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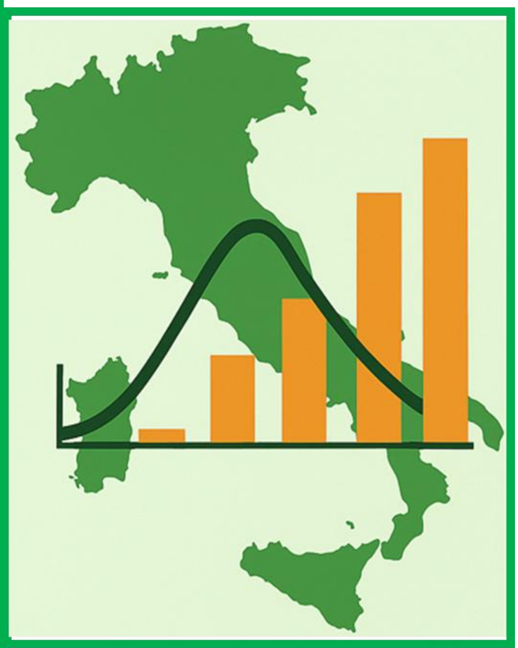
Guidelines for statistically sound and risk-based surveys

Application to Pest Free Areas for *Anoplophora chinensis* (Forster)



Council for Agricultural Research and Economics – CREA
Research Centre for Plant Protection and Certification
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Guidelines for Risk-Based Statistical Surveys
Application in Pest-Free Areas for Anoplophora chinensis (Forster)

Prepared by
Council for Agricultural Research and Economics – CREA
Research Centre for Plant Protection and Certification
Centro di Ricerca CREA Difesa e Certificazione
Registered Office
Via della Navicella, 2/4 - 00184 Roma
T +39 06 47836.1
C.F. 97231970589 ∫ P.I. 08183101008
crea@pec.crea.gov.it

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Authors: Dario Cascione, Angela Piersante, Daniela Cesare, Gianluca Dell'Unto, Giuseppe Luigi Barreca, Laura Damiano, Leonardo Marianelli, Emanuela Maurizi

Scientific Coordinator: Emanuela Maurizi

Project Coordinator: Laura Damiano

Editors: Laura Tomassoli, Dario Cascione

Foto: Luciano Nuccitelli – SFR Lazio, Matteo Maspero

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Acronyms

CFN	Comitato Fitosanitario Nazionale (National Plant Protection Committee)
CL	Confidence Level
CREA-DC	Consiglio per la Ricerca in Agricoltura e l’Analisi dell’Economia Agraria - Centro di Ricerca Difesa e Certificazione (Council for Agricultural Research and Economics Analysis – Research Centre for Plant Protection and Certification)
DP	Design Prevalence
DS	Diagnostic Sensitivity
DTU	Documento Tecnico Ufficiale per le indagini (Official Technical Document for survey)
EFSA	European Food Safety Authority
EPPO	European and Mediterranean Plant Protection Organisation
EU	European Union
EPIUNIT	Epidemiological Unit
FAO	Food and Agriculture Organization of the United Nations
GdL	Gruppo di Lavoro (Technical Working Group)
IPPC	International Plant Protection Convention
ISPM	International Standards for Phytosanitary
MASAF-DISR5	Ministero dell’Agricoltura, della Sovranità Alimentare e delle Foreste. Direzione Generale dello Sviluppo Rurale, Ufficio V - Servizio fitosanitario centrale
M.Orga.N.A.	Monitoraggio Organismi Nocivi Agricoli Nazionali (Monitoring of National Agricultural Harmful Organisms)
MS	Method sensitivity
NPPO	National Plant Protection Organisation
NUTS	Nomenclature of Territorial Units for Statistics
OCL	Overall Confidence Level
PCR	Polymerase Chain Reaction
PIZ	Potentially infested zone
PNI	Piano Nazionale di Indagine (National Survey Plan)
PRA	Pest Risk Analysis
RIBESS+	Risk-based Estimation and Sampling Survey Tool
RiPEST	Risk-based Pest Survey Tool
RNQPs	Regulated Non-Quarantine Pests
RUOP	Official Register of Professional Operators
SE	Sampling Effectiveness
SFN	National Plant Protection Service
SFC	Servizio Fitosanitario Centrale (Central Plant Protection Service)

SFR	Servizio Fitosanitario Regionale (Regional Plant Protection Service)
SS.FF.RR.	Servizi Fitosanitari Regionali (Regional Plant Protection Services)
ST	Sottogruppo Tecnico (Technical Subgroup)
SPS	Sanitary and Phytosanitary Measures
VE	Visual Examination

1. Introduction

The global economic system is undergoing constant transformation, profoundly influencing production processes, trade models, and market dynamics. The emergence of new industrial areas, the development of more agile and integrated logistics systems, the reduction of customs barriers, the intensification of international tourism, and the decentralization of manufacturing activities have all contributed to a significant increase in the global movement of people and goods. This has led to a **higher risk of introduction and spread of harmful organisms within the territory of the European Union**, which were previously contained thanks to the geographic isolation between continents or the stability of natural geo-climatic barriers.

The progressive decline of natural control mechanisms in newly affected areas, combined with the **low resistance or tolerance of host plants**, has had devastating effects on crop protection and ecosystem stability, resulting in substantial **economic and ecological damage**.

To counter this growing threat, it has been internationally recognized that **regulations are needed to assess phytosanitary risks** associated with harmful organisms, as well as to adopt **measures aimed at minimizing those risks to manageable levels and within acceptable limits**. Among these measures, a central role is played by the development of more effective surveillance strategies, designed to ensure early detection, eradication of harmful organisms, and, in more complex cases, their **containment**, before they become established, spread, or cause irreversible damage.

In line with these needs, **plant protection organizations** are redefining their surveillance strategies, moving towards a risk-based approach supported by statistical criteria. This model allows for the optimization of resource allocation by focusing monitoring **efforts on areas and contexts most at risk**, thereby making detection activities more targeted and effective, and aligned with **the biological and ecological characteristics of harmful organisms**.

To address these needs, the European Food Safety Authority[1] (**EFSA**) has developed the *General guidelines for statistically sound and risk-based surveys of plant pests*[2], which define the principles for designing phytosanitary surveys in line with international standards. In addition, EFSA has created **RiPEST** (Risk-based Pest Survey Tool), an operational tool that applies these principles **to support Member States in planning surveillance and monitoring activities**, ensuring consistency with international standards while maintaining the flexibility needed to adapt to national specificities.

[1] https://www.efsa.europa.eu/it
[2] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2020.EN-1919

As part of this methodological approach, which integrates the recommendations provided by EFSA and the use of RiPEST, the Research Centre for Plant Protection and Certification[3] (the **National Reference Institute for Plant Protection**)[4], has developed these guidelines to steer activities in the field. Their implementation has benefited from the contribution of the technical working group, composed of experts from the **Regional Plant Protection Services (SS.FF.RR.)**, involved in strategic decisions and operational phases. This collaboration has ensured high-quality standards, calibrating the model to the specific features of the national context.

This document describes how this framework has been applied to the specific conditions of the Italian territory in **pest-free areas**, and how it contributes to the continuous improvement of plant health surveillance. Furthermore, it aims to **foster dialogue among the SS.FF.RR.**, **harmonize the practical use of risk-based statistical tools** for surveillance surveys, and strengthen detection capacity in light of the increasing spread of harmful organisms across the country.

2. Legal framework

The risk-based statistical approach is a methodology developed to meet regulatory requirements emerging at the global, European, and national levels, within a context that demands phytosanitary surveillance systems that are consistent, scientifically grounded, and aligned with international standards for plant protection (Regulation (EU) 2016/2031; ISPM6) [5].

The legal foundations lie in international agreements, particularly the International Plant Protection Convention[6] (IPPC), a multilateral treaty whose Secretariat operates under the Food and Agriculture Organization of the United Nations[7](FAO).

The IPPC defines the essential principles through the International Standards for Phytosanitary Measures[8] (ISPMs) aimed at preventing the introduction and spread of

[3] https://www.crea.gov.it/en/web/difesa-e-certificazione

[4] Designation as the National Reference Institute for Plant Protection pursuant to Article 8 of Legislative Decree No. 19 of 2 February 2021.
https://www.gazzettaufficiale.it/atto/serie_generale/caricaArticolo?art.versione=1&art.idGruppo=2&art.flagTipoArticolo=0&art.codiceRedazionale=21G00021&art.idArticolo=8&art.idSottoArticolo=1&art.idSottoArticolo1=10&art.dataPubblicazioneGazzetta=2021-02-26&art.progressivo=0

[5] Reg. (UE) 2016/2031, Articles 22-23, 25-27, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R2031;
ISPM 6, https://www.ippc.int/static/media/files/publication/en/2018/06/ISPM_06_2018_En_Surveillance_2018-05-20_PostCPM13_KmRiysX.pdf

[6] https://www.ippc.int/en/publications/131/

[7] https://www.fao.org/plant-production-protection/in-action/governance-and-normative-work/ippc/en

[8] https://www.ippc.int/en/core-activities/standards-setting/ispms/

plant pests. It requires national authorities, the National Plant Protection Organizations[9] (NPPOs), to implement the prescribed phytosanitary measures, ensuring alignment with international standards and contributing to global plant health protection.

These principles are also recognized by the World Trade Organization[10](WTO) through the Agreement on the Application of Sanitary and Phytosanitary Measures[11] (SPS Agreement), which promotes science-based interventions and the adoption of shared standards, while avoiding unjustified barriers to trade.

In this framework, the European and Mediterranean Plant Protection Organization[12] (EPPO), plays a strategic role in developing technical standards and guidelines, acting as a bridge between the international regulatory framework and its application at the national level.

Alongside EPPO, the EFSA contributes to the definition of plant health policies through scientific risk assessment, providing expert consultation and methodological tools that support evidence-based measures and promote the harmonization of practices among Member States.

2.1 European Union Legislation

In the EU context, the main regulatory reference for protective measures against harmful organisms is Regulation (EU) 2016/2031[13] , subsequently amended by Regulation (EU) 2024/3115[14].

This legislative framework, which replaced the former Council Directive 2000/29/EC, introduces updated and targeted measures to counter the spread of harmful organisms, in response to increasing pressures from international trade and ongoing climate change.

