### **TECHNICAL REPORT**



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# Guidance for reporting laboratory data on African swine fever (ASF)

European Food Safety Authority (EFSA), Sofie Dhollander, Davide Gibin, Lina Mur, Alexandra Papanikolaou, Gabriele Zancanaro

#### **Abstract**

This technical report is aimed at guiding the reporting of data on analytical test results, and related metadata, to EFSA in the context of the activities for the surveillance and monitoring of African Swine Fever. The objective is to explain in detail the individual data elements that are included in the EFSA Standard Sample Description version 2 (SSD2) data model. The guidance is intended to support the reporting countries in data transmission using eXtensible Markup Language (XML) data file transfer through the Data Collection Framework (DCF) according to the protocol described in the EFSA Guidance on Data Exchange version 2 (GDE2). The data elements are explained, including information about data type, list of allowed terms and associated business rules. Instructions about how to report common sampling schemes are also provided to ensure harmonised reporting among the countries.

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Key words: African swine fever, swine, wild boar, surveillance, data collection, data model

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**Correspondence:** zoonoses\_support@efsa.europa.eu



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## **Summary**

Data collection is an important task of the European Food Safety Authority (EFSA) and a fundamental component of risk assessment (Articles 22 and 23 of Regulation (EC) No 178/2002). EFSA receives a large volume of data from Member States and other reporting countries in support of its risk assessments. To facilitate data reporting, EFSA regularly publishes reporting guidance documents for the different data collections.

This guidance covers the technical aspects of reporting laboratory data for the African swine fever (ASF) data collection according to the EFSA Standard Sample Description version 2 (SSD2) data model as adapted by the SIGMA project<sup>1</sup>. The reporting countries are requested to transmit their data using eXtensible Markup Language (XML) data file transfer through the Data Collection Framework (DCF) according to the protocol described in the EFSA Guidance on Data Exchange version 2 (GDE2).

The objective of this report is to present the individual data elements that are included in the SIGMA version of SSD2 and to provide specific reporting guidelines through detailed examples. Additional information about the data type, the list of controlled terminologies (catalogues of allowed terms) and business rules or any additional requirements that apply for the ASF data collection are also described.

 $<sup>^1\,\</sup>text{More information on the SIGMA project: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2022.EN-7254}$ 



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#### 1. Introduction

### 1.1. Background and Terms of Reference as provided by EFSA

Data collection is an important task of the European Food Safety Authority (EFSA) and a fundamental component of risk assessment (Articles 22 and 23 of Regulation (EC) No 178/2002). By virtue of article 33, paragraph 3 ("the Member States shall take the necessary measures to enable the data they collect in the fields referred to in paragraphs 1 and 2 to be transmitted to the Authority"), EFSA receives a large volume of data from Member States (MSs) and other reporting countries in support of its risk assessments. Manuals and reporting guidance documents are published and/or updated regularly to support the reporting countries in the data preparation, transmission and validation.

In the context of the SIGMA project (EFSA, 2019; SIGMA Consortium, 2022), the EFSA Standard Sample Description version 2 (SSD2) data model was extended to allow the collection of laboratory test results on animal diseases in a standardised and harmonised way. The present reporting guidance provides an overview of the implementation of this data model on the African swine fever (ASF) data collection, describing the relevant data elements and the complete set of business rules applied for data validation. Reporting Countries (Member States, pre-accession countries and other countries, referred to as RCs hereinafter) have the possibility to transmit eXtensible Markup Language (XML) data files through the Data Collection Framework web application (DCF) of EFSA. The data model is in accordance with the harmonised terminology of EFSA<sup>2</sup>.

This data model was used for the collection of ASF laboratory data in 2021 allowing EFSA to address the Terms of Reference of the ASF mandate as provided by the European Commission and leading to: (i) submission of ASF laboratory results according to the EFSA SSD2 data model, inclusion of the data in the EFSA scientific Data Warehouse (DWH) with the consequent possibility of benefitting of the EFSA Business Intelligence tool (MicroStrategy) for data validation; (ii) improved harmonisation and data quality; (iii) in case of sampling in domestic pigs, possibility of linking the test results to the farm where the samples were collected. This laboratory data model can be used as the basis to accommodate the collection of laboratory test results (and related metadata) on any animal health disease. For the countries that need to submit data but do not have an automated process to format the national data according to the EFSA standards, EFSA together with the SIGMA consortium developed a web application for mapping and translating national data to the EFSA standards: the SIGMA EST tool<sup>3</sup> (SIGMA Consortium, 2022).

The collection of data on laboratory results of ASF is essential for the regular epidemiological assessment on ASF situation that EFSA develops as result of the request of the European Commission<sup>4</sup>. The laboratory data submitted to EFSA will be used to create visualisations (graphs and maps) on interactive dashboards that will allow to follow up the evolution of the disease in Europe over time. These visualisations, together with the interpretation of the data, will be the basis for the development of the annual scientific epidemiological reports on ASF situation. Based on the frequency the countries will submit the data, there will be the possibility of reducing the time gap between the findings and the visualisation. In addition, these laboratory data will be of use in the risk factor analysis to investigate the main factors involved in ASF introduction, spread and persistence in Europe.

#### 1.2. Purpose of this guidance

The present guidance is addressed to all data providers reporting ASF laboratory data to EFSA based on the standards developed in the SIGMA project. It is possible that not all sections are relevant for all data providers. This document supports the data providers in understanding the data model structure and business rules implemented for the automatic validation and provides technical guidance on reporting data using XML through the DCF<sup>5</sup>.

www.efsa.europa.eu/publications

<sup>&</sup>lt;sup>2</sup> https://doi.org/10.5281/zenodo.779880

<sup>&</sup>lt;sup>3</sup> https://sigma-est.izs.it/sigma/

<sup>&</sup>lt;sup>4</sup> https://open.efsa.europa.eu/questions/EFSA-Q-2022-00369

<sup>&</sup>lt;sup>5</sup> https://dcf.efsa.europa.eu/dcf-war/dc



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The technical requirements for collecting laboratory data in the context of animal health risk assessment were defined by the SIGMA project (EFSA, 2019). Since 2021 the ASF data collection is following the extended version of SSD2 as developed in the SIGMA project with the input of the SIGMA Working Group, the Animal Health and Welfare Network and the SIGMA consortium. The following sections cover the technical aspects for reporting ASF analytical test results in accordance with the SSD2 data model as adapted by the SIGMA project.

# 1.3. General reporting guidelines

SSD2 (EFSA, 2013) is the standard data model used by EFSA to collect information about the samples and the analytical results of tests performed in laboratories. The SIGMA project tailored the SSD2 data model to the needs of the animal health domain. The SSD2 data model as adapted by SIGMA was implemented to collect data on analytical tests results, and related metadata, performed in the context of the activities for the surveillance and monitoring of ASF. Additionally, a link was created between SSD2 and the SIGMA animal population data model that collects information about animal population at the farm level (EFSA, 2022). The collected data are used by EFSA to perform the necessary risk assessment activities addressing the terms of reference provided by the EC to EFSA.

The positive and negative laboratory results of the samples collected within the surveillance and monitoring activities of ASF shall be reported at single test result level following the SSD2 standard. This applies to samples taken from domestic pigs as well as from wild boar.

Regarding the results from domestic animals, the SSD2 data model, as modified by the SIGMA project, allows to report the identifier of the subunit where the animal was raised (considering 'subunit' as management group of animals of the same animal species, sharing the same geographical location and the same rearing purpose in the context of a given 'establishment'; see Figure 1 and EFSA, 2022). This information can be used to link the results of the analysed sample to additional information about the specific establishment (e.g., farm) where the animal was bred (as provided by the country in the SIGMA animal population data model).

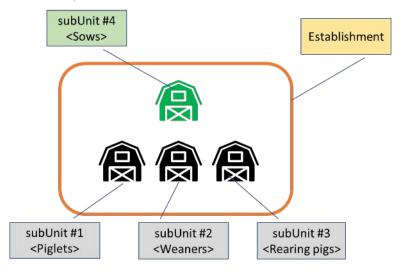


Figure 1: Visual representation of the relationship between establishment and subunit

The countries are expected to transmit the laboratory result information at least once per year. However, more frequent submission of data (i.e., twice a year) might be requested to have a more updated status of the ASF situation.

Please note that all the 'data elements' (also referred to as 'variables', see Section 2) in the SIGMA SSD2 data model represent the set of information required by EFSA to perform epidemiological analysis and related risk assessment.

In case of the animal laboratory data model, these data elements are necessary to:

• identify, locate, characterise and assess each reported 'case' (i.e., a sample tested positive for a given disease)



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• assess the overall situation considering the 'cases' and the 'non-cases' (i.e., the samples tested negative for the same disease), the sampling effort and the overall target population by estimating epidemiological parameters, prevalence, incidence, temporal trends etc.

