Certification Scheme

Products and components in contact with food according to MOCA (FCM) regulations
SCPE MOCA

06	30.03.2022	Review and regulatory update	OPE	GEA DIR GOV	DIR OPE
05	12/03/2021	Regulatory update and additions to the Initial Tests and Surveillance Tests paragraphs following Accredia requests	OPE	ISG	DIR OPE
04	21/10/2019	Integration after Accredia requests	OPE	ISG	DIR OPE
03	26/07/2019	Integration after Accredia requests	OPE	ISG	DIR OPE
02	31/01/2019	Revision after ACCREDIA document verification	OPE	ISG	DIR OPE
01	20/03/2018	Addition of annex 4	OPE	ISG	DIR OPE
00	15/08/2017	Issue	OPE	ISG	DIR OPE
Rev.	***Date***	***Description***	***Drawn up***	***Verified***	***Approved***
IDENTIFICATION: 0445CS_06_EN					

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PRODUCT/SERVICE DESCRIPTION

DEFINITION
The certification scheme defines the methods and conditions that an Organisation must comply with to obtain and maintain Certification of its products as "Materials and articles intended to come into direct or indirect contact with foodstuffs", in short MOCA, issued by ICIM and to be registered in the Registry of Businesses/Product in possession of Certification (Registry). *The relevant regulations and regulatory documents state that all materials and articles, including active and intelligent materials and articles, must be produced in accordance with good manufacturing practice and, under normal or foreseeable conditions of use, must not transfer components to the food in quantities that:* ▪ *constitute a danger to human health* ▪ *lead to an unacceptable change in the composition of foodstuffs* ▪ *lead to a deterioration of the organoleptic characteristics.* *The scheme is applied to certify materials and articles, including active and intelligent (defined below as **products**), to the status of finished products:* *a) that are intended to come into contact with foodstuffs;* *b) that are already in contact with foodstuffs and are intended for this purpose;* *c) which are reasonably expected to be put in contact with foodstuffs or to transfer their components to foodstuffs under normal or foreseeable conditions of use, according to the requirements defined in the Annexes of this certification scheme.* *These requirements have been developed with reference to national, European and national laws and standards.* *No substances or materials for the manufacture of products and components, or impurities associated with these substances or materials, must remain in food in concentrations higher than those permitted for the purpose of their use and must not, either directly or indirectly, reduce the protection of human health.*
REFERENCE STANDARDS

Standards and Regulations valid at the date of this document

REGULATIONS

ICIM 0001CR *ICIM General Regulation*

ICIM 0003CR *Regulation for the certification of products and services*

ICIM 0260CR *User manual of the ICIM S.p.A. Certification Marking*

LAWS

Decree of the President of the Republic no. 777 of 23 August 1982, *Implementation of (EEC) Directive no. 76/893 concerning materials and articles intended to come into contact with foodstuffs.* (*O.J. no. 298 of 28 October 1982)*

Legislative Decree no. 108 of 25 March 1992, *Implementation of Directive no. 89/109/EEC concerning materials and articles intended to come into contact with foodstuffs. (Ordinary Supplement no. 31 of the Official Journal no. 39 of 17 February 1992)*

Regulation (EC) no. 1935/2004 *of the European Parliament and of the Council concerning materials and articles intended to come into contact with foodstuffs and repealing Directives 80/590/EEC and 89/109/EEC. (Official Journal of the European Union series L 338 of 13 November 2004)*

Regulation (EC) no. 2023/2006 *on good manufacturing practices of materials and articles intended to come into contact with foodstuffs (Official Journal of the European Union series L 384 of 29 December 2006)*

Legislative Decree no. 29 of 10 February 2017 *Discipline of sanctions for the violation of provisions set forth in regulations (EC) no. 1935/2004, n. 1895/2005, n. 2023/2006, n. 282/2008, n. 450/2009 and n. 10/2011, on materials and objects intended to come into contact with food and food products (O.J. no. 65 of 18 March 2017)*

-applicable only to operators of the FCM supply chain who carry out their activities in Italy

List of specific provisions

The specific applicable provisions are indicated in the sheets referred to in Annex 1

STANDARDS

UNI EN ISO 22000 *Food Safety Management Systems - Requirements for any organisation in the food supply chain*

UNI EN 15593 *Packaging. Hygiene management in the foodstuffs packaging production. Requirements*

UNI EN 1672-2 *Food processing machinery - Basic concepts - Part 2*: *Hygiene requirements*

DESCRIPTION

To certify products, materials and articles, which in the finished product state, are intended to come into contact with food substances, which, due to the composition or disposal of components do not:

a) make food substances noxious or harmful to public health;

b) change the organoleptic properties of foods unfavourably.

These provisions also apply to materials and articles that may come into contact with food substances during processing or the preparation thereof.

The certification scheme verifies and approves products that meet the purity requirements and disposal tests to which the materials and articles must be subjected to determine the suitability for their intended use, as well as the limitations, tolerances and conditions of use, both for the limits of food contamination and for any dangers resulting from oral contact.

This diagram applies to the following MATERIALS which make up the finished product:

- *Plastics, including adhesives, paints and coatings*
- *Regenerated cellulose*
- *Elastomers and natural rubber*
- *Paper and paper board*
- *Ceramics*
- *Glass*
- *Metals and alloys*
- *Wood, including cork*
- *Textile products*
- *Paraffin and microcrystalline waxes*
- *Silicones*
- *Ion exchange resins*

This certification scheme does not apply to:

a) materials and articles which are supplied as antiques;

(b) covering or coating materials, such as the materials covering cheese rinds, prepared meat products or fruits, which form part of the foodstuffs [...] and may be consumed together with it;

(c) fixed public or private water supply equipment.

