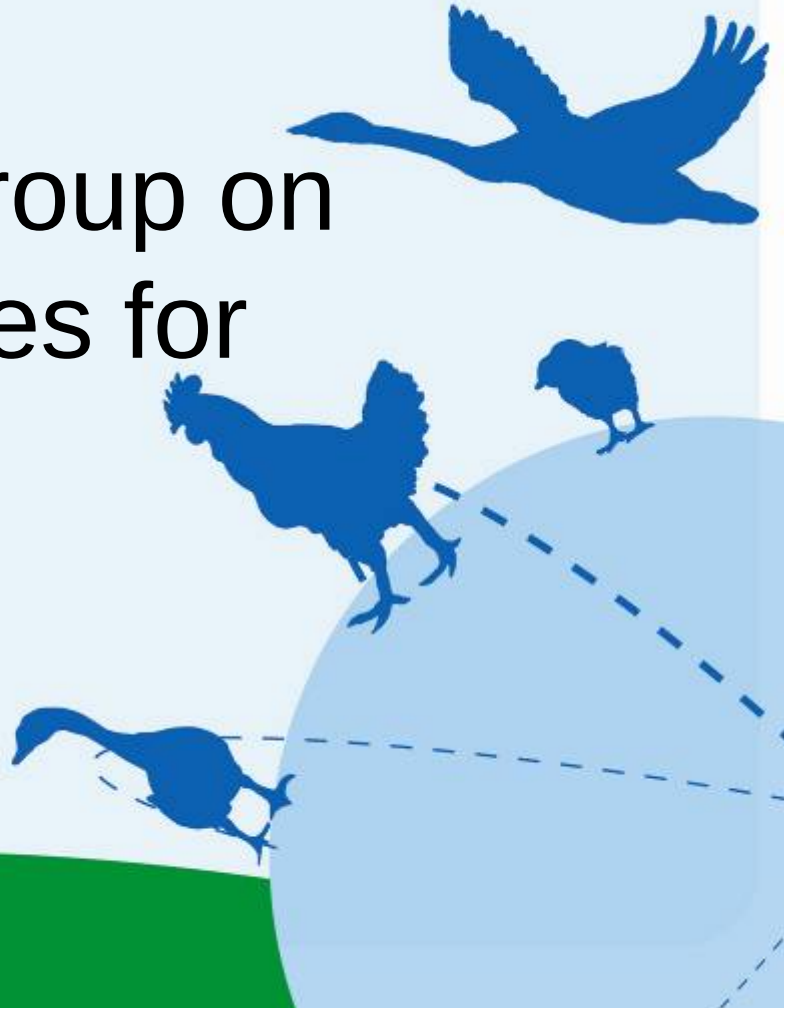
OFFLU Technical Group on Developing Guidelines for Proficiency Tests



PT Technical Group Participants

- **Dr. Ian Brown** – VLA, Weybridge, UK
- **Dr. Giovanni Cattoli** – IZSVe, Padova, Italy
- **Dr. Hualan Chen** – National AI Ref. Lab., Harbin, China
- **Dr. Gwenaelle Dauphin** – FAO, Rome, Italy
- **Dr. Timm Harder** - Friedrich-Loeffler-Institut, Isl. Riems, Germany
- **Dr. Maja Lievre** – WHO EPR/HSE Geneva, Switzerland
- **Dr. John McCauley** – National Institute for Med. Res., London, UK
- **Dr. John Pasick** – NCFAD, Winnipeg, Canada
- **Dr. Yoshihiro Sakoda** – School of Vet. Med., Hokkaido, Japan
- **Dr. Vladimir Savic** – Croatian Vet. Institute, Zagreb, Croatia
- **Dr. Paul Selleck** – AAHL, Geelong, Australia
- **Mr. Dennis Senne** – NVSL, Ames, IA, USA
- **Dr. Erica Spackman** – SEPRL, Athens, GA, USA
- **Dr. Wenging Zhang** – WHO EPR/HSE, Geneva, Switzerland

Objectives

- Enhance diagnosis of avian influenza worldwide through…
  - Consistency in diagnostic testing
- Develop guidelines for proficiency tests for harmonization purposes
  - OIE reference labs
  - National reference labs
  - Local testing laboratories
- Compliment chapter on Laboratory Proficiency Testing (Chapter 4, OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Disease, 2008)

Questionnaire

- August 15, 2008 - sent to all participants
- Compiled responses…developed consensus
- Initial focus on assays for type-specific detection
  - Serologic tests
  - Molecular assays
- Ultimate goal to focus on subtyping (H5 & H7)
  - Serologic tests
  - Molecular assays
  - May need to be regionalized to account for genetic variations

