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Laboratory Data Flows at country level: African Swine Fever and Avian Influenza surveillance

SIGMA Consortium

Abstract

The Framework Working Contract (FWC) number OC/EFSA/ALPHA/2018/01 between the European Food Safety Authority (EFSA), the contracting authority, and the SIGMA consortium, the contractor, is in force from 23 May 2018 until 22 November 2021. The subject matter of the FWC is the provision of technical support to improve and automatize the collection and reporting to EFSA by the European Union (EU) Member States of data on animal disease outbreaks and surveillance (SIGMA). The contracting authority orders services by sending the contractor Order forms by e-mail. Among other tasks, EFSA requested the preparation of two External Reports on Country Data Flows: one on Animal Population and a second on Laboratory data. The present report describes the data flows in place in contributing countries for the management and updated of national databases on laboratory (surveillance) data.

 ${\ensuremath{\mathbb C}}$ Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise "G. Caporale", 2022

Key words: SIGMA data collection, laboratory data, testing data, African Swine Fever, Avian Influenza, ASF, AI

Question number: EFSA-Q-2022-00225 Correspondence: <u>BIOHAW@efsa.europa.eu</u>



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Summary

The European Food Safety Authority (EFSA) has been receiving requests for support by the European Commission (EC) in the analysis of certain animal disease outbreaks and related risk factors (i.e. African swine fever, ASF; lumpy skin disease, LSD; avian influenza, AI). These types of epidemiological analysis require the availability of high resolution and up to date data about the susceptible animal population and the results of surveillance and control activities, such as laboratory testing or vaccination actions, carried out by the European Union (EU) Member States (MSs).

In the remit of the Framework Working Contract (FWC) number OC/EFSA/ALPHA/2018/01, the SIGMA Consortium has been appointed by EFSA to study and define the possible data collection flows from MSs to EFSA, considering all possible difficulties and relative technical solutions to minimise the workload of the data providers (MSs), ensuring, at the same time, the level of data quality needed for risk assessment studies.

The main objective of the service, therefore, was to provide EFSA with all necessary technical support in developing and implementing an automated data collection and reporting system on:

- susceptible livestock,
- animal testing to detect animal diseases (LSD, AI, ASF).

To properly achieve this objective a "bottom-up" approach was chosen, starting from the collection of all available information about the organization of data flows at national level.

Four types of questionnaires were prepared by the SIGMA Consortium (regarding pig and poultry population data, ASF and AI surveillance data) and submitted to the EU MSs and 4 IPA countries, including questions about the institutions generating or collecting the basic data, the level of details of collected data, the existing data repositories at local or national levels, the existing data exchanges between Institutions and technical means used.

Overall, 50 filled questionnaires were received from 21 countries (17 EU MS and 4 IPA countries).

In relation to the quality and completeness of data collected at national level on ASF or Ai surveillance, two main aspects must be considered: the presence of a national database and the ways the data is updated. For the first aspect, in the great majority of countries a national database, either at the central veterinary authority or at NRL level, is present, thus facilitating the possible exchange of data with EFSA.

However, in some countries the detailed (sample-based) data remain stored in multiple LIMS, where samples have been analysed, without a further consolidation of data at national level. In these situations, the SIGMA-EST tool might be used to facilitate the establishment and updating of a national database, managing the mapping and harmonisation of data coming from the different LIMS. However, a careful preliminary analysis of the flow of samples must be performed to avoid to double register results for the same sample (in case same screening tests are repeated by more than one laboratory).

Usually the great majority of problems related to not complete or wrong registration of sampling data occurs, when data accompanying samples are registered into the LIMS by the laboratories analysing the samples. A possible solution could be the development of web-based sampling forms, where the sampling information are registered by the personnel performing the sampling activities. A unique sampling identification code could be generated and dispatched together with the samples to allow laboratories to automatically (e.g. through web-services) retrieve the sampling data without double insertion. Similar solutions could be provided by EFSA to those countries unable to develop tools like this by themselves.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

This contract was awarded by EFSA to:

Contractor:

Leading Partner:

Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise "G. Caporale" (IZSAM) Campo Boario, 64100 Teramo, Italy VAT registration number: 00060330677

Appointed as the leader of the group by the members of the group that submitted the joint tender and

Partner 2:

Friedrich-Loeffler-Institut, Bundesforschungsinstitut für Tiergesundheit (FLI) Südufer 10, 17493 Greifswald Insel Riems, Germany VAT registration number: DE811354798

Partner 3:

Statens veterinärmedicinska anstalt (SVA) Ulls väg 2B, 751 89 Uppsala, Sweden VAT registration number: SE202100186801

Partner 4:

Bulgarian Food Safety Agency (BFSA) 15 A Pencho Slaveikov blvd, 1606 Sofia, Bulgaria VAT registration number: PIC 959622359

Partner 5:

Estonian University of Life Sciences (EMU) Fr.R.Kreutzwaldi 1, 51014 Tartu, Estonia VAT registration number: EE100018015

collectively 'the contractor',

Contract title: Technical support to improve and automatize data collection and reporting on animal disease outbreaks and surveillance (SIGMA)

Contract number: OC/EFSA/ALPHA/2018/01

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1.1.1. Background

The European Food Safety Authority (EFSA) has been receiving requests for support by the European Commission (EC) in the analysis of certain animal disease outbreaks and related risk factors (i.e. African swine fever, ASF; lumpy skin disease, LSD; avian influenza, AI). These types of epidemiological analysis require the availability of high resolution and up to date data about the susceptible animal population, e.g. number and spatial distribution of establishments breeding susceptible hosts, and the results of surveillance and control activities, such as laboratory testing or vaccination actions, carried out by the European Union (EU) Member States (MSs).

In the remit of the Framework Working Contract (FWC) number OC/EFSA/ALPHA/2018/01, the SIGMA Consortium has been appointed by EFSA to study and define the possible data collection flows from MSs to EFSA, considering all possible difficulties and relative technical solutions to minimise the workload of the data providers (MSs), ensuring, at the same time, the level of data quality needed for risk assessment studies.

The main objective of the service, therefore, was to provide EFSA with all necessary technical support in developing and implementing an automated data collection and reporting system on:

- susceptible livestock,
- animal testing to detect animal diseases (LSD, AI, ASF).

To properly achieve this objective a "bottom-up" approach was chosen, starting from the collection of all available information about the organization of data flows at national level.

This report summarises the main relevant findings about the organization of national databases and data flows obtained through the submission of specific questionnaires to contributing EU Member States (MS) and four EU candidate countries (Instrument for Pre-accession Assistance - IPA countries). The present report describes the data flows in place in contributing countries for the management and updated of national animal (pig or poultry) population databases.

The present report describes the data flows in place in contributing countries for the management and updated of national databases on laboratory data concerning surveillance activities for ASF and AI.

1.1.2. Terms of reference

In the context of the FWC, the Order Form number 13 (OF13), signed on the 6th of May 2021, foresaw the preparation of two External Reports on Country Data Flows: one on Animal Population and a second on Laboratory data.

So far, the data flows on population and laboratory data have not been published but submitted to EFSA as Internal Reports. The aim is to publish two external reports, i.e. one on animal population data flows and one on laboratory data flows, including for both all the available data flows.

Each report should be a collection and a re-elaboration of the information provided to EFSA with the Internal Reports related to OF 03 and 04. In detail the Consortium shall:

- i) revise all internal reports to make them consistent and harmonised (the quality has improved over time and the first reports may require some complementation);
- ii) liaise with the data providers, should some information be missing;
- iii) give a final overall assessment and overview at European level of the similarities and diversities across the EU countries in terms of IT architectural solutions for the generation and management of the animal health data;

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iv) assess the feasibility of a full automation of the data submission (from push to pull, machineto-machine solutions, etc.)

2. Methodologies

Considering the "bottom-up" approach chosen by the SIGMA project, the first step was the collection of all available information about the organization of data flows at national level.

For this purpose, EFSA produced a comprehensive overview of the competent authorities in the framework of the animal health and welfare, describing the ownership of the data domains and all the competent authorities in each MS involved in the generation, collection and storing of data on animal diseases. The data are retrieved by means of an online survey. The results are elaborated in the format of Country Cards on Data sources on animal diseases and published in a public website¹.

In addition to this preliminary picture of the national Institutions involved in the collection of data on animal diseases, more specific information on the organization of the data flows in each country should be gathered. For this objective, the following questionnaires were prepared:

- For African swine fever:
 - Questionnaire regarding the technical description of the data repositories and the related data flows of pig population data;
 - Questionnaire regarding the technical description of the data repositories and the related data flows of ASF surveillance in pigs and wild boars.
- For Avian Influenza:
 - Questionnaire regarding the technical description of the data repositories and the related data flows of poultry population data;
 - Questionnaire regarding the technical description of the data repositories and the related data flows of avian influenza surveillance.

The questionnaires include questions about the institutions generating or collecting the basic data, the level of details of collected data, the existing data repositories at local or national levels, the existing data exchanges between Institutions and technical means used. The possibility of data exchange with EFSA is also explored.

The questionnaires were submitted to the EU MS, directly through the Consortium partners and through the EFSA Scientific Network for Risk Assessment (RA) in Animal Health and Welfare (AHAW). Also four IPA countries, namely Montenegro, Serbia, North Macedonia and Kosovo were involved. The dissemination of the questionnaires was also supported by the EFSA ENCO unit through the Focal Points (FPs).

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¹ https://www.efsa.europa.eu/en/search?s=Data+sources+on+animal+diseases%3A+Country+Card

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3. Results

Overall, 26 filled questionnaires were received from 21 countries (17 EU MS and 4 IPA countries) (**Table 1**).

Country	ASF surveillance	AI surveillance
Austria	X	X
Bulgaria	X	X
Cyprus	Х	
Czechia	X	X
Estonia	Х	Х
Finland	Х	
France		Х
Germany		X
Greece	Х	
Italy		Х
Latvia	Х	
Lithuania	X	
Poland	Х	
Romania	Х	
Slovakia	Х	
Spain	Х	Х
Sweden		Х
Kosovo	Х	
Montenegro	X	
North Macedonia	X	
Serbia	X	
Total	17	9

Table 1: Filled questionnaires received back from the EU MS and IPA countries

Concerning the laboratory data, 17 EU MS and the 4 IPA countries provided information about data flows and data storing inherent to surveillance activities for ASF or AI. In particular, 13 EU MS and 4 IPA countries answered for ASF-related surveillance data, whereas 9 EU MS for data on AI surveillance (**Table 1**).

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3.1. Structure of national database

The presence of a single national database where laboratory data is validated and then registered in a harmonised way, represents a critical issue for all countries.

According to the answers received through the questionnaires, various different solutions are in place in the countries:

- Collection of ASF or AI surveillance data by the National competent authority. An optimal system structure can be observed in Austria, where the Austrian Agency for Health and Food Safety (AGES) is managing a national veterinary information system which includes also a Laboratory Information Management System (LIMS) used by the Institute for Veterinary Disease Control, which is NRL for ASF and AI. Similarly, in France, for AI surveillance on poultry, 11 regional laboratories (public or private), performing AI testing, report their results by e-mail with PDF and XML attachments to the Ministry of Agriculture and Food. The Ministry enters the results into a specific database system (SIGAL). In other countries, such as Bulgaria, Cyprus, Greece and Montenegro, the central competent authority receive mainly aggregated data about the surveillance activities performed (with the exception of data on positive confirmed cases, for which details are received in order to comply with the notification obligations towards the European Commission and OIE).
- **Data stored in LIMS**. Two main different organizational framework can be observed in the countries:
 - Presence of a single laboratory performing AI or ASF tests. In this case, the whole laboratory activities, with all details related to samples taken and results, are registered into the LIMS of the laboratory. This situation can be observed in Czechia, Estonia, Finland, Latvia, Lithuania, Poland, Romania, Slovakia, Sweden, Kosovo and North Macedonia. In some countries, the LIMS is interconnected with the national veterinary information system for retrieving data on animal population and exchanging data on laboratory results (for example, in Czechia the Laboratory of State Veterinary Institutes (SVI) records laboratory results into its LIMS (called LABSYS), which transfer data through web services with the information system (IS), called OIS, of SVA (State Veterinary Administration). In Spain, the central competent authority has developed a website application (RASVE), where the regional authorities upload the data either manually or through an excel file. Currently, the laboratory databases and RASVE are not connected, but this is planned for the future.
 - Presence of multiple laboratories performing AI or ASF tests. In this case some countries have activated procedures for the periodical transfer of detailed data from the laboratories to the NRL (for example in Italy and Germany). In Serbia, ASF laboratory data are stored at level of regional laboratories into different LIMS (5 authorized laboratories for ASF diagnostics in Serbia. The national reference laboratory for ASF is the Institute of Veterinary Medicine of Serbia in Belgrade), which currently are not interconnected or able to transfer detailed (sample-based) data in a single central database.

It is clear the importance of the presence of a **central national database in the countries**, collecting the data for the whole country in a harmonised manner, especially for possible future data exchanges with EFSA. However, the SIGMA-EST tool might be used to facilitate the establishment and updating of a national database when more than one veterinary laboratory is involved in a diagnostic activity in a country. In fact, SIGMA-EST may manage the mapping and harmonisation of data coming from different LIMS, avoiding to force them in changing their own systems and their data manipulation procedures. Under this scenario, a careful preliminary analysis of the flow of samples must be performed to avoid to double register results for the same sample (in case same screening tests are repeated by more than one laboratory).

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3.2. Data Flows

With few exception (e.g. Austria, France, where veterinarians collecting the samples may register the data on sampling events, such as farm localisation, type of birds, etc., directly into the national information systems) the samples are dispatched to the laboratories, accompanied by paper forms, where the data on sampling are reported. This is the first critical point possibly affecting the completeness and quality of the data registered for each sampling event.

EFSA data models for the collection of ASF and AI surveillance data require groups of well organised and detailed information regarding the sampling event and samples taken, which must be included in the information accompanying samples to the laboratories to properly register all these data into the LIMS.

At this point in time, 22 variables are requested by EFSA for the Avian Influenza data submission. The metadata requested to contextualise the test result are about the legal framework, the type of activity, the sampling session, the site of provenience of the sample and the sampled animal. In this case, the lack of interoperability between LIMS and the national animal register, may seriously affect the quality of data related to establishments and subunits, with the impossibility of linking the samples taken from poultry to the right locations where the birds were kept.

For ASF (and eventually also for Avian Influenza when the SIGMA approach will be adopted) 33 variables are requested, but in this case the variables included in the SIGMA laboratory data model pertain only to information that the laboratory generates or can ascertain, with the exception of the information received in the paper forms accompanying the samples.

In addition, the large number of information requested and the numerous business rules existing over these sampling data do not facilitate the controls possibly applied by the laboratories on the completeness and quality of data accompanying the samples.

4. Conclusions

In relation to the quality and completeness of data collected at national level on ASF or AI surveillance, two main aspects must be considered: the presence of a national database and the ways the data is updated.

For the first aspect, in the great majority of countries a national database, either at the central veterinary authority or at NRL level, is present, thus facilitating the possible exchange of data with EFSA.

However, in some countries the detailed (sample-based) data remain stored in multiple LIMS, where samples have been analysed, without a further consolidation of data at national level. In these situations, the SIGMA-EST tool might be used to facilitate the establishment and updating of a national database, managing the mapping and harmonisation of data coming from the different LIMS. However, a careful preliminary analysis of the flow of samples must be performed to avoid to double register results for the same sample (in case same screening tests are repeated by more than one laboratory).

Usually the great majority of problems related to not complete or wrong registration of sampling data occurs, when data accompanying samples are registered into the LIMS by the laboratories analysing the samples. The use of paper forms bearing the requested data and manually inserted by the laboratory personnel when samples are registered is not the optimal solutions. Manual errors and mistakes in the interpretation of written data may be common. One possible solution can be the development of web-based sampling forms, where the sampling information are registered by the personnel performing the sampling activities. A unique sampling identification code could be generated and dispatched together with the samples to allow laboratories to automatically (e.g. through web-services) retrieve the sampling data without double insertion. Similar solutions could be provided by EFSA to those countries unable to develop tools like this by themselves.

