CONTROL PLAN

MORTADELLA BOLOGNA
Protected Geographical Indication

Drafted AUT: *Alessio Lodolo* RSCH: *Gabriele Belloni* IS: *Laura Cappellato*	Approved AU: *Ludovico Picotti*

TABLE OF CONTENTS

1. INTRODUCTION

Regulation (EU) no. 1151/2012 on quality schemes for agricultural products and foodstuffs requires that agri-food products benefiting from a PDO/PGI be obtained in accordance with the relevant Specification (Article 7) and that verification of compliance with the regulated requirements be carried out by competent authorities and/or control bodies authorised by member states (Article 37).

IFCQ Certificazioni SRL a socio unico (hereafter only IFCQ), as the Authorised Control Body for Mortadella Bologna PGI pursuant to Art. 14 of Law No. 526/99, has defined this CP - MB document as a guide for carrying out self-control and conformity control activities.

The CP, drawn up on the basis of the Production Specification (hereafter only Specification) filed with the Ministry of Agricultural Food and Forestry Policies (hereafter only MIPAAF) and forwarded to the competent Services of the European Union, describes the set of controls the product must undergo in order to be identified with the distinctive signs of Mortadella Bologna PGI. The Specification can be downloaded from the MIPAAF website www.politicheagricole.it.

The overall set of controls consists of both the activities directly borne by the Operators concerned along the regulated production chain (self-control activities) and the controls carried out by IFCQ in order to ascertain process and product conformity.

Operators who intend to join the PGI must submit to the control activity carried out by IFCQ and operate in accordance with the Specification and the Control System approved by MIPAAF.

2. PURPOSE AND SCOPE OF APPLICATION

The purpose of this CP is to identify and ensure, through inspection, testing and evaluation activities, compliance with the regulated requirements of the production chain of the Protected Geographical Indication product "Mortadella Bologna" and is applied, for the specific activities, to all Operators included in the PGI Control System: Producers and Portioners/Slicers, as defined in Section 4.

For its activities, IFCQ makes use of information systems that ensure product identification, traceability and retraceability through the recording of activities carried out by the Operators.

3. REFERENCE DOCUMENTS

- Commission **Regulation (EC) No. 1549/1998** of 18 July 1998, on the registration of the protected geographical indication "Mortadella Bologna" pursuant to Article 17 Regulation (EEC) No. 2081/1992
- **Law 24 April 1998, No. 128** provisions for the fulfilment of obligations arising from Italy's membership in the European Community - Community law 1995/1997 with particular reference to Article 53
- **Official Journal 28 October 1998, No. 252**: Publication of the specification for the protected geographical indication "Mortadella Bologna"
- **Law No. 526 of 21 December 1999** laying down provisions for the fulfilment of obligations arising from Italy's membership in the European Community - Community Law 1999 - and in particular Article 14, which contains special provisions on controls and supervision of protected designations of agricultural products and foodstuffs

- **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
- **Regulation (EC) No. 852/2004** of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
- **Regulation (EC) No. 853/2004** of the European Parliament and of the Council of 29 April 2004, laying down specific hygiene rules for food of animal origin
- **Legislative Decree no. 297 of 19 November 2004:** "Penalty provisions pursuant to Regulation (EEC) No. 2081/92 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs"
- **MIPAAF Decree of 22 December 2004** on the recognition of the Protection Consortium and assignment to carry out the functions referred to in Article 14, paragraph 15, of Law No. 526 of 21 December 1999, and subsequent renewals
- Commission **Regulation (EC) No. 2074/2005** of 05 December 2005 laying down implementing measures for certain products under Regulation (EC) No. 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulations (EC) No. 854/2004 and (EC) No. 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No. 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No. 853/2004 and (EC) No. 854/2004
- Commission **Regulation (EC) No. 2076/2005** of 05 December 2005 laying down transitional arrangements for the implementation of Regulations (EC) No. 853/2004 and (EC) No. 854/2004 of the European Parliament and of the Council
- **UNI CEI EN ISO IEC 17025, September 2005** "General requirements for the competence of testing and calibration laboratories"
- **Legislative Decree No. 114 of 08 February 2006:** implementation of Directives 2003/89/EC, 2004/77/EC and 2005/63/EC on the indication of ingredients in foodstuffs
- **Legislative Decree No. 190 of 05 April 2006**, "Penalty discipline for violations of Regulation (EC) No. 178/2002 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"
- **Law 27 December 2006, no. 296:** Provisions for the formation of the annual and multi-year budget of the State (Finance Law)" - Art. 1, Paragraph 1047 on state functions of supervision over the control activity of public and private bodies within the framework of registered quality agri-food production schemes delegated to the Central Inspectorate for Quality Control of Agri-Food Products
- **Legislative Decree no. 193 of 06 November 2007:** Implementation of Directive 2004/41/EC on food safety controls and enforcement of Community regulations in the same sector
- **MIPAAF note dated 29 November 2007** (prot. 0022897): Control plans on Italian protected designations. Suspension or revocation measures as a result of non-compliance with tariff obligations by operators
- **MIPAAF note dated 30 November 2007** (prot. 0022966): Separation of protected designation agri-food productions from generic ones
- **Regulation (EU) No. 1169/2011** of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers and amending Regulations (EC) No. 1924/2006 and (EC) No. 1925/2006 of the European Parliament and of the Council and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC, and Commission Regulation (EC) No. 608/2004
- **UNI CEI EN ISO/IEC 17065:2012:** General requirements for bodies operating product certification systems
- **Regulation (EU) No. 1151/2012** of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs
- **MIPAAF (DG PQA III) note dated 23 October 2012** (prot. 0002039): translation of “Certified by Control Body authorised by Mipaaf”
- **Regulation (EU) 1308/2013** of 17 December 2013 establishing a common organisation of the markets of agricultural products and repealing EEC Regulations No. 922/72, No. 234/79, No. 1037/2001 and 1234/2007 and subsequent amendments and supplements
- **MIPAAF (DG VICO I) note of 19 December 2013** (prot. 0026712): transmission of Decree No. 26588 of 18 December 2013 on "Integration of the Decree of 15 April 2013 on the procedure for the authorisation of inspection bodies for inspection and certification activities of agri-food productions"
- Commission **Delegated Regulation (EU) No. 664/2014** of 18 December 2013 supplementing Regulation (EU) 1151/2012 with regard to the definition of Union symbols for protected designations of origin, protected geographical indications and traditional specialties guaranteed and with regard to certain rules of origin, certain procedural rules and certain additional transitional rules
- Commission **Implementing Regulation (EU) No. 668/2014** of 13 June 2014 laying down procedures for the

application of Regulation (EU) No. 1151/2012 on quality schemes for agricultural products and foodstuffs

- **Corrigendum** Commission **Regulation (EU) No. 668/2014** of 13 June 2014 laying down procedures for the implementation of Reg. (EU) No. 1151/2012 (OJEU No. L. 39/23 of 14 February 2015)
- **Regulation (EU) 625/2017** of the European Parliament and of the Council of 15 March 2017, on official controls and other official activities carried out to ensure the enforcement of food and feed law, animal health and animal welfare rules, plant health rules, and plant protection products, amending Regulations (EC) No. 999/2001, (EC) No. 396/2005, (EC) No. 1069/2009, (EC) No. 1107/2009, (EU) No. 1151/2012, (EU) No. 652/2014, (EU) No. 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No. 1/2005 and (EC) No. 1099/2009, and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No. 854/2004 and (EC) No. 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 92/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC, and Council Decision 92/438/EEC (Official Control Regulation)
- **MIPAAF (DG PREF II) Note of 24 May 2017** (prot. 0006976): Supervisory database - Information obligations of supervisory bodies
- **Official Journal of 26 February 2018, General Series No. 47:** Proposed amendment to the specification for the protected geographical indication "Mortadella Bologna"
- **MIPAAF (DG PQAI IV) Note of 07 February 2019** (prot. 0008738): approval of application for minor amendment to "Mortadella Bologna" PGI specification
- **MIPAAFT (DG VICO I) Note of 17 October 2019** (prot. 0014769): change the name Mipaaft to Mipaaf on geographical indication products
- **MIPAAF (DG VICO I) Decree of 22 December 2020** (prot. 9394977): authorisation for the body named "IFCQ Certificazioni Srl" to carry out controls for the protected geographical indication "Mortadella Bologna", registered within the European Union
- **MIPAAF (DG VICO I) note of 27 January 2021** (prot. 0038970): authorisation of PDO and PGI labels in control plans
- **MIPAAF (DG VICO I) note of 04 March 2021** (prot. 0105162): authorisation of PDO and PGI labels in control plans
- **MIPAAF (DG VICO I) note of 18 October 2021** (prot. 0539187): test methods for analytical control on GI productions
- **MIPAAF (DG VICO I) note of 16 December 2021** (prot. 0663094): analytical controls on GI productions

