

ICO Quality Management Manual – Public Summary

Public Information Document

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1 What is the ICO?

The International Certification Office (ICO) of the Biodynamic Federation Demeter International (Federation) was established for the purpose of certifying operators and products in countries that do not have their own Demeter certifying organisation (Figure 1).

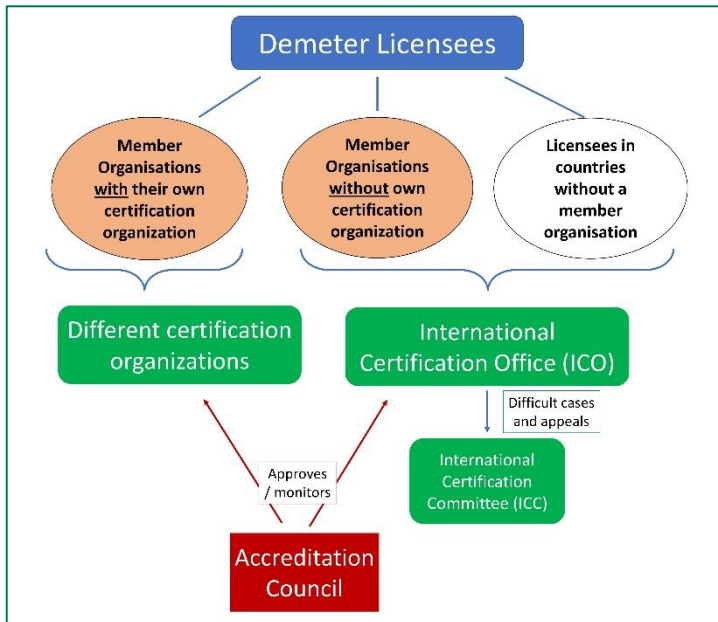


Figure 1: The ICO's role in the Federation

The ICO is committed to supporting the integrity of the trademark and development of biodynamic agriculture through the delivery of its certification programme.

2 To which standard does the ICO certify?



Figure 2: The Demeter standard in relation to general organic production rules. “ICO Annex” refers to those sections of the Demeter standard, which leave the definition and interpretation to each certification organisation.

The ICO certifies to the Demeter Standard (<https://www.demeter.net/certification/standard/>). This is a standard that requires compliance with organic standards (Regulation (EU) 2018/848 in Europe, NOP in the USA, etc.), but in many aspects goes far beyond the general organic requirements. The ICO requires a valid organic certificate for Demeter operators.

Wherever there is a risk of non-compliance with basic organic rules, ICO has the right and duty to also verify compliance and to issue sanctions related to non-compliance with these rules, where applicable. The ICO may decide differently on these issues than the organic IB.

In several sections, the Demeter standard reads, e.g., “this must be decided by each certification body”. For these parts, the ICO Annex applies (Figure 2, blue box). This Annex will be published on the Demeter website.

3 Co-operation with Organic Inspection Bodies

In most cases, the ICO works together with organic inspection bodies (IBs). The ICO chooses the IBs it trusts. Inspectors must be approved by the ICO. When organic CBs conduct

inspections, they normally combine the organic and the Demeter inspection in one. In some cases, the ICO has its own inspectors.

The organic IBs submit their inspection reports (for organic and Demeter) and organic certification decision to the ICO, which then makes the Demeter certification decision.

4 Conversion to Demeter

Farmers starting conversion must submit a written conversion plan. According to the ICO Annex, farms with more than 5 ha cash crops **must** have the support of a recognised Demeter advisor for this purpose (see <https://www.biodynamic-advisors.org/>). The conversion plan must be signed by the responsible farm manager and the Demeter advisor.

The conversion period starts with the approval of the conversion plan, which is also the date of signing the license agreement. The normal conversion time for a farm to achieve Demeter certification is three years. The whole farm must convert to Demeter, including all fields, crops, and animals, and must comply with the standard from the beginning of conversion. The only exception to this general rule: when the **approved** conversion plan specifies certain development steps for a later date. One of the most basic requirements is application of the biodynamic preparations on all productive areas belonging to the farm.

If the farm has been certified organic before, the conversion period may be reduced. For further details, refer to <https://www.demeter.net/certification/standard/>. If ICO finds that the farm is not ready for certification, the conversion may be prolonged. If inspectors find critical non-conformities during conversion, the farm must start again from the beginning or comply with suspension periods.

