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I

(Resolutions, recommendations and opinions)

RECOMMENDATIONS

EUROPEAN CENTRAL BANK

RECOMMENDATION OF THE EUROPEAN CENTRAL BANK

of 2 June 2023

to the Council of the European Union on the external auditors of the Banca d'Italia

(ECB/2023/14)

(2023/C 202/01)

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

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

Having regard to the Statute of the European System of Central Banks and of the European Central Bank, and in particular Article 27.1 thereof,

Whereas:

- (1) The accounts of the European Central Bank (ECB) and the national central banks of the Member States whose currency is the euro are audited by independent external auditors recommended by the ECB's Governing Council and approved by the Council of the European Union.
- (2) The mandate of the Banca d'Italia's current external auditors, Deloitte & Touche S.p.A., ended following the audit for the financial year 2022. It is therefore necessary to appoint external auditors from the financial year 2023.
- (3) The Banca d'Italia has selected Deloitte & Touche S.p.A. as its external auditors for the financial years 2023 to 2027,

HAS ADOPTED THIS RECOMMENDATION:

It is recommended that Deloitte & Touche S.p.A. should be appointed as the external auditors of the Banca d'Italia for the financial years 2023 to 2027.

Done at Frankfurt am Main, 2 June 2023.

The President of the ECB
Christine LAGARDE

II

(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES
AND AGENCIES

EUROPEAN COMMISSION

Communication from the Commission concerning Part B of the Annex to Commission Regulation (EU) No 284/2013 setting out the data requirements for plant protection products 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

(Text with EEA relevance)

(2023/C 202/02)

This guidance has been developed in consultation with the Member States. It does not intend to produce any legally-binding effects and, by its nature, cannot prejudice any measure taken by a Member State in the implementation of Regulation (EC) No 1107/2009, nor any case law developed with regard to this provision. Only the Court of Justice is empowered to authoritatively interpret and apply Union law.

The present Commission Communication fulfils Point 6 of the Introduction of the Annex to Regulation (EU) No 284/2013 that provides that, for purposes of information and of harmonisation, the list of test methods and guidance documents relevant to the implementation of this Regulation must be published in the *Official Journal of the European Union*. The list below represents this list for Part B of the Annex to Regulation (EU) No 284/2013, as amended by Commission Regulation (EU) 2022/1440 ⁽¹⁾, and will be updated regularly.

Where provisions of Part B of the Annex to Regulation (EU) No 284/2013 require generation of data based on requirements laid down in Part A of the Annex to Regulation (EU) No 284/2013, the relevant test methods and guidance are listed in the Commission Communication relevant to the implementation of Part A of the Annex to Regulation (EU) No 284/2013 (i.e. regarding plant protection products containing chemical active substances).

Listing of a document for a section means that it is relevant for all the sub-sections. In case there is no document listed for a section, no agreed test method or guidance document is currently available. In these cases, potential applicants should discuss proposals during the pre-submission meeting with the Rapporteur Member State and the European Food Safety Authority (EFSA), e.g. based on draft test methods.

Test methods

Where Commission Regulation (EC) No 440/2008 ⁽²⁾ provides for cross-reference to an OECD test guideline (by indicating that a test method is replicate, analogous to or equivalent to, an OECD test guideline) only the OECD test guideline is listed to avoid duplication.

⁽¹⁾ Commission Regulation (EU) 2022/1440 of 31 August 2022 amending Regulation (EU) No 284/2013 as regards the information to be submitted for plant protection products and the specific data requirements for plant protection products containing micro-organisms (OJ L 227, 1.9.2022, p. 38).

⁽²⁾ Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 142, 31.5.2008, p. 1).

Only test methods that have been validated (i.e. ring-tested by the OECD or equivalent international organisations) are listed. Test methods only described in scientific publications have not been included.

The listing of a test method should be read as referring to the most updated version of that test method available at the time of the initiation of the study.

For plant protection products containing an active substance that is a micro-organism, ad-hoc test protocols may be needed to address some data requirements. During the pre-submission phase ⁽³⁾, applicants, the Rapporteur Member State, and EFSA may discuss this kind of ad-hoc test protocols, in particular if test protocols listed in the Commission Communication relevant to the implementation of Part A of the Annex to Regulation (EU) No 284/2013 can be used as surrogates or whether they can be adapted to be more suitable for plant protection products containing an active substance that is a micro-organism.

In view of minimising testing on vertebrate animals, tests already carried out based on older test methods should be considered as part of the risk assessment, as provided for in Article 62 of Regulation (EC) No 1107/2009. However, during the pre-submission meeting, applicants, the Rapporteur Member State and EFSA may consider whether new test according to newer test methods are needed, if scientifically justified.

In all cases, in accordance with Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes ⁽⁴⁾, Regulation (EC) No 1107/2009 (Recitals 11 and 40, Articles 8.1(d), 18(b), 33.3(c) and 62.1) and Commission Regulation (EU) No 283/2013 ⁽⁵⁾, unnecessary animal testing must be avoided. More specifically, Article 62 of Regulation (EC) No 1107/2009 provides that testing on vertebrate animals for the purposes of the approval of active substances for plant protection products shall be undertaken only where no other methods are available. Alternative methods include *in-vitro* testing, *in-silico* methods or other approaches such as read-across, as described for instance in the EURL ECVAM Status Report on the Development, Validation and Regulatory Acceptance of Alternative Methods and Approaches and the EURL ECVAM Status Report on Non-animal Methods in Science and Regulation ⁽⁶⁾. Furthermore, availability of guidance documents on non-animal testing and validated and reliable *in-vitro* study protocols should be considered as a valid scientific justification when considering point 1.5 of the Introduction of the Annex to Regulation (EU) No 283/2013.

If several test methods are available to fulfil a data requirement, the order of test methods listed indicates a preference in case a new test is needed. The order prioritises methods where no or fewer test animals are needed and/or this method is associated with less severe suffering of the test animals. However, during the pre-submission meeting, upon advice by EFSA and the Rapporteur Member State, the order of priority can be changed when scientifically justified (e.g. due to limitations of the applicability domain of some methods) in order to ensure the scientific quality of the assessment.

Guidance documents

Guidance documents qualify to be listed when they:

- have been endorsed by the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) before the publication of this Communication,
- have been developed under the auspices of an official body (e.g. EFSA, the Commission, national authorities) with the aim to address a certain area of risk assessment or procedural issues, and were consulted with relevant stakeholders, or
- have been endorsed by an intergovernmental organisation (such as OECD, FAO, WHO, or EPPO) where the Member States take part in the endorsement process.

The following types of guidance documents have been considered for listing:

- Technical guidance documents, including guidance documents that are of horizontal nature that are relevant for several or all sections of the data requirements, including implementation of point 1.5 of the Introduction of the Annex to Regulation (EU) No 284/2013;

⁽³⁾ Article 32a of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31 1.2.2002, p. 1).

⁽⁴⁾ OJ L 276, 20.10.2010, p. 33.

⁽⁵⁾ OJ L 93, 3.4.2013, p. 1.

⁽⁶⁾ Available at <https://publications.jrc.ec.europa.eu/repository/>

- Administrative/procedural guidance documents if they are relevant for the implementation of the data requirements;
- Models or calculation tools, if they are relevant for the data requirements and can be linked to or are supportive to a guidance document;
- Scientific Opinions of the EFSA Panels and guidance documents from the interzonal Steering Committee relevant for all the Member States have been listed following a consideration on a case by case basis, if they are relevant for the implementation of specific data requirements.

Documents such as zonal guidance documents, EFSA statements, peer-reviewed publications, technical reports, scientific reports, strategies are generally not included in the list below, except for some which were subject to a public consultation.

The listing of a guidance document should be read as referring to the most updated version of that guidance document available at the time of the initiation of the study.

As regards the EPPO standards series concerning the efficacy evaluation of plant protection products, the most relevant standards are indicated in the list below. However, the list must be considered not exhaustive since the EPPO global database is updated regularly and other standards may be needed on a case-by-case approach. Therefore, the EPPO global database, the General Standards of the EPPO standard series PP1 and the Specific Standards of the EPPO standard series PP1 are also included in the list.

Reference to Part B of the Annex to Regulation (EU) No 284/2013	Test methods (1)	Guidance documents (2)
General test methods and guidance documents		EFSA Guidance on the use of the weight of evidence approach in scientific assessments (EFSA Journal 2017;15(8):4971)
General test methods and guidance documents		ECHA Guidance on the Application of the CLP Criteria
General test methods and guidance documents		OECD Guidance Document for the Use of Adverse Outcome Pathways in Developing Integrated Approaches to Testing and Assessment (IATA) No. 260
General test methods and guidance documents		OECD Guidance Document on Good In Vitro Method Practices (GIVIMP)
1. Identity of the applicant, identity of the plant protection product and manufacturing information		EU Guidance document for the assessment of the equivalence of technical grade active ingredients for identical microbial strains or isolates approved under Regulation (EC) No. 1107/2009 (SANCO/12823/2012)
1.4 Detailed quantitative and qualitative information on the composition of the preparation		OECD Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No. 65
1.4 Detailed quantitative and qualitative information on the composition of the preparation		EU Guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 of the EU Parliament and Council on placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (SANCO/12638/2011)
2.6 Storage stability and shelf-life		OECD Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No. 65.
2.6 Storage stability and shelf-life		OECD Guidance document on storage stability of microbial pest control products. Series on Pesticides No. 85 (ENV/JM/MONO(2016)54)
2.6.2 Effects of temperature and packaging	CIPAC MT 39 Stability of liquid formulations at 0°C	
2.6.2 Effects of temperature and packaging	CIPAC MT 46 Accelerated storage procedure	

2.7.1 Wettability	CIPAC MT 53 Wettability	
2.7.2 Persistent foaming	CIPAC MT 47 Persistent foaming	
2.7.3 Suspensibility, spontaneity of dispersion and dispersion stability	CIPAC MT 41 Dilution stability of herbicide aqueous solutions	
2.7.3 Suspensibility, spontaneity of dispersion and dispersion stability	CIPAC MT 160 Spontaneity of dispersion of suspension concentrates	
2.7.3 Suspensibility, spontaneity of dispersion and dispersion stability	CIPAC MT 174 Dispersibility of water dispersible granules	
2.7.3 Suspensibility, spontaneity of dispersion and dispersion stability	CIPAC MT 179 Dissolution degree and solution stability	
2.7.3 Suspensibility, spontaneity of dispersion and dispersion stability	CIPAC MT 180 Dispersion stability Suspo-emulsions	
2.7.3 Suspensibility, spontaneity of dispersion and dispersion stability	CIPAC MT 184 Suspensibility of formulations forming suspensions on dilution with water	
2.7.3 Suspensibility, spontaneity of dispersion and dispersion stability	CIPAC MT 196 Solution Properties of Water Soluble Tablets	
2.7.4 Dry sieve test and wet sieve test	CIPAC MT 170 Dry sieve analysis of water dispersible granules	
2.7.4 Dry sieve test and wet sieve test	CIPAC MT 187 Particle size analysis by laser diffraction	
2.7.4 Dry sieve test and wet sieve test	CIPAC MT 185 Wet sieve test	
2.7.5 Particle size distribution (dustable and wetttable powders, granules), content of dust/fines (granules), attrition and friability (granules)	CIPAC MT 170 Dry sieve analysis of water dispersible granules	
2.7.5 Particle size distribution (dustable and wetttable powders, granules), content of dust/fines (granules), attrition and friability (granules)	CIPAC MT 171 Dustiness of granular products	
2.7.5 Particle size distribution (dustable and wetttable powders, granules), content of dust/fines (granules), attrition and friability (granules)	CIPAC MT 178 Attrition resistance of granules	

2.7.5 Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)	CIPAC MT 185 Wet sieve test	
2.7.5 Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)	CIPAC MT 187 Particle size analysis by laser diffraction	
2.7.5 Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)	CIPAC MT 193 Attrition of tablets	
2.7.5 Particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)	CIPAC MT 197 Disintegration of Tablets	
2.7.6 Emulsifiability, re-emulsifiability and emulsion stability	CIPAC MT 36 Emulsion characteristics of emulsifiable concentrates	
2.7.7 Flowability, pourability (rinsability) and dustability	CIPAC MT 148 Pourability of suspension concentrates	
2.7.7 Flowability, pourability (rinsability) and dustability	CIPAC MT 171 Dustiness of granular products	
2.7.7 Flowability, pourability (rinsability) and dustability	CIPAC MT 172 Flowability of water dispersible granules after heat test under pressure	
2.8 Physical and chemical compatibility with other plant protection products including plant protection products with which its use is to be authorised	ASTME1518 – 05 Standard Practice for Evaluation of Physical Compatibility of Pesticides in Aqueous Tank Mixtures by the Dynamic Shaker Method	
2.9 Adherence and distribution to seeds	CIPAC MT 194 Adhesion to Treated Seed	
2.9 Adherence and distribution to seeds	CIPAC MT 175 Seed treatment formulations, liquid, determination of seed-seed uniformity of distribution	

2.9 Adherence and distribution to seeds	European Seed Association, 2011. Assessment of free floating dust and abrasion particles of treated seeds as a parameter of the quality of treated seeds: Heubach test. ESA STAT Dust Working Group	
3. Data on application		EPPO Global Database ⁽³⁾
3.3. Function, target organisms, plants or plants products to be protected and possible risk mitigation measures		EPPO PP 1/248 Harmonized classification and coding of the uses of plant protection products ⁽⁴⁾
3.4. Application rate		EPPO PP1/239 Dose expression of plant protection products
4.1. Procedures for cleaning and decontaminating of application equipment		EPPO PP1/292 Cleaning pesticide application equipment (PAE) – efficacy aspects
5.1. Methods for the analysis of the preparation		EU Guidance document: Technical Active Substance and Plant protection products: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex (Section 4) of Regulation (EU) No 283/2013 and Annex (Section 5) of Regulation (EU) No 284/2013 (SANCO/3030/99)
5.1. Methods for the analysis of the preparation		OECD Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No. 65
5.2. Methods to determine and quantify residues		Residues Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (SANTE/2020/12830)
6. Efficacy data	Specific Standards of the EPPO standard series PP1 ⁽⁵⁾	
6. Efficacy data		EU guidance document on data requirements on efficacy for the dossier to be submitted for the approval of new active substances contained in plant protection products. (SANCO/10054/2013)

6. Efficacy data		EU Guidance document on the efficacy composition of core dossier and national addenda submitted to support the authorization of plant protection products under regulation (EC) No 1107/2009 of the EU parliament and council on placing of plant protection products on the market. (SANCO/10055/2013)
6. Efficacy data		General Standards of the EPPO standard series PP1 ⁽⁶⁾ (Efficacy evaluation of plant protection products), in particular: EPPO PP1/276 Principles of efficacy evaluation for microbial plant protection products, EPPO PP1/296 principles of efficacy evaluation for low-risk plant protection products, and, EPPO PP1/319 General principles for efficacy evaluation of plant protection products with a mode of action as plant defence inducers.
6.6.1. Impact on succeeding crops	OECD Guidelines for Testing of Chemicals No. 208 'Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test' (2006)	
6.6.1. Impact on succeeding crops		EPPO PP1/207 Effects on succeeding crops
6.6.2. Impact on other plants, including adjacent crops		EPPO PP1/256 Effects on adjacent crops
6.6.2. Impact on other plants, including adjacent crops		OECD (2006) Guidelines for the Testing of Chemicals No. 227 'Terrestrial Plant Test: Vegetative Vigour Test'
6.6.2. Impact on other plants, including adjacent crops		OECD (2006) Guidelines for Testing of Chemicals No. 208 'Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test'
7.2. Assessment of potential toxicity of the plant protection product		EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2022;20(1):7032)
7.3 Acute toxicity		OECD (2016) Guidance Document on Considerations for Waiving or Bridging of Mammalian Acute Toxicity Tests Series on Testing & Assessment No. 237

7.3.1 Acute oral toxicity	OECD Test Guideline 423: Acute Oral toxicity - Acute Toxic Class Method	
7.3.1 Acute oral toxicity	OECD Test Guideline 420: Acute Oral Toxicity - Fixed Dose Procedure	
7.3.2. Acute dermal toxicity	OECD Test Guideline 402: Acute Dermal Toxicity - Fixed Dose Procedure	
7.3.3. Acute inhalation toxicity	OECD Test Guideline 436: Acute Inhalation Toxicity – Acute Toxic Class Method	
7.3.3. Acute inhalation toxicity	OECD Test Guideline 403: Acute Inhalation Toxicity	
7.3.4. Skin irritation	OECD Test Guideline 439: In vitro Skin Irritation: Reconstructed Human Epidermis Test Method	
7.3.4. Skin irritation	OECD Test Guideline 404: Acute Dermal Irritation/Corrosion	
7.3.4. Skin irritation	OECD Test Guideline 430: In Vitro Skin Corrosion: Transcutaneous Electrical Resistance Test Method (TER)	
7.3.4. Skin irritation	OECD Test Guideline 431: In vitro skin corrosion: reconstructed human epidermis (RHE) test method	
7.3.4. Skin irritation	OECD Test Guideline 435: In vitro Membrane Barrier Test Method for Skin Corrosion	
7.3.4. Skin irritation		OECD Guidance Document on an Integrated Approach on Testing and Assessment (IATA) for Skin Corrosion and Irritation, No. 203
7.3.5. Eye irritation	OECD Test Guideline 437: Bovine Corneal Opacity and Permeability Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage	
7.3.5. Eye irritation	OECD Test Guideline 438: Isolated Chicken Eye Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage	

7.3.5. Eye irritation	OECD Test Guideline 460: Fluorescein Leakage Test Method for Identifying Ocular Corrosives and Severe Irritants	
7.3.5. Eye irritation	OECD Test Guideline 491: Short Time Exposure In Vitro Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage	
7.3.5. Eye irritation	OECD Test Guideline 492: Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage	
7.3.5. Eye irritation	OECD Test Guideline 405: Acute eye irritation/corrosion	
7.3.6. Skin sensitisation	OECD Test Guideline 442A: Skin Sensitisation – Local Lymph Node Assay: DA	
7.3.6. Skin sensitisation	OECD Test Guideline 442B: Skin Sensitisation - Local Lymph Node Assay: BrdU-ELISA or –FCM	
7.3.6. Skin sensitisation	OECD Test Guideline 442C: In Chemico Skin Sensitisation	
7.3.6. Skin sensitisation	OECD Test Guideline 442D: In Vitro Skin Sensitisation	
7.3.6. Skin sensitisation	OECD Test Guideline 442E: In Vitro Skin Sensitisation: In Vitro Skin Sensitisation Assays Addressing the Key Event on Activation of Dendritic Cells on the Adverse Outcome Pathway for Skin Sensitisation	
7.3.6. Skin sensitisation	OECD Guideline No. 497: Defined Approaches on Skin Sensitisation	
7.3.6. Skin sensitisation	OECD Test Guideline 406: Skin Sensitisation Guinea Pig Maximisation Test and Buehler Test	
7.3.6. Skin sensitisation	OECD Test Guideline 429: Skin Sensitisation – Local Lymph Node Assay	
7.5. Data on exposure	OECD Test Guideline 428: Skin Absorption: In Vitro Method	

7.5. Data on exposure	OECD Test Guideline 427: Skin Absorption: In Vivo Method	
7.5. Data on exposure		EU Guidance on dermal absorption (SANTE/2018/10591)
7.5. Data on exposure		EU Guidance document on the risk assessment of metabolites produced by microorganisms used as plant protection active substances (SANCO/2020/12258)
7.5. Data on exposure		EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015)
7.5. Data on exposure		EFSA Guidance on dermal absorption (EFSA Journal 2017;15(6):4873)
7.5. Data on exposure		FAO Operator exposure models and local risk assessment (7)
8. Residues in or on treated products, food and feed		EU Guidance document on the risk assessment of metabolites produced by microorganisms used as plant protection active substances (SANCO/2020/12258)
8. Residues in or on treated products, food and feed		EFSA Guidance on the establishment of the residue definition for dietary risk assessment (EFSA Journal 2016;14(12):4549)
8. Residues in or on treated products, food and feed		EFSA Reporting data on pesticide residues in food and feed according to Regulation (EC) No 396/2005 (2018 data collection) (EFSA Journal 2019;17(4):5655)
10. Effects on non-target organisms	Test methods indicated either in the Commission Communication for the implementation of Part B of the Annex to Regulation (EU) No 283/2013, or in the Communication relevant to the implementation of Part A of the Annex to Commission Regulation (EU) No 284/2013 may be used as a basis and re-adapted. The applicability of the methods selected, or adaptations of them, must be justified in light of the specificities of the case at stake and it may be discussed in pre-submission meetings.	

10. Effects on non-target organisms		EU Guidance document on the risk assessment of metabolites produced by microorganisms used as plant protection active substances (SANCO/2020/12258)
10. Effects on non-target organisms		OECD Guidance to the environmental safety evaluation of microbial biocontrol agents, Series on Pesticides No. 67 (ENV/JM/MONO(2012)1)

(¹) With exception of methods described in Regulation (EC) No 440/2008, most of the test methods cited are only available in English (some also in French). Detailed information about the test methods:

- CIPAC <http://www.cipac.org/>
- ASTM <http://www.astm.org/Standard/index.shtml>
- ISO http://www.iso.org/iso/home/store/catalogue_ics.htm
- OECD <http://www.oecd.org/env/chemicalsafetyandbiosafety/testingofchemicals/>
- EPPO <http://www.eppo.int/STANDARDS/standards.htm>

(²) Most of the guidance documents cited are available only in English. Detailed information about the guidance documents:

- European Commission: https://food.ec.europa.eu/plants/pesticides/approval-active-substances/guidelines-active-substances-and-plant-protection-products_en
- OECD <http://www.oecd.org/env/chemicalsafetyandbiosafety/testingofchemicals/>
- EPPO: <http://www.eppo.int/STANDARDS/standards.htm>
- ECHA: <http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation>
- EFSA: <http://www.efsa.europa.eu/en/publications.htm>
- FOCUS: <https://esdac.jrc.ec.europa.eu/projects/focus-dg-sante>

(³) <https://gd.eppo.int/>

(⁴) Please consider only those uses which are deemed relevant under the scope of Reg (EC) No 1107/2009, and not those in EPPO PP 1/248 which refer to biostimulant claims as defined both under the scope of Reg (EU) No 2019/1009 and under the technical specifications CEN/TS 17724, CEN/TS 17700-1, CEN/TS 17700-2, CEN/TS 17700-3, CEN/TS 17700-4, CEN/TS 17700-5, even if these biostimulants are identified as plant growth regulators in EPPO PP1/248.

