

Title	Regulation for the accreditation of Certification Bodies operating certification of conformity to the standard UNI EN ISO 22005 “Traceability in the feed and food chain - General principles and basic requirements for system design and implementation”
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CONTENTS	2
1. SCOPE AND FIELD OF APPLICATION	3
2. REFERENCE STANDARDS	4
3. DEFINITIONS	4
4. GENERAL REQUIREMENTS	4
5. STRUCTURAL REQUIREMENTS	4
6. REQUIREMENTS FOR RESOURCES	4
7. REQUIREMENTS OF THE PROCESS	6
8. REQUIREMENTS OF THE MANAGEMENT SYSTEM	11

1. SCOPE AND FIELD OF APPLICATION

The present technical regulation defines the rules of application –with the effective implementation of the general requirements of the applicable reference standards – for the granting and maintenance of ACCREDIA accreditation for certifications of conformity issued against UNI EN ISO 22005:2008. The contents of the present document are to be considered as an integral part of the certification scheme.

The contents of the present document were drawn up by a working group consisting of the interested parties, and ACCREDIA cannot modify it autonomously; therefore any revision involves convening the working group.

For simplicity of consultation, the present document is structured according to the numbering of UNI CEI EN ISO/IEC 17065 and it provides details, comments and integrations, where applicable, in the order as set out in this standard.

The content of the present document is applicable to traceability systems applied inside single organizations/companies (ex UNI 11020) and inter-organizational (of the production chain - ex UNI 10939) used by any organization in the feed and food chain irrespective of the number of juridical entities or organizations intervening in the chain and irrespective of the positioning of the applicant organization within the feed and food chain, including, by way of example, organizations operating in the restaurant and catering sector, in the seed and plant sector for use in the feed and food chain and producers of food contact materials.

It is applicable to Certification Bodies (CBs) accredited by ACCREDIA and to the evaluations performed by the CBs, and its objective is to endure the effectiveness and consistency of certifications, in order to create trust in the market with regard to the capability of the traceability system certified to support the organization in ensuring the attainment of aims set out by the traceability system.

Legislative conformity to requirements of health and hygiene of products for which the traceability system for certification is applied, is mandatory for obtaining certification.

If, during the assessment, the assessor finds a failure to respect the mandatory requirements which do not come directly within the ambit of his/her mandate, s/he shall (being directly and personally responsible for his/her professional services) record such situation. The auditor shall formally inform, by means of a separate report, the CB which commissioned the assessment.

The present document may be submitted for revision, both after publication by ISO of a revision of the reference standard ISO 22005 and also according to legislative dispositions and on the basis of experience gained in the during the period of its application.

2. REFERENCE STANDARDS

- ISO 22005:2007 Traceability in the feed and food chain -- General principles and basic requirements for system design and implementation;
- UNI CEI EN 45011:1999 General requirements for Bodies managing product certification systems;
- IAF GD 5:2006 IAF Guidance on the Application of ISO/IEC Guide 65:1996 General Requirements for Bodies operating Product Certification System Issue 2;
- UNI CEI EN ISO/IEC 17065:2012 General requirements for Bodies providing certification of products, process and services.

NOTE: the transition period for transfer from UNI CEI EN 45011 to ISO/IEC 17065:2012 ends on 15 Sept. 2015. During this period the two standards co-exist as do the rules as defined in ACCREDIA communication DC2013UTN006 “Dispositions for the transition of accreditations of CBs of products, process and services from UNI CEI EN 45011:1999 to ISO/IEC 17065:2012”, available on ACCREDIA’s website.

3. DEFINITIONS

The definitions contained in UNI EN ISO 22005 are applicable, as well as those defined below:

Primary production: all the phases of production, of breeding or cultivation of products including harvest, milking and livestock production before slaughter and including hunting and fishing and gathering of wild products (art. 3 of Reg. CE 178/2002).

Length: the phases of production, processing, marketing etc., covered continuously by the traceability system.

Extent: the components of the product covered in a continuous way by the traceability system.

Elements: information which the traceability system intends to create or obtain in support of the objectives.

Minimum traceable unit (UMR): minimum homogeneous quantity expressed in weight or volume for which the need exists to recuperate predefined information which can be priced, ordered or invoiced and which is the object of an internal conformity assessment within the traceability system.