The level of detail of the reported laboratory test results will define the type and accuracy of analysis that can be performed. Therefore, despite the data model contains elements that are mandatory and others that are optional (see Section 2.1), from a risk assessment perspective all data elements requested are of high importance to produce informative scientific outputs.

### 1.4. SIGMA-EST mapping tool

To facilitate the data preparation, EFSA and the SIGMA consortium developed the <u>SIGMA-EST</u><sup>6</sup>, a web tool that allows RCs to map the laboratory data stored in their national databases (or Laboratory Information Management System - LIMS) to the SIGMA SSD2 data model and to generate XML files to be uploaded to the DCF. A user manual <u>SIGMA-EST and Data submission operative manual</u> is available in Zenodo<sup>7</sup>.

The RCs can either use the SIGMA-EST application to generate XML files compatible with the SIGMA SSD2 data model and the DCF or create their own XML files for direct upload to the DCF.

SIGMA EST is updated with the latest version of the data model, its related catalogue values and definitions. The RCs will be informed in case of changes.

#### 2. Data elements definition

#### 2.1. Data

The SIGMA SSD2 data model includes three types of data elements:

• **Simple data elements** can contain only one instance of an 'element value', which may be a 'text value', a 'numeric value' or a 'catalogue value' (i.e., an alphanumeric code chosen among a predefined list of values).

Example of XML tag used for a simple data element (e.g., to identify the sampling year sampY):

```
<sampY>2021</sampY>
```

- **Repeatable data elements** may contain one or more instances of an 'element value' for the specified data type. Different values can be provided either using nested XML structure or using the '\$' character as a value separator.
- Compound data elements contain more than one 'simple elements' called 'attributes' of the 'compound element'. A compound data element can contain independent attributes, or a main attribute (called 'base term') followed by auxiliary attributes (called 'facets') which further define the main one. Each attribute can have a value which can be 'text', 'numeric' or 'catalogue'. Three different ways for reporting compound data elements are allowed: (i) nested XML structure, (ii) concatenation according to the SSD2 specifications (EFSA, 2013) and (iii) use of simplified XML tags.

# Example:

SSD2 concatenated string:

<sup>7</sup> https://zenodo.org/record/5903276#.YioQ9YnMLIU

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<sup>&</sup>lt;sup>6</sup> https://sigma-est.izs.it/sigma/



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<sampEventInfo>birthCountry=AT\$birthYear=2012\$birthMonth=3</sampEventInfo>

- Simplified XML tags:
  - <sampEventInfo.birthCountry>AT</sampEventInfo.birthCountry>
  - <sampEventInfo.birthYear>2012</sampEventInfo.birthYear>
  - <sampEventInfo.birthMonth>3</sampEventInfo.birthMonth>

In the following sections, examples are mostly based on the simplified XML tags, but all the syntaxes are accepted by the DCF.

Data elements have a unique name, which is case sensitive and should be used as tag in the XML data file. A data type is associated with each data element, and it defines the values that the element can contain.

Based on the restrictions for submission, data elements can be mandatory, optional or mandatory under certain conditions.

- Mandatory data elements contain information that is essential for the analysis of the reported data (or is required by the SSD2 standard). They represent the minimal set of information required to run descriptive statistics or a basic risk assessment.
   Mandatory data elements shall always be reported. An XML Schema Definition (XSD) checks the structure of the incoming XML files in the DCF. XML files that do not satisfy the XSD schema (i.e., a mandatory element is missing) will be rejected without undergoing further checks (i.e., control terminology check, business rules validation).
- **Optional data elements** contain information that is, from a risk assessment point of view, <u>as necessary as the mandatory elements</u>. If missing, the data submitted will not be rejected, but they will only allow a *basic* risk assessment or simple descriptive statistics. The main reason that these elements are *'optional'* is linked to the unavailability of the information across all RCs: as an example, the analytical test applied for the detection of the target pathogen is certainly recorded by the laboratory of all countries and, therefore, is mandatory, while the official national registration number of the farm (*subUnitId*) in which the sampled animal was bred may not be available to the laboratory and, therefore, cannot be mandatory in the SIGMA SSD2 data model. Nonetheless, the *subUnitId* is <u>indispensable</u> for a proper risk assessment (e.g., assessment of potential risk factors comparing the number of positive and negative tests in the different farms). Optional data elements which are not filled in should not be reported in the XML file (i.e., the file should not contain empty tags such as <anMethInfo.methSensitivity/> or <anMethInfo.methSensitivity></anmethInfo.methSensitivity>).
- **Mandatory under certain conditions:** an optional data element can be required under certain conditions checked by means of specific business rules.

Section 3 contains a summary of all data elements (mandatory, optional, mandatory under certain conditions). Data elements which are mandatory under certain conditions are indicated as 'Mandatory\*'.



# 3. Summary of relevant data elements

Table 1 summarises the variables relevant for reporting ASF laboratory results. The data elements marked as 'Mandatory\*' are mandatory only under certain conditions. The reported alphanumeric codes used to identify the data elements are referred to the EFSA SSD2 data model.

**Table 1:** Data elements for reporting ASF laboratory results

Element code	Element label	Element name (for XML transfer)	Constraint	Data type	Catalogue	Hierarchy
B.01	Sampling programme identification code	progId	mandatory	xs:string (100)		
B.04	Sampling programme type	progType	optional	xs:string (5)	PRGTYP	LegalFwk
B.02	Programme legal reference	progLegalRef	mandatory*	xs:string (5)	LEGREF	
B.03	Sampling programme strategy	sampStrategy	optional	xs:string (5)	SAMPSTR	anSampstr
B.07	Sampling point	sampPoint	optional	xs:string (5)	SAMPNT	AnSampnt
B.08	Additional sampling programme information	progInfo.targetGroup	mandatory	xs:string (6)	TARGETGROUP	AnTargetGroup
B.08	Additional sampling programme information	progInfo.com	optional	xs:string (1000)		
C.02	Sampling unit type	sampUnitType	mandatory	xs:string (5)	SAMPUNTYP	
C.01	Sampling event identification code	sampEventId	mandatory	xs:string (100)		
C.05	Other sampling unit identifications	sampUnitIds.animalId	optional	xs:string (250)		
C.05	Other sampling unit identifications	sampUnitIds.subUnitId	optional	xs:string (100)		
C.05	Other sampling unit identifications	sampUnitIds.sampHuntingGround	optional	xs:string (100)		
D.01	Sample taken identification code	sampId	mandatory	xs:string (100)		
D.09	Sample taken size	sampSize	optional	xs:integer (2)		
D.10	Sample taken size unit	sampSizeUnit	mandatory*	xs:double		
D.06	Year of sampling	sampY	mandatory	xs:integer (4)		
D.07	Month of sampling	sampM	mandatory	xs:integer (2)		
D.08	Day of sampling	sampD	mandatory	xs:integer (2)		
D.03	Country of sampling	sampCountry	mandatory	xs:string (2)	Country	
D.04	Area of sampling	sampArea	mandatory	xs:string (5)	Nuts Gaul	
D.12	Municipality of sampling	sampMunicipality	optional	xs:string (500)		
D.11	Additional sample taken information	sampInfo.latitude	optional	xs:integer(10,6)		
D.11	Additional sample taken information	sampInfo.longitude	optional	xs:integer(10,6)		
D.11	Additional sample taken information	sampInfo.coordPrecision	mandatory*	xs:string(5)	COORDPRE	
E.01	Type of matrix	sampMatType	mandatory	xs:string(5)	MTXTYP	
E.02	Coded description of the matrix of the sample taken	sampMatCode.base	mandatory	xs:string(5)	MTX	
E.02	Coded description of the matrix of the sample taken	sampMatCode.source	mandatory	xs:string(5)	MTX	Source
E.02	Coded description of the matrix of the sample taken	sampMatCode.part	optional	xs:string(5)	MTX	Part-nature
E.02	Coded description of the matrix of the sample taken	sampMatCode.prod	mandatory	xs:string(5)	MTX	Production-method
E.02	Coded description of the matrix of the sample taken	sampMatCode.animage	mandatory*	xs:string(5)	MTX	Animal-age-class