(⁵) EPPO standards are available at <http://pp1.eppo.org/> - EPPO standards of series PP1 describe how to evaluate the efficacy of plant protection products. The series contain General Standards and Specific Standards. Specific Standards should be used together with relevant General Standards and vice versa.

(⁶) <https://pp1.eppo.int/standards/general>

(⁷) <http://www.fao.org/pesticide-registration-toolkit/registration-tools/assessment-methods/method-detail/en/c/1187029/>

Communication from the Commission concerning Part B of the Annex to Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances 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

(Text with EEA relevance)

(2023/C 202/03)

This guidance has been developed in consultation with the Member States. It does not intend to produce any legally-binding effects and, by its nature, cannot prejudice any measure taken by a Member State in the implementation of Regulation (EC) No 1107/2009, nor any case law developed with regard to this provision. Only the Court of Justice is empowered to authoritatively interpret and apply Union law.

The present Commission Communication fulfils Point 6 of the Introduction of the Annex to Regulation (EU) 283/2013 that provides that, for purposes of information and of harmonisation, the list of test methods and guidance documents relevant to the implementation of this Regulation must be published in the *Official Journal of the European Union*. The list below represents this list for Part B of the Annex to Regulation (EU) 283/2013, as amended by Commission Regulation (EU) 2022/1439 ⁽¹⁾, and will be updated regularly.

Where provisions of Part B of the Annex to Regulation (EU) No 283/2013 require generation of data based on requirements laid down in Part A of the Annex to Regulation (EU) No 283/2013, the relevant test methods and guidance are listed in the Commission Communication relevant to the implementation of Part A of the Annex to Regulation (EU) No 283/2013 (i.e. regarding chemical active substances).

Listing of a document for a section means that it is relevant for all the sub-sections. In case there is no document listed for a section, no agreed test method or guidance document is currently available. In these cases, potential applicants should discuss proposals during the pre-submission meeting with the Rapporteur Member State and the European Food Safety Authority (EFSA), e.g. based on draft test methods.

Test methods

Only test methods that have been validated (i.e. ring-tested by the OECD or equivalent international organisations) are listed. Test methods only described in scientific publications have not been included.

The listing of a test method should be read as referring to the most updated version of that test method available at the time of the initiation of the study.

For active substances that are micro-organisms, ad-hoc test protocols may be needed to address some data requirements. During the pre-submission phase ⁽²⁾, applicants, the Rapporteur Member State, and EFSA may discuss this kind of ad-hoc test protocols, in particular if test protocols listed in the Commission Communication relevant to the implementation of Part A of the Annex to Regulation (EU) No 283/2013 can be used as surrogates or whether they can be adapted to be more suitable for active substances that are micro-organisms.

In view of minimising testing on vertebrate animals, tests already carried out based on older test methods should be considered as part of the risk assessment, as provided for in Article 62 of Regulation (EC) No 1107/2009. However, during the pre-submission meeting, applicants, the Rapporteur Member State and EFSA may consider whether new test according to newer test methods are needed, if scientifically justified.

⁽¹⁾ Commission Regulation (EU) 2022/1439 of 31 August 2022 amending Regulation (EU) No 283/2013 as regards the information to be submitted for active substances and the specific data requirements for micro-organisms (OJ L 227, 1.9.2022, p. 8).

⁽²⁾ Article 32a of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

In all cases, in accordance with Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes ⁽³⁾, Regulation (EC) No 1107/2009 (Recitals 11 and 40, Articles 8.1(d), 18(b), 33.3(c) and 62.1) and Commission Regulation (EU) No 283/2013 ⁽⁴⁾, unnecessary animal testing must be avoided. More specifically, Article 62 of Regulation (EC) No 1107/2009 provides that testing on vertebrate animals for the purposes of the approval of active substances for plant protection products shall be undertaken only where no other methods are available. Alternative methods include *in-vitro* testing, *in-silico* methods or other approaches such as read-across, as described for instance in the EURL ECVAM Status Report on the Development, Validation and Regulatory Acceptance of Alternative Methods and Approaches and the EURL ECVAM Status Report on Non-animal Methods in Science and Regulation ⁽⁵⁾. Furthermore, availability of guidance documents on non-animal testing and validated and reliable *in-vitro* study protocols should be considered as a valid scientific justification when considering point 1.5 of the Introduction of the Annex to Regulation (EU) No 283/2013.

If several test methods are available to fulfil a data requirement, the order of test methods listed indicates a preference in case a new test is needed. The order prioritises methods where no or fewer test animals are needed and/or this method is associated with less severe suffering of the test animals. However, during the pre-submission meeting, upon advice by EFSA and the Rapporteur Member State, the order of priority can be changed when scientifically justified (e.g. due to limitations of the applicability domain of some methods) in order to ensure the scientific quality of the assessment.

Guidance documents

Guidance documents qualify to be listed when they:

- have been endorsed by the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) before the publication of this Communication,
- have been developed under the auspices of an official body (e.g. EFSA, the Commission, national authorities) with the aim to address a certain area of risk assessment or procedural issues, and were consulted with relevant stakeholders, or
- have been endorsed by an intergovernmental organisation (such as OECD, FAO, WHO, or EPPO) where the Member States take part in the endorsement process.

The following types of guidance documents have been considered for listing:

- Technical guidance documents, including guidance documents that are of horizontal nature that are relevant for several or all sections of the data requirements, including implementation of point 1.5 of the Introduction of the Annex to Regulation (EU) No 283/2013;
- Administrative/procedural guidance documents if they are relevant for the implementation of the data requirements;
- Models or calculation tools, if they are relevant for the data requirements and can be linked to or are supportive to a guidance document;
- Scientific Opinions of the EFSA Panels and guidance documents from the interzonal Steering Committee relevant for all the Member States have been listed following a consideration on a case by case basis, if they are relevant for the implementation of specific data requirements.

Documents such as zonal guidance documents, EFSA statements, peer reviewed publications, technical reports, scientific reports, strategies are generally not included in the list below, except for some which were subject to a public consultation.

The listing of a guidance document should be read as referring to the most updated version of that guidance document available at the time of the initiation of the study.

As regards the EPPO standards series concerning the efficacy evaluation of plant protection products, the most relevant standards are indicated in the list below. However, the list must be considered not exhaustive since the EPPO global database is updated regularly and other standards may be needed on a case-by-case approach. Consequently, the EPPO global database is also included in the table below.

⁽³⁾ OJ L 276, 20.10.2010, p. 33.

⁽⁴⁾ OJ L 93, 3.4.2013, p. 1.

⁽⁵⁾ Available at <https://publications.jrc.ec.europa.eu/repository/>

Reference to Part B of the Annex to Regulation (EU) No 283/2013	Test methods (1)	Guidance documents (2)
General test methods and guidance documents		EFSA Guidance on submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA Journal 2011;9(2):2092)
General test methods and guidance documents		EFSA Guidance on the use of the weight of evidence approach in scientific assessments (EFSA Journal 2017;15(8):4971)
General test methods and guidance documents		EU Guidance document on the assessment of new isolates of baculovirus species already included in Annex I of Council Directive 91/414/EEC (SANCO/0253/2008)
General test methods and guidance documents		EFSA Statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA Journal 2021;19(7):6506)
General test methods and guidance documents		OECD Guidance Document on Good In Vitro Method Practices (GIVIMP)
General test methods and guidance documents		OECD Guidance Document for the Regulatory Framework for the Microorganism Group: Bacteriophages Series on Pesticides No. 108
1. Identity of the applicant, identity of the active substance and manufacturing information		EU Guidance Document for the assessment of the equivalence of technical grade active ingredients for identical microbial strains or isolates approved under Regulation (EC) No 1107/2009 (SANCO/12823/2012)
1.4.2.2. Identity and content of relevant contaminating microorganisms		OECD Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No. 65
2.7. Genetic stability and factors affecting it		EFSA Statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA Journal 2021;19(7):6506)
2.8 Information on metabolites of concern		EU Guidance document on the risk assessment of metabolites produced by microorganisms used as plant protection active substances (SANCO/2020/12258)
2.8 Information on metabolites of concern		EFSA Statement on the requirements for whole genome sequence analysis of microorganisms intentionally used in the food chain (EFSA Journal 2021;19(7):6506)
2.9. Presence of transferrable antimicrobial resistance genes		EU Guidance document on the approval and low-risk criteria linked to 'antimicrobial resistance' applicable to microorganisms used for plant protection in accordance with Regulation (EC) No 1107/2009 (SANTE/2020/12260)
3.1 Function and target organism		EPPO PP1/248 Harmonized classification and coding of the uses of plant protection products (3)

3.3. Crops or products protected or treated		EPPO Global database (4)
3.3. Crops or products protected or treated		EPPO PP1/248 Harmonized classification and coding of the uses of plant protection product (5)
3.4. Information on possible development of resistance in the target organism(s)		EPPO PP1/213: Resistance risk analysis
3.5 Literature data		EFSA Guidance on submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA Journal 2011;9(2):2092 - including appendix (6))
4.1. Methods for the analysis of the MPCA as manufactured		EU Guidance document: Technical Active Substance and Plant protection products: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex (Section 4) of Regulation (EU) No 283/2013 and Annex (Section 5) of Regulation (EU) No 284/2013 (SANCO/3030/99)
4.1. Methods for the analysis of the MPCA as manufactured		OECD Issue Paper on Microbial Contaminants Limits for Microbial Pest Control Products No. 65
4.2. Methods to determine density of the micro-organism and quantify residues		Residues Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (SANTE/2020/12830) (7)
5.1.3. Information on sensitisation and allergenicity	US EPA OPPTS 885.3400 hypersensitivity Incidents	
5.3.1.1. Oral infectivity and pathogenicity	US EPA OPPTS 885.3050 Acute Oral Toxicity/ Pathogenicity	
5.3.1.2. Intratracheal/ intranasal infectivity and pathogenicity	US EPA OPPTS 885.3150 Acute pulmonary toxicity/ pathogenicity	
5.3.1.3. Intravenous, intraperitoneal or subcutaneous single exposure	US EPA OPPTS 885.3200 Microbial pesticide test guidelines. Acute injection toxicity/pathogenicity	
5.3.2. Cell culture study	US EPA OPPTS 885.3500 Cell culture	

5.4. Specific infectivity and pathogenicity studies on the micro-organism	US EPA OPPTS 885.3600 Subchronic Toxicity/ Pathogenicity	
5.4. Specific infectivity and pathogenicity studies on the micro-organism	US EPA OPPTS 885.3650 Reproductive/fertility effects	
5.5 Information and toxicity studies on metabolites		European Commission draft guidance document Guidance for the setting of an acute reference dose (ARfD) (7199/VI/99)
5.5 Information and toxicity studies on metabolites		ECHA Guidance on the application of the CLP criteria. Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures
5.5 Information and toxicity studies on metabolites		EFSA Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment (EFSA Journal 2019;17(6):5708)
5.5 Information and toxicity studies on metabolites		OECD Series on Testing and Assessment No. 124, Guidance for the Derivation of an Acute Reference Dose. (ENV/JM/MONO(2010)15)
6.1. Estimation of consumer exposure to residues		EFSA Guidance on the use of the Threshold of Toxicological Concern approach in food safety assessment (EFSA Journal 2019;17(6):5708)
7.1.1. Predicted environmental density of the micro-organism		EFSA Guidance document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments, Section 2 (EFSA Journal 2014;12(3):3615)
7.1.1.1. Soil		EU Working document to the Environmental Safety Evaluation of Microbial Biocontrol Agents, section 3.1.2 (SANCO/12117/2012)
7.1.1.1. Soil		EFSA Guidance document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil, section 2.7 'Applicability of the tiered assessment scheme for microbial actives substances' (EFSA Journal 2017;15(10):4982)
7.1.1.2. Water		EU Working document to the Environmental Safety Evaluation of Microbial Biocontrol Agents, section 3.2.1 (SANCO/12117/2012)
7.2.1. Predicted environmental concentration		Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies in Pesticides in EU Registration (based on –among others- Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration - Final Report of the Work Group on Degradation Kinetics of FOCUS (Sanco/10058/2005); Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil (SANCO/12117/2014))

7.2.1. Predicted environmental concentration		Generic guidance for Tier 1 FOCUS Ground water assessments (based on –among others–the European Commission (2014) Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU - Final Report of the Ground Water Work Group of FOCUS (Sanco/13144/2010); FOCUS (2000) 'FOCUS groundwater scenarios in the EU review of active substances' Report of the FOCUS Groundwater Scenarios Workgroup (Sanco/321/2000); Scientific Opinion of the Panel on Plant Protection Products and their Residues on a request from EFSA related to the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil.(doi: 10.2903/j.efsa.2008.622); Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies in Pesticides in EU Registration (including Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration - Final Report of the Work Group on Degradation Kinetics of FOCUS (Sanco/10058/2005); Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil (SANCO/12117/2014)); section 3.3.1 of European Food Safety Authority. Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil (doi:10.2903/j.efsa.2017.4982); section 3.3 of Scientific report of EFSA on the 'repair action' of the FOCUS surface water scenarios (doi:10.2903/j.efsa.2020.6119))
8. Ecotoxicological studies	The relevant methods indicated under this Section may need to be adapted on a case-by-case basis. Hence the applicability of the methods selected, or adaptations of them, must be justified in light of the biological and ecological characteristics of the active substance to be assessed and it may be discussed in pre-submission meetings.	
8. Ecotoxicological studies		EU Working document to the Environmental Safety Evaluation of Microbial Biocontrol Agents (SANCO/12117/2012)
8. Ecotoxicological studies		US EPA 885.4000 (1996) Background for non-target organism testing of microbial pest control agents
8. Ecotoxicological studies		Environment and Climate Change Canada (2016), guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS1/RM/44)
8.1. Effects on terrestrial vertebrates	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS1/RM/44), 14.1 Birds	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS1/RM/44), 14.1 Birds

8.1. Effects on terrestrial vertebrates	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 14.2 Small Mammals	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 14.2 Small Mammals
8.2. Effects on aquatic organisms		Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 11.1 Freshwater Fish
8.2.1. Effects on fish	OECD Test No. 203 (2019) Fish, Acute Toxicity Test	
8.2.1. Effects on fish	OECD Test No. 210 (2013) Fish, Early-life Stage Toxicity Test	
8.2.1. Effects on fish	US EPA OCSPP 885.4200 freshwater fish Tier I	
8.2.1. Effects on fish	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 11.1 Freshwater Fish	
8.2.2. Effects on aquatic invertebrates	OECD Test No. 233 (2010) Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment	
8.2.2. Effects on aquatic invertebrates	US EPA OCSPP 885.4240 Freshwater invertebrate Tier I	

8.2.2. Effects on aquatic invertebrates	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 10.1 Freshwater Invertebrates	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 10.1 Freshwater Invertebrates
8.2.3. Effects on algae	OECD Test No. 201 (2011) Freshwater Alga and Cyanobacteria, Growth Inhibition Test	
8.2.3. Effects on algae	US EPA OCSPP 885.4300 Non target plant studies Tier I	
8.2.3. Effects on algae	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 9.1 Freshwater plants	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 9.1 Freshwater plants
8.2.4. Effects on aquatic macrophytes	OECD Test No. 221 (2006): Lemna sp. Growth Inhibition Test	
8.2.4. Effects on aquatic macrophytes	OECD Test No. 239 (2014): Water-Sediment Myriophyllum Spicatum Toxicity Test	
8.2.4. Effects on aquatic macrophytes	OECD Test No. 238 (2014): Sediment-Free Myriophyllum Spicatum Toxicity Test	
8.3. Effects on bees	OECD Test Guideline 213 Honeybees, Acute Oral Toxicity Test	

8.3. Effects on bees	OECD Test Guideline 214 Honeybees, Acute Contact Toxicity Test.	
8.3. Effects on bees	OECD Test Guideline 245 Honey Bee, Chronic Oral Toxicity Test	
8.3. Effects on bees	OECD guidance document 239 Honey Bee Larval Toxicity Test, Repeated Exposure	
8.3. Effects on bees	OECD guidance document 75: Honey Bee Brood Test Under Semi-Field Conditions	
8.3. Effects on bees	EPPO Bulletin (2019) 49 Oomen Bee Brood Feeding Test	
8.3. Effects on bees	EPPO Bulletin (2010) 40 Side-Effects On Honeybees	
8.3. Effects on bees	OECD Test No. 247 (2017) Bumblebee, Acute Oral Toxicity Test	
8.3. Effects on bees	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 13.2.1 Honey bees	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 13.2.1 Honey bees
8.3. Effects on bees	US EPA OCSPP 885.4380 Honey bee Tier I	
8.4. Effects on non-target arthropods other than bees	US EPA OCSPP 885.4340 Non-target Insect Tier I	

8.4. Effects on non-target arthropods other than bees	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 13.3.1 Tests for Plant-Dwelling Invertebrates	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 13.3.1 Tests for Plant-Dwelling Invertebrates
8.5. Effects on non-target meso- and macroorganisms in soil	OECD Test No. 222 (2016): Earthworm Reproduction Test (<i>Eisenia fetida</i> / <i>Eisenia andrei</i>)	
8.5. Effects on non-target meso- and macroorganisms in soil	OECD Test No. 232 (2016): Collembolan Reproduction Test in Soil	
8.5. Effects on non-target meso- and macroorganisms in soil	OECD Test No. 226 (2016): Predatory mite (<i>Hypoaspis</i> (<i>Geolaelaps</i>) <i>aculeifer</i>) reproduction test in soil	
8.5. Effects on non-target meso- and macroorganisms in soil	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 13.2.2 Springtails	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 13.2.2 Springtails
8.5. Effects on non-target meso- and macroorganisms in soil	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 13.3.2 Earthworms	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 13.3.2 Earthworms

8.6. Effects on non-target terrestrial plants	OECD Test No. 227 (2006): Terrestrial Plant Test: Vegetative Vigour Test	
8.6. Effects on non-target terrestrial plants	OECD Test No. 208 (2006): Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test	
8.6. Effects on non-target terrestrial plants	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 12.2 Terrestrial plants	Environment and Climate Change Canada (2016) Guidance document for testing the pathogenicity and toxicity of new microbial substances to aquatic and terrestrial organisms (EPS 1/RM/44), 12.2 Terrestrial plants

(¹) Most of the test methods cited are only available in English. Detailed information about the test methods:

- ISO http://www.iso.org/iso/home/store/catalogue_ics.htm
- OECD <http://www.oecd.org/env/chemicalsafetyandbiosafety/testingofchemicals/>
- Eppo <http://www.eppo.int/STANDARDS/standards.htm>
- US EPA OCSPP <https://www.epa.gov/>

(²) Most of the guidance documents cited are available only in English. Detailed information about the guidance documents:

- European Commission: https://food.ec.europa.eu/plants/pesticides/approval-active-substances/guidelines-active-substances-and-plant-protection-products_en
- OECD <http://www.oecd.org/env/chemicalsafetyandbiosafety/testingofchemicals/>
- Eppo: <http://www.eppo.int/STANDARDS/standards.htm>
- ECHA: <http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation>
- EFSA: <http://www.efsa.europa.eu/en/publications.htm>

(³) Please consider only those uses which are deemed relevant under the scope of Reg (EC) No 1107/2009, and not those in Eppo PP 1/248 which refer to biostimulant claims as defined both under the scope of Reg (EU) No 2019/1009 and under the technical specifications CEN/TS 17724, CEN/TS 17700-1, CEN/TS 17700-2, CEN/TS 17700-3, CEN/TS 17700-4, CEN/TS 17700-5, even if these biostimulants are identified as plant growth regulators in Eppo PP 1/248.

(⁴) <https://gd.eppo.int/>

(⁵) Please consider only those uses which are deemed relevant under the scope of Reg (EC) No 1107/2009, and not those in Eppo PP 1/248 which refer to biostimulant claims as defined under the scope of Reg (EU) No 2019/1009 and the technical specifications CEN/TS 17724, CEN/TS 17700-1, CEN/TS 17700-2, CEN/TS 17700-3, CEN/TS 17700-4, CEN/TS 17700-5, even if they are identified as plant growth regulators in Eppo PP1/248.

(⁶) <https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903/j.efsa.2011.2092&file=efs22092-sup-0001-Appendix.pdf>

(⁷) if relevant for residues of metabolites of concern.

COMMUNICATION FROM THE COMMISSION**Notice to stakeholders on the withdrawal of the United Kingdom and EU rules in the field of state aid**

(2023/C 202/04)

Since 1 February 2020, the United Kingdom has withdrawn from the European Union and has become a ‘third country’ ⁽¹⁾. The Withdrawal Agreement ⁽²⁾ provided for a transition period which ended on 31 December 2020. The Withdrawal Agreement provided also, in some cases, for separation provisions at the end of the transition period.

All interested parties are reminded of the legal situation applicable since the end of the transition period (Part A below). This notice also explains the rules applicable in respect of Northern Ireland after the end of the transition period (Part B below).

A. Legal situation since the end of the transition period**1. State aid procedures**

Since the end of the transition period, EU State aid control ceased to apply to any State aid granted by the United Kingdom as from that date, unless it affects trade between Northern Ireland and the European Union that is subject to the Protocol on Ireland/Northern Ireland (the ‘Protocol’) ⁽³⁾ / Windsor Framework ⁽⁴⁾. Outside the specific provisions of the Windsor Framework (see below), the European Commission therefore no longer has the power to investigate, and take decisions on, potential State aid measures granted by the United Kingdom after that date. Consequently, stakeholders are no longer able to make formal complaints to the European Commission about such measures.

As regards State aid granted by the United Kingdom before the end of the transition period, the following rules apply:

Pursuant to Article 92(1) of the Withdrawal Agreement, the European Commission will remain competent to continue any ongoing procedures ⁽⁵⁾ concerning State aid granted by the United Kingdom.

Pursuant to Article 93(1) of the Withdrawal Agreement, the European Commission will also remain competent to initiate new administrative proceedings concerning State aid granted by the United Kingdom before the end of the transition period, if such proceedings are started within four years of the end of the transition period.

Pursuant to Article 95(1) of the Withdrawal Agreement, the European Commission’s decisions are binding and enforceable on the United Kingdom in these cases.