4. ABBREVIATIONS AND DEFINITIONS

AA.CC.: Competent Authorities

"Year": the calendar year (12-month period between 1 January and 31 December); "year," unless "calendar" is specified, means the calendar year throughout the Control System (in addition to the CP, also in the Annexes, Control Scheme, and Tariff System)

"Calendar year": 12-month period between any X day of a year and X-1 day of the following year (e.g., between 20 October 2021 and 19 October 2022)

Self-control: verification of compliance requirements, implemented and recorded by all Operators in the Mortadella Bologna PGI supply chain, for activities carried out at their production sites

Supervisory authority: MIPAAF and regions affected by the PGI

SD: Supervisory Database

Co. Ce: Certification Committee

Certification of Conformity: statement by which IFCQ certifies that the production of "Mortadella Bologna" complies with the requirements of the relevant Specification and CP approved by the competent Authorities

Protection consortium: Protection consortium recognised by the MIPAAF that is assigned to carry out the functions set forth in Article 14, paragraph 15, of Law No. 526 of 21 December 1999

Compliance Monitoring: activity by which IFCQ ascertains, in application of the CP, the adherence to the compliance requirements prescribed by the Specification

DDT: Transport Document or equivalent document

Specification: EU regulations defining the requirements of Mortadella Bologna PGI

PPE: Personal Protective Equipment

GDA: Appeals Council, collegial body deciding appeals filed by Operators

PGI: Protected Geographical Indication

Mixing batch: set of produced mortadella units related to a mixture; for each mixture, the Operator fills in a Mixing Sheet in which it defines some technical data of the batch (batch number, production date, ingredients weight...)

Reinforced Control Measure (MCR): specific additional control activity on a specific aspect defined in the Specification and/or CP consisting of one or more Supplementary Inspection Checks (SIC). The treatment is communicated to the data subject with an indication of the charge to the Operator already provided by the Tariff System. This measure also applies in case of a repetition of the same non-compliance within one year

Non-conformity (NC): failure to meet the requirements for compliance with the Specification or failure to comply with the provisions of the Control Plan

Mild non-conformities (MNC): failure to meet the requirements for compliance with the Specification or failure to comply with the provisions of the Control Plan that do not affect the certifiability of the product

Major non-conformities (MNC): failure to meet the requirements of compliance with the Specification or failure to comply with the provisions of the Control Plan that affect the certifiability of the product

CB Control Body

Operator: entity included in the PGI Control System for the specific activities performed

CP: Control Plan

"Mortadella Portal": computer system that collects, aggregates and organises data entered by Producers and Portioners/Slicers and makes it available to Operators through customised interfaces and according to specific access privileges

Finished product: product obtained in accordance with the requirements prescribed in the Specification and suitable for identification by the PGI

Producer: Approved operator who processes the raw material to obtain the finished product, which may also portion and/or slice, identifying it, if compliant, with the PGI

Portioner/Slicer: Approved operator who does not process product for PGI purposes, but only portions and/or slices the finished product, identifying it, if compliant, with the PGI

Complaint: communication by which the Operator expresses dissatisfaction/irregularity to IFCQ regarding the service provided by the CB or communication by which a customer expresses dissatisfaction to the Operator regarding the product received from the Operator

Applicant: entity that applies to IFCQ for inclusion in the PGI Control System

Recognition: a measure by which IFCQ enters an Operator into the PGI Control System

Appeal: a petition in which the Operator requests the Appeals Council to review an order issued by IFCQ

Calibration status: a condition of a measuring instrument whereby the instrument is found to have failed the established calibration deadline; calibration allows the metrological characteristics of a measuring instrument to be defined with the aim of verifying its accuracy

Traceability: process that reconstructs the history of the product "from upstream to downstream" in the supply chain, documenting and recording each stage of its processing. Traceability enables **Retraceability**, a process that links all recorded information to trace back "from downstream to upstream" the history of the product and related responsibilities along the supply chain

SIC: single Supplementary Inspection Check with charges borne by the Operator; where possible, multiple SIC may be conducted within the same inspection visit

Test Result Evaluator (TRE): an officer of IFCQ who, after evaluating the results of the chemical and chemical-physical controls found in the Test Report completed by the testing laboratory, issues an evaluation report for the conformity of the sample(s) examined (Test Evaluation Report). Resolution on certification is the responsibility of the Certification Committee

5. ACCESS TO THE SYSTEM OF CONTROLS

5.1 SUBMISSION OF APPLICATION FOR RECOGNITION

The Applicant who intends to operate within the PGI Control System must submit the request for recognition, directly or through the Protection Consortium by virtue of specific delegation, in which it must be specified that the responsibilities arising from any non-compliance (including economic relations) are in any case the responsibility of the individual Applicant, by sending it to the e-mail address anagrafica@ifcq.it completed in its entirety and complete with the indicated documentation, using the template:

- **Annex no. 1** for the Producer;
- **Annex no. 2** for the Portioner/Slicer.

By submitting the application, the Applicant fully accepts the contents of the Control System (CP, Tariff System, Control Scheme and any other relevant documents) and assumes direct responsibility for the activities carried out for the purpose of recognition and subsequent maintenance of the requirements.

5.2 RECOGNITION PROCEDURE IN THE MORTADELLA BOLOGNA PGI CONTROL SYSTEM

The recognition procedure consists of the following steps:

a) Documentary verification:
IFCQ, upon receipt of the request and the required ancillary documentation, verifies within 10 working days:

- that the Applicant's production facility is located in the delimited territory as defined in Articles 2 and 7 of the Specification;
- that the request has been formalised using the appropriate form and is completed in its entirety; if the documentation is incomplete or inadequate, a request for supplementation will be sent.

b) Initial inspection verification:
IFCQ within 30 working days after having received all the required documentation, successfully completed the document verification, conducts the initial inspection. During the course of the same, it is assessed by the CB whether the conditions in place correspond to what is communicated in the application and whether the Applicant is able to meet the regulated requirements in relation to its specific activities and the following is then verified:

- **for Producers**, that the equipment and facilities declared with the application for recognition and suitable for processing the product for PGI purposes are in place, and a system is available to ensure traceability checks of incoming raw material, individual processed doughs, bagged, cooked and cooled mortadella, and outgoing packaged mortadella;
- **for the Portioners/Slicers**, that the equipment and facilities declared with the application for recognition are in place and a system is available to ensure all the

feedback on the traceability of incoming PGI mortadella and subsequent portioned and/or sliced outgoing product.

The inspection includes the control of any production lines dedicated to the exclusive production of the PGI. In the event that the visit reveals circumstances that differ from what is stated, the procedure is suspended until the requirement is met, where possible. Where the Operator fails to comply with the adjustment requests within 30 working days, IFCQ closes the investigation by sending a corresponding notice.

c) Recognition:

IFCQ evaluates the results of the initial inspection audit, and if these findings do not reveal any non-conformities, the Certification Committee of IFCQ examines the inquiry.

If the initial inspection visit is successful, the Certification Committeee, having acquired the relevant documentation, shall decide within 15 working days on the recognition or non-recognition due to the Applicant's lack of the requirements prescribed in the CP.

