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**GUIDANCE ON CRITERIA FOR GLUTEN-FREE CERTIFICATION BODIES**

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**GUIDANCE ON CRITERIA FOR  
GLUTEN-FREE  
CERTIFICATION BODIES**

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## **I. FOREWORD**

The International Natural Accreditation Forum (i-NAF) is an independent, non-government network of natural accreditation agencies all mandated to enforce Natural, Vegan, Vegetarian, Halal Gluten-Free, Gluten-Free and Eco Global Labels etc. Life Chain Standards in their economies and regions.

It has been established with the aim of unifying and harmonizing Natural accreditation practices on global level to comply with natural principles, requirements and to develop and maintain Natural Multi-Lateral Arrangements (MLA) among i-NAF member natural accreditation bodies (NABs), this will result in removing technical barriers facing natural / vegan / vegetarian / halal / gluten-free / eco products and services, and facilitating international natural products and services trade, hence protecting the growing number of consumers.

This guide provides the requirements for natural certification bodies of gluten-free. This guide endorsed by i-NAF Board of Directors.

This guide is a reference document for Gluten-Free Certification Bodies (GFCBs).

It is prepared based on the requirements of the international standard ISO/IEC 17065:2012 Conformity Assessment — Requirements for Bodies Certifying Products, Processes and Services and ISO/IEC 17021-1:2015 ISO/IEC 17021-1:2015 Conformity Assessment — Requirements For Bodies Providing Audit And Certification Of Management Systems — Part 1: Requirements. It includes criteria for the application of ISO/IEC 17065 (Including ISO/IEC 17021-1:2015) requirements for natural accredited certification bodies.

The effective date for implementation of this document is the date of endorsed by i-NAF Board of Directors.

The guide is published on the i-NAF website ([www.i-naf.org](http://www.i-naf.org)).



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## **II. INTRODUCTION**

i-NAF role is to provide and maintain confidence in natural certificates (Natural, Vegan, Vegetarian, Halal Vegan, Gluten-Free, Eco Global Label etc.) and marks issued by Natural Conformity Assessment Bodies through approving gluten-free certification schemes and having a mutual acceptance for these schemes between member accreditation bodies in the field of gluten-free.

The purpose of this guide is to set the evaluation criteria for gluten-free certification schemes to complement the implementation of the international standard ISO/IEC 17065:2012 Conformity Assessment — Requirements for Bodies Certifying Products (including ISO/IEC 17021-1:2015), Processes and Services to fulfil the requirements of gluten-free.

To provide confidence on gluten-free certificates and marks; gluten-free product certification bodies shall adopt certification schemes and seek accreditation for its certification activities as per the scheme requirements by an i-NAF signatory accreditation body. This will facilitate the global gluten-free trade.



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## **1. SCOPE**

This guide elaborates on the requirements specified in ISO/IEC 17065:2012, as applicable to the gluten-free certification bodies (GFCBs) operating the NSO-NAP 12 gluten-free certification scheme for food and cosmetic products and also specifies some NSO-NAP 12 Gluten-Free Standard specific additional requirements that the certification bodies operating this scheme shall need to fulfil.

Schemes Owners shall ensure that their food and cosmetic product certification schemes are complying with the requirements of ISO/IEC 17065, ISO/IEC 17021 and this document. Certification bodies who are willing to obtain accreditation from i-NAF's member accreditation body as a Gluten-Free certification body (GFCBs) shall comply with these requirements.

Requirements specified in this guide are general requirements for gluten-free product and are applicable to any sub-scope; e.g. food, cosmetics and services etc. during all stages of processing.

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**2. NORMATIVE REFERENCES**

- 2.1 ISO/IEC 17000: Conformity assessment — Vocabulary and general principles.
- 2.2 ISO/IEC 17007: Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment.
- 2.3 ISO/IEC 17065: Requirements for bodies certifying products, processes and services.
- 2.4 ISO/IEC 17067: Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes.
- 2.5 ISO/IEC Guide 23: Methods of indicating conformity with standards for third-party certification systems
- 2.6 ISO/IEC 17030:2003: Conformity assessment — General requirements for third-party marks of conformity.
- 2.7 ISO/IEC 17021-1:2015 Conformity Assessment — Requirements For Bodies Providing Audit And Certification Of Management Systems — Part 1: Requirements
- 2.8 ISO 22000 Food Safety Management Systems-Requirements for any organization in the food chain
- 2.9 ISO/TS 22003:2013 Food Safety Management Systems — Requirements for Bodies Providing Audit and Certification of Food Safety Management Systems
- 2.10 ISO 22005: Traceability in the feed and food chain — General principles and basic requirements for system design and implementation.
- 2.11 ISO 22716:2007: Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices
- 2.12 NSO-NAP 12: Gluten-Free Product/Service Standard for Life Chain.
- 2.13 i-NAF NMG 8: Guidance on Criteria for Gluten-Free Accreditation Body (i-NAF Rules Document).
- 2.13 i-NAF NMG 10: 2020: Guidance on Gluten-Free Certification Criteria for Evaluating Gluten-Free Schemes

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**3. TERMS AND DEFINITIONS**