Furthermore, the European Commission retains the right to bring an action before the Court of Justice of the European Union for non-compliance with such decisions for a period of four years after the end of the transition period or the date of the decision concerned, whichever is later ⁽⁶⁾. The Court’s judgments on these matters remain binding and enforceable on the United Kingdom.

⁽¹⁾ A third country is a country not member of the European Union.

⁽²⁾ Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (OJ L 29, 31.1.2020, p. 7) (‘Withdrawal Agreement’).

⁽³⁾ For further details on the State aid provisions of the Windsor Framework, see Part B of this notice.

⁽⁴⁾ Pursuant to Joint Declaration No 1/2023 of the Union and the United Kingdom in the Withdrawal Agreement Joint Committee of 24 March 2023, reflecting the arrangements laid down in Decision No 1/2023 of the Joint Committee, the Protocol, as amended by that Joint Committee Decision, should now be known as the ‘Windsor Framework’. Therefore, wherever relevant in dealings between the Union and the United Kingdom under the Withdrawal Agreement, the Protocol, as amended by Joint Committee Decision No 1/2023, will, consistent with the requirements of legal certainty, be referred to as the ‘Windsor Framework’. The Protocol, as amended by Joint Committee Decision No 1/2023, may also be referred to as the ‘Windsor Framework’ in the domestic law of the Union and the United Kingdom.

⁽⁵⁾ The term ‘ongoing procedures’ refers to procedures that have been allocated an internal case number before the end of the transition period (see Article 92(3)(a) of the Withdrawal Agreement).

⁽⁶⁾ See respectively Articles 87(1) and (2) of the Withdrawal Agreement.

As a result, stakeholders can continue to inform the European Commission – by way of formal complaints or otherwise – of any potentially illegal State aid granted by the United Kingdom before the end of the transition period. This includes cases where such aid is only paid out or otherwise disbursed at a later stage, provided that the legal right to receive the aid was conferred on the beneficiary before the end of the transition period.

2. *Substantive State aid provisions*

Exceptionally, certain compatibility criteria set out in the European Commission's State aid guidelines refer to cooperation between EU Member States and/or a certain EU or EEA dimension ⁽⁷⁾. Since the end of the transition period, the United Kingdom is no longer be counted towards such criteria, and Member States have to take due account of this for any new aid granted under the relevant provisions.

B. **rules applicable in respect of Northern Ireland**

1. *Application of the State aid rules under Article 10 of the Windsor Framework*

Since the end of the transition period, the Protocol, now known as the Windsor Framework, applies ⁽⁸⁾. The Windsor Framework is subject to periodic consent of the Northern Ireland Legislative Assembly, the initial period of application extending to four years after the end of the transition period ⁽⁹⁾.

Article 10(1) of the Windsor Framework provides that *'the provisions of Union law listed in Annex 5 to this Protocol shall apply to the United Kingdom, including with regard to measures supporting the production of and trade in agricultural products in Northern Ireland, in respect of measures which affect that trade between Northern Ireland and the Union which is subject to this Protocol'*.

This means that EU State aid rules will continue to apply to the EU Member States, as well as to the United Kingdom in respect of aid that has an effect on the trade between Northern Ireland and the European Union that is subject to the Windsor Framework. It follows from other provisions of the Windsor Framework, and in particular its Articles 5 and 9, that trade in goods and wholesale electricity is subject to the Windsor Framework ⁽¹⁰⁾.

As regards the production of and trade in agricultural and fisheries products in Northern Ireland, Article 10(2) of the Windsor Framework provides for an exemption from the application of Union law up to a determined maximum overall annual level of support, provided that a determined minimum percentage of that exempted support complies with the provisions of Annex 2 to the WTO Agreement on Agriculture. The said maximum level and minimum percentage have been determined by the Joint Committee (European Union and United Kingdom) with Decision No 05/2020 of 17 December 2020 ⁽¹¹⁾. All measures taken to support the production of and trade in agricultural and fisheries products in Northern Ireland which do not fall within the scope of the exemption and that have an effect on the relevant trade between Northern Ireland and the Union fall within the scope of Article 10(1) of the Windsor Framework.

The European Commission, as well as the Court of Justice of the European Union and the General Court (the 'Union Courts'), remain competent as regards such aid as falls within scope of Article 10(1) of the Windsor Framework ⁽¹²⁾.

⁽⁷⁾ For example, certain instruments foresee increased aid intensities in case of cross-border cooperation between EU Member States and/or with Contracting Parties to the EEA.

⁽⁸⁾ Article 185 of the Withdrawal Agreement.

⁽⁹⁾ Article 18 of the Windsor Framework.

⁽¹⁰⁾ For a detailed explanation on which trade is covered by the Windsor Framework, see its Articles 5 to 9. For the purpose of this Notice, a reference to goods will include the electricity market, as appropriate.

⁽¹¹⁾ Decision No 5/2020 of the Joint Committee established by the Agreement on the Withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community of 17 December 2020 determining the initial maximum exempted overall annual level of support and the initial minimum percentage referred to in Article 10(2) of the Protocol on Ireland/Northern Ireland to the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (OJ L 443, 30.12.2020, p. 13).

⁽¹²⁾ See Article 12(4) of the Windsor Framework.

On 17 December 2020, the EU released a unilateral declaration in the Joint Committee in charge of overseeing the implementation of the Withdrawal Agreement. The declaration states as follows: *'When applying Art. 107 TFEU to situations referred to in Art. 10(1) of the Protocol, the European Commission will have due regard to Northern Ireland's integral place in the United Kingdom's internal market. The European Union underlines that, in any event, an effect on trade between Northern Ireland and the Union which is subject to this Protocol cannot be merely hypothetical, presumed, or without a genuine and direct link to Northern Ireland. It must be established why the measure is liable to have such an effect on trade between Northern Ireland and the Union, based on the real foreseeable effects of the measure.'*

This declaration clarifies the application of Article 10(1) of the Protocol, now known as the Windsor Framework. It is, however, without prejudice to the interpretation of the notion of 'effect on trade' by the Union Courts.

The conditions for a genuine and direct link to Northern Ireland to exist, based on the real foreseeable effects of the measure, were further explained in a Joint Declaration of the Union and the United Kingdom in the Withdrawal Agreement Joint Committee of 24 March 2023 on the application of Article 10(1) of the Windsor Framework as follows:

'This Joint Declaration on the application of Article 10(1) of the Windsor Framework builds upon the Union Unilateral Declaration, affirming Northern Ireland's place in the United Kingdom's internal market, and at the same time ensuring that the Union internal market is protected. It clarifies the conditions of application of Article 10(1) of the Windsor Framework setting out the particular circumstances in which it is likely to be engaged when subsidies are granted in the United Kingdom, and can be used to interpret that provision.'

For a measure to be considered to have a genuine and direct link to Northern Ireland and thus to have an effect on the trade between Northern Ireland and the Union that is subject to the Windsor Framework, that measure needs to have real foreseeable effects on that trade. The relevant real foreseeable effects should be material, and not merely hypothetical or presumed.

For measures granted to any beneficiary that is located in Great Britain, factors relevant to materiality may include the size of the undertaking, the size of the subsidy, and the market presence of the undertaking in the relevant market in Northern Ireland. While the mere placement of goods on the Northern Ireland market is not sufficient, on its own, to represent a direct and genuine link engaging Article 10(1) of the Windsor Framework, measures that are granted to beneficiaries located in Northern Ireland are more likely to have material effects.

For measures granted to any beneficiary that is located in Great Britain that have a material effect, it must be further demonstrated that the economic benefit of the subsidy would be wholly or partially passed on to an undertaking in Northern Ireland, or through the relevant goods placed on the market in Northern Ireland, for example through selling below market price, for there to be a direct and genuine link engaging Article 10(1) of the Windsor Framework.'

As affirmed by the Joint Declaration, Article 10(1) of the Windsor Framework applies to measures that affect the relevant trade between Northern Ireland and the Union, irrespective of whether a beneficiary is located in Northern Ireland and/or is engaged itself in the relevant trade.

It is for the European Commission to establish that a measure has a sufficiently genuine and direct link to Northern Ireland, based on its real foreseeable effects, to fall within the scope of application of Article 10(1) of the Windsor Framework. In this regard, the European Commission will take into account the following considerations:

Measures granted to beneficiaries located in Northern Ireland are more likely to present a genuine and direct link to Northern Ireland and therefore to engage Article 10(1) of the Windsor Framework.

For measures granted to beneficiaries located in other parts of the United Kingdom than Northern Ireland, the European Commission has to demonstrate a genuine and direct link to Northern Ireland based on the real foreseeable effects of the measure:

- The European Commission considers that to demonstrate such real foreseeable effects on the relevant trade between Northern Ireland and the Union, any effects of a measure have to be sufficiently material. To assess whether this is the case, the European Commission will refer to a set of indicators, based in particular on the size of the undertaking, the size of the subsidy, and the market presence of the undertaking in Northern Ireland.

- The European Commission needs to further show that an economic benefit of the measure would be wholly or partially passed on to an undertaking in Northern Ireland, or through the relevant goods placed on the market in Northern Ireland, for example through selling below market price. In this respect, the European Commission will also take into account any conditions or features of the measure designed to avoid such a passing on of an economic benefit.

In case of measures in favour of service providers, the European Commission needs to establish that an advantage is passed on to undertakings engaged in the relevant trade in goods between Northern Ireland and the Union. Such an indirect advantage is normally only present if the measure is designed in such a way as to channel its secondary effects towards identifiable undertakings or groups of undertakings ⁽¹³⁾.

To clarify the above by means of examples:

- A subsidy scheme aimed at providing support to manufacturers of goods located in Northern Ireland will normally fall within the application of Article 10(1) of the Windsor Framework, to the extent that it qualifies as State aid.
- A subsidy of limited amount provided to a small enterprise located outside Northern Ireland and without a significant market presence on the Northern Ireland market would normally not produce effects that are material enough to indicate the presence of a genuine and direct link to Northern Ireland based on real foreseeable effects.
- For substantial subsidies to large manufacturers located in other parts of the United Kingdom than Northern Ireland, the European Commission will assess whether there is a material effect on trade with Northern Ireland, based on a series of parameters, such as the market presence of the beneficiary in Northern Ireland. If in addition there is a real risk that an economic benefit could be passed on so as to affect the market in Northern Ireland, the European Commission is likely to consider that Article 10(1) of the Windsor Framework applies. The European Commission would normally not reach this conclusion if the measure is designed in a way to avoid that there is a real risk that the economic benefit could be passed on so as to affect the market in Northern Ireland.
- A subsidy scheme to cover certain training costs of service providers would normally not fall within the application of Article 10(1) of the Windsor Framework, as it would not be designed to channel secondary effects to identifiable undertakings or groups of undertakings engaged in the relevant trade between Northern Ireland and the Union. However, a subsidy scheme aimed at providing financial incentives to service providers (e.g. in the financial sector) designed to reduce the cost of services for undertakings located in Northern Ireland engaged in trade in goods between Northern Ireland and the Union could involve an indirect advantage being passed on to the latter.

2. Article 5(6) of the Windsor Framework

Customs duties levied by the United Kingdom in accordance with Article 5(3) of the Windsor Framework are not remitted to the Union. Article 5(6) of the Windsor Framework states that the UK may under certain circumstances waive tariff debt or reimburse traders ⁽¹⁴⁾. These measures, in so far as they constitute State aid and affect relevant trade between Northern Ireland and the Union, are subject to the provisions of Article 10 of the Windsor Framework on State aid. If called upon to assess the compatibility of such measures, the European Commission shall take the circumstances in Northern Ireland into account as appropriate ⁽¹⁵⁾.

The explanations provided herein do not intend to be exhaustive. Their purpose is to give guidance on the application of the notion of effect on trade between Northern Ireland and the Union to the courts and granting authorities of the EU Member States and of the United Kingdom. The present notice replaces the previous notice to stakeholders published on 10 February 2021.

⁽¹³⁾ For the concept of indirect advantage, reference is made to points 115 and 116 of Commission Notice on the notion of State aid as referred to in Article 107(1) of the Treaty on the Functioning of the European Union; *Official Journal of the European Union* (OJ C 262, 19.7.2016, p. 1).

⁽¹⁴⁾ The United Kingdom reimbursing duties on goods brought into Northern Ireland; the waiving (by the United Kingdom) of customs debts for goods brought into Northern Ireland; the establishment (by the United Kingdom) of conditions under which customs duties are reimbursed on goods 'shown not to have entered the Union'; and to 'compensate undertakings to offset' the application of these provisions (by the United Kingdom).

⁽¹⁵⁾ Article 5(6) of the Windsor Framework.

The website of the European Commission on EU rules on State aid (https://competition-policy.ec.europa.eu/state-aid_en) provides general information concerning Union legislation on State aid. These pages will be updated with further information, where necessary.

IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Euro exchange rates ⁽¹⁾

8 June 2023

(2023/C 202/05)

1 euro =

Currency	Exchange rate	Currency	Exchange rate		
USD	US dollar	1,0737	CAD	Canadian dollar	1,4342
JPY	Japanese yen	149,98	HKD	Hong Kong dollar	8,4126
DKK	Danish krone	7,4498	NZD	New Zealand dollar	1,7696
GBP	Pound sterling	0,86113	SGD	Singapore dollar	1,4460
SEK	Swedish krona	11,6480	KRW	South Korean won	1 399,86
CHF	Swiss franc	0,9751	ZAR	South African rand	20,3284
ISK	Iceland króna	149,50	CNY	Chinese yuan renminbi	7,6541
NOK	Norwegian krone	11,7580	IDR	Indonesian rupiah	15 979,46
BGN	Bulgarian lev	1,9558	MYR	Malaysian ringgit	4,9589
CZK	Czech koruna	23,625	PHP	Philippine peso	60,228
HUF	Hungarian forint	368,65	RUB	Russian rouble	
PLN	Polish zloty	4,4788	THB	Thai baht	37,408
RON	Romanian leu	4,9530	BRL	Brazilian real	5,2866
TRY	Turkish lira	25,0875	MXN	Mexican peso	18,6188
AUD	Australian dollar	1,6061	INR	Indian rupee	88,6170

⁽¹⁾ Source: reference exchange rate published by the ECB.

NOTICES FROM MEMBER STATES

Announcement pursuant to Article 13 of Directive 2001/24/EC of the European Parliament and of the Council on the reorganisation and winding up of credit institutions concerning the liquidation and subsequent winding-up of Baltic International Bank SE [Latvian credit institution in liquidation]

(2023/C 202/06)

Invitation to lodge a claim. Time limits to be observed.

By decision of the Court of Economic Affairs dated 24 March 2023 in civil case No. C75010823, Baltic International Bank SE, reg. No. 40003127883, was recognised as the institution to be liquidated, and the process of its liquidation was initiated. Olavs Cers, a sworn attorney, has been approved as the liquidator of Baltic International Bank SE.

Claims of creditors and claims of other persons, as well as other claims against the Baltic International Bank SE being liquidated must be submitted to the liquidator until **30 June 2023**. Claims of creditors submitted after the specified deadline shall be considered and satisfied in accordance with the procedure established by Paragraph 3, Section 139.3 of the Credit Institution Law.

The place of work of the liquidator of Baltic International Bank SE during the liquidation process is Riga, 6 Grēcinieku Street, LV-1050, contact phone +371 67000444 or +371 67365865 (working days from 9:00 a.m. to 5:00 p.m.). E-mail address for communication bib.likvidators@cersjurkans.lv.

The creditor's application must be drawn up in the Latvian language. A notarized translation into Latvian must be attached if it is drawn up in another language. The creditor's application must be accompanied by the original documents, or, upon presentation of the originals, notarized copies of documents that comply with the requirements of the Hague Convention Abolishing the Requirement of Legalisation for Foreign Public Documents 1961.

Creditors must calculate the total amount of their claims in foreign currency in the claim and specify it in **euro** in accordance with the foreign exchange rate set by the European Central Bank as of 12 December 2022.

Claims of the creditors of Baltic International Bank SE being liquidated and supporting documents can be submitted by addressing them to the liquidator of Baltic International Bank SE being liquidated, Olavs Cers:

- in person in Riga, 9-4 Strēlnieku Street, on working days from 9:00 a.m. to 5:00 p.m.;
- by sending by mail as registered mail to the address 9-4 Strēlnieku Street, Riga, LV-1010, Latvia;
- by sending the creditor's claim, drawn up in accordance with the Electronic Documents Law of Latvia in the form of an electronic document signed with a secure electronic signature and containing a time stamp, to the liquidator's e-mail address: bib.likvidators@cersjurkans.lv.

If the creditor attaches derivative documents to the creditor's claim, the liquidator shall have the right to demand the presentation of the original documents, and the creditor shall be obliged to submit them. The liquidator has the right to request other documents or their derivatives if it is necessary for making a decision on the creditor's claim.

Detailed information on the requirements for filing a creditor's claim can be found on the website of Baltic International Bank SE being liquidated: <https://www.bib.eu/en/news/03/29/notification-commencement-liquidation-baltic-international-bank-se-filing-creditors-claims-claims>

Information communicated by Member States regarding closure of fisheries

(2023/C 202/07)

In accordance with Article 35(3) of Council Regulation (EC) No 1224/2009 of 20 November 2009 establishing a Union control system for ensuring compliance with the rules of the common fisheries policy ⁽¹⁾, a decision has been taken to close the fishery as set down in the following table:

Date and time of closure	18.05.2023
Duration	18.05.2023 - 31.12.2023
Member State	Portugal
Stock or Group of stocks	JAX/08C. (including special condition JAX/*09.)
Species	Horse mackerel (<i>Trachurus</i> spp.)
Zone	8c
Type(s) of fishing vessels	—
Reference number	01/TQ194

⁽¹⁾ OJ L 343, 22.12.2009, p. 1.

Update of the list of border crossing points as referred to in Article 2(8) of Regulation (EU) 2016/399 of the European Parliament and of the Council on a Union Code on the rules governing the movement of persons across borders (Schengen Borders Code) ⁽¹⁾

(2023/C 202/08)

The publication of the list of border crossing points as referred to in Article 2(8) of Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (Schengen Borders Code) ⁽²⁾ is based on the information notified by the Member States to the Commission pursuant to Article 39 of the Schengen Borders Code.

In addition to the publication in the Official Journal, a regular update is available on the website of the Directorate-General for Migration and Home Affairs.

LIST OF BORDER CROSSING POINTS

GERMANY

Replacement of the information published in OJ C 286, 27.7.2022, p. 33.

Ports on the North Sea

- (1) Borkum
- (2) Brake
- (3) Brunsbüttel
- (4) Büsum
- (5) Bützflether Sand
- (6) Bremen
- (7) Bremerhaven
- (8) Cuxhaven
- (9) Eckwarderhörne
- (10) Elsfleth
- (11) Emden
- (12) Fedderwardsiel
- (13) Glückstadt
- (14) Hamburg
- (15) Hamburg-Neuenfelde
- (16) Helgoland
- (17) Horumersiel
- (18) Husum
- (19) Leer
- (20) Lemwerder
- (21) List/Sylt
- (22) Norddeich
- (23) Nordenham
- (24) Norderney
- (25) Papenburg
- (26) Stadersand

⁽¹⁾ See the list of previous publications at the end of this update.

⁽²⁾ OJ L 77, 23.3.2016, p. 1.

- (27) Wangerooge
- (28) Wedel
- (29) Wewelsfleth
- (30) Wilhelmshaven

Baltic ports

- (1) Eckernförde (Federal German Navy port facilities)
- (2) Port of Flensburg
- (3) Port of Greifswald-Ladebow
- (4) Jägersberg (Federal German Navy port facilities)
- (5) Kiel
- (6) Kiel (Federal German Navy port facilities)
- (7) Kiel-Holtenau
- (8) Lubmin
- (9) Lübeck
- (10) Lübeck-Travemünde
- (11) Mukran
- (12) Neustadt
- (13) Puttgarden
- (14) Rendsburg
- (15) Port of Rostock (amalgamation of the overseas ports of Warnemünde and Rostock)
- (16) Sassnitz
- (17) Stralsund
- (18) Surendorf (Federal German Navy port facilities)
- (19) Vierow
- (20) Wismar
- (21) Wolgast

ODERHAFF

- (1) Ueckermünde

Airports, aerodromes, air fields**IN THE FEDERAL STATE OF BADEN WÜRTTEMBERG**

- (1) Aalen-Heidenheim-Elchingen
- (2) Baden Airport Karlsruhe Baden-Baden
- (3) Donaueschingen-Villingen
- (4) Freiburg/Brg.
- (5) Friedrichshafen-Löwental
- (6) Heubach (District of Schwäb. Gmünd)
- (7) Lahr
- (8) Laupheim
- (9) Leutkirch-Unterzeil
- (10) Mannheim-City
- (11) Mengen
- (12) Niederstetten
- (13) Schwäbisch Hall

(14) Stuttgart

IN THE FEDERAL STATE OF BAVARIA

- (1) Aschaffenburg
- (2) Augsburg-Mühlhausen
- (3) Bayreuth – Bindlacher Berg
- (4) Coburg-Brandebsteinsebene
- (5) Giebelstadt
- (6) Hof-Plauen
- (7) Ingolstadt
- (8) Landshut-Ellermühle
- (9) Lechfeld
- (10) Memmingerberg
- (11) München 'Franz Joseph Strauß'
- (12) Neuburg
- (13) Nürnberg
- (14) Oberpfaffenhofen
- (15) Roth
- (16) Straubing-Wallmühle

IN THE FEDERAL STATE OF BERLIN

- (1) Berlin-Tegel

IN THE FEDERAL STATE OF BRANDENBURG

- (1) Berlin Brandenburg 'Willy Brandt'
- (2) Schönhagen

IN THE FEDERAL STATE OF BREMEN

- (1) Bremen

IN THE FEDERAL STATE OF HAMBURG

- (1) Hamburg

IN THE FEDERAL STATE OF HESSE

- (1) Allendorf/Eder
- (2) Egelsbach
- (3) Frankfurt/Main
- (4) Fritzlar
- (5) Kassel-Calden
- (6) Reichelsheim

IN THE FEDERAL STATE OF MECKLENBURG-WESTERN POMERANIA

- (1) Neubrandenburg-Trollenhagen
- (2) Rostock-Laage

IN THE FEDERAL STATE OF LOWER SAXONY

- (1) Borkum
- (2) Braunschweig-Waggum
- (3) Bückeberg-Achum
- (4) Celle

- (5) Damme/Dümmer-See
- (6) Diepholz
- (7) Emden
- (8) Fassberg
- (9) Ganderkesee
- (10) Hannover
- (11) Leer-Nüttermoor
- (12) Nordholz
- (13) Osnabrück-Atterheide
- (14) Wangerooge
- (15) Wilhelmshaven-Mariensiel
- (16) Wittmundhafen
- (17) Wunstorf

IN THE FEDERAL STATE OF NORTH RHINE-WESTPHALIA

- (1) Aachen-Merzbrück
- (2) Arnsberg
- (3) Bielefeld-Windelsbleiche
- (4) Bonn-Hardthöhe
- (5) Dortmund-Wickede
- (6) Düsseldorf
- (7) Essen-Mülheim
- (8) Bonn Hangelar
- (9) Köln/Bonn
- (10) Marl/Loemühle
- (11) Mönchengladbach
- (12) Münster-Osnabrück
- (13) Nörvenich
- (14) Paderborn-Lippstadt
- (15) Porta Westfalica
- (16) Rheine-Bentlage
- (17) Siegerland
- (18) Stadtlohn-Wenningfeld
- (19) Weeze-Lahrbruch

IN THE FEDERAL STATE OF RHINELAND-PALATINATE

- (1) Büchel
- (2) Föhren
- (3) Hahn
- (4) Koblenz-Winningen
- (5) Mainz-Finthen
- (6) Pirmasens-Pottschütthöhe
- (7) Ramstein (US Air Base)
- (8) Speyer
- (9) Spangdahlem (US Air Base)

(10) Zweibrücken

IN THE FEDERAL STATE OF SAARLAND

(1) Saarbrücken-Ensheim

(2) Saarlouis/Düren

IN THE FEDERAL STATE OF SAXONY

(1) Dresden

(2) Leipzig-Halle

(3) Rothenburg/Oberlausitz

IN THE FEDERAL STATE OF SAXONY-ANHALT

(1) Cochstedt

(2) Magdeburg

IN THE FEDERAL STATE OF SCHLESWIG-HOLSTEIN

(1) Helgoland-Düne

(2) Hohn

(3) Kiel-Holtenau

(4) Lübeck-Blankensee

(5) Schleswig/Jagel

(6) Westerland/Sylt

IN THE FEDERAL STATE OF THURINGIA

(1) Altenburg-Nobitz

(2) Erfurt-Weimar

SPAIN

Replacement of the information published in OJ C 420, 22.11.2014, p. 9.