This regulation sets out a revised plant health regime that emphasizes:

- Prevention and early detection of quarantine pests
- Mandatory surveys for priority pests
- Demarcated areas for eradication and containment
- Notification obligations for professionals and the public
- Multi-annual surveillance programmes to be implemented at the national level

Together with Regulation (EU) 2016/2031 as amended, Regulation (EU) 2017/625[15] on official controls, defines how plant health inspections and surveillance activities are to be conducted by competent authorities. It ensures that surveys are carried out with

[9] https://www.ippc.int/static/media/files/publication/en/2018/06/Establishing_an_NPPO_Guide_Final_WEB.pdf
[10] https://www.wto.org/
[11] https://notifications.wto.org/en/notification-requirements/sanitary-and-phytosanitary-measures
[12] https://www.eppo.int/ABOUT_EPPO/about_eppo
[13] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R2031
[14] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32024R3115
[15] https://eur-lex.europa.eu/eli/reg/2017/625/oj/eng

scientific rigor and transparency, and that the results are used to inform **risk management decisions**.

A key element of this legal basis is the classification of pests into categories[16] with distinct regulatory implications, as follows:

- *European Union quarantine pests* - subject to mandatory surveillance and eradication measures
- *Priority pests* - require enhanced monitoring, contingency planning, and public awareness campaign
- *Regulated non-quarantine pests* (RNQPs) - managed through quality standards for plant reproductive material.

These categories are detailed in Regulation (EU) 2019/2072, which sets out the conditions for the implementation of Regulation (EU) 2016/2031, and provides:

- Official lists of harmful organisms and acceptable threshold levels for their presence
- Specific requirements for the introduction and movement of plants, plant products, and other relevant items
- Definitions of protected zones, obligations for surveys, and phytosanitary measures to be adopted

Furthermore, with the aim of more precisely defining the category of priority pests, Regulation (EU) 2019/1702[17] establishes a list of **20 harmful organisms** regarded as particularly significant. Selected for their potential to cause substantial economic, environmental, and social impact within the European Union, these organisms are subject to intensified surveillance and emergency management protocols.

For some of these harmful organisms, European legislation has established that surveillance activities in pest-free areas must be planned based on risk, following a statistical approach, as outlined below:

- Regulation (EU) 2020/1201[18], *Xylella fastidiosa*, effective from 2023
- Regulation (EU) 2022/2095[19], *Anoplophora chinensis*, effective from 2025
- Regulation (EU) 2023/1584[20], *Popillia japonica*, effective from 2026
- Regulation (EU) 2024/2004[21], *Agrilus planipennis*, effective from 2027

[16] Regulation (EU) 2016/2031 of the European Parliament and of the Council, Articles 3–5 (Union quarantine pests), Article 6(2) (priority pests), and Articles 36–37 (regulated non-quarantine pests – RNQPs)
[17] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32019R1702
[18] https://eur-lex.europa.eu/eli/reg_impl/2020/1201/oj/eng
[19] https://eur-lex.europa.eu/eli/reg_impl/2022/2095/oj/eng
[20] https://eur-lex.europa.eu/eli/reg_impl/2023/1584/oj/eng
[21] https://eur-lex.europa.eu/eli/reg_impl/2024/2004/oj/eng

2.2 National Legislation

In Italy, the legal framework for phytosanitary surveillance is defined by Legislative Decree No. 19 of 2 February 2021, which, in implementation of European provisions, reorganizes the National Plant Protection Service (Servizio Fitosanitario Nazionale – SFN)[22] and formally designates it as Italy's **National Plant Protection Organization (NPPO).**
The National Plant Protection Service is composed of:

- the **Central Phytosanitary Service** (Servizio Fitosanitario Centrale - SFC)
- **21 Regional Phytosanitary Services** (Servizi Fitosanitari Regionali – SS.FF.RR.), including those of the two autonomous provinces of Trento and Bolzano
- the **National Reference Institute for Plant Protection** (Centro di Ricerca Difesa e Certificazione del Consiglio per la Ricerca in Agricoltura e l'Analisi dell'Economia Agraria - CREA-DC)

These bodies operate in coordination under the guidance of the **National Phytosanitary Committee** (Comitato Fitosanitario Nazionale - CFN), which serves as the technical decision-making body. The State, Regions, and Autonomous Provinces jointly participate in the implementation of surveillance activities, each according to their respective legal frameworks and competencies.[23]

Within this organizational framework, the SFN carries out several key activities, aimed at ensuring effective and coordinated pest surveillance across the country, including:

- Conducting official surveys in accordance with EU and IPPC standards
- Implementing risk-based surveillance strategies
- Coordinating with SS.FF.RR.
- Ensuring compliance with plant health regulations throughout the supply chain.

In line with the European and national plant health legislation (Regulation (EU) 2016/2031 and Legislative Decree No. 19/2021), Italy has established a **National Survey Plan** (Piano Nazionale di Indagine – PNI)[24] for plant pests. This plan is implemented annually and aims to determine the phytosanitary status of harmful organisms (**Pest Risk Analysis – PRA**) across the national territory. The PNI encompasses planned surveillance activities and provides for the implementation of surveys in: (i) **sites producing plant material** (where operators are registered in the Official Register of Professional Operators – RUOP), and (ii) **areas of the national territory** where quarantine pests are not known to be present, with

[22] https://www.gazzettaufficiale.it/atto/vediMenuHTML?atto.dataPubblicazioneGazzetta=2021-02-26&atto.codiceRedazionale=21G00021&tipoSerie=serie_generale&tipoVigenza=originario

[23] Legislative Decree No. 19 of 2 February 2021. Art.4, https://www.gazzettaufficiale.it/atto/vediMenuHTML?atto.dataPubblicazioneGazzetta=2021-02-26&atto.codiceRedazionale=21G00021&tipoSerie=serie_generale&tipoVigenza=originario

[24] https://www.protezionedellepiante.it/piano-nazionale-di-indagine-pni-per-gli-organismi-nocivi-delle-piante-da-realizzare-nellanno-2023-2/

the objective of promptly detecting any introductions and activating emergency phytosanitary measures.

Moreover, the PNI includes the programming of harmful organisms for which the use of risk-based statistical methodologies is required.
The methodological approach requires that the survey be conducted by stratifying the target population according to three criteria:

- grouping survey sites into **epidemiological units**, that is, homogeneous areas where interactions among the pest, host plants, and abiotic and biotic factors would result in similar epidemiology if the pest were present
- dividing the territory into representative **geographical areas**
- focusing on **host plants** considered at highest risk

To ensure the statistical robustness of these surveys, the implementation of the PNI relies on **EFSA Plant Pest Survey Toolkit** [25]**, which supports the calculation of statistical parameters and the estimation of sample size**.

[25] https://storymaps.arcgis.com/stories/810dcf6ec5a94a9d8c159711a24c8124

3. Principles, Objectives, and Workflow of Risk-Based Statistical Surveys

The general principles of the EFSA General guidelines for statistically sound and risk-based surveys of plant pests[26], in alignment with the ISPMs[27] and including the adoption of their **concepts and definitions** (Annex 1), have been applied and adapted to the regulatory and environmental context specific of each harmful organism. This approach enables a more effective response to regulatory requirements through a set of key objectives, among which:

- **Complying with regulatory obligations** established by Regulation (EU) 2016/2031 and related legislation, which require the use of statistical methods to demonstrate the absence of harmful organisms and provide objective bases for official decisions.
- **Providing robust scientific evidence** through surveys based on statistical methods, as these allow for an objective estimation of the extent of infestation/infection of a harmful organism within the target population and for quantifying the confidence level regarding its presence or absence. Such evidence is essential for decisions such as declaring the "Pest Status" of the territory, confirming a pest-free area, or initiating targeted intervention plans such as delimitation, eradication or containment.
- **Using resources efficiently** through risk-based approaches that focus efforts on areas and host plants with the highest probability of infestation, thereby reducing costs and increasing the effectiveness of interventions.
- **Ensuring consistency among Member States** through the adoption of harmonized methods, which enable the comparison of results over time and ensure uniformity in assessments. This harmonization improves transparency and promotes coordination at EU level.

This structured set of principles, criteria and procedures initially involves **selecting the most appropriate type of survey**, defined by the 'status' of the harmful organism in the area under analysis. This choice is based on three key criteria: absence/presence of the pest, degree of distribution and risk of establishment, from which the types of survey to be adopted are derived: **detection, monitoring and delimitation**.

The methodology involves codified steps which cover the definition of operational phases, consideration of the necessary variables and statistical parameters, and

[26] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2020.EN-1919
[27] https://www.ippc.int/en/core-activities/standards-setting/ispms/#:~:text=International%20Standards%20for%20Phytosanitary%20Measures%20%28ISPMs%29%20are%20standards,body%20of%20the%20International%20Plant%20Protection%20Convention%20%28IPPC%29.

implementation of the surveillance process. The identification of these elements, the collection of relevant information and the execution of the surveillance program are the responsibility of the SFN/NPPO, which is also tasked with ensuring compliance with technical standards, as well as managing reporting and interpreting the results obtained from the activities carried out.

In these guidelines, the approach is applied to **pest-free areas**, with the objective of confirming the absence of the harmful organism; for this purpose, a **detection survey** has been adopted, organized into five operational phases: initiation, preparation, design, implementation and reporting (Figure 1).

