COMMISSION IMPLEMENTING REGULATION (EU) 2023/1032
of 25 May 2023
establishing measures to prevent the introduction into and the spread within the Union territory of Tomato brown rugose fruit virus (ToBRFV) and amending Implementing Regulation (EU) 2020/1191

THE EUROPEAN COMMISSION,

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


Whereas:

(1) Tomato brown rugose fruit virus (ToBRFV) (‘the specified pest’) is currently not listed as a Union quarantine pest, or as a Union regulated non-quarantine pest, in Commission Implementing Regulation (EU) 2019/2072 (3). However it fulfils the criteria set out in Subsection 2 of Section 3 of Annex I to Regulation (EU) 2016/2031 for a preliminary assessment to identify pests which provisionally qualify as a Union quarantine pest requiring temporary measures as referred to in Article 30(1) of that Regulation.

(2) Commission Implementing Regulation (EU) 2020/1191 (4) established measures to prevent the introduction into and the spread within the Union of the specified pest. That Regulation is to expire on 31 May 2023.

(3) After the adoption of Implementing Regulation (EU) 2020/1191, more recent scientific information has been collected on the spread of the specified pest and on testing methods and the audits carried out by the Commission services provided feedback on the implementation of the provisions and on their impact on the protection against the spread of the disease. That justifies the need for the adoption of a new act with more detailed measures than those provided for in that Regulation.

(4) In order to ensure the most proactive approach concerning phytosanitary protection, measures should be established for situations where any person within the Union territory suspects or becomes aware of the presence of the specified pest, and with regards to the corresponding notification to the competent authority, and the actions to be taken by it.

(4) Commission Implementing Regulation (EU) 2020/1191 of 11 August 2020 establishing measures to prevent the introduction into and the spread within the Union of Tomato brown rugose fruit virus (ToBRFV) and repealing Implementing Decision (EU) 2019/1615 (OJ L 262, 12.8.2020, p. 6).
Where the presence of the specified pest is officially confirmed in the territory of a Member State, the competent authority of the Member State concerned should establish a demarcated area to ensure the eradication of that pest and the prevention of its spread to the rest of the Union territory. In order to ensure the most appropriate and proportionate approach, different rules for the demarcation should be adopted for the case where the presence of the specified pest is confirmed in production sites with physical protection, because of the reduced phytosanitary risk resulting from that protection.

In order to ensure a more proactive approach for the protection of the Union territory from the specified pest, Member States should conduct annual surveys for the presence of the specified pest in their territory.

Rules should be established for the movement within the Union of seeds of Solanum lycopersicum L. and hybrids thereof, and of Capsicum spp. (‘specified seeds’), and of plants for planting, other than specified seeds, of Solanum lycopersicum L. and hybrids thereof and of Capsicum spp. (‘specified plants for planting’), because those seeds and other plants for planting are most likely to host and spread the specified pest.

Those rules should include, as appropriate for the type of plant and its production, pest freedom in the production site, visual inspection, sampling and testing, appropriate handling of lots, and measures on mother plants. Such an approach is necessary in order to adapt to the technical circumstances of each case of production and movement of the specified seeds and specified plants.

In particular, all lots of specified seeds should undergo sampling and testing by the competent authority in order to detect the presence of the specified pest. Those specified seeds should also be tested by the competent authority or professional operator, as applicable, prior to further processing, and have been found, according to those tests, to be free from the specified pest. This is necessary for the protection of the Union territory from the specified pest, as the specified seeds are the starting material for the production of all respective plants.

In order to protect the Union territory from the specified pest, requirements should be set out for the introduction into the Union of specified seeds and specified plants for planting from third countries. Those requirements should be similar to the ones concerning the movement of the specified seeds and specified plants for planting within the Union, in order to ensure a non-discriminatory approach.

It is proportionate to except from those requirements specified seeds and specified plants belonging to varieties which are known to be resistant to the specified pest, because the respective phytosanitary risk is reduced to an acceptable level in the case of those plants. Members States should notify to the Commission and to the other Members States a list of those resistant varieties, regularly updated.

