

2nd IMAGE Dialogue Forum Tallinn, Estonia, 27th August 2017

Sanitary regulations - Outcomes

The second annual IMAGE Dialogue Forum was held on August 27th 2017 in Tallinn, Estonia. The topic was '**Sanitary regulations - Possibilities and hindrances for the exchange of gene bank material for breeding and science**'. Like in the year before, the discussion event was set after the annual meeting of the ERF and on the day before the annual EAAP conference. The event was designed as a four hour workshop with input presentations, group work and a conclusive discussion.

Waltraud Kugler from SAVE opened the Dialogue Forum with an introductory presentation. She outlined the legal framework in which exchange of genetic material is currently happening and potential shortcomings of these legislations. This included the *Animal Health Code* of the World Organisation for Animal Health (OIE), the EU *Animal Health Law*, as well as national regulations.

IMAGE project leader Michèle Tixier-Boichard continued with a presentation on the objectives of IMAGE and all achievements that have been reached since the project was launched in March 2016. She also delved into regulatory issues for gene banks related to animal health, which pose fundamental challenges in collecting samples of local breeds under highly demanding regulations designed for international commercial exchange, all the while offering promising approaches to these issues. This included the challenges of storage and transportation of animal germplasm (e.g. requirement of different locations for different species), as well as the usage of old collections and the storage of infected tissue for research.

The National gene bank manager and ERF national coordinator for Austria Beate Berger finished the input part of the Dialogue Forum. She addressed some of the results of the IMAGE gene bank survey, the regulations in place, as well as presenting two case studies (bluetongue disease and *M. agalactiae*). In conclusion she pointed out, that the current sanitary/veterinary regulations are not tailored for gene banking and breed conservation, that action is needed to achieve derogations on a national level. Furthermore, she argued that sanitary/veterinary regulations should make use of modern diagnosis methods, which would facilitate working with old material. Generally, germplasm collection should be given a special position in these regulations.

In the second part of the Dialogue Forum, participants were split into groups according to their affiliation to 'Science', 'NGO' or 'Government'. The groups should discuss four topics:

- What are the OPPORTUNITIES for the exchange of „germinal products“
- What are the CHALLENGES to exchange material?
- What are the OBSTACLES?
- SUGGESTIONS and DEMANDS

Outcomes of the Discussions in Groups

Group Science

OPPORTUNITIES

- Distinguish national exchange / international
 - National: support to management of local breeds
 - International: transboundary occurring breeds need exceptions
- Distinguish commercial mainstream breeds and endangered breeds
- Today “clean” material maybe in 5-10 years not useable because of new diseases
- Ways to proceed
 - Exceptions to the rules
 - Split case by case
 - Treat material of rare breeds different to commercial breeds (example: FMD, Scrapie)
 - A revised Animal Health law could be an opportunity for the future
- What is the motivation for exchange of material?
 - Use in breeding programs
 - Breed reconstruction
 - Genetic analysis
- Document cases where old material is useful.

CHALLENGES

- Organise semen collection outside of AI Center: How to guarantee the sanitary quality of material not collected in an AI center or not documented at collection?
- Test for 5 specific diseases : procedure does exist, monitor health status of the recipient animal, costly but possible.
- Testing needs material, therefore material is going to be lost through testing.
- Changing sanitary status with time is a danger or not ?
(Reordering the straws every 6 months! not practical)

OBSTACLES?

- The current EU regulation is an obstacle for the exchanges between countries within a transboundary rare breed
- No possible exception if interference with commercial sector : avoid side-effects !
- Highly strict rules for AI centers: is a compartmentalization within AI center possible?
- Separation of the species for storage maybe cost intensive
- Testing of material: cost intensive, therefore takes financial resources

SUGGESTIONS and DEMANDS

- List exceptions and identify the goals for which we can get derogations
- Implementation act for genebanks
- Should we separate old material / new material?
- PCR tests for qualifying the sanitary status of semen
- Make the rules and regulations clearer
- Ask for a specific implementation act probably better than listing possible derogations
- Avoid interference, collateral effects: do not complicate things that are working now

Group Government/Authorities

OPPORTUNITIES

- Reconstruct disappeared breeds
- Resilience of breeds
- Enhancing biodiversity
- Introgression of genes
- Establishment of new breeds
- Organize a backup of genebanks
- Genes and genotypes under changing (environmental) conditions

CHALLENGES

- Finances
- Lack of documentation
- Phenotypes/pedigree
- Sanitary conditions
- Lack of protocols
- Quality of the material
- Genebanks are only core collections: access is difficult
- Lack of collaboration of stakeholders
- Lack of public awareness

OBSTACLES?

- Not mentioned in rules
- Trade obstacles
- Ownership of the material (old owners!)
- Restricted access rules (Nagoya rules)
- Use of material to third countries
- Commercial interests
- Political: not on the top of the political agenda

SUGGESTIONS and DEMANDS

- Promote EUGENA
- Publish success stories
- Information and awareness raising
- Change Animal health law
- National Level: formulate derogations in the national law
- Develop a long term strategy
- Analysis of freedom of zoonosis
- Third countries: characterization of the material; environmental conditions

Group NGOs

The group worked result oriented

SUGGESTIONS and DEMANDS

- Value and Key issue of the use of old material are rare breeds
- Existing rules are made for live animals (ELISA, PCR; quarantine), not for stored material
- Discuss with the European Commission
- Demonstrate to EC and ministries the value of the genetic material. This is a precondition
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- Discuss with member states: it is in the interest of member states (obligations of internat. Conventions etc.)
- The possibilities of use of old material depends on how it was collected: e.g. no pre quarantine
- Old material cannot fit the rules (missing protocols)
- PCR testing is possible to guarantee an exception of the rules. But: cost intensive
- In general: material needs to be safe

Plenum Discussions

The Discussions in groups were followed by a general discussion to find a consensus on how to work with the sanitary regulations in terms of conservation of animal genetic resources. The two favored actions to be taken were:

- IMAGE shall push a **direct discussion with the European Commission** on sanitary rules and exceptions from the current regulations in context with the exchange of genetic material especially for science, conservation and management of Animal Genetic Resources. At the moment gene banks not mentioned at all in the new Animal Health Law (Reg. 2016/429).
- Participants shall push the respective persons responsible in their own countries to **push national derogations** from particularly challenging sanitary regulations for gene banks.
- Image (WP1 Task 1.4) should ask at the commission for an **EU implementation act** specifically considering the needs of gene banks
- **Identify and list exceptions** for which national derogations from EU Animal Health Law would be beneficial for gene bank management.
- **Use PCR test** to guarantee safety (freedom of zoonosis) within the single countries.
- Promote the European gene bank network (**EUGENA**).
- Collect and publish **success stories** (like in countries with national derogations).
- Transboundary exchange: promote Bi- or multilateral rules

The session was followed by personal discussions and networking with drinks and Estonian nibbles. The organisers look back on a successful discussion event with a clear outcome and are looking forward to the next Dialogue Forum, which will be held in August 2018 in Dubrovnik, Croatia.