ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

Member States seeking a financial contribution from the Community for national programmes for the control and monitoring of avian influenza, shall submit applications containing at least the information set out in this form.

The central database keeps all submissions. However only the information in the last submission is shown when viewing and used when processing the data.

If encountering difficulties, please contact SANCO-VET-PROG@ec.europa.eu, describe the issue and mention the version of this document: 2014 1.22

Instructions to complete the form:

1) Be informed that you need to have at least the Adobe Reader version 8.1.3 or higher to fill and submit this form.
2) To verify your data entry while filling your form, you can use the "verify form" button at the top of each page.
3) When you have finished filling the form, verify that your internet connection is active and then click on the submit notification button below. If the form is properly filled, the notification will be submitted to the server and a Submission number will appear in the corresponding field.
4) IMPORTANT: Once you have received the Submission number, save the form on your computer.
5) If the form is not properly filled, an alert box will appear indicating the number of incorrect fields. Please check your form again and try to re-submit it according to steps 3), 4) and 5). Should you still have any difficulties, please contact SANCO-BO@ec.europa.eu.
6) For simplification purposes you are invited to submit multi annual programmes
7) As mentioned during the Plenary Task Force of 28/2/2014, you are invited to submit your programmes in English.

IMPORTANT: AFTER SUBMITTING THE FORM DO NOT FORGET TO SAVE IT ON YOUR COMPUTER FOR YOUR RECORDS!
ANNEX 4: Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

1. **Identification of the programme**

<table>
<thead>
<tr>
<th><strong>Member state:</strong></th>
<th>BULGARIA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Disease</strong></td>
<td>avian influenza in poultry and wild birds</td>
</tr>
<tr>
<td><strong>This program is multi annual:</strong></td>
<td>no</td>
</tr>
<tr>
<td><strong>Request of Union co-financing from beginning of:</strong></td>
<td>2015</td>
</tr>
</tbody>
</table>
ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

1.1  Contact

Name : Dr. Pencho Kamenov

Phone : +359 2 915 98 42

Fax. : +359 2 915 98 42

Email : p_kam@bfsa.bg

2. Description and implementation of the surveillance programme in poultry

2.1.1  Designation of the central authority in charge of supervising and coordinating the departments responsible for implementing the programme

Bulgarian Food Safety Agency (BFSA) is the competent authorities for control and surveillance of the AI programme.
Department “Infectious diseases” within Directorate “Animal health and Welfare” at the Headquarters of BFSA has the following responsibilities:
1. To draft the AI surveillance programme and to submit it for approval to the European Commission.
2. To control the implementation of the surveillance programme.
3. To collect and analyze the data on the animals tested
4. To summarize the data on positive holdings.
5. To keep a register in the database of all holdings under the porgramme
6. To send annual report to the European Commission containing the data referred to in points 3-5.
At regional level the Regional Food Safety Department (RFSD) and the heads of departments “Animal health” have the following responsibilities:
1. To control and to implement the AI surveillance programme at regional level.
2. To collect and analyse the data on the poultry tested in the region.
ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

3. To summarize the data on positive animals.
4. To summarize the data on the surveillance costs incurred at regional level.
5. To keep a register in the database of all holdings
6. To send annual reports containing the data referred to in points 1-5 to Directorate “Animal health and welfare” at BFSA.

The municipal veterinarian has the following responsibilities:
1. To control and to implement the AI surveillance programme at the relevant municipality.
2. To control the sampling and the sending samples to the laboratories.
3. To collect and analyze the data on the poultry tested in the veterinary units located on the territory of the relevant municipality.
4. To summarize the data on positive animals.
5. To summarize the data on the AI surveillance costs incurred by the relevant municipality.
6. To keep a register in the database of all holdings

The Programme is been performed under the assistance rendered by the local associations of ornithologists and by the local units of the national Union of Hunters and Anglers of Bulgaria.

2.1.2 System in place for the registration of holdings

All commercial holdings are registered in accordance with Article 137 of the law of the Veterinary activity. The register of commercial holdings are entered into the national electronic database and maintained by Headquarter at the BFSA. The records on registration of farms are kept at central level (Headquarter at BFSA) and local level (RFSDs).

2.1.3 Design (risk based or surveillance based on representative sampling)

The surveillance design in the programme is based on two approaches- risk based sampling and the representative sampling.
Risk-based surveillance:
The data on AI surveillance data in the country, AI positive cases recorded in the country and neighbor countries in past years and location of the poultry holding in areas with a high density of migratory wild birds or areas where the migratory wild water birds may gather are the main criteria and risk factors used to draft the surveillance design in the country based on the risk.
10 administrative regions located in the northern part of the country, especially all regions bordering
ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

Romania are being identified as such of higher risk with regards to AI (Vidin, Montana, Vratsa, Pleven, Veliko Turnovo, Ruse, Silistra, Dobrich, Varna and Burgas) taking into account:
- number of AI positive cases recorded in Romania and in the Danube Delta.
- number of AI positive cases recorded in Bulgaria (Vidin, Dobrich, Varna and Burgas). Please see point 5 of the programme regarding the descriptive data on the epidemiological situation of the disease in wild birds during the last five years.
- the migratory route of wild birds observed in north-eastern regions of the country (Silistra, Dobrich, Varna and Burgas are the regions where pass a migratory route, named Via Pontica).