For the procedures for verifying the compliance of the materials with the reference standards see Annexes 2 and 3 of this scheme.

Definitions used in the scheme:

Manufacturing and Control Plan (MCP): *Operational planning tool of the Organisation which sets forth in detail the sequences of the manufacturing activities and/or processes and the control methods which affect product quality with reference to the relative regulatory documents.*

Series/Family: *Group of products which have homogeneous technical and construction features.*

Traceability*: this means the possibility of reconstructing and following the path of materials or articles through all stages of processing, transformation and distribution.*

Intelligent materials and articles*: this means materials and articles intended to come into contact with foodstuffs, which control the conditions of the packaged foodstuff or its environment.*

Good manufacturing practice (GMP) *for groups of materials and articles intended to come into contact with food contain all aspects of quality assurance which ensure that materials and articles are constantly manufactured and controlled, to ensure conformity with the standards applicable to them and with the quality standards appropriate to their intended use, by not endangering human health or causing an unacceptable change in the composition of the foodstuff or causing a deterioration in the organoleptic characteristics thereof;*

Non-food-contact side*: this means the surface of the material or article that is not directly in contact with foodstuff;*

Food-contact side: *this means the surface of a material or article that is directly in contact with the foodstuff.*

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IDENTIFICATION CHARACTERISTICS
The basic characteristics that identify the series/family of homogeneous products (models) are the following: *a) TYPE: The products belonging to the same series/family must be of the same type, i.e. perform the function for which they are designed in the same way.* *b) MATERIALS: The products belonging to the same series/family must have homogeneity of materials and treatments used for the components.*
*The characteristics that are allowed in the **variants**, provided they are declared in the construction drawings and in the bill of materials, are the following:* *MATERIALS: Alternative surface treatments or materials used for customisation as long as they come with suitable documentation provided by the manufacturer*

GENERAL CONDITIONS OF CERTIFICATION

CERTIFICATION TYPE
VOLUNTARY *Involves affixing the ICIM mark as per the document ICIM 0260CR.*
TYPE OF INTERVENTION
ICIM operates according to ICIM regulation 0003CR, there are no additional requirements to those indicated by the reference standards and laws.

CERTIFICATION APPLICATION

ADDITIONAL DOCUMENTATION
The additional documentation in relation to what is required by ICIM regulation 0003CR, is the following: ▪ *Document illustrating the production of the Organisation (catalogues, advertising material, etc.);* ▪ *copy of the Quality System Certification in compliance with the UNI EN ISO 9001 standards* ▪ *technical documentation of the product subject to the Application (see following paragraph)* *The Application, where required, shall be accompanied by specification of the place where the product subject to certification can be examined and taken.* *This documentation should not include detailed plans of the construction details and other detailed information, concerning the sub-assemblies used for the manufacture of the product, unless the Organisation deems that knowledge of them is necessary for verification of conformity with the reference standards and regulations.*

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TECHNICAL DOCUMENTATION
The technical documentation of the product **SUBJECT** *to the Application must be drafted in Italian (if the Organisation is not Italian, then English or another language accepted beforehand by ICIM can be used) and sent to ICIM, for each type, for each variant and for each Production Unit, possibly on electronic support (CD rom or non rewritable DVDs) or sent by email.* *It provides details on the characteristics and technical requirements of the products, according to the normative reference document; in particular, it also provides details on the characteristics of compatibility of the materials and articles in contact with food.* *Any subsequent changes to what is indicated in the technical documentation must be documented and communicated to ICIM before actually proceeding to the execution phase, in accordance with the provisions of this certification scheme and regulation ICIM 0003CR.* *The technical documentation must have an index and include at least:* ▪ *Manufacturing and Control Plan, with any support procedures, and the product traceability system,* ▪ *facsimile of the marking (on product, packaging and accompanying documents),* ▪ *reproduction of the registered trademark and/or product mark (if any),* ▪ *elements to identify the series/family of products subject to certification (identification of models and construction variants),* ▪ *product bill of materials,* ▪ *assembly drawings with an explanatory section on the operation of the product and reference to the materials of the components in direct contact with the food or that may come into contact with the food;* ▪ *list of materials of components of the product classified according to European standards;* ▪ *verifiable or documentable chemical-physical characteristics of the materials used* ▪ *for components made of plastic declaration of conformity to Reg. EU no. 10/2011 of the raw material and of the materials used as auxiliaries (e.g. additives)* ▪ *for components in elastomeric material: declaration by the manufacturer with the reference compound and declaration that the material contains substances permitted by national or international legislation (eg FDA) relating to materials intended for contact with food with the conditions, limitations and tolerances of use provided therein.* ▪ *for components in metallic material data relating to the composition of the metallic material* ▪ *for all other materials, all data regarding the composition thereof* ▪ *any heat treatment (where applicable),* ▪ *any surface treatments (e.g. galvanising, painting, etc.),* ▪ *installation, use and maintenance instructions,* ▪ *information on:*   ▪ *Name of the Production Unit, if different from the Organisation requesting product certification*   ▪ *Place or places of manufacture,*   ▪ *Relations between the applying organisation and the manufacturer (for example contracts),*   ▪ *copy of the agreements with main suppliers (where applicable)*

