

EU best practice guidelines for the operation of certification schemes relating to agricultural products and foodstuffs

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1. Introduction

1.1 Certification schemes

Recent years have seen a substantial growth in private, local and national certification schemes for agricultural products and foodstuffs. A preliminary inventory done for the Commission in 2006 arrived at close to 400 different schemes, although this figure has been disputed and the inventory is currently under revision.

Certification schemes for agricultural products and foodstuffs provide assurance (through a certification mechanism) that certain characteristics or attributes of the product or its production method or system, as laid down in a specification, have been observed. They cover a wide range of different initiatives, both public and private, that function at different stages of the food supply chain (pre- or post-farm gate, covering the whole or part of chain, affecting all sectors or just one market segment, etc.). They can operate at the business-to-business (B2B) level (where the supermarket or processing business is the intended recipient of the information) or at the business-to-consumer (B2C) level. They can make use of logos but, especially at the B2B-level, many do not.

While certification schemes by definition employ third-party attestation, there are other schemes in the market which operate on the basis of a label or logo (often registered as a trademark) without involving any certification mechanism. Adherence to these schemes is done by self-declaration or through selection by the scheme owner (often a public authority). In line with the definitions provided below, these schemes will be referred to as self-declaration schemes. While the use of certification is best when the undertakings made are complex, laid down in a detailed specification and checked periodically, self-declaration schemes are often used for relatively straightforward (single-issue) claims.

The development of certification schemes is mainly driven by factors such as societal demands for certain characteristics of the product or its production process on the one hand (mostly for B2C schemes), and legal obligations for operators to ensure that the requirements of food law are met on the other hand (mostly for B2B schemes). Regulation (EC) No. 178/2002 puts the responsibility for ensuring that foods or feeds satisfy the requirements of food law and for verifying that such requirements are met in the hands of food and feed business operators. Especially large players in the food supply chain therefore often rely on certification schemes in order to protect their reputation and liability in the event of food safety incidents.

Certification schemes can bring benefits

- to consumers by providing information on product and process attributes and increasing choice;
- to producers by increasing market access, market share and product margins for certified products; potentially also by increasing efficiency and reducing transaction costs; and
- to intermediate actors in the food supply chain by protecting liability and reputation.

Some stakeholders have argued that private schemes can have drawbacks: threats to the single market¹, questions as to the transparency of scheme requirements and credibility of the claims particularly for schemes that certify to baseline requirements, potential for misleading consumers, costs and burdens on farmers (particularly where they have to join several schemes according to the demands of their buyers), and impacts on international trade, especially with developing countries.

On the positive side, the Commission has noted that the issue of consumer confusion arising from different schemes with similar objectives is being taken up by private initiatives² which aim to create "Codes of Good Practice" for private standard setting organisations mainly in the social and environmental field. Moreover, proponents of existing schemes claim they have already taken major steps to align requirements with similar schemes. In fact, some existing certification schemes (mostly at the B2B level) have emerged from a harmonisation process of various individual standards, thereby decreasing the number of audits for producers and manufacturers.

1.2 Guidelines

In its Communication on "Agricultural Product Quality Policy" (COM (2009)234) published on 28.05.2009, the Commission stated that in the light of these developments, legislative action was not warranted at this stage. The Commission however stated that, drawing on comments from stakeholders, it will develop guidelines for certification schemes relating to agricultural products and foodstuffs in consultation with the Advisory Group on Quality.

These guidelines are aiming to improve the credibility and effectiveness of voluntary certification schemes. Rather than setting minimum criteria, they will highlight best practice in the operation of such schemes, thereby offering guidance on how to

- avoid consumer confusion and increase transparency and clarity of scheme requirements
- reduce the burden on farmers and producers, including those in developing countries
- ensure compliance with internal market rules and principles.

The guidelines are primarily directed to scheme developers and operators.

¹ In its Communication "A better functioning food supply chain in Europe" (COM (2009) 591), the Commission stated its intention to review selected environmental standards and origin labelling schemes that may impede cross-border trade.

² E.g., ISEAL Alliance (www.isealalliance.org)

Uptake of the guidelines will be voluntary.