Surveillance based on Representative Sampling:
The rest regions of the country have also been included in the programme as the surveillance design in these regions is based on the representative sampling.

Sampling procedure used in the poultry holdings located in the regions with higher risk with regards to AI and regions with a Representative Sampling:

- In high risk regions all commercial poultry holdings with laying hens, breeders, turkey, farmed game and duck and geese holdings will be included to be tested for the AI serological purposes.
Number of poultry holdings located in other regions in the country to be AI serological sampled is being determined so that this sampling to be considered as representative for the whole of the country according to the Tables 1 and 2 in Annex of Decision 2010/367/EC.

Please see the attached table regarding the number of poultry holdings included in the programme per poultry categories and region.

- The number of samples to be taken per poultry category will be defined in accordance with the sampling procedures laid down in point 5.2.1, and 5.2.2. of the Annex I of Decision 2010/367/EC. This procedure will be followed in the poultry holdings located in whole country, namely:
  - Blood samples from at least 5 to 10 birds (except ducks, geese and mallards) per poultry holding, and from the different sheds in holdings with more than one shed.
  - Blood samples from at least 20 ducks, geese or mallards in the poultry holding.

2.1.3.1 Short description of predominant poultry population and types of poultry production

(max. 32000 chars):
The numbers of poultry flocks, per poultry production category located in the country as by the end of 2013 and to be included in the programme are as follows:

Laying hens:
No of holdings - 147 laying hen holdings
No of Poultry - 2 346 142 poultry
ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

Breeders
No of holdings - 32
No of poultry 1,361,889 poultry
Turkey:
No of breeder holdings - 1
No of breeder Poultry - 7,410 poultry
No of fattening holdings - 1
No of fattening Poultry - 10,800 poultry

Farmed game:
No of holdings - 5 holdings with breeding rock partridges and pheasants

Broilers
No of holdings - 179
No of poultry - 9,500,000 poultry for a period of one year.

Backyards holdings:
No of holdings - 307,034
No of poultry - 1,688,687 birds.

Waterfowl - geese and mallards:
No of holdings - 151 fattening
No of poultry 1,538,856
No of holdings - 3 breeding
No of poultry - 39,460 breeding.

Please see:
- map- No 2 location of the holdings with breeding hen, laying hens, Turkey and farmed game
- map- No 3 location of duck and geese holdings

2.1.3.2 Criteria and risk factors for risk based surveillance

(max. 32000 chars):

Please see explanations regarding the risk based surveillance in point 2.1.3.
Please see the tables in point 2.2. of the poultry holdings to be tested under the programme according to the above mentioned surveillance designs.
- map- No 1 Via Pontica migration route
- map No 4 location of the holdings with breeding hen, laying hens, turkey and farmed game to be tested under the programme
2.2 **Target populations** (2)

(max. 32000 chars):

The sampling of the following poultry species and production categories shall be included in the surveillance programme:
(a) laying hens;
(b) chicken breeders;
(c) fattening turkeys;
(d) breeding turkey;
(e) fattening waterfowl;
(f) breeding waterfowl;
(j) farmed game birds

However, some broiler holding will be included because (1) they are kept in significant numbers in free range production and (2) they are considered to pose a higher risk of infection with avian influenza.

(2) including MS specific exceptional circumstances as described in Annex I point 3 of Commission Decision 2010/367/EU)
ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

2.2.1 POULTRY HOLDINGS (a) (except ducks, geese and farmed game birds (waterfowl e.g. mallards) to be sampled

Serological investigation according to Annex I to Commission Decision 2010/367/EU

<table>
<thead>
<tr>
<th>Category</th>
<th>Targets for year</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>laying hens</td>
<td>delete this category</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NUTS (2) (b)</th>
<th>Total number of holdings (c)</th>
<th>Total number of holdings to be sampled</th>
<th>Number of samples per holding</th>
<th>Total number of tests</th>
<th>Method of laboratory analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulgaria</td>
<td>147</td>
<td>42</td>
<td>10</td>
<td>420</td>
<td>ELISA test</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>147</td>
<td>42</td>
<td>1</td>
<td>42</td>
<td>Haemagglutination inhibition test</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(a) Holdings or herds or flocks or establishments as appropriate.
(b) Refers to the location of the holding of origin. In case NUTS (Nomenclature of Territorial Units for Statistics) can not be used, region as defined in the programme by the Member States is requested.
(c) Total number of holdings of one category of poultry in concerned NUTS 2 region.
ANNEX 4: Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

**Category:** turkey breeders

<table>
<thead>
<tr>
<th>NUTS (2) (b)</th>
<th>Total number of holdings (c)</th>
<th>Total number of holdings to be sampled</th>
<th>Number of samples per holding</th>
<th>Total number of tests</th>
<th>Method of laboratory analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulgaria</td>
<td>1</td>
<td>1</td>
<td>10</td>
<td>10</td>
<td>agar gel immune diffusion test</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>haemagglutination inhibition test</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>2</td>
<td>2</td>
<td>11</td>
<td>11</td>
<td>X</td>
</tr>
</tbody>
</table>

(a) Holdings or herds or flocks or establishments as appropriate.
(b) Refers to the location of the holding of origin. In case NUTS (Nomenclature of Territorial Units for Statistics) can not be used, region as defined in the programme by the Member States is requested.
(c) Total number of holdings of one category of poultry in concerned NUTS 2 region.

