

COMMISSION DELEGATED REGULATION (EU) 2022/2404**of 14 September 2022****supplementing Regulation (EU) 2016/2031 of the European Parliament and of the Council by laying down detailed rules for the surveys on protected zone quarantine pests and repealing Commission Directive 92/70/EEC**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC ⁽¹⁾, and in particular Article 32(5), second subparagraph, and Article 34(1), second subparagraph, thereof,

Whereas:

- (1) Regulation (EU) 2016/2031 provides for the basic rules on plant health in the Union.
- (2) Article 32(4), point (b), of that Regulation establishes the obligation for Member States to include, when applying for a new protected zone, the results of surveys of at least three preceding years to demonstrate the absence of the protected zone quarantine pest ('the pest') in the territory concerned.
- (3) Article 34(1) of Regulation (EU) 2016/2031 establishes the obligation for Member States to carry out annual surveys of each protected zone as regards the pests and to report to the Commission and the other Member States each year the results of those surveys.
- (4) The rules concerning the preparation of the surveys should include requirements concerning the consideration of the biology of the pest and host plants concerned, and that the timing of the survey is appropriate for the detection of the pest. Those elements are important for the preparation of the survey to be complete and well-suited for the survey concerned.
- (5) The content of the survey should include indications on maps, description of the survey area, examinations, sampling and testing, target populations, detection methods and risk factors, to ensure their completeness, effectiveness and efficiency.
- (6) The surveys should also be carried out in a buffer zone surrounding the protected zone and be more intensive than the ones in the protected zone, because the pest is not prohibited in the buffer zone and no measures against it are applicable there. This is necessary to confirm the absence of the pest from the buffer zone and better preserve the pest-free status of the protected zone. This is also in line with the applicable International Standards for Phytosanitary Measures for the establishment of pest free areas ⁽²⁾ used correspondingly for the establishment of protected zones pursuant to Union law. Those international standards require the establishment of buffer zones for the establishment and the maintenance of pest free areas, where geographic isolation is not considered adequate to prevent introduction to or re-infestation of such areas, or where there are no other means of preventing pest movement to such areas.
- (7) For the same reasons, the surveys in the inner bands of the protected zone, along the border with the protected zone, should be intensified compared with the ones in the rest of the protected zone.

⁽¹⁾ OJ L 317, 23.11.2016, p. 4.

⁽²⁾ ISPM 4 Requirements for the establishment of pest free areas and ISPM 26 Establishment of pest free areas for fruit flies (*Tephritidae*).

- (8) In order for the content of surveys to be consistent, a reporting template should be established. Commission Implementing Regulation (EU) 2020/1231 ⁽³⁾ established the format and instructions for the annual reports on the results of surveys in areas where the pests are not known to be present. In order to have a harmonised approach in the reporting of survey results within the Union, a similar format should be adopted for the reporting of survey results in protected zones, taking into account the specific elements of these surveys.
- (9) Commission Directive 92/70/EEC ⁽⁴⁾ also lays down detailed rules for surveys to be carried out for the purpose of the recognition of protected zones. As it was adopted under the previous Union legal acts on plant health, that Directive is now obsolete and should be repealed,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down detailed rules for:

- (a) surveys for the establishment of a new protected zone pursuant to Article 32(3) or (6) of Regulation (EU) 2016/2031; and
- (b) the preparation and the content of annual surveys pursuant to Article 34(1) of Regulation (EU) 2016/2031.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

- (a) 'buffer zone' means an area surrounding a protected zone in order to minimize the probability of introduction and spread of the pest into the protected zone;
- (b) 'inner band' means an area inside of a protected zone, of a width equivalent to the width of the buffer zone, surrounding the protected zone on the inner side along its outer border;
- (c) 'survey' means a detection survey targeting the pest in a protected zone and, where appropriate, a buffer zone;
- (d) 'demarcated area' means an area demarcated, following a finding of the pest in a protected zone, as described in Article 18 of Regulation (EU) 2016/2031;
- (e) 'statistically-based survey' means a survey carried out on the basis of the European Food Safety Authority General guidelines for statistically sound and risk-based surveys for plant pests ⁽⁵⁾.

