

GUIDANCE ON THE APPLICATION OF ISO/IEC 17065 FOR ORGANIC CERTIFICATION

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# INTRODUCTION

ISO/IEC 17065:2012 is an International standard which sets out criteria for bodies operating certification of products, processes and services. One of the important certifications in this area is certification of organic products and/or processes.

In many countries, organic farming and production is governed by regulations. Even if this is not the case in a country of production, the regulatory requirements of import markets must be complied with in case of exports. Further, in case there are no regulations, there may be voluntary standards for responding to the market needs. The compliance to such regulations and standards for organic production is generally verified through conformity assessment activities carried out by Certification Bodies (CBs) accredited to ISO/IEC 17065:2012.

Since there is an increasing demand for organic products in many developed markets, there is also a greater demand for certification of organic products by the accredited CBs operating in the respective countries as well as those interested in exporting to developed markets.

*Note The term “organic production standard” or “standard” is used throughout this document to cover the normative documents which describe the requirements for organic production. These may be contained in standards (including private standards) or regulations.*

# PURPOSE OF THIS DOCUMENT

If CBs are to be accredited in a worldwide harmonized manner as complying with ISO/IEC 17065:2012, some guidance on the requirements specified in ISO/IEC 17065:2012 as applicable to organic certification is felt necessary. This is more so, since there are many specific requirements pertaining to organic farming and consequently requirements with respect to certification of such products and processes.

This document intends to provide such guidance and has three main purposes:

* to enable accreditation bodies (ABs) to harmonize their application of the standards against which they are required to assess the CBs;
* to facilitate mutual recognition of accreditation process, especially to facilitate the recognition of different organic certification schemes for mutual acceptance; and
* to assist CBs themselves and to those stakeholders (such as regulators, scheme owners or buyers), whose decisions are guided by the certificates issued by the CBs.

For the convenience of usage this document has been structured on the same lines as ISO/IEC 17065:2012 and the headings from that document are first given in bold. Additional guidance, where provided is, for ease of reference, then identified with the letters “G”. Where no additional guidance’s/interpretations are felt necessary, “Nil” has been stated against those clauses.

Since this is a guidance document, the requirements have been described using the term “should“, which indicates the recognised means of meeting the requirements.

Although currently the document is written in the form of a guidance document, the CBs are encouraged to implement the certification scheme and certification processes in general based on the guidance provided. This would eventually help the ABs in assessing the CBs for the purpose of accreditation in a harmonized way. Further the ABs have an option of incorporating the requirements provided in this document as a part of their policy document on accreditation of organic CBs, thereby making them mandatory to be followed.

1. SCOPE

This document provides clause-based guidance/interpretation on application of ISO/IEC 17065: 2012 to organic certification.

1. NORMATIVE REFERENCES

Those specified in clause 2 of ISO/IEC 17065:2012 apply.

1. TERMS AND DEFINITIONS

For the purpose of this document, the terms and definitions given in ISO/IEC 17065 apply. In respect of the organic production/certification, specific terms definitions/explanations are provided in a note form wherever the terms have been referred to in the first instance.

**4. GENERAL REQUIREMENTS**

**4.1 Legal and contractual matters**

**4.1.1 Legal Responsibility**

Nil - No additional guidance.

**4.1.2 Certification Agreement**

G.4.1.2.1 The certification should be based on written agreements, with clear responsibilities of all parties involved in the chain of operations for production of an organic certified product.

G.4.1.2.2 The certified clients should sign agreements requiring them to:

1. follow the requirements given in organic production standards and other documents such as the certification scheme or any other document describing the certification process;
2. not to use any prohibited items in its production of organic products in accordance with the buyer’s requirement or the prevalent organic production standard in country of production/sale;
3. accept inspections, including unannounced inspections and direct inspections by the CB or any other party as per the applicable requirements specified in the certification process;
4. supply accurate information;
5. notify the relevant parties (including the CB) of any changes in accordance with the requirements specified in the certification scheme;
6. inform the CB of all complaints received by the certified clients relating to the certified products; and
7. any other requirement as per the certification scheme or the relevant regulation.

