

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**

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 30,

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC ⁽²⁾, and in particular Article 22(3) and Article 52 thereof,

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⁾.
- (2) However, since 2018 Member States have reported outbreaks of the specified pest on tomato crops in their territories and the measures taken to control it. Germany, in 2018, and Italy, in 2019, carried out pest risk analyses showing that the specified pest and its damaging effects could be of significant plant health concern to the Union, in particular for the production of *Solanum lycopersicum* L. and *Capsicum* spp.
- (3) Based on this, Commission Implementing Decision (EU) 2019/1615 ⁽⁴⁾ was adopted in order to establish measures to prevent the introduction into and the spread within the Union of the specified pest.
- (4) After the adoption of Implementing Decision (EU) 2019/1615, more recent scientific information has been collected on the spread of the specified pest and on testing methods, which justifies the need for more detailed measures than those provided for under Implementing Decision (EU) 2019/1615.
- (5) In particular, seeds of *Solanum lycopersicum* L. and *Capsicum* spp. should be tested regardless of their origin. This is necessary because of the uncertainties surrounding the presence of the pest worldwide and because seeds of different origins are often mixed in the lots when traded, thus increasing the risk of spread of the specified pest.
- (6) Moreover, the establishment of pest free production sites has to be subject to certain measures, in order to ensure that healthy material is produced.

⁽¹⁾ OJ L 317, 23.11.2016, p. 4.

⁽²⁾ OJ L 95, 7.4.2017, p. 1.

⁽³⁾ Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019

(OJ L 319, 10.12.2019, p. 1).

⁽⁴⁾ Commission Implementing Decision (EU) 2019/1615 of 26 September 2019 establishing emergency measures to prevent the introduction into and the spread within the Union of Tomato brown rugose fruit virus (ToBRFV) (OJ L 250, 30.9.2019, p. 91).

- (7) *Capsicum* spp. varieties which are known to be resistant to the specified pest, are not considered to represent a risk of infection and spread of the specified pest. Therefore, these varieties should be exempt from the requirements for testing if they are officially attested as resistant.
- (8) Sampling and testing should be carried out under specific conditions on the basis of the most recent information collected at Union and international level. Real time PCR methods are most effective in detecting and identifying the specified pest. The ELISA method is less sensitive and less specific since this method was found to cross-react with other tomato viruses. However, due to the COVID-19 pandemic there is a shortage of kits required for the Real Time PCR detection methods. Until 1 October 2020, the ELISA method should also be considered as an acceptable method of detecting and identifying the specified pest. This sampling and testing should take place in addition to the sampling for physical checks that takes place in accordance with the provisions of Commission Implementing Regulation (EU) 2019/2130 ⁽⁵⁾, to ensure an increased level of phytosanitary protection of the Union.
- (9) The conditions for the movement of plants for planting should not apply to plants already produced in accordance with Implementing Decision (EU) 2019/1615 because it would not be proportionate to require additional testing for those seeds and because in most of the cases those conditions could not be practically implemented.
- (10) Annex III to Implementing Regulation (EU) 2019/2130 sets out rules on the operations to be carried out during physical checks on plants for planting including sampling. In addition to those rules, and in order to adapt the frequency of sampling and testing in relation to the phytosanitary risk of the specified pest, Member States should define the frequency of sampling and testing, at import, of the consignments of the specified seeds and specified plants for planting. The rate of that frequency should not be lower than 20 % of the imported specified seeds and specified plants for planting, to ensure that an adequately representative sample is checked.
- (11) Implementing Decision (EU) 2019/1615 should be repealed and replaced by this Regulation to take account of Regulation (EU) 2016/2031 of the European Parliament and of the Council and of Commission Implementing Regulation (EU) 2019/2072, which are applicable since 14 December 2019.
- (12) This Regulation should apply until 31 May 2022 in order to allow the necessary time for monitoring the situation and determining the phytosanitary status of the specified pest in respect of the Union territory and the world distribution.
- (13) In order to swiftly address the phytosanitary risk of the specified pest, the rules of this Regulation should become applicable within the shortest possible delay. Therefore, this Regulation should enter into force the third day following that of its publication.
- (14) 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

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 for planting' means plants for planting of *Solanum lycopersicum* L. and *Capsicum* spp. other than seeds;
- (c) 'specified seeds' means seeds of *Solanum lycopersicum* L. and *Capsicum* spp;
- (d) 'specified fruits' means fruits of *Solanum lycopersicum* L. and *Capsicum* spp.

⁽⁵⁾ Commission Implementing Regulation (EU) 2019/2130 of 25 November 2019 establishing detailed rules on the operations to be carried out during and after documentary checks, identity checks and physical checks on animals and goods subject to official controls at border control posts (OJ L 321, 12.12.2019, p. 128).

*Article 2***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 3***Detection or suspected 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 the specified pest.
2. On receiving such information, the competent authority shall:
 - (a) immediately record the information provided;
 - (b) take all necessary measures to confirm the presence or suspected presence of the specified pest;
 - (c) ensure that any person having plants which may be infected with the specified pest under their 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 4***Measures concerning the confirmed presence of the specified pest**

Where the presence or the suspected presence of the specified pest is 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.