5 The Role of the Advisor

5.1 General

Advice and certification must be strictly separated. Advisors must not get involved in certification decisions, while inspectors and certifiers must not provide advice to licensees.

5.2 Advisory During Conversion

Good quality advice is especially important for those converting to biodynamic production and working toward Demeter certification. Therefore, it is a requirement for farmers to have a recognised Demeter advisor during their conversion period. This requirement ends with the licensee's first full Demeter certificate. It is recommended, however, to maintain a relationship with an advisor as long as the farm needs their advice.

5.3 Relationship and Communication with Advisors

The task of the advisor is to provide advice and support. Advisors co-sign the conversion plan with the licensee, so it is clear that the conversion is a joint effort.

The ICO has a direct relationship with licensees. This has a legal basis in the license agreement that the Federation and the licensee sign, but also a practical basis in that it is the licensee who is certified. Therefore, all communication regarding applications, certification, approvals, derogations, exemptions, corrective actions, appeals, termination of license agreement etc. takes place **directly** between ICO and the licensee (Figure 3). Advisors should support licensees to undertake this communication directly with the Federation. All parties should be working with the aim in mind that the licensee will become independent of the advisor by the end of the conversion period.

If the licensee signs a data release declaration, the Demeter advisor can be copied into communications.

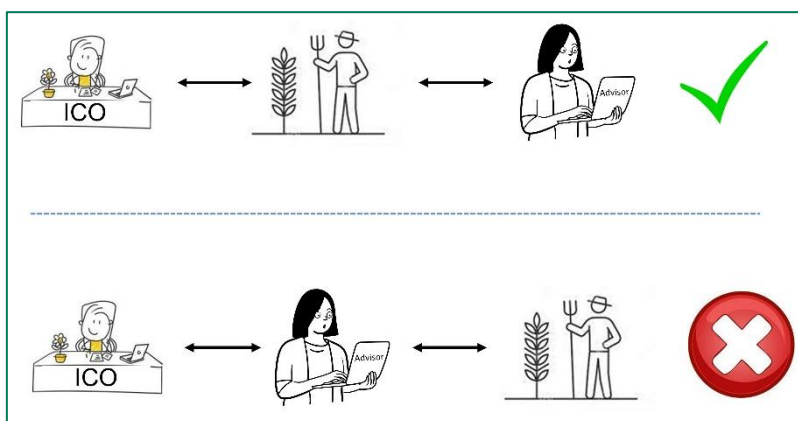


Figure 3: Communication between ICO, Licensee and Demeter Advisor.

5.4 Advisor's Presence at Inspection

Inspections for Demeter certification look at the systems and practices of the licensee to see whether these meet the requirements of the Demeter Standard. As it is the licensee who is responsible for the daily work on the farm, it is also the licensee who must take responsibility for inspections. The advisor can provide support in preparing for the inspection and can be present for the inspection itself, but should play a supporting role only. The inspector will address the licensee during inspection including the closing meeting when any issues are summarised. It is the licensee's responsibility to clarify any issues raised during the certification process. The inspector has the right to talk to the licensee in private.

6 The Application and Certification Process

Figure 4 describes the application process for new farms, from first contact to Demeter certification. For processors or traders, the process is simpler, because they do not need to undergo conversion (Figure 5). The application process is put on hold if there are outstanding financial issues.

