



REMADE IN ITALY® TECHNICAL REGULATIONS

REQUIREMENTS FOR REMADE IN ITALY® CERTIFICATION

PRODUCT CERTIFICATION SCHEME UNDER ACCREDITATION

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1. PURPOSE AND SCOPE

The purpose of these Regulations is to set out the requirements, conditions and procedures for the voluntary certification of the content of recycled material and/or by-products present in materials, semi-finished or final products.

In particular, the audit procedures of the accredited Conformity Assessment Bodies for the ReMade in Italy® conformity assessment service and the general requirements of the Organisations manufacturing ReMade in Italy® certified products, including their subcontractors, are described below.

The focus of the ReMade in Italy® certification is the preparation of a model for the traceability of material flows in the production process and the transparency of the operations carried out. It is an effective tool to respond to the growing attention paid to materials obtained from recycling and by-products built around the recent global model of sustainable development known as “Circular Economy”, characterised by maintaining, for as long as possible, the value of products, materials and resources, which are returned in the product cycle at the end of their use, so that the generation of waste is reduced to a minimum, to help develop a sustainable, low-carbon, resource-efficient and competitive economy.

In addition, products obtained from recovery are increasingly required by public administrations. The Public Procurement Code (Legislative Decree 50/2016, Article 34) has made it compulsory to include in all public tenders the minimum environmental criteria (so-called CAM), issued by decree of the Ministry of Environment. The ReMade in Italy® product certification is a means of proof of the recycled material content and is accepted at the tender and at the award stage, in accordance with the provisions of the Public Procurement Code and the CAM.

ReMade in Italy® is a certification scheme recognised by Accredia (the Italian Accreditation Body), developed in an open and widely participatory process which involved Companies belonging to the sector, within the owing association of the same name, founded by a number of competent Institutions, including Conai (Italian Packaging Consortium), the Chamber of Commerce of Milan, MonzaBrianza and Lodi, the Lombardy Region and Amsa Spa.

The following provisions apply only to the possibility of including materials qualified as recycled and/or by-products for the purposes of the issue of the ReMade in Italy® certification and do not in any way relieve the declarant from the mandatory provisions and resulting responsibilities as set out in the Environmental Code (Legislative Decree 152/2006) and the regulations in force.

2 . TERMS, DEFINITIONS AND ABBREVIATIONS

In accordance with the terminology used in this document, the definitions provided in UNI EN ISO 9000:2005, UNI EN ISO 19011:2018, UNI CEI EN ISO/IEC 17065:2012 apply, with particular reference to the following definitions.

Audit: a systematic, independent and documented process for obtaining audit evidence and assessing it objectively to determine the extent to which the audit criteria have been met.

Auditor: a qualified assessor who is competent to audit operators, suppliers and subcontractors under the ReMade in Italy® scheme.

Organisation: an ordered set of people and means, with defined responsibilities, authorities and interrelationships. The organisation can be public or private. For the purposes of these Technical Regulations we refer to the subject, natural or legal entity, who professionally develops, manufactures, processes, sells or imports products that it intends to certify according to the ReMade in Italy® scheme.

Client: Organisation that requests the audit activity to certify the production of a product with certain specifications within the ReMade in Italy® supply chain.

Subcontractor: organisation that operates under subcontract on behalf of an operator within the supply chain.

Non-compliance: deviation of the product from the specified requirements, or the absence of, or failure to implement and maintain one or more necessary elements of the management system provided for in these regulations.

OTHER DEFINITIONS

For the purposes of these Technical Regulations, the following definitions are used.

Product category: one or more group(s) of goods having the same function in terms of use or in terms of functional characteristics with respect to the methods of use. A product category may have subcategories that define its functions or methods of use in a more precise way than the general product category.

European Waste Code (EWC): numerical code consisting of 3 pairs of digits assigned by the waste producer to classify the waste before it is removed from the place of production. The List of EWCs is provided in Annex D to Part IV of Legislative Decree 152/2006, which transposes the contents of Decision 2014/955/EC and introduces the new European waste list (the nature of this Community act does not require a national transposition act).

Recycled material and/or by-products content: proportion, in mass, within a product, of material obtained from recycling and/or reuse of by-products.

