SOP.006 FPR
EFCI Register

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SOP.006
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1. Definitions

1.1

The in this document mentioned terms are defined in the RD.004 (GNG TIC list of terms and conditions). EFCI Register is part of GNG TIC.

2. Purpose

2.1

This document clarifies certain work procedures that EFCI Register maintains for FPR 2019/1009.

2.2

In case of FPR 2019/1009 EFCI Register follows as general guidance the documents of the Notified Body coordination group.

2.3

This SOP is binding for clients and EFCI Register.

3. Testing

3.1

Where testing is required for the purposes of assessing conformity to a standard, or set of standards, the client is obliged to have the tests carried out and submit test reports hereof. If determined by applicable laws, regulations, standards, or other documents at the discretion of EFCI Register, these test reports must be issued by an EN ISO/IEC 17025:2017 accredited laboratory with an accreditation scope relevant to the required testing work. In addition, the laboratory must meet the requirements of the laws relating to the NANDO scope of EFCI Register (based on EU Decision 768/2008 Article R17 where applicable) if the conformity assessment is carried out under notification.

3.2

If a test report is not issued by an EN ISO/IEC 17025:2017 accredited laboratory, or if the laboratory does not meet other set requirements, the test must be re-performed by a laboratory as defined in 3.1.

3.3

The EFCI Register lead auditor is tasked with reviewing lab test reports to determine whether they show conformity against the aforementioned requirements/standard or set of standards and whether the laboratory has the appropriate accreditation.

3.4

Where performing testing under accreditation, as documented in 3.1, is not possible due to the state of the art of the certification scheme, a test report must be accompanied by a validation report and/or any other relevant (to the judgement of the Lead Auditor) documentation to prove the EN ISO/IEC 17025:2017 accredited laboratory has the *scope relevant* ability to perform the testing. In addition, the scope of the laboratory must indicate activities relevant to the standard for which testing is required.

3.5

Test reports from Client Laboratories that do not comply with article 3.1 cannot be used.

3.6

A test report can only be accepted if form FO.005 has been completed by the laboratory that issued the test report. The form must be evaluated & approved by the lead auditor.

4. Sampling - sample's

4.1

Sampling for testing must be done in accordance with the requirements from FPR 2019/1009. Sampling as required by the Notified Body for Module D1 is described in article 5 and annex 1.

4.2

FPR 2019/1009 has appointed the manufacturer as the responsible party for providing the sample.

4.3

In case of FPR 2019/1009 Module B certification the manufacturer is responsible for ensuring the sample is representative of production envisaged, as confirmed by the FPR Notified Body coordination group.

4.4

EFCI Register will always retain the right to ask for samples of the product where it sees fit. The client is obliged to comply with this right.

4.5

For certification against FPR 2019/1009 Module the client may be obliged to send a sample to EFCI Register of the product. The sample will be retained for 3 months after the date of the certification.

5. Module D1

EFCI Register will, when notified, perform Module D1 audits. For this, we will have a Module D1 notification and accreditation scope. Due to the special nature of Module D1 specific provisions are required. Article 5 lays down the provisions for carrying out Module D1 audits and the specific technical resources required hereto. These provisions are considered as binding and inserted in PD.001. In TD.001 relevant provisions are made binding on the client.

5.1. Procedures

The audit will be carried out in accordance with PD.001, this document (especially Annex 1), and the requirements from Annex IV of the FPR regulation EU 2019/1009.

The time for the audit will be carried out in accordance with article 5.2. For this EFCI Register will charge according to PD.009. The audit time to be spent and audit plan (including assessment times across the entire cycle) must be documented in the certification advice before a contract is signed. Here the audit team (including their competency) must be documented as well. The times indicated in the certification advice are indicative and may be changed based on the actual situation in accordance with EFCI register procedures. Planning of surveillance visits happens with the client and the first surveillance visit must be planned immediately at the start of the certification period. The subsequent surveillance visit must be planned during the first surveillance visit.