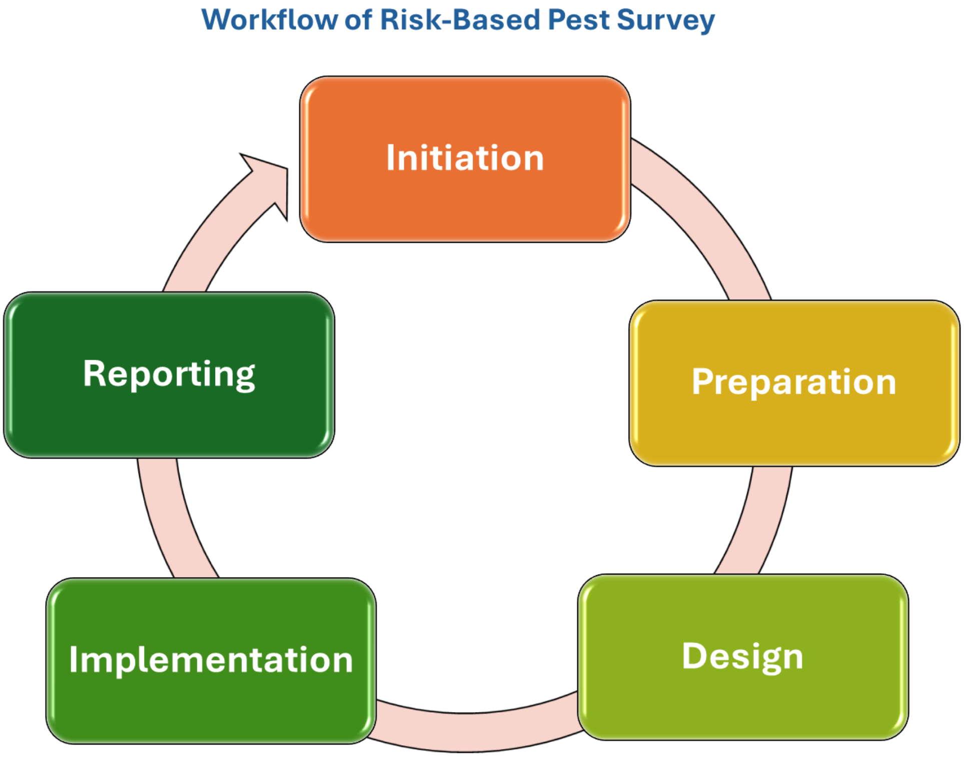

Figure 1. Risk-based phytosanitary survey workflow

- **Initiation phase** – Involves the formal decision to start the survey, based on regulatory obligations or the planning of surveillance activities. During this phase, the objectives and scope of the survey are defined, and coordination among the competent parties involved is initiated.
- **Preparation** – This phase includes gathering the necessary baseline information, such as the biological characteristics of the organism, analysis of host plants and the environment, as well as defining inspection units and detection methods.
- **Design** – The structure of the host population is defined, along with the determination of statistical parameters such as confidence level, design prevalence, and risk levels,

for estimating the sample size. This includes quantifying the number of visual inspections and/or plant samples and/or traps.

- **Implementation** – Covers the practical execution of the survey according to NPPO guidelines, including site selection, on-site and real-time data collection, and data recording and storage in compliance with international standards (ISPM 6)[28], to ensure traceability, integrity, and availability for verification and analysis.

- **Reporting** – Involves systematic documentation and communication of survey results. It includes data analysis, interpretation of results, and formulation of evidence-based conclusions regarding the presence or absence of the organism.

Although not formally included in the general EFSA guidelines, the NPPO has introduced an additional phase of **evaluation and improvement**, aimed at ensuring a critical review and qualitative evolution over time of the planning, the parameters used, and the results obtained. This iterative process supports continuous improvement and strengthens methodological robustness.

The following chapters illustrate the process of planning and implementation of national statistically risk-based surveys in pest-free areas for the priority quarantine pest ***Anoplophora chinensis*** (Forster), in accordance with Regulation (EU) 2022/2095[29].

[28] https://www.ippc.int/static/media/files/publication/en/2018/06/ISPM_06_2018_En_Surveillance_2018-05-20_PostCPM13_KmRiysX.pdf

[29] https://eur-lex.europa.eu/eli/reg_impl/2022/2095/oj/eng

4. Planning of Phytosanitary Surveillance Surveys for Anoplophora chinensis

The program development of surveillance activities for *A. chinensis* began with the establishment of a dedicated organizational framework. The **Technical Working Group** (Gruppo di Lavoro - GdL), set up to coordinate phytosanitary initiatives at the national level, decided to create a **Technical Subgroup** (Sottogruppo Tecnico - ST), composed of experts from the SS.FF.RR. and CREA-DC. This subgroup has been entrusted with the responsibility of planning the surveys, overseeing their design and methodological preparation.

The surveillance activities are coordinated by the CFN, while implementation in the field is entrusted to the respective SS.FF.RR. [30], which carry out the surveys in accordance with the standard protocols agreed upon during the planning phase. These surveys, designed to provide the necessary evidence for declaring pest-free areas based on statistical parameters such as an appropriate **Confidence Level** (CL) and a low **Design Prevalence** (DP) of host plant infestation, represent the practical implementation by the SFN of the measures laid down in Regulation (EU) 2022/2095 of 28 October 2022[31], aimed at preventing the introduction and spread of A. chinensis within the territory of the European Union.

4.1 Initiation phase

The initial phase of the process focuses on reviewing the scientific and regulatory evidence that supports the phytosanitary relevance and potential risk posed by *A. chinensis* (Forster, 1771) within the EU context, laying the groundwork for the implementation of the subsequent phases.

Figure 2. Male specimen of A. chinensis

In particular, the ST took into account that the species has been included in the list of Union quarantine pests (Annex II, Part B) under Regulation (EU) 2019/2072 and is also classified as a priority pest for plants under Regulation (EU) 2019/1702, due to the high phytosanitary risk it represents.

This polyphagous cerambycid beetle was accidentally introduced into the EU, primarily through the trade of host plants and, likely, via

[30] Legislative Decree of 2 February 2021, No. 19, Articles 4, 5 and 6, https://www.gazzettaufficiale.it/eli/id/2021/02/26/21G00021/sg
[31] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022R2095

wood packaging materials. Its ability to infest a wide range of broadleaf trees and shrubs continues to pose a serious threat to urban greenery, orchards, and forest ecosystems, justifying its classification both as Union quarantine pest and as a priority pest. Climate conditions across the EU are considered favourable for its establishment and, combined with the widespread availability of suitable host plants, make it unlikely that the spread of the species can be effectively limited within EU territory.

The insect has been detected primarily in China, Korea, and Japan, and occasionally in Malaysia, Myanmar, the Philippines, Taiwan, and Vietnam. In Europe, it has mainly been found in Croatia and Türkiye (EPPO Global Database).

In Italy, several outbreaks have been detected over time, including those in Lazio and Tuscany, which were successfully eradicated. More recently, the presence of the insect has been confirmed in restricted areas of Lombardy and Tuscany, as shown in the map in Figure 3, where measures have been implemented to limit its spread[32].

Figure 3: Distribution map of Anoplophora chinensis in Italy - 2024

The experience gained in the fight against the pest has proven to be particularly complex, due to the diversity of host plants, the difficulty in detecting larvae, and the limited effectiveness of both natural enemies and chemical treatments. Eradication strategies primarily rely on the removal of infested plants and the treatment of root systems.

[32] https://www.protezionedellepiante.it/anoplophora-chinensis/

Consequently, regular inspections and restrictions on the movement of high-risk materials are essential to prevent the introduction and spread of the harmful organism.

Based on this information, the ST assessed the risk in pest-free areas and selected the survey type deemed most appropriate, identifying the **detection survey** as the preferred method for phytosanitary surveillance. This approach allows for **the verification of the absence of the harmful organism in a statistically sound manner and in accordance with international standards.**

4.2 Preparation

Following the definition of the survey method, and drawing on data gathered during previous investigations, the TS moved forward with identifying the key survey parameters. This phase relied on insights into the insect's characteristics, laid out in the EFSA Pest Survey Card[33], a technical document that brings together biological, epidemiological, and methodological aspects essential for survey design, and in the Official Technical Document for Surveys[34] (Documento tecnico Ufficiale per le indagini – DTU), which sets out operational criteria and standardised protocols for carrying out official surveys.

In addition, the preliminary data collection involves checking for any **updates to the current regulatory framework**, which establishes the commencement of risk-based statistical survey activities from **1st January 2025**, in accordance with Regulation (EU) 2022/2095.

This phase is aimed at ensuring accurate identification of the pest and provide the basis for defining the **strategy to select the appropriate type of statistical survey**.

To achieve this, the preparation activities are organised into three key components: **the composition of the target population, the definition of inspection units by detection method, and the methods used for the detection and identification of the harmful organism** (Figure 4).

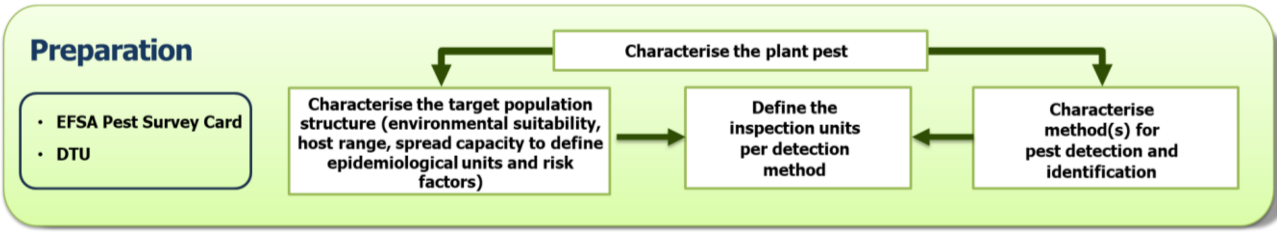

Figure 4. Activities for the preparation phase of the survey (EFSA)

33 Technical document drawn up by EFSA. https://www.efsa.europa.eu/en/supporting/pub/en-1749

34 Document drawn up and approved respectively by the competent authorities of the National Phytosanitary Service (DTU No.35). https://www.protezionedellepiante.it/wp-content/uploads/2023/07/dtu-n.-35-anolcn-29_03_2023_signed.pdf

4.2.1 Composition of the target population

The analysis of the target population is a crucial step for identifying **epidemiological units** and assessing plant health risk. In this context, it is necessary to consider a set of key parameters, including:

- The life cycle generally spans one to two years, both in its native range and in southern European regions. In more continental environments, such as northern Europe and certain islands, this duration may vary. During summer, females lay eggs in characteristic "T-shaped slits" carved into the bark, at the base of the trunk or near the roots of host trees. The larvae bore into the wood to feed and develop, moving toward the roots and causing significant structural damage. Pupation takes place within pupal cells excavated in the wood, from which adults emerge between late spring and early summer through circular exit holes approximately 10–15 mm in diameter.
- Environmental suitability is assessed through climatic models, which show that large areas of Italy, particularly in the northern and central regions, offer favourable conditions for the establishment and spread of the species, due to mild winters and adequate thermal accumulation during the growing season.
- As for host range, as previously noted, the species is highly polyphagous and can attack numerous broadleaf trees and shrubs. Its host spectrum includes over **twenty families and more than seventy genera**, such as *Citrus, Acer, Betula* and *Salix*, all of which are widely distributed and of economic and ecological importance (Annex 2).
- Finally, the species' dispersal capacity is enhanced both by adult mobility and by passive transport through infested plant materials. The combination of high polyphagy, climatic adaptability, and dispersal potential makes *A. chinensis* a concrete threat to forest, agricultural, and urban ecosystems.

The combination of high polyphagy, climatic adaptability, and dispersal potential makes A. chinensis a tangible threat to forest, agricultural, and urban ecosystems. These considerations provided the key elements for planning the surveys, which include dividing the territory into **epidemiological units** and assessing the main **risk factors**.