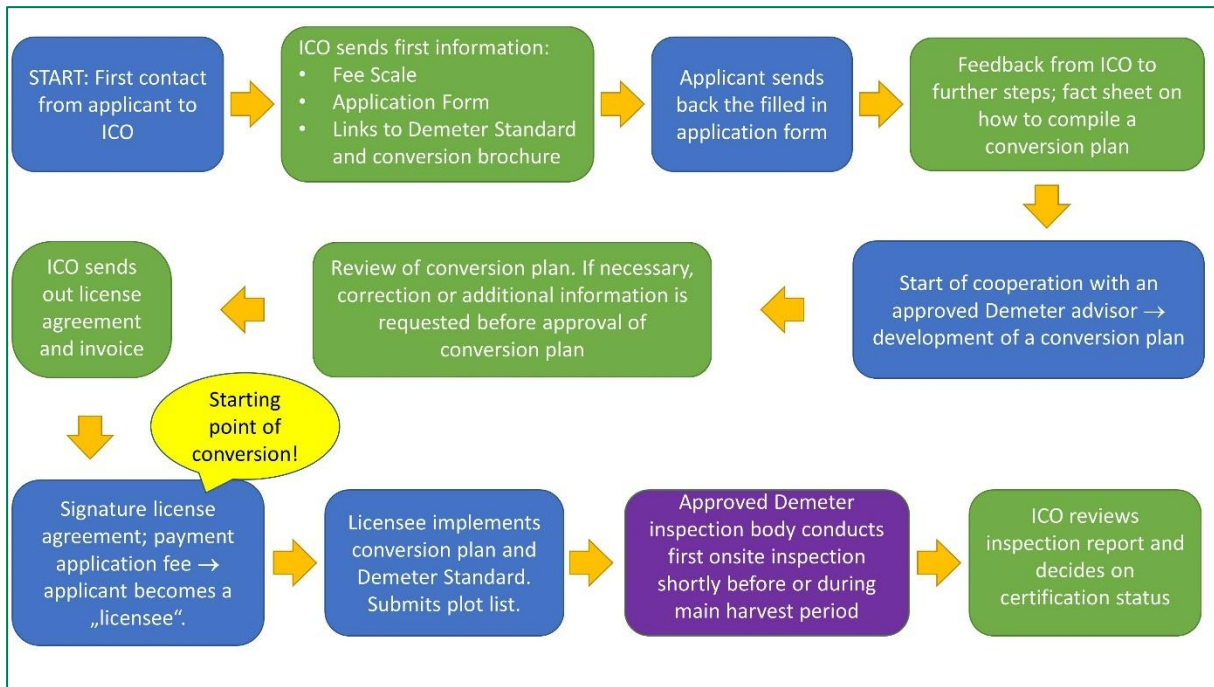


Figure 4: The application process for new farms. Please follow the arrows. Blue represents the applicant's steps (who becomes a licensee, once he / she has signed a license agreement), green the steps by ICO, purple the inspection body.

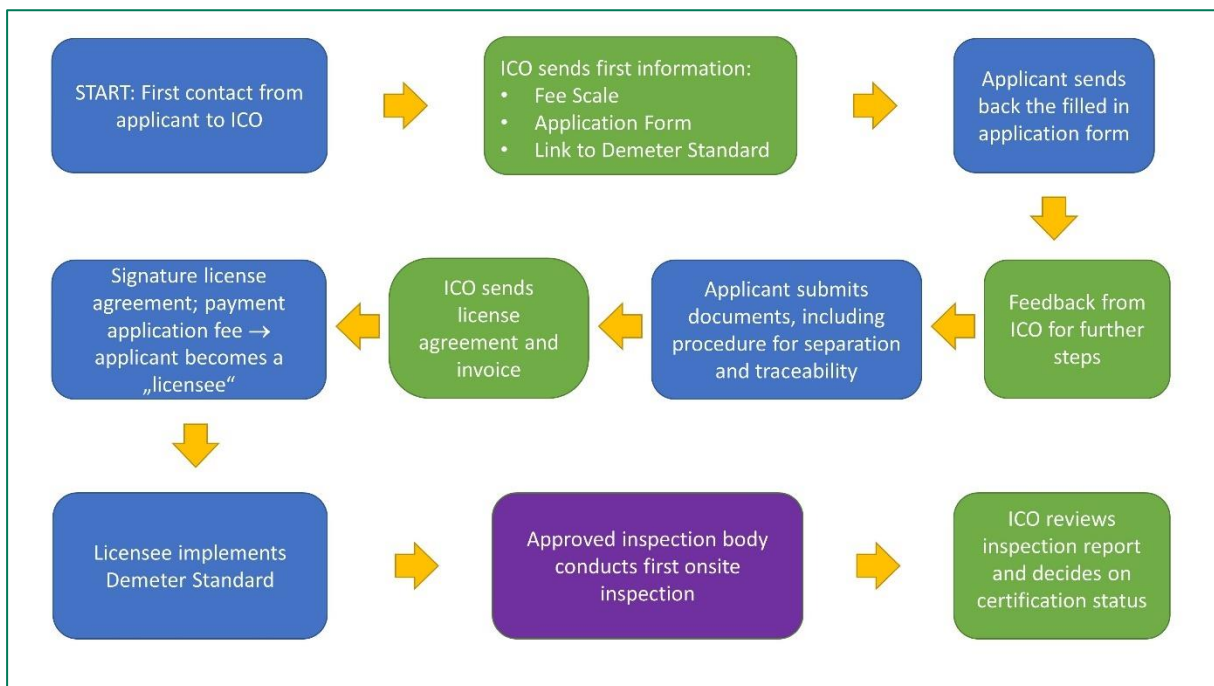


Figure 5: Simplified application process for new processors, traders, or distributors.

