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Protocol for the descriptive epidemiological analysis on African swine fever

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Abstract

This technical report describes the protocol for the first Term of Reference (TOR 1) of the European Commission request for the scientific and technical assistance on African swine fever (ASF). This TOR 1 requests annual descriptive epidemiological analysis of the spread and impact of ASF in the domestic pig and wild boar populations in the affected EU Member States and neighbouring countries. This report presents the interpretation of the TOR, the questions and elements of the mandate, and the data and methods chosen to address those questions. The ASF epidemiological reports to be produced from 2023 to 2028 will include data from six different sources to address: i) the surveillance activities performed for ASF and their performance; iii) the spatial and temporal dynamics of the disease in the last year, and iii) the impact of the disease in domestic pigs and wild boar populations.

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Summary

In 2022, EFSA received a new request from the European Commission for the scientific and technical assistance on African swine fever (ASF). The first Term of Reference (TOR1) of this request asks for annual descriptive epidemiological analysis of the spread and impact of ASF in the domestic pig and wild boar populations in the affected EU Member States and neighbouring countries. The TOR 2 will result in biannual reports analysing the risk factors involved in the occurrence, spread and persistence of ASF. Considering that these TOR are going to be published in separate outputs, require different methodologies and have different timelines, two different protocols are developed.

Therefore, this technical report focuses on the protocol for annual epidemiological analysis of ASF from 2023 to 2028 (TOR 1). It covers the different steps of the problem formulation, from the interpretation of the TORs and mandate elements to the translation of those into assessment questions and methodology chosen to address those questions. The epidemiological reports will address the three mandate elements identified: i) the surveillance activities performed for ASF and their performance; iii) the spatial and temporal dynamics of the disease in the last year and, iii) the impact of the disease in domestic pigs and wild boar populations.

To elaborate the reports, six different data sources are used: a) ASF laboratory results on samples collected from domestic pigs and wild boars, submitted by affected countries to the Data Collection Framework (DCF) of EFSA; b) data on the domestic pig population (location of pig establishment type of establishment, number of animals, etc.) submitted by affected countries to the DCF; c) data on ASF Genotype II outbreaks notified to the EU Animal Diseases Information System (ADIS); d) data on annual wild boar hunting bags (number of harvested animals per km²) that was collected by ENETWILD Consortium, e) modelled wild boar abundance as published in ENETWILD Consortium, 2022 and, f) data on EU restricted zones measures for ASF.

All data sources are used and combined to produce tables, maps and graphs that summarise the evolution of the disease, surveillance efforts, incidence, etc. All the graphs, maps and analyses included in the report were carried out using the statistical software R. To ensure reproducibility of the analyses and speed up the elaboration of the reports, a specific online application was developed using R shiny package accessible in R4EU platform.



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1 Introduction

1.1 Background and terms of reference as provided by the requestor

African swine fever is caused by a highly virulent virus of the Asfviridae family, which in Europe affects wild boar (*Sus scrofa*) and domestic pigs leading to almost 100% lethality of infected individuals. It can be transmitted via direct animal contact, via indirect contact through contaminated food, equipment and other materials, or via soft ticks of genus *Ornithodoros*. The transmission via competent arthropod vectors has not been demonstrated in Europe. This disease has serious economic implications for the pig meat and related sectors, including indirect costs related to trade restrictions. There is no vaccine or cure despite active ongoing research. The persistence of the disease in wild boar represents a challenge for the whole European Union (EU) agricultural sector, in particular the pig farming industry.

After its first appearance in the European Union in 2014, Genotype II of ASFV has been notified by Lithuania, Estonia, Latvia, Poland, Czech Republic, Hungary, Romania, Bulgaria, Belgium, Slovakia, Greece, Germany and Italy. In addition, the disease has been reported outside the EU in Belarus, North Macedonia, Moldova, Serbia, Russian Federation and Ukraine, which creates a constant risk for all the Member States that share a border with these third countries. In addition, since 2018 ASF is present in many Asian countries and in 2021 the disease entered as well into the Americas, affecting Dominican Republic and Haiti, increasing the global risk of future spread to other unaffected areas of the world.