- 3.1** Terms and definitions contained in clause 3 of ISO/IEC 17000, ISO/IEC 17065:2012 and ISO/IEC 17021-1:2015 are applied for Gluten-Free compliant natural certification process.
- 3.2** **Scheme Owner (NSO-NAP 12 Gluten-Free Standard Certification Scheme)**  
NSO-NBE Global ([www.nbeglobal.org](http://www.nbeglobal.org)) / IBI-Integrated Business Institute
- 3.3** **Gluten:**  
It is a complex group of proteins containing products as (cereal) wheat, barley, oats, rye, etc. (e.g. gluten, gliadin, secallin, hordein) (NSO-NAP 12)
- 3.4** **Gluten-Free:**  
Food (including water and beverages) or cosmetic product that does not contain gluten in the structure or contains less than 20 ppm.( 20/1.000.000, % 0,00002) of gluten. (NSO-NAP 12)
- 3.5** **Certification Body - CBs (Gluten-Free Certification Body - GFCBs/NCBs):**  
Natural Conformity assessment body performs activities that are fully complying with the NSO-NAP 12 Gluten-Free Standard certification requirements. The term “Gluten-Free” covers products/services.
- 3.6** Whenever “certification” is mentioned in this guide, it means “Gluten-Free Compliant Natural Certification Process”.

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## **4 GENERAL REQUIREMENTS**

### **4.1 Legal and contractual matters**

#### 4.1.1 Legal responsibility

4.1.1.1 In addition to the requirements specified in clause 4.1.1 of ISO/IEC 17065:2012 the following requirements shall also apply.

4.1.1.2 Certification bodies which are part of government, or are government departments, shall be deemed to be legal entities on the basis of their governmental status. Such bodies' status and structure shall be formally documented and the bodies shall comply with all the requirements of this standard.

4.1.1.3 The accreditation shall be granted to a legal entity, who can be legally held responsible for its work irrespective of whether the entire organization or a part of it performs the certification functions.

4.1.1.4 The certification body shall be responsible for and shall retain authority for its decisions relating to certification. This includes the granting, maintaining, renewing, extending, reducing, suspending and withdrawing of certification.

#### 4.1.2 Certification agreement

4.1.2.1 The certification body shall have a legally enforceable agreement for the provision of certification activities to its client organizations. Certification agreements shall take into account the responsibilities of the certification body and its client organizations.

4.1.2.2 The certification body shall ensure that its certification agreement requires that the client comply at least, with the following:

- a) always fulfill the certification requirements including product requirement as specified in the i-NAF Rules Document "i-NAF NMG 10: 2020 Guidance on Gluten-Free Certification Criteria for Evaluating Gluten-Free Schemes" Certification scheme and process requirements as specified in the document "Certification Process" and the requirements specified in this document as applicable and the changes in them as communicated by the certification body, time to time;
- b) the certified product always fulfils the certification requirements;
- c) liability on account of non-conforming product shall rest with the client organization.
- d) makes all necessary arrangements for:
  - i. the conduct of the initial and recertification audit and evaluation, surveillance audits (announced and unannounced)/evaluation, special/short notice audits for the purpose of complaints investigation, etc. It shall also include provision for examining documentation and records, and access to the relevant equipment and facilities, products, location(s), area(s), personnel, and client's subcontractors;
  - ii. investigation of complaints;
  - iii. the participation of observers, if applicable;
  - iv. drawal of samples from the production.
- e) shall makes claims regarding certification only in respect of the scope for which certification has been granted;
- f) does not use its product certification in such a manner as to bring the certification body into disrepute and does not make any statement regarding its product certification that the certification body may consider misleading or unauthorized;



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- g) upon suspension or withdrawal of certification, discontinues its use of all advertising matter that contains any reference thereto and returns as required by the certification scheme any certification documents and takes any other measure;
- h) endeavours to ensure that no certificate or report nor any part thereof is used in a misleading manner;
- i) If the client provides copies of the certification documents to others, the documents shall be reproduced in their entirety;
- j) in making reference to its product certification in communication media such as documents, brochures or advertising, complies with the requirements of the certification body if applicable;
- k) uses the certification mark (NSO-NAP 12 Gluten-Free Mark/Label/Logo) only on products it has found to comply with the requirements and for the level certified for;
- l) applies a mark to each certified product, or to product packaging, or on information accompanying each product if applicable;
- m) keeps a record of all complaints made known to the client relating to the compliance with certification requirement and to make these records available to the certification body for its verification. The client shall also agree to take appropriate action with respect to such complaints and any deficiencies found in products/process in accordance with the requirements of the Scheme;
- n) the client shall inform the certification body, without delay, of matters that may affect its ability to conform to the certification requirements. These shall include changes in:
  - i. the legal, commercial, organizational status or ownership,
  - ii. organization and management (e.g. key managerial, decision-making or technical staff),
  - iii. contact address and production sites/premises,
  - iv. modifications to the products and or processes and the production method,
  - v. major changes in manufacturing/testing equipment and in the internal control measures
  - vi. major changes to the ISO 22000 / HACCP / ISO 22716-GMP / GHP and other systems as specified in the certification criteria.
  - vii. any other information indicating that the product may no longer comply with the requirements of the product standard and the certification scheme.