CERTIFICATION

APPLICATION EXAMINATION
METHOD TO BE APPLIED

ICIM evaluates the completeness and the contents of the documentation of the Application and of the annexes as per ICIM regulation 0003CR.
From the detailed analysis of the data provided by the Organisation, ICIM carries out the assessment of the materials that the product is made up of and the verification of the conformity of all the substances used for the manufacture of the product with the requirements defined in the Annexes. In addition, ICIM defines the congruity of the product families submitted for certification.
ICIM proceeds, therefore, with the definition of the following actions:

- *characteristics and number of samples to be examined;*
- *initial tests to be carried out defining the substances/parameters to be analysed against the Annexes;*
- *initial audit programme.*

APPLICATION EXAMINATION REPORT

The completeness of the information contained in the certification application is checked by the Sales Manager for the specific scheme with the support of the Technical Manager for the specific scheme and is drafted in a specific report, specifying, where necessary, recommendations or nonconformities and indicating the adequacy or inadequacy of each applicable item. The points marked with the letters "NA" mean 'not adequate' and if not resolved correctly entail a negative judgment on the safety of the product. The points marked with "A" (adequate) are considered compliant.

INITIAL AUDIT (IA)

METHOD TO BE APPLIED

The initial audit (IA) is carried out as indicated in ICIM regulation 0003CR to ensure compliance with the requirements set forth in the documentation taken as reference and involves at least the verification:

- *of the design (design status and modifications), where applicable*
- *of the Manufacturing and Control Plan (checks in acceptance, intermediate finished products, storage, etc.), also by analysing the possible pollutants that remain on the product during the processing phases*
- *of the availability and adequacy of the means of production and control in production*
- *of traceability during production phases*
- *of non-conformity management*
- *of the quality records*
- *of measuring instruments and test and testing equipment management*
- *of the company laboratory and internal test procedures (if applicable)*

During this phase the products to be tested are taken (sampling, see ITT)

IA REPORT

The audit is drafted in a specific report, specifying, where necessary, recommendations or nonconformities and indicating the adequacy or inadequacy of each applicable item. The Organisation is issued a copy of the report as a notification of the operation. The checklist is countersigned by the Organisation as acceptance of all issued findings.

Other

The Organisation can however initiate a review procedure following the procedure described in ICIM Regulation 0001CR.

INITIAL TESTS (ITT)

METHOD TO BE APPLIED

The type tests are performed on representative samples in external or internal laboratories UNI EN ISO IEC 17025 accredited and/or qualified and periodically verified by ICIM.
The samples will be taken by ICIM during the IA and sent by the Organisation to the testing laboratory.

Sampling
The selection and conformation of the testing sample/s representing the type subject to the Application must be such to allow the ITT to classify the product according to the reference standards.
As part of the Initial Audit, the GI performs the sampling for the Initial tests by choosing the samples for the initial tests from the current production and/or from the factory warehouse or from the retailer.

The type of samples representative of the current production to be taken at the factory or from the market for the execution of the tests is defined by the series/family type of materials and any treatments that characterise the components).

During the Initial Tests all materials in contact with food are tested ***all materials*** *in contact with food by choosing a model / component for each of the families in certification as indicated below:*

a) *The model / component that will be tested will be the one that (within the series / family) will have the most critical geometry in relation to the Surface / Volume ratio (higher S / V ratio are more critical).*
b) *If it is not possible through documentary analysis to uniquely identify the most "critical" model / component, samples will also be taken of other variants, which will be subjected to pre-tests (partial tests to analyze any critical issues).*

The tests to be carried out are those required for the verification of the requirements of the regulations, laws, and regulations in Annexes 1, 2, 3 and 4 relating to the individual materials that characterize the components of the product in contact with food or that may come into contact with food.

The initial tests, if carried out at the Organisation, are conducted in the presence of inspectors appointed by ICIM. The conducted audit is recorded on the report forms issued by ICIM.
The test laboratories must be accredited or qualified by ICIM according to the established procedures (reference standard UNI EN ISO IEC 17025). The individual analysis tests must be accredited in accordance with UNI EN ISO IEC 17025; if they cannot be accredited, ICIM will intervene by qualifying them against the requirements of UNI EN ISO 17025. The purchase order relating to the initial tests must refer to the Annex to the RDA document relating to the tests to be carried out according to this scheme; where a contract is available between ICIM and the Laboratory in charge of the tests, the aforementioned conditions must be indicated in the same.
Objective of the tests
Verify that all materials (including the variants) used in products intended for contact with food, or that may come into contact with food, do not alter the characteristics of the food as per the regulatory documents and regulations of reference.
During the tests, the requirements of purity and transfer data will be verified, as well as the limitations, tolerances and conditions of use both for the limits of food contamination and for any dangers resulting from oral contact.

Evaluation of results
ICIM asks the Laboratory in charge of the tests to indicate in the test reports the conformity of the result with the applicable legislation and accepts the decision-making rule on the basis of which this conformity is expressed.
If the results of the tests carried out on the individual materials that the product is made of are within the range of the provisions of the Annexes, the product tests (Series/family) comply with this scheme.
In the case of negative results, the provisions of ICIM regulation 0003CR apply.
Any "border line" values will result in the repetition of the test in the next visit after modifying the sampling already planned and if the test confirms the aforementioned values, an additional quotation will be prepared for its repetition.

