European Union Reference Laboratory for Zootechnics Work Plan 2016-2017

INTERBULL CENTRE, Department of Animal Breeding and Genetics, SLU (Uppsala, Sweden)

9/29/2015

European Union Reference Laboratory for Zootechnics (Bovine Breeding)

INTERBULL CENTRE
Department of Animal Breeding and Genetics
Swedish University of Agricultural Sciences - SLU
PO Box 7023, 750 07 Uppsala, Sweden
Phone: +46(0)18-67 20 98
Contact person: Toine Roozen, Interbull Centre Director
E-mail: Toine.Roozen@slu.se
www.interbull.org

European Union Reference Laboratory for Zootechnics (Bovine Breeding) Work Plan 2016-2017

The following work plan presents the work programme for the period January 2016 to December 2017, according to the Commission Implementation Decision SANTE/10305/2015. Most activities are of a continuous operational nature and follow previous work plans and activity reports. As requested, a hierarchical structure of activity, sub-activity, objectives, expected outputs and performance indicators is provided in Table 1. The performance indicators proposed for all EURLs in the field of animal health cannot be applied to the EURL in Zootechnics given the nature of the entrepreneurship, which differs substantially from the other EURLs. Hence alternative performance indicators have been shown in Table 1. These are the performance indicators that were discussed and agreed for the work plan for 2015. The expected outputs and performance indicators are given on an annual basis.

Developments on genomic evaluations continue to be the major topic in the dairy cattle breeding industry, both at the national and international levels. Interbull has invested significant resources to discuss and develop methodologies and strategic issues related to the incorporation of genomic information on international genetic evaluations of dairy cattle since 2009. In an effort to provide guidance to importing and exporting countries within and outside EU, Interbull has implemented an official validation of genomically enhanced breeding values (GEBVs) in August 2010. This initiative establishes ground according to the requirements of the EC regulation 427/2006 for evaluation of the genetic merit and the correspondent reliability for young bulls without progeny which have been genomically evaluated. The procedure was officially acknowledged by communication from the Director Bernhard Van Goethem on October 25, 2010, to all member states (D1/SPG/eg (10) D/764080/Ars(2010)789624) and has been instrumental for the commercialization of semen from genomically proven bulls within Europe.

Another major genomic-related area that the EURLZ is involved with is the development of tools that can handle genomic data coming from many different sources and in different formats. This has been referred to as genomic multi-trait across country evaluations (GMACE), which is a modification of the method used by the EURLZ for international comparisons of conventional breeding values. A procedure to compare young bulls (without progeny) using GMACE methodologies was first implemented in August 2014, after the participating organizations had been able to study and understand the new methodology, evaluate the impact on the national contexts and communicate the changes to the farmers who are the final beneficiaries of the international comparisons. GMACE has since been applied routinely.

The project referred to as “Intergenomics” has the objective of improving the prediction ability of the genomic equations which is particularly important for minor breeds by creating an international shared genotype database for cattle at the Interbull Centre, based on the fact that genomic predictions are highly dependent on the size of the reference populations. The Brown Swiss breed is being used as the pilot population given the diligent cooperation established among the breed representatives worldwide, and the routine international genomic evaluations for Brown Swiss cattle has been run successfully since December 2011. This is a key project to enable the EURLZ to continue providing guidance and cutting-edge methodologies to access genetic value of breeding livestock.

There has been a clear evolution on the concept of sharing genotypes internationally, and most countries recognize the need of a common repository of bovine genotypes at the Interbull Centre as the means to:

- reduce costs and optimize investments on genotyping bovine animals;
- improve reference populations for prediction of genomically enhanced genetic merit, especially for low heritability health and functional traits, such as somatic cell count, mastitis, calving difficulty, longevity and female fertility;

- make it possible to screen large populations for recessive alleles detection;
- maintain a worldwide parentage verification data base, using the SNP based methods that are about to be officially recommended by ISAG and ICAR;
- use the genomic data to study diversity within the bovine populations in a more complete way than is possible with the methods based on pedigree information only.

In order to address these needs the Interbull Steering Committee has decided during the 2014 ICAR/Interbull meetings in Berlin, Germany, that Interbull will implement immediately the International Genotype Exchange Platform (GENOEX). The objectives of the GENOEX project are:

a) establishing the infrastructure necessary for international cooperation based on SNP data;
b) optimizing customer investments in genotyping by avoiding duplication;
c) establishing standard protocols for genomic data exchange;
d) becoming the international source of bovine parentage SNPs;
e) facilitating multilateral SNP data exchange by establishing a common repository and customer driven access rules; and
f) providing affordable genomic data storage for small populations.

