### **Annexes**

## Selected references for further information

- 1. Guiding principles for highly pathogenic avian influenza surveillance and diagnostic networks in Asia. http://www.fao.org/ag/againfo/subjects/en/health/diseases-cards/Guiding%20principles.pdf
- 2. FAO position paper on AI control strategy.
- 3. Global strategy for the progressive control of highly pathogenic avian influenza (HPAI). http://www.fao.org/ag/againfo/subjects/documents/ai/HPAIGlobalStrategy31Oct05.pdf
- 4. Ausvetplan. *Disease Strategy Avian influenza; Operational Procedures Manual Destruction; Operational Procedures Manual Disposal.*www.animalhealthaustralia.com.au/aahc/index.cfm
- 5. FAO EMPRES Good Emergency Management Practice. http://www.fao.org/ag/aga/agah/empres/gemp/intro/2300-gemp.html
- 6. Geering WA, Forman AJ and Nunn MJ (1995). *Exotic Diseases of Animals: A field guide for Australian Veterinarians*. Bureau of Resource Sciences, Australian Government Publishing Service, Canberra.
- 7. Geering WA, Roeder PL and Obi TU (1999). *Manual on the Preparation of National Animal Disease Emergency Preparedness Plans*. FAO Animal Health Manual No. 6. FAO. Rome, 1999.
- 8. *OIE Manual for Diagnostic Tests and Vaccines for Terrestrial Animals.* http://www.oie.int/eng/normes/mmanual/A\_summry.htm
- 9. OIE Guidelines for HPAI surveillance.
- 10. OIE Terrestrial Animal Health Code.

# Sample - Tender document for inactivated avian influenza vaccines

To be used for the purchase of inactivated avian influenza vaccine by governments or donor organizations for control of disease in infected countries.

#### INTRODUCTION

These are specifications for the purchase of inactivated avian influenza vaccine for use in poultry, including chickens and ducks. Vaccination is used to provide protection in the face of possible exposure or to reduce the viral load in an infected environment. Vaccinated birds are generally not fully protected from infection but have increased resistance to infection, suffer less clinical disease and shed substantially less virus.

There are several options for vaccine. Conventional vaccine, for which this specification is written, is prepared from the allantoic fluid of infected eggs, which is inactivated and emulsified with adjuvant. Attenuated live influenza virus vaccines are not recommended because of the risk that the vaccine virus could either mutate or re-assort with other influenza viruses to become pathogenic. However, recombinant vaccines have been produced, including fowl-pox virus, with the influenza haemagglutinin gene inserted and haemagglutinin produced in a baculovirus expression system. This specification does not cover the requirements for recombinant vaccines.

The virus type used for vaccine production must be of the same haemagglutinin type as the outbreak virus. For maximum potency, it is preferable for the vaccine virus to be closely related to the outbreak strain. If post-vaccination monitoring depends on serology to determine whether antibody-positive birds have been infected or vaccinated (the DIVA test), the neuraminidase type should be different to that of the outbreak strain.

#### **TENDER SPECIFICATION**

#### **General requirements**

- 1. Vaccine manufacture must be undertaken in accordance with OIE Guidelines Chapters 1.1.7 and 2.7.12 of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, 5th edition 2004. It must be produced under Good Manufacturing Practice (GMP) and under acceptable third-party audited quality assurance.
- 2. In assessing the acceptability of a vaccine, [FAO or other purchaser] may require documentation to be furnished to validate GMP and quality assurance practices and the production details for a specific vaccine batch. [The purchaser] may also seek to undertake an audit of the manufacturing plant(s).

3. The vaccine must be registered or otherwise acceptable for use, by the government of [insert country].

#### **Specific requirements**

- 1. The requirement is for [insert number] of doses of vaccine for use in [insert species].
- 2. The vaccine must contain haemagglutinin antigen of H [insert type for current SE Asia epidemic, H5] type. Evidence (challenge or VN test) should be provided that the vaccine protects against the virus strains currently circulating in [insert country/region].
- 3. Evidence should be provided that vaccine produced by the same means (i.e. not an individual batch requirement) in the same manufacturing plant significantly reduces virus transmission from vaccinated birds when subsequently infected.
- 4. The vaccine virus must be derived from an LPAI virus strain.
- 5. The virus should be grown in specific antibody negative or specific pathogen free eggs.
- 6. The virus is to be inactivated with formalin or beta-propiolactone.
- 7. The vaccine should be emulsified with a mineral oil adjuvant or with an alternative adjuvant with similar immuno-stimulating efficacy.
- 8. The vaccine must have undergone appropriate sterility, safety and potency tests in accordance with international standards.
- 9. The vaccine must have a minimum of one microgramme per dose of haemagglutinin protein. Vaccine of a higher haemagglutinin concentration will be considered favourably. Alternatively, the potency of the batch may be demonstrated by live bird challenge with virulent virus or by a minimum HI antibody response of 1:32 in vaccinated birds.
- 10. Packaging of the vaccine should be in containers of [insert number of doses].
- 11. Labelling in [*insert language/s*] must indicate manufacturer, type of vaccine, batch identification, volume of contents, storage recommendations and expiry date. Package insert in [*insert language/s*] to include instructions for vaccinating poultry, recommended species to which the vaccine applies, vaccination regime and dose.
- 12. Vaccine to have a minimum of six months period prior to expiry, on delivery.
- 13. Vaccine must be delivered to cold storage in [insert place or country]. Verification will be required of continuity of appropriate storage of the vaccine from production to delivery.