IFCQ, within 10 working days after the resolution of the Certification Committee, notifies the Applicant of the outcome of the decision. In case of positive evaluation, it issues the measure of recognition, including the identification code, and enters the Applicant in the registry list of recognised subjects; the measure is notified to the Operator by certified e-mail (PEC), and, for information, to the Recognised Protection Consortium, including the notification of documents related to the Control System (CP, Control Scheme, Tariff System and any other useful document). In the case, on the other hand, of a negative evaluation, the non-inclusion order is notified by certified mail (PEC) to the unrecognised Applicant and for information to the Protection Consortium.

With the assignment of the identification code:

- **Producers** are sent credentials to access the "Mortadella Portal" for the registration of the Mixing Sheet, Certification Statement and, if they portion and/or slice product at the same production site, the Portioning and/or Slicing Register, to be completed according to the instructions defined respectively in Annexes No. 3, No. 4 and No. 5;
- **Portioners/Slicers** are sent the credentials to access the "Mortadella Portal" for filling out the Portioning and/or Slicing Register as specified in Annex No. 5.

Where production and portioning/slicing are carried out at the same production site, a single identification code is given (when the health approval given by the ASL appears to be the same).

IFCQ maintains a Register of all Recognised Operators by taking care of updating the file of each of them, including measures for dealing with non-conformities, and the SD.

5.2.1 Validity of recognition

The validity of the recognition of the Operator with its inclusion in the registry of all recognised entities, except in cases of withdrawal and cancellation, operates in continuity to that of the authorisation issued by MIPAAF to IFCQ for the purpose of carrying out conformity checks of Mortadella Bologna PGI.

The validity of the controls and certificates of conformity is related to the authorisation issued by MIPAAF to IFCQ for the purpose of carrying out conformity controls of Mortadella Bologna PGI.

Operators agree to cooperate with IFCQ by facilitating control activities to verify the proper fulfilment of the requirements under their responsibility, making available all required documents and records (e.g. DDT, complaints).

5.2.2 Subsequent changes in the initial conditions for recognition and any other additional changes

For the purposes of maintaining recognition in the PGI Control System, the Operator concerned must formally notify IFCQ possibly in advance and in any case within 10 working days of their occurrence, at the e-mail address anagrafica@ifcq.it, of all substantial changes that affect the state of conformity of the product, the production process and the traceability of the productions in addition to those that affect the ownership of obligations and rights (e.g.: changes in the company, ownership or company registry, ASL code, structural and/or production set-up).

IFCQ, within 10 working days of receipt of the communication, will evaluate the reported variations, reserving the right to carry out inspections and/or requests for additional documentation in relation to the nature of the changes.

In the event of suspension or revocation of the sanitary permit, the Operator must notify IFCQ within 24 hours by certified e-mail (PEC) and immediately suspend activities for the purpose of the PGI.

5.2.3 Voluntary suspension of activity for the purposes of the PGI by the Operator

An Operator who temporarily suspends activity under the CP must give written notice to IFCQ to be sent to the e-mail address anagrafica@ifcq.it.

IFCQ takes note of this and issues a corresponding order suspending its inspection activities at the Operator itself, which does not result in any change of registry.

The "suspended" Operator is not required to report any changes specified in Section 5.2.2 during the suspension period.

The "suspended" Operator is obliged to immediately suspend the activity for the purpose of the PGI. Any resumption of activity by a "suspended" Operator must always be communicated in advance and in writing to IFCQ at the e-mail address anagrafica@ifcq.it, including any changes that may have occurred during the period of suspension. If the suspension period has lasted at least 12 months and/or in the case where

the Operator has communicated substantial changes (as defined in Section 5.2.2) that occurred during the suspension, IFCQ shall, within 10 working days of receipt of the communication in which the Operator declares its intention to resume operations for the purposes of the PGI, conduct a SIC.

Resumption of activity for PGI purposes by the Operator is always subject to specific authorisation by IFCQ.

5.2.4 Take over recognition

In cases of the takeover of a new Operator for the same activity, if it is found from the request for takeover/conversion that the takeover involves only the mere subjective transfer of the business complex registered for the PGI, leaving unchanged the essential objective elements that allowed the recognition of the Operator taken over in the registry of recognised entities, the registration of the Operator taking over in the relevant registry takes place following only the documentary control (thus without the initial inspection verification) and the consequent resolution of the Certification Committee The file will not be brought to the evaluation of the Certification Committee in case there is no change in the CUAA and/or in case there is a change in the registered office only.

In all other cases in which the takeover does not involve exclusively the subjective transfer of the set of rights and obligations arising from the transferor's membership of the PGI, IFCQ reserves the right to conduct an inspection visit to verify corporate compliance. In the case of confirmation of the company's compliance following such a visit, and where IFCQ considers that it has sufficient documentary evidence to confirm the Operator's compliance without the need for an inspection visit, the company may be recognised in the relevant registry after final evaluation of the file by the Certification Committee

5.3 WITHDRAWAL FROM THE CONTROL SYSTEM AND DELETION FROM THE REGISTRY

An Operator who intends to withdraw from the PGI Control System (due to closure or transfer of the Company, cessation of production activity for PGI purposes, or other different reason) is required to give corresponding written notice to IFCQ to be sent to the email address anagrafica@ifcq.it.

In the event of a request for withdrawal, the Operator will pay to IFCQ its rates for the year in which the request is formalised.

IFCQ, having perfected all procedures referring to the withdrawal request, submits the request to the Certification Committee which will take a corresponding resolution. Upon the outcome, IFCQ will issue the withdrawal order, notifying the Operator concerned by certified electronic mail (PE), and remove it from the registry of recognised entities. The procedure is completed upon receipt of the relevant order by the Operator who submitted the relevant request. Until then, the latter is required to fulfill all the burdens associated with its status as a recognised entity.

5.3.1 Procedure for managing positions that are no longer active

IFCQ submits for evaluation by Certification Committee the deletion of the Operator's registry position from the relevant lists of recognised entities in cases where:

- it has ceased operations without having given the prescribed notice and these circumstances are established by documentary verification about the "chamber of commerce cessation" and/or inspection verification that the same no longer operates for the purposes of the PGI;
- the production settlement and/or recognised entity is no longer in existence, the settlement is effectively disused, closed or abandoned, or the Operator is declared bankrupt;
- it has suspended activity for the purposes of the PGI for a period exceeding 12 full and consecutive months without written notice. In such a case, IFCQ will send a note to the Operator concerned, informing it that after 30 working days have elapsed without it expressing, by written communication to IFCQ, its willingness to continue the activity for the purposes of the PGI, the CB will remove it from the lists of subjects included in the PGI Control System.

The deletion of an Operator from the registry results in the same Operator being prohibited from using:

- mortadella bagged and/or cooked and/or packaged and identified with PGI, as of the date indicated in the notice regarding its cancellation;
- graphic labels, letterhead and all documents/publications in which references to Mortadella Bologna PGI appear.

In case of deletion from the registry, IFCQ will request the party concerned to pay the fees for which it is responsible.

If the "deleted" Operator wishes to resume activity for the purposes of the Mortadella Bologna PGI, it must initiate a new recognition process.