In addition to experience in quality management systems (competency profile 1.2.5), the auditing team shall have at least one member with experience of evaluation in the FPR and they shall qualify as a Module B auditor under the FPR (competency profile 1.2.5).
If the audit team consists of a single person, he/she must comply with both profiles.

A lead auditor who has the competency code MODULE_D1 must do the audit reporting. If the audit team consists of multiple auditors with this code a single team lead must be identified in the certification advice who is fully responsible.

Annex 1: Module D1 procedures

1. Registration and process

FPR Module D1 certification is handled in the same flow as Module B through PD.001.

Companies with a main location and subsidiary location(s) belonging to the same legal entity fall under the same certification agreement and certificate. During an initial audit, all CMCs and PFCs that fall under the scope of the certificate are audited (main location and, if applicable, the subsidiary location(s)). After the initial audit, a three-year certification cycle with regular audits starts.

During this cycle, the main location is audited annually and subsidiary locations are audited once every three years, unless a subsidiary location uses other CMCs and/or produces PFCs that are not used or produced at the main location. In that case, a subsidiary location is also audited annually. A recalculation of audit time and costs is drawn up for each three-year certification cycle, or in the interim if applicable.

After the application is received, the audit time is calculated and a time and cost statement (Appendix 4) is drawn up. The time and cost statement is sent to the company in writing with the certification agreement. After receipt of the signed certification agreement, an appointment is made for an initial audit.

2 Audits

The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 2 of Annex IV of the FPR 2019/1009 in order to verify the manufacturer's ability to identify the relevant requirements of the FPR 2019/1009 and to carry out the necessary examinations with a view to ensuring compliance of the EU fertilising product with those requirements. This audit shall be carried out according to PD.001 and SOP.006. The audit will be carried out against the guidelines for Modules of the FPR 2019/1009 coordination group.
The steps required by this guideline will be implemented in our Module D1 audits.

2.1 Company audit resources

EFCI Register has the following resources available to carry out the audit work at the company:

- Administrative check. For this purpose, written documents about the company to be audited can be requested from the company concerned. Administrative checks are also carried out on site during a company visit.
- Visual and/or physical check (audit). Audit visits are paid to the company. During the visit, samples of fertilisers, including raw materials and end products, can be taken. For the purpose of the audit, photos can be taken of the facilities, the documents present, fertilisers and all other goods. If the auditor believes this is necessary for the audit, he or she may include administrative records in the check or assessment. After (completion of) the audit or assessment, the documents must be returned to the company concerned in person or by registered mail as soon as possible.

2.2 Cooperation by the company

For the purpose of the audit or assessment, each company is at all times obliged to cooperate with the performance of the audit and assessment of the audit and to comply with any related instructions or regulations issued by or on behalf of EFCI Register, including;

- to grant EFCI Register or the auditors engaged by it free and immediate access to all of the company's sites and business areas, including manufacturing, inspection, testing and storage areas, access to which is necessary for the performance of the audit or assessment;
- to allow EFCI Register or the auditors engaged by it to take samples of fertilisers, including raw materials and end products;
- to allow EFCI Register or the auditors engaged by it to inspect all relevant administrative records;
- to provide EFCI Register or the auditors engaged by it with all information that they consider necessary for the performance of the audit or assessment.

2.3 Structure of the audit

The audit at the main location consists of the opening interview, the assessment of the quality management system, the technical documentation and quality files, the company tour and interviews with employees, an evaluation of the audit findings and a closing interview. The auditor allocates the determined audit time between these elements at their discretion, depending on the size and activities of the company and taking into account the time required for reporting. The audit at the subsidiary location(s) includes a company tour and interviews with employees. If a subsidiary location uses a quality manual and/or technical documentation and quality files that partially or completely deviate from the quality manual and/or technical documentation and quality files of the main location, the audit of the subsidiary location is expanded with the part that deviates from the main location.

During the audit, samples of fertilisers can be taken, if necessary, to carry out product tests to check that the quality system is functioning properly.

