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<sup>(1)</sup> Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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## II

*(Non-legislative acts)*

## REGULATIONS

## COMMISSION DELEGATED REGULATION (EU) 2021/1686

of 7 July 2021

**amending Delegated Regulation (EU) 2016/161 as regards the evaluation of notifications by national competent authorities to the Commission and the inclusion of cicatrizants with ATC code D03AX and pharmaceutical form fly larvae in the list of medicinal products that shall not bear the safety features**

*(Text with EEA relevance)*

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use <sup>(1)</sup>, and in particular Article 54a(2), points (b) and (c), thereof,

Whereas:

- (1) Article 54a(1) of Directive 2001/83/EC provides that medical products subject to prescription are to bear the safety features referred to in Article 54, point (o), of that Directive, unless they have been listed in accordance with the procedure pursuant to Article 54a(2), point (b), of that Directive. That list is to be established considering the risk of and the risk arising from falsification relating to medicinal products or categories of medicinal products applying the criteria set out in Article 54a(2), point (b), of Directive 2001/83/EC.
- (2) Article 47 of Commission Delegated Regulation (EU) 2016/161 <sup>(2)</sup> provides that where, following a notification as referred to in Article 46 of that Regulation, the Commission or a Member State considers, on the basis of casualties or hospitalisations of citizens of the Union due to exposure to falsified medicinal products, rapid action is required to protect public health, the Commission is to assess the notification without delay and at the latest within 45 days. In order to better fulfil the objective of that Article, the reference to citizens of the Union should be replaced by a reference to people in the Union as all adverse events in the Union should be considered and monitored regardless of citizenship.
- (3) Article 46(2) of Delegated Regulation (EU) 2016/161 establishes that national competent authorities may inform the Commission of medicinal products which they deem not to be at risk of falsification.
- (4) Annex I to Delegated Regulation (EU) 2016/161, sets out a list of medicinal products or product categories subject to prescription that shall not bear the safety features. The product category ‘cicatrizants with ATC code D03AX’ with pharmaceutical form ‘fly larvae’ is not included in that list.

<sup>(1)</sup> OJ L 311, 28.11.2001, p. 67.

<sup>(2)</sup> Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1).

- (5) On 22 August 2019, the Commission received a notification from the competent German authority stating that it deemed the prescription medicinal product BioBag (ATC code D03AX and pharmaceutical form 'fly larvae') not to be at risk of falsification in accordance with the criteria set out in Article 54a(2), point (b), of Directive 2001/83/EC, and that the medicinal product should therefore be exempted from the requirement to bear safety features.
- (6) The Commission assessed the risks of and arising from falsification of the medicinal product concerned taking into account the criteria listed in Article 54a(2), point (b), of Directive 2001/83/EC. In particular, the specific characteristics and short shelf life of the pharmaceutical form fly larvae means that risk of falsification is negligible and, therefore, those criteria can be considered to be met.
- (7) The Commission consulted the expert group 'Delegated act on safety features for medicinal products for human use', which noted the extremely short shelf life and the fact that the product contains living organisms <sup>(7)</sup>.
- (8) It is, therefore, appropriate to include the product category 'cicatrizants with ATC code D03AX' with pharmaceutical form 'fly larvae' in the list of medicinal products or product categories subject to prescription that shall not bear the safety features, set out in Annex I to Delegated Regulation (EU) 2016/161.
- (9) Delegated Regulation (EU) 2016/161 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

Delegated Regulation (EU) 2016/161 is amended as follows:

- (1) Article 47 is replaced by the following:

*'Article 47*

#### **Evaluation of the notifications**

Where, following a notification as referred to in Article 46, the Commission or a Member State considers, on the basis of casualties or hospitalisations of persons in the Union due to exposure to falsified medicinal products, that rapid action is required to protect public health, the Commission shall assess the notification without delay and at the latest within 45 days.;

- (2) Annex I is amended as set out in the Annex to this Regulation.