6. GENERAL FULFILMENTS OBSERVED BY OPERATORS

Recognised entities in the PGI Control System are required to:

- maintain the structural and organisational characteristics with respect to the elements acquired at the time of recognition and any other elements acquired subsequently as specified in Section 5.2.2, with particular reference to the valid sanitary authorisation; in the case of the supervening changes specified in Section 5.2.2, the Operators must communicate them to IFCQ in accordance with the methods and timelines defined in that Section;
- carry out any processing for PGI purposes exclusively at recognised sites/locations;
- perform and comply with self-control, traceability and retraceability procedures; the product must be processed, handled and/or stored in such a way that it is always identifiable; in particular, Operators must keep at the company documentation suitable to guarantee, at any stage of processing, the traceability of the product intended for the PGI;
- carry out the processing for PGI purposes separately from that of the generic or otherwise qualified product by physical separation of lines or temporal separation of processing;

in the case of physical separation of lines, Operators must identify with plan evidence the processing lines, facilities and premises dedicated to the PGI; in the case of temporal separation, they must record processing dates for PGI purposes;

- fulfill their obligations for the purpose of PGI protected production by complying with the requirements defined in the Specification and the requirements of the CP;
- record, compile, manage, and file the documentation required by the CP so as to facilitate verification by IFCQ and the official control authorities;
- complete the specific documents stipulated in the CP (Mixing Sheet, Certification Statement, Portioning and/or Slicing Register) before marketing the product; as an exception to this requirement, Operators are granted, for one "calendar year" from the effective date of this CP, the possibility of ensuring these registers even after marketing; the purpose of this concession is to give Operators, during the period of application of this exception, the opportunity to structure and organise themselves in such a way as to adapt to the required recording times;
- allow, also for the purpose of ensuring the continued effectiveness of the recognition itself, any form of verification by IFCQ, without or with prior notice, directed at ascertaining the exact fulfilment of the obligations placed on them. The following is defined in Art. 3, Paragraph 2 of Legislative Decree No. 297/2004: "Without prejudice to the application of the applicable criminal laws, the person placed in the control system who engages in conduct aimed at not allowing inspections and/or preventing the taking of samples or hindering or obstructing the document verification activity by the persons in charge of the control structure referred to in paragraph 1 or the supervisory agents of the Protection Consortium referred to in Article 1, paragraph 1, letter c), number 1), shall be subject to an administrative fine, subject to verification by the Ministry of Agricultural and Forestry Policies, of euro five hundred sixteen";
- notify formally IFCQ, if possible in advance and in any case within 10 working days of their occurrence, of all substantial changes (defined in Section 5.2.2) affecting the conformity status of the product, the production process and traceability of productions in addition to those affecting the ownership of obligations and rights;
- authorise IFCQ to use the data acquired through its activities for purposes related to the operation of the Control System;
- accept the measures for dealing with any non-conformities established in application of the Control System;
- authorise access to their production facility also to the officials of the authorities responsible for accreditation and supervision under the regulations in force for them;
- authorise IFCQ to use mobile devices and cameras for video screen shots and for photographic survey of sites, equipment, documents to be acquired in exclusive support of its activities for purposes related to the performance of controls authorised by MIPAAF;
- record:

  - complaints received from customers, making them available to the CB, and the related corrective actions taken;
  - non-conformities by providing objective evidence of the exclusion of the non-conforming product from the PGI;

- keep at its recognised production site, unless waived by the CB, all documents produced (including self-control records) and received in the course of its activities for PGI purposes for at least 5 years from the date of compilation/issuance;
- exclude the product from the PGI in all cases in which it is ordered by the CB or in the case of a finding of non-compliance with the conformity requirements of the Specification and the CP;

Operators must provide objective evidence to IFCQ of compliance with the prescribed compliance requirements, as well as of any non-compliance situations encountered and how they have been dealt with;
- use measuring instruments in a state of calibration for measurements made in self-control; to this end, Operators must maintain a documented and efficient system for the corresponding management of their "external" or "internal" calibration, which, if required, must be made available to IFCQ;
- keep/segregate, if they have appealed to IFCQ, what is indicated in the non-compliance order until the Appeals Council acquires its final decision;
- notify IFCQ of any measures notified by the Competent Authorities that may affect process and/or product conformity;
- use, obligatorily, the computer structure of the "Mortadella Portal," through the registration of data and information in the sections dedicated to them; the "Mortadella Portal" also serves as a data archive and will be available for consultation, in separate ways, by Operators and the Supervisory Authority; the archived data can be made available and requested within the limits and in the manner provided for by the regulations in force; in the event of malfunctioning of the portal, Operators are still required to compile the required documentation (e.g. in paper format), reporting the data defined in the relevant annexes of the CP;
- provide to IFCQ personnel (inspecting and/or shadowing) detailed information on the specific risks that exist in the areas where they will be assigned to work and the prevention and emergency measures, in relation to their activities (including the PPE provided and available), in order to enable them to carry out their inspections safely.

7. COMPLIANCE REQUIREMENTS OBSERVED BY OPERATORS

7.1 FULFILMENTS OF THE PRODUCER

The meat used to produce "Mortadella Bologna PGI" consists exclusively of a mixture of pork obtained from striated muscles belonging to the carcass reduced to a fine grain using a meat grinder. A carcass is defined as "the body of a pig for slaughter after depilation, exsanguination, abdominal and thoracic evisceration excluding the use of the heart, tongue and diaphragm". Mechanically separated meat cannot be used for PGI purposes.

The Producer for the processing of "Mortadella Bologna PGI" must:

- comply with the processing program relating to the preparation of the mixture and, if it carries out portioning and/or slicing activities, also to these operations; this program is sent to IFCQ at the same time as the recognition procedure and can subsequently be modified; all changes to the program must be notified to the CB at least 24 hours in advance which, exclusively for portioning/slicing operations, can be reduced, if documented and occasional, to 18 hours in the case of urgent necessity (e.g. fulfilment of a sudden order); notification to IFCQ must be made in any case by 12:00 noon on the previous working day (it is permissible not to operate for PGI purposes on notified dates, but not for it to operate on non-notified dates, unless explicitly authorised by IFCQ);
- use raw materials, including optional-use ingredients where applicable, in accordance with the requirements of Art. 3 of the Specification;

in particular, if the Producer uses sugar (sucrose), it can use it at the maximum dose of 0.5%; on the other hand, the maximum total allowable dose for the possible use of nitrite (sodium and/or potassium) is 140 parts per million;

- if it has used sugar (sucrose) and/or sodium nitrite and/or potassium nitrite, record the quantities used in self-monitoring, so as to give evidence of compliance with the quantities prescribed in Art. 3 of the Specification concerning the raw materials used;
- keep appropriate documentation issued by the supplier regarding the requirements and characteristics of raw materials;
- comply with the processing method defined in Art. 4 of the Specification; in particular, the Producer must:

  - use for grinding a series of plates with holes of decreasing diameter (each preceded by a knife and with an outlet plate with holes not exceeding 0.9 mm in diameter) not subjecting the refined mass obtained to other grinding processes; the diameter of the holes of the outlet plate of the grinding plant must be documented by means of the stamping affixed by the Producer on each mould or by a special declaration of the Producer kept on file by the Producer itself;
  - prepare lards using cubed, heated, water-washed and drained pork throat fat used in such a quantity, taking into account weight loss, that, after the processing process is completed, it is not less than 15% of the total mass referring to the finished product (total mass means the mixture formed by the meat to be minced, the cubed lards and the ingredients prescribed and permitted by the Specification);
  - use vacuum or atmospheric pressure machines for kneading;
  - carry out, after kneading, the bagging of the product, which can be done, according to as indicated in Art. 3 of the Specification, using either natural or synthetic wrappings indifferently;
  - use dry air stoves for cooking;

- complete in the "Mortadella Portal", for each production batch, the Mixing Sheet, in accordance with the requirements of Annex 3, by the 5th working day following that of production and in any case, except for the period of application of specific derogation defined in Section 6, before the product is marketed; in the event that the product has been marketed as PGI without the prescribed registration, IFCQ will urge the Producer to comply within the period of 5 working days from the receipt of the reminder notice, warning it that in case of non-compliance the batch not recorded in the Mixing Sheet cannot be destined for PGI;
- self-monitor the temperature of the refined mass obtained from the grinding plant, the cooking temperature and the cooling temperature of the bagged product, and the pH of the finished product, keeping the relevant records, so as to give evidence of compliance with the requirements defined in Art. 4 of the Specification (T of the refined mass ≤+1°C, T of cooking at the core ≥+70°C, T at the core of the cooled product <+10°C, pH of the finished product ≥6);
- complete in the "Mortadella Portal" for each individual batch identified at the time of bagging and destined for the PGI or for one or more pieces of the same, the "Certification Statement", following the instructions defined in Annex 4, by the 5th working day following the end date of the process (understood as the date on which the company has completed the processing of the entire batch or individual pieces to be certified) and in any case, except for the period of application of specific derogation defined in Section 6, before the product is marketed. In the event that, after the prescribed period has elapsed, it has not

yet been recorded, IFCQ will urge the Producer to comply within the period of 5 working days from receipt of the reminder notice, warning it that if it fails to do so, the unregistered mortadella will be excluded from the PGI.