# OIE/FAO reference laboratories and experts for avian influenza

#### Dr Ilaria Capua

Istituto Zooprofilattico Sperimentale delle Venezie, Laboratorio Virologia Via Romea 14/A, 35020 Legnaro, Padova ITALY

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#### Dr Paul W. Selleck

CSIRO, Australian Animal Health Laboratory (AAHL) 5 Portarlington Road, Private Bag 24, Geelong 3220, Victoria AUSTRALIA

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#### Dr B. Panigrahy

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#### **Dr Ortrud Werner**

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For more information, visit the OFFLU website www.offlu.net

# Information for shipping international diagnostic specimens

OIE/FAO AND NATIONAL REFERENCE LABORATORY FOR NEWCASTLE DISEASE AND AVIAN INFLUENZA VIROLOGY DEPARTMENT. ISTITUTO ZOOPROFILATTICO SPERIMENTALE (IZS) DELLE VENEZIE (ITALY) (As of November 2005)

**Important:** Contact the IZSVe in order to discuss testing and testing materials before shipping. Provide the name and details of a contact person.

#### Types of specimen

Specimens submitted may be virus isolates made in the submitting country or clinical specimen, such as tissues or swabs, collected from diseased birds.

#### Packaging requirements

All materials should be in leak-proof containers. Packaging should be composed of (1) a primary receptacle, (2) a secondary packaging and (3) a rigid outer packaging. Packaging of "diagnostic samples" should be coded UN3373 and comply with IATA PI650 standard. "Virus isolates" should be coded UN2814 for AIV and UN2900 for NDV complying with IATA PI602 standards.

Contact couriers to confirm the provision of boxes complying with these requirements.

#### Documents to be accompanied for clearing

Import permissions from the Italian Ministry of Health (formerly provided by the IZSVe) and a *signed proforma invoice* (The template will be formerly provided by the IZSVe) should be attached firmly to the box.

#### Shipping modality

Air freight or couriers to Milan Malpensa Airport (recommended), Rome Fiumicino Airport (courier only) or Venice Marco Polo Airport (no virus isolates). Informing the IZSVe 1 week in advance is recommended. *Arrange for shipments to arrive in Italian airports from Monday to Thursday only.* 

#### **Shipping Address**

Instituto Zooprofilattico Sperimentale delle Venezie Virology Department Viale dell'Università 10, 35020 Legnaro Padova, Italy

#### Notification of shipment

Before shipping, please supply the following information to the IZS contact person

- Embarkation date
- Airline name and flight number
- Name of the destination airport
- Date of arrival in Italy
- Airway bill number (the air bill should be faxed as soon as possible to: Fax + 39 049 8084360 or sent via e-mail to the contact person)
- Contact person to whom the results should be sent (name, fax number, e-mail address)

#### Contact people at the IZS

To ship diagnostic samples and virus isolates:

#### Elena Ormelli

E-mail: eormelli@izsvenezie.it

#### Micaela Mandelli

E-mail: mmandelli@izsvenezie.it

For reagents:

#### William Dundon

E-mail: wdundon@izsvenezie.it

#### Micaela Mandelli

E-mail: mmandelli@izsvenezie.it

Other contact persons:

#### Giovanni Cattoli

E-mail: gcattoli@izsvenezie.it

#### Alessandro Cristalli

E-mail: acristalli@izsvenezie.it

#### Paola De Benedictis

E-mail: pdebenedictis@izsvenezie.it

## AVIAN VIROLOGY LABORATORY, VETERINARY LABORATORIES AGENCY, WEYBRIDGE, UK. FROM OUTSIDE THE EU (As of February 2006)

#### Packaging requirements

All materials should be in leak-proof containers. At least two layers of packaging should be used and the inner layer treated lightly with disinfectant.

The outer packaging must be marked as follows:

## ANIMAL PATHOGEN – PACKAGE ONLY TO BE OPENED AT THE AVIAN VIROLOGY SECTION, VETERINARY LABORATORIES AGENCY, WEYBRIDGE, SURREY

and with one of the following IMPORT LICENCE NUMBERS:

For Newcastle disease:

#### AHZ/2232/2002/5

For Avian Influenza, other viruses, avian tissue, serum, faeces and eggs:

AHZ/2074C/2004/3

#### **Shipping Address**

#### Ruth Manvell

Avian Virology, VLA Weybridge

New Haw, Addlestone, Surrey KT15 3NB,

United Kingdom

A letter should accompany the parcel with as much history about the isolates as possible, to include species and age, area/country of isolation, any clinical history, etc. If sending by **AIR FREIGHT** it is essential that the **AIRWAY BILL NUMBER** is given to VLA-Weybridge by FAX, telephone or e-mail before the arrival of the materials in order to facilitate an early delivery.

Packages sent by air freight should be clearly marked: CARE OF TRANSGLOBAL to ensure rapid processing at the airport.

#### Notification of shipment

Please notify the VLA-Weybridge, Avian Virology Laboratory of the shipment details and the contact person for information on the result (name, fax number, e-mail address) before dispatch.