Air borders

(1) Albacete

(2) Alicante

(3) Almería

(4) Asturias

(5) Badajoz

(6) Barcelona

(7) Bilbao

(8) Burgos

(9) Castellón

(10) Ciudad Real

(11) Fuerteventura

(12) Gerona

(13) Gran Canaria

(14) Granada

(15) Huesca-Pirineos

(16) Ibiza

(17) Jerez de la Frontera

(18) La Coruña

- (19) La Palma
- (20) Lanzarote
- (21) León
- (22) Lleida-Alguaire
- (23) Logroño-Agoncillo
- (24) Madrid-Barajas
- (25) Málaga
- (26) Matacán (Salamanca)
- (27) Menorca
- (28) Murcia
- (29) Palma de Mallorca
- (30) Pamplona
- (31) Reus
- (32) San Sebastián
- (33) Santander
- (34) Santiago
- (35) Sevilla
- (36) Tenerife North
- (37) Tenerife South
- (38) Teruel
- (39) Valencia
- (40) Valladolid
- (41) Vigo
- (42) Vitoria
- (43) Zaragoza

Sea borders

- (1) Algeciras (Cádiz)
- (2) Alicante
- (3) Almería
- (4) Arrecife (Lanzarote)
- (5) Avilés (Asturias)
- (6) Barcelona
- (7) Bilbao
- (8) Cádiz
- (9) Cartagena (Murcia)
- (10) Castellón
- (11) Ceuta
- (12) Ferrol (La Coruña)
- (13) Gijón
- (14) Huelva
- (15) Ibiza
- (16) La Coruña
- (17) La Línea de la Concepción
- (18) La Luz (Las Palmas)

- (19) Mahón
- (20) Málaga
- (21) Melilla
- (22) Motril (Granada)
- (23) Palma de Mallorca
- (24) Puerto del Rosario (Fuerteventura)
- (25) Puerto de Santa Cruz de La Palma (La Palma)
- (26) Sagunto (Provincia de Valencia)
- (27) San Sebastian
- (28) Santa Cruz de Tenerife
- (29) Santander
- (30) Sevilla
- (31) Tarifa
- (32) Tarragona
- (33) Valencia
- (34) Vigo

Land borders

- (1) Ceuta
- (2) Melilla
- (3) La Seo de Urgel
- (4) La Línea de la Concepción (*)

(*) The customs post and police checkpoint at 'La Línea de la Concepción' does not correspond to the outline of the border as recognised by Spain in the Treaty of Utrecht.

FRANCE

Replacement of the information published in OJ C 229, 14.6.2022, p. 8.

Air borders

- (1) Ajaccio-Napoléon-Bonaparte
- (2) Albert-Bray
- (3) Angers-Marcé
- (4) Angoulême-Brie-Champniers
- (5) Annecy-Methet
- (6) Auxerre-Branches
- (7) Avignon-Caumont
- (8) Bâle-Mulhouse
- (9) Bastia-Poretta
- (10) Beauvais-Tillé
- (11) Bergerac-Dordogne-Périgord
- (12) Béziers-Vias
- (13) Biarritz-Pays Basque
- (14) Bordeaux-Mérignac
- (15) Brest-Bretagne
- (16) Brive-Souillac
- (17) Caen-Carpiquet

- (18) Calais-Dunkerque
- (19) Calvi-Sainte-Catherine
- (20) Cannes-Mandelieu
- (21) Carcassonne-Salvaza
- (22) Châlons-Vatry
- (23) Chambéry-Aix-les-Bains
- (24) Châteauroux-Déols
- (25) Cherbourg-Mauperthus
- (26) Clermont-Ferrand-Auvergne
- (27) Colmar-Houssen
- (28) Deauville-Normandie
- (29) Dijon-Longvic
- (30) Dinard-Pleurtuit-Saint-Malo
- (31) Dôle-Tavaux
- (32) Epinal-Mirecourt
- (33) Figari-Sud Corse
- (34) Grenoble-Alpes-Isère
- (35) Hyères-le Palivestre
- (36) Istres-Le-Tubé
- (37) La Môle-Saint-Tropez (annual opening from 1 July to 15 October)
- (38) La Rochelle-Ile de Ré
- (39) La Roche-sur-Yon
- (40) Laval-Entrammes
- (41) Le Castellet (Annual opening from 1 June to 31 July. Opening exceptional from 22 to 31 October 2022.)
- (42) Le Havre-Octeville
- (43) Le Mans-Arnage
- (44) Le Touquet-Côte d'Opale
- (45) Lille-Lesquin
- (46) Limoges-Bellegarde
- (47) Lorient-Lann-Bihoué
- (48) Lyon-Bron
- (49) Lyon-Saint-Exupéry
- (50) Marseille-Provence
- (51) Metz-Nancy-Lorraine
- (52) Monaco-Héliport
- (53) Montpellier-Méditerranée
- (54) Nantes-Atlantique
- (55) Nice-Côte d'Azur
- (56) Nîmes-Garons
- (57) Orléans-Bricy
- (58) Orléans-Saint-Denis-de-l'Hôtel
- (59) Paris-Charles de Gaulle
- (60) Paris-Issy-les-Moulineaux

- (61) Paris-le Bourget
- (62) Paris-Orly
- (63) Pau-Pyrénées
- (64) Perpignan-Rivesaltes
- (65) Poitiers-Biard
- (66) Quimper-Pluguffan (open from the beginning of May to the beginning of September)
- (67) Rennes Saint-Jacques
- (68) Rodez-Aveyron
- (69) Rouen-Vallée de Seine
- (70) Saint-Brieuc-Armor
- (71) Saint-Etienne Loire
- (72) Saint-Nazaire-Montoir
- (73) Salon de Provence (10 May 2023–27 May 2023)
- (74) Strasbourg-Entzheim
- (75) Tarbes-Lourdes-Pyrénées
- (76) Toulouse-Blagnac
- (77) Toulouse-Francazal
- (78) Tours-Val de Loire
- (79) Troyes-Barbèrey
- (80) Valence – Chabeuil (as of 1 June 2021)
- (81) Vélizy-Villacoublay

Sea borders

- (1) Ajaccio
- (2) Bastia
- (3) Bayonne
- (4) Bordeaux
- (5) Boulogne
- (6) Brest
- (7) Caen-Ouistreham
- (8) Calais
- (9) Cannes-Vieux Port
- (10) Carteret
- (11) Cherbourg
- (12) Dieppe
- (13) Douvres
- (14) Dunkerque
- (15) Granville
- (16) Honfleur
- (17) La Rochelle-La Pallice
- (18) Le Havre
- (19) Les Sables-d'Olonne-Port
- (20) Lorient
- (21) Marseille
- (22) Monaco-Port de la Condamine

- (23) Nantes-Saint-Nazaire
- (24) Nice
- (25) Port-de-Bouc-Fos/Port-Saint-Louis
- (26) Port-la-Nouvelle
- (27) Port-Vendres
- (28) Roscoff
- (29) Rouen
- (30) Saint-Brieuc
- (31) Saint-Malo
- (32) Sète
- (33) Toulon

Land borders

- (1) Bourg Saint Maurice railway station (open from the beginning of December to mid-April)
- (2) Moûtiers railway station (open from the beginning of December to mid-April)
- (3) Ashford International railway station
- (4) Cheriton/Coquelles
- (5) Chessy-Marne-la-Vallée railway station
- (6) Fréthun railway station
- (7) Lille-Europe railway station
- (8) Paris-Nord railway station
- (9) St-Pancras railway station
- (10) Ebbsfleet railway station
- (11) Pas de la Case-Porta
- (12) Roissy TGV railway station - airport

CROATIA

Replacement of the information published in OJ C 242, 23.8.2013, p. 2.

REPUBLIC OF CROATIA - BOSNIA AND HERZEGOVINA

Permanent border crossing points for international transport of passengers and goods with inspection services in road traffic (BIP) ^(?):

- 1. Stara Gradiška,
- 2. Nova Sela.

Permanent border crossing points for international transport of passengers and goods in road traffic:

- 1. Županja,
- 2. Gunja,
- 3. Slavonski Šamac,
- 4. Slavonski Brod,
- 5. Jasenovac,
- 6. Maljevac,
- 7. Ličko Petrovo Selo,
- 8. Strmica,
- 9. Kamensko,

^(?) Border Inspection Post

10. Vinjani Gornji,
11. Vinjani Donji,
12. Gornji Brgat,
13. Klek,
14. Zaton Doli.

Permanent border crossing points for international transport of passengers and goods in railway traffic:

1. Drenovci,
2. Volinja,
3. Ličko Dugo Polje,
4. Slavonski Šamac,
5. Metković.

Permanent border crossing points for international transport of passengers in road traffic:

1. Hrvatska Kostajnica,
2. Užljebić,
3. Aržano,
4. Orah,
5. Čepikuće,
6. Prud,
7. Metković,
8. Mali Prolog,
9. Dvor.

Permanent border crossing points for local border traffic (*):

1. Pašin Potok,
2. Bogovolja,
3. Kordunski Ljeskovac,
4. Lička Kaldrma,
5. Bili Brig,
6. Aržano Pazar,
7. Dvorine,
8. Cera,
9. Jovića Most,
10. Sebišina,
11. Slivno,
12. Podprolog,
13. Unka,
14. Vukov Klanac,
15. Imotica,
16. Slano,
17. Hrvatska Dubica,
18. Gabela Polje.

(*) Opened every day from 06:00 till 22:00

REPUBLIC OF CROATIA – MONTE NEGRO

Permanent border crossings points for international transport of passengers and goods with inspection services in road traffic (BIP) ^(?):

1. Karasovići.

Permanent border crossing points for international transport of passengers in road traffic:

1. Vitaljina.

REPUBLIC OF CROATIA - REPUBLIC OF SERBIA

Permanent border crossing points for international transport of passengers and goods with inspection services in road traffic (BIP) ⁽⁶⁾:

1. Bajakovo.

Permanent border crossing points for international transport of passengers and goods in road traffic:

1. Batina.
2. Erdut,
3. Ilok,
4. Principovac,
5. Tovarnik,
6. Principanovac II
7. Ilok II

Permanent border crossing points for international transport of passengers and goods in railway traffic:

1. Tovarnik,
2. Erdut.

River border crossing points

Permanent border crossing points for international transport of passengers and goods in river traffic:

1. Osijek,
2. Slavonski Brod,
3. Sisak,
4. Vukovar.

Maritime border crossing points

Permanent border crossing points for international transport of passengers and goods with inspection services in maritime traffic (BIP) ^(?):

1. Rijeka,
2. Ploče.

Permanent border crossing points for international transport of passengers and goods in maritime traffic:

1. Zadar,
2. Šibenik,
3. Split,
4. Dubrovnik,
5. Raša-Bršica.

⁽⁵⁾ Border Inspection Post

⁽⁶⁾ Border Inspection Post

⁽⁷⁾ Border Inspection Post

Permanent border crossing points for international transport of passengers in maritime traffic:

1. Umag,
2. Pula,
3. Mali Lošinj,
4. Ubli,
5. Vis,
6. Cavtat.

Seasonal border crossing points for international transport of passengers in maritime traffic:

Airport border crossing points

Permanent border crossing points for international transport of passengers and goods with inspection services in air traffic (BIP) ⁽⁸⁾:

1. Zagreb.

Permanent border crossing points for international transport of passengers and goods in air traffic:

1. Pula,
2. Rijeka,
3. Zadar,
4. Split,
5. Dubrovnik,
6. Osijek.

Permanent border crossings points for international transport of passengers in air traffic:

1. Mali Lošinj,
2. Brač.

Remark:

- Permanent border crossing point: border crossing point which is opened 24 hours per day
- Seasonal border crossing point: border crossing point which is opened from April 1st till October 31th (In case when Easter holidays started before April 1st, mentioned border crossing point has to be opened seven days prior Easter holidays).

List of previous publications

- | | |
|------------------------------|------------------------------|
| OJ C 247, 13.10.2006, p. 25. | OJ C 263, 5.11.2009, p. 22. |
| OJ C 77, 5.4.2007, p. 11. | OJ C 298, 8.12.2009, p. 17. |
| OJ C 153, 6.7.2007, p. 22. | OJ C 74, 24.3.2010, p. 13. |
| OJ C 164, 18.7.2008, p. 45. | OJ C 326, 3.12.2010, p. 17. |
| OJ C 316, 28.12.2007, p. 1. | OJ C 355, 29.12.2010, p. 34. |
| OJ C 134, 31.5.2008, p. 16. | OJ C 22, 22.1.2011, p. 22. |
| OJ C 177, 12.7.2008, p. 9. | OJ C 37, 5.2.2011, p. 12. |
| OJ C 200, 6.8.2008, p. 10. | OJ C 149, 20.5.2011, p. 8. |
| OJ C 331, 31.12.2008, p. 13. | OJ C 190, 30.6.2011, p. 17. |
| OJ C 3, 8.1.2009, p. 10. | OJ C 203, 9.7.2011, p. 14. |
| OJ C 37, 14.2.2009, p. 10. | OJ C 210, 16.7.2011, p. 30. |
| OJ C 64, 19.3.2009, p. 20. | OJ C 271, 14.9.2011, p. 18. |
| OJ C 99, 30.4.2009, p. 7. | |
| OJ C 229, 23.9.2009, p. 28. | |

⁽⁸⁾ Border Inspection Post

- OJ C 356, 6.12.2011, p. 12.
OJ C 111, 18.4.2012, p. 3.
OJ C 183, 23.6.2012, p. 7.
OJ C 313, 17.10.2012, p. 11.
OJ C 394, 20.12.2012, p. 22.
OJ C 51, 22.2.2013, p. 9.
OJ C 167, 13.6.2013, p. 9.
OJ C 242, 23.8.2013, p. 2.
OJ C 275, 24.9.2013, p. 7.
OJ C 314, 29.10.2013, p. 5.
OJ C 324, 9.11.2013, p. 6.
OJ C 57, 28.2.2014, p. 4.
OJ C 167, 4.6.2014, p. 9.
OJ C 244, 26.7.2014, p. 22.
OJ C 332, 24.9.2014, p. 12.
OJ C 420, 22.11.2014, p. 9.
OJ C 72, 28.2.2015, p. 17.
OJ C 126, 18.4.2015, p. 10.
OJ C 229, 14.7.2015, p. 5.
OJ C 341, 16.10.2015, p. 19.
OJ C 84, 4.3.2016, p. 2.
OJ C 236, 30.6.2016, p. 6.
OJ C 278, 30.7.2016, p. 47.
OJ C 331, 9.9.2016, p. 2.
OJ C 401, 29.10.2016, p. 4.
OJ C 484, 24.12.2016, p. 30.
OJ C 32, 1.2.2017, p. 4.
OJ C 74, 10.3.2017, p. 9.
OJ C 120, 13.4.2017, p. 17.
OJ C 152, 16.5.2017, p. 5.
OJ C 411, 2.12.2017, p. 10.
OJ C 31, 27.1.2018, p. 12.
OJ C 261, 25.7.2018, p. 6.
OJ C 264, 26.7.2018, p. 8.
OJ C 368, 11.10.2018, p. 4.
OJ C 459, 20.12.2018, p. 40.
OJ C 43, 4.2.2019, p. 2.
OJ C 64, 27.2.2020, p. 17.
OJ C 231, 14.7.2020, p. 2.
OJ C 58, 18.2.2021, p. 35.
OJ C 81, 10.3.2021, p. 27.
OJ C 184, 12.5.2021, p. 8.
OJ C 219, 9.6.2021, p. 9.
OJ C 279, 13.7.2021, p. 4.
OJ C 290, 20.7.2021, p. 10.
OJ C 380, 20.9.2021, p. 3.
OJ C 483, 1.12.2021, p. 19.
OJ C 201, 18.5.2022, p. 82.
OJ C 229, 14.6.2022, p. 8.
OJ C 241, 24.6.2022, p. 6.
OJ C 286, 27.7.2022, p. 33.
OJ C 335, 2.9.2022, p. 15.
-

Commission information notice pursuant to Article 16(4) of Regulation (EC) No 1008/2008 of the European Parliament and of the Council on common rules for the operation of air services in the Community

Imposition of public service obligations in respect of scheduled air services

(Text with EEA relevance)

(2023/C 202/09)

Member State	France
Route concerned	La Rochelle (Ile de Ré) - Lyon (Saint Exupéry)
Original date of entry into force of the public service obligations	1 November 2005
Date of entry into force of the changes	1 November 2023
Address where the text and any relevant information and/or documentation relating to the public service obligation can be obtained	<p>Order of 30 January 2023 imposing public service obligations on air services between La Rochelle and Lyon NOR No: TREA2302709A http://www.legifrance.gouv.fr/initRechTexte.do</p> <p>For further information please contact: Direction Générale de l'Aviation Civile DTA/SDS1 50 rue Henry Farman 75720 Paris CEDEX 15 FRANCE Tel. +33 158094321</p>

Commission information notice pursuant to Article 17(5) of Regulation (EC) No 1008/2008 of the European Parliament and of the Council on common rules for the operation of air services in the Community

Invitation to tender in respect of the operation of scheduled air services in accordance with public service obligations

(Text with EEA relevance)

(2023/C 202/10)

Member State	France
Route concerned	La Rochelle (Ile de Ré) - Lyon (Saint Exupéry)
Period of validity of the contract	9 December 2023 – 31 October 2027
Deadline for the submission of applications and tenders	9 August 2023, 18.00 Paris time
Address where the text of the invitation to tender and any relevant information and/or documentation relating to the public tender and the public service obligation can be obtained	Syndicat Mixte des Aéroports de La Rochelle – Ile de Ré et Rochefort – Charente Maritime Rue du Jura 17 000 LA ROCHELLE FRANCE Tel. +33546428671 Email: comptabilite@larochelle.aeroport.fr Buyer profile: http://www.e-marchespublics.com

V

(Announcements)

PROCEDURES RELATING TO THE IMPLEMENTATION OF COMPETITION
POLICY

EUROPEAN COMMISSION

Prior notification of a concentration

(Case M.11078 – CONTARGO / ZIEGLER / SCHMID / JV)

Candidate case for simplified procedure

(Text with EEA relevance)

(2023/C 202/11)

1. On 31 May 2023, the Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 ⁽¹⁾.

This notification concerns the following undertakings:

- Contargo GmbH & Co. KG ('Contargo'), controlled by Rhenus SE & Co. KG, belonging to the Rethmann-Group (all GERMANY),
- Ziegler Holding GmbH ('Ziegler', GERMANY),
- SFI GmbH, controlled by the Schmid Group ('Schmid', GERMANY).

Rhenus SE & Co. KG, Ziegler Holding GmbH and SFI GmbH will acquire within the meaning of Article 3(1)(b) and 3(4) of the Merger Regulation joint control of the JV.

The concentration is accomplished by way of purchase of shares in a newly created company constituting a joint venture.

2. The business activities of the undertakings concerned are the following:

- Contargo is active in the provision of services related to freight transport, contract logistics, transport logistics and port logistics;
- Ziegler is active in the provision of services related to freight transport, transport logistics;
- Schmid is active in the provision of services related to freight transport, transport logistics.

3. The business activities of the JV are the following: container handling.

4. On preliminary examination, the Commission finds that the notified transaction could fall within the scope of the Merger Regulation. However, the final decision on this point is reserved.

Pursuant to the Commission Notice on a simplified procedure for treatment of certain concentrations under Council Regulation (EC) No 139/2004 ⁽²⁾ it should be noted that this case is a candidate for treatment under the procedure set out in the Notice.

5. The Commission invites interested third parties to submit their possible observations on the proposed operation to the Commission.

⁽¹⁾ OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation').

⁽²⁾ OJ C 366, 14.12.2013, p. 5.