- Epidemiological Units - Epidemiological units are homogeneous areas where interactions among the harmful organism, host plants, and abiotic and biotic factors result in similar epidemiological behaviour in the event of pest introduction. Identifying these units allows for the application of consistent sampling protocols and the optimization of available resources.

  In defining these units, a distinction was made between two types of territorial contexts:

  - Under Physically closed conditions areas. In this case, the limited dispersal capacity of the pest was taken into account, estimated at a maximum natural spread of approximately 200 meters per year, with a 95% uncertainty interval ranging from 42 to 904 meters (EFSA et al., 2019). This category includes sensitive sites, goods handling locations, and production and distribution centres of host plants, where certain practices, such as those involving bonsai and pre-bonsai, may increase the phytosanitary risk

- Open-field areas. In these contexts, the main threat concerns ornamental plantations, public and private parks and gardens, as well as orchards. The pest's spread may be facilitated by greater environmental exposure and the widespread presence of host plants, which amplify the potential for establishment and propagation

Drawing on these considerations, the ST designed the survey to encompass three epidemiological units and grouped the sites, accordingly, as illustrated in Table 2[35].

Epidemiological Units	Survey sites
Production area	1.3 Nursery 3.1 Greenhouse
Urban and Natural Area	1.2 Orchard/vineyard 1.4 Forest 2.1 Private gardens 2.2 Public sites 2.3 Conservation area 2.4 Wild plants in areas other than conservation areas 2.5.1 Commercial sites that use wood packaging material 2.5.2 Garden centre 2.5.7 Points of entry
Commercial sites and movement area	2.5.1 Commercial sites that use wood packaging material 2.5.12 Checks on movement 2.5.13 Other - biomass plants 2.5.13 Other - composting/biodigester sites 2.5.2 Garden centre 2.5.7 Points of entry 3.4.1 Commercial sites that use wood packaging material 3.4.2 Garden centre

Table 1. Classification of epidemiological areas and survey sites

[35] Source: DTU No. 35, concerning the coding system EUROPHYT, managed by the European Commission. https://www.protezionedellepiante.it/wp-content/uploads/2023/07/dtu-n.-35-anolcn-29_03_2023_signed.pdf

- Risk Factors - The final step of the analysis is concerned with identifying and characterizing the main biotic and abiotic risk factors associated with the introduction and spread of the insect. Among the factors considered, the following are particularly relevant:
    - the entry of host plants through import flows, especially when originating from infested areas, represents a primary pathway for pest introduction
    - the trade and storage of container-grown plants, including bonsai and pre-bonsai, which are particularly vulnerable to infestation
    - the movement of infested nursery material and wooden packaging, which may facilitate the accidental spread of the harmful organism across the territory

4.2.2 Methods Used for Detection and Identification

Once the target population had been defined and the main risk factors assessed, the next step was to identify the most appropriate methods for the detection and identification of the harmful organism. The choice of methods takes into account the biological characteristics of the pest, its establishment pathways, and the environmental conditions that influence its visibility and spread.

Since *A. chinensis* can be detected both during the appearance of symptoms on host plants and during the emergence of adult insects, two complementary approaches can be adopted, **visual inspection** and **trapping.** The ST considered the use of both methods suitable for detection, establishing the operational schedule shown in Figure 5.

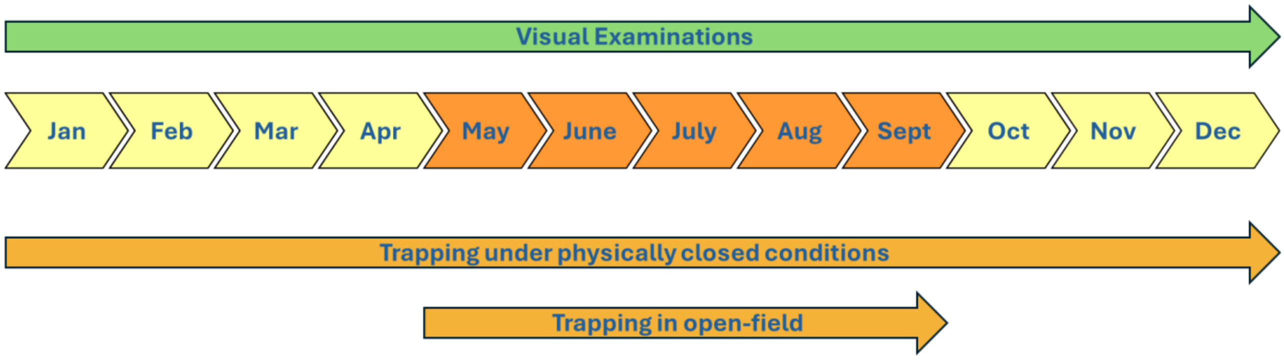

Figure 5. Operational Schedule for Anoplophora chinensis Surveillance

During the phase to determine the surveillance strategy, the ST designated **visual inspection** as the primary method, due to its effectiveness in directly detecting symptoms and signs of infestation.

On the other hand**, trapping** was considered an auxiliary method, to be adopted upon evaluation by the SS.FF.RR., particularly in high-risk areas such as border entry points, nurseries producing and distributing woody plants and shrubs, and bonsai import sites.

In these contexts, where visual inspection may be less effective, pheromone traps provide useful support for surveillance. In these circumstances, where visual inspection may be less effective, pheromone traps provide valuable support for surveillance activities. However, due to their **limited and complementary application**, traps contribute only marginally from a quantitative standpoint and, therefore, trapping was **not included in the statistical calculation of the survey.**

Additional information on the two selected survey methods was provided based on the Pest Survey Card[36] for *A. chinensis*.

- Visual Inspection - This method relies on the direct observation of characteristic symptoms, including:
  - Bark gnawing and oviposition scars, often with T-shaped incisions
  - Accumulations of frass and exit holes, typically ranging from 10 to 15 mm in diameter
  - Presence of larvae or larval galleries within the trunk or root system.

  In cases where larvae or adults are identified, and morphological recognition is not exhaustive, molecular diagnostics are employed. Specifically, **Real-Time-PCR**[37], followed by EPPO-accredited **sequencing** enables accurate identification with 100% sensitivity, provided that the larvae are properly preserved.

- Trapping - The use of traps, as previously mentioned, is not considered fully effective for *A. chinensis*. For this reason, the ST has established that pheromone traps should be deployed primarily in areas adjacent to zones where the pest may potentially spread, or in locations at risk of incursions. Although the effectiveness of this method is limited during early detection phases, traps still provide valuable support for surveillance activities at points of entry and other high-risk sites. A recommended deployment density is **one trap per hectare**.

4.2.3 Definition of Inspection Units by Detection Method

The two previous steps provide the basis for **selecting the inspection units**, defined as elementary units and/or entities from which samples are collected to detect the harmful organism, depending on the detection method adopted. These are, respectively:

- Visual Examination - The inspection unit is identified by the **individual host plant**. This procedure involves the observation of symptoms caused by pest attack and may continue with the sampling of plant parts, collection of larval frass, and any larvae or adults found. The collected material is then sent to the laboratory for diagnostic analysis (see Annex 3 and Annex 4).

[36] https://storymaps.arcgis.com/stories/c2d0d8458061414583f26d8c3ddf52ac
[37] EPPO – Diagnostic activity, https://www.eppo.int/ACTIVITIES/plant_quarantine/diagnostics

- Trapping - The inspection unit is defined by the **effective area covered by the trap**, expressed in hectares, and therefore corresponds to the trapping station (see Annex 5).

4.2.4 Strategy for Selecting the Type of Statistical Survey

This section presents the strategy developed on the basis of the analyses described above, aimed at identifying the most appropriate type of statistical survey. The choice was guided by the following considerations:

- The combination **of Italy's high environmental suitability** and the **polyphagy of the pest** results in an extremely high estimate of host plants, making it non-enumerable. This condition prevents the application of traditional stratified statistical methods.
- Due to the impossibility of enumerating the population, it must be statistically considered as an **infinite population**
- Based on this evidence, it is not possible to divide the units into **risk levels** to calculate statistical samples. Risk assessments therefore serve as operational guidance for inspectors, without implying formal stratification for statistical purposes
- The **main detection method** adopted is **visual inspection**, which forms the basis of the statistical sample considered in the survey. **Trapping**, on the other hand, is provided as an auxiliary method, to be used at the discretion of the SS.FF.RR., if deemed necessary. Consequently, as previously highlighted, trapping is not included in the statistical calculation of the sample.

Taking all the above elements into account, the ST has established that the operational and statistical approach should follow a **Multi-Stage Stratified design**, structured into the following stages:

Level	Method	Rationale
1st stage	**Geographical stratification**	Division of the Italian territory into 19 regions and 2 autonomous provinces (NUTS 2)[38], consistent with the administrative structure and useful for operational management.
2nd stage	**Cluster stratification**	Grouping into Epidemiological Units, which represent survey sites homogeneous in terms of risk, vegetation type, presence of introduction pathways, etc.
3rd stage	**Random sampling**	Random selection of sites within clusters, considering territorial specificity and host plant distribution.
4th stage	**Temporal sampling**	Planning inspections based on the seasonality of the harmful organism and the type of site (e.g., field trapping vs. sensitive points active year-round).

Table 2. Multi-stage stratified Structure

[38] https://ec.europa.eu/eurostat/web/nuts/

The application of the Multi-Stage Stratified method provides several advantages, including:

- Flexibility: it allows the sampling design to be adapted to various levels of variability (geographical, temporal, operational)
- Efficiency: it reduces costs and time compared to a simple random sampling conducted at the national level
- Representativeness: it enhances territorial coverage and accounts for diverse environmental conditions
- Management of incomplete information: it is suitable when a comprehensive list of the plant population is not available

4.3 Design

After setting up the survey, its design was developed based on the EFSA Pest Survey guidelines[39], which are summarized in Figure 6.