**Category:** fattening turkeys

<table>
<thead>
<tr>
<th>NUTS (2) (b)</th>
<th>Total number of holdings (c)</th>
<th>Total number of holdings to be sampled</th>
<th>Number of samples per holding</th>
<th>Total number of tests</th>
<th>Method of laboratory analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulgaria</td>
<td>1</td>
<td>1</td>
<td>10</td>
<td>10</td>
<td>agar gel immune diffusion test</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>haemagglutination inhibition test</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>2</td>
<td>2</td>
<td>11</td>
<td>11</td>
<td>X</td>
</tr>
</tbody>
</table>
ANNEX 4: Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

(a) Holdings or herds or flocks or establishments as appropriate.
(b) Refers to the location of the holding of origin. In case NUTS (Nomenclature of Territorial Units for Statistics) can not be used, region as defined in the programme by the Member States is requested.
(c) Total number of holdings of one category of poultry in concerned NUTS 2 region.

### Farmed game birds (gallinaceous)

<table>
<thead>
<tr>
<th>NUTS (2) (b)</th>
<th>Total number of holdings</th>
<th>Total number of holdings to be sampled</th>
<th>Number of samples per holding</th>
<th>Total number of tests</th>
<th>Method of laboratory analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulgaria</td>
<td>5</td>
<td>5</td>
<td>10</td>
<td>50</td>
<td>agar gel immune diffusion test</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>6</td>
<td>5</td>
<td>1</td>
<td>6</td>
<td>haemagglutination-inhibition test</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td><strong>55</strong></td>
<td></td>
</tr>
</tbody>
</table>

### Chicken breeders

<table>
<thead>
<tr>
<th>NUTS (2) (b)</th>
<th>Total number of holdings</th>
<th>Total number of holdings to be sampled</th>
<th>Number of samples per holding</th>
<th>Total number of tests</th>
<th>Method of laboratory analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>BG</td>
<td>32</td>
<td>15</td>
<td>10</td>
<td>150</td>
<td>ELISA test</td>
</tr>
<tr>
<td>BG</td>
<td>32</td>
<td>15</td>
<td>1</td>
<td>15</td>
<td>haemagglutination-inhibition test</td>
</tr>
</tbody>
</table>

Add a new row

---

(a) Holdings or herds or flocks or establishments as appropriate.
(b) Refers to the location of the holding of origin. In case NUTS (Nomenclature of Territorial Units for Statistics) can not be used, region as defined in the programme by the Member States is requested.
(c) Total number of holdings of one category of poultry in concerned NUTS 2 region.
ANNEX 4: Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

<table>
<thead>
<tr>
<th>Total</th>
<th>165</th>
</tr>
</thead>
<tbody>
<tr>
<td>Add a new row</td>
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</tr>
</tbody>
</table>

(a) Holdings or herds or flocks or establishments as appropriate.
(b) Refers to the location of the holding of origin. In case NUTS (Nomenclature of Territorial Units for Statistics) cannot be used, region as defined in the programme by the Member States is requested.
(c) Total number of holdings of one category of poultry in concerned NUTS 2 region.

<table>
<thead>
<tr>
<th>Add a category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Totals</td>
</tr>
<tr>
<td>Total poultry 2015</td>
</tr>
</tbody>
</table>

2.2.2 DUCKS, GEESE AND FARMED GAME BIRDS (WATERFOWL e.g. MALLARD) HOLDINGS (a) to be sampled.

Serological investigation according to Annex I to Commission Decision 2010/367/EU

**Targets for year**

**2015**
### Category: fattening ducks

<table>
<thead>
<tr>
<th>NUTS (2) (b)</th>
<th>Total number of duck and goose holdings</th>
<th>Total number of duck and goose holdings to be sampled</th>
<th>Number of samples per holding</th>
<th>Total number of tests</th>
<th>Method of laboratory analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulgaria</td>
<td>151</td>
<td>78</td>
<td>20</td>
<td>1 560</td>
<td>ELISA test</td>
</tr>
<tr>
<td>BG</td>
<td>151</td>
<td>78</td>
<td>2</td>
<td>156</td>
<td>haemagglutination-inhibition test</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td><strong>1 716</strong></td>
<td></td>
</tr>
</tbody>
</table>

(a) Holdings or herds or flocks or establishments as appropriate.

(b) Refers to the location of the holding of origin. In case NUTS (2) code can not be used, region as defined in the programme by the Member State is requested.

### Category: duck breeders

<table>
<thead>
<tr>
<th>NUTS (2) (b)</th>
<th>Total number of duck and goose holdings</th>
<th>Total number of duck and goose holdings to be sampled</th>
<th>Number of samples per holding</th>
<th>Total number of tests</th>
<th>Method of laboratory analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>BG</td>
<td>3</td>
<td>3</td>
<td>20</td>
<td>60</td>
<td>ELISA test</td>
</tr>
<tr>
<td>BG</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>8</td>
<td>haemagglutination-inhibition test</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td><strong>68</strong></td>
<td></td>
</tr>
</tbody>
</table>

(a) Holdings or herds or flocks or establishments as appropriate.