4.1.2.3 The Certification body shall document clear instructions regarding appropriate use of certification mark and for providing information about certification status by its clients. It shall also identify the aspects that would be considered as misleading and unauthorised as relevant to the relevant certification standard or scheme. The certification agreement shall make appropriate cross references to the above document, so as to make it legally binding.

4.1.2.4 Records kept by the client in respect of the complaints received and their resolution shall be verified by the CB (GFCB/NCB) during the surveillance visits to the client's premises.

4.1.2.5 The client shall agree for re-audit/evaluation by the CB (GFCB/NCB) as per the requirement of the certification scheme, in the event of changes significantly affecting the product's capability to comply with the requirements of the product standard and the certification scheme.

4.1.2.6 The client shall also agree for re-evaluation by the CB(GFCB/NCB), in the event of changes in the standards to which compliance of the product is certified.

4.1.2.7 In addition to the requirements as specified above the requirements specified vide clauses 4.1.3 and 4.5 shall also be part of the agreement with the client.

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#### 4.1.3 Use of certificates and marks of conformity

4.1.3.1 The following requirements are additional to those stated in clause 4.1.3 of ISO/IEC 17065:2012.

4.1.3.2 The certification body shall ensure that the Certification mark is affixed only to products covered under the scope of the certificate. It shall also ensure of the Certification mark is as prescribed by the NSO-NAP 12 Gluten-Free Logo Usage Guide. The certification body should not allow the accreditation mark to be used on certified food products.

4.1.3.3 The certification body shall ensure that the applicants are not applying the Certification mark on products prior to certification.

4.1.3.4 The certification body should have procedures to ensure that its marks are not used in a way that may be likely to confuse or mislead the market.

4.1.3.5 The certification body should have documented procedures to ensure a traceable link from its mark to the relevant certification requirements.

4.1.3.6 The certification body shall have documented procedures for the use of its mark (see also ISO/IEC 17030), and for the measures to be adopted in case of misuse, including false claims as to certification and false use of certification body marks and these shall be part of its agreement with the certified client organizations.

4.1.3.7 The Certification Body shall have a documented procedure for dealing with instances of non-compliances with respect to the specified requirements for use and display of NSO-NAP 12 Gluten-Free Mark, certificates client organizations, as per its own procedure and those prescribed in the Certification Process requirements for NSO-NAP 12 Gluten-Free Standard.

4.1.3.8 The procedure shall include the process steps and the actions (including penal actions as relevant), the CB intends to take in the event of observing misuse/misleading use of NSO-NAP 12 Gluten-Free certificates and NSO-NAP 12 Gluten-Free mark/logo/label on the product used for indicating a product is certified, found in documentation or other publicity.

4.1.3.9 If a certification body incorrectly claims accredited status for certificates issued before appropriate accreditation has been granted, the accreditation body shall require it subsequently to withdraw them and also impose any other sanctions as deemed appropriate.

## 4.2 Management of impartiality

4.2.1 The top management's commitment to impartiality shall be demonstrated through:

- a) Documenting the CB's policy on safeguarding impartiality and ensuring that it is understood at all levels of the organization. Implementing good practices like establishing "Code of Conduct" and requiring internal and external personnel to abide by it.
- b) Having a defined institutional structure and impartiality policy and procedures, appropriate implementation of these policy and procedures and operation and conduct of its activities and personnel.
- c) Having a system that ensures appropriate management of conflict of interest for ensuring objectivity of its certification functions.
- d) Taking action to respond to any threats to its impartiality arising from the actions of other parts of the organization, persons outside of the organization, subcontractors, related bodies or other bodies or organizations.
- e) Maintaining a professional environment and culture in the organization that supports a behaviour of all personnel that is consistent with impartiality.
- f) Making available to public through its website, its policy on impartiality.

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4.2.2 The certification body shall establish and implement a documented procedure for analysing threats against impartiality of the CB. The analysis shall cover all existing potential sources of conflict of interests, arising from CB's activities (its own activities, activities of the related bodies and activities of personnel it employs) and from its relationships (organizational as well as individual's).

The CB shall ensure that a conflict of interest analysis is carried out at least once annually and whenever a significant change occurs in the CB's activities, such as changes in the organizational structure and business activities or of the legal status and mergers with, or acquisitions of other organizations.

**NOTE 1:** A relationship that threatens the impartiality of the certification body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing and payment of a sales commission or other inducement for the referral of new clients, etc.

**NOTE 2:** While carrying out the conflict of interest analysis the following risks, but not limited to them, shall be considered:

- a) *Self-interest threats: threats that arise from a person or body acting in their own interest. A concern related to certification, as a threat to impartiality, is financial self-interest.*
- b) *Self-review threats: threats that arise from a person or body reviewing the work done by themselves. Certification of a client, whose product was designed or who was provided service regarding internal evaluation by the CB or the personnel it employs would be a self-review threat.*
- c) *Familiarity (or trust) threats: threats that arise from a person or body being too familiar with or trusting of another person instead of seeking audit evidence. Repeat evaluation of a client by the same assessor/evaluator/auditor, over and over again may also present a familiarity threat.*
- d) *Intimidation threats: threats that arise from a person or body having a perception of being coerced openly or secretly, such as 4.2.3 When a relationship poses an unacceptable threat to impartiality then certification shall not be provided. Some of these situations requiring prohibitions as mitigation measures have been described vide clause 4.2.6 of ISO/IEC 17065:2012. These shall be implemented together with the additional ones provided in this guide.*

4.2.4 Further, where risks to impartiality have been identified as a result of risk analysis (clause 4.2.3), the CB shall establish and implement a documented procedure for mitigation of threats against impartiality. These shall be through any of the following mitigation means:

- a) Not provide certification, since the situation poses unacceptable threat to impartiality – prohibition.
- b) Carry out the certification in a restricted manner based on disclosures
- c) Minimize the risks on the basis of clearly defined control points to ensure mitigation.