Direct FAX: +44 (0)1932 357856 Direct Tel: +44 (0)1932 357 736 E-mail: r.manvell@vla.defra.gsi.gov.uk

#### **Contact**

If you wish to discuss a submission and options for support from the International Reference Laboratory for Avian Influenza and Newcastle Disease, please contact:

#### Dr. I.H.Brown

Direct Tel: +44 (0)1932 357 339 Direct FAX: +44 (0)1932 357 239 E-mail: i.h.brown@vla.defra.gsi.gov.uk

## **AUSTRALIAN ANIMAL HEALTH LABORATORY (AAHL)** (As of November 2005)

#### Types of specimen

Specimens submitted to AAHL for disease diagnosis may be either virus isolates made in the submitting country or clinical specimens, such as tissues or swabs, collected from diseased birds.

#### Import permit and packing

Copies of Australian import permits are available from AAHL by contacting aahlaccessions@csiro.au. All specimens must be packed in leak-proof containers in accordance with the appropriate IATA regulation and appropriately labelled. Suitable transport containers and packing instructions are also available from AAHL by contacting aahlaccessions@csiro.au. Copies of the import permit and other consignment details should be attached to the outside of the package to expedite clearance through Australian customs.

#### Notification of shipment

If submitting specimens, please notify the accessions clerk on accessions@csiro.au, the Duty Veterinarian on dutyvet@csiro.au or Dr. Peter Daniels on + 61 3 5227 5000 of the consignment details so that specimens can be collected upon arrival in Australia. Alternatively send the information by fax to +61 3 5227 5555. Consignment details include the consignment note/air weigh bill number, courier/airline and expected arrival date.

#### Shipping address

The Director

Australian Animal Health Laboratory 5 Portarlington Road, Geelong, 3220 Australia

Telephone: +61 3 5227 5000 Facsimile: +61 3 5227 5555 http://www.csiro.au/aahl

#### Contact for Avian Influenza

You may also wish to discus the testing required with Peter Daniels (peter.daniels@csiro. au) or Paul Selleck (paul.selleck@csrio.au) on +61 3 5227 5000 prior to submitting the specimens.

#### NATIONAL VETERINARY SERVICES LABORATORIES (NVSL), AMES, IOWA, USA (As of November 2005)

#### Import permit

Packages containing diagnostic specimens or organisms (infectious materials) imported from foreign locations into the United States must be accompanied by a permit issued by the U.S. Department of Agriculture. The importation permit, with proper packaging and labelling, will expedite clearance of the package through U.S. customs. One copy of the permit should be attached to the outside of the shipping container and a second copy placed just inside the lid of the outer shipping container. The importation permit can be obtained from the laboratory (NVSL, Ames, Iowa).

#### Packaging requirements

All materials should be in leak-proof containers and packaged to withstand breakage. All materials should be properly labelled.

#### Shipping address

#### Director,

National Veterinary Services Laboratories Diagnostic Virology Laboratory 1800 Dayton Avenue, Ames Iowa, USA 50010

#### **Notification shipment**

Please notify the Diagnostic Laboratory with shipping information (date of arrival, airline/courier, weigh bill number, etc.) as soon as it is available. Fax information to +1 (515) 663-7348 or telephone +1 (515) 663-7551.

#### Contact for Avian Influenza

Dr. Beverly J. Schmitt

Direct Tel: +1 515/663-7532 Direct Fax: +1 515/663-7348 E-mail: beverly.j.schmitt@usda.gov

## Criteria for defining infected areas and disease control zones

#### **INFECTED PLACES**

A place classified as an *infected place* (IP) will be a defined area (village, farm) in which *highly pathogenic avian influenza* (HPAI) disease or a highly virulent strain of AI virus exists, or is believed to exist. An IP will be subject to quarantine. A mildly or lowly virulent AI virus may be declared an agent for eradication if it has the potential to mutate into virulent AI virus.

#### **DANGEROUS CONTACT PLACES**

Places classified as *dangerous contact places* (DCPs) will be those that contain birds, poultry products or poultry waste that have recently been introduced from an IP (usually up to 21 days before the premises were declared infected) and are likely to be infected or contaminated or any of these items that may have been in substantial contact with people, vehicles and equipment that have been associated with an infected premises within three days of visiting the DCPs.

#### SUSPECT PLACES

Places classified as *suspect places* (SPs) will be those that contain birds that have possibly been exposed to an Al virus, such that quarantine and surveillance, but not pre-emptive slaughter, are warranted; or birds not known to have been exposed to an Al virus but showing clinical signs requiring differential diagnosis.

The classification SPs is a temporary classification and should be treated as infected until determined otherwise. High priority should be given to clarifying the status of the suspect birds so that the SPs can be reclassified as either an infected premise (IP) and appropriate quarantine and movement controls implemented, or as free from disease, in which case no further disease control measures are required.

#### **RESTRICTED AREA**

A restricted area (RA) will be a relatively small declared area compared to a control area (CA) around IP that are subject to intense surveillance and movement controls. Movement out of the area will, in general, be prohibited, while movement into the area would only be by allowed. Multiple RAs may exist within one CA.