*Article 5***Surveys on the presence of the specified pest in the Member States**

1. Member States shall conduct annual surveys for the presence of the specified pest on specified plants for planting, specified seeds and specified fruits in their territory, including in places of production of specified seeds and specified plants for planting.
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. Member States shall notify the Commission and the other Member States by 30 April of each year of the results of the surveys that were carried out during the preceding calendar year.

*Article 6***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 and if both of the following conditions are fulfilled:
 - (a) the specified plants 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, and, where specified plants are displaying symptoms of the specified pest, these plants have been subjected to sampling and testing by the competent authority, and these tests have shown them to be free of the specified pest;
 - (b) the lots of the specified plants for planting have been kept separate from other lots of specified plants by applying appropriate hygiene measures and physical separation.

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

2. Paragraph 1 shall not apply to:
 - (a) specified plants of *Capsicum* spp. varieties which are known to be resistant to the specified pest;
 - (b) specified plants for planting produced in accordance with Implementing Decision (EU) 2019/1615.

*Article 7***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 and if they fulfil all of the following conditions:
 - (a) their mother plants 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;
 - (b) they or their mother plants have undergone sampling and testing for the specified pest by the competent authority, or have been subjected to sampling and testing by professional operators under official supervision of the competent authority, and have been found, according to those tests, to be free from the specified pest;

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 point (c) of Article 87(3) of Regulation (EU) 2016/2031.

 - (c) the origin of all lots of specified seeds are recorded and documented.
2. Specified seeds which were still in storage prior to 15 August 2020 shall be sampled and tested for the specified pest by the competent authority or by professional operators under official supervision of the competent authority, before being moved within the Union and found free from those pests.
3. Seed sampling and testing shall be carried out as set out in the Annex.
4. Paragraphs 1 and 2 shall not apply to specified seeds of *Capsicum* spp. varieties which are known to be resistant to the specified pest.

*Article 8***Introduction into the Union of the specified plants for planting**

1. Specified plants for planting, other than the ones of *Capsicum* spp. 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 specified seeds which have undergone sampling and testing for the specified pest as set out in the Annex, and these tests have shown them to be free from the specified pest;

(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 carried out at the appropriate time to detect that pest, and, in case of symptoms, have undergone official sampling and testing for the specified pest and have been found, according to those tests, to be free from the specified pest;

(c) the name of the registered production site.

2. Specified plants of *Capsicum* spp. 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 9

Introduction of the specified seeds into the Union

1. Specified seeds originating from third countries, other than the ones of *Capsicum* spp. varieties which are known to be resistant to the specified pest, may only be introduced into the Union if they are accompanied by a phytosanitary certificate, which, under the heading 'Additional Declaration', contains 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) the specified seeds concerned or their mother plants have undergone official sampling and testing for the specified pest and have been found, according to those tests, to be free from the specified pest;

(b) the name of the registered production site.

2. Specified seeds of *Capsicum* spp. 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

Official checks on introduction into the Union

No less than 20 % of the consignments of specified seeds and specified plants for planting shall be sampled and tested by the competent authority at the border control post of first arrival into the Union, as set out in the Annex.

Article 11

Repeal of Implementing Decision (EU) 2019/1615

Implementing Decision (EU) 2019/1615 is repealed from 15 August 2020.

Article 12

Application period

This Regulation shall apply until 31 May 2022.

*Article 13***Entry into force**

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

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

Done at Brussels, 11 August 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

1. Sampling schemes of seeds, other than seeds of *Capsicum* spp. 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 table of the International Standards for Phytosanitary Measures No 31 Methodologies for sampling of consignments (ISPM31):

- for seed lots 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;
- for seed lots of more than 3 000 but less than 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;
- for seed lots 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.

Sub samples shall consist of 250 seeds maximum for the Enzyme Linked Immuno Sorbent Assay (ELISA) method.

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

In the case of plants for planting, other than those of *Capsicum* spp. varieties which are known to be resistant to the specified pest, 200 leaves shall be collected per site of production and cultivar, preferably young leaves on the top of the plants.

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

3. Testing methods for detecting and identifying the specified pest on seeds, other than seeds of *Capsicum* spp. 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:

- ELISA, until 1 October 2020, only for confirmation of pest freedom for the issuance of plant passports or phytosanitary certificates;
- 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 (*Acta Horticulturae*, in press).

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.

4. Testing methods for detecting and identifying the specified pest on plants for planting, other than plants for planting of *Capsicum* spp. 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 for planting, other than specified plants for planting of *Capsicum* spp. 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⁾ Protocol developed by the International Seed Federation (International Seed Health Initiative for Vegetable Crops (ISHI-Veg).

- conventional RT-PCR using the primers of Rodriguez-Mendoza *et al.* (2019);
- real-time RT-PCR using the primers and probes described in the ISF protocol (2020) ⁽²⁾;
- real-time RT-PCR using primers and probe of Menzel and Winter (*Acta Horticulturae*, in press).

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.

⁽²⁾ Protocol developed by the International Seed Federation (International Seed Health Initiative for Vegetable Crops (ISHI-Veg)).