1.3 Relevant reference documents:

A number of documents exist which provide guidance for different aspects related to the development and operation of certification schemes. While none of them addresses the exact same scope as the present guidelines, they are relevant for certain types of certification schemes. Following is a list of examples of such documents.

- EN ISO/IEC 1700: Conformity assessment – Vocabulary and general principles
- EN 45020:2006 (ISO Guide 2:2004): Standardization and related activities – General vocabulary
- EN 45011 (ISO/IEC Guide 65:1996) General requirements for bodies operating product certification systems
- ISO/IEC 17021: Conformity assessment – requirements for bodies providing audit and certification of management systems (replaced EN 45012 in 2006)
- ISO/IEC 17030: Conformity assessment – General requirements for third-party marks of conformity
- ISO Guide 59:1994: Code of good practice for standardization
- ISO Guide 14024:1999: Environmental labels and declarations – Type 1 environmental labelling – Principles and procedures
- OECD GD (97)137. Processes and Production Methods (PPM): Conceptual Framework and Considerations on Use of PPM-based Trade Measures
- ISEAL Code of Good Practice and Guidance for Setting Social and Environmental Standards –Version 5.0 – approved January 2010
- ISEAL Code of Good Practice for Assessing the Impacts of Social and Environmental Standards Systems, version 0.2 under consultation, approval of version 1.0 expected June 2010
- ISEAL Common Requirements for the Certification of Producer Groups, version 1.0 approved November 2010
- GFSI Guidance document (to be completed)
- CODEX documents on good agricultural and processing practices

(to be completed)

2. Scope and definitions

2.1 Scope

The guidelines shall apply to certification schemes covering

- agricultural products, whether or not intended for human consumption (including feed);
- foodstuffs covered by Article 2 of Regulation (EC) No.178/2002 (General Food Law);
- processes and management systems related to the production and processing of agricultural products and foodstuffs.

They shall cover private, national, regional and local certification schemes. Trademarks from individual operators shall not be covered by these guidelines.

2.2 Definition of terms³

- a. **Specified requirements:** need or expectation that is stated (e.g. in normative documents such as regulations, standards and technical specifications)
- b. **Conformity assessment:** demonstration that **specified requirements** relating to a **product**, process, system, person or body are fulfilled
- c. **Review:** verification of the suitability, adequacy and effectiveness of selection and determination activities, and the results of these activities, with regard to fulfilment of **specified requirements** by an object of conformity assessment
- d. **Attestation:** issue of a statement, based on a decision following **review** that fulfilment of **specified requirements** has been demonstrated.
- e. **Declaration:** first-party **attestation**. For the purpose of these guidelines, the term "self-declaration schemes" is used for collective schemes and label claims that are not certified, and which rely on the producer's self-declaration.
- f. **Certification:** third-party **attestation** related to products, processes, systems or persons
- g. **Accreditation:** third-party **attestation** related to a **conformity assessment body** conveying formal demonstration of its competence to carry out specific conformity assessment tasks. In the EU⁴, accreditation shall mean an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity.
- h. **Certification system:** **conformity assessment** system that includes selection, determination, review and finally certification as the attestation activity. While there is

³Based on EN ISO/IEC 17000 Conformity assessment –Vocabulary and general principles

⁴Article 2(10) of Regulation (EC) No. 765/2008

no definition of the term "certification scheme" in the reference documents cited above, it shall be understood here to mean the same as the term "certification system".

- i. **Inspection:** examination of a product design, product, process or installation and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements. In the area of official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules⁵, **inspection** means the examination of any aspect of feed, food, animal health and animal welfare in order to verify that such aspect(s) comply with the legal requirements of feed and food law and animal health and animal welfare rules.
- j. **Audit:** systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled. In the area of official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules⁶, **audit** means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

2.3 Scheme types

The great diversity of conformity assessment schemes both in terms of their scope, their objectives, their structure and their operational methods makes their classification very difficult. However, one important distinction that can be drawn is whether or not they rely on a third party attestation procedure, thereby grouping them into self-declaration schemes on the one hand and certification schemes on the other. The certification schemes can be further distinguished based on whether they operate only at the business-to-business (B2B) level or whether they are aimed at providing information from the business to the consumer (B2C).