2.4 Audit procedure

The audit will be carried out against Article 5 of Annex IV of the FPR 2019/1009.

The findings of all types of audits are recorded in an audit report according to the prescribed format. This should at least include:

- audit date;
- unique registration number, e.g. Chamber of Commerce number;
- name and address details of the main location and any subsidiary location(s);
- scope of certification;
- all checked regulations with conclusion (compliant, minor, major, major +);
- an explanation of any identified non-conformities;
- a summary of identified non-conformities, corrective measure(s) imposed; - the date on which the non-conformity(ies) must be rectified at the latest.

3. Types of audits

EFCI Register can perform both regular and additional audits. The regular audits are part of the regular three-year certification cycle and additional audits are a supplement to it.

3.1 Regular audits:

- Initial audit / recertification audit: The initial audit is the first audit of the certification cycle and is performed if the company does not have a valid FPR certificate for the location in question at the time of the audit. The recertification audit is the first audit of a subsequent certification cycle. During this first audit of the certification cycle, all CMCs and PFCs that fall under the scope of the certificate will be audited (main location and, if applicable, all subsidiary location(s)). If this audit is concluded positively, a certificate is issued with a validity of three years.
- Surveillance audits 1 and 2: This concerns the annual audits (every 12 months, with a margin of 11 to 14 months after the previous audit) in the years following the issuance of a certificate. During the audit, it is assessed whether the certification can be continued. During surveillance audits, the main location is always audited. If present, subsidiary locations are audited in either surveillance audit 1 or 2 provided that the certification scope of the subsidiary location is equal to the main location. If the certification scope is different, subsidiary locations are also audited every 12 months.

  During surveillance audits, half the CMCs and PFCs that fall under the scope of the certificate are audited, so all CMCs and PFCs are audited once during surveillance audit 1 or 2. To this end, an audit schedule is drawn up in advance. This audit schedule is documented in the PD.001 certification advice. This advice will have a plan for the initial certification and the surveillance audits. At least the first surveillance audit will be scheduled unless this is explicitly left to the auditor to conclude in the final report.

The regular audits will always be announced and planned.

3.2 Additional audits

Additional audits take place if rectification after a major non-conformity cannot be demonstrated administratively, if a major+ non-conformity is found and after one or more reports of non-conformity of fertilising products. Audits can also take place if EFCI Register deems this necessary. Additional audits can take place at any time, whether announced or not. In general EFCI Register maintains the below additional audits.

- Unannounced audit: EFCI Register can perform unannounced audits at the company to determine whether the company complies with the provisions of or pursuant to the FPR.
- Changes to the certification scope: EFCI Register can decide to carry out an additional audit in the meantime if the company adjusts the scope of certification or changes take place in the company that require new audits such as updated rules, new personnel, a merger or takeover or other matters that effect the certification. A coordination group document for determining what is a significant change may be used if available, if not the rule from the 6th Coordination group meeting notes will be used.
- Compliance audit: When a non-conformity is identified, for which rectification cannot be demonstrated administratively, a compliance audit is performed. This audit is in addition to the regular audits and focuses on the rectification after the non-conformity.
- Stricter supervision: After a major + non-conformity has been identified and after suspension, the certificate holder is placed under stricter supervision. The stricter supervision lasts for a minimum of three months and a maximum of six months, with at least one audit taking place on site. This concerns the location where the major + non-conformity was found in the event that a company has several locations.
- Recheck: A recheck is an audit that is carried out on the basis of one or more reports of nonconformity of fertilising products. The recheck focuses on the

(alleged) non-conformity, but can also focus on all of the conditions of the FPR scheme. A recheck may be carried out at the request of the notifying authority, with or without the presence of an auditor from the notifying authority.

4. Frequency of and time spent on audits

4.1 Frequency of audits

The initial audit is only performed if the company concerned does not have a valid FPR certificate for the location in question at the time of the audit. If this audit is concluded positively, a certificate with a 3 year validity period is issued. In the years following the issue of a certificate, a regular/surveillance audit takes place once every 12 months, with a margin of 11 to 14 months after the previous regular audit. Recertification will also take place at the end of the 3-year period.