ITT TEST REPORT
The conducted audit is recorded in the report forms issued by the laboratory. The outcome of the tests is reported on a special report stating if the test is positive or negative.
NOTE
In the event of complaints or appeals related to the results of laboratory analyzes carried out both during ITT and subsequently in annual surveillance or renewal, ICIM will use for the product reviews an alternative laboratory to the one that carried out the finished tests under complaint. ICIM in this case will use laboratories or accredited for specific tests by ACCREDIA (or other ILAC MRA body) or qualified by ICIM for specific tests, if there are no accredited laboratories available.

ISSUING THE CERTIFICATION

OUTCOME
The technical documents submitted by the Organisation, the results of the audits and the outcome of the tests are evaluated. ***For the final assessment set forth in ICIM Regulation 0003CR is followed.*** *The findings issued are managed according to ICIM doc regulation 0003CR.* *In the event of a negative outcome, the Organisation can however initiate a review procedure following the procedure described in ICIM Regulation 0001CR.*
APPROVAL COMMITTEE
No variation with respect to the specific procedure of the Approval Committee. The proposer is the Technical Coordinator or the Competence Center Manager, the Decision Maker is the Technical Director assisted if necessary by a Technical Expert.
CERTIFICATE
After successful completion of previous interventions and after the review and evaluation of the Approval Committee, ICIM draws up a Product Certificate specifying at least: ▪ *Name and address of the Organisation,* ▪ *Identification of the Production Unit (also with code) if different from the Organisation,* ▪ *Certificate Number thus composed ICIM/MOCA/XXXXXX (XXXXXX certificate number)* ▪ *Product definition with possible description* ▪ *Normative/Regulatory/Law reference document* ▪ *Date of issue and validity of the certificate (and current issue)* ▪ *Any conditions that the issue is subject to* *The Certificate is sent to the Organisation, after verification of complete payment of the operations carried out by ICIM.*
TRANSFER
The procedures for transferring the certificates are those described in doc. IAFMD02
TRADEMARK
The ICIM Mark must be applied according to the ICIM regulation 0260CR for product certifications. *In addition to the ICIM mark on the product there must be at least:* ▪ *trademark of the Organisation,* ▪ *item code,* ▪ *production date (also coded) or serial number (or batch)* ▪ *ICIM scheme.* *If the dimensions of the product do not allow the above information to be affixed to it, it must be stated on the primary packaging and on all the documentation supplied with the product, including shipping documents (see also Regulation 0003CR).*
Other

NOTES
All verification documents, as well as all documents in the check list and the certificates must be retained for the amount of time established in the ICIM procedures for products subject to voluntary certification, so that they can be made available to the public administration and ACCREDIA upon request formal.

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ANNUAL MONITORING (AM)

METHOD TO BE APPLIED
Verification of the maintenance of the characteristics of the product against this scheme, takes place through at least one monitoring audit every year *<u>Monitoring audit</u>* *Annual monitoring (AM) is carried out as indicated in ICIM regulation 0003CR to ensure maintenance of compliance with the requirements set forth in the normative reference document and entails the verification of at least:* ▪ *the last inspection report* ▪ *complaints about the certified product* ▪ *the production statistics* ▪ *the design (design status and modifications)* ▪ *maintenance of the Manufacturing and Control Plan (checks on acceptance, intermediates, finished product, storage, etc.)* ▪ *the maintenance of availability and adequacy of the means of production and control in production* ▪ *of non-conformity management* ▪ *of the quality records* ▪ *the marking on the product, packaging and documents* ▪ *the use of the ICIM Mark* *During the monitoring audit the products to be tested are taken (sampling)* *<u>Unplanned monitoring is possible as per ICIM regulation 0003CR</u>* *<u>Monitoring Tests (MT)</u>* *he tests are carried out by taking samples of the product, so as to be able to test at least all the types of MATERIALS (as divided in the DESCRIPTION par.) Present in the product during the 4 years of surveillance.* *In the case of multiple types of MATERIALS, samples of the product are taken in order to test 1/4 of the MATERIAL types sampled in Initial Verification every year, changing, where possible, the models to be tested within the family / series. For components belonging to the plastic / rubber / paint families, laboratory tests will be performed twice over the 4-year surveillance period.* *Withdrawals must be scheduled in such a way that all the materials sampled in the Initial Visit are tested over the next 4 years of maintenance of the certificate.* *The verification carried out is recorded on the report forms issued by ICIM. The test laboratories must be accredited or qualified by ICIM according to the established procedures (reference standard UNI EN ISO IEC 17025).* *The purchase order relating to surveillance tests must refer to the Annex to the RDA document relating to the tests to be carried out according to this scheme; where a contract is available between ICIM and the Laboratory in charge of the tests, the aforementioned conditions must be indicated therein.* *ICIM asks the Laboratory in charge of the tests to indicate in the test reports the conformity of the result with the applicable legislation and accepts the decision-making rule on the basis of which this conformity is expressed.* *The outcome of the tests is recorded in a special report indicating whether the test is positive or negative. The test is positive if the products are within the range of the provisions of the Annexes. In the event of a negative result, what indicated in 0003CR is applied.* *Any "border line" values will result in the repetition of the test in the next visit after modifying the sampling already planned and if the test confirms the aforementioned values, an additional quotation will be prepared for its repetition. In the event of a negative outcome of the tests, the Resolution Committee may decide to suspend the use of the trademark pending clarification from the Organization or to have the tests repeated on a new sampling (retries).*