The impartiality risk analysis together with mitigation strategies should be made available to the Impartiality Committee (see 5.2.1)

4.2.5 In addition to those prescribed in clause 4.2.6 of ISO/IEC 17065:2012 the other type of product related consultancy services that shall be considered are barriers to certification would be participation in an active creative manner in the ongoing development and monitoring/improvement of the product, process, or service, for example;

- a) providing specific support/advise on elements of the design.
- b) preparing or producing manual, handbooks or procedures.

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- c) involvement in the supplier's monitoring, review and decision making process applicable to the product.

4.2.6 In addition to the requirement specified in ISO/IEC 17065:2012 clause 4.2.6, the following shall also apply:

- a) The CB shall not have any direct relationship with its client other than certification work and third party conformity assessment.
- b) If the certification body and its client are both part of government, the two bodies shall not directly report to a person or group having operational responsibility for both. The certification body shall, in view of the impartiality requirement, be able to demonstrate how it deals with a case where both itself and its client are part of government. The certification body shall demonstrate that the applicant receives no advantage and that impartiality is assured.
- c) The certification body, any group within its control and organizations related or linked to certification bodies or personnel, employed or contracted, in an organization within its control, shall not offer or provide consultancy or training on the product that it certifies.
- d) The certification body, any group within its control and organizations related or linked to certification bodies or personnel, employed or contracted, in an organization within its control, shall not offer or provide management system consultancy or internal auditing to its clients/prospective clients.

**NOTE:** *The certification body is allowed to explain its findings and/or clarify the requirements of the normative documents but shall not give prescriptive advice or consultancy as part of an evaluation. This does not preclude normal exchange of information with the clients and other interested parties or the provision of different determination activities e.g., inspection, testing, audit, required for specific product certification schemes which is considered acceptable.*

- e) The certification body shall not certify a product on which a client has received consultancy or internal evaluations, where the relationship between the consultancy organization and the certification body poses an unacceptable threat to the impartiality of the certification body. Allowing a minimum period of two years to elapse following the end of the product consultancy is one way of reducing the threat to impartiality to an acceptable level.
- f) The CB shall not outsource/subcontract any part of the certification work, evaluation, etc, to a legal entity that is engaged in designing, manufacture, installation, distribution or maintenance of the certified/to be certified, product, process and service. It shall also not be outsourced to organizations who are likely to provide consultancy / internal auditing services to clients / prospective clients of the CB.
- g) The CB shall not use external evaluators/auditors for the purpose of evaluation of any client, if they, or the organization that employs them, have been engaged in any other activities as stated in "e" above.
- h) The CB shall not use personnel who have been involved in, or have had relationships with the Product certification client in any way within the last two years as a minimum, to take part in valuation/auditing. The period of separation shall be determined by the nature of association.
- i) In case they had been designing of the product/process/service being certified then the CB shall not use such person at all.

4.2.7 The certification body's activities shall not be marketed or offered as linked with the activities of an organization that provides product related consultancy (the designing,

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manufacturing, installing, maintaining or distributing of a certified/to be certified product/process/service). The certification body shall take action to correct inappropriate claims by any consultancy organization stating or implying that certification would be simpler, easier, faster or less expensive if the certification body were used. A certification body shall not state or imply that certification would be simpler, easier, faster or less expensive if a specified consultancy organization were used.

4.2.8 The CB shall require its personnel, internal and external, to reveal any situation known to them that may present them or the certification body with a conflict of interests. The provision for this aspects shall be covered in an agreement with the CB, as well as can be part of evaluation team nomination process. Based on the revelations made if any, the CB shall use this information as input to identifying threats to impartiality raised by the activities of such personnel or by the organizations that employ them, and shall not use such personnel, internal or external, unless any potential conflict of interests has been addressed and the measures taken to address these potential conflicts have been documented and implemented.

The CB shall require its personnel, internal and external, to report any situation of influence or pressure from the client that may threaten their independence in the course of certification activities. Based on such report, the CB shall take appropriate actions to ensure its independence in its certification work.

4.2.9 The CB's personnel involved in certification activities shall be bound by the CB's impartiality policy and act impartially in their work through contractual or employment conditions and assignment conditions for each evaluation/audit activity.

4.2.10 The CB's personnel involved in certification activities shall not provide, while carrying out evaluation/audit, any advice, consultancy or recommendation to the client on how to address any deficiencies that may be identified during the evaluation/audit.

The certification body should be responsible for ensuring that neither related bodies, nor sub-contractors, nor external assessors/auditors operate in breach of the undertakings that they have given. It should also be responsible for implementing appropriate corrective action in the event that such a breach is identified.