The services to be provided through the implementation of GENOEX platform at the Interbull Centre are differentiated into three categories: parentage SNP exchange service (PSE), genomic data exchange service (GDE) and customized genomic repository service (CGR). A step-wise implementation process will be adopted, starting by PSE followed by GDE and CGR.

A three-year ICAR project to develop a system for international evaluations of beef breeds and traits commenced in 2007 and ended in May 2010. A new compromise to ensure the continuation of the research and development project has been established between ICAR, SLU and the participating countries. This system is operating at the Interbull Centre from the beginning of 2012 and currently involves two major beef breeds, and a growing number of countries with the current participation as follows: Charolais (7 Member States, and one third country) and Limousin (9 Member States and one third country).

All the EURLZ activities have basically doubled the amount of work and also the responsibilities of the EURLZ in an extremely short period of time. **It is important to note that all the activities existent prior to the "genomic revolution" are still taking place, meaning that this is not a simple update in methods, but in fact 100% additional services**. The conventional MACE evaluations that have been provided by the EURLZ over the years as a means for international comparisons, have actually acquired a more strategic importance than ever before, since they provide the only means for countries to utilize information on foreign animals in their reference populations. In other words, national genomic evaluations are highly dependent on the international breeding values regularly supplied by the EURLZ.

The support received by the EURLZ has been extremely instrumental in developing the new methods and infrastructure (data base and genotype exchange and harmonization). At this stage, although important steps of the new developments are completed, there are still fundamental questions to be addressed for the adoption of genomic technologies in animal breeding schemes and assure that international trading of bovine genetics can count on sound methodologies and unbiased comparisons between cattle populations within Europe and with other continents. The EC funding plays a key role to make these advances possible, since development costs cannot be directly transferred into service fees.

Therefore, the EURLZ is **requesting the maintenance of the financial support of € 150,000 per annum for 2016 and 2017, hence a total of € 300,000 for the two years,** in order to assure the minimum leverage needed to establish and maintain the necessary framework to quickly respond to the novel technologies being applied in bovine breeding worldwide.

Table 1 – Work programme for the European Union Reference Laboratory for Zootechnics (Bovine Breeding) in 2016-2017. Activities and sub-activities defined according to the 96/463/EC Council Decision, Annex II. NOTE: The Performance Indicators in this table are per annum.

Sector-specific requirements and sectoral regulation applies. Indicators that measure the implementation of requirements of sector-specific legislation go beyond the scope of this exercise.

Adaptations of Interbull Centre's PI are marked with [EURLZ: ...]

Main requirements of EU RLs set in legislation (Article 32 (2), 32(4)) and AWPs) [EURLZ: Main requirements of EURL in Zootechnics set in the 96/463/EC Council Decisionlegislation (Annex II)]	**Activity-based indicators**		**COMMENTS FROM EURLZ**	**EURL (%)**	**Sum (d)**
1. To **coordinate the methods employed** in the Member States for diagnosing diseases; [EURLZ: Be the documentation and information centre for the methods of testing and assessing the genetic value of pure-bred breeding animals of the bovine species for the Member States] **Baldrige criterion:** Measurement, Analysis and	**AH.PT.1** Number of ring tests to be organised [EURLZ: Number of records added to the international database]	Expected ex-ante:		14,0	57
		Performance record: 500,000 pedigrees: 20,000 genotypes (SNPs): 2,500			
		Achieved ex-post:			
	AH.PT.2 Number of reference samples/material generated (if applicable; could be through ring trials, animal experiments or from samples collected in large volume from the field)	Expected ex-ante:		0,8	3
		80 (conventional EBVs) 100 (genomic EBVs)			
		Achieved ex-post:			

Knowledge management	[EURLZ: Number of population-trait-method combinations to be validated (% of all combinations)]				
	AH.PT.3 Expected use by NRLs of diagnostic/analytical methods recommended by EURL as fit for purpose as determined by ring trials and/or outlined in the OIE manual (i.e. the expected take-up refers to the totality of the analytical methods developed by the EURL over many years, not only to those methods relevant for the individual comparative tests) [EURLZ: Number of test evaluations performed by the EURL (breed-population-trait combinations) to evaluate changes/updates in NRL methodologies]	Expected ex-ante:		5,6	23
		171 (breed-traits) X 2 test-runs = 342			
		Achieved ex-post:			
	AH.PT.4 Average rates of NRL success (share of NRLs that are expected to meet all the test thresholds)	Expected ex-ante:			
		100%			
		Achieved ex-post:			