(b) Refers to the location of the holding of origin. In case NUTS (2) code can not be used, region as defined in the programme by the Member State is requested.

Add a category
**ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)**

<table>
<thead>
<tr>
<th>NUTS (2) (b)</th>
<th>Total number of tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total ducks and geese 2015</td>
<td>1,782</td>
</tr>
</tbody>
</table>

**TOTALS for Poultry (2.2.1) + Ducks and Geese (2.2.2) for year:**

<table>
<thead>
<tr>
<th>Poultry +Ducks/Geese</th>
<th>Total number of tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grand Total</td>
<td>2,486</td>
</tr>
<tr>
<td>Grand Total ELISA</td>
<td>2,190</td>
</tr>
<tr>
<td>Grand Total agar</td>
<td>70</td>
</tr>
<tr>
<td>Grand Total HI tests (H5)</td>
<td>0</td>
</tr>
<tr>
<td>Grand Total HI tests (H7)</td>
<td>0</td>
</tr>
<tr>
<td>Grand Total Virus Isolation test</td>
<td>0</td>
</tr>
<tr>
<td>Grand Total PCR test</td>
<td>0</td>
</tr>
<tr>
<td>Grand Total Other test</td>
<td>226</td>
</tr>
<tr>
<td>Grand Total Samplings</td>
<td>0</td>
</tr>
</tbody>
</table>
2.3 Sampling procedures, sampling periods and frequency of testing

2.3.1 Sampling procedures in domestic poultry.
The number of poultry holdings (for each poultry production category, except those of ducks, geese and mallards) to be sampled is defined so as to ensure the identification of at least one infected poultry holding where the prevalence of infected poultry holdings is at least 5%, with a 95% confidence interval. The number of duck, goose and mallard holdings to be sampled is defined so as to ensure the identification of at least one infected poultry holding where the prevalence of infected poultry holdings is at least 5%, with a 99% confidence interval.

2.3.2 Sampling procedures for serological testing
Serological testing for Avian influenza shall be carried out in the following species and birds category:
- the gallinaceous species /breeding stocks, laying hens, turkeys, ratites/;
- the waterfowls species / breeders and fattening ducks and geese/;

2.3.3 Sampling for virological testing
Sampling for virological testing for avian influenza shall not be used as an alternative to serological testing and must be performed solely within the framework of investigations to follow-up serological positive testing results for avian influenza.

2.3.4 Frequency and period for testing
The sampling of poultry holdings shall be carried out annually. The time period for sampling in the poultry holding shall coincide with seasonal production for each poultry production category.
ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

In order to optimise efficiency and also to avoid the unnecessary entry of persons onto poultry holdings, whenever it possible sampling may be combined with sampling for other purposes, such as within the framework of Salmonella control.

Sampling shall be carried out in accordance with the approved surveillance programme from 1 January to 31 December 2015.

2.4. Laboratory testing : description of the laboratory tests used and follow up investigations

Description of the used serological tests : (max 32000 chars)

For serological analyses are sent serum samples of clinically healthy birds.

Blood obtained by a single-use closed blood sampling system. The blood is collected of the internal part of the wing from v. cutanea ulnaris and v. Brachialis, using vacuum container type butterfly.

The samples are chilled immediately on ice and submitted to the laboratory as quickly as possible. If rapid transportation cannot be guaranteed the samples can be stored for 48 to 72 hours at 0 - 4°C and for a longer period – at -70°C. The specimens for virological sampling should not be transported on dry ice, since the CO2 inactivate immediately the avian influenza virus.

The plan for laboratory surveillance for 2015 is based on a regional principle as regards to the samples which have to be taken from different bird species and sent for analyses. The programme includes examination of live poultry. It is preferable the samples taken from domestic poultry from gallinaceous species and waterfowls to be sent with a separate cover letters. The samples should be taken within the migratory period of the wild birds and can include considerable number of slaughtered domestic poultry.

In case of taking samples from one settlement the latter must be collected from at least three different backyards/ flocks.

Laboratory tests shall be carried out in accordance with the avian influenza diagnostic manual (Commission Decision 2006/437/EC) laying down the procedures for the confirmation and differential diagnosis of avian influenza (including examination of sera from ducks and geese by haemagglutination-inhibition (HI) test).

Testing of samples shall be carried out at National Reference Laboratory for Avian Influenza under the National Diagnostic and Research Veterinary Institute /NDRVI/, Sofia National Reference Laboratory for Diagnostics of Avian Influenza and Newcastle Disease in Varna.

All positive serological findings shall be confirmed by the National Laboratories for avian influenza by a haemagglutination-inhibition test, using designated strains supplied by the Community Reference Laboratory for Avian Influenza.
ANNEX 4: Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

a) for H5 subtype:
- initial testing using teal/England/7894/06 (H5N3);
- testing of all positives with chicken/Scotland/59(H5N1) to eliminate N3 cross reactive antibodies;

b) for H7 subtype:
- initial testing using turkey/England/647/77 (H7N7);
- testing of all positive with African starling/983/79 (H7N1) to eliminate N7 cross reactive antibodies.