If a company consists of a main location and subsidiary locations that form part of the same legal entity, the following frequency is used:

- Initial audit: all main and subsidiary locations that form part of the same legal entity are audited.
- Regular/surveillance audit: the main location is audited every 12 months (margin of 11 to 14 months). A subsidiary location is audited every three years (margin of 2 years and 9 months to 3 years and 6 months), provided the certification scope of the subsidiary location is equal to the main location. If the certification scope is different, subsidiary locations are also audited every 12 months (margin of 11 to 14 months).
- Additional audits take place if rectification after a major non-conformity cannot be demonstrated administratively, if a major+ non-conformity is found and after one or more reports of non-conformity of fertilising products. Audits can also take place if EFCI Register deems this necessary. Additional audits can take place at any time, whether announced or not.

4.2 Minimum time spent on audits

To guarantee the quality of the audits to be performed, a minimum audit and reporting duration has been established in article 4.2.1. For secondary locations EFCI Register may choose to spend less time if deemed appropriate. This does not include the certification time (assessment and certification decision). The minimum time is seen as the bare minimum time the audit team must spend (in man-hours) on site to conduct the assessment against Module D1 (not including any NC's). EFCI Register cannot go below this minimum unless approval by the board is given and documented.

EFCI Register always is responsible for determining the audit time.

4.2.1 Minimum audit time main location

Main location		
Activities	Specification	Time (hours)
Preparing and reporting audit	0-4 CMCs/PFCs	6.5
	5-8 CMCs/PFCs	7
	9-12 CMCs/PFCs	7.5
	>12 CMCs/PFCs	8
Assessing the quality management system, the technical documentation and quality files	0-4 CMCs/PFCs	5.5
	5-8 CMCs/PFCs	8
	9-12 CMCs/PFCs	11
	>12 CMCs/PFCs	14
	Company without valid ISO 9001 certificate (additional audit time)	2.5
Production site visit (if applicable: manufacture, inspection, testing and storage sites) and interviews with employees	0-4 CMCs/PFCs	4
	5-8 CMCs/PFCs	4
	9-12 CMCs/PFCs	4.5
	>12 CMCs/PFCs	5

5. Conformity of EU fertilising products

The FPR sets mandatory requirements for EU fertilising products that apply independently of standards. It is up to the manufacturer to prove that the product meets these requirements. The manufacturer bears full responsibility for the conformity of EU fertilising products placed on the market. It is the manufacturer's responsibility to demonstrate, for example, that samples taken, analysis methods and analysis results are reliable and complete. The manufacturer analyses raw materials and/or (end) products on a regular basis, for example by sampling and analysing (for example √n - where n = total number of raw materials and/or end products) raw materials and/or (end) products per year. A company must take the range in contents into account, so the entire range in contents is analysed regularly.

In the period prior to the adoption of harmonised standards by the CEN, and in all cases where a manufacturer does not wish to use such standards, analyses of the raw materials and/or (end) products are preferably carried out by laboratories that, according to accreditation by the Dutch Accreditation Council demonstrably comply with the NEN-EN-ISO/IEC 17025 standard. A company may deviate from this, provided it is demonstrated that analyses that use deviating methods have at least the same performance characteristics (limit of quantification, repeatability, reproducibility, etc.). The company can use a copy of FO.005 for this if desired.

If necessary, EFCI Register can take samples of fertilisers for verification purposes. The costs of these analyses shall be at the company's expense. After adopting the applicable harmonised standards and any other requirements, EFCI Register is allowed to carry out additional conformity assessment activities at any time.

6. Assessment

The audits can be performed by multiple auditors or by a single auditor in accordance with SOP.006.