Despite the fact that three of the EU affected countries managed to eradicate ASF, namely the Czech Republic (recognised as officially ASF-free in March 2019), and Belgium (recognised as officially ASF-free in October 2020) and Greece that reported and eradicated one single outbreak in domestic pigs in February 2020, there is a risk of re-introduction into those territories, as well as in previously unaffected areas of the EU. This was confirmed by the unexpected introduction of the ASF genotype II in mainland Italy in January 2022.

There is knowledge, legislation, technical and financial tools in the EU to properly control ASF. EU legislation primarily targets domestic pigs and, when needed, lays down specific aspects related to wild boar. The main pieces of the EU legislation relevant for ASF are:

1. Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law').
2. Commission Delegated Regulation (EU) 2020/6874 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases.
3. Commission Implementing Regulation (EU) 2021/605 of 7 April 2021 laying down special control measures for African swine fever (ASF Regulation)

In addition, a strategic approach to the management of ASF for the EU has been developed based on earlier scientific recommendations by EFSA. However, considering the rapid evolution of the epidemiological situation of ASF in Europe (and in the world), the important developments in science and the new experiences gained in affected territories, it is essential to continue updating this strategy. The ASF strategic approach is aimed to the EU countries affected by the disease, as well as to those EU countries free from the disease with a risk of introduction. Still, several questions remain unclear about the risk and main factors involved in ASF introduction, maintenance and spread in susceptible populations, both domestic pigs and wild boar.



The resources that need to be made available for eradication programs are most of the time limited, for this reason understanding which strategy or combination of strategies is more likely to be effective in ASF eradication is a fundamental prerequisite to allocate resources, to draft policies, and to evaluate them in an adaptive management framework.

The Commission is in need of regular updated epidemiological analysis of the ASF evolution, based on the data collected from the Member States affected by ASFV Genotype II. In addition, updated insights on the risk factors involved in ASF introduction into new territories, disease spread and persistence in Europe are required to be able to update the disease prevention, control and management policies.

These analyses should take into account the knowledge acquired in previous EFSA opinions and scientific reports on ASF. The analyses will be based on data collected by Member States and submitted to the EFSA Data Collection Framework on ASF surveillance and pig population data, in line with Art 33(3) of Regulation (EC) no 178/2002. Also, existing mechanism to estimate the wild boar population data should be also employed in the analyses. The analyses will include data from EU and non-EU neighbouring countries shared with EFSA through data collection mechanisms already established. EFSA is requested to develop interactive dashboards to allow the consultation of the data submitted by the Member States in the form of graphs and maps. Also, EFSA is requested to draft two scientific reports using those data and additional sources of information, as well as expert elicitations, with the support of the ASF working group of experts. The two scientific reports will cover Terms of Reference (TOR) 1 and TOR 2 starting in 2022 and continue in an iterative manner up to 2028 with yearly deliverables, as detailed in the TOR here below, until the ASF Regulation will cease its applicability (20 April 2028).

According to Article 29 of Regulation (EC) No. 178/2002, EFSA can be requested to provide ad hoc Scientific Opinions. The need to drafting such ad hoc Scientific Opinions could arise from the conclusions and recommendations of the above-mentioned scientific reports.

2 Terms of Reference as provided by the requestor

In the context of Article 31 of Regulation (EC) No. 178/2002, EFSA should provide technical and scientific assistance to the Commission and deliver once per year a Scientific Report for TOR 1 and every two years a Scientific Report for TOR 2, as described here below:

1. Provide a descriptive epidemiological analysis of the spread and impact of ASF in the domestic pig and wild boar populations in the affected countries in the EU Member States and neighbouring countries affected by ASF, including a description and better understanding of the:
 - a. Spatio-temporal dynamics of the disease during the reporting period;
 - b. Disease monitoring parameters, such as incidence;
 - c. Disease characteristics in wild boar and domestic pig populations, such as the mortality and the seasonality observed during the reporting period.
2. Review, identify and describe risk factors involved in the occurrence, spread and persistence of the ASF virus in the wild boar population and in the domestic pig population flagging the emergences of new risks factors, with a view to inform risk management and enable the preparation of future risk assessment mandates.



