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Legislation

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I

(Legislative acts)

DIRECTIVES

DIRECTIVE (EU) 2021/1187 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 7 July 2021****on streamlining measures for advancing the realisation of the trans-European transport network (TEN-T)**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 172 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Having regard to the opinion of the Committee of the Regions ⁽²⁾,

Acting in accordance with the ordinary legislative procedure ⁽³⁾,

Whereas:

- (1) Regulation (EU) No 1315/2013 of the European Parliament and of the Council ⁽⁴⁾ sets out a common framework for the creation of state-of-the-art, interoperable networks in the Union, at the service of its citizens, with the objective of strengthening the social, economic and territorial cohesion of the Union and contributing to the creation of a single European transport and mobility area, thereby strengthening the internal market. The trans-European transport network (TEN-T) comprises a dual-layer structure, consisting of a comprehensive network and a core network. The comprehensive network ensures connectivity of all regions of the Union, whereas the core network consists of those elements of the comprehensive network which are of the highest strategic importance for the Union. Regulation (EU) No 1315/2013 sets binding completion targets, with the core network to be completed by 2030 and the comprehensive network by 2050, in particular by prioritising cross-border connections, by improving interoperability, and by contributing to the multimodal integration of Union transport infrastructure.
- (2) Notwithstanding the need to complete the TEN-T and the binding timelines for doing so, experience has shown that many investments aiming to complete the TEN-T are confronted with multiple, different and complex permitting procedures, cross-border procurement procedures and other procedures. This situation jeopardises the timely implementation of projects and, in many cases, results in significant delays and increased costs. Furthermore, uncertainty may arise for project promoters and potential private investors, and could in certain cases even lead to

⁽¹⁾ OJ C 62, 15.2.2019, p. 269.

⁽²⁾ OJ C 168, 16.5.2019, p. 91.

⁽³⁾ Position of the European Parliament of 13 February 2019 (OJ C 449, 23.12.2020, p. 576) and position of the Council at first reading of 14 June 2021 (OJ C 273, 8.7.2021, p. 1). Position of the European Parliament of 6 July 2021 (not yet published in the Official Journal).

⁽⁴⁾ Regulation (EU) No 1315/2013 of the European Parliament and of the Council of 11 December 2013 on Union guidelines for the development of the trans-European transport network and repealing Decision No 661/2010/EU (OJ L 348, 20.12.2013, p. 1).

projects not being realised as initially planned. This Directive aims to address those issues and make synchronised and timely TEN-T completion possible through harmonised action at Union level. When drawing up their national plans and programmes, Member States should take into account the development of the TEN-T, in accordance with Article 49(2) of Regulation (EU) No 1315/2013.

- (3) This Directive should cover project-related procedures, including those related to the environmental impact assessment. However, this Directive should be without prejudice to urban or land-use planning, to procedures related to the award of public procurements, and to steps undertaken at strategic level that are not project-related, such as strategic environmental assessments, public budgetary planning, as well as national or regional transport plans. In order to increase the efficiency of permit-granting procedures and ensure high quality project documentation, project promoters should carry out the preparatory work, such as preliminary studies and reports before the start of the permit-granting procedure. This Directive should not be applicable to procedures before an administrative appeal authority, a court or a tribunal.
- (4) This Directive should apply to projects that are part of pre-identified sections of the core network listed in the Annex to this Directive and to other projects on the core network corridors with a total cost exceeding EUR 300 000 000. Projects exceeding that amount are frequently of strategic importance with respect to the achievement of the Union strategy for smart, sustainable and inclusive growth and contribute to the achievement of the objectives of Regulation (EU) No 1315/2013. The core network corridors are identified through the alignments contained in Regulation (EU) No 1316/2013 of the European Parliament and of the Council ⁽³⁾ and the maps of the core network contained in Regulation (EU) No 1315/2013. The technical basis of those maps is provided by the interactive geographical and technical information system for the TEN-T (TENtec), which contains a higher level of detail concerning the trans-European transport infrastructure.
- (5) Projects exclusively related to telematic applications, new technologies and innovation should be excluded from the scope of this Directive since their deployment is not limited to the core network.
- (6) Member States may however apply this Directive to other projects on the core network and the comprehensive network, including projects exclusively related to telematic applications, new technologies and innovation, in order to achieve a harmonised approach for transport infrastructure projects. The publication by national authorities of lists of individual projects falling within the scope of this Directive could increase transparency for project promoters regarding ongoing, as well as future works along the TEN-T.
- (7) Given the different environmental assessments provided for in relevant Union and national law, which are necessary for granting permits to projects in the core network, Member States should put in place, where feasible and appropriate, a simplified procedure which fulfils the requirements of that Union and national law in order to help achieve the objectives set out in this Directive aimed at increasing the streamlining of measures.
- (8) Priority treatment should be given to projects falling within the scope of this Directive, where relevant. Such treatment may include shorter timelines, simultaneous procedures or limited timeframes for appeals, while ensuring that the objectives of other horizontal policies, such as environmental policies that aim to avoid, prevent, reduce or offset adverse effects on the environment are also reached in accordance with Union and national law. In the legal frameworks of many Member States, priority treatment is given to certain project categories based on their strategic importance for the economy. When such priority treatment exists within a national legal framework, it should

⁽³⁾ Regulation (EU) No 1316/2013 of the European Parliament and of the Council of 11 December 2013 establishing the Connecting Europe Facility, amending Regulation (EU) No 913/2010 and repealing Regulations (EC) No 680/2007 and (EC) No 67/2010 (OJ L 348, 20.12.2013, p. 129).

automatically apply to projects falling within the scope of this Directive. Nevertheless, Member States should be allowed to test specific permit-granting procedures on a limited number of projects in order to evaluate their potential extension to other projects. During this testing period, the Member State concerned should not be obliged to apply such testing procedures to other projects falling within the scope of this Directive.

- (9) In order to make clear management of the overall procedure possible and to provide a point of contact for project promoters, projects on the core network corridors should be supported by efficient permit-granting procedures. To that end, Member States should designate one or more authorities depending on their national legal frameworks and administrative set-ups and the types of projects concerned. Where a Member State designates several authorities, it should ensure that only one authority is designated for a given project and a given permit-granting procedure.
- (10) The designation of an authority serving as point of contact for the project promoter should reduce the complexity, improve the efficiency and increase the transparency of the procedures. It should also, where appropriate, enhance the cooperation between Member States. The procedures should promote real cooperation between project promoters and the designated authority.
- (11) The designated authority may, inter alia, be entrusted with tasks related to the coordination and the authorisation, in compliance with Union and national law, of specific projects for the reconstruction of infrastructure on the core network in the event of natural or man-made disasters.
- (12) The procedure provided for in this Directive should be without prejudice to the fulfilment of the requirements of international and Union law, including requirements to protect the environment and human health. This Directive should not lead to the lowering of standards that are intended to avoid, prevent, reduce or offset adverse effects on the environment.
- (13) Given the urgency of completing the core network, the simplification of permit-granting procedures should be accompanied by a time-limit for procedures leading to the adoption of an authorising decision to build the transport infrastructure. That time-limit should encourage a more efficient handling of procedures and should, under no circumstances, compromise the Union's high standards for environmental protection and public participation. It should be possible to extend the time-limit for the permit-granting procedures in duly justified cases, including when unforeseeable circumstances arise or where necessary for environmental protection. The extension could, for instance, be expressed as a period of time or indicated by reference to a date, or a certain future event. The extended time-limit should in particular not include the time necessary to undertake administrative or judicial appeal procedures or to seek judicial remedies before a court or tribunal. Member States should not be held responsible where the failure to comply with that time-limit is due to the project promoter, for example where the project promoter has not complied with the time-limits set out in national law or the indicative time-limits set by the designated authority or where the project promoter has acted with undue delay.
- (14) Member States should endeavour to ensure that appeals challenging the substantive or procedural legality of an authorising decision are handled in the most efficient way possible.
- (15) TEN-T infrastructure projects that concern two or more Member States face particular challenges as regards the coordination of permit-granting procedures. Therefore, the designated authorities of the Member States concerned should cooperate in order to coordinate their timetables and establish a joint schedule concerning the permit-granting procedure, to the extent that such coordination of their timetables and such establishment of a joint schedule are possible and appropriate given the state of preparation, or of maturity, of the project, which depends mainly on the project promoter, in particular on the date on which the project promoter has notified the project to the designated authority of each of those Member States.

- (16) The European Coordinators designated in accordance with Regulation (EU) No 1315/2013 should be informed about the relevant procedures in order to facilitate their synchronisation and completion in view of the timely implementation of the core network by 2030.
- (17) Where the TEN-T is extended to third countries, in line with the indicative maps set out in Regulation (EU) No 1315/2013, those third countries should be invited to apply, where relevant, similar rules as the ones provided for by this Directive.
- (18) Public procurement in cross-border projects should be carried out in accordance with the Treaties and, where relevant, Directive 2014/24/EU ⁽⁶⁾ or 2014/25/EU ⁽⁷⁾ of the European Parliament and of the Council. In order to ensure the efficient completion of the cross-border core network projects, public procurement carried out by a joint entity should be subject to the national law of one Member State. By way of derogation from Union law on public procurement, the applicable national law should, in principle, be that of the Member State where the joint entity has its registered office. It should remain possible to determine the applicable national law by means of an intergovernmental agreement. For a public procurement conducted by a subsidiary of a joint entity, that subsidiary should apply the national law of one of the Member States concerned, which could be the national law applicable to the joint entity. For reasons of legal certainty, current procurement strategies should remain applicable to a joint entity set up before the date of entry into force of this Directive.
- (19) The Commission is not systematically involved in the authorisation of individual projects. However, in some cases, certain aspects of the project preparation are subject to clearance at Union level. Where the Commission is involved in the procedures, it will give priority treatment to Union projects and ensure certainty for project promoters. In some cases, State aid approval might be required. Without prejudice to the deadlines set out in this Directive and in line with the Code of Best Practices for the conduct of State aid control procedures, Member States should be able to ask the Commission to deal with projects on the core network that they consider to be of priority by applying more predictable timelines under the case portfolio approach or the mutually agreed planning.
- (20) The implementation of infrastructure projects on the core network should be also supported by Commission guidelines that bring more clarity as regards the implementation of certain types of projects while respecting the Union *acquis*. In this respect, the Commission's Communication of 27 April 2017 entitled 'Action Plan for nature, people and the economy' provides guidance and brings more clarity as regards how to comply with Directive 2009/147/EC of the European Parliament and of the Council ⁽⁸⁾ and Council Directive 92/43/EEC ⁽⁹⁾. In order to ensure the best value for public money, direct support related to public procurement should be made available for projects.
- (21) Since the objective of this Directive, namely to streamline measures for advancing the realisation of the TEN-T, cannot be sufficiently achieved by the Member States but can rather, by reason of the need for strengthening the framework of the permit-granting procedures for TEN-T projects through harmonised action at Union level, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.
- (22) For reasons of legal certainty, this Directive should not apply to permit-granting procedures which started before the date of transposition of this Directive,

⁽⁶⁾ Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65).

⁽⁷⁾ Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (OJ L 94, 28.3.2014, p. 243).

⁽⁸⁾ Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds (OJ L 20, 26.1.2010, p. 7).

⁽⁹⁾ Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p. 7).

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Subject matter and scope

1. This Directive shall apply to the permit-granting procedures required in order to authorise the implementation of:
 - (a) projects that are part of pre-identified sections of the core network as listed in the Annex;
 - (b) other projects on the core network corridors, as identified pursuant to Article 44(1) of Regulation (EU) No 1315/2013, with a total cost exceeding EUR 300 000 000,

with the exception of projects exclusively related to telematic applications, new technologies and innovation within the meaning of Articles 31 and 33 of that Regulation.

This Directive shall also apply to public procurements in cross-border projects falling within the scope of this Directive.

2. Member States may decide to apply this Directive to other projects on the core network and comprehensive network, including projects exclusively related to telematic applications, new technologies and innovation referred to in paragraph 1. Member States shall notify their decision to the Commission.

Article 2

Definitions

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

- (1) 'authorising decision' means the decision or a set of decisions, which may be of an administrative nature, taken simultaneously or successively by an authority or by authorities of a Member State, not including administrative and judicial appeal authorities, under a national legal system and administrative law that determine whether or not a project promoter is entitled to implement the project on the geographical area concerned, without prejudice to any decision taken in the context of an administrative or judicial appeal procedure;
- (2) 'permit-granting procedure' means any procedure that has to be followed related to an individual project falling within the scope of this Directive in order to obtain the authorising decision as required by the authority or authorities of a Member State, under Union or national law, with the exception of urban or land use planning, of procedures related to the award of public procurements, and of steps undertaken at strategic level that do not refer to a specific project, such as strategic environmental assessment, public budgetary planning, as well as national or regional transport plans;
- (3) 'project' means a proposal for the construction, adaptation or modification of a defined section of the transport infrastructure which aims to improve the capacity, safety and efficiency of that infrastructure and of which the implementation has to be approved by means of an authorising decision;
- (4) 'cross-border project' means a project covering a cross-border section between two or more Member States;
- (5) 'project promoter' means the applicant for authorisation of the implementation of a project or the public authority which initiates a project;
- (6) 'designated authority' means the authority which is the point of contact for the project promoter and which facilitates the efficient and structured processing of permit-granting procedures in accordance with this Directive;
- (7) 'joint authority' means an authority established by mutual agreement between two or more Member States to facilitate the permit-granting procedures related to cross-border projects, including joint authorities established by designated authorities where those designated authorities have been empowered by Member States to establish joint authorities.