SV REPORT
The audit is drafted in a specific report, specifying, where necessary, recommendations or nonconformities and indicating the adequacy or inadequacy of each applicable item. Copy of the report and, if tests have been carried out, the test report is issued to the Manufacturer as a notification of the operation. The checklist is countersigned by the Organisation as acceptance of all issued findings.
NOTE
The Organisation can however initiate a review procedure following the procedure described in ICIM Regulation 0001CR. *In the event of complaints or appeals related to the results of laboratory analyzes carried out during the annual surveillance tests, ICIM will use for the product reviews an alternative laboratory to the one that carried out the finished tests under complaint. ICIM in this case will use laboratories or accredited for specific tests by ACCREDIA (or other ILAC MRA body) or qualified by ICIM for specific tests, if there are no accredited laboratories available.*

CERTIFICATION VALIDITY

METHOD TO BE APPLIED
The validity of the Product Approval applies until the product is modified. *The validity of the Product Certificate is 5 (five) years.* *The conditions for retaining the certificate are also indicated in ICIM regulation 0001CR and ICIM 0003CR.* *If the validity of the certificate is not renewed, the Organisation must immediately cease using the ICIM Mark, as per ICIM regulation 0001CR.*
Other
NOTES

RENEWAL

METHOD TO BE APPLIED
Renewal takes place when the certificate expires (five years). ***Renewal audit*** *The renewal visit (RV) is carried out as indicated in ICIM regulation 0003CR to ensure compliance with the requirements set forth in the reference standard and laws.* *The certification renewal verification is carried out at least 60 (sixty) days before expiry.* *During the renewal audit, at least the following points must be assessed:* ▪ *last inspection report* ▪ *complaints about the certified product* ▪ *production statistics* ▪ *design (project status and modifications)* ▪ *Manufacturing and Control Plan (checks on acceptance, intermediate finished products, storage, etc.)* ▪ *availability and adequacy of the means of production and control in production* ▪ *traceability* ▪ *non-conformity management* ▪ *quality records* ▪ *installation, use and maintenance instructions* ▪ *marking on the product, packaging and documents* ▪ *use of the ICIM Mark* *During the renewal audit, ICIM takes the products to be tested (sampling) in the same way as the monitoring procedure* ***Renewal tests (RT)*** *The renewal tests follow the same procedure as the monitoring tests.* *ICIM asks the Laboratory in charge of the tests to indicate in the test reports the conformity of the result with the applicable legislation and accepts the decision-making rule on the basis of which this conformity is expressed.* *The test is positive if the products are within the range of the provisions of the Annexes. In the event of a negative result, what indicated in 0003CR is applied.* *Any "border line" values will result in the repetition of the test in the next visit after modifying the sampling already planned and if the test confirms the aforementioned values, an additional quotation will be prepared for its repetition.*
RV REPORT
The audit is drafted in a specific report, specifying, where necessary, recommendations or nonconformities and indicating the adequacy or inadequacy of each applicable item. Copy of the report and, if tests have been carried out, the test report is issued to the Manufacturer as a notification of the operation. The checklist is countersigned by the Organisation as acceptance of all issued findings.
Other
With the successful result of the renewal, the certificate is re-issued as per regulation 0003CR
NOTES
The Organisation can however initiate a review procedure following the procedure described in ICIM Regulation 0001CR. *In the event of complaints or appeals related to the results of laboratory analyzes carried out during the annual surveillance tests, ICIM will use for the product reviews an alternative laboratory to the one that carried out the finished tests under complaint. ICIM in this case will use laboratories or accredited for specific tests by ACCREDIA (or other ILAC MRA body) or qualified by ICIM for specific tests, if there are no accredited laboratories available.*

CHANGES TO CERTIFICATION CONDITIONS

METHOD TO BE APPLIED
The organisation must inform ICIM of all changes, even minor ones, which it has made or intends to make to the product covered by the certificate. *ICIM examines said changes and decides whether:* *a) the change is not significant, in which case the Application is accepted without the need for additional inspections or tests; therefore ICIM informs the Manufacturer or Authorised representative that the EC certificate is valid with a supplement of the original examination document.* *b) the change is significant but not such to produce a new product, in which case verifications or additional tests are required; ICIM therefore informs the Organisation that the certificate remains valid with a supplement of the original examination document issued upon the positive outcome of the additional inspections or tests.* *c) the change is significant to the extent that it produces a completely new product, in which case ICIM informs the Organisation that the operations for Certification must be carried out in their entirety.*
Other *The Organisation can however initiate a review procedure following the procedure described in ICIM Regulation 0001CR.*