	AH.PT.5 Methods and activities to ensure follow-up of poor results in ring trials* [EURLZ: Methods and activities to ensure follow-up of poor results in validation tests: Methods I-III, and GEBV-test]	Expected ex-ante:			
		Non-conforming cases will be excluded from international genetic evaluations.			
		Achieved ex-post:			
	**Follow-up work to significantly improve the performance of laboratories with poor results*				
	AH.PT.6 Progress* (direct after training or based on past few years' experience) made by NRLs on similar comparative tests with possible discussion of influential factors (factors that can be influenced by the EURL and factors that cannot be influenced)	Expected ex-ante:			
		Advice to modify national genetic evaluations are offered.			
		Achieved ex-post:			
	**Progress is understood as either a reduction of deviation (e.g. 5% instead of 10%) or a reduction in the number of NRLs failing a similar comparative test*				
Any EURL is accredited according to CEN ISO 17025 fixed scope: necessary quality assurance for this accreditation is in place	**Qualification indicators**				
	AH.PT.QI Presence of additional specific quality assurance schemes* (type of	Expected ex-ante:			

	training that staff involved in this type of activities would receive, ISO acquisition planned, etc); solely quantitative answers are of limited informational value, please provide concrete descriptions. [EURLZ: Ensure that NRLs update the national methods description]	Documentation (GE Form and GENO Form) complies with the practice at the NRLs MACE: 80 GMACE: 100 Achieved ex-post:			
	**Additional schemes are welcome, but there is no obligation to acquire them at high supplementary cost.*				
Main requirements of EU RLs set in legislation (Article 32 (2), 32(4)) and AWPs)	**Activity-based indicators**				
2. to **assist actively in the diagnosis** of disease outbreaks in Member States by receiving pathogen isolates for confirmatory diagnosis, characterisation and epizootic studies; [EURLZ: Provide assistance	**AH.ANA.1** Number of newly available diagnostic/analytical methods disseminated to NRLs: description of the situation* with specification e.g. of new analytical methods developed by the EURL or in general, or description whether partially modified methods (with improvement in some	Expected ex-ante: 5 (Robust MACE, Left censured MACE, truncated MACE, Beef calving traits, beef fertility traits) Achieved ex-post:		5,4	22

in order to contribute to the harmonization of the various methods of testing and assessing the genetic value of pure-bred breeding animals of the bovine species] **Baldrige criterion:** Operations focus	steps) or completely new methods are expected* [EURLZ: Number of new methods tested with participation of the NRLs]				
	**With regard to establishment of (standardized) methods or establishment of the criteria approach allowing a wide range of modifications depending also on the available technical equipment and limited standardization*				
	AH.ANA.2 Number of non-commercial* diagnostic/analytical methods to be validated (in relation to expected feasibility) [EURLZ: Number of new users by database functionality]	Expected ex-ante:		10,8	44
		60 (GENOEX-PSE)			
		Achieved ex-post:			
	**Information on commercial diagnostic/analytical methods validated is to be provided*				
Any EURL is accredited according to CEN ISO 17025 fixed scope: necessary quality assurance for this accreditation is in place	**Qualification indicators**				
	AH.ANA.QI Presence of additional specific quality assurance schemes (type of	Expected ex-ante:			

	training that staff involved in this type of activities would receive, ISO acquisition planned, etc); solely quantitative answers are of limited informational value, please provide concrete descriptions. [EULRZ: Maintain an integrated policy of validation of national breeding values]	ISO certification anticipated, and staff trainings to ensure that NRLs and EURL follow the same practices (including description of non-conformities)			
		Achieved ex-post:			
Main requirements of EU RLs set in legislation (Article 32 (2), 32(4)) and AWPs)	**Activity-based indicators**				
3. to facilitate the **initial or further training** of experts in laboratory diagnosis with a view to the harmonisation of diagnostic techniques throughout the Union; conducting initial and further training courses for the benefit of staff from NRLs and of experts from developing countries; [EURLZ: Provide assistance in order to permit the comparison of the results of the methods of testing and assessing the genetic value of animals in the various Member States]	**AH.NRL.1** Number of participating NRLs in the annual workshop (attendance rate)/ Actions taken to ensure all NRL's participation [EURLZ: Number of protocols published or reviewed]	Expected ex-ante:		17,1	70
		Manifests for SNP chips: 10 File formats: 2			
		Achieved ex-post:			