7 The Annual Certificate Renewal Process

Once the process described in Section 6 has been completed and the first valid Demeter certificate has been obtained, then the certificate must be renewed every year. The process is similar to Figure 5, but simpler, as shown in Figure 6.

ICO puts the renewal process on hold when there are outstanding financial issues.

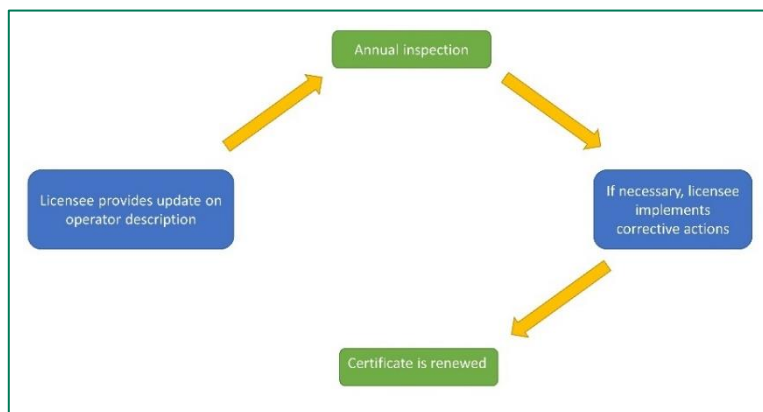


Figure 6: Simplified scheme for annual certificate renewal process

8 Announced and Unannounced Inspections

The “organic” inspection (verifying compliance with the EU Regulation on organic farming and/or other government standards) may be combined with the Demeter inspection, or they may be separate.

The ICO or the organic IB will inform the licensee of the date of inspection several weeks’ before. This allows the licensee to prepare, including all documentation typically required by the inspector (Table 1).

Table 1: Overview of records which Demeter operators should keep. For more details, refer to the Demeter standard.

Farm	Processor / Trader (as applicable – including on-farm processing)
<ul style="list-style-type: none"> • Farm map • ICO plot list • Floor plan for farm buildings • Conversion plan, evidence of implementation (during conversion time) • Inspection report, certificate with certified areas and crops from organic certifier • Evidence of correcting non-conformities from organic certifier • Invoices for purchase of all farm inputs, including seeds/seedlings and biodynamic preparations • Technical datasheets and evidence of compliance with the Demeter standard for all farm inputs • Invoices for sale of all products • Bookkeeping 	<ul style="list-style-type: none"> • List of all products requested for certification • Floor plan for all processing and storage facilities • Inspection report, certificate, and evidence of corrective actions from organic certifier • Invoices for purchase of all raw materials / ingredients / additives / processing aids • Recipes • Technical datasheets and evidence of compliance with the Demeter standard for all additives and processing aids • Invoices for sales of all products • Processing records • Storage records • Transport records

Farm	Processor / Trader (as applicable – including on-farm processing)
<ul style="list-style-type: none"> • Farm diary, including application records for fertilizers, crop protection products, biodynamic preparations • Larger or complex farms: quality manual with detailed procedures • Labels 	<ul style="list-style-type: none"> • Bookkeeping • Quality manual with detailed procedures • Labels

Announced inspections normally follow a standardised procedure, as shown in Figure 7. This may change, because inspectors are encouraged to adapt their procedures to the specific situation at each operation. Typical inspection time, depending on size and complexity of each operation, varies between two hours and two days. In exceptional cases, it may take longer.

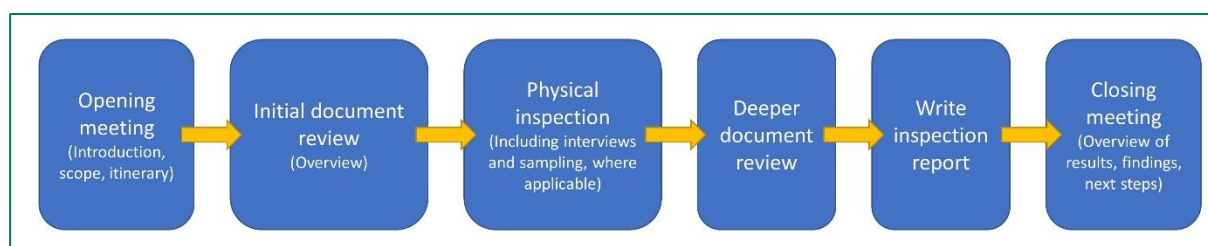


Figure 7: Standard procedure of an announced inspection.