Observations must reach the Commission not later than 10 days following the date of this publication. The following reference should always be specified:

M.11078 – CONTARGO / ZIEGLER / SCHMID / JV

Observations can be sent to the Commission by email or by post. Please use the contact details below:

Email: COMP-MERGER-REGISTRY@ec.europa.eu

Postal address:

European Commission
Directorate-General for Competition
Merger Registry
1049 Bruxelles/Brussel
BELGIQUE/BELGIË

Prior notification of a concentration
(Case M.10920 – AMAZON / IROBOT)

(Text with EEA relevance)

(2023/C 202/12)

1. On 31 May 2023, the Commission received notification of a proposed concentration pursuant to Article 4 of Council Regulation (EC) No 139/2004 ⁽¹⁾.

This notification concerns the following undertakings:

- Amazon.com, Inc. ('Amazon', United States)
- iRobot Corporation ('iRobot', United States)

Amazon will acquire within the meaning of Article 3(1)(b) of the Merger Regulation sole control of the whole of iRobot.

The concentration is accomplished by way of purchase of shares.

2. The business activities of the undertakings concerned are the following:

- Amazon operates a range of businesses including retail, entertainment, consumer electronics and technology services. It also provides online intermediation services to third party sellers through its online Amazon marketplaces which allow third party sellers to advertise and sell products to customers.
- iRobot is a global manufacturer of floor care products, primarily active in the design and supply of robot vacuum cleaners.

3. On preliminary examination, the Commission finds that the notified transaction could fall within the scope of the Merger Regulation. However, the final decision on this point is reserved.

4. The Commission invites interested third parties to submit their possible observations on the proposed operation to the Commission.

Observations must reach the Commission not later than 10 days following the date of this publication. The following reference should always be specified:

M.10920 – AMAZON / IROBOT

⁽¹⁾ OJ L 24, 29.1.2004, p. 1 (the 'Merger Regulation').

Observations can be sent to the Commission by email or by post. Please use the contact details below:

Email: COMP-MERGER-REGISTRY@ec.europa.eu

Postal address:

European Commission
Directorate-General for Competition
Merger Registry
1049 Bruxelles/Brussel
BELGIQUE/BELGIË

OTHER ACTS

EUROPEAN COMMISSION

Publication of an application for approval of an amendment, which is not minor, to a product specification pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs

(2023/C 202/13)

This publication confers the right to oppose the amendment application pursuant to Article 51 of Regulation (EU) No 1151/2012 of the European Parliament and of the Council ⁽¹⁾ within three months from the date of this publication.

APPLICATION FOR APPROVAL OF AN AMENDMENT TO THE PRODUCT SPECIFICATION OF PROTECTED DESIGNATIONS OF ORIGIN/PROTECTED GEOGRAPHICAL INDICATIONS WHICH IS NOT MINOR

Application for approval of an amendment in accordance with the first subparagraph of Article 53(2), of Regulation (EU) No 1151/2012**'PARMIGIANO REGGIANO'****EU No: PDO-IT-0016-AM06 — 2.12.2021****PDO (X) PGI ()****1. Applicant group and legitimate interest**

Consorzio del Formaggio Parmigiano-Reggiano ['Parmigiano Reggiano' Cheese Consortium]
Head office: Via J.F. Kennedy, 18
42124 Reggio Emilia (RE)
ITALIA

Tel. + 39 0522307741

Fax + 39 0522307748

Email: staff@parmigianoreggiano.it

The 'Parmigiano Reggiano' Cheese Consortium is formed by 'Parmigiano Reggiano' cheesemakers. It is entitled to submit an amendment application under Article 13(1) of Ministry of Agricultural, Food and Forestry Policy Decree No 12511 of 14 October 2013.

2. Member State or Third Country

Italy

3. Heading in the product specification affected by the amendment(s)

- Name of product
 Description of product

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

- Geographical area
- Proof of origin
- Method of production
- Link
- Labelling
- Other: packaging, Cow Feeding Rules

4. Type of amendment(s)

- Amendment to product specification of a registered PDO or PGI not to be qualified as minor in accordance with the third subparagraph of Article 53(2) of Regulation (EU) No 1151/2012.
- Amendment to product specification of registered PDO or PGI for which a Single Document (or equivalent) has not been published not to be qualified as minor in accordance with the third subparagraph of Article 53(2) of Regulation (EU) No 1151/2012

5. Amendment(s)

The *Cheesemaking Standard* has been divided into articles to make it more structured and facilitate consultation, as well as bringing it into line with the *Rules on Identity Markings* and the *Cow Feeding Rules*, which were already structured in articles.

'Description of product' heading

Cheesemaking Standard

— Article 1

In the first paragraph, the Italian word for 'skimmed' has been changed from *scremato* to *decremato*.

This amendment has been included in point 3.2 of the single document.

The term previously used, *parzialmente scremato*, means 'semi-skimmed', which might suggest a required percentage fat content, whereas the process of skimming the cream off the milk to make 'Parmigiano Reggiano' cheese is based on experience and artisan technique, rather than a specific value.

The reference to 'cows' in the first paragraph has been changed to 'dairy cows'.

This amendment has been included in points 3.2 and 3.3 of the single document.

The aim here was to align the terminology with Article 1 of the *Cow Feeding Rules*, which refers to the dairy herd as comprising all milking cows, dry cows and heifers from the sixth month of gestation.

The following sentence from the first paragraph: *The milk must not undergo any heat treatment and additives may not be used.*

has been amended to read:

The milk must not undergo any heat treatment or physical or mechanical treatments such as centrifugation, bactofugation or microfiltration, and additives may not be used.

This amendment has been partially included in point 3.2 of the single document.

This change aims to make it clear that the milk cannot be subject to any heat treatment, physical treatment or mechanical treatment by expressly mentioning physical and mechanical treatments too and giving some examples of banned processes, to emphasise that the milk must be raw and untreated when it is used.

— Article 4

In the first paragraph:

— The following sentence: *'Parmigiano Reggiano' has the following characteristics:*

has been amended to read:

'Parmigiano Reggiano' may not be subjected to any treatment that impairs its chemical/physical or organoleptic characteristics and has the following characteristics:

This amendment has been included in point 3.2 of the single document.

Verbal or graphical references to 'Parmigiano Reggiano' PDO or the protected name 'Parmesan' (Court of Justice of the European Union, Case C-132/05, 26 February 2008) can be found in the labelling, presentation or advertising of a great many pre-packaged compound, prepared and processed foods currently on the market, particularly within the EU. The use of such references has increased significantly, both because of the reputation of the name 'Parmigiano Reggiano' (or 'Parmesan') and because 'Parmigiano Reggiano' cheese is such a versatile ingredient that can be used in many food preparations. These products often present several problems, particularly because the ingredient referred to as 'Parmigiano Reggiano' or 'Parmesan' is not in fact 'Parmigiano Reggiano' but rather a semi-finished product made from 'Parmigiano Reggiano' but which no longer has the characteristics required by the product specification because the cheese has been subjected to specific treatments such as dehydration or freeze-drying, or mixed with other ingredients.

It is necessary to prevent the reputation of 'Parmigiano Reggiano' from being exploited through the use of the name for the sole purpose of adding value to a final food product containing a semi-finished product made from 'Parmigiano Reggiano'. However, with the rules currently in force, difficulties have been encountered on the EU market in attempting to put a stop to this use of the PDO 'Parmigiano Reggiano' or the protected name 'Parmesan' for products which, despite being made from 'Parmigiano Reggiano' are no longer compliant with the product specification. Accordingly, the text now specifically states that 'Parmigiano Reggiano' may not be subjected to any treatment that impairs its chemical/physical or organoleptic characteristics, with the aim of making it clear that any product obtained using such treatments may no longer be referred to as 'Parmigiano Reggiano' PDO.

This amendment has been made because of specific difficulties identified in solving the problems described above, due to the lack of any clear provision in the 'Parmigiano Reggiano' PDO product specification. The amendment is necessary because of the numerous unlawful uses of 'Parmigiano Reggiano' PDO taking place on the EU market as a result of the product's reputation. The purpose of this amendment is therefore to help to ensure that the authenticity and reputation of 'Parmigiano Reggiano' PDO are protected on the EU market.

In the first paragraph, amendments have been made to the characteristics of 'Parmigiano Reggiano' cheese:

— The following sentence: *wheels measure 35-45 cm in diameter across the flat faces and 20-26 cm high;*

has been amended to read:

wheels measure 35-43 cm in diameter across the flat faces and 20-26 cm high;

— The following sentence: *external appearance: natural straw-coloured rind;*

has been amended to read:

rind colour: natural straw colour, which may change over time;

These amendments have been included in point 3.2 of the single document.

For many years, the wheels of cheese produced weighed around 40 kg on average, corresponding to a diameter of 40 cm across the flat faces, and values were rarely even close to the maximum limit. In recent years, however, there has been a gradual tendency towards making increasingly larger cheeses, in some cases nearing the maximum permitted diameter of 45 cm. While they are within the limits laid down in the product specification, at these maximum dimensions the cheeses can weigh around 50 kg, creating serious problems in moving, cleaning and portioning them, as the machinery used for these processes is usually designed for the average dimensions. Therefore, the maximum diameter of the flat faces has been reduced from 45 to 43 cm in order to prevent the problems in such operations as a result of cheeses being made at a diameter close to the maximum currently permitted by the product specification. This amendment will reduce the weight of a wheel of 'Parmigiano Reggiano' by around 4 kg, without compromising its quality characteristics, bringing the total weight down to around 46 kg.

While the rind is usually a natural straw colour, fluctuations in environmental conditions during maturing (humidity, temperature) and the techniques used to clean cheeses and the frequency of cleaning can cause the rind colour to vary over the minimum 12-month maturing period. This means that the colour may not be uniform and can have some variation owing to natural causes, and the amendment has been made to make this clear.

The following has been inserted as a second paragraph: *For the textural characteristics of the cheese, reference should be made to the product categories defined in the Rules on Identity Markings.*

In order to ensure a more systematic reading of the product specification, the text now specifies that, in addition to the characteristics of 'Parmigiano Reggiano' cheese described and listed in Article 5 of the *Cheesemaking Standard*, account must also be taken of the textural characteristics (along with any permitted defects) defined and categorised in the *Rules on Identity Markings* section of the product specification, and more specifically in the *Product Categories* annex.

— Article 5

The first paragraph: *Grated 'Parmigiano Reggiano' and portions (with or without rind) must be packaged within the area of origin in order to guarantee quality, traceability and control.*

has been amended to read:

Grating, portioning and the subsequent packaging of grated 'Parmigiano Reggiano' and portions (with or without rind) must take place within the area of origin in order to guarantee quality, traceability and control.

This paragraph has been amended to match the terms already used in the second paragraph of point 3.5 of the single document.

The third paragraph: *As already established by the Prime Ministerial Decree of 4 November 1991, the designation of origin 'Parmigiano Reggiano' can also be used for grated cheese obtained exclusively from a whole cheese eligible for that designation of origin, provided that grating takes place within the cheesemaking area and that the grated cheese is then packaged immediately, without any treatment and without the addition of any substance capable of altering its shelf life or its original organoleptic characteristics.*

has been amended to read:

As already established by the Prime Ministerial Decree of 4 November 1991, the designation of origin 'Parmigiano Reggiano' can also be used for grated cheese obtained exclusively from a whole cheese eligible for that designation of origin, provided that grating takes place within the cheesemaking area and that the grated cheese is then packaged immediately, without any treatment and without the addition of any substance.

This amendment has been included in point 3.5 of the single document.

In the text referring to the packaging of grated 'Parmigiano Reggiano', the phrase 'without the addition of any substance capable of altering its shelf life or its original organoleptic characteristics' has been changed to 'without the addition of any substance'. The aim of this rewording is to make it unequivocally clear that the ban on adding substances applies to all substances.

A new paragraph has been added, reading as follows: *However, the use of 'trimmings' is also permitted under the conditions set out above.*

This amendment has been included in point 3.5 of the single document.

The possibility of using 'trimmings', as well as whole cheeses, for grated 'Parmigiano Reggiano' is now expressly stated.

Over the years, the market has been evolving in line with varying consumer requirements, meaning that there are now many more formats and types of portioned 'Parmigiano Reggiano' available on the market. In particular, whereas 1 kg used to be almost the only portion size available, consumers' changing habits mean that there is now demand for increasingly smaller formats (fixed weight of 150/200 g, rind-free miniature 'snack' portions, etc.). Obtaining these formats from 'Parmigiano Reggiano' cheeses results in a lot more offcuts (for example, the flat faces of the wheels of cheese, the core portion from the centre of the wheel, or portions that are over or under the fixed weight) that were not created in preparing large formats.

These offcuts, known as 'trimmings', are not packaged as portions but instead re-used by operators within the control system to prepare other formats, in particular grated 'Parmigiano Reggiano' as per Article 8. The purpose of this amendment was therefore to make it clear that grated cheese can be obtained from 'trimmings' as well as from whole cheeses.

In the fifth paragraph, amendments have been made to the characteristics of grated 'Parmigiano Reggiano' cheese:

- The following sentence: *rind content not more than 18 %*;

has been amended to read:

rind content not more than 18 % by weight;

- The following sentence: *homogenous, non-powdery appearance, with the proportion of particles measuring less than 0.5 mm in diameter not exceeding 25 %*.

has been amended to read:

homogenous, non-powdery appearance, with the proportion of particles measuring less than 0,5 mm in diameter not exceeding 35 %.

The first of these amendments has been included in point 3.5 of the single document.

The intention behind adding the expression 'by weight' is to define how this percentage is to be calculated.

Rather than a product quality parameter, this limit on the quantity of 'fine' particles in grated cheese was originally introduced, years ago, because of the risk of operators preparing grated 'Parmigiano Reggiano' PDO partially or entirely made up of dried cheese (by its nature fine and powdery). A limit was therefore established for particles measuring less than 0,5 mm in diameter.

Particle size is influenced by a number of factors (moisture, maturing, type of grater, grating pressure) and is therefore highly variable.

The market and production technology have evolved over recent years. There is increasing demand from operators for finer, more homogenous grated cheese, especially when it is to be mixed with other ingredients. On top of this, more mature cheese (30 months plus) and small formats (bite-size cubes and small portions) have become increasingly popular. Preparing these small formats produces a lot of offcut cheese (including small-sized offcuts), which is more susceptible to drying out, and when the cheese being grated is very mature, this makes it even more resistant, meaning that applying the same amount of pressure to the cheese gives a smaller grated particle size. This is why the percentage of particles measuring less than 0,5 mm in diameter is being changed from a minimum of 25 % to a minimum of 35 %, which is a more accurate reflection of the grated 'Parmigiano Reggiano' currently being produced, without compromising its quality characteristics.

- Article 7

A new paragraph has been added, reading as follows: *Offcuts of 'Parmigiano Reggiano' which are to be used by operators within the control system to prepare other formats are referred to as 'trimmings'*.

This last amendment has been included in point 3.5 of the single document.

As already stated for Article 5, and for the same reasons, the concept of 'trimmings' has been explained.

'Method of production' heading

Cheesemaking Standard

- Article 3

The following rule has been removed from the third paragraph: *The milk cannot be subjected to centrifugation processes*. This is because it has been moved to Article 1 and reworded to read: *The milk must not undergo any heat treatment or physical or mechanical treatments such as centrifugation [...]*. The reasons for this amendment are those given for the amendment to Article 1 under the *Description of product heading*.

The fifth paragraph: *The evening milk is partially skimmed [using the Italian term scremato] by letting the cream rise naturally to the surface in open-topped steel tanks. On delivery to the cheese dairy, the morning milk is mixed with the partially skimmed [scremato] milk from the previous evening. It may also be partially skimmed [scrematuro] by letting the cream rise naturally to the surface*.

has been amended to read:

*The evening milk is partially skimmed [using the Italian term *decremato*] by letting the cream rise naturally to the surface in open, naturally ventilated steel tanks. On delivery to the cheese dairy, the morning milk is mixed with the partially skimmed [*decremato*] milk from the previous evening. It may also be partially skimmed [*decrematura*] by letting the cream rise naturally to the surface.*

In point 3.4 of the single document the word 'previous' has been inserted in front of 'evening' in the interests of clarity.

Traditionally, the tanks were open vats in which the milk was left to settle so that the cream would rise to the surface. New technologies have been developed over the years, both to reduce space and to make plants cleaner and more efficient, and those tanks have been replaced by multi-level installations with lids that can be opened, so the description of the steel tanks as 'open-topped' has been changed to 'open, naturally ventilated'.

The Italian terms for skimmed milk and the skimming process, *scremato* and *scrematura*, have been changed to *decremato* and *decrematura* in line with the amendment to Article 1 under the *Description of product heading*.

This last amendment has been included in point 3.4 of the single document.

The sixth paragraph: *The fat-to-casein ratio of the milk in the heating vats, calculated as the weighted average of all vat batches in a given day's production, cannot exceed 1,1 + 12 %.*

has been amended to read:

The fat-to-casein ratio of the milk in the heating vats, calculated as the weighted average of all vat batches in a given day's production, cannot exceed 1,10 + 10 %.

This last amendment has been included in point 3.4 of the single document.

The fat-to-casein ratio has been revised, reducing the tolerance from 12 % to 10 %, and '1,1' has been changed to '1,10' for clarity.

Based on various statistics and scientific studies, the average reference value for the fat-to-casein ratio in 'Parmigiano Reggiano' was found to be around 1,1, and since the artisan cheesemaking techniques used to make this cheese and differences in the fat content of the milk used, influenced both by season and by farming technique, can cause some fluctuation in this ratio, a tolerance was established, initially estimated at around 10 %.

An additional 2 % (from 10 to 12 %) was added to account for measurement and sampling uncertainty, as well as the fluctuations referred to above, which is why a ratio of 1,1 + 12 % was proposed when a minor amendment to the product specification was approved (OJ C 132, 13.4.2018, p. 7).

After that approval, when drawing up the control plan, the authorised control body (OCQPR Soc. Coop.) sent the Ministry of Agricultural, Food and Forestry Policy a request for clarification regarding the fat-to-casein ratio required for 'Parmigiano Reggiano' on 23 May 2018, asking whether the requirement that 'the fat-to-casein ratio of the milk in the heating vats [...] cannot exceed 1,1 + 12 %', as stated in the text, included measurement uncertainty.

The reply from the Ministry of Agricultural, Food and Forestry Policy was that this value of 1,1 + 12 % does not in itself cover measurement uncertainty, so the tolerance needs to be reduced by 2 percentage points in order to align the rule in the product specification with the principle underlying the original decision.

The seventh paragraph: *Up to 15 % of the morning milk can be set aside for the next day's cheesemaking. In this case, the milk, which must be kept at the dairy in suitable steel containers at a temperature not lower than 10 °C, must be left to stand in the skimming tanks, together with the evening milk, to allow the cream to rise to the surface.*

has been amended to read:

Up to 15 % of the morning milk can be set aside for the next day's cheesemaking. More than 15 % can be set aside as long as this quantity allows no more than one wheel of cheese to be made. This milk, which must be kept at the dairy in steel containers at a temperature not lower than 10 °C, must be left to stand in the skimming tanks, together with the evening milk, to allow the cream to rise to the surface.

The text now allows more than 15 % of the morning milk to be set aside for the next day's cheesemaking, provided that a larger percentage is needed to make at most one wheel of cheese. This addition to the text should allow small cheese dairies to have enough milk in the heating vat at certain times of year to make a whole cheese.

The eighth paragraph: *A continuous whey starter, a natural culture of lactic ferments obtained by leaving whey left over from the previous day's cheesemaking to spontaneously turn sour, is added to the milk.*

has been amended to read:

A continuous whey starter, a natural culture of lactic acid bacteria obtained by leaving 'sweet' whey left over from previous cheesemaking operations to spontaneously ferment in controlled temperature conditions, is added to the milk.

This amendment has been included in point 3.4 of the single document.

The following has been added in that same paragraph: *Neither lactic acid bacteria cultures for adjustment or strengthening nor nutritional supplements promoting the development of lactic flora may be added to the continuous whey starter. Only the addition of a single portion of milk is permitted.*

In the description of the characteristics of the continuous whey starter, 'lactic ferments' has been changed to the more technically correct 'lactic acid bacteria'. The ban on certain practices – the addition of lactic acid bacteria cultures or nutritional supplements that encourage the development of natural lactic acid bacteria – has also been made explicit. This change aims to make it clear that the continuous whey starter is a natural ingredient and highlight the role it plays in 'Parmigiano Reggiano' cheesemaking: the strong link between territory and product. This is why the continuous whey starter may only be obtained from the fermentation of the sweet whey left over from previous cheesemaking operations. The word 'day' has been removed with a view to giving cheesemakers the possibility of also adding, in consideration of the chemical, physical and microbiological characteristics of the milk, small quantities of continuous whey starter – the same starter that will be added to the milk in the heating vat the next day – to the evening milk left in tanks to allow the cream to rise to the surface. The purpose of this practice is to contribute lactic flora and slightly sour the milk overnight, making it more suitable for cheesemaking the next morning.

Finally, it has been made explicitly clear that it is possible to add a single portion of the dairy's milk, an authentic and unvarying local practice that was already an established tradition. This practice makes it possible to provide the lactic acid bacteria in the whey starter with growth-promoting nutrients.

The following sentence has been added at the end of the thirteenth paragraph: *The cheeses may be matured on wooden-shelved racks.*

This amendment has been partially included in point 3.4 of the single document.

In the interests of transparency, the possibility of maturing cheeses on wooden-shelved racks has been made clear, since the use of wood in 'Parmigiano Reggiano' cellars is a well-established and well-founded tradition which cannot be changed. As potential health or hygiene issues relating to the use of wood have been raised on some foreign markets (the United States in particular) in recent years, it is considered important to make it clear in the product specification that wood is an essential material and that – precisely as a result of forming part of an established tradition – it has never caused any health problems.

'Labelling' heading

Cheesemaking Standard

— Article 8

The following paragraph has been added:

Except when used as 'trimmings', offcuts from the faces and sides of wheels of cheese (pieces with more than 18 % rind) cannot bear the name 'Parmigiano Reggiano'.

This amendment has been included in point 3.6 of the single document.