*Note 1 Clients are also popularly known as “Operator” or “Producer” in the field of organic farming, production and processing. The terms “Inspection” or “Inspector”. may be referred as “audit” or “auditor” in some certification schemes for organic certification.*

*Note 2 The document describing the certification process may be contained in a certification scheme developed by some independent organization, the CB or a regulation.*

G.4.1.2.3 The CB should ensure that its certification agreement requires that its clients (applicants and certified clients, as applicable) comply with the following organic certification specific requirements:

1. provide access to the inspector(s)) of the CB, to all relevant facilities of organic production, including accounts and sales related records and other relevant documentation to provide adequate audit trails and traceability of organic certified products;
2. access to its record keeping system adapted to the type of production that enables the CB to retrieve necessary information and to seek verification of the production, storage, processing, purchase and sale;
3. provide access to non-organic production units or units associated by ownership or management to the client, to enable the CB to assess any impact on contamination or mix up with the certified organic produce;
4. should provide the CB with updated information on the scheme of inspection and testing, which the certified client maintains or intends to maintain for ensuring organic integrity; and
5. should permit the CB to share information with other CBs and authorities when appropriate and essential (see 4.5.1).

*Note The term “client” applies to both certified clients and applicants.*

**4.1.3 Use of Licenses, Certificates and Marks of Conformity**

G.4.1.3.1 The certification mark which indicates organic status should not be used on non-organic products or on documentation accompanying such product.

G.4.1.3.2 The certification mark should only be applied to product where compliance with the certification requirements has been ensured. The CB that certified the last process (processing, packing, labelling) should be identified.

*Note The definition of “Certification requirements” is that given in clause 3.7 of ISO/IEC 17065: 2012. These include the requirements as specified in the certification scheme or the certification process as defined by the CB.*

 G.4.1.3.3 Conformity of the certified product should be monitored in accordance with the certification requirements.

**4.2 Management of Impartiality**

G.4.2.1 The CBs that are administered by membership organizations (member’s may be farmers) or are owned by the membership organization or organic producer organizations, should ensure clear separation of activities and all requirements with respect to impartiality in decision making and other activities should be ensured by the CB. Further, it should be ensured that the requirements specified in clause 4.2.6 of ISO/IEC 17065: 2012 regarding the activities of the CB should be complied with at all times.

G.4.2.2 The CB should not offer any services that question its objectivity and impartiality. Such services may however include marketing and promotion activities for organic products in a generic way.

**4.3 Liability and Financing**

Nil - No additional guidance.

**4.4 Non-discriminatory Conditions**

Nil - No additional guidance.

**4.5 Confidentiality**

G.4.5.1 Whilst maintaining confidentiality of information, the CB should have provision for exchange of information as necessary. For example, when laboratory tests show that pesticides were found in organic products, the CB should notify other related CBs, such as, the certifier of the manufacturer of organic products using as raw material the organic agricultural products found to contain the pesticides. It should also inform, where relevant, the competent authorities and any other relevant stake holders.

*Note Generally, this communication should be based on investigation to establish beyond doubt that the products contain pesticides or other undesirable chemicals beyond acceptable limits for organic products. Single test results may in normal circumstances be considered too limiting to establish contamination beyond reasonable doubt.*

**4.6 Publicly Available Information**

G.4.6.1 The CB operating the organic certification scheme should have processes for informing all concerned including the prospective and present certified clients about the applicable standards for the different organic product categories and the program changes including updates of procedures and standards. This should be in a language appropriate to the clients.

G.4.6.2 The CB should identify clearly the standards and requirements used for the different product categories. These should be available to the applicant. The detailed information regarding organic production standards against which the products will be certified and the certification requirements and the general information on fees charged should be made available through publications and electronic media, and should generally be made available on the CB’s website.

**5. STRUCTURAL REQUIREMENTS**

**5.1 Organizational Structure and Top Management**

G.5.1.3.1 In absence of a certification scheme for certification of organic products developed by an independent organization, the CB should be responsible for development of the certification scheme or simply the description of the certification process requirements (clause 7 of ISO/IEC 17065: 2012). See clause G.7.1.2 of this document for details.

G.5.1.3.2 Normally the organic production standard only specifies requirements for organic production. In absence of certification scheme for organic production, the CB should identify individual(s) or a group of individuals with necessary competence, having responsibility for development of the certification scheme or the certification process requirements. A stakeholder committee with collective competence can fulfil this requirement.

**5.2 Mechanism for Safeguarding Impartiality**

Nil - No additional guidance.