COMMERCIAL CERTIFICATION EXTENSIONS

METHOD TO BE APPLIED
See regulation 0003CR
Other
NOTES

AUDITOR REQUIREMENTS

ADDITIONAL QUALIFICATIONS
As per the qualification procedure for inspectors, with a minimum specific experience for engineering graduates of 2 (two) years in the mechanic, chemistry, nuclear, aeronautics sector and comparable degrees (biology, natural sciences, food science and technology, physics, chemistry, etc.), optimal if specific to the design, manufacture, maintenance, inspection of products in the sector of products and components in contact with drinking water. For other technicians and non-graduates the minimum number of years of experience defined in the qualification procedure for the inspectors is always required in the sectors indicated above. *For technical experts, where necessary, the same level of minimum knowledge is required for inspectors with superior technical knowledge on specific topics related to a specific type of product in the field of products and components in contact with foodstuffs.*
ADDITIONAL CHARACTERISTICS
The GVI must be composed of one or more inspectors who can cover all the requirements indicated in the previous paragraph on "Additional Qualifications".
OTHER PERSONNEL IN CHARGE
▪ *Documentation Review (Coordinator competent for the specific scheme / sector)* ▪ *Final reviewer (Coordinator competent for the specific scheme / sector; the Competence Center Manaager; the Operation Manager; the Technical Director)* ▪ *Decision Maker, Technical Director*

ANNEX 1 (regulatory)

METHOD TO BE APPLIED
List of specific provisions ***Ministerial Decree of 21 March 1973*** *Hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (Ordinary Supplement no. 69 of O.J. no. 104 of 20 April 1973)* ***Ministerial Decree of 3 August 1974*** *Update of the ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 227 of 31 August 1974)* ***Ministerial Decree of 19 November 1974*** *Update of the ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 319 of 6 December 1974)* ***Ministerial Decree of 27 March 1975*** *Amendment to ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers, equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 96 of 10 April 1975)* ***Ministerial Decree of 13 September 1975*** *Amendment to ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers, equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 272 of 13 October 1975)* ***Ministerial Decree of 18 June 1979*** *Update of the ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 180 of 3 July 1979)* ***Ministerial Decree of 2 December 1980*** *Update of the ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 347 of 19 December 1980)* ***Decree of 25 June 1981*** *Update of the ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 198 of 21 July 1981)* ***Decree of 2 June 1982*** *Update of the ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 200 of 22 July 1982)* ***Decree of 20 October 1982*** *Update of the ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 340 of 11 December 1982)* ***Decree of 18 February 1984*** *Discipline of tinplate containers welded with tin-lead alloy and other means. (O.J. no. 76 of 16 March 1984)* ***Decree of 4 April 1985*** *Discipline of ceramic articles intended to come into contact with foodstuffs.* *(O.J. no. 98 of 26 April 1985)* ***Decree of 4 April 1985*** *Update of the ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 120 of 23 May 1985)* ***Decree of 7 August 1987, no. 395*** *Update of the ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 226 of 28 September 1987)* ***Decree 1 June 1988, no. 243*** *Discipline of painted chrome plate articles intended to come into contact with food. (O.J. no. 153 of 1 July 1988)* ***Decree 18 January 1991, no. 90*** *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 67 of 20 March 1991)* ***Ministerial Decree 26 April 1993, no. 220*** *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. Transposition of directives 82/711/EEC, 85/572/EEC, 90/128/EEC and 92/39/EEC. (Ordinary Supplement no. 64 of Official Journal no. 162 of 13 July 1993 Errata corrige (O.J. no. 257 of 2 November 1993)*

Decree 15 July 1993, no. 322 *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 199 of 25 August 1993)*

Decree 3 June 1994, no. 511 *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 198 of 25 August 1994)*

Decree 28 October 1994, no. 735 *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. Implementing directives 93/8/EEC and 93/9/EC. (O.J. no. 1 of 2 January 1995)*

Decree of 8 February 1995 *Transposition of Commission Directive 93/11/EEC of 15 March 1993 concerning the release of N-nitrosamines and N-nitrosatable substances from pacifiers and teats of elastomer or natural rubber. (O.J. no. 68 of 22 March 1995)*

Decree 24 February 1995, no. 156 *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 103 of 5 May 1995)*

Decree 13 July 1995, no. 405 *Regulation updating the ministerial decree of 18 February 1984 concerning the regulation of tinplate containers welded with tin-lead alloy and other means. (O.J. no. 228 of 29 September 1995)*

Decree 24 September 1996, no. 572 *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. Transposition of Directive 95/3/EC. (Ordinary Supplement no. 195 of Official Journal no. 264 of 11 November 1996)*

Decree 6 February 1997, no. 91 *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. Transposition of Directive 96/11/EC. (O.J. no. 77 of 3 April 1997)*

Decree 22 July 1998, no. 338 *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. Transposition of Directive no. 97/48/EC. (O.J. no. 228 of 30 September 1998)*

Decree of 4 August 1999, no. 322 *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 218 of 16 September 1999) Errata corrige (O.J. no. 252 of 26 October 1999)*

Decree of 17 December 1999, no. 538 *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 28 of 4 February 2000)*

Decree 15 June 2000, no. 210 *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. Transposition of Directive no. 99/91/CE (O.J. no. 175 of 28 July 2000)*

Decree of 1 December 2000, no. 411 *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 11 of 15 January 2001)*

Decree of 30 May 2001, no. 267 *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 155 of 6 July 2001)*

Decree of 28 March 2003, no. 123 *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. Transposition of directives 2001/62/EC, 2002/16/EC and 2002/17/EC. (O.J. no. 125 of 31 May 2003)*

Regulation (EC) no. 1895/2005 *concerning the restriction of the use of some epoxy derivatives in materials and articles intended to come into contact with foodstuffs (Official Journal of the European Union series L 302 of 19 November 2005)*

Decree of 22 December 2005, no. 299 *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 37 of 14 February 2006)*