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Appendix A – National laboratory dataflows

A.1. Austria

A.1.1. ASF surveillance questionnaire (IZSAM)

A.1.1.1. Results

The description of the authorities responsible for data collection and management of animal diseases in Austria has been already provided in a published EFSA report¹. For the sake of clarity, the organization of the main authorities is reported here (**Figure 1**).

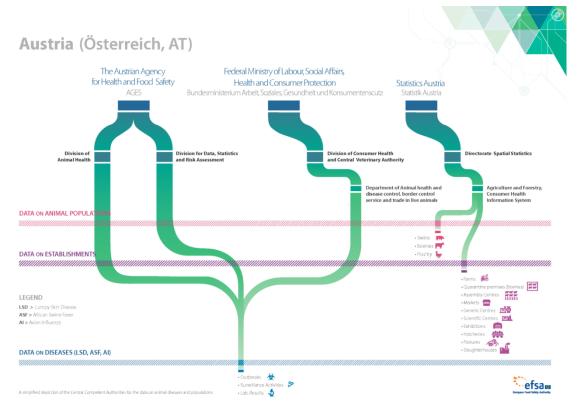


Figure 1: A simplified depiction of the central competent authorities for the data on animal diseases and animal populations in Austria (source: EFSA, 2019).

The Austrian Agency for Health and Food Safety (AGES) supports the Austrian Ministry of Social Affairs, Health, Care and Consumer Protection in questions related to animal health, e.g. by providing data on animal diseases (surveillance activities, outbreaks, laboratory results). The two involved AGES's divisions are the Division of Animal Health and the Division for Data, Statistics and Risk Assessment (Figure 1).

Samples in the framework of the African swine fever (ASF) active/passive surveillance programme in pigs and wild boar are taken by the 9 different Provincial Veterinary Services. The official veterinarians collect all relevant data manually and register samples taken, in the Veterinary Information System (VIS). All relevant sampling data are then imported into the laboratory information management system (LIMS) of the Austrian Agency for Health and Food Safety. The LIMS is a client-server application developed by Triestram und Partner GmbH (Bochum, Germany), and is called LISA.

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Analysis is done by the national reference laboratory at the AGES Institute for Veterinary Disease Control in Mödling/Austria and test results are documented in LISA and transmitted back to VIS.

Data on ASF surveillance is therefore mainly collected in the LIMS of the Austrian Agency for Health and food safety. Data of the LIMS database, implemented on an Oracle platform, is merged via an ETL process (Extract, Transform, Load) in the AGES in-house environment for data retrieval. The Department for Data Management (Division for Data, Statistics and Risk Assessment) at AGES uses different software solution (e.g. Oracle SQL Developer, QlikView, etc.) for data validation, for assembling the codified data in the appropriate order, for converting it in XML and CSV/EXCEL format and for reporting. All information on the samples and laboratory results are registered also in the VIS, which uses db2 as relational database. All results have to be reported to the Austrian Ministry of Social Affairs, Health, Care and Consumer Protection (Division of Consumer Health and Central Veterinary Authority) weekly. Individual test results are reported by E-mail generated within LISA and via interface also into VIS. In the case of a positive sample, the official veterinarian, federal government and ministry will be informed immediately. Furthermore, the Division for Data, Statistics and Risk Assessment together with the Division of Animal Health are generating guarterly a targetperformance comparison on ASF, which is sent to the Austrian Ministry of Social Affairs, Health, Care and Consumer Protection and the nine Provincial Veterinary Services for monitoring. There is an interface between AGES LIMS and VIS for data exchange. Until now there is no service to provide external access to LIMS data. The data aggregated on NUTS2 level (federal state) are sent from the Division for Data, Statistics and Risk Assessment together with the Division of Animal Health per E-mail to the veterinary authorities on a quarterly basis. EFSA has no direct access to the LIMS and VIS databases. Data can be provided via files (e.g. xlsx, csv, xml, etc.) and no specific discussion on this topic has been initiated until now.

In **Figure 2** a conceptual description of the ASF surveillance data flows is provided.

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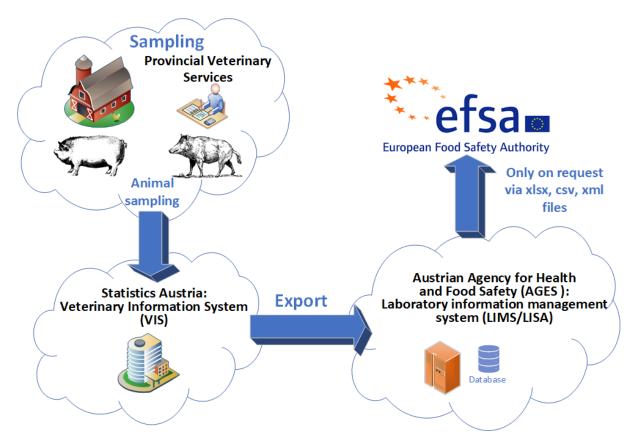


Figure 2: Conceptual description of the ASF surveillance data flows.

A.1.1.2. Conclusive remarks

In principle, the workflow for domestic pigs and wild boar is similar. The individual federal states are responsible for animal health control, yet despite this fact, a central database exists. The veterinary information system (VIS) is the storage point for information on the samples and the results of these. All relevant competent authorities have got access to this system.

The original laboratory data of the examination of samples for ASF are stored in the LIMS (professional database called LISA).

Currently there is no exchange of data or transmission of data to EFSA. However, the custombuilt database provides extensive options for exporting data.

A.1.2. AI surveillance (FLI)

A.1.2.1. Summary

The Austrian Agency for Health and Food Safety (AGES) supports the Austrian Ministry of Labour, Social Affairs, Health and Consumer Protection in questions related to animal health, e.g. by providing data on animal diseases (surveillance activities, outbreaks, laboratory results). The two divisions involved are the Division of Animal Health and the Division for Data, Statistics and Risk Assessment.

Samples in the framework of the avian influenza surveillance programme are taken by the Provincial Veterinary Services. The staff of the veterinary services is made up of official veterinarians permanently

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employed by the provinces. The official veterinarians have to collect all relevant data manually or register samples taken in the Veterinary Information System (VIS). Mostly, the sampling activity is documented manually in paper forms by the Provincial Veterinary Services. This submission form / paper documentation – together with the sample – is sent to AGES and data is entered into the LIMS (laboratory information management system) of the Austrian Agency for Health and Food Safety by the national reference laboratory of the Institute for Veterinary Disease Control. Analysis is also done by the national reference laboratory of the Institute for Veterinary Disease Control in Mödling/Austria and documented in LIMS.

There is also a possibility for the Provincial Veterinary Services to collect data digitally via the web-based computer programme VIS. However, so far, the electronic way is hardly used.

Data on AI surveillance is therefore mainly collected in the LIMS of the Austrian Agency for Health and food safety. Data of the LIMS database (Oracle) is merged via an Extract, Transform, Load process (ETL) in the AGES in-house environment for data retrieval. The Department for Data Management (Division for Data, Statistics and Risk Assessment) uses the Oracle SQL Developer as an integrated development environment (IDE) for writing SQL and PL/SQL scripts. QlikView is used for data validation, for assembling the codified data in the appropriate order, for converting it in XML format and for reporting.

All results must be reported to the Austrian Ministry of Labour, Social Affairs, Health and Consumer Protection (Division of Consumer Health and Central Veterinary Authority) and until 2018 to the EC every 6 months. From 2019 onwards avian influenza surveillance data should be submitted from Member States to the European Food Safety Authority (EFSA) using the EFSA Standard Sample Description version 2 (SSD2) standard.

If the information was registered in VIS and sent to AGES, results are available in this system. There are no feedback-reports sent to the sender of the sample when using paper forms. Until now, there is no service to give external access to the LIMS data.

The Division for Data, Statistics and Risk Assessment together with the Division of Animal Health are generating quarterly a target-performance comparison on AI, which is sent to the Austrian Ministry of Labour, Social Affairs, Health and Consumer Protection and the nine Provincial Veterinary Services for monitoring.

The national reference laboratory of the Institute for Veterinary Disease Control in Mödling/Austria is in contact with the EURL and must transmit positive AI-isolates as well as serum samples (positive on H5 respectively H7) to the EURL. Official outbreaks need to be reported in ADNS.

No specific discussion has taken place until now, whether the data exchange can be initiated by EFSA or if it can be initiated by the Member State. Also, no webservice is in place for an automatic transfer.

A.2. Bulgaria

A.2.1. ASF surveillance (IZSAM)

A.2.1.1. Results

The description of the authorities responsible for data collection and management of animal diseases in Bulgaria has been already provided in a published EFSA report¹. For the sake of clarity, the organization of the main authorities is reported here (**Figure 1**).

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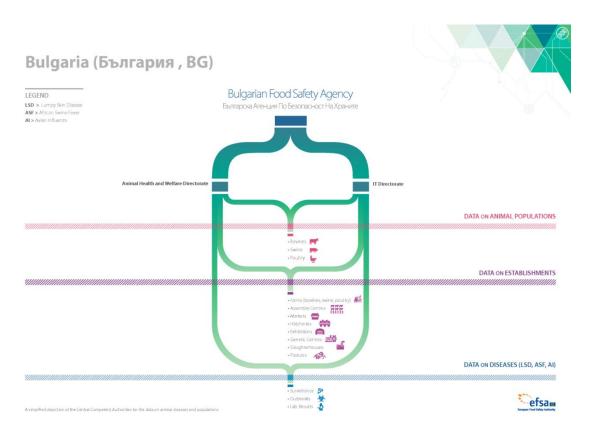


Figure 1: A simplified depiction of the central competent authorities for the data on animal diseases and animal populations in Bulgaria (source: EFSA, 2019).

The laboratory data on Africa Swine Fever (ASF) in domestic pigs and wild boar are collected / generated using two different pathways.

1. Surveillance activities in swine farms:

In domestic pig surveillance, the data is collected by private veterinarians (within the active or passive surveillance on the farms) and by official veterinarians during the regular official controls. The samples from domestic pig surveillance are accompanied by a sample letter. Data is recorded in the laboratory journal (Microsoft Excel files) in the National Reference Laboratory (NRL). The letter with the laboratory results is uploaded into the Veterinary Information System database (VetIS). The data is managed by the Headquarter (HQ) of the Bulgarian Food Safety Agency (BFSA) via the VetIS and can be analysed at individual farm level, as well as at village, municipality and regional levels.

2. Hunting activity and passive surveillance in wild boar:

The surveillance data is collected by hunters, representatives of the Executive Forestry Agency or official veterinarians. Several options exist for the provision of samples to the National Reference Laboratory (NRL): (a) samples are taken by the hunters and sent directly to the laboratory; (b) samples are taken by the hunters and provided either to the representative of the Executive Forestry Agency or the official veterinarian who send the samples to the NRL. The samples from wild boar surveillance are only marked with a barcode. The metadata and investigation results are recorded in a special database "BG lov", that was created to collect surveillance data form wildlife (including ASF). Access to the database can be generated via a mobile app that can be downloaded for free. Data from WB surveillance consists of information about the type of surveillance, type of carcass (found dead, healthy shot), age, GPS coordination, barcode, etc.

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The individual laboratories are connected with the database and record the results automatically. Furthermore, the results of ASF examinations in wild boar in the "BG Ioy" database are also reported on an public website (e.g. https://www.bfsa.bg/bg/Page/asf_map/index/asf_map/%D0%92%D0%B8%D0%B7%D1%83%D0%

<u>B0%D0%B8%D0%B7%D0%B0%D1%86</u>; Figure 2).

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			Sama Buckler	•	Актуални болести по животните > Задай выпрос тук

Figure 2: Web interface of the wildlife surveillance database "BG lov".

The data is physically stored at a computer centre/data processing centre. The computer centre uses a relational database (Oracle) for the central administrative levels. Via a website and a VPN address it is possible to access the data. All data is automatically exchanged via a webservice.

EFSA could have direct access via the webservice and VPN address, if it is granted. It is not clarified, whether the data exchange can be initiated by EFSA or if it has to be initiated by the Member State.Page Break

In **Figure 3** a conceptual description of the ASF surveillance data flows is provided.

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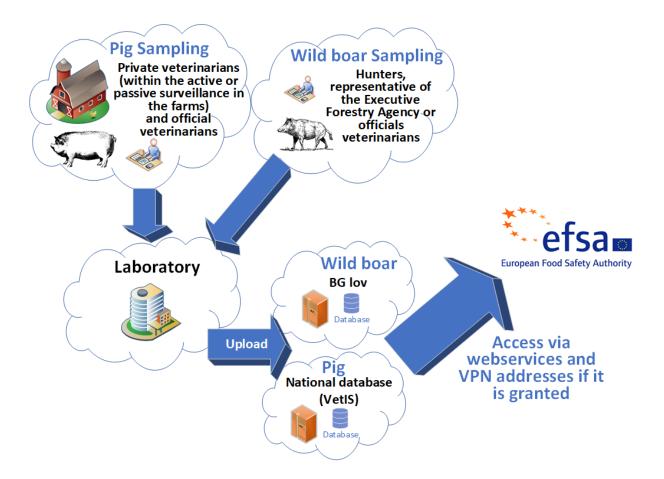


Figure 3: Conceptual description of the ASF surveillance data flows.

A.2.1.2. Conclusive remarks

There are differences for data related to ASF investigations, depending on the origin of the sample (domestic pigs versus wild boar). For domestic pigs, the information is sent to the laboratory accompanying the sample. All information at the laboratory is then stored in Excel databases. From the laboratory the information is sent via letter to the central level, where data is uploaded into the central database (VetIS), managed by the headquarter of the Bulgarian Food Safety Agency. This database contains not only information about ASF surveillance, but also on pig population and offers extensive analytical options. The database would be accessible for EFSA, if granted access.

For information originating from samples of wild boar, a custom-built central database is available, which contains information on wild life diseases, including ASF. The individual laboratories are connected to this database and can enter data via a mobile app. Data stored in this database can be accessed through a website and VPN access. EFSA could be granted such a VPN access to directly access the information.

A.2.2. AI surveillance (FLI)

A.2.2.1. Summary

The basic data about the Avian Influenza surveillance in wild birds is collected by the Bulgarian Food Safety Agency (BFSA).

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The BFSA (Animal Health Department) keep records (an Excel file is used) on AH outbreaks and cases confirmed in the country.

Once the NRL for AI confirms the positive samples, the notification letter is send to the Animal Health Department (via e-mail). Animal Health Department enforces the relevant control measures and drafts the records on confirmed AI cases/outbreaks.

The data on AI surveillance /positive cases and etc. is drafted on Excel files.

The basic data of AI surveillance is collected and reported via e-mail and e-mail attachment.

The NRL is using a template of notification letter (Word format) when sending the confirmation about positive results.

Data on surveillance is provided by the NRL via a template (Excel file) created by the Animal Health Department.

The basic data is collected two times per year (annual and intermediate (6 month) reporting) and upon request by the Animal Health Department.

The basic information is stored in the electronic journal kept in the NRL.

The basic data is not aggregated on a higher level, the data is stored in the NRL and Animal Health Department at the BFSA.

The data is reported to the European Commission, following the deadlines requested by the Commission. The reporting is upon request by the EU or EFSA.

EFSA can access the basic data through the excel file provided by the BFSA.

It is not clarified whether the data exchange can be initiated by EFSA or if it has to be initiated by the Member State.

A.3. Cyprus

A.3.1. ASF surveillance (IZSAM)

A.3.1.1. Results

The description of the authorities responsible for data collection and management of animal diseases in Cyprus has been already provided in a published EFSA report¹. For the sake of clarity, the organization of the main authorities is reported here (**Figure 1**).