*Article 3***Priority status**

1. Member States shall endeavour to ensure that all authorities, including the designated authority, involved in the permit-granting procedure, excluding courts and tribunals, give priority to projects falling within the scope of this Directive.
2. Where specific permit-granting procedures for priority projects exist under national law, Member States shall, without prejudice to the objectives, requirements and time-limits of this Directive, ensure that projects falling within the scope of this Directive are handled under those procedures. This shall not prevent Member States from testing specific permit-granting procedures on a limited number of projects, in order to evaluate their potential extension to other projects, without having to apply such procedures to projects falling within the scope of this Directive.
3. This Article shall be without prejudice to any budgetary decisions.

*Article 4***Designated Authority**

1. By 10 August 2023, each Member State shall designate, at the appropriate administrative level, the authorities that are to act as a designated authority.
2. A Member State may, where relevant, designate different authorities as the designated authority depending on the project or category of projects, transport mode, or the geographical area. In such a case, the Member State shall ensure that there is only one designated authority for a given project and for a given permit-granting procedure.
3. Member States shall take all necessary measures to provide project promoters with easily available information about the identity of the designated authority for a given project.
4. Member States may empower the designated authority to take the authorising decision.

When empowered to take the authorising decision in accordance with the first subparagraph, the designated authority shall verify that all the permits, decisions and opinions necessary for the adoption of the authorising decision have been obtained and shall notify the authorising decision to the project promoter.

5. Where the designated authority is not empowered to take the authorising decision, Member States shall take the necessary measures to ensure that the project promoter is notified of the adoption of the authorising decision.
6. Member States may empower the designated authority to establish indicative time-limits for different intermediary steps of the permit-granting procedure in accordance with Article 5(1), without prejudice to the four-year time-limit referred to in that paragraph.
7. The designated authority shall:
 - (a) be the point of contact for information for the project promoter and for other relevant authorities involved in the procedure leading to the authorising decision for a given project;
 - (b) provide the project promoter, where required to do so under national law, with the detailed application outline referred to in Article 6(4), including information on the indicative time-limits relating to the permit-granting procedures, in accordance with the four-year time-limit referred to in Article 5(1);
 - (c) oversee the timeframe of the permit-granting procedure, and in particular record any extension of the time-limit referred to in Article 5(4);

- (d) if requested, provide guidance to the project promoter concerning the submission of all relevant information and documents, including all the permits, decisions and opinions which have to be obtained and provided for the authorising decision.

The designated authority may also provide guidance to the project promoter as to what additional information and/or documents should be delivered in the event that the notification referred to in Article 6(1) has been rejected.

8. Paragraph 7 is without prejudice to the competence of any other authorities involved in the permit-granting procedure and to the possibility for the project promoter to contact the individual authorities for the specific permits, decisions or opinions which form part of the authorising decision.

Article 5

Duration of the permit-granting procedure

1. Member States shall provide for a permit-granting procedure, including the deadlines for that procedure which shall not exceed four years from the start of the permit-granting procedure. Member States may adopt necessary measures in order to break down the available period into different steps in accordance with Union and national law.
2. The four-year period referred to in paragraph 1 shall be without prejudice to obligations arising from international and Union law and shall not include periods necessary to undertake administrative and judicial appeal procedures and to seek judicial remedies before a court or tribunal, as well as any periods necessary to implement any resulting decisions or remedies.
3. The four-year period referred to in paragraph 1 shall be without prejudice to the right of a Member State to provide that the permit-granting procedure is to be finalised by the adoption of a specific act of national legislation, in which case, the procedure for adoption of that act may, by way of derogation from paragraph 1, exceed the four year period provided that the preparatory work, on the basis of which the national legislative act is adopted, is concluded within that period. The preparatory work shall be considered to end when the specific act of national legislation is introduced to the national parliament.
4. Member States shall adopt the necessary measures to ensure that, in duly justified cases, an appropriate extension of the four-year period referred to in paragraph 1 may be granted. The duration of the extension shall be determined on a case-by-case basis, be duly justified and be limited to the purpose of completing the permit-granting procedure and delivering the authorising decision. When such an extension has been granted, the project promoter shall be informed of the reasons for granting it. A further extension may be granted once, under the same conditions.
5. Member States shall not be held responsible where the four-year period referred to in paragraph 1, as extended in accordance with paragraph 4, is not complied with where the delay incurred is due to the project promoter.

Article 6

Organisation of the permit-granting procedure

1. The project promoter shall notify the project to the designated authority or, where appropriate, to the joint authority established in accordance with Article 7(2). The notification of the project by the project promoter, shall serve as the start of the permit-granting procedure.
2. In order to facilitate the assessment of the maturity of the project, Member States may define the level of detail of information and the relevant documents to be provided by the project promoter when notifying a project. If the project is not mature, the notification shall be rejected by a duly justified decision not later than four months after the receipt of the notification.

3. Member States shall take the necessary measures to ensure that project promoters receive general information as a guide to notification, adapted, where relevant, to the mode of transport concerned, containing information about the permits, decisions and opinions that may be required for the implementation of a project.

That information shall, for each permit, decision or opinion, include the following:

- (a) general information about the material scope and the level of detail of the information to be submitted by the project promoter;
- (b) applicable time-limits or, if there are no such time-limits, indicative time-limits; and
- (c) details of the authorities and stakeholders normally involved in consultations linked to the different permits, decisions and opinions.

That information shall be easily accessible to all relevant project promoters, in particular through electronic or physical information portals.

4. In order to facilitate successful notification, Member States may require the designated authority to establish, upon request by the project promoter, a detailed application outline comprising the following information customised for the individual project:

- (a) the individual stages of the procedure and applicable time-limits or, if there are no such time-limits, indicative time-limits;
- (b) the material scope and the level of detail of the information to be submitted by the project promoter;
- (c) a list of permits, decisions and opinions to be obtained by the project promoter during the permit-granting procedure, in accordance with Union and national law;
- (d) the details of the authorities and stakeholders to be involved in connection with the respective obligations, including during the formal phase of the public consultation.

5. The detailed application outline shall remain valid during the permit-granting procedure. Any amendment to the detailed application outline shall be duly justified.

6. The designated authority may provide the project promoter, on request, with the information supplementing the elements referred to in paragraph 4.

7. When the project promoter has submitted the complete project application file, the authorising decision shall be adopted within the time-limit referred to in Article 5(1).

8. Authorities involved in the permit-granting procedure shall notify the designated authority that the required permits, decisions, opinions, or the authorising decision, have been issued.

Article 7

Coordination of cross-border permit-granting procedures

1. Member States shall ensure, for projects that concern two or more Member States, that the designated authorities of those Member States cooperate with a view to coordinating their timetables and agreeing on a joint schedule concerning the permit-granting procedure.

2. For cross-border projects, a joint authority may be established.

3. Member States shall take the necessary measures to ensure that the European Coordinators designated in accordance with Article 45 of Regulation (EU) No 1315/2013 receive information on the permit-granting procedures and that the European Coordinators may facilitate contacts between the designated authorities in the context of the permit-granting procedures for projects that concern two or more Member States.

4. Member States shall, if the time-limit referred to in Article 5(1) is not observed, and upon request, provide information to the European Coordinators concerned about the measures taken or planned to be taken in order to enable the permit-granting procedure to be concluded with the least possible delay.

*Article 8***Public procurement in cross-border projects**

1. When the procurement procedures are conducted by a joint entity in a cross-border project, Member States shall take the necessary measures to ensure that the joint entity applies the national law of one Member State and, by way of derogation from Directives 2014/24/EU and 2014/25/EU, that law shall be determined in accordance with point (a) of Article 39(5) of Directive 2014/24/EU or point (a) of Article 57(5) of Directive 2014/25/EU, as applicable, unless an agreement between the participating Member States provides otherwise. Such an agreement shall, in any case, provide for the application of the national law of one Member State to the procurement procedures conducted by a joint entity.
2. For public procurement conducted by a subsidiary of a joint entity, the Member States concerned shall take the necessary measures to ensure that the subsidiary applies the national law of one Member State. In this respect, the Member States concerned may decide that the subsidiary is to apply the national law applicable to the joint entity.

*Article 9***Transitional provisions**

1. This Directive shall not apply to projects for which the permit-granting procedures started before 10 August 2023.
2. Article 8 shall only apply to such contracts for which the call for competition has been sent, or, in cases where a call for competition is not foreseen, where the contracting authority or contracting entity commenced the procurement procedure, after 10 August 2023.
3. Article 8 shall not apply to a joint entity set up before 9 August 2021, if the procurement procedures of that entity continue to be governed by the law applicable to its procurements on that date.

*Article 10***Reporting**

1. For the first time by 10 February 2027, and at regular intervals thereafter, the Commission shall report to the European Parliament and to the Council on the implementation of this Directive and on its results.
2. The report shall be based on information to be provided by Member States every two years and for the first time by 10 August 2026, concerning the number of permit-granting procedures falling within the scope of this Directive, the average length of the permit-granting procedures, the number of permit-granting procedures exceeding the time-limit and the establishment of any joint authority during the reporting period.

*Article 11***Transposition**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 10 August 2023. They shall immediately inform the Commission thereof.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main measures of national law which they adopt in the field covered by this Directive.

*Article 12***Entry into force**

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

This Directive is addressed to the Member States.

Done at Strasbourg, 7 July 2021.

For the European Parliament
The President
D. M. SASSOLI

For the Council
The President
A. LOGAR

ANNEX

Pre-identified sections of cross-border links and missing links in the core network corridors [referred to in point (a) of Article 1(1)]

Core network corridor 'Atlantic'		
Cross-border links	Évora – Mérida	Rail
	Vitoria-Gasteiz – San Sebastián – Bayonne – Bordeaux	
	Aveiro – Salamanca	
	Douro river (Via Navegável do Douro)	Inland waterways
Missing links	Non-UIC gauge interoperable lines on the Iberian Peninsula	Rail
Core network corridor 'Baltic – Adriatic'		
Cross-border links	Katowice/Opole – Ostrava – Brno Katowice – Žilina Bratislava – Wien Graz – Maribor Venezia – Trieste – Divača – Ljubljana	Rail
	Katowice – Žilina Brno – Wien	Road
Missing links	Gloggnitz – Mürzzuschlag: Semmering base tunnel Graz – Klagenfurt: Koralm railway line and tunnel Koper – Divača	Rail
Core network corridor 'Mediterranean'		
Cross-border links	Barcelona – Perpignan	Rail
	Lyon – Torino: base tunnel and access routes	
	Nice – Ventimiglia	
	Venezia – Trieste – Divača – Ljubljana	
	Ljubljana – Zagreb	
	Zagreb – Budapest	
	Budapest – Miskolc – UA border	
	Lendava – Letenye	Road
	Vásárosnamény – UA border	
Missing links	Almería – Murcia	Rail
	Non-UIC gauge interoperable lines on the Iberian Peninsula	
	Perpignan – Montpellier	
	Koper – Divača	
	Rijeka – Zagreb	
	Milano – Cremona – Mantova – Porto Levante/Venezia – Ravenna/Trieste	Inland waterways

Core network corridor 'North Sea – Baltic'		
Cross-border links	Tallinn – Rīga – Kaunas – Warszawa: Rail Baltic new UIC gauge fully interoperable line	Rail
	Świnoujście/Szczecin – Berlin	Rail and inland waterways
	Via Baltica Corridor EE-LV-LT-PL	Road
Missing links	Kaunas – Vilnius: part of Rail Baltic new UIC gauge fully interoperable line	Rail
	Warszawa/Idzikowice – Poznań/Wrocław, incl. connections to the planned Central Transport Hub	
	Nord-Ostsee-Kanal	Inland waterways
	Berlin – Magdeburg – Hannover; Mittellandkanal; western German canals	
	Rhine, Waal	
	Noordzeekanaal, IJssel, Twentekanaal	
Core network corridor 'North Sea – Mediterranean'		
Cross-border links	Brussel or Bruxelles – Luxembourg – Strasbourg	Rail
	Terneuzen – Gent	Inland waterways
	Seine – Scheldt Network and the related Seine, Scheldt and Meuse river basins	
	Rhine-Scheldt corridor	
Missing links	Albertkanaal/Canal Albert and Kanaal Bocholt-Herentals	Inland waterways
Core network corridor 'Orient/East-Med'		
Cross-border links	Dresden – Praha/Kolín	Rail
	Wien/Bratislava – Budapest	
	Békéscsaba – Arad – Timișoara	
	Craiova – Calafat – Vidin – Sofia – Thessaloniki	
	Sofia – RS border/MK border	
	TR border – Alexandroupoli	
	MK border – Thessaloniki	
	Ioannina – Kakavia (AL border)	Road
	Drobeta Turnu Severin/Craiova – Vidin – Montana	
	Sofia – RS border	
	Hamburg – Dresden – Praha – Pardubice	Inland waterways
Missing links	Igoumenitsa – Ioannina	Rail
	Praha – Brno	
	Thessaloniki – Kavala – Alexandroupoli	
	Timișoara – Craiova	