The Producer, after declaring the product suitable in the Certification Statement:

- if it transfers the product to another recognised entity authorised to portion/slicing, it must identify the mortadella with symbols/designations recalling the PGI, and accompany the delivery with a DDT supplemented by the words "Mortadella Bologna PGI" or other wording equivalent to that sales designation, ensuring traceability of the batch handled by indicating the batch, date of production, weight and size of the mortadella being delivered;
- if it portions and/or slices in the same production plant product received from another approved party or product processed in its own plant, it must follow the same requirements as for the Portioner/Slicer in Section 7.2 below; in the case of movement, to the portioning/slicing department, of product obtained in its own plant, this passage, although an "internal" operation within the company, must still be documented (a record making the movement traceable is sufficient).

7.2 FULFILMENTS OF THE PORTIONER/SLICER

The Portioner/Slicer must:

- comply with the portioning and/or slicing program; this program is sent to IFCQ at the same time as the recognition procedure and can subsequently be modified; all changes to the program must be notified to the CB at least 24 hours in advance which can be reduced, if documented and occasional, to 18 hours in the case of urgent necessity (e.g. fulfilment of a sudden order); notification to IFCQ must be made in any case by 12:00 noon on the previous working day (it is permissible not to operate for PGI purposes on notified dates, but not for it to operate on non-notified dates, unless explicitly authorised by IFCQ);
- ensure all documentation suitable for ensuring the traceability of incoming PGI mortadella and outgoing packages;
- verify that each delivery comes from an approved entity and is accompanied by a DDT supplemented by the words "Mortadella Bologna PGI" or other wording equivalent to that sales designation and an indication of the batch, date of production, weight and size of the mortadella being delivered, and that the containers used for the delivery are identified with wording recalling the PGI;
- having finished the portioning and/or slicing operations, record them in the Portioning and/or Slicing Register in the "Mortadella Portal", following the instructions in Annex 5, within 5 working days and in any case, except for the period of application of specific derogation defined in Section 6, before marketing the product; in the event that, after the prescribed period has elapsed, registration has not yet been carried out, IFCQ will urge the Operator to comply within the period of 5 working days from receipt of the reminder notice, warning it that in case of non-conformity the unregistered product will be excluded from the PGI;
- record the amount of packages diverted from the protected circuit already identified with the PGI;

- use only compliant graphic labels in compliance with the requirements of Section 10.

8. IFCQ CHECKS AT OPERATORS

The recipients of the controls are those included in the Mortadella Bologna PGI Control System.

IFCQ checks:

- registry data and the maintenance of structural and technical-organisational characteristics with respect to the elements acquired at the time of recognition and any other elements acquired subsequently as specified in Section 5.2.2;
- compliance with self-control, traceability and retraceability procedures; the product to be destined for the PGI must be processed, handled and/or stored in such a way that it is always identifiable in order to avoid any admixture with non-PGI product; in particular, during inspection visits IFCQ checks that, in order to avoid such admixtures, the processing of product destined for the PGI is carried out separately from that of non-PGI product by physical separation of the lines or temporal separation of processing;
- compliance with the requirements prescribed in the Specification and the proper fulfilment of the obligations on Operators provided for the purpose of protected production of the PGI in the CP;
- proper recording and drafting of the required documentation; IFCQ, on the basis of these records made by the Operator, performs a mass balance on at least one batch of finished product obtained during a year, comparing the quantity of product processed for PGI purposes with the quantity of finished product (whole, portioned or sliced) actually intended for PGI.

Checks are also carried out at IFCQ headquarters through the use of databases and related documentation entered by Operators in the "Mortadella Portal".

IFCQ, during inspection visits, may use Operator's instruments for weight, temperature and pH measurements in addition to its own instrumentation, verifying their calibration status.

Checks are distinguished into:

- **ordinary:** in execution of the CP without prior notice (except for controls related to the activity of taking samples, for which the day of the visit can be agreed with the company);
- **additional:** in execution of non-compliance measures or targeted activities with or without prior notice and with additional costs borne by the Operator.

Inspection checks at Operators are conducted by IFCQ staff in adversarial with an Operator's officer. At the end of each inspection, IFCQ staff will prepare appropriate reports describing the operations and checks carried out. This report is signed by CB officers and an officer/representative of the Operator at which the verification was conducted. The data and information contained in the report are computerised and processed by IFCQ for institutional control purposes and in execution of obligations under current regulations. A copy of the report is issued to the Operator at which the verification was conducted.

Routine checks are carried out by IFCQ in order to ensure:

- annually at each Producer the performance of processing stage audits (according to the procedures defined in Sections 8.1.1, 8.1.2 and 8.1.3) and routine sampling activity (according to the requirements of Section 8.1.4);
- annually at each Portioner/Slicer the verification of the portioning and/or slicing activity (according to Section 8.2);
- at least once every three years at each Operator the verification of the maintenance of structural and technical-organisational characteristics with respect to the elements acquired at the time of recognition and any other elements acquired subsequently as specified in Section 5.2.2.

Operators deleted from the PGI Control System or who have communicated in writing the temporary suspension of activity for the purposes of the PGI are excluded from the annual schedule of ordinary controls.

The finding of non-conformity involves the execution by IFCQ, as defined in the Control Scheme, of SIC in application of MCR for the specific non-conformities found.

In addition, IFCQ performs, based on the number and type of non-conformities issued during a specific six-month period, additional SIC to monitor the activities and procedures performed. In case of issuance, against an Operator by the CB within a six-month period (understood as the period between 1 January and 30 June and between 1 July and 31 December), of more than one non-conformity measures not related to laboratory analytical results, such additional SIC are required, to be carried out at the Operator's premises in the following six-month period.

IFCQ performs within the six-month period 1 SIC in case of notification of non-conformity measures in the previous six-month period related to:

- at least 3 minor non-conformities and none major;
- 1 major and 1 minor non-conformity.

IFCQ performs within the six-month period 2 SIC in case of notification of non-conformity measures in the previous six-month period related to:

- 1 major non-conformity and at least 2 minor ones;
- at least 2 major non-conformities (regardless of the number of minor non-conformities that may have been found).

8.1 IFCQ CHECKS AT THE PRODUCER

IFCQ conducts, for the purpose of routine inspection activities, at least one inspection visit per year at all Producers.

8.1.1 CONTROL of grinding, preparation of the mixture and subsequent bagging

IFCQ, with respect to the grinding, the preparation of the mixture and the bagging operation, checks each year at each Producer, based on the quantity of mortadella produced in the previous year (calculated by summing the quantities of mixtures obtained indicated in the Mixing Sheets), the following number of batches already bagged and recorded in the "Mortadella Portal":

- at least 3 for production in the previous year less than or equal to 100,000 kg;
- at least 6 for production in the previous year between 100,001 kg and 1,000,000 kg;
- at least 10 for production in the previous year exceeding 1,000,000 kg.

A batch is defined as the set of mortadella obtained from the mixture related to a single Mixing Sheet. For the first year of operation of a Producer for PGI purposes, the number of batches to be checked is determined on the basis of a company self-declaration sent by the Operator to IFCQ at the same time as the application for recognition, in which the company indicates the estimated quantity of mixture in kg that it expects to produce for PGI purposes over the course of an annual period; if the quantity of mixture produced for PGI purposes during the year is significantly different from the estimated quantity, the number of batches to be checked is consistently redetermined.