In addition to the annual announced inspections, ICO conducts additional inspections, which may be announced or unannounced. These are more focused on specific issues, e.g.:

- Verifying implementation of corrective actions (see Section 9)
- Verifying compliance with the Demeter standard during critical periods of the year (e.g., typical time of fertilizer use, or crop protection, or harvest)
- If the annual inspection to a processing facility takes place at a time when no Demeter products are being processed, an additional visit may be conducted when Demeter processing takes place
- Complaints from insiders or third parties may lead to additional inspection visits.

ICO aims to conduct additional inspections with approximately 10% of licensees per year. “Unannounced” really means “unannounced”. The licensee should not expect to be notified one or two days before, as in some other certification programmes. Based on the license agreement, during such unannounced inspections the inspector must be given access to all fields, premises, and records. Figure 8 describes the simplified procedure for such inspections.

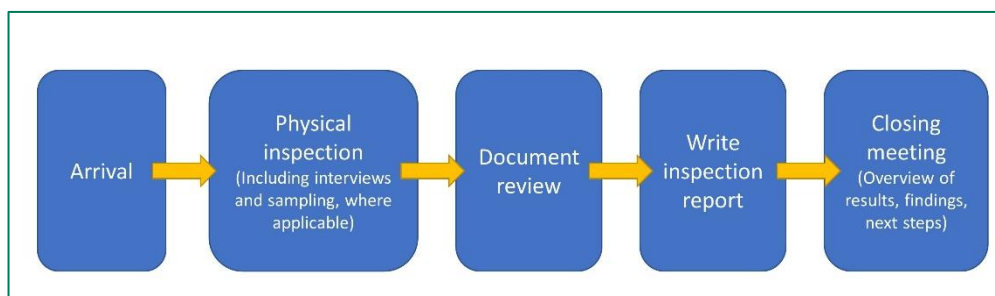


Figure 8: Simplified procedure for unannounced additional inspections. A formal opening meeting is not required. Inspectors are instructed to be flexible; therefore, e.g., they may sometimes review documents before the physical inspection. The report for such an inspection is typically much shorter.

The operator must actively supply all information that is relevant for the inspection, both during announced and un-announced inspection. Operators must allow inspectors to speak to any staff they consider appropriate. The ICO asks inspectors to conduct such interviews preferably in the absence of management. Per the contract, sampling must be allowed, as well as taking pictures, or collecting any other kind of evidence the inspector considers necessary during unannounced inspections. Inspectors must be given access even if the manager is absent or does not have time. In most operations, a deputy should be available, if the manager is not. Refusal to co-operate with inspectors, may lead to cancellation of the license agreement.

In special situations, when there is a high risk for the inspector (pandemic, violence, etc.), the ICO may decide to allow onsite inspections to be replaced by online inspections.

Starting from January 2023, the cost for additional risk-based inspections, sampling and testing will be invoiced to the licensee.

9 Non-Conformities and Corrective Actions

Inspections (announced or unannounced) can have different outcomes:

- (a) the operator is fully compliant
- (b) there are non-conformities, but these are correctable
- (c) there are critical non-conformities, which cannot be corrected (at least not in the short term).

Figure 9 provides an overview on how the ICO manages these different cases. If major non-conformities are repeated, or not corrected within the agreed timeline, this may lead to suspension or withdrawal of certification.