#### *Article 2*

This Regulation shall enter into force on the twentieth 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, 7 July 2021.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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<sup>(7)</sup> Minutes of the 29th Expert Group on the delegated act on safety features for medicinal products for human use: <https://ec.europa.eu/transparency/expert-groups-register/screen/meetings/consult?lang=en&meetingId=20450&fromExpertGroups=true>

## ANNEX

In Annex I to Delegated Regulation (EU) 2016/161, the following entry is added:

| Name of active substance or product category | Pharmaceutical form | Strength | Remarks |
|----------------------------------------------|---------------------|----------|---------|
| 'Cicatrizants with ATC code D03AX            | Fly larvae'         |          |         |

**COMMISSION IMPLEMENTING REGULATION (EU) 2021/1687****of 14 September 2021****registering a geographical indication of a spirit drink under Article 30(2) of Regulation (EU) 2019/787 of the European Parliament and of the Council ‘Madarasi birspálinka’**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/787 of the European Parliament and of the Council of 17 April 2019 on the definition, description, presentation and labelling of spirit drinks, the use of the names of spirit drinks in the presentation and labelling of other foodstuffs, the protection of geographical indications for spirit drinks, the use of ethyl alcohol and distillates of agricultural origin in alcoholic beverages, and repealing Regulation (EC) No 110/2008 <sup>(1)</sup>, and in particular Article 30(2) thereof,

Whereas:

- (1) In accordance with Article 17(5) of Regulation (EC) No 110/2008 of the European Parliament and of the Council <sup>(2)</sup>, the Commission has examined Hungary's application of 6 March 2019 for the registration of the geographical indication ‘Madarasi birspálinka’.
- (2) Regulation (EU) 2019/787, which replaces Regulation (EC) No 110/2008, entered into force on 25 May 2019. Under Article 49(1) thereof, Chapter III of Regulation (EC) No 110/2008 on geographical indications is repealed with effect from 8 June 2019.
- (3) After concluding that the application complied with Regulation (EC) No 110/2008, the Commission published the main specifications of the technical file in the *Official Journal of the European Union* <sup>(3)</sup> as required by Article 17(6) of that Regulation, in accordance with the first subparagraph of Article 50(4) of Regulation (EU) 2019/787.
- (4) No notice of opposition has been received by the Commission under Article 27(1) of Regulation (EU) 2019/787.
- (5) The name ‘Madarasi birspálinka’ should therefore be registered as a geographical indication,

HAS ADOPTED THIS REGULATION:

*Article 1*

The geographical indication ‘Madarasi birspálinka’ is hereby entered in the register. This Regulation grants the name ‘Madarasi birspálinka’ the protection referred to in Article 21 of Regulation (EU) 2019/787 in accordance with Article 30(4) of that Regulation.

*Article 2*

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

<sup>(1)</sup> OJ L 130, 17.5.2019, p. 1.

<sup>(2)</sup> Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89 (OJ L 39, 13.2.2008, p. 16).

<sup>(3)</sup> OJ C 205, 31.5.2021, p. 13.

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

Done at Brussels, 14 September 2021.

*For the Commission,  
On behalf of the President,  
Janusz WOJCIECHOWSKI  
Member of the Commission*

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**COMMISSION IMPLEMENTING REGULATION (EU) 2021/1688****of 20 September 2021****amending Implementing Regulation (EU) 2020/1201 as regards the lists of host plants and specified plants, and the tests for the identification of *Xylella fastidiosa***

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 <sup>(1)</sup>, and in particular Article 28(1) and (2) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2020/1201 <sup>(2)</sup> has been applied since August 2020 with the aim to prevent further spread within and introduction into the Union of *Xylella fastidiosa* (Wells *et al.*) ('the specified pest').
- (2) Implementing Regulation (EU) 2020/1201 contains a provision on official checks at introduction into the Union. That provision refers to the official checks to be performed at the point of entry into the Union or at the place of destination established in accordance with Commission Directive 2004/103/EC <sup>(3)</sup>. Within the new framework for official checks established by Regulation (EU) 2017/625 of the European Parliament and of the Council <sup>(4)</sup>, Commission Delegated Regulation (EU) 2019/2123 <sup>(5)</sup> established new rules on official checks performed at control points other than border control posts. Delegated Regulation (EU) 2019/2123 repealed Directive 2004/103/EC with effect from 14 December 2020. It is therefore appropriate to replace the reference to that Directive by a reference to Delegated Regulation (EU) 2019/2123.
- (3) On 23 June 2021, the European Food Safety Authority updated the database of host plants susceptible to *Xylella fastidiosa* (Wells *et al.*). Annexes I and II to Implementing Regulation (EU) 2020/1201 should therefore be amended accordingly.
- (4) For reasons of transparency and clarity, it is appropriate to indicate, for each of the tests listed in Annex IV to Implementing Regulation (EU) 2020/1201, the Digital Object Identifier (DOI) which allows direct access to the scientific articles describing those tests.

