

Certification Regulation for Regulation (EU) 2019/1009

Standard or Certification scheme:

Regulation (EU) 2019/1009

(References made in the present Regulation to Annexes, Articles and points, refer to the relevant sections of Regulation (EU) 2019/1009)

KYA 2172/304447/2020

Accreditation Standard:

ISO/IEC 17065:2012
ISO/IEC 17020:2012

Obligations of economic operators⁷ - Manufacturers

1. When placing EU fertilising products on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements set out in Annexes I and II.

2. Before placing EU fertilising products on the market, manufacturers shall draw up the technical documentation and carry out the relevant conformity assessment procedure referred to in Article 15, or have it carried out.

Where compliance of an EU fertilising product with the applicable requirements laid down in this Regulation has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 5 years after the EU fertilising product covered by those documents has been placed on the market.

On request, manufacturers shall make a copy of the EU declaration of conformity available to other economic operators.

4. Manufacturers shall ensure that procedures are in place for EU fertilising products that are part of a series production to remain in conformity with this Regulation. Changes in the production process or in the characteristics of those EU fertilising products and changes in the harmonised standards, common specifications referred to in Article 14 or other technical specifications by reference to which conformity of an EU fertilising product is declared or by application of which its conformity is verified shall be adequately taken into account.

When deemed appropriate with regard to the performance of, or the risks presented by, an EU fertilising product, manufacturers shall carry out sample testing of such EU fertilising products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming EU fertilising products and recalls of such EU fertilising products, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that the packaging of the EU fertilising products which they have placed on the market bears a type number, batch number or other element allowing their identification or, where the EU fertilising products are supplied without packaging, that the required information is provided in a document accompanying each fertilising product.

6. Manufacturers shall indicate their name, registered trade name or registered trade mark and the postal address at which they can be contacted on the packaging of the EU fertilising product or, where the EU fertilising product is supplied without packaging, in a document accompanying the EU fertilising product. The postal address shall indicate a single point at which the manufacturer can be contacted. Such information shall be in a language easily understood by end-users and market surveillance authorities and shall be clear, understandable and legible.

7. Manufacturers shall ensure that EU fertilising products are accompanied by the information required under Annex III. Where an EU fertilising product is supplied in a package, the information shall appear on a label which is affixed to that package. Where the package is too small to contain all the information, the information that cannot be provided on the label shall be provided in a separate leaflet accompanying that package. Such a leaflet shall be regarded as part of the label. Where the EU fertilising product is supplied without packaging, all the information shall be provided in a leaflet. The label and the leaflet shall be accessible for inspection purposes when the EU fertilising product is

	<p>made available on the market. The information shall be in a language which can be easily understood by end-users, as determined by the Member State concerned, and shall be clear, understandable and intelligible.</p> <p>8. Manufacturers who consider or have reason to believe that an EU fertilising product which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that EU fertilising product into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where manufacturers consider or have reason to believe that an EU fertilising product which they have placed on the market presents a risk to human, animal or plant health, to safety or to the environment, they shall immediately inform the competent national authorities of the Member States in which they made the EU fertilising product available on the market to that effect, giving details, in particular, of any non-compliance and of any corrective measures taken.</p> <p>9. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the EU fertilising product with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by an EU fertilising product which they have placed on the market.</p>
<p>Obligations of economic operators' - Authorised representative</p>	<p>The obligations laid down in Article 6(1) and the obligation to draw up technical documentation referred to in Article 6(2) shall not form part of the authorised representative's mandate.</p> <p>2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:</p> <p>(a) keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 5 years after the EU fertilising product covered by those documents has been placed on the market;</p> <p>(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of an EU fertilising product;</p> <p>(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by EU fertilising products covered by the authorised representative's mandate.</p>
<p>Obligations of economic operators' - Importers</p>	<p>1. Importers shall place only compliant EU fertilising products on the market.</p> <p>2. Before placing an EU fertilising product on the market, importers shall ensure that the appropriate conformity assessment procedure referred to in Article 15 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the EU fertilising product is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 6(5) and (6).</p> <p>Where an importer considers or has reason to believe that an EU fertilising product is not in conformity with this Regulation, the importer shall not place the EU fertilising product on the market until it has been brought into conformity. Furthermore, where the EU fertilising product presents a risk to human, animal or plant health, to safety or to the environment, the importer shall inform the manufacturer and the market surveillance authorities to that effect.</p> <p>3. Importers shall indicate their name, registered trade name or registered trade mark and the postal address at which they can be contacted on the packaging of the EU fertilising product or, where the EU fertilising product is supplied without packaging, in a document</p>

