OF THE CALL FOR PROPOSALS

This call for proposals aims at obtaining representative data of the levels of appropriate deoxynivalenol biomarkers of exposure in human urine samples collected from different regions in Europe and analysed by a highly sensitive and precise method such as LC-MS. In order to achieve the objectives, the beneficiary shall perform the following tasks:

1. To elaborate a protocol for collecting urine samples from human volunteers that shall comply with the following requirements:

    a. The samples shall be taken from at least 3 different European countries (preferably not from neighbouring countries);

    b. At least 200 samples (100 volunteers, each providing 2 samples for two consecutive days) shall be taken from each country;

    c. A written and approved informed consent shall be obtained from all the volunteers participating;

    d. Ethical approval shall be obtained from the relevant authorities;

    e. Sampling shall be representative for the European population considering age and gender.

    f. The selection of different groups of the population (children, pregnant women, vegetarians) is considered as an asset.

2. To collect the samples;

    a. First morning urine samples shall be collected.

    b. Each sample should be accompanied by detailed information taken from the participants in relation to:

        i. Type and quantity of the food consumed. This should be obtained by an appropriately designed and tested semi-quantitative Food Frequency Questionnaire (FFQ), which shall be harmonised between participating countries. The food list in the FFQ shall specifically include food categories to permit the capture of food sources of DON with a focus on the amount and type of cereals and cereal-based products. The food classification shall be done in accordance with EFSA's Food Classification System FoodEx[2] (EFSA to provide the detailed Food Classification System). The FFQ should be designed to obtain information about the food frequency and semi-quantitative dietary intake consumed during the previous week or month. Within the FFQ more detailed information should be included on the intake of the selected food groups during the first day of the urine sampling and the day before.

        ii. Gender

        iii. Age

        iv. And possible background information relevant to the experimental work is considered as an asset.

3. To analyse the collected samples using a validated method based on state of the art analytical techniques such as LC-MS and that has sensitivity comparable to currently available methods in the literature[1].

[2] EFSA (European Food Safety Authority), 2011. Evaluation of the FoodEx, the food classification system applied to the development of the EFSA Comprehensive European Food Consumption Database. The EFSA Journal, 1970, 27 pp.

4. To prepare an Interim and Final External Scientific Report, a database providing the results of the analyses carried out for human urine samples and a database providing the information from the FFQ. The Interim and Final External Scientific Reports as well as the databases will be prepared in line with the time schedule reported in 1.4 of the present call for proposal.

   The Final as well as the Interim Scientific Reports shall be written in English and follow the template structure provided by EFSA and EFSA citation Standards[3]. The Final External Scientific Report shall contain the following information from the experimental study:

   - The justification of the biomarker/ biomarkers of DON exposure selected for the analysis;
   - The justification of the choice and the description of the analytical method applied;
   - Detailed information of the method's performance characteristics;
   - The description of the sampling procedure applied;
   - Detailed description of the sample preparation applied;
   - The concentrations of DON and DON metabolites in the individual urine samples expressed as both corrected and uncorrected for creatinine;
   - The result of each individual urine sample shall be accompanied by the corresponding information from the FFQ;
   - Common statistical descriptors (e.g. mean, median, standard deviation) of the measured concentrations in urine;
   - Statistical analysis of the results of the FFQ and related DON and DON metabolites concentrations in urine;
   - An evaluation of the reliability of the results from the experimental study and the related uncertainties;

   Two databases will be generated. The database with the results of the analyses carried out for human urine samples shall be written in English and shall follow the latest version of EFSA Guidance on Standard Sample Description[4] and shall be submitted via DCM's (Dietary and Chemical Monitoring Unit) call for continuous collection of chemical contaminants occurrence data. The database including the results from the FFQ will be delivered to EFSA as a MS Excel database and shall be written in English. The data in both databases shall be linked via a sample identification.

1.4 MEETINGS, REPORTING AND PAYMENTS

Below mentioned meetings with EFSA are foreseen:

1. **Kick off meeting (1 day physical meeting, held at EFSA premises)**: It is regarded as the start of the project. It takes place not later than 1 month after the entry into force of the grant agreement. At this meeting, details of the project will be discussed and the objectives, the final report structure and timeframe will be clarified. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.

   The presence at kick-off meeting of a beneficiary's staff member responsible for administrative/finance issues of the project is advised. This is because the understanding by beneficiary of the grant principles and related financial reporting requirements (declaration and documentation of incurred costs) will significantly ease and speed up the financial management of the grant agreement, both for EFSA and the beneficiary.

[3] To be provided by EFSA after the signature of the grant agreement.

[4] Available on the EFSA website: http://www.efsa.europa.eu/en/datex/datexsubmitdata.htm

2. **Interim tele-meeting N.1 will be held 1 week after the submission of the interim report 1**: The purpose of this meeting is to discuss the first interim report as well as any problems or difficulties **(technical or financial)** encountered during the project. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.
   An additional interim tele-meeting could be included during the project development if needed.

3. **Final meeting (1 day physical meeting, held at EFSA premises) will be held 1 month before the end of the project. The purpose of this meeting is to discuss the draft final report as well as any problems or difficulties (technical or financial) encountered during the project.**

Below mentioned reports must be drafted in the English language and **will be** published by EFSA. The reports will include a full description of the experimental protocols, a clear and full description of the experimental results and the conclusions drawn from the studies.

1. **Interim report**: Six months after the start date of the project (the kick off meeting) **a written interim report** must be submitted to EFSA one week before the interim meeting. The written interim report must describe the progress of the project and the results already achieved. It must contain the results of tasks 1, 2 and 3 of the project.

2. **Draft final report and draft databases: Eleven months** after the start of the project (the kick off meeting) and one week before the final meeting, a **written draft final report and draft databases** must be submitted to EFSA**.**

3. **The final report and final databases: Twelve months after** the start date of the project (the kick off meeting) **a final report** must be submitted to EFSA. The final report shall contain all the parts specified above in '1.3. Objectives of the call for proposals' and the modifications agreed for the interim report and the draft final report during the previous interim meeting and final meeting. The scientific report shall follow the template structure provided by EFSA and EFSA citation standards[3]. The final report shall be submitted in electronic format (Word file). The dataset generated in the experimental studies shall be also delivered to EFSA. Two databases will be generated. The database with the results of the analyses carried out for human urine samples shall be written in English and shall follow the latest version of EFSA Guidance on Standard Sample Description[5] and shall be submitted via DCM's (Dietary and Chemical Monitoring Unit) call for continuous collection of chemical contaminants occurrence data. The database including the results from the FFQ will be delivered to EFSA as a MS Excel database and shall be written in English. The data in both databases shall be linked via a sample identification. The final databases shall be submitted not later than twelve months from the beginning of the project. The final databases shall contain all the modifications agreed in the final meeting and after submission of the draft database.

Please note that all reporting, minutes, outcome of the discussions could be submitted at EFSA's discretion to EFSA's Panel and WG members.

			Month												
	Signature of the grant agreement 0	**Start of the project 1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**End of the Project 13**	**16**
Deliverables								Interim Report (to be submitted one week before interim meeting)					Draft final report+ draft database (to be submitted one week before Final meeting)	Final Report + Final Databases	
Meetings		Kick-off meeting (1 month after signature of the grant agreement)						Interim meeting					Final Meeting		

[5] Available on the EFSA website: http://www.efsa.europa.eu/en/datex/datexsubmitdata.htm

Payments	Pre-financing														Final payment

1.5 STRUCTURE OF THE PROPOSAL

The applicant shall provide, in the proposal, **using the EFSA STANDARD APPLICATION FORM (in part 2.1)**, beside other requested information, a description of **the methodology** it proposes to achieve the objectives of the call and to deliver the expected deliverables and to execute successfully the project. In the proposal, the applicant shall also describe **the involvement of various partners and the task division between the proposed team members**, and also indicate a detailed and realistic **project timeline (WHEN)**, which must be in any case in line with the meeting and reporting requirements of this call.

In particular, the applicant must describe in detail the proposed approach including the following information:

1) A detailed description of the used analytical method, including:
   a. Justification of the method chosen which should be a sensitive chromatographic method such as LC-MS validated for the analysis of DON and DON metabolites and that has a sensitivity comparable to methods that have recently been published in the literature, e.g. Turner et al., 2008[1]
   b. justification of the DON biomarker/biomarkers selected;
   c. storing procedures for the urine samples before and after sample pre-treatment;
   d. sample pre-treatment and sample preparation steps;
   e. instrumental determination of DON and DON metabolites including calibrants and the instrumentation to be used;
   f. the quality control of the analytical method;

2) A validation report (including type of calibration, limit of detection, limit of quantification, recovery, repeatability, within-laboratory reproducibility, ruggedness) obtained from the validation of the proposed method for the analysis of DON biomarkers in human urine. The validation report should also include the estimation of the measurement uncertainty. In addition, the validation report shall compare the performance of the proposed method to those methods recently reported for DON biomarkers in the literature.

3) Example on reporting of the results expressed as both corrected and uncorrected for creatinine.

4) A sampling plan for a representative collection of samples from European countries that includes:
   a. a justification of the choice and number of countries where the human urine samples will be collected;
   c. the number of urine samples to be analysed;
   d. information on how the volunteers will be selected and how it will be achieved that the samples are representative for the European population (e.g. gender, age, dietary habits)
   e) information on the selected sub-group of the population to be participated in the survey: e.g. vegetarians, children, pregnant women);

5) Proposed protocol for the collection of dietary information with a semi-quantitative FFQ including compilation, testing in the local language, harmonisation between countries, protocol for checking completed FFQs at return (completeness, correctness) and how the personnel will be trained.

This information will be used for the assessment of the award criterion 1 (1.1 and 1.2)

6) Description of quality control mechanisms to be put in place to guarantee high quality of deliverables.

This information will be used for the assessment of the award criterion 2.1

7) Description of the measures put in place in order to assure a sound project management, including the way the various tasks are distributed within the team; internal communication inside the project team, and communication with EFSA;

This information will be used for the assessment of the award criterion 2.2

8) A clear indication of the timelines for the completion of the project's tasks providing detailed milestones for each task (e.g. via a project Gantt chart) as well as a description of the risks that might be foreseen per each

individual task, and a description of the measures put in place to assure that the deadlines for providing deliverables are met. In addition, a contingency plan in case deviations from the project programme is required.

This information will be used for the assessment of the award criterion 2.3

1.6 AMOUNT AVAILABLE FOR EFSA GRANT AND MAIN GRANT PRINCIPLES

The EFSA grant co-financing rate will equal up to **90%** of the total eligible project costs, provided that EFSA grant doesn't exceed **300.000 €** which is the maximum grant which might be received from EFSA for this project. The applicant is free to ask for EFSA grant co-financing rate lower than 90%. EFSA grant will not be awarded for more than the amount requested. **EFSA intends to fund 1 proposal.** EFSA reserves the right not to award all the funds available.

The total amount of estimated eligible costs, which serves as a basis for calculation of the EFSA grant, will be verified by EFSA during evaluation of received proposals. If **RULES ON ELIGIBILITY OF COSTS** (annex 1 of this Call) were not correctly applied by the applicant, when establishing the Estimated budget, EFSA reserves the right to impose the necessary corrections.

Main grant principles:
In compliance with the Financial Regulation and its Implementing Rules, the proposals must comply with the following principles:

- **Co-financing**: co-financing from a source other than EU budget is required. The project costs not covered by EFSA grant must be financed from the applicant or partners` resources. In addition to these resources, only financial contributions from other public bodies are allowed. Contributions from private sector are not allowed.
- **Non-profit**: EFSA grant may not have the purpose or effect of producing a profit for the applicant or partner organisation. Profit is defined as a surplus of the receipts over the eligible costs incurred by the beneficiary, when request is made for payment of the balance. Where a profit is made, EFSA shall be entitled to recover the percentage of the profit corresponding to the Union contribution to the eligible costs actually incurred by the beneficiary to carry out the project. The verification of the non-profit rule doesn't apply to low value grants, i.e. grants </= 60.000 €.
- **Non-retroactivity**: the costs eligible for financing must be incurred after the entry into force of the Grant agreement.
- **Non-cumulative:** A project may only receive one grant from the EU budget. In no circumstances shall the same costs be financed twice by the Union budget. To ensure this, applicants shall indicate the sources and amounts of Union funding received or applied for the same project or part of the project or for its functioning during the same financial year as well as any other funding received or applied for the same project.

1.7 FURTHER INFORMATION

Any questions regarding the Call may be sent to **RASA.PROCUREMENT@efsa.europa.eu** no later than by 25/09/2013, clearly indicating the Call reference. Replies will be given no later than by 04/10/2013. Questions together with the answers will be published on the EFSA website.

2. SUBMITTING PROPOSALS

2.1 APPLICATION FORM

The proposal must be submitted using the **EFSA STANDARD APPLICATION FORM** (hereinafter referred to as "Application form") together with all the requested annexes correctly completed. Application form may be downloaded from the EFSA website http://www.efsa.europa.eu, where this Call for Proposals is published. Applicant organisation (hereinafter referred to as "applicant") must complete and submit the application form together with all indicated annexes.

The applicant should keep strictly to the format of the application form and fill in the paragraphs and the pages in order. A duly authorised representative of the applicant must sign the application form. The application form must be completed carefully and clearly so that it can be properly assessed. The applicant should be precise and provide enough detail to ensure the application form is clear and complete. Any major inconsistency with the submission requirements (see point 3.1) may lead to the immediate rejection of the proposal.

Please note that, in submitting a proposal, the applicant accepts the procedures and conditions as described in this Call and in the documents referred to in it.

2.2 LANGUAGE OF THE PROPOSAL AND THE SUPPORTING DOCUMENTS

Proposals may be submitted in any official language of the European Union. Please note that EFSA working language is English and accordingly the submission of proposals in English will speed up the evaluation process.

Please note that a number of supporting documents is required in support of the proposal. These supporting documents are an integral part of the proposal. For more information on the relevant supporting documents to be submitted with the proposal, please refer to part 3 of this Call. Where these supporting documents are in a language other than English, in order to facilitate and speed up the evaluation, it would be appreciated if a reliable translation of the relevant parts of the documents into English is provided with the proposal.

The EFSA may ask for further clarification in the course of the evaluation.

2.3 FINAL DEADLINE AND ADDRESS FOR SUBMISSION OF PROPOSALS

The final deadline for submission of proposals is **15/10/2013.**

You can submit your proposal:

- either by registered mail or by courier service to the below address (the post office stamp or the date of the deposit slip from the courier service will be considered as proof of the date of submission). In this case, you are requested to send a message to EFSA's dedicated e-mail address (**RASA.PROCUREMENT@efsa.europa.eu**) shortly stating that you have sent a proposal. Any proposal posted after the final deadline will automatically be rejected.
- or by hand to the below address, not later than 17.00 hours (Italy time)**.** Any proposal hand delivered after the final deadline will automatically be rejected.

The proposal must be sent to the following postal address:

European Food Safety Authority - EFSA
RASA Planning and Monitoring Team
GP/EFSA/CONTAM/2013/04
Via Carlo Magno 1/A
I – 43126 Parma

Information of expected duration of procedure – time to grant:

- Applicants will be informed on the decision regarding their application at the latest by 6 months since the deadline for submission of proposals.
- Signature of grant agreement will take place at the latest by 3 months since the successful applicant/s have been informed on the decision on their application.

2.4 HOW TO SEND THE PROPOSALS

Your proposal must be submitted **using the double envelope system**. The outer envelope should be sealed with adhesive tape, signed across the seal and carry the following information:

- the Call reference: **GP/EFSA/CONTAM/2013/04**
- the title of the Call: **Study of deoxynivalenol biomarkers in urine**
- the name of the applicant;
- the indication: "Proposal - Not to be opened by EFSA reception – to be passed without opening to the RASA – Planning and Monitoring Team";
- the address for submission of proposal (see above);
- the posting date (if applicable) should be legible on the outer envelope.

Proposal must include: The completed Application form (including all documents as indicated in Part 2 of the Application Form under the Checklist) in 1 original paper version and 1 CD containing the complete set of documents as submitted on paper. This electronic version must be identical to the paper version. In case of any discrepancies between the electronic and original paper version, the latter will prevail. All documents presented by the applicant become the property of EFSA and are deemed confidential.

3. SELECTING PROPOSALS

No modification to the application is allowed once the deadline for submission of proposals has elapsed. However, if there is a need to clarify certain aspects or for the correction of clerical mistakes, EFSA may contact the applicant for this purpose during the evaluation process.

An Evaluation Committee will be established in accordance with article 133 of the Financial Regulation and article 204 of its Implementing Rules in order to evaluate the submitted proposals. EFSA intends to finalise the evaluation of proposals within 6 months since the final deadline for submission of proposals. In compliance with article 133 (3) of the Financial Regulation, the applicant will be informed in writing of the decision on their proposal. Please note that EFSA has the right not to award a grant and to cancel the procedure at any time before the signature of the Grant agreement without any compensation to be paid to the applicant.

Evaluation will proceed in 5 steps:

1. verification of compliance with all submission requirements (see 3.1)
2. eligibility criteria (see 3.2)
3. exclusion criteria (see 3.3)
4. selection criteria (see 3.4)
5. award criteria (see 3.5)

If the proposal fails at any step it is automatically excluded from further evaluation.

3.1 VERIFICATION OF SUBMISSION REQUIREMENTS

The following will be assessed:

- The final deadline for submission of proposals: If this deadline has not been respected the proposal will automatically be rejected.
- The proposal is submitted on Application form and is duly signed by the authorised representative of the applicant. If the applicant did not submit the proposal using the Application form or if this form is not signed then the proposal may be rejected on that sole basis.
- The proposal is complete, including all supporting documents. If any of the requested information/documents is missing or is not complete the proposal may be rejected on that sole basis.

The proposal which meets all the submission requirements will be considered admissible and will pass to the next stage of evaluation process – verification of eligibility criteria.

3.2 ELIGIBILITY CRITERIA

Eligible applicants:

Applicants should apply as a consortium with partners established for the purpose of implementation of the project. The applicant is responsible for identifying consortium partners.