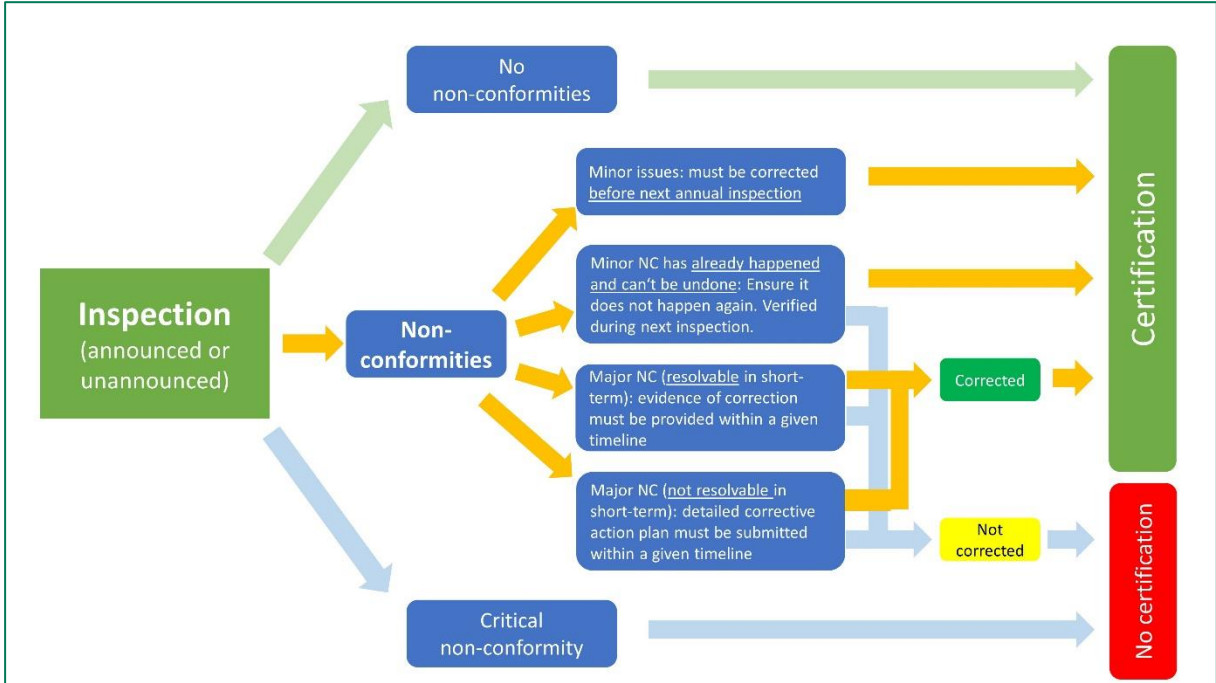


Figure 9: Possible outcome of inspections and different ways to follow up on non-conformities found during the inspection, depending on the type of non-conformity (=NC).

10 Sampling and Testing

Based on a risk analysis, ICO takes samples from certain licensees. Inspectors may take samples from crops on the field, from soil, from harvested, stored, or processed products, from farm inputs, or whatever may be appropriate for verifying compliance with the Demeter standard. Inspectors are trained for following standardised sampling procedures, ensuring the integrity (chain of custody) of the sample, and avoiding cross contamination during sampling, storage, or transport of the sample.

Samples are sent to accredited laboratories, accepted by ICO. The licensee receives a copy of the laboratory test report.

If test results raise suspicion that substances or methods may have been used which are not allowed under the Demeter standard, the licensee has the opportunity to comment on the result before the ICC decides. Only when the result is clear (e.g., a test shows a Demeter farm has used synthetic pesticides), a suspension or withdrawal of certificate may be issued without the opportunity to comment. This does not affect the right to present an appeal (Section 11).

11 Appeals and Complaints

If the licensee feels that a certification decision is incorrect or unfair, he/she can file an appeal within one month. The appeal should be backed by as much evidence as possible. The appeal will be reviewed by a person that is different from the one who made the initial decision and then a decision is made in the International Certification Committee (ICC, see Figure 1).

If the licensee is not happy with the result of this appeal process, a second level appeal can be filed within two weeks. The Supervisory Board of the Federation will then appoint an appeals committee, composed of experts as appropriate for each case. Prior to this, the appellant must deposit 750 €, which the Federation will refund in case the committee finds the appeal to be justified.

Appeal can be put on hold if there are outstanding financial issues.

Not only licensees, but also consumers may present complaints, workers on a Demeter farm, neighbours, non-governmental organisations, or whoever believes that something is going wrong, e.g., with an inspector, or in a Demeter operation. Complainants should preferably disclose their identity. If the complainant believes that confidentiality should be respected, the source of information will not be disclosed. However, anonymous complaints will also be investigated, provided they are plausible and substantiated by evidence.