The RA does not need to be circular but can have an irregular perimeter provided the boundary is initially an appropriate distance from the nearest IP, DCP or SP. This distance will vary with the size and nature of the potential source of virus, but will be approximately

1-5 km around the IP, depending on the density of poultry premises. The boundary could be the perimeter fence of the IP if the IP is in an isolated location. The boundary in a densely populated area will take into account the distribution of susceptible birds and traffic patterns to markets, service areas, abattoirs and areas that constitute natural barriers to movement. If possible, hatcheries should be kept out of the RA.

#### **CONTROL AREA**

The control area (CA) will be a larger declared area around the RA(s) and, initially, possibly as large as a province where restrictions will reduce the risk of disease spreading from the RA(s). The boundary of the CA will be adjusted as confidence about the extent of the outbreak becomes clearer but must remain consistent with the OIE Code chapters on surveillance and zoning (Chapters 1.3.4 and 1.3.5; see Appendix 3). In general, surveillance and movement controls will be less intense and animals and products may be permitted to move under permit from the area.

The declaration of a CA also helps to control the spread of the outbreak from within the RA. The CA is a buffer zone between the RA and the rest of the country. The boundary does not have to be circular or parallel to that of the RA but should be 2–10 km from the boundary of the RA. In general, the movement of possibly contaminated things and materials within the CA is allowed but movement out of the CA is prohibited without CVO approval. This type of control area allows reasonable commercial activities to continue.

NB: When declaring RAs and CAs, the areas must not be larger than necessary, thus restricting the number of properties to be quarantined to only those deemed prudent. If flocks in a quarantine area are not depopulated, then the cost of keeping the birds beyond their normal market age could be substantial.

#### INTERNATIONAL CONSIDERATIONS

Under *OIE Code* definitions, an *infected zone* means a clearly defined territory in which a disease (listed in the *Code*) has been diagnosed. This area must be clearly defined and decreed by the veterinary authorities in accordance with the environment, the different ecological and geographical factors as well as all the epidemiological factors and the type of husbandry being practised. The territory in question should have a radius from the centre or centres of the disease of at least 10 km in areas with intensive livestock raising, and 50 km in areas where extensive livestock raising is practised.

In June 1993, the European Union published a decision laying down the criteria for classifying 'third countries' with regard to avian influenza and Newcastle disease. Annex C point 4 of this decision states:

Around confirmed outbreaks of disease a protection zone with a minimum radius of 3 km and a surveillance zone with a minimum radius of 10 km shall be implemented. In these zones stand still measures and controlled movements of poultry shall be in force until at least 21 days after the end of disinfection operations on the infected holding. Before lifting the measures in these zones the authorities shall carry out the necessary inquiries and sampling of the poultry holdings to confirm that disease is no longer present in the region concerned. The practicality of declaring a zone, the intensity of the industry and the transmissibility of virus causing an outbreak might mean a decision is taken to declare larger areas than those used by the EU.

### Leaflet example

#### **BIRD FLU (HIGHLY PATHOGENIC AVIAN INFLUENZA)**

The purpose of this leaflet is to inform the public, especially poultry farmers and those responsible for meat markets with basic information on Avian Influenza, commonly known as Bird Flu. This leaflet also informs them about the rights and responsibilities in case of eventual disease outbreaks.

#### WHAT IS BIRD FLU

Bird Flu (avian influenza) is a highly contagious viral disease of poultry and other birds. According to the virulence (ability and degree to cause disease), the bird flu virus is often characterized as:

- Highly pathogenic causing illness with a high death rate (over 75%)
- Low pathogenic causing mild signs of disease, but in case of secondary infections can cause serious problems with death rates of up to 50%.

Some low pathogenic types can change over time to become highly pathogenic.

A current strain of avian flu virus, known as H5N1, is circulating in many countries in Southeast Asia, and has recently been confirmed also in Russia, Romania, Croatia and Turkey. The H5N1 can cause disease in humans, too.

#### WHO CAN BE INFECTED BY BIRD FLU?

Domestic poultry – chickens and turkeys - are most often affected, while ducks and geese often develop only mild signs of the disease. Wild birds, especially wild ducks may be naturally resistant to the infection and do not show clinical signs of the disease.

Birds that do not show signs of the disease can still carry the virus and represent a danger for the introduction of the virus in poultry operations.

#### **HOW IS THE DISEASE SPREADING?**

The main sources of infection in poultry are the following:

- Live infected birds even if they don't appear sick
- Faecal droppings and discharges from sick birds
- Dead Birds
- Contaminated objects, including equipment (egg crates, cages), shoes or clothing, and contaminated ground

It is believed that the disease can be spread over long distances by migrating birds (especially wild ducks and geese, but possibly other water or shore birds). If infected wild birds have contact with domestic poultry during their resting times along their migrating routes, transmission of the virus could occur.

Within the country the disease is most commonly spread in poultry through the movement of people, birds and goods in an infected area and marketing practices used when infected poultry come into contact with healthy birds. Humans play a very important role in spreading the disease since the virus can easily be carried on dirty clothes, shoes, contaminated equipment, vehicles and in the transportation of sick poultry.

Though rare, the disease can be introduced by importing healthy live poultry or poultry products (meat, unprocessed feathers, laying eggs etc.). The virus can also be introduced to an unaffected area or country through illegal trade, especially live birds.