For each previously prepared batch examined, IFCQ checks at the document level that:

- the processing schedule filed, as specified in Section 7.1, has been adhered to;
- the raw materials prescribed in Art. 3 of the Specification have been used;
- appropriate documentation issued by the supplier regarding the requirements and characteristics of the ingredients is kept at the company;
- in the case of the use of sugar (sucrose) and/or sodium and/or potassium nitrite in the preparation of the mixture, records are kept by the Producer giving evidence of the relevant weighing; in particular, IFCQ verifies that sugar and nitrite (sodium and/or potassium) have been used in compliance with the maximum allowable doses as defined in Art. 3 of the Specification;
- records are present at the company giving evidence of the compliance of the temperature of the refined mass obtained from the grinding plant (≤ +1°C);
- the lards of pork throat fat used in the preparation of the mixture have been used in such a quantity, taking into account the weight loss, that, once the processing procedure has been completed, it is not less than 15% of the total mass referring to the finished product (the total mass being the mixture formed by the meat to be minced, the cubed lards and the ingredients prescribed and permitted by the Specification);
- the Mixing Sheet has been filled out correctly in compliance with as specified in Annex 3 and the prescribed recording times.

To control the processing method, IFCQ at each Producer also verifies annually, for at least one batch "in preparation", that:

- the processing schedule filed, as specified in Section 7.1, is adhered to;
- the processing method as defined in Article 4 of the Specification is adhered to; in particular, with regard to the grinding stage, IFCQ verifies that:

- the holes in the outlet plate of the grinding equipment have a diameter of no more than 0.9 mm (this can be checked by verifying the stamping affixed by the Producer on each mould or by acquiring a statement from the Producer kept on file by the Producer);
- the temperature of the refined mass obtained from grinding is no higher than +1°C;

- raw materials are used and bagging of the mortadella is carried out in compliance with as specified in Art. 3 of the Specification; in particular, with regard to the quantities of ingredients, IFCQ verifies, based on weighing, that if sugar (sucrose) and/or nitrite (sodium and/or potassium) are used, they are used in quantities that do not exceed the prescribed maximum limits;
- appropriate documentation attested by the Producer as part of its self-monitoring or issued by the supplier regarding the requirements and characteristics of the ingredients is kept at the company.

8.1.2 CONTROL of the cooking and cooling stages and pH of the finished product

IFCQ, with respect to the cooking and cooling phases, checks at the documentary level the records made by the Producer verifying compliance with the regulated values of cooking temperature and cooling temperature measured at the core of the product and compliance with the prescribed pH values of the finished product. Specifically, IFCQ checks the following number (determined by the same criteria specified at the beginning of Section 8.1.1) of finished product batches at each Producer each year at the document level, based on the quantity of mortadella produced in the previous year:

- at least 3 for production in the previous year less than or equal to 100,000 kg;
- at least 6 for production in the previous year between 100,001 kg and 1,000,000 kg;
- at least 10 for production in the previous year exceeding 1,000,000 kg.

A batch is defined as the set of mortadella obtained from the mixture related to a single Mixing Sheet.

IFCQ, for each batch of finished product examined, checks that the relevant Certification Statement has been filled out correctly in compliance with as defined in Annex 4 and with the prescribed recording times, and that the records, made in self-control by the company, of the cooking temperature, cooling temperature and pH of the finished product are consistent with as stated in the Certification Statement. If such self-control records give evidence of non-compliance with the prescribed temperature and/or pH values, the IFCQ officer shall order the exclusion of the unsuitable product from the PGI. If the Certification Statement has not yet been completed, IFCQ verifies that the prescribed recording time has not elapsed.

In addition, IFCQ, every year with physical-inspection for at least one batch being cooked and/or freshly cooked and/or with the cooling cycle completed, verifies that:

- if the product is being cooked, it is cooked in dry air stoves;

- if there is mortadella that has just completed the cooking cycle, has reached a core temperature of +70°C or higher. The check is carried out on a sample, randomly selected from the batch:

  - equal to 3 units for a mixing batch weighing 5,000 kg or less,
  - equal to 6 units for a mixing batch weighing between 5,001 and 10,000 kg,
  - equal to 9 units for a mixing batch weighing more than 10,000 kg.

  In the case of finding one or more mortadella that have not reached the regulated temperature, the IFCQ officer shall, for the purpose of reaching the prescribed minimum cooking temperature (measured at the core), order a resumption of the cooking of the same and all the mortadella whose cooking temperature it has not assessed that, compared to those checked, belong to the same batch, have the same size, and have been cooked in the same stove. If the officer finds that the cooking process to which such mortadella are subjected does not allow the regulated minimum core temperature to be reached, it shall order the exclusion from the PGI of the non-compliant product with the same size and cooked in the same stove;

- if available mortadella that have completed the cooling cycle, have a measured core temperature of the product below +10°C. The core temperature check is carried out by the IFCQ officer on 3 mortadella from the batch under examination; in case of non-compliant result of at least one mortadella, the officer orders the exclusion of the batch from the PGI;

- if there is mortadella that has finished the cooling cycle, their pH is 6 or higher. The pH verification is performed by IFCQ according to the following procedure. The control is carried out on a sample of a randomly chosen batch:

  - equal to 3 units for a mixing batch weighing 5,000 kg or less,
  - equal to 6 units for a mixing batch weighing between 5,001 and 10,000 kg,
  - equal to 9 units for a mixing batch weighing more than 10,000 kg,

  ordering, for all non-compliant mortadella, the diversion from the PGI.

  In the event that the mortadella checked are found to be unsuitable in quantities of one third or more and thus equal to at least:

  - 1 out of 3,
  - 2 out of 6,
  - 3 out of 9,

  the officer proceeds to extend the inspection to an additional randomly selected sample from the same batch:

  - equal to 9 units for a mixing batch weighing 5,000 kg or less,
  - equal to 18 units for a mixing batch weighing between 5,001 and 10,000 kg,
  - equal to 27 units for a mixing batch weighing more than 10,000 kg.

  In the event that mortadella continue to be found to be unsuitable in quantities of one third or more, also taking into account the units checked with the first sampling, IFCQ shall order the exclusion from the PGI of all the mortadella in the batch, except those evaluated as compliant following the control procedure specified above. By way of example, if

the IFCQ officer initially checked 3 mortadella and, having found 2 non-conforming mortadella, subsequently checked 9 more, must order the exclusion (except for mortadella evaluated as conforming) of the entire batch if overall (thus including the first 3) at least 4 out of 12 were found to be non-conforming (i.e. at least 2 of the 9 checked in the second sample were found to be non-conforming).

8.1.3 CONTROL of the portioning and/or slicing activity

IFCQ must check at least 2 batches each year at the Producer carrying out portioning/slicing activities, which can be incoming batches received from another approved entity or "in-house" batches, in the case of product obtained in its own plant and subsequently moved to the portioning/slicing department.

Verification is carried out on already portioned and/or sliced product or, preferably, during the execution of portioning and/or slicing operations.

For each batch examined, IFCQ verifies that:

- in the case of a batch received from another party, the supplier is recognised in the PGI Control System;
- it is accompanied by a DDT supplemented by the wording "Mortadella Bologna PGI" or other wording equivalent to this sales designation and that traceability of the batch handled is guaranteed by indicating the batch, date of production, weight and size of the mortadella being delivered (in the case of product obtained in the same factory and handled to the portioning/slicing department, a record documenting the handling is sufficient, making the movement of the mortadella clearly traceable).

IFCQ, in addition, for each batch to be controlled:

- if the product has already been portioned and/or sliced verifies that:
  - in case the company has not yet recorded the portioning and/or slicing operations in the "Mortadella Portal", the prescribed recording time has not elapsed; on the other hand, in case the company has already recorded the operations in the portal, IFCQ verifies the correctness of the completion in compliance with as specified in Annex 5 and the prescribed recording time;
  - if there are still at the company packages related to the batch under consideration, compliant graphics have been used for these packages in compliance with the requirements of Section 10;
  - the portioning/slicing operations took place in accordance with the processing schedule as specified in Section 7.1;

- in case the control is carried out during portioning and/or slicing operations, checks:
  - the conformity of the PGI mortadella to be used;
  - that the product intended for the PGI is packaged in compliant graphics, in accordance with the definition in Section 10;

- that portioning/slicing operations are carried out in accordance with the processing schedule as defined in Section 7.1.