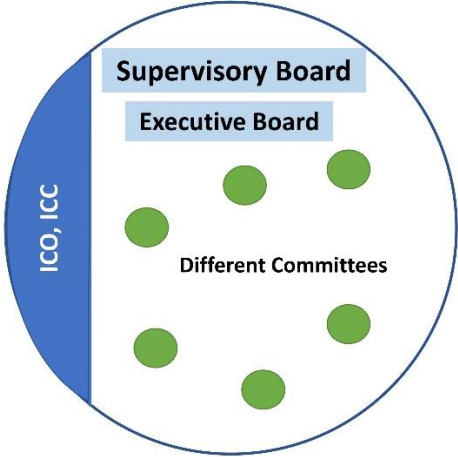

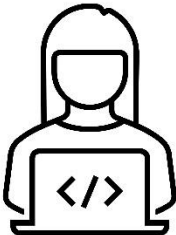

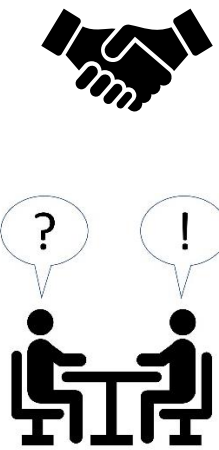

12 Impartiality and Non-Discrimination

The Federation recognises the need for, and importance of, impartiality in the process of certifying products and processes and is committed to safeguarding the impartiality and the integrity of its affairs.

The Demeter certification programme is accessible to all applicants who fall in the scope of the standard, regardless of size or type of operation, provided they commit themselves to comply with the International Demeter Biodynamic Standard. All applicants to and licensees of the schemes shall be treated on a non-discriminatory basis. In very rare cases, however, where an applicant/licensee is considered to be a risk for the reputation and/or credibility of the

international trademark community, the ICO may turn down an application or cancel a contract without specifying the reasons.

How the ICO ensures impartiality:

<p>The ICO is part of the Federation, and the Executive Board (EB) of the Federation is responsible for the ICO’s quality management. Neither the EB nor the Supervisory Board get involved in individual certification decisions. Both the ICO and the International Certification Committee (ICC) are completely autonomous in this regard.</p>		
<p>At least two different persons (the inspector and the certifier) participate in each certification process. The inspector, who collects the facts on the ground, is not the one who makes the final certification decision. A second person looking at things more distantly, helps to achieve more objectivity.</p>	 <p style="text-align: center;">Inspector</p>	 <p style="text-align: center;">Certifier</p>
<p>The second person (certifier) forwards complex cases to the ICC – a committee composed of several experts with long-term experience.</p>		
<p>There is a clear separation between any commercial or consultancy activities on the one hand, and inspection and certification on the other hand.</p> <p>The ICO decides if a person involved in production, processing, trade, or consultancy can conduct inspections or certification to other licensees, or to other industries only, or will lose his/her approval as a whole. If a person is, e.g., involved in Demeter wine making, he/she can be an inspector on cereal or livestock farms, but not in other wineries.</p>	 <p style="text-align: center;">Business / Consultancy</p>	 <p style="text-align: center;">Inspection / Certification</p>

Anybody involved in inspection or certification, must annually declare his/her conflicts of interest.



The ICO takes seriously and investigates complaints from licensees, whistle-blowers or third parties, concerning lack of impartiality or even corruption. If they hold true, the involved person (or organisation) will lose the approval. If necessary, inspections conducted by that person will be repeated.



13 Competence management

The ICO is responsible for the competence of everybody for their respective tasks. This refers especially to inspector and certifiers. Demeter inspectors must be trained and approved by the ICO. Rigorous selection of staff, detailed work instructions, regular trainings and monitoring during internal audits are essential for ensuring the necessary competence.

14 Responsibility

The overall responsibility for the Quality Management of the international Demeter certification scheme lies with the Executive Board of the Federation.

Day-to-day responsibility for the implementation of quality management lies with the Head of the ICO with the support of the ICC.

The Accreditation Council of the Federation regularly monitors the ICO, to ensure the organisation follows fair, transparent, and rigorous procedures, as outlined above.