Decree of 4 May 2006, no. 227 *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. Transposition of directives 2004/1/EC, 2004/13/EC and 2004/19/EC. (O.J. no. 159 of 11 July 2006)*

Decree of 1 February 2007 *Implementation of Commission Directive no. 2005/31/EC of 29 April 2005 amending Council Directive 84/500/EEC with regard to a declaration of conformity and criteria for the efficiency of methods of analysis for ceramic articles, intended to come into contact with foodstuffs. O.J. no. 66 of 20 March 2007)*

Regulation (EC) no. 372/2007 *which sets transitory migration limits for plasticizers used in the gaskets of lids intended to come into contact with food. (Official Journal of the European Union series L. 92 of 3 April 2007)*

Decree 18 April 2007, no. 76 *Regulation on the hygiene control of materials and articles of aluminium and aluminium alloys intended to come into contact with food. (O.J. no. 141 of 20 June 2007)*

Decree 18 April 2007, no. 82 *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. Transposition of Directive 2005/79/EC (Ordinary Supplement no. 149/L of Official Journal no. 151 of 2 July 2007)*

Decree 25 September 2007, no. 217 *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (O.J. no. 270 of 20 November 2007)*

Decree of 12 December 2007, no. 270 *Regulation updating decree of 21 March 1973 concerning the regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. (Official Journal General Series no. 33 of 8 February 2008)*

Regulation (EC) no. 282/2008 of 27 March 2008 *concerning recycled plastic and articles intended for contact with food and amending Regulation (EC) no. 2023/2006. (Official Journal of the European Union 86 of 20 March 2008)*

Regulation (EC) no. 597/2008 of 24 June 2008 *amending regulation (EC) no. 372/2007 which sets transitory migration limits for plasticizers used in the gaskets of lids intended to come into contact with food. (Official Journal of the European Union L 164 of 25 June 2008)*

Decree of 24 September 2008, no. 174 *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. Transposition of Directive 2007/19/EC. (Ordinary Supplement no. 246/L no 261 of 7 November 2008)*

Decree of 23 April 2009 *Update of the ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use. Transposition of Directive 2008/39/EC (Official Journal General Series no. 144 of 24 June 2009) Errata corrige (Official Journal General Series no. 147 of 27 June 2009 and Official Journal General Series no. 160 of 13 July 2009)*

Regulation (EC) no. 450/2009 of 29 May 2009 *concerning active and intelligent material intended to come into contact with food (Official Journal of the European Union series L 135 of 20 May 2009)*

Regulation (EC) no. 975/2009 of 19 October 2009 *amending Directive 2002/72/EC relating to materials and plastic articles intended to come into contact with foodstuffs (Official Journal of the European Union series L. 274 of 20 October 2009)*

Decree of 18 May 2010, no. 113 *Regulation amending ministerial decree of 21 March 1973 concerning the hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use limited to polyethylene terephthalate plastic bottles (Official Journal General Series no. 168 of 21 July 2010)*

Regulation (EU) no. 10/2011 *of the Council of 14 January 2011 concerning plastic materials and articles intended to come into contact with foodstuffs" Official Journal of the European Union L 12 of 15 January 2011) Correction (Official Journal of the European Union L. 278 of 25 October 2011)*

Decree of 16 February 2011 *Implementation of Council Directive no. 2011/8/EU of 28 January 2011 amending Directive 2002/72/EC as regards restrictions on the use of Bisphenol A in plastic infant feeding bottles (Official Journal General Series no. 63 of 18 March 2011)*

Regulation (EU) No 284/2011 *of the Council of 22 March 2011 laying down special conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in the People's Republic of China and the special administrative region of Hong Kong, China, or coming from them (Official Journal of the European Union L 77 of 23 March 2011)*

Regulation (EU) no. 321/2011 *of the Council of 1 April 2011 amending Regulation (EU) no. 10/2011 as regards restrictions on the use of Bisphenol A in plastic infant feeding bottles (Official Journal of the European Union L 87 of 2 April 2011)*

Regulation (EU) no. 1282/2011 *of the Council of 28 November 2011 amending and correcting the regulation (EU) no. 10/2011 of the Council concerning plastic materials and articles intended to come into contact with foodstuffs (Official Journal of the European Union 328 of 10 December 2011)*

Decree 4 April 2012, no. 72 *Regulation updating of Ministry of Health decree of 21 March 1973, concerning «Hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use», limited to paper and paper board. (Official Journal General Series no. 129 of 5 June 2012)*

Decree 16 April 2012, no. 77 *Regulation updating Ministry of Health decree of 21 March 1973, concerning: "Hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances*

for personal use, limited to polyethylene terephthalate plastic bottles (Official Journal General Series no. 135 of 12 June 2012)

Decree 9 July 2012, no. 139 *Regulation integrating Ministry of Health decree of 21 March 1973, concerning: "Hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use, concerning recycled polyethylene terephthalate plastic bottles. (Official Journal General Series no. 191 of 17 August 2012)*

Regulation (EU) no. 1183/2012 *of the Council of 30 November 2012 amending and correcting the regulation (EU) no. 10/2011 concerning plastic materials and articles intended to come into contact with foodstuffs (Official Journal of the European Union L 338 of 12 December 2012)*

Decree 4 February 2013, no. 23 *Regulation updating Ministry of Health decree of 21 March 1973, concerning: «Hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use», (Official Journal General Series no. 71 of 25 March 2013)*