Both applicant and partners must comply with the essential condition of being on the list of competent organisations designated by the Member States in accordance with Art 36 of Regulation (EC) 178/2002 and Commission Regulation (EC) 2230/2004. This list is regularly updated by EFSA Management Board. You may consult the list of competent organization at this link: http://www.efsa.europa.eu/en/networks/art36.htm.

Applicant may not submit more than 1 proposal under this Call

Documents to be provided on support of eligibility:

- **LEGAL ENTITY FORM** (download template here) to be completed and signed by the applicant, and by partner/s. In case of public bodies this legal entity form should be provided together with a copy of the resolution or decision establishing the public company/body, or other official document establishing the public law entity. In case of private bodies an extract from the official journal, copy of articles of association, extract of trade or association register, certificate of liability to VAT (if, as in certain countries, the trade register number and VAT number are identical, only one of these documents is required).
- **FINANCIAL IDENTIFICATION FORM** (download template here) to be completed and signed by the applicant.

Please note that you don't have to submit legal entity form and/or the financial identification form if it/they has/have already been submitted to EFSA under another procurement or grant procedure and provided that this/these document(s) is/are still valid. In this case, please clearly indicate in the application the reference of the call under which the document(s) was/were submitted to EFSA.

Both applicant and the partners must participate in the project both financially and intellectually.

Regarding the applicant, please note the following:

- There may be only one applicant per project;
- The applicant must submit the proposal on behalf of consortium to EFSA;
- The applicant must act as the intermediary for any communications between the partners and EFSA;
- The applicant shall be liable vis-à-vis EFSA for the correct and timely fulfilment of the obligations of the partners, and receive and answer all claims EFSA might have in relation to the performance of the action;
- The applicant shall inform EFSA and the partners of any event they are aware of that is liable to substantially affect the implementation of the project;
- The applicant participates in the project, for which its costs are borne;
- The applicant shall request and receive all payments made by EFSA, and shall be responsible for distributing them among the partners.

Regarding the partner organisations, please note the following:

- Partners participate in the project, for which their costs are borne;
- Partners shall forward to the applicant the data needed to draw up the reports, financial statements and other documents provided for in the Grant agreement;
- Partners shall immediately inform the applicant of any event liable to substantially affect or delay the implementation of the project.

As mentioned in point 3.2.1 above, the partners must satisfy the same eligibility criteria as the applicant organisation.

The Grant agreement will be signed between EFSA, the applicant and the partners. In the case of selection of its proposal, the applicant will become the Coordinator-Beneficiary (hereinafter referred to as "the Coordinator") and its possible partners will become the Co-beneficiaries within the framework of the Grant agreement. For the purposes of the proposal, it is required that the applicant and his partners provide EFSA with **PARTNERSHIP STATEMENT** defining the technical/intellectual and financial involvement of each of them. Each organisation (applicant and all partners) must sign this partnership statement.
Should a member of a consortium already be either directly or indirectly financially supported by the EU budget, its costs, direct or indirect, are not eligible under the present project, unless adequate proof is provided to EFSA that there is no double financing of costs.

Additional document to be provided:

- **PARTNERSHIP STATEMENT** defining the intellectual and financial involvement of each member of the consortium (applicant and partners) signed individually by each member of consortium. **No template is provided by EFSA.**

Eligibility of implementation contracts/subcontracting:
Where the implementation of the project requires the award of procurement contracts (implementation contracts), the beneficiary must award the contract to the bid offering best value for money or the lowest price (as appropriate), avoiding conflicts of interests and retain the documentation for the event of an audit.

Entities acting in their capacity of contracting authorities in the meaning of Directive 2004/18/EC6 or contracting entities in the meaning of Directive 2004/17/EC[7] shall abide by the applicable national public procurement rules.

Sub-contracting, i.e. the externalisation of specific tasks or activities which form part of the project as described in the proposal must satisfy the conditions applicable to any implementation contract (as specified above) and in addition to them the following conditions:

[6] Directive 2004/18/EC on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts.

[7] Directive 2004/17/EC coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors.

- Recourse to the award of sub-contracts must be justified with regard to the nature of the project and what is necessary for its implementation;
- Project management, organisation or any core tasks cannot be subcontracted;
- Subcontracting may only be used to subcontract ancillary and assistance related tasks.
- The tasks intended to be subcontracted and the corresponding estimated costs must be set out in the Estimated budget and approved by EFSA before the signature of the Grant agreement;
- In case subcontracting needs are identified after the Grant Agreement signature: Any recourse to the award of sub-contracts while the project is in progress, if not envisaged from the outset in the proposal, is subject to prior authorisation in writing by the EFSA through an amendment.
- The Coordinator and the possible Co-beneficiaries retain sole responsibility for implementing the project and complying with the provision of the Grant agreement;
- The Coordinator and the possible Co-beneficiaries undertake to ensure that the conditions applicable to them as regards responsibility, conflict of interests, ownership and use of results, confidentiality, publicity, transfer of claims, and controls and audits also apply to the sub-contractor.

Please note that sub-contractors are not consortium partners. Subcontractors are organisations formally contracted by the applicant or its possible partners to carry out specific tasks. Cost of subcontracting is borne by the applicant and/or the possible partners and the subcontractor doesn't contribute financially to the project.

External expertise to the project can be provided only under the following conditions:

- External experts should be recruited, also temporarily, based on an employment contract and the payment for expert should be based on a monthly salary slip as contrary to the invoice (i.e.: the expert does not issue invoices for carrying out the tasks foreseen, but is recruited by the applicant/partner and he/she receives a monthly salary for his/her work);
- Subcontracting - may be used only for ancillary and assistance related tasks.

Eligibility of actions:
As defined in part 1 of this Call. The application may not envisage provision of financial support to third parties.

Eligibility implementation period:
Activities may not start before the grant agreement signature by both parties and must be executed in the deadlines stipulated in part 1 of this Call.

Eligibility of costs:
Please refer to Annex 1 of this Call – Rules on eligibility of the costs..

3.3 EXCLUSION CRITERIA

Exclusion from participation:
Applicants will be excluded from participating in the call for proposals procedure if they are in any of the following situations:

- they are bankrupt or being wound up, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are the subject of proceedings concerning those matters, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
- they or persons having powers of representation, decision making or control over them have been convicted of an offence concerning their professional conduct by a judgment of a competent authority of a Member State which has the force of res judicata;
- they have been guilty of grave professional misconduct proven by any means which the contracting authority can justify including by decisions of the EIB and international organisations;
- they are not in compliance with their obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the RAO or those of the country where the grant agreement is to be performed;
- they or persons having powers of representation, decision making or control over them have been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organisation, money laundering or any other illegal activity, where such an illegal activity is detrimental to the Union's financial interests;
- they are currently subject to an administrative penalty referred to in Article 109(1) of EU Financial Regulation.

Exclusion from award:
Applicants will not be granted financial assistance if, in the course of the grant award procedure, they:

- are subject to a conflict of interest;
- are guilty of misrepresentation in supplying the information required by the Commission as a condition of participation in the grant award procedure or fail to supply this information;
- find themselves in one of the situations of exclusion, referred above.

Applicants must sign a declaration on their honour certifying that they are not in one of the exclusion situations referred to in the Articles 106(1) and 107 to 109 of EU Financial Regulation.

Please note that, according to Article 200 of the Rules of Application of EU Financial Regulation, financial or administrative penalties, or both, may be imposed on applicants who have made false declarations or substantial errors, or committed irregularities or fraud, in accordance with the conditions laid down in Article 145 of Rules of Application of EU Financial Regulation. Such financial or administrative penalties, or both, may also be imposed on beneficiaries who have been found in serious breach of their contractual obligations.

Document to be provided by the applicant and partner(s):

- **THE DECLARATION ON HONOUR (template available at EFSA's website as published together with this Call for Proposals)** to be completed and signed separately by the applicant and by each (of its) partner(s). This declaration covers both exclusion criteria and financial and operational capacity selection criteria.

3.4 SELECTION CRITERIA

The selection criteria are used to evaluate **the financial and operational capacity** of the applicant's and its partners.

Financial capacity of applicants and partners:
The applicant and its possible partners must have stable and sufficient financial resources to:

1. maintain their activity throughout the period during which the project is being carried out, and
2. participate in its funding.

Documents to be provided by the applicant and partner(s):

- **THE DECLARATION ON HONOUR** (this declaration is covered in the document requested under point 3.3 above). This declaration covers both exclusion criteria and financial and operational capacity selection criteria.
- **Additional document for private bodies in case of grant > 60.000 €: SIMPLIFIED FINANCIAL STATEMENT (template available at EFSA's website as published together with this Call for Proposals)** completed for last 3 closed financial years.
- **Additional document in case other public bodies financially contribute to project, bodies other than EFSA, applicant or partners: LETTER OF COMMITMENT** signed by the public body confirming the commitment of this public body to financially contribute to the project. **No template is provided by EFSA.**

Operational capacity of applicants and partners:
The whole consortium as a whole, must have the professional competencies as well as appropriate qualifications necessary to complete the proposed project.

Documents to be provided by the applicant and partner(s):

- **THE DECLARATION ON HONOUR** (this declaration is covered in the document requested under point 3.3 above). This declaration covers both exclusion criteria and financial and operational capacity selection criteria
- **THE CURRICULUM VITAE** of the project manager/s and scientific staff to be involved in the project, ***including for each member a brief description of the expertise and a list of publications relevant to the project***.

3.5 AWARD CRITERIA

The award criteria serve to assess the quality of the proposals in relation to the objectives of the Call. The following **award criteria** are applicable to this Call:

AWARD CRITERIA	WEIGHT
1. **QUALITY OF THE PROPOSAL** addressing the related requirements as outlined in Section 1.5.	max **60 points**
1. The extent to which the proposal achieves the objectives of the Call, guarantees an excellent level of science output and demonstrates its capacity to provide significant and sustainable impact and added value to the existing knowledge.	max 30 points
2. The extent to which the project is described in detail, as well as the proposed methodology is well described and of high quality	max 30 points
2. QUALITY CONTROL AND PROJECT MANAGEMENT addressing the related requirements as outlined in Section 1.5. **(INCLUDING CONSORTIUM)**	max **30 points**
1. The extent to which the quality control mechanisms to be put in place will guarantee high quality of deliverables.	max 10 points
2. The extent to which the measures put in place in order to assure a sound project management, including the way the various tasks are distributed within the team; internal communication inside the project team, and communication with EFSA have been clearly described and appear to be suitable.	max 10 points
3. The extent to which a clear indication of the timelines for the completion of the project's tasks with detailed milestones for each task (e.g. via a project Gantt chart) as well as a description of the risks that might be foreseen per each individual task, a description of the measures put in place to assure that the deadlines for providing deliverables are met have been clearly described. In addition, the suitability of the proposed contingency plan in case deviations from the project programme will be assessed	max 10 points
3. FINANCIAL COHERENCE AND COST EFFECTIVENESS	
• The extent to which the Estimated budget is cost–effective (comparison between the costs and the anticipated achievement of the objectives and results obtained) and the consistency between proposed budget and technical part of proposal.	max **10 points**
TOTAL	**100**

In order to be considered for funding, the proposal must:

- **score a minimum of 70 points in total out of possible 100 points and**
- **for each sub-criterion (1.1, 1.2, 2.1, 2.2, 2.3, 3), score at least half of the points attributed to that criterion.**

Proposals which have satisfied these quality thresholds will be ranked. Depending on budget availability the highest ranked proposal will be awarded a grant from EFSA.

4. GRANT AGREEMENT, IMPLEMENTATION AND PAYMENTS

According to article 133 (3) of the Financial regulation, applicants will be informed in writing of the decision on their proposal. If the grant requested is not awarded, EFSA will give the reasons for the rejection of the application. Following the decision to award a grant, a Grant agreement will be proposed to the successful applicant/s. The project may begin at the earliest on the day the Grant agreement has been signed by the last of the parties (usually EFSA signature). Costs incurred prior to the date of the signature of the Grant agreement will not be considered as eligible.

4.1 ESTIMATED BUDGET

All proposals must be supported by **ESTIMATED BUDGET (template available at EFSA's website as published together with this Call for Proposals)** which must be establish in line with the **RULES ON ELIGIBILITY OF COSTS (template available at EFSA's website as published together with this Call for Proposals)**. Estimated budget must show all the costs and income which the applicant considers necessary to carry out the project. Estimated budget must:

- Be sufficiently detailed to permit identification, monitoring and checking of the proposed costs;
- Be balanced, i.e. total income and costs must equal;
- Be consistent with the work plan;
- Be expressed in Euros. This requirement is due to the fact that EFSA grant will be expressed in Euros only. Applicants which foresee that costs will not be incurred in Euros are invited to use the exchange rate published at: http://www.ecb.int/stats/exchange/eurofxref/html/index.en.html.

Estimated budget - costs:

- Eligible direct costs:
    1. Costs of permanent or temporary staff
    2. Travel and subsistence costs
    3. Equipment
    4. Consumables and supplies
    5. Subcontracting of ancillary and assistance tasks
    6. Miscellaneous costs directly linked to the project. These are costs arising directly from requirements imposed by the Grant agreement.
- Eligible indirect costs:
    7. The indirect costs incurred in carrying out the project may be eligible for a flat-rate funding fixed at not more than 10% of the total eligible direct costs.

Estimated budget – incomes:

- Applicant's financial contribution
- In case of consortium: partners` financial contribution
- Grant requested from the EFSA
- OPTIONAL - financial contributions from **public bodies** other than EFSA, applicant and consortia partners. Applicant must attach to application a letter signed by such public body confirming the public body is committed to contribute the indicated amount to the project.

4.2 APPROVED ESTIMATED BUDGET

The Estimated budget as presented by the applicant with the proposal is analysed by EFSA in order to:

- assess whether it is consistent with the proposed project and decide whether the Estimated budget is sufficiently detailed to consider funding of the project;
- assess whether the Estimated budget matches the specific objectives/expected results of the project;
- eliminate any item of costs which cannot be accepted according to the Rules on eligibility of costs;
- if necessary, propose a downward revision of the Estimated budget in relation to some items of costs considered as being excessive compared to the nature of the project and/or to the volume of work that has to be implemented in order to achieve the planned results.

The proposal should enable EFSA to evaluate the estimated budget, i.e. it should contain the detailed justification of the necessity of the proposed expenditure for performance of the project. An over - or underestimation of costs will have a negative impact on the evaluation score under the award criteria named "Cost effectiveness".

The analysis of Estimated budget is made in accordance with the Rules on eligibility of costs. It is EFSA who takes the final decision as regards the nature and amount of the costs to be considered eligible.

If, following the financial analysis, EFSA regards the Estimated budget as realistic, established in accordance with the Rules on eligibility of costs and no modification is needed, it will become **APPROVED ESTIMATED BUDGET** and the EFSA grant may correspond to the applicant's request. In some cases, however, the analysis of the Estimated budget could result in suggestions for reductions as a consequence of, e.g. the correct application of the Rules on eligibility of costs. Accordingly, if following the financial analysis of Estimated budget, EFSA suggests some modifications to it, EFSA will present those proposed modifications to the applicant. After the proposed modifications are agreed by the applicant and EFSA, the Estimated budget, as modified, will become Approved Estimated Budget for the project.
Following the financial analysis of the Estimated budget and having agreed to Approved Estimated Budget, the evaluation committee will decide the exact amount of EFSA grant which will be expressed as an amount in € and as a percentage of the total eligible project cost (EFSA co-financing rate).

4.3 DETERMINATION OF FINAL EFSA GRANT

THE FINAL EFSA GRANT will be determined after completion of the project based on actually incurred costs and after approval by EFSA of final report. Remember that EFSA grant as expressed in Grant agreement was calculated on the basis of **estimated eligible costs**. The final EFSA grant determination process can be summarised as follows:

- EFSA will analyse the final statement of actually incurred costs and receipts submitted according to Grant agreement by beneficiary to EFSA and will establish the amount of actually incurred eligible costs.
- If the total actually incurred eligible costs are lower than total eligible costs as estimated in the Estimated budget, EFSA will consider as ceiling for final EFSA grant 90% (EFSA co-financing rate) of total actually incurred eligible costs. If there is no profit identified during analysis of actually incurred costs/receipts, this ceiling will also correspond to final EFSA grant. If there is profit identified EFSA will deduct 90% of such profit in order to establish the final EFSA grant.
- If the total actually incurred eligible costs are higher than total eligible costs as estimated in the Estimated budget EFSA will consider as ceiling the amount of EFSA grant stipulated in the Grant agreement. If there is no profit identified during analysis of actually incurred costs/receipts, this ceiling will also correspond to Final EFSA grant. If there is profit identified EFSA will deduct 90% of such profit in order to establish the final EFSA grant.
- If the total of earlier payments is higher than the final EFSA grant, the beneficiary will be required to reimburse the amount paid in excess by EFSA through a recovery order.

The verification of the non-profit rule doesn't apply to grants </= 60.000 €.

4.4 REPORTS AND PAYMENTS

Within 30 days from the date of the signature of the Grant agreement by EFSA, **a pre-financing payment** between 10% and 40% of EFSA's grant will be made to the bank account indicated in the Grant agreement. Please note the exact amount of pre-financing will be determined at the time of awarding grant.

The payment of the balance will be made according to the Grant agreement and will be linked to approval by EFSA of the final deliverable/s (see part 1.4 of this Call).

4.5 PUBLICITY

By the beneficiaries:
Beneficiaries must clearly acknowledge the EU contribution in all publications or in conjunction with activities for which the grant is used. In this respect, beneficiaries are required to give prominence to the name and emblem of EFSA on all their publications, posters, programmes and other products realised under the co-financed project. Those publications shall contain a disclaimer stating that EFSA is not responsible for the views displayed in the publications and/or in conjunction with the activities for which the grant is used. If this requirement is not fully complied with, the beneficiary's grant may be reduced in accordance with the provisions of the grant agreement or grant decision.

By EFSA:
All information relating to grants awarded in the course of a financial year shall be published on an internet site of EFSA no later than the 30 June of the year following the financial year in which the grants were awarded. EFSA will publish the following information:

- name of the beneficiary,
- address of the beneficiary,
- subject of the grant,
- amount awarded.

Upon a reasoned and duly substantiated request by the beneficiary, the publication shall be waived if such disclosure risks threatening the rights and freedoms of individuals concerned as protected by the Charter of Fundamental Rights of the European Union or harm the commercial interests of the beneficiaries.