15 Glossary of terms

Additional Inspection	This is an inspection that takes place in addition to the annual regular inspection. Such additional inspections may be announced or <u>unannounced</u> .
Advisor	Farmers with more than 5 ha must work with a recognised Demeter advisor (= consultant; see https://www.biodynamic-advisors.org/en/directory-advisors).
Applicant	A legal entity that is in the process of application. From the first contact until signing a license agreement, the entity is considered an applicant.
Federation	Biodynamic Federation Demeter International. A federation of the biodynamic organisations in more than 40 countries, with its legal residence in Darmstadt, Germany.
Biodynamic	The agricultural practices as defined in the <u>Demeter Standard</u>

Certificate	A Demeter certificate confirms compliance with the <u>Demeter Standard</u> and allows the <u>licensee</u> to use the Demeter trademark and claim Demeter quality of the products, within the terms defined in the license agreement.
Certification	The entire process from reviewing applications through making certification decisions, is called “certification”
Certifier, certification officer	Any certification process involves, as a minimum, two persons (“four eyes principle”). In the case of Demeter, the two persons are the <u>inspector</u> who collects evidence on the ground and writes an inspection report, and the certifier, who reviews the report, issues non-compliances, and makes a certification decision. Sometimes also called “reviewer”, “evaluator” or “evaluation officer”.
Contract = license agreement	Operators sign a license agreement with the Federation.
Conversion	Conversion is the period from a conventional or organic farm to a Demeter farm. A farm can either go through organic and Demeter conversion at the same time, or, if it is already certified organic, undergo an additional conversion from organic to Demeter. In either of these cases, minimum time from signing a contract with the Federation and selling products with reference to Demeter, is 12 months.
Corrective Action	When the ICO finds a major non-conformity during the certification process, the applicant or licensee must resolve it with a corrective action. The certifier assesses if the corrective action is appropriate and satisfying. In some cases, the corrective action consists of something that has already been done at that point (e.g., submitting a picture showing that Demeter products are now being stored in a separate shelf). In other cases, a detailed corrective action plan is expected, including timelines for the implementation of each step.
Demeter Standard	Refers to the entire International Demeter Biodynamic Standard, as published at https://www.demeter.net/certification/standard/
Executive Board	The operational management of the Federation
ICC	International Certification Committee. The ICC monitors and advises the <u>ICO</u> . In complex cases, it is not the <u>certifier</u> who decides, but by the ICC.
ICO	International Certification Office. The certification department of the Federation.
Inspection, inspector	Verification of compliance of an operation with the <u>standard</u> . In the Demeter context, the terms “inspection”, “audit” and “control” are used synonymously.
Licensee	A licensee is a contract partner of the Federation, who has permission (license) to use the Demeter trademark for his/her products. Conditions for being an approved licensee are: (a) signing a <u>license agreement</u> , (b) having a valid <u>certificate</u> , and (c) payment of the license fees.
Non-conformity: Minor	Any deviation from the Demeter <u>standard</u> and from requirements of the license agreement, which does not directly compromise the integrity of the product, but needs correction.

Non-conformity: Major	<p>The integrity of the operation, product or batch has been directly compromised, but the integrity of the <u>operation</u> can be recovered. Examples:</p> <ul style="list-style-type: none"> • Accidental contamination with prohibited materials • Non-intentional commingling of Demeter with non-Demeter products • Excessive number of minor non-conformities • Use of conventional seeds or propagation material for sales crops without exemption • Lack of biodiversity
Non-conformity: Critical	<p>A serious or repeated failure of the system in which the integrity of Demeter products is compromised, which leads to no certification of the licensee. Examples:</p> <ul style="list-style-type: none"> • Deliberate fraud • Intentional commingling of Demeter with non-Demeter products • Obstruction of the work of the inspector / refusal to allow samples to be taken • Storage or use of prohibited materials (e. g. chemical fertilisers/pesticides) • Contamination of Demeter products through systems failure • Excessive uncorrected major non-conformities
Operation, operator	<p>Synonym to “unit” or “entity”, often used in the certification context. An “operation” can be a farm, a processing unit, or a trader. Not necessarily identical to a “legal entity”, because one legal entity can own several operations.</p>
Premises	<p>Buildings and land belonging to an <u>operation</u>. By signing the <u>contract</u>, the <u>applicant</u> or <u>licensee</u> agrees to give the inspector access to the premises at any time, for announced or <u>unannounced inspections</u>.</p>
Processing	<p>Any post-harvest (after harvest) handling of agricultural produce. As opposed to EU food law, the term “processing” in our context is not restricted to activities that significantly change the characteristics of the product (e.g., by converting flour to bread), but includes simple processes like cleaning, sorting, packaging, or labelling. However, transport and storage are not defined as processing. According to the Demeter <u>standard</u>, processing must be done in a way that preserves or enhances the <u>biodynamic</u> quality of food.</p>
Unannounced Inspection	<p>Additional <u>inspection</u> conducted without warning. “Unannounced” normally really means what the word says.</p>