If a Producer transfers, for the purpose of portioning and/or slicing, product to another recognised entity, IFCQ randomly checks that the deliveries have been made accompanied by a DDT supplemented with the words "Mortadella Bologna PGI" or other wording equivalent to this sales denomination and with the indication of batch, date of production, weight and size of the mortadella being delivered.

8.1.4 CONTROL of the product for release for consumption

IFCQ, for mortadella to which the Producer has attributed PGI, performs an activity aimed at ascertaining the conformity of the characteristics prescribed by Art. 5 of the Specification, by sampling mixing batches to be subjected to analytical controls every year.

In the first year of application of the CP (year in which the new CP comes into effect or the first year in which the CP is applied to a newly recognised entity) the number of batches to be subjected to chemical and chemical-physical laboratory analysis is:

- at least 3 for production in the previous year less than or equal to 100,000 kg;
- at least 6 for production in the previous year between 100,001 kg and 1,000,000 kg;
- at least 10 for production in the previous year exceeding 1,000,000 kg.

"One year's production" related to a Producer means the total quantity of mixing obtained quantified in the Mixing Sheets completed by the Operator over the year.

For the first year of operation of a Producer for PGI purposes, the number of batches to be submitted for analysis is determined on the basis of a company self-declaration sent by the Operator to IFCQ at the same time as the application for recognition, in which the company indicates the estimated quantity of mixture in kg that it expects to produce for PGI purposes over the course of an annual period; if the quantity of mixture produced for PGI purposes during the year is significantly different from the estimated quantity, the number of batches to be checked is consistently redetermined.

Each batch to be checked is randomly chosen by IFCQ from those recorded in the "Mortadella Portal". The sampled batch is given by the set of all the mortadella from a single Mixing Sheet.

Relative to each Producer, with respect to the number of samples analysed in the first year of CP implementation ("base sampling level"), the number of batches to be sampled in subsequent years varies according to the outcome of laboratory analytical testing of the samples taken.

If all batches sampled in the first year of CP implementation are found to be in compliance, in the following year the minimum number of batches for analysis is reduced to:

- 2 batches for production less than or equal to 100,000 kg/year;
- 4 batches for production between 100,001 kg/year and 1,000,000 kg/year;
- 7 batches for production exceeding 1,000,000 kg/year.

If even a single batch submitted for analysis is found to be non-compliant in the following year, the "base sampling level" is reinstated; otherwise, in the absence of analytical findings of non-compliance, IFCQ will sample the following minimum number of batches in the following year:

- 2 batches for production less than or equal to 100,000 kg/year;
- 3 batches for production between 100,001 kg/year and 1,000,000 kg/year;
- 5 batches for production exceeding 1,000,000 kg/year.

This number of sampling remains until the analytical finding of non-conformity, which results in the "base sampling level" being reinstated for the following year.

In the case of non-compliant laboratory analytical results for at least one batch sampled in the first year of application of the CP, IFCQ increases in the following year the minimum number of batches to be analysed to:

- 4 batches for production less than or equal to 100,000 kg/year;
- 8 batches for production between 100,001 kg/year and 1,000,000 kg/year;
- 13 batches for production exceeding 1,000,000 kg/year.

If all batches sampled are found to be in compliance, the "base sampling level" will be restored. On the other hand, in the case of an analytical finding of non-conformity of at least one sampled batch, IFCQ further increases in the following year the minimum number of batches to be submitted for analysis to:

- 5 batches for production less than or equal to 100,000 kg/year;
- 9 batches for production between 100,001 kg/year and 1,000,000 kg/year;
- 15 batches for production exceeding 1,000,000 kg/year.

This minimum number of batches to be analysed remains until no non-conforming batches are found; this circumstance results in the reinstatement of the "base sampling level."

The date the sample was taken is considered for determining the sampling level.

It is also clarified that for the count of non-conformities for the purpose of determining the sampling level to be applied in a year, laboratory analytical results of any additional sampling in application of MCR are not included.

Sampling procedures

The IFCQ officer, for each mortadella chosen for sampling operations, shall verify compliance with the organoleptic characteristics prescribed in Art. 5 of the Specification.

In case of a non-compliant result, the IFCQ officer orders the exclusion of the entire batch from the PGI and samples another batch to replace the one found to be non-compliant.

On the other hand, in the case of a compliant result, the sampled mortadella is destined for chemical and chemical-physical laboratory analysis. These analyses do not cover pH testing, which is performed by the CB according to the procedures defined in Section 8.1.2.

It is specified that the evaluation of the shape of the mortadella can be carried out by IFCQ on a sample basis, in addition to the sampling stage just mentioned, for any whole PGI mortadella present at any Operator.

The sampling operations of the sampled mortadella are carried out using the following specific operational procedure: the mortadella is partly minced, obtaining three vacuum-packed aliquots, each with a minimum weight of 250 g; of these aliquots, two are taken by the IFCQ officer (one is delivered to the laboratory for chemical and chemical-physical analysis and one is kept by the CB for any related counter-analyses) and one is left at the company identified by the IFCQ officer. Aliquots intended for chemical and chemical-physical analysis should be preserved by freezing.

Chemical and chemical-physical laboratory controls

Chemical and chemical-physical controls are carried out in analytical laboratories accredited in accordance with UNI CEI EN ISO/IEC 17025 using, in line with the provisions contained in Art. 34 of Regulation (EU) No. 625/2017 and the relevant notes of MIPAAF, accredited methods.

The outcomes are reviewed by the Test Result Evaluator (TRE) who issues a "Test Evaluation Report", which is sent to the related Producer. In this document, IFCQ informs the Operator that the sample taken:

- is non-compliant when the results of analysis do not meet the regulated compliance values even when applying the measurement uncertainty;
- is compliant when the results of analysis are within, with or without the application of measurement uncertainty, the compliance values prescribed by the Specification.

In the event that the result of the analysis is compliant, but the analytical result found by the laboratory for at least one of the chemical and chemical-physical parameters analysed is within a range obtained by applying (either by adding or subtracting) the measurement uncertainty to the regulated compliance limit value, IFCQ with the "Test Evaluation Report" notifies the Operator, in addition to the result of the analysis, that additional sampling has been performed regarding another batch to be subjected to the chemical and chemical-physical controls. This sampling activity must be carried out by IFCQ within 30 days after notification of the above Test Evaluation Report.

By way of example: the fat/protein ratio, according to as indicated in Art. 5 of the Specification, must be ≤ 2.00; if in the Test Report issued by the laboratory the uncertainty related to this parameter is ±0.09 and the fat/protein ratio found is between 2.00-0.09 and 2.00+0.09 and that is between the values 1.91 and 2.09 inclusive, IFCQ informs the Operator concerned that the result of the analysis is compliant and further sampling is planned, as specified above.

Request for any counter-analyses

In the event that chemical and chemical/physical laboratory analysis results are found to be non-compliant, the company has five (5) working days from receipt of the Test Evaluation Report to request counter-analyses.

The counter-analysis activity must be carried out using accredited methods, in accordance with the provisions contained in Art. 34 of Regulation (EU) No. 625/2017 and the relevant notes of the

MIPAAF. Revision of the analyses must be performed by an accredited laboratory other than the one that performed the initial analyses.

If Operators wish, they may attend the counter-analysis being properly informed.

Exclusion from PGI of non-compliant product following chemical and chemical-physical laboratory analyses

If the analytical result of the laboratory shows that the product does not comply with the parameters set forth in Article 5 of the Specification, IFCQ shall issue a major non-conformity against the Operator concerned and, if the product has already been marketed, the requirements defined in Section 11.3 shall apply.

8.2 IFCQ CHECKS AT THE PORTIONER/SLICER

IFCQ conducts at least one inspection visit at **100% of the Portioners/Slicers** each year for the purpose of routine inspection activities. Verification may be carried out on already portioned and/or sliced product or, preferably, during the execution of portioning and/or slicing operations.

Each year IFCQ checks at least 2 batches of PGI product received verifying that:

- they are from a recognised entity;
- they are accompanied by a DDT supplemented by the words "Mortadella Bologna PGI" or other wording equivalent to this sales designation with the batch, date of production, weight and size of the mortadella being delivered;
- the portioning/slicing operations took place in accordance with the processing schedule as specified in Section 7.2.