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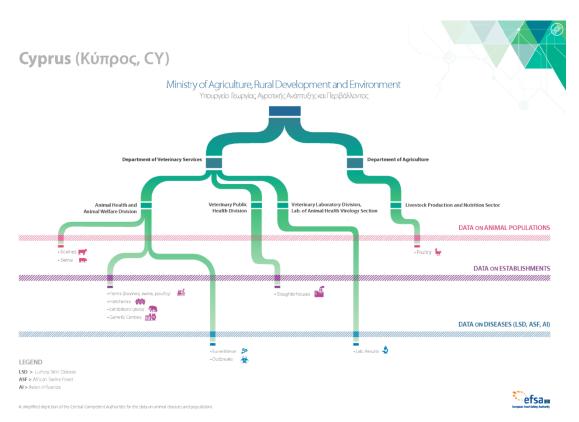


Figure 1: A simplified depiction of the central competent authorities for the data on animal diseases and animal populations in Cyprus (source: EFSA, 2019).

The laboratory data on Africa Swine Fever (ASF) in domestic pigs and wild boar are collected / generated at the National Reference Laboratory (NRL). The metadata regarding the sample and investigation results are recorded in Microsoft Excel and Word documents. These data are submitted by E-mail and attachments to the veterinary authorities. The same information can also be sent by letter or FAX to the Director of the Veterinary Services (VS), the Head of the Animal Health Division, the district veterinary offices, the rural veterinary offices and stations. Summaries of the surveillance activities are reported every six month and annually to the central VS.

The surveillance data are stored locally on PC hard disks at the NRL and VS offices as well as an internal server database of the VS. Data can be saved in electronic files such as Microsoft Excel and Word.

Currently, the data is not aggregated on a higher level and is not provided to Eurostat or to FAO. If a web-based record system of the surveillance data or the aggregated data could be established in the VS, EFSA could have directly access to them. At the moment, EFSA can get access to the basic data or the aggregated data, by E-mail communication with the Veterinary Services. An exchange can be initialised by EFSA.

In **Figure 2** a conceptual description of the ASF surveillance data flows is provided.

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Figure 2: Conceptual description of the ASF surveillance data flows.

A.3.1.2. Conclusive remarks

In Cyprus no central database exists for ASF surveillance data. Instead, data is stored in Excel and Word-documents on local computers at different levels. The is an internal database at the veterinary services, but without direct exchange possibilities.

Data exchange is only manually through E-mail and attachments to central and various district levels and management. Summaries of the data generated are produced regularly every six months.

Currently there is no automated data exchange with EFSA; data can be sent only per E-mail and attachment via the Veterinary service.

A.4. Czechia

A.4.1. ASF surveillance (IZSAM)

A.4.1.1. Results

The description of the authorities responsible for data collection and management of animal diseases in Czech Republic has been already provided in a published EFSA report¹. For the sake of clarity, the organization of the main authorities is reported here (**Figure 1**).

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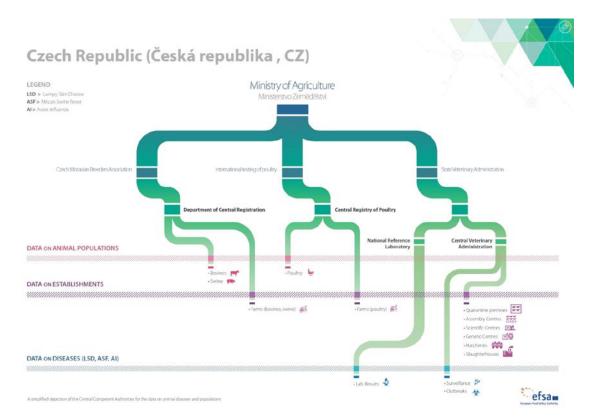


Figure 1: A simplified depiction of the central competent authorities for the data on animal diseases and animal populations in Czech Republic.

The laboratory data on ASF is collected by the State Veterinary Institute Jihlava (SVI), which is the national reference laboratory for ASF (NRL). Basic data regarding the sampled farms and wild boars are collected and reported at the local veterinary office. The private veterinarian usually sends a manually completed form. The laboratory of SVI creates the result data after examination of the samples in the laboratory management system LIMS (LABSYS, from the software company CROSS). The laboratory data are transferred through web services to the information system (IS), called OIS, of SVA. Parallel, SVI sends the examination protocol to the SVA via E-mail attachment. Data communication takes place daily, but data validation is required. The data are reported to entities under veterinary supervision or to territorial locations (cadastral territory, GPS).

The OIS is managed by the company SOLITEA and the data are physically stored in a relational database (Microsoft SQL) located at a computer centre/data processing centre. The database is only accessible for the SVA and SVI via a secured login, which is assigned by the IT department of the SVA. After entering specific requirements, it is possible to filter different data that have been entered into the OIS database, to aggregate and export data in different digital file formats, like MS Excel, MS Word, PowerPoint, PDF or TIFF. Selected data are also published in the Report on Activities in the Field of Animal Health Protection. Furthermore, SVA provides these data also for other stakeholders (e.g. MoA, breeders associations, EC, etc.), manually per file (MS Excel or Word).

The data are reported only to EFSA and the exchange is initiated by the Czech Republic (the Member State).

In **Figure 2** a conceptual description of the ASF surveillance data flows is provided.

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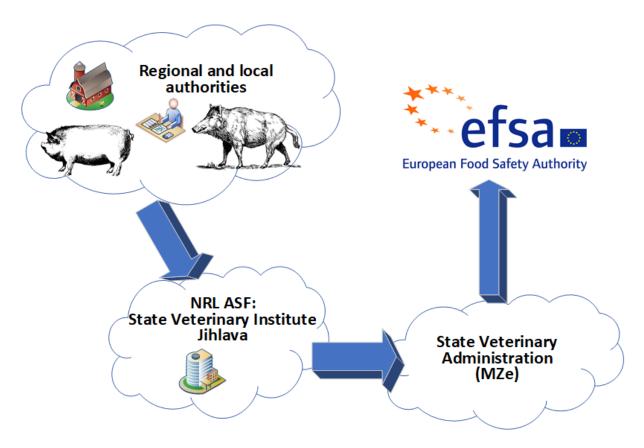


Figure 2: Conceptual description of the ASF surveillance data flows.

A.4.1.2. Conclusive remarks

In the Czech Republic the laboratory data on samples for ASF in domestic pigs, as well as for wild boar, are stored in the LIMS of the laboratory of the State Veterinary Institute (SVI). This LIMS is a commercially built database.

The laboratory data is then transferred through web services to the information system (OIS), of the State Veterinary Administration (SVA). This is a central database (relational database), where only all relevant authorities of SVI and SVA have got access through secured login. Data can be extracted from this database using several options. Data is also provided to EFSA through SVA and initiated through the Member State.

A.4.2. AI surveillance (IZSAM)

A.4.2.1. Results

The description of the authorities responsible for data collection and management of animal diseases in Czech Republic has been already provided in a published EFSA report¹. For the sake of clarity, the organization of the main authorities is reported here (**Figure 1**).

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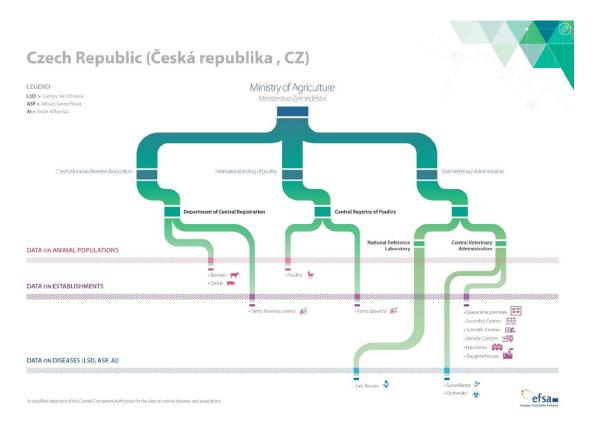


Figure 1: A simplified depiction of the central competent authorities for the data on animal diseases and animal populations in Czech Republic.

The Laboratory of State Veterinary Institutes (SVI), the State Veterinary Administration (SVA) and private veterinarian collect / generate the laboratory data on Avian Influenza surveillance in poultry and wild birds. The basic data regarding the sampled farms and wild birds are collected and reported at the local veterinary office. The private veterinarian usually sends a manually completed form. The laboratory of SVI creates the result data after examination of the samples in the laboratory management system LIMS (LABSYS, from the software company CROSS). The laboratory data are transferred through web services to the information system (IS), called OIS, of SVA. Parallel, SVI sends the examination protocol to the SVA via E-mail attachment. Data communication takes place daily, but data validation is required. The data are reported to entities under the veterinary supervision or to territorial locations (cadastral territory, GPS).

The OIS is managed by the company SOLITEA and the data are physically stored in a relational database (Microsoft SQL) located at a computer centre/data processing centre. The database is only accessible for the SVA and SVI via a secured login, which is assigned by the IT department of the SVA. After entering specific requirements, it is possible to filter different data that have been entered into the OIS database, to aggregate and export data in different digital file formats, like MS Excel, MS Word, PowerPoint, PDF or TIFF.

The data are reported only to EFSA and the exchange is initiated by the Czech Republic (the Member State).

In **Figure 2** a conceptual description of the AI surveillance data flows is provided.

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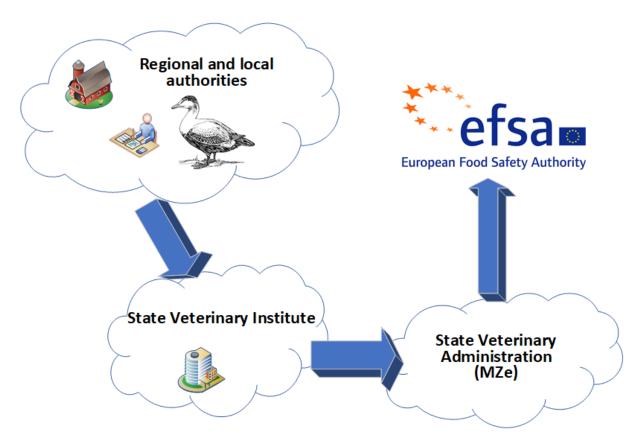


Figure 2: Conceptual description of the AI surveillance data flows.

A.4.2.2. Conclusive remarks

In the Czech Republic the laboratory data on samples for AI are stored in the LIMS of the laboratory of the State Veterinary Institute (SVI). This LIMS is a commercially built database. The laboratory data is then transferred through web services to the information system (OIS), of the State Veterinary Administration (SVA). This is a central database (relational database), where only all relevant authorities of SVI and SVA have got access through secured login. Data can be extracted from this database using several options. Data is also provided to EFSA through the SVA and initiated through the Member State.

A.5. Estonia

A.5.1. ASF surveillance (FLI)

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A.5.1.1. Summary

Veterinarians from the Veterinary and Food Board (VFB) collect the field data (herd, animal, sample, sampling, inspections) about the ASF surveillance in pigs. The Estonian Veterinary and Food Laboratory (VFL) collects the samples (laboratory) and summarises the results. The samples are submitted personally to the laboratory by the veterinary officials or by door-to-door currier service together with a submission form on paper. Data from the submission forms are entered into the LIMS database (Relational database: Microsoft SQL) at the VFL. The VFB keeps a separate database of herds tested positive for ASF in a Microsoft EXCEL data table.

Surveillance data are continuously submitted (registered) by all data providers at a state (central) level (VFL). The data are forwarded to VFB on monthly interval and upon request. The data is not aggregated on another level and can only be accessed by file sharing. Outbreaks are reported to ADNS.

EFSA can access the data at the moment by file sharing. The exchange of data has been so far initiated by EFSA and Estonia has been agreeing with it.

A.5.2. AI surveillance (IZSAM)

A.5.2.1. Results

The description of the authorities responsible for the data collection and management on animal diseases in Estonia has been already provided in a published EFSA report¹. For the sake of clarity here the organization of the main authorities is reported (**Figure 1**).

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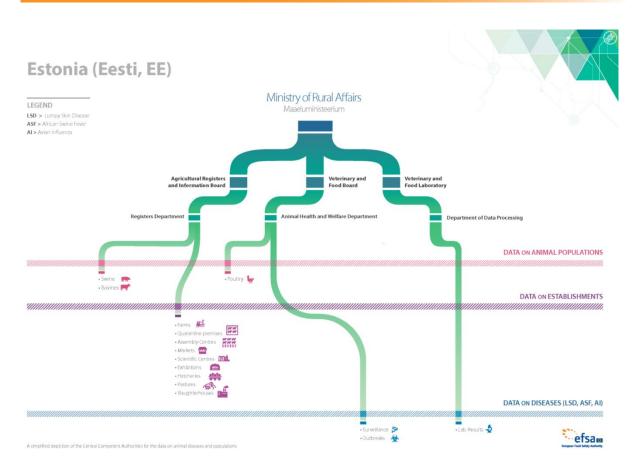


Figure 1: A simplified depiction of the central competent authorities for the data on animal diseases and animal populations in Estonia (source: EFSA, 2019).

Concerning the collection and management of AI surveillance data, under the Ministry of Rural Affairs, the Veterinary and Food Laboratory (VFL), located in Tartu, is responsible for performing the laboratory examination on samples collected within the framework of AI surveillance activities and to register all relevant information related to the samples taken.

Concerning the samples collected in domestic poultry farms the official veterinarians belonging to the Veterinary and Food Board (VFB) are those responsible to collect samples and send them to the Veterinary Food Laboratory in Tartu.

In relation to wild birds sampling, hunters and personnel working in natural conservation centres are usually those providing samples from wild bird species.

Only the VFL in Tartu is in charge to process the samples taken in the framework of the AI surveillance.

Samples are dispatched to the VFL together with a paper form bearing the main relevant identification and epidemiological information, including the type of sample (mainly cloacal swabs, organs, sometimes carcases of dead animals) and the place where it has been taken, with the indication of municipality level for samples taken from wild birds, and exact indication of farm for domestic poultry. Usually the farm's national identification code is reported, but sometimes only the name of the farm owner is available.

The quality of data accompanying the samples is sometimes rather low, especially that concerning samples taken from wild birds, which can be affected by mistakes and data inconsistencies.

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All data accompanying the samples are registered in the Laboratory Information Management System (LIMS) of the VFL, together with result of analytical determinations.

The AI surveillance data stored at LIMS of VFL include information about the Municipality (LAU2 level) where the sample have been taken both for domestic poultry and wild birds.

Concerning domestic poultry, the national register of poultry farm is managed by the Agricultural Registers and Information Board. The VFL has not direct access (e.g. through dblink or web-services) to the data of the national register. Therefore, the information related to the poultry farm where the samples are taken cannot be verified by the VFL directly to the national register on real time. Twice a year LIMS is updated with an extraction of data from the national registers as a reference support for the farm's data during samples registration.

The LIMS of the VFL is a relational database based on Microsoft SQL and it is technically managed by an external private company under a service contract.

Although it would be technically possible, at the moment it is not possible for the veterinary services or any other external organization to directly access the data stored in the LIMS or to download data from LIMS. A request for data extraction must be addressed to the VFL, which can produce data extractions in Excel format. XML format data files can be also produced, with more difficulties.

In case specific, not already implemented in LIMS, data extractions or data services are requested the VFL must ask the private company managing the LIMS to make the necessary interventions.

The VFB is developing a national information system to collect surveillance data and laboratory results, through direct link or web-services with LIMS, but it is currently operative only for food safety related matters, and not for animal diseases surveillance and monitoring activities. Therefore, the AI surveillance data stored in the LIMS are currently not transmitted directly to the national information system managed by the VFB. Laboratory results are provided to the Veterinary Services of the VFB by e-mail. The transfer of data on Animal Health matters from LIMS to the national veterinary system will be in place in the early future, but currently the whole data concerning the AI surveillance remain stored in the LIMS of the VFL.

