



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Working Document
SANTE/7098/2016

ANNEX II

TERMS OF REFERENCE

**to Call for selection and designation of a European Union reference centre responsible
for the scientific and technical contribution to the harmonisation and improvement
of the methods of performance testing and genetic evaluation of purebred breeding
animals of the bovine species**

1. INTRODUCTION

1.1. Purpose

The purpose of this call is to select from applying candidates and designate a European Union reference centre responsible for the scientific and technical contribution to the harmonisation and improvement of the methods of performance testing and genetic evaluation of purebred breeding animals of the bovine species ("the EU reference centre").

The intention is to designate the EU reference centre that will become operational as of 1 November 2018, on the day when Regulation (EU) 2016/1012 the European Parliament and of the Council¹ will be applicable.

As of 1 November 2018, Council Decision 96/463/EC² designating INTERBULL Centre as the reference body responsible for collaborating in rendering uniform the testing methods and the assessment of the results for pure-bred breeding animals of the bovine species will be repealed and therefore there is a need of designation of the EU reference centre to continue work which was already done in the area of competence of INTERBULL Centre.

The EU reference centre will support Member States by establishing, harmonising and improving the rules and standards of the methods of performance testing and genetic evaluation of purebred breeding animals of the bovine species. Those standards and methods are used by breed societies, or third parties designated by those breed societies in accordance with Article 27(1)(b) of Regulation (EU) 2016/1012., to carry out performance testing and genetic evaluation within the framework of their breeding programmes.

1.2. The principles of the call for selection

Considering the responsibilities of the EU reference centre in the framework of Regulation (EU) 2016/1012, as well as the support required by the national competent authorities (NCAs) for any EU reference centre located in their country, the NCAs are responsible for submitting the dossiers of the respective applicant centres to the Commission, after they have performed a preliminary check that the selection criteria are fulfilled by the candidate centres.

A selection panel will be set up within Directorate-General for Health and Food Safety (DG SANTE), with possible external support as appropriate, in order to evaluate the respective merits of the applicant centres on the basis of the dossiers submitted through the NCAs.

The procedure can be summarised as follows:

- DG SANTE shall send to the NCAs an invitation to submit applications for candidate centres in their country, together with the terms of reference.
- The NCAs shall organise a preselection of candidate centres, on the basis of the eligibility and selection criteria set under chapters 4 and 5 below, and submit relevant applications. NCAs shall not submit more than one candidate centre.
- A Commission selection panel will evaluate the applications by following the eligibility, selection and preference criteria.

¹ Regulation (EU) 2016/1012 of the European Parliament and of the Council on zootechnical and genealogical conditions for the breeding, trade in and entry into the Union of purebred breeding animals, hybrid breeding pigs and the germinal products thereof and amending Regulation (EU) No 652/2014, Council Directives 89/608/EEC and 90/425/EEC and repealing certain acts in the area of animal breeding ('Animal Breeding Regulation') (OJ L 171, 29.6.2016, p. 66).

² Council Decision 96/463/EC of 23 July 1996 designating the reference body responsible for collaborating in rendering uniform the testing methods and the assessment of the results for pure-bred breeding animals of the bovine species (OJ L 192, 2.8.1996, p. 19).

- The NCAs will be informed about the outcome of the call.

Thereafter, the relevant EU reference centre will be designated by Commission Decision, in accordance with comitology procedure (Standing Committee on Zootechnics).

1.3. Legal framework

1.3.1. Designation of European Union reference centres

Article 29(1) of Regulation (EU) 2016/1012 provides that where there is a recognised need to promote the harmonisation or improvement of the methods of performance testing or genetic evaluation of purebred breeding animals used by breed societies or by third parties designated by breed societies in accordance with Article 27(1)(b) of that Regulation, the Commission may adopt implementing acts, designating the European Union reference centres responsible for the scientific and technical contribution to the harmonisation or improvement of those methods.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 62(2) of that Regulation.

In accordance with Article 29(3) of that Regulation, the designations provided for in paragraph 1 of that Article shall follow a public selection process and shall be limited in time or reviewed regularly.

1.3.2. EU financial assistance to European Union reference centres

In accordance with Article 30 of Commission Regulation (EC) No 652/2014 of the European Parliament and of the Council³ the European Union provides financial assistance to European Union reference centres. This assistance is in the form of a grant for the costs that they incur in work programmes approved by the Commission. The eligible costs for implementation of the work programmes of European Union reference centres are listed in paragraph 2 of Article 30 of that Regulation⁴.

The EU funding may cover up to 100% of the eligible expenditures.