⁽³⁾ Commission Implementing Regulation (EU) 2020/1231 of 27 August 2020 on the format and instructions for the annual reports on the results of the surveys and on the format of the multiannual survey programmes and the practical arrangements, respectively provided for in Articles 22 and 23 of Regulation (EU) 2016/2031 of the European Parliament and the Council (OJ L 280, 28.8.2020, p. 1).

⁽⁴⁾ Commission Directive 92/70/EEC of 30 July 1992 laying down detailed rules for surveys to be carried out for purposes of the recognition of protected zones in the Community (OJ L 250, 29.8.1992, p. 37).

⁽⁵⁾ EFSA, General guidelines for statistically sound and risk-based surveys of plant pests, 8 September 2020, doi:10.2903/sp.efsa.2020.EN-1919.

*Article 3***Preparation of surveys**

1. The competent authority of the Member State concerned, or other persons under the official supervision of the competent authority, shall prepare the surveys referred to in Article 1 ('the surveys') in accordance with paragraphs 2 to 6.
2. The surveys shall be:
 - (a) risk-based;
 - (b) based on sound scientific and technical principles;
 - (c) carried out taking into account the biology of the pest and the presence of host species within the protected zone; and
 - (d) carried out at the most appropriate times for the detection of the pest.
3. The surveys shall be extended to a buffer zone surrounding the protected zone.

The surveys in the buffer zones shall be more intensive than in the protected zone, with a higher number of survey activities (visual examinations, samples, traps and tests, where appropriate).

The width of the buffer zone shall be determined on the basis of the biology of the pest and its potential spread capacity.

No surveys in the buffer zone shall be required when due to the biology of the pest, the absence of host plants, the geographical location of the protected zone or the nature of its spatial isolation, there is no risk of introduction of the pest into the protected zone through the natural spread from the neighbouring areas.

4. If there is no possibility to establish a buffer zone in the territory adjacent to the protected zone, an inner band shall be established within the protected zone.

The inner band shall not be established when due to the biology of the pest, the absence of host plants, the geographical location of the protected zone or the nature of its spatial isolation, there is no risk of introduction of the pest into the protected zone through the natural spread from the neighbouring areas.

The surveys in the inner bands shall be more intensive than in the rest of the protected zone, with a higher number of survey activities (visual examinations, samples, traps and tests, where appropriate).

5. In case of the competent authority decides to carry out a statistically-based survey, the survey design and the sampling scheme used shall be suitable to identify within the protected zone concerned, with a sufficient level of confidence, a low level of presence of infested plants by the pest.
6. In case of the competent authority decides to carry out a statistically-based survey in the buffer zone or the inner band, the survey design and sampling scheme used shall be suitable to identify, with a higher level of confidence than in the protected zone itself, a low level of presence of the pest.

*Article 4***Content of the surveys**

The surveys shall contain the following elements:

- (a) a map with the geographical delimitation of the protected zone and, where appropriate, the buffer zone or the inner band, detailing the location of the survey activities carried out and indicating the survey points, the findings or outbreaks and any demarcated areas established;

- (b) a description of:
 - (i) the survey area, including the survey sites;
 - (ii) the plant material or commodity, and
 - (iii) where appropriate, the buffer zone or the inner band;
- (c) the list of host plants;
- (d) the identification of the risk areas where the pest can be present;
- (e) information about the months of the year, during which the survey is carried out;
- (f) where appropriate:
 - (i) the number of visual examinations to detect symptoms or signs of the presence of the pest,
 - (ii) the number of samples, type and number of tests and of traps which attract the pest;
 - (iii) any other measure that is appropriate to ensure the detection of the pest;
- (g) in the case of statistically-based surveys, the underlying assumptions for the survey design per pest, including a description of:
 - (i) the target population, epidemiological unit and inspection units;
 - (ii) the detection method and method sensitivity;
 - (iii) any risk factors, indicating risk levels and corresponding relative risks and proportion of host plants; and
 - (iv) in the case of a finding of the pest, measures taken or the reference to EUROPHYT-Outbreaks.

Article 5

Reporting on the results of the surveys

Member States shall report, for each protected zone and using the template set out in Annex I, general information and the results of the surveys.

Member States shall use one of the templates set out in Annex II to this Regulation to report on the results of the surveys pursuant to:

- (a) Article 32(4), point b, of Regulation (EU) 2016/2031; or
- (b) Article 34(2) of Regulation (EU) 2016/2031.