Twice a year (but sometimes more frequently) an excel report is sent to the veterinary service by the VFL. The report summarises the data in aggregated manner.

Veterinary services of the VFB are the national authority in charge to send data to EFSA. When sample-based data are requested, the VFB asks VFL for such data. VFB verifies the correctness of data provided by the VFL and corrects them in case mistakes or missing data are observed.

VFL has no feed-back about corrections or other changes made by VFB in the data submitted to EFSA.

In **Figure 2** a conceptual description of the AI surveillance data flows is provided.

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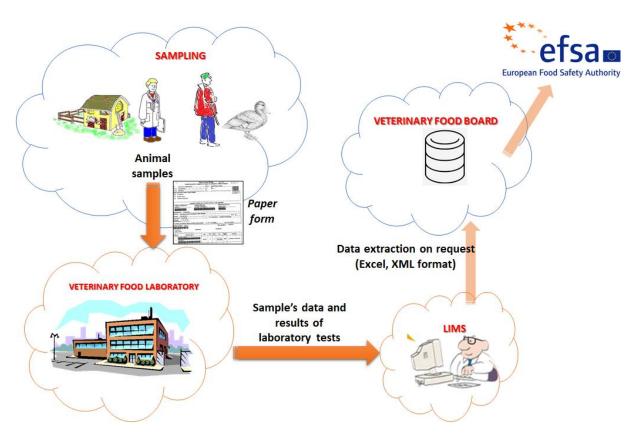


Figure 2: Conceptual description of the AI surveillance data flows.

A.5.2.2. Conclusive remarks

The possible technical obstacles that could hamper the submission of good quality, samplebased data to EFSA are mainly represented by the quality of data accompanying the samples to the VFL and the possibility for the VFL to immediately verify the correctness of the information provided and perform the consequent corrections or integrations.

In case of samples taken in poultry farms the possibility for VFL to check directly on real time the correctness of farm's data in the national farm register would be relevant.

For samples taken in wild bird species the quality of data could be increased by asking hunters and the other samples providers to directly register the main data through dedicated apps. This would allow a precise registration of place of sampling and a better recognition of species sampled.

Although not yet implemented, no technical obstacles exist to prepare automatic data extraction services to fulfil the requirements of national veterinary services and EFSA. The presence of a single national database at VFL collecting AI surveillance data facilitates the consolidation of a single national database with all necessary data at the level of national veterinary authority.

A.6. Finland

A.6.1. ASF surveillance (IZSAM)

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A.6.1.1. Results

The description of the authorities responsible for data collection and management of animal diseases in Finland has been already provided in a published EFSA report¹. For the sake of clarity, the organization of the main authorities is reported here (**Figure 1**).

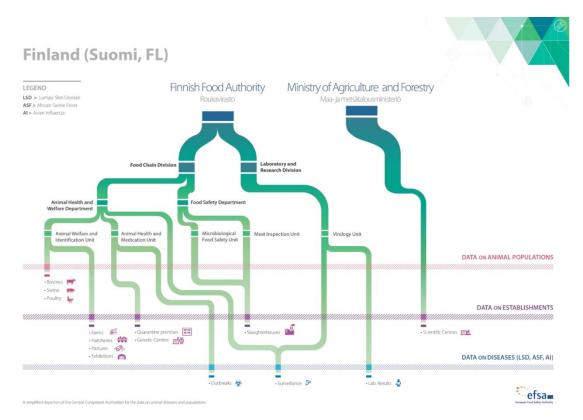


Figure 1: A simplified depiction of the central competent authorities for the data on animal diseases and animal populations in Finland (source: EFSA, 2019).

Within the Finnish Food Authority, the national laboratory reference laboratory (NRL) for African Swine Fever (ASF) is based. This is the only laboratory in Finland carrying out ASF diagnostics (Figure 1). Data regarding ASF investigations in domestic pigs and wild boars are collected whenever samples are received in the lab. Data on the laboratory investigations are collected in the Laboratory Management System (LIMS) called ELMO. Data accompanying the sample are transferred to LIMS/ELMO manually by the laboratory personnel.

The LIMS/ELMOs server is currently located the Finnish Food Authority's office in Viikki, Helsinki and only authorized personnel has access to it. Maintenance is executed by the digital services of the Finnish Food Authority.

The results of laboratory examinations are reported from LIMS/ELMO as an attachment of a secured E-mail to the customer and veterinary authorities. Results of ASF examinations in wild boar are also reported in aggregated form, using an open data format at the https://avointieto.ruokavirasto.fi/#/elain/luonnonvaraiset-elaimet (Figure 2).

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Figure 2: Screenshot of the open data website regarding the surveillance data on animal diseases.

For the yearly reporting, the data is extracted from the LIMS/ELMO using Qlik or BO programs/interface. No data are gathered directly from municipality or district level.

The ASF data are not reported to Eurostat or FAO. Data from ASF examinations of wild boar can be accessed by EFSA directly via the open data website (<u>https://avointieto.ruokavirasto.fi/#/elain/luonnonvaraiset-elaimet</u>) at any time without any contact between EFSA and the member state.

Page Break

In **Figure 3** a conceptual description of the ASF surveillance data flows is provided.

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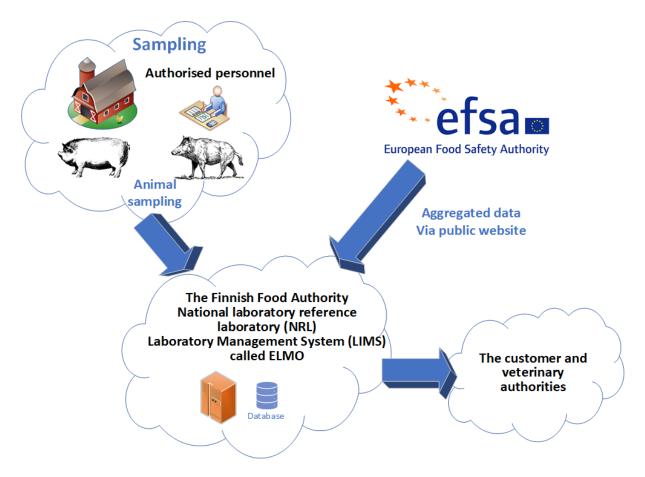


Figure 3: Conceptual description of the ASF surveillance data flows.

A.6.1.2. Conclusive remarks

In Finland there is one central laboratory database, which contains all the information available. This LIMS database is located at the Finnish Food Authority's office. Communication between the central level and the district level is via E-mail and attachments.

Data is only based on the information provided with the samples; no additional data is collected from the district level.

Information from this database is available at a publicly available webpage, including all the information relating to surveillance of ASF in wild boar and domestic pigs. EFSA can access the data through this webpage, but there are also different options to export data.

A.7. France

A.7.1. AI surveillance (IZSAM)

A.7.1.1. Results

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The description of the authorities responsible for data collection and management of animal diseases in France has been already provided in a published EFSA report¹. For the sake of clarity, the organization of the main authorities is reported here (**Figure 1**).

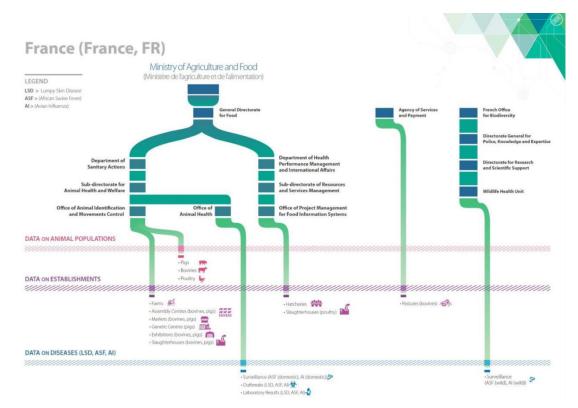


Figure 1: A simplified depiction of the central competent authorities for the data on animal diseases and animal populations in France (source: EFSA, 2021).

The laboratory data on Avian Influenza (AI) in poultry and wild birds are collected / generated using several pathways depending on the bird species and sampling scheme. 1. AI suspicions in poultry:

Suspicions of AI are declared to the French Ministry of Agriculture and Food, which plans the sample collection in suspected flocks by official veterinarians. The 11 regional laboratories (public or private), approved for AI testing by the Ministry, perform the analyses and report their results by E-mail with PDF and XML attachments to the Ministry and affected local veterinary authorities. The Ministry enters the results into a specific database system (SIGAL) daily, using the XML attachment. In case of detection of H5 or H7 AI viruses, the French national reference laboratory (NRL) for AI at the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) carries out the pathotyping and sub-typing analyses and reports by E-mail to the Ministry.

The Ministry declares confirmed cases through the ADNS/ADIS system. Complementary epidemiological and sequence data are prepared by ANSES (on behalf of the French ministry) for sending upon request to the EURL and EC, for its quarterly reports on AI monitoring.

2. Annual serological survey in poultry:

The visits for sampling are planned by the Ministry. The visits are created in a specific data system (SIGAL), managed by the French Ministry of Agriculture and Food, which collects data

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on sampling events (farm localisation, type of birds, etc.) and lab results for serological screening. Results of the AI confirmation test (serology and RT-PCR) done by the NRL at ANSES are sent by E-mail as PDF and XML attachment from the NRL to the Ministry. The results are then reported into the SIGAL database using the XML attachment by the Ministry. The results for AI screening and information on sampling events are transmitted to the SIGAL database on a daily basis. In general, the data are available in SIGAL within a week after the sampling event. Results are summarised annually by ANSES (on behalf of the French Ministry), using the specific file format, and are transmitted to EFSA.

3. AI suspicions in wild birds:

The 11 regional laboratories receive the dead birds along with information about species, municipality of collection, and date. These 11 labs send results in PDF format by E-mail to the French Office for Biodiversity (OFB), which has a custom-built specific database in MS Access®. Also, paper forms can be used, but it is not expected. In case of detection of H5 or H7 AI viruses, the NRL for AI at ANSES carries out the pathotyping and sub-typing analyses and reports by E-mail to the French Ministry of Agriculture and Food and OFB.

The wild bird surveillance results are integrated by the OFB into the Access database approximately once a month. The database is shared with the authorities twice a year. The Ministry declares HPAI-positive cases through the ADNS/ADIS system. Furthermore, the local prescriber, who had collected the bird (it can be an agent from OFB, or the local federation of hunters) receives the investigation results and the local veterinary authorities in the case of a higher risk. Non-aggregated data can be shared with the stakeholders, including the scientific community, using EXCEL spreadsheets. Comprehensive data on wild bird surveillance are prepared annually by the OFB and ANSES (on behalf of the French ministry) using the specific file format for sending to EFSA.

At the French NRL at ANSES, all the data are stored in a specific laboratory information management system (Lab Informatics Solution, Labvantage), only accessible within the laboratory.

EFSA is granted access to poultry data on AI screening and sampling events, which are extracted from SIGAL, through excel files. Files are sent to ANSES that formats the data using the EFSA tool and adds the data on AI confirmation. The files are sent as a xml file to EFSA. The exchange is initiated by the competent authority. Data are extracted, formatted and sent to EFSA upon EFSA request.

Page Break

In **Figure 2** a conceptual description of the AI surveillance data flows is provided.

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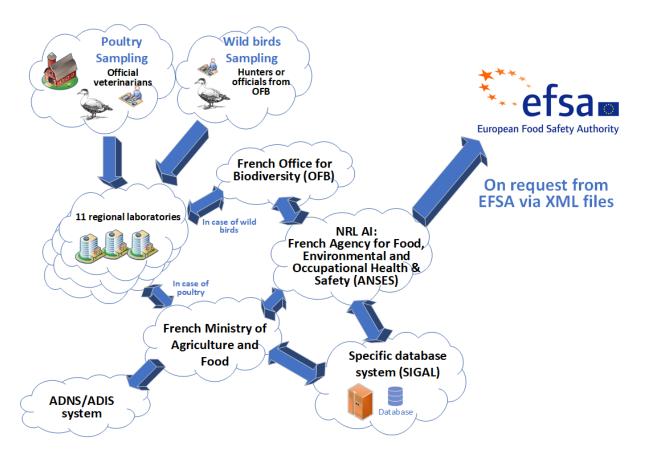


Figure 2: Conceptual description of the AI surveillance data flows.

A.7.1.2. Conclusive remarks

In France there are 11 regional laboratories and one national reference laboratory at ANSES. Nevertheless, all data are recorded centrally.

Three different pillars of surveillance exist: AI suspicion in poultry, AI annual serological survey in poultry and AI suspicion in wild birds.

At the ministry level, a custom-built central database (SIGAL) for the poultry surveillance is available. For wild birds, a custom-built central MS Access database is available. All laboratory information in stored in the LIMS system.

Data is exchanged between the central and the district levels via E-mail and attachments. In addition, regular summaries are produced and distributed from central to district level.

Data can be exported into Excel-files. These are prepared by ANSES for provision of data to EFSA upon EFSA request.

A.8. Germany

A.8.1. AI surveillance (IZSAM)

A.8.1.1. Results

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Germany is a Federal State with 16 Länder. The Federal Government is responsible for policy and federal legislation. The Länder are responsible for official controls to comply with the legislation in the relevant areas. At national level, the Federal Ministry of Food and Agriculture (BMEL) has almost exclusive competence for food and feed safety, animal health and animal welfare. Its remit encompasses higher federal authorities, public institutions and federal research institutions, including in particular the Federal Office of Consumer Protection and Food Safety (BVL), the Federal Institute for Risk Assessment (BfR), the Federal Agency for Agriculture and Food (BLE), and the Friedrich Loeffler Institut (FLI), which is the Federal Research Institute for Animal Health and the National reference Centre for Avian Influenza (AI).

FLI maintain a strict link with the 22 veterinary laboratories of the Federal States (Bundesländer Laboratories – BL), thus constituting a solid diagnostic laboratory network.

Local district veterinary offices (401 districts) are in charge of collecting sampling in the poultry farms and related information. Sampling is performed directly by official veterinarians or private authorised veterinarians (officially appointed by the veterinary services). Samples are dispatched to and analysed by 22 (BL), which also record all data accompanying samples in their Laboratory Information Management Systems (LIMS). A central national database collecting all data from LIMS does not exist.

Concerning wild birds, the samples can also originate from private citizens, farmers, workers at nature conservation centres, ornithologists, etc. In this case they inform or directly delivery the samples (i.e. carcasses) to the local district veterinary offices.

Data accompanying the samples are provided to the laboratory on paper forms or digital documents, such as pdf files, by emails. Data is digitalised and recorded in each LIMS by laboratory personnel for each dispatched sample.

Samples are collected and analysed according to an annual national plan or when additional control measures are needed as a consequence of the detection of confirmed AI cases.

Concerning domestic poultry, the data flow is the following:

• Data regarding the farm where samples have been taken (name and district, municipality or village) are accompanying the samples delivered to the competent BL by each veterinary office of districts.

• Each BL reports the data about the results of laboratory examinations to the Federal State veterinary authority. In particular, detailed, non-aggregated data, without exact location, are provided for positive samples, whereas aggregate information (by district) for all the others.

• Federal State authorities report data (without farm names) to the FLI and BMEL.

• FLI converts the EXCEL data of the Federal States authorities to XML-format of SSD2 and submits data to EFSA.

In relation to surveillance data on wild birds:

• Detailed, non-aggregated data accompanying the samples are recorded into the LIMS by personnel of the BL. The location of all sampled wild birds is recorded at municipality level.

• BL reports detailed, non-aggregated laboratory data to the national avian influenza database in place at FLI (AI-DB; https://ai-db.fli.de). Data is uploaded manually or automatically into the AI-DB, following a specific csv-format, in a continuous basis throughout the whole year. The location of the HPAI positive wild

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birds in the AI-DB are updated with coordinates provided by the German Animal Disease Notification System (TSN; https://tsn.fli.de/; https://tsis.fli.de/).