Objectives: results related to the minimum traceable unit, which the applicant for certification intends to obtain/divulge by applying the traceability system;

Mass balances: activities for assessment by means of comparison of the compatibility of incoming and outgoing material flows of the traceability system (for primary production it is better to use the term "productive yield").

4. GENERAL REQUIREMENTS

The standard is applicable with the following specifications:

4.1. Use of certification

The use of certification by certified organizations shall be limited to the objectives and the length of the traceability system. Use of the certification for promotional and commercial purposes shall be in line with the specifications of point 7.4 regarding the scope of certification.

The use of certification should not mislead the purchaser of a certified product (example of this are the use of the sole title of the standard, whether the production chain is not entirely certified or the length of the chain certified is not unequivocally indicated). Declarations claiming product characteristics which are not directly related to the objectives of the traceability system are not permitted except as specified in § 7.4.2 below.

5. STRUCTURAL REQUIREMENTS

The requirements of the standard are applicable.

6. Requirements for resources

The requirements of the standard are applicable with the following specifications:

6.1 Qualifications of auditors

Auditors shall be qualified for both the animal and plant chains.

The necessary qualifications for auditors in one of the above categories are as follows:

	To be appointed lead auditor	To be appointed auditor
<u>Education</u>	<u>University degree</u> – in agricultural sciences, food science and technology, science of animal production, chemistry, biology, veterinary and equivalent. <u>diploma</u> as agrarian expert, agri-technician, chemical expert, food expert.	<u>University degree</u> – in agricultural sciences, food science and technology, science of animal production, chemistry, biology, veterinary and equivalent. <u>diploma</u> as agrarian expert, agri-technician, chemical expert, food expert.
<u>Work experience in types of companies which are part of the chains:</u>		
School diplomas	5 years	5 years
Degree	3 years	3 years
<u>Audit activities in the feed and food sector</u>	4 audits as trainee auditor plus 3 audits as auditor as trainee lead auditor under the supervision of a lead auditor – 7 audits as trainee lead auditor	4 audits as trainee auditor
<u>Training:</u>		
Management systems and audit techniques - UNI EN ISO 19011	40 hour course	24 hour course for internal auditors
HACCP	Course or proven experience	Course or proven experience
Traceability	Specific training (at least 16 hours) or proven experience	Specific training (at least 16 hours) or proven experience

An auditor who is qualified in one of the above chains can be qualified for the other after 10 days of auditing in the chain.

Note 1: 30 audit days are equivalent to one year of work experience..

Note 2: Work experience related to both chains is ok as long as the person in question shows that he/she has worked continuously for at least one year in at least one of the two chains.

7. REQUIREMENTS OF THE PROCESS

The requirements of the standard are applicable with the following specifications:

7.1 General requirements of a traceability system

A certified traceability system must be able to document systematically the raw materials, products, services used in the cultivation and/or breeding and/or processing and/or distribution and/or logistics processes covered by the system itself.

The traceability system, which shall identify the certified product clearly, shall be fully defined in terms of UMR, objectives, elements, extent and length.

7.1.1 Exclusions

Exclusions from the traceability system of phases of the production chain or ingredients/components of the product, are possible.

The CB's personnel responsible for making the certification decision which issues the certification shall accept or not accept any exclusions and relative explanations for such, giving documental evidence.

Exclusion of phases of the production chain (applicable only to a traceability system applied inter-organizational)

It is possible to exclude phases of the production chain in the case of a traceability system applied **inter-organizational** if it can be shown to be irrelevant concerning the objectives of the traceability system. In order for this to be done, the CB and applicant organization shall perform and document the necessary verification actions.

Any exclusion in the primary production (animal and/or plant) shall be of an exceptional nature and can be done only if it is impossible to include it in the traceability system or if its inclusion is irrelevant.

Similarly, except in exceptional cases where it is demonstrable that it does not compromise the objectives of the traceability system, exclusions of phases of the production chain performed directly by the applicant organization are not permitted.

See § 7.4.1 regarding details on the modalities for communicating exclusions of phases of the production chain to the certified organization's clients, especially with regard to product labeling.