4.6 ACCOUNTING RECORDS OF THE PROJECT AND AUDIT

Accounting records:
The coordinator, and the possible co-beneficiaries in case of consortium, must keep accurate and regular accounting records as well as separate and transparent accounts of the implementation of the project. They must keep all the accounting records and all the supporting documents underlying the accounting records regarding the project for the period of five years after the payment of the balance.

Audit:
The coordinator, and the possible co-beneficiaries in case of consortium, will have to provide any detailed information requested by EFSA or by any other outside body authorised by EFSA to check that the project and the provisions of the grant agreement are being properly implemented. They must agree that EFSA may have an audit of the use made of the grant carried out either directly by its own staff or by any other outside body authorised to do so on its behalf. Such audits may be carried out throughout the period of implementation of the grant agreement until five years from the date of payment of the balance.

Please note that by virtue of Council Regulation (Euratom, EC) No 2185/96 and Regulation (EC) No 1073/1999 of the European Parliament and the Council, the European Anti-Fraud Office (OLAF) may also carry out on-the-spot checks and inspections in accordance with the procedures laid down by Union law for the protection of the financial interests of the European Union against fraud and other irregularities.

Finally the European Court of Auditors shall have the same rights as EFSA, notably right of access, as regards checks and audits.

5. PROTECTION OF PERSONAL DATA AND PUBLIC ACCESS TO DOCUMENTS

5.1 PROTECTION OF PERSONAL DATA IN RELATION TO GRANT PROCEDURES

Processing your application in the context of this grants procedure, will involve the recording and processing of personal data (i.e. the name, any CV and contact details and/or financial details of individuals contained in your application) pursuant to Regulation (EC) N° 45/2001[8].

Unless indicated otherwise, the questions and any personal data requested are required to evaluate the application in accordance with the specifications of the Call will be processed solely for that purpose.

Detailed information on the processing of personal data in the context of grant award procedures of EFSA is given in the privacy statement available on the EFSA website. This on-line privacy statement details the following:

- The legal basis, purpose and controller of the personal data processing;
- What personal information EFSA is collecting and/or further processing;
- To whom personal data is disclosed;
- What technical means are applied for the data processing and the way in which EFSA secures the information;
- How data subjects can access, modify and delete their information;
- How long EFSA keeps the personal data;
- The contact details for data subjects to exercise their rights;
- The right of recourse to the European Data Protection Supervisor.

Personal data may be registered in the Central Exclusion Database (CED) by the Accounting Officer of the Commission, should the beneficiary be in one of the situations mentioned in:

- the Commission Regulation 2008/1302 of 17.12.2008 on the Central Exclusion Database (for more information see the Privacy Statement on:

http://ec.europa.eu/budget/explained/management/protecting/protect_en.cfm).

5.2 PUBLIC ACCESS TO DOCUMENTS

In the general implementation of its activities and for the processing of grant procedures in particular, EFSA observes Regulation (EC) N° 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

LIST OF ANNEXES

ANNEX 1: Rules on eligibility of costs

[8] Regulation (EC) N° 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, Official Journal of the European Union, L.8, 12.1.2001, pp.1-22

Annex 1

RULES ON ELIGIBILITY OF COSTS

Please note that it is the related Call for proposals and guide for applicants which stipulates which headings of eligible direct costs are eligible within the Call.

Please note that it is the related Call for proposals and guide for applicants which stipulates whether the applicant has to submit proposal alone, or whether he can do so in a consortium with others.

1. General principles

Eligible costs are an essential instrument for guaranteeing compliance with the principle of sound financial management and ensuring that an EFSA grant serves to reimburse the real costs. Eligible costs are the cost base from which the maximum EFSA grant is determined and expressed as a maximum amount and as a percentage of such eligible costs.

In accordance with the Financial Regulation, eligible costs of the project receiving EFSA grant must be shown in detail in the Estimated budget. These costs must satisfy the eligibility criteria laid down by EFSA. It must be stressed that subject to these criteria, it is always up to EFSA to take the final decision on the nature and amount of the costs to be considered eligible, either when analysing proposals for the establishment of the Estimated budget to be annexed to the Grant agreement (before the project actually starts) or when examining final statements of costs actually incurred for the purpose of determining the final amount of the EFSA grant (after the project has been completed).

The costs eligible for an EFSA grant are those that are:

- directly linked to the subject of the Grant agreement and are included in the Estimated budget;
- necessary for the implementation of the project;
- reasonable and justified, and provided for in the Grant agreement in the overall estimated budget and consistent with the principles of sound financial management, in particular regarding economy and efficiency;
- generated during the implementation of the project and following the signature of the Grant agreement with the exception of costs relating to final reports and audit certificates;
- actually incurred by the beneficiary[1] recorded in its accounts in accordance with the applicable accounting principles, and declared in accordance with the requirements of the applicable tax and social legislation (in case of consortium[2] this equally relates to the beneficiary-coordinator and to other beneficiaries forming consortium);
- identifiable and verifiable and proven by relevant original supporting evidence; the beneficiary's internal accounting and auditing procedures must permit direct reconciliation of the costs and income declared in respect to the project with the corresponding accounting records, statements and supporting documents (in case of consortium this equally relates to the beneficiary-coordinator and to other beneficiaries forming consortium);

The dates which determine the eligibility of costs are the dates when the costs were generated, and not when the accounting documents were drawn up or the payment was made.

It is important to emphasise that only the eligible costs can be taken into account as a basis for calculating the EFSA grant. The attention of the applicant is drawn to the fact that the eligible costs as presented in the Estimated budget must be as realistic as possible and cannot take the form of lump sums (except for daily subsistence allowance and eligible indirect costs as explained below). Any costs contained in the Estimated budget must be justified and supported by a detailed calculation.

[1] In case there is no consortium there is only a single applicant. Having signed the Grant agreement with EFSA the successful applicant becomes the beneficiary. In case there is a consortium then there are an applicant and his partners. Having signed the Grant agreement with EFSA they become the coordinator-beneficiary and other beneficiaries respectively.

[2] Please note that in some cases the Call for proposals and guide for applicants specifies that the eligible organisation can apply only alone. Please refer to the Call for proposals and guide for applicants to see if this is the case for this particular Call.

The applicant must ensure that:

- all costs presented in the Estimated budget are necessary for the performance of the project;
- EFSA grant may not have the purpose or effect of producing a profit for the applicant or partner organisation. Profit is defined as a surplus of the receipts over the eligible costs incurred by the beneficiary, when request is made for payment of the balance. Where a profit is made, EFSA shall be entitled to recover the percentage of the profit corresponding to the EFSA contribution to the eligible costs actually incurred by the beneficiary to carry out the project. The verification of the non-profit rule doesn't apply to low value grants, i.e. grants </= 60.000 €.each item of costs is only included under one heading of the Estimated budget.

Decision to award an EFSA grant to a project is always subject to the condition that the checking process which precedes the signing of the Grant agreement does not reveal any problems requiring changes to the Estimated budget. These checks may give rise to requests for clarification and might even lead to a reduction of the EFSA grant based on the new information received from applicant.

Please note that at the end of the project, all costs (except for items based on lump sums as daily subsistence allowance and eligible indirect costs) must be justified by supporting documents, e.g. received invoices or other accounting supporting documents of an equivalent value. It is worth underlining that **EFSA reserves the right to audit (itself or by an external audit body contracted by EFSA) all actual costs and incomes (sources of financing, income established – both amounts already collected and not yet collected) of the project.** E.g., EFSA reserves the right to ask any supporting document in order to verify that the costs declared as eligible were actually incurred and paid. **The European Court of Auditors and the European Anti-Fraud Office (OLAF) shall have the same audit inspection rights as EFSA. These audits may take place also at any time during or after the implementation of the project.** For the purposes of these audits the beneficiary must continue keeping all the supporting documents of costs and incomes of the project for the period of 5 years from the date when the balance of the EFSA grant was paid (in case of consortium this equally relates to the beneficiary-coordinator as well as to other beneficiaries forming consortium). For grants under 60.000 euro the beneficiary must continue keeping all the supporting documents of costs and incomes of the project for the period of 3 years from the date when the balance of the EFSA grant was paid.

2. Eligible Direct Costs

The eligible direct costs for the project are those costs which, with due regard for the conditions of eligibility set out above, are identifiable as specific costs directly linked to implementation of the project and which can therefore be booked to it direct and in full. The following text describes headings of the Estimated budget dedicated to eligible direct costs.

2.1 Staff working for the beneficiary

The costs of salaried staff employed by beneficiary and who are assigned to the project corresponding to their actual salaries plus social security charges and other statutory costs forming part of their remunerations are eligible provided they do not exceed the average rates corresponding to the beneficiary's usual remuneration policy. The costs of the personnel of national administrations are eligible to the extent that they relate to the cost of activities which the relevant public authority would not carry out if the project concerned were not undertaken;

The amounts paid to persons who are not bound by an employment contract (such as consultants) can not enter into this heading. Instead, the heading "subcontractors" should be used.

Remuneration costs must be expressed per year. The amount per day will be calculated by dividing this yearly salary by 220 productive days. Thus, staff working full-time will be considered for budget calculation purposes to be working 220 days per year and half-time staff 110 days per year. Please note that 220 is a generally expected number of productive days in the given organisation. In case the actual number of productive days is different in your organisation for the given staff member you may use that number in the budget calculations, however you must provide the exact calculation of the number of

productive days you used, taking into account: 52 weekends equalling to 104 days, public holidays in the country concerned and annual leave allowed in the organisation.

The number of days spent on the project is calculated by dividing the sum of hours accumulated in a given month by 7.5 (7.5 hours is a working day according to EFSA methodology).

The costs of a seconded person to be recruited to work on the project and to be paid monthly salary based on the temporary contract of employment (where this person becomes temporary staff of the beneficiary) should be included in the heading “Staff working for the beneficiary” of the Estimated budget.

The beneficiary must be able to justify the staff costs at the end of the project through supporting documents. At EFSA’s request, the beneficiary shall submit the timesheets of which a template is annexed to the grant agreement and which are to be used obligatorily, salary slips and all other supporting documents required.

In case of consortium, these above rules apply equally to both beneficiary–coordinator and other beneficiaries forming the consortium.

2.2 Daily subsistence allowances and travel costs

Daily subsistence allowances and travel costs of staff and other persons taking part in the project are eligible provided that they are in line with the beneficiary’s usual practices on travel costs and do not exceed the scales approved annually by the European Commission. This means that the internal rules of the beneficiary shall apply first. If such internal rules do not exist at the beneficiary organisation, the scales of the European Commission shall apply.

Daily subsistence allowances

Flat-rate daily subsistence allowance covers all subsistence expenses during missions, including accommodation, meals, local transport (taxi and/or public transport) and telecommunications costs (fax, internet). They apply for each day of a mission at a minimum distance of 100 km from the normal place of work in the context of the implementation of the project forming the subject of the Grant agreement. The daily subsistence allowance varies depending on the country in which the mission is carried out. The applicable daily subsistence allowances to be used for calculations when preparing Estimated budget are shown in the table below. Please note that if there is no overnight stay, no hotel bill can be presented or the cost of accommodation is reimbursed by another EU institution, another administration or third party, the daily subsistence allowance shall be reduced by 70% for the day concerned.

Daily subsistence allowances are to be calculated according to the length of the mission:

- less than twenty-four hours: the daily allowance;
- more than twenty-four hours but not more than thirty-six hours: one and a half times the daily allowance;
- more than thirty-six hours but not more than forty-eight hours: twice the daily allowance;
- and so on.

The beneficiary should declare all meals or accommodation provided by or reimbursed by any of the EU Institutions or by another administration or third party. The daily allowance is to be reduced by 10% for each meal provided by others.

The length of a mission is calculated from the time of departure of the means of transport used to the time of this arrival on return to the place of employment.

Travel must be organised so that the mission lasts as short a time as possible given the means of transport used and is as cost-effective as possible.

Missions in other countries not mentioned in the below table shall be submitted to the prior agreement by EFSA. This agreement shall be related to the objectives of the mission, its costs and its motivation. For those countries not mentioned in the below table, a lump sum corresponding to the addition of the daily

allowance and the maximum hotel price as forecast in the Commission Decision C(2004) 13134 shall apply.

When the internal regulations of the beneficiary organising the journey impose a lower limit than those amounts detailed in the below table, these must be used as a basis of calculation when preparing Estimated budget.

DESTINATIONS	**Daily subsistence allowance in €** covering accommodation, meals, local transport (taxi and/or public transport) and telecommunications costs (fax, internet).
Austria	225
Belgium	232
Bulgaria	227
Cyprus	238
Czech Republic	230
Denmark	270
Estonia	181
Finland	244
France	245
Germany	208
Greece	222
Hungary	222
Ireland	254
Italy	230
Lettonia	211
Lithuania	183
Luxemburg	237
Malta	205
Netherland	263
Poland	217
Portugal	204
Romania	222
Slovakia	205
Slovenia	180
Spain	212
Sweden	257
United Kingdom	276

Travel costs

Only travel/mission directly related to the project and concerning precise activities, which must be clearly identifiable, shall be eligible. No lump sums will be applied to travel costs. These costs are obviously only estimates when preparing the Estimated budget, however they must be estimated as precisely as possible.

The following rules will be applied to travel costs:

Travel costs for missions/journeys in the context of the Grant agreement are eligible under the following conditions:

- travel by the most direct and most economic route;
- distance of at least 100 km between the place of the meeting and the normal place of work;
- travel by rail: first class;
- travel by air: non flexible economy class, unless a cheaper fare can be used (e.g. Apex);
- air travel is allowed only for return journeys of more than 800 km (this is the distance in km between departure and arrival place);
- travel by car or taxi: reimbursed on the basis of one equivalent first class rail fare (regardless of how many people are travelling in the car). The beneficiary is required to keep documents justifying this cost (document of travel agency, railway reservation office,…).

It is worth stressing that when organising missions in the context of the project the most economical fares must be sought. Several travel agencies should be contacted in order to obtain the best possible prices.

Cost for luggage surcharge will be regarded as ineligible.

Please note also that when preparing the final summary statement of costs and incomes of the project the actual travel costs will have to be taken into account and not those foreseen in the Estimated budget. In any case it is important to repeat that EFSA reserves the right to verify all the supporting documents for travel/missions organised, e.g. boarding passes, travel agency invoices etc.

When preparing estimates for this heading of the Estimated budget, you shall bear in mind several calculation factors as, e.g., the number of missions to be organised during the implementation of the project, the number of participants required to take part at meetings, the length of the missions, the need for overnight stays or the distance between destination and departing point.

Finally, please note that daily subsistence allowances and travel costs of EFSA representatives shall in no case enter into any heading of the Estimated budget. This is because when there is a meeting foreseen within the project between the beneficiary and EFSA representatives outside Parma (e.g. at the premises of the beneficiary) the daily subsistence allowances and travel costs of EFSA representatives will be borne in full by EFSA itself.

In case of consortium, these above rules apply equally to both beneficiary–coordinator and other beneficiaries forming the consortium.

2.3 Equipment (new or second-hand) provided that, it is purchased in accordance with Article II.9 of the Grant Agreement and is directly assigned to the project;

The costs relating to the acquisition of equipment shall be eligible if such acquisition is strictly necessary for the performance of the project. The costs of such equipment must be written off linearly in accordance with the tax and accounting rules applicable to the beneficiary and generally accepted for items of the same kind. However, the minimum depreciation periods accepted by EFSA for the purpose of establishing the Estimated budget are as follows: computer equipment (hardware) is written off over a period of 3 years, office furniture and equipment (photocopiers, fax, etc.) over 5 years and specific computer software (not common software which is supposed to be covered by indirect costs) is covered in full.

It is important to emphasise that only the portion of the equipment's depreciation corresponding to the duration of the project and the rate of actual use for the purposes of the project can be considered by EFSA as eligible, except where a different arrangement is justified by the nature or context of the equipment's use.

Because of the principle that grants may not be awarded retrospectively equipment items purchased prior to the project start (signature of the Grant agreement by EFSA), even if they are used for the purposes of the project, cannot be considered eligible direct costs of the project. Please note that the use of existing equipment and the beneficiary’s installations is partly covered via the eligible indirect costs.

Finally, please note that the property of purchased equipment after the completion of the project continues to rest with beneficiary.

In case of consortium, these above rules apply equally to both beneficiary–coordinator and other beneficiaries forming the consortium.

2.4 Consumables and supplies provided that, they are purchased in accordance with Article II.9 of the Grant Agreement and are directly assigned to the project;

Costs of consumables and supplies, provided that they are identifiable and assigned in full to the project are eligible.

Unlike the equipment, these are "consumables", i.e. items that are not entered as fixed assets in the accounts (or inventory) of the beneficiary and are not written off. The terms "identifiable" and "assigned in full to the project" are of utmost importance in order to avoid double cover by way of indirect costs. The nature of the project and the fact that the costs are specific to the project are key factors justifying direct cover of these costs.

In case of consortium, these above rules apply equally to both beneficiary–coordinator and other beneficiaries forming the consortium.

2.5 Workshops, seminars, conferences provided that, they are purchased/hired in accordance with Article II.9 of the Grant Agreement and are directly assigned to the project;
This item of eligible costs must cover all costs linked to organisation of a workshop, seminar or conference. This item of the Estimated budget must in particular cover:

1. hire of premises;
2. hire of equipment;
3. travel and subsistence costs for participants and speakers (conditions regarding travel and subsistence costs – point 2.2. of these Rules must be adhered to);
4. interpretation (interpreters and hiring of booths); max 400 € per speaker per day;
5. external speakers` fees; max 500 € per speaker per day;
6. translation costs in connection with workshop/seminar/conference;
7. other costs (e.g. reproduction costs for documentation to be distributed to participants, various supplies, reception staff).

2.6 Translations provided that, they are purchased/hired in accordance with Article II.9 of the Grant Agreement and are directly assigned to the project;
These are the costs linked to the translations of documents if this is required in the Call for proposals. A typical case where these costs are eligible is, e.g., when one of the eligible activities within the project is to collect various data/information from various countries. To be able to efficiently work in the project with the collected data these must be translated into one language.
Translation costs must include details of the number of languages, the number of pages, the rate applied per page. In addition, applicants should explain the nature of the documents to be translated in the detailed budget explanation. Translation costs may not be higher than the market prices in the country where the translation is done.