**6. RESOURCES REQUIREMENTS**

**6.1 Certification body personnel**

**6.1.1 General**

G.6.1.1 The CB should ensure that its personnel have sufficient knowledge on organic agriculture, organic certification and regulatory requirements relevant to organic certification.

**6.1.2 Management of competence for personnel involved in certification process**

G.6.1.2.1 The following criteria should be applied to CB personnel, which should include but not be limited to, as appropriate, the contract review personnel, inspection and evaluation personnel, technical reviewers and decision makers. The CB personnel should:

1. have sufficient background and knowledge in agriculture and/or food science/technology (if applicable), organic farming, aquaculture and organic processing/packaging, etc. The requirements may vary based on the functions undertaken by the personnel and the product category. Knowledge may be gained typically through educational qualification, work/audit experience and/or appropriate training, adequate to provide knowledge of organic products/product categories; relevant regulations and standards; production and processes: certification process and certification scheme requirements, as applicable to the functions undertaken;
2. have initial training for inspection which should typically include aspects such as organic agriculture, food and feed processing, trade, specific production areas {such as unprocessed plant products, aquaculture – see d) below} and relevant organic production standards, certification requirements and where appropriate, training on evaluation and certification of smallholder groups;
3. be qualified and authorized on the basis of use of appropriate evaluation methods;

*Note A combination of evaluation methods such as review of records; feedback; interviews; observations/witness; examination should generally be used to evaluate knowledge and skills.*

1. depending upon the initial qualification and experience of individuals, should undergo a qualification process which may include an evaluation of knowledge and skills, an induction period or a supervised working period with experienced inspectors or a combination of these measures. Before being authorized for carrying out inspection activities independently, the inspection personnel may participate in scope-based inspections, as observers or under observation of experienced inspection personnel. The number of such inspections they need to undergo for getting qualified and authorized should be decided by the CB, based on their initial competence level; and
2. during the qualification and authorization process, be qualified for different product categories such as crop production; livestock, poultry, etc; aquaculture; food processing and handling, etc.

G.6.1.2.2 The CB should ensure that the inspection team has competence in the product category of the client who is being inspected. The competence can be built through nomination of a technical expert qualified in the same product category.

G.6.1.2.3 The CB should have access to experts or group of experts knowledgeable in certification requirements as applicable to certification of organic production processes and products, for the purpose of development of certification requirements appropriate for ensuring that sufficient objective evidence is obtained as a base for its decision making. The ultimate objective of this exercise should be to ensure that the production processes and products certified continue to comply with the organic product requirements specified in the relevant organic production standards and other related documents.

G.6.1.2.4 The CB should actively identify training needs at entry level as well as based on needs identified through systematic performance reviews and provide, as necessary, training to its staff on the requirements of the standards, the certification program and relevant methodologies. Adequacy of such training plans, training and evaluation records, and the related records should be maintained.

G.6.1.2.5 The performance monitoring for each evaluator/inspector should include observation in on-site inspection, normally not longer than every three years, unless there is sufficient supporting evidence that the auditor is continuing to perform competently.

**6.1.3 Contract with the personnel**

Nil - No additional guidance.

**6.2 Resources for Evaluation**

**6.2.1 Internal Resources**

See G.6.1.1, G.6.1.2.1 – G.6.1.2.5 above.

**6.2.2 External Resources**

G.6.2.2.1 Outsourcing of testing (of input materials, organic certified products, etc. for residue requirements, genetically modified organisms and others) should be carried out on a risk based assessment by the CB.

*Note Residues” is a generic term used for any type of chemical residues such as pesticide residues, veterinary drug residues, etc.*

G.6.2.2.2 The CB should ensure that the testing activities are subcontracted to competent laboratories as demonstrated either by the sub-contracted laboratory having accreditation to ISO/IEC 17025 for the relevant tests and providing endorsed (logo/mark) reports or the CB itself assessing the competence of the sub-contracted laboratory to the requirements of ISO/IEC 17025.

G6.2.2.3 Where the assessment of the sub-contractor is carried out by the CB, it should be able to demonstrate that the assessment team is technically competent and knowledgeable in the application of ISO/IEC 17025 for the relevant fields of testing.