### **4.3 Liability and financing**

4.3.1 The certification body shall also be able to demonstrate that it has evaluated the risks arising from its certification activities and that it has adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations in each of its fields of activities and the geographic areas in which it operates.

4.3.2 The certification body shall be able to demonstrate that it has a reasonable expectation of being able to provide and to continue to provide the service in accordance with its contractual obligations. Certification bodies shall also be able to provide sufficient evidence to demonstrate its viability, e.g. management reports or minutes, annual reports, financial audit reports, financial plans, etc.

The means by which the certification body obtains financial support should be such as to allow the certification body to retain its impartiality.

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4.3.3 In addition to the above the CB shall also demonstrate to the Impartiality committee, that initially, and on an ongoing basis, commercial, financial or other pressures do not compromise its impartiality.

#### **4.4 Non-discriminatory conditions**

4.4.1 The certification body shall have means of demonstrating compliance to this requirements of ISO/IEC 17065:2012 (clause 4.4), through its policies and procedures as well as actual practice.

4.4.2 The CB's policies and procedures should ensure that it does not practice any form of hidden discrimination by speeding up or delaying the processing of applications.

##### **4.4.3 Certification Fees**

4.4.3.1 A fee to be charged to the organization for various activities of the NSO-NAP 12 Gluten-Free certification scheme, without any discrimination between units, geographical location, size of the unit.

4.4.3.2 The CBs fee structure shall be publically accessible and also be provided on request.

4.4.3.3 CB shall notify and obtain consent to its fee structure from the organizations prior to grant of certification. As and when the fee undergoes a change, the same shall be communicated to all including applicants and the manufacturing units certified under this scheme of certification for their acceptance.

#### **4.5 Confidentiality**

In addition to the requirements specified in ISO 17065:2012 (clause 4.5) following shall apply:

4.5.1 The Certification Body shall have a documented policy and mechanism to safeguard the confidentiality of information obtained or created during the course of certification activities. It shall also be part of the certification agreement.

4.5.2 Personnel, including any committee members, contractors, personnel of external bodies or individuals acting on the certification body's behalf, shall keep confidential all information obtained or created during the performance of the certification body's activities. There shall be a mechanism such as obtaining signed confidentiality agreements, etc, for ensuring the same.

4.5.3 The certification body shall have available and use equipment and facilities that ensure the secure handling of confidential information (e.g. documents, records).

4.5.4 When confidential information is made available to other bodies (e.g. accreditation body, agreement group of a peer assessment scheme), the certification body shall inform its client of this action, in advance, through agreements, etc.

4.5.5 Information about the client obtained from sources other than the client (e.g. from the complainant or from regulators) through the evaluation process, if used for certification decision by the CB, shall guide.

4.5.6 In case of transfer of certificate or application, when the client decides to move from one CB to another CB, the CB to which the client is now moving may ask the previous CB for information on the reasons for such movement or the performance of the client with respect to the certification requirements. Such information shall not be considered as confidential and the certification body shall inform its client of this requirement, in advance, through agreements, etc.

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**4.6 Publicly available information**

4.6.1 Making the information publicly available through the CB's website shall be the only means of meeting this requirement.

4.6.2 The following information with respect to NSO-NAP 12 Gluten-Free scheme shall be made publicly available on the CB's website. The information provided shall be accurate, non-misleading and where relevant detailed enough for the reader to clearly understand.

- a) The certification processes, from application stage to the grant of certification including the evaluation processes; the system for maintenance of test and certification, including processes for surveillance, market sampling, recertification, scope extension and reduction, suspension and withdrawal. The information shall also cover the terms and conditions of certification and the use of certificates or NSO-NAP 12 Gluten-Free Mark/Logo/Label, as contained in the Certification Agreement
- b) The specific rules and conditions for granting, for maintaining, for extending or reducing the scope of, for suspending, for withdrawing or for refusing certification.
- c) Requirements of NSO-NAP 12 Gluten-Free certification scheme, including the NSO-NAP 12 Gluten-Free certification criteria and application form shall be available to the applicant. The CB may also provide any other guidance documents on the certification criteria for the benefit of the applicant, as long as they are not advisory/consultative in nature.
- d) The certification body shall make publicly available on its website the information about applications registered and certifications granted, suspended or withdrawn.
- e) On request from any party, the certification body shall provide the means to confirm the validity of a given certification and the provision for the same shall be made available on the website.
- f) The certification body shall maintain and make publicly available on its website, a certification scheme wise, directory of valid certifications.
- g) A description of the rights and duties of applicants and clients, including requirements, restrictions or limitations on the use of the certification body's name and certification mark and on the ways of referring to the certification granted.

4.6.3 The CB shall have procedure for frequent updating of the information on its website. The responsibilities for ensuring accuracy of the information made available on the website, ensuring frequent updates, etc shall be documented.

4.6.4 The CB shall list out the sources of its finances.

4.6.5 The information about fees charged shall clearly provide the basis on which the fees are charged. It may be generic in nature; however it shall give some basic information about the CB's fee structure.

4.6.6 The information on complaints handling process and the CB's procedure shall be directly available to the public, without the public having to go through layers of cross linkages.