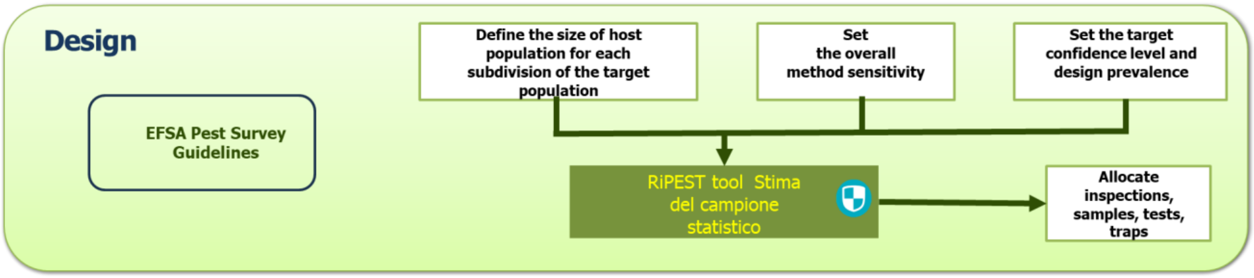

Figure 6. Activities for the Survey Design Phase (EFSA)

4.3.1 Population size

At this stage, it is necessary to define the size and structure of the host population for each of the identified epidemiological units, assess the sensitivity of the different methods employed, and determine the confidence level and expected prevalence, as described below:

- Epidemiological Structure of the Population - The epidemiological units identified by the ST include: i) commercial and movement sites, ii) production areas, iii) urban and natural areas. A detailed breakdown of these categories is provided in Table 2.

- Statistical Parameters for Sample Size Calculation - As previously mentioned, the ST has assumed that, for statistical purposes, the size of the host population is infinitely large for each of the three epidemiological units. This assumption allows the use of

[39] https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2018.EN-1399

probabilistic sampling methods without the need for finite population correction. The sample size is estimated based on the evaluation of several parameters, including**: i) confidence level, ii) expected prevalence, iii) structure of the host population, iv) method sensitivity**.

- Inclusion of Risk Parameters in Sampling Methodology - To enhance the efficiency and accuracy of the sampling strategy, the ST provided specific recommendations during the survey design phase for integrating relevant risk parameters. Among these, the following elements were identified as particularly sensitive:
    - proximity to points of entry
    - presence and density of host plants
    - commercial movement and trade of host plant material

  For sites that show greater sensitivity to the identified risk factors, it has been recommended to give them priority in the survey by implementing more intensive monitoring.

4.3.2 Setting the Overall Method Sensitivity

Method Sensitivity (MS) refers to the overall effectiveness of the survey procedure and the diagnostic method used to detect the pest. The ST decided to distinguish between visual inspection and trapping methods, due to their differing detection capabilities and diagnostic characteristics. Although trapping data are not included in the statistical calculation of sample size, the ST considered it appropriate to integrate them in the reporting process to ensure comprehensive information.

Therefore, based on the experience gained, the ST has established the parameters required for the calculation of MS, as follows:

- Sampling Effectiveness (SE): Estimated at 95% for visual inspections, based on the inspectors' ability to detect the presence of the pest through symptoms observed on the host plant. While, for traps, the effectiveness is estimated at 67%, due to the limited attractiveness of the pheromones used.

- Diagnostic Sensitivity (DS): Estimated at 90% for the molecular techniques employed, such as Polymerase Chain Reaction (PCR), Real-time-PCR, and PCR followed by sequencing. These methods allow for accurate species identification, provided that sample collection, transport, and storage procedures are correctly performed.

Since the joint probability of two events is obtained by multiplying their respective probabilities, the MS is calculated as follows:

$$MS_{ve}=SE_{ve}\times DS_{ve}=0,95\times 0,90=0,855$$

$$MS_{trap}=SE_{trap}\times DS_{trap}=0,67\times 0,90=0,6$$

where:

MS = *Method Sensitivity*

SE = *Sampling Effectiveness*

DS = *Diagnostic sensitivity*

ve= *visual examinations*

$trap$ = *traps*

4.3.3 Setting the Designed Confidence Level and Expected Prevalence

The risk analysis concerning the potential spread of the harmful organism in pest-free areas informs the selection of key parameters: the Confidence Level (CL) and the Design Prevalence (DP).

The **DP was set at 1%,** based on experience gained during previous survey seasons, the likely actual prevalence of the organism in open field conditions, and the resources available. Considering the method's sensitivity and the chosen DP value, the regional confidence level (CL_{reg}) was set at 80%[40], while the **overall national target**, referred to as the Overall Confidence Level (OCL)[41], was calculated to be **99.99%**.

4.3.4 Statistical Sample Estimation

As previously highlighted, the survey has been developed according to a Multi-Stage Stratified Sampling Design, based on the application of the binomial model and assuming an infinitely large population.

The sample size has been calculated for each stratum, defined both by geographical levels (the **19 Italian regions and the two autonomous provinces of Trento and Bolzano**), and by the **three epidemiological units** considered.

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[40] The confidence level established for each region is set at **80%.** This value is calculated using the **binomial** model, which estimates the probability of detecting at least one infested individual based on the sample size, the expected prevalence, and the sensitivity of the detection method.

$$CL(r) = 1 - (1 - DP * MS)^n \ \forall r \in (Regions)$$

[41] The Overall Confidence Level (**OCL**) for Italy has been set as a target at **99.99%.** This value is calculated using the following formula:

$$OCL = 1 - \prod_{r=1}^{21}(1 - Cr) \ \forall r \in (Regions)$$

The calculation is based on the detection method adopted, namely visual inspection, which constitutes the statistical unit of reference. Each visual inspection therefore represents a sampling unit, associated with at least one inspected host plant within a homogeneous site, identified by GPS coordinates and a unique date.

The formula used to determine the sample size for each stratum is as follows:

$$n(u) = \frac{\ln(1 - CL_u)}{\ln(1 - MS_u * DP_u)} \quad \forall u \in (Epid.unit)$$

where:
CL = Predictive Confidence Level
DP = Expected Prevalence
MS = Method Sensitivity
n = Number of Statistical Sampling Units
u = Epidemiological Units

For each SS.FF.RR. and for every epidemiological unit, the sample size was estimated using the RiPEST tool, taking into account the parameters defined during the design phase. The calculation was performed exclusively with reference to visual inspections, which represent both the adopted detection method and the basic statistical unit of the survey.

4.3.5 Allocation of Inspections, Sampling, and Diagnostic Analyses

Each Regional Plant Health Service (SFR) independently determines, based on its knowledge of the territory and the resources available, how to allocate inspections, collect samples, and distribute the related diagnostic analyses by epidemiological units. In addition, it decides whether to use trapping methods as an additional or alternative approach.

These decisions are influenced by the heterogeneity and diversity of the territory, both in terms of climate and the composition of the epidemiological units.

Therefore, the judgmental adaptation of the planning is entrusted to the sensitivity, knowledge, and ability of each SFR to identify and reach the areas at highest risk.

The design of the risk-based survey in pest-free areas, together with the use of RiPEST, provides the statistical and operational model applied during the **planning** phase at **regional and national level**, in order to ensure continuous surveillance and certification of the pest-free area.

The survey planning takes into account both the relevant regulatory framework and a resource allocation plan (including inspection personnel, budget, laboratories, etc.) established by the SS.FF.RR. This plan is partially supported by EU co-financing through the Pest Fund. The annual survey programme is communicated through the following official documents:

- European Survey Plan, pursuant to Regulation (EU) 2016/2031, which requires the demonstration of pest-free status through official annual surveys. These are documented via the **Multiannual Programme** and submitted using the Block-2B template (Annex 6) through the EUROPHYT Web Portal – European Commission[42]
- National Survey Plan (known as PNI), in accordance with Legislative Decree 19/2021, which annually regulates data transmission and the management of phytosanitary emergencies. The PNI is communicated using the template provided by the SFC, following approval by the CFN.

The data pertaining to programming activities from all SS.FF.RR. are collected through the dedicated web platform **M.Orga.N.A. Plan**, which manages the database for the entire multiannual period and handles reporting for transmission purposes.

4.4 Implementation

The implementation of surveys is entrusted to the SS.FF.RR., each of which adapts tools and procedures to the specific territorial and organizational context.

Figure 7. Activities for the Implementation Phase of the Survey (EFSA)

The implementation phases of the survey are organised into the steps described in detail below.

1. Selection of survey sites: surveillance activities focus on the programmed host species (Annex 2) and the sites listed in Table 2. The selection of the area or site for the survey takes into account:
   - the previously reported presence, distribution, and phytosanitary status of the harmful organism
   - the previously documented absence of the harmful organism
   - the undetermined phytosanitary status of the area
   - the biological characteristics of the harmful organism

[42] https://food.ec.europa.eu/plants/plant-health-and-biosecurity/europhyt/network_en

- the suitability of the climate and ecological conditions of the area for the survival and spread of the pest
    - the geographical distribution of host plants and production areas
    - the degree of isolation of the area
    - the presence of pest management programmes
    - the proximity to points of entry, import areas, or tourist zones.

2. Data collection: before starting operations, all relevant documentation and information necessary for carrying out the planned activities must be made available to the designated personnel. To ensure full compliance with current regulatory and methodological updates, reference must be made to the most recent versions of the following documents:
    - **Regulation (EU) 2016/2031**, on protective measures against plant pests
    - **Regulation (EU) 2022/2095**, which establishes operational procedures for phytosanitary surveillance
    - International Standards - ISPMs, specifically: **ISPM 23**, concerning visual inspections and **ISPM 6,** concerning phytosanitary surveillance
    - **EPPO Standards**, including **PM 3/79(1),** which provide operational guidelines for inspection and sampling activities
    - **National technical documents,** including **DTU No. 35**, developed by the SFN and approved by the CFN.
3. Integration of Survey Planning: phytosanitary inspectors receive operational instructions from their respective SFR, tailored to the specific territorial context. The SS.FF.RR. integrate planning information with technical guidelines for inspectors, in accordance with international standards, particularly EPPO PM 7/149(1).

    In addition, the SS.FF.RR. are responsible for training inspection personnel and publishing the relevant operational instructions, adapting survey procedures to local characteristics. As an example, the Region **Campania** has developed and disseminated the Technical Sheet for *A. chinensis*[43] and the related survey procedures (STZ-06) [44], specifically calibrated to its territorial context.

4. Survey Execution: during this phase, it is necessary to provide information on detection methods and diagnostic protocols, as well as to define the survey calendar.
    - **Detection Methods and Diagnostic Protocols.** The SS.FF.RR. establish that each inspection unit is linked to a detection method and defined through visual examination according to the following definition:

[43] https://agricoltura.regione.campania.it/difesa/schede/Anoplophora_chinensis.pdf
[44] https://agricoltura.regione.campania.it/difesa/schede/anoplophora.pdf

"A single inspection action of at least one host plant carried out in a specific homogeneous survey site (including territorially continuous areas), associated with a specific pair of GPS coordinates and a unique date of visual inspection."