**7. Process Requirements**

**7.1 General**

G.7.1.1 The requirements and procedures set up by the CB should take into account the requirements stated in the relevant organic production standards and certification requirements specified in a scheme or otherwise. These should include any other supporting requirements as prescribed by the regulator or the scheme owner.

G.7.1.2 Any organic certification scheme followed by the CB could have defined requirements for CB’s functioning as well as certification process requirements. CB requirements covering organic certification should primarily be based on ISO/IEC 17065:2012 and the certification process requirements should be based on clause 7 of ISO 17065:2012 as applied to certification of organizations engaged in organic farming/production in accordance with the relevant organic production standard. In case the requirements specific to organic certification have been documented by the Regulator / Accreditation Body / Scheme owner then the CB can directly base its certification system on the prescribed requirements. However, in absence of these, it becomes incumbent upon the CB to describe the certification system related requirements covering CB requirements (based on ISO/IEC 17065:2012), as applicable and certification process requirements (covering clause 7 and based on provisions in relevant regulations, if any). The CB should be able to provide justification for choice of a particular provision in its certification process requirements, for example, evaluation mechanism used, process for reasons for suspensions, etc.

G.7.1.3 The certification scheme should address the aspects, such as retrospective recognition of conversion period, separation and inspection of conventional production units, parallel /split production, group certification and wild collection, in accordance with the relevant organic standard and certification requirements.

*Note The terms in respect of organic production, as used above, are described below:*

1. *‘buffer zone’ is a clearly defined and identifiable area bordering an organic production site from that of a conventional production unit;*
2. *‘conventional farming’ is described as the farming systems dependent on input of artificial fertilizers and/or chemicals and pesticides or which are not in conformity with the basic standards of organic production;*
3. *‘conversion’ is the process of changing an agricultural farm from conventional to organic farm. This is sometimes also called transition. Conversion does not apply to handling and processing facilities;*
4. *‘conversion period’ is the time between the start of organic management and the certification of crops as organic;*
5. *‘retroactive conversion’ means a recognition by the CB of a period of management before the operator applied for certification. Recognition should be based on production records and/or affidavits that the management during that period complied with the organic standard;*
6. *‘split production’ means any production where the same unit is growing, breeding, handling or processing products both in a certified organic quality and a noncertified organic quality. Similarly a situation with “organic” and “in conversion” production of products is also split production;*
7. *‘parallel production’ means any production where the same unit is growing, breeding, handling or processing products which are indistinguishable both in a certified organic quality and a noncertified organic quality. Similarly a situation with “organic” and “in conversion” production of the same product is also parallel production;*
8. *‘group certification‘, please see Note below clause G.7.4.2.1*
9. *‘wild collection‘ is the collection of wild plants and parts thereof, grown naturally, and without intervention.*

G.7.1.4 The certification scheme used by the CB or the certification process developed by the CB should have available and implement policies and procedures for aspects such as, risk assessment methodology and risk based inspections; procedure for estimation of minimum inspection time; policy and procedure forsampling;surveillance assessments including provisions for unannounced inspections; management of deviations; categorization of non-conformities and corrective actions;procedure for accepting client’s from other CBs; exchange of information with other CBs and authorities (approval bodies or accreditation bodies) as appropriate and a policy for the annual report to the regulator as per requirements specified in the relevant standard / regulation, as applicable.

G.7.1.5 The schemes / regulations covering organic certification generally have provision for acceptance of certificates of organic products in accordance with the specific requirements when the products in the manufacturing chain have been certified by other bodies only if the two certification bodies have the equivalent certification procedures and requirements. Accordingly, the CB needs to develop as part of its certification procedure (in case not detailed in the certification scheme) the acceptance procedures of certificates by other CBs by taking into account the following:

1. on the basis of the same certification scheme and reputation;
2. on the basis of the different certification scheme and reputation;
3. cooperation between the CBs in accordance with specific agreement

The acceptance procedures of certificates of organic certification among different certification bodies should ensure the harmonization of certification results and requirements.

G.7.1.6 The certification process developed/used by the CB should have documented policies and procedures on residue testing, testing of genetically modified organisms, input materials and others as relevant to establish organic integrity and in accordance with the relevant standard/regulation. These should generally include the following:

1. system for identification of cases in which samples are to be taken for analysis, such as where use of a substance prohibited by the standards, is suspected;
2. a procedure on how to take samples and send them to laboratory for testing purposes; and
3. the number of samples taken per annum should generally be based on risk assessment and should be appropriate to the requirement specified in the relevant certification scheme/regulation, if any.