Article 6

Repeal of Directive 92/70/EEC

Directive 92/70/EEC is repealed.

Article 7

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2023.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 14 September 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Template for general information results of surveys

Member State	
Competent Authority	
Contact person (full name, job title within the competent authority, organisation name, telephone number and functional email account)	
Organisations taking part in the survey	
Laboratories taking part in the survey	
Protected zone quarantine pest	
Name/Description of the protected zone (PZ), as listed in Annex III to Commission Implementing Regulation (EU) 2019/2072	
Year of establishment of the PZ	
Year(s) of the survey. In the case of a request for a new PZ, please indicate the years covered by the survey.	
Size of the PZ (ha)	
Establishment of a buffer zone or an inner band (yes/no). Please justify in case this zone is not established.	
Width (m) of the buffer zone or inner band, if applicable	
Map of the boundaries of the PZ, including the buffer zone or the inner band, if applicable. Please indicate the survey points, the findings/outbreaks and, where applicable, the demarcated areas established.	
Statistically-based survey (yes/no)	
Findings/outbreaks during the last survey (yes/no)	
Description of the findings/outbreaks ⁽¹⁾ and actions taken or reference to EUROPHYT-Outbreak	

⁽¹⁾ Including a reference to the notification(s) of actions taken in accordance with Article 33(3) of Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

Templates for reporting results of the annual surveys or of surveys to request a new protected zone quarantine pest

PART A

1. Template for the reporting of the results of annual surveys

1. Year of the survey	2. Protected zone quarantine pest	3. Name of the protected zone	4. Zone (Protected zone, buffer zone or inner band)	5. Survey sites		6. Risk areas	7. Target population area	8. Surveyed area of the target population (%)	9. Plant material/Commodity	10. List of plant species	11. Timing	12. Survey details											Findings/Outbreaks (to be linked with EUOPHYT – Outbreaks)		15. Comments	
				Description	Number							A) Number of visual examinations B) Total number of samples C) Number of asymptomatic samples, where applicable D) Type of traps (or other alternative method (e.g. sweep nets)) E) Number of traps (or other alternative method) F) Number of trapping sites (when different from number of traps or alternative method) G) Type of tests (e.g. microscopic identification, PCR, ELISA, etc.) H) Total number of tests I) Other measures (e.g. sniffer dogs, drones, helicopters, etc.) J) Number of other measures											13. Number of positive results	14. Notification number(s) of the outbreaks, in accordance with Implementing Regulation (EU) 2019/1715		
												A	B	C	D	E	F	G	H	I	J			Number (s)	Date (s)	

2. Instructions on how to fill in the template

If this template is filled for a protected zone quarantine pest, the template in Part B of this Annex is not to be filled for the same pest.

For column 1:	Indicate the year of the survey. In the case of a survey report to request a protected zone, include the data of at least the three preceding years, using a separate row for each year.
For column 2:	Indicate the scientific name of the protected zone quarantine pest (as listed in Annex III to Implementing Regulation (EU) 2019/2072 or the most accepted scientific name when the pest is not yet listed), using one row per pest.
For column 3:	Indicate the name of the protected zone, using separate rows when there is more than one protected zone for the same pest in the territory of the Member State, as listed in Annex III to Commission Implementing Regulation (EU) 2019/2072.
For column 4:	Indicate the zone: PZ (protected zone), BZ (buffer zone) or IB (inner band), using different rows.
For column 5:	Indicate the number and the description of the survey sites, by choosing one (or more) of the following entries for the description, and the number of surveys done: 1. Open air (production area): 1.1 field (arable, pasture); 1.2. orchard/vineyard; 1.3. nursery; 1.4. forest; 2. Open air (other): 2.1. private gardens; 2.2. public sites; 2.3. conservation area; 2.4. wild plants in areas other than conservation areas; 2.5. other, with specification of the particular case (e.g. garden centre, commercial sites that uses wood packaging material, wood industry, wetlands, irrigation and drainage network, etc.); 3. Physically closed conditions: 3.1. greenhouse; 3.2. private site, other than greenhouse; 3.3. public site, other than greenhouse; 3.4. other, with specification of the particular case (e.g. garden centre, commercial sites that uses wood packaging material, wood industry).
For columns 6, 7 and 8:	Optional.
For column 6:	Indicate which are the risk areas identified based on the biology of the pest(s), presence of host plants, eco-climatic conditions and risk locations.
For column 7:	Indicate the total area covered by the target population (ha) in the protected zone.
For column 8:	Indicate the proportion of the surveyed area of the target population (surveyed area/target population area) in percentage.
For column 9:	Indicate plants, fruits, seeds, soil, packaging material, wood, machinery, vehicles, vector, water, other, specifying the specific case, using as many rows as necessary.
For column 10:	Indicate the list of plant species/genera that were surveyed, using one row per plant species/genera.
For column 11:	Indicate the months of the year when the surveys were carried out.