Baldrige criterion: Workforce focus					
	AH.NRL.2 Number of positive satisfaction surveys above 85% received for the annual workshop [EURLZ: Number of official international evaluations performed by the EURL (breed-population-trait combinations) to provide comparisons of multi-country populations standardized to each Member State genetic base.]	Expected ex-ante: 171 X 3 = 513 Achieved ex-post:		18,6	76
	AH.NRL.3 Measures to address relevant negative feedback from satisfaction surveys [EURLZ: Number of international breeding values distributed in each Member State scale]	Expected ex-ante: 85 million X 3 = 255 million Achieved ex-post:		3,4	14
	AH.NRL.4 Number of NRLs visited for training	Expected ex-ante:		2,9	12

	[EURLZ: Number of articles from the EURL published in the Interbull Bulletin]	5			
		Achieved ex-post:			
	AH.NRL.5 Number of workshops/trainings to be organised other than the annual workshop	Expected ex-ante:			
		2 Technical workshops			
		Achieved ex-post:			
	AH.NRL.6 Attendance rate and number of positive satisfaction surveys above 85% received for such workshops	Expected ex-ante:			
		2			
		Achieved ex-post:			

Any EURL is accredited according to CEN ISO 17025 fixed scope: necessary quality assurance for this accreditation is in place	**Qualification indicators**				
	AH.NRL.QI Presence of additional specific quality assurance schemes (type of training that staff involved in this type of activities would receive, ISO acquisition planned, etc); solely quantitative answers are of limited informational value, please provide concrete descriptions. [EURLZ: Streamlining of international genetic evaluations.]	Expected ex-ante: Reduce time for MACE test runs by 1 day per year Achieved ex-post:			
Main requirements of EU RLs set in legislation (Article 32 (2), 32(4)) and AWPs) [EURLZ: Main requirements of EURL in Zootechnics set in the 96/463/EC Council Decisionlegislation (Annex II)]	**Activity-based indicators**				
4. to have **trained personnel available** for **emergency situations** occurring within the Union (if appropriate) and	**AH.COM.1** Number of qualified staff with relevant completed training able to travel, to assist during outbreaks/ crisis situations and/or to engage on-	Expected ex-ante: 25 Achieved ex-post:		12,0	49

- to assist the **Commission**, EFSA, ECDC and EMA in case of specific requests [EURLZ: Help the bodies responsible for setting the rules for performance recording and assessing the genetic value and for publication of the evaluation results of pure-bred breeding animals of the bovine species appointed by Member States to take part in a comparison of the results of the assessment of genetic value at international level] **Baldrige criterion:** Strategic planning (for contingency) **Baldrige criterion:** Customer focus (help-desk function for COM)	site [EURLZ: Number of participating NRLs in the annual workshop (attendance rate)]				
	AH.COM.2 Adequacy of response to requests in terms of 1) content and 2) timely delivery* [EURLZ: Number of NRLs joining evaluations for additional breed-trait combinations]	Expected ex-ante: 10 Achieved ex-post:		1,7	7
	**Adequacy in terms of timeline and quality to be agreed upon with the lab in a quantifiable manner*				
	AH.COM.3 [EURLZ: Number of official EURL documents with reccommendations reviewed]	Expected ex-ante: 2 (Code of Practice + Guidelines) Achieved ex-post:		2,4	10

Any EURL is accredited according to CEN ISO 17025 fixed scope: necessary quality assurance for this accreditation is in place	**Qualification indicators**				
	AH.COM.QI Presence of additional specific quality assurance schemes (type of training that staff involved in this type of activities would receive, ISO acquisition planned, etc); solely quantitative answers are of limited informational value, please provide concrete descriptions. [EURLZ: Standardization of procedures at the NRLs]	Expected ex-ante:			
		Recommendations to standardize national reliabilities			
		Achieved ex-post:			