lement code	Element label	Element name (for XML transfer)	Constraint	Data type	Catalogue	Hierarchy
E.02	Coded description of the matrix of the sample taken	sampMatCode.gender	optional	xs:string(5)	MTX	Gender
E.03	State of decomposition	sampMatText	optional	xs:string (250)		
F.03	Year of analysis	analysisY	mandatory	xs:integer (4)		
F.04	Month of analysis	analysisM	mandatory	xs:integer (2)		
F.05	Day of analysis	analysisD	mandatory	xs:integer (2)		
H.01	Sample analysed portion sequence	anPortSeq	optional	xs:string(100)		
L.01	Analytical method identification	anMethRefId	mandatory	xs:string (50)		
L.03	Analytical method type	anMethType	mandatory	xs:string (5)	ANLYTYP	
L.04	Analytical method code	anMethCode	mandatory	xs:string (5)	ANLYMD	ASFAnlymd
L.06	Additional information on the analytical method	anMethInfo.methSensitivity	optional	xs:double		
L.06	Additional information on the analytical method	anMethInfo.methSpecificity	optional	xs:double		
J.01	Laboratory identification code	<i>labId</i>	optional	xs:string (50)		
J.03	Laboratory country	labCountry	optional	xs:string (2)	Country	
K.01	Type of the parameter	paramType	mandatory	xs:string (5)	PARAMTYP	
K.02	Coded description of parameter code	paramCode	mandatory	xs:string (15)	PARAM	
M.01	Result identification code	resId	mandatory	xs:string (100)		
M.16	Type of result	resType	mandatory	xs:string (3)	VALTYP	pestvalTyp
M.15	Result qualitative value	resQualValue	mandatory	xs:string (3)	POSNEG	tseTestResult
N.06	Additional information on the evaluation	evalInfo.nationalCaseId	optional	xs:string (100)		
	Amendment type	amType	optional	xs:string(1)		



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# 4. Sections and data elements of the SIGMA SSD2 laboratory data model

This document provides guidance for reporting ASF laboratory data at individual result level using the SSD2 data model. The sections of the SSD2 data model are extensively described in the SSD2 guidance (EFSA, 2013). The alphanumeric codes used here to identify the data elements also refer to the SSD2 standard. To ensure simplicity and clarity, the SSD2 data elements which are not considered relevant for the SIGMA ASF data collection have been excluded from this document. Codes and sections are, therefore, not always sequential.

#### 4.1. Section B – Sampling programme

The data elements belonging in this section contain the set of information related to the <u>legal framework</u> of the surveillance activities, the methodology for sampling, the goal of the sampling activity, as well as the target group of animals (e.g., hunted, found dead).

#### 4.1.1. B.01 – Sampling programme identification code (progId)

**Definition**: The unique national identification code of the programme for which the sampling activity was performed.

**Mandatory**: Yes

**Data type**: Free text element up to 100 characters

**Note**: If no national identification code exists, one can be created (e.g., ASF\_wb\_dead\_surv or ASF\_farm\_dead) and used in a harmonised way across datasets and years.

#### 4.1.2. B.04 – Sampling programme type (progType)

**Definition**: The legal and administrative framework within which the sampling activity was performed.

Mandatory: No

**Data type**: Catalogue **PRGTYP**, hierarchy *LegalFwk* (see Table 2).

**Table 2:** Applicable values for the sampling programme type

Sampling programme type	Description	Code
Private	Sampling activities performed by private industries (e.g., HACCP)	K012A
National / regional programme	In case the sampling activity has not a European legal basis and follows national legislation only	K005A
EU programme	Sampling activities related to EU legislation (fully funded / co-funded / not funded)	K009A
EU programme - Fully funded	The sampling activity is related to EU legislation, and it is fully funded by the EU.	K035A
EU programme – co-funded	The sampling activity is related to EU legislation, and it is cofunded by the EU.	K036A
EU programme - not funded	The sampling activity is related to EU legislation, and it is not funded by the EU.	K037A

# 4.1.3. B.02 - Programme legal reference (*progLegalRef*)

**Definition**: The relevant European legislation.

**Mandatory**: Under conditions, i.e., mandatory when the sampling programme type (*progType*) is 'EU programme' (with or without information about funding).

Data type: Catalogue LEGREF

**Example**: Samples might be collected under the 'Regulation (EU) No 2016/429 (Animal Health Law)' (code N361A) and reported in the XML syntax:

cprogLegalRef>N361A/progLegalRef>



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#### 4.1.4. B.03 - Sampling programme strategy (sampStrategy)

**Definition**: The description of the underpinning methodology for the selection of the samples.

Mandatory: No

**Data type**: Catalogue **SAMPSTR**, hierarchy *anSampstr* (see Table 3).

**Note**: the values in this data element must be carefully chosen and consistent with the values chosen for programme goal and target group (see section 4.1.5).

Table 3: Admissible values for sampling strategy

Sampling strategy	Description	Code
Objective sampling - Simple Random Sampling	A simple random sample is a subset of a statistical population in which each member of the subset has an equal probability of being chosen. A simple random sample is meant to be an unbiased representation of a (target) group.	ST44A
Objective sampling - Clustered Sampling	A 'cluster' is a collection of study subjects with one or more characteristics in common. In a cluster sample, the sampling unit is larger than the unit of concern - e.g., selection of some farms (clusters) in which all animals (units of concern) are sampled. Application: estimation of the prevalence at animal level (not the prevalence of infected farms).	ST45A
Selective sampling - Risk Based	Risk based sampling makes use of relevant risk factors (having an impact on the presence / absence of the agent that has to be detected) and related relative risk values. If no relative risk has been estimated or calculated, the sampling is not risk based, but 'Biologically driven'.	ST21A
Selective sampling - Biologically driven	The sampling is driven by biological considerations (e.g., location, season, type of pig establishment), but not supported by scientific evidence (relative risk is missing).	ST22A
Convenient sampling - Testing the game bag at game handling establishment	Samples originating from animals hunted during the hunting season.	ST41A
Convenient sampling - Accidental sampling	The samples are obtained without a pre-defined sampling calculation, they are accidentally found or brought to the laboratory (e.g., road kills).	ST43A
Census	This option is relevant when all animals in all establishments are sampled.	ST50A

# 4.1.5. B.08 Additional sampling programme information (*progInfo*)

• The attribute **'Target group**' (*progInfo.targetGroup*), contains the description of the clinical characteristics of the sampled animal.

**Mandatory**: Yes

**Data type**: Catalogue **TARGETGROUP**, hierarchy *AnTargetGroup* (see Table 4)

**Note**: The values must be consistent with those chosen for sampling strategy (sampStrategy, Section 4.1.4) and programme goal (progInfo.com, see next item in this section).

**Table 4:** Applicable values for target group

Target group	Description	Code
Alive	The animal was alive at the moment of the sample collection.	TG024A
Alive Symptomatic	The animal was showing clinical signs at the moment of the sample collection or pathognomonic lesions.	TG016A
Alive Non-symptomatic	The animal had no clinical identifiable at the moment of the sample collection.	TG017A
Found dead	The animal was dead at the moment of the sample collection.	TG020A
Dead Symptomatic	The carcass presents pathognomonic lesions at the moment of the sample collection or pathognomonic lesions.	TG025A
Dead Non-symptomatic	The carcass didn't present any pathognomonic lesion identifiable at the moment of the sample collection.	TG026A
Hunted	The animal was shot and killed in the context of a hunting session.	TG027A
Hunted Symptomatic	Hunted with clinical signs (including injured)	TG018A



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Target group	Description	Code
Hunted Non-symptomatic	Hunted without clinical signs	TG019A
Road kills	The animal was killed due to the impact with a means of transport at the moment of the sample collection.	TG009A
Slaughtered	The animal was stunned and killed during a regular slaughtering session in an authorised slaughterhouse, intended for human consumption.	TG028A
Culled	The animal was killed on site or at a slaughterhouse for urgent, sanitary reasons, including stamping out. Not intended for human consumption.	TG029A

• The attribute '**Programme goal**' (*progInfo.com*), describes the goal to be achieved with the sampling activity.

**Mandatory**: No (but **highly recommended**)

**Data type**: see Table 5 for applicable values.

**Note**: The values must be consistent with those chosen for sampling strategy (sampStrategy, Section 4.1.4) and target group (progInfo.targetGroup, see previous item in this section).

**Example**: reporting an animal that was hunted (code 'TG027A') as part of regular sampling activity (programme goal '**DET**') using XML syntax:

com=DET\$targetGroup=TG027A

**Table 5:** Applicable values for programme goal

Programme goal	Description	Code
Freedom from disease	Sampling performed with the specific aim of demonstrating freedom from a given disease / parasite / pathogen / agent	FFD
Outbreak containment	Sampling performed following a positive laboratory test result	CONT
Detection	Regular sampling activity performed with different aims as, e.g., prevalence / incidence / trends estimation (monitoring), detection (surveillance).	DET

To facilitate the consistent reporting of these three elements, the most common sampling schemas have been summarised below, clarifying the best way to report them (Table 6).

**Table 6:** Examples of most common sampling schemes and how they should be reported in the SIGMA version of SSD2 for ASF laboratory data. The codes to be used are provided in parentheses.