In addition, for each batch examined, IFCQ checks:

- whether the product has already been portioned and/or sliced:
  - that, in case the relevant recording of portioning and/or slicing operations in the "Mortadella Portal" has not yet been carried out, the prescribed recording time has not elapsed; on the other hand, in case the company has already recorded the operations in the portal, IFCQ verifies the correctness of the completion in compliance with as specified in Annex 5 and the prescribed recording time;
  - if there are still packages present at the company, that compliant graphics have been used, according to the requirements of Section 10;

- whether verification is carried out during portioning and/or slicing operations:
  - the conformity of the PGI mortadella to be used;
  - that the product intended for the PGI is packaged in compliant graphics, in accordance with the definition in Section 10.

9. SUMMARY CERTIFICATIONDOCUMENT

IFCQ, having acquired the production of one or more months, having performed the controls that confirmed the suitability of the mortadella with respect to the requirements of the Specification and the CP, shall issue a summary document certifying its conformity, specifying the total weight of mortadella produced suitable for the PGI and, in the case of an Operator carrying out portioning and/or slicing activities, also the total number of packages obtained for the purposes of the PGI.

10. DESIGNATION AND PRESENTATION

Operators may use only graphics for the PGI:

- conform to the requirements defined in the Specification;
- with the words "Certified by Inspection Body authorised by the Ministry of Agriculture Food and Forestry", indicating the reference to the Ministry in full or using the acronym "Mipaaf."

IFCQ verifies, prior to marketing, that the graphics used for marketing for PGI purposes meet these requirements. The inspection is carried out at each Operator at least once a year.

11. NON-CONFORMITY MANAGEMENT

Non-conformity is defined as failure to meet the requirements specified in the Specification or failure to comply with the provisions set forth in the CP, with which subjects must comply for the purpose of placing productions in the Mortadella Bologna PGI circuit. Non-conformities can be detected either by Operators as part of their own self-control activities or by IFCQ during inspection visits or by means of office-based document control.

The Certification Committee is the decision-making body of the CB that decides to adopt the non-conformities inferred from the findings during on-site inspections or in the course of office-based document control activities.

Any major non-conformities detected must be properly handled with the aim of preventing product that does not meet the requirements of the Specification and CP from entering the PGI circuit.

11.1 NON-CONFORMITY MANAGEMENT BY OPERATORS

Operators who detect a non-conformity situation in self-control must proceed according to the following criteria:

- record the non-conformity and define how to manage the non-conforming product in order to bring it back within the expected compliance requirements, if possible;
- make available objective evidence of non-conformities detected and treatments taken;

- provide adequate evidence of the exclusion of the product from the PGI in case the conditions of conformity cannot be restored.

Where the disputed non-conformity involves the exclusion of the product from the PGI, the Operator is required to notify IFCQ of the manner in which the non-conforming product was excluded from the PGI and the corrective actions arranged in order to prevent the recurrence of such non-conformity, retaining the relevant documentation proving the exclusion and corrective actions.

11.2 NON-CONFORMITY MANAGEMENT BY IFCQ

Non-conformity management by IFCQ is applied based on the following general definitions and procedures.

The **determination** by IFCQ of a non-conformity consists of the detection, as a result of control activities carried out during an inspection visit or by means of an ex officio documentary assessment, of failure to meet the compliance requirements of the Specification and/or the CP.

In the case of an inspection visit, the inspector prepares special inspection report in which it formalises what was ascertained in the field by reporting any finding identified. If provided, the survey must contain the precise indication of the batch/batches for which a failure to meet the requirements was found.

IFCQ conducts the review of the inspection documentation including any documentary additions following the audit, which form part of the file for subsequent deliberation by the Certification Committee.

In the specific case of finding, following chemical and chemical-physical laboratory analysis, of non-compliant results, the company has 5 working days from receipt of the Test Evaluation Report to request counter-analyses. After this period has elapsed without a request for counter-analyses, the analytical results are considered confirmed and there may be resolution of the Certification Committee. In case, on the other hand, the Operator requests counter-analyses, their results have final value and the Certification Committee can resolve on the matter only after the counter-analyses themselves have confirmed the non-compliant result. It is specified that in the event that the counter-analyses confirm the non-compliant result, the cost of the counter-analyses shall be borne by the Operator who requested them.

The non-compliance measure, once resolved by the Certification Committee, must be notified to the Operator concerned within 5 working days from the date of resolution of the Certification Committee and no later than 30 working days after the determination of non-compliance itself. Non-conformity **provision** means the provision by which IFCQ defines the circumstances, details and measures applicable to the treatment of a given non-conformity. Specifically, the document sent to the Operator to which the non-conformity is formalised must state:

- the type and date of the assessment;
- the identification abbreviation of the non-conformity;
- the type of document originating the non-conformity and a summary description of it that outlines the details necessary for fact-finding (e.g. identifying details of documents issued in self-control, documents issued in control activities

originating the assessment and/or other useful elements to better focus on the circumstances of non-compliance established);
- the identifying elements of the object of non-conformity involved (e.g. the batch code of the non-conforming product);
- the procedures for handling the non-conformity.

An integral part of the CP is the "Control Scheme", a document in which all non-conformities with their level of severity, the treatment of the non-conformity, and the resulting activity carried out by IFCQ are indicated. The non-conformity is differentiated into "minor - L" and "major - G" as defined in Section 4. Pursuant to Legislative Decree No. 297/2004, a "major" non-conformity must be reported by IFCQ to ICQRF, which will take the prescribed penalty measures.

11.3 MAJOR NON-CONFORMITY FOR ALREADY MARKETEDPRODUCT

In the case of exclusion from the PGI, as a result of a major non-conformity, of product already marketed, the Operator must inform the customer, within 3 working days of receipt of the non-conformity order, that the product does not meet the prescribed requirements; the Operator must give evidence to IFCQ of the communication to the customer and of the actions taken as a result of the information given to the customer (withdrawal of the product from the customer or only downgrading of the product). If the Operator has not informed the customer within the prescribed 3 working days, IFCQ will formalise an additional major non-conformity against the Operator by notifying the relevant measure. IFCQ shall report such major non-conformity to ICQRF with jurisdiction within 3 working days of the notification of such non-conformity.

12. COMPLAINTSAND APPEALS

12.1 COMPLAINTS

If Operators believe that during the inspection activities carried out by IFCQ, non congruous situations (related to, for example, conduct of officers, handling of files, etc.) have occurred, they may submit a formal complaint to IFCQ. The complaint should be addressed to IFCQ management and should contain a description of the situations deemed to be inappropriate. IFCQ will handle the complaint pursuant to specific procedure within 30 days of documented receipt of the complaint. The form for filling out complaints is available at www.ifcq.it.

12.2 APPEALS

Operators may appeal an order issued by IFCQ within 30 days of documented receipt of the order to be appealed. The Appeals Council, appointed according to the current Regulation published on the institutional website of IFCQ, reviews the appeal and makes a judgement on it within 30 days of its receipt. Costs related to the appeal shall be borne by the losing party. The filing of the appeal suspends the effect of the appealed order until the Appeals Council rules. Decisions of the decision-making body on appeals are binding on IFCQ and the appellant and may be appealed only to the Judicial Authority.

13. CONFIDENTIALITY

Without prejudice to the fullfillment of its obligations to the Competent Authorities in charge of the control and supervision of the denomination, IFCQ assures the Operators of the PGI Control System that it will maintain the confidentiality and non-disclosure of all information of which its officers (inspection, technical/administrative staff or members of the Certification Committee) may become aware for relations with Operators for the purpose of carrying out compliance checks.

14. LIST OF ANNEXES

Annex no.	Document name
1	Application for recognition as a Producer
2	Application for Recognition as a Portioner/Slicer
3	Instructions for filling out the Mixing Sheet
4	Instructions for completing the Certification Statement
5	Instructions for filling out the Portioning and/or Slicing Register