In order to ensure effective official controls against the entry of the specified pest into the Union, at least 20 % of the consignments of specified seeds and of specified plants for planting should be sampled and tested by the competent authority at the border control posts of first arrival into the Union, or at a control point as referred to in Commission Delegated Regulation (EU) 2019/2123 (2). For consignments of specified seeds and specified plants for planting originating in Israel and China, that sampling and testing rate should be 50 % and 100 %, respectively, due to the higher number of interceptions of the specified pest in commodities originating from those third countries.

In order to allow sufficient time for the third countries, the competent authorities and the professional operators to adapt to the provisions of this Regulation, it should apply from 1 September 2023. For this reason, and in order to avoid any legal gap, the expiration of the application of Implementing Regulation (EU) 2020/1191 should be extended from 31 May 2023 to 31 August 2023.

(2) Commission Delegated Regulation (EU) 2019/2123 of 10 October 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards rules for the cases where and the conditions under which identity checks and physical checks on certain goods may be performed at control points and documentary checks may be performed at distance from border control posts (OJ L 321, 12.12.2019, p. 64).
The full assessment of the specified pest is still pending, in order to determine its risk for the Union territory. For this reason, this Regulation should apply until 31 December 2024, in order to allow time for that assessment to happen by then.

In order to swiftly address the phytosanitary risk of the specified pest, the rules of this Regulation should become applicable after the shortest possible delay. Therefore, this Regulation should enter into force on the day following that of its publication.

The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation establishes measures to prevent the introduction into and the spread within the Union of Tomato brown rugose fruit virus (ToBRFV).

Article 2

Definitions

For the purpose of this Regulation, the following definitions shall apply:
(a) ‘specified pest’ means Tomato brown rugose fruit virus (ToBRFV);
(b) ‘specified plants’ means plants of Solanum lycopersicum L. and hybrids thereof, and of Capsicum spp., other than specified seeds and specified fruits;
(c) ‘specified plants for planting’ means plants for planting of Solanum lycopersicum L. and hybrids thereof and of Capsicum spp., other than specified seeds;
(d) ‘specified seeds’ means seeds of Solanum lycopersicum L. and hybrids thereof, and of Capsicum spp.;
(e) ‘specified fruits’ means fruits of Solanum lycopersicum L. and hybrids thereof, and of Capsicum spp.

Article 3

Prohibitions concerning the specified pest

The specified pest shall not be introduced into, moved within, or held, multiplied or released within the Union territory.

Article 4

Measures in the case of suspicion or awareness of the presence of the specified pest

1. Any person within the Union territory who suspects or becomes aware of the presence of the specified pest, shall immediately inform the competent authority and provide it with all relevant information concerning the presence, or suspected presence, of that pest.

2. On receiving such information, the competent authority shall:
(a) immediately record the information provided;
(b) take all necessary measures to confirm or refute the presence or suspected presence of the specified pest;
(c) ensure that any person having specified plants, specified seeds or specified fruits which may be infected with the specified pest under its control, is immediately informed of:

(i) the presence or the suspected presence of the specified pest; and

(ii) of the possible risks associated with the specified pest and of the measures to be taken.

Article 5

Surveys on the presence of the specified pest

1. The competent authorities shall conduct annual surveys for the presence of the specified pest in their territory.

2. Those surveys shall:

(a) include sampling and testing as laid down in the Annex; and

(b) be based on:

(i) the assessed risk of introduction and spread of the specified pest into and within the Member State concerned; and

(ii) sound scientific and technical principles, with regard to the possibility to detect the specified pest.

3. By 30 April of each year, Member States shall notify the Commission and the other Member States the results of the surveys carried out during the preceding calendar year.

Article 6

Measures in case of confirmed presence of the specified pest

1. Where the presence of the specified pest is officially confirmed in the territory of a Member State, the competent authority of the Member State concerned shall ensure that appropriate measures are taken to eradicate the specified pest in accordance with Article 17 of Regulation (EU) 2016/2031.

That competent authority shall take the measures laid down in paragraphs 2 and 3 of this Article, unless the conditions set out in Article 18(4) of Regulation (EU) 2016/2031 are fulfilled with regard to the specified pest.