Sampling scheme	Programme goal (progInfo.com)	Sampling strategy (sampStrategy)	Target group (progInfo.targetGroup)
Testing healthy pigs before movement	Detection ( <b>DET</b> )	Selective sampling - Biologically Driven (ST22A)	Alive Non-symptomatic ( <b>TG017A</b> )
Testing healthy pigs randomly in a farm	Freedom from disease (FFD) OR Detection (DET)	Objective sampling - simple random sampling (most frequent) ( <b>ST44A</b> )	Alive Non-symptomatic ( <b>TG017A</b> )
Testing all pigs at slaughter	Detection ( <b>DET</b> ) OR Freedom from disease ( <b>FFD</b> )	Census (ST50A)	Slaughtered ( <b>TG028A</b> )
Testing pigs in protection and surveillance zones	Detection ( <b>DET</b> ) OR Outbreak containment ( <b>CONT</b> )	Selective sampling - Biologically Driven (ST22A)	Alive ( <b>TG024A</b> ) OR Alive Non-symptomatic ( <b>TG017A</b> ) OR Alive Symptomatic ( <b>TG016A</b> )
Systematic sampling and testing of two dead pigs per week (Reg 2021/605)	Detection ( <b>DET</b> )	Selective sampling - Biologically Driven (ST22A)	Found dead ( <b>TG020A</b> ) OR Dead Non-symptomatic ( <b>TG026A</b> )



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Sampling scheme	Programme goal (progInfo.com)	Sampling strategy (sampStrategy)	Target group (progInfo.targetGroup)
Testing pigs with ASF clinical signs	Detection ( <b>DET</b> )	Selective sampling - Biologically Driven (ST22A)	Alive Symptomatic ( <b>TG016A</b> ) OR Dead symptomatic ( <b>TG025A</b> )
Testing pigs culled during stamping-out activities after outbreak	Outbreak containment ( <b>CONT</b> )	Selective sampling - Biologically Driven (ST22A)	Culled (TG029A)
Sanitary slaughter of pigs for other sanitary reasons (e.g., uterus prolapse)	Detection ( <b>DET</b> )	Selective sampling - Biologically Driven (ST22A)	Alive Symptomatic ( <b>TG016A</b> )
Testing hunting bag to detect disease or estimate prevalence	Detection ( <b>DET</b> )	Convenient sampling - Testing the game bag at game handling establishment ( <b>ST41A</b> )	Hunted (TG027A) OR Hunted Symptomatic (TG018A) OR Hunted Non-symptomatic (TG019A)
Testing wild boar carcasses found dead in the forest	Detection ( <b>DET</b> )	Convenient sampling - Accidental sampling ( <b>ST43A</b> )	Found dead ( <b>TG020A</b> ) OR Dead Symptomatic ( <b>TG025A</b> ) OR Dead Non-symptomatic ( <b>TG026A</b> )
Testing wild boar killed in vehicle collision	Detection ( <b>DET</b> )	Convenient sampling - Accidental sampling (ST43A)	Road kills ( <b>TG009A</b> )
Sanitary shooting of symptomatic wild boars	Detection ( <b>DET</b> ) OR Outbreak containment ( <b>CONT</b> )	Selective sampling - Biologically Driven (ST22A)	Hunted Symptomatic ( <b>TG018A</b> )
Culling of wild boar as ASF countermeasure (e.g., in response to an outbreak, depopulation, sanitary culling of symptomatic wild boar)	Outbreak containment (CONT) OR Detection (DET)	Selective sampling - Biologically Driven (ST22A)	Hunted (TG027A) OR Hunted Symptomatic (TG018A) OR Hunted Non-symptomatic (TG019A)

# 4.1.6. B.07 – Sampling point (*sampPoint*)

**Definition**: The point in the food chain, where the sample was taken.

Mandatory: No

**Data type**: Catalogue **SAMPNT**, hierarchy *AnSampnt* (see Table 7)

**Example**: reporting the *sampPoint* as 'Slaughterhouse' (code 'E311A') in the XML syntax:

<sampPoint>E311A</sampPoint>

**Table 7:** Admissible values for sampling point

Sampling point	Description	Code
Border Control Posts	Samples collected in the context of a border inspection activity (e.g., samples taken on transported animals crossing a country border).	E010A
Zoo	Artificial parks open to the public dedicated to different animal species, including exotic species.	E012A
Veterinary clinics	Veterinary clinic. Mainly for clinical visits of pet animals.	E013A
Unspecified	The sampling point is not specified.	E098A
Game handling establishment	Authorised establishment for the handling of game.	E170A
Wildlife research station	Stations dedicated to wildlife protection and management.	E190A
Processing plant	Establishment where the edible portions of animal origin are further processed before going on the market for human consumption.	E301A
Slaughterhouse	Establishment used for slaughtering terrestrial animals.	E311A
Water source	Location at or nearby a natural or artificial source of water.	E420A



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Sampling point	Description	Code
Conservation facilities	Premises designed for the conservation of carcasses (as a whole or portioned), processed products of animal origin (e.g., slices of meat, minced meat) under certain conditions of temperature and humidity with the goal of slowing down the natural decomposition process.	E720A
Health and Research Centre	Permanent, geographically limited and approved establishment (e.g., research laboratories, veterinary hospitals) where one or more animal species are habitually: (i) kept for fundamental or applied scientific research; (ii) bred for the research purposes; (iii) kept undergoing veterinary medicine practices.	E961A
Pen	The place where the animals are kept in an outdoor farm (i.e., not in the shelter, not in the milking room, etc.).	E973A
Forest	Natural habitat, covered mainly by trees and undergrowth.	E976A
Grassland	Natural habitat, normally a large open area of country covered by grass, especially one used for grazing.	E977A
Rendering plant	Premises dedicated to the incineration of animal carcasses or part of them for sanitary purposes. Typically used for the destruction of dead diseased animals.	E978A
Urban area	Urban context, characterised by high human population density, infrastructure and built environment.	E979A
Nursery	The space in a farm dedicated to the new-borns.	E981A
Quarantine premises	Establishments where the animals are kept in isolation with no direct or indirect contact with animals outside this epidemiological unit, for the purpose of ensuring that there is no spread of one or more specified diseases while the animals in isolation are undergoing observation for a specified length of time and, if appropriate, testing and treatment. [based on Regulation (EU) 2016/429 (AHL), art. 4(38)]	E988A
Genetic centre	Establishment where the animals (bovines, equines, swine, sheep, goats) are kept by humans, for the collection of germinal products.	E994A
Circus	Itinerant premises where different animal species are kept for ludic purposes.	E996A
Pet shop	Private shop for the selling of pets/small animals to private citizens.	E997A
Petting centre	Premises where different animal species (pets or farming animals) are kept, and visitors can get close to them. Similar or synonymous of farmhouse.	E998A
Stall	The place where the animals are kept in an indoor farm (i.e., not in the paddock, not in the milking room, etc.).	E999A

#### 4.2. Section C – Sampling event

In SSD2 the sampling event represents the epidemiological unit sampled at a certain time. Each sampling event includes all samples taken at a certain time to investigate chemical or microbiological properties of the sampling unit under consideration. A sampling event can comprise, for example, one or more samples from the same animal at a certain point in time (i.e., the sampling event is used to group different samples taken from the same animal). For the ASF data collection, the sampling unit is the animal. Different samples can be taken from the same animal and in this case, they belong to the same sampling unit (the animal) and the same sampling event. Exceptionally, in the case of samples pooled from different animals and tested negative, the individual animals cannot be differentiated and, therefore, in this case the sampling event refers to the pooled sample.

#### 4.2.1. C.01 – Sampling event identification code (*sampEventId*)

**Definition**: A unique identifier for the sampled animal. This could be the official identification number of a domestic animal (if it is unique for each animal) or, if necessary, a dummy identifier (e.g., for wild animals). It can correspond to more than one sample (relationship one to many samples) when more than one sample were taken from one animal. In the case of pooled samples, the *sampEventId* can be equal to the sample identification code (see section 4.3 below).