The quality characteristics of 'Parmigiano Reggiano' are well defined in the product specification, and they include specific references to the cheese paste:

- *characteristic aroma and taste of the paste: fragrant, delicate and flavoursome without being strong;*
- *texture of the paste: fine-grained and flaky.*

Moreover, the product specification has capped the amount of rind present in grated cheese at 18 % since 1991 (Prime Ministerial Decree of 4 November 1991). Only grated cheese was concerned by the addition of this requirement, since the rind component is always less than 18 % on the formats with rind (whole cheeses and portions with rind). As described earlier in relation to 'trimmings', offcuts from the faces and sides of wheels of cheese (pieces with more than 18 % rind) are left over from the preparation of sales formats. If these offcuts are not to be used in the preparation of grated 'Parmigiano Reggiano', in which case the addition of cheese paste corrects the paste-rind balance, they can be sold. However, such offcuts comprise a large amount of rind and thus do not contain enough actual cheese paste to comply with the definition of the typical characteristics of 'Parmigiano Reggiano'. Accordingly, as they are no longer compliant with the product specification, they can no longer be sold as 'Parmigiano Reggiano'.

For the above reasons, as well as to provide consumers with accurate information and ensure fair competition between operators, unless used as 'trimmings', offcuts from the faces and sides of wheels of cheese (pieces with more than 18 % rind) cannot use the name 'Parmigiano Reggiano' PDO.

— Article 9

The following from the first paragraph: [...] *the logo shown below, depicting a wedge and a wheel of 'Parmigiano Reggiano' cheese and a small knife above the words 'PARMIGIANO REGGIANO', must be displayed on every pack. This logo must be printed in CMYK following the technical specifications laid down by the pertinent Consortium agreement.*



has been amended to read:

[...] *the logo shown below, containing a stylised depiction of a wedge and a wheel of 'Parmigiano Reggiano' cheese above the words 'PARMIGIANO REGGIANO', must be displayed on every pack. This logo must be printed in colour following the technical specifications laid down by the pertinent Consortium agreement.*



This amendment has been partially included in point 3.6 of the single document.

The logo has been changed to make it stylistically more modern and current. It, too, has been included under point 3.6 of the single document.

The second paragraph: *To allow consumers to find out how mature 'Parmigiano Reggiano' is, the minimum maturing time must be stated on the labelling of all pre-packaged portions of more than 15 g placed on the market.*

has been amended to read:

To make it possible to find out how mature 'Parmigiano Reggiano' is, the minimum maturing time must be stated on the label of all pre-packaged portions of more than 15 g placed on the market.

This amendment has been included in point 3.6 of the single document.

The reference to 'consumers' has been deleted, since the obligation to state the minimum maturity of the cheese has to apply to all pre-packaged cheese in portions of more than 15 g, including when it is to be sold to commercial operators (processing companies, mass catering businesses such as restaurants, etc.) and not just to end consumers. This amendment aims to make that clearer. On the basis of the definitions established in Article 2(2)(i) and (j) of Regulation (EU) No 1169/2011, 'labelling' has been changed to 'label' because the minimum maturity time must be stated on the packaging or container, and may not be stated in the documents.

The following has been added as a third paragraph:

As the aroma and taste of the paste of 'Parmigiano Reggiano' evolve over the course of the maturing process, in order to convey the organoleptic characteristics, the following descriptive adjectives may be used on the label, as well as the maturing time, for certain maturity classes:

- *delicato [delicate] (12-19 months);*
- *armonico [harmonious] (20-26 months approx.);*
- *aromatico [aromatic] (27-34 months approx.);*
- *intenso [intense] (35-45 months approx.).*

This amendment has been included in point 3.6 of the single document.

Introducing the requirement to state the minimum maturity of 'Parmigiano Reggiano' placed on the market in portions of more than 15 g gave rise to a need to express an organoleptic assessment using 'descriptive' adjectives that vary according to maturity. Because 'Parmigiano Reggiano' is matured for a long time, from 12 to more than 40 months, its aromas and flavours evolve, which is why the possibility of using 'descriptive' adjectives on labels has been added, to help consumers in their choice of product.

The fourth paragraph: *Stating the dairy's registration number or name on the labelling is only compulsory for grated cheese or portions originating from cheeses marked as 'Premium' pursuant to Article 15 of the 'Rules on Identity Markings'.*

has been amended to read:

Stating the dairy's registration number or name on the label is only compulsory for grated cheese or portions originating from cheeses marked as 'Premium' pursuant to Article 15 of the 'Rules on Identity Markings'.

On the basis of the definitions established in Article 2(2)(i) and (j) of Regulation (EU) No 1169/2011, 'labelling' has been changed to 'label' because the dairy's registration number or name must be stated on the packaging or container, and may not be stated in the documents.

Rules on Identity Markings

— Article 1: 'The markings'

The second paragraph: *2. Each dairy must mark its cheeses with origin information by:*

- (a) *attaching a casein disc to each wheel of cheese with the codes identifying it;*
- (b) *printing the words 'Parmigiano-Reggiano' in pin-dot lettering (see Image 1), the dairy's registration number and the year and month of production around the sides of the wheel using stencilling bands.*

has been amended to read:

2. Each dairy must mark its cheeses with origin information by:

- (a) *attaching a casein disc to each wheel of cheese or using an equivalent system that ensures the unique identification of each cheese (hereinafter 'disc' or 'discs');*
- (b) *printing the words 'Parmigiano-Reggiano' in pin-dot lettering (see Image 1 and Image 1-bis), the dairy's registration number, the year and month of production and the acronym 'DOP' [PDO] around the sides of the wheel using stencilling bands.*

These amendments have been included in point 3.6 of the single document.

Since technological developments might bring other ways of uniquely identifying 'Parmigiano Reggiano' cheeses in the future, the text now states the possibility of using other systems than casein discs.

A reference has been added to 'Image 1-bis', which has been added to the 'Sample Images' section.

The text now states that the stencilling bands used to imprint origin markings into the cheeses must also include the acronym DOP (PDO), as this acronym is already on the stencils being used today.

The third paragraph: *3. Selection markings are made by the 'Parmigiano Reggiano' Cheese Consortium in accordance with Art. 4, 5, 6, 7 and 8 below, once the checks have been performed by the authorised control body.*

has been amended to read:

3. *Selection markings are made by the 'Parmigiano Reggiano' Cheese Consortium, as established in Articles 4, 5, 6, 7 and 8 below, once the checks have been performed by the authorised control body.*

The word 'Articles' spelt out in full has replaced the abbreviation 'Art.'

— Article 3: 'Dairies' obligations'

The first paragraph: *1. At least 4 months before commencing activity, dairies intending to make 'Parmigiano Reggiano' cheese must apply to the Consortium, declaring that they have been included in the control system, in order to be allocated a registration number and request stencilling bands and casein discs for origin markings.*

has been amended to read:

1. *Before commencing activity, dairies intending to make 'Parmigiano Reggiano' cheese must apply to the Consortium, declaring that they have been included in the control system, in order to be allocated a registration number and request stencilling bands and discs for origin markings.*

The reference to '4 months' has been removed as this was considered too long a timeframe. The word 'casein' has been deleted in line with the amendment to Article 1.

The second paragraph: *2. The dairies are responsible for the proper use and preservation of stencilling bands and casein discs, which are supplied to them on the basis of trust.*

has been amended to read:

2. *The dairies are responsible for the preservation and proper use of stencilling bands and discs, which are supplied to them on the basis of trust.*

This amendment consists of rewording the sentence about preservation and proper use of stencilling bands and discs into a more logical order.

The fifth paragraph: *5. [...] In the event of non-compliance, the Consortium shall order the withdrawal of stencilling bands and discs and/or the imposition of a penalty, following the procedures established in the control plan.*

has been amended to read:

6. *[...] In the event of non-compliance, the Consortium shall order the withdrawal of stencilling bands and discs and/or the imposition of a penalty, in compliance with current legislation.*

It is clarified that any withdrawal of stencilling bands or discs and/or imposition of penalties by the Consortium must be in compliance with current legislation.

— Article 6: 'Cheese classification'

The second paragraph: *2. To make the quality inspection process as objective as possible, the inspection panels must cut into at least one wheel of cheese per batch, and never fewer than one cheese per thousand or part thereof, in order to assess the textural and organoleptic characteristics. [...]*

has been amended to read:

2. *To help the inspectors in their assessment of the cheeses, the inspection panels must cut into at least one wheel of cheese per batch, and in any case as many cheeses as are necessary in order to assess the textural and organoleptic characteristics. [...]*

The inspectors' activity in assessing 'Parmigiano Reggiano' cheese is now described more correctly by specifying that the purpose of cutting into the cheeses is to help them in the quality assessment process. Moreover, instead of referring to the minimum number of cheeses that inspection panels must cut into, the text now requires them to cut into as many cheeses as are necessary for the best assessment of the textural and organoleptic characteristics of the cheese paste, thus improving their assessment.

— Article 7: 'Ink-stamping'

The first paragraph: *During the quality inspections referred to in Article 6, the cheeses shall be stamped in indelible ink with a provisional marking assigning one of the following categories as defined in the Annex:*

has been amended to read:

During the quality inspections referred to in Article 6, the cheeses shall be stamped in indelible ink, or using an equivalent system, with a provisional marking assigning one of the following categories as defined in the Annex:

Following the quality inspection and classification, it is current practice for the inspectors to mark the cheeses with an ink stamp provisionally marking them with the quality category they have been assigned – one, two or three – until the cheeses undergo the subsequent marking process, that can take place with effect from 7 days after the inspection, as instructed by the control body. As technology is evolving, this amendment aims to make it possible to use different mechanisms for this temporary identification of cheeses.

— Article 9: 'Cancellation of markings'

The following paragraph: *The markings shall be removed from category three cheeses [...] by Consortium staff [...].*

has been amended to read:

The origin markings shall be removed from around the sides of category three cheeses [...] by Consortium staff [...].

The origin markings on cheeses are: the words 'Parmigiano Reggiano' in pin-dot lettering (as well as the registration number of the dairy that made it, the year and month of production, and the abbreviation DOP [PDO]), printed around the sides of the wheel of cheese using a stencilling band; and the casein disc for traceability purposes, which is usually attached to the flat face of the wheel. When a cheese does not meet the requirements to use the PDO, the origin markings around the sides, including the words 'Parmigiano-Reggiano' in pin-dot lettering, are removed so that the cheese is no longer presented to consumers as 'Parmigiano Reggiano', whereas the casein disc, which is usually found on one of the flat faces of the wheel of cheese and needs to remain place to ensure traceability, is left attached. The purpose of the amendment is to make it clearer that the cancellation of origin markings concerns only those around the side of the wheel of cheese.

— Article 11: 'Appeals'

The first paragraph: *1. Dairies may appeal against the verdict of a quality inspection by contacting the Consortium in writing by recorded delivery up to 4 days after the end of each individual quality inspection session.*

has been amended to read:

1. *Dairies may appeal against the verdict of a quality inspection by contacting the Consortium in writing up to two (2) days after the end of each individual quality inspection session.*

The window of time in which the verdict of a quality inspection can be appealed against has been reduced from 4 days to 2 days. In order to simplify the administrative process, the text now states that appeals must be submitted in writing, and not necessarily sent by recorded delivery.

— Article 12: 'Requesting the correction of origin markings'

This article, which currently reads: *If work has to be performed on the part of the rind where the disc is located to correct defects that have developed during maturing, the dairy shall ask the Consortium to replace the disc with an indelible stamp. Dairies must keep removed discs and hand them over to the Consortium.*

has been amended to read:

1. *If a disc no longer adheres properly to the cheese following maturing, or work has to be performed on the part of the rind where the disc is located to correct defects that have developed during maturing, the dairy shall promptly ask the Consortium to replace the disc with an indelible stamp. Dairies must keep removed discs and hand them over to the Consortium.*

The text now also requires dairies to ask the Consortium to replace discs with indelible stamps when the disc no longer adheres properly to the cheese, and specifies that this request must be made promptly.

— Article 13: 'Requesting the cancellation of origin markings'

This article, which currently reads: *If defects develop during maturing that are so serious that the maturing process cannot continue, dairies are entitled to request, prior to the quality inspection, that the Consortium cancel the origin markings of the affected cheese or that the cheese be handed over in accordance with Article 9.*

has been amended to read:

If defects develop during maturing that are so serious that the minimum maturing process cannot continue, dairies are entitled to request, prior to the quality inspection, that the Consortium cancel the origin markings around the sides of the affected cheese or that the cheese be handed over in accordance with Article 9.

'Minimum' has been added to make it clear that dairies may request the cancellation of markings during the minimum 12-month maturation period. Moreover, in line with the amendment to Article 9 and the provisions of that article, it is specified that the cancellation of origin markings concerns only those found around the sides of the wheel of cheese.

— Article 16: 'Costs'

The third paragraph: *Dairies shall be required to cover the cost of replacing stencilling bands that have worn out ahead of time or are otherwise damaged.*

has been amended to read:

Dairies may be required to cover the cost of replacing stencilling bands that have worn out ahead of time or are otherwise damaged.

'Shall' has been changed to 'may' because requesting payment of these costs is an option, not an obligation.

Annex

'Product Categories'

In point 3, concerning 'Parmigiano Reggiano' mezzano [medium], the following phrase: *well-executed corrections made to the sides or flat faces of the wheel that are minimal enough to avoid significantly impairing the cheese's external appearance, without any olfactory defects.*

has been amended to read:

corrections made to the sides or flat faces of the wheel that are minimal enough to avoid significantly impairing the cheese's external appearance, without any olfactory defects.

In application of the customs and practices relevant to the definition of the commercial categories of 'Parmigiano Reggiano' cheese, as referred to in Article 6 of the *Rules on Identity Markings* and more specifically in point (b) (*Market choice categories 0-1*) of the *Cheese classification* heading within section four (*Parmigiano-Reggiano Cheese*) of the 1990 *Provincial Compendium of Customs of the Reggio Emilia Chamber of Commerce, Craft Trades and Agriculture*, 'category 0' cheese may have 'certain minor well-executed corrections or minor issues awaiting correction that do not result in the cheese wheel becoming deformed'. This concept of 'correction' encompasses both aesthetic defects still present on the rind of a cheese, varying in terms of size, depth and possibly moisture content ('issue awaiting correction'), and the result of correcting an aesthetic defect, usually through cauterisation, to resolve or diminish the problem or remove moisture ('executed correction').

In the *Product Categories* annex to the *Rules on Identity Markings*, point 2 ('*Parmigiano Reggiano*' category 0 and category 1), item (a) (category 0) does not distinguish between 'executed corrections' or 'issues awaiting correction', but refers only to the fact that any correction must be small in size and not cause the cheese to be deformed.

Nowadays it is common practice for dairies to submit 'issues awaiting correction' to the quality inspection panel, in which case the cheeses are assigned the product category appropriate to the extent of the defect.

As the inclusion of the word 'well-executed' meant that this passage covered only 'executed corrections', this word has been removed, leaving it possible for category two cheeses to be submitted for inspection with both 'executed corrections' and 'issues awaiting correction'.

SAMPLE IMAGES

An image of the words 'Parmigiano-Reggiano' in pin-dot lettering around the side of a wheel of 'Parmigiano Reggiano' has been included for illustrative purposes.

'Other' heading

'Packaging' sub-heading

Cheesemaking Standard

— Article 6

This paragraph: *Portions of 'Parmigiano Reggiano' may be packaged for immediate sale in person at the same business that cut the portion.*

has been amended to read:

Grating, portioning, and pre-packaging for direct sale may be carried out at the retail outlet solely for the purpose of sale to the end consumer.

This amendment has been included in point 3.5 of the single document.

The current version of the product specification provides for the possibility of portioning and packaging 'Parmigiano Reggiano' for immediate sale in person at the retail outlet at which portioning takes place. That possibility was included on the basis of the principles expressed by the Court of Justice of the European Union (paragraph 62 of the judgment of 20 May 2003 in Case C-469/00). This also makes it possible for businesses to provide a service to end consumers, as cutting portions from wheels or parts of wheels of cheese is a time-consuming process and it would be very difficult for points of sale – particularly when busy – if portions could only be cut on request from the consumer.

As the Court of Justice judgment also cites the grating process, this amendment includes the express possibility of grating and packaging also taking place at the retail outlet for direct sale to the end consumer, for the same reasons given above. This clarification is also necessary because of the frequent objections raised in recent years with the bodies responsible for checks in relation to the possibility of grating and packaging 'Parmigiano Reggiano' cheese at retail outlets for direct sale.

'Cow Feeding Rules' heading

Cow Feeding Rules

— Article 1: 'Scope'

A second, a third and a fourth paragraph have been added to Article 1.

The second paragraph reads:

The milk must be produced on farms located in the area of origin and included in the control system.

This sentence has been inserted into point 3.3 of the single document, and the following have been deleted: the sentence from point 3.3 that read *The milk is from cows reared in the defined geographical area*; the sentence from point 3.4 that read *The farms that rear the dairy cows whose milk is to be processed into 'Parmigiano Reggiano' must be located within the defined geographical area*; and the reference to the milk being 'produced' from point 3.4 of the single document.

It has been made clear that the cow's milk used as raw material must be produced in the defined geographical area on farms that are subject to official controls to verify compliance with the product specification.

The third paragraph reads:

The rearing of replacement dairy cows ('restocking') must be carried out in the area of origin and included in the control system as a specific activity of a dairy farm. The rules laid down in Article 9 apply to livestock originating from other production sectors.

This amendment has been included in point 3.3 of the single document.

The text now includes an explicit reference to the rearing of replacement dairy cows ('restocking'), i.e. the rearing of female calves and heifers that will join the dairy herd in the future, together with the necessary reference that this is a specific activity of a dairy farm. Given this structural and functional link with dairy farming, the text now requires restocking to take place in the defined geographical area and be subject to official controls to verify compliance with the product specification.

Finally, a reference is made to Article 9 of the *Cow Feeding Rules*, which governs the entry of livestock from production chains other than the 'Parmigiano Reggiano' chain onto dairy farms or restocking units.

The fourth paragraph reads:

Dairy farms that had restocking activities located outside the area of origin as at 5 January 2021 may continue to conduct this activity outside the area of origin provided that it is included in the control system.

This amendment has been included in point 3.3 of the single document.

The amendment gives consideration to the representations made by certain businesses engaged in rearing livestock and producing milk to be made into 'Parmigiano Reggiano' cheese, which – as permitted by the current version of the product specification – have long been managing their own production cycles by using a restocking unit located outside the defined geographical area. The only purpose of this activity is to rear female calves and young heifers which, once mature, will replace dairy cows on dairy farms owned by the same businesses within the defined geographical area. This amendment therefore makes it possible to ensure the continuity of a business model organised in this way, albeit counterbalanced by making those businesses' restocking activities located outside the defined geographical area subject to the basic requirements laid down in Articles 5 and 9 of the *Cow Feeding Rules* and official controls to verify compliance with the product specification, provided that those activities were already in place when the application for an amendment was published in the Official Gazette of the Italian Republic.

— Article 4: 'Permitted fodder'

The second point of the first paragraph: *Dairy cows may be fed:*

— [...]

— *forage ryegrass, forage rye, forage oats, forage barley, forage wheat, forage maize [...];*

has been amended to read:

Dairy cows may be fed:

— [...]

— *forage ryegrass, forage rye, forage oats, forage barley, forage wheat, forage triticale, forage maize [...];*

Forage triticale, which has similar characteristics to other forage crops already permitted (barley, wheat, rye, etc.), has been included in the list of permitted fodder. As the use of forage triticale, either fresh or dried, may be of particular interest in the hillier parts of the defined geographical area, where it is particularly prevalent, the text now expressly includes the possibility of its use in order to maximise the possibility of using fodder from the local area.

— Article 5: 'Banned forages and by-products'

The first two paragraphs:

In order to prevent the environment of the cattle housing in which female calves, heifers up to the sixth month of gestation and dairy cows are reared from being contaminated with silage – including preventing contamination through soil and fodder – the use and possession of silage of any kind are prohibited.

Farms on which dairy cows are reared must ensure that entirely separate areas are used for any farming activities from other production chains (beef cattle, digesters, etc.). Cereal silage and by-products may be kept and used for those other farming activities.

have been amended to read:

In order to prevent the environment of the cattle housing from being contaminated with silage – including preventing contamination through soil and forage – and to permit the animals' rumens to adapt physiologically to a silage-free diet, dairy farms and restocking units are prohibited from using and possessing silage of any kind.

Farms on which dairy cows are reared and restocking units must ensure that entirely separate areas are used for any farming activities from other production chains (beef cattle, digesters, etc.). Cereal silage and by-products may be kept and used for those other farming activities.

The amendment to the first paragraph has been included in point 3.3 of the single document.

The purpose of this amendment is firstly to adapt the Article to reflect the amendments to Article 1 of the *Cow Feeding Rules*, including harmonising the terminology used, by establishing that, as was already the case for dairy farms, restocking units are also banned from using and possessing any kind of silage. Secondly, the amendment expressly includes a second fundamental reason for banning the possession and use of silage, in addition to preventing contamination of the housing environment: the need to allow the physiological adaptation of the animals' rumens to a silage-free diet (from a young age). For this second aspect, please refer to the reasons given for the amendments to Article 9 of the *Cow Feeding Rules*.

Similarly, the amendment to the second paragraph is also aimed at bringing the article into line with the amendments made to Article 1 of the *Cow Feeding Rules*.

The reference to *molasses in liquid form (except where use is permitted under Article 6)*, previously the sixth bullet item under point (b) of the fourth paragraph, has been deleted.

The absolute ban the use of molasses, originally brought in because of the frequent poor quality and highly variable characteristics of this product, has been removed (albeit with usage still regulated by Article 6) because this product is now entirely reliable thanks to modern production technology, the use of which is required by law. The use of molasses is even advisable in certain rations, such as hay-based rations, which have less sugar than fresh grass because the mild fermentation that turns grass into hay causes the loss of some sugar content.

Cattle housing is managed very differently nowadays, meaning that the risk of troughs and farm equipment becoming soiled – originally one of the main reasons advising extreme caution in the use of molasses inside housing – is now easily manageable.

— Article 6: 'Raw materials in non-forage feedstuffs'

The following paragraphs: *The following may also be used in complementary compound feed:*

— *carob up to a maximum quantity of 3 %;*

— *molasses up to a maximum quantity of 3 %.*

The administration of feedstuffs in the form of molasses blocks, including in crushed form, is permitted up to a maximum of 1 kg per head per day. The use of molasses blocks is not, however, compatible with the use of feedstuffs that contain molasses.