Core network corridor ‘Rhine – Alpine’		
Cross-border links	Zevenaar – Emmerich – Oberhausen	Rail
	Karlsruhe – Basel	
	Milano/Novara – CH border	
	Basel – Antwerpen/Rotterdam – Amsterdam	Inland waterways
Missing links	Genova – Tortona/Novi Ligure	Rail
	Zeebrugge – Gent	
Core network corridor ‘Rhine – Danube’		
Cross-border links	München – Praha	Rail
	Nürnberg – Plzeň	
	München – Mühldorf – Freilassing – Salzburg	
	Strasbourg – Kehl Appenweier	
	Hranice – Žilina	
	Košice – UA border	
	Wien – Bratislava/Budapest	
	Bratislava – Budapest	
	Békéscsaba – Arad – Timișoara – RS border	
	București – Giurgiu – Rousse	
	Danube (Kehlheim – Constanța/Midia/Sulina) and the related Váh, Sava and Tisza river basins	Inland waterways
	Zlín – Žilina	Road
	Timișoara – RS border	
Missing links	Stuttgart – Ulm	Rail
	Salzburg – Linz	
	Craiova – București	
	Arad – Sighișoara – Brașov – Predeal	
Core network corridor ‘Scandinavian – Mediterranean’		
Cross-border links	RU border – Helsinki	Rail
	København – Hamburg: Fehmarn belt fixed link access routes	
	München – Wörgl – Innsbruck – Fortezza – Bolzano – Trento – Verona: Brenner base tunnel and its access routes	
	Göteborg – Oslo	
	København – Hamburg: Fehmarn belt fixed link	Rail/Road

II

(Non-legislative acts)

REGULATIONS

COUNCIL IMPLEMENTING REGULATION (EU) 2021/1188

of 19 July 2021

implementing Article 2(3) of Regulation (EC) No 2580/2001 on specific restrictive measures directed against certain persons and entities with a view to combating terrorism, and repealing Implementing Regulation (EU) 2021/138

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EC) No 2580/2001 of 27 December 2001 on specific restrictive measures directed against certain persons and entities with a view to combating terrorism ⁽¹⁾, and in particular Article 2(3) thereof,

Having regard to the proposal of the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 5 February 2021, the Council adopted Implementing Regulation (EU) 2021/138 ⁽²⁾ implementing Article 2(3) of Regulation (EC) No 2580/2001, establishing an updated list of persons, groups and entities to which Regulation (EC) No 2580/2001 applies ('the list').
- (2) The Council has provided, where practically possible, all the persons, groups and entities with statements of reasons explaining why they were entered into the list.
- (3) By way of a notice published in the *Official Journal of the European Union*, the Council informed the persons, groups and entities on the list that it had decided to keep them thereon. The Council also informed those persons, groups and entities concerned that it was possible to request a statement of the Council's reasons for entering them into the list where such a statement had not already been communicated to them.
- (4) The Council has reviewed the list as required by Article 2(3) of Regulation (EC) No 2580/2001. When carrying out that review, the Council took into account the observations submitted to it by those concerned as well as the updated information received from the competent national authorities on the status of listed individuals and entities at the national level.
- (5) The Council has verified that competent authorities, as referred to in Article 1(4) of Council Common Position 2001/931/CFSP ⁽³⁾, have taken decisions with regard to all persons, groups and entities on the list to the effect that they have been involved in terrorist acts within the meaning of Article 1(2) and (3) of Common Position 2001/931/CFSP. The Council has also concluded that the persons, groups and entities to which Articles 2, 3 and 4 of Common Position 2001/931/CFSP apply should continue to be subject to the specific restrictive measures provided for in Regulation (EC) No 2580/2001.

⁽¹⁾ OJ L 344, 28.12.2001, p. 70.

⁽²⁾ Council Implementing Regulation (EU) 2021/138 of 5 February 2021 implementing Article 2(3) of Regulation (EC) No 2580/2001 on specific restrictive measures directed against certain persons and entities with a view to combating terrorism, and repealing Implementing Regulation (EU) 2020/1128 (OJ L 43, 8.2.2021, p. 1).

⁽³⁾ Council Common Position 2001/931/CFSP of 27 December 2001 on the application of specific measures to combat terrorism (OJ L 344, 28.12.2001, p. 93).

(6) The list should be updated accordingly, and Implementing Regulation (EU) 2021/138 should be repealed,

HAS ADOPTED THIS REGULATION:

Article 1

The list provided for in Article 2(3) of Regulation (EC) No 2580/2001 is set out in the Annex to this Regulation.

Article 2

Implementing Regulation (EU) 2021/138 is hereby repealed.

Article 3

This Regulation shall enter into force on the 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, 19 July 2021.

For the Council
The President
J. PODGORŠEK

ANNEX

List of persons, groups and entities referred to in Article 1**I. PERSONS**

1. ABDOLLAHI Hamed (a.k.a. Mustafa Abdullahi), born 11.8.1960 in Iran. Passport number: D9004878.
2. AL-NASSER, Abdelkarim Hussein Mohamed, born in Al Ihsa (Saudi Arabia), citizen of Saudi Arabia.
3. AL YACOUB, Ibrahim Salih Mohammed, born 16.10.1966 in Tarut (Saudi Arabia), citizen of Saudi Arabia.
4. ARBABSAR Manssor (a.k.a. Mansour Arbabsar), born 6.3.1955 or 15.3.1955 in Iran. Iranian and US national, Passport number: C2002515 (Iran); Passport number: 477845448 (USA). National ID number: 07442833, expiry date 15.3.2016 (USA driving licence).
5. ASSADI Assadollah, born 22.12.1971 in Teheran (Iran), Iranian national. Iranian diplomatic passport number: D9016657.
6. BOUYERI, Mohammed (a.k.a. Abu ZUBAIR, a.k.a. SOBIAR, a.k.a. Abu ZOUBAIR), born 8.3.1978 in Amsterdam (The Netherlands).
7. EL HAJJ, Hassan Hassan, born 22.3.1988 in Zaghdrayia, Sidon, Lebanon, Canadian citizen. Passport number: JX446643 (Canada).
8. HASHEMI MOGHADAM Saeid, born 6.8.1962 in Teheran (Iran), Iranian national. Passport number: D9016290, valid until 4.2.2019.
9. IZZ-AL-DIN, Hasan (a.k.a. GARBAYA, Ahmed, a.k.a. SA-ID, a.k.a. SALWWAN, Samir), Lebanon, born 1963 in Lebanon, citizen of Lebanon.
10. MELIAD, Farah, born 5.11.1980 in Sydney (Australia), Australian citizen. Passport number: M2719127 (Australia).
11. MOHAMMED, Khalid Shaikh (a.k.a. ALI, Salem, a.k.a. BIN KHALID, Fahd Bin Adballah, a.k.a. HENIN, Ashraf Refaat Nabith, a.k.a. WADOOD, Khalid Adbul), born 14.4.1965 or 1.3.1964 in Pakistan, passport number 488555.
12. ŞANLI, Dalokay (a.k.a. Sinan), born 13.10.1976 in Pülümür (Turkey).
13. SHAHLAI Abdul Reza (a.k.a. Abdol Reza Shala'i, a.k.a. Abd-al Reza Shalai, a.k.a. Abdorreza Shahlai, a.k.a. Abdolreza Shahla'i, a.k.a. Abdul-Reza Shahlaee, a.k.a. Hajj Yusef, a.k.a. Haji Yusif, a.k.a. Hajji Yasir, a.k.a. Hajji Yusif, a.k.a. Yusuf Abu-al-Karkh), born circa 1957 in Iran. Addresses: (1) Kermanshah, Iran, (2) Mehran Military Base, Ilam Province, Iran.
14. SHAKURI Ali Gholam, born circa 1965 in Tehran, Iran.

II. GROUPS AND ENTITIES

1. 'Abu Nidal Organisation' – 'ANO' (a.k.a. 'Fatah Revolutionary Council', a.k.a. 'Arab Revolutionary Brigades', a.k.a. 'Black September', a.k.a. 'Revolutionary Organisation of Socialist Muslims').
2. 'Al-Aqsa Martyrs' Brigade'.
3. 'Al-Aqsa e.V'.

4. 'Babbar Khalsa'.
 5. 'Communist Party of the Philippines', including 'New People's Army' – 'NPA', Philippines.
 6. Directorate for Internal Security of the Iranian Ministry for Intelligence and Security.
 7. 'Gama'a al-Islamiyya' (a.k.a. 'Al-Gama'a al-Islamiyya') ('Islamic Group' – 'IG').
 8. 'İslami Büyük Doğu Akıncılar Cephesi' – 'İBDA-C' ('Great Islamic Eastern Warriors Front').
 9. 'Hamas', including 'Hamas-Izz al-Din al-Qassem'.
 10. 'Hizballah Military Wing' (a.k.a. 'Hezbollah Military Wing', a.k.a. 'Hizbullah Military Wing', a.k.a. 'Hizbollah Military Wing', a.k.a. 'Hezbollah Military Wing', a.k.a. 'Hisbollah Military Wing', a.k.a. 'Hizbu'llah Military Wing' a.k.a. 'Hizb Allah Military Wing', a.k.a. 'Jihad Council' (and all units reporting to it, including the External Security Organisation)).
 11. 'Hizbul Mujahideen' – 'HM'.
 12. 'Khalistan Zindabad Force' – 'KZF'.
 13. 'Kurdistan Workers' Party' – 'PKK' (a.k.a. 'KADEK', a.k.a. 'KONGRA-GEL').
 14. 'Liberation Tigers of Tamil Eelam' – 'LTTE'.
 15. 'Ejército de Liberación Nacional' ('National Liberation Army').
 16. 'Palestinian Islamic Jihad' – 'PIJ'.
 17. 'Popular Front for the Liberation of Palestine' – 'PFLP'.
 18. 'Popular Front for the Liberation of Palestine – General Command' (a.k.a. 'PFLP – General Command').
 19. 'Devrimci Halk Kurtuluş Partisi-Cephesi' – 'DHKP/C' (a.k.a. 'Devrimci Sol' ('Revolutionary Left'), a.k.a. 'Dev Sol') ('Revolutionary People's Liberation Army/Front/Party').
 20. 'Sendero Luminoso' – 'SL' ('Shining Path').
 21. 'Teyrbazen Azadiya Kurdistan' – 'TAK' (a.k.a. 'Kurdistan Freedom Falcons', a.k.a. 'Kurdistan Freedom Hawks').
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COMMISSION DELEGATED REGULATION (EU) 2021/1189**of 7 May 2021****supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the production and marketing of plant reproductive material of organic heterogeneous material of particular genera or species****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 ⁽¹⁾, and in particular Article 13(3) and Article 38(8)(a)(ii) thereof,

Whereas:

- (1) Regulation (EU) 2018/848 provides that operators are to be allowed to market plant reproductive material of organic heterogeneous material without complying with the requirements for registration and without complying with the certification categories of pre-basic, basic and certified material or with the quality, health and identity requirements for CAC, standard or commercial categories, set out in Directives 66/401/EEC ⁽²⁾, 66/402/EEC ⁽³⁾, 68/193/EEC ⁽⁴⁾, 98/56/EC ⁽⁵⁾, 2002/53/EC ⁽⁶⁾, 2002/54/EC ⁽⁷⁾, 2002/55/EC ⁽⁸⁾, 2002/56/EC ⁽⁹⁾, 2002/57/EC ⁽¹⁰⁾, 2008/72/EC ⁽¹¹⁾ and 2008/90/EC ⁽¹²⁾, or in acts adopted pursuant to those Directives. It also states that marketing should comply with harmonised requirements adopted by the Commission.
- (2) In order to address the needs of operators and consumers of plant reproductive material of organic heterogeneous material concerning the identity, health and quality of such material, rules should be established concerning the description, minimum quality requirements for seed lots, including identity, analytical purity, germination rates and sanitary quality, packaging, and labelling of plant reproductive material of the organic heterogeneous material, and, where possible, the maintenance of such material by operators and the information to be kept by such operators.
- (3) In order to promote the adaptation of organic heterogeneous material to diverse agro-ecological conditions, the transfer of limited quantities of plant reproductive material of organic heterogeneous material for the purpose of research on, and development of, such material should be exempted from the requirements of this Regulation.

⁽¹⁾ OJ L 150, 14.6.2018, p. 1.

⁽²⁾ Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed (OJ L 125, 11.7.1966, p. 2298).

⁽³⁾ Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed (OJ L 125, 11.7.1966, p. 2309).

⁽⁴⁾ Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine (OJ L 93, 17.4.1968, p. 15).

⁽⁵⁾ Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants (OJ L 226, 13.8.1998, p. 16).

⁽⁶⁾ Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (OJ L 193, 20.7.2002, p. 1).

⁽⁷⁾ Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed (OJ L 193, 20.7.2002, p. 12).

⁽⁸⁾ Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed (OJ L 193, 20.7.2002, p. 33).

⁽⁹⁾ Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes (OJ L 193, 20.7.2002, p. 60).

⁽¹⁰⁾ Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants (OJ L 193, 20.7.2002, p. 74).

⁽¹¹⁾ Council Directive 2008/72/EC of 15 July 2008 on the marketing of vegetable propagating and planting material, other than seed (OJ L 205, 1.8.2008, p. 28).

⁽¹²⁾ Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants intended for fruit production (OJ L 267, 8.10.2008, p. 8).