Measures laid down in paragraphs 2 and 3 shall not apply to specified plants for planting of varieties which are known to be resistant to the specified pest. Members States shall notify to the Commission and to the other Members States a list of those resistant varieties, regularly updated.

2. The competent authority shall establish without delay a demarcated area as follows:

(a) if the specified pest is present in production sites with physical protection, the demarcated area shall consist of at least the production site where the specified pest has been found;

(b) if the specified pest is present in production sites other than those referred to in point (a), the demarcated area shall consist of:

(i) an infested zone including at least the production site where the specified pest has been found;

(ii) a buffer zone of at least 30 m surrounding the infested zone.

3. In the demarcated area, the competent authority, or the professional operator under the official supervision of the competent authority, shall:

(a) for production sites intended for the production of specified plants for planting or for the production of specified seeds:

(i) immediately remove and destroy all infected lots of the specified plants for planting and, where applicable, their growing medium and the specified seeds originating from those lots. That removal and destruction shall be carried out in such a way that there is no risk of spreading the specified pest;
apply specific hygiene measures on personnel, production site structures, tools and machinery, materials and means of transport, to prevent the spread of the specified pest to the other lots present in the production site and to the successive crops of the specified plants or to other production sites;

(iii) destroy or treat the growing medium, at least at the end of the cropping season such that there is no identifiable risk of spreading the specified pest;

(b) for production sites intended for the production of specified fruits:

(i) remove and destroy all infected specified plants from the production site, at least at the end of the cropping season. The removal shall be carried out in such a way that there is no identifiable risk of spreading the specified pest;

(ii) apply specific hygiene measures on personnel, production site structures, tools and machinery, materials and means of packing and transport of the fruits, to prevent the spread of the specified pest to successive crops of the specified plants or to other production sites;

(iii) destroy or treat the growing medium at least at the end of the cropping season such that there is no identifiable risk of spreading the specified pest.

Article 7

Movement of the specified plants for planting within the Union

1. The specified plants for planting may only be moved within the Union if they are accompanied by a plant passport, issued after the competent authority or the professional operator concerned has concluded all of the following conditions are fulfilled:

(a) the specified plants for planting derive from specified seeds which comply with the requirements laid down in Articles 8 and 10;

(b) the specified plants for planting have been grown in a production site where the specified pest is known not to occur, on the basis of official inspections carried out at the appropriate time to detect the specified pest;

(c) the specified plants for planting that have displayed symptoms of the specified pest have been subjected to sampling and testing by the competent authority, and those tests have shown that those plants are free from the specified pest;

(d) the lots of the specified plants for planting have been kept separate from other lots of specified plants, by applying appropriate hygiene measures.

Sampling for testing, as referred to in this paragraph, shall be carried out as set out in the Annex.

2. The conditions laid down in paragraph 1 for issuance of a plant passport shall not apply to specified plants for planting of varieties which are known to be resistant to the specified pest. Members States shall notify to the Commission and to the other Members States a list of those resistant varieties, regularly updated.

Article 8

Movement of the specified seeds within the Union

1. Specified seeds may only be moved within the Union, if they are accompanied by a plant passport issued after the competent authority or the professional operator concerned has concluded that the following conditions are fulfilled:

(a) the mother plants of the specified seeds have been produced in a production site where the specified pest is known not to occur, on the basis of official inspections carried out at the appropriate time to detect the specified pest;
in the case of a specified seed lot originating from more than 30 mother plants that specified seed lot, prior to processing, has undergone sampling and testing as set out in the Annex by the competent authority for the presence of the specified pest, or has been subjected by the professional operators to sampling and testing under the official supervision of the competent authority, and has been found, according to those tests, to be free from the specified pest. Any presence of the specified pest has been notified to the competent authority and the infected specified seed lots shall not move within the Union territory;

c) in the case of a specified seed lot originating from less than or equal to 30 mother plants, sampling and testing, as set out in the Annex, have been carried out by the competent authority for the presence of the specified pest, or by the professional operators under the official supervision of the competent authority on the specified seeds or on each mother plant of those specified seeds. Specified seeds or mother plants have been found, according to those tests, to be free from the specified pest. Any presence of the specified pest has been notified to the competent authority and the specified seed lots originating from the infected mother plants shall not move within the Union territory;

d) in case of suspicion of the presence of the specified pest, that sampling and testing shall only be carried out by the competent authorities in accordance with Article 87(3), point (c), of Regulation (EU) 2016/2031;

e) the origin of all lots of specified seeds are recorded and documented.