<sup>(1)</sup> OJ L 317, 23.11.2016, p. 4.

<sup>(2)</sup> Commission Implementing Regulation (EU) 2020/1201 of 14 August 2020 as regards measures to prevent the introduction into and the spread within the Union of *Xylella fastidiosa* (Wells *et al.*) (OJ L 269, 17.8.2020, p. 2).

<sup>(3)</sup> Commission Directive 2004/103/EC of 7 October 2004 on identity and plant health checks of plants, plant products or other objects, listed in Part B of Annex V to Council Directive 2000/29/EC, which may be carried out at a place other than the point of entry into the Community or at a place close by and specifying the conditions related to these checks (OJ L 313, 12.10.2004, p. 16).

<sup>(4)</sup> 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 (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

<sup>(5)</sup> 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).

- (5) Implementing Regulation (EU) 2020/1201 should therefore be amended accordingly.
- (6) 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*

Implementing Regulation (EU) 2020/1201 is amended as follows:

- (1) in Article 33, paragraph 1 is replaced by the following:

‘1. All consignments of host plants, introduced into the Union from a third country, shall be officially checked at the border control post of first arrival into the Union or at a control point in the cases and conditions set out in Commission Delegated Regulation (EU) 2019/2123’;

- (2) Annex I is replaced by the text set out in Annex I to this Regulation;
- (3) Annex II is replaced by the text set out in Annex II to this Regulation;
- (4) Annex IV is replaced by the text set out in Annex III to this Regulation.

*Article 2*

This Regulation shall enter into force on the twentieth 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, 20 September 2021.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX I

Annex I to Implementing Regulation (EU) 2020/1201 is replaced by the following:

## 'ANNEX I

**List of plants known to be susceptible to one or more subspecies of the specified pest ('host plants')**

*Acacia*

*Acer*

*Adenocarpus lainzii*

*Albizia julibrissin* Durazz.

*Alnus rhombifolia* Nutt.

*Amaranthus retroflexus* L.

*Ambrosia*

*Ampelopsis arborea* (L.) Koehne

*Ampelopsis brevipedunculata* (Maxim.) Trautv.

*Ampelopsis cordata* Michx.

*Anthyllis hermanniae* L.

*Artemisia*

*Asparagus acutifolius* L.

*Athyrium filix-femina*

*Baccharis*

*Brassica*

*Calicotome spinosa* (L.) Link

*Calicotome villosa* (Poirot) Link

*Callicarpa americana* L.

*Callistemon citrinus* (Curtis) Skeels

*Calluna vulgaris* (L.) Hull

*Carya*

*Catharanthus roseus*

*Celtis occidentalis* L.

*Cercis canadensis* L.

*Cercis occidentalis* Torr.

*Cercis siliquastrum* L.

*Chamaecrista fasciculata* (Michx.) Greene

*Chenopodium album* L.

*Chionanthus*

*Chitalpa tashkentensis* T. S. Elias & Wisura

*Cistus*

*Citrus*

*Clematis cirrhosa* L.

*Coelorachis cylindrica* (Michx.) Nash *Coffea*

*Conium maculatum* L.

*Convolvulus cneorum* L.

*Coprosma repens* A.Rich.

*Coronilla*

*Cyperus eragrostis* Lam.

*Cytisus*

*Digitaria*

*Diospyros kaki* L.f.

*Diplocyclos palmatus* (L.) C.Jeffrey

*Dodonaea viscosa* (L.) Jacq.

*Echium plantagineum*

*Elaeagnus angustifolia* L.