Minimum Environmental Criteria (in Italian, CAM): environmental requirements for the specific categories of services, supplies and products, contained in decrees issued by the Ministry of Environment. The Contracting Authorities are obliged, according to Article 34 of the Public Procurement Code (Legislative Decree 50/2016), to implement at least the parts related to the technical specifications and contractual clauses of the CAM in force in the design and tender documentation.

Circular Economy: “(...) an economy that is regenerative by design, both in terms of biological and technical cycles” (Ellen MacArthur Foundation). From the point of view of materials, a Circular Economy is achieved by implementing actions to improve efficiency in the use of resources and to prevent or reduce the negative impact due to waste generation and management, through the recycling of waste as well as the reuse of production and processing waste, allowing its continuous development and innovation. These actions are considered effective in reducing Europe’s dependence on imports of raw materials and improving the overall environment and the well-being of citizens.

End of waste: waste that ceases to be waste when it has undergone a recovery operation, including recycling and preparation for reuse, and meets the conditions set out in Article 184-ter of Legislative Decree 152/2006 and defined

by Community provisions or, failing that, by decrees issued by the Ministry of Environment. Pending the adoption of Community or national provisions dedicated to specific categories, authorisations are issued pursuant to Articles 207, 208, 211 of Legislative Decree 152/2006 and the Decrees of 5 February 1998 (simplified recovery of non-hazardous waste), no. 161 of 12 June 2012 (simplified recovery of hazardous waste), no. 269 of 17 November 2005 (recovery of ship-generated waste) continue to apply. [Legislative Decree 152/2006, Article 184-ter]

Family: set of products having the following characteristics:

- a) they belong to the same product category, with the same production process;
- b) they are made up of the same components relevant to the content of recycled material (e.g. additives, paints, dyes etc. without recycled material content are not to be considered);
- c) their overall weight is the same, except if the difference in overall weight is given only by different scale measurements (e.g. thicknesses, gauges, sizes, etc.).

Green public Procurement (o “Appalti verdi”): the approach according to which Public Administrations implement environmental criteria in all phases of the purchasing process, encouraging the diffusion of environmental technologies and the development of environmentally valid products, through the research and the choice of results and solutions that have the least possible impact on the environment throughout the entire life cycle. It is an environmental policy instrument that aims to encourage the development of a market of products and services with reduced environmental impact by means of public demand. In Italy, GPP has been made mandatory by the Public Procurement Code (Legislative Decree 50/2016, Article 34), within which environmental product certifications with high reliability requirements are recognised as a means of proof.

Preparation for reuse: the check, cleaning, disassembly and repair procedures through which products or components of products that have become waste are prepared so that they can be reused without any further pre-treatment; [Legislative Decree 152/2006, Article 183, paragraph 1, letter q)]

Process: a set of related or interactive activities that transform inputs into outputs.

Product: it is the result of a process and it is the good subject to ReMade in Italy® certification, whose components are made in whole, or in part, of recycled material and/or by-products. The certified product can be a material, a semi-finished or final product. Packaging used to contain and protect certain goods, to allow their handling and delivery from the producer to the consumer or user, and to ensure their presentation, as well as disposable items used for the same purpose are not part of the product; the packaging may be a product subject to certification.

Material recovery: any recovery operation, other than energy recovery and processing of materials that are to be used as fuels or other means to produce energy. It includes, inter alia, preparation for reuse, recycling, backfilling and other forms of material recovery, such as the reprocessing of waste into secondary raw materials for engineering purposes in road or other infrastructure construction. The latter cases can be considered as recycling operations if the use of materials is based on adequate quality control and meets all standards, norms, specifications and environmental and health protection requirements for the specific use.

Recycling: any recovery operation through which waste is processed to obtain products, materials or substances to be used for its original function or for other purposes. It includes the processing of organic material but does not include energy recovery or reprocessing into materials to be used as fuels or for backfilling operations. [Legislative Decree 152/06 and subsequent amendments and additions]

Waste: any substance or object which the holder discards, intends to discard or is required to discard. [Legislative Decree 152/2006, Article 183, paragraph 1, letter a)]

The qualification of waste entails the implementation of the regulatory provisions contained in Part IV of Legislative Decree 152/2006, including, but not limited to, those pertaining to all aspects of its qualification (assignment of the EWC

code), transport (identification forms and loading/unloading registers and/or Sistri), authorised management.