All positive serological findings must be followed up at the poultry holding by epidemiological investigations and further sampling for testing by virological methods in order to determine, if active infection of avian influenza virus is present on the poultry holding. The conclusions of all those investigations shall be reported to the Commission.

All avian influenza virus isolates shall be submitted to the EURL in accordance with Union legislation according to the functions and the duties of the National reference laboratories as laid down in Annex VIII to Directive 2005/94/EC, unless a derogation has been granted as provided for in paragraph 4(d) of Chapter V of the Diagnostic Manual. Viruses of the H5/H7 subtype shall be submitted to the EURL without delay and shall be subjected to the standard characterisation tests (nucleotide sequencing/IVPI) according to the Diagnostic Manual.

The specific protocols provided by the EURL for the submission of samples and diagnostic material shall be used. The samples should be addressed to: Avian Virology, VLA Weybridge, New Haw, Addlestone, and Surrey KT15 3NB, United Kingdom

Community Reference Laboratory contacts
Ian H. Brown, Director of the Reference Laboratory
Direct TEL: +44 1932 357 339;
Direct FAX: +44 1932 357 239;
Email: i.h.brown@vla.defra.gsi.gov.uk

Ruth Manvell, Reference Laboratory Manager
Direct TEL: +44 1932 357 736 or +44 1932 357 708
Direct FAX: +44 1932 357 856
Email: r.manvell@vla.defra.gsi.gov.uk
ANNEX 4: Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

3. **Description and implementation of the surveillance programme in wild birds**

3.1.1 **Designation of the central authority in charge of supervising and coordinating the departments responsible for implementing the programme and relevant collaborating partners (e.g. epidemiologists, ornithologists, nature bird observation and hunter organisations).**

| Bulgarin Food Safety Agency (BFSA) is the competent authorities for control and surveillance of the AI programme. |
| Department “Infectious diseases” within Directorate “Animal health and Welfare” at the Headquarters of BFSA has the following responsibilities: |
| 1. To draft the AI surveillance programme and to submit it for approval to the European Commission. |
| 2. To control the implementation of the surveillance programme. |
| 3. To collect and analyze the data on the animals tested |
| 4. To summarize the data on positive holdings. |
| 5. To keep a register in the database of all holdings under the programme |
| 6. To send annual report to the European Commission containing the data referred to in points 3-5. |

At regional level the Regional Food Safety Department (RFSD) and the heads of departments “Animal health” have the following responsibilities:

| At regional level the Regional Food Safety Department (RFSD) and the heads of departments “Animal health” have the following responsibilities: |
| 1. To control and to implement the AI surveillance programme at regional level. |
| 2. To collect and analyse the data on the poultry tested in the region. |
| 3. To summarize the data on positive animals. |
| 4. To summarize the data on the surveillance costs incurred at regional level. |
| 5. To keep a register in the database of all holdings |
| 6. To send annual reports containing the data referred to in points 1-5 to Directorate “Animal health and welfare” at BFSA. |
ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

<table>
<thead>
<tr>
<th>The municipal veterinarian has the following responsibilities:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. To control and to implement the AI surveillance programme at the relevant municipality.</td>
</tr>
<tr>
<td>2. To control the sampling and the sending samples to the laboratories.</td>
</tr>
<tr>
<td>3. To collect and analyze the data on the poultry tested in the veterinary units located on the territory of the relevant municipality.</td>
</tr>
<tr>
<td>4. To summarize the data on positive animals.</td>
</tr>
<tr>
<td>5. To summarize the data on the AI surveillance costs incurred by the relevant municipality.</td>
</tr>
<tr>
<td>6. To keep a register in the database of all holdings</td>
</tr>
</tbody>
</table>

The Programme is been performed under the assistance rendered by the local associations of ornithologists and by the local units of the national Union of Hunters and Anglers of Bulgaria.

### 3.1.2 Description and delimitation of the geographical and administrative areas in which the programme is to be applied

(max. 32000 chars):

The Programme is been implemented over the territory of the whole country.

### 3.1.3 Estimation of the local and/or migratory wildlife population

(max. 32000 chars):

n/a
3.2 Design, criteria, risk factors and target population (3)

3.2 DESIGN AND IMPLEMENTATION:
(a) A risk-based surveillance (RBS) shall be implemented as a 'passive' surveillance system by laboratory investigation of moribund wild birds or birds found dead and it shall be specifically directed towards water bird species.
(b) Wild birds, in particular migratory water birds, that have been shown to be at a higher risk of becoming infected with, and transmitting the HPAI H5N1 virus, the 'target species' (TS) (listed in Table 3.1.1), shall be specifically targeted.
(c) Areas close to the sea, lakes and waterways where birds were found dead; and in particular when these areas are in close proximity to poultry holdings (listed in Table 3.1.2), especially in areas where there is a high density of poultry holdings, shall be targeted.
(d) It is necessary the participation of ornithological institutions and organizations responsible for the ringing of birds. Where necessary this must be done under the supervision of these organizations or by the hunters.
(e) If the epidemiological situation for the HPAI H5N1 virus so requires, surveillance activities shall be enhanced by awareness raising and active searching and monitoring for dead or moribund wild birds, in particular for those belonging to TS.