6.1 Category classification non-conformities

When performing assessments EFCI Register has the following possible non-conformities:

- MINOR: a minor non-conformity, which has no impact on the conformity of the EU fertilising product with the requirements of the FPR and is clearly incidental in nature. Minor nonconformities can be concludes for structural problems only if these have no impact on the conformity of the EU fertilizing product. Minor nonconformities must be rectified within six weeks in order to be able to issue the certificate or continue certification. Evidence of corrective measures must be sent to EFCI Register and/or rectification is demonstrated through a compliance audit. If minor non-conformities are not rectified (in good time), the non-conformities will be scaled up to major non-conformities.
- MAJOR: a major non-conformity, which has an impact on the conformity of the EU fertilising product with the requirements of the FPR, and/or several minor non-conformities on the same regulation where a structural problem across the minor NC's can be concluded. A Major non-conformity can also always be concluded for an incidental issue if the auditor concludes this is the case. Major non-conformities must be rectified within three weeks in order to be able to issue the certificate or continue certification. Evidence of corrective measures must be sent to EFCI Register and/or rectification is demonstrated through a compliance audit. If major non-conformities are not rectified (in good time), the non-conformities can be scaled up to suspension of the certificate in consultation with the board.

- MAJOR+: A major + non-conformity, posing a plausible danger to human, animal or plant health, product safety or the environment. The following sanctions can be applied if a critical nonconformity is identified:
    - Depreciation of the non-conformity and stricter supervision
      The company must have taken corrective measures immediately when the nonconformity is identified.
      The stricter supervision lasts for a minimum of three months and a maximum of six months, with at least one audit taking place on site. This concerns the location where the major+ non-conformity was found in the event that a company has several locations.
    - Suspension of the certificate for a maximum of three months
      The non-conformity must be rectified within the suspension period. The suspension may be revoked early if the resolution of the nonconformity has been established during an enhanced supervisory audit. The stricter supervision lasts for a minimum of three months and a maximum of six months, with at least one audit taking place on site.
      This concerns the location where the major+ non-conformity was found in the event that a company has several locations.
      If insufficient rectification is demonstrated, the certificate can still be revoked.
    - Revocation of the certificate
      The company's certificate is revoked. After revocation of the certificate, a company can register for an admission audit.
- Major Exit (MAJOR EXIT) – The lead auditor has determined that the uploaded evidence, interaction with the auditee or other matters warrant the audit to be cancelled abruptly. The quality manager must be informed immediately. This can only be concluded in cases where there is no confidence an audit can be correctly finalized and will automatically lead to denial or revocation. This option will be used in cases of client based fraud, criminal activity or other untruthful or unethical activities.

- Suspension:
    - If an already certified company does not rectify a major or major+ non-conformity within the stipulated time and/or if it can reasonably be assumed there has been gross negligence and/or fraudulent actions with regard to the conformity of EU fertilising products and/or product safety, a company's certificate can be suspended for a period of up to three months. The suspension can be lifted (early) if proof of corrective action has been sent to and approved by EFCI Register.
    - A company's certificate can also be suspended for a period of up to three months if it refuses and/or does not cooperate with (planning/performing) audits and/or additional conformity assessment activities by EFCI Register, if a company does not meet the criteria as laid down in the certification agreement between the company and NoBo, and/or if payment is not made on time. The suspension can be lifted (early) when a company complies with the aforementioned points again.
    - During a suspension, a company ceases to be permitted to market EU fertilising products with CE marking with immediate effect. After a suspension has been lifted, a company is placed under stricter supervision for a period of at least three months and a maximum of six months. During the period of stricter supervision, at least one on-site audit will take place. This concerns the location where the major+ non-conformity was found in the event that a company has several locations.
- Revocation of the certificate: A company's certificate may be revoked if insufficient, or no, rectification has taken place within the suspension period. After revocation of the certificate, a company can register for an admission audit. A revocation can also be concluded without a suspension if the auditor concludes a MAJOR EXIT non-conformity or if the company can no longer function correctly (ie due to bankruptcy).

Rectification of non-conformities should be done in accordance with ISO 9001 or where relevant another method at the description of the manufacturer.

All non-conformities will be raised as CAPA's (and the CAPA will be marked as minor/major/major+). Additionally non-conformities will also be listed as markings in the audit report provided to the company.