Backfilling: any recovery operation in which suitable non-hazardous waste is used for reclamation purposes in excavated areas or for engineering purposes in landscaping, and where the waste is a substitute for non-waste materials, if suitable and to the extent strictly necessary.

Reuse: any operation by which products or components that are not waste are used again for the same purpose for which they were conceived. [Legislative Decree 152/2006, Article 183, paragraph 1, letter r)]

Recycling: any recovery operation through which waste is processed to obtain products, materials or substances to be used for its original function or for other purposes. It includes the processing of organic material but does not include energy recovery or reprocessing into materials to be used as fuels or for backfilling operations. [Legislative Decree 152/2006, Article 183, paragraph 1, letter u)]

Industrial symbiosis: interaction between different production plants aimed at maximising the reuse of resources normally considered waste (waste and by-products). From an industrial symbiosis perspective, waste produced by a company is reused by another to replace production inputs or to be transformed into new products for the end-user market.

By-product: it is a by-product and not a waste any substance or object that meets all of the following conditions:

- a) it is generated by a production process, of which it is an integral part, and whose primary purpose is not its production;
- b) it is certain that it will be used during the same or a subsequent production process, by the producer or a third party;
- c) it can be used directly without any further processing other than normal industrial practice;
- d) further use is legal and will not lead to adverse environmental or human health impacts. [Legislative Decree 152/2006, Article 184-bis]

These conditions must be proven by those who intend to qualify a substance or object as a by-product. By-products are also the types of substances or objects that fulfil the qualitative or quantitative criteria established by decrees of the Ministry of Environment. To demonstrate the existence of a by-product, please refer to the Ministry of Environment Decree no. 264 of 13 October 2016, and to the Ministry of Environment Explanatory Circular no. 7619 of 30 May 2017, and to the criteria and methods provided for therein.

Materials obtained from a manufacturing process and recovered in the same process that generated them are excluded from the scope of this Technical Regulations.

Traceability: a process that keeps track of the origin and provenance of materials and recycled material and/or by-products during manufacture and up to the release of the final ReMade in Italy® certified product, as well as the subsequent ways in which the product is identified in distribution and sale. The traceability of a ReMade in Italy® certified product must be verifiable by any external party at any time during the period of validity of the certification.

ABBREVIATIONS

For the purposes of these Regulations, the following abbreviations shall apply

RMI: ReMade in Italy®

TR RMI Producers: ReMade in Italy® Technical Regulations “Requirements for ReMade in Italy® certification” (in the latest updated version, as published on www.remadeinitaly.it).

TR RMI CABs: ReMade in Italy® Technical Regulations “Requirements for the recognition of Conformity Assessment Bodies and their accreditation for the purposes of ReMade in Italy® certification” (in the latest updated version, as published on www.remadeinitaly.it).

TR RMI Trademarks: ReMade in Italy® Technical Regulations “Regulations for the use of ReMade in Italy® logos and trademarks” (in the latest updated version, as published on www.remadeinitaly.it).

CAB: Conformity Assessment Body

GPP: Green Public Procurement (or “Appalti verdi”)

CAM: Minimum Environmental Criteria

3. REGULATORY FRAMEWORK OF REFERENCE

These Technical Regulations are part of the current regulatory framework in force (of international, EU, national and regional source) consisting of the rules on:

- protection of the environment, waste management, recycling and use of by-products, including, but not limited to:
 - Legislative Decree 152/2006, Part IV
 - Ministerial Decree of 5 February 1998 (Simplified recovery of non-hazardous waste)
 - Ministerial Decree no. 161 of 12 June 2002 (Simplified recovery of hazardous waste)
 - “End of waste” regulations: Regulation 333/2011/EC for iron, steel and aluminium scrap; Regulation 1179/2012/EU for glass cullet; Regulation 715/2013/EU for copper scrap; Regulation 2019/1009/EU for fertilising products; Ministerial Decree 62/2019 for absorbent hygiene products; Ministerial Decree 69/2019 for bituminous conglomerate; as well as future European regulations or specific national standards, issued pursuant to Article 184-bis of Legislative Decree 152/2006;
 - “Public Procurement Code” (Legislative Decree no. 50 of 18 April 2016, implementation of Directives 2014/23/EU, 2014/24/EU and 2014/25/EU on the award of concession contracts, on public procurement and procurement procedures of entities operating in the water, energy, transport and postal services sectors, as well as for the reorganization of the current regulations on public works contracts, public service contracts and public supply contracts), with special emphasis on the integration of minimum environmental criteria (CAM) in procurements, so-called “Green Public Procurement” (in particular, reference is made to Articles 34, 69 and 82);
 - “Action Plan for sustainable consumption in the Public Administration (PAN GPP)”, Ministerial Decree of 11 April 2008, updated with Ministerial Decree of 10 April 2013;
 - Minimum environmental criteria (“CAM”) implemented by decrees of the Ministry of Environment and published on <http://www.minambiente.it/pagina/i-criteri-ambientali-minimi>
 - Circular Economy rules; so-called “Circular Economy Package” (in particular, Directives 2018/851/EU, 2018/852/EU, 2018/849/EU, 2018/850/EU);
 - technical regulations on environmental labels, environmental management systems and product certifications.

Below are the regulatory references on which these Regulations are based:

- UNI CEI EN ISO/IEC 17065:2012 “Conformity assessment – Requirements for bodies certifying products, processes and services”
- ISO 19011:2018 “Guidelines for quality and/or environmental management systems auditing”
- ISO 9001:2015 “Quality management systems”
- ISO 14001:2015 “Environmental management systems”
- ISO/IEC 14021:2016 “Environmental labels and declarations. Self-declared environmental claims”

The certification scheme under ReMade in Italy® accreditation consists of:

- ReMade in Italy® Technical Regulations “Requirements for ReMade in Italy® certification” (TR RMI Producers, this Technical Regulations, in the latest updated version, as published on remadeinitaly.it/documentazione-tecnica);
- Requirements for the recognition of Conformity Assessment Bodies and their accreditation for the purposes of ReMade in Italy® certification (TR RMI CABs, in the latest updated version, as published on remadeinitaly.it/documentazione-tecnica);
- ReMade in Italy® Technical Regulations “Regulations for the use of ReMade in Italy® logos and trademarks” (TR RMI Trademarks, in the latest updated version, as published on www.remadeinitaly.it).
- Explanatory notes and other documentation published on remadeinitaly.it/documentazione-tecnica.

The prerequisite of ReMade in Italy® certification is the compliance with the applicable mandatory regulations, which are therefore not subject to verification.

4. PRODUCT CERTIFICATION

4.1 CERTIFICATION PROCEDURE

The procedure for the issue of ReMade in Italy® certification is carried out by the CAB accredited and recognised by ReMade in Italy®, or provisionally recognised by ReMade in Italy®, and includes the following steps:

- a) submission of the application for certification to the CAB, by the applicant Organisation;
- b) review of the application for certification;
- c) planning of assessment activities;
- d) assessment of compliance with these Regulations, including verification of the quantification of the content of recycled material and/or by-product used, carried out by the CAB by means of analysis of the documentation submitted and field audits;
- e) review of all information and results related to the assessment;
- f) decision on the issue of ReMade in Italy® certification;
- g) in the event of a positive outcome, issue of the certificate with assignment of the ReMade in Italy® class (see TR RMI Trademarks, point 4.2);
- h) assessment of continued compliance with these Regulations.

The certificate issued by the CAB is valid for three years and must be reviewed at least once a year.

4.2 GENERAL REQUIREMENTS OF THE ORGANISATIONS

4.2.1 Scope of the certification

The Organisation must define the scope of the certification, i.e. it must unambiguously identify the products it intends to have certified according to these Regulations.

It must also identify the physical size to which the percentage of recycled material and/or by-products should be referred, where weight cannot be used.

Changes to the products included in the scope of certification (e.g. the class to which they belong, see TR RMI Trademarks, point 4.2), must be promptly notified to ReMade in Italy® and the CAB.

4.2.2 Product related documents

For the certification of a product, the Organisation must prepare a technical data sheet, constantly updated, in which the components and the percentage by weight of these components are clearly indicated, with specific indication of those coming from recycling and/or by-products.

A single technical data sheet can also be prepared for all the products to be certified.