#### HOW TO RECOGNIZE THE DISEASE IN THE FLOCK

Bird flu spreads very quickly within the flock, so almost all units will be infected in a very short time and birds may die within days. The spread of the disease is likely to be slower in layers - chickens that are used to produce eggs – since they are often in cages and do not mix with each other.

Signs of disease are:

- Depression and lack of appetite
- Drastic drop in egg production
- Swollen head and neck
- Dark and swollen wattles and combs
- Bleeding under the skin
- Sudden death which can reach 100% of the flock

If any of your birds show these signs you should immediately report to the nearest veterinary station or to the veterinary inspector. Failure to notify the authorities could put more animals -and even humans - at risk of becoming infected.



#### **HOW TO PREVENT BIRD FLU**

Basic prevention measures include:

- Decrease the opportunity for wild birds coming into contact with domestic poultry through the use of protective nets, or keeping the poultry in enclosed and protected buildings.
- · Apply bio-safety measures:
  - Fence the farms to keep unwanted animals and visitors out.
     Lock doors!
  - Disinfect vehicles before they enter the farm.
  - Prohibit the entrance of unauthorized people to the farm.
  - Establish disinfection areas (foot-baths) before entering the farm or in each of the poultry houses.
  - Use boots and outer clothing that can be cleaned or changed between houses or farms. Use rubber gloves as well.
  - Clean and disinfect all surfaces regularly (cages, walls, poultry eating and watering areas).
  - Do not borrow equipment from other farms, as these may be contaminated.
  - Disinfect with detergents or hypochlorite solutions
- Replace animals from within the flock or from controlled and healthy flocks.
- Apply the principle of "all in all out". This means that all animals in a poultry house are taken off the farm at the same time (for the market), the ground and house must be cleaned and disinfected, and only then can young stock be introduced into the cleaned house. Lock doors!
- Avoid keeping ducks, chickens and turkeys in the same yard.
- In case of an outbreak on your farm, you should immediately report to the veterinary authorities. Do not sell your animals. Do not eat or feed sick or dead birds to other animals.



#### PLANS FOR ERADICATING BIRD FLU

If the disease appears, the following measures would be undertaken:

- killing of all poultry in affected yards/farms and settlement areas
- safe disposal of poultry carcasses
- disinfection of contaminated yards/farms
- prohibition for movement of all kinds of live poultry, meat and other poultry products from contaminated settlement areas
- increased control for movement of people, mechanical equipment, vehicles, etc. from contaminated yards, farms and settlement areas
- other measures ordered by the veterinary inspectors.

Owners will be compensated for slaughtered birds as part of the measures for preventing the spread of the disease. Compensation will also be paid for destroyed poultry products and equipment according to their market value.

#### IS BIRD FLU A THREAT FOR HUMAN HEALTH?

The bird flu virus rarely infects people. If it does, the disease is usually not serious and is often characterized as reddening of the eye (conjunctivitis) with mild respiratory symptoms.

However, the highly pathogenic avian influenza H5N1 strain can be a serious health problem, and can kill people that are infected. Avoid contact with birds that are thought to be affected.

#### **HOW DO PEOPLE BECOME INFECTED?**

Avian influenza is not a food-borne disease. The bird flu virus is killed by the heat of normal cooking. There is no risk of getting avian influenza from properly cooked poultry meat and eggs. However, sick chickens should not be eaten, as a sick bird often releases toxins and has other microorganisms that may pose a danger to you and your family.

#### WHICH GROUPS OF PEOPLE ARE AT RISK?

People that are at higher risk are those who work with poultry (breeders, buyers, transporters, slaughterhouse workers and also veterinarians), who are in contact with infected poultry material or are employed in disease control activities (veterinarians employed in laboratories). Hunters and ornithologists are only at risk if they are handling sick or animals that have died due to avian influenza virus.

#### **HOW PEOPLE CAN BE PROTECTED?**

Currently, there is no medicine that could fully protect people from bird flu. Present seasonal vaccines against human flu are only effective against known circulating human influenza. Should you or anyone in your family have a fever with flu-like symptoms, it is advised to see medical attention immediately.

| WHO DO I CONT | ract?   |
|---------------|---|
|               | ed for information for local or regional veterinar<br>cic laboratory, help desk, or call-free number. |
|               |   |
|               |   |

NB: this poster was designed by authorities of Macedonia

# Avian influenza vaccine producers and suppliers

Compiled by FAO's Emergency Prevention System for Transboundary Animal and Plant Pests and Diseases (EMPRES). The manufacturers/suppliers and their vaccines are not necessarily endorsed by FAO and it is the [importing] country's responsibility to establish independent quality assurance/quality control for safety, purity, potency and efficacy parameters.

Annex 7: Avian influenza vaccine producers and suppliers

#### China

| Laboratory  | Affiliation  | Location                               | Strain  | Туре   | Antibody levels  | Established<br>Production | Website                                       | Comments  |
|---|--|--|---|--|--|---------------------------|---|---|
| Harbin Veterinary<br>Research Institue            |  | Harbin,<br>Heilongjiang province       | A/Turkey/England/N-28/73<br>subtype H5N2,<br>Low pathogenicity                                  | Inactivated<br>monovalent                          | 8log2 reached by the fifth week after vaccination and maintained for 4 weeks, protective antibody titers maintained for 23 weeks       | Dec. 2003                 | www.hvri.ac.cn                                |   |
| Harbin Veterinary<br>Research Institue            |  | Harbin,<br>Heilongjiang province       | A/Goose/Guandong/1996,<br>Subtype H5N1  | Inactivated<br>monovalent                          |  |                           |   | Used for ducks and other waterfowl in Vietnam   |
| Harbin Veterinary<br>Research Institue            |  | Harbin,<br>Heilongjiang province       | A recombinant virus from<br>A/Goose/Guangdong/1996<br>and human influenza<br>vaccine virus H5N1 | Inactivated<br>recombinant                         | 9log2 reached by the third week after vaccination and maintained for 4 weeks, protective antibody titers maintained for 25 weeks       | Jan. 2005                 | www.hvri.ac.cn                                | High specificity, antibody level<br>and long maintain time,<br>vaccinated water fowl do not<br>shed virus and are resistant<br>against infection proved by the<br>laboratory results                        |
| Harbin Veterinary<br>Research Institue            |  | Harbin,<br>Heilongjiang province       | A recombinant avian pox<br>virus expressed H5 from<br>A/Goose/Guangdong/1996                    | Live recombinant<br>avian pox virus<br>vectored H5 | 7log2 reached by the second week<br>after vaccination protective antibody titers<br>maintained for26 weeks                             | Jan. 2005                 | www.hvri.ac.cn                                | Induced only antibody against specific protein, helpful in differentiation of the immune and the infection. The immune efficiency is less than the other two vaccines, and price is higher Only for chicken |
| Zhengzhou<br>Bio-pharm Co. Ltd                    | China Animal<br>Husbandry Group  | Zhengzhou City,<br>Shandong province   | A/Turkey/England/N-28/73<br>subtype H5N2  | Inactivated<br>monovalent                          | 8log2 reached by the fifth week<br>after vaccination and maintained for 4 weeks,<br>protective antibody titers maintained for 23 weeks | Dec. 2003                 |   |   |
| Qingdao Yebio<br>Bioengineering<br>Co. Ltd        | National Animal<br>Quarantine Institute<br>of the Ministry<br>of Agriculture | Qingdao City,<br>Shandong province     | A/Turkey/England/N-28/73<br>subtype H5N2  | Inactivated<br>monovalent                          | 8log2 reached by the fifth week after vaccination<br>and maintained for 4 weeks, protective antibody<br>titers maintained for 23 weeks | Dec. 2003                 | www.yebio.com.cn                              |   |
| Qingdao Yebio<br>Bioengineering<br>Co. Ltd        | National Animal<br>Quarantine Institute<br>of the Ministry<br>of Agriculture | Qingdao City,<br>Shandong province     | Н9  | Inactivated  |  |                           | www.yebio.com.cn                              |   |
| Qingdao Yebio<br>Bioengineering<br>Co. Ltd        | National Animal<br>Quarantine Institute<br>of the Ministry<br>of Agriculture | Qingdao City,<br>Shandong province     | H5N2/H9   | Inactivated<br>bivalent                            |  |                           | www.yebio.com.cn                              |   |
| Guangdong Yongshun<br>Bio-pharm Co. Ltd           |  | Guangdong province                     | A/Turkey/England/N-28/73<br>subtype H5N2  | Inactivated<br>monovalent                          | 8log2 reached by the fifth week after vaccination<br>and maintained for 4 weeks, protective antibody<br>titers maintained for23 weeks  | Dec. 2003                 |   |   |
| Zhaoqing Dahua<br>agriculture<br>Bio-pahrm Co.Ltd | Veterinay College<br>of Southern China<br>Agriculture University             | Zhaoqing City,<br>Guangdong            | A/Turkey/England/N-28/73<br>subtype H5N2  | Inactivated<br>monovalent                          | 8log2 reached by the fifth week after vaccination<br>and maintained for 4 weeks, protective antibody<br>titers maintained for23 weeks  | Dec. 2003                 | http://www.un-pur.org<br>zhaoqing/zhaoqing.ht | /gongyingshang mulu/yiyao/<br>m   |
| iaonong Yikang<br>Bioengineering<br>Co.Ltd        |  | Liaoyang City,<br>liaoning<br>Province | A/Turkey/England/N-28/73<br>subtype H5N2  | Inactivated<br>monovalent                          | 8log2 reached by the fifth week after vaccination<br>and maintained for 4 weeks, protective antibody<br>titers maintained for 23 weeks | Dec. 2003                 |   |   |
| Nanjing Merial<br>Animal Products<br>Co., Ltd     | China Animal<br>Husbandry Group  | Nanjing City,<br>Jiangsu<br>province   | A/Turkey/England/N-28/73<br>subtype H5N2  | Inactivated<br>monovalent                          | 8log2 reached by the fifth week after vaccination<br>and maintained for 4 weeks, protective antibody<br>titers maintained for 23 weeks | Dec. 2003                 |   |   |
| ilu Animal Health<br>Products Factory             |  | Ji'nan City,<br>Shandong<br>province   | A/Turkey/England/N-28/73<br>subtype H5N2  | Inactivated<br>monovalent                          | 8log2 reached by the fifth week after vaccination<br>and maintained for 4 weeks, protective antibody<br>titers maintained for 23 weeks | Dec. 2003                 | www.qiludb.com                                |   |
| Chengdu Jianghua<br>Bioproducts Co.Ltd            | Jianghua Group   | Ziyang City,<br>Sichuan<br>province    | A/Turkey/England/N-28/73<br>subtype H5N2  | Inactivated<br>monovalent                          | 8log2 reached by the fifth week after vaccination<br>and maintained for 4 weeks, protective antibody<br>titers maintained for 23 weeks | Dec. 2003                 | http://www.jinghuagro                         | oup.net/main.asp  |
| Merial International<br>Trading Company           | Merial (France)  |  | H5N2  | Inactivated<br>monovalent                          |  |                           |   | Commercial name:<br>FLU H5N2 Formalin inactivated.<br>Mineral oil adjuvant  |

Annex 7: Avian influenza vaccine producers and suppliers

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|   |   |   |   |   |   |

| Laboratory           | Affiliation | Location               | Strain   | Туре                      | Antibody levels   | Established<br>Production | Website        | Comments   |
|----------------------|-------------|------------------------|--|---------------------------|---|---------------------------|----------------|--|
| Merial               |             |                        | H9N2 or H7N1<br>(Some H7N3) strains<br>as separate vaccines            | Inactivated<br>monovalent |   |                           |                |  |
| Merial               |             |                        | A/chicken/ltaly/1067/99<br>(H7N1) and<br>A/chicken/ltaly/22A/98 (H5N9) | Inactivated<br>bivalent   |   |                           | www.merial.com | Commercial name:<br>BioFlu H7N1 and H5N9.<br>For chicken   |
| Merial               |             |                        | H5 from A/Turkey/Ireland/83<br>recombinant Fowlpox vector              | Recombinant<br>live       |   |                           | www.merial.com | Commercial name:<br>Trovac AIV H5.<br>Protection after day old vaccination<br>birds up until 20 weeks of age.<br>The vaccine is produced in USA              |
| Laprovet S.A.S       |             | Tours, Cedex 2, France | H5N2   | Inactivated<br>monovalent |   |                           |                | Commercial name: ITA-FLU.<br>Formalin inactivated.<br>Mineral oil adjuvant.<br>The vaccine is produced in Mexico.  |
| Ceva Santé Animale 9 | 5A          | Libourne, France       | A/Chicken/Mexico/232/94/CPA.<br>Oil emusified. H5N2                    | Inactivated               | 8Log 2.Four weeks after vaccination at 10 days/Subcutaneous | Approved 2004             | www.ceva.com   | Commercial name: FLU-KEM.<br>Binary ethyleneimine (BEI)<br>inactivated. Mineral oil adjuvant.<br>The vaccine is produced in Mexico<br>through CEVA de MEXICO |

#### Germany

| Laboratory                              | Affiliation | Location                       | Strain   | Туре                      | Antibody levels   | Established<br>Production | Website | Comments  |
|---|-------------|--------------------------------|--|---------------------------|---|---------------------------|---------|---|
| Boheringer Ingelheim<br>Vetmedica, GmBH |             | Ingelheim am Rehin,<br>Germany | H5N2.<br>A/Chicken/Mexico/232/94/CPA.<br>Oil emusified | Inactivated<br>monovalent | 8Log 2.Four weeks after vaccination at<br>10 days/Subcutaneous. |                           |         | Mineral oil adjuvant. *The vaccine is produced in Mexico by Boehringer Ingelheim Vetmedica S.A. de C.V. |

#### Italy

| Laboratory       | Affiliation     | Location | Strain | Туре                       | Antibody levels  | Established<br>Production | Website          | Comments   |
|------------------|-----------------|----------|--------|----------------------------|--|---------------------------|------------------|--|
| Merial Italy Spa | Merial (France) | Italy    | H5N9   | Inatctivated<br>monovalent | Minimum HI antibody response of 1:32 in vaccinated birds |                           | Commercial name: | Gallimune Flu H5N9.<br>Beta-propriolactone inactivated.<br>Mineral oil adjuvant. |

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Annex 7: Avian influenza vaccine producers and suppliers

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| Laboratory                                   | Affiliation                       | Location             | Strain  | Туре                      | Antibody levels  | Established<br>Production | Website             | Comments   |
|--|-----------------------------------|----------------------|---|---------------------------|--|---------------------------|---------------------|--|
| Intervet                                     |                                   | Mexico City          | A/Chicken/Mexico/232/94/CPA.<br>Oil emusified.      | Inactivated<br>monovalent | 8log 2. Four weeks after vaccination at<br>10 days of age/Subcutaneous | Approved 2004             | www.intervet.com.mx |  |
| Intervet Mexico                              | Intervet<br>(Netherlands)         | Huixquilucan         | H5N2 or H5N6  | Inactivated<br>monovalent |  |                           |                     | Commercial name:<br>Nobilis influenza H5.<br>Mineral oil adjuvant.<br>The same vaccine is supplied by<br>Intervet international b.v. in<br>Netherlands |
| Boheringer Ingelheim<br>Vetmedica, S.A. de C |                                   | Guadalajara, Jalisco | A/Chicken/Mexico/232/94/CPA.<br>Oil emusified H5N2  | Inactivated<br>monovalent | 8Log 2. Four weeks after vaccination at<br>10 days/Subcutaneous.       | Approved 2004             | www.lineavolvac.com | Mineral oil adjuvant.<br>This same vaccine produced in<br>Mexico is supplied in Germany<br>through Boehringer Ongelheim<br>Vetmedica GmBH              |
| Avimex laboratories                          |                                   | Mexico City          | A/Chicken/Mexico/232/94/CPA.<br>Oil emusified. H5N2 | Inactivated<br>monovalent | 8Log 2. Four weeks after vaccination at 10 days/Subcutaneous.          | Approved 2004             | www.avimex.com.mx   |  |
| Investigación<br>Aplicada S.S. (IASA)        |                                   | Tehuacan, Puebla     | A/Chicken/Mexico/232/94/CPA.<br>Oil emusified. H5N2 | Inactivated<br>monovalent | 8Log 2. Four weeks after vaccination at 10 days/Subcutaneous.          | Approved 2004             | www.iasa.com.mx     |  |
| Ceva de Mexico                               | Ceva Santé Animale<br>SA (France) | Mexico City          | A/Chicken/Mexico/232/94/CPA.<br>Oil emusified. H5N2 | Inactivated<br>monovalent | 8Log 2. Four weeks after vaccination at<br>10 days/Subcutaneous.       | Approved 2004             | www.ceva.com        | Commercial name:<br>FLU-KEM. Mineral oil adjuvant.<br>This vaccine is supplied in France<br>through CEVA Santé Animale                                 |
| Ceva de Mexico                               | Ceva Santé Animale<br>SA (France) | Mexico City          | A/Chicken/Mexico/232/94<br>(H5N2+LaSota NDV)        |                           |  |                           |                     | Commercial name:<br>NEW-FLU-KEM AI and<br>Newcastle disease  |

#### Netherlands

| Laboratory                     | Affiliation | Location             | Strain                                      | Туре        | Antibody levels | Established<br>Production | Website          | Comments   |
|--------------------------------|-------------|----------------------|---|-------------|-----------------|---------------------------|------------------|--|
| Intervet<br>International b.v. |             | Boxmeer, Netherlands | A/Chicken/Mexico/232/94/CPA<br>H5N2 or H5N6 | Inactivated |                 |                           | www.intervet.com | Commercial name: Nobilis Influenza H5N2 or Nobilis Influenza H5N6. Formalin or beta-propriolactone inactivated. Mineral oil adjuvant. The vaccine is produced in Mexico and Spain. |
| Intervet                       |             |                      | A/CK/Italy/473/99 (H7N1)                    | Inactivated |                 |                           | www.intervet.com | Commercial name:<br>Nobilis Influenza H7N1.<br>Oil adjuvant.   |
| Intervet                       |             |                      | A/duck/Potsdam/15/80 (H7N7)                 | Inactivated |                 |                           | www.intervet.com | Commercial name:<br>Nobilis Influenza H7N7.  |

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| Laboratory                         | Affiliation | Location             | Strain   | Туре     | Antibody levels | Established<br>Production | Website | Comments |
|------------------------------------|-------------|----------------------|--|----------|-----------------|---------------------------|---------|----------|
| Sindh Vaccine<br>Production Centre |             | Karachi, Pakistan    | H7N3 and H9N2 strains, separate or combined produc   | ts       |                 |                           |         |          |
| Biolab (pvt) Ltd                   |             | Rawalpindi, Pakistan | H7N3 and H9N2 strains for both separate and combined | products |                 |                           |         |          |
| Avicina Laboratories               |             | Lahore, Pakistan     | H7N3 and H9N2 strains for both separate and combined | products |                 |                           |         |          |
| Otoman Pharma                      |             | Lahore, Pakistan     | H7N3 and H9N2 strains for both separate and combined | products |                 |                           |         |          |

#### USA

| Laboratory                  | Affiliation              | Location                | Strain                                 | Туре          | Antibody levels | Established<br>Production | Website | Comments   |
|-----------------------------|--------------------------|-------------------------|--|---------------|-----------------|---------------------------|---------|--|
| Biomune vaccines            | Ceva Santé<br>Animale SA | Lenexa - Kansas,<br>USA | A/Turkey/Wisconsin/68 (H5N9)           | Inactivated   |                 |                           |         | Commercial name:<br>Layermune AIV H5N9.<br>Beta-propriolactone inactivated.<br>Mineral oil adjuvant.                     |
| Biomune vaccines            | Ceva Santé<br>Animale SA |                         | A/Chicken/New York/273874/03<br>(H7N2) | 3 Inactivated |                 |                           |         | Commercial name:<br>Layermune AIV H7N2   |
| Biomune vaccines            | Ceva Santé<br>Animale SA |                         | A/Turkey/Utah/24721-10/95<br>(H7N3)    | Inactivated   |                 |                           |         | Commercial name:<br>Layermune AIV H7N3   |
| Fort Dodge<br>Animal Health |                          | Overland Park,<br>USA   | H5N3                                   | Inactivated   |                 |                           |         | Commercial name:<br>Poulvac Flu Fend I H5N3 RG<br>Formalin inactivated.<br>Water in oil adjuvant.                        |
| Fort Dodge<br>Animal Health |                          | Overland Park,<br>USA   | H5N3                                   | Inactivated   |                 |                           |         | Commercial name:<br>Inactivated AIV type A, H5N2,<br>H5N9, H7N2, H7N3<br>Formalin inactivated.<br>Water in oil adjuvant. |

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