2.7 Subcontracting of tasks forming part of the project in accordance with Article II.10 of the Grant Agreement and is directly assigned to the project;

The rules for subcontracting are already laid down in the Call for proposals and guideline for applicants. In addition to these rules you are reminded that when preparing the Estimated budget it is necessary to justify the awarding of contracts. It means that flat-rate amounts are not permitted under the heading "Subcontracting" of the Estimated budget. All subcontracting shall be foreseen at the time of preparation of the Estimated budget as precisely as possible and the corresponding estimated costs shall be shown in the Estimated budget.

Also, you are reminded that the costs of a seconded person to be recruited to work on the project and to be paid on the basis of the invoice (where this person is actually a service provider) should be also included in the heading “Subcontracting” of the Estimated budget. The condition is that these persons hold nationality of one of the eligible countries, or alternatively be permanently employed by an eligible organisation.

Finally, when estimating the costs of subcontracting, bear in mind all the costs which will have to be paid to the subcontractor (e.g. travel costs). All the costs directly linked to subcontracting must be declared under the heading “Subcontracting” of the Estimated budget, whatever the nature of these costs.
In case subcontracting needs are identified after the Grant Agreement signature: Any recourse to the award of sub-contracts while the project is in progress, if not envisaged from the outset in the proposal, is subject to prior authorisation in writing by the EFSA through an amendment.

In case of consortium, these above rules apply equally to both beneficiary–coordinator and other beneficiaries forming the consortium.

2.8 Miscellaneous costs directly linked to the project and arising directly from requirements imposed by the Grant agreement

This heading of the Estimated budget may include any other additional costs not falling within any of the other categories mentioned above and it is supposed to cover the costs arising directly from the requirements of the Grant agreement.

These costs may be allowed, provided they are:

- necessary for the performance of the project;
- clearly itemised in the Estimated budget;
- not indicated under any other heading of the Estimated budget;
- fully documented and, recorded in the beneficiary’s accounts or tax documents and duly identifiable.

An example of these costs might be financial service costs, e.g. translations, the cost of establishment and management of a dedicated bank account to be opened specifically for the project (e.g. costs of bank transactions or bank statements). However, regarding management costs of a bank account, you are reminded that any exchange losses, charges relating to establishing or maintaining lines of credit or overdraft are not eligible.

Another example might be production costs of reports to be submitted to EFSA. However, costs incurred in producing these documents are eligible for this heading of the Estimated budget only when those activities are performed by the beneficiary. If this is not the case, these costs could be considered as eligible, if fulfilling the restrictions on subcontracting, for the heading “Subcontracting” of the Estimated budget.

In case of consortium, these above rules apply equally to both beneficiary–coordinator and other beneficiaries forming the consortium.

2.9 Eligible VAT

Value added tax ("VAT") is an eligible cost where it is not recoverable under the applicable national VAT legislation and is paid by a beneficiary other than a non-taxable person as defined in the first subparagraph of Article 13(1) of Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax. The eligible VAT cost should be declared in the same heading of the Estimated Budget in which the related cost is declared.

3. Eligible Indirect Costs (Overheads)

The eligible indirect costs for the project are those costs which, with due regard for the conditions of eligibility described above under point 1, are not identifiable as specific costs directly linked to performance of the project which can be booked to it direct in full, but which can be identified and justified

by the beneficiary using its accounting system as having been incurred in connection with the eligible direct costs for the project.

Indirect costs are all the structural and support costs of an administrative, technical and logistical nature which are cross-cutting for the operation of the beneficiary's various activities and cannot therefore be booked in full to the project for which the grant is awarded because this grant is only one part of those activities.

Indirect costs comprise costs connected with infrastructures and the general operation of the organisation such as renting or depreciation of buildings and plant, water/gas/electricity, maintenance, cleaning, insurance, supplies, small office equipment such as toner, paper, stationary, communication and connection costs (phone, internet, fax, etc.), postage, and costs connected with horizontal services such as administrative and financial management, human resources, training, legal advice, documentation, IT, etc.

Please note that eligible indirect costs may not include any eligible direct costs.

Indirect costs shall be calculated on the basis of an estimate of the actual costs borne by the beneficiary for the project. The indirect costs expected to be incurred in carrying out the project may be eligible for a flat-rate funding of not more than 10% of the total eligible direct costs.

Please note that indirect costs are not eligible where beneficiary already receives an operating grant from EU budget for the calendar years in which the project is implemented.

In case of consortium, these above rules apply equally to both beneficiary–coordinator and other beneficiaries forming the consortium.

4. Ineligible Costs

The following items of costs are not eligible and should therefore not be included under any headings of the eligible costs in the Estimated budget.

- return on capital;
- debt and debt service charges
- interest owed;
- doubtful debts;
- currency exchange losses;
- deductible VAT
- extravagant, excessive or reckless costs;
- purchases of land or buildings;
- entertainment or representation costs;
- replacement costs of persons involved in the project;
- provisions for losses or potential future liabilities;
- provisions for liquidation, winding up of business, breaking off of a lease or legal liabilities;
- provisions for contractual or moral obligations;
- fines, financial penalties and costs of legal proceedings;
- external co-financing involving real estate;
- contributions in kind;
- costs declared by the beneficiary and already covered by another project receiving a grant from EU budget. If there should be complementarity between funds, this must be explicitly justified, clarified and proved;
- costs not entered in the accounts which are not identifiable or not verifiable;
- costs incurred before signature of the Grant agreement by the second party (EFSA signature) and after the end of project indicated in the Grant agreement.

5. Flexibility within the Approved budget

After the Estimated budget has been approved by EFSA it becomes the Approved budget and it will be attached to the Grant agreement. Due to the fact that the Estimated budget and the Approved budget are both based on estimates, from a practical point of view, it is important that the beneficiary has the opportunity to adjust, to a certain extent, the Approved budget during the course of the project implementation, if it proves necessary.

If the beneficiary wishes to replace a staff member by another of his employees (for example because of dismissal), prior approval of EFSA should be sought. No budgetary implications in direction of increase can be associated with this change.

The approved budget may be adjusted by making transfers provided that such adjustments do not affect the basic purpose and the completion of the project is not jeopardised.

Annex II Description of the project as presented in the application form submitted and approved by the Authority

APPLICATION FORM

Call reference: GP/EFSA/CONTAM/2013/04
Call title: Experimental study of deoxynivalenol biomarkers in urine

Restricted to the list adopted by EFSA Management Board according to article 36 of European Parliament and Council Regulation (EC) No 178/2002

The **Application form** has to be supported by all documents indicated under the **Application Submission Completeness Checklist**.
Incomplete application forms will not be accepted.

Table of Contents

1. PART 1 – APPLICATION FORM

1.1 INFORMATION ON THE APPLICANT AND POTENTIAL PARTNERS

1.1.1 IDENTITY

All this information has to be provided for the applicant and all potential partners of consortium. The information given here must be taken from official documents such as memorandum and articles of association or equivalent documents as indicated in the CALL FOR PROPOSALS AND GUIDE FOR APPLICANTS.

1.1.2 APPLICANT - IDENTITY

Official name in full: Istituto Superiore di Sanità
Short name or acronym: ISS
Official legal form: Public body
Legal representative of the applicant (he/she will sign the grant agreement in case of award): Fabrizio Oleari

Applicant's official address:
Street: Viale Regina Elena
Number: 299
Post code: 00161
City: Rome
Country: Italy
Telephone: +39 06 4486 9455
Fax: +39 06 4486 9440
E-mail address: presidenza@iss.it
Internet site: www.iss.it

Contact person responsible for this proposal:
Name: Carlo Brera
Position: Senior Researcher
Telephone: +39 06 49902377
Fax: +39 06 49902363
E-mail address: carlo.brera@iss.it

1.1.3 PARTNER 1 - IDENTITY

Official name in full: Policlinico "Agostino Gemelli"
Short name or acronym: UNICATT
Official legal form: Public body
Legal representative of the partner (he/she will sign the grant agreement or power of attorney in case of award): Marco Elefanti

Street: Largo Agostino Gemelli
Number: 8
Post code: 00168
City: Rome
Country: Italy
Telephone: +39 06-3015.1
Fax: +39 063057794
E-mail address: alanzone@rm.unicatt.it
Internet site: http://www.policlinicogemelli.it

Contact person responsible for this proposal:
Name: Prof. Antonio Lanzone
Position: Director of Dysfunctional Gynaecology and Physiology of human reproductive system (Hospital).
Telephone: +39 063057794
Fax: +39 063057794
E-mail address: alanzone@rm.unicatt.it

1.1.4 PARTNER 2 - IDENTITY

Official name in full: Norwegian Veterinary Institute
Short name or acronym: NVI
Official legal form: Public body
Legal representative of the partner (he/she will sign the grant agreement or power of attorney in case of award): Gudmund Holstad

Street: Ullevaalsveien
Number: 68
Post code: N- 0106
City: Oslo
Country: Norway
Telephone: +47 2321 6000
Fax: +47 23 21 60 01
E-mail address: postmottak@vetinst.no
Internet site www.vetinst.no

Contact person responsible for this proposal:
Name: Gunnar Sundstøl Eriksen
Position: Senior Researcher
Telephone: +47 23 21 62 24
Fax: +47 23 21 62 01
E-mail address: gunnar.eriksen@vetinst.no

1.1.5 PARTNER 3 - IDENTITY

Official name in full: Norwegian Institute of Public Health
Short name or acronym: NIPH
Official legal form: Public body
Legal representative of the partner (he/she will sign the grant agreement or power of attorney in case of award): Toril Attramadal

Street: Lovisenberggata
Number: 8
Post code: N- 0403, Nydalen
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Country: Norway
Telephone: +47 21077000
Fax: +47 22353605
E-mail address: folkehelseinstituttet@fhi.no
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Contact person responsible for this proposal:
Name: Anne Lise Brantsaeter
Position: Senior Scientist
Telephone: +47 21076326
Fax: 22353605
E-mail address: AnneLise.Brantsaeter@fhi.no

1.1.6 PARTNER 4 - IDENTITY

Official name in full: University of Hull
Short name or acronym: UoH
Official legal form: Public Body, Higher Education Institution
Legal representative of the partner (he/she will sign the grant agreement or power of attorney in case of award): John Hay

Street: Salmon Grove
Number: 11
Post code: HU6 7SX
City: Hull
Country: UK
Telephone: +44 1482 305202
Fax: +44 1482 305206
E-mail address: O.Al-Janabi@hull.ac.uk
Internet site: www.hull.ac.uk

Contact person responsible for this proposal:
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Fax: +44 1482 675395
E-mail address: thozhukat.sathyapalan@hyms.ac.uk

1.2 INFORMATION ON THE PROJECT FOR WHICH THE GRANT IS REQUESTED

1.1.1. DESCRIPTION OF THE PROJECT

Title: Occurrence data collection of deoxynivalenol (DON) and its metabolites in urine of human group populations

Specific objective(s) of the project:

Describe in detail how the project achieves the objectives of the Call

The study proposed will provide EFSA with high quality, fit for purpose data regarding typical deoxynivalenol exposure assessment across representative European countries and population groupings, which can support the development of regulations regarding the setting of new legal limits for dietary exposure to deoxynivalenol. To meet this objective, an international consortium comprising experts in the field of mycotoxins and human mycotoxin exposure assessment has been convened. This comprises Italian and Norwegian partners who are National Reference Laboratories for mycotoxins and colleagues at the University of Leeds who have developed, validated and published methodologies for deoxynivalenol urinary biomarker assessment. The clinical centres who will be collecting the urine samples represent centres of excellence for clinical research, with particular expertise in nutrition related studies and populations that will allow them to recruit across the age spectrum needed. The volunteer recruitment sites (Policlinico Agostino Gemelli in Rome, Italy, University of Hull in UK and Norwegian Institute of Public Health in Oslo, Norway) have appropriate expertise and facilities for volunteer recruitment, Food Frequency Questionnaire (FFQ) administration and sample collection, processing and storage. To meet the project goals in a comprehensive fashion, the study design proposed is rigorous and will apply the following criteria:

- Choice of the partnership: In order to achieve appropriate and required demographic spread for geographical distribution and dietary patterns of cereal intake (i.e. Mediterranean versus Northern European) and possible associated DON risk as identified from the literature, Italy, United Kingdom and Norway have been selected. As indicated above, for the three participating countries, only groups with expertise in mycotoxins and volunteer recruitment and nutrition related experience have been included in the consortium.
- Selection of groups of population to be considered in the study: A distribution of the sample size based on equal age classes and gender of the population in all three countries was rejected because of the particularly low number of subjects that would have been recruited in each category, especially for those which represent a potentially higher risk of DON exposure and associated health effects (e.g. children and adolescents due to lower bodyweight and immature hepatic detoxification systems). The number of subjects to be included is therefore stratified according to body weight, diet and age. On the basis of this criterion, in each country, at least 200 subjects subdivided in subgroups of Children (aged 3-9, 20%), Adolescents (aged 10-17, 20%), Adults (aged 18-64, 10%), Vegetarians (15%), Pregnant women (20%) and Elderly (aged above 65, 15%) will be recruited.

Only healthy people, not on prescribed medication will be recruited. The acutely ill and individuals with chronic gastrointestinal conditions (e.g. celiac disease), gluten sensitivity or eating disorders will not be taken into consideration since dietary habits are likely to be altered in these individuals, rendering them unrepresentative of the general population.

- Choice of the analytical method: a unique harmonized validated LC-MS/MS method will be applied to the analysis of urine samples following verification of performance characteristics by all of the involved laboratories.

Specifically, the established, validated LC-MS/MS urinary analytical method developed by Turner and colleagues at the University of Leeds (Turner et al., 2008: Hepworth et al., 2011; Turner et al., 2011) will be selected and subject to validation and verification across participating laboratories at the start of the study. To monitor method performance, Internal and External Quality Control measures will be put in place as described in the following sections.

UDP-glucuronosyltransferases (UGTs) are a family of phase Ⅱ enzymes that catalyse the transfer of glucuronide to a substrate/toxin, increasing its water solubility and thus facilitating excretion in the urine. DON-glucuronide formation appears to be a major detoxification route for DON in humans (Meky et al., 2003) and in the majority of UK adult samples tested to date >75% of the total urinary DON load is excreted as DON-glucuronides (Turner, personal communication). Free DON is also regularly detectable in human urine samples. The compounds will be measured in volunteer urine samples by the previously reported LC-MS/MS analytical method (Turner et al., 2011).

There will also be scope to assess the presence of the lesser metabolite de-epoxy deoxynivalenol (DOM-1). In animals DOM-1 is excreted in the urine as the DOM-1-glucuronide and can be detected following β - glucuronidase treatment in a manner analogous to that undertaken for total urinary DON measurement reported

by Turner et al., (2008). Recently, the Leeds group, have established a sensitive LC-MS assay for DOM-1, and spiking experiments indicate that the assay is reproducible and has similar sensitivity to the assay for urinary DON. It is important to understand if this detoxification product occurs in humans; and understanding the level and frequency of DOM-1 occurrence will enhance understanding of the potential health consequences of DON exposure beyond the hepatic UGT route alone.

-Validation of the obtained results: all the results of the analyses will be accurately subjected to a validation process to provide reliable and robust data. The collected data will be reported with the mean, the median, 95 and 99 percentile, corrected and uncorrected for creatinine values, corrected for recovery and calculating the uncertainty measurement based on the validation data (reproducibility data) following the top-down approach as described by the EURACHEM/CITAC Guide "Quantifying Uncertainty in Analytical Measurement".

References

Hepworth SJ, Hardie LJ, Fraser LK, Burley VJ, Mijal RS, Wild CP, Azad R, McKinney PA, Turner PC, 2011. Deoxynivalenol exposure assessment in a cohort of pregnant women from Bradford, UK. Food Additives and Contaminants. Part A, E pub DOI:10.1080/19440049.2010.551301

Meky FA, Turner PC, Ashcroft AE, Miller, JD, Qiao, YL, Roth, MJ & Wild, CP (2003). Development of a urinary biomarker of human exposure to deoxynivalenol. *Food Chem. Toxicol.* 41(2): 265-273.

Turner P.C., Burley V.J., Rothwell J.A., White K.L.M., Cade J.E., Wild C.P. (2008) Deoxynivalenol: Development and application of an IAC – LC/MS urinary assay to assess exposure in UK adults. Food Add. Cont. 25(7): 864-871.

Turner PC, Ji BT, Shu XO, Zheng W, Chow W-H, Gao YT, Hardie LJ (2011).A biomarker survey of urinary deoxynivalenol in China: the Shanghai Women's Health Study. *Food Additives and Contaminants.* 28 ,9, 1220-1223.

EURACHEM/CITAC Guide "Quantifying Uncertainty in Analytical Measurement". Available on-line at: http://www.eurachem.org/images/stories/Guides/pdf/QUAM2012_P1.pdf

Detailed description of the project

describe in detail how the project guarantees an excellent level of scientific output, how the project provides significant and sustainable impact and added value to the existing knowledge, the methodology to be applied and all the activities/tasks to be carried out in order to achieve the objectives of the project, the expected deliverables/results of the project for each stage

Following the description of the outline of the project.

Database development

Analytical Results

A database will be built in order to organize and provide to EFSA both the urine analyses results carried out by the consortium and the information gathered from the Food Frequency Questionnaire.

The database with the results of the analyses carried out for human urine samples shall follow the latest version of EFSA Guidance on Standard Sample Description and shall be submitted via DCM's (Dietary and Chemical Monitoring Unit) call for continuous collection of chemical contaminants occurrence data.

Food Frequency Questionnaire

Type, frequency and quantity of the food consumed will be obtained by an appropriately designed and tested semi-quantitative Food Frequency Questionnaire, which shall be harmonised among partners.

The database including the results from the FFQ will be delivered to EFSA as a MS Excel. Food Frequency Questionnaire will be defined in order to gather the crucial information considering the food classification as in FOODEX2, food frequency and dietary intake. The agreed FFQ will be translated from English to Italian and Norwegian and shared among the consortium. The database sent to EFSA will be written in English.