The technical data sheet must include the following information:

- a) name and identification data of the Organisation which issues this document;
- b) trade name and type of product;
- c) minimum unit of reference, and relevant physical size, for the declaration of percentage of recycled material and/or by-products, as per sales specification (e.g. piece, kg, m²);
- d) weight of the certified product and total percentage of recycled material and/or by-products contained;
- e) description of product components;

- f) indication of the percentage by weight of the components containing
- g) for each component containing recycled material and/or by-products, the name and type of the raw materials used for its production;
- h) European waste codes from which the recycled material is obtained;
- i) the references of the contract and/or the technical data sheet for the qualification of by-products (paragraph 4.3.2.2).

For products subject to continuous processing, the declared percentages may be indicated as six-month averages.

For each certified product, a flow chart must be attached to the technical data sheet, specifying the different units of the process of which the production system is composed, describing all material inputs, all material flows and all material outputs.

4.2.3 Responsabile per la certificazione ReMade in Italy®

Within the Organisation, a person must be appointed who is responsible for ensuring compliance with these Regulations. The person of the Organisation in charge for compliance with these Regulations is responsible for:

- a) implementing the actions necessary for the Organisation to comply with these Regulations;
- b) reporting to the Management on the implementation of these Regulations;
- c) ensuring check of the documentation necessary for compliance with the Regulations;
- d) maintaining relations with ReMade in Italy® and the CAB.

4.2.4 Human Resources

Personnel involved in any capacity in compliance with these Regulations must be competent and aware of their role in the implementation of the same.

The Organisation shall provide training and education to the personnel involved in compliance with these Regulations to ensure their competence and awareness and shall keep record of these activities.

The Organisation shall also periodically assess training and education needs and ensure that such activities have been effective in terms of the objectives to be achieved.

4.2.5 Documentation

4.2.5.1 Records

Up-to-dated and complete records concerning all relevant points of these Regulations must be kept and stored.

4.2.5.2 Instructions and operating procedures and other documentation

The Organisation shall prepare the necessary instructions, operating procedures and other documentation, including computerised documentation, to ensure the effective implementation of the requirements of these Regulations. This documentation should be checked and periodically updated.

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The Organisation shall prepare the necessary instructions, operating procedures and other documentation, including computerised documentation, to ensure the effective implementation of the requirements of these Regulations. This documentation should be checked and periodically updated.

4.2.6 Internal audits

The Organisation must define a programme that includes, at least annually, internal audits to ensure the correct compliance with the ReMade in Italy® Regulations.

This programme shall take into account all applicable points in these Regulations, including the activities of subcontractors. In particular, a traceability test and a mass balance must be carried out as described in requirements 4.3.3.3 and 4.3.3.4, respectively.

Note: the audit plan and programme must be developed taking into account the status and importance of the processes and areas to be audited and the results of previous audits.

The selection of auditors should ensure product competence and the conduct of audits shall ensure the objectivity and impartiality of the audit process.

Records of the results of the audit, including any corrective actions resulting from findings made during the audit, must be kept and reported to the Management, as well as made known to the personnel concerned by the findings.

4.2.7 Periodic review by Management

The Management must review the system of compliance with the Regulations at least annually, or whenever the production processes of the ReMade in Italy® certified product are changed.

On the basis of this examination, the necessary corrective or improvement actions must be taken.

This examination must include at least the following:

- a) the results of the traceability tests and the mass balance concerning each certified product;
- b) the results of internal and external audits (e.g. the CAB);
- c) process changes;
- d) information relating to the certified product, its components or raw materials;
- e) assessment of the Organisation's need for resources;
- f) corrective actions to problems and non-conformities related to traceability and internal and external audits;

Note: corrective actions are those actions aimed at eliminating the causes of the problems and non-conformities.

- g) any feedback from ReMade in Italy® Association and clients, including complaints;
- h) new or amended laws and regulations affecting traceability or impacting on the certified product or parts thereof with particular attention to the recycled component;
- i) the actions taken after previous periodic reviews.

4.3 MONITORING THE PERCENTAGE OF RECYCLED MATERIALS AND/OR BY-PRODUCTS IN THE PRODUCTION PROCESS

4.3.1 Monitoring of suppliers

4.3.1.1 List of suppliers

The Organisation must define, and keep updated, a list of its suppliers and the recycled materials and/or by-products supplied by them that make up the ReMade in Italy® certified product.