Exclusion of ingredients/components (applicable both to a traceability system applied inside single organizations/companies and inter-organizational)

It is possible to exclude product ingredients from the traceability system as long as this does not compromise the objectives of the traceability system and also that the hygiene and safety requirements are met.

For this, the CB and applicant organization shall perform and document the necessary verification actions.

Additional components or ingredients such as additives, technical aids, spices, water, packaging etc. shall not necessarily be included in the traceability system and they can be managed through documental identification of the supplier, according to the reference legislation.

See § 7.4.1 regarding details on the modalities for communicating exclusions of ingredients/components to the certified, especially with regard to product labeling.

7.2 Audits

7.2.1 Minimum contents concerning initial and surveillance audits

During the initial and surveillance audits the CB shall always:

- check the conformity of the traceability system to the requirements of UNI EN ISO 22005;
- perform and document a traceability test, verifying the presence in the traceability system's document of a control plan, of the procedure for managing NCs and of the assignment of responsibilities within the organizations included into the traceability system;
- perform and document the conduct of a mass balance in order to verify the reliability of mass balances undertaken autonomously by the certified organizations;
- check the proper and effective use, by the organization, of mass balances as an instrument for evaluating the effectiveness of the traceability system.

Regarding the above, the CB shall be able to provide evidence to its own committees and to those of the AB.

7.2.2 Multisite organizations – determination of the number of sites to be audited

In the case of a traceability system applied to a production chain it is possible to verify a sample of the operative sites of the certified product in the following circumstances:

- during first certification it is necessary to audit a number of sites which is at least equivalent to the sum of $\sqrt{N_i}$, where N_i is the number of sites attributable to the n th group of homogeneous sites in the production chain (e.g. number of processing plants, suppliers of raw materials or ingredients, farms etc.);
- during the annual surveillance it will be necessary to audit at least 60% of the sites included in the initial audit, determined as above.

The number of sites to be audited in the annual surveillance may be modified and shall therefore be fixed on an annual basis. The number may also be calculated, at the discretion of the CB, according to the following equation:

$$n = \left[1 - (1 - a)^{1/D} \right] \left(N - \frac{D-1}{2} \right)$$

where:

N = the total number of productive sites (homogeneous) in the production chain

D = 0.1N

a = level of trust

N ≥ 1000 a = 0.95

501 < N < 999 a = 0.85

N ≤ 500 a = 0.75

7.3 Use of other certifications of the traceability system

For the certification of a traceability system of a feed and food chain, the CB can use certifications of segments of the production chain already issued by another CB, provided that the other CB possesses valid accreditation to issue conformity certifications against UNI EN ISO 22005 and that the objectives of the certification used are compatible with those of the chain in question.

In such cases the CB shall ask the client to specify the situation when the application is made and it shall refer to the other certification used in its records. In the contractual agreement with the client the CB shall request to have access to all records, audit reports and findings which were raised to ensure the validity and the conformity of the certification used. The CB shall keep updated evidences of records, as well as the evaluations performed and the decisions taken accordingly.

With regard to the operative modalities, the requirements of UNI CEI EN ISO/IEC 17065:2012 and the EA/IAF Guides are applicable.

7.4 Documentation regarding certification

7.4.1 Definition of the scopes of certifications issued

The scope of certification shall contain adequate information with regard to the following:

- object of the traceability system (product or component to which the traceability system is applied).
- objectives of the traceability system – for the definitions of these it is possible to refer to the objectives listed in UNI EN ISO 22005 § 4.3. They must be unambiguous and clear for users of the certification and related to the object of the traceability system.
- extent of the certified traceability system;
- length of the certified traceability system;
- elements of the certified traceability system;
- UMR.

Exclusion of phases of the production chain (applicable only to a traceability system applied inter-organizational)

In cases of the exclusion of primary production phases it is not permitted to use, in certificates and in the commercial and/or promotional use of certificates, the words “breeding”, “field”, “agricultural producer” or synonyms of these words, or any expressions implying that the primary production (as defined in article 3 of Reg. CE 178/2002) is an integral part of the certified traceability system.

In the case of animal production chains, the starting location of the chain may be different from the birthplace of the animals, granted that the time spent by the animals at the first location of the chain is the important one. In such cases the certificate shall show the typology of the initial breeding.