This definition allows for the standardization of the value of visual examinations (VE) reported in the programming and reporting data of each SFR, aligning with the statistical sample size calculated using the RiPEST methodology.

The definition may be included among the assumptions provided in the annual reporting, according to the "Block-2B" template (Annex 6). In this context, the adopted detection methods include:

- Visual inspection, aimed at identifying larval feeding damage and emergence holes, preferably carried out on the basal portion of the trunk and exposed roots. The inspection also allows for the detection of bark erosion caused by adult feeding activity, which should be checked on the trunk, young branches, and/or the canopy of host plants. Sample collection involves taking portions of wood from the trunk or roots containing active larvae. Larvae, regardless of their developmental stage, must be extracted from feeding galleries using appropriate tools. Eggs and pupae may also be collected. Adult specimens, if present, can be directly collected in the field during feeding or mating phases.
- Trapping for capturing adults, such as *Multi-funnel* and *Cross-vane* traps baited with pheromones (Annex 5), are useful support tools that contribute to the implementation of an integrated surveillance system. Their use is recommended not only in open field conditions but especially in high-risk sites, such as points of entry, nurseries of woody and shrub plants, and production nurseries.

The diagnostic protocol implemented requires that laboratory analyses include the morphological identification[45] of collected specimens (eggs, larvae, adults). Confirmation of species identity always requires the execution of diagnostic tests. Molecular analyses, such as PCR[46], Real-time PCR[47], and PCR+Sequencing[48], can confirm the accurate identification of *A. chinensis* (see Annex 3).

- **Definition of the Survey Calendar**
  The SS.FF.RR. adapt the frequency of surveillance activities based on territorial specificities, taking into account the climatic diversity along the Italian latitudinal gradient. Moreover, the choice of the operational calendar depends on the epidemiological unit considered: for example, in production areas, inspections are

[45] https://www.academia.edu/4552017/09_Pennacchio_Sabbatini_2
[46] https://doi.org/10.1111/epp.12065
[47] https://doi.org/10.1111/epp.12797
[48] https://www.protezionedellepiante.it/documento-tecnico-ufficiale-del-servizio-fitosanitario-nazionale-n-35-schede-tecniche-organismi-nocivi/

mandatory and extend throughout the year. Survey planning must also consider the biological cycle of the harmful organism and the phenology of host plants.

These considerations have led to the setting of the start and end dates of the survey activities, as outlined in Table 3.

Epidemiological Unit	Start - End Date	Detection Method
Productive areas **Urban and Natural areas** **Commercial and Movement areas**	January to December	Visual examinations: larval feeding damage and emergence holes
	June to August	Visual examinations: active adults and feeding damage
	June to October	Sampling/collection of specimens: adults
	January to December	Sampling/collection of specimens: eggs, larvae and pupae; plant parts and bark; larval feeding damage
	May – September (open-field area)	Traps
	January to December (High-risk sites, ports, airports; customs warehouses; nurseries, etc.)	Traps

Table 3. Calendar of the survey

The recommended frequency for trap inspections by inspectors or designated technical staff is every 15 to 30 days, in order to ensure timely detection of adult specimens.

5. Survey Results: the operations carried out as part of the survey are recorded by the SS.FF.RR. within the M.Orga.N.A. Field database, or, for regions not participating in the service, through alternative management applications.
   The collected data are stored for the purpose of summary reporting, to be submitted to requesting authorities or presented during potential audits or inspections.
   This archiving system ensures traceability of the activities performed and methodological consistency with the original project design.

4.5 Reporting

Reporting is the process through which the results of the surveys conducted are documented and transmitted to the European Commission **via the Block-2B form** (**Errore. L'origine riferimento non è stata trovata.**) on the EUROPHYT portal. The data obtained from statistical surveys are processed using the RiPEST methodology, in order to determine the achieved CL, at both regional and national levels, according to a pre-established DP.

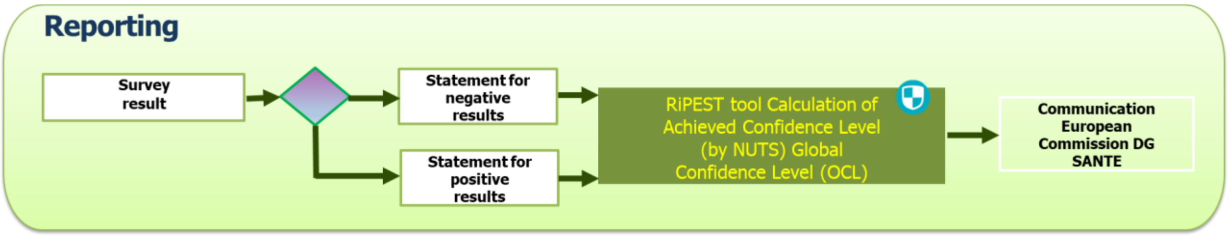


Figure 8. Activities for the Reporting Phase of the Survey (EFSA)

The key premise when conducting a statistical survey on a population to detect a harmful organism is to avoid assuming its absolute absence if no specimens are found. Nevertheless, the survey allows for estimating the probability that the organism may be present below a certain threshold. Therefore, the result of the survey serves as a **proxy for absence**.

In detail, at the conclusion of the survey, the statement accompanying the report may take one of two forms, depending on whether the harmful organism has been detected or not:

1. A **negative result**, meaning no detection of *A. chinensis*, the planned values for CL and DP are confirmed as the confidence level achieved by the survey. The statement accompanying the results is formulated as follows:

   "The survey conducted in the year XXXX on pest-free areas was carried out without detecting the presence of Anoplophora chinensis. This result allows us to declare that, in the Italian territory, with an achieved confidence level of 99.99%, if A. chinensis were present, its prevalence would be below 1%."

2. A **positive result**, meaning the harmful organism is detected in a pest-free area, the number of positive findings is reported in the Block-2B form, along with the respective outbreak numbers and Europhyt notification dates. Consequently, the pest status of the organism is updated to "present," and the base used to calculate the population in pest-free areas is revised, as the affected area will be excluded and managed according to the relevant legislation.

The ST considered it appropriate to use the RiPEST tool across all SS.FF.RR. and for each epidemiological unit to calculate both the CL achieved by each individual SFR and the OCL for Italy as a Member State. Moreover, survey results obtained through trapping methods have been excluded from the RiPEST statistical analysis.

4.6 Evaluation and Improvement Plan

The evaluation and improvement plan aims to ensure the effectiveness, consistency, and adequacy of plant health survey activities, while promoting a continuous process of optimization of the methodologies applied. The plan is organised into several operational phases and is based on objective criteria and performance indicators.

- **Main Objectives**
  - Verify the achievement of the goals of the plant health survey
  - Identify any operational or methodological critical issues
  - Propose corrective and improvement actions
  - Strengthen the response capacity of the SS.FF.RR.
  - Ensure alignment with international standards and European regulations

- **Evaluation Indicators**
  - Territorial coverage of inspections in relation to risk areas
  - Number and quality of samples collected
  - Timeliness of diagnostic analyses
  - Accuracy in the identification of the harmful organism
  - Consistency between collected data and epidemiological evidence
  - Compliance with regulatory provisions (e.g., Regulation (EU) 2016/2031, ISPM 6 and ISPM 23)

- **Implementation Methods**
  - Periodic monitoring of activities is carried out through mid-year reviews of data collected by June 30
  - Analysis of data collected during surveys, using statistical and GIS tools
  - Coordination meetings among the SS.FF.RR., the Working Group (GdL), and the CFN, to share results and plan improvement areas
  - Continuous training of inspection and technical staff through targeted courses.
  - Updating of operational guidelines based on results obtained and regulatory developments

- **Documentation and Traceability**

All evaluation and improvement activities are systematically documented through minutes, summary reports, monitoring sheets, and audit logs. Traceability of changes made to operational protocols is essential to ensure transparency and accountability.

The evaluation and improvement plan document is drafted following the annual survey report and prior to the new survey cycle. It is shared with the NPPO and made available for potential programme audits.

5. Conclusions

The application of the guidelines for risk-based statistical surveys in pest-free areas represents a significant innovation in terms of survey efficiency, cost-effectiveness, and methodological/statistical rigor. In the case of *A. chinensis*, the Italian survey programme was designed in accordance with the methodological process and calculation methods provided by the RiPEST tool.

This process has been further strengthened by the adoption of an evaluation and improvement plan, which allows for the progressive refinement of objectives, methodologies, and the accuracy of inspection activities, promoting a dynamic and adaptive approach.

The entire survey system has been designed to ensure transparency, traceability, and consistency with international standards and European regulations, systematically documenting communications, interactions with national and European bodies, decision-making processes, planning, and the results achieved.

Looking ahead, the experience gained may serve as a replicable methodological foundation for designing statistical surveys targeting other harmful organisms, thereby contributing to the strengthening of plant health surveillance capacities at both national and EU levels.

6. Annexes

Annex 1. Concepts and definitions

Term	Definition
Component (of a survey)	An entity of the survey that can be distinguished based on the target population, the detection method (e.g. visual inspection, laboratory testing, trapping), and the inspection unit (e.g. vectors, branches, twigs, leaves, fruits). A phytosanitary survey includes various components. The overall confidence of the survey results from the combination of its different components.
Confidence level (CL)	The confidence level reflects the degree of accuracy (or reliability) associated with the conclusions drawn from a survey. When it is stated that a harmful organism is absent from a given area (or present at a level below the design prevalence) with a 95% confidence level, this means that — based on the methods applied and the assumptions made, such a statement would be, on average, correct in at least 95% of cases. In general, a confidence level of 95% is adopted. However, its definition should be determined by risk managers, taking into account available resources and the epidemiological context, which, may vary across different regions of the Member State. Increasing the sample size enhances the level of certainty that the harmful organism is truly absent, or — if present — that its prevalence remains below the maximum acceptable threshold.
Delimiting survey	Survey conducted to establish the boundaries of an area considered to be infested by or free from a pest. (FAO, 1990 – ISPM 5: FAO, 2019)
Design prevalence (DP)	In the 'pest-free area' approach, it is not statistically possible to state that a pest is truly absent from a plant population (except in the rare case where a census of the population can be completed with 100% detection efficiency). Instead, the maximum prevalence that a pest could have reached can be estimated — this is called the design prevalence. Therefore, if no pests are found during a survey, the actual prevalence is estimated to lie between zero and the design prevalence. In other words, the survey will be designed to yield at least one positive test result when the infestation/infection prevalence exceeds the defined design prevalence value. Clearly, the more intensive and sensitive the survey, the lower the design prevalence.
Detection survey	Survey conducted in an area to determine whether pests are present (ISPM 5: FAO, 2019).