Sugar-based products and/or propylene glycol- and glycerol-based products are also permitted, either in liquid form or mixed into feed, up to a maximum of 300 g per head per day.

have been amended to read:

Carob, beet and cane molasses, malt extract, propylene glycol and glycerol may also be used in complementary compound feed up to a maximum overall quantity of 6 %.

The use of sugar-based products, including those in liquid or molasses-based form (cane or beet molasses), malt extract, propylene glycol and glycerol, in the diets of milking cows, whether administered to individual cows or added to the total mixed ration, is limited to 800 g per head per day. These products may not be administered via drinking water.

The article simply merges the limits on carob and molasses (and other similar sugar products), previously divided into 3 % molasses + 3 % carob, into a single overall limit of 6 %.

The use of sugar products, including molasses which were previously banned by Article 5, has been extended from only molasses blocks to a broader group of similar products and regulated by the setting a maximum daily limit that is considered appropriate for supplementing the high-fibre rations typical of the 'Parmigiano Reggiano' production chain.

The use of these products is particularly suitable today compared to when the previous version of the product specification was drafted, because the total mixed ration has now entered widespread use, and they can perform a useful function: they bind the ration and make it less powdery, resulting in a more homogenous mixture and a more hygienic housing environment.

The fifth paragraph: *Without prejudice to Article 8, other products and feedstuffs permitted by current legislation for use in dairy cows may also be used subject to testing by the 'Parmigiano Reggiano' Cheese Consortium, which shall notify the competent bodies once it has verified the compatibility of such products and feedstuffs.*

is now the fourth paragraph and has been amended to read:

Without prejudice to Article 8, other products and feedstuffs permitted by current legislation for use in dairy cows may also be used subject to assessment by the 'Parmigiano Reggiano' Cheese Consortium, which shall notify the competent bodies once it has verified the compatibility of such products and feedstuffs with the principles laid down in Article 2.

In relation to the ban on the use of certain raw materials in non-forage feedstuffs and products for feeding dairy cows, the term 'testing' has been changed to 'assessment'. It is now specified that compatibility must be checked against the 'General principles governing feed' laid down in Article 2 of the *Cow Feeding Rules*.

— Article 7: 'Use of simple and compound complementary feed, fortified and non-fortified'

The fourth paragraph has been deleted. It read: *The total quantity of crude fat from products and by-products of soya, flax, sunflower, maize germ and wheat germ must not exceed 300 g per head per day.*

Without changing the rationale underlying this specific requirement or the overall approach of the product specification to the use of fats – which must be strictly regulated – the above method of quantifying the fat contribution of certain ingredients used to make non-forage feedstuffs has been replaced by the method described in the last paragraph in order to make checks more feasible, since it is extremely difficult to distinguish between the fats provided by 'products and by-products of soya, flax, sunflower, maize germ and wheat germ' alone, and much easier to check the overall fat quantity administered, both in terms of paperwork (based on feed information sheets or the ingredients placed in the TMR mixer) and from an analytical perspective.

The following, previously the second paragraph of Article 8, has been moved here to become the fourth paragraph: *Dairy cows cannot be fed any soap or fat of animal or vegetable origin (oil, tallow, lard, butter), either directly or as an ingredient in feed.*

The third paragraph of Article 8: *Lipids of vegetable origin may be used to carry and protect micronutrients, up to a maximum quantity of 100 g per head per day.*

is now the fifth paragraph of Article 7 and has been amended as follows:

Vegetable oils and fats of any type or form may be used only as premix carriers and for the protection of amino acids, vitamins, minerals and other nutrients up to a maximum quantity of 50 g per head per day.

The changes to the text that used to be in Article 8 consist of changing 'lipids of vegetable origin' and 'micronutrients' to 'vegetable oils and fats' and 'amino acids, vitamins, minerals and other nutrients' respectively, as they are more exhaustive terms.

The limit of vegetable oils and fats added 'as is' in any type or form is reduced from 100 g to 50 g per head per day because these substances must have the sole function of protecting amino acids, vitamins, minerals and other nutrients, rather than being used as a covert way of adding fats that are otherwise banned, a practice that is rendered pointless by reducing the overall quantity, while maintaining their use as a carrier for amino acids such as methionine or vitamins such as choline.

The following has been added as a sixth paragraph: *In order to avoid negative interference with ruminal fermentation and deterioration of milk quality, the daily amount of lipids (assessed as ether extract) administered to milking cows:*

- *must not exceed 4,0 % of total dry matter;*
- *must not exceed 700 g in terms of quantity administered through non-forage feedstuffs as defined in Article 2 of these Rules.*

The maximum daily limit of lipids that can be administered to milking cows through the permitted products has been set at 4 % of total dry matter in the ration. This overall limit is met through the limit on fat administered through non-forage feedstuffs. Instead of a limit of 300 g on fat that could be administered through oilseeds (soya, flax, sunflower, maize germ and wheat germ), which was very difficult to verify, this has been replaced with a limit of 700 g of fats that can be administered in non-forage feedstuffs via the fats naturally present in all of the feed materials (therefore also including maize, for example).

— Article 8: 'Banned feed materials and banned products'

The following from the first bullet point of the first paragraph: *all food of animal origin: fishmeal, meat, blood, plasma, feathers, miscellaneous slaughter by-products and dried milk and egg processing by-products;*

has been amended to read:

all food of animal origin: fishmeal, meat, blood, plasma, feathers, miscellaneous slaughter by-products as well as dried milk and egg processing by-products;

The text has been reworded by replacing the conjunction *and* with *as well as*.

In the eighth bullet point of the first paragraph, *farmed algae* has been changed to just *algae*, as its origin cannot be verified and because the products currently on the market and therefore subject to the rules in force guarantee sufficient levels of overall safety.

The following from the second bullet point of the fourth paragraph: *the antioxidants butylated hydroxyanisole, butylated hydroxytoluene and ethoxyquin.*

is now the second bullet point of the second paragraph and has been amended to read:

the antioxidants butylated hydroxyanisole, butylated hydroxytoluene and ethoxyquin, unless administered with vitamins for technological purposes as stabilising agents.

The expression 'unless administered with vitamins for technological purposes as stabilising agents' has been added because the listed antioxidants have actually always been used in feed in that way, since they are contained in the vitamin premixes that feed mills use to produce the feedstuffs, in order to ensure the stability and quality of fat-soluble vitamins, such as vitamin A (which is easily oxidised and therefore cannot be used without stabilising agents). However, recent amendments to legislation mean that ingredients have to be listed on the end product, meaning that they could appear on information leaflets, giving rise to apparent non-compliance even though the situation has not actually changed.

Therefore, the text has been adapted to reflect the fact that the law requires these products to be listed in information leaflets when used in premixes. The ban on these products as stand-alone ingredients in feedstuffs, however, remains, as the intention behind that rule is to prevent them from being used as a solution to problems arising from the use of poor-quality feed materials.

— Article 9: 'Livestock originating from other production sectors'

The first two paragraphs of Article 9:

Dairy cows from production chains other than the 'Parmigiano Reggiano' chain may not be introduced into the environments in which milking cows and dry cows are kept until at least four months after their arrival on the holding.

During this period the dairy cows must be fed in compliance with these Rules and any milk they produce may not be delivered to cheese dairies.

have been amended to read:

The introduction of livestock from production chains other than the 'Parmigiano Reggiano' chain, and therefore not included in the control system, onto dairy farms or restocking units must take place no later on the day on which the animal reaches 10 months of age.

This amendment has been included in point 3.3 of the single document.

The key elements that make 'Parmigiano Reggiano' cheese unique can be summarised as follows:

- Territory: this is to be understood in terms of soil, air and water and is essential for its ability to generate food for livestock and keep active the 'good' microflora that are crucial for making and maturing the cheese. In particular, the ban on the use of silage of any kind for dairy cows and the role of forage from pasture such as permanent and temporary grasslands are recognised as key elements for preserving this territory. The delicate microbiological balance necessary for cheesemaking can only be preserved through careful management of the soil, cattle housing and cheese dairies.
- Livestock: livestock management, proper nutrition in particular, helps animals to develop the ability to transform the rations they are fed into milk, their productive response, health and longevity. It therefore makes sense for the product specification to encourage greater focus on these issues, including when new information becomes available.
- 'Good' microorganisms for cheesemaking: these have always been considered to play an essential role in making 'Parmigiano Reggiano' cheese unique.

All the rules of the current product specification are designed to promote a favourable microbiological habitat from the field to the farm to the dairy. In particular, banning silage of all kinds in the rearing of female calves, heifers up to the sixth month of gestation and dairy cows, coupled with a hay-based diet, form the cornerstones of an approach to the selection of the flora specific to the 'Parmigiano Reggiano' production area, in terms of both 'good' and 'bad' flora.

On the basis of these brief fundamentals, it is considered important that the product specification evolve and lay down rules on managing the female calves and heifers that, once mature, will produce milk to be made into cheese. For a long time now, the rules on the diet fed to milking cows in the product specification have also applied to dry cows and heifers from the sixth month of gestation. These rules are not just aimed at preventing any deterioration in the quality characteristics of the milk, since the latter two categories do not produce milk, but also (and above all) to guide producers towards a farming model that is consistent with the basic cornerstones: the ban on use of silage, hay-based rations, ruminal ability to process fibre and a focus on all the cattle on the farm. As already mentioned, the current product specification extends the ban on the use and possession of silage of all kinds to the rearing of female calves and heifers up to the sixth month of gestation.

The main aim behind requesting an amendment whereby the introduction of any livestock from other production chains onto a dairy farm, or onto the units, listed in the control system, on which a dairy farm's specific restocking activities are conducted, must take place by the age of 10 months is to improve and increase the cow's capacity to adapt for life to the typical diet of the holdings included in the 'Parmigiano Reggiano' PDO control system and already fed to the cows reared directly in the production area, with the use of forage and a ban on the feeding of silage.

While theoretically speaking these animals should ideally be brought onto holdings as soon as they are weaned so that they can be adapted for life to the typical diet of the farms included in the control system for 'Parmigiano Reggiano' PDO, 10 months of age is considered sufficiently early to achieve a clear improvement on the situation under the current product specification. This proposal represents a fair compromise, avoiding imposing a major economic burden on those who are currently rearing young livestock outside the 'Parmigiano Reggiano' PDO production chain.

Moreover, in view of the general tendency to impregnate heifers at an increasingly early age, in some cases close to 12 months, the requirement that animals be introduced by 10 months would ensure that fertilisation takes place on farms within the PDO production chain with the aim of genetic improvement.

Requiring that cattle be fed a silage-free diet from their 10th month of life aims to ensure that their rumens develop with hay, which means that they can be expected to develop anatomical and histological characteristics that are better suited to the subsequent stage of milk production, meaning that the cows will function better on that type of diet. It is widely thought that feeding female calves and heifers a diet based on the predominant use of dry forage, rather than silage, has a positive influence on their morphological development, resulting in greater abdominal depth and increased ingestion capacity, and reduces the risk of excessive fat cover (something which the misuse of maize silage is particularly prone to causing).

Recent research has found that feeding hay to heifers brings benefits in terms of dry matter intake and growth, and that consuming hay rather than silage has a positive impact on the animal's forage utilisation capacity, presumably as a result of a better morpho-functional development of the growing heifer's rumen. It should also be added that the use of rations that are acidogenic due to a starch-heavy imbalance, as rations based on cereal silage (and maize silage in particular) typically tend to be, can cause tissue damage in the ruminal mucosa (erosion) and the liver (abscesses). This damage, which is irreversible, makes the animals more susceptible to other diseases and less efficient in processing rations based on high-fibre, bulky forage, such as the hay-based rations that are typical of the farms included in the 'Parmigiano Reggiano' PDO control system. This damage is very rare in animals whose diet is based on unensiled forage, hay in particular.

In comparison with silage use, feeding heifers fresh forage and hay also drastically reduces the risk of them ingesting mycotoxins, the potential effects of which include impairing the animal's immune system, making it more prone to disease and thus reducing its longevity.

This amendment also seeks to improve controls in the certified production system of 'Parmigiano Reggiano' cheese, giving the end consumer increased assurance that the product complies with the product specification.

The product specification currently prohibits the use and possession of silage of any kind in the rearing of female calves, heifers up to the sixth month of gestation, and dairy cows. The 'quarantine' requirement laid down in Article 9 of the *Cow Feeding Rules* in the current product specification is specifically aimed at reducing the risk of spore contamination in the environment in which dairy cattle whose milk is used to make 'Parmigiano Reggiano' are housed, which is why during this 'quarantine' period operators are required to properly segregate cows from production chains other than the 'Parmigiano Reggiano' chain, keep their milk separate and keep the relevant farm records.

Over time, the checks carried out to make sure that the 'quarantine' rules are being followed in compliance with the current product specification have revealed numerous failures to respect the 'quarantine' requirement in the terms laid down in the control plan for 'Parmigiano Reggiano' PDO.

More specifically, the authorised 'Parmigiano Reggiano' PDO control body found 12 instances of 'major non-compliance' in checks on compliance with the 'quarantine' requirement between 2012 and 2017. These instances of 'major non-compliance' led to the consequences laid down in the 'control table' relating to the handling of the raw material and, in particular, to the exclusion of the product from the PDO, as well as the adoption of remedial measures by the affected operators in order to eliminate the cause or causes. In the same period, the authorised control body found 639 instances of 'minor non-compliance' that led to the adoption of remedial measures by the affected operators in order to eliminate the cause or causes.

Moreover, instances of 'major non-compliance' recorded in 2018 (5) and 2019 (4) show a proportional increase on the previous period (2012-2017), implying that it is becoming more common.

Requiring that cows be brought into the chain by the age of 10 months would, firstly, be much easier for the authorised control body to check, since the animal's age (since birth) can be easily found out from databases, whereas the current 'quarantine' checks centre on a stage in the cow's life (sixth month of gestation, milking or dry period) which varies depending on when impregnation occurred.

Furthermore, 'quarantine' as it is currently understood would no longer be necessary since, as already mentioned, from the age of 10 months the cow would have sufficient time to adapt to the typical diet (because, on average, it will still be approximately another 12-14 months before it starts producing milk) and there would be no risk of the operator mismanaging the segregation of animals in 'quarantine' and their milk flows that might cause issues with the cheese (something that could occur at present if a cow is already lactating when brought onto the farm).

— Article 10: 'Entry of new farms into the production chain'

The third paragraph of Article 9: *Agricultural holdings not belonging to the 'Parmigiano Reggiano' production chain are not authorised to provide milk until at least four months after the inspection visit.*

is now Article 10, entitled 'Entry of new farms into the production chain' and has been amended as follows:

Agricultural holdings not belonging to the 'Parmigiano Reggiano' production system are not authorised to provide milk until at least four months after the inspection by the authorised control body.

The text now specifies that the party responsible for checking compliance with these requirements is the control body.

— Article 11

Article 10 is now Article 11, retaining the title 'Total mixed ration feeding'.

— Article 12: 'New products and technology'

Article 11: *Any use of foodstuffs not covered by these Rules, variations in the prescribed quantities or the introduction of methods of preparation and administration not laid down herein are subject to a positive outcome in the tests and studies assessed by the Parmigiano-Reggiano Consortium. If the outcome is positive, an application for the product specification to be amended may be made accordingly.*

is now Article 12 and has been amended as follows:

Any use of foodstuffs not covered by these Rules, variations in the prescribed quantities or the introduction of methods of preparation and administration not laid down herein are subject to a positive outcome in the tests and studies assessed by the Parmigiano-Reggiano Cheese Consortium. If the outcome is positive, as well as being adopted based on the provisions of Article 6, must be added to the product specification the next time it is being amended.

It is specified that any use of animal feed and technology not covered by the Cow Feeding Rules, variations in the prescribed quantities or the introduction of methods of preparation and administration must first have a positive outcome in the tests and studies assessed the Consortium. If the outcome is positive, as well as being adopted based on the provisions of Article 6, they must (no longer 'may') be added to the product specification the next time it is being amended.

Finally, the word 'Cheese' has been inserted to give the Consortium's proper name.

SINGLE DOCUMENT

'PARMIGIANO REGGIANO'

EU No: PDO-IT-0016-AM06 — 2.12.2021

PDO (X) PGI ()

1. **Name(s)**

'Parmigiano Reggiano'

2. **Member State or Third Country**

Italy

3. **Description of the agricultural product or foodstuff**

3.1. *Type of product*

Class 1.3. Cheeses

3.2. Description of the product to which the name in (1) applies

'Parmigiano Reggiano' is a hard, cooked-curd, slow-matured cheese made from raw cow's milk, which is partially skimmed by allowing the cream to rise to the surface. The milk must not undergo any heat treatment or physical or mechanical treatments and must come from dairy cows fed primarily on forage from the area of origin. The cheese must be matured for at least 12 months. 'Parmigiano Reggiano' can be sold as whole wheels, in portions or grated.

'Parmigiano Reggiano' may not be subjected to any treatment that impairs its chemical/physical or organoleptic characteristics and has the following characteristics:

- wheels of cheese with slightly convex or almost straight sides with a slightly raised edge on the flat faces;
- dimensions: wheels measure 35-43 cm in diameter across the flat faces and 20-26 cm high;
- minimum weight: 30 kg per wheel;
- rind colour: natural straw colour, which may change over time;
- rind thickness: around 6 mm;
- cheese paste colour: from light straw-coloured to straw-coloured;
- characteristic aroma and taste of the paste: fragrant, delicate and flavoursome without being strong;
- texture of the paste: fine-grained and flaky;
- minimum fat content in dry matter: 32 %;
- no additives;
- cyclopropane fatty acid ratio: less than 22 mg per 100 g of fat (already accounting for measurement uncertainty, determined by gas chromatography-mass spectrometry [CG-MS]).

3.3. Feed (for products of animal origin only) and raw materials (for processed products only)

The rearing of replacement dairy cows ('restocking') must be carried out in the defined geographical area and included in the control system as a specific activity of a dairy farm. The use and possession of silage of any kind are prohibited.

The introduction of livestock from production chains other than the 'Parmigiano Reggiano' chain, and therefore not included in the control system, onto dairy or restocking farms must take place no later on the day on which the animal reaches 10 months of age.

Dairy farms that had restocking activities located outside the defined geographical area as at 5 January 2021 may continue to conduct this activity outside the area of origin provided that it is included in the control system.

The dairy cows' diet is based on forage from the defined geographical area and is specified by quantity and quality.

At least 75 % of forage dry matter must be produced within the geographical area.

Non-forage feedstuffs may make up at most 50 % of the dry matter of the ration.

The use and possession of silage of any kind are prohibited.

Cow's milk, salt, calf rennet.

The milk must be produced on farms located in the defined geographical area and included in the control system.

3.4. Specific steps in production that must take place in the identified geographical area

The milk must be made into cheese within the defined geographical area. The milk from the evening and morning milkings is delivered to the dairy raw and untreated, observing the product specification. The morning milk is placed in copper vats and mixed with the milk from the previous evening, partially skimmed by allowing the cream to rise to the surface. The fat-to-casein ratio of the milk in the heating vats, calculated as the weighted average of all vat batches in a given day's production, cannot exceed $1,10 \pm 10$ %. A continuous whey starter, a natural culture of lactic acid bacteria obtained by leaving 'sweet' whey left over from previous cheesemaking operations to spontaneously ferment

in controlled temperature conditions, is added to the milk. The use of commercial starter cultures is not permitted. Following coagulation, for which only calf rennet can be used, the curds are broken up and scalded. Once the cheese mass has sunk to bottom of the vat, it is set in moulds. The cheeses are then marked. After some days, the cheeses are soaked in brine and then matured for at least 12 months. The cheeses may be matured on wooden-shelved racks.

The minimum 12-month maturing period must take place in the defined geographical area.

After the minimum maturing period, a quality inspection is performed to check compliance with the product specification.

3.5. *Specific rules concerning slicing, grating, packaging, etc. of the product the registered name refers to*

'Parmigiano Reggiano' can be sold as whole wheels, in portions or grated.

In the interests of consumer protection, in order to guarantee the authenticity of pre-packaged, grated or portioned 'Parmigiano Reggiano' placed on the market, grating, portioning and subsequent packaging must take place in the defined geographical area. This is necessary because the markings that identify a whole cheese as 'Parmigiano Reggiano' are lost or are not visible on grated cheese or portions, so the origin of the pre-packaged product has to be guaranteed. This is also necessary because the cheese needs to be packaged quickly after portioning and using procedures that prevent it from becoming dehydrated or oxidised, or from losing its original 'Parmigiano Reggiano' organoleptic characteristics. Cutting into a wheel of cheese deprives the cheese of the natural protection afforded by the rind, which – itself being highly dehydrated – insulates the cheese very well from the surrounding environment.

Only whole cheeses bearing the protected designation of origin 'Parmigiano Reggiano' may be grated. It must be packaged immediately after grating and may not be subject to any processing or have any substance added to it. However, the use of 'trimmings' is also permitted under the conditions set out above. The rind content in grated 'Parmigiano Reggiano' cheese must be no more than 18 % by weight.

Offcuts of 'Parmigiano Reggiano' which are to be used by operators within the control system to prepare other formats are referred to as 'trimmings'.

Grating, portioning, and pre-packaging for direct sale may be carried out at the retail outlet solely for the purpose of sale to the end consumer.

3.6. *Specific rules concerning labelling of the product the registered name refers to*

The identity markings found on each 'Parmigiano Reggiano' cheese are the words 'Parmigiano Reggiano' in pin-dot lettering, together with the registration number of the dairy that made it, the year and month of production, and the abbreviation DOP (PDO), printed around the sides of the wheel of cheese using a stencilling band, an oval stamp with the words *Parmigiano Reggiano Consorzio Tutela* ('Parmigiano Reggiano Protection Consortium'), a casein disc or an equivalent system that ensures the unique identification of each cheese, and, the 'category two' stamp for cheeses from that category.

Pre-packaged, grated and portioned 'Parmigiano Reggiano' cheese placed on the market is identified by a logo containing a stylised depiction of a wedge and a wheel of 'Parmigiano Reggiano' cheese above the words 'PARMIGIANO REGGIANO'.



This logo, which is a mandatory component of the labelling, must be printed in colour following the technical specifications laid down by the pertinent Consortium agreement.

To make it possible to find out how mature 'Parmigiano Reggiano' is, the minimum maturing time must be stated on the label of all pre-packaged portions of more than 15 g placed on the market.