2. THE NEED FOR DESIGNATION OF EU REFERENCE CENTRE.

Currently, INTERBULL Centre is the EU reference body responsible for the harmonisation in the Union and improvement of the methods of performance testing or genetic evaluation of purebred breeding animals of the bovine species and for the assessment of the obtained results. As of 1 November 2018, Decision 96/463/EC designating INTERBULL Centre as that reference body will be repealed.

During the Commission Working Group on Zootechnics, which took place on 15 November 2016, experts from the Member States expressed that there is a need to promote the harmonisation and improvement of the methods of performance testing and genetic evaluation

³ Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC (OJ L 189, 27.6.2014, p. 1).

⁴ 2. The following costs may be eligible for grants under paragraph 1:

(a) costs of personnel, regardless of their status, directly involved in activities of the laboratories which are carried out in their capacity of Union reference laboratory or centre;
 (b) costs of capital equipment;
 (c) cost of consumables;
 (d) costs of shipment of samples, missions, meetings, training activities.

of purebred breeding animals of the bovine species used by breed societies or by third parties designated by those breed societies, therefore the public selection to designate the European Union reference centre responsible for the scientific and technical contribution to the harmonisation and improvement of those methods should be launched by the Commission to ensure continuity in this field after 31 October 2018.

3. REQUIREMENTS AND TASKS OF A EUROPEAN UNION REFERENCE CENTRE

3.1. Requirements

In accordance with Article 29(4)(a) of Regulation (EU) 2016/1012, European Union reference centre designated in accordance with paragraph 1 of this Article shall comply with the following requirements set out in point 1 of Annex IV to this Regulation.

Such European Union reference centres shall:

- (a) have suitably qualified staff:
 - (i) who have adequate training in performance testing and genetic evaluation of purebred breeding animals,
 - (ii) who have been instructed to respect the confidential nature of certain subjects, results or communications; and
 - (iii) who have sufficient knowledge of research activities at national, Union and international level;
- (b) possess or have access to the infrastructure, equipment and products necessary to carry out the tasks referred to in point 3.2.

3.2. Tasks

In accordance with Article 29(4)(b)(i) of Regulation (EU) 2016/1012, European Union reference centre designated in accordance with paragraph 1 of this Article shall be responsible for the tasks set out in point 2 of Annex IV to this Regulation.

Such European Union reference centres shall:

- (a) work with breed societies and third parties designated by breed societies in accordance with Article 27(1)(b) to facilitate the uniform application of methods for performance testing and genetic evaluation for purebred breeding animals of the bovine species, referred to in Article 25;
- (b) inform breed societies, third parties designated by those breed societies in accordance with Article 27(1)(b), or competent authorities on methods of performance testing and genetic evaluation of purebred breeding animals of the bovine species;
- (c) review regularly the results of performance testing and genetic evaluations of purebred breeding animals of the bovine species carried out by breed societies or third parties designated by those breed societies in accordance with Article 27(1)(b) and the data on which they are based;
- (d) compare methods of performance testing and genetic evaluation of purebred breeding animals of the bovine species;
- (e) at the request of the Commission or a Member State:
 - (i) provide assistance in the harmonisation of methods of performance testing and genetic evaluation of purebred breeding animals of the bovine species;
 - (ii) recommend calculation methods to be used for the performance testing and genetic evaluation of purebred breeding animals of the bovine species;

- (iii) establish a platform for the comparison of the results of the methods of performance testing and genetic evaluation of purebred breeding animals of the bovine species used in Member States, in particular by:
 - developing control protocols for performance testing and genetic evaluation of purebred breeding animals of the bovine species carried out in Member States to improve the comparability of the results and the effectiveness of breeding programmes,
 - carrying out an international assessment of livestock on the basis of the combined results of performance testing and genetic evaluation of purebred breeding animals of the bovine species carried out in Member States and third countries,
 - disseminating the results of those international assessments;
 - publishing the conversion formulae and the related information based on which the formulae were established;
- (f) provide data on the genetic evaluation of purebred breeding animals of the bovine species and training to support breed societies or third parties designated by those breed societies in accordance with Article 27(1)(b), which are participating in international comparisons of the results of genetic evaluations;
- (g) facilitate the resolution of emerging problems in Member States linked to the genetic evaluation of purebred breeding animals of the bovine species;
- (h) cooperate, within the scope of their tasks, with internationally recognised organisations;
- (i) provide, at the request of the Commission, technical expertise to the Standing Committee on Zootechnics,

if those tasks are included in the reference centres' annual or multiannual work programmes established in conformity with the objectives and priorities of the relevant work programmes adopted by the Commission in accordance with Article 36 of Regulation (EU) No 652/2014.