The data in both databases shall be linked via sample identification.

Method of analysis

All first morning samples of urine samples will be measured for all countries using the validated methodology for urinary DON analysis established by the participating centre at the University of Leeds (Turner et al., 2008; Turner et al., 2011).

The full description of the method is reported at points 1 a-e.

Selection of biomarkers

The DON metabolites reported in the literature include de-epoxy deoxynivalenol (DOM-1), deoxynivalenol-3-β-D-glucoside (D3G), deoxynivalenol-glucuronide (DON-GlcA) and the acetylated forms (3-AcOH DON and 15-AcOH DON). DON-glucuronide formation appears to be a major detoxification route for DON in humans (Meky et al., 2003) and for the majority of UK adult samples tested to date, >75% of the total urinary DON load is excreted as the DON-glucuronide (Turner, personal communication). Free DON is also regularly detectable in human urine samples. Therefore, these compounds will be measured in volunteer urine samples by the previously reported LC-MS/MS analytical method (Turner et al., 2011).

There will also be scope to assess the presence of the lesser metabolite de-epoxy deoxynivalenol (DOM-1). In animals DOM-1 is excreted in the urine as the DOM-1-glucuronide and can be detected following β-glucuronidase treatment in a manner analogous to that undertaken for total urinary DON measurements reported by Turner et al. (2008). Recently, the Leeds group have established a sensitive LC-MS assay for DOM-1 and spiking experiments indicate that the assay is reproducible and has similar sensitivity to the assay for urinary DON. It is important to understand if this detoxification product occurs in humans; and understanding the level and frequency of DOM-1 occurrence will enhance understanding of the potential health consequences of DON exposure beyond the hepatic UGT route alone.

Deoxynivalenol-3-β-D-glucoside (D3G) and the acetylated forms (3-AcOH DON and 15-AcOH DON), do not seem to be present in significant amounts in urine. These forms are, in fact, mainly found in plants and *in vivo* they are rapidly converted into other metabolic forms. For this reason, these metabolites will not be assessed in the proposed study.

In particular, the applicant must describe in detail the proposed approach including the following information:

1) *Description of the used analytical method*

a. Justification of the method chosen.

A between-laboratory harmonized method of analysis will be used after verification of the performance characteristics as described in section 2.

The Leeds grouping developed the methodology for urinary deoxynivalenol biomarker analysis (Turner et al., 2008). This methodology will be applied as previously reported and full validation and calibration analysis among all the involved laboratories, HoU in UK,, ISS in Italy and NVI in Norway will be performed. A recently completed study has indicated that good agreement can be obtained across laboratories using different HPLC MS/MS approaches for DON urinary biomarker analysis (DON, DON glucuronide and DOM-1) and Leeds was one of the participating centres in this study (Solfrizzo et al. (2013). For this and logistical reasons of analysis capacity, inclusion of 3 analysis centres can be justified.

The Leeds laboratory uses the original, established methodology of Turner et al., 2008. In brief, urine samples (50 ml) will be removed from storage at -80°C, allowed to thaw, and samples centrifuged (2000g; 15 min; 4°C). Aliquots (1ml) will be mixed with 13C-DON internal standard, (Biopure, Tulln, Austria) to give a final concentration of 20ng/ml.

DON glucuronide detection: Each sample will be adjusted to pH 6.8 and digested with β-glucuronidase (Type IX-A from E. coli; Sigma; 16,000 units) in a shaking water bath for 18h at 37°C. After this period the samples will be removed, centrifuged (2000g; 15 min; 4°C), and the supernatant diluted to a final 4ml with PBS (pH 7.2). The diluted material will be passed through wide bore DON immunoaffinity columns (Vicam or R-Biopharm) as per manufacturers' instructions. DON will be eluted from columns with methanol (4ml) and extracts dried under vacuum using a Savant Speed Vac or equivalent and reconstituted in 10% ethanol (250µl) for analysis. Extracts will be analysed using the instruments available in the three laboratories as summarised in Table 1. Separation of DON will be achieved using reversed phase chromatographic columns and a mobile phase sequence of 27min duration starting with 20% methanol, changing to a wash of 75% methanol after 10min and reverting to 20% methanol after 16min (flow rate 1 ml/min; injection volume 25µl). One fifth of the eluent is directed into the desolvation chamber of the MS and the remainder pumped to waste. Selective ion recording will be used to quantify DON by reference to 13C-DON internal standard. Two masses each of DON (m/z 297.2 and 319.2) and 13C-DON (m/z 333.2 and 334.2) will be monitored for 0.25s each and summed to produce one total ion current peak each for analyte and internal standard. Two quality control (QC) samples (urine spiked with 10 ng/ml DON) and two PBS blanks will be included with each batch of twenty samples. The standard curve is 2-250 ng/ml DON and generates an R^2 value

around 0.999. The limit of quantification (LOQ) is 0.5 ng DON/ml urine and the CV for in-house QC samples is 2.5%.
Free DON detection: The β -glucuronidase treatment is omitted from the above protocol so free DON in urine can be measured.
DOM-1 detection: This analysis provides a measure of DOM-1 in previously extracted urine samples. The available data, coming from previous experience, indicate that urinary digestion using β-glucuronidase will release DOM-1. For this reason samples already extracted will be used to assess DOM-1. Extracts will be analysed using the same instrumentation described in Table 1. Separation of DOM-1 will be achieved using the same chromatographic column used for DON glucuronide and summarised in Table 1 and a mobile phase sequence of 35min duration starting with 20% methanol, changing to a wash of 75% methanol after 20min and reverting to 20% methanol after 26min (flow rate 1 ml/min; injection volume 25µl). One fifth of the eluent is directed into the desolvation chamber of the MS and the remainder pumped to waste. Selective ion recording will be used to quantify DOM-1 by reference to the eight point standard curve, using least squares regression analysis. Two masses of DOM-1 (m/z 281.3 and 303.3) will be monitored for 0.25s each and summed to produce one total ion current peak each for DOM-1.
Creatinine analysis: Since only first morning samples of urine will be collected, levels of DON will be adjusted for creatinine to correct for variable dilutions. Urine creatinine will be assessed by the enzymatic method described by Mazzachi et al. (2000). The daily urinary creatinine clearance as a function of body mass, age and sex (http://www.clinicalculator.com/english/nephrology/excrea/excrea.htm) will be used to estimate the daily urinary DON excretion expressed as ng DON/mg creatinine.

References:

Solfrizzo M, Gambacorta L, Warth B, White K, Srey C, Sulyok M, Krska R, Gong YY (2013) Comparison of single and multi-analyte methods based on LC-MS/MS for mycotoxin biomarker determi- nation in human urine. World Mycotoxin J. doi:10.3920/ WMJ2013.1575

Mazzachi BC, Peake MJ, Ehrhardt V. Reference range and method comparison studies for enzymatic and Jaffe creatinine assays in plasma and serum and early morning urine. Clin Lab. 2000;46:53–5.

b. Justification of the DON biomarker/biomarkers selected.
As indicated above, free DON and DON-glucoronides will be the primary biomarkers selected for analysis as these are the best-established and validated urinary biomarkers for DON exposure in the literature. There will also be opportunity for DOM-1 analysis although this biomarker is less well established and likely to be less abundant but is important from the perspective that it represents an alternative detoxification route.

c. Storing procedures for the urine samples before and after sample pre-treatment.
Samples will be stored at -80°C following collection in 50ml aliquots. Between laboratory processing steps, samples will be held at -20°C.

d. Sample pre-treatment and sample preparation steps.

Urine samples will be removed from storage at -80°C, allowed to thaw, and centrifuged (2000g; 15 min; 4°C).
DON glucuronide detection: Each sample will be adjusted to pH 6.8 and digested with β-glucuronidase (Type IX-A from E. coli; Sigma; 16,000 units) in a shaking water bath for 18h at 37°C. After this period the samples will be removed, centrifuged (2000g; 15 min; 4°C), and the supernatant diluted to 4ml with PBS (pH 7.2). Clean up: The diluted material will be passed through wide bore DON immunoaffinity columns (Vicam or R-Biopharm) as per manufacturers' instructions. DON will be eluted from columns with methanol (4ml) and extracts dried under vacuum using a Savant Speed Vac or equivalent and reconstituted in 10% ethanol (250µl) for analysis for MS/MS analysis.

e. Instrumental determination of DON and DON metabolites including calibrants and the instrumentation to be used:
The instrumentation to be utilised is detailed in Table 1 for each analysis site.
Calibrants will include a DON 13C-DON internal standard. Two quality control (QC) samples (urine spiked with 10 ng/ml DON) and two PBS blanks will be included with each batch of twenty samples. Calibrants and QC samples will be shared across sites. The standard curve is 2-250 ng/ml DON. The same measures will be included for DOM-1 analysis.

Table 1. Analytical methodology for DON and associated metabolite detection

METHODOLOGY DETAILS	UoL, UK	NIV, Norway	ISS, Italy
a) REFERENCE			
	Leeds (Turner et al., 2008)	Leeds (Turner et al, 2008	Leeds (Turner et al., 2008)
a) Extraction			
Sample intake	5 mL	5 mL	5 mL
Centrifugation	Yes	Yes	Yes
Enzymatic digestion	Yes, β-glucuronidase	Yes, β-glucuronidase	Yes, β-glucuronidase
b) ENZYMATIC PRE-TREATMENT (β-glucuronidase)			
	Yes		Yes
c) URINE DILUTION			
Urine sample volume Volume and type of solvent	1 ml 3 ml PBS pH 7.4	1 ml 3 ml PBS pH 7.4	1 ml 3 ml PBS pH 7.4
d) CLEAN UP			
	Immunoaffinity column (VICAM)	Immunoaffinity column (VICAM)	Immunoaffinity column (R-Biopharm)
e) CALIBRATION			
	External standard calibration + labeled IS addition	External standard calibration + labeled IS addition	External standard calibration + labeled IS addition
f) CHROMATOGRAPHY			
Injected Matrix	100 µl urine (in 25 µl injection volume)	50 µl urine (in 10 µl injection volume)	100 µl urine (in 25 µl injection volume
LC column	Phenomenex C18, 5µ, 4.6x150mm [with corresponding guard column]	Acquity UPLC HSS T3 1.8 µm, 2.1 x 100 mm [with corresponding guard column]	Acquity UPLC BEH C18 1.7um 2.1 x 100mm [with corresponding guard column]
Mobile phase	Gradient: MeOH in H_2O	Gradient : MeCN + H2O (+5mM acetate buffer)	Gradient: MeOH in H_2O
Flow	1 ml/min	0.5 ml/min	1 ml/min
g) MS DETECTION			
Instrument model	Waters 2795 separation module coupled to a Micromass Quattro Micro triple quadropole mass spectrometer	Waters Acquity UPLC coupled to a Thermo Scientific Q Exactive ™	Waters Acquity UPLC coupled to a Quattro Premier XE Micromass triple quadrupole mass spectrometer.
Ion source	ESI	ESI	ESI
Mass Analyzer	Triple Quadrupole	Orbitrap	Triple Quadrupole.
Acquisition mode	SIM	t-SIM+ddMS2	SIM
Number of Ions	1 transition	1 (R=70,000)	1 transition
Limit of Quantification	DON= 0.5ng/ml urine	DON= 0.5ng/ml	DON= 0.5ng/ml urine

f. Quality control of the analytical method.
As detailed above, the standard methodology incorporates a number of quality control procedures, which include the presence of a DON internal standard, standard curves, spiked and blank QC material.

2) *A validation report (including type of calibration, limit of detection, limit of quantification, recovery, repeatability, within-laboratory reproducibility, ruggedness) obtained from the validation of the proposed method for the analysis of DON biomarkers in human urine. The validation report should also include the estimation of the measurement uncertainty. In addition, the validation report shall compare the performance of the proposed method to those methods recently reported for DON biomarkers in the literature.*

A Validation study will be organized within the consortium as described by the International standards (EURACHEM/NORDTEST/AOAC).
Technical parameters referred to the MS/MS technique will be defined including the type of calibration and signal to noise ratio.
The scope, the field of application, the principles of the analytical method, the limit of detection and quantification, recovery, the precision parameters (in term of repeatability and reproducibility) and ruggedness will be assessed and reported. Moreover the uncertainty will be assessed by the top down EURACHEM approach from the reproducibility of the study.
The scope of the analytical method will cover the detection of DON and its major metabolite (DON-glucuronide in addition to DOM-1 in human urine samples in the expected range 2.5-250ng/ml by LC- (ESI) MS/MS. The principle of the analytical method will be based on the well-established methodology in Leeds and detailed above (Turner et al., 2008).
During the validation phase, results will be compared with internationally accepted performance characteristics and validation studies as reported in literature [Turner / others]. This will include LOD, LOQ, recovery and precision parameters. These parameters will also be monitored and reported during the analysis phase.

3) Example on reporting of the results expressed as both corrected and uncorrected for creatinine.
The results will be expressed both as ng DON/ml urine and as ng DON/ mg creatinine in urine. The latter allow a correction for different degrees of dilution of the urine between individuals.

4) *A sampling plan for a representative collection of samples from European countries that includes:*

a. Choice and number of countries:
The selection of the countries where the study will be carried out, namely United Kingdom, Norway and Italy, is to represent the geographical differences in settlement and food habits concerning cereal intake and DON risk exposure. It is in agreement to what requested by EFSA to have at least 3 non neighbouring countries involved.

b. The number of urine samples to be analysed
At least 200 subjects per country will be enrolled corresponding to a number of at least 400 first morning urine samples per country taken over two consecutive days. A total of at least 1200 urine samples will be analysed.
All samples will be kept at -80°C until analysis.

c. Information on how the volunteers will be selected and how it will be achieved that the samples are representative for the European population (e.g. gender, age, dietary habits).
The population groups to be included in the study will be divided according to the age sub-groups used within the EFSA Comprehensive European Food Consumption Database (Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment, http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm) considering a number for each subgroup as representative according to a risk-based criterion, in particular taking into account the categories for which an higher risk associated to DON intake is expected (i.e. children and adolescent). In each group the number of subject will be equally distributed by gender.
On the basis of this criterion at least 200 subjects per country will be selected within these age categories: Children (aged 3-9 years, 20%), Adolescents (aged 10-17, 20%), Adults (aged 18-64, 10%), the Elderly (aged above 65, 15%), Vegetarians (15%) and Pregnant women (20%). In each group the number of subject will be equally distributed by gender.
Only healthy people, not on prescribed medication will be recruited. The acutely ill and individuals with chronic gastrointestinal conditions (e.g. celiac disease), gluten sensitivity or eating disorders will not be taken into consideration since dietary habits are likely to be altered in these individuals, rendering them unrepresentative of the general population
All enrolled patients will be requested to read and subscribe an Informed Consent and Ethics approval that will be submitted in the original language of the countries involved in the study.
The evaluation of the ethic aspects related to the study protocol and its approval by an Ethics Committee will be requested by each institution and centre involved in the project. In order to respect the study deadline, the approval will be submitted to Ethics Committee before the starting date of the study.
For each centre involved in recruitment and sample collection, a number of research assistants will be trained in order to harmonize:
- the recruitment and the enrolment of the subjects according to inclusion criteria and to willingness to participate;

- the way they will clearly inform the recruited subject on the scientific purpose of the study;
- the way they will explain to participants on how to fill in the Food Frequency Questionnaire and signing the informed consent;
- the procedures for urine samples collection and samples delivery according to the protocols agreed by the Consortium;
- the instructions for participants on how to use disposable sampling vessels for urine;
- the use of an univocal alphanumeric anonymous code for each sample and questionnaire

Only people meeting the inclusion criteria will be recruited by the specialized centres (hospitals, clinics, Institutions). Inclusion criteria will include either not being on any medication or stable medication (for more than three months) that does not affect appetite (such as oral steroid use). Exclusion criteria include not being able to give informed consent, those unable to fill in the questionnaire, food allergies, eating disorders, those recently on a weight loss diet, depression and psychosis, hospitalised subjects within 3 months of admission, any chronic illness (chronic renal, hepatic or cardiac problems, cancer for example).

As far as possible, a harmonized recruitment strategy will be used. In all the centres involved in sample collection, a large normal volunteer database will be used to recruit all of the subjects over the age of 18 years, that also details if subjects are vegetarian or not. For those less than 18 years of age, links with local scouting and youth groups from previous and current studies on exercise and diet will be used. Also for pregnant women will be possible to have access from already existing database linked to running research projects. In parallel, public calls will be launched via email asking for the participation at the study.

All subjects fulfilling the inclusion criteria for the study will be asked to participate in the study by filling in the questionnaire, signing the informed consent and providing the two samples of urine taken over two consecutive days. A common randomization criterion among partners will be established.

d. Information on the selected sub-groups of the population to be participated in the survey: e.g. vegetarians, children, pregnant women);

Vegetarians will be recruited by addressing a specific request to the national Associations of vegetarians and by contacting employees of the Institutions and hospitals in each country, asking them to participate to the study; the pregnant women will be enrolled by the Gynaecologic Units of the Hospitals or other specialised centres or ultimately by contacting employees of the Institutions; children will be recruited by the Paediatric Units of Hospitals or other specialised centres or ultimately by contacting employees of the Institutions; all the other subgroups (adolescents, adults and the elderly) will be recruited by contacting employees of the Institutions.

5) Proposed protocol for the collection of dietary information with a semi-quantitative FFQ including compilation, testing in the local language, harmonisation between countries, protocol for checking completed FFQs at return (completeness, correctness) and how the personnel will be trained.

Since diet plays a capital role in the DON exposure, a uniform semi-quantitative food frequency questionnaires will be developed and agreed by the partners prior to the onset of the study as dietary assessment method. The basis for setting the questionnaire will be the recent validated questionnaire used in a Spanish study targeted to pregnant women (Vioque et. al, 2013) and the National Health and Nutrition Examination Survey (NHANES) Food Frequency Questionnaire (http://appliedresearch.cancer.gov/archive/usualintakes/FFQ.English.June0304.pdf) developed by the National Cancer Institute (NCI) in US. Other key features will be the recognized dietary instruments that will be administered by registered dieticians who are familiar with these questionnaires. The completeness of the FFQ will be assessed and checked by the dietician administering the FFQ.