2. By way of derogation from paragraph 1, points (a), (b), (c) and (d), specified seeds that have been harvested prior to 31 August 2023 and before their first movement within the Union have been found by the competent authority or the professional operator concerned to comply with the requirements of Implementing Regulation (EU) 2020/1191, may move within the Union accompanied by a plant passport attesting compliance with those requirements.

3. The lots of specified seeds moved for the first time within the Union since 1 April 2021, and which have been tested before 30 September 2020 with the enzyme-linked immunosorbent assay (ELISA) method, shall be tested again with a testing method, other than ELISA, as referred to in point 3 of the Annex.

4. Sampling and testing shall be carried out as set out in the Annex.

5. The conditions laid down in paragraphs 1 and 2 for issuance of a plant passport shall not apply to specified seeds of varieties which are known to be resistant to the specified pest. Members States shall notify to the Commission and to the other Members States a list of those resistant varieties, regularly updated.

### Article 9

**Introduction into the Union of the specified plants for planting**

1. Specified plants for planting, other than the ones belonging to varieties which are known to be resistant to the specified pest, originating from third countries may only be introduced into the Union if they are accompanied by a phytosanitary certificate which, under the heading 'Additional declaration', includes the following elements:

   a) an official statement that the specified plants for planting derive from seeds which comply with the requirements laid down in Article 10;

   b) an official statement that the specified plants for planting have been produced in a production site which is registered and supervised by the national plant protection organisation in the country of origin and known to be free from the specified pest on the basis of official inspections, sampling and testing carried out at the appropriate time to detect that pest;

   c) the name of the registered production site.

2. Specified plants for planting of varieties which are known to be resistant to the specified pest, originating from third countries, may only be introduced into the Union if they are accompanied by a phytosanitary certificate, which, under the heading 'Additional Declaration', confirms that resistance.
Article 10

Introduction into the Union of the specified seeds

1. Specified seeds originating from third countries, other than the ones belonging to varieties which are known to be resistant to the specified pest, may only be introduced into the Union if they are accompanied by a phyto sanitary certificate, which, under the heading 'Additional Declaration', contains all of the following:

(a) an official statement that all of the following conditions have been fulfilled:

(i) the mother plants of the specified seeds concerned have been produced in a production site where the specified pest is known not to occur, on the basis of official inspections carried out at the appropriate time to detect the specified pest;

(ii) in the case of a specified seed lot originating from more than 30 mother plants, that specified seed lot, prior to processing, has undergone official sampling and testing for the specified pest as set out in the Annex and have been found, according to those tests, to be free from the specified pest;

(iii) in the case of a specified seed lot originating from less than or equal to 30 mother plants, sampling and testing, as set out in the Annex have been carried out on the specified seeds, or on each individual mother plant of those specified seeds. Specified seeds or mother plants have been found, according to those tests, to be free from the specified pest;

(b) information ensuring the traceability of the production site of the mother plants.

2. Specified seeds of varieties which are known to be resistant to the specified pest, originating from third countries, may only be introduced into the Union if they are accompanied by a phyto sanitary certificate, which, under the heading 'Additional Declaration' confirms that resistance.

3. By way of derogation from paragraph 1, point (a), specified seeds that have been harvested prior to 31 August 2023 and before their introduction within the Union have been found to comply with the requirements of Implementing Regulation (EU) 2020/1191, may be introduced into the Union territory accompanied by a phyto sanitary certificate indicating under the heading 'Additional Declaration', the following statement: 'These seeds have been harvested before 31 August 2023 and have been found to comply with Regulation (EU) 2020/1191'.