3.3. Amendments of requirements and tasks

In accordance with Article 29(5) of Regulation (EU) 2016/1012, the Commission is empowered to adopt delegated acts in accordance with Article 61 to this Regulation amending:

- (a) the requirements for European Union reference centres set out in point 1 of Annex IV;
- (b) the tasks of European Union reference centres set out in point 2 of Annex IV.

Those delegated acts shall take due account of the species of purebred breeding animals for which the methods of performance testing and genetic evaluation are to be harmonised or improved and the scientific and technical advances in the area of performance testing or genetic evaluation.

4. ELIGIBILITY AND EXCLUSION CRITERIA

4.A. ELIGIBILITY CRITERIA

In order for the applicant centre to be eligible:

- The applicant centre shall be viable without the EU financial assistance.

Means of proof: NCAs shall provide a certificate stating that they will ensure that the required support in relation to human and financial resources necessary for the

satisfactory operation of the EURC will be provided by the NCAs, or an appropriate body.

- The applicant centres shall have been entrusted to perform tasks of public interest in the area of competence of the call, under the supervision of the competent authorities

Means of proof: Description and certification to be provided with the application.

4.B EXCLUSION CRITERIA

Candidates shall be excluded if:

- they have been excluded by the national authorities from the centres involved in official controls pursuant to relevant EU legislation.
- they have conflicting interests with private or public companies or organisations that could restrict the ability of the centre to receive samples from throughout the EU, restrict the dissemination of information derived during the execution of EURC activities, or that could prevent it from acting in an unbiased manner when assisting the Commission, especially in case where Member States contest the results of analyses.
- it is bankrupt, subject to insolvency or winding up procedures, its assets are being administered by a liquidator or by a court, it is in an arrangement with creditors, its business activities are suspended or it is in any analogous situation arising from a similar procedure provided for under national legislation or regulations; they have been convicted of an offence concerning their professional conduct by a judgement, which has the force of *res judicata*;
- it has been established by a final judgement that the person is guilty of any of the following:
 - i. fraud, within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995;
 - ii. corruption, as defined in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of EU Member States, drawn up by the Council Act of 26 May 1997, and in Article 2(1) of Council Framework Decision 2003/568/JHA, as well as corruption as defined in the legal provisions of the country where the contracting authority is located, the country in which the person is established or the country of the performance of the contract;
 - iii. participation in a criminal organisation, as defined in Article 2 of Council Framework Decision 2008/841/JHA;
 - iv. money laundering or terrorist financing, as defined in Article 1 of Directive 2005/60/EC of the European Parliament and of the Council;
 - v. terrorist-related offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting, aiding, abetting or attempting to commit such offences, as referred to in Article 4 of that Decision;
 - vi. child labour or other forms of trafficking in human beings as defined in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council;
- it has been established by a final judgement or a final administrative decision that the person is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the law of the country in which it is established, with those of the country in which the contracting authority is located or those of the country of the performance of the contract;

- it has been established by a final judgement or a final administrative decision that the person is guilty of grave professional misconduct by having violated applicable laws or regulations or ethical standards of the profession to which the person belongs, or by having engaged in any wrongful conduct which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence, including, in particular, any of the following:
 - i. fraudulently or negligently misrepresenting information required for the verification of the absence of grounds for exclusion or the fulfilment of selection criteria or in the performance of a contract;
 - ii. entering into agreement with other persons with the aim of distorting competition;
 - iii. violating intellectual property rights;
 - iv. attempting to influence the decision-making process of the contracting authority during the award procedure;
 - v. attempting to obtain confidential information that may confer upon it undue advantages in the award procedure;
- the person has shown significant deficiencies in complying with the main obligations in the performance of a contract financed by the Union's budget, which has led to its early termination or to the application of liquidated damages or other contractual penalties, or which has been discovered following checks, audits or investigations by an Authorising Officer, OLAF or the Court of Auditors;
- it has been established by a final judgment or final administrative decision that the person has committed an irregularity within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95;
- for the situations of grave professional misconduct, fraud, corruption, other criminal offences, significant deficiencies in the performance of the contract or irregularity, the applicant is subject to:
 - i. facts established in the context of audits or investigations carried out by the Court of Auditors, OLAF or internal audit, or any other check, audit or control performed under the responsibility of an authorising officer of an EU institution, of a European office or of an EU agency or body;
 - ii. non-final administrative decisions which may include disciplinary measures taken by the competent supervisory body responsible for the verification of the application of standards of professional ethics;
 - iii. decisions of the ECB, the EIB, the European Investment Fund or international organisations;
 - iv. decisions of the Commission relating to the infringement of the Union's competition rules or of a national competent authority relating to the infringement of Union or national competition law; or
 - v. decisions of exclusion by an authorising officer of an EU institution, of a European office or of an EU agency or body.