• FLI submits the data to EFSA.

Different LIMS are used by the BL, based on different technical solutions.

The AI-DB of FLI, is developed on a Microsoft SQL relational database, and is based on a webapproach with a closed user community (laboratories, Federal State and district veterinary authorities, BMEL).

BMEL is responsible to provide detailed and aggregated data to external authorities. In particular, data on AI surveillance in poultry are provided to EC through standardized Excel spreadsheet manually sent by email twice a year. In parallel, FLI is in charge of converting the data provided by the Federal State authorities into the XML-format of SSD2 required by EFSA and submits the file to EFSA according to the reporting deadlines. In addition, FLI exports the data stored in of the AI-DB in XML-format of SSD2 and submits the file to EFSA.

In addition, detailed outbreak data and aggregated data for reporting co-financing activities are submitted to the European Commission (EC) within 24 hours and twice a year respectively. In **Figure 1** a conceptual description of the AI surveillance data flows is provided.

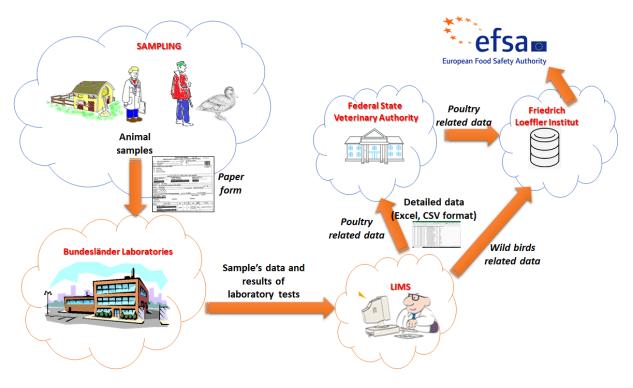


Figure 1: Conceptual description of the AI surveillance data flows.

A.8.1.2. Conclusive remarks

The main technical obstacle hampering the submission of good quality, sample-based data to EFSA is represented by the fact that the data collected from the BL on AI surveillance in poultry are on aggregated-basis for all negative samples.

Another critical point is represented by the need of manually manipulate the poultry surveillance data before submission to EFSA and that the data transfer of wild bird surveillance

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data cannot be activated through direct link or web services. This can cause inefficiencies to the data flow and be source of possible mistakes.

A.9. Greece

A.9.1. ASF surveillance (FLI)

A.9.1.1. Summary

The collection of the basic data about the pig ASF surveillance is performed by the veterinary authorities of the regional units all over Greece. Data are collected and reported through Microsoft Excel files.

The basic data are collected following a suspicious event or following any surveillance activity according to the national and community legislation. They are reported to the regional unit administrative level.

The basic data are physically stored centrally in the file server in Athens.

The format of the saved basic data is Microsoft excel files.

The competent authority accesses the data for the purpose of analysing the data.

The basic data are exchanged between the administrative authorities as soon as the results of surveillance activities have been collected. The exchange is done manually through excel files send by email.

The basic data are aggregated at the administrative level of NUTS3.

The data are reported to the European Commission through ADNS as soon as there is a confirmed case of ASF disease. Furthermore, the data are reported to the competent European Authorities in the case of co-financed projects. This report is done on an annual basis.

Currently, EFSA cannot access the basic or aggregated data. As soon as a respective application is developed, EFSA can access the basic data or the aggregated data through a web service. This web service is currently not available, but can be developed in cooperation with EFSA.

The data exchange will have to be initiated by the Member State.

A.10. Italy

A.10.1. AI surveillance (IZSAM)

A.10.1.1. Results

The description of the authorities responsible for the data collection and management on animal diseases in Italy has been already provided in a published EFSA report¹. For sake of clarity here the organization of the main authorities is reported (**Figure 1**).

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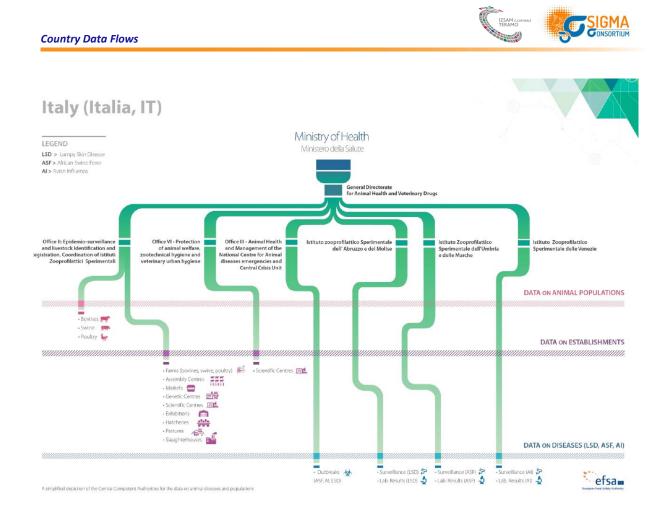


Figure 1: A simplified depiction of the central competent authorities for the data on animal diseases and animal populations in Estonia (source: EFSA, 2019).

Concerning the collection and management of Avian Influenza (AI) surveillance data, under the Ministry of Health (MoH), the Office III of the General Directorate of Animal Health and Veterinary Drugs is responsible for the collection of the data related to outbreaks.

The Istituto Zooprofilattico Sperimentale delle Venezie (IZSVe), located in Padua, as National Reference Laboratory and OIE/FAO Reference Centre for Avian Influenza and Newcastle Disease, was commissioned by the Italian Ministry of Health to develop a dedicated system to collect, manage, store and dispatch reports on data generated within the framework of the national surveillance activities for avian influenza in the domestic poultry sector and wild birds.

The aim of this system, named eFlu, is twofold. Firstly, it allows evaluating the on-going national surveillance activities and secondly, it facilitates the transmission of data to the EU.

Since January 2016, in accordance with the Ministry of Health provision n. 7517 of 24/03/2016-DGSAF, all the other nine Italian Istituti Zooprofilattici Sperimentali (IIZZSS), which are the sole official laboratories in charge for sample testing, started uploading data of the surveillance activity for avian influenza on eFlu. The portal is an institutional archive accessible at http://e-flu.izsvenezie.it/

Each submission consists of an Excel file (xls or xlsx format) that must comply with the record layout for either domestic poultry or wild birds. The record layouts, along with the data dictionary are provided below in **table 1 and 2**. Each file uploaded for submission is subjected to formal checks by the system. For each validation error, the system identifies and report the row(s) in the Excel file where the record does not comply with the criteria specified for each

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element in the record layout. If no errors are detected, the data submitted are saved and will be available for consultation.

Table 1. Instructions Menu– Final record layout and data dictionary for domestic poultry (PH)

HOLDING IDENTIFIER	001VIxxx
OWNER	X00XX00XX X00X000X00X XX00XX00X
LOCALIZATION	AGUGLIARO
PROVINCE	VI
CATEGORY/SPECIES	FATTENING TURKEY
CATEGORY SPECIES DETAILS	
LABORATORY ID	IZSVE
LABORATORY SUBMISSION NUMBER	
SAMPLING DATE	gg/mm/aaaa
RECEPTION DATE	gg/mm/aaaa
REASON FOR SAMPLING	MON
SAMPLE SIZE	1
SAMPLE TYPE	TRACHEAL O OROPHARYNGEAL SWAB
POOL	
ANALYSIS	INF
ТҮРЕ	PCR
RESULT	NEGATIVE
END DATE ANALYSIS	gg/mm/aaaa

Table 2. Instructions Menu- Final record layout and data dictionary for wild birds (WB)

Bird identifier	xxxxxxx/1
GroupIdentifier	XXXXXX
Laboratory identifier	IZSFG
RingNumber	unapplicable
StatusOfBird	found dead
EuringCode	06829
LocalizationDate	gg/mm/aaaa
NUTSCode	075052
CodeType	NUTS5
AreaStatus	unknown
Sample identifier	xxxxxx/1/1
ReceptionDate	gg/mm/aaaa
SampleType	tissue
Туре	Real-time RT-PCR
Result	negative
Virusisolation	not performed
Туре8	
Result9	
Subtype	
HSubtype	
NSubtype	

The frequency of data submission to eFlu is twice a year: in January the data are collected for the time period July-December of the previous year, in July the data are collected for the time period January-June of the same year.

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Concerning the level of detail of the submitted data, for poultry farms the farm ID, together with the municipality (LAU level) are provided. Through the poultry ID it is possible, in case of necessity, to retrieve the exact lat/lon localization in farm register.

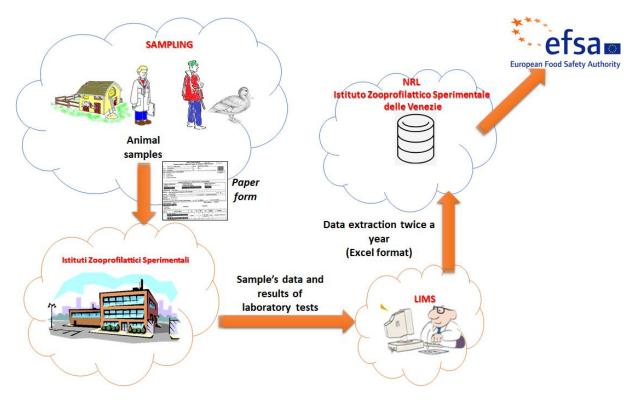
In relation to samples taken from wild birds the municipality (LAU level) where the animal has been found is provided.

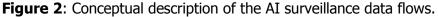
Data submitted by each IIZZSS are stored in a relation MySQL database on a server located at IZSVe.

Each regional veterinary service can access its own data submitted via the eFlu portal (website: http://e-flu.izsvenezie.it/). The MoH has access to the whole database, via the same portal. The MoH can also access the Microstrategy platform to assess the surveillance data to be submitted to EFSA.

Avian influenza surveillance data are submitted twice a year (end of January and end of July) by IZSVe to the EFSA using the Standard Sample Description version 2 (SSD2) standard.

In **Figure 2** a conceptual description of the AI surveillance data flows is provided.





A.10.1.2. Conclusive remarks

The presence of a unique national database collecting all information regarding AI surveillance activities in the country facilitate the possibility of data exchange with EFSA and also the possible implementation, in future, of automatic exchange data flows through web services or other technical solutions.

As possible improvements of the system, the establishment of web services between IZSVe and the other IIZZSS would allow a continuous monitoring of the surveillance activities. In

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addition, a strict real-time exchange of information with the national register of poultry farm would assure a more efficient real-time verification of data quality.

A.11. Latvia

A.11.1. ASF surveillance (IZSAM)

A.11.1.1. Results

The description of the authorities responsible for the data collection and management on animal diseases in Latvia has been already provided in a published EFSA report¹. For the sake of clarity here the organization of the main authorities is reported (**Figure 1**).

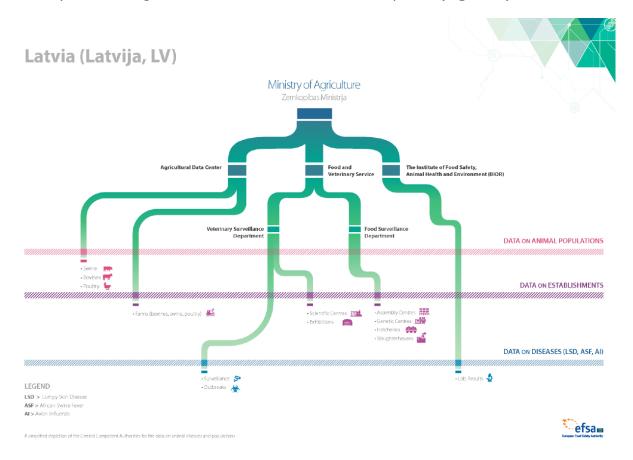


Figure 1: A simplified depiction of the central competent authorities for the data on animal diseases and animal populations in Latvia (source: EFSA, 2019).

Concerning the collection and management of African swine fever (ASF) surveillance data, under the Ministry of Agriculture, the Institute of Food Safety, Animal Health and Environment (BIOR), located in Riga, is responsible for performing the laboratory examination on samples collected within the framework of ASF surveillance activities and to register all relevant information related to the samples taken.

Official veterinarians (belonging to the Latvian Food and Veterinary Services - FVS) are those in charge for the dispatch of samples to veterinary laboratory (Institute of Food Safety, Animal

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Health and Environment - BIOR), both for pigs and wild boars. Only exceptionally other Authorities can directly submit wild boar's samples to the laboratory for ASF examinations.

Concerning wild boards, hunters must sample all hunted wild boars and deliver the samples at the corresponding regional FVS office. Hunters get an economic compensation for that. The FVS also promotes the active searching for dead animals, giving an economic compensation for it. Normally the hunters are the ones reporting these cases, as they find these animals during normal hunting activities.

Samples are accompanied by paper forms and at the BIOR all data reported in the forms are registered into the Laboratory Information Management System (LIMS). For each sample data are recorded immediately after it arrives and before to proceed for laboratory examinations.

In case of samples taken from wild boars, geographical coordinates are provided. Sometimes only the information about county or parish is available. The indication of hunting ground is not always available (around 50% of samples).

In case of samples taken from farmed pigs, the ID code of the pig herd is provided, together with the information about county or parish.

LIMS is structured with a single database at national level storing all data related to laboratory examinations and information accompanying samples.

Web services are in place with the Agriculture Data Centre (ADC), which manage the national livestock register, in order to provide the LIMS of BIOR with the data about pig farms. This allows a correct registration of pigs herds data in LIMS.

Laboratory analyses reports are dispatched to veterinary services by email, however there is a continuous (real time) synchronization through web services between data recorded at LIMS and Veterinary Services (FVS) Information System. No other direct access by FVS or other Institutions to data stored in the LIMS is in place.

In **Figure 2** a conceptual description of the ASF surveillance data flows is provided.

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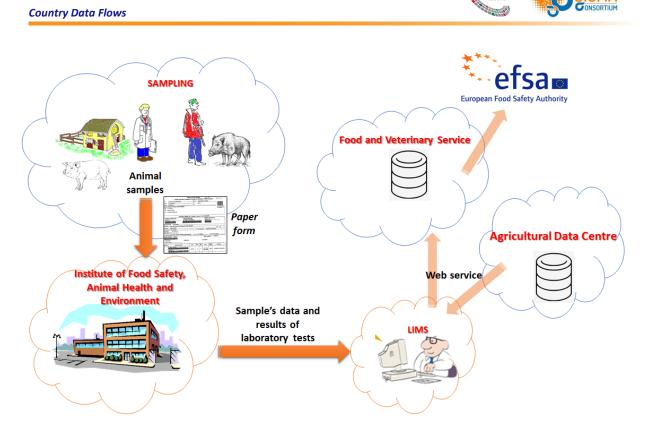


Figure 2: Conceptual description of the ASF surveillance data flows.

Concerning the technological infrastructure, the LIMS at BIOR is an Oracle-based relational database. The LIMS is managed by an external IT private company, under a service contract. Any update or change of the LIMS, therefore, is done by the IT company, following specific orders by BIOR.

FVS is the national authority responsible to provide data on ASF surveillance to the EU institutions, including EFSA. ASF surveillance data is provided to FVS by BIOR through web services. In case agreed by FVS, BIOR could activate one or more web services to provide EFSA with the data needed.

A.11.1.2. Conclusive remarks

The possible technical obstacles that could hamper the submission of good quality, samplebased data to EFSA are mainly represented by the quality of data accompanying the samples to the BIOR, although the web services in place between BIOR and ADC assures the correctness of data on samples collected in pig farms and the possibility to establish a clear and unambiguous link between farm's information and laboratory results.

In relation to samples taken from wild boars, the fact that the great majority of these samples are directly managed by the official veterinarians, reduces the possibilities of data inconsistencies.

For samples taken from wild boars a better precision of localization could be achieved through the use by hunters of dedicated apps.