Term	Definition
Diagnostic analysis	Official examination of plants, plant products or other regulated articles, other than visual inspection, to determine the presence of pests, identify pests, or verify compliance with specific phytosanitary requirements (ISPM 5: FAO, 2019).
Diagnostic protocols	Procedures and methods for the detection and identification of regulated pests relevant to international trade (ISPM 27: FAO, 2016a).
Epidemiological Unit	A homogeneous area in which interactions between the pest, host plants, and abiotic and biotic factors would result in similar epidemiological dynamics in the event of pest presence. Epidemiological units are subdivisions of the target population and reflect its structure within a given geographical area. These are the units of interest for which sample size is estimated (e.g., a tree, an orchard, a field, a greenhouse, a nursery).
EUROPHYT	The acronym combines the words "Europe" and "Phytosanitary". It is a web portal and database that connects the Plant Protection Authorities of EU Member States and Switzerland, the European Food Safety Authority (EFSA), and the Directorate-General for Health and Food Safety of the European Commission. The portal supports the sharing of data related to interceptions, outbreak notifications, and reporting (PFA and DA).
Host plant	A host plant is a plant species belonging to the host range on which the pest can shelter, feed, or persist for at least a certain period of time.
Host range	Species capable, under natural conditions, of sustaining a specific pest or other organism (ISPM 5: FAO, 2019). This definition is limited to a set of host plant species and does not include commodities other than plants or plant parts.
Identification	Information and guidance on methods that, used individually or in combination, lead to the identification of the pest (ISPM 27: FAO, 2016a).
Infected vs Infested	"Infected" is used when referring to a pest in relation to its hosts (e.g., trees are infected by bacteria). "Infested" is used when referring to an arthropod or nematode pest in relation to its hosts (e.g., trees are infested by beetles) or in relation to an area (e.g., an infested zone).
Inspection	Official visual examination of plants, plant products or other regulated articles to determine the presence of pests or compliance with phytosanitary regulations (ISPM 5: FAO, 2019).

Term	Definition
Inspection Unit	Inspection units are plants, plant parts, commodities, or vectors of harmful organisms that are examined for the detection and identification of such organisms. These units are located within epidemiological units, which may host harmful organisms and are the basis for diagnostic activities (EFSA, 2018). They are analogous to the sampling units used in the Methodologies for Sampling of Consignments (ISPM 31: FAO, 2016b).
Inspector	Person authorized by a national plant protection organization to perform its functions (ISPM 5: FAO, 2019).
M.Orga.N.A. Field	This is a free software provided to Italian Regions to: • Manage phytosanitary surveillance across the territory. • Simplify and standardize the collection and processing of survey and monitoring data. • Support Regional Plant Protection Services in all operational phases, with differentiated hierarchical and functional levels.
M.Orga.N.A. Plan	M.Orga.N.A. Plan is the application component dedicated to the planning of phytosanitary surveys. Specifically, it allows for: • The design of monitoring activities on harmful organisms. • The compilation and management of the Block-2B – Programming model, required by the European Commission through the EUROPHYT platform. • The definition of surveillance targets, geographic areas, host species, and survey periods.
Method Sensitivity (MS)	Method sensitivity is defined as the combination of sampling effectiveness and diagnostic sensitivity. It represents the probability that a truly positive inspection unit is correctly confirmed as positive. Method sensitivity has two components: Sampling effectiveness (e.g., the probability of selecting an infested sample from an infested inspection unit), and Diagnostic sensitivity (e.g., the probability that a truly positive sample tests positive, as determined by the laboratory test used in the identification process). Once the target population is defined, it is necessary to establish the procedures that inspectors and technicians will follow regarding: i. Field inspection and visual examination of inspection units (or the capture method), ii. The sampling procedure, and the identification method applied during laboratory analysis of the samples.
Pest	Any species, strain or biotype of plant, animal or pestic agent injurious to plants or plant products (ISPM 5: FAO, 2019).

Term	Definition
Pest diagnosis	The process of detection and identification of a pest (ISPM 27: FAO, 2006).
Pest freedom	Pest freedom can be defined, for a given target population, in a statistical context, as the confidence level of absence of a specific pest relative to a predefined design prevalence (threshold of concern).
Population size	Estimate of the number of plants in the region to be surveyed (EFSA, 2018).
Prevalence	The prevalence of a harmful organism is defined as the fraction of infested/infected units within the total population. In plant pathology, the term incidence is often used to represent this concept. In fact, in ISPM 5 (FAO, 2019), incidence is defined as the proportion or number of units in which a harmful organism is present in a sample, in a consignment, meaning: • a phytosanitary consignment • an export/import consignment • a shipment lot in a field, or in another defined population This distinction is also reflected in EFSA (2020, Supporting Publication EN-1919), where prevalence is used as a key parameter for the design of statistically valid and risk-based surveys.
Representative sample	A sample that best describes the characteristics of the target population (FAO, 2014).
RiBESS+	Risk-based Estimation and Sampling Survey Tool refers to surveillance systems grounded in risk assessment. Specifically, it is an online application that implements statistical methods to estimate sample size, overall (and group) sensitivity, and the probability of pest absence. Free access upon user registration: https://shiny-efsa.openanalytics.eu/
RiPEST	Risk-based PEst Survey Tool is a statistical tool developed by EFSA to support the planning of phytosanitary surveys in pest-free or demarcated areas.
Relative Risk	The ratio between the risk of infestation in the exposed group and the risk of infestation in the unexposed group (Dohoo et al., 2010).
Risk Assessment	Assessment of the likelihood of introduction and spread of a pest and the magnitude of the potential associated economic consequences. (ISPM No. 5: FAO, 2019)

Term	Definition
Risk factor	A factor that may be involved in the cause of the disease (FAO, 2014). It is defined as a biotic or abiotic factor that increases the likelihood of infestation/infection of the epidemiological unit by the pest. Relevant risk factors for surveillance must have more than one risk level for the target population. For each level, the relative risk must be estimated as the probability of infestation/infection relative to a reference baseline with level 1. Considering risk factors in survey design allows efforts to be focused in areas with a higher probability of pest detection.
Risk-based survey	A survey design that takes into account risk factors and strengthens survey efforts in proportion to the corresponding segment of the target population.
SAMPELATOR	Sample size calculator. It is an online application that implements statistical methods to estimate sample size for surveys on pest prevalence. Free access to the software is available upon user registration at: https://shiny-efsa.openanalytics.eu/
Sample size	The sample size refers to the outcome of statistical tools used for survey design (RiBESS+ and SAMPELATOR). A well-chosen sample will contain most of the information about a particular population parameter, but the relationship between the sample and the population must allow for valid inferences about the population. The survey sample consists of the required number of 'inspection units' or their samples to be examined and/or tested in order to obtain sufficient information on the presence or prevalence of the pest in the total population. For risk-based surveys, the sample size is calculated based on statistical principles that incorporate risk factors. If the examination for pest presence is conducted through laboratory testing, at least one sample is taken from each inspection unit. These samples will be subjected to the relevant laboratory tests.
Sampling effectiveness (SE)	For plants, it is the probability of selecting infested plant parts from an infested plant. For vectors, it is the effectiveness of the method in capturing a positive vector when it is present in the survey area. For soil, it is the effectiveness of selecting a soil sample containing the pest when it is present in the survey area.
Specificity of the Analysis	The conditional probability of obtaining a negative result given that the unit does not contain the pest of interest (Dohoo et al., 2010). The diagnostic specificity of the test is the probability that a truly negative epidemiological unit yields a negative result, and it is related to analytical specificity. In pest freedom assessments, it is assumed to be 100%.
Specified Plant	The plant species known to be susceptible to the pest. For example, in the case of Xylella fastidiosa, the list of specified plants is available in Annex II of Commission Implementing Regulation (EU) 2020/1201.

Term	Definition
Trapping site	A fixed or mobile site designated for the systematic placement of one or more phytosanitary traps, used for monitoring, early detection, or capture of pests. Traps may be activated by visual, chemical, sexual, or food-based attractants, and their placement is an integral part of a phytosanitary surveillance program in accordance with international standards. (ISPM 5, ISPM 6, ISPM 9: FAO/IPPC)
Survey	Official procedure conducted over a defined period to determine the characteristics of a pest population or to determine which species are present in an area (ISPM 5: FAO, 2019).
Target population	Set of individual plants, commodities or vectors in which the pest under investigation can be detected directly (e.g., by searching for the pest) or indirectly (e.g., by searching for symptoms suggesting the pest's presence) in a given habitat or area of interest. The different components of the target population that must be specified are: • Definition of the target population: the target population must be clearly identified • Size of the target population and geographic boundary. (EFSA, 2018)
Trapping (Method)	Trapping is an active surveillance technique used to detect the presence of harmful organisms (such as insects or other pests) in a given geographical area. In the case of A. chinensis, this method is considered additional/secondary in surveys conducted in pest-free areas and is therefore reported in Block-2A for information purposes, but it is not included in the calculation of the RiPEST sampling estimate.
Visual inspection	Single action carried out at a specific survey site (including territorial continuity), associated with a specific pair of GPS coordinates and a unique date of visual inspection, even if the action is performed by multiple operators or by a mixed team (Official/Contract). (Pestfund Guidelines, 2021)

Table 4. Concepts and definitions

Annex 2. List of host species

Following is the list of host plants scheduled for surveys by the SS.FF.RR.:

Acacia sp.; Acer campestre; Acer negundo; Acer palmatum; Acer platanoides; Acer pseudoplatanus; Acer saccharinum; Acer sp.; Aesculus hippocastanum; Aesculus sp.; Albizia sp.; Alnus glutinosa; Alnus sp.; Amelanchier sp.; Betula pendula; Betula sp.; Camellia sp.; Carpinus sp.; Castanea sativa; Castanea sp.; Celtis australis; Celtis sp.; Cercis sp.; Chaenomeles sp.; Citrullus sp.; Citrus sp.; Cornus sp.; Corylus avellana; Corylus sp.; Cotoneaster sp.; Crataegus sp.; Cryptomeria sp.; Cydonia sp.; Diospyros kaki; Eriobotrya japonica; Eriobotrya sp.; Fagus sp.; Ficus carica; Ficus sp.; Fragaria sp.; Fraxinus sp.; Hibiscus sp.; Juglans regia; Juglans sp.; Lagerstroemia indica; Lagerstroemia sp.; Laurocerasus sp.; Laurus sp.; Ligustrum sp.; Liquidambar sp.; Magnolia sp.; Malus domestica; Malus sp.; Melia sp.; Morus sp.; Olea europaea; Olea sp.; Ostrya sp.; Parrotia sp.; Photinia sp.; Platanus sp.; Populus sp.; Prunus avium; Prunus cerasifera; Prunus laurocerasus; Prunus pissardii; Prunus sp.; Punica granatum; Pyracantha sp.; Pyrus communis; Pyrus pyrifolia; Pyrus sp.; Quercus sp.; Robinia sp.; Rosa sp.; Salix sp.; Sambucus sp.; Sophora sp.; Sorbus sp.; Styphnolobium japonicum; Tamarix sp.; Thuja sp.; Tilia sp.; Ulmus sp.; Vaccinium corymbosum; Vaccinium sp.; Vitis sp.; Vitis vinifera; Zelkova sp.; Ziziphus sp.