For column 12:	Indicate the details of the survey, taking into account the biology of the pest. Indicate with N/A when the information of certain column is not applicable for the given pest. Use different rows (e.g. to report different types of tests and their number).
For column 13:	Indicate the number of positive results. This number may differ from the number of outbreaks when several positive results are included in one outbreak notification.
For column 14:	Indicate the outbreak notifications of the year when the survey took place. The outbreak notification number does not need to be included when the competent authority has decided that the finding is one of the cases referred to in Article 14(2), Article 15(2) or Article 16 of Regulation (EU) 2016/2031. In that case, please indicate the reason for not providing this information in column 15 ('Comments').
For column 15:	Include any other relevant information and, where applicable, information about the results of the surveys of asymptomatic plants with positive results.

	1. Year of the survey					
	2. Protected zone quarantine pest					
	3. Name of the protected zone					
	4. Zone (Protected zone, buffer zone or inner band)					
	Description	5. Survey sites				
	Number					
	6. Timing					
	A. Survey definition (input parameters for RiBESS+)					
	Host species	7. Target population				
	Area (ha or other more relevant unit))					
	Inspection units					
	Description	8. Epidemiological units				
	Units					
	Visual examinations					
	Trapping	9. Detection methods				
	Testing					
	Other measures					
	10. Sampling effectiveness					
	11. Method sensitivity					
	Risk factor	12. Risk factors (activities, locations and areas)				
	Risk levels					
	N° of locations					
	Relative risks					
	Proportion of the host plant population					
	B. Sampling effort					
	13. Number of epidemiological units inspected					
	14. Number of visual examinations					
	15. Number of samples					
	16. Number of traps					
	17. Number of trapping sites					
	18. Number of tests					
	19. Number of other measures					
	Positive	20. Results				
	Negative					
	Undetermined					
	Number(s)	21. Notification number(s) of the outbreaks notified, as applicable, in accordance with Implementing Regulation (EU) 2019/1715				
	Date(s)					
	22. Achieved Confidence level					
	23. Design prevalence					
	24. Comments					

2. Instructions on how to fill in the template

If this template is filled for a protected zone quarantine pest, the template in Part B of this Annex is not to be filled for the same pest.

Explain the underlying assumptions for the survey design per pest. Summarise and justify:

— the target population, epidemiological unit and inspection units,

— the detection method and method sensitivity,

— the risk factor(s), indicating the risk levels and corresponding relative risks and proportions of host plant population.

- | | |
|---------------|--|
| For column 1: | Indicate the year of the survey. In the case of a survey report to request a protected zone, include the data of at least the three preceding years, using a separate row for each year. |
| For column 2: | Indicate the scientific name of the protected zone quarantine pest (as listed in Annex III to Implementing Regulation (EU) 2019/2072 or the most accepted scientific name when the pest is not yet listed), using one row per pest. |
| For column 3: | Indicate the name of the protected zone, using separate rows when there is more than one protected zone for the same pest in the territory of the Member State, as listed in Annex III to Commission Implementing Regulation (EU) 2019/2072. |
| For column 4: | Indicate the zone: PZ (protected zone), BZ (buffer zone) or IB (inner band), using different rows. |
| For column 5: | <p>Indicate the number and the description of the survey sites, by choosing one (or more) of the following entries for the description, and the number of surveys done:</p> <ol style="list-style-type: none"> 1. Open air (production area): 1.1 field (arable, pasture); 1.2 orchard/vineyard; 1.3 nursery; 1.4 forest; 2. Open air (other): 2.1 private gardens; 2.2 public sites; 2.3 conservation area; 2.4 wild plants in areas other than conservation areas; 2.5 other, with specification of the particular case (e.g. garden centre, commercial sites that uses wood packaging material, wood industry, wetlands, irrigation and drainage network, etc.); 3. Physically closed conditions: 3.1 greenhouse; 3.2 private site, other than greenhouse; 3.3 public site, other than greenhouse; 3.4 other, with specification of the particular case (e.g. garden centre, commercial sites that uses wood packaging material, wood industry). |
| For column 6: | Indicate the months of the year when the surveys were carried out. |
| For column 7: | Indicate the chosen target population providing accordingly the list of host species and area covered. The target population is defined as the ensemble of inspection units. Its size is defined typically for agricultural areas as hectares, but could be lots, fields, greenhouses etc. Please justify the choice made in the underlying assumptions. Indicate the inspection units surveyed. 'Inspection unit' means plants, plant parts, commodities, materials, pest vectors that had been scrutinised for identifying and detecting the pests. If the area of the target population is not available, indicate N/A and include the number of inspection units that compose the target population. |