- (4) Specific criteria and conditions for the performance of official controls should also be set out to ensure the traceability at all stages of production, preparation and distribution, and compliance with Regulation (EU) 2018/848 concerning controls performed on operators marketing plant reproductive material of organic heterogeneous material.
- (5) Organic heterogeneous material is characterised by its high level of phenotypic and genetic diversity, and its dynamic nature to evolve and adapt to certain growing conditions. In contrast to seed mixtures that are rebuilt annually based on varieties, or synthetic varieties derived by intercrossing of a defined set of parental materials which are repeatedly cross-pollinated to reconstruct a stable population, or conservation and amateur varieties including landraces as defined in Commission Directive 2008/62/EC⁽¹³⁾ and Commission Directive 2009/145/EC⁽¹⁴⁾, organic heterogeneous material is intended to adapt to various biotic and abiotic stresses due to repeated natural and human selection and therefore is expected to change over time.
- (6) Rules should be established concerning the identification of seed lots of organic heterogeneous material, in order to take into account the particular characteristics of that material. The rules concerning minimum quality requirements such as health, analytical purity and germination should ensure the same standards as for the lowest category of seeds and other plant reproductive material (CAC, standard, commercial or certified category) as provided in Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 98/56/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC. Such rules are necessary in order to serve the interests of the users of that organic heterogeneous material, namely farmers and gardeners, who should be assured about its adequate quality and identity. Experience has shown that plant reproductive material of organic heterogeneous material can fulfil those standards.
- (7) Operators should have the possibility to place on the market seed of organic heterogeneous material, which does not satisfy the conditions with respect to germination, to ensure greater flexibility for the marketing of that material. However, and in order to allow users to make informed choices, the supplier should indicate the germination rate of the seed concerned on the label or directly on the package of the plant reproductive material of organic heterogeneous material.
- (8) In accordance with Article 37 of Regulation (EU) 2018/848, organic production is subject to official controls and to other official activities carried out in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council⁽¹⁵⁾. Accordingly, Member States should designate relevant competent authorities for the official control of operators dealing with organic heterogeneous material, in order to ensure compliance with the rules on organic production. Organic heterogeneous material should be subject to risk-based official controls to guarantee the fulfilment of the requirements established in this Regulation. The controls of identity, analytical purity, germination rate, and plant health and their compliance with Regulation (EU) 2016/2031 should be conducted in accordance with official testing protocols carried out in laboratories, designated by the competent authorities, in accordance with the relevant international standards.

⁽¹³⁾ Commission Directive 2008/62/EC of 20 June 2008 providing for certain derogations for acceptance of agricultural landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion and for marketing of seed and seed potatoes of those landraces and varieties (OJ L 162, 21.6.2008, p. 13).

⁽¹⁴⁾ Commission Directive 2009/145/EC of 26 November 2009 providing for certain derogations, for acceptance of vegetable landraces and varieties which have been traditionally grown in particular localities and regions and are threatened by genetic erosion and of vegetable varieties with no intrinsic value for commercial crop production but developed for growing under particular conditions and for marketing of seed of those landraces and varieties (OJ L 312, 27.11.2009, p. 44).

⁽¹⁵⁾ 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).

- (9) Operators should keep the necessary records to ensure the traceability, plant health controls and best possible management of the organic heterogeneous material, which is under their control.
- (10) Organic heterogeneous material is not stable and therefore the current methods for testing uniformity and stability used for variety registration are not appropriate. The identification and traceability of organic heterogeneous material should thus be guaranteed through the description of its production methods and its phenotypic and agronomic characteristics.
- (11) Rules should be set out for the maintenance of organic heterogeneous material to ensure identity and quality, if such maintenance is possible.
- (12) This Regulation should apply from 1 January 2022, as does Regulation (EU) 2018/848,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation establishes rules concerning the production and marketing of plant reproductive material of organic heterogeneous material within the meaning of Regulation (EU) 2018/848 which are seeds of agricultural and vegetable species, vegetable propagating material other than seeds, propagating material of ornamental plants, vine propagating material and fruit plant propagating material, within the meaning of Directives 66/401/EEC, 66/402/EEC, 68/193/EC, 98/56/EC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC.

This Regulation shall not apply to any transfer of limited quantities of plant reproductive material of organic heterogeneous material intended for research on, and development of, organic heterogeneous material.

Article 2

Definitions

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

- (1) 'organic heterogeneous material' means a plant grouping within the meaning of Article 3(18) of Regulation (EU) 2018/848, which is produced according to the requirements of Article 3(1) of that Regulation;
- (2) 'parental material' means any plant material the crossing or propagation of which resulted in organic heterogeneous material;
- (3) 'small packages' means packages containing seed up to the maximum quantities provided for in Annex II.

Article 3

Production and marketing within the Union of plant reproductive material of organic heterogeneous material

Plant reproductive material of organic heterogeneous material shall only be produced or marketed within the Union, if all of the following requirements are fulfilled:

- (1) it complies with the requirements on:
 - (a) identity, as referred to in Article 5;

- (b) sanitary and analytical purity and germination, as referred to in Article 6;
- (c) packaging and labelling, as referred to in Article 7;
- (2) its description includes the elements referred to in Article 4;
- (3) it is subject to the official controls pursuant to Article 9;
- (4) it is produced or marketed by operators who comply with the requirements concerning information in Article 8; and
- (5) it is maintained in accordance with Article 10.

Article 4

Description of organic heterogeneous material

1. The description of organic heterogeneous material shall include all of the following elements:
 - (a) a description of its characteristics, including:
 - (i) the phenotypic characterisation of the key characters which are common to the material, together with the description of the heterogeneity of the material by characterising the phenotypic diversity observable between individual reproductive units;
 - (ii) documentation of its relevant characteristics, including agronomic aspects such as regards yield, yield stability, suitability for low input systems, performance, resistance to abiotic stress, disease resistance, quality parameters, taste or colour;
 - (iii) any available results from tests concerning the characteristics referred to in point (ii);
 - (b) a description of the type of technique used for the breeding or production method of the organic heterogeneous material;
 - (c) a description of the parental material used to breed or produce the organic heterogeneous material and own production control programme used by the operator concerned with a reference to the practices as referred to in paragraph (2)(a) and, if applicable, in paragraph 2(c);
 - (d) a description of the on-farm management and selection practices with a reference to paragraph 2(b) and, if applicable, of the parental material with a reference to paragraph 2(c);
 - (e) a reference to the country of breeding or production, with information on the year of production and description of the pedo-climatic conditions;
2. The material referred to in paragraph 1 may be generated by one of the following techniques:
 - (a) crossing of several different types of parental material, using crossing protocols to produce diverse organic heterogeneous material by bulking of the progeny, repeatedly re-sowing and exposing the stock to natural and/or human selection, provided that this material shows a high level of genetic diversity which is in accordance with Article 3(18) of Regulation (EU) 2018/848;
 - (b) on-farm-management practices, including selection, establishing or maintaining material, which is characterized by a high level of genetic diversity in accordance with Article 3(18) of Regulation (EU) 2018/848;
 - (c) any other technique used for breeding or production of organic heterogeneous material, taking into account particular features of propagation.

*Article 5***Requirements concerning the identity of seed lots of plant reproductive material of organic heterogeneous material**

Plant reproductive material of organic heterogeneous material shall be identifiable on the basis of all of the following elements:

- (1) the parental material and the production scheme used in the crossing for creation of the organic heterogeneous material, as provided for in Article 4(2)(a) or, if applicable, in Article 4(2)(c), or the history of the material and the on-farm management practices, including whether the selection has occurred naturally and/or through human intervention, in the cases of Articles 4(2)(b) and 4(2)(c);
- (2) the country of breeding or production;
- (3) characterisation of the common key characters and of the phenotypic heterogeneity of the material.

*Article 6***Requirements concerning the sanitary quality, analytical purity and germination of plant reproductive material of organic heterogeneous material**

1. Plant reproductive material of organic heterogeneous material shall comply with the provisions of Regulation (EU) 2016/2031, Commission Implementing Regulation (EU) 2019/2072 ⁽¹⁶⁾ and the other relevant acts adopted pursuant to Regulation (EU) 2016/2031 concerning the presence, and the measures against, Union quarantine pests, protected zone quarantine pests and Union regulated non-quarantine pests.

2. For the production and marketing of plant reproductive material of organic heterogeneous material of fodder plant species listed in Article 2(1)(A) of Directive 66/401/EEC, the following provisions shall apply:

- (a) point 1 and the last column of the table in point 5 of Annex I to Directive 66/401/EEC, and
- (b) Section I, points 2 and 3 and Section III of Annex II to Directive 66/401/EEC.

3. For the production and marketing of plant reproductive material of organic heterogeneous material of cereal species listed in Article 2(1)(A) of Directive 66/402/EEC, the following provisions shall apply:

- (a) point 1 and the last column of the table in point 6 of Annex I to Directive 66/402/EEC;
- (b) the third, sixth, tenth, thirteenth, sixteenth, twentieth and twenty-first row of the table in point 2(A) and point 2(B) of Annex II to that Directive,
- (c) the last column in the table in point 3 of Annex II to that Directive;
- (d) the third and the sixth row in the table in point 4 of Annex II to that Directive.

⁽¹⁶⁾ 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. For the production and marketing of plant reproductive material of organic heterogeneous material of vine within the meaning of Directive 68/193/EEC, the following provisions shall apply:

- (a) Sections 2, 3, 4, 6 and 7 and point 6 of Section 8 of Annex I to Directive 68/193/EEC;
- (b) Annex II to Directive 68/193/EEC, with the exception of point 1(1).

5. For the production and marketing of plant reproductive material of organic heterogeneous material of ornamental plants within the meaning of Directive 98/56/EC, Article 3 of Directive 93/49/EEC ⁽¹⁷⁾ shall apply.

6. For the production and marketing of plant reproductive material of organic heterogeneous material of beet within the meaning of Directive 2002/54/EC, points A(1), B(2) and B(3) of Annex I to that Directive shall apply.

7. For the production and marketing of plant reproductive material of organic heterogeneous material of vegetable species listed in Article 2(1)(b) of Directive 2002/55/EC, points 2 and 3 of Annex II to that Directive shall apply.

8. For the production and marketing of plant reproductive material of organic heterogeneous material of seed potatoes within the meaning of Directive 2002/56/EC, the provisions for the lowest category of seed potatoes in point 3 of Annex I and in Annex II shall apply.

9. For the production and marketing of plant reproductive material of organic heterogeneous material of oil and fibre plants as listed in Article 2(1)(b) of Directive 2002/57/EC, the following provisions shall apply:

- (a) point 1 and the last column of the table in point 4 of Annex I to Directive 2002/57/EC;
- (b) the table in point I(4)(A) of Annex II, except the requirements for basic seed of *Brassica* ssp. and *Sinapis alba*, and the last column of the table in point I(5) of Annex II to Directive 2002/57/EC.

10. For the production and marketing of organic heterogeneous vegetable propagating and planting material, other than seed within the meaning of Directive 2008/72/EC, Articles 3 and 5 of Commission Directive 93/61/EEC ⁽¹⁸⁾, shall apply.

11. For the production and marketing of plant reproductive material of organic heterogeneous fruit plant propagating material and fruit plants intended for fruit production within the meaning of Directive 2008/90/EC, the following provisions shall apply:

- (a) Article 23, except point (1)(b), Articles 24, 26, 27 and 27a of Commission Implementing Directive 2014/98/EU ⁽¹⁹⁾;
- (b) Annexes I, II and Annex III and the requirements concerning CAC material in Annex IV to Implementing Directive 2014/98/EU.

12. Paragraphs 2 to 11 shall only apply with regard to the analytical purity and germination requirements for seed and the quality and health requirements for other propagating material, but not with regard to varietal identity and varietal purity and field inspection requirements for varietal identity and varietal purity of the plant reproductive material of organic heterogeneous material.

13. By way of derogation from the provisions of paragraphs 1 to 12, operators may place on the market seed of organic heterogeneous material, which does not satisfy the conditions with respect to germination, provided that the supplier indicates the germination rate of the seed concerned on the label or directly on the package.

⁽¹⁷⁾ Commission Directive 93/49/EEC of 23 June 1993 setting out the schedule indicating the conditions to be met by ornamental plant propagating material and ornamental plants pursuant to Council Directive 91/682/EEC (OJ L 250, 7.10.1993, p. 9).

⁽¹⁸⁾ Commission Directive 93/61/EEC of 2 July 1993 setting out the schedules indicating the conditions to be met by vegetable propagating and planting material, other than seed pursuant to Council Directive 92/33/EEC (OJ L 250, 7.10.1993, p. 19).

⁽¹⁹⁾ Commission Implementing Directive 2014/98/EU of 15 October 2014 implementing Council Directive 2008/90/EC as regards specific requirements for the genus and species of fruit plants referred to in Annex I thereto, specific requirements to be met by suppliers and detailed rules concerning official inspections (OJ L 298, 16.10.2014, p. 22).

*Artikel 7***Anforderungen an die Verpackung und Kennzeichnung von Pflanzenvermehrungsmaterial aus ökologischem/biologischem heterogenem Material**

1. Plant reproductive material of organic heterogeneous material not contained in small packages shall be contained in packages or containers, which are closed in such a manner that they cannot be opened without leaving evidence of tampering on the package or container.