Exclusion of components (applicable both to a traceability system applied inside single organizations/companies and inter-organizational)

In cases of exclusion of accessory components (processing aids, spices, water, packaging etc.) as set out in point 7.1.1, it is not necessary to point out any exclusions and it is possible to refer to the final product.

Likewise, it is possible to refer to the final product in the case of exclusion of admissible components in accordance with point 7.1.1. But in these cases the exclusions shall be clearly signaled and communicated to the clients of the owner organizations of the certification, including in particular the labeling of products.

If the traceability system is not applied to a finished product but to one or more components with relevance to the characteristics of the product, the scope of certification – in the identification of the object of the traceability system – shall be limited to the component/s to which the traceability system is applied and the intended use shall be identified.

Below there are three examples of a correct formulation of certification scopes for a traceability system applied inter-organizational to a products sold packaged (ex UNI 10939) Case A – where the UMR is clearly identifiable; in the case of a traceability system applied inter-organizational to bulk products (ex UNI 10939) Case B – where the UMR may not be identifiable in advance; in the case of an traceability system applied inside single organizations/companies (ex UNI 11020) Case C.

Case A

Product covered by the traceability system	Tomato Preserved in tin
Objectives of the traceability system	To ascertain the history/origin of the product and to facilitate the verification of information concerning the cultivation methods and processing of the product
Length of the traceability system	Production of plant propagation material, cultivation, harvesting, transport, storage, processing and delivery to the distributor
Extent of the traceability system	Tomato, additives, processing aids, packaging
Elements of the traceability system	Plant nursery companies, batches of material for propagation used and of the varieties used, agricultural producers, agricultural production records, fertilizers, quantities of product obtained, transport documents, production and packaging plan, batches of packaging material, transport to the distributor
UMR:	250g tin with brand name "Fattoria Bella"

Case B

Object of the traceability system:	Common wheat sold in bulk
Object of the traceability system:	To ascertain the history/origin of the product and to facilitate the verification of information concerning the cultivation methods and processing of the product
Objectives of the traceability system	Production of seed, cultivation, harvesting, transport, storage, cleaning, sale
Length of the traceability system	Common wheat grain
Extent of the traceability system	Identification of the origin of the wheat through the processes of receipt, storage, processing and sale. Identification of cultivation methods starting from procurement and delivery of seed and including the cultivation techniques, identification of batches of seed and varieties used.
Elements of the traceability system	batches of seed and varieties used, agricultural producers, agricultural production records, fertilizers, quantities of product obtained, transport documents, production program and packaging, transport to the distributor
UMR:	“sales unit” (e.g. package or container)

Case C

Object of the traceability system:	white table wine
Objectives of the traceability system:	To ascertain the history/origin of the product and to facilitate the verification of information concerning the cultivation methods and processing of the product
Length of the traceability system	Receipt of grapes, crushing, vinification, bottling, storage, sale
Extent of the traceability system	Grapes, additives, processing aids, packaging
Elements of the traceability system	Agricultural producers, agricultural production records, fertilization, product quantities, transport documents, receipt of grapes, crushing, vinification, bottling storage, sale and identification of the batch of packaging materials.
UMR:	375 ml bottle

7.4.2 Traceability system applied to products with defined qualitative characteristics

The organization can show on the certificate, over the objectives of the traceability system, also certain qualitative characteristics of the products, only if these characteristics are covered by a product certification issued by an accredited CB or authorized by the competent authority for the issuing of such product certification.

This is not applicable for indications of product origin – which are implicit in the traceability – provided that the indications are not regulated differently or that any product qualitative characteristic is not intended to be associated to these indications.

In particular, the indications regarding regulated qualitative characteristics (e.g. product certification: PDO, PGI, TSG) may appear on certification documents provided that it is clearly stated that the regulated qualitative characteristic is not covered and is not certified against ISO 22005.

7.5 Modifications affecting certification – management of the list of organizations in the certified traceability system

The CBs shall keep an updated list of organizations certified against ISO 22005 and to make available, on demand, information with regard to its contents without infringing the privacy laws.

8. REQUIREMENTS OF THE MANAGEMENT SYSTEM

The requirements of the standard are applicable.