SUPPLEMENTARY INDICATORS					
Main requirements of EU RLs set in legislation (Article 32 (2), 32(4)) and AWPs) [EURLZ: Main requirements of EURL in Zootechnics set in the 96/463/EC Council Decisionlegislation (Annex II)]	**Activity-based indicators**				
5. To carry out a mutual and **reciprocal exchange of information** with competent laboratories in third countries or with the global/regional laboratory responsible for a analysing food and feed designated by the OIE, FAO, WHO (when applicable), to contribute to FAO, OIE,	**AH.OIE.1** Provision of consultant expertise to FAO/WHO/OIE (independently of a mandate as FAO/OIE reference laboratory) [EURLZ: Number of NRLs adopting the recommended new methods]	Expected ex-ante:		5,3	22
		5 new (Member States sending GEBVs for GMACE)			
		Achieved ex-post:			

WHO risk assessment and/or reviews of manuals or codes [EURLZ: Evaluate the problems of assessing pure-bred breeding animals and attempt to resolve the problems linked to the genetic assessments carried out in the various Member States] **Baldrige criterion:** Leadership (visibility in international networks)					
Any EURL is accredited according to CEN ISO 17025: necessary quality assurance for this accreditation is in place	**Qualification indicators**				
	AH.OIE.QI Presence of additional specific quality assurance schemes, systems, procedures as regards qualifications of staff in terms of consultancy expertise relevant to be provided to OIE/FAO/WHO at the request of the COM [EURLZ: Monitor within breeds genetic diversity]	Expected ex-ante:			
		Establish an inbreeding watch service for the Guernsey breed			
		Achieved ex-post:			

Main requirements of EU RLs set in legislation (Article 32 (2), 32(4)) and AWPs)	**Activity-based indicators**				
6. to take account of scientific development activities at national and Union level and perform applied **research and development activities** whenever appropriate **Baldrige criterion:** Results orientation	**AH.R&D.1** Provision of high quality communication items to NRLs on follow-up of research other than analytical method-related [EURLZ: Number of high quality communication items to NRLs on follow-up of research other than analytical method-related]	Expected ex-ante: 1 scientific article + 1 extension article + respective methodological service documentation (if adopted) Achieved ex-post:			
Any EURL is accredited according to CEN ISO 17025 fixed scope: necessary quality assurance for this accreditation is in place	**Qualification indicators**				
	AH.R&D.QI Presence of additional specific quality assurance schemes (type of training that staff involved in this type of activities would receive, ISO acquisition planned, etc); solely	Expected ex-ante: Internal Audit for ISO certification (by Dr. Friedrich Reinhardt from VIT, Germany) performed in May 2015. First audit of the ISO			

	quantitative answers are of limited informational value, please provide concrete descriptions.	certification process has been successfully performed during August 2015. Final Audit is scheduled for November 2015.			
		Achieved ex-post:			
Other Activities					
Potential issues: - Number of relevant publications in peer-reviewed journals? - Number of invitations as speaker to scientific conferences? - Number of presentations or posters/papers presented at conferences? - Validation of newly established international standard sera or reference material?	Are these activities routine or do they involve a large amount of development?	Expected ex-ante:			
		Achieved ex-post:			
Additional Comments					

Potential issues: **e.g.** Why success rate in PTs has been different from envisaged success rate?	The performance indicators proposed do not apply to the EURL for Zootechnics. Therefore, a new set of indicators is presented here, as indicated in separate correspondence to Mrs. Corina VASILESCU. Neither the EURL nor the NRLs comply with CEN ISO 17025, given the nature of the work developed. The inclusion of additional criteria based on ISO 9001 does not seem to be the case here.	Expected ex-ante:			
		Achieved ex-post:			
	Number of articles published in the Interbull Bulletin (http://www-interbull.slu.se/ojs/index.php/ib/index)	Expected ex-ante:			
		80			
		Achieved ex-post:			
	Number of articles published by the EURL staff	Expected ex-ante:			
		5			
		Achieved ex-post:			

Uppsala, September 29, 2015.

Toine Roozen
Interbull Centre Director

Certification by the laboratory:

We certify that:

- the expenditure listed above will be incurred in connection with the tasks defined in the work programme and will be necessary to the performance of those tasks,
- the expenditure will actually be incurred, accurately accounted for and eligible under the provisions of this Regulation,
- all supporting documents relating to the expenditure will be available for inspection,
- no other Union contribution will be requested for the Union reference laboratories activities regarding the financial report to be submitted,
- the grant will not have the purpose or effect of producing a profit for the beneficiary regarding the financial report to be submitted.

Date: September 29, 2015

Toine Roozen
Interbull Centre Director

Date: September 29, 2015

H. Jorjani

Hossein Jorjani
Head, Department of Animal Breeding & Genetics
Swedish University of Agricultural Sciences