4.6.7 Information exchange between a certification body and its clients

4.6.7.1 Information on the certification activity and requirements- The certification body shall provide and update clients on the following:

- a) a detailed description of the initial and continuing certification activity, including the application, initial evaluation, surveillance evaluation, and the process for granting, maintaining, reducing, extending, suspending, withdrawing certification and recertification;
- b) the certification criteria for NSO-NAP7 Gluten-Free certification scheme;
- c) information about the fees for application, initial certification and continuing certification;

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- d) the certification body's requirements for prospective clients;
- e) documents describing the rights and duties of certified clients as well as obligations on part of the certification body;
- f) information on procedures for handling complaints (both by the certification body as well by the client organization, in respect of complaints against certified products) and appeals;

## **5 STRUCTURAL REQUIREMENTS**

### **5.1 Organizational structure and top management**

5.1.1 All the requirements as specified in clause 5 of ISO/IEC 17065:2012 shall apply and in addition the following requirements shall also apply.

5.1.2 The organization structure shall include structure of the parent body (legal entity) if separate from the department/division that offers certification.

5.1.3 It shall also include structure of the related departments in relation to the department offering certification services. In addition all requirements specified vide clause clause 5.1.2 of ISO/IEC 17065:2012.

5.1.4 The CB shall identify and document all related bodies (separate legal entities) as well as other departments of the same legal entity and their activities and functions and their relationships with the CB when describing its organizational structure. This should cover all relationships, such as those described in Note 1 of Clause 4.2.2 of this guide. The CB shall also have a system for disclosure and documentation of the types of activities carried out by its internal and external personnel and subcontractors in general and in particular regarding the designing of relevant product/process/testing/service, consultation, internal evaluation/auditing, training, etc. The above information shall also be used for identification of actual/potential risks to impartiality (see clause 4.2.1).

5.1.5 An organization chart(s) shall be used for showing the structure, supported by the documented responsibilities and authorities for the functions described in the organization chart.

5.1.6 The Impartiality committee and any other committees involved in operation of the CB and the certification process, shall also be shown as part of the organizational structure.

5.1.7 The identification of responsibilities, however done, shall clearly and unambiguously reflect the responsibilities for activities/functions as described vide clause 5.1.3 a) to n) of ISO/IEC 17065:2012.

5.1.8 The requirement specified vide clause 5.1.4 of ISO/IEC 17065:2012 shall cover the Impartiality committee and any other committees, if established by the CB for certification scheme development, planning for certification evaluation (sampling and determination), certification review and decision making, appeals process, etc.

### **5.2 Mechanism for safeguarding impartiality**

5.2.1 An Impartiality committee with specific responsibility for safeguarding the CB's impartiality in its certification functions and for ensuring that the policy on safeguarding impartiality and related procedures and other systems are effectively implemented shall be the means of fulfilling this requirement.

5.2.2 The Impartiality Committee shall:



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- a) assist the CB in developing the policies relating to impartiality of its certification activities,
- b) counteract any tendency on the part of a certification body to allow commercial or other considerations to prevent the consistent objective provision of certification activities,
- c) advise on matters affecting confidence in certification, including openness and public perception,
- d) conduct a review, as least once annually, of the impartiality of the audit, certification and decision making processes of the certification body.
- e) Approve the conflict of interest analysis and the mitigation measures described in clauses 4.2.3 & 4.2.4 of ISO/IEC 17025:2012.

Other tasks or duties may be assigned to the committee provided these additional tasks or duties do not compromise its essential role of ensuring impartiality.

The composition, terms of reference, duties, authorities, competence of members and responsibilities of this committee shall be formally documented and authorized by the top management of the certification.

This committee shall meet regularly, at least once a year, and a complete record of the proceedings of this committee shall be maintained.

5.2.3 The mechanism shall be formally documented to ensure the following requirements specified in clause 5.2.4 of this guide.

5.2.4 The CB shall ensure that;

- a) The committee for safeguarding impartiality shall be separated from the management of the CB operations and established at the highest level within the organization, independent of its day-to-day operations.
- b) In the composition of the committee, participation of key interested parties shall be ensured, with a representation of a balance of interests such that no single interest predominates. Internal or external personnel of the certification body are considered to be a single interest, and shall not predominate.
- c) Its chairman shall be a person independent from and external to the CB.

5.2.5 Impartiality Committee meetings may be observed by the Accreditation Body's Assessment Teams as part of the Certification Body's accreditation process.

5.2.6 Although every interest cannot be represented in the mechanism, a certification body shall identify and invite significantly interested parties.

Such interests may include: clients of the certification body, customers of organizations whose management systems are certified, representatives of industry trade associations, representatives of governmental regulatory bodies or other governmental services, or representatives of non-governmental organizations, including consumer organizations.

## **6 RESOURCE REQUIREMENTS**

### **6.1 Certification Body Personnel**

#### **6.1.1 General**

6.1.1.1 The certification body shall be able to conduct all audits using resources under its control and in accordance with its scope of accreditation.

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The certification body shall ensure that all employees responsible for executing the NSO-NAP 12 program, including auditors and contract auditors, employ and retain qualifications, skills and experience necessary to perform their duties.

6.1.2 Management of competence for personnel involved in the certification process.

6.1.2.1 The certification body shall demonstrate that programs are in place for all employees responsible for executing the NSO-NAP 12 Gluten-Free certification program including: NSO-NAP 12 Gluten-Free auditors and contract auditors, witness assessors, technical reviewers, certification managers and administration personnel. These programs will provide trainings required for maintaining their qualifications and awareness of the NSO-NAP 12 Gluten-Free certification program, regulations, current food safety and quality issues, and how they relate to the technical judgments they make.