**Mandatory**: Yes

**Data type**: Free text element up to 100 characters.

**Note**: If strictly necessary, a dummy identifier can be provided instead of the official ID.



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#### 4.2.2. C.02 – Sampling unit type (*sampUnitType*)

**Definition**: The sampling unit from which the sample is taken (e.g., animal).

**Mandatory**: Yes

Data type: Catalogue SAMPUNTYP

**Note**: In the ASF data collection, the only admissible value is 'Animal' (code 'G199A').

**Example**: reporting an animal as sampling unit type with the default value 'Animal' in the XML syntax:

<sampUnitType>G199A</sampUnitType>

## 4.2.3. C.05 – Other sampling unit identifications (sampUnitIds)

This compound data element contains three attributes that can be used to report identification codes for the sampling unit:

The animal identification code (sampUnitIds.animalId)

**Mandatory**: No

Data type: Free text element up to 100 characters

**Note**: For the ASF data collection it can be the same as the *sampEventId*.

• The **subunit identification code** (*sampUnitIds.subUnitId*)

Mandatory: No (but highly recommended when reporting farmed animals)

Data type: Free text element up to 100 characters

**Note**: This field is used to link the laboratory results to the population data submitted in the SIGMA animal population data model. To link the information, it is important that the same identifiers are used in the population and the laboratory data model.

• The hunting ground identification code (sampUnitIds.sampHuntingGround).

**Mandatory**: No (but **highly recommended** for wild animals)

**Data type**: Free text element up to 100 characters

**Note**: The information about the hunting ground is useful for the analysis of data referring to wild animals but <u>longitude and latitude are always preferred</u>, <u>when available</u>. EFSA might ask RCs to provide separately additional information on the national hunting grounds (e.g., full list, shapefiles).

# 4.3. Section D – Sample taken

The data elements included in this section describe information related to the samples (e.g., date of sampling). It is complemented by Section 4.4, which describes the matrix (e.g., species of the animal, sampled part) of the sample.

#### 4.3.1. D.01 – Sample taken identification code (*sampId*)

**Definition**: The unique identification code for each sample tested at country level for a specific reporting year.

Mandatory: Yes

**Data type**: Free text element up to 100 characters.

**Note**: For the same sample taken (*sampId*), all sample descriptors must be constant across multiple records (i.e., analytical results) referring to the same sample.



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#### 4.3.2. D.09 - Sample taken size (*sampSize*)

**Definition**: The number of sampling units (i.e., animals) included in the **pooled sample**, independently from the material collected.

**Mandatory:** Under conditions (to be reported for pooled samples)

Data type: Numerical value.

**Note:** To avoid duplication of data, <u>results of pooled samples should only be reported if they are negative and have not been retested individually</u>. If they have been retested individually, the individual results should be reported. For example, if a pooled sample gives a positive result and those samples are retested individually, only the individual results should be reported to avoid duplicated data.

#### 4.3.3. D.09 – Sample taken size unit (sampSizeUnit)

**Definition**: The unit of measurement of the sample size.

**Mandatory**: Under conditions, i.e., becomes **mandatory** when *sampSize* is reported.

Data type: catalogue SAMPUNTYP

**Note**: For the ASF data collection the only admissible value for this data element is '**Animal**' (code 'G199A').

**Example:** reporting a pooled sampled containing material from five pigs using XML syntax:

<sampSize>5</sampSize>
<sampSizeUnit>G199A</sampSizeUnit>

# 4.3.4. D.06 - Year of sampling (*sampY*), D.07 - Month of sampling (*sampM*) and D.08 - Day of sampling (*sampD*)

**Definition**: The year, month, day when the sample was collected.

**Mandatory**: Yes

**Data type**: Numerical variables up to 4 / 2 / 2 digits, respectively.

**Note**: When the sampling was performed over a period of time, the starting date of the procedure should be reported as date of sampling. If this information is not available, the date of acceptance of the sample at the laboratory can be reported instead.

**Example**: reporting a sample taken on 14 June 2022 using XML syntax:

<sampY>2022</sampY> <sampM>6</sampM> <sampD>14</sampD>

#### 4.3.5. D.03 - Country of sampling (*sampCountry*)

**Definition**: The country where the sample was taken.

Mandatory: Yes

**Data type**: Catalogue **Country** 

**Example**: reporting a sample taken in Estonia using XML syntax:

<sampCountry>EE</sampCountry>



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#### 4.3.6. D.04 - Area of sampling (*sampArea*)

**Definition**: The area where the sample was taken, reported according to the level 3 of the NUTS classification (Nomenclature of territorial units for statistics) as published by Eurostat<sup>8</sup>.

Mandatory: Yes

Data type: Catalogue Nuts Gaul – NUTS 3 level codes, hierarchy NUTS2021

**Comment**: The values reported here should be the codes published by Eurostat. These values have been made available in SIGMA EST as a catalogue.

#### 4.3.7. D.12 - Municipality of sampling (*sampMunicipality*)

**Definition**: The Local Administrative Units (LAU) where the sample was taken. The codes of LAUs are published by Eurostat<sup>9</sup>.

**Mandatory**: No

**Data type**: Free text element up to 500 characters.

**Comment**: The values reported here should be the codes published by Eurostat. These values have been made available in SIGMA EST as a catalogue.

#### 4.3.8. D.11 - Additional sample taken information (sampInfo)

This compound data element can be used to provide additional spatial information for the sample. The attributes are:

• The **latitude** (*sampInfo.latitude*) and **longitude** (*sampInfo.longitude*) of the sampling location.

Mandatory: No (but highly recommended)

**Data type:** Numerical – Number of decimals: min = 4, max = 6

**Note**: The longitude and latitude are highly recommended and should be reported in <u>WGS84 format</u>. If a value is reported for longitude, then a value should be reported for latitude and *vice versa*. The dot should be used as decimal separator (see example below)

• The **precision** of the provided coordinates (*sampInfo.coordPrecision*).

**Mandatory**: Under conditions (becomes **mandatory** when the geo-coordinates are provided).

**Data type**: Catalogue **COORDPRE** (see Table 8).

**Table 8:** Applicable values for coordinate precision

Precision	Code	
Centroid Admin	Lat / Lon coordinates of the centroid of the administrative unit	XY01A
Exact	Exact Lat / Lon coordinates	XY03A
Estimated	Estimated Lat / Lon coordinates	XY05A
Unknown	The degree of precision of coordinates is not known	XY04A

**Example**: reporting a wild boar sampled in Cremona, Italy (NUTS3 code ITC4A) with exact information about geocoordinates:

<sampInfo.longitude>10.02613</sampInfo.longitude>

<sampInfo.latitude>45.13350</sampInfo.latitude>

<sampInfo.coordPrecision>XY03A</sampInfo.coordPrecision>

<sampMunicipality>ITC4A-019036</sampMunicipality>

\_

<sup>&</sup>lt;sup>8</sup> https://ec.europa.eu/eurostat/web/nuts/background

<sup>&</sup>lt;sup>9</sup> https://ec.europa.eu/eurostat/web/nuts/background



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#### <sampArea>ITC4A</sampArea>

#### 4.4. Section E – Matrix sampled

The data elements of this section describe the matrix sampled.

#### 4.4.1. E.01 – Type of matrix (sampMatType)

**Definition**: The type of the sample taken.

Mandatory: Yes

Data type: Catalogue MTXTYP

**Note**: For the ASF data collection the only admissible value is '**Animal sample**' (code 'S000A').

**Example:** reporting animal as type of sampled matrix in the XML syntax:

<sampMatType>S000A</sampMatType>

# 4.4.2. E.02 - Coded description of the matrix of the sample taken (sampMatCode)

This compound data element contains encoded values from the MTX catalogue as defined in the FoodEx2 classification system (EFSA, 2011).

According to FoodEx2, it shall contain a base term (mandatory) that can be further defined using facets:

• The **category of matrix** tested (*sampMatCode.base*)

**Mandatory**: Yes

Data type: Catalogue

**Note**: For the ASF data collection the only applicable value is 'NON-FOOD' (code 'A0BYQ').

• F01: the **animal species** (*sampMatCode.source*)

**Mandatory**: Yes

**Data type**: Catalogue **MTX (FoodEx2 Matrix)**, hierarchy *Source* (see Table 9)

**Table 9:** Admissible values for the animal species/source (F01)

Species/source	Code
Pig (as animal)	A16DS
Wild boar (as animal)	A16BX
Wild boar – domestic pig hybrids (as animal)	A16BY

F02: the part of the animal (tissue/material) that is sampled (sampMatCode.part)

**Mandatory**: No

**Data type:** Catalogue **MTX (FoodEx2 Matrix)**, hierarchy *Part-nature* (see Table 10)

**Note**: If several matrices are mixed in one sample (e.g., different lymph nodes from the same animal), a generic code as 'Lymph nodes' can be reported or the value 'Non-food animal related matrices' (code 'AOCEG') which is used to describe the sampled part of the animal when other values are not applicable.