2. The operator shall affix on packages or containers of seeds or plant reproductive material of organic heterogeneous material a label in at least one of the official languages of the Union.

That label shall:

- (a) be legible, printed or written on one side, unused and easily visible;
- (b) include the information set out in Annex I to this Regulation;
- (c) be yellow with a green diagonal cross.

3. Instead of a label, the information set out in Annex I may be directly printed or written on the package or the container. In that case, point 2(c) shall not be applicable.

4. In the case of small, transparent packages, the label may be placed inside the package provided it is clearly legible.

5. By way of derogation from paragraphs 1 to 4, seed of organic heterogeneous material contained in closed and labelled packages and containers may be sold to final users in unmarked and unsealed packages up to the maximum quantities provided for in Annex II, provided that, on request, the purchaser is informed in writing at the time of delivery about the species, the denomination of the material and the reference number of the lot.

*Article 8***Requirements concerning information to be kept by operators**

1. Any operator producing or marketing plant reproductive material of organic heterogeneous material shall:

- (a) keep a copy of the notification submitted in accordance with Article 13(2) of Regulation (EU) 2018/848, a copy of the declaration submitted under Article 39(1)(d) thereof and, where applicable, a copy of the certificate received in accordance with Article 35 thereof;
- (b) ensure the traceability of the organic heterogeneous material in the production scheme as provided for in Article (4)(2) (a) or, if applicable, in Article (4)(2)(c) by keeping information allowing to identify the operators which have supplied parental material of organic heterogeneous material.

The operator shall keep those documents for 5 years.

2. The operator producing plant reproductive material of organic heterogeneous material intended for marketing shall also record and keep the following information:

- (a) name of the species and denomination used for each notified organic heterogeneous material; type of technique used for the production of organic heterogeneous material as referred to in Article 4;
- (b) characterisation of the notified organic heterogeneous material as provided for in Article 4;
- (c) location of breeding of organic heterogeneous material and location of production of organic plant reproductive material of the organic heterogeneous material as provided for in Article 5;
- (d) surface area for the production of organic heterogeneous material and quantity produced.

3. The responsible official bodies in accordance with Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 98/56/EC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC shall have access to the information referred to in paragraphs 1 and 2 of this Article.

Article 9

Official controls

The competent authorities of the Member States or the delegated bodies, where the competent authorities have delegated control tasks in accordance with Chapter III of Title II of Regulation (EU) 2017/625, shall carry out risk-based official controls in relation to the production and marketing of plant reproductive material of organic heterogeneous material to check compliance with the requirements of Articles 4, 5, 6, 7, 8 and 10 of this Regulation.

The testing of germination and analytical purity shall be carried out in accordance with the applicable methods of the International Seed Testing Association.

Article 10

Maintenance of organic heterogeneous material

Where maintenance is possible, the operator who has notified the organic heterogeneous material to the competent authorities pursuant to Article 13 of Regulation (EU) 2018/848, shall preserve the main characteristics of the material at the time of its notification, by maintaining it as long as it remains on the market. That maintenance shall be undertaken according to accepted practices adapted to the maintenance of such heterogeneous material. The operator responsible for the maintenance shall keep records of duration and content of maintenance.

At all times, the competent authorities shall have access to all records kept by the operator responsible for the material, in order to check its maintenance. The operator shall keep those records for 5 years after the moment the plant reproductive material of organic heterogeneous material is not marketed anymore.

Article 11

Entry into force and application

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 2022.

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

Done at Brussels, 7 May 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

INFORMATION TO BE SET OUT ON THE LABEL OF THE PACKAGES AS PROVIDED FOR IN ARTICLE 7(2)(b)

- A. The label shall include the following information:
1. the denomination of the heterogeneous material, together with the phrase 'Organic heterogeneous material';
 2. 'Union rules and standards';
 3. the name and address of the professional operator responsible for affixing the label, or its registration code;
 4. country of production;
 5. reference number given by the professional operator responsible for affixing the labels;
 6. month and year of closing, following the term: 'closed';
 7. species, indicated at least under its botanical name, which may be given in abridged form and without the authors names, in roman characters;
 8. declared net or gross weight, or declared number in case of seeds, except for small packages;
 9. where weight is indicated and pelleting substances, or other solid additives are used, the nature of the additive and also the approximate ratio between the weight of pure seeds and the total weight;
 10. information on the plant protection products applied to the plant reproductive material as required under Article 49(4) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council ⁽¹⁾;
 11. the germination rate where, pursuant to Article 6(13) of this Regulation, organic heterogeneous material does not satisfy the conditions with respect to germination.
- B. The denomination referred to in point A.1. shall not cause its users difficulties as regards recognition or reproduction and shall not:
- (a) be identical or likely to be confused with a denomination under which another variety or organic heterogeneous material of the same or of a closely related species is entered in an official register of plant varieties or a list of organic heterogeneous material;
 - (b) be identical or likely to be confused with other designations which are commonly used for the marketing of goods or which have to be kept free under other legislation;
 - (c) mislead or cause confusion concerning the characteristics, the value or the identity of the organic heterogeneous material, or the identity of the breeder.
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⁽¹⁾ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

ANNEX II

MAXIMUM QUANTITIES OF SEED IN SMALL PACKAGES AS REFERRED TO IN ARTICLE 7(5)

Species	Maximum net mass of the seed (kg)
Fodder plants	10
Beet	10
Cereals	30
Oil and fibre plants	10
Seed potatoes	30
Vegetable seed:	
Legumes	5
Onions, chervil, asparagus, spinach beet or chard, red beet or beetroot, turnips, water melon, gourd, marrows, carrots, radishes, scorzonera or black salsify, spinach, corn-salad or lamb's lettuce	0,5
All other vegetable species	0,1

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1190**of 15 July 2021****laying down the technical specifications of data requirements for the topic 'ICT usage and e-commerce' for the reference year 2022, pursuant to Regulation (EU) 2019/2152 of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/2152 of the European Parliament and of the Council of 27 November 2019 on European business statistics, repealing 10 legal acts in the field of business statistics ⁽¹⁾, and in particular Article 7(1) and Article 17(6) thereof,

Whereas:

- (1) To ensure the correct implementation of the topic 'ICT usage and e-commerce' listed in Annex I to Regulation (EU) 2019/2152, the Commission should specify the variables, the measurement unit, the statistical population, the classifications and breakdowns and the data transmission deadline in order to produce data on ICT usage and e-commerce which is comparable and harmonised between Member States.
- (2) Member States should provide metadata and quality reports for the national statistical business registers and all business statistics. It is therefore necessary to define the arrangements for, content of and deadlines of those reports.
- (3) The measures provided for in this Regulation are in accordance with the opinion of the European Statistical System Committee,

HAS ADOPTED THIS REGULATION:

Article 1

For the topic 'ICT usage and e-commerce', as referred to in Annex I to Regulation (EU) 2019/2152, Member States shall transmit the data according to the technical specifications of data requirements for the reference year 2022 laid down in the Annex to this Regulation.

Article 2

The annual metadata report for the topic 'ICT usage and e-commerce', as referred to in Annex I to Regulation (EU) 2019/2152, shall be transmitted to the Commission (Eurostat) by 31 May 2022.

The annual quality report for the topic 'ICT usage and e-commerce', as referred to in Annex I to Regulation (EU) 2019/2152, shall be transmitted to the Commission (Eurostat) by 5 November 2022.

⁽¹⁾ OJ L 327, 17.12.2019, p. 1.

Article 3

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, 15 July 2021.

For the Commission
The President
Ursula VON DER LEYEN

Technical specifications of data requirements for the topic 'ICT usage and e-commerce'

Mandatory/optional	Scope (filter)	Variable
Mandatory variables	(i) for all enterprises:	(1) main economic activity of the enterprise, in the previous calendar year (2) average number of employees and self-employed persons, in the previous calendar year (3) total value of turnover (excluding VAT), in the previous calendar year (4) number of employees and self-employed persons or percentage of the total number of employees and self-employed persons who have access to the internet for business purposes (5) employment of ICT specialists (6) provision of any type of training to develop ICT-related skills for ICT specialists, in the previous calendar year (7) provision of any type of training to develop ICT-related skills for other persons employed, in the previous calendar year (8) recruitment of or the attempt to recruit ICT specialists in the previous calendar year (9) performance of ICT functions (such as maintenance of ICT infrastructure, support for office software, development or support of business management software/systems and/or web solutions, security and data protection) by own employees (including those employed in parent or affiliate enterprises), in the previous calendar year (10) performance of ICT functions (such as maintenance of ICT infrastructure, support for office software, development or support of business management software/systems and/or web solutions, security and data protection) by external suppliers, in the previous calendar year (11) Use of industrial robots (12) Use of service robots (13) application of measures to affect the following in the enterprise: Amount of paper used for printing and copying (14) application of measures to affect the following in the enterprise: Energy consumption of the ICT equipment (15) consideration by the enterprise of environmental impact of ICT services, or ICT equipment when selecting them (for example energy consumption) (16) disposal of ICT equipment (such as computers, monitors, mobile phones) in electronic waste collection/recycling (including leaving it to the retailer to dispose of) when it is no longer used (17) keeping of ICT equipment (such as computers, monitors, mobile phones) in the enterprise when it is no longer used (for example to be used as spare parts, fear of sensitive information being disclosed) (18) selling, returning to a leasing enterprise or donating ICT equipment (such as computers, monitors, mobile phones) when it is no longer used

Mandatory/optional	Scope (filter)	Variable
	(ii) for enterprises with employees and self-employed persons who have access to the internet for business purposes:	(19) internet connection: use of any type of fixed line connection (20) conduct of remote meetings (21) remote access (via computers or portable devices such as smartphones) of persons employed to email system of the enterprise (22) remote access (via computers or portable devices such as smartphones) of persons employed to documents of the enterprise (such as files, spreadsheets, presentations, charts, photos) (23) remote access (via computers or portable devices such as smartphones) of persons employed to business applications or software of the enterprise (such as access to accounting, sales, orders, CRM (excluding applications used for internal communication)) (24) web sales of goods or services via the enterprise's websites or apps (including extranets), in the previous calendar year (25) web sales of goods or services via e-commerce marketplace websites or apps used by several enterprises for trading goods or services, in the previous calendar year (26) EDI-type sales (receipt of orders placed via Electronic Data Interchange messages) of goods or services, in the previous calendar year (27) application of the ICT security measures on enterprise's ICT systems: authentication via strong password (such as minimum length, use of numbers and special characters, changed periodically) (28) application of the ICT security measures on enterprise's ICT systems: authentication via biometric methods used to access the enterprise's ICT system (such as authentication based on fingerprints, voice, face) (29) application of the ICT security measures on enterprise's ICT systems: authentication based on a combination of at least two authentication mechanisms (i.e. combination of for example user-defined password, one-time password (OTP), code generated via a security token or received via a smartphone, biometric method (such as based on fingerprints, voice, face)); (30) application of the ICT security measures on enterprise's ICT systems: encryption of data, documents or e-mails (31) application of the ICT security measures on enterprise's ICT systems: data backup to a separate location (including backup to the cloud) (32) application of the ICT security measures on enterprise's ICT systems: network access control (management of user rights in enterprise's network) (33) application of the ICT security measures on enterprise's ICT systems: VPN (Virtual Private Network, which extends the private network across a public network to enable secure exchange of data over public network); (34) application of the ICT security measures on enterprise's ICT systems: ICT security monitoring system that allows to detect suspicious activity in the ICT systems and alerts the enterprise about it, other than standalone anti-virus software (35) application of the ICT security measures on enterprise's ICT systems: maintaining log files that enable analysis after ICT security incidents

Mandatory/optional	Scope (filter)	Variable
		(36) application of the ICT security measures on enterprise's ICT systems: ICT risk assessment, i.e. periodical assessment of probability and consequences of ICT security incidents (37) application of the ICT security measures on enterprise's ICT systems: ICT security tests (such as performing penetration tests, testing security alert system, reviewing security measures, testing of backup systems) (38) making persons employed aware of their obligations in ICT security related issues through voluntary training or internally available information (such as information on the intranet) (39) making persons employed aware of their obligations in ICT security related issues through compulsory training courses or viewing compulsory material (40) making persons employed aware of their obligations in ICT security related issues through a contract (such as a contract of employment) (41) availability of document(s) on measures, practices or procedures on ICT security, such as documents on ICT security and confidentiality of data covering employee training in ICT use, ICT security measures, the evaluation of ICT security measures, plans for updating ICT security documents (42) ICT related security incidents experienced in the previous calendar year leading to the following consequences: unavailability of ICT services due to hardware or software failures (43) ICT related security incidents experienced in the previous calendar year leading to the following consequences: unavailability of ICT services due to attack from outside, such as ransomware attacks, Denial of Service attacks (44) ICT related security incidents experienced in the previous calendar year leading to the following consequences: destruction or corruption of data due to hardware or software failures (45) ICT related security incidents experienced in the previous calendar year leading to the following consequences: destruction or corruption of data due to infection of malicious software or unauthorised intrusion (46) ICT related security incidents experienced in the previous calendar year leading to the following consequences: disclosure of confidential data due to intrusion, phishing, phishing attack, intentional actions by own employees (47) ICT related security incidents experienced in the previous calendar year leading to the following consequences: disclosure of confidential data due to unintentional actions by own employees (48) ICT security related activities such as security testing, ICT training on security, resolving ICT security incidents (excluding upgrades of pre-packaged software) carried out by enterprise's own employees (including those employed in parent or affiliate enterprises) (49) ICT security related activities such as security testing, ICT training on security, resolving ICT security incidents (excluding upgrades of pre-packaged software) carried out by external suppliers (50) availability of an insurance against ICT security incidents