Although not already implemented, no technical obstacles exist to prepare automatic data extraction services to fulfil the requirements of national veterinary services and EFSA. The presence of a single national database at BIOR collecting ASF surveillance data facilitates the consolidation of a single national database with all necessary data at the level of national veterinary authority.

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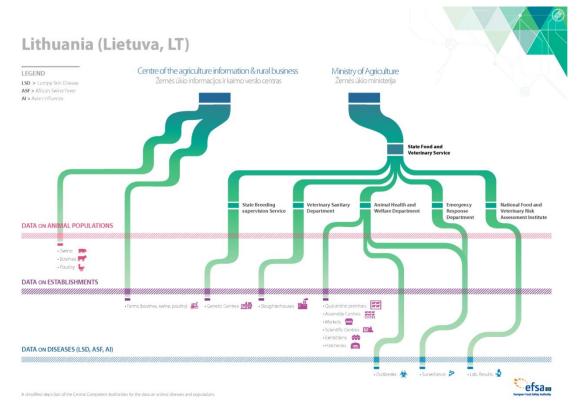


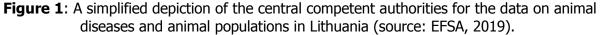
A.12. Lithuania

A.12.1. ASF surveillance (IZSAM)

A.12.1.1. Results

The description of the authorities responsible for data collection and management of animal diseases in Lithuania has been already provided in a published EFSA report¹. For the sake of clarity, the organization of the main authorities is reported here (**Figure 1**).





The laboratory data on Africa Swine Fever (ASF) in domestic pigs and wild boar are collected / generated using two different pathways.

1. Hunting activity and passive surveillance in wild boar:

Before ASF occurred in 2014, the wild boar hunting seasons have started 1 May and lasted until 1 February of the following year. The sows were hunted in October-December only. Since 2014, when the first case of ASF was reported in wild boar, the hunting season is not terminated and the wild boar can be hunted all year round. Almost 97% of Lithuania is considered as infected area at the moment. All carcasses found, all wild boar killed in road accidents and all sick shot wild boar have to be tested for ASF using PCR, independent of the area, they are found.

Information on hunted wild boar is recorded in the regional State Food and Veterinary Services (SFVS) databases, and the primary information remains in the relevant hunting club data

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registers. Samples for analysis in the National Reference Laboratory (NRL) are submitted to the Lithuanian National Food and Veterinary Risk Assessment Institute (NFVRAI) with documents provided and approved by the central SFVS.

2. Surveillance activities in pig farms:

Regular inspections are carried out in non-commercial pig farms, as they are inspected at least once a year before the ASF season starts (main ASF outbreaks occur in Lithuania during the summer time) and in commercial farms, which are inspected at least twice a year with a minimal interval of 4 month, as set out in the Commission Implementing Decision 2014/709. Information on pigs is recorded in the regional SFVS databases. Samples for analysis in the NRL laboratory are submitted to the NFVRAI with documents approved by the central SFVS.

For both surveillance activities the basic data is collected and reported via E-mail or E-mail attachment and the samples and the associated documents are mainly submitted to the NRL directly via a state organised sample collection and delivery system.

Records and paper versions of ASF surveillance programmes are collected at the regional SFVS and NFVRAI. The non-aggregated data are stored on local computers using EXCEL spreadsheets and in the Laboratory Information Management System (LIMS) on a server of the NFVRAI, only accessible for authorized users inside the NFVRAI.

The reporting on the samples tested for ASF is done at the end of every working day through E-mail attachment of an Excel table to the central competent veterinary authority (State Food and Veterinary Service of the Republic of Lithuania (SFVS)) and in parallel to the affected territorial units of the SFVS. Positive cases are mapped using the smallest Lithuanian unit – eldership.

The data is not reported to Eurostat or FAO, but to EFSA within the agreed timeframe. It is not stated, whether the data exchange can be initiated by EFSA or if it has to be initiated by the Member State.

In **Figure 2** a conceptual description of the ASF surveillance data flows is provided.

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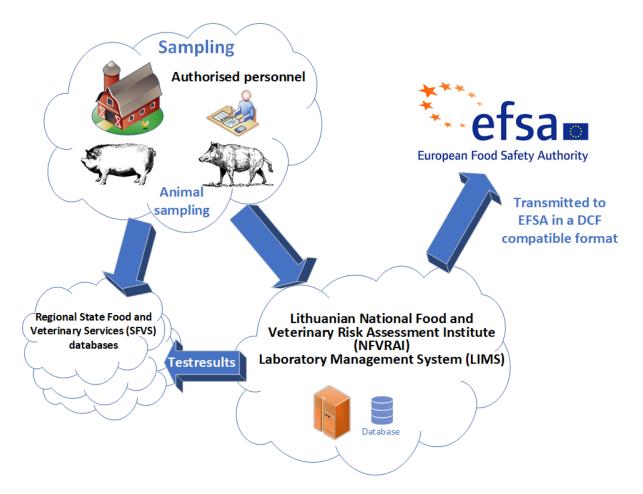


Figure 2: Conceptual description of the ASF surveillance data flows.

A.12.1.2. Conclusive remarks

Data are mainly stored on local computers at the different levels. For the laboratory results on examinations of samples for ASF, a central database exists (LIMS) at the National reference laboratory.

In principle, surveillance of wild boar and domestic pigs are similar. Samples and associated documents are sent to the NRL at central level. Exchange of data is only feasible manually through E-mails and attachments.

Data is regularly transmitted to EFSA in a DCF compatible format.

A.13. Poland

A.13.1. ASF surveillance – Wild boars (IZSAM)

A.13.1.1. Results

The description of the authorities responsible for data collection and management of animal diseases in Poland has been already provided in a published EFSA report¹. For the sake of clarity, the organization of the main authorities is reported here (**Figure 1**).

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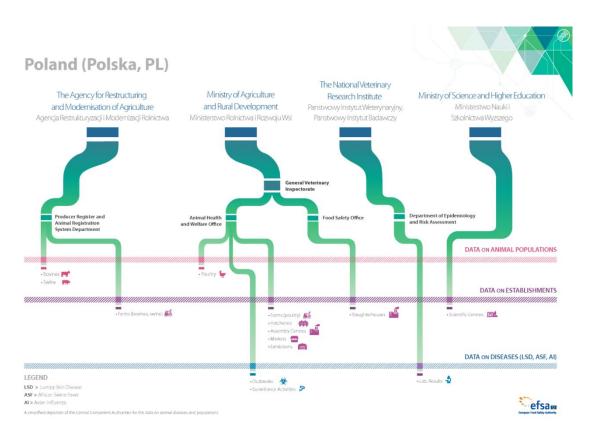


Figure 1: A simplified depiction of the central competent authorities for the data on animal diseases and animal populations in Poland (source: EFSA, 2019).

The General Veterinary Inspectorate with the Chief Veterinarian (pol. GIW / GLW) and the National Veterinary Research Institute (NVRI, pol. PIWet) are units under the Ministry of Agriculture and Rural Development (pol. MRiRW) (Figure 1). The national reference laboratory (NRL) at the PIWet, collects data on laboratory tests and surveillance.

The samples of the national monitoring programmes from the restricted areas and free regions are sent together with sample forms to the national reference laboratory at the NVRI. After examination, the sample forms and results are recorded in a database in the National Veterinary Research Institute servers. The CELAB-CBD database, administered by NVRI, is a MySQL database and only accessible for authorized users inside the NVRI network or via VPN. In the case of a positive result, the test report in PDF format is provided immediately by the national reference laboratory for ASF at the National Veterinary Research Institute (pol. PIWet) to the Ministry of Agriculture and Rural Development. This report is provided by E-mail and attachment. The information is also transferred to the Poviat Veterinary Inspectorate (district) and the Poviat official veterinarian to take appropriate actions in their area.

Updated .xlsx/.xls files with a table on the cases are regularly sent by email from the National Veterinary Research Institute (pol. PIWet), national reference laboratory for ASF, to the Crisis Management Center of the Ministry of Agriculture and Rural Development / General Veterinary Inspectorate. The data is transferred with the most precise location possible. The level of accuracy of the location provided with the sample sent (from wild boar) to the laboratory can be very diverse - for found dead wild boars, geographical coordinates are most often given (but they are not entered into the database by the sample reception point), and for hunted wild boars it is most often a commune or hunting circuit. The information is stored by the Ministry of Agriculture and Rural Development on its own database servers.

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A public website of the Chief Veterinary Inspectorate informs about the current situation in the country (<u>https://www.wetgiw.gov.pl/nadzor-weterynaryjny/asf-w-polsce</u>). Aggregated data on outbreaks in pigs and cases in wild boar are available on the website.

Data regarding outbreaks are reported by the Ministry of Agriculture and Rural Development / General Veterinary Inspectorate to the European Commission and laboratory data are provided by the NVRI to the DCF of EFSA using XML files.

In **Figure 2** a conceptual description of the ASF surveillance data flows is provided.

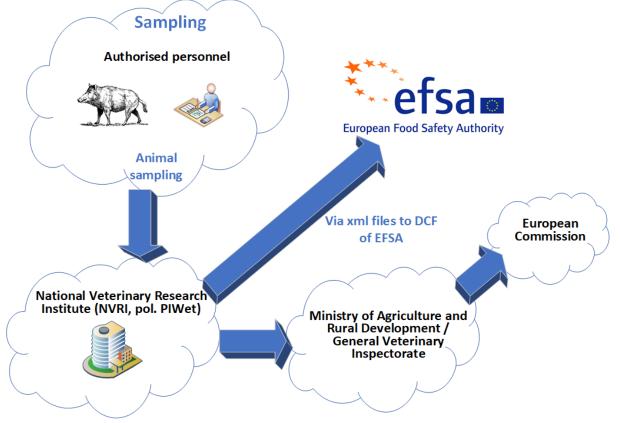


Figure 2: Conceptual description of the ASF surveillance data flows.

A.13.1.2. Conclusive remarks

Data are provided by the National Veterinary Research Institute (NVRI) to the Ministry of Agriculture and Rural Development, to the Crisis Management Center of this Ministry and to the General Veterinary Inspectorate (central level).

Information is also provided to the Poviat Veterinary Inspectorate at the district level.

The databases, where information is stored, is only accessible internally, it is not possible to access the database from outside. However, data can be accessed through a public website and are available through Excel-tables.

Laboratory information is provided to EFSA through the DCF, in a format which is compatible to the DCF via XML

A.13.2. ASF – Domestic Pigs (IZSAM)

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A.13.2.1. Results

The description of the authorities responsible for data collection and management of animal diseases in Poland has been already provided in a published EFSA report¹. For the sake of clarity, the organization of the main authorities is reported here (**Figure 1**).

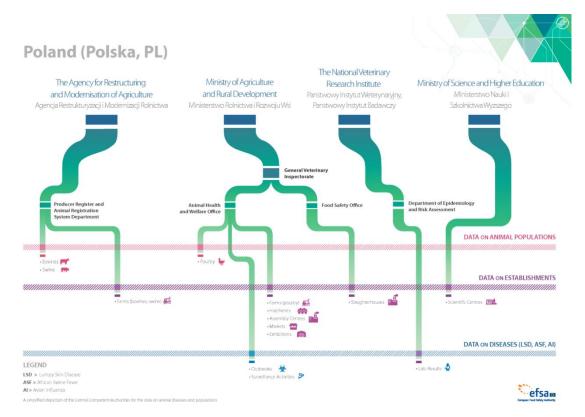


Figure 1: A simplified depiction of the central competent authorities for the data on animal diseases and animal populations in Poland (source: EFSA, 2019).

The General Veterinary Inspectorate with the Chief Veterinarian (pol. GIW / GLW) and the National Veterinary Research Institute (NVRI, pol. PIWet) are units under the Ministry of Agriculture and Rural Development (pol. MRiRW) (Figure 1). The national reference laboratory at the PIWet collects data on laboratory tests and surveillance.

The samples of the national monitoring programmes from the restricted areas and free regions are sent together with sample forms to the national reference laboratory at the NVRI. After examination, the sample forms and results are recorded in a database in the National Veterinary Research Institute servers. The CELAB-CBD database, administered by NVRI, is a MySQL database and only accessible for authorized users inside the NVRI network or via VPN.

In the case of a positive result, the test report in PDF format is provided immediately by the national reference laboratory for ASF at the National Veterinary Research Institute (pol. PIWet) to the Ministry of Agriculture and Rural Development. This report is provided by E-mail and attachment. The information is also transferred to the Poviat Veterinary Inspectorate (district) and the Poviat official veterinarian to take appropriate actions in their area.

Updated .xlsx/.xls files with a table on outbreaks are regularly sent by E-mail from the national reference laboratory for ASF at the National Veterinary Research Institute (pol. PIWet) to the Crisis Management Center of the Ministry of Agriculture and Rural Development / General

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Veterinary Inspectorate. The data is transferred with the most precise location possible (most often it is the farm address) and stored by the Ministry of Agriculture and Rural Development on its own database servers.

A public website of the Chief Veterinary Inspectorate informs about the current situation in the country (<u>https://www.wetgiw.gov.pl/nadzor-weterynaryjny/asf-w-polsce</u>). Aggregated data on outbreaks in pigs and cases in wild boar are available on the website.

Data regarding outbreaks are reported by the Ministry of Agriculture and Rural Development / General Veterinary Inspectorate to the European Commission and laboratory data are provided by the NVRI to the DCF of EFSA using XML files.

In **Figure 2** a conceptual description of the ASF surveillance data flows is provided.

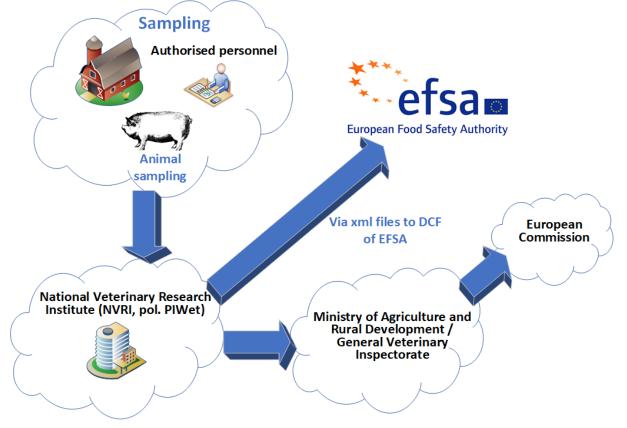


Figure 2: Conceptual description of the ASF surveillance data flows.

A.13.2.2. Conclusive remarks

Data are provided by the National Veterinary Research Institute (NVRI) to the Ministry of Agriculture and Rural Development, to the Crisis Management Center of this Ministry and to the General Veterinary Inspectorate (central level).

Information is also provided to the Poviat Veterinary Inspectorate at the district level.

The databases, where information is stored, is only accessible internally, it is not possible to access the database from outside. However, data can be accessed through a public website and are available through Excel-tables.

Laboratory information is provided to EFSA through the DCF, in a format which is compatible to the DCF via XML.

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A.14. Romania

A.14.1. ASF surveillance (IZSAM)

A.14.1.1. Results

A veterinary laboratory is present in each of the 42 Regional Veterinary Directorates (42 county RVD offices). Most of them are allowed for PCR testing on ASF. All samples are sent to the Institute for Diagnosis and Animal Health (IDAH) in Bucharest for confirmation (99% concordance between results of IDAH and county lab).

Samples taken from farmed pigs: only official veterinarians are allowed to sample pigs within the framework of the ASF surveillance. They bring samples to the competent county laboratory. Samples are accompanied by a paper form filled with all data related to the farm, animals and laboratory tests requested.

Samples taken from wild boars: official veterinarians or more frequently the responsible of the hunting grounds (managed by private or state hunting associations). Samples are accompanied by a paper form.

In both cases (pigs and wild boars) the data related to the sample can be inserted directly into the Laboratory Information Management System (LIMS) by the sampler or these by the laboratory personnel.