*Encelia farinosa* A. Gray ex Torr.

*Eremophila maculata* (Ker Gawler) F. von Müller.

*Erigeron*

*Erodium moschatum* (L.) L'Hérit.

*Erysimum hybrids*

*Euphorbia chamaesyce* L.

*Euphorbia terracina* L.

*Euryops chrysanthemoides* (DC.) B.Nord

*Euryops pectinatus* (L.) Cass.

*Fagus crenata* Blume

*Fallopia japonica* (Houtt.) Ronse Decr.

*Fatsia japonica* (Thunb.) Decne. & Planch.

*Ficus carica* L.

*Fortunella*

*Frangula alnus* Mill.

*Fraxinus*

*Genista*

*Ginkgo biloba* L.

*Gleditsia triacanthos* L.

*Grevillea juniperina* Br.

*Hebe*

*Helianthus*

*Helichrysum*

*Heliotropium europaeum* L.

*Hemerocallis*

*Hevea brasiliensis* (Willd. ex A.Juss.) Müll.Arg.

*Hibiscus*

*Humulus scandens* (Lour.) Merr.

*Ilex aquifolium* L.

*Ilex vomitoria* Sol. ex Aiton

*Iva annua* L.

*Jacaranda mimosifolia* D. Don

*Juglans*

*Juniperus ashei* J. Buchholz

*Koelreuteria bipinnata* Franch.

*Lagerstroemia*

*Laurus nobilis* L.

*Lavandula*

*Lavatera cretica*

*Ligustrum lucidum* L.

*Liquidambar styraciflua* L.

*Lonicera implexa*

*Lonicera japonica* Thunb.

*Lupinus aridorum*

*Lupinus villosus*

*Magnolia grandiflora* L.

*Mallotus paniculatus* (Lam.) Müll.Arg.

*Medicago arborea* L.

*Medicago sativa* L.

*Metrosideros*

*Mimosa*

*Modiola caroliniana* (L.) G. Don

*Morus*

*Myoporum insulare* R. Br.

*Myrtus communis* L.

*Nandina domestica* Murray

*Neptunia lutea* (Leavenw.) Benth.

*Nerium oleander* L.

*Olea*

*Osteospermum ecklonis* DC.

*Osteospermum fruticosum* (L.) Norl.

*Parthenocissus quinquefolia* (L.) Planch.

*Paspalum dilatatum* Poir.

*Pelargonium*

*Perovskia abrotanoides*

*Persea americana* Mill.

*Phagnalon saxatile* (L.) Cass.

*Phillyrea angustifolia* L.

*Phillyrea latifolia* L.

*Phlomis fruticosa* L.

*Phoenix*

*Pinus taeda* L.

*Pistacia vera* L.

*Plantago lanceolata* L.

*Platanus*

*Pluchea odorata* (L.) Cass.

*Polygala grandiflora*

*Polygala myrtifolia* L.

*Prunus*

*Psidium*

*Pteridium aquilinum*

*Pyrus*

*Quercus*

*Ratibida columnifera* (Nutt.) Wooton & Standl.

*Rhamnus*

*Rhus*

*Robinia pseudoacacia* L.

*Rosa*

*Rosmarinus*

*Rubus*

*Ruta chalapensis*

*Salvia mellifera* Greene

*Salvia officinalis*

*Salvia rosmarinus*

*Sambucus*

*Santolina chamaecyparissus* L.

*Santolina magonica*

*Sapindus saponaria* L.

*Sassafras*

*Setaria magna* Griseb.

*Solidago fistulosa* Mill.

*Solidago virgaurea* L.

*Sorghum halepense* (L.) Pers.

*Spartium*

*Stewartia pseudocamellia*

*Strelitzia reginae* Aiton

*Streptocarpus*

*Symphyotrichum divaricatum* (Nutt.) G.L.Nesom

*Teucrium capitatum* L.

*Trifolium repens* L.

*Ulex*

*Ulmus*

*Vaccinium*

*Vinca*

*Vitis*

*Westringia fruticosa* (Willd.) Druce

*Westringia glabra* R.Br.

*Xanthium strumarium* L.'