6.2 Measures

If a company has not, or not properly, complied with the provisions of or pursuant to the FPR and/or the certification agreement between the company and EFCI Register, EFCI Register (described in 6.1.) the company will be suspended.

If during the supervision, EFCI Register finds that a company has not, or not properly, complied with the provisions of or pursuant to the FPR and/or the certification agreement due to an obvious mistake or due to force majeure, this will be taken into account during the decision to issue and/or renew a certificate and/or when announcing a sanction, if:

- the company demonstrates there is (a certain degree of) absence of fault and/or force majeure and;
- the company demonstrates that it has taken all possible measures to prevent and rectify the error or, in the event of force majeure, it has taken all possible measures to rectify the situation that has arisen.

7.Reporting

After each audit, EFCI Register assesses the audit report. Based on this assessment, EFCI Register identifies which rectification actions should or should not be taken by the company. EFCI Register also, in the conclusion, determines if certification can be granted/retained. If the nature of non-conformities is such that certification cannot be granted/retained the conclusion must indicate this.

If non-conformities are concluded the conclusion must indicate the correction measures and timeline for this.

The report must contain the conclusions of the audit and the reasoned assessment decision.

In the event of non-conformities, EFCI Register will send the company a written assessment report within two weeks of the audit.

The assessment report will at least state:

- Date of the site visit(s)
- unique registration number, e.g. Chamber of Commerce number;
- name and address details of the main location and any subsidiary location(s);
- identified non-conformity(ies);
- corrective measure(s) imposed;
- Conclusion as described above
- the date on which the non-conformity(ies) must be rectified at the latest.

If the proof of corrective action has been sent, EFCI Register assesses this proof and creates a new report with an amended conclusion. In the event of a compliance audit, EFCI Register assesses the audit report and takes appropriate action if necessary.

EFCI Register sends the assessment report containing the certification decision to the company. The company will also receive the certificate, if applicable.

EFCI Register will inform the notifying authority of any approvals granted or revoked for the FPR scheme and it will periodically or upon request provide it with a list of denied, suspended, revoked or otherwise restricted approvals for the FPR scheme.

EFCI Register will inform the other notified bodies of the approvals it has refused, withdrawn, suspended, revoked or otherwise restricted for the FPR scheme and, upon request, of the approvals it has granted for the FPR scheme.

8. Certificate

A certificate can only be issued by EFCI Register to a company that has no open non conformities.

The following information is provided on the certificate at least:

- First issue date and issue date (certification date, i.e. the date on which the certification decision was made);
- Expiration date (certification date + 3 years)
- Certificate number as issued by EFCI Register;
- Certificate number of previous certificate as issued by EFCI Register (if applicable);
- A characteristic of EFCI Register itself (for example, a logo, name and notified body number);
- The name (registered name) and address details of the main location and (if applicable) the subsidiary location(s);
- The scope of the certificate per location (CMCs and PFCs per location) on page 2 of the certificate;
- The conformity assessment procedure (e.g. the assessment was carried out in accordance with conformity assessment procedure Module D1).

A certificate is issued per legal entity and remains valid as long as the harmonised standards and common specifications, the conformity assessment procedure, and the EU fertilising product(s), the quality system and the manufacturer's technical documentation are not significantly amended, unless EFCI Register suspends or revokes the certificate.

The issue date on the certificate is the certification date (the date on which the certification decision was made). Subsequently, a new regular/surveillance audit must be performed every 12 months (with a margin of 11 to 14 months after the previous regular audit). Publication of the certificate is permitted.

If a company is suspended EFCI Register will suspend the certificate.

If an audit is concluded with non-conformities that require revocation (after a suspension), EFCI Register will revoke the certificate.

9. Changes to FPR and assessment and certification criteria

Both the FPR and the assessment and certification criteria, as laid down in this document, can be changed unilaterally. Participating companies are obliged to comply with these changes and/or ensure they are complied with.