The certification body shall have procedures in place to ensure all employees responsible for executing the NSO-NAP 12 Gluten-Free certification program and the certification process including, NSO-NAP 12 Gluten-Free certification auditors and contract auditors, technical reviewers, certification managers, and administration personnel are made aware of their role and responsibilities. Certification bodies shall ensure that these employees are competent and qualified to schedule audits, report audits in NSO-NAP 12 Gluten-Free certification assessment database system, undertake desk audits, certification audits, test control, surveillance audits and re-certification audits, review audit reports and make technical judgments and recommendations as necessary.

All certification body personnel who review NSO-NAP 12 Gluten-Free audit reports and/or make technical judgments and recommendations must be registered as an NSO-NAP 12 Gluten-Free certification auditor or technical reviewer, as outlined in the Criteria for NSO-NAP 12 Gluten-Free Certification Auditors, Food Safety Auditors, Quality Auditors and Technical Reviewers.

The certification body shall have established competencies for personnel involved in the certification process that address:

- i. The training of personnel involved in certification and NSO-NAP 12 Gluten-Free certification program management;
- ii. The defined competency including qualifications, experience and monitoring;
- iii. Auditor selection and orientation; and
- iv. Implementation of auditors new to the certification body's NSO-NAP 12 Gluten-Free certification program including at least two (2) witness audits by NBE Global (Scheme Owner) registered auditors or technical reviewers. The first two (2) audits of each new auditor shall be witnessed and the remaining eight (8) audits shall be supervised audits, which is a combination of witness audits and review of audit reports, as part of the witness assessment.

Auditor calibration programs shall include calibration of auditors using existing audit data and on-going auditor training at least annually. The certification body shall require all NSO-NAP 12 Gluten-Free certification auditors in a certification body to be witnessed at least once every two (2) years, under any NSO-NAP 12 Gluten-Free scheme, with one witness audit being an NSO-NAP 12 Gluten-Free certification or re-certification audit at least every four (4) years.

The certification body shall ensure that criteria on auditor performance is developed so that corrective action can be taken when performance criteria is not achieved. Corrective action items should be prescribed based on data results from calibration activities.

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The NSO-NAP 12 Gluten-Free certification auditor calibration program shall include a review of NSO-NAP 12 Gluten-Free certification program audits and shall be reviewed by the certification body.

No NSO-NAP 12 Gluten-Free certification auditor shall perform an NSO-NAP 12 Gluten-Free certification audit for the same site for more than three (3) consecutive certification cycles.

The certification body shall ensure that each NSO-NAP 12 Gluten-Free certification auditor, who is assigned to conduct an NSO-NAP 12 Gluten-Free certification audit, is registered as a NSO-NAP 12 Gluten-Free certification auditor in good standing and maintains such registration for the term of their employment or engagement.

Auditors who lack the auditing experience necessary to enable them to be registered as NSO-NAP 12 Gluten-Free certification auditors can be engaged in audits of products and processes utilizing the certification body audit tool (i.e., non-NSO-NAP 12 Gluten-Free certification certification audits) to gain experience in second and third party auditing.

The certification body shall follow their management systems when adding new auditors to conduct NSO-NAP 12 Gluten-Free audits. The Accreditation Body's related manager shall be notified when an auditor no longer audits under that certification body.

The certification body shall ensure NSO-NAP 12 Gluten-Free certification auditors do not audit NSO-NAP 12 Gluten-Free Certification Systems that relate to or include food sector categories in which the NSO-NAP 12 Gluten-Free certification auditor is not registered to audit, unless accompanied by a technical expert.

When using a technical expert, the certification body shall adhere to the auditor/technical expert criteria.

6.1.2.2 The certification body shall retain detailed records of all NSO-NAP 12 Gluten-Free certification auditors, including technical reviewers, and personnel involved in the certification process. Compliance records shall be made available to Accreditation Body upon request.

The information shall include as a minimum:

- i. Name and address;
- ii. Organization affiliation and position held;
- iii. Educational qualification and professional status;
- iv. Experience and training in the relevant fields of competence in relation to Gluten-Free requirements,
- v. Audit activities (audit log);
- vi. Performance monitoring activities such as results of surveillance and witness audits, appraisals and reviews;
- vii. Refresher training activities related to certification program updates, emerging issues, regulatory updates, etc.

#### 6.1.3 Contract with the personnel

The certification body shall ensure an NSO-NAP 12 Gluten-Free certification auditor and personnel involved in the certification process disclose to it any personal or professional existing, former or proposed link between themselves or their organization and the site.

## 6.2 Resources for Evaluation

### 6.2.1 Internal resources

6.2.2.1 The certification body shall determine the scope of certification of the site in conjunction with the site. The scope of certification shall include all the products / processes requested by the

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site in the scope of certification, the site description of the facility including any site exemptions/exclusions, the Gluten-Free scope/sub-scope.

The scope of certification shall be defined by the certification body and the site prior to the start of the certification audit. Once the certification audit has begun, the scope of the certification shall not be altered.