Mandatory/optional	Scope (filter)	Variable
	(iii) for enterprises using any type of fixed line internet connection:	(51) maximum contracted download speed of the fastest fixed line internet connection in the ranges: [0 Mbit/s, < 30 Mbit/s], [30 Mbit/s, < 100 Mbit/s], [100 Mbit/s, < 500 Mbit/s], [500 Mbit/s, < 1 Gbit/s], [$\geq$ 1 Gbit/s]
	(iv) for enterprises conducting remote meetings	(52) having any ICT security guidelines for conducting remote meetings via the internet such as password requirement, end-to-end encryption (53) availability of guidelines to favour remote meetings via internet instead of business travelling
	(v) for enterprises having employees or self-employed persons with remote access to the email system of the enterprise	(54) number of employees and self-employed persons or percentage of the total number of employees and self-employed persons having remote access to the email system of the enterprise
	(vi) for enterprises having employees or self-employed persons with remote access to the documents or business applications or software of the enterprise	(55) number of employees and self-employed persons or percentage of the total number of employees and self-employed persons having remote access to documents, business applications or software of the enterprise
	(vii) for enterprises having employees or self-employed persons with remote access to the email system of the enterprises or to documents of the enterprise or to business applications or software of the enterprise	(56) having any ICT security guidelines for remote access such as requirement to conduct password-secured remote meetings, prohibition of using of public Wi-Fi for work, use of VPN, requirements concerning privacy of data
	(viii) for enterprises which had web sales, in the previous calendar year:	(57) value of web sales of goods or services, or percentage of total turnover generated by web sales of goods and services, in the previous calendar year (58) percentage of value of web sales generated by web sales to private consumers (Business to Consumers: B2C), in the previous calendar year (59) percentage of value of web sales generated by web sales to other enterprises (Business to Business: B2B) and to public sector (Business to Government: B2G), in the previous calendar year

Mandatory/optional	Scope (filter)	Variable
	(ix) for enterprises which had web sales of goods and services via the enterprise's websites or apps and via e-commerce marketplace websites or apps used by several enterprises for trading goods or services, in the previous calendar year:	(60) percentage of value of web sales of goods or services generated by sales via the enterprise's websites or apps, in the previous calendar year (61) percentage of value of web sales of goods or services generated by sales via e-commerce marketplace websites or apps used by several enterprises for trading goods or services, in the previous calendar year
	(x) for enterprises which had EDI-type sales of goods and services, in the previous calendar year:	(62) value of EDI-type sales of goods or services or percentage of the total turnover generated by EDI-type sales of goods or services, in the previous calendar year
	(xi) for enterprises which have recruited or tried to recruit ICT specialists in the previous calendar year	(63) vacancies for ICT specialists that were difficult to fill
	(xii) for enterprises which have document(s) on measures, practices or procedures on ICT security	(64) most recent definition or review of enterprise's document(s) on measures, practices or procedures on ICT security: within the last 12 months, more than 12 months and up to twenty-four months ago, more than twenty-four months ago
	(xiii) for enterprises using industrial or services robots	(65) reasons which influenced the decision to use robots in the enterprise: high cost of labour (66) reasons which influenced the decision to use robots in the enterprise: difficulties to recruit personnel (67) reasons which influenced the decision to use robots in the enterprise: to enhance safety at work (68) reasons which influenced the decision to use robots in the enterprise: to ensure high precision or standardized quality of processes and/or goods and services produced (69) reasons which influenced the decision to use robots in the enterprise: to expand the range of goods produced or services provided by the enterprise (70) reasons which influenced the decision to use robots in the enterprise: tax or other government incentives

Mandatory/optional	Scope (filter)	Variable
Optional variables	(i) for enterprises with employees and self-employed persons who have access to the internet for business purposes:	(1) number of employees and self-employed persons, or percentage of the total number of employees and self-employed persons, using a portable device provided by the enterprise that allows connection to the internet via mobile telephone networks for business purposes
	(ii) for enterprises which had web sales, in the previous calendar year:	(2) web sales to customers located in the enterprise's own country, in the previous calendar year (3) web sales to customers located in other Member States, in the previous calendar year (4) web sales to customers located in the rest of the world, in the previous calendar year
	(iii) for enterprises which had web sales to customers located in at least two of the following geographic areas: own country, other Member States or rest of the world, in the previous calendar year:	(5) percentage of value of web sales generated by web sales to customers located in enterprise's own country, in the previous calendar year (6) percentage of value of web sales generated by web sales to customers located in other Member States, in the previous calendar year (7) percentage of value of web sales generated by web sales to customers located in the rest of the world, in the previous calendar year
	(iv) for enterprises which had web sales to customer located in other Member States, in the previous calendar year:	(8) difficulties experienced when selling to other Member States: high costs of delivering or returning products, in the previous calendar year (9) difficulties experienced when selling to other Member States: difficulties related to resolving complaints or disputes, in the previous calendar year (10) difficulties experienced when selling to other Member States: adapting product labelling for sales to other Member States, in the previous calendar year (11) difficulties experienced when selling to other Member States: lack of knowledge of foreign languages for communicating with customers in other Member States, in the previous calendar year (12) difficulties experienced when selling to other Member States: restrictions from enterprise's business partners to sell to certain Member States, in the previous calendar year (13) difficulties experienced when selling to other Member States: difficulties related to the VAT system in other Member States (such as uncertainty regarding VAT treatment in different countries), in the previous calendar year
	(v) for enterprises with vacancies for ICT specialists that were difficult to fill, when trying to recruit ICT specialists in the previous calendar year:	(14) difficulties to recruit ICT specialists due to lack of applications, in the previous calendar year (15) difficulties to recruit ICT specialists due to applicants' lack of relevant ICT related qualifications from education and/or training, in the previous calendar year

Mandatory/optional	Scope (filter)	Variable
		(16) difficulties to recruit ICT specialists due to applicants' lack of relevant work experience, in the previous calendar year (17) difficulties to recruit ICT specialists due to applicants' too high salary expectations, in the previous calendar year
	(vi) for enterprises having industrial or service robots	(18) number of industrial and service robots used by the enterprise

Measurement unit	Absolute figures, except for characteristics related to turnover in national currency (thousands) or percentage of (total) turnover
Statistical population	<i>Activity coverage:</i> NACE Sections C to J, L to N and group 95.1 <i>Size class coverage:</i> Enterprises with 10 or more employees and self-employed persons. Enterprises with less than 10 employees and self-employed persons may be covered optionally
Breakdowns	<i>Activity breakdown</i> for calculation of national aggregates: — aggregates of NACE sections and group C+D+E+F+G+H+I+J+L+M+N+95.1, D+E — NACE sections: C, F, G, H, I, J, L, M, N — NACE divisions: 47, 55 — aggregates of NACE divisions: 10 + 11 + 12 + 13 + 14 + 15 + 16 + 17 + 18, 19 + 20 + 21 + 22 + 23, 24 + 25, 26 + 27 + 28 + 29 + 30 + 31 + 32 + 33 — aggregate of the divisions and groups: 26.1 + 26.2 + 26.3 + 26.4 + 26.8 + 46.5 + 58.2 + 61 + 62 + 63.1 + 95.1 for contribution to the European totals only — NACE sections: D, E — NACE divisions: 19, 20, 21, 26, 27, 28, 45, 46, 61, 72, 79 — NACE group: 95.1 — aggregates of NACE divisions: 10 + 11 + 12, 13 + 14 + 15, 16 + 17 + 18, 22 + 23, 29 + 30, 31 + 32 + 33, 58 + 59 + 60, 62 + 63, 69 + 70 + 71, 73 + 74 + 75, 77 + 78 + 80 + 81 + 82 <i>Size class of number of employees and self-employed persons:</i> 10+, 10-49, 50-249, 250+; optional: 0-9, 0-1, 2-9
Data transmission deadline	5 October 2022

COMMISSION IMPLEMENTING REGULATION (EU) 2021/1191**of 19 July 2021****renewing the approval of the active substance clopyralid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 20(1) thereof,

Whereas:

- (1) Commission Directive 2006/64/EC ⁽²⁾ included clopyralid as an active substance in Annex I to Council Directive 91/414/EEC ⁽³⁾.
- (2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁴⁾.
- (3) The approval of the active substance clopyralid, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 April 2022.
- (4) An application for the renewal of the approval of the active substance clopyralid was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ⁽⁵⁾ within the time period provided for in that Article.
- (5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.
- (6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 31 May 2017.
- (7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the draft renewal assessment report to the applicant and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.
- (8) On 6 July 2018, the Authority communicated to the Commission its conclusion ⁽⁶⁾ on whether clopyralid can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented a renewal report and the draft Regulation for clopyralid to the Standing Committee on Plants, Animals, Food and Feed on 24 March 2021.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2006/64/CE of 18 July 2006 amending Council Directive 91/414/EEC to include clopyralid, cyprodinil, fosetyl and trinexapac as active substances (OJ L 206, 27.7.2006, p. 110).

⁽³⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

⁽⁵⁾ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

⁽⁶⁾ EFSA Journal 2018;16(8):5389. Available online: www.efsa.europa.eu.

- (9) As regards the criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605 ⁽⁷⁾, the conclusion of the Authority indicates that, based on the scientific evidence, it is highly unlikely that clopyralid is an endocrine disrupter since no toxic effects on endocrine organs have been observed. Thus, the Commission concludes that clopyralid is not to be considered as having endocrine disrupting properties.
- (10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with the third paragraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments on the draft renewal report, which have been carefully examined.
- (11) It has been established with respect to one or more representative uses of at least one plant protection product containing clopyralid that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (12) The risk assessment for the renewal of the approval of the active substance clopyralid is based on representative uses as herbicide on winter cereals and grassland. While it is not necessary, in the light of this risk assessment, to maintain the restriction to use only as an herbicide, it is, however, necessary to provide, in accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, for certain conditions and restrictions. It is, in particular, appropriate to require further confirmatory information.
- (13) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (14) Commission Implementing Regulation (EU) 2021/566 ⁽⁸⁾ extended the approval period of clopyralid to 30 April 2022 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should start to apply earlier than that date.
- (15) 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

Renewal of the approval of the active substance

The approval of the active substance clopyralid is renewed as set out in Annex I.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

⁽⁷⁾ Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

⁽⁸⁾ Commission Implementing Regulation (EU) 2021/566 of 30 March 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances abamectin, *Bacillus subtilis* (Cohn 1872) strain QST 713, *Bacillus thuringiensis* subsp. Aizawai strains ABTS-1857 and GC-91, *Bacillus thuringiensis* subsp. Israeliensis (serotype H-14) strain AM65-52, *Bacillus thuringiensis* subsp. Kurstaki strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, *Beauveria bassiana* strains ATCC 74040 and GHA, clodinafop, clopyralid, *Cydia pomonella* Granulovirus (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, mepanipyrim, *Metarhizium anisopliae* (var. *anisopliae*) strain BIPESCO 5/F52, metconazole, metrafenone, pirimicarb, *Pseudomonas chlororaphis* strain MA342, pyrimethanil, *Pythium oligandrum* M1, rimsulfuron, spinosad, *Streptomyces* K61 (formerly '*S. griseoviridis*'), *Trichoderma asperellum* (formerly '*T. harzianum*') strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly '*T. harzianum*') strain T11, *Trichoderma gamsii* (formerly '*T. viride*') strain ICC080, *Trichoderma harzianum* strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram (OJ L 118, 7.4.2021, p. 1).

*Article 3***Entry into force and date of application**

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 October 2021.

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

Done at Brussels, 19 July 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Clopyralid CAS No 1702-17-6 CIPAC No 455	3,6-dichloropyridine- 2-carboxylic acid or 3,6dichloropicolinic acid	≥ 950 g/kg	1 October 2021	30 September 2036	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on clopyralid, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the specification of the technical material as commercially manufactured; — the protection of operators, ensuring that conditions of use for operators include the application of adequate personal protective equipment; — possible presence of clopyralid residues in rotational crops; — the possible transfer of clopyralid residues via compost or manure of animals whose feed originates from treated areas, to avoid damage to susceptible crops; — the protection of groundwater under vulnerable conditions. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water. The applicant shall submit this information within two years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

⁽¹⁾ Further details on the identity and the specification of the active substance are provided in the renewal report.

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

- (1) in Part A, entry 129 on clopyralid is deleted;
- (2) in Part B, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
147	Clopyralid CAS No 1702-17-6 CIPAC No 455	3,6-dichloropyridine-2-carboxylic acid or 3,6dichloropicolinic acid	≥ 950 g/kg	1 October 2021	30 September 2036	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on clopyralid, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the specification of the technical material as commercially manufactured; — the protection of operators, ensuring that conditions of use for operators include the application of adequate personal protective equipment; — possible presence of clopyralid residues in rotational crops; — the possible transfer of clopyralid residues via compost or manure of animals whose feed originates from treated areas, to avoid damage to susceptible crops; — the protection of groundwater under vulnerable conditions. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water. The applicant shall submit this information within two years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

⁽¹⁾ Further details on the identity and the specification of the active substance are provided in the renewal report.’