The samples taken from farmed pigs are collected by the official veterinarians. The veterinarian also fills:

a) a request for analysis in 2 copies and

b) annex tables with sample details (farm ID, other farm's identification data, LAU, geographical coordinates, etc.).

The procedure is detailed in the Order No. 145/2018 of the National Sanitary Veterinary and Food Safety Authority (ANSVSA).

The samples together with the other request for analysis and annex tables are send to the laboratory. The laboratory performs the analyses. The electronic results are sent by e-mail to the official veterinarians. At laboratory level the farm's identification data cannot be checked automatically on real-time on the national animal register (no direct link or web services are in place between LIMS and national animal register), but only manually on a case-by-case basis (an access to the national animal register is provided to the county laboratories).

Concerning the samples taken from wild boars, these are collected by the official veterinarians or trained hunting ground managers/hunters. A wild boar questionnaire is also filled, with sample details (including ID, date of shooting or finding, age, type of carcass, location [LAU] and geographical coordinates [not always available], etc). The samples together with the questionnaire are send to the laboratory. The laboratory performs the analyses. The electronic results are sent by e-mail.

Data are stored into the LIMS application (https://gamait.ro/atlas-vet/), which has a centralised database, managed by a private IT company and based on a Oracle relational database.

In relation to the accessibility of data stored into the LIMS, the data can be accessed through an account in LIMS application (the access level may vary depending on the account). Data stored in the LIMS may be also exported on request. Some possibilities of data extraction (Excel tables) are already in place in the LIMS, but for new request, not already considered, a request of modification to the private IT company must be addressed.

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Data on eligible activities performed within the ASF surveillance are reported by ANSVSA to the European Commission (DG SANTE D4) twice a year, on the basis of the ASF Eradication Programme for Romania, approved and co-financed by the EC.

In addition, ASF surveillance data are reported twice a year to EFSA. For this purpose, data are manually extracted from the LIMS and from animal national register, and manually consolidated and standardised according to the SSD2 standards.

Technically web-services could be prepared to give the access to EFSA to data stored in LIMS. However, since the LIMS is managed by an external private IT company, the costs of this additional work should be assessed.

In **Figure 1** a conceptual description of the ASF surveillance data flows is provided.

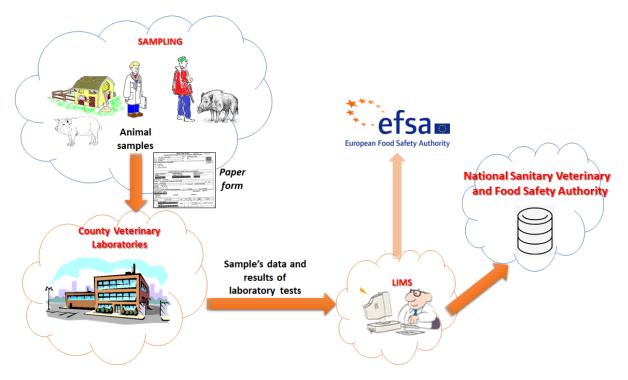


Figure 1: Conceptual description of the ASF surveillance data flows.

A.14.1.2. Conclusive remarks

Data on ASF surveillance are stored in the LIMS at county level, with increased difficulties in the consolidation of a unique database collecting all information about ASF surveillance activities.

In addition, the absence of a real-time automatized check on the national livestock database about farm's identification data may contribute to errors and to reduce the quality of data. The management of the LIMS by an external private company could represent a possible technical obstacle for the submission of good quality, sample-based data to EFSA.

A.15. Slovakia

A.15.1. ASF surveillance (IZSAM)

A.15.1.1. Results

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The description of the authorities responsible for the data collection and management on animal diseases in Slovakia has been already provided in a published EFSA report¹. For the sake of clarity here the organization of the main authorities is reported (**Figure 1**).

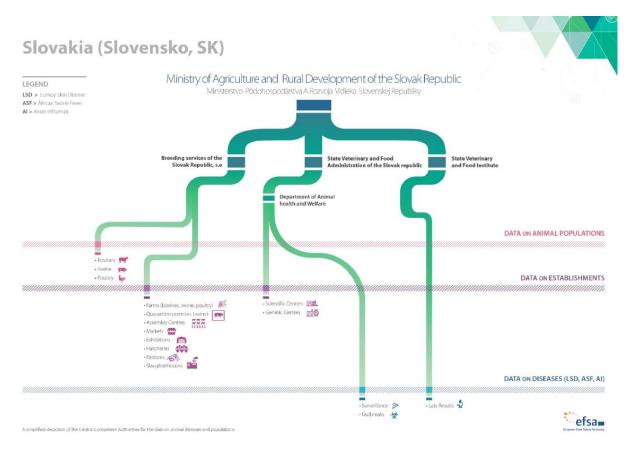


Figure 1: A simplified depiction of the central competent authorities for the data on animal diseases and animal populations in Slovakia (source: EFSA, 2019).

The State Veterinary and Food Institute (SVFI) collects the samples (both from farmed pigs and wild boars) from the District Veterinary and Food Administration (DVFA).

SVFI is the sole laboratory performing the laboratory tests for ASF.

Samples are accompanied by paper forms (application form), on which the basic identification information is reported: ID of pig farms, description of municipality and district, cause of death, and other information. Latitude and longitude are rarely provided for wild boars, and in general detailed information about geographical coordinates (latitude and longitude) where samples have been taken are not provided in the application forms. Information on Municipality (LAU) is provided, and for wild boar smaller geo-units (terrestrial areas) information is available.

All accompanying data are manually entered into the Laboratory Information Management System (LIMS).

There is no direct link or web service between LIMS and national livestock register. However, every two weeks a data export from the national livestock register is uploaded into the LIMS. Therefore, data on pig farms registered in the LIMS is updated every two weeks.

Further specific checks on the identification data of samples can be manually performed on a case-by-case basis on the national livestock register, using the access account provided to the SVFI.

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Automatized data exchanges by web services are in place between the national livestock register and State Veterinary and Food Administration (SVFA). The synchronisation between the national livestock register and the veterinary information system is made every two weeks. With the same frequency the data stored in the SVFI is synchronised with those recorded in the veterinary information system at SVFA. Therefore, a maximum delay of 4 weeks can affect the data recorded in the SVFI.

In addition, each night, sample-based data are reported to the SVFA and DVFA via webservices.

The LIMS of the SVFI is based on Microsoft SQL.

Sample-based data is currently sent to EFSA by the SVFI. Data are extracted from LIMS. If agreed with the national veterinary authorities, it would be technically possible to develop links or web services for an automatic data exchange with EFSA.

In **Figure 2** a conceptual description of the ASF surveillance data flows is provided.

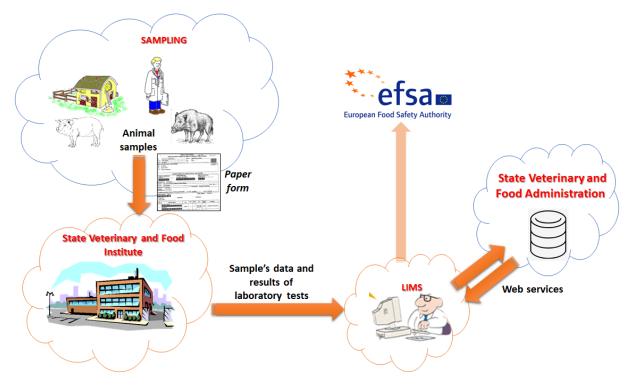


Figure 2: Conceptual description of the ASF surveillance data flows.

A.15.1.2. Conclusive remarks

The collection of ASF surveillance data in Slovakia is well organised and an effective network of data exchange is in place among the various national authorities.

A single national laboratory performs the laboratory tests for ASF and collects all basic data on ASF surveillance. This facilitates the collection of standardised and coherent data from Slovakia.

No major technical obstacles are identified for the submission of good quality, sample-based data to EFSA.

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A.16. Spain

A.16.1. ASF surveillance

The analysis of the answers provided in the questionnaire are ongoing.

A.16.2. AI surveillance – domestic poultry (FLI)

A.16.2.1. Summary

Data is firstly collected by the regional competent authorities and afterwards send to the central competent authority that collates and analysed the data at national level.

The central competent authority has developed a website application (RASVE), where the regional authorities upload the data either manually or through an excel file.

The data from the regional authorities is uploaded in the central database twice a year (January and July). The surveillance data is currently stored per month and at holding level.

The results of the tests are reported initially from the official laboratories (regional or national, depending on the test to be used and the diagnostic capability of each region) to the regional authorities that collate the surveillance information in each region. Afterwards, the regional authorities upload the data into the central website app (RASVE).

Regional and national laboratories are not connected.

In the future, the national laboratory will be connected through RASVE (surveillance national app) via Web service.

Data storage at regional level depends on the region. At the national level, data is stored in the web application RASVE.

The data format at the national authority is saved within the web application for surveillance information and outbreaks. The data from the national laboratory are saved in the national application for laboratory results. The format of the data storage at the regional authorities depends on the region.

The laboratory results for the official analysis performed by the national reference laboratory are currently sent by email to the central and regional authorities, as soon as they become available. Currently, the national laboratory database and RASVE are not connected, but this is planned for the future. The exchange of laboratory reports from regional laboratory to other administrative units depends on the region.

Twice a year, the regional authorities upload the surveillance information into the RASVE application.

Data for poultry surveillance is currently collected at holding level in RASVE.

The technical surveillance data are reported twice a year to EFSA (July and January), and reported to the EC in April for co-financing. This is currently through an XML file to EFSA.

The data exchange is initiated by the Member State (uploading the XML file into the DCF).

A.17. Sweden

A.17.1. AI surveillance – Domestic poultry (FLI)

A.17.1.1. Summary

The veterinary authority in charge of collecting data is the National veterinary Institute (SVA).

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Information is given to the SVA through submission forms, which are manually entered into the LIMS-system.

All avian influenza surveillance samples are analysed and all data is collected at SVA. The data is stored on site in a relational database (Microsoft SQL Server). Sampling and data collection is done continuously throughout the year.

Data access at SVA is via an internal web site / application. Access is only feasible from within the SVA network, using tools used to generate XML file for transfer to EFSA (Altova MapForce). The data is not reported to the European Commission, but to EFSA.

Data is transferred to EFSA as XML using the DCF portal.

Transfer is initiated by the Member State twice annually as requested by EFSA.

A.17.2. AI surveillance – Wild birds (FLI)

A.17.2.1. Summary

The veterinary authority in charge of collecting data is the National veterinary Institute (SVA). Information is given to the SVA through submission forms, which are manually entered into the LIMS-system.

All avian influenza surveillance samples are analysed and all data is collected at SVA. The data is stored on site in a relational database (Microsoft SQL Server). Sampling and data collection is done continuously throughout the year.

Data access at SVA is via an internal web site / application. Access is only feasible from within the SVA network, using tools used to generate XML file for transfer to EFSA (Altova MapForce).

The data is not reported to the European Commission, but to EFSA.

Data is transferred to EFSA as XML using the DCF portal.

Transfer is initiated by the Member State twice annually as requested by EFSA.

A.18. Kosovo

A.18.1. ASF surveillance (IZSAM)

A.18.1.1. Results

The description of the authorities responsible for the data collection and management on animal diseases in Kosovo has been provided in an EFSA report₁. Here the organization chart of the main authorities is provided (**Figure 1**).

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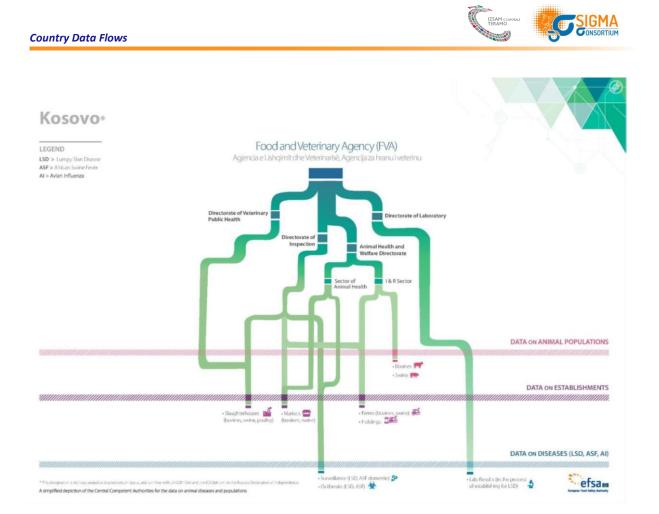


Figure 1: A simplified depiction of the central competent authorities for the data on animal diseases and animal populations in Kosovo (source: EFSA, 2020).

The Food and Veterinary Agency (FVA; <u>https://auvk.rks-gov.net/</u>) is the central source of data related to animal diseases in Kosovo (Figure 1). There are three directorates of FVA that are involved in data collection and management on animal diseases (outbreaks, surveillance activities, laboratory results). The Animal Health and Welfare Directorate is responsible for data on surveillance and outbreaks of African Swine Fever (ASF). The Directorate of Laboratory is responsible for managing the data on laboratory testing of samples and the Directorate of Veterinary Public Health oversees the data coming from slaughterhouses.

In Kosovo different local authorities are also participating in the collection and management of the data at the primary level. The Directorate of Inspection which has 6 regional offices is responsible for providing data on outbreaks and surveillance activities (EFSA 2020).

ASF surveillance in domestic pigs is based solely on passive surveillance thus no data on active surveillance are collected. The suspected cases are reported by field veterinarians to regional veterinary offices (6) using the animal disease notification form available for

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¹ EFSA (European Food Safety Authority), 2020. Data sources on animal diseases: Country Card of Kosovo. EFSA Supporting publication 2020:EN-1840. 10 pp. DOI: https://doi.org/10.2903/sp.efsa.2020.EN-1840

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downloading from the website of the FVA (Fig.2). From regional veterinary office the information is forwarded to the central veterinary office of the FVA.

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Figure 2: Animal disease notification form of the Food and Veterinary Agency of Kosovo (Source: FVA of Kosovo, 2020 <u>https://auvk.rks-gov.net/sg/shendeti-i-kafsheve-124</u>).

In wild boar the ASF surveillance is also based on passive surveillance (testing of carcasses found dead). Registered private hunters (members of Hunters Federation) report the findings of dead wild boar carcasses to the FVA. FVA (the Directorate of Animal Health) organizes the sampling of carcasses. The sampling is performed by the laboratory pathologists form the National Veterinary Laboratory (Directorate of Laboratory) who also

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fills in the sampling protocol on paper. The sampling protocol is submitted to the laboratory together with samples and data are inserted in laboratory data registry in Excel.

The laboratory reports the testing results sample by sample immediately to the Directorate of Animal Health of the FVA. Twice a year (every 6 months) the summary table of the results of the surveillance is submitted to the Directorate of Animal Health of the FVA, Ministry of Agriculture and Ministry of Environment.

The surveillance data are stored at the National Veterinary laboratory in Excel files and no relational database exists for these data. The data is shared with other bodies by exchange of files.

A.18.1.2. Conclusive remarks

The collection of ASF surveillance data is well organised in Kosovo and a single central authority (FVA) assures the management and consolidation of all data.

No major technical obstacles are identified for the submission of ASF surveillance data to EFSA. Despite the data are not stored in a relational database they are inserted in a computer data registry in a spreadsheet form, which can be organised into a format that would meet the EFSA requirements and data can be provided by file sharing. The amounts of data on ASF surveillance to be managed by data providers in Kosovo at present is limited and their manual handling should not be an obstacle for timely data provision. However, this may change as soon the ASF will reach the wild boar or domestic pig population in which case manual handling of all laboratory and surveillance data may become impossible. Therefore, establishment of databases for laboratory and surveillance data as soon as possible is highly recommended.

A.19. Montenegro

A.19.1. ASF surveillance (IZSAM)

A.19.1.1. Results

The description of the authorities responsible for the data collection and management on animal diseases in Montenegro has been already provided in a published EFSA report¹. For the sake of clarity here the organization of the main authorities is reported (Figure 1).