**Table 10:** Admissible values for the sampled part of the animal (F02)

Sampled part	Code
Tonsils	А16НЈ
Lymph nodes	AOCJN
Gastro-hepatic lymph nodes	A18LR
Submandibular lymph nodes	A18LT



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Sampled part	Code
Retropharyngeal lymph nodes	A16YZ
Spleen	A069Q
Liver	A069M
Kidney	A069N
Lung	A069P
Bone tissue	A18LY
Long bone	A18LZ
Short bone	A18MA
Bone marrow	A06AE
Blood	A06AL
Blood anticoagulated	A18LV
Blood clotted	A18LX
Blood serum	AOCEY
Skin	A06AK
Muscle	A069H
Fat	A069J
Salivary glands	A16AA
Heart	A06AC
Stomach	A06AD
Non-food animal related matrices	A0CEG

• F21: the **production system** of the sampled animal (*sampMatCode.prod*)

**Mandatory**: Yes

**Data type**: Catalogue **MTX (FoodEx2 Matrix)**, hierarchy *Production-method* (see Table 11)

**Table 11:** Admissible values for the production system of the sampled animal (F21)

Production system	Description	Code
Farmed	The animal is raised under controlled conditions and not in a wild status	A07RV
Wild	The animal grew in wild conditions	A07RY

• F31: the **age class** of the sampled animal at the time of sampling (*sampMatCode.animage*).

**Mandatory**: Under conditions (becomes **mandatory** for wild animals)

**Data type**: Catalogue **MTX (FoodEx2 Matrix)**, hierarchy *Animal-age-class* (see Table 12)

Note: For the different age classes the respective months are the following: Juvenile – New-

born: <12 months, Juvenile – Immature: 12-24 months, Adult: >24 months

**Table 12:** Admissible values for the age class of the sampled animal (F31)

Age class	Description	Code
Embryo / Unhatched egg	An unborn or unhatched offspring in the process of development	A18GB
Juvenile - New-born	An individual that can be directly and recently linked to the last breeding episode (i.e., individual at nest/den)	A18GC
Juvenile - Immature	A juvenile that has not yet reached the sexual maturity, but is not anymore, a newly born individual.	A18GD
Adult	An individual that has reached full growth or alternatively is capable of reproduction	A18GE
Unknown	The age class of the animal or of the carcass is not known or impossible to assess	A16PN

• F32: the **sex** of the animal (*sampMatCode.gender*)

**Mandatory**: No

**Data type:** Catalogue **MTX (FoodEx2 Matrix)**, hierarchy *Gender* (see Table 13)



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**Table 13:** Admissible values for the sex of the animal (F32)

Gender	Code
Female	A0C8Z
Male	A0C9A

**Example**: reporting a blood (part F02: A06AL) sample of a wild (production F21: A07RY), female (sex F32: A0C8Z), adult (age F31: A18GE), wild boar (species F01: A056Y).

<sampMatCode>A0BYQ#F01.A056Y\$F02.A06AL\$F21.A07RY\$F31.A18GE\$F32.A0C8Z</sampMatCode>

The same code can also be provided as nested XML:

Or it can be provided with the simplified XML tagging:

<sampMatCode.base>A0BYQ</sampMatCode.base>

<sampMatCode.source>A056Y</sampMatCode.source>

<sampMatCode.part>A06AL</sampMatCode.part>

<sampMatCode.prod>A07RY</sampMatCode.prod>

<sampMatCode.animage>A18GE</sampMatCode.animage>

<sampMatCode.gender>A0C8Z</sampMatCode.gender>

#### 4.4.3. E.03 - State of decomposition (sampMatText)

**Definition**: The state of decomposition of the carcass when the sample was taken.

Mandatory: No

Data type: see Table 14

**Example**: reporting sample taken from a decayed animal:

<sampMatText>sampCarcassStatus=A18GG</sampMatText>

Note: This information can only be reported for animals found dead or for road kills.

**Table 14:** Applicable values for state of decomposition

State of decomposition	Description	Code
Fresh stage	The carcass basically does not show signs of decomposition. The time elapsed between the death and the finding / sampling of the carcass is short.	sampCarcassStatus=A18GF
Decayed stage	The typical decomposition processes (bloat, active decay, advanced decay) are ongoing. The time elapsed between the death and the finding / sampling of the carcass is relatively short.	sampCarcassStatus=A18GG
Dry/skeletonised stage	The carcass is essentially reduced to its skeleton and dry skin. The time elapsed between the death and the finding / sampling of the carcass is very long (> 2 years)	sampCarcassStatus=A18GH

#### 4.5. Section F - Sample analysed

This section contains information related to the date of the laboratory analysis.



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# 4.5.1. F.03 - Year of analysis (*analysisY*), F.04 - Month of analysis (*analysisM*) and F.05 - Day of analysis (*analysisD*)

**Definition**: The year, month, day when the analysis was performed.

Mandatory: Yes

**Data type:** Numerical variables up to 4 / 2 / 2 digits, respectively

**Example:** reporting a sample analysed on 9 September 2021 in the XML syntax:

<analysisY>2021</analysisY> <analysisM>9</analysisM> <analysisD>8</analysisD>

#### 4.6. Section H - Sample analysed portion

The data elements belonging to this section provide a set of information related to the portion of the original sample undergoing the analytical test.

#### 4.6.1. H.01 – Sample analysed portion sequence (anPortSeq)

**Definition**: The sequential number assigned to analysis performed on **different portions** of the **same** sample.

Mandatory: No

**Data type**: Free text element up to 100 characters.

**Note**: The data element becomes mandatory when more than one analytical results are reported for the same sample (e.g., one result for ELISA and one for PCR). If left empty, the result identifier (*resId*) is automatically copied here by the DCF.

#### 4.7. Section L - Analytical method

The data elements of this section describe the information related to the analytical methods used in the laboratory.

#### 4.7.1. L.01 - Analytical method identification (anMethRefId)

**Definition**: The identifier of the applied analytical method, at country level.

**Mandatory**: Yes

**Data type**: Free text element up to 50 characters

**Note**: If the applied analytical method is not classified with an id at country level, a dummy identifier can be provided instead.

# 4.7.2. L.03 - Analytical method type (anMethType)

**Definition**: The type of analytical method used on the sample.

**Mandatory**: Yes

Data type: Catalogue ANLYTYP

**Note**: For the ASF collection the only allowed values are 'Screening' (code 'AT06A') and 'Confirmation', (code 'AT08A').

**Example:** Reporting a sample analysed with Screening as analytical method in the XML syntax:

<anMethType>AT06A</anMethType>



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#### 4.7.3. L.04 - Analytical method code (anMethCode)

**Definition**: The diagnostic or analytical methods used in the laboratory to test the specimens.

**Mandatory**: Yes

**Data type**: Catalogue **ANLYMD**, hierarchy *ASFAnlymd* (see Table 15)

**Table 15:** Applicable values for analytical method description

Analytical method description	Code
PCR	F086A
Quantitative polymerase chain reaction (QPCR)	F087A
Enzyme-linked immunosorbent assay (ELISA)	F080A
Immunoblotting (IB)	F151A
Immunoperoxidase test (IPT)	F590A
Molecular characterisation/Genotyping method	F089A
Tissue culture infection test	F563A
Direct fluorescent antibody test (FAT)	F694A

# 4.7.4. L.06 - Additional information on the analytical method - Test sensitivity (anMethInfo.methSensitivity), L.07 - Additional information on the analytical method - Test specificity (anMethInfo.methSpecificity)

**Definition**: The diagnostic sensitivity and the diagnostic specificity of the laboratory test. The diagnostic sensitivity of the laboratory test expresses the probability that the method returns a positive result given that the sample is truly positive. The diagnostic specificity of the laboratory test expresses the probability that the method returns a negative result given that the sample is truly negative.

Mandatory: No

Data type: Numeric value

**Note**: The values are expressed in probabilistic terms, ranging from 0 to 1.

#### 4.8. Section N – Evaluation

The data elements in this section contain information about the laboratory executing the analysis.

#### 4.8.1. J.01 - Laboratory identification code (labId)

**Definition**: The identification code of the laboratory conducting the analysis.

**Mandatory**: Under conditions (becomes **mandatory** if the *labCountry* is reported)

**Data type**: Free text element up to 50 characters

**Note**: This code should be nationally unique and consistent through all data domain transmissions.

#### 4.8.2. J.03 - Laboratory country (*labCountry*)

**Definition**: The country where the analysis laboratory is located.

Mandatory: No

Data type: Catalogue Country

#### 4.9. Section K – Parameter

The data elements belonging to this section describe the target parameters for which samples have been analysed.