*Note: Number of samples taken per annum representing 5% of the clients under the scheme are generally considered as adequate.*

**7.2 Application**

G.7.2.1 The certification scheme should not generally allow clients to switch in and out of the certification system. Information collected at application stage should include information on the status and details of previous certification of organic production, if any. While accepting an application for change of CB, the CB receiving such applications should ensure availability of all the background information in respect of the applicant production unit, and whether another CB had denied certification to the applicant for organic certification and whether its previous certification was suspended/withdrawn on account of violations. CBs should also have a documented system for corroborating the information received from the CB who had previously certified the client.

G.7.2.2 The CB should have appropriate provisions in its system for receipt of the following minimum information from the applicant. The CB’s system should also have provision for inspection of additional areas as given below, based on the information received from the applicants for certification:

1. the CB and its inspectors should have information of and access to all relevant facilities of organic production, including accounts and sales related records and other relevant documentation to provide adequate audit trails and traceability of organic certified produce and products;
2. the applicant should have a record keeping system adapted to the type of production that enables the CB to retrieve necessary information and to seek verification of the production, storage, processing, purchase and sales;
3. the CB should have access to and inspect non-organic production units or units associated by ownership or management to the applicant/client. Inspection stages should include review of such units when there is sufficient reason for doing so, such as production of the same kind of products, etc.
4. where existing, the CB should have information about the units conducting repackaging or storage (or other processes) on behalf of the applicants as well as all outsourced activities and processes. The CB should have a system for inspecting the units where such outsourced activities are carried out on a risk based approach; and
5. the applicant should provide complete and accurate information in respect of the above.

G.7.2.3 The applicant should also inform in detail any scheme of inspection and testing, which the applicant maintains or intends to maintain for ensuring organic integrity.

**7.3**  [**Application revie**](#page20)**w**

G.7.3.1 The CB’s system should have provision for review of information on antecedents of the applicant organizations regarding previous applications made/certifications held by the organization as received at application stage. In case the previous history does not provide the CB regarding the applicant organization’s capability to fulfil certification requirements on a consistent basis, the CB may reject the application after recording appropriate justification.

**7.4 Evaluation**

 **Preparation for evaluation**

G.7.4.1 While assigning evaluators/inspectors for the purpose of evaluation, the CB should generally ensure that the same inspector is not assigned to one client on a continuous basis. Normally change after one certification cycle is or 3 years is considered appropriate.

G.7.4.2 The team nominated for the purpose of evaluation/inspection of the applicant should carry out an offsite review of the relevant information received through application process as stated in clause 7.2 and ask for any additional information if necessary. Based on this review, an appropriate plan for evaluation may be drawn up and this should include visits to all facilities/farms and others like suppliers of non-organic farm products in the neighborhood etc., as applicable. The review should highlight areas for specific investigation at the on-site evaluation. This planning should also include as appropriate sampling strategies and requirements for testing based on review of risk analysis conducted by the client.

 **Evaluation related**

G.7.4.3 For smallholder group certification, where prescribed in the certification scheme / regulation, the CB should evaluate the proper functioning of the group’s internal control (quality management) system, manual and documentation as described in relevant standards and certification requirements.

*Note Smallholder groups (sometimes called grower groups) are organized groups of producers who intend to produce organic products/engage in organic processes in accordance with some common standard. In some certification schemes/ regulations, group certification is permitted based on the concept of implementation of an internal quality management system which includes internal inspection. The scheme is required to describe the requirements of functioning of the internal quality management system as well as the requirements to be followed by the CB for evaluating such a system and the process for certifying the same.*

G.7.4.4 Inspection procedures and methods used by the CB should essentially include, but are not restricted to the following:

1. visits of facilities, storage units, fields/farms (which may also include visits to non-organic areas when necessary), etc.;
2. verification of information provided by the client;
3. Identification and investigation of areas of risk to organic integrity;
4. Review of records, accounts, sales figures, etc.;
5. Sampling and analysis, when necessary;
6. Calculation and confirmation of input/output norms, production estimates, etc.;
7. Interview not only with designated responsible persons on the farm/production units, but also with other levels of employees like farm workers, production staff, etc.;
8. Verification that changes to the standards and to requirements of the CB have been effectively implemented, when necessary; and
9. Verification that corrective actions of nonconformities have been taken, when necessary.