accompanying the EU fertilising product. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4. Importers shall ensure that EU fertilising products are accompanied by the information required under Annex III. Where an EU fertilising product is supplied in a package, the information shall appear on a label which is affixed to that package. Where the package is too small to contain all the information, the information that cannot be provided on the label shall be provided in a separate leaflet accompanying that package. Such a leaflet shall be regarded as part of the label. Where the EU fertilising product is supplied without packaging, all the information shall be provided in a leaflet. The label and the leaflet shall be accessible for inspection purposes when the EU fertilising product is made available on the market. The information shall be in a language which can be easily understood by end-users, as determined by the Member State concerned.

5. Importers shall ensure that, while an EU fertilising product is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the requirements set out in Annex I or III.

6. When deemed appropriate with regard to the performance of, or the risks presented by an EU fertilising product, importers shall carry out sample testing of such EU fertilising products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming EU fertilising products and recalls of such EU fertilising products, and shall keep distributors informed of any such monitoring.

7. Importers who consider or have reason to believe that an EU fertilising product which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that EU fertilising product into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where importers consider or have reason to believe that an EU fertilising product which they have placed on the market presents a risk to human, animal or plant health, to safety or to the environment, they shall immediately inform the competent national authorities of the Member States in which they made the EU fertilising product available on the market to that effect, giving details, in particular, of any non-compliance and of any corrective measures taken.

8. Importers shall, for 5 years after the EU fertilising product has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

On request, importers shall make a copy of the EU declaration of conformity available to other economic operators.

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the EU fertilising product with this Regulation in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by an EU fertilising product which they have placed on the market.

Obligations of economic operators' - Distributors

1. When making an EU fertilising product available on the market distributors shall act with due care in relation to the requirements of this Regulation.

2. Before making an EU fertilising product available on the market distributors shall verify that it is accompanied by the required documents, including the information referred to in Article 6(7) or Article 8(4) provided in the manner specified therein, in a language which can be easily understood by end-users in the Member State in which the EU fertilising product is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 6(5) and (6) and Article 8(3) respectively.

Where a distributor considers or has reason to believe that an EU fertilising product is not in conformity with this Regulation, the distributor shall not make the EU fertilising product available on the market until it has been brought into conformity. Furthermore, where the EU fertilising product presents a risk to human, animal or plant health, to safety or to the environment, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3. Distributors shall ensure that, while an EU fertilising product is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the requirements set out in Annex I or III.

4. Distributors who consider or have reason to believe that an EU fertilising product which they have made available on the market is not in conformity with this Regulation shall make sure that the corrective measures necessary to bring that EU fertilising product into conformity, to withdraw it or to recall it, as appropriate, are taken. Furthermore, where distributors consider or have reason to believe that an EU fertilising product which they have made available on the market presents a risk to human, animal or plant health, to safety or to the environment, they shall immediately inform the competent national authorities of the Member States in which they made the EU fertilising product available on the market to that effect, giving details, in particular, of any non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the EU fertilising product with this Regulation. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by EU fertilising products which they have made available on the market.

Additional obligations of economic operators for EU fertilising products presenting a risk - Formal non-compliance

Where the market surveillance authorities of one Member State have sufficient reason to believe that an EU fertilising product presents a risk to human, animal or plant health, to safety or to the environment, they shall carry out an evaluation in relation to the EU fertilising product concerned covering all relevant requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the EU fertilising product does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take all appropriate corrective action, within a reasonable period prescribed by the market surveillance authorities and commensurate with the nature of the risk, to bring the EU fertilising product into compliance with those requirements, to withdraw the EU fertilising product from the market or to recall it.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

The economic operator shall ensure that all appropriate corrective action is taken in respect of all the EU fertilising products concerned that the economic operator has made available on the market throughout the Union.