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## ANNEX II

Annex II to Implementing Regulation (EU) 2020/1201 is replaced by the following:

## ‘ANNEX II

**List of plants known to be susceptible to specific subspecies of the specified pest ('specified plants')****Specified plants susceptible to *Xylella fastidiosa* subspecies *fastidiosa***

*Acer*

*Ambrosia artemisiifolia* L.

*Calicotome spinosa* (L.) Link

*Cercis occidentalis* Torr.

*Cistus monspeliensis* L.

*Citrus sinensis* (L.) Osbeck

*Coffea*

*Erysimum*

*Genista lucida* L.

*Juglans regia* L.

*Lupinus aridorum*

*Magnolia grandiflora* L.

*Medicago sativa* L.

*Metrosideros*

*Morus*

*Nerium oleander* L.

*Pluchea odorata* (L.) Cass.

*Polygala myrtifolia* L.

*Psidium*

*Prunus*

*Rhamnus alaternus* L.

*Salvia rosmarinum*

*Rubus rigidus* Sm.

*Rubus ursinus* Cham. & Schldl.

*Ruta chalapensis*

*Sambucus*

*Spartium junceum* L.

*Streptocarpus*

*Teucrium capitatum* L.

*Ulmus americana* L.

*Vaccinium corymbosum*

*Vinca*

*Vitis*

**Specified plants susceptible to *Xylella fastidiosa* subspecies *multiplex***

*Acacia*

*Acer griseum* (Franch.) Pax

*Acer pseudoplatanus* L.  
*Acer rubrum* L.  
*Adenocarpus lainzii*  
*Alnus rhombifolia* Nutt.  
*Ambrosia*  
*Ampelopsis cordata* Michx.  
*Anthyllis hermanniae* L.  
*Artemisia*  
*Athyrium filix-femina*  
*Asparagus acutifolius* L.  
*Baccharis halimifolia* L.  
*Calicotome spinosa* (L.) Link  
*Calicotome villosa* (Poir.) Link  
*Callistemon citrinus* (Curtis) Skeels  
*Calluna vulgaris* (L.) Hull  
*Carya*  
*Celtis occidentalis* L.  
*Cercis canadensis* L.  
*Cercis occidentalis* Torr.  
*Cercis siliquastrum* L.  
*Chionanthus*  
*Cistus*  
*Clematis cirrhosa* L.  
*Convolvulus cneorum* L.  
*Coprosma repens* A. Rich.  
*Coronilla*  
*Cytisus*  
*Dodonaea viscosa* (L.) Jacq.  
*Echium plantagineum*  
*Elaeagnus angustifolia* L.  
*Encelia farinosa* Gray ex Torr.  
*Erigeron*  
*Erodium moschatum*  
*Euryops chrysanthemoides* (DC.) B.Nord.  
*Euryops pectinatus* (L.) Cass.  
*Fallopia japonica* (Houtt.) Ronse Decr.  
*Ficus carica* L.  
*Frangula alnus* Mill.  
*Fraxinus*  
*Genista*  
*Ginkgo biloba* L.  
*Gleditsia triacanthos* L.  
*Grevillea juniperina* Br.

*Hebe*  
*Helianthus*  
*Helichrysum*  
*Hibiscus syriacus*  
*Ilex aquifolium* L.  
*Iva annua* L.  
*Koelreuteria bipinnata* Franch.  
*Lagerstroemia*  
*Laurus nobilis* L.  
*Lavandula*  
*Lavatera cretica*  
*Liquidambar styraciflua* L.  
*Lonicera*  
*Lupinus aridorum*  
*Lupinus villosus* Willd.  
*Magnolia grandiflora* L.  
*Medicago arborea* L.  
*Medicago sativa* L.  
*Metrosideros*  
*Myrtus communis* L.  
*Nerium oleander*  
*Olea*  
*Osteospermum ecklonis* (DC.) Norl.  
*Pelargonium*  
*Perovskia abrotanoides*  
*Phagnalon saxatile* (L.) Cass.  
*Phillyrea angustifolia* L.  
*Phillyrea latifolia*  
*Phlomis fruticosa* L.  
*Pistacia vera* L.  
*Plantago lanceolata* L.  
*Platanus*  
*Polygala myrtifolia* L.  
*Polygala grandiflora*  
*Prunus*  
*Pteridium aquilinum*  
*Quercus*  
*Ratibida columnifera* (Nutt.) Wooton & Standl.  
*Rhamnus*  
*Robinia pseudoacacia* L.  
*Rosa*  
*Rosmarinus*  
*Rubus*