A detailed description of the number of samples per villages, please see Table 3.2.1.

The Bulgarian Food Safety Agency has prepared model cover letters, according to the European Commission requirements, for submission of the samples to the National Reference Laboratories “Newcastle disease and Avian Influenza A”.

Areas at risk (wetlands in particular where links with high density poultry populations), previous positive findings as referred to in point 2 of Part 1 of Annex II to Commission Decision 2010/367/EC should be taken into account and if possible complemented by a map.
### ANNEX 4: Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

#### 3.2.1 WILDBIRDS focussed on target species

*Investigations according to the surveillance programme set out in Part 2 of Annex II to Decision 2010/367/EC*

<table>
<thead>
<tr>
<th>NUTS (2) code/region (a)</th>
<th>Total number of birds to be sampled</th>
<th>Estimated total number of samples to be taken for passive surveillance</th>
<th>Type of test</th>
<th>Number of tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulgaria</td>
<td>200</td>
<td>200</td>
<td>PCR test</td>
<td>200</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>50</td>
<td>50</td>
<td>Virus isolation test</td>
<td>50</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Add a new row**

(a) Refers to the place of collection of birds/samples. In case NUTS 2 (Nomenclature of Territorial Units for Statistics) cannot be used, region as defined in the programme by the Member State is requested. Please fill-in these values directly in the field.
(b) General description of the wild birds are intended to be sampled in the framework of the active and passive surveillance.
(c) Voluntary, to be included for information purposes, not eligible for cofinancing.
ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

<table>
<thead>
<tr>
<th>Total number of tests</th>
<th>250</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Virus isolation tests</td>
<td>90</td>
</tr>
<tr>
<td>Total PCR tests</td>
<td>200</td>
</tr>
<tr>
<td>Total Other tests</td>
<td>0</td>
</tr>
</tbody>
</table>

3.3 Sampling procedures and sampling periods

Sampling procedures:
(a) Sampling procedures shall be carried out in accordance with the Diagnostic Manual.
(b) Cloacal and tracheal/oropharyngeal swabs and/or tissues from wild birds found dead or moribund shall be sampled for molecular detection (PCR) and/or virus isolation.
(c) Specific care must be taken for the storage and transport of samples in accordance with paragraphs 5 and 6 of Chapter IV of the Diagnostic Manual. All avian influenza virus isolates of cases in wild birds shall be submitted to the EURL, unless a derogation has been granted as provided for in paragraph 4(d) of Chapter V of the Diagnostic Manual. Viruses of the H5/H7 subtype shall be submitted to the EURL without delay and shall be subjected to the standard characterisation tests (nucleotide sequencing/IVPI) according to the Diagnostic Manual.

3.4 Laboratory testing : description of the laboratory tests used

1. Laboratory tests shall be carried out in accordance with the Diagnostic Manual (Commission Decision 2006/437/EC).
2. Testing of samples shall be carried out at National Reference Laboratory for Avian Influenza under the National Diagnostic and Research Veterinary
ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

Institute /NDRVI/, Sofia National Reference Laboratory for Diagnostics of Avian Influenza and Newcastle Disease in Varna.

Initial screening using M gene PCR shall be carried out, followed by rapid testing of positive findings for H5 which shall be carried out within a period of not more than 2 weeks. In case of a positive finding for H5, an analysis of the cleavage site shall be undertaken as soon as possible to determine whether or not it has a highly pathogenic avian influenza (HPAI) or a low pathogenic avian influenza (LPAI) motif. Where H5 HPAI is confirmed, further analysis to determine the N type must be done rapidly, even though this can only provide evidence to eliminate N1.

3. All positive serological findings shall be confirmed by the National Laboratories for avian influenza by a haemagglutination-inhibition test, using designated strains supplied by the Community Reference Laboratory for Avian Influenza


4. Description of the epidemiological situation of the disease in poultry during the last five years

4.1. Each year since 2000, an annual AI Surveillance Programme in poultry has been implemented in Bulgaria.

Measures included in the programme for poultry surveillance:
- Observation of health status of the poultry kept in the poultry farms of intensive mode of keeping /the large poultry holdings/;
- Observation of health status of the poultry kept in backyards;
- Testing of samples taken from the birds kept in all regions of the country considered to be of higher risk with regards to AI;
- Testing of poultry carcasses collected in case of mortality rates higher than the normal poultry ones;
- Strict control on the movements of poultry and poultry products;
- Thorough disinfection of transport vehicles entering into the country from third countries;
- Control on the implementation of bio-security measures.

Epidemiological situation in birds throughout the last 5 years:
During the last 5 years not a single case of highly pathogenic Avian influenza (HPAI) has ever been identified in poultry populations in Republic of Bulgaria.