Where, having carried out an evaluation under Article 38(1), a Member State finds that although an EU fertilising product is in compliance with this Regulation it presents a risk to human, animal or plant health, to safety or to the environment, it shall without delay require

	<p>the relevant economic operator to take all appropriate measures, within a reasonable period prescribed by the market surveillance authority and commensurate with the nature of the risk, to ensure that the EU fertilising product concerned, when made available on the market, no longer presents that risk, to withdraw the EU fertilising product from the market or to recall it.</p> <p>The economic operator shall ensure that corrective action is taken in respect of all the EU fertilising products concerned that the economic operator has made available on the market throughout the Union.</p> <p>Without prejudice to Article 38, where a Member State makes one of the following findings with regard to an EU fertilising product, it shall require the relevant economic operator to put an end to the non-compliance concerned:</p> <p>(a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 18 of this Regulation;</p> <p>(b) the identification number of the notified body has been affixed in violation of Article 18 or has not been affixed, where required by Article 18;</p> <p>(c) the EU declaration of conformity has not been drawn up or has not been drawn up correctly;</p> <p>(d) the technical documentation is either not available or not complete;</p> <p>(e) the information referred to in Article 6(6) or Article 8(3) is absent, false or incomplete;</p> <p>(f) any other administrative requirement provided for in Article 6 or Article 8 is not fulfilled.</p>
<p>Cases in which obligations of manufacturers apply to importers and distributors</p>	<p>An importer or distributor shall be considered a manufacturer for the purposes of this Regulation, and shall be subject to the obligations of the manufacturer under Article 6, where that importer or distributor places an EU fertilising product on the market under his or her name or trademark or modifies an EU fertilising product already placed on the market in such a way that compliance with this Regulation may be affected.</p>
<p>Packaging and repackaging by importers and distributors</p>	<p>Where an importer or distributor packages or repackages an EU fertilising product and is not considered a manufacturer pursuant to Article 10, that importer or distributor shall:</p> <p>(a) ensure that the packaging bears his or her name, registered trade name or registered trade mark and postal address preceded by the words 'packaged by' or 'repackaged by'; and</p> <p>(b) keep a specimen of the original information referred to in Article 6(7) or Article 8(4) at the disposal of the market surveillance authorities for 5 years after having made the EU fertilising product available on the market.</p>
<p>Additional obligations of the manufacturer per Conformity Assessment Procedure</p>	<p>Module A1</p> <p>The manufacturer fulfils the obligations laid down under points 2, 3, 4, and 5, and ensures and declares on his or her sole responsibility that the EU fertilising products concerned satisfy the requirements of this Regulation that apply to them.</p> <p>The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the EU fertilising product's conformity with the relevant requirements and shall include an adequate analysis and assessment of the risk(s). The technical documentation consists of the elements mentioned below.</p> <p>The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured EU fertilising products with the technical documentation and with the requirements of this Regulation that apply to them.</p>

The thermal cycles and tests referred to in points 4.1 to 4.4 shall be carried out on a representative sample of the EU fertilising product every 3 months on behalf of the manufacturer.

The thermal cycles and tests shall be carried out under the responsibility of TÜV Austria.

Module B

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the EU fertilising product's conformity with the relevant requirements and shall include an adequate analysis and assessment of the risk(s). The technical documentation consists of the elements mentioned below.

TÜV Austria proceeds with the assessment of the adequacy of the technical design of the EU fertilising product, through examination of the technical documentation and supporting evidence, plus examination of samples, representative of the production envisaged.

The manufacturer lodges an application for EU-type examination with TÜV Austria. The application includes his or her name and address and, if the application is lodged by the authorized representative, his or her name and address as well, a written declaration that the same application has not been lodged with any other notified body, the technical documentation, the samples representative of the production envisaged and the supporting evidence for the adequacy of the technical design solution.