Means of proof: Candidates must certify that they are not in one of the situations listed above.

5. SELECTION CRITERIA

5.A ECONOMIC AND FINANCIAL CAPACITY

The centres shall provide evidence of financial and economic standing based on the following documents: balance sheets, profit and loss accounts or annual reports for the

last three financial years balance. Where available, audits reports of the last 3 years should be provided as well.

Furthermore, applications must be provided by a written evidence of financial support of the EURC by NCA imperatively (see point 4.A.).

5.B TECHNICAL CAPACITY

The selection criteria below are extracted from the requirements laid down in Article 29(4)(a) of Regulation (EU) 2016/1012.

- (a) The centre has suitably qualified staff with adequate training in performance testing and genetic evaluation of purebred breeding animals.

Requirement: the Director of the European Union reference centre must have a post-graduate degree and 5 years professional experience (from which 2 years of experience in the area of competence of the European Union reference centre); the scientific staff shall have a post-graduate degree and 2 years of experience (from which 1 year in the area of competence of the European Union reference centre); the technical staff shall have a technical degree and 1 year experience; The Director of the centre has satisfactory knowledge of English.

In addition to the Director, the European Union reference centre shall have at least 1 scientist, one technician staff and one administrative staff at its disposal.

- Means of proof: CVs and copies of degrees of all staff involved in European Union reference centre's tasks.

- (b) The centre has suitably qualified staff instructed to respect the confidential nature of certain subjects, results or communications.

Requirement: the centre shall have mechanisms/ arrangements/ procedures in place to respect the confidential nature of certain subjects, results or communications

- Means of proof: description of mechanisms/ arrangements/ procedures in place, or that could be initiated.

- (c) The centre has suitably qualified staff with sufficient knowledge of research activities at national, Union and international level.

Requirement: the staff of the centre shall have sufficient knowledge of research activities at national, Union and international level

- Means of proof: statement supported by list of publications; description of standards and practices implemented.

- (d) The centre possesses the equipment and products needed to carry out the tasks assigned to them.

Requirement: the centre shall possess the equipment and products necessary to fulfil the tasks in the area of competence of the European Union reference centres, according to the specifications for the European Union reference

- Means of proof: statement accompanied by description of technical equipment and informatics.

(e) The centre has an appropriate infrastructure needed to carry out the tasks assigned to them.

Requirement: the centre shall have appropriate technical and administrative support

- Means of proof: statement and description of infrastructure.

6. PREFERENCE CRITERIA

The applicant centres mentioned hereinafter shall provide adequately and detailed evidence of the following issues to support their submission.

TEAM COMPOSITION and EXCELLENCE

Rate: 20%

In the area of competence, level of experience, knowledge of scientific background for the area of competence, including scientific publications, references of research work and activities in the area of competence, to assist the Member States and the Commission, availability of validated methods.

STRUCTURE

Rate: 10%

An appropriate infrastructure needed to carry out the assigned tasks.

TECHNICAL COMPETENCE

Rate: 20%

Capability for and experience in establishing, harmonisation and improvement of methods for performance testing and genetic evaluation for purebred breeding animals of the bovine species. Capability to compare those methods used in Member States. Possession, or access to, a platform for the comparison of the results of the methods of performance testing and genetic evaluation for purebred breeding animals of the bovine species.

CAPACITY TO DEVELOP TASKS AS A EURC

Rate: 15%

Evidence of understanding of the mission as a European Union reference centre through a presentation of a simulation Working Program⁵ (description of the activities, objectives, expected outputs) to be developed along two years including budget (maximum ten pages).

INTERNATIONAL:

Rate: 20%

Involvement and participation in international standardisation activities, including a service for exchanging standardised sets for genotyped animals, networks or projects, cooperation with international organisations, including ICAR.

COORDINATION:

Rate: 15%

Carrying out an international assessment of livestock on the basis of the combined results of performance testing and genetic evaluation of purebred breeding animals of the bovine species carried out in Member States and third countries and disseminating the results of those international assessments. Organisation of workshops and training activities, capacity/capability to organise those workshops, activities as the European Union reference centre.

⁵ See Commission Implementing Decision C(2015)4993 final.

7. SELECTION

The application selected will be the one with the highest score.

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