G.7.4.5 Additional evaluation activities may become necessary based on the observations made during planning and inspection stages. Some of the examples are:

1. in case high risk of mixing of organic and non- organic product such as partial conversion and parallel production is observed during the inspection, then the CB should verify whether handling and documentation regarding production or processing, storage and sales is well managed and makes clear distinctions between certified and non-certified products. In cases where products are not visibly distinguishable, specified measures should be applied during harvest and post-harvest handling to reduce the risk;
2. where a client is certified also by other CBs within the same certification scope, the CB should verify the sales records and records of products with different certification symbols when the same certification scope may be doubly or triply covered under certification and transaction certificates, when necessary in order to prevent the sales of non-organic products instead of organic products.

 **Evaluation reporting**

G.7.4.6 The report should follow a format appropriate to the type of organic operations inspected/evaluated. Likewise, the report should cover all relevant aspects of the organic standards and certification process and adequately validate the information provided by the client, including:

1. date and duration of the inspection, persons interviewed, details of fields/farms and facilities visited;
2. details of the on-site-visit activities including a record of the documents viewed and verifications performed;
3. evaluator’s/Inspector’s observations and evaluation of compliance to organic production standards and the certification requirements; and
4. appropriate recording of the compliance aspects as well as non-conformities, both with details of relevant audit evidences and objective evidence for nonconformities detected.

G.7.4.7 Reports should be designed to allow for elaboration and analysis by the inspector on areas where compliance might be partial, standards might not be clear, etc. for ensuring appropriate decision with respect to scope of organic certification. The report and accompanying documentation should provide sufficient information to allow verification that the relevant standards have been complied with.

**7.5 Review**

Nil - No additional guidance.

**7.6 Certification Decision**

Nil - No additional guidance.

**7.7 Certification Documentation**

G.7.7.1 In addition to the formal certification documentation the CB may be required to issue certificates of inspection for each shipment of products in the format provided by the relevant certification requirements. Before issue of such certificates the CB should verify (through comparison with production estimates and/or physical verification) whether the products listed and quantities included have been produced/prepared by the certified client. In some cases, the CB may also ask for additional evidences in terms of test reports.

**7.8 Directory of Certified Products**

G.7.8.1 The CB should publish a list of certified, suspended and withdrawn clients on its webpage. The list should be updated periodically and in general not later than 2 weeks after the decision has been taken and not later than two days after a decision of withdrawal of certification of a client has been taken.

*Note The heading has been aligned with the standard (ISO/IEC 17065: 2012). What is stated here is meant to be additional guidance.*

**7.9 Surveillance**

G.7.9.1 The CB should conduct periodic on-site inspections of all certified clients. In respect of organic certification, onsite surveillance assessment at a frequency of at least once per year is generally considered essential. This frequency is also prescribed in some certification schemes / regulations.

G.7.9.2 In addition, the CB should have a system and documented procedure for conducting client based risk assessment, which should determine the frequency and type of surveillance activities to be conducted. The system for risk analysis should also be used for determining the number of announced and unannounced inspections. The number of additional and or unannounced inspections per annum should generally represent 10% of the certified clients under the scheme, unless otherwise specified in the certification scheme / relevant regulation.

G.7.9.3 The following aspects, as minimum should be considered while conducting the risk assessment for each client:

1. the results of the previous control;
2. the complexity of the certified client (type and structure of certified client);
3. quantity of products concerned;
4. risk of mixing of organic and non-organic product such as partial conversion and parallel production;
5. intensive production and high dependence of external inputs, short production cycles;
6. previous track record both with respect to running the scheme as well as rejects from the market, previous NCs, feedbacks, test result etc.; and
7. complaints/denunciations/alerts received.

Depending on the risks identified, the CB should decide whether it is appropriate to increase the frequency of inspections, than those planned in accordance with generic scheme requirements.

G.7.9.4 Surveillance activities in respect of the organic production certification scheme should include the following:

1. additional visits to the certified client’s premises during the certification period on the basis of a risk based system; and
2. end product testing for residues and GMOs based on the results of risk assessment.