When evaluation activities are conducted, the certification body shall ensure the relevant international standard requirements are followed.

#### 6.2.2 External resources (outsourcing)

6.2.2.1 The certification body shall ensure that the outsourcing of inspection or testing activity within the scope of NSO-NAP 12 Gluten-Free certification is conducted by nationally recognized ISO/IEC 17025 accredited testing laboratories (i-NAF Member/Licensed) utilizing the services of qualified personnel.

## 7 PROCESS REQUIREMENTS

**7.1** All the Gluten-Free scheme specific certification process requirements as specified vide the document NSO-NAP7 Gluten-Free Certification Standard shall be applicable.

**7.2** For the purpose of operationalising the requirements, the certification body shall establish and documented internal processes and procedures strictly based on the requirements specified in the above referred document.

**7.3** The certification body shall also develop and document any additional guidance documents considered essential for uniform application of the certification criteria and certification/scheme requirements by its personnel and for the purpose of knowledge sharing.

## 8 MANAGEMENT SYSTEM REQUIREMENTS

### 8.1 Options

#### Options A.

8.1.1 The certification body shall develop a management system, maintained in accordance with ISO/IEC 17065: 2012 clause 8, which shall also address the NSO-NAP 12 Gluten-Free System additional requirements given in clause 9 requirements outlined in this guide.

8.1.2 The certification body shall have included in the management system provisions that address:

- General management system documentation
- Control of document
- Control of records
- Its policies, procedures and activities related to its accreditation with NSO-NAP 12 Gluten-Free.

Records must be maintained for all quality system activities to verify compliance and be available to Accreditation Body on request.

- Management review (review of inputs and review of outputs)
- Internal audits: The certification body shall conduct annual internal audits of its certification procedures applicable to its NSO-NAP 12 Gluten-Free certification program. Management reviews and internal audits shall cover the activities of contract service providers.

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The internal audits shall cover all activities in nominated territories and the country where the accreditation is granted.

The certification body shall review its management system and certification procedures applicable to these requirements at least annually. Records of internal audits and management reviews shall be reported annually and made available to the Accreditation Body on request.

The certification body shall have included in the management system provisions that address:

- Corrective actions
- Preventive actions

## **9 SCHEME OWNER REQUIREMENTS**

### **9.1 Certification Body Approval**

9.1.1 The “NSO-NAP 12 Gluten-Free Standard Certification” for food and cosmetic Products/services is owned by the Scheme Owner. The Client Organization who wishes to use this mark on his product shall be required to obtain formal approval from the scheme owner for the use of the mark only after they have been assessed to be compliant to all the scheme requirements by the certification body approved by the scheme owners.

9.1.2 Only the Certification Bodies who are approved by the scheme owner are permitted to evaluate and certify the food and cosmetic Products/services for use of NSO-NAP 12 Gluten-Free Mark on their products. The Certification Body shall apply and get approval for use of NSO-NAP 12 Gluten-Free Standard Certification by the client organization certified by them from the scheme owner for NSO-NAP 12 Gluten-Free Standard Certification.

9.1.3 The prerequisite for approval of the certification bodies by the scheme owner are accreditation by i-NAF Member of Accreditation Bodies as against ISO/IEC 17065:2012, ISO/IEC 17021-1 (ISO 22000 / ISO 22716 GMP) and the NSO-NAP 12 Gluten-Free Scheme specific requirements as contained in various sections of the NSO-NAP 12 Gluten-Free scheme documents. Initially for a limited period Certification bodies approved under NBE Global (Scheme Owner) approval scheme shall also be eligible for approval under this scheme.

### **9.2 Requirements of Certification Bodies approved under the scheme**

9.2.1 All certification bodies that have been accredited by i-NAF Member of Accreditation Bodies as per ISO/IEC 17065:2012 for the NSO-NAP 12 Gluten-Free scheme and/or recommended by NBE Global shall be authorized for operating the certification scheme.

9.2.2 The certification bodies shall ensure that the NSO-NAP 12 Gluten-Free Mark/Logo/Label is affixed only on products conforming to the Certification Criteria in the prescribed design, size, colour etc..

9.2.3 The approved certification bodies shall monitor the usage and application of the NSO-NAP 12 Gluten-Free Mark/Logo/Label by the client organizations who are applicants with them or certified by them.

9.2.4 The scheme owner shall maintain information about approved certification bodies on its website.

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**9.3 Obligations of the product certification body approved under the Scheme**

9.3.1 The approved product certification body shall commit to fulfill continually the requirements for approval set by Scheme Owner the areas where approval is sought or granted.

9.3.2 The approved product certification body shall claim approval only with respect to the scope for which it has been granted approval.

9.3.3 The approved product certification body shall not use and permit the use of the NSO-NAP 12 Gluten-Free Mark in such a manner as to bring the Scheme owner into disrepute.

9.3.4 The approved certification body shall inform without delay, any significant changes relevant to its approval to the Accreditation Body as well as NBE Global, in any aspect of its status or operation relating to;

- a) its legal, commercial, ownership or organizational status,
- b) the organization, top management and key personnel,
- c) main policies,
- d) resources and premises,
- e) scope of accreditation, and
- f) other such matters that may affect the ability of the Product certification body to fulfil requirements for accreditation.