DECISIONS

COUNCIL DECISION (CFSP) 2021/1192

of 19 July 2021

updating the list of persons, groups and entities subject to Articles 2, 3 and 4 of Common Position 2001/931/CFSP on the application of specific measures to combat terrorism, and repealing Decision (CFSP) 2021/142

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 29 thereof,

Having regard to the proposal of the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 27 December 2001, the Council adopted Common Position 2001/931/CFSP ⁽¹⁾.
- (2) On 5 February 2021, the Council adopted Decision (CFSP) 2021/142 ⁽²⁾ updating the list of persons, groups and entities subject to Articles 2, 3 and 4 of Common Position 2001/931/CFSP ('the list').
- (3) In accordance with Article 1(6) of Common Position 2001/931/CFSP, it is necessary to review at regular intervals the names of persons, groups and entities in the list to ensure that there are grounds for keeping them thereon.
- (4) This Decision sets out the result of the review that the Council has carried out in respect of persons, groups and entities to which Articles 2, 3 and 4 of Common Position 2001/931/CFSP apply.
- (5) The Council has verified that competent authorities, as referred to in Article 1(4) of Common Position 2001/931/CFSP, have taken decisions with regard to all persons, groups and entities on the list to the effect that they have been involved in terrorist acts within the meaning of Article 1(2) and (3) of Common Position 2001/931/CFSP. The Council has also concluded that the persons, groups and entities to which Articles 2, 3 and 4 of Common Position 2001/931/CFSP apply should continue to be subject to the specific restrictive measures provided for in Common Position 2001/931/CFSP.
- (6) The list should be updated accordingly, and Decision (CFSP) 2021/142 should be repealed,

HAS ADOPTED THIS DECISION:

Article 1

The list of persons, groups and entities to which Articles 2, 3 and 4 of Common Position 2001/931/CFSP apply is set out in the Annex to this Decision.

Article 2

Decision (CFSP) 2021/142 is hereby repealed.

⁽¹⁾ Council Common Position 2001/931/CFSP of 27 December 2001 on the application of specific measures to combat terrorism (OJ L 344, 28.12.2001, p. 93).

⁽²⁾ Council Decision (CFSP) 2021/142 of 5 February 2021 updating the list of persons, groups and entities subject to Articles 2, 3 and 4 of Common Position 2001/931/CFSP on the application of specific measures to combat terrorism, and repealing Decision (CFSP) 2020/1132 (OJ L 43, 8.2.2021, p. 14).

Article 3

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

Done at Brussels, 19 July 2021.

For the Council

The President

J. PODGORŠEK

ANNEX

LIST OF PERSONS, GROUPS AND ENTITIES REFERRED TO IN ARTICLE 1

I. PERSONS

1. ABDOLLAHI Hamed (a.k.a. Mustafa Abdullahi), born 11.8.1960 in Iran. Passport number: D9004878.
2. AL-NASSER, Abdelkarim Hussein Mohamed, born in Al Ihsa (Saudi Arabia), citizen of Saudi Arabia.
3. AL YACOUB, Ibrahim Salih Mohammed, born 16.10.1966 in Tarut (Saudi Arabia), citizen of Saudi Arabia.
4. ARBABSAR Manssor (a.k.a. Mansour Arbabsiar), born 6.3.1955 or 15.3.1955 in Iran. Iranian and US national, Passport number: C2002515 (Iran); Passport number: 477845448 (USA). National ID number: 07442833, expiry date 15.3.2016 (USA driving licence).
5. ASSADI Assadollah, born 22.12.1971 in Teheran (Iran), Iranian national. Iranian diplomatic passport number: D9016657.
6. BOUYERI, Mohammed (a.k.a. Abu ZUBAIR, a.k.a. SOBIAR, a.k.a. Abu ZOUBAIR), born 8.3.1978 in Amsterdam (The Netherlands).
7. EL HAJJ, Hassan Hassan, born 22.3.1988 in Zaghdraiya, Sidon, Lebanon, Canadian citizen. Passport number: JX446643 (Canada).
8. HASHEMI MOGHADAM Saeid, born 6.8.1962 in Teheran (Iran), Iranian national. Passport number: D9016290, valid until 4.2.2019.
9. IZZ-AL-DIN, Hasan (a.k.a. GARBAYA, Ahmed, a.k.a. SA-ID, a.k.a. SALWWAN, Samir), Lebanon, born 1963 in Lebanon, citizen of Lebanon.
10. MELIAD, Farah, born 5.11.1980 in Sydney (Australia), Australian citizen. Passport number: M2719127 (Australia).
11. MOHAMMED, Khalid Shaikh (a.k.a. ALI, Salem, a.k.a. BIN KHALID, Fahd Bin Adballah, a.k.a. HENIN, Ashraf Refaat Nabith, a.k.a. WADOOD, Khalid Abdul), born 14.4.1965 or 1.3.1964 in Pakistan, passport number 488555.
12. ŞANLI, Dalokay (a.k.a. Sinan), born 13.10.1976 in Pülümür (Turkey).
13. SHAHLAI Abdul Reza (a.k.a. Abdol Reza Shala'i, a.k.a. Abd-al Reza Shalai, a.k.a. Abdorreza Shahlai, a.k.a. Abdolreza Shahla'i, a.k.a. Abdul-Reza Shahlaee, a.k.a. Hajj Yusef, a.k.a. Haji Yusif, a.k.a. Hajji Yasir, a.k.a. Hajji Yusif, a.k.a. Yusuf Abu-al-Karkh), born circa 1957 in Iran. Addresses: (1) Kermanshah, Iran, (2) Mehran Military Base, Ilam Province, Iran.
14. SHAKURI Ali Gholam, born circa 1965 in Tehran, Iran.

II. GROUPS AND ENTITIES

1. 'Abu Nidal Organisation' — 'ANO' (a.k.a. 'Fatah Revolutionary Council', a.k.a. 'Arab Revolutionary Brigades', a.k.a. 'Black September', a.k.a. 'Revolutionary Organisation of Socialist Muslims').
2. 'Al-Aqsa Martyrs' Brigade'.
3. 'Al-Aqsa e.V'.
4. 'Babbar Khalsa'.
5. 'Communist Party of the Philippines', including 'New People's Army' — 'NPA', Philippines.
6. Directorate for Internal Security of the Iranian Ministry for Intelligence and Security.
7. 'Gama'a al-Islamiyya' (a.k.a. 'Al-Gama'a al-Islamiyya') ('Islamic Group' — 'IG').
8. 'İslami Büyük Doğu Akıncılar Cephesi' — 'İBDA-C' ('Great Islamic Eastern Warriors Front').
9. 'Hamas', including 'Hamas-Izz al-Din al-Qassem'.

10. 'Hizballah Military Wing' (a.k.a. 'Hezbollah Military Wing', a.k.a. 'Hizbullah Military Wing', a.k.a. 'Hizbollah Military Wing', a.k.a. 'Hezbollah Military Wing', a.k.a. 'Hisbollah Military Wing', a.k.a. 'Hizbu'llah Military Wing' a.k.a. 'Hizb Allah Military Wing', a.k.a. 'Jihad Council' (and all units reporting to it, including the External Security Organisation)).
 11. 'Hizbul Mujahideen' — 'HM'.
 12. 'Khalistan Zindabad Force' — 'KZF'.
 13. 'Kurdistan Workers' Party' — 'PKK' (a.k.a. 'KADEK', a.k.a. 'KONGRA-GEL').
 14. 'Liberation Tigers of Tamil Eelam' — 'LTTE'.
 15. 'Ejército de Liberación Nacional' ('National Liberation Army').
 16. 'Palestinian Islamic Jihad' — 'PIJ'.
 17. 'Popular Front for the Liberation of Palestine' — 'PFLP'.
 18. 'Popular Front for the Liberation of Palestine — General Command' (a.k.a. 'PFLP — General Command').
 19. 'Devrimci Halk Kurtuluş Partisi-Cephesi' — 'DHKP/C' (a.k.a. 'Devrimci Sol' ('Revolutionary Left'), a.k.a. 'Dev Sol') ('Revolutionary People's Liberation Army/Front/Party').
 20. 'Sendero Luminoso' — 'SL' ('Shining Path').
 21. 'Teyrbazen Azadiya Kurdistan' — 'TAK' (a.k.a. 'Kurdistan Freedom Falcons', a.k.a. 'Kurdistan Freedom Hawks').
-

COUNCIL DECISION (CFSP) 2021/1193**of 19 July 2021****extending the mandate of the European Union Special Representative in Bosnia and Herzegovina and amending Decision (CFSP) 2019/1340**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 33 and Article 31(2) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 8 August 2019, the Council adopted Decision (CFSP) 2019/1340 ⁽¹⁾ appointing Mr Johann SATTLER as the European Union Special Representative (EUSR) in Bosnia and Herzegovina. The EUSR's mandate is to expire on 31 August 2021.
- (2) The mandate of the EUSR should be extended for a period of 24 months and a new financial reference amount for the period from 1 September 2021 to 31 August 2023 should be established.
- (3) The EUSR will implement the mandate in the context of a situation which may deteriorate and could impede the achievement of the objectives of the Union's external action as set out in Article 21 of the Treaty,

HAS ADOPTED THIS DECISION:

Article 1

The mandate of Mr Johann SATTLER as the European Union Special Representative (EUSR) in Bosnia and Herzegovina is extended until 31 August 2023. The Council may decide that the mandate of the EUSR be extended or terminated earlier, based on an assessment by the Political and Security Committee and a proposal from the High Representative of the Union for Foreign Affairs and Security Policy.

Article 2

Decision (CFSP) 2019/1340 is amended as follows:

- (1) in Article 5(1), the following subparagraph is added:

'The financial reference amount intended to cover the expenditure related to the EUSR's mandate for the period from 1 September 2021 to 31 August 2023 shall be EUR 12 800 000.:'

- (2) in Article 14, the second sentence is replaced by the following:

'The EUSR shall present the Council, the HR and the Commission with regular progress reports and a final comprehensive mandate implementation report by 31 May 2023.'

⁽¹⁾ Council Decision (CFSP) 2019/1340 of 8 August 2019 appointing the European Union Special Representative in Bosnia and Herzegovina (OJ L 209, 9.8.2019, p. 10).

Article 3

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 19 July 2021.

For the Council

The President

J. PODGORŠEK

COUNCIL DECISION (CFSP) 2021/1194**of 19 July 2021****extending the mandate of the European Union Special Representative in Kosovo * and amending
Decision (CFSP) 2020/1135**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 33 and Article 31(2) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 30 July 2020, the Council adopted Decision (CFSP) 2020/1135 ⁽¹⁾ appointing Mr Tomáš SZUNYOG as the European Union Special Representative (EUSR) in Kosovo. The EUSR's mandate is to expire on 31 August 2021.
- (2) The mandate of the EUSR should be extended for a period of 24 months and a new financial reference amount for the period from 1 September 2021 to 31 August 2023 should be established.
- (3) The EUSR will implement the mandate in the context of a situation which may deteriorate and could impede the achievement of the objectives of the Union's external action as set out in Article 21 of the Treaty,

HAS ADOPTED THIS DECISION:

Article 1

The mandate of Mr Tomáš SZUNYOG as the European Union Special Representative (EUSR) in Kosovo is extended until 31 August 2023. The Council may decide that the mandate of the EUSR be extended or terminated earlier, based on an assessment by the Political and Security Committee and a proposal from the High Representative of the Union for Foreign Affairs and Security Policy.

Article 2

Decision (CFSP) 2020/1135 is amended as follows:

- (1) in Article 5(1), the following subparagraph is added:

‘The financial reference amount intended to cover the expenditure related to the EUSR's mandate for the period from 1 September 2021 to 31 August 2023 shall be EUR 6 600 000.’;

- (2) in Article 14, the second sentence is replaced by the following:

‘The EUSR shall present the Council, the HR and the Commission with regular progress reports and a final comprehensive mandate implementation report by 31 May 2023.’.

* This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

⁽¹⁾ Council Decision (CFSP) 2020/1135 of 30 July 2020 appointing the European Union Special Representative in Kosovo (OJ L 247, 31.7.2020, p. 25).

Article 3

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 19 July 2021.