In order to ensure the harmonized data collection, a unique format for the collection of dietary habits will be used, after sharing the overall experiences and deeply discussing any detail in such a way to harmonize our results in the due way. The FFQ will be tested in subgroups of potential participants in each country. This is particularly important for children and vegetarians as most FFQs have been developed and validated for the general adult population.

More specifically, the FFQ adopted in this study will include information about portion size and usual food frequency intake, with a recall period up to one month as well as the day before each urine sampling. FFQ will be translated into the three languages of countries involved in the study.

The food list in the FFQ will specifically include food categories containing the main food sources of DON that have previously been correlated with DON urinary biomarkers. More specifically, wheat, maize and barley products with emphasis for breads (wholemeal, white, soft grain, other), breakfast cereals (high-fibre and other), pasta, pizza, fruit pies, biscuits, and buns/cakes will be included in the semi-quantitative FFQ, taking country specific food habits into account.

In order to capture such food categories we will use the EFSA's Food Classification System FoodEx2 database (http://www.efsa.europa.eu/it/datex/datexfoodclass.htm). The FFQ will be designed to obtain information about the food frequency and semi-quantitative dietary intake of the selected food groups consumed during the previous week or month. Within the FFQ, more detailed information will be included on the intake of the selected food groups during the first day of the urine sampling and the day before.
The FoodEx2 code number for each food will be retained and included in the database including the results from the FFQ.
A harmonized database will be developed to collect all the data related to the enrolled subjects concerning individual information (age, gender, BMI, and other information), urine testing results and food intake. The questionnaire will be made anonymous, by coding the individual IDs. The dataset will be sent to the partner and at the end of the data collection, the three Datasets will be merged for analyses.

References:

Jesús Vioque, Eva-María Navarrete-Muñoz, Daniel Gimenez-Monzó, Manuela García-de-la-Hera, Fernando Granado, Ian S Young, Rosa Ramón, Ferran Ballester, Mario Murcia, Marisa Rebagliato, Carmen Iñiguez. Reproducibility and validity of a food frequency questionnaire among pregnant women in a Mediterranean area. Nutr J. 2013 Feb 19;12:26. doi: 10.1186/1475-2891-12-26.

Description of the organisation / implementation of the project

a) describe in detail the quality control mechanisms to be put in place to guarantee high quality of deliverables.

Each Laboratory will use the agreed validated analytical method as previously described and will perform the analyses of urine sample collected in its own countries.
Since the analytical method for DON and its major metabolites in human urine samples is already established (Turner et al., 2008) with validation parameters already provided, a preliminary study aimed at verifying that these parameters are met by all three laboratories will be performed through the organisation of an inter-laboratory study on laboratory control samples (e.g. blank and naturally or artificially fortified human urine samples) at levels of concentration of interest. These levels will be chosen according to the expected contamination levels derived from the existing experience of the consortium partners.
With this scheme in mind, the Coordinator will collect, process, store and finally dispatch to the other two laboratories the contaminated urine samples. The urine samples will be stored at -80°C and delivered frozen to each of the remaining laboratories by a specialised courier.
Each out of three laboratories will analyse the contaminated urine samples, within a period of time not exceeding one week, and the analytical results will be statistically processed to evaluate if the obtained performance characteristics fall within pre-set requirements.
These reference values will be predetermined according to the following criteria:
Repeatability within 10%; reproducibility within 20%; trueness within the range 70%-110%; measurement expanded uncertainty 25%.
Together with the external quality control, also internal quality control actions will be performed, as follows: analytical laboratory quality control samples derived from the same batch used for the inter-laboratory validation study will be included in each analytical run related to unknown samples. The results of these laboratory quality control samples will be statistically processed by building up control charts for each metabolite and for any of the parameters that will be considered (precision, recovery factors, measurement uncertainty).
The tendency of results laboratory quality control and unknown samples of all participating laboratories will be inserted in an Excel format previously agreed by all participants and monitored for the evaluation of its respect of the pre-set values. For this task, specialised personnel will be involved.

Quality control activities will be performed as follows:

- Harmonized protocol for collection and storage conditions of samples
- Purchase of a shared unique batch of reference (certified) standard, if commercially available
- Proper storage conditions of (certified) reference standards.
- Control of the nominal concentration of the reference standards by UV spectrophotometer assessment
- Analysis of at least two quality control laboratory samples in each analytical session/cycle and adoption of rules of acceptance criteria
- Calculation of recovery factors for each sample batch

- Validation of Excel calculation sheet

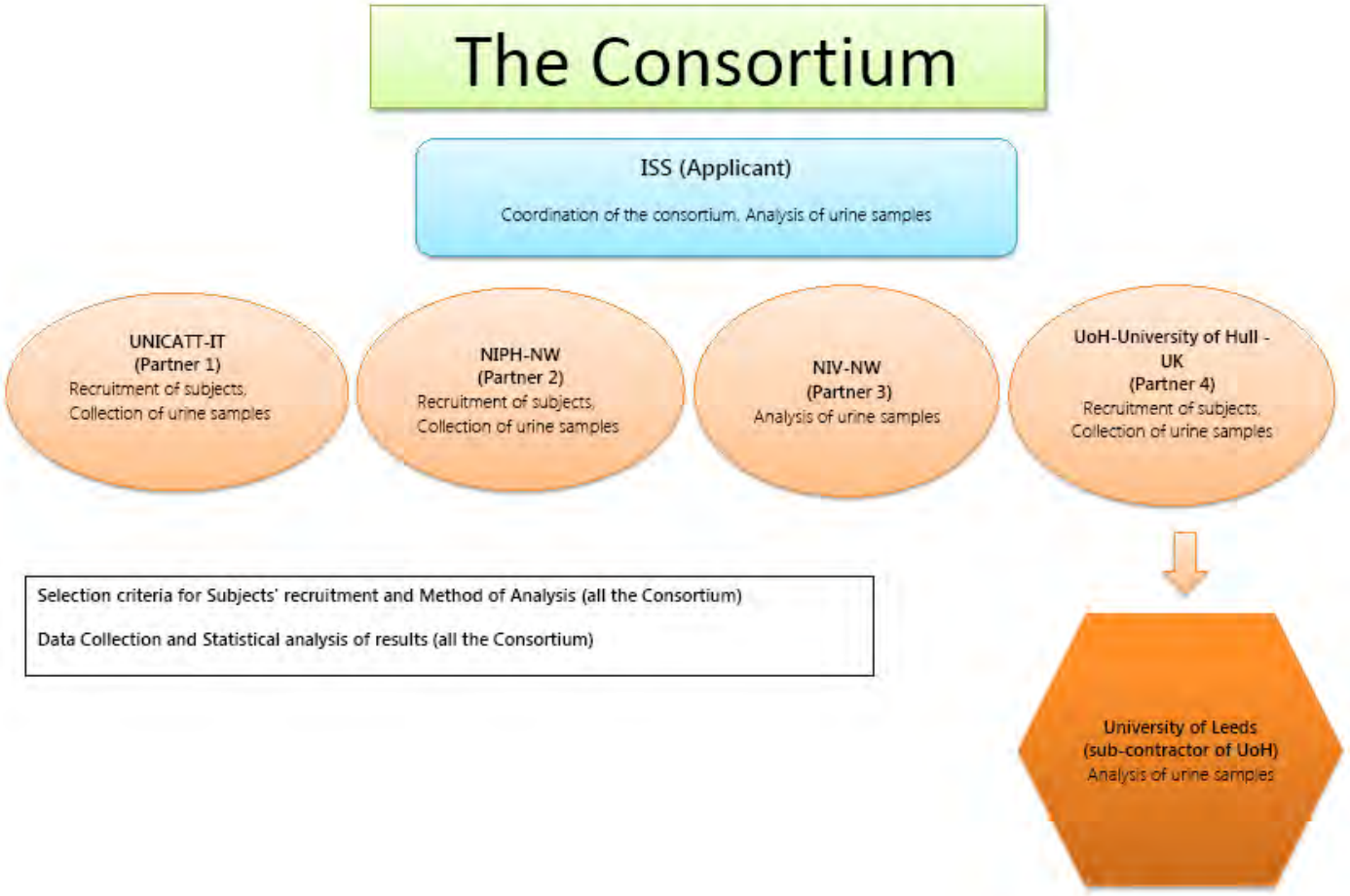
As regards the FFQ, its validation in each country and study group (children, adults, elderly, vegetarian and pregnant women) is not feasible within the frame of the study. However, making a comparison with already existing food consumption data available in literature review and reports will assess the relative external validity of the FFQ.

b) describe in detail the measures put in place in order to assure a sound project management, including the way the various tasks are distributed within the team; internal communication inside the project team, and communication with EFSA;

The measures adopted to guarantee a sound project management will be mainly focused on the progress monitoring of the scientific activities along the development of the research for each partner.
A meeting among all participants will be planned before the official start of the project in Parma. This will be organised with the aim to gain full knowledge of the components of the Consortium, to update on any information for the project and to compose the team that will participate in the Parma meeting.
To assess the progress, share the findings and discuss any possible drawbacks or constraints, call conferences (or equivalent) will be systematically planned at monthly basis with the aim to discuss and solve them. Nevertheless, any need to share the evolution of any issue will be taken into consideration and *ad hoc* call conferences with all participants will be organised.
Another key point will regard the full harmonisation of the procedures performed at level of each country. So, both for the actions in the recruitment of subjects (criteria for selection, number of subjects, frequency of sampling) and for the analysis of samples (method of analysis employed, feeding of the format for results, internal quality control procedures) the same protocols will be preliminarily discussed, agreed and finally shared among participants.
By keeping in mind the requested aims of the present call, it was decided in the consultations within the Consortium, preceding the submission of the proposal, to analyse all samples individually, i.e. each country will analyse its own samples. The alternative was to centralize in a unique laboratory the analysis of all samples collected in each country, but this case was rejected since some issues were considered unfeasible for the following reasons: i) considering an average number of subjects as 200, two samples per subject, two replicate analyses per sample and considering all three countries, a total number of 2400 analyses should be foreseen; ii) a huge task would derive from the delivery of 400 samples per two out of the three countries at frozen conditions with a high impact for the financial resources and possible drawbacks if some failure in the delivery period of time (defrosting or delay) should occur.
As regards communication with EFSA, including the delivery of reports to EFSA (interim, final), direct connections such as conference call or email will be used.
In particular the following meetings with EFSA will be scheduled:

- Kick off meeting. It will take place at the start of the project, within 1 month after the entry into force of the grant agreement. At this meeting, details of the project and the report structure will be discussed. Minutes of the meeting will be provided to EFSA by the beneficiary.
- Interim tele-meeting (1 week after the submission of the interim report 1), in order to discuss the first interim report as well as any problems or difficulties encountered during the project. Minutes of the meeting will be provided to EFSA by the beneficiary.
- An additional interim tele-meeting could be included during the project development if needed.
- Final meeting will be held 1 month before the end of the project, with the purpose to discuss the draft final report.

The way the various tasks will be distributed within the team is shown in the outline underneath.


The Consortium
ISS (Applicant)
Coordination of the consortium. Analysis of urine samples
UNICATT-IT
(Partner 1)
Recruitment of subjects,
Collection of urine samples
NIPH-NW
(Partner 2)
Recruitment of subjects,
Collection of urine samples
NIV-NW
(Partner 3)
Analysis of urine samples
UoH-University of Hull - UK
(Partner 4)
Recruitment of subjects,
Collection of urine samples
Selection criteria for Subjects' recruitment and Method of Analysis (all the Consortium)
Data Collection and Statistical analysis of results (all the Consortium)
University of Leeds
(sub-contractor of UoH)
Analysis of urine samples

- *Provide clear indication of the timelines for the completion of the project's tasks providing detailed milestones for each task (e.g. via a project Gantt chart) as well as a description of the risks that might be foreseen per each individual task, and a description of the measures put in place to assure that the deadlines for providing deliverables are met. In addition, a contingency plan in case deviations from the project programme is required.*

The timeline of the activities is reported in the following GANTT chart:

Month n°	1	2	3	4	5	6	7	8	9	10	11	12
Task												
1. Set up of the study												
Ethics Committee approval and Informed consent agreement*												
Food Frequency Questionnaire building up												
Collection of the administered questionnaires												
Recruitment of subjects												
Collection of urine samples												
2. Analysis of urine samples												
Interlaboratory validation study												
Analysis of DON and its metabolites and creatinine												
Statistical data treatment												
3. Milestones												
Kick-off meeting												
Preparation of the interim report												
Interim Meeting												
Building up of the database of the preliminary results												
Building up of the database of the final results												
Preparation of the final report												
Final Meeting												
Month n°	1	2	3	4	5	6	7	8	9	10	11	12

*The period foreseen for the request of approval to Ethics Committee and Informed consent agreement will be planned at least one month before the start of the project (month -1). So, two months will be effectively taken into consideration for the completion of this task.

The deliverables foreseen in the study are as follows:

- Draft database with the results from the FFQ: months 4-5
- Interim report: month 5-6
- Draft database with the results of preliminary urine analysis: month 6
- Draft database with the final results DON occurrence: months 10-11
- Final report and final databases: months 10-12

The approval of Ethics Committee and Informed consent agreement could not be received consistently with the planned deadline (month1). For this reason the request of the approval will start at least one month before the potential date of start of the project.

The building up of the Food Frequency Questionnaire should not pose particular risk since the format will be duly discussed among all the partners involved in its collection in due time before the collection of urine samples.
However, potential drawbacks occurring in the data collection could be caused by a lower number of subjects interviewed with FFQ compared to what expected and/or the use of a partially validated questionnaire for those subgroups (namely vegetarian) for which few information is available.
To mitigate the impact of these two situations, the use of data obtained form already existing national and international food consumption databases can provide an estimate of the exposure for at least some of the population subgroups, while specific data collection will be enforced for the subgroups for which no or few data are already available.
The consultation of international/national existing food consumption databases will act also as validation of the adopted FFQ and in case of evident discrepancies, two 24-h interviews in a subset of participants to evaluate the comparability of the data collected will be set up in each country.

The recruitment of subject could not reach the pre-set number of subjects due to the failure of the approach put in place by all or some partner. This condition could regard more the recruitment adolescents and adults since for these subgroups no specific Institution does exist. In addition, as regards vegetarians, a refusal of collaboration from the Associations of vegetarians could occur. For avoiding these risks, more than one approach for recruitment of all the cited subgroups will be followed, i.e. the launch of a public call, the spread of information to the employees of the Institutions where partners work or to relatives and or friendships.

The collection of urine samples could be not consistent with the pre-set number but it should be solved after finding the solution at the previous task. The necessary attention for guaranteeing a proper training of all the assistants involved in the collection of urine samples will be provided.

The inter-laboratory validation study could fail to give reliable results in terms of performance characteristics of the analytical methodology performed in the involved laboratories.
In order to minimize this risk, laboratories already experienced in the requested analysis and equipped with comparable instrumentation were chosen since the establishment of the criteria to be followed in searching for partners. However, an extended timing for matching this task has been foreseen.

The failure of the analyses of DON and its metabolites, including the creatinine test, strongly depends on the success of the previous task. For this strict correlation, no particular risk is expected.

Statistical data treatment should not lead to any risk since all data will be treated according to reference guidance such as the EFSA guidance on Sample Standard Description and FOODEX2. However, the partnership can account for the consultancy of statisticians in case of trouble.

The preparation of interim and final reports will be organized with a large timing advance in order to harmonize the contents as much as possible. Also the correctness of the English form will be assured by the presence of mother tongue partners.

The building up of preliminary and final database could correspond to a risk deriving from wrong inclusion of data, misinterpretation of the data and wrong calculation of the measurement uncertainty. To overcome this risk, a full validation of the Excel files and crossed calculation by different operators will be performed.

From the above, it follows that the contingency plan is represented by all the corrective actions previously described.

Indication of work to be subcontracted

- *justify in detail any requested sub-contracting, including the amounts estimated; This information must be in compliance with the data introduced in the Estimated Budget (Part A.5):*

  The following sub-contracting will be activated:
  The University of Hull will cover the collection of all urine samples by each subgroup as previously cited. The collected samples will be sent for the performance of analyses to the laboratory of University of Leeds (that is not listed under art. 36), which originally developed and validated the urinary DON biomarker methodology (Turner et al., 2008). The reference to the cited laboratory is justified by the highly documented experience gained in the last ten years by the Leeds laboratory team in covering very similar issues such as the one related to DON exposure assessment of UK population. The estimated budget to be assigned for this laboratory accounts for 36.000 Euro.

1.2. OTHER SOURCES OF EXTERNAL FINANCING OTHER THAN FINANCING FROM EFSA FOR APPLICANT AND PARTNERS

NOT TO BE APPLIED

1.3. GRANT REQUESTED FROM EFSA

Estimated total costs of the project in EURO (D=X+A+B)	**363.793,73**
Estimated total ineligible costs of the project in EURO (X)	**0,00**
Estimated total eligible costs of the project in EURO (C=A+B)	**363.793,73**
Estimated total eligible direct costs of the project in EURO (A)	**330.721,57**
Estimated total eligible indirect costs of the project in EURO (B)	**33.072,16**
Amount of grant requested from EFSA in EURO	**244.929,24**

- ***The applicant commits to inform EFSA as soon as possible of any changes of operational or financial nature, both in the applicant's structure (and also partners` structure in case of consortium), which might affect him/them or the project covered by the grant application.***

- ***The applicants confirms that both the applicant and possible partners comply with the essential condition of being on the list of competent organisations designated by the Member States in accordance with Art 36 of Regulation (EC) 178/2002 and Commission Regulation (EC) 2230/2004. This list is regularly updated by EFSA Management Board. You may consult the list of competent organization at this link:***
  http://www.efsa.europa.eu/en/networks/art36.htm

Signature of the legal representative of the applicant:

Signature:

Place: Roma

Date (day/month/year): 11.10.2013

Name of the legal representative of the applicant: Dott. Fabrizio Oleari

Stamp of the applicant organisation (if available):

2. PART 2 – APPLICATION SUBMISSION COMPLETENESS CHECKLIST

- The below checklist is designed to help the applicants to ensure that all requested documentation is provided to EFSA.
- The application must be submitted in line with guidelines described in the Call for Proposals and Guide for Applicants.
- This checklist should be signed and included in the Application Form.
- Please tick ✓ in the boxes provided if the document is attached to the application.