3 Problem formulation

3.1 Interpretation of the Terms of Reference (TOR)

Considering that the two TOR provided by the requestor are going to be published in separate outputs, require different methodologies and have different timelines (TOR 1 will produce annual reports starting from 2023, while TOR 2 will result in biannual reports starting in 2024), two separate protocols will be developed. This protocol addresses only the TOR 1 of the request for scientific and technical assistance on ASF.

Based on the background provided by the EC, the epidemiological assessment will be mainly based on the data collected on ASF surveillance activities and pig population, following SIGMA data model standards through the Data Collection Framework (DCF). This data will be complemented by outbreak data, wild boar related data and restricted zones data for certain analysis as described below.

Data collection period: The data collection will cover the period from the end of the previous epidemiological report until the 31st December. Consequently, the first-year report (2023) will cover the period from September 2021 to December 2022, and subsequent reports will cover the calendar years (from January to December). Data collected previously by EFSA will be used to generate the temporal trends and other time data analyses.

Data submission: Data will be submitted to EFSA's DCF at least once per year by affected countries. The deadline for data submission will be at the end of January of the year after the sampling year. Data submission twice per year might be requested, if considered necessary.

Report schedule: The epidemiological reports will be produced every calendar year in April. Therefore, although for the first report the collected data refer to samples taken starting from September 2021, the focus will be on the calendar year (2022). From then onwards, data will be collected and analysed on calendar year basis.

Targeted countries: The countries included in the report will be those EU Member States and neighbouring countries affected by ASFv Genotype II in the period of analysis that voluntarily submitted data to EFSA. Previously affected countries that became free of the disease before that period will be excluded from the analysis. Sardinia (Italy), affected by Genotype I of ASFv will not be considered in these reports neither due to the important differences in the epidemiological situation. From now herein, the group of ASF affected countries contributing in the report will be named 'affected countries'.

3.2 Interpretation of the mandate elements

The TOR 1 requests a descriptive epidemiological analysis of ASF, including the evaluation of the spread and impact that the disease caused in the ASF affected countries. The mandate specifies the three elements expected in this analysis, namely 'spatial and temporal dynamics of the disease', 'disease monitoring parameters' and 'disease characteristics in domestic pigs and wild boar'.

For report clarity, it was agreed to start the report addressing the mandate element 'disease monitoring parameters', herein known as '**disease surveillance**'. For this work, the Working Group on ASF (WG) understands this element as the characterization of the surveillance activities performed in the reporting period per country, including details, such as the surveillance strategy used (passive, active, risk-based), efforts of the different surveillance components, type of tests used, and type



of animal sampled. The original mandate element mentioned incidence as one of the monitoring parameters. However, considering the structure proposed for the report, it was agreed to address the incidence analysis in the third mandate element 'disease characteristics, a.k.a. 'disease impact'.

The second mandate element is the '**spatial and temporal dynamics of the disease**', which was understood as the study of the disease dynamics in the reporting period. This section will include the geographical analysis, the temporal characteristics of the disease (seasonality and temporal evolution since the first introduction), and the speed of spread in wild boar by estimation of secondary cases. These analyses will be complemented by the identification and description of specific long-distance translocation events of epidemiological concern, which occurred during the reporting period.

The third mandate element addresses the description of the '**disease characteristics in wild boar and domestic pig populations**, such as the mortality and the seasonality observed during the reporting period'. As previously mentioned, the seasonality will be addressed in the spatial and temporal dynamics, together with all the other measurements of disease spread. Therefore, this mandate element was understood as the evaluation of the impact of ASF in the affected populations, domestic pigs and wild boar. Henceforth, this element will be referred as '**disease impact**'. This last element will include summary statistics of the number of outbreaks, their size and animals lost due to ASF outbreaks, spatial distribution of ASF incidence, estimation of the areas restricted due to ASF and the temporal evolution of estimated wild boar abundance and harvest.

3.3 Translation of TOR into assessment questions and sub-questions (using APRIO)

Step 1: Formulate the problem

Steps 1.1: Translate mandate into assessment question

Following the Technical report on Problem Formulation (Risk Sciences International, 2022), the APRIO approach was used to formulate the assessment question and subsequent sub-questions to be answered in this TOR. The process for questions formulation can be found in Table 1.