Changes to the FPR are announced by or on behalf of the European Commission through implementing acts and delegated acts. Changes to the assessment and certification criteria will be announced by EFCI Register to the participating companies.

10. Surveillance additional to PD.001

10.1.

The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system. EFCI Register will perform surveillance under its work as Module D1 Notified Body.

10.2.

The manufacturer shall, for assessment purposes, allow EFCI Register notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

- the quality system documentation,
- the technical documentation referred to in point 2,
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.

10.3. EFCI Register shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

10.4. For compost belonging to CMC 3, 5, 12, 13, 14, and 15, as defined in Annex II, EFCI Register shall (via a subcontractor) take and analyse output material samples during each audit, and the audits shall be carried out with the following frequency:

(a) during EFCI Register's first year of surveillance of the plant in question: the same frequency as the sampling frequency indicated in the table included in point 5.1.3.1(f) of the FPR 2019/1009; and

(b) during the following years of surveillance: half the sampling frequency indicated in the table included in point 5.1.3.1(f).

10.5. In addition, EFCI Register may pay unexpected visits to the manufacturer. During such visits EFCI Register may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. EFCI Register shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

11. Subcontracted work under Module D1

11.1

As per RD.002 this article defines the criteria for subcontracting evaluation activities under Module D1 of the FPR.

11.2

FPR 2019/1009 Annex IV Module D1 requires that certain tests and sampling activities (in case of CMC 3/5/12/13/14/15 and other CMC's) are carried out by the Notified Body. EFCI Register has chosen to subcontract these activities.

11.3

All subcontractors must fill in FO.005, be compliant for use in Module B and comply according to PD.001. This already ensures a quality standard.

FO.005 must be re-affirmed every year. All subcontractors must also sign TD.017.

11.4

GNG TIC must assess the scope of the subcontractors and ensure they are appropriate. Within the meaning of FPR 2019/1009, in the short term (2023-2025), appropriate is determined as that the scope is relevant to testing fertilizing products. Some parameters must at the least be under accreditation but not all parameters must be under accreditation. This is in accordance with the defined criteria also listed in the criteria for accepting test reports.

11.4.1

The laboratory must strive to work against the harmonized standards 1 year from the date these are adopted. This also means being accredited for them when possible. Until this is done other standards can be used to the acceptance of EFCI Register.

11.4.2

GNG TIC may decide to implement a specific provision in TD relating to this accreditation.

11.4.3

Every year in the management review and the IA a review of each FPR subcontractor and the status of their accreditation must be performed.

11.5
Unless non-accredited labs are used or in cases of non-conformity or doubt GNG TIC will not carry out an ISO 17011 assessment of the laboratory against ISO 17025.
11.6

At the start of the certification GNG TIC will make a plan with the client on how many samples of output materials must be taken and how many tests must be carried out as required by Annex IV 6.3.2. EFCI Register shall take and analyze output material samples during each audit, and those audits shall be carried out with the frequency defined in the plan. This plan must be finalized by the time the certification is issued, and will be uploaded to CETOOL, for the first year of the certification starting period.
11.6.1
The plan will be determined from the expected volume of production at the date of application for the rest of the calendar year. Volume will be based on the estimation given by the manufacturer for the next year as per the requirements from the coordination group (6th meeting).
11.6.2
During EFCI Register first year of surveillance of the plant in question the frequency of sampling based on production shall be the same frequency as the sampling frequency indicated in the tables included in points 5.1.3.1(f) and, respectively, 5.1.3.1(fa)
11.6.3

During the following years of EFCI Register surveillance the frequency of sampling based on production shall be half the sampling frequency indicated in the table included in point 5.1.3.1(f) and, respectively, 5.1.3.1(fa).
11.6.4
3 months before the end of the calendar year the client must inform GNG TIC of the expected production volume, and a new plan will be made for the subsequent year.
11.6.5
All sampling costs and testing costs will be invoiced per quarter and must be paid upfront within 14 days of receipt. This will be done pro-rata and may be subject to an administrative fee.