As the aroma and taste of the paste of 'Parmigiano Reggiano' evolve over the course of the maturing process, in order to convey the organoleptic characteristics, the following descriptive adjectives may be used on the label, as well as the maturing time, for certain maturity classes:

- *delicato* [delicate] (12-19 months);
- *armonico* [harmonious] (20-26 months approx.);
- *aromatico* [aromatic] (27-34 months approx.);
- *intenso* [intense] (35-45 months approx.).

Except when used as 'trimmings', offcuts from the faces and sides of wheels of cheese (pieces with more than 18 % rind) cannot bear the name 'Parmigiano Reggiano'.

4. Concise definition of the geographical area

The defined geographical area comprises the part of the province of Bologna to the left of the River Reno, the part of the province of Mantua to the right of the River Po, and the provinces of Modena, Parma and Reggio Emilia.

5. Link with the geographical area

Among the most important natural factors are the characteristics of the soil found within the defined geographical area – which extends from the Apennine ridge to the Po – coupled with climate conditions that directly influence both the composition of the natural flora and fermentation processes in the product. With regard to human factors, as well as the historical importance of the cheese to the local economy, it should be noted that the complex operations performed on 'Parmigiano Reggiano' cheese have been developed over centuries of traditional cheesemaking practices within the production area, handed down from generation to generation with respect for authentic and unvarying local practices.

A fine-grained and flaky texture, a fragrant aroma, a delicate taste – flavoursome without being strong – and high solubility and digestibility are distinguishing features of 'Parmigiano Reggiano' cheese.

These features reflect the unique qualities of the milk used for cheesemaking – raw milk is processed daily in copper vats and coagulated using calf rennet with a high rennin content – and the criteria used to select it, as well as the practice of soaking the cheeses in saturated brine and the extended maturation period.

The specific physical, chemical and microbiological properties of the milk that guarantee the specific characteristics and quality of 'Parmigiano Reggiano' cheese are basically the result of the diet fed to the dairy cows, based on forage from the area of origin and with a strict ban on the use of silage of any kind. The minimum twelve-month maturing period, which – due to the specific climate conditions present – must take place within the defined geographical area, is a necessary stage to bring about the specific enzyme processes through which the product obtained by processing milk can take on the characteristics that are unique to 'Parmigiano Reggiano'.

Reference to publication of the specification

<http://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/3335>

Publication of the single document referred to in Article 94(1)(d) of Regulation (EU) No 1308/2013 of the European Parliament and of the Council and of the reference to the publication of the product specification for a name in the wine sector

(2023/C 202/14)

This publication confers the right to oppose the application pursuant to Article 98 of Regulation (EU) No 1308/2013 of the European Parliament and of the Council ⁽¹⁾ within 2 months from the date of this publication.

SINGLE DOCUMENT

‘Terres du Midi’

PGI-FR-02484

Date of submission of the application: 28.9.2018

1. Name(s) to be registered

Terres du Midi

2. Member State

France

3. Geographical indication type

PGI – Protected geographical indication

4. Categories of grapevine product

1. Wine

5. Description of the wine(s)

The protected geographical indication ‘Terres du Midi’ covers still red, rosé and white wines.

These wines are noted for their fruity aromas, the character and intensity of which vary according to the grape varieties and technologies used.

The reds, which have good depth of colour (raspberry to garnet) and are blended to obtain a fleshy, supple and harmonious structure, generally reveal notes of red or spicy fruit.

The whites range in colour from greenish yellow to golden yellow. Also made from a blend of different varieties, they exhibit the freshness of white-fleshed fruit with notes of citrus fruit.

The rosés have excellent balance as they are made from a blend of Grenache, Syrah and sometimes Cinsault and Carignan, resulting in the colour deepening from peach to raspberry pink. These fresh rosé wines develop aromas of red fruit and flowers.

As regards oenological practices, the wines must comply with all the requirements of EU legislation.

General analytical characteristics

Maximum total alcoholic strength (in % volume)	
Minimum actual alcoholic strength (in % volume)	10

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

Minimum total acidity	
Maximum volatile acidity (in milliequivalents per litre)	
Maximum total sulphur dioxide (in milligrams per litre):	

6. Wine-making practices

a. Essential oenological practices

As regards oenological practices, the wines must comply with the requirements of EU and national legislation.

b. Maximum yields

'Terres du Midi' PGI red, rosé and white wines

120 hectolitres per hectare

7. Demarcated geographical area

The grapes used to make wines bearing the 'Terres du Midi' PGI must be harvested and the wines made and developed in the geographical area, within the territory of the following municipalities:

- all of the municipalities in the departments of Aude, Hérault, Gard and Pyrénées-Orientales;
- in the department of Lozère: Gorges du Tarn Causses, Ispagnac, La Malène, Massegros Causses Gorges, only for the territory of the delegated municipality of Les Vignes.

8. Main grape variety (varieties)

Alicante Henri Bouschet N

Alphonse Lavallée N

Altesse B

Alvarinho - Albariño

Aramon N

Aramon blanc B

Aramon gris G

Aranel B

Arinarnoa N

Arvine B - Petite Arvine

Aubun N - Murescola

Auxerrois B

Baco blanc B

Bourboulenc B - Doucillon blanc

Cabernet franc N

Cabernet-Sauvignon N

Caladoc N

Cardinal Rg

Carignan N

Carignan blanc B

Carmenère N
Chambourcin N
Chardonnay B
Chasan B
Chasselas B
Chasselas rose Rs
Chenanson N
Chenin B
Cinsaut N - Cinsault
Clairette B
Clairette rose Rs
Colombard B
Côt N - Malbec
Couderc noir N
Counoise N
Danlas B
Egiodola N
Fer N - Fer Servadou, Braucole, Mansois, Pinenc
Gamay N
Gamay de Chaudenay N
Gewürztraminer Rs
Grenache N
Grenache blanc B
Grenache gris G
Gros Manseng B
Jurançon blanc B
Landal N
Listan B - Palomino
Lival N
Lledoner pelut N
Macabeu B - Macabeo
Marsanne B
Marselan N
Mauzac B
Merlot N
Meunier N
Mondeuse N
Morrastel N - Minustellu, Graciano
Mourvèdre N - Monastrell
Muscadelle B
Muscat d'Alexandrie B - Muscat, Moscato
Muscat de Hambourg N - Muscat, Moscato

Muscat à petits grains blancs B – Muscat, Moscato
Muscat à petits grains roses Rs – Muscat, Moscato
Muscat à petits grains rouges Rg - Muscat, Moscato
Nielluccio N - Nielluciu
Négrette N
Parrellada B
Petit Manseng B
Petit Verdot N
Pinot gris G
Pinot noir N
Portan N
Ravat blanc B
Riesling B
Rivairenc N - Aspiran noir
Rivairenc blanc B - Aspiran blanc
Roussanne B
Sauvignon B - Sauvignon blanc
Sauvignon gris G - Fié gris
Savagnin rose Rs
Sciaccarello N
Semillon B
Servant B
Seyval B
Sylvaner B
Syrah N - Shiraz
Tannat N
Tempranillo N
Terret blanc B
Terret gris G
Terret noir N
Ugni blanc B
Verdelho B
Vermentino B - Rolle
Villard blanc B
Villard noir N
Viognier B

9. Description of the link(s)

9.1. Specificity of the geographical area

Located in the South of France, bordering the Mediterranean coastline, the ‘Terres du Midi’ PGI covers the departments of Gard, Hérault, Aude and Pyrénées-Orientales, as well as some municipalities belonging to Lozère. The Bas Languedoc area - more specifically the departments of Gard, Hérault and Aude - form a territory in the Mediterranean arc, known as the ‘Midi vineyards’, which has been almost exclusively devoted to winegrowing since the beginning of the 19th century.

This geographical area features different soil conditions, the most representative being acidic schists on the high slopes, calcareous soils on the wine-growing plateaux and plains and stony alluvial terraces. All of these offer dry, low-fertility soils that are suitable for vines and allow for deep rooting to take place. From the mountains of the Cévennes, the Montagne Noire and the foothills of the Pyrenees to the shores of the lagoon, the 'Terres du Midi' PGI area is criss-crossed by the rivers Aude, Orb, Hérault, Vidourle and Gardon and forms a large amphitheatre overlooking the Mediterranean.

This area benefits from a Mediterranean climate that is ideal for winegrowing, with hot, dry summers and mild winters, as well as two rainy seasons in autumn and spring.

There are a number of different winds in the area. A 'sea wind' sweeps through the Gulf of Lion regularly and sometimes forcefully, especially during the period that the grapes are ripening. The spray it carries has a moderating effect on excessive temperatures. There are dry and strong northerly or westerly winds (Tramontane, Cers and Mistral) that help ensure the good health status of the vineyards. These aspects of the climate are conducive to planting grape varieties in different environments, of which there are three in this area: mountains and highlands, foothills and intermediate plains, and finally, the coastal plain. Vines are the monoculture from the Rhône delta to the Spanish border.

9.2. Specificity of the product

'Terres du Midi' PGI is a product linked to the history of the wine-growing South of France. Wine has been produced in this area since the first vineyards in Western Europe were planted in the surroundings of Agde, around the year 600 BC.

A crisis in the wine-growing sector involving aspects linked to wine production, social issues and the economy of the wine-growing enterprises culminated in 1907. Multiple taxes, overproduction and fraud acted as a catalyst for discontent. Prices fell and the quality of the wines weakened. Faced with the intransigence of the authorities, the winegrowers of the Languedoc set up numerous wine protection committees with delegations in the majority of the municipalities in the South of France. These then rapidly regrouped under the *Confédération Générale des Vignerons du Midi* (General Confederation of 'Midi' Winegrowers). The idea of the 'Midi Viticole' (i.e. the wine-growing South of France) started to take shape when this Confederation was recognised by the State. This allowed dialogue to resume and solutions to be found for tackling the crisis (lower taxes, fraud prevention, rules on the declaration and movement of wines, amnesty). The deed founding this movement makes clear reference to the contours of the 'Midi Viticole', comprising the four wine-growing departments of Pyrénées-Orientales, Aude, Hérault and Gard. This land is almost exclusively devoted to winegrowing.

A precise statutory definition of 'vin de canton' (canton wine) was established in 1964 in reference to wines tied to an administrative area of production with a specific set of soil and climatic conditions. A 1968 decree changed 'vin de canton' to 'vin de pays' (regional wine). Regional wines were initially identified by the name of the department where they were produced and had to conform to specific production criteria that required a higher level of quality. This stage allowed the 'vins du Midi' to benefit from specific recognition that led to the emergence of the PGI 'Terres du Midi'.

Some 100 000 hectolitres of wine in the three colours are produced under the PGI 'Terres du Midi'. Reds account for the majority (55 % of production). Rosés (35 %) are gradually advancing and whites make up the remainder.

The PGI 'Terres du Midi' is mainly expressed by blending grape varieties that are either traditionally grown in the region or brought in from other wine-growing regions.

It is thanks to the winegrowers' expertise in growing the vines, taking advantage of the different soil conditions in the geographical area in order to produce quality grapes, that these varieties can be established. The hot, dry Mediterranean climate is key to ensuring that the grapes reach full ripeness in all areas and for all varieties, and that the primary aromas are preserved and even strengthened. The resulting wines are thus characterised by their aromatic quality (fruity and floral), the intensity and nature of which vary depending on the varieties included in the blends.

In the case of the reds, the blends result in the fruity, supple wines with ripe, harmonious tannins that are characteristic of the wines bearing this PGI. As for the whites and rosés, blending allows to maintain excellent balance, preserving the freshness of the wines and their aromatic quality, which tends to be fruity in the case of the whites but also floral in the case of the rosés.

9.3. *Causal link between the specificity of the geographical area and the specificity of the product*

The link to the origin of the product is based on the characteristics of the product. It is derived from the interplay between the specific soil and climate profiles in the geographical area and the grape varieties selected, which have a major influence on these characteristics.

Thanks to the essential influence of the hot, dry and well-ventilated Mediterranean climate on the PGI varieties, the grapes reach full ripeness in all areas and are noted for their aromas.

The name 'Terres du Midi' reflects the characteristics of the area and its Mediterranean soil and climate conditions, which are conducive to the ripening of different varieties and the expression of their primary aromas. The name is shared by the winegrowers involved, who offer aromatic wines with a pleasant gourmet profile from this area that is mainly devoted to winegrowing.

From the mountains of the Cévennes, the Montagne Noire and the foothills of the Pyrenees to the shores of the lagoon, the 'Terres du Midi' PGI area is criss-crossed by the rivers Aude, Orb, Hérault, Vidourle and Gardon and forms a large amphitheatre overlooking the Mediterranean.

While the geographical area has different soil conditions, the soils have certain features in common. They are dry and low in fertility, thus allowing for the deep rooting that enables many varieties to be planted. The vegetative vigour of the vines therefore remains constant, allowing for regular yields of fleshy grapes. The relief of this well-ventilated area, which has a moderating effect on excess heat, from the mountains to the sunny coastline, guarantees good conditions for the development and ripening of the various vine varieties, thus preserving the freshness and aromatic potential of the grapes that are the hallmarks of the wines bearing this PGI. In the case of the white wines, the positive influence of winds on the vines grown mostly on the plain protects the grapes against dryness and this is what gives the wines their fresh, fruity flavours. The reds, characterised by their aromas of red or spicy fruit, with a good balance between tannins and alcohol, owe their expression to the influence of the dry, sunny and well-ventilated climate on the grape varieties. The rosés, which are fresh, fruity or floral depending on the blends, owe their structure balanced between aromatic quality and freshness to the combined influence of the sun and the sea wind.

In artfully blending the primary characteristics of the varieties (colour, aromas, tannins, vivacity) as expressed by the terroir, the winegrowers preserve these distinctive and invariably aromatic, supple and fresh traits in the organoleptic profile of each colour of wine produced. The reds made from strong, colourful varieties have a depth of colour ranging from raspberry to garnet. Their bouquet features notes of red or spicy fruit. Their flavours reveal tannic notes that are supple and harmonious. The whites range in colour from greenish yellow to golden yellow. Made from aromatic and acidic varieties, they exhibit the freshness of white-fleshed fruit and reveal notes of citrus fruit. The rosés are made from varieties with good colour intensity and fruity characteristics, resulting in fresh wines with hints of red fruit and floral tints.

These aspects, together with the blending expertise and the organisation of 'Midi Viticole' into tight-knit collective wine-growing structures, are all characteristic of the 'Terres du Midi' PGI.

This is a solid foundation for the development of the wine-growing economy in this region. Winegrowing and winemaking are the main economic activity in three-quarters of the rural villages in the departments in the South of France.

10. **Essential further conditions**

Labelling

Legal framework:

National legislation

Type of further condition:

Additional provisions relating to labelling

Description of the condition:

It is strictly prohibited for one or more grape varieties to be mentioned.

The European Union PGI logo must appear on the label if the words 'Indication Géographique Protégée' ('Protected Geographical Indication') are replaced by the traditional term 'Vin de Pays'.

Area in immediate proximity

Legal framework:

National legislation

Type of further condition:

Derogation concerning production in the demarcated geographical area

Description of the condition:

The 'area of immediate proximity' defined by derogation for the production and development of wines eligible for the 'Terres du Midi' PGI comprises the cantons that border the departments of Aude, Hérault, Gard and Pyrénées-Orientales:

Arles, Avignon (No 1, No 2, No 3), Haute-Ariège (municipalities of Ax-les-Thermes, Artigues, Ascou, Carcanières, Ignaux, Mérens-les-Vals, Mijanès, Montailou, Orgeix, Orlu, Ormolac-Ussat-les-Bains, Perles-et-Castelet, Le Pla, Prades, Le Puch, Quérigut, Rouze, Savignac-les-Ormeaux, Sorgesat, Tignac and Vaychis), Collet de Dèze (municipalities of Le Collet-de-Dèze, Barre-des-Cévennes, Bassurels, Cassagnas, Cans and Cévennes only for the territory of Saint-Julien-d'Arpaon, Fraissinet-de-Fourques, Gabriac, Moissac-Vallée-Française, Molezon, Le Pompidou, Saint-André-de-Lancize, Saint-Etienne-Vallée-Française, Saint-Germain-de-Calberte, Saint-Hilaire-de-Lavit, Saint-Julien-des-Points, Saint-Martin-de-Boubaux, Saint-Martin-de-Lansuscle, Saint-Michel-de-Dèze, Saint-Privat-de-Vallongue, Sainte-Croix-Vallée-Française and Ventalon en Cévennes), Bollène, Bourg-Saint-Andéol (municipalities of Bourg-Saint-Andéol, Bidon, Gras, Larnas, Saint-Just-d'Ardèche, Saint-Marcel-d'Ardèche, Saint-Martin-d'Ardèche and Saint-Montan), Causses-Rougiers (municipalities of La Cavalerie, Arnac-sur-Dourdou, Brusque, Camarès, Le Clapier, Cornus, La Couvertouade, Fayet, Fondamente, Gissac, L'Hospitalet-du-Larzac, Lapanouse-de-Cernon, Marnhagues-et-Latour, Mélargues, Montagnol, Peux-et-Couffouleux, Saint-Beaulize, Saint-Jean-et-Saint-Paul, Sainte-Eulalie-de-Cernon, Saucières, Sylvanès, Tauriac-de-Camarès and Viala-du-Pas-de-Jaux), Tarn et Causses (municipalities of Campagnac, La Capelle-Bonance, La Cresse, Mostuéjols, Peyreleau, Rivière-sur-Tarn, La Roque-Sainte-Marguerite, Saint-André-de-Vézines, Saint-Laurent-d'Olt, Saint-Martin-de-Lenne, Saint-Saturnin-de-Lenne and Veyreau), Châteaurenard (municipalities of Châteaurenard, Barbentane, Boulbon, Eyragues, Graveson, Saint-Pierre-de-Mézorgues, Noves, Rognonas and Tarascon), Haute-Ardèche (municipalities of Coucouron, Issanlas, Issarlès, Le Lac-d'Issarlès, Lachapelle-Graillouse, Lanarce, Lavillatte and Lespéron), La Montagne Noire, Le Pastel (municipalities of Garrevaques, Palleville, Soual and Viviers-lès-Montagnes), Hautes Terres d'Oc (municipalities of Lacaune, Anglès, Barre, Berlats, Escroux, Espérausses, Gijounet, Lamontélarie, Lasfaillades, Moulin-Mage, Murat-sur-Vèbre, Nages, Senaux and Viane), Pays d'Olmes (municipalities of Lavelanet, L'Aiguillon, Bélesta, Bénaix, Carla-de-Roquefort, Dreuilhe, Fougax-et-Barrineuf, Ilhat, Lesparrou, Leychert, Lieurac, Montferrier, Montségur, Nalzen, Péreille, Raissac, Roquefixade, Roquefort-les-Cascades, Saint-Jean-d'Aigues-Vives, Sautel and Villeneuve-d'Olmes), Saint-Etienne-du-Valdonnez (municipalities of Altier, Pied-de-Borne, Pont-de-Montvert-Sud, Mont Lozère, Pourcharesses, Prévenchère, Saint-André-Capcèze, Vialas and Villefort), Le Pontet (municipalities of Le Pontet and Vedène), Cévennes Ardéchoises (municipalities of Les Vans, Les Assions, Banne, Beaumont, Berrias-et-Casteljau, Chambonas, Dompnac, Gravières, Laboule, Loubarette, Malarce-sur-la-Thines, Malbosc, Montselgues, Saint-André-de-Cruzières, Saint-Mélany, Saint-Paul-le-Jeune, Saint-Pierre-Saint-Jean, Saint-Sauveur-de-Cruzières, Sainte-Marguerite-Lafigère, Les Salles and Valgorge), Mazamet-1, Mazamet-2, Vallée du Thoré, Castres (municipality of Saint-Salvy-de-la-Balme), Florac (municipalities of Gatuzières, Hures-la-Parade, Meyrueis, Le Rozier and Saint-Pierre-des-Tripiers), Mirepoix, Escalquens (municipalities of Auragne, Caignac, Calmont, Gibel, Mauvaisin, Monestrol, Montgeard, Nailloux, Saint-Léon and Seyre), Millau-2 (municipalities of Nant and Saint-Jean-du-Bruel), Orange, Revel (municipalities of Revel, Avignon-et-Lauragais, Beateville, Bélesta-en-Lauragais, Cessales, Falga, Folcarde, Gardouch, Juzes, Lagarde, Lux, Mauremont, Maurens, Montclair-Lauragais,

Montégut-Lauragais, Montesquieu-Lauragais, Montgaillard-Lauragais, Mourvilles-Hautes, Nogaret, Renneville, Rieumajou, Roumens, Saint-Félix-Lauragais, Saint-Germier, Saint-Julia, Saint-Rome, Saint-Vincent, Trébons-sur-la-Grasse, Vallègue, Vaudreuille, Vaux, Vieillevigne, Villefranche-de-Lauragais and Villenouvelle), Les Portes d'Ariège (municipalities of Saverdun, La Bastide-de-Lordat, Brie, Canté, Esplas, Gaudiès, Justiniac, Labatut, Lissac, Mazères, Montaut, Saint-Quirc, Trémoulet and Le Vernet), Sorgues, Salon de Provence-1 (municipalities of Mas-Blanc-des-Alpilles and Saint-Etienne-du-Grès), Vallon-Pont-d'Arc (municipalities of Vallon-Pont-d'Arc, Balazuc, Bessas, Labastide-de-Virac, Lagorce, Organc-d'Aven, Pradons, Ruoms, Saint-Remèze, Salavas, Sampzon and Vagnas), Vaison-la-Romaine (municipalities of Camaret-sur-Aigues, Travaillan and Violès).

Reference to publication of the specification

https://info.agriculture.gouv.fr/gedei/site/bo-agri/document_administratif-e251ee13-3a0d-45e8-a272-733874b7a36a

CORRIGENDA

Corrigendum to Publication of a communication of approval of a standard amendment to a product specification for a name in the wine sector, as referred to in Article 17(2) and (3) of Commission Delegated Regulation (EU) 2019/33

(Official Journal of the European Union C 104 of 4 March 2022)

(2023/C 202/15)

On page 39, in the third paragraph:

for: 'Languedoc / Coteaux du Languedoc',

read: 'Languedoc'.

On page 40, under point 1, 'Name(s)':

for: 'Languedoc

Coteaux du Languedoc',

read: 'Languedoc'.

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