Another important classification criterion pertains to whether the scheme assesses conformity of products and processes (mostly B2C), or whether management systems are assessed (mostly B2B). In terms of specified requirements, schemes can attest conformity with provisions laid down in regulation (baseline), or they can add criteria which are not legally required (above baseline). The distinction between the two is not always easy to make: on the one hand, schemes often combine baseline criteria in some areas with higher requirements in others; on the other hand, certain baseline requirements particularly in the environmental and farming area require operators to use good and best practice, and judgment about due care so that the concrete actions to be taken can differ between actors and Member States. Indeed, the technical requirements of some certification schemes are used by operators to interpret and make concrete these general obligations

The following table illustrates this classification:

⁵ Article 2(7) of Regulation (EC) No. 882/2004

⁶ Article 2(6) of Regulation (EC) No. 882/2004

Classification of schemes					
Type of attestation:	Self-declaration	Certification (third-party attestation)			
Audience:	B2C	B2C		B2B	
Objects of specified requirements:	products and processes	mostly products (incl. services) and processes		mostly management systems	
Content of requirements:	mostly above baseline	above baseline	baseline	above baseline	baseline

The guidelines will focus on certification schemes as outlined in the right-hand side of the table above.

3. Existing legal provisions at EU level⁷

3.1 Rules related to the operation of schemes

Certification schemes are subject to some EU legal provisions, namely:

- **rules of the internal market.** Certification services shall be freely available across borders. Schemes shall also not result in de facto barriers to trade in goods in the internal market.
- **rules on state involvement in schemes.** Certification schemes supported by public bodies, such as regional or national authorities, shall not lead to restrictions to national producers or impede the single market.
- **rules on competition.** Certification schemes shall not lead to restrictive horizontal or vertical agreements that abuse market power (e.g. buying power) or foreclose other competitors.
- **consumer information and labelling requirements.** The labelling, advertising and presentation of food must not be such as could mislead a purchaser to a material degree, particularly:
 - (i) as to the characteristics of the foodstuff and, in particular, as to its nature, identity, properties, composition, quantity, durability, origin or provenance, method of manufacture or production;
 - (ii) by attributing to the foodstuff effects or properties which it does not possess;

⁷ References to the underlying legal documents to be added

- (iii) by suggesting that the foodstuff possesses special characteristics when in fact all similar foodstuffs possess such characteristics.

3.2 Rules related to the content of schemes

In addition, **specific legislation** exists on many subjects covered by the requirements of certification schemes (e.g. regulatory requirements for food safety and hygiene; organic farming; animal welfare; environmental protection; marketing standards for specific products).

3.3 Rules governing conformity assessment, certification and accreditation

Rules on the organisation and operation of accreditation of conformity assessment bodies performing conformity assessment activities have been laid down in Regulation (EC) No. 765/2008. While this regulation does not contain a requirement for conformity assessment bodies to become accredited, such a requirement is part of some other EU legislation⁸.

In addition, the internationally recognised rules for operating product/process or system certification schemes are set out in the International Standards Organisation (ISO) Guide 65 (EN 45011) or ISO 17021, respectively. While product/process or system certification schemes are voluntary initiatives, to deliver product/process or system certificates under accreditation, certification bodies have to be accredited against EN 45011/ISO 65 or ISO 17021.

Furthermore, Regulation (EC) No. 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules includes rules on private control bodies and accreditation.

4. Recommendations regarding scheme participation and development

- (1) Schemes shall have a **supervisory structure** which allows for the contribution of **all concerned stakeholders in the food chain** (farmers and their organisations⁹, agricultural and agri-food traders, food industry, wholesalers, retailers and consumers, as appropriate) in the development of the scheme and in decision-making in a representative and balanced way. Mechanisms for stakeholder participation and the organisations involved shall be documented and publicly available.
- (2) Schemes operating in **different countries and regions** shall facilitate the participation of all concerned stakeholders from those regions in scheme development.

⁸ E.g., Article 11(3) of Regulation (EC) No. 510/2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs requires that "The product certification bodies referred to in paragraphs 1 and 2 shall comply with and, from 1 May 2010 be accredited in accordance with European standard EN 45011 or ISO/IEC Guide 65 (General requirements for bodies operating product certification systems)".