Decree 20 September 2013, no. 134 *Regulation updating Ministry of Health decree of 21 March 1973, concerning: "Hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use, limited to recycled polyethylene terephthalate plastic bottles and trays (Official Journal General Series no. 285 of 5 December 2013)*

Decree 11 November 2013, no. 140 *Regulation updating Ministry of Health decree of 21 March 1973, concerning: "Hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use" limited to stainless steels, (Official Journal General Series no. 294 of 16 December 2013)*

Regulation (EU) no. 202/2014 *of the Council of 3 March 2014 amending Regulation (EU) no. 10/2011 concerning plastic materials and articles intended to come into contact with foodstuffs" (Official Journal of the European Union L 62 of 4 March 2014)*

Regulation (EU) no. 174/2015 *of the Council of 5 February 2015 which amending and correcting Regulation (EU) no. 10/2011 concerning plastic materials and articles intended to come into contact with foodstuffs" (Official Journal of the European Union L 30 of 6 February 2015)*

Decree of 6 August 2015, no. 195 *Regulation updating limited to stainless steel to Ministry of Health decree of 21 March 1973, concerning: "Hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use", (Official Journal General Series no. 288 of 11 December 2015)*

Decree of 31 May 2016, no. 142 *Regulation amending ministerial decree of 21 March 1973 concerning the "Hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use limited to articles made of regenerated cellulose (Official Journal General Series no. 173 of 26 July 2016)*

Decree of 9 May 2019, no. 72 *Regulation updating to Ministry of Health decree of 21 March 1973, concerning: "Hygiene regulation of packaging, containers and equipment intended to come into contact with foodstuffs or with substances for personal use", limited to stainless steel to (Official Journal General Series no. 179 of 01 August 2019)*

Regulation (EU) 1416/2016 of 24 August 2016 *amending and correcting the regulation (EU) no. 10/2011 concerning plastic materials and articles intended to come into contact with foodstuffs*

Regulation (UE) 2017/752 of 28 April 2017 *amending and correcting the regulation (UE) n. 10/2011 concerning plastic materials and articles intended to come into contact with foodstuffs (Official Journal of the European Union L113 of 29 April 2017)*

Regulation (UE) 2018/79 of 18 January 2018, *amending and correcting the regulation (UE) n. 10/2011 concerning plastic materials and articles intended to come into contact with foodstuffs (Official Journal of the European Union L14 of 19 January 2018)*

Regulation (UE) 2018/213 of 12 February 2018, *on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials (Official Journal of the European Union L41 of 14 February 2018*)

Regulation (UE) 2018/831 of 5 June 2018, *amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Official Journal of the European Union L140 of 6 June 2018)*

Regulation (UE) 2019/37 *of 10 January 2019 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Official Journal of the European Union L9 of 11 January 2019)*

Regulation (UE) 2019/988 *of 17 June 2019 correcting the French language version of Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Official Journal of the European Union L160 of 18 June 2019)*

Regulation (UE) 2019/1338 *of 8 August 2019 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Official Journal of the European Union L209 of 9 August 2019)*

Regulation (UE) 2020/1245 *of 2 September 2020 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food* (*Official Journal of the European Union L288 of 3 September 2020)*

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ANNEX 2 (regulatory)

METHOD TO BE APPLIED
In the event of Materials indicated in par. DESCRIPTION, which do not have a decree or a normative document referred to in Annex 1, the general requirements of non-release of harmful substances and non-alteration of the organoleptic characteristics remain valid. *As migration tests with food simulants are not applicable (as provided for in the decrees referred to in Annex 1), ICIM carries out an analysis of the composition characteristics of the material and its behaviour in relation to the contact food, applying the methods provided in the following documents, in particular for the following materials:* *Ion exchange resins; non standardized metallic alloys (except stainless steel and aluminum alloys for which there is a specific national reference standard); silicones* *ICIM applies the following documents published by the Council of Europe:* ***Resolution Res AP (2004)3** on ion exchange and adsorbent resins used in the processing of foodstuffs.* ***Resolution CM/RES (2013)9** "Metal and alloys used in food contact materials and articles"* ***Resolution RES AP (2004)5** on silicones used for food contact applications* *The certification will be managed as indicated in this scheme by applying the expected method.*

ANNEX 3 (regulatory)

METHOD TO BE APPLIED
In case the certified product contains the following materials: *a. Plastic materials regulated by Reg. 10/11/CE* *with reference to Chapter 2, point 2.2.1 of Annex V of the aforementioned Regulation, ICIM applies a material screening approach with reference to chapter 2, point 2.2.1 of Annex V of the aforementioned Regulation, ICIM applies a screening approach of materials verifying the overall migration, the specific migration of heavy metals and primary aromatic amines and the migration of dyes, reserving the right to proceed with further analytical investigations if the results obtained are indicative of an anomalous transfer by the material* NOTE: *Following the publication of Regulation (EU) no. 1245/2020 "Commission Regulation (EU) 2020/1245 of 2 September 2020 amending and correcting Regulation (EU) no. 10/2011 concerning plastic materials and objects intended to come into contact with food products "it is considered useful to specify that plastic materials and objects compliant with regulation (EU) no. 10/2011 in the version applicable before the entry into force of this regulation and placed on the market for the first time before March 23, 2021, can continue to be placed on the market until September 23, 2022 and remain on the market until stocks are exhausted*.