**7.10 Changes Affecting Certification**

G.7.10.1 In case the CB makes any changes in the certification requirements, then it should ensure, by any means that it chooses, that the information is immediately transmitted to the certified clients and also inform about the transition period for the client to comply with the changed requirements. The transition period should be decided based on the changed requirements and should also take in to account considerations such as the decision regarding the products under production/ already produced before the changes are made known to the client. In case changes are driven by the changes in organic production requirements as per the relevant regulation / certification scheme, then the transition period and other production as well as certification requirements should take in to account the relevant regulation / scheme requirements. The CB should also require the client to confirm the receipt of the information and his confirmation on following the instructions transmitted.

G.7.10.2 The CB’s procedure should require the certified client to inform them in cases of any changes, such as, modification in organic product composition, manufacturing process, farming practices, extension/reduction in farm acreage, site changes, etc. The CBs should determine whether the announced changes require further visits and confirmation. The CB should inform the certified client of all conditions under which the client should not release the organic certified material to the market before getting confirmation from the CB.

G.7.10.3 If the certified client outsources parts of production/processing activities to other organic producers, this should be informed to the CB in advance, allowing the CB to inspect the same if necessary. In case of outsourcing, the CB should require the certified client to be held fully responsible for the outsourced activities. This should also be made part of the legally enforceable agreement between the CB and the client. Any further changes in the outsourcing arrangements should be promptly brought to the notice of the CB.

**7.11 Termination, Reduction, Suspension or Withdrawal of Certification**

G.7.11.1 CBs should have documented procedures for dealing with violation of the organic standards and certification procedures by the certified clients. These should include requirements for minor deviations as well as major deviations affecting the organic integrity of the certified products. In case of major deviations affecting organic integrity, the CB should ensure that the indication of certification is removed from the entire lot of the production run which is affected by the major deviation. Where a serious violation is made by the client, the CB should withdraw certification from the client. The CB should have clearly documented procedures for withdrawal and cancellation of certificates and certification marks, including aspects like product recall, etc. The CB should also take note of any sanctions, if any, imposed by the relevant regulators on the certified client or the product related to alerts issued.

**7.12 Records**

G.7.12.1 The CB should maintain records to demonstrate the certification procedures on organic production have been effectively implemented. Such records should include but are not limited to:

1. full description of the production unit and/or collection areas, showing the storage and production premises and land parcels and, where applicable, premises where certain preparation and/or packaging operations take place;
2. information about individual members of a grower group as well as the organic certified unit’s sub – contractors, if any; and
3. any specific requirements imposed by the respective regulators with respect to information exchange the same should also be complied with.

**7.13 Complaints and Appeals**

G.7.13.1 The CB should have a procedure which describes how to deal with complaints received from stakeholders like importers of the certified organic products, competent authorities, regulators and other relevant sources, especially regarding the organic products supplied by its certified clients. Response time, responsibilities and the handling procedures including investigation processes should be clearly described. In case the complaint investigation indicates violation of product integrity, then the CB should decide about undertaking additional or unannounced audits of the client’s premises.

G.7.13.2 The CB should have a system in place that ensures that the clients inform them of any complaints received by them regarding the quality of an organic product. The clients should also inform the CB of the measures taken by them to correct the defects, if any, identified based on their investigation of the complaint received. They should also inform of the measures taken to prevent reoccurrences.

**8. Management System Requirements**

**8.1 Options**

Nil – No additional guidance.

**8.2 General Management System Documentation (Option A)**

Nil – No additional guidance.

**8.3 Control of Documents (Option A)**

Nil - No additional guidance.

**8.4 Control of Records (Option A)**

Nil - No additional guidance.

**8.5 Management Review (Option A)**

Nil - No additional guidance.

**8.6 Internal Audits (Option A)**

G.8.6.1 The CB should ensure that during the internal audit the whole organic certification scheme is reviewed at least once a year.

**8.7 Corrective Actions (Option A)**

Nil - No additional guidance.

**8.8 Preventive Actions (Option A)**

Nil - No additional guidance.

1. AMENDMENT TABLE

This table provides a summary of the changes to the document with this issue.

|  |  |
| --- | --- |
| **Section(s)** | **Amendment(s)** |
| All | New issue on establishment of APAC. Document transposed to new format from PAC-TECH-008 Guidance on the Application of ISO/IEC 17065 for Organic Certification (Issue 1.0) |
| End |  |