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#### 4.9.1. K.01 - Type of parameter (*paramType*)

**Definition**: The type of the parameter reported for the examined sample.

Mandatory: Yes

Data type: Catalogue PARAMTYP

Note: For the ASF data collection the only admissible value is 'Individual' (code 'P001A')

**Example**: reporting the type of the parameter with the default value 'Individual' in the XML syntax:

<paramType>P001A</paramType>

#### 4.9.2. K.02 - Coded description of parameter code (*paramCode*)

**Definition**: The description of the analytical parameter targeted by the performed test.

**Mandatory**: Yes

Data type: Catalogue PARAM

**Note**: In the ASF data collection the only admissible values are the generic code for African Swine fever virus (code 'RF-00002657-MCG') and its genotypes present in Europe (code 'RF-00012057-PAR' for African swine fever virus - genotype I, code 'RF-00012058-PAR' for African swine fever virus - genotype II).

**Example**: reporting the analytical parameter for African Swine fever virus in the XML syntax:

<paramCode>RF-00002657-MCG</paramCode>

#### 4.10. Section M – Result

The data elements belonging to this section provide a set of information related to the outcome of the performed analysis.

#### 4.10.1. M.01 - Result identification code (*resId*)

**Definition**: The unique record identifier of a single test result.

Mandatory: Yes

**Data type**: Free text element up to 100 characters.

**Note**: The result identification code must be assigned by the data provider and be unique at organisation level for a specific data collection. The result identification code needs to be used to identify records during potential corrections performed through an amendment operation (see section 4.11) performed by the data provider if needed.

#### 4.10.2. M.16 - Type of result (*resType*)

**Definition**: The type of result (qualitative/quantitative). In the context of the ASF data collection, only qualitative results can be reported and, therefore, the only applicable value is 'BIN'.

**Mandatory**: Yes

Data type: Catalogue VALTYP

**Note**: For the ASF data collection the only applicable value is 'Qualitative' (code 'BIN').

#### 4.10.3. M.15 - Result qualitative value (*resQualValue*)

**Definition**: Indication of the qualitative test result (POS/NEG).

**Mandatory**: Yes

**Data type**: Catalogue **POSNEG**, hierarchy *tseTestResult* (see Table 16).



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**Example**: reporting a negative result of a performed test in the XML syntax:

<resOualValue>NEG</resOualValue>

Table 16: Admissible values for the result qualitative value

Value	Description	Code
Positive/Present	The pathogen / the genetic material / the antigens / the antibodies are found in the sample.	POS
Negative/Absent	The pathogen / the genetic material / the antigens / the antibodies are NOT found in the sample.	NEG
Inconclusive	The method was not conclusive regarding the detection of the pathogen or antibodies in the sample	INC

#### 4.11. Amendment operations

#### 4.11.1. Amendment type (amType)

This data element is **optional**. It allows RCs to modify records of datasets which are 'ACCEPTED DWH'. As defined in the GDE2 (EFSA, 2014), a dataset enters the 'Accepted DWH' state when the reporting officer accepts the submitted dataset. The accepted datasets will be used in EFSA outputs. This state is a final state for the dataset, which cannot be modified thereafter. If an amendment to the content is needed, the data provider shall upload a new dataset with the insert operation to perform an 'amendment operation' on the records already loaded in the DWH.

Amendment operations are transmitted as new datasets.

The field 'amType' (amendment type) must be used to specify which type of amendment is requested by the data provider for each of the records to be amended. The records are identified by the record unique identifier (see the *resId* element described in Section 4.9.1).

The amendment operations supported by the system are the following:

- amType = 'U' (update):
  - This operation is used to update records in the database.
  - This operation will result in a new version of the record in the database.
- amType = 'D' (delete):
  - This operation is used to perform a deletion of accepted records in the database.
  - The records flagged as 'deleted' will reach their final status in the DWH and can no longer be modified.



# 5. EFSA business rules applied for data reported on ASF

Table 17 describes the business rules that are applied during transmission of the laboratory data on ASF. Please note that during the reporting season business rules might be slightly modified in case discrepancies or inconsistencies are reported to EFSA. DCF provides always the most up-to-date list of business rules.

Table 17: Data element names of the SSD2 model and related business rules for transmission of ASF laboratory data

Element code	Element label	Error type	Error code	Rule description	Error Message
K.01	paramType	error	ASF01	The only allowed value for paramType is 'Individual' (code 'P001A').	The specified type of parameter (paramType) is not applicable.
E.01	sampMatType	error	ASF02	The only allowed value for sampMatType is 'Animal sample' (code 'S000A').	The specified type of matrix (sampMatType) is not applicable.
C.02	SampUnitType	error	ASF03	The only allowed value for sampUnitType is 'Animal' (code 'G199A').	The specified sampling unit type (sampUnitType) is not applicable.
E.02	sampMatCode.base	error	ASF04	The only allowed value for sampMatCode.base is 'Non-food matrices' (code 'A0BYQ').	The specified sampMatCode.base is not applicable.
E.02	sampMatCode.prod	error	ASF05	sampMatCode.prod must be reported.	The production system (sampMatCode.prod) has not been reported, though mandatory.
E.02	sampMatCode.prod	error	ASF06	The only allowed values for sampMatCode.prod are 'Farmed' (code 'A07RV') or 'Wild' (code 'A07RY').	The specified production system (sampMatCode.prod) is not applicable.
E.02	sampMatCode.source	error	ASF07	The animal species (sampMatCode.source) must be reported.	The animal species (sampMatCode.source) has not been reported, though mandatory.
E.02	sampMatCode.source	error	ASF08	The only allowed values for the animal species (sampMatCode.source) are pig (code 'A057F') or wild boar (code 'A056Y') or wild boar - domestic pig hybrids (code 'A16AB').	The specified animal species (sampMatCode.source) is not applicable.
D.11 D.11 D.11	sampInfo.coordPrecision sampInfo.longitude sampInfo.latitude	error	ASF09	If the coordinates of the sample are provided (i.e., sampInfo.latitude and sampInfo.longitude are reported), then the precision of the coordinates (sampInfo.coordPrecision) must be reported.	The precision of the coordinates (sampInfo.coordPrecision) is not reported, though the coordinates (i.e., sampInfo.latitude, sampInfo.longitude) are provided.
D.11 D.11	sampInfo.longitude sampInfo.latitude	error		If a value is reported for longitude (sampInfo.longitude), then a value should be reported for latitude (sampInfo.latitude).	The latitude (sampInfo.latitude) is missing, though the longitude (sampInfo.longitude) is reported.
D.11 D.11	sampInfo.longitude sampInfo.latitude	error	ASF10b	If a value is reported for latitude (sampInfo.latitude), then a value should be reported for longitude (sampInfo.longitude).	The longitude (sampInfo.longitude) is missing, though the latitude (sampInfo.latitude) is reported.
K.02	paramCode	error	ASF11	The paramCode should be 'African Swine Fever virus' (code 'RF-00002657-MCG') or one of its genotypes.	The specified paramCode is not 'African Swine Fever virus' (code 'RF-00002657-MCG') or one of its genotypes.
B.08	progInfo.targetGroup	error	ASF12	progInfo.targetGroup must be reported.	The target group (progInfo.targetGroup) has not been reported, though mandatory.



Element code	Element label	Error type	Error code	Rule description	Error Message
B.02 B.04	progLegalRef progType	error	ASF13	If the programme type (progType) is an EU programme, then the legal reference (progLegalRef) must be reported.	The legal reference (progLegalRef) is not reported, though the programme type (progType) is an EU programme.
D.01 C.05	sampId sampUnitIds.animalId	error	ASF14	The animal identifier (sampUnitIds.animalId) shall be constant for all records with the same sample identifier (sampId).	For the same sample (sampId), different animal identifiers (sampUnitIds.animalId) have been provided.
C.01 C.05	sampEventId sampUnitIds.animalId	error	ASF15	The animal identifier (sampUnitIds.animalId) shall be constant for all records with the same sampling event identifier (sampEventId).	For the same sampling event (sampEventId), different animal identifiers (sampUnitIds.animalId) have been provided.
B.08	progInfo.com	error	ASF16	If a value is provided for progInfo.com, it should be one of the following: Freedom from disease (FFD) or Outbreak containment (CONT) or Detection (DET).	The specified progInfo.com is not one of the following: Freedom from disease (FFD) or Outbreak containment (CONT) or Detection (DET).
E.02 E.02	sampMatCode.animage sampMatCode.prod	error	ASF18	The age of the animal (sampMatCode.animage) must be reported for wild animals (i.e., when sampMatCode.prod equal to 'A07RY').	The age of the animal (sampMatCode.animage) has not been reported, though mandatory for wild animals (i.e., when sampMatCode.prod equal to 'A07RY').
E.02	sampMatCode.animage	error	ASF19	The only allowed values for the animal age (sampMatCode.animage) in SIGMA data collections are Embryo/Unhatched egg (A18GB) or Juvenile – new-born (A18GC) or Juvenile - immature (A18GD) or Adult (A18GE) or Unknown (A16PN).	The specified animal age (sampMatCode.animage) is not applicable.
B.08 E.03	progInfo.targetGroup sampMatText	error	ASF20	The decomposition status (sampMatText) can only be reported for animals that were found dead (progInfo.targetGroup equal to 'TG020A' or one of its children) or road kills (progInfo.targetGroup equal to 'TG009A').	The decomposition status (sampMatText) has been reported, though the animal was not found dead (progInfo.targetGroup not equal to `TG020A' or one of its children) or road kills (progInfo.targetGroup not equal to `TG009A').
E.03	sampMatText	error	ASF21	If a value is provided for decomposition status (sampMatText), it should be one of the following: Fresh stage ('sampCarcassStatus=A18GF') or Decayed stage ('sampCarcassStatus=A18GG') or Dry/skeletonised stage ('sampCarcassStatus=A18GH').	The specified decomposition status (sampMatText) is not applicable.
L.04	anMethCode	error	ASF22	The analytical method (anMethCode.base) must be reported.	The analytical method (anMethCode.base) has not been reported, though mandatory.
L.03	anMethType	error	ASF25	The only allowed values for type of analytical method (anMethType) are 'Screening' (AT06A) and 'Confirmation' (AT08A).	The specified type of analytical method (anMethType) is not applicable.
E.02	sampMatCode.gender	error	ASF26	The only allowed values for the sex of the animal (sampMatCode.gender) are 'Female' (A0C9A) and 'Male' (A0C8Z).	The specified sex of the animal (sampMatCode.gender) is not applicable.