For column 8:	Indicate the epidemiological units surveyed, indicating its description and unit of measurement. 'Epidemiological unit' means a homogeneous area where the interactions between the pest, the host plants and the abiotic and biotic factors and conditions would result into the same epidemiology, should the pest be present. The epidemiological units are a subdivision of the target population that are homogenous in terms of epidemiology with at least one host plant. In some cases the whole host plant population in a region/area/country may be defined as epidemiological unit. They could be NUTS (Nomenclature of Territorial Units for Statistics) regions, urban areas, forests, rose gardens or farms, or hectares. The choice of the epidemiological units has to be justified in the underlying assumptions.
For column 9:	Indicate the methods used during the survey including the number of activities in each case, depending on the specific legal pest survey requirements of each pest. Indicate with NA when the information of certain column is not available.
For column 10:	Indicate an estimation of the sampling effectiveness. Sampling effectiveness means the probability of selecting infected plant parts from an infected plant. For vectors, it is the effectiveness of the method to capture 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 the pest is present in the survey area.
For column 11:	'Method sensitivity' means the probability of a method to correctly detect pest presence. The method sensitivity is defined as the probability that a truly positive host is detected and confirmed as positive and it is not misidentified. It is the multiplication of the sampling effectiveness (i.e. probability of selecting infected plant parts from an infected plant) by the diagnostic sensitivity (characterised by the visual examinations and/or laboratory test used in the identification process).
For column 12:	Provide the risk factors in different rows, using as many rows as necessary. For each risk factor indicate the risk level and corresponding relative risk and proportion of host plant population.
For column B:	Indicate the details of the survey, depending on the specific legal pests survey requirements for each pest. Indicate with N/A when the information of certain column is not applicable. The information to be provided in these columns is related to the information included in the column 9 'Detection methods'.
For column 18:	Indicate the number of trapping sites in case this number differs from the number included in the column 16 'No of traps' (e.g. the same trap is used in different places).
For column 20:	Indicate the number of samples found positive, negative or undetermined. 'Undetermined' are those analysed samples for which no result was obtained due to different factors (e.g. below detection level, unprocessed sample-not identified, old).
For column 21:	Indicate the outbreak notifications of the year when the survey took place. The outbreak notification number does not need to be included when the competent authority has decided that the finding is one of the cases referred to in Articles 14(2), Article 15(2) or Article 16 of Regulation (EU) 2016/2031. In this case, please indicate the reason for not providing this information in column 24 ('Comments').
For column 22:	Indicate the sensitivity of the survey, as defined in the International Standard for Phytosanitary Measures (ISPM) No 31 ('Methodologies for sampling of consignments'). This value of the achieved confidence level of pest freedom is calculated based on the examinations (and/or samples) performed given the method sensitivity and the design prevalence.
For column 23:	Indicate the design prevalence based on a pre-survey estimate of the likely actual prevalence of the pest in the field. The design prevalence is set as a goal of the survey and corresponds to the compromise the risk managers are making between the risk of having the pest and the resources available for the survey. Typically, for a detection survey a value of 1 % is set.
For column 24:	Include any other relevant information and, where applicable, information about the results of the surveys of asymptomatic plants with positive results.