The main question to be addressed by this scientific report is: '**How did ASF spread and what was its impact in the affected EU Member States and neighbouring countries in the last year¹?**'.

¹ Despite the data collection period, the epidemiological report will be focused in the last calendar year events.



Step 1.2: Define the sub-questions of each assessment question and their relationship (conceptual model)

Following the assessment elements mentioned in the TOR 1, this assessment question was broken down into three higher order sub-questions and five lower order sub-questions.

Table 1: APRIO elements for formulating the assessment question and sub-questions

Mandate element	Agent	Pathway	Receptor	Intervention	Output	Lower or higher order sub-questions
Descriptive epidemiological analysis of ASF	ASFV	All forms of transmission (direct and indirect)	European swine population (domestic pigs and wild boar)	Collection of ASF surveillance data Collection of ASF outbreak data Collection of swine population data Collection of information from affected countries on surveillance activities and control measures applied Collection of wild boar hunting data	Epidemiological analysis of the spread and impact of ASF in the affected countries in the last year	AQ: How did ASF spread and what was its impact in the affected countries the last year?
1. Disease surveillance	ASFV	All forms of transmission (direct and indirect)	European swine population (domestic pigs and wild boar)	Collection of ASF surveillance data and information on surveillance activities from the affected countries Collection of wild boar abundance information	Characterization of ASF surveillance activities and their performance in ASF affected countries	SQ1: How was ASF surveillance conducted and how did it perform in affected countries in the last year?
2. Spatial and temporal dynamics	ASFV	All forms of transmission (direct and indirect)	European swine population (domestic pigs and wild boar)	Collection of ASF surveillance data Collection of ASF outbreak data Collection of swine population data	Assessment of spatial and temporal dynamics of ASF in the affected countries in the last year	SQ2: What were the dynamics of ASF spread in affected countries in the last year?
Spatial dynamics	ASFV	All forms of transmission (direct and indirect)	European swine population (domestic pigs and wild boar)	Collection of ASF surveillance data Collection of ASF outbreak data	Assessment of spatial spread of ASF	SQ2.1: What were the spatial characteristics of ASF spread in affected countries in the last year?
Temporal dynamics	ASFV	All forms of transmission (direct and indirect)	European swine population (domestic pigs and wild boar)	Collection of ASF surveillance data Collection of ASF outbreak data	Assessment of temporal dynamics	SQ2.2: What were the temporal characteristics of ASF dynamics in affected countries in the last year?
Secondary cases	ASFV	All forms of transmission (direct and indirect)	European swine population (domestic pigs and wild boar)	Collection of ASF outbreak data	Assessment of ASF secondary cases in wild boar in affected populations per country	SQ2.3: Which was the number of ASF secondary cases in wild boar in affected countries in the last year?



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3. Disease impact	ASFV	All forms of transmission (direct and indirect)	European swine population (domestic pigs and wild boar)	Collection of ASF surveillance data Collection of swine population data Collection of wild boar hunting data	Assessment of ASF impact in affected populations	SQ3: What was the impact of ASF in affected countries in the last year?
Impact of ASF in domestic pigs	ASFV	All forms of transmission (direct and indirect)	European domestic pig population	Collection of ASF surveillance data Collection of swine population data	Assessment of ASF impact on domestic pigs in affected countries	SQ3.1: What was the impact of ASF in domestic pigs in affected countries in the last year?
Impact of ASF in wild boar populations	ASFV	All forms of transmission (direct and indirect)	European wild boar population	Collection of ASF surveillance data and wild boar hunting data	Assessment of ASF impact on wild boar population in affected countries	SQ3.2: What was the impact of ASF in wild boar population in affected countries in the last year?



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Step 1.3: Select the approach to be followed

For all the sub-questions defined before, a quantitative approach will be followed, that will be complemented with qualitative assessment of the evidence.