Results – Types of PTs Available

- Only a limited number of labs routinely provide PTs – some for molecular and virus isolation, but mostly for serologic tests
  - No international reference standard exists for AGID/ELISA testing (most use a working in-house standard or one obtained from a reference lab)
  - Most use transcribed RNA for molecular assays

Results – Interlab Testing

- Most felt the OIE reference labs should participate in PT
  - 2-3 year intervals
- Size of PT panel - serology
  - 10 and 20 samples of 250-600 µl each in plastic screw-cap cryovials (sealed containers)
- Size of PT panel - molecular
  - 10 and 20 samples of 100-1000 µl each in plastic screw-cap cryovials (sealed containers)

RT-PCR Testing

- Limited to type A tests (matrix or NP assays)
  - Mix of viruses – Eurasian and North American lineages
  - Labs should use the equipment and protocols already in place
  - Testing at the laboratory level, not individuals
    - Reduce number of PTs
    - Training responsibility of individual labs

Reporting PT Results

- Provide answer sheets and general instructions
  - Additional materials such as protocols, reagents, controls etc. should be fee-based

Costs for PTs

- Should cover all expenses associated with production, maintenance, distribution, and follow-up correspondence
- Shipping charges should be assed separately (will vary considerably)
  - Use World Courier (will handle infectious substances and dry ice shipments) – expensive but reliable
- Permits handled country-by-country

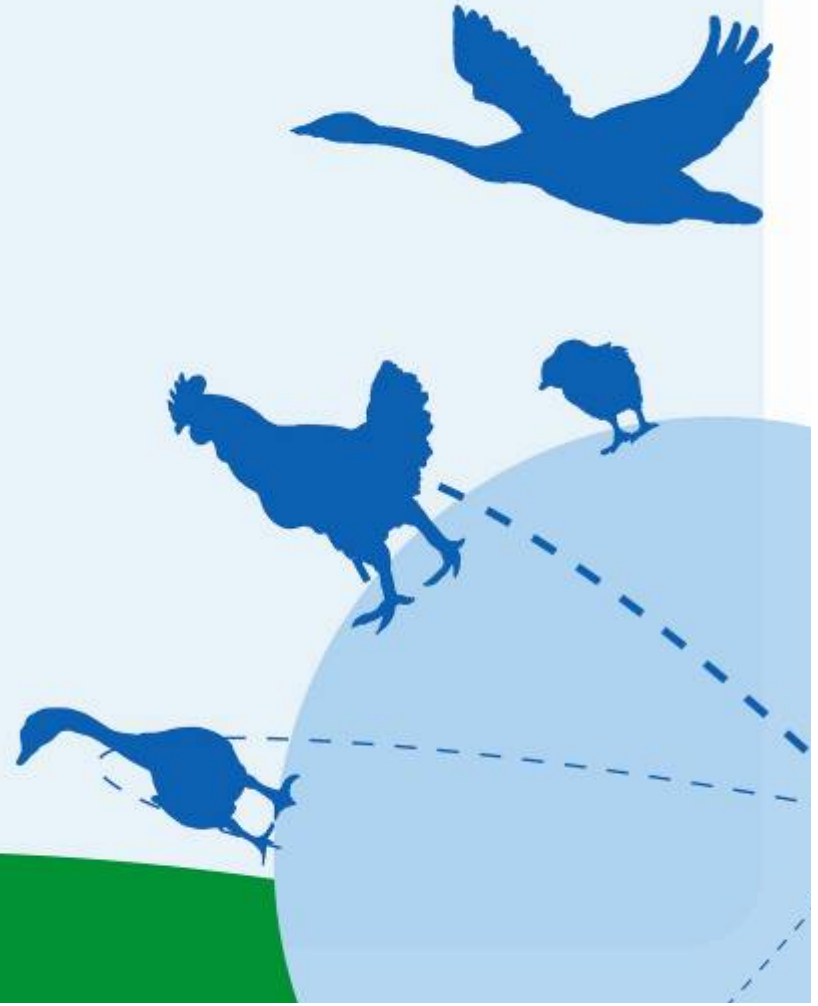
How to Monitor Quality of PT

- Ship freeze-dried samples to reduce impact of adverse/prolonged shipping conditions
  - Monitor frozen shipments with freeze-thaw indicators
  - Require immediate notification from receiving labs on receipt and condition of the PT on arrival
  - Establish a time limit for testing to avoid sample degradation because of prolonged or improper storage after receipt

Analysis of Results

- No consensus
- Will need to involve statistician
  - Z-scores (+/- 2)
  - Cumulative Poisson Probability Distribution curves to establish 0.95 probabilities – will work with a low number of samples

Thank you for your attention



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