Annex 3. Diagnostic Tests

- ## Morphological Identification

The identification of adults and larvae is based on morphological analyses using dichotomous keys. However, for juvenile stages, the use of taxonomic keys requires caution: while they allow for the exclusion of *A. chinensis* with certainty, specific confirmation requires molecular support.

- ## PCR (Polymerase Chain Reaction)

This is a molecular biology technique that enables the rapid and precise amplification of specific DNA fragments. Through controlled temperature cycles, PCR replicates millions of copies of a target sequence, making it analysable even from minimal starting quantities.

- ## Real-Time PCR (Quantitative PCR)

This molecular biology technique allows monitoring of DNA amplification in real time during each reaction cycle. It uses fluorescent probes or dyes that emit a signal proportional to the amount of amplified DNA, enabling fast and accurate quantification of genetic material.

- ## PCR + Sequencing

This is a combined technique that allows amplification of a specific fragment via PCR, followed by determination of its nucleotide sequence through sequencing.

Annex 4. Sampled materials

The list of materials to be sampled as part of official surveys on *A. chinensis*, in accordance with Article 3 of Regulation (EU) 2022/2095, has been defined by a working group composed of experts from CREA-DC and the SS.FF.RR.

This selection was based on the guidelines provided in the Pest Survey Card and the DTU, and complies with EPPO and ISPM standards. The materials subject to sampling, identified according to the harmonized EUROPHYT nomenclature, include **plants, traps, wood, wood packaging material, bark, and larval frass**.

Annex 5. Traps and operational instructions

This annex provides an overview of the traps used for surveillance activities, including technical specifications, attractants used, and operational instructions for their application in the field.

In the detection method for *A. chinensis*, the traps employed are baited with attractive pheromones, which are useful for intercepting adults during their flight period.

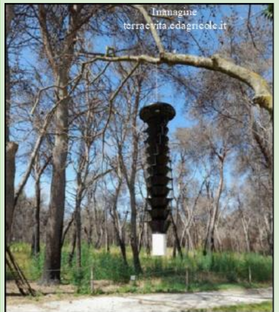
PEST	TYPE OF TRAPS	EXPOSURE PERIOD		ATTRACTANT	ATTRACTANT REPLACEMENT	NUMBER OF TRAPS TO BE USED PER UNIT AREA	INSTRUCTIONS FOR TRAP POSITIONING
		Under Physically closed conditions	In Open-Field				
Anoplophora chinensis [ANOLCN]	 Cross-vane Trap  Multifunnel Trap	**During the period of wood and/or host species importation. All year round.**	**May to September**	**Trap baited with pheromone 4-(n-heptyloxy) butanal, 4-(n-heptyloxy) butanol**	**45 – 60 days**	**In high-risk sites, place 1 to 3 traps per hectare**	**Trap Placement in High-Risk Sites:** 1.3 Nurseries 2.1 Private gardens 2.5.1 Commercial sites using wood packaging material 2.5.2 Garden centres 2.5.7 Points of entry 2.5.12 Movement control checkpoints **Trap Inspection Frequency:** Traps should be checked every 15 to 30 days.

Table 5. Traps and Operational Guidelines of the Regional Plant Protection Services

Sources: DTU n.35; Template IO04

Annex 6. Templates for reporting the results of annual statistically-based surveys

Regulation (EU) 2020/1231[49] sets out the structure of the templates to be completed for reporting the results of annual surveys (Annual Report) and the data from the Multiannual Survey Programme via the EUROPHYT portal. Both documents must be pre-approved by the CFN prior to submission.

Detailed instructions for completing the templates are provided in Annexes I and II of the Regulation (UE), as well as in the EUROPHYT Plant Health Surveys PROPLANTS User Guides.

Specifically, the templates include:

- **Block-2B Template – Multiannual Programme**, found in **Part II of Annex II**, is intended for the *"Multiannual survey programme for [years] concerning Union quarantine pests and pests subject to measures pursuant to Articles 29 and 30 of Regulation (EU) 2016/2031 in areas where the pests are not known to be present".*

- **Block-2B Template – Annual Report**, found in **Part II of Annex I**, intended for the "*Report of annual results of the surveys of [year] for Union quarantine pests and pests subject to the measures of Articles 29 and 30 of Regulation (EU) 2016/2031, in areas where those pests are not known to be present ".*

[49] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R1231

					A. Survey definition (input parameters for RiBESS+)																B. Sampling effort planned										
					6. Target population			7. Epidemiological units		8. Detection methods planned						11. Risk factors (activities, locations and areas)															
1. Year	2. Pest	3. Geographical location	4. Survey sites	5. Timing	Host species	Area (ha or other more relevant unit))	Number of inspection units	Description	Units	Visual examinations	Trapping	Testing	Other measures	9. Sampling effectiveness	10. Method sensitivity	Risk factors	Risk levels	N° of locations	Relative risks	Proportion of the host plant population	12. N° of epidemiological units to be inspected	13. N° of examinations	14. N° of samples	15. N° of traps	16. N° of trapping sites	17. N° of tests	18. N° of other measures	19. Expected Confidence level	20. Design prevalence	21. Comments	22. Underlying assumptions

Table 6. Template for Submitting the National Survey Plan (Block-2B)

1. Indicate the year in which the survey is planned.
2. Enter the name of the pest: *Anoplophora chinensis*.
3. Specify the NUTS geographical area corresponding to the reported EPIUNIT.
4. Provide a list of survey sites within the EPIUNIT.
5. List the months during which the survey will be conducted.
6. List the inspected host species. For *A. chinensis*, the area is considered infinite, and the estimated number of plants is also considered infinite.
7. Specify the type of investigation conducted in the EPIUNIT. For A. chinensis, the method may involve either “plants” or “traps”.
8. For *A. chinensis*, if the EPIUNIT involves visual examination, enter "yes" in the visual examination column. In the trapping column, list the types of traps used. In the testing column, specify the types of tests performed during the survey. In the "other measures" column, list any additional measures adopted.
9. Unless otherwise specified by the SFR, use 0.95 for visual examination and 0.67 for trapping.
10. Unless otherwise specified by the SFR, use 0.86 for visual examination and 0.6 for trapping.
11. Indicate specific risk factors based on the EPIUNIT. For *A. chinensis*, environmental suitability risk is considered, except for production sites. Since the population is considered infinite, do not compile risk levels, number of locations, relative risks, or proportion of host plants.
12. Report the total number of sites to be investigated.
13. Indicate the total number of visual examinations to be carried out.
14. Indicate the total number of samples to be collected.
15. Indicate the total number of traps to be installed.
16. Specify the number of sites where traps will be installed.
17. Indicate the total number of tests to be performed within the EPIUNIT.
18. Indicate the total number of other measures adopted.
19. Specify the confidence level for the individual EPIUNIT investigated.
20. Unless otherwise decided by the SFR, the default value is 0.01 (1%).
21. Add any relevant comments.
22. Enter any assumptions or premises regarding the EPIUNIT under consideration.

1. Pest	2. Geographical location	3. Survey sites	4. Timing	A. Survey definition (input parameters for RiBESS+)																B. Sampling effort							C. Results of the survey							22. Comments
				5. Target			6.		7. Detection methods				8. Sampling effectiveness	9. Method sensitivity	10. Risk factors (activities,					11. N° of epidemiological units inspected	12. N° of visual examinations	13. N° samples	14. N° of traps	15. N° of trapping sites	16. N° of tests	17 N° of other measures	18 Results			19.		20. Achieved Confidence level	21. Design prevalence	
				Host species	Area (ha or other more relevant unit)	Inspection units	Description	Units	Visual examinations	Trapping	Testing	Other measures			Risk factor	Risk levels	N° of locations	Relative risks	Proportion of the host plant population								Positive	Negative	Undetermined	Number(s)	Date(s)			

Table 7. Template for Submitting the National Survey Annual Report (Block-2B)

1. Enter the name of the organism: *Anoplophora chinensis*.
2. Specify the NUTS geographical area corresponding to the reported EPIUNIT.
3. Provide a list of survey sites within the EPIUNIT.
4. List the months during which the survey was conducted.
5. List the inspected host species. For *A. chinensis,* both the area and the estimated number of plants are considered infinite.
6. Specify the investigated epidemiological unit. For *A. chinensis,* the investigation method may involve either "plants" or "traps".
7. For *A. chinensis*:
   - In the visual examinations' column, enter "yes" if visual examinations were conducted.
   - In the trapping column, list the types of traps used.
   - In the testing column, specify the types of tests performed.
   - In the other measures column, list any additional measures adopted.
8. Unless otherwise specified by the SFR, use 0.95 for visual examinations and 0.67 for traps.
9. Unless otherwise specified by the SFR, use 0.86 for visual examinations and 0.6 for traps.
10. Specify any risk factors based on the epidemiological area. For A. chinensis, environmental suitability risk is considered, except for production sites. Since the population is considered infinite, do not define risk levels, number of locations, relative risks, or proportion of host plants.
11. Report the total number of investigated sites.
12. Indicate the total number of visual examinations carried out.
13. Indicate the total number of samples collected.
14. Indicate the total number of traps used.
15. Specify the number of sites where traps were installed.
16. Indicate the total number of tests carried out within the EPIUNIT.
17. Indicate the total number of other measures adopted.
18. The sum of positive, negative, and indeterminate results must match the total number of visual examinations and traps.
19. In case of positive findings, report the number of outbreaks and the corresponding notification dates.
20. Specify the confidence level for the individual investigated EPIUNIT.
21. Unless otherwise decided by the SFR, the default value is 0.01 (1%).
22. Add any relevant comment

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