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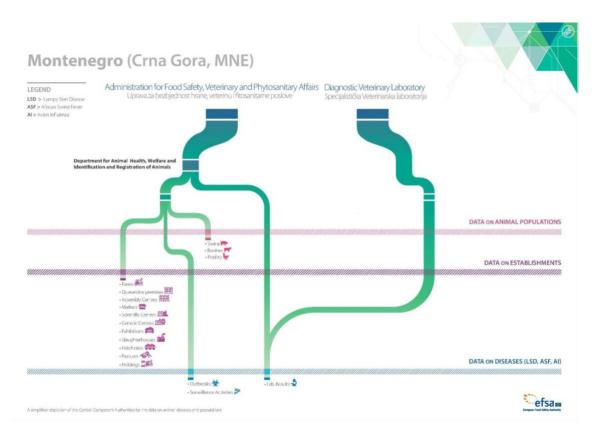


Figure 1: A simplified depiction of the central competent authorities for the data on animal diseases and animal populations in Montenegro.

Concerning the collection and management of African swine fever (ASF) surveillance data, the Department for Animal Health, Welfare and Identification and Registration of Animals under the Administration for Food Safety, Veterinary and Phytosanitary Affairs (AFSVPA) and the Diagnostic Veterinary Laboratory (DVL), located in Podgorica are the two central institutions responsible for collecting, managing and registering data on sampling, laboratory testing and results within the framework of ASF surveillance activities. (Figure 1).

The Department for Animal Health, Welfare and Identification and Registration of Animals is in charge of collecting the data on animal population, outbreak management and surveillance activities in domestic and wild animals. Whereas the data on laboratory results of animals is managed by the Diagnostic Veterinary Laboratory.

The ASF surveillance data is collected by Administration for Food Safety, Veterinary and Phytosantary Affairs through information AFSVPA gets from Diagnostic Veterinary Laboratory (DVL), private veterinary clinics and hunting organisations.

The samples from wild boar are taken by the hunters and further provided to the veterinary clinics to be sent to the DVL. The samples for ASF surveillance are accompanied by an official letter providing the relevant information about the samples (registration and location of animal holding, animal health status, geo coordinates in case of WB sampling, number and type of samples, etc..). Annex II provides templates of letters accompanying the samples to the DVL.

The DVL through means of e-mail attachment, as a Word Excel form, provides monthly reports on ASF diagnostic analysis to AFSVPA.

The basic data on ASF surveillance is collected and reported in paper form, as side documentation alongside sent invoices from the veterinary practices, hunting organisations and DVL by AFSVPA. As explained above the e-mail attachment, as Word Excel form, is used for data reporting to the AFSVPA.

Depending on the type of ASF surveillance and results in wild boar the data is reported to AFSVPA by DVL at different intervals. Samples taken within the passive surveillance and positive samples from active surveillance are reported immediately as a suspicion, and the latest in 24 hours from the moment

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of suspicion. The samples taken within the active surveillance with negative results are reported on monthly intervals. The AFSVPA further collect the basic data about ASF monitoring and surveillance in AFSVPA's yearly report in African swine fever subtitle.

Basic data is physically stored in data processing centre/AFSVPA's archive. At the time being, the ASF surveillance data is not recorded into the national central database, it is collected and stored physically in archive. The veterinary Informational System is being under construction and it is expected the surveillance data to be stored in electronic format in near future, as well. The DVL saves the basic data using Microsoft Excel file, through system created by private contractor.

The type of data exchanging to AFSVPA is manually. In case of active surveillance, the data is exchanged as added documentation to invoices sent to AFSVPA and as monthly Microsoft Excel reports from DVL The basic data can be accessed physically in AFSVPA's archive, or in yearly work report from AFSVPA as Word file.

AFSVPA reports the basic data to the European Commission in line with the Grant signed with EC for refund of some parts of monitoring. The reporting frequency used is every six-month. EFSA can access the basic data upon request.

A.19.1.2. Conclusive remarks

The possible technical obstacles that could hamper the submission of good quality, sample based data to EFSA are mainly refer to manual storage (via paper form) and reporting (via e-mail attachment) of data in AFSVPA, the lack of web services in place to report the data to AFSVPA and automatically exchanging data between AFSVPA and DVL.

Concerning the ASF surveillance in wild boar, comparing data on sampling of wild boar provided by the DVL with other supporting document (invoices) could ensure the quality of the data in a sense, but it is associated with time consuming manual work.

EFSA could be provided with the data on ASF surveillance from one source, namely AFSVPA, via Microsoft Excel forms, upon request.

A.20. North Macedonia

A.20.1. ASF surveillance (IZSAM)

A.20.1.1. Results

The description of the authorities responsible for the data collection and management on animal diseases in North Macedonia has been already provided in a published EFSA report¹. For the sake of clarity here the organization of the main authorities is reported (Figure 1).

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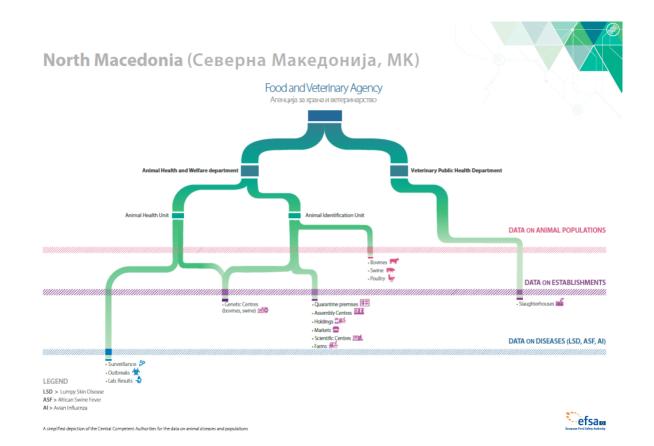


Figure 1: A simplified depiction of the central competent authorities for the data on animal diseases and animal populations in North Macedonia.

The Food and Veterinary Agency (FVA), located in Skopje is the central source of data related to animal diseases and animal populations in North Macedonia (Figure 1). Within this Agency, the Animal Identification Unit and Animal Health Unit are responsible for the data on diseases (LSD, ASF, AI) such as those for outbreaks, for laboratory results and for the surveillance activities as well as registration and identification of animals and animal holdings. The Veterinary Public Health Department in the Food and Veterinary Agency is responsible for the collection of the data for slaughterhouses.

In North Macedonia different regional and local authorities are also participating in the collection and management of the data at the primary level in order to make them available to the central authorities.

With regard to the ASF surveillance in domestic pig and wild boar (WB) the basic data is collected by the Department for animal health and welfare, at the FVA. Data on ASF surveillance is recorded in the central database, maintained by the FVA - ISFVA (information system of the FVA). Central data base Information system in Food and Veterinary Agency (ISFVA) keeping records and store data of sampled farm, animals and results. ISFVA is connected with a laboratory information system (LABIS), via web services.

Samples are taken by the contracted veterinarians and sent for laboratory diagnostic to the Faculty of veterinary medicine (upon contract). According methodology of ISFVA (Information system of Food and Veterinary Agency) each sample from WB and pigs must be sent for the laboratory examination with barcode and accompanied by a cover letter. Cover letter is obtained from the database (DB) upon the entering the data by the contracted veterinarians (private vet – PVP) (Annex 2 - template No. 1).

Concerning the WB samples, the samples are taken by the hunters and sent to the laboratory either by the PVP or by the Official veterinarian with cover letter (Annex 2 - template No. 2). The PVPs are engaged to send the samples to the laboratory and record data in the ISFVA, if only the hunter ground has registration number in the database. The samples sent by the PVP are all registered via barcode,

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according ISFVA protocol. If the hunting ground is not registered in the database, the samples are provided and sent to the laboratory by the official veterinarians, as no record is done in the database (those samples taken by the official veterinarians are recorded only in the laboratory and further transferred into the ISFVA).

The data on ASF surveillance is collected at local level (municipal level) and recorded on time /immediate by the contracted veterinarians and laboratory into the ISFVA.

Physically the basic data is stored by means of hard copies/official vet report and kept in the local FVA offices, using the format of the relational database (Oracle PostgreSQL)

The basic data could be accessed via the web application (access) development by private contractor at the FVA (central level).

The basic data on ASF surveillance is exchanged between the local levels –laboratory – central level automatically via the ISFVA, as in addition, the data on the positive cases are provided manually by means of an e-mail notification with electronic signature.

The basic data could be aggregated on both NUTS3 and NUTS level of region, municipalities and villages

In general, the FVA notifies to the European Commission data related to the diseases outbreak or control measures financial from the EU.

EFSA could access the basic data and aggregated data via the web service. So far, it has not been clarified whether the data exchange can be initiated by EFSA or if it has to be initiated by the Member State.

A.20.1.2. Conclusive remarks

The FVA has maintained and recorded the ASF surveillance data at a central database (ISFVA) as the data could be clear aggregated to different local levels which consequently could provide the submission of good quality, sample based data to EFSA.

EFSA could access the basic data and aggregated data via the web service, however, it has not been still clarified whether the data exchange can be initiated by EFSA or if it has to be initiated by the Member State.

A.21. Serbia

A.21.1. ASF surveillance (IZSAM)

A.21.1.1. Results

The description of the authorities responsible for the data collection and management on animal diseases in Serbia has been provided in an EFSA report₁. Here the organization chart of the main authorities is provided (**Figure 1**).

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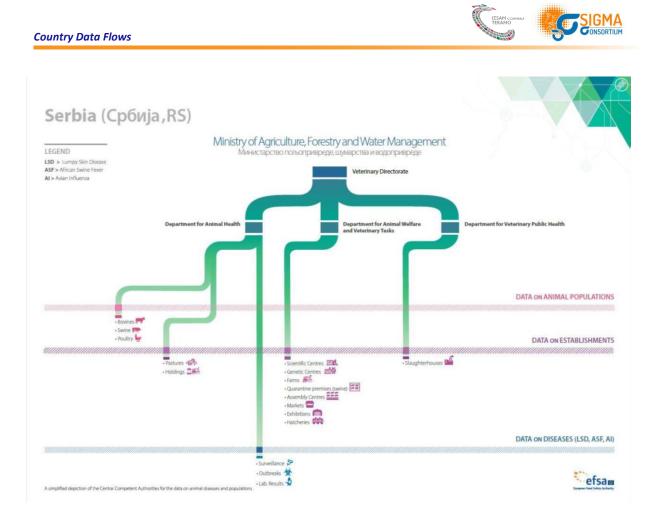


Figure 1: A simplified depiction of the central competent authorities for the data on animal diseases and animal populations in Serbia (source: EFSA, 2020).

The Veterinary Agency (VA; <u>http://www.vet.minpolj.gov.rs</u>) of the Ministry of Agriculture, Forestry and Water Management is the central source of data related to animal diseases in Serbia (Figure 1). Department of Animal Health of the VA is responsible for data collection and management on animal diseases (outbreaks, surveillance activities, laboratory results) including African Swine Fever (ASF).

In Serbia different regional and local authorities are also participating in the collection and management of the data at the primary level in order to make them available to the central authorities (EFSA 2020).

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¹ EFSA (European Food Safety Authority), 2020. Data sources on animal diseases: Country Card of Serbia. First published: 28 April 2020 DOI: <u>https://doi.org/10.2903/sp.efsa.2020</u>. EN-1851

Surveillance of ASF in Serbia is based on active and passive surveillance components. In pigs the active surveillance (regular sampling of pig herds) is conducted according to the surveillance plan composed by the VA. Private veterinary practitioners are responsible for collecting samples according to the plan and for submitting samples with submission documents containing basic data on herds and sampled animals to the official (authorized) diagnostic laboratories (veterinary institutes). There are 5 authorized laboratories for ASF diagnostics in Serbia. The national reference laboratory for ASF is the Institute of Veterinary

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Medicine of Serbia in Belgrade. In case of the suspicion of ASF the veterinary practitioners or farmers report to the local office of the VA and official veterinarian conducts sampling and collects basic data on suspected case.

In wild boar the sampling of hunted animals (active surveillance) is performed mostly by private or official veterinarians. However, occasionally the hunters may collect the samples as well as the sample information and fill in the sampling form.

Found dead wild boar (passive surveillance) are sampled in most cases by official veterinarians. Sometimes also hunter may take samples and collect sample information.

The samples from wild boar are also submitted to the authorized veterinary laboratories for testing.

For pigs and **wild boar** special paper forms (see figure 2) are filled in by sample collectors and submitted to the laboratories together with samples. Data from submission sheets are entered into the laboratory database by the laboratory staff.

For pigs second form is filled at sampling and submitted to the regional veterinary office (regional crisis center). The veterinarian, who has collected the data on paper form will enter the information into the central ASF/CSF surveillance database.

When **reporting suspicion** of ASF (passive surveillance), both for **pigs** and **wild boar** the sample collectors (official veterinarians) fill in the sampling forms on paper and submit them to the laboratory together with samples. Data from submission forms are entered into laboratory database by the laboratory staff.

Laboratory test results both for pigs and wild boar are reported on official document form to the regional and central veterinary office in case there are positive test results. In case of the suspicion of ASF in domestic pigs the negative results are also reported to the VA. Otherwise the results are stored in laboratory database and reported in aggregated form to regional and central veterinary office monthly and quarterly.

ASF surveillance data on suspected cases as well as data on active surveillance in pigs are collected according to the surveillance plan continuously through the year. In wild boar the active surveillance data (data on hunted animals) are collected in high risk areas continuously and in low risk areas during hunting season, from May to January/February.

There is an ASF/CSF surveillance databases (relational databases) for domestic pigs and for wild boar kept by the central office of the VA. This includes the laboratory test results. These databases are accessible over the internet for the field veterinarians for data entering.

Laboratory data are stored in laboratory database (LIMS, relational databases). The laboratory databases of regional laboratories are connected, but laboratory data are kept separately in every laboratory (not united into one central database).

The regional veterinary offices regularly report the surveillance data in aggregated form (summary tables) to the central office. The regional laboratories report to the National Reference laboratories.

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ОБРАЗАЦ ЗА УЗОРКОВАЊЕ И СЛАІ	е, шумарства и водиопривред ЊЕ МАТЕРИЈАЛА НА ЛАБОРАТ(А/АФРИЧКУ КУГУ СВИЊА КОД	ОРИЈСКО ИСПИТИВАЊЕ НА			
ПОДАЦИ О ЛОВИШТУ:					
Назив ловишта	Идентификациони број Географске координате				
Локација (ловни ревир), ограђени део	Географск	е координате			
ПОДАЦИ О ДИВЉОЈ СВИЊИ:					
Пол: Мушки / женски Гравидна женка	ДА / НЕ Број	фетуса			
Идентификациони број/ознака одстрељене / у	Латум угниува (процена)				
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Преглед на трихинелозу: ДА / НЕ	преглед врши				

Figure 2. Sample submission form for samples from wild boar in official monitoring plan for classical swine fever and African swine fever in wild boar 2018/2019 in Serbia (Source: Veterinary Agency of Serbia²)

A.21.1.2. Conclusive remarks

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²Monitoring plan for classical swine fever and African swine fever in wild boar 2018/2019. Ministry of Agriculture, Forestry and Water Management, Veterinary Agency, 01.11.2018. https://www.vet.minpolj.gov.rs/www.vet.minpolj.gov.rs/index.php?option=com_content&view=article&id=80

<u>https://www.vet.minpolj.gov.rs/index.php?option=com_content&view=article&id=80</u> <u>0&Itemid=457</u> [Accessed: 24.05.2021]

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The collection of ASF surveillance data is well organized in Serbia and a single central authority (VA) assures the management and consolidation of all data.

No major technical obstacles are identified for the submission of ASF surveillance data to EFSA. Data are not stored in relational databases (Oracle 11G). At present data can be provided to EFSA by file sharing. Data exchange should be initiated by EFSA.

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