4.1.1. The BFSA of Bulgaria is the national competent authority responsible for the implementation of the AI Surveillance Programme.
ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

This Programme is directly performed by registered veterinarians exercising private practice /registered private practitioners/ under the control of the official veterinarians directly responsible for all the country municipalities located within the 28 administrative districts (= 28 veterinary regions) of Bulgaria.
The outcomes of implementation of the AI Surveillance Programme are reported in writing on monthly basis by the 28 “Animal Health” Department Chiefs (with the 28 Regional Food Safety Departments) to the “Animal Health and Welfare ” Directorate at the BFSA Central Administration.
Each week the National reference Laboratory send information, regarding the samples from the Surveillance Programme to the Animal Health and Welfare Directorate in the BFSA.

4.1.2 All poultry holdings (including backyard poultry) are registered and have an identification number according to the Law of veterinary activity.

4.1.3 The prophylactic vaccination against Avian Influenza is prohibited. In Republic of Bulgaria the vaccination against the disease was never carried on.

5. Description of the epidemiological situation of the disease in wild birds during the last five years

(max. 32000 chars):

5. 1. Each year since 2000, an annual AI Surveillance Programme in wild birds has been implemented.

Measures included in the programme for wild birds surveillance:

- Monitoring of the wild birds migration;
- monitoring of the mortality in wild birds;
- capture and taking samples from wild bird;
- survey and laboratory testing of samples from wild birds;

Epidemiological situation in wild birds throughout the last 5 years:

AI in poultry has never been found out up to 31.01.2006:
On 31.01.2006 in river Danube near the town of Vidin a sick swan was found. AI virus, strain H5 was isolated from the swan at the National Reference
ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

Laboratory on AI in Sofia. The isolate was sent to Central Reference Laboratory of the European Community in Waybridge, Great Britain and on 10.2.2006 the isolate was confirmed as influenza A H5N1;

- On 09.02.2006 in samples taken from dead swans found in the lake of Durankulak, region of Dobrich, a virus was isolated determined as influenza of the type A-H5;
- On 09.02.2006 virus H5N1 was isolated from a dead swan found out in the dam Tzonevo, region of Varna.
- On 11.02.2006 a virus of influenza H5 was confirmed in dead swan found out on the beach of Karimorie residential quarter, town of Burgas.

All data for surveillance of wild birds for 2007 were on-line submitted to DG SANCO;

On 08.02.2008 a Low pathogenic avian influenza virus H7N7 was confirmed in a mallard duck shot near to the village of Han Krum, municipality of Veliki Preslav, administrative district of Shoumen.
On 01.04.2010 a highly pathogenic avian influenza (H5N1) was confirmed in a buzzard (Buteo buteo) found dead at the Black sea coast in Varna region, Bulgaria.

5.1.1 The BFSA is the national competent authority responsible for the implementation of the AI Surveillance Programme. The Programme is been performed under the assistance rendered by the local associations of ornithologists and by the local units of the national Union of Hunters and Anglers of Bulgaria.

5.1.2 The Programme is been implemented over the territory of the whole country. Based on the AI risk analysis 10 administrative regions have been considered as such of higher risk with regards to AI and samples for serological surveillance will be taken from all poultry holdings located in these regions.

In the other regions of the country the number of poultry holdings to be sampled under the programme has been determined so that this sampling to be representative for the whole of the country.

5.1.3 Throughout the whole season of intensive wild bird migration, the “Animal Health Welfare” Directorate at the BFSA Central Administration would receive the daily information about the numbers and the health status of the wild birds observed.

6. Measures in place as regards the notification of the disease

The Law on Veterinary Activities, Art.124 and Ordinance No.23 / 14.12.2005 on the order and the way of notification and registration of infectious diseases in animals, which is harmonized with Council Directive 82/894/EEC.
ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

7. Costs

7.1 Detailed analysis of the costs

7.1.1 Poultry

(max. 32000 chars):
1. Costs related to taking and transportation of samples for testing to diagnostics laboratories
2. Costs for the purchase of the required diagnostics kits
3. Costs for compensations to the owners of compulsively killed or slaughtered birds
4. Costs for remuneration of the labor of the executers of the program

7.1.2 Wild birds

(max. 32000 chars):
1. Costs related to taking and transportation of samples of wild birds for testing to diagnostics laboratories
2. Costs for the purchase of the required diagnostics kits
3. Costs for remuneration of the labor of the executers of the program
ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

7.2 Summary of the annual costs:

7.2.1 Poultry surveillance

**Detailed analysis of the cost of the programme - poultry**

<table>
<thead>
<tr>
<th>Targets for year</th>
<th>2015</th>
</tr>
</thead>
</table>

### Laboratory testing

<table>
<thead>
<tr>
<th>Methods of laboratory analysis</th>
<th>Number of tests</th>
<th>Indicative unitary test cost (per method) in € (*)</th>
<th>Total cost (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ELISA test</td>
<td>2 190</td>
<td>3.26</td>
<td>7 139.4</td>
</tr>
<tr>
<td>agar gel immune diffusion test</td>
<td>70</td>
<td>1.8</td>
<td>126</td>
</tr>
<tr>
<td>HI-Test for H5 (specify number of tests for H5)</td>
<td>113</td>
<td>9.64</td>
<td>1 089.32</td>
</tr>
<tr>
<td>HI-Test for H7 (specify number of tests for H7)</td>
<td>113</td>
<td>9.64</td>
<td>1 089.32</td>
</tr>
<tr>
<td>Virus isolation test</td>
<td>50</td>
<td>37.87</td>
<td>1 893.5</td>
</tr>
<tr>
<td>PCR test</td>
<td>50</td>
<td>19.74</td>
<td>987</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