The application submission must contain one original unbound signed paper version and one electronic version (on CD Rom or USB key, in PDF format) of all the following documents:

√	Completed, signed/dated **Application Form**
√	This **checklist** signed and dated.
√	**Legal Entity Form and supporting documents** to be provided for the Applicant and for each partner.
√	**BANK ACCOUNT IDENTIFICATION FORM** to be provided for the Applicant.
√	**THE DECLARATION OF HONOUR** - to be provided for the Applicant and for each partner.
☐	**Applicable only if Applicant and/or each partner are not Public Bodies: SIMPLIFIED FINANCIAL STATEMENT**
√	**CURRICULUM VITAE** to be provided for each member of the proposed project team including for each member a brief description of the expertise and a list of publications relevant to the project
√	**PARTNERSHIP STATEMENT** - defining the technical and financial involvement of each member of consortium (applicant and partners) signed individually by each of the member of consortium (applicant and partners).
☐	**Applicable only when the project involves other sources of funding than EFSA grant and contributions from applicant and potential partners: LETTER OF COMMITMENT** signed by other contributing public sector body; the letter must express confirmation of commitment of the public sector body to financially contribute to the project - to be provided for the Applicant and for each possible partner
√	**ESTIMATED BUDGET** - one common Estimated Budget for the project covering all costs and incomes

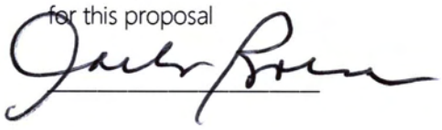
It is important to ensure that:

√ The Application form is formulated in one of the official languages of the EU (with a preference for the use of English, French or Italian).

√ The Application form is signed/dated by legal representative of the applicant

√ The Application form is perfectly legible in order to rule out any ambiguity.

Carlo Brera
Contact person responsible
for this proposal



Annex III **Approved estimated budget of the project (comprising a consolidated version together with a breakdown of costs and incomes between each beneficiary)**

Estimated budget - Summary
Project reference: GP/EFSA/CONTAM/2013/04

Estimated budget 6 items version 1.0

Please read before completing the Estimated budget:
The Estimated budget will serve for EFSA to determine the amount of EFSA grant, using the amount of eligible costs as a basis to which 90% rate will be applied.
The Estimated budget must be in balance; therefore total project costs must equal the total project income.
The Estimated budget must be presented in Euro.
The Estimated budget must be detailed and each item of eligible direct costs must be supported by detailed information on calculation of estimates.
When establishing the Estimated budget you have to bear in mind the Rules on eligibility of costs annexed to the Call for proposals and guide for applicants.
The indirect costs incurred in carrying out the project may be eligible for a flat-rate funding fixed at not more than 10% of the total eligible direct costs.
Any information which cannot be included in the excel table should be included and explained in the detailed budget explanations to be provided with this Estimated budget.
Value added tax ("VAT") is an eligible cost where it is not recoverable under the applicable national VAT legislation and is paid by a beneficiary other than a non-taxable person as defined in the first subparagraph of Article 13(1) of Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax. The eligible VAT cost should be declared in the same heading of the Estimated Budget in which the related cost is declared.

Item	Costs	Applicant	Partner 1 *	Partner 2 *	Partner 3 *	Partner 4 *	Totals
X	Ineligible costs	0.00 €	0.00 €	0.00 €	0.00 €	0.00 €	0.00 €
A.1	Staff working for the applicant and partners	75,481.38 €	30,405.15 €	45,000.00 €	42,411.32 €	32,581.22 €	225,879.07 €
A.2	Daily subsistence allowances and travel costs	5,456.00 €	320.00 €	2,460.00 €	2,460.00 €	2,460.00 €	13,156.00 €
A.3	Equipment (new or second-hand)	0.00 €	0.00 €	0.00 €	0.00 €	0.00 €	0.00 €
A.4	Consumables and supplies	18,420.00 €	2,160.00 €	0.00 €	7,000.00 €	1,514.50 €	29,094.50 €
A.5	Subcontracting of some tasks	0.00 €	0.00 €	0.00 €	0.00 €	36,000.00 €	36,000.00 €
A.6	Miscellaneous costs arising directly from requirements imposed by the grant agreement	0.00 €	1,440.00 €	15,000.00 €	0.00 €	10,000.00 €	26,440.00 €
A	**Eligible direct costs**	99,357.38 €	34,325.15 €	62,460.00 €	51,871.32 €	82,555.72 €	330,569.57 €
B	**Eligible indirect costs**	9,935.74 €	3,432.51 €	6,246.00 €	5,187.13 €	8,255.57 €	33,056.96 €
C=A+B	**Total eligible costs**	109,293.12 €	37,757.66 €	68,706.00 €	57,058.45 €	90,811.30 €	363,626.53 €
D=X+A+B	**Total project costs (eligible + ineligible)**	109,293.12 €	37,757.66 €	68,706.00 €	57,058.45 €	90,811.30 €	363,626.53 €

Item	Income	Applicant	Partner 1 *	Partner 2 *	Partner 3 *	Partner 4 *	Totals
E.1	Contribution by aplicant and partners (MANDATORY)	17,027.26 €	3,404.55 €	45,000.00 €	42,411.32 €	11,021.36 €	118,864.48 €
E.2	Grant requested from EFSA**	244,762.04 €					244,762.04 €
E.3	Contribution from other public sector bodies***	0.00 €					0.00 €
E.4	Any revenue generated by the project	0.00 €					0.00 €
E	**Total income**						363,626.53 €

* Regarding this part of table, add more columns in the case there are more than 2 partners involved in the consortium.

** Grant requested from EFSA doesn't have to equal to the maximum possible as calculated in the cost part of the Estimated budget (green cell). Grant requested from EFSA could be lower, the same but in no case higher than the amount in green cell.

*** These contributions are not mandatory. Add more rows for this item of income if there are more public sector bodies financially contributing to the budget of the project. In each case, specify the name of the public sector body. Please note that the proof of financial commitment of the public sector body to the project is one of the supporting documents required as part of the proposal.

THE ESTIMATED BUDGET IS IN BALANCE

Estimated budget - Item A.1 - Staff working for the applicant and partners

No.	Name of staff member	Organisation/ Employed by	Position/Function	Yearly salary (a)	Amount per day (b)=(a)/220*	Number of days on project (c)	Eligible costs (d)=(b)x(c)
1	**Carlo Brera**	ISS Applicant	Senior Researcher	81,752.00 €	371.60 €	18.33	6,811.43 €
2	**Barbara De Santis**	ISS Applicant	Resercher	50,710.00 €	230.50 €	18.33	4,225.07 €
3	**Luca Busani**	ISS Applicant	Senior Researcher	75,279.00 €	342.18 €	9.16	3,134.34 €
4	**Cinzia La Rocca**	ISS Applicant	Senior Researcher	68,604.00 €	311.84 €	9.16	2,856.42 €
5	Temporary Staff	ISS Applicant	Technician	46,765.00 €	212.57 €	220	46,765.00 €
6	Temporary Staff	ISS Applicant	Administrator	46,765.00 €	212.57 €	54.99	11,689.12 €
7	**Antonio Lanzone**	UNICATT Partner 1	Full Professor	140,000.00 €	636.36 €	5.35	3,404.55 €
8	Temporary Staff	UNICATT Partner 1	Gynecologist	16,000.60 €	72.73 €	220	16,000.60 €
9	Temporary Staff	UNICATT Partner 1	Laboratory technician	3,000.80 €	13.64 €	220	3,000.80 €
10	Temporary Staff	UNICATT Partner 1	Pediatrician	7,999.20 €	36.36 €	220	7,999.20 €
11	**Anne Lise Brantsaeter**	NIPH Partner 2	Senior scientist	110,000.00 €	500.00 €	90	45,000.00 €
12	**Gunnar Sundstøl Eriksen**	NVI Partner 3	Senior scientist	102,300.00 €	465.00 €	30	13,950.00 €
13	**Silvio Uhlig**	NVI Partner 3	Senior scientist	100,707.00 €	457.76 €	30	13,732.77 €
14	**Belinda Valdecanas**	NVI Partner 3	Senior technician	81,007.00 €	368.21 €	40	14,728.55 €
15	**Sathyapalan Thozhukat**	HULL Partner 4	Reader Dep. Endocrinology Diabetes and Metabolism	118,278.00 €	537.63 €	20.5	11,021.36 €
16	Nurse	HULL Partner 4	Band 6 nurse	27,901.00 €	126.82 €	170	21,559.86 €
						Total costs of staff working for the applicant and partners	225,879.07 €

* 220 is a generally expected number of productive days in the given organisation; in case the actual number of productive days is different in your organisation for the given staff member you may use that number in these calculations, however you must provide the exact calculation of the number of productive days you used, taking into account: 52 weekends equalling to 104 days, public holidays in the country concerned and annual leave allowed in the organisation

Estimated budget - Item A.2 - Daily subsistence allowances and travel costs

No.	Organisation/ Employed by	From	Destination	Justification for mission	Mode of transport	Number of persons (a)	Subsistence allowance per person per day (b)	Number of days on mission (c)	Estimated cost per person per journey (d)	Eligible costs (e)=(a)x(b)x(c)+(a)x(d)
1	ISS Applicant	Rome	Parma	Kick-off Meeting	train	3	40.00 €	1	100.00 €	420.00 €
2	ISS Applicant	Rome	Parma	Final Meeting	train	3	40.00 €	1	100.00 €	420.00 €
3	ISS Applicant	Rome	HULL	Technical visit (standardization of methodologies).	airplane	1	276.00 €	6	700.00 €	2,356.00 €
4	ISS Applicant	Rome	OSLO	Technical visit (standardization of methodologies).	airplane	1	260.00 €	6	700.00 €	2,260.00 €
5	UNICATT Partner 1	Rome	Parma	Kick-off Meeting	train	1	40.00 €	1	120.00 €	160.00 €
6	UNICATT Partner 1	Rome	Parma	Final Meeting	train	1	40.00 €	1	120.00 €	160.00 €
7	NIPH Partner 2	Oslo	Parma	Kick-off Meeting A/R	airplane	1	230.00 €	1	1,000.00 €	1,230.00 €
8	NIPH Partner 2	Oslo	Parma	Final Meeting A/R	airplane	1	230.00 €	1	1,000.00 €	1,230.00 €
9	NIV Partner 3	Oslo	Parma	Kick-off Meeting	airplane	1	230.00 €	1	1,000.00 €	1,230.00 €
10	NIV Partner 3	Oslo	Parma	Final Meeting	airplane	1	230.00 €	1	1,000.00 €	1,230.00 €
11	HULL Partner 4	HULL	Parma	Kick-off Meeting	airplane	1	230.00 €	1	1,000.00 €	1,230.00 €
12	HULL Partner 4	HULL	Parma	Final Meeting	airplane	1	230.00 €	1	1,000.00 €	1,230.00 €
13						0	0.00 €	0	0.00 €	0.00 €
14						0	0.00 €	0	0.00 €	0.00 €
15						0	0.00 €	0	0.00 €	0.00 €
16						0	0.00 €	0	0.00 €	0.00 €
17						0	0.00 €	0	0.00 €	0.00 €
18						0	0.00 €	0	0.00 €	0.00 €
Total daily subsistence allowances and travel costs										13,156.00 €

Estimated budget - Item A.3 - Equipment (new or second-hand)

No.	Description of equipment	Purpose of equipment for the project	Planned day of purchase	Quantity (a)	Cost per item (b)	The rate in % of actual use for project (c)	Yearly depreciation rate in % to be applied (d)	Duration of the project in years (put value "1" for software) (e)	Eligible costs (f)=(a)x(b)x(c)x(d)x(e)
1				0	0.00 €	0.00%	0.00%	0	0.00 €
2				0	0.00 €	0.00%	0.00%	0	0.00 €
3				0	0.00 €	0.00%	0.00%	0	0.00 €
4				0	0.00 €	0.00%	0.00%	0	0.00 €
5				0	0.00 €	0.00%	0.00%	0	0.00 €
6				0	0.00 €	0.00%	0.00%	0	0.00 €
7				0	0.00 €	0.00%	0.00%	0	0.00 €
8				0	0.00 €	0.00%	0.00%	0	0.00 €
9				0	0.00 €	0.00%	0.00%	0	0.00 €
10				0	0.00 €	0.00%	0.00%	0	0.00 €
11				0	0.00 €	0.00%	0.00%	0	0.00 €
12				0	0.00 €	0.00%	0.00%	0	0.00 €
13				0	0.00 €	0.00%	0.00%	0	0.00 €
14				0	0.00 €	0.00%	0.00%	0	0.00 €
15				0	0.00 €	0.00%	0.00%	0	0.00 €
								Total costs of equipment (new or second-hand)	0.00 €

Estimated budget - Item A.4 - Consumables and supplies

No.	Title of item	Purpose of consumables and supplies for the project	Planned day of purchase	Quantity (a)	Cost per item (b)	Eligible costs (c) = (a)x(b)
1	Primary reference standards	To perform chemical analyses (Applicant)	01/01/2014	10	452.00 €	4,520.00 €
2	Solvents and reagents	To perform chemical analyses (Applicant)	01/01/2014	10	25.00 €	250.00 €
3	Immunoaffinity Columns	To perform chemical analyses (Applicant)	01/01/2014	500	15.00 €	7,500.00 €
4	Consumables (columns, etc)	To perform chemical analyses (Applicant)	01/01/2014	10	615.00 €	6,150.00 €
5	Tubes	To perform chemical analyses (Partner 1)	01/01/2014	1,000	0.36 €	360.00 €
6	Office supplies	To perform chemical analyses (Partner 1)	01/01/2014	500	1.00 €	500.00 €
7	Creatinine assay	To perform chemical analyses (Partner 1)	01/01/2014	500	2.60 €	1,300.00 €
8	Consumables (columns, etc)	To perform chemical analyses (Partner 3)	01/01/2014	10	700.00 €	7,000.00 €
9	Sample potes	To perform chemical analyses (Partner 4)	01/01/2014	10	146.25 €	1,462.50 €
10	Tubes	To perform chemical analyses (Partner 4)	01/01/2014	400	0.13 €	52.00 €
11				0	0.00 €	0.00 €
12				0	0.00 €	0.00 €
13				0	0.00 €	0.00 €
14				0	0.00 €	0.00 €
15				0	0.00 €	0.00 €
					Total costs of consumables and supplies	29,094.50 €

Estimated budget - Item A.5 - Subcontracting of some tasks/external assistance

No.	Task to be subcontracted	Proposed subcontractor name, if known	Procedure followed to subcontract: Public bodies must follow national procurement rules when awarding contracts	Justification for using sub-contracting	For external consultants contracted - amount per day (a)	For external consultants contracted - number of days on project (b)	Other costs (c)	Eligible costs (d)=(a)x(b)+(c)
1	University of Hull	University of Leeds (Laura J Hardie)			200.00 €	180	0.00 €	36,000.00 €
2					0.00 €	0	0.00 €	0.00 €
3					0.00 €	0	0.00 €	0.00 €
4					0.00 €	0	0.00 €	0.00 €
5					0.00 €	0	0.00 €	0.00 €
6					0.00 €	0	0.00 €	0.00 €
7					0.00 €	0	0.00 €	0.00 €
8					0.00 €	0	0.00 €	0.00 €
9					0.00 €	0	0.00 €	0.00 €
10					0.00 €	0	0.00 €	0.00 €
11					0.00 €	0	0.00 €	0.00 €
12					0.00 €	0	0.00 €	0.00 €
13					0.00 €	0	0.00 €	0.00 €
14					0.00 €	0	0.00 €	0.00 €
15					0.00 €	0	0.00 €	0.00 €
							Total costs of subcontracting	36,000.00 €

to me moved to miscellaneous A.6

to me moved to miscellaneous A.6

Estimated budget - Item A.6 - Miscellaneous costs directly linked to the project and arising directly from requirements imposed by the grant agreement

No.	Title of item	Justification of costs within the project	Quantity (a)	Cost per item (b)	Total costs (c) = (a)x(b)
1	Materials transport (Partner 1)	To perform chemical analyses	12	120.00 €	1,440.00 €
2	For collection and transport of urinary samples (Partner 2)	(containers for urine collection)	1,200	12.00 €	14,400.00 €
3	Printing (Partner 2)	Dietary assessment questionnaire	600	1.00 €	600.00 €
4	HULL Partner 4	Patient travel costs East Yorkshire-HULL remuneration for travel expenses for volunteers participating in clinical and other research studies	400	18.75 €	7,500.00 €
5	Shipping (Partner 4)	To perform chemical analyses	4	625.00 €	2,500.00 €
6			0	0.00 €	0.00 €
7			0	0.00 €	0.00 €
8			0	0.00 €	0.00 €
9			0	0.00 €	0.00 €
10			0	0.00 €	0.00 €
11			0	0.00 €	0.00 €
12			0	0.00 €	0.00 €
13			0	0.00 €	0.00 €
14			0	0.00 €	0.00 €
		Total miscellaneous costs directly linked to the project			26,440.00 €

Details of ineligible costs

No.	Type of costs	Who incurs the costs (applicant, partner 1,2,...)	Total costs
1			0.00 €
2			0.00 €
3			0.00 €
4			0.00 €
5			0.00 €
6			0.00 €
7			0.00 €
8			0.00 €
9			0.00 €
10			0.00 €
11			0.00 €
12			0.00 €
13			0.00 €
14			0.00 €
15			0.00 €
		Total ineligible costs	0.00 €

Annex IV Financial statements and supporting financial documents

Interim financial statement of the costs actually incurred and income established/received

Please note that EFSA will verify in detail the accuracy of calculations. EFSA reserves the right to verify the veracity of supporting documents on which these calculations are based. For this purpose, EFSA will ask, on a random basis, the evidence of incurred expenditures, such as, e.g., salary slips, usual practices on travel costs, invoices, travel tickets, boarding passes, timesheets or proofs of payment of declared costs. Finally, EFSA reserves the right to ask any other document in order to ascertain whether the declared costs were actually incurred.