TÜV Austria may request further samples if needed for carrying out the test programme. The manufacturer agrees with TÜV Austria on a location where the examinations and tests will be carried out.

The supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his or her behalf and under his or her responsibility.

TÜV Austria shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the requirements of this Regulation and shall determine whether such changes require further investigation. If so, TÜV Austria shall inform the manufacturer accordingly.

The manufacturer shall inform TÜV Austria that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the EU fertilising product with the requirements of this Regulation or the conditions for validity of the EU-type examination certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

Module D1

The manufacturer fulfils the obligations laid down in points 2, 4, and 7, and ensures and declares on his or her sole responsibility that the EU fertilising products concerned satisfy the requirements of this Regulation that apply to them.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 5 years after the EU fertilising product has been placed on the market.

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the EU fertilising products concerned as specified in point 5, and shall be subject to surveillance as specified in point 6.

The manufacturer shall implement a quality system with the quality management elements set out in points 5.1.1 to 5.1.5 and documented as set out in point 5.1.6, which shall ensure

compliance of the EU fertilising products with the requirements of this Regulation that apply to them.

On the application process the manufacturer lodges an application for assessment of his or her quality system with TÜV Austria, for the EU fertilising products concerned. The application includes his or her name and address and, if the application is lodged by the authorized representative, his or her name and address as well, a written declaration that the same application has not been lodged with any other notified body, all relevant information for the EU fertilising product category envisaged, the documentation concerning the quality system and the technical documentation.

TÜV Austria assesses the quality system to determine whether it satisfies the requirements referred to in point 5.1. TÜV Austria presumes conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard. (5.3.2.) The audit includes an assessment visit to the manufacturer's premises. TÜV Austria's auditing team review the technical documentation in order to verify the manufacturer's ability to identify the relevant requirements of this Regulation and to carry out the necessary examinations with a view to ensuring compliance of the EU fertilising product with those requirements. (5.3.3.) The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

The manufacturer shall keep TÜV Austria that has approved the quality system informed of any intended change to the quality system. TÜV Austria shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 5.1 or whether reassessment is necessary. TÜV Austria shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision. (5.5.2.&3.)

In order to assure that the manufacturer duly fulfils the obligations arising out of the approved quality system, TÜV Austria conducts surveillance assessments at predefined intervals as mentioned below. In addition, TÜV Austria may pay unexpected visits to the manufacturer. During such visits TÜV Austria may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. TÜV Austria shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

The initial assessment is carried out in two stages. Stage 1 is not implemented at the manufacturer's premises. Stage 1 includes the review of the technical documentation of the product and the documentation concerning the quality system. The interval between the two stages shall not exceed six months. If this period elapses or any change occur to the technical documentation, stage 1 must be repeated. Stage 1 findings may lead to postponement or cancellation of Stage 2.

During Stage 1, the auditor evaluates the adequacy of the technical design of the EU fertilising product through examination of the technical and quality system documentation,. In case of positive outcome of the assessment, the stage 2 is conducted in order to assess whether the production process is in line with the technical documentation and the quality system requirements.

Based on the result of both stages, TÜV Austria shall decide on the certification of the products. Based on the decision date of the certification, annual surveillance assessments are conducted in the below timeframe:

Certification Decision	1 st Surveillance audit	2 nd Surveillance audit	3 rd Surveillance audit
17/7/2022	17/7/2023	17/7/2024	17/7/2025

The manufacturer shall, for assessment purposes, allow TÜV Austria 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 and the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned. (6.2.)

The manufacturer shall, for 5 years after the EU fertilising product has been placed on the market, keep at the disposal of the national authorities, the documentation referred to in point 5.1.6, the information on the changes referred to in points 5.5.1 and 5.5.2, as approved, and the decisions and reports of TÜV Austria (8.).

For all Modules (A1, B, D1), the manufacturer is obliged to

Upon request provide to TÜV Austria the sampling plan and relevant risk assessment for its products.