The supplier list must always include the following information:

- a) name and address of the supplier;
- b) type of product supplied;
- c) any authorisations required to carry out the activity;
- d) whether the product supplied is derived from recycling activities and/or by-products in whole or in part;
- e) any ReMade in Italy® certifications, or equivalent certifications, i.e. having the same subject as ReMade in Italy® certification, issued by an accredited CAB for the specific certification scheme by an Accreditation Body signatory to the EA-IAF/MLA multilateral agreements for the field of accreditation of interest (see paragraph 5).

4.3.1.2 Qualification criteria

Criteria must be defined and applied for the selection, assessment and periodic re-assessment of suppliers to ensure their effective monitoring for the purposes of these Regulations.

The presence of a fully valid ReMade in Italy® certification is a sufficient criterion for the qualification of the supplier and the product to which this certification refers.

4.3.2 Input material

4.3.2.1 Documentation relating to input material

The Organisation must be in possession of the documentation provided by the supplier proving the content of waste, recycled material and/or by-products in the material used, in the semi-finished or final product it intends to certify.

Examples of such documentation may be:

- a) binding documentation such as waste accompanying forms;
- b) compliance documentation required by EU or national standards on the so-called “End of waste”;
- c) declarations by authorized waste recyclers to certify the characteristics of the recycled material;
- d) declarations by entities authorised to perform the activity of preparation for re-use, to certify the characteristics of the reused material;
- e) documentation suitable to qualify a substance or material as a by-product, in accordance with the regulations in force and as indicated in paragraph 4.3.2.2;
- f) ReMade in Italy® certification or equivalent certification recognised by ReMade in Italy®, i.e. with the same subject of certification and issued by an accredited CAB for the specific certification scheme.

A list of certifications allowed under point f) above is published on the remadeinitaly.it website (Technical Documentation Section). The list, which is constantly updated, is not to be regarded as exhaustive and may be checked on a case-by-case basis. If none of the above provisions apply, the relative amount of material shall be considered as not recycled and/or not containing by-products.

4.3.2.2. By-products

The documentation indicated below is suitable for the qualification as a by-product, within the scope of the purpose of these Technical Regulations:

- a) a contract between the waste producer, any intermediaries and the users, from which information on the technical characteristics, the methods of use and the conditions of transfer of by-products must be obtained, which must be advantageous and ensure the production of an economic or other benefit; or, failing that
- b) technical data sheet containing the information indicated in Annex 2 to the Ministry of Environment Decree 264/2016, necessary to allow the identification of the by-products whose use is envisaged and the identification of their technical characteristics, as well as the sector of activity or the type of plants suitable for their use. The technical data sheet also indicates the appropriate timing and methods for the storage and handling of by-products, from the production of the waste to its use in the destination process. In case of substantial changes in the production or destination process of the by-product, such as to involve changes in the information yielded, a new technical data sheet must be prepared. The data sheets are sent, without economic burden for the producer, to the territorially competent Chambers of Commerce, according to the provisions of the Ministry of Environment Decree 264/2016; documentation must be provided to prove the sending.

4.3.2.3 Input material inspection

The Organisation must verify, upon receipt or before further use, that the material supplied corresponds to what is specified in the supplier's documents, and to the order placed, and that it is therefore considered suitable both in nature and origin, so as to guarantee its correct use for the purposes of ReMade in Italy® certification.

4.3.2.4 Identification of input materials

In order to ensure that their characteristics are maintained, products supplied for the manufacture of products subject to ReMade in Italy® certification must always be clearly identified so that they cannot be confused or miscible with other stored products.

4.3.3 Mass balance and traceability

Certified products and their components must be identified and traceable throughout all stages of their manufacture.

4.3.3.1 Product composition

The Organisation must define, for each product falling within the scope of ReMade in Italy® certification, the raw materials necessary to produce it, specifying their percentage in the product, in absolute terms and in terms of weight. If the certified product is composed of more than one raw material/component, the percentage of recycled raw material present must be specified and demonstrated for each of them, as provided for in the technical data sheet (see point 4.2.2 above).

4.3.3.2 Register

A registration system shall be in place for each certified product to allow for the monitoring of the declarations concerning the percentage of recycled material in each production batch.