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Element code	Element label	Error type	Error code	Rule description	Error Message
D.11	sampInfo.coordPrecision	error	ASF27	The only allowed values for the precision of the sample coordinates (sampInfo.coordPrecision) are 'Centroid of area' (XY01A), 'Exact location' (XY03A), 'Near location' (XY05A) and 'Unknown' (XY04A).	The specified precision of the sample coordinates (sampInfo.coordPrecision) is not applicable.
E.02	sampMatCode.part	error	ASF30	The only allowed values for the sampled part of the animal (sampMatCode.part) are tonsils (A16HJ), lymph nodes (A0CJN), retropharyngeal lymph nodes (A16YZ), spleen (A069Q), liver (A069M), kidney (A069N), lung (A069P), bone marrow (A06AE), blood (A06AL), blood serum (A0CEY), skin (A06AK), muscle-meat (A069H), fat (A069J), salivary glands (A16AA), heart (A06AC), stomach (A06AD), non-food animal-related matrices (A0CEG).	The specified sampled part of the animal (sampMatCode.part) is not applicable.
D.12	sampMunicipality	error	ASF31	If a value is reported for the municipality where the sample was taken (sampMunicipality), it should not be 'VALUE NOT FOUND'.	The specified municipality (sampMunicipality) is not valid. Check the catalogue mapping in SIGMA EST.
C.02 E.02 E.02 E.02 E.02 E.03	sampEventId sampMatCode.source sampMatCode.prod sampMatCode.animage sampMatCode.gender sampMatText	error	ASF32	The combination of values in animal species (sampMatCode.source), production (sampMatCode.prod), age (sampMatCode.animage), sex (sampMatCode.gender) and decomposition status (reported in sampMatText) should be constant for all records with the same sampEventId (representing one animal).	The combination of values in sampMatCode.source, sampMatCode.prod, sampMatCode.animage, sampMatCode.gender and sampMatText are not constant for all records with the same sampEventId (representing one animal).
E.02 E.02	sampMatCode.source sampMatCode.prod	error	ASF33	If the value reported in animal species (sampMatCode.source) is 'Pig' (AI6DS) the production system (sampMatCode.prod) cannot be 'Wild' (A07RY).	The specified production system (sampMatCode.prod) value 'Wild' (A07RY) is not applicable when the value reported in animal species (sampMatCode.source) is 'Pig' (AI6DS).
E.02 B.08	sampMatCode.source progInfo.targetGroup	error	ASF34	If the value reported in animal species (sampMatCode.source) is 'Pig' (AI6DS) the target group (progInfo.targetGroup) cannot be 'Hunted' (TG027A).	The specified target group (progInfo.targetGroup) value 'Hunted' (TG027A) is not applicable when the value reported in animal species (sampMatCode.source) is 'Pig' (AI6DS).
D.09 M.15	sampSize resQualValue	error	ASF35	The qualitative value of the result (resQualValue) must be 'Negative' (code 'NEG') when a value is reported in the element number of sampling units included in the pooled sample (sampSize).	The specified value of the qualitative result (resQualValue) is not applicable for pooled samples (i.e., when a value is reported in sampSize).
D.01 B.08	sampId progInfo.targetGroup	error	ASF36	The value reported for the target group (progInfo.targetGroup) must be consistent for all the records with the same sampId (representing one animal or one pooled sample).	The combination of values reported in sampId and progInfo.targetGroup are not consistent for all the records with the same sampId (representing one animal or one pooled sample).



Element code	Element label	Error type	Error code	Rule description	Error Message
B.08 B.03	progInfo.targetGroup sampStrategy	error	ASF37	If the value reported in target group (progInfo.targetGroup) is 'Road kills' (TG009A) or 'Found dead' (TG020A) or 'Dead Symptomatic' (TG025) or 'Dead Non-symptomatic' (TG026A) the only allowed values for sampling strategy (sampStrategy) are 'Convenient sampling - Accidental sampling' (ST43A) or 'Selective sampling - Risk Based (ST21A) or Selective sampling - Biologically driven (ST22A).	The specified value for sampling strategy (sampStrategy) is not applicable when the value reported for target group (progInfo.targetGroup) is 'Road kills' or 'Found dead' or 'Dead Symptomatic' or 'Dead Non-symptomatic'.
B.08 B.03	progInfo.targetGroup sampStrategy	error	ASF38	If the value reported in target group (progInfo.targetGroup) is 'Hunted' (TG027A) or 'Hunted Symptomatic' (TG018A) or 'Hunted Non-symptomatic' (TG019A) the only allowed values for sampling strategy (sampStrategy) are 'Selective sampling - Risk Based (ST21A) or Selective sampling - Biologically driven (ST22A) or 'Convenient sampling - Testing the game bag at game handling establishment' (ST41A).	The specified value for sampling strategy (sampStrategy) is not applicable when the value reported for target group (progInfo.targetGroup) is 'Hunted' or 'Hunted Symptomatic' or 'Hunted Nonsymptomatic'.
B.08 B.03	progInfo.targetGroup sampStrategy	error	ASF39	If the value reported in target group (progInfo.targetGroup) is 'Alive' (TG024A) or 'Alive Symptomatic' (TG016A) or 'Alive Nonsymptomatic' (TG017A) the only allowed values for sampling strategy (sampStrategy) are 'Selective sampling - Risk Based (ST21A) or Selective sampling - Biologically driven (ST22A) or 'Objective - Simple Random Sampling' (ST44A) or 'Objective - Clustered Sampling' (ST45A) or 'Census' (ST50A).	The specified value for sampling strategy (sampStrategy) is not applicable when the value reported for target group (progInfo.targetGroup) is 'Alive' or 'Alive Symptomatic' or 'Alive Nonsymptomatic'.
B.08 B.03	progInfo.targetGroup sampStrategy	error	ASF40	If the value reported in target group (progInfo.targetGroup) is 'Slaughtered' (TG028A) the only allowed values for sampling strategy (sampStrategy) are 'Selective sampling - Risk Based' (ST21A) or 'Selective sampling - Biologically driven' (ST22A) or 'Objective - Simple Random Sampling' (ST44A) or 'Objective - Clustered Sampling' (ST45A) or 'Census' (ST50A).	The specified value for sampling strategy (sampStrategy) is not applicable when the value reported for target group (progInfo.targetGroup) is 'Slaughtered'.
B.08 B.03	progInfo.targetGroup sampStrategy	error	ASF41	If the value reported in target group (progInfo.targetGroup) is 'Culled' (TG029A) the only allowed values for sampling strategy (sampStrategy) are 'Selective sampling - Risk Based' (ST21A) or 'Selective sampling - Biologically driven' (ST22A).	The specified value for sampling strategy (sampStrategy) is not applicable when the value reported for target group (progInfo.targetGroup) is 'Culled'.

### **Abbreviations**

ASF African Swine Fever

DCF Data Collection Framework

EFSA European Food Safety Authority

EC European Commission

GDE2 Guidance on Data Exchange ver. 2.0
GDPR General Data Protection Regulation

LAU Local Administrative Units

LIMS Laboratory Information Management System

MS Member State

NUTS Nomenclature of territorial units for statistics

RC Reporting country

S-DWH EFSA Scientific Data Warehouse

XML eXtensible Markup Language

XSD XML Schema Definition

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