Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (Text with EEA relevance)

ANNEX IV

Conformity assessment procedures

PART I

APPLICABILITY OF CONFORMITY ASSESSMENT PROCEDURES

This Part sets out the applicability of conformity assessment procedure modules, as specified in Part II of this Annex, to EU fertilising products depending on their CMCs as specified in Annex II, and their PFCs as specified in Annex I.

1. APPLICABILITY OF INTERNAL PRODUCTION CONTROL (MODULE A)

1.1. Module A may be used for an EU fertilising product composed solely of one or more of the following component materials:

(a) virgin material substances or mixtures as specified in CMC 1 in Part II of Annex II, except a nitrification inhibitor, a denitrification inhibitor or a urease inhibitor,

(b) fresh crop digestates as specified in CMC 4 in Part II of Annex II,

(c) food industry by-products as specified in CMC 6 in Part II of Annex II,

(d) micro-organisms as specified in CMC 7 in Part II of Annex II,

(e) nutrient polymers as specified in CMC 8 in Part II of Annex II,

(f) by-products within the meaning of Directive 2008/98/EC as specified in CMC 11 in Part II of Annex II.

1.2. Module A may also be used for a fertilising product blend as specified in PFC 7.

1.3. By derogation from points 1.1 and 1.2, Module A must not be used for:

(a) a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content, as specified in PFC 1(C)(I)(a)(i-ii)(A), or a fertilising product blend as specified in PFC 7 containing 28 % or more by mass of nitrogen (N) from an EU fertilising product belonging to PFC 1(C)(I)(a)(i-ii)(A),

(b) an inhibitor as specified in PFC 5, or

(c) a plant biostimulant as specified in PFC 6.

2. APPLICABILITY OF INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT TESTING (MODULE A1)

Module A1 shall be used for a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content, as specified in PFC 1(C)(I)(a)(i-ii)(A), and for a fertilising product blend as specified in PFC 7 containing 28 % or more by mass of nitrogen (N) from an EU fertilising product belonging to PFC 1(C)(I)(a)(i-ii)(A).

3. APPLICABILITY OF EU-TYPE EXAMINATION (MODULE B) FOLLOWED BY CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL (MODULE C)

3.1. Module B followed by Module C may be used for an EU fertilising product composed solely of one or more of the following component materials:

(a) nitrification inhibitor, denitrification inhibitor or urease inhibitor as specified in CMC 1 in Part II of Annex II,

(b) plants, plant parts or plant extracts as specified in CMC 2 in Part II of Annex II,

(c) polymers other than nutrient polymers as specified in CMC 9 in Part II of Annex II,

(d) derived products within the meaning of Regulation (EC) No 1069/2009 as specified in CMC 10 in Part II of Annex II,

(e) CMCs referred to in point 1.1 of this Part.

3.2. Module B followed by Module C may also be used for:

(a) an inhibitor as specified in PFC 5,

(b) a plant biostimulant as specified in PFC 6, and

(c) a fertilising product blend as specified in PFC 7.

3.3. By derogation from points 3.1 and 3.2, Module B followed by Module C must not be used for a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content, as specified in PFC 1(C)(I)(a)(i-ii)(A), or a fertilising product blend as specified in PFC 7 containing 28 % or more by mass of nitrogen (N) from an EU fertilising product belonging to PFC 1(C)(I)(a)(i-ii)(A).

4. APPLICABILITY OF QUALITY ASSURANCE OF THE PRODUCTION PROCESS (MODULE D1)

4.1. Module D1 may be used for any EU fertilising product.

4.2. By derogation from point 4.1, Module D1 must not be used for a straight or compound solid inorganic macronutrient ammonium nitrate fertiliser of high nitrogen content, as specified in PFC 1(C)(I)(a)(i-ii)(A), or a fertilising product blend as specified in PFC 7 containing 28 % or more by mass of nitrogen (N) from an EU fertilising product belonging to PFC 1(C)(I)(a)(i-ii)(A).

PART II

DESCRIPTION OF CONFORMITY ASSESSMENT PROCEDURES

MODULE A – INTERNAL PRODUCTION CONTROL

1. Description of the module

Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down under points 2, 3 and 4, 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.

2. Technical documentation

2.1. 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).

2.2. 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,

(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) 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,

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

(h) test reports,

(i) 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,

(j) where the EU fertilising product contains total chromium (Cr) above 200 mg/kg, information about the maximum quantity and exact source of total chromium (Cr).

3. Manufacturing

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 referred to under point 2 and with the requirements of this Regulation that apply to them.

4. CE marking and EU declaration of conformity

4.1. The manufacturer shall affix the CE marking 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.

4.2. The manufacturer shall draw up a written EU declaration of conformity for an EU fertilising product or 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 or type for which it has been drawn up.

4.3. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representative

The manufacturer's obligations set out under point 4 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.

MODULE A1 – INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT TESTING

1. Description of the module

Internal production control plus supervised product testing is the conformity assessment procedure whereby 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.

2. Technical documentation

2.1. 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).

2.2. 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,

(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,

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

(i) test reports, including the reports from product checks for oil retention and detonation resistance, referred to in point 4 and

(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 acts 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.

3. Manufacturing

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 referred to in point 2 and with the requirements of this Regulation that apply to them.

4. Product checks for oil retention and detonation resistance

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 a notified body chosen by the manufacturer.

4.1. Thermal cycles prior to a test for compliance with the oil retention requirement referred to in point 4 under PFC 1(C)(I)(a)(i-ii)(A) in Annex I

4.1.1. Principle and definition

In a closed suitable laboratory flask, heat the sample from ambient temperature to 50 °C and maintain at this temperature for a period of two hours (phase at 50 °C). Thereupon cool the sample until a temperature of 25 °C is achieved and maintain at that temperature for two hours (phase at 25 °C). The combination of the successive phases at 50 °C and 25 °C forms one thermal cycle. After being subjected to two thermal cycles, the test sample is held at a temperature of 20 (± 3) °C for the determination of the oil retention value.

4.1.2. Apparatus

Normal laboratory apparatus, in particular:

(a) water baths or ovens thermostated at 25 ± 1 °C and 50 ± 1 °C respectively,

(b) suitable laboratory flasks with an individual capacity of 150 ml.

4.1.3. Procedure

4.1.3.1. Put each test sample of 70 ± 5 g into a suitable laboratory flask which is then closed.

4.1.3.2. After attaining the temperature of 50 °C and maintain that temperature for two hours, change the temperature of the flask to the 25 °C bath or oven and proceed as described in 4.1.1.

4.1.3.3. If using a water bath maintain the water of each bath at constant temperature and keep in motion by rapid stirring. Ensure the water level comes above the level of the sample. Protect the stopper from condensation by a foam rubber cap.

4.2. Oil retention test referred to in point 4 under PFC 1(C)(I)(a)(i-ii)(A) in Annex I

4.2.1. Description

The oil retention of an EU fertilising product shall be the quantity of oil retained by the EU fertilising product determined under the operating conditions specified and expressed as a % by mass.

The test shall be carried out on a representative sample of the EU fertilising product. Before being tested, the whole mass of the sample shall be thermally cycled two times in accordance with point 4.1.

The method is applicable to both prilled and granular fertilisers which do not contain oil soluble materials.

4.2.2. Principle

Total immersion of the test sample in gas oil for a specified period, followed by the draining away of surplus oil under specified conditions. Measurement of the increase in mass of the test portion.

4.2.3. Reagents

Gas oil with the following characteristics:

(a) viscosity max.: 5 mPas at 40 °C;

(b) density: 0,8 g/ml to 0,85 g/ml at 20 °C;

(c) sulphur content: ≤ 1,0 % (m/m);

(d) ash: ≤ 0,1 % (m/m).

4.2.4. Apparatus

Ordinary laboratory apparatus, and:

(a) balance, capable of weighing to the nearest 0,01 g;

(b) beakers, of capacity 500 ml;

(c) funnel, of plastic materials, preferably with a cylindrical wall at the upper end, diameter approximately 200 mm;

(d) test sieve, aperture 0,5 mm, fitting into the funnel;

Note: The size of the funnel and sieve is such as to ensure that only a few granules lie one above another and the oil is able to drain easily.

(e) filter paper, rapid filtering grade, creped, soft, mass 150 g/m^2;

(f) absorbent tissue (laboratory grade).

4.2.5. Procedure

4.2.5.1. Two individual determinations are carried out in quick succession on separate portions of the same test sample.

4.2.5.2. Remove particles smaller than 0,5 mm using the test sieve. Weigh to the nearest 0,01 g approximately 50 g of the sample into the beaker. Add sufficient gas oil to cover the prills or granules completely and stir carefully to ensure that the surfaces of all the prills or granules are fully wetted. Cover the beaker with a watch glass and leave to stand for one hour at 25 (± 2) °C.

4.2.5.3. Filter the entire contents of the beaker through the funnel containing the test sieve. Allow the portion retained by the sieve to remain there for one hour so that most of the excess oil can drain away.

4.2.5.4. Lay two sheets of filter paper (about 500 mm x 500 mm) on top of each other on a smooth surface; fold the four edges of both filter papers upwards to a width of about 40 mm to prevent the prills or granules from rolling away. Place two layers of absorbent tissue in the centre of the filter papers. Pour the entire contents of the sieve over the absorbent tissues and spread the prills or granules evenly with a soft, flat brush. After two minutes lift one side of the tissues to transfer the prills or granules to the filter papers beneath and spread them evenly over these with the brush. Lay another sheet of filter paper, similarly with its edges turned upward, on the sample and roll the prills or granules between the filter papers with circular movements while exerting a little pressure. Pause after every eight circular movements to lift the opposite corners of the filter papers and return to the centre the prills or granules that have rolled to the periphery. Keep to the following procedure: make four complete circular movements, first clockwise and then anticlockwise. Then roll the prills or granules back to the centre as described above. This procedure is to be carried out three times (24 circular movements, corners lifted twice). Carefully insert a new sheet of filter paper between the bottom sheet and the one above it and allow the prills or granules to roll onto the new sheet by lifting the edges of the upper sheet. Cover the prills or granules with a new sheet of filter paper and repeat the same procedure as described above. Immediately after rolling, pour the prills or granules into a tared dish and reweigh to the nearest 0,01 g to determine the mass of the quantity of gas oil retained.

4.2.5.5. Repeating the rolling procedure and reweighing

If the quantity of gas oil retained in the portion is found to be greater than 2,00 g, place the portion on a fresh set of filter papers and repeat the rolling procedure, lifting the corners in accordance with point 4.2.5.4 (two times eight circular movements, lifting once). Then reweigh the portion.

4.2.5.6. Two oil retention tests per sample are to be carried out.

4.2.6. Test report

4.2.6.1. Expression of the results

4.2.6.1.1. Method of calculation and formula

The oil retention, from each determination (point 4.2.5.1) expressed as a % by mass of the sieved test portion, is given by the equation:

$$\text{Oil retention} = \frac{m_2 - m_1}{m_1} \times 100$$

where:

m_1 is the mass, in grams, of the sieved test portion (point 4.2.5.2),

m_2 is the mass, in grams, of the test portion according to points 4.2.5.4 and 4.2.5.5 respectively as the result of the last weighing.

4.2.6.1.2. Take as the result the arithmetic mean of the two individual determinations.

4.2.6.2. The test report shall form part of the technical documentation.

4.3. Thermal cycles prior to the detonation resistance test referred to in point 5 under PFC 1(C)(I)(a)(i-ii)(A) in Annex I

4.3.1. Principle and definition

In a tight box heat the sample from ambient temperature to 50 °C and maintain at this temperature for a period of one hour (phase at 50 °C). Thereupon cool the sample until a temperature of 25 °C is achieved and maintain at that temperature for one hour (phase at 25 °C). The combination of the successive phases at 50 °C and 25 °C forms one thermal cycle. After being subjected to the required number of thermal cycles, the test sample is held at a temperature of 20 ± 3 °C pending the execution of the detonation resistance test.

4.3.2. Apparatus
Method 1

(a) A water bath, thermostated in a temperature range of 20 to 51 °C with a minimum heating and cooling rate of 10 °C/h, or two water baths, one thermostated at a temperature of 20 °C, the other at 51 °C. The water in the bath(s) is continuously stirred; the volume of the bath shall be large enough to guarantee ample circulation of the water.

(b) A stainless steel box, watertight all around and provided with a temperature recording device in the centre. The outside width of the box is 45 ± 2 mm and the wall thickness is 1,5 mm (see Figure 1 as an example). The height and length of the box can be chosen to suit the dimensions of the water bath, e.g. length 600 mm, height 400 mm.