⁹ E.g., cooperatives

- (3) Scheme requirements shall be developed by **technical committees of experts** and submitted to a broader group of stakeholders for inputs
- (4) Schemes shall ensure the participation of concerned stakeholders (as mentioned in paragraph 4.1 above) in the development of **inspection criteria and checklists**, as well as in the design and determination of thresholds for **sanctions**.
- (5) Schemes shall adopt a **continuous development approach** where feedback mechanisms exist to regularly review rules and requirements in a participatory manner. In particular, scheme participants (those actors who have to follow the rules and requirements of the scheme) shall be involved in the future development of the scheme.
- (6) **Changes** to scheme requirements should only be made when they are **justified and needed** (e.g., due to a change in the underlying legislation), so as to avoid unnecessary adaptation costs for scheme participants. Scheme participants must be given **appropriate notice of any change** to the scheme requirements.
- (7) Schemes shall include **contact information** on all documentation associated with the scheme (including on the website) and establish a process to receive and reply to comments on the scheme.

5. Recommendations regarding scheme requirements and corresponding claims

5.1 Clarity and transparency of scheme requirements and claims made

- (1) Schemes shall clearly state their social, environmental, economic and/or legal **objectives**
- (2) **Claims** and **requirements** should be clearly linked to the objectives of the scheme.
- (3) The **scope** of the scheme in terms of products and/or processes shall be clearly defined.
- (4) **Scheme specifications¹⁰, including a public summary of the specifications, shall be freely available on the Internet** and should be translated into the appropriate languages in light of the production or marketing of certified products.
- (5) Scheme specifications shall be **clear, detailed and easily understandable**.
- (6) Schemes using consumer logos or labels shall provide information about where consumers can find **further details on the scheme**, such as the website address, either on the product packaging or in store.
- (7) Schemes shall clearly state (on their website) that they have been **certified by an independent body** and provide contact details of that certification body.

¹⁰ Exceptions should be made where scheme specifications are based on standards which are not freely available (e.g., ISO and CEN standards)

5.2 Evidence base of scheme claims and requirements:

- (1) All claims shall be based on verifiable evidence and, if appropriate, have a **scientific underpinning**. These scientific underpinnings (e.g., studies and indicators) shall be freely available on the Internet¹¹.
- (2) Schemes operating in different countries and regions shall **adapt their requirements in line with the relevant local agro-ecological, socio-economic and legal conditions and agricultural practices**, while ensuring consistent results across different contexts.

5.3 Positioning of the scheme within the legal framework:

- (1) Schemes shall **clearly indicate** (on their website) whether, where and to what extent their **specifications go beyond the relevant legal requirements**, including in the areas of reporting and inspections, if applicable.
- (2) In areas where relevant standards and/or legislation exist, **claims shall take into account and be consistent with these standards or legislation** and reference them in their specifications (e.g., if a scheme is making organic farming claims, it shall be based on Regulation (EC) No. 834/2007; schemes making claims on nutrition and health shall be in accordance with Regulation (EC) No. 1924/2006, and go through the required scientific assessment by EFSA; In the area of animal welfare, private schemes shall take into account and are consistent with the OIE animal welfare standards and with EU legislation.)

6. Recommendations regarding certification and inspections¹²

6.1 Impartiality and independence of certification

- (1) Certification of compliance with the scheme requirements shall be carried out by an **independent body accredited¹³ under** standard EN 45011 and/or ISO Guide 65 for product/process certification) or ISO/IEC 17021 (for management systems certification).by the national accreditation body appointed by Member States according to Regulation (EC) No. 765/2008, or accredited by a signatory to the multi-lateral recognition arrangement (MLA) for product certification of the International Accreditation Forum (IAF).¹⁴

¹¹ An exception shall be made for confidential and/or proprietary information, which should be clearly indicated.

¹² This part of the guidelines does not apply to the official controls carried out by public authorities

¹³ In cases where public authorities are acting as certification bodies, no accreditation is required.

¹⁴ The issue of accepting international accreditation bodies (IABs) which offer scheme-specific accreditation of CBs according to ISO/IEC 17011 but are not members of the IAF needs to be resolved. E.g. the International Organic Accreditation System is accrediting certification bodies for IFOAM but is not member of IAF.