Step 2. Plan the methods for conducting the assessment

Table 2: Assessment methods chosen to address the mandate sub-questions

Mandate elements	Sub question	2.1 Evidence needs	Data collection	2.2. Assessment methods to be used
1. Disease surveillance	SQ1: How was ASF surveillance conducted and how did it perform in affected countries in the last year?	Information on ASF surveillance strategies ASF surveillance data Wild boar modelled abundance data	Questionnaire on surveillance strategies sent to affected countries SIGMA laboratory data Wild boar abundance data	<ul style="list-style-type: none"> - Description of ASF surveillance activities in affected countries, including indicators on the performance of the different surveillance components (e.g. active, passive, dead animals, road kills). - Summary table of surveillance samples and positive results by type of surveillance, laboratory test and population tested in affected countries. - Maps of surveillance samples in wild boar in relation with the abundance of wild boar per NUTS 3.
2. Spatial and temporal dynamics	SQ2.1: What were the spatial characteristics of ASF spread in affected countries in the last year?	Information on potential pathways for virus translocation ASF outbreak data Information on ASF restricted zones	Request of information to affected countries ASF outbreak data	<ul style="list-style-type: none"> - Maps of ASF geographical spread in Europe highlighting relevant changes and disease spread. - Description of long-distance translocation events of epidemiological relevance and insights on the pathways of virus introduction.
	SQ2.2: What were the temporal characteristics of ASF dynamics in affected countries in the last year?	ASF surveillance data ASF outbreak data	SIGMA laboratory data ASF outbreak data	<ul style="list-style-type: none"> - Temporal evolution of ASF notifications in domestic pigs and wild boar. - Time-profile of monthly positive rate by laboratory test (ELISA and PCR) in domestic pigs and wild boar by type of surveillance (active vs passive). - Monthly seasonality of ASF in the relevant target species (domestic pigs and wild boar) per country.
	SQ2.3: Which was the number of ASF secondary	ASF outbreak data	ASF outbreak data	<ul style="list-style-type: none"> - Network analysis of ASF outbreaks to identify secondary cases in wild boar population.



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cases in wild boar in affected countries in the last year?

3. Disease impact	SQ3.1: What was the impact of ASF in domestic pigs in affected countries in the last year?	ASF outbreak data Domestic pig population data Information on ASF restricted zones	ASF outbreak data SIGMA population data Restricted zones data	- Summary statistics of outbreaks, incidence of affected farms and proportion of pigs lost by ASF per farm size. - Assessment of areas restricted due to ASF in domestic pigs in affected countries. - Maps of incidence of affected farms and proportion of pigs lost per NUTS 3 in affected countries in the last year.
	SQ3.2: What was the impact of ASF in wild boar population in affected countries in the last year?	ASF outbreak data Wild boar hunting bags and other abundance indicators data Information on wild boar hunting management Information on ASF restricted zones	ASF outbreak data Wild boar abundance indicators data Wild boar hunting management information Restricted zones data	- Summary statistics of outbreaks and wild boar found dead (total and by surface) in affected countries. - Assessment of areas restricted due to ASF in wild boar in affected countries. - Assessment of wild boar abundance indicators in the context of ASF management strategies in affected countries.



4 Data and Methodologies


4.1 Data

The annual epidemiological report is performed using five different sources of data: i) laboratory surveillance data; ii) pig population data, iii) outbreak data, iv) wild boar data and v) data on EU zoning measures for ASF.