4.3.3.3 Traceability plan

To ensure the traceability of the materials used in the manufacture of the certified product, the Organisation must establish and implement a traceability plan.

This plan must consider the requirements relating to input raw materials (see point 4.3.2 above) and output products (point 4.3.4) in order to ensure the correct application of these Regulations.

4.3.3.4 Mass balance

Periodically or at least once a year (six months for products subject to continuous processing), the Organisation, for each product falling within the scope of ReMade in Italy® certification, must verify, by calculating the mass balance, that the quantities of products manufactured and the declared percentage of recycled material and/or by-products used are consistent with the raw materials used.

Any conversion factors may be used in the calculation, provided that their validity can be demonstrated by the Organisation itself.

4.3.4 Output products

4.3.4.1 Identification and storage

In order to ensure that their characteristics are maintained, output certified products must be clearly identified so that they cannot be confused or miscible with other stored products.

4.3.4.2 Certified product sales documents

The Organisation shall ensure that the sales and delivery documents include at least the following information:

- a) name and address of the Organisation;
- b) date of issue of the certificate and related code;
- c) description and quantity of the certified product;
- d) indication of the percentage of recycled material and/or by-products contained in the certified product.

4.3.5 Subcontracting

The Organisation may subcontract a process included in the production of the products subject to certification. The Organisation is responsible for all activities subcontracted related to the manufacture of ReMade in Italy® certified products.

4.3.5.1 Contract

The Organisation must prepare a written agreement with all subcontractors involved in the manufacture of ReMade in Italy® certified products to ensure that:

- a) the material used for the manufacture of ReMade in Italy® certified products can be traced and checked and cannot be mixed with other materials;

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- b) the subcontractor keeps records of inputs, outputs and delivery documentation for the products involved in the agreement;
- c) it is forbidden to subcontract again the process to subcontractors who do not have a written agreement with the

Organisation or who are not certified by ReMade in Italy®;

d) the subcontractor cannot use the ReMade in Italy® trademarks, or make any communication, for promotional purposes with reference to ReMade in Italy® certification.

The Organisation reserves the right to carry out and/or have carried out, by the accredited CAB, audits on the process.

4.3.5.2 List

The Organisation shall draw up a list including:

- a) name of the subcontractor;
- b) subcontracted activities;
- c) risk analysis.

4.3.5.3 Risk analysis

The Organisation must carry out a risk analysis on its subcontractors, who are not ReMade in Italy® certified for the required processing. This analysis is aimed at identifying the activities at risk that require auditing in order to ensure that the product complies with the requirements of these Regulations.

Note 1: subcontractors who have one or more of the following characteristics are considered to be at risk:

- a) the subcontractor classifies the input material, i.e. manages materials made up of different percentages of recycled material and/or by-products that are not clearly identifiable;
- b) the production site is in a different country than that of the Organisation;
- c) the subcontractor does not make the material available to the Organisation at the end of its process, i.e. sends the product directly;
- d) the subcontractor affixes the ReMade in Italy® label to the product.

4.3.6 "Italianità" (Italian identity) of the product

Products having the following characteristics may be included in the certification for the purposes of these Regulations:

- a) the final products to which the writing "Made in Italy" is affixed, which must be indelibly and immovably affixed to the product and/or its primary packaging;
- b) the products whose main production process or at least last stage of processing that modified the physical, dimensional, performance or content characteristics took place in Italy. This category does not include those products packed in Italy or filled in Italy in which the last significant stage of processing took place abroad.

4.3.7 List of necessary documentation

The Organisation shall prepare and keep updated the following documentation:

- a) organisation chart identifying the roles and responsibilities of the subjects involved in the ReMade in Italy® certification and the related job description;
- b) procedure for the qualification of the supplier of products related to ReMade in Italy® certification;
- c) procedure for the control and acceptance of the incoming product;
- d) procedure for the identification of the product during storage and processing;
- e) procedure for the verification and traceability and for the calculation of the annual mass balance;
- f) procedure for the labelling of certified products;

- g) the Register indicated in point 4.3.3.2;
- h) the Traceability Plan indicated in point 4.3.3.

4.3.8 Definition of the percentage of recycled material

Recycled material and/or by-products content declarations concerning ReMade in Italy® certified products must always be made stating the percentage of recycled material and/or by-products contained therein.