6.2 Inspections

As a general principle, inspections should be effective, clear, transparent, based on documented procedures and related to the verifiable criteria underlying the claims made by the certification scheme. Unsatisfactory inspection results should lead to sanctions.

- (2) **Regular inspections** shall be carried out of scheme participants. There shall be **clear and documented procedures** for inspections, including frequency, sampling, and laboratory/analytical tests in parameters related to the scope of the certification scheme.
- (3) The **frequency of inspections** shall take into account previous inspection results, the risk of the product/process/system, as well as the existence of internal audits in collective producer organisations which can complement third-party inspections. A **minimum inspection frequency** for all scheme participants shall be determined by the scheme supervisory structure.
- (4) There shall be a systematic **evaluation of the results of inspections**.
- (5) **Unannounced inspections** and very short notice (max. 48 hours) inspections shall be used where appropriate.
- (6) Inspections and audits shall be based on **publicly available guidelines, checklists and plans**.
- (7) There shall be clear and documented **procedures for dealing with non-compliance** which are effectively implemented. **Knock-out criteria** shall be defined which would lead to non issuing or withdrawal of the certificate and/or withdrawal of membership and/or reporting to the relevant official enforcement body. These knock-out criteria should at least include not fulfilling the basic legal requirements in the area covered by the certification.
- (8) Inspections shall focus on **analysing the verifiable criteria** which are underlying the claims made by certification schemes.

6.3 Transparency of costs

- (9) Schemes shall **publish their membership fees** (if any) and require their certification bodies to **publish the costs associated with certification and inspection** for different types of scheme participants.

6.4 Qualification of auditors/inspectors

As a general principle, auditors/inspectors shall be impartial, qualified and competent.

- (10) Auditors carrying out the certification audits shall have the **relevant knowledge in the specific sector** (e.g., dairy) and work for certification bodies that

are accredited under the relevant European or international standards, e.g. for product certification schemes EN 45011 (ISO 65) and for management system certification schemes ISO/IEC 17021 (replacing EN 45012 (ISO 62)). The required auditor skills shall be described in the scheme specifications.

6.5 Provisions for small-scale producers

- (11) Schemes shall make provisions to enable the **participation of small-scale producers (especially in developing countries, if relevant)** in the scheme.

7. Recommendations regarding mutual recognition and benchmarking / overlap with other schemes

- (1) Schemes which are entering a new sector and/or are expanding their scope shall justify the need for their standard. They shall make **explicit reference** (on their website) to other relevant schemes operating in the same sector, policy area and geographical region and **identify where their approaches converge and agree**. They shall actively explore **possibilities for mutual recognition** for parts or all of their requirements.
- (2) In areas where schemes have identified (partial or total) overlap with the requirements of other schemes, schemes should **accept partially or totally inspections and audits** already carried out under those schemes (and not re-audit the same requirements)
- (3) If mutual acceptance cannot be achieved, schemes should promote **combined audits** based on combined audit checklists (one combined checklist, one combined audit for two or more different schemes).
- (4) Schemes overlapping in their requirements should as much as practically and legally possible also **harmonise their auditing protocols and documentation requirements**.
- (5) Schemes shall actively pursue **closer collaboration with official control bodies** in those areas where scheme requirements overlap with official controls. The ultimate aim would be recognition by public authorities of certification against certain standards, which could result in lower control priority or financial incentives for certified producers in the context of official controls. For this purpose, schemes should undertake to make available results of audits to the extent that they cover legal requirements and especially information of any non-compliance in this field to the public authorities.

8. Guidelines per policy area

In addition to the general recommendations outlined above, these guidelines can also provide specific recommendations for schemes in different policy areas. These can be developed in a modular way on a case-by-case basis, if and when needed. Developing such guidelines in a defined policy area presents a "light" alternative to the development of new EU schemes or new legislation. For each policy area, specific recommendations should take into account existing legislation, international standards and be based on a consultation of stakeholders.

Examples of policy areas for which specific guidelines could be developed in the future are:

- Geographical origin (other than the EU PDO/PGI schemes)
- Traditional/artisanal product (other than the EU TSG scheme)
- Organoleptic quality
- Animal welfare
- Fair trade
- Environmental claims
- Carbon footprint labelling
- Sustainable use of water resources
- Sustainable fisheries / aquaculture