Where sampling is conducted, keep two (2) identical samples in case of any differences to the results of the approved laboratory (non-compliance).

Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the EU fertilising product's conformity with the relevant requirements and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and intended use of the EU fertilising product. The technical documentation shall contain, where applicable, at least the following elements:

- (a) a general description of the EU fertilising product, the PFC corresponding to the claimed function of the EU fertilising product and description of the intended use,
- (b) a list of component materials used, the CMCs as referred to in Annex II to which they belong and information about their origin or manufacturing process,
- (c) the EU declarations of conformity for the component EU fertilising products of the fertilising product blend,
- (d) drawings, schemes, descriptions and explanations necessary for the understanding of the manufacturing process of the EU fertilising product. **Additionally for Module D1, and, in relation to materials belonging to CMCs 3, 5, 12, 13 or 14 as defined in Annex II, a written description and a diagram of the production process, where each treatment, storage vessel and area is clearly identified,**
- (e) a specimen of the label or the leaflet, or both, referred to in Article 6(7) containing the information required in accordance with Annex III,
- (f) The names and addresses of the sites, and of the operators of the sites, at which the product and its principal components were manufactured, **(Applicable only for Module A1)**
- (g) or (f) a list of the harmonised standards referred to in Article 13, common specifications referred to in Article 14 and/or other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,

(h) or (g) results of calculations made, including the calculations to demonstrate conformity with point 5 of Part II of Annex I, examinations carried out, etc.,

(ga) Hazardous waste calculations for EU fertilising products containing or consisting of CMC 13; the testing referred to in point 6 in CMC 13 in Part II of Annex II shall be carried out at least every year, or sooner than scheduled in case of any significant change that may affect the safety or quality of the EU fertilising product (for example processing of input material batches of different composition, modification of process conditions). For a representative input material batch that is processed at the plant, the hazardous property identified (in accordance with point 5.1.3.1) and the total mass shall be measured on the different input materials (1, ..., n) and on the output material that will be incorporated in the EU fertilising product. The incorporation rate of the hazardous property into the output material shall then be calculated as follows:

$$\text{incorporation rate (\%)} = \frac{HPC_{\text{output material}} \times M_{\text{output material}}}{\sum_{i=1}^n (HPC_{\text{input material},i} \times M_{\text{input material},i})}$$

Where:

HPC = the concentration of the hazardous property (mg/kg),

M = the total mass (kg), and

i (1-n) = the different input materials used in the production process.

The removal of the hazardous property during the production process shall be such that the incorporation rate multiplied by the concentration of the hazardous property of each individual input material is below the limit values laid down in Annex III to Directive 2008/98/EC for that hazardous property (**Applicable only for Module D1**)

(i) or (h) test reports. **Additionally for Module A1, including the reports from product checks for oil retention and detonation resistance**

(i) where the EU fertilising product contains or consists of derived products within the meaning of Regulation (EC) No 1069/2009, the commercial documents or health certificates required pursuant to that Regulation, and evidence that the derived products have reached the end point in the manufacturing chain within the meaning of that Regulation (**Applicable only for Modules B and D1**)

(j) where the EU fertilising product contains or consists of by-products within the meaning of Directive 2008/98/EC, technical and administrative evidence that the by-products comply with the criteria established by delegated act referred to in Article 42(7) of this Regulation, and with the national measures transposing Article 5(1) of Directive 2008/98/EC and, where applicable, implementing acts referred to in Article 5(2) or national measures adopted under Article 5(3) of that Directive, and

(k) where the EU fertilising product contains total chromium (Cr) above 200 mg/kg dry matter, information about the maximum quantity and exact source of total chromium (Cr) (**Applicable only for Modules B and D1**)

The Technical Documentation is reviewed by TUV Austria only for Module B and D1.

Testing

Module A1

The thermal cycles and tests referred to in points 4.1 to 4.4 shall be carried out on a representative sample of the EU fertilising product every 3 months on behalf of the manufacturer, in order to verify conformity with:

(a) the oil retention requirement referred to in point 4 under PFC 1(C)(I)(a)(i-ii)(A) in Annex I, and

(b) the detonation resistance requirement referred to in point 5 under PFC 1(C)(I)(a)(i-ii)(A) in Annex I.

The thermal cycles and tests shall be carried out under the responsibility of TÜV Austria.

Module B

TÜV Austria

(a) carries out appropriate examinations and tests on the sample(s), or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;

(d) carries out appropriate examinations and tests on the sample(s), or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, or where relevant harmonised standards or common specifications do not exist, the solutions adopted by the manufacturer meet the corresponding requirements of this Regulation;

(e) agrees with the manufacturer on a location where the examinations and tests will be carried out.

Module D1

For materials belonging to CMCs 3, 5, 12, 13 and 14, as defined in Annex II, the TÜV Austria shall take and analyse output material samples during each audit, and those audits shall be carried out with the following frequency:

(a) during the TÜV Austria's first year of surveillance of the plant in question: 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); and

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

During unexpected visits to the manufacturer, TÜV Austria may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. TÜV Austria shall provide the manufacturer with a test report, if tests have been carried out during visit.

Non-Conformities – Corrective Actions / Suspension – Withdrawal

Where TÜV Austria finds that the requirements set out in Annex I, II or III, or corresponding harmonised standards, common specifications referred to in Article 14 or other technical specifications, have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.

Where, in the course of the monitoring of conformity following the issue of a certificate or an approval decision, TÜV Austria finds that an EU fertilising product no longer complies, it shall require the manufacturer to take appropriate corrective measures and *it* shall suspend or withdraw the certificate or the approval decision, if necessary.

Where corrective measures are not taken or do not have the required effect, TÜV Austria shall restrict, suspend or withdraw any certificates or approval decisions, as appropriate.

Module A1

Initial assessment of testing results: No certificate is issued until samples meet all applicable requirements.

Subsequent assessments of testing results: If non-conformities are raised during the assessment of the testing results, TÜV Austria shall request for a root cause analysis and will evaluate the sampling plan and risk assessment of the manufacturer in order to decide whether the deviation is acceptable. Depending on the result of the assessment, TÜV Austria decides whether to continue certification or suspend certification until adequate corrective actions are implemented or withdraw certification.

Module B

Initial assessment of technical documentation and laboratory results: No certificate is issued until nonconformities are treated and samples meet all applicable requirements.

	<p>After the <u>initial assessment</u> and in the event that TÜV Austria finds that an EU fertilising product no longer complies with the requirements of the Regulation, asks the manufacturer to provide root cause analysis, relevant corrective actions and correction evidence to eliminate the NC detected. Depending on the result of the assessment, TÜV Austria decides whether to continue certification or suspend certification until further corrective actions are implemented or withdraw certification.</p> <p>Module D1</p> <p><u>Initial assessment of technical and quality documentation:</u> No certificate is issued until nonconformities are treated. Maximum timeframe for the completion of relevant corrective actions and corrections, 2 months from the last day of Stage 2 audit.</p> <p><u>Surveillance assessments:</u> nonconformities shall be treated 2 months after the last day of the onsite assessment or no later than the due date of the completion of stage 2 of the Certification Assessment.</p> <p><u>Recertification Assessment:</u> nonconformities shall be treated 2 months after the last day of the onsite assessment or no later than the due date of the completion of stage 2 of the Certification Assessment.</p> <p>In case these timeframes are not respected, the certificate is suspended for 6 months and after that period, the certificate is withdrawn.</p>
<p>Appeal against decisions</p>	<p>When TÜV Austria is informed by the market surveillance authorities, in accordance with paragraph 1 of Article 38, that an EU fertilising product for which it has performed a conformity assessment procedure, poses a risk to human, animal or plant health, to safety or to the environment, it shall require the relevant economic operator to take appropriate corrective measures, and if necessary it shall restrict, suspend or revoke the certificate or approval decision which it has issued.</p> <p>TÜV Austria's decisions relating to the restriction, suspension or withdrawal of a certificate or approval decision shall be adequately reasoned, and shall be notified to the interested parties within a period of fifteen (15) days from their issue. Pursuant to Article 33 those who have a legal interest are entitled to appeal against such a decision within thirty (30) days from its notification and submit in writing their views to TÜV Austria within thirty (30) days from the submission of their appeal. If TÜV Austria rejects the appeal, it shall immediately notifies the relevant decision to the applicant.</p>
<p>CE Marking and EU Declaration of Conformity / EU-type examination certificate</p>	<p>By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the EU fertilising product with the requirements laid down in this Regulation.</p> <p>Module A1 and Module D1</p> <p>The manufacturer shall affix the CE marking and, under the responsibility of TÜV Austria, the latter's identification number to each individual packaging of the EU fertilising product that satisfies the applicable requirements of this Regulation or, where it is supplied without packaging, in a document accompanying the EU fertilising product.</p> <p>The manufacturer shall draw up a written EU declaration of conformity for an EU fertilising product type and keep it together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market. The EU declaration of conformity shall identify the EU fertilising product type for which it has been drawn up.</p> <p>A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.</p> <p>Module B</p> <p>Where the type meets the requirements of this Regulation that apply to the EU fertilising product concerned, TÜV Austria shall issue an EU-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the</p>

conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured EU fertilising products with the examined type to be evaluated.

Where the type does not satisfy the requirements of this Regulation, TÜV Austria shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 5 years after the EU fertilising product has been placed on the market.

Information requirements

TÜV Austria shall inform the Directorate of Environment, Land planning and Climate change of the Ministry of Rural Development and Food of Hellenic Republic of the following:

- (a) any refusal, restriction, suspension or withdrawal of a certificate or approval decision;
- (b) any circumstances, affecting the scope of or conditions for notification;
- (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
- (d) on request, conformity assessment activities performed within the scope of its notification and any other activity performed, including cross-border activities and subcontracting.

TÜV Austria shall provide the other bodies notified under this Regulation carrying out similar conformity assessment activities covering the same EU fertilising products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

TÜV Austria, annually and by the end February each year, submits a list to the Directorate of Environment, Land planning and Climate change of the Ministry of Rural Development and Food of Hellenic Republic and to the Hellenic Accreditation System (ESYD), with the total of the companies and the products or types of EU fertilising products which it certified, audited or inspected during the previous calendar year and which are available in the Greek market.

Module A1

TÜV Austria shall, without undue delay, inform the Directorate of Environment, Land planning and Climate change of the Ministry of Rural Development and Food of Hellenic Republic and other bodies notified under this Regulation carrying out similar conformity assessment activities covering the same EU fertilising products of the following:

- (a) any case where the manufacturer has not complied with the 3-month period for performing the tests required under point 4;
- (b) any test results which demonstrate non-conformity with the detonation resistance requirement referred to in point 5 under PFC 1(C)(I)(a)(i-ii)(A) in Annex I.

Module B

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by TÜV Austria.

Module B and Module D1

TÜV Austria shall inform the Directorate of Environment, Land planning and Climate change of the Ministry of Rural Development and Food of Hellenic Republic of the EU-type

examination certificates and/or any additions thereto / quality system approvals which it has issued or withdrawn, and shall, periodically or upon request, make available to the aforementioned authority the list of the EU-type examination certificates and/or any additions thereto / quality system approvals which it has refused, suspended or otherwise restricted.

TÜV Austria shall inform the other notified bodies of the EU-type examination certificates and/or any additions thereto / quality system approvals which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the EU-type examination certificates / quality system approvals which it has issued.

Certificate**Module A1**

The Certificate issued by TÜV Austria is valid for 3 months.

Module B

The certificate issued by TÜV Austria is valid for 5 years under the following conditions

1. no changes occur on the technical documentation of the product and/or
2. no changes occur on the technology development used and/or
3. no changes occur on the requirements of the Regulation (EU) 2019/1009

Module D1

The certificate issued by TÜV Austria is valid for 3 years under the condition that a successful surveillance onsite audit is conducted every year and for materials belonging to CMCs 3, 5, 12, 13 and 14, successful testing as described above.