*Salvia mellifera* Greene  
*Salvia officinalis*  
*Salvia rosmarinus*  
*Sambucus*  
*Santolina chamaecyparissus* L.  
*Santolina magonica*  
*Sapindus saponaria* L.  
*Solidago virgaurea* L.  
*Spartium*  
*Strelitzia reginae* Aiton  
*Ulex*  
*Ulmus*  
*Vaccinium*  
*Vinca*  
*Westringia fruticosa* Guerin.  
*Xanthium strumarium* L.

**Specified plants susceptible to *Xylella fastidiosa* subspecies *pauca***

*Acacia*  
*Amaranthus retroflexus* L.  
*Asparagus acutifolius* L.  
*Catharanthus roseus* (L.) G. Don  
*Chenopodium album* L.  
*Cistus albidus* L.  
*Cistus creticus* L.  
*Citrus*  
*Coffea*  
*Dodonaea viscosa* (L.) Jacq.  
*Eremophila maculata* (Ker Gawler) F. von Müller.  
*Erigeron*  
*Euphorbia chamaesyce* L.  
*Euphorbia terracina* L.  
*Grevillea juniperina* Br.  
*Hebe*  
*Heliotropium europaeum* L.  
*Hibiscus*  
*Laurus nobilis* L.  
*Lavandula*  
*Myoporum insulare* Br.  
*Myrtus communis* L.  
*Nerium oleander* L.  
*Olea europaea* L.  
*Osteospermum fruticosum* (L.) Norl.

*Pelargonium*

*Phillyrea latifolia* L.

*Pistacia vera*

*Polygala myrtifolia* L.

*Prunus*

*Rhamnus alaternus* L.

*Spartium junceum* L.

*Ulmus parviflorus*

*Vinca minor* L.

*Westringia fruticosa* (Willd.) Druce

*Westringia glabra* Br.'

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## ANNEX III

Annex IV to Implementing Regulation (EU) 2020/1201 is replaced by the following:

## ‘ANNEX IV

**Tests for the identification of *Xylella fastidiosa* and its subspecies****A. Tests for the screening and identification of the presence of *Xylella fastidiosa***

1. Real time PCR based on Harper *et al.*, 2010 (and erratum 2013) <sup>(1)</sup>;
2. Loop-mediated isothermal amplification (LAMP) based on primers developed by Harper *et al.* 2010 (and erratum 2013) <sup>(2)</sup>;
3. Real time PCR based on Ouyang *et al.*, 2013 <sup>(3)</sup>
4. Conventional PCR based on Minsavage *et al.* 1994 <sup>(4)</sup>

**B. Molecular tests for the identification of the subspecies of *Xylella fastidiosa***

1. Multi Locus Sequence Typing (MLST) based on Yuan *et al.*, 2010 determining all subspecies <sup>(5)</sup>;
2. PCR based on Hernandez-Martinez *et al.*, 2006 determining the subspecies *fastidiosa*, *multiplex* and *sandyi* <sup>(6)</sup>;
3. PCR based on Pooler & Hartung 1995 determining the subspecies *pauca* <sup>(7)</sup>.

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<sup>(1)</sup> DOI: 10.1094/PHYTO-06-10-0168.

<sup>(2)</sup> DOI: 10.1094/PHYTO-06-10-0168.

<sup>(3)</sup> DOI: 10.1371/journal.pone.0081647.

<sup>(4)</sup> DOI:10.1094/Phyto-84-456.

<sup>(5)</sup> DOI: 10.1094/PHYTO-100-6-0601.

<sup>(6)</sup> DOI: 10.1094/PD-90-1382.

<sup>(7)</sup> DOI: 10.1007/BF00294703.’

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