For the Council

The President

J. PODGORŠEK

COMMISSION IMPLEMENTING DECISION (EU) 2021/1195**of 19 July 2021****on the harmonised standards for *in vitro* diagnostic medical devices drafted in support of Regulation (EU) 2017/746 of the European Parliament and of the Council**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council ⁽¹⁾, and in particular Article 10(6) thereof,

Whereas:

- (1) In accordance with Article 8 of Regulation (EU) 2017/746 of the European Parliament and of the Council ⁽²⁾, devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the *Official Journal of the European Union*, are to be presumed to be in conformity with the requirements of that Regulation covered by those standards or parts thereof.
- (2) By Commission Implementing Decision C(2021) 2406 ⁽³⁾, the Commission made a request to the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) for the revision of existing harmonised standards on *in vitro* diagnostic medical devices developed in support of Directive 98/79/EC of the European Parliament and of the Council ⁽⁴⁾ and the drafting of new harmonised standards in support of Regulation (EU) 2017/746.
- (3) On the basis of the request set out in Implementing Decision C(2021) 2406, CEN revised the existing harmonised standards EN ISO 11135:2014, EN ISO 11137-1:2015, EN ISO 11737-2:2009 and EN ISO 25424:2011, in order to include the latest technical and scientific progress, and to adapt them to the relevant requirements of Regulation (EU) 2017/746. This resulted in the adoption of the new harmonised standards EN ISO 11737-2:2020 and EN ISO 25424:2019, and of the amendments EN ISO 11135:2014/A1:2019 to EN ISO 11135:2014 and EN ISO 11137-1:2015/A2:2019 to EN ISO 11137-1:2015.
- (4) The Commission together with CEN has assessed whether the standards revised and drafted by CEN comply with the request set out in Implementing Decision C(2021) 2406.
- (5) The harmonised standards EN ISO 11737-2:2020 and EN ISO 25424:2019 and the amendments EN ISO 11135:2014/A1:2019 to EN ISO 11135:2014 and EN ISO 11137-1:2015/A2:2019 to EN ISO 11137-1:2015 satisfy the requirements which they aim to cover and which are set out in Regulation (EU) 2017/746. It is therefore appropriate to publish the references of those standards in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 316, 14.11.2012, p. 12.

⁽²⁾ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

⁽³⁾ Commission Implementing Decision of 14.4.2021 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and *in vitro* diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council.

⁽⁴⁾ Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

- (6) Compliance with a harmonised standard confers a presumption of conformity with the corresponding essential requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the date of its publication,

HAS ADOPTED THIS DECISION:

Article 1

The references of harmonised standards for *in vitro* diagnostic medical devices drafted in support of Regulation (EU) 2017/746 and listed in the Annex to this Decision are hereby published in the *Official Journal of the European Union*.

Article 2

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, 19 July 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

No	Reference of the standard
1.	EN ISO 11135:2014 Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014) EN ISO 11135:2014/A1:2019
2.	EN ISO 11137-1:2015 Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013) EN ISO 11137-1:2015/A2:2019
3.	EN ISO 11737-2:2020 Sterilization of health care products – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
4.	EN ISO 25424:2019 Sterilization of health care products – Low temperature steam and formaldehyde – Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2018)

COMMISSION IMPLEMENTING DECISION (EU) 2021/1196**of 19 July 2021**

amending Implementing Decision (EU) 2020/167 as regards harmonised standards for certain radio equipment concerning ground- and wall-probing radio determination devices, radio frequency identification equipment, radio equipment for Euroloop railway systems, networked short range devices, wireless industrial applications and broadband communication radiolink for ships and off-shore installations

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council ⁽¹⁾, and in particular Article 10(6) thereof,

Whereas:

- (1) In accordance with Article 16 of Directive 2014/53/EU of the European Parliament and of the Council, ⁽²⁾ radio equipment which is in conformity with harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, is to be presumed to be in conformity with the essential requirements set out in Article 3 of that Directive, covered by those standards or parts thereof.
- (2) By Implementing Decision C(2015) 5376 ⁽³⁾, the Commission made a request to the European Committee for Electrotechnical Standardisation (CENELEC) and the European Telecommunications Standards Institute (ETSI) for the drafting and revision of harmonised standards for radio equipment in support of Directive 2014/53/EU ("the Request").
- (3) On the basis of the Request, ETSI drafted harmonised standard EN 303 258 V1.1.1 for wireless industrial applications.
- (4) On the basis of the Request, ETSI revised harmonised standards EN 302 066-2 V1.2.1, EN 302 208 V3.1.1, EN 302 609 V2.1.1, EN 303 204 V2.1.2 and EN 303 276 V1.1.1, the references of which are published in the C series of the *Official Journal of the European Union* ⁽⁴⁾. This resulted in adoption of, respectively, harmonised standards EN 302 066 V2.2.1 for ground- and wall-probing radio determination devices, EN 302 208 V3.3.1 for radio frequency identification equipment, EN 302 609 V2.2.1 for radio equipment for Euroloop railway systems, EN 303 204 V3.1.1 for networked short range devices and EN 303 276 V1.2.1 for broadband communication radiolink for ships and off-shore installations.
- (5) The Commission, together with ETSI, has assessed whether those harmonised standards comply with the Request.
- (6) Harmonised standards EN 303 204 V3.1.1 and EN 303 276 V1.2.1 satisfy the essential requirements which they aim to cover and which are set out in Directive 2014/53/EU. It is therefore appropriate to publish the references of those standards in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 316, 14.11.2012, p. 12.

⁽²⁾ Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62).

⁽³⁾ Commission Implementing Decision C(2015) 5376 final of 4 August 2015 on a standardisation request to the European Committee for Electrotechnical Standardisation and to the European Telecommunications Standards Institute as regards radio equipment in support of Directive 2014/53/EU of the European Parliament and of the Council.

⁽⁴⁾ OJ C 326, 14.9.2018, p. 114.

- (7) Harmonised standard EN 302 066 V2.2.1, in the final sentence of the ninth paragraph of its clause 6.2.5 and the tenth and eleventh paragraph of its clause 6.2.5, allows for a subjective interpretation and definition of the specifications laid down in that harmonised standard. The reference of that harmonised standard should therefore be published in the *Official Journal of the European Union* with restrictions.
- (8) European Conference of Postal and Telecommunications Administrations Recommendation 74-01 on unwanted emissions in the spurious domain (ERC Recommendation 74-01 (2019)) lays down requirements for the efficient use of radio spectrum. Table 6 of ERC Recommendation 74-01 (2019) provides that protection should be up to the limit of 694 MHz frequency range. Table 2 of harmonised standard EN 302 208 V3.3.1 is not aligned with ERC Recommendation 74-01 as the limit indicated in that Table is different to the limit indicated in ERC Recommendation 74-01(2019). The reference of that harmonised standard should therefore be published in the *Official Journal of the European Union* with restriction.
- (9) Harmonised standard EN 302 609 V2.2.1 contains, in Table 3, inconsistencies as regards the frequency ranges for the measuring receiver. The reference of that harmonised standard should therefore be published in the *Official Journal of the European Union* with restriction.
- (10) Clauses 4.2.8.2, 4.2.9.3 and 4.2.10.3 of harmonised standard EN 303 258 V1.1.1 do not provide test methods for demonstrating compliance with the specifications set out in those clauses. The reference of that harmonised standard should therefore be published in the *Official Journal of the European Union* with restrictions.
- (11) Annex I to Commission Implementing Decision (EU) 2020/167 ⁽⁵⁾ lists the references of harmonised standards conferring a presumption of conformity with Directive 2014/53/EU, while Annex II to that Implementing Decision lists the references of harmonised standards conferring a presumption of conformity with Directive 2014/53/EU with restriction. In order to ensure that the references of harmonised standards drafted in support of Directive 2014/53/EU are listed in one act, the references of standards EN 303 204 V3.1.1 and EN 303 276 V1.2.1 should be included in Annex I to Implementing Decision (EU) 2020/167 and the references of standards EN 302 066 V2.2.1, EN 302 208 V3.3.1, EN 302 609 V2.2.1 and EN 303 258 V1.1.1 should be included in Annex II to that Implementing Decision.
- (12) It is therefore necessary to withdraw the references of harmonised standards EN 302 066-2 V1.2.1, EN 302 208 V3.1.1, EN 302 609 V2.1.1, EN 303 204 V2.1.2 and EN 303 276 V1.1.1, from the C series of the *Official Journal of the European Union* ⁽⁶⁾, given that they have been revised. Annex III to Implementing Decision (EU) 2020/167 lists the references of harmonised standards drafted in support of Directive 2014/53/EU that are withdrawn from the C series of the *Official Journal of the European Union*. It is therefore appropriate to include those references in that Annex.
- (13) In order to give manufacturers sufficient time to prepare for applying harmonised standards EN 302 066 V2.2.1, EN 302 208 V3.3.1, EN 302 609 V2.2.1, EN 303 204 V3.1.1 and EN 303 276 V1.2.1, it is necessary to defer the withdrawal of the references of harmonised standards EN 302 066-2 V1.2.1, EN 302 208 V3.1.1, EN 302 609 V2.1.1, EN 303 204 V2.1.2 and EN 303 276 V1.1.1.
- (14) Compliance with a harmonised standard confers a presumption of conformity with the corresponding essential requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force as a matter of urgency,

HAS ADOPTED THIS DECISION:

Article 1

Implementing Decision (EU) 2020/167 is amended as follows:

- (1) Annex I is amended in accordance with Annex I to this Decision;
- (2) Annex II is amended in accordance with Annex II to this Decision;

⁽⁵⁾ Commission Implementing Decision (EU) 2020/167 of 5 February 2020 on the harmonised standards for radio equipment drafted in support of Directive 2014/53/EU of the European Parliament and of the Council (OJ L 34, 6.2.2020, p. 46).

⁽⁶⁾ OJ C 326, 14.9.2018, p. 114.

(3) Annex III is amended in accordance with Annex III to this Decision.

Article 2

This Decision shall enter into force on the day of its publication in the Official Journal of the European Union.

Done at Brussels, 19 July 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

In Annex I to Implementing Decision (EU) 2020/167, the following rows are added:

No	Reference of the standard
'10.	EN 303 204 V3.1.1 Fixed Short Range Devices (SRD) in data networks; Radio equipment to be used in the 870 MHz to 876 MHz frequency range with power levels ranging up to 500 mW e.r.p.; Harmonised Standard for access to the radio spectrum
11.	EN 303 276 V1.2.1 Maritime Broadband Radiolink operating within the bands 5 852 MHz to 5 872 MHz and/or 5 880 MHz to 5 900 MHz for ships and off-shore installations engaged in coordinated activities; Harmonised Standard for access to radio spectrum'.

ANNEX II

In Annex II to Implementing Decision (EU) 2020/167, the following rows are added:

No	Reference of the standard
'10.	EN 302 066 V2.2.1 Short Range Devices (SRD); Ground- and Wall- Probing Radio determination (GPR/WPR) devices; Harmonised Standard for access to radio spectrum <i>Notice:</i> Compliance with this harmonised standard shall not confer a presumption of conformity with the essential requirement set out in Article 3(2) of Directive 2014/53/EU if any of the following is applied: — in the ninth paragraph of clause 6.2.5 of that standard, the sentence 'For the emission measurements, a combination of bicones and log periodic dipole array antennas (commonly termed "log periodics") could also be used to cover the entire 30 MHz to 1 000 MHz band'; — the tenth paragraph of clause 6.2.5 of that standard; — the eleventh paragraph of clause 6.2.5 of that standard.
11.	EN 302 208 V3.3.1 Radio Frequency Identification Equipment operating in the band 865 MHz to 868 MHz with power levels up to 2 W and in the band 915 MHz to 921 MHz with power levels up to 4 W; Harmonised Standard for access to radio spectrum <i>Notice:</i> For the purposes of presumption of conformity with the essential requirement set out in Article 3(2) of Directive 2014/53/EU, in Table 2 of this harmonised standard, the limit '692 MHz' is replaced by the following: '694 MHz'.
12.	EN 302 609 V2.2.1 Short Range Devices (SRD); Radio equipment for Euroloop communication systems; Harmonised Standard for access to radio spectrum <i>Notice:</i> For the purposes of presumption of conformity with the essential requirement set out in Article 3(2) of Directive 2014/53/EU: — in the second row of Table 3 of this harmonised standard, the limit '29 090 MHz' shall be read as '27 090 MHz'; — in the third row of Table 3 of this harmonised standard, the limit '29 100 MHz', shall be read as '27 100 MHz'.
13.	EN 303 258 V1.1.1 Wireless Industrial Applications (WIA); Equipment operating in the 5 725 MHz to 5 875 MHz frequency range with power levels ranging up to 400 mW; Harmonised Standard for access to radio spectrum <i>Notice:</i> Compliance with this harmonised standard shall not confer a presumption of conformity with the essential requirement set out in Article 3(2) of Directive 2014/53/EU, in case that the appropriate test methods are not carried out in order to demonstrate compliance with clauses 4.2.8.2, 4.2.9.3 and 4.2.10.3 of this harmonised standard.'

ANNEX III

In Annex III to Implementing Decision (EU) 2020/167, the following rows are added:

No	Reference of the standard	Date of withdrawal
'17.	EN 302 066-2 V1.2.1 Electromagnetic compatibility and Radio spectrum Matters (ERM); Ground- and Wall- Probing Radar applications (GPR/WPR) imaging systems; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive	20 January 2023
18.	EN 302 208 V3.1.1 Radio Frequency Identification Equipment operating in the band 865 MHz to 868 MHz with power levels up to 2 W and in the band 915 MHz to 921 MHz with power levels up to 4 W; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU	20 January 2023
19.	EN 302 609 V2.1.1 Short Range Devices (SRD); Radio equipment for Euroloop railway systems; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU	20 January 2023
20.	EN 303 204 V2.1.2 Network Based Short Range Devices (SRD); Radio equipment to be used in the 870 MHz to 876 MHz frequency range with power levels ranging up to 500 mW; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU	20 January 2023
21.	EN 303 276 V1.1.1 Maritime Broadband Radiolink operating within the bands 5 852 MHz to 5 872 MHz and/or 5 880 MHz to 5 900 MHz for ships and off-shore installations engaged in coordinated activities; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU	20 January 2023'

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