The content of recycled material and/or by-products must be expressed quantitatively as a percentage, calculated as follows. As there are no methods available for the direct measurement of the content of recycled material and/or by-products in a product, the mass of the material obtained from the recovery process should be used, after calculating losses and other deviations.

$$X (\%) = (A/P) \times 100$$

X is the recycled material content, expressed as a percentage

A is the mass of recycled material

P is the mass of the product

5. RECOGNITION OF PRODUCTS WITH OTHER CERTIFICATIONS

For the purposes of the ReMade in Italy® certification, other product certifications may be recognised as proof of some of the requirements of these Regulations, in particular those set out in point 4.3.

The certifications assessed and approved by ReMade in Italy® for this purpose can be found in the Annex “Other recognised certifications”, published on the website www.remadeinitaly.it, where it will be indicated, in addition to the identifier, also the specific point considered fulfilled by the relative possession.

6. AUDITS

6.1 SAMPLING AND DURATION OF AUDITS

The duration of the audits for the issue of the ReMade in Italy® certification depends on the number of samples to be taken, determined as follows.

During the audits, which must be carried out at least once a year, all the requirements of this document must be assessed; for sampled products, the implementation of the requirements of the previous chapter 4.3 must be fully verified.

The documents analysis must be carried out every time products to be certified are evaluated for the first time; during inspections, in the absence of new products or significant changes to the production process, only the field audit is carried out.

For the determination of the number of samples, the following instructions apply:

- 1) according to the number of families subject to certification, the number of samples is determined as follows (Table 1):
- 2) the sampling must be representative of all product categories, provided that the production processes of the products subject to certification are different, during the three-year period of validity of the certification.

TABLE 1 – SAMPLING BY FAMILY, AUDIT DURATION AND FEE

NUMBER OF FAMILIES SUBJECT TO CERTIFICATION	MINIMUM NUMBER OF FAMILIES TO BE SAMPLED*	MINIMUM AUDIT DURATION		FEE**
		MINIMUM DOCUMENTARY ANALYSIS DURATION	MINIMUM FIELD ANALYSIS DURATION	
from 1 to 5	1	0,5 days	0,5 day	FEE x 2
from 6 to 10	2	0,5 days	1,0 day	FEE x 2,5
from 11 to 20	3	0,5 days	1,5 days	FEE x 3,0
from 21 to 30	4	0,5 days	2,0 days	FEE x 3,5
from 31 to 45	5	0,5 days	2,5 days	FEE x 4
Over 45	The $\sqrt{\quad}$ approximated by excess	0,5 days	previous range, over 0.5 days	To be determined

* If the family includes more than 20 products, it is necessary to audit at least two products within the family.

** FEE are collected by the Conformity Assessment Body on behalf of ReMade in Italy® Association. The economic value in Euro of the FEE is set out in the Agreement signed by ReMade in Italy® Association with the Conformity Assessment Body (ref. Point 6.6 TR RMI_CABs).

6.2 INCREASE AND REDUCTION IN AUDIT TIME

Reduction

Audit time may be reduced, according to the assessment of the Conformity Assessment Body, in the following cases:

- 1) for Organisations holding an ISO 14001 certificate issued under accreditation, by bodies that are signatories to the EA/MLA agreements for such schemes, and whose scope is the manufacture of the products for which certification has been requested: reduction in the duration of field audit by 0.5 days. In this case the CAB, in making its decisions, during the entire certification process, must also evaluate the results of the ISO 14001 audits;
- 2) for Organisations holding the certifications listed in Section 5: reduction in the duration of field audit by 0.5 days;
- 3) for Organisations that manufacture products with all RMI certified recycled components: reduction in the duration of field audit by 0.5 days.

The reduction in duration mentioned in the previous points cannot be cumulated. In any case, the minimum duration of the audit is 1 day.

Increase

Audit time may be increased in the following cases:

- 1) in case of multi-site Organisations: increase in the duration of field audit by 0.5 days for each production site, without sampling;
- 2) in cases of subcontracting, the CAB must assess the qualification and control criteria of the subcontractors used by the company: increase in the duration of the audit by 0.5 days for each subcontractor audited.

Any increase or reduction in the duration of the audit, applied at the Conformity Assessment Body's discretion, do not affect the determination of the FEE, for which reference is made to in Table 1.