The reported period		
	from	
	to	

Item	The eligible costs actually incurred in the reported period	Coordinator	Co-beneficiary 1	Co-beneficiary 2	Total	
A.1	Staff working for coordinator and co-beneficiaries	0.00 €	0.00 €	0.00 €	0.00 €	details see on sheet A.1
A.2	Daily subsistence allowances and travel costs	0.00 €	0.00 €	0.00 €	0.00 €	details see on sheet A.2
A.3	Equipment (new or second-hand)	0.00 €	0.00 €	0.00 €	0.00 €	details see on sheet A.3
A.4	Consumables and supplies	0.00 €	0.00 €	0.00 €	0.00 €	details see on sheet A.4
A.5	Subcontracting of some tasks	0.00 €	0.00 €	0.00 €	0.00 €	details see on sheet A.5
A.6	Miscellaneous costs arising directly from requirements imposed by the grant agreement	0.00 €	0.00 €	0.00 €	0.00 €	details see on sheet A.6
A	**Eligible direct costs**	**0.00 €**	**0.00 €**	**0.00 €**	**0.00 €**	
B	**Eligible indirect costs**	**0.00 €**	**0.00 €**	**0.00 €**	**0.00 €**	
C=A+B	**Total eligible costs**	**0.00 €**	**0.00 €**	**0.00 €**	**0.00 €**	

Item	The ineligible costs actually incurred in the reported period	Coordinator	Co-beneficiary 1	Co-beneficiary 2	Total	
X.1		0.00 €	0.00 €	0.00 €	0.00 €	details see on sheet X
X.2		0.00 €	0.00 €	0.00 €	0.00 €	details see on sheet X
X	**Total ineligible costs**	**0.00 €**	**0.00 €**	**0.00 €**	**0.00 €**	

Item	The income established in the reported period	Coordinator	Co-beneficiary 1	Co-beneficiary 2	Total	
E.1	Contribution by beneficiary/co-beneficiary	0.00 €	0.00 €	0.00 €	0.00 €	details see on sheet E.1, free format
E.2	Grant requested from EFSA - shall be 90% of total eligible actually incurred costs declared for the period		0.00 €		0.00 €	details see on sheet E.2, free format
E.3	Contribution from other public sector bodies		0.00 €		0.00 €	details see on sheet E.3, free format
E.4	Any revenue generated by the project - e.g. fees collected during workshops		0.00 €		0.00 €	details see on sheet E.4, free format
E	**Total established income**				**0.00 €**	

Item	The income received in the reported period	Coordinator	Co-beneficiary 1	Co-beneficiary 2	Total	
E.1	Contribution by beneficiary/co-beneficiary	0.00 €	0.00 €	0.00 €	0.00 €	details see on sheet E.1
E.2	Grant from EFSA		0.00 €		0.00 €	details see on sheet E.2
E.3	Contribution from other public sector bodies		0.00 €		0.00 €	details see on sheet E.3
E.4	Any revenue generated by the project - e.g. fees collected during workshops		0.00 €		0.00 €	details see on sheet E.4
E	**Total received income**				**0.00 €**	

Certification - by the most senior accouting officer of Coordinator (on behalf of Coordinator and Co-beneficiaries)

From my position of the most senior accounting officer in the organisational structure of Coordinator, I hereby certify that the costs declared above and in the attached tables, both eligible and ineligible: 1. were actually incurred, 2. were incurred in the reported period, 3. were incurred by the Coordinator or Co-beneficiary, 4. are accurately presented above and that 5. "incurrence" of these costs can be immediately evidenced by supporting documents stored at Coordinator/Co-beneficiary. All these supporting documents are ready for immediate audit or check by EFSA or other bodies entitled to do so in accordance with the Grant Agreement. I also declare that all the income generated by the project in the reported period or to be received to the project from EFSA, internal resources of Coordinator/Co-beneficiaries or from any other publis sector body contributing financially to the project have been declared above. Regarding the EFSA contribution to the project this equals to 80% of eligible costs actually incurred in the reported period by the Coordinator/Co-beneficiaries.

Signature	
Exact title of the position	
Date, place	

Final financial statement of the costs actually incurred and income established/received

Please note that EFSA will verify in detail the accuracy of calculations. EFSA reserves the right to verify the veracity of supporting documents on which these calculations are based. For this purpose, EFSA will ask, on a random basis, the evidence of occurrence of expenditures, such as, e.g. , salary slips, usual practices on travel costs, invoices, travel tickets, boarding passes, timesheets or proofs of payment of declared costs. Finally, EFSA reserves the right to ask any other document in order to ascertain whether the declared costs were actually incurred.

The reported period	from	
	to	

Item	The eligible costs actually incurred in the reported period	Coordinator	Co-beneficiary 1	Co-beneficiary 2	Total	
A.1	Staff working for coordinator and co-beneficiaries	0.00 €	0.00 €	0.00 €	0.00 €	details see on sheet A.1
A.2	Daily subsistence allowances and travel costs	0.00 €	0.00 €	0.00 €	0.00 €	details see on sheet A.2
A.3	Equipment (new or second-hand)	0.00 €	0.00 €	0.00 €	0.00 €	details see on sheet A.3
A.4	Consumables and supplies	0.00 €	0.00 €	0.00 €	0.00 €	details see on sheet A.4
A.5	Subcontracting of some tasks	0.00 €	0.00 €	0.00 €	0.00 €	details see on sheet A.5
A.6	Miscellaneous costs arising directly from requirements imposed by the grant agreement	0.00 €	0.00 €	0.00 €	0.00 €	details see on sheet A.6
A	**Eligible direct costs**	**0.00 €**	**0.00 €**	**0.00 €**	**0.00 €**	
B	**Eligible indirect costs**	**0.00 €**	**0.00 €**	**0.00 €**	**0.00 €**	
C=A+B	**Total eligible costs**	**0.00 €**	**0.00 €**	**0.00 €**	**0.00 €**	

Item	The ineligible costs actually incurred in the reported period	Coordinator	Co-beneficiary 1	Co-beneficiary 2	Total	
X.1		0.00 €	0.00 €	0.00 €	0.00 €	details see on sheet X
X.2		0.00 €	0.00 €	0.00 €	0.00 €	details see on sheet X
X	**Total ineligible costs**	**0.00 €**	**0.00 €**	**0.00 €**	**0.00 €**	

Item	The income established in the reported period	Coordinator	Co-beneficiary 1	Co-beneficiary 2	Total	
E.1	Contribution by beneficiary/co-beneficiary	0.00 €	0.00 €	0.00 €	0.00 €	details see on sheet E.1, free format
E.2	Grant requested from EFSA - shall be 80% of total eligible actually incurred costs declared for the period		0.00 €		0.00 €	details see on sheet E.2, free format
E.3	Contribution from other public sector bodies		0.00 €		0.00 €	details see on sheet E.3, free format
E.4	Any revenue generated by the project - e.g. fees collected during workshops		0.00 €		0.00 €	details see on sheet E.4, free format
E	**Total established income**				**0.00 €**	

Item	The income received in the reported period	Coordinator	Co-beneficiary 1	Co-beneficiary 2	Total	
E.1	Contribution by beneficiary/co-beneficiary	0.00 €	0.00 €	0.00 €	0.00 €	details see on sheet E.1
E.2	Grant from EFSA		0.00 €		0.00 €	details see on sheet E.2
E.3	Contribution from other public sector bodies		0.00 €		0.00 €	details see on sheet E.3
E.4	Any revenue generated by the project - e.g. fees collected during workshops		0.00 €		0.00 €	details see on sheet E.4
E	**Total received income**				**0.00 €**	

Certification - by the most senior accouting officer of Coordinator (on behalf of Coordinator and Co-beneficiaries)

From my position of the most senior accounting officer in the organisational structure of Coordinator, I hereby certify that the costs declared above and in the attached tables, both eligible and ineligible: 1. were actually incurred, 2. were incurred in the reported period, 3. were incurred by the Coordinator or Co-beneficiary, 4. are accurately presented above and that 5. "incurrence" of these costs can be immediately evidenced by supporting documents stored at Coordinator/Co-beneficiary. All these supporting documents are ready for immediate audit or check by EFSA or other bodies entitled to do so in accordance with the Grant Agreement. I also declare that all the income generated by the project in the reported period or to be received to the project from EFSA, internal resources of Coordinator/Co-beneficiaries or from any other publis sector body contributing financially to the project have been declared above. Regarding the EFSA contribution to the project this equals to 80% of eligible costs actually incurred in the reported period by the Coordinator/Co-beneficiaries.

Signature	
Exact title of the position	
Date, place	

Summary financial statement of the costs actually incurred and income established/received

Project reference:

The reported period	from	
	to	

Item	The eligible costs actually incurred in the reported period	Coordinator	Co-beneficiary 1	Co-beneficiary 2	Total
A.1	Staff working for coordinator and co-beneficiaries	0.00 €	0.00 €	0.00 €	0.00 €
A.2	Daily subsistence allowances and travel costs	0.00 €	0.00 €	0.00 €	0.00 €
A.3	Equipment (new or second-hand)	0.00 €	0.00 €	0.00 €	0.00 €
A.4	Consumables and supplies	0.00 €	0.00 €	0.00 €	0.00 €
A.5	Subcontracting of some tasks	0.00 €	0.00 €	0.00 €	0.00 €
A.6	Miscellaneous costs arising directly from requirements imposed by the grant agreement	0.00 €	0.00 €	0.00 €	0.00 €
A	**Eligible direct costs**	**0.00 €**	**0.00 €**	**0.00 €**	**0.00 €**
B	**Eligible indirect costs**	**0.00 €**	**0.00 €**	**0.00 €**	**0.00 €**
C=A+B	**Total eligible costs**	**0.00 €**	**0.00 €**	**0.00 €**	**0.00 €**

Item	The ineligible costs actually incurred in the reported period	Coordinator	Co-beneficiary 1	Co-beneficiary 2	Total
X.1		0.00 €	0.00 €	0.00 €	0.00 €
X.2		0.00 €	0.00 €	0.00 €	0.00 €
X	**Total ineligible costs**	**0.00 €**	**0.00 €**	**0.00 €**	**0.00 €**

Item	The income established in the reported period	Coordinator	Co-beneficiary 1	Co-beneficiary 2	Total
E.1	Contribution by beneficiary/co-beneficiary	0.00 €	0.00 €	0.00 €	0.00 €
E.2	Grant requested from EFSA - shall be 80% of total eligible actually incurred costs declared for the period		0.00 €		0.00 €
E.3	Contribution from other public sector bodies		0.00 €		0.00 €
E.4	Any revenue generated by the project - e.g. fees collected during workshops		0.00 €		0.00 €
E	**Total established income**				**0.00 €**

Item	The income received in the reported period	Coordinator	Co-beneficiary 1	Co-beneficiary 2	Total
E.1	Contribution by beneficiary/co-beneficiary	0.00 €	0.00 €	0.00 €	0.00 €
E.2	Grant from EFSA		0.00 €		0.00 €
E.3	Contribution from other public sector bodies		0.00 €		0.00 €
E.4	Any revenue generated by the project - e.g. fees collected during workshops		0.00 €		0.00 €
E	**Total received income**				**0.00 €**

Certification - by the most senior accouting officer of Coordinator (on behalf of Coordinator and Co-beneficiaries)

From my position of the most senior accounting officer in the organisational structure of Coordinator, I hereby certify that the costs declared above and in the attached tables, both eligible and ineligible: 1. were actually incurred, 2. were incurred in the reported period, 3. were incurred by the Coordinator or Co-beneficiary, 4. are accurately presented above and that 5. "incurrence" of these costs can be immediately evidenced by supporting documents stored at Coordinator/Co-beneficiary. All these supporting documents are ready for immediate audit or check by EFSA or other bodies entitled to do so in accordance with the Grant Agreement. I also declare that all the income generated by the project in the reported period or to be received to the project from EFSA, internal resources of Coordinator/Co-beneficiaries or from any other publis sector body contributing financially to the project have been declared above. Regarding the EFSA contribution to the project this equals to 80% of eligible costs actually incurred in the reported period by the Coordinator/Co-beneficiaries.

Signature	
Exact title of the position	
Date, place	

Annex V Monthly timesheet template

Staff member's name: Month:

Organisation: Project: CFP/EFSA/…

Department/Unit:

TIMESHEET[1]

Date	Cat. [2]	Task description[3]	No. hours
		Total of month:	

Staff member's signature + date	Signature of the linemanager/supervisor + name, function and date

(1) Use 1 line per day per task category
(2) Choose 1/2/3/4 (1=administratif, 2=scientific, 3=meetings and workshops)
(3) Provide a detailed and exact description of the tasks carried out

Annex VI

Declaration on honour concerning Quality Assurance[2]

(To be completed, signed, dated and submitted by the Grant co-rdinator together with each deliverable foreseen under the Grant Agreement)

Att.: European Food Safety Authority

Reference of the Grant Agreement: [INSERT REFERENCE]

Linked to the submission of Deliverable No [INSERT NUMBER] for approval by the Authority: [INSERT NAME]

I, [legal representative, project leader or quality manager], [INSERT NAME]:

DECLARE that the quality assurance measures and activities presented in our proposal, which is Annex II of the Grant Agreement, were respected and adhered to throughout the preparation of this deliverable, thereby guaranteeing a high quality deliverable in subject of this declaration;

UNDERSTAND that the Authority reserves the right to request evidence on the quality assurance measures taken and activities carried out to guarantee a high quality of the deliverable in subject of this declaration.

Yours faithfully,

SIGNATURE & DATE:

<Original signature and date of [legal representative, project leader or quality manager] of the legal entity >

< Name and position in the legal entity >

[2] To be completed, dated and signed by the legal representative, project manager or quality manager of the Grant beneficiary on headed paper.

Annex VII Partnership statement

Istituto Superiore di Sanità

PARTNERSHIP STATMENT

GP/EFSA/CONTAM/2013/04
Experimental study of deoxynivalenol biomarkers in urine

Dear Sir or Madam,
I would like to confirm on behalf of Istituto Superiore di Sanità that we wish to lead the consortium for the above project. We have a consortium of 4 European partners in addition to ourselves. We believe this will provide a strong network of expertise to develop harmonized EU schemes which would not be possible from an organization working alone.

We have the technical and financial capacity to provide the services detailed in the attached application form and budget from in order to satisfy the requirements of the project. The technical involvement of all institutes and involved in the consortium is described within the project workplan. More details on the institutes are given in the supporting documentation. Their agreements to join this partnership are attached.

Yours faithfully,

Dr. Carlo Brera
Applicant

Dr. Umberto Agrimi
Director Dep. Veterinary Public Health
and Food Safety

Date, 8 ottobre 2013

PARTNERSHIP STATMENT

GP/EFSA/CONTAM/2013/04
Experimental study of deoxynivalenol biomarkers in urine

Dear Sir or Madam,
I would like to confirm on behalf of Catholic University of Sacred Heart, Rome, Gemelli Hospital that, for the above project, we wish to be part of the consortium of 5 European partners in addition to ourselves. We believe this will provide a strong network of expertise to develop harmonized EU schemes which would not be possible from an organization working alone.

We have the technical and financial capacity to provide the services detailed in the attached application and budget form in order to satisfy the requirements of the project. The technical involvement of all institutes composing the consortium is described within the project workplan. More details on the institutes are given in the supporting documentation. The agreements to join this partnership are attached.

Yours faithfully,

Prof. Antonio Lanzone

ISTITUTO DI CLINICA OSTETRICA E GINECOLOGICA
Direttore Prof. Antonio Lanzone

Oslo, October 7th 2013

PARTNERSHIP STATMENT

GP/EFSA/CONTAM/2013/04
Experimental study of deoxynivalenol biomarkers in urine

Dear Sir or Madam,
I would like to confirm on behalf of the Norwegian Institute of Public Health (NIPH) that, for the above project, we wish to be part of the consortium of 5 European partners in addition to ourselves. We believe this will provide a strong network of expertise to develop harmonized EU schemes which would not be possible from an organization working alone.

We have the technical and financial capacity to provide the services detailed in the attached application and budget form in order to satisfy the requirements of the project. The technical involvement of all institutes composing the consortium is described within the project workplan. More details on the institutes are given in the supporting documentation. The agreements to join this partnership are attached.

Yours faithfully,

Anne Lise Brantsæter

Anne Lise Brantsæter, Senior Scientist

Toril Attramadal

Toril Attramadal, Division Director

Oslo, October 8th, 2013

Partnership statement

GP/EFSA/CONTAM/2013/04

Experimental study of deoxynivalenol biomarkers in urine

Dear Sir or Madam

We would like to confirm on behalf of the Norwegian Veterinary Institute (NVI) that, for the above project, we wish to be part of the consortium of 5 European partners in addition to ourselves. We believe this will provide a strong network of expertise to develop harmonized EU schemes which would not be possible for an organization working alone.

We have the technical and financial capacity to provide the services detailed in the attached application and budget form in order to satisfy the requirements of the project. The technical involvement of all institutes composing the consortium is described within the project workplan. More details on the institutes are given in the supporting documentation. The agreements to join this partnership are attached.

Yours faithfully

Gunnar S Eriksen

Gunnar Sundstøl Eriksen

On behalf of

Gudmund Holstad

Merete Hofshagen

MERETE HOFSHAGEN

Date, 9th October 2013

PARTNERSHIP STATMENT

GP/EFSA/CONTAM/2013/04
Experimental study of deoxynivalenol biomarkers in urine

Dear Sir or Madam,
I would like to confirm on behalf of Hull University that, for the above project, we wish to be part of the consortium of 5 European partners in addition to ourselves. We believe this will provide a strong network of expertise to develop harmonized EU schemes which would not be possible from an organization working alone.

We have the technical and financial capacity to provide the services detailed in the attached application and budget form in order to satisfy the requirements of the project. The technical involvement of all institutes composing the consortium is described within the project workplan. More details on the institutes are given in the supporting documentation. The agreements to join this partnership are attached.

Yours faithfully,

09/10/2013

Dr Thozhukat Sathyapalan
Reader in Diabetes and Endocrinology
Michael White Diabetes Centre
Hull Royal Infirmary
220-236 Anlaby Road
Hull Royal Infirmary
HU3 2RW

Annex VIII Powers of attorney, for the co-beneficiaries