Gene Banks

Quality management and Quality standards

S.J. Hiemstra

Rome, Friday 3 February 2016

FAO CGRFA

IMAGE
Innovative Management of Animal Genetic Resources

IMAGE

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Innovative Management of Animal Genetic Resources

supporting

EUGENA

RFP
EUROPE

European Gene Bank Network for Animal Genetic Resources

Quality management and Quality standards

- Framework:
  - FAO Guidelines Ex Situ Conservation (2012)
  - Certification systems
  - Different approaches to quality assurance
- This meeting
  - Issues related to Quality Management
  - Useful deliverables from IMAGE and FAO

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Centre for Genetic Resources, the Netherlands

- CGN
  - Plant Genetic Resources
  - Forest Genetic Resources
  - **Animal Genetic Resources**

→ Statutory Research Tasks for Ministry

→ 5-year programmes

→ www.cgn.wur.nl

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Aim of Dutch AnGR Gene Bank

Long term

- To safeguard all rare/native/endangered breeds of farm animals in the gene bank
- To promote and facilitate conservation of back-up samples of all (commercial) breeds in the gene bank

Short term

- To support breeding programs of endangered breeds - by distribution of gene bank semen
- Facilitate scientific research projects

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Collections @CGN

- CGN Gene bank collections = reproductive material
  - Semen (+ embryo's, oocytes/ovarian tissue)
  - Blood samples
  - "Core collections" per breed

Species	# breeds	# donors/breed	# straws
Cattle	19	1 - 4,781	221,925
Chicken	31	1 - 20	18,828
Dog	5	1 – 8	342
Duck	3	14 – 34	1,588
Goat	4	1 - 33	5,555
Goose	1	7	76
Horse	8	1 - 37	25,769
Pig	21	1 - 69	75,081
Sheep	9	8 - 71	27,738
Rabbit			

Species and breed diversity in CGN gene bank

Quality Management

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Certificate No:
203913-2016-AQ-NLD-RvA

Initial certification date:
18 November 2007

Valid:
03 August 2016 - 18 November 2016

This is to certify that the management system of

Stichting DLO
Droevendaalsesteeg 1, 6708 PB Wageningen, The Netherlands

has been found to conform to the Quality Management System standard:
ISO 9001:2008

This certificate is valid for the following scope:
Conservation of genetic material of plants and animals, documentation of associated data, promotion of use of genetic resources and supportive research.

Place and date:
Barendrecht, 03 August 2016

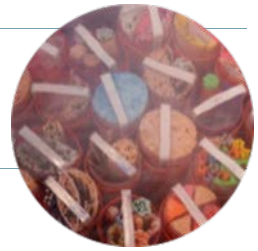
MGMT. SYS.
RvA C 024

The RvA is a signatory to the IAF MLA

For the issuing office:
DNV GL - Business Assurance
Zwolseweg 1, 2994 LB, Barendrecht,
The Netherlands

Henk de Gooijer
Management Representative

Why ISO certification ?



- To control process for good and constant quality of the products (gene bank operational process)
- To increase efficiency of the processes
- To guarantee good quality level of our work, for the Ministry of Economic Affairs
- To focus on critical points in the process
- To minimize mistakes, complaints and customary dissatisfaction
- To guarantee safety of working conditions

→ To guarantee long term conservation of genetic diversity

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QUALITY ISO 9001:2008 CERTIFICATION

Relevant key processes

- Development of gene bank strategy/policy
- Acquiring and collecting Material
- Material processing
- Material storage and documentation
- Access to Material and distribution

Quality Management System

SCOPE

- Management
  - Policy and strategy
  - Programme/project management
  - Client, stakeholder and target group orientation
  - Independence
- Operations
  - Key procedures
  - Standard Operating Procedures
  - Standardized forms and templates

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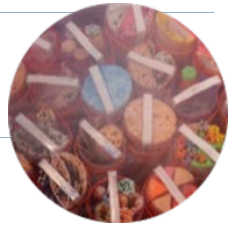
Performance indicators

- Cost-efficiency of acquiring genetic material
- Contracts with providers of genetic material (complete and in time)
- Quality of material – before and after freezing and thawing (in comparison to quality standards)
- Documentation of material (complete and in time)
- Growth of gene bank collection per year (overall, by species)
- Handling of requests for getting access to gene bank material (within certain time period)

→ In order to improve or maintain the quality of the gene bank processes

Compliance with relevant regulations



- Veterinary legislation
    - Specific derogation for cattle
- Breeding legislation
- Employee working conditions and safety
    - In particular working with liquid nitrogen
- ABS
    - Model MAA and MTA

From ISO-9001-2008 to ISO-9001-2015

→Risk based approach

→Not necessarily describing all processes in detail

Main risks?

- Material (and data): legal uncertainty, ownership, access conditions
- Safety issues – liquid nitrogen (for materials or staff)
- Non-compliance with veterinary standards
- Non-validated protocols, methods, equipment
- External threats (fire, flooding, earthquake, ...)
- Dis-continuity in necessary/crucial expertise
- Unsatisfied clients, stakeholders, society
- Incomplete documentation

ISO 9001:2015

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