- i. Data on ASF laboratory surveillance. ASF affected countries (EU and neighbouring countries affected by ASF) are invited annually to submit their data on ASF laboratory results for wild boar and domestic pigs at sample level to EFSA for this report. This data, coming from the Laboratory Information Management System (LIMS) of the national laboratories is sent to the EFSA DCF following the SIGMA standards (EFSA, 2019). Data providers were trained the first year of reporting according to the SIGMA standards, and a guidance document was produced (EFSA, 2022a) to assist the data preparation and ensure harmonisation of data reported by different countries.
- ii. Data on pig population. Affected countries were also invited to submit data on pig population at farm level to the DCF following the SIGMA standards detailed in the guidance for reporting pig population data (EFSA, 2022b). The submitted data should be one snapshot of each country's pig population data at the time of the year that they considered most representative for the reporting period. Only surveillance and pig population data submitted to the EFSA DCF following SIGMA standards are considered for the elaboration of the epidemiological analysis, not been allowed manual submissions by email or other forms.
- iii. Data on ASF outbreaks collected from other diseases databases (e.g., Animal Disease Information System (ADIS) and World Animal Health Information System (WAHIS)) was used in the report for certain visualizations and analysis.
- iv. Data on wild boar annual hunting bags at country level (number of harvested animals per km²) collected by ENETWILD Consortium.
- v. Outcome of the modelled wild boar abundance developed by ENETWILD (ENETWILD Consortium et al., 2022) was used as indicators of wild boar abundance in the analysis.
- vi. Data on EU zoning measures for ASF were used as a representation of restricted zones I, II and III (as listed in Annex I of Commission Implementing Regulation (EU) 2021/605) and indication of the extent of disease impact. The latest zones can be consulted in the interactive tool developed by the EC <https://santegis.maps.arcgis.com/apps/webappviewer/index.html?id=45cdd657542a437c84bfc9cf1846ae8c>

4.2 Methodologies

All the graphs, maps and analyses included in the report were carried out using the statistical software R (R Core Team, 2022). To ensure reproducibility of the analyses and speed up the elaboration of the reports, a specific online application was developed using R shiny package (Chang et. Al., 2021) accessible in R4EU platform.



Most of the analysis and visualizations included in the report are purely descriptive (eg. tables, maps and graphs summarising the number or percentages of samples, positive results, incidence) and therefore, self-explanatory. However, some analysis included in the report are more elaborated and therefore require further clarifications, provided below.

Evolution of ASF restricted areas over time: For this report, we considered two types of restricted areas: the restricted areas III (approximating the restricted areas due to the occurrence of ASF outbreaks in domestic pigs) and the union of restricted areas II and III (approximating the restricted areas due to the occurrence of ASF in wild boar and/or domestic pigs). Restricted zones I were considered, when relevant, in the impact assessment as despite been free of the disease, trade restrictions apply on them with the consequent economic impact for the country. For the spatial evolution, the surface affected of each area type was calculated per country in each time point using Geographic Information System software, and plotted over time.

Time profile of positive rates: As previously done in former annual epidemiological analysis (EFSA, 2021, 2022c) the proportion of positive animals divided by the total number of tested animals was plotted over time to provide an indication of the evolution of disease presence in wild boar. For domestic pigs, this analysis was only done when the data reported by the countries allowed the aggregation of samples by farm, representing therefore the proportion of positive farms per total farms tested.

Only positive PCR and ELISA results were considered in the analysis, due to the lack of consistency found when using other tests among laboratories. The trends and uncertainty (displayed as confidence bands in the graphs) were calculated using the same methodology as previously reported (EFSA, 2022c).

Monthly seasonality plots: The monthly seasonal patterns of ASF were evaluated per country, considering the PCR positive samples. Serology results were not included in the analysis, as they do not allow identifying the moment of infection due to the longer presence of antibodies in infected animals. The approach for developing the curves in wild boar was the same as in previous report (EFSA, 2022c), with the average proportions of positive samples per month and associated uncertainties also displayed in the plots.

For domestic pigs, two different approaches were followed. For the countries submitting information about the farm of origin of the pigs in the laboratory data, laboratory results were aggregated by farm. Then, the same method as for wild boar was followed. For those countries that didn't specify the farm of origin of the pig sampled, outbreak records were simply plotted per month.


Secondary wild boar cases: As an estimator of the speed of ASF spread in the different populations, Directed Acyclic Graphs were produced using ASF outbreak data. The detailed methodology can be consulted in EFSA, 2022c. In summary, potential secondary cases in wild boar were identified for each case considering a window of 1km and 60 days, creating a network. The total number of edges was calculated per country and year, allowing comparisons of disease evolution in wild boar over years for the same spatial unit.



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Abbreviations



ADIS	Animal Disease Information System
ASF	African swine fever
ASFv	African swine fever virus
DCF	Data collection framework
EFSA	European Food Safety Authority
ELISA	Enzyme-linked immunoassay
EU	European Union
IPA	Instrument for Pre-accession Assistance
PCR	Polymerase chain reaction