Article 11

Official checks on introduction into the Union

At least 20 % of the consignments of specified seeds and of specified plants for planting shall be sampled and tested by the competent authority at the border control posts of first arrival into the Union, or at a control point as referred to in Article 2 of Delegated Regulation (EU) 2019/2123, as set out in the Annex to this Regulation.

For consignments of specified seeds and specified plants for planting originating in Israel and China, that sampling and testing rate shall be 50 % and 100 %, respectively.

Article 12

Amendment of Implementing Regulation (EU) 2020/1191

In Article 12 of Implementing Regulation (EU) 2020/1191, the date '31 May 2023' is replaced by '31 August 2023'.
Article 13

Entry into force and date of application

This Regulation shall enter into force on the day following that of its publication in the Official Journal of the European Union. It shall apply from 1 September 2023 until 31 December 2024.

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


For the Commission
The President
Ursula VON DER LEYEN
1. Sampling schemes of specified seeds, other than those of varieties which are known to be resistant to the specified pest

Sampling of seeds for testing shall be carried out under the following sampling schemes depending on the seed lots as referred to in the relevant tables of the International Standards for Phytosanitary Measures No 31 Methodologies for sampling of consignments (ISPM31):

a) for a seed lot originating from less than or equal to 30 mother plants:

   — application of a hypergeometric sampling scheme able to identify with 95 % reliability a level of presence of infected plants of 10 % or above; or

   — testing of each mother plant of the seed lot;

b) for a seed lot less than or equal to 3 000 seeds: application of a hypergeometric sampling scheme able to identify with 95 % reliability a level of presence of infected plants of 10 % or above;

c) for a seed lot of more than 3 000 but less than or equal to 30 000 seeds: application of a sampling scheme able to identify with 95 % reliability a level of presence of infected plants of 1 % or above;

d) for a seed lot of more than 30 000 seeds: application of a sampling scheme able to identify with 95 % reliability a level of presence of infected plants of 0,1 % or above.

Sub samples shall consist of 1 000 seeds maximum for Polymerase Chain Reaction (PCR) methods.

2. Sampling schemes of specified plants, other than those varieties which are known to be resistant to the specified pest

a) In the case of those specified plants, at least one sample of up to 200 young leaves from the top of the plant, or sepals from fruits, shall be collected per site of production and per cultivar when applicable.

b) In the case of symptomatic plants, sampling for testing shall be performed on at least 3 symptomatic leaves.

c) In case of testing of mother plants, young leaves from the top of plant, or sepals from fruits, shall be collected as appropriate.

3. Testing methods for detecting and identifying the specified pest on seeds, other than those of varieties which are known to be resistant to the specified pest

One of the following testing methods shall be used for the detection of the specified pest on the specified seeds:

— real-time RT-PCR using the primers and probes described in the ISF protocol (2020) (1);

— real-time RT-PCR using primers and probe of Menzel and Winter (2021) (2);

— real-time RT-PCR using primers and probe from Bernabé-Orts et al. (2021) (3).

In case of a positive result of the detection test, a second testing method, different from the one used for detection, shall be carried out with one of the real-time RT-PCR methods listed above, using the same sample to confirm the identification. In the case of inconsistency between detection and identification results obtained for coated seeds, the coating of the seeds shall be removed and the seeds shall be retested, if applicable.


4. Testing methods for detecting and identifying the specified pest on the specified plants, other than those of varieties which are known to be resistant to the specified pest, and on the specified fruits

One of the following testing methods shall be carried out for the detection of the specified pest on the specified plants, other than those varieties which are known to be resistant to the specified pest, and on the specified fruits:

— ELISA, only for symptomatic material;
— conventional RT-PCR using the primers of Alkowni et al. (2019) (1);
— conventional RT-PCR using the primers of Rodríguez-Mendoza et al. (2019) (2);
— real-time RT-PCR using the primers and probes described in the ISF protocol (2020) (3);
— real-time RT-PCR using primers and probe of Menzel and Winter (2021) (4);
— real-time RT-PCR using primers and probe from Bernabé-Orts et al. (2021) (5).

In case of a positive result of the detection test, a second testing method, different from the one used for detection, shall be carried out with one of the RT-PCR methods listed above, using the same sample to confirm the identification.