### Sampling

<table>
<thead>
<tr>
<th>Number of samples</th>
<th>Unitary cost in € (*)</th>
<th>Total cost (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(*) The unitary cost reflects the average cost per test.
ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

<table>
<thead>
<tr>
<th>Samples</th>
<th>Number of samples</th>
<th>Unitary cost in €</th>
<th>Total cost (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4 164</td>
<td>1.19</td>
<td>4955.16</td>
</tr>
</tbody>
</table>

**Other measures**

<table>
<thead>
<tr>
<th>Transport</th>
<th>Number of samples</th>
<th>Unitary cost in €</th>
<th>Total cost (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4 164</td>
<td>1</td>
<td>4164</td>
</tr>
</tbody>
</table>

**Total poultry**

<table>
<thead>
<tr>
<th>Testing + Sampling + Other measures</th>
<th>Total cost (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>21 443.70 €</td>
</tr>
</tbody>
</table>

(*) as per cofinancing decision for 2014 programmes
ANNEX 4: Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

### 7.2.2 Wild bird surveillance

#### Detail analysis of the cost of the programme - wild birds

<table>
<thead>
<tr>
<th>Targets for year</th>
<th>2015</th>
</tr>
</thead>
</table>

#### Laboratory testing

<table>
<thead>
<tr>
<th>Methods of laboratory analysis</th>
<th>Number of tests</th>
<th>Unitary test cost (per method) in € (*)</th>
<th>Total cost (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virus isolation test</td>
<td>50</td>
<td>37.89</td>
<td>1894.5</td>
</tr>
<tr>
<td>PCR test</td>
<td>200</td>
<td>19.74</td>
<td>3948</td>
</tr>
<tr>
<td>Other cost</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

#### Delivery of wild animals

<table>
<thead>
<tr>
<th>Delivery of wild animals</th>
<th>No of wild birds</th>
<th>Eligible cost in € (*)</th>
<th>Total cost (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>200</td>
<td>1</td>
<td>200</td>
</tr>
</tbody>
</table>

#### Other measures

<table>
<thead>
<tr>
<th>Other measures</th>
<th>Number</th>
<th>Unitary cost in €</th>
<th>Total cost (€)</th>
</tr>
</thead>
</table>
ANNEX 4: Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

<table>
<thead>
<tr>
<th>Other please specify here</th>
<th>0</th>
<th>0</th>
<th>0</th>
<th>X</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Total wild birds Testing + Delivery + Other measures</th>
<th>450</th>
<th>6 042,50 €</th>
</tr>
</thead>
</table>

(*) as per cofinancing decision for 2014 programmes

TOTALS for Poultry (7.2.1) + Ducks and Geese (7.2.2) for year:

<table>
<thead>
<tr>
<th>Total Cost</th>
<th>27 486</th>
</tr>
</thead>
</table>

7.3 Co-financing rate:

The maximum co-financing rate is in general fixed at 50%. However based on provisions of Article 5.2 and 5.3 of the Common Financial Framework, we request that the co-financing rate for the reimbursement of the eligible costs would be increased:

☐ Up to 75% for the measures detailed below
☐ Up to 100% for the measures detailed below
☐ Not applicable
ANNEX 4: Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

7.4 Source of national funding

Please specify the source of the national funding:

☒ public funds
☐ food business operators participation
☐ other

Please give details on the source of national funding (max 32000 characters)

The costs are from the national budget and then co-financed by the Community
ANNEX 4: Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

Attachments

IMPORTANT:

1) The more files you attach, the longer it takes to upload them.
2) This attachment files should have one of the format listed here: .jpg, jpeg, .tiff, .tif, .xls, .xlsx, .doc, .docx, .ppt, .pptx, .bmp, .pna, .pdf.
3) The total file size of the attached files should not exceed 2500 Kb (+- 2.5 Mb). You will receive a message while attaching when you try to load too much.
4) IT CAN TAKE **SEVERAL MINUTES TO UPLOAD** ALL THE ATTACHED FILES. Don’t interrupt the uploading by closing the pdf and wait until you have received a Submission Number!
5) Only use letters from a-z and numbers from 1-10 in the attachment names, otherwise the submission of the data will not work.

List of all attachments

<table>
<thead>
<tr>
<th>Attachment name</th>
<th>File will be saved as (only a-z and 0-9 and -_):</th>
<th>File size</th>
</tr>
</thead>
<tbody>
<tr>
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<td>3739_3298.xlsx</td>
<td>31 kb</td>
</tr>
<tr>
<td>3739_3299.png</td>
<td>3739_3299.png</td>
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<td>3739_3303.png</td>
<td>3739_3303.png</td>
<td>318 kb</td>
</tr>
</tbody>
</table>

Total size of attachments: 2134 kb
ANNEX 4 : Standard requirements for the submission of surveillance programmes for avian influenza in poultry and wild birds as referred to in Article 1(d)

Attachments in RED have an attachment extension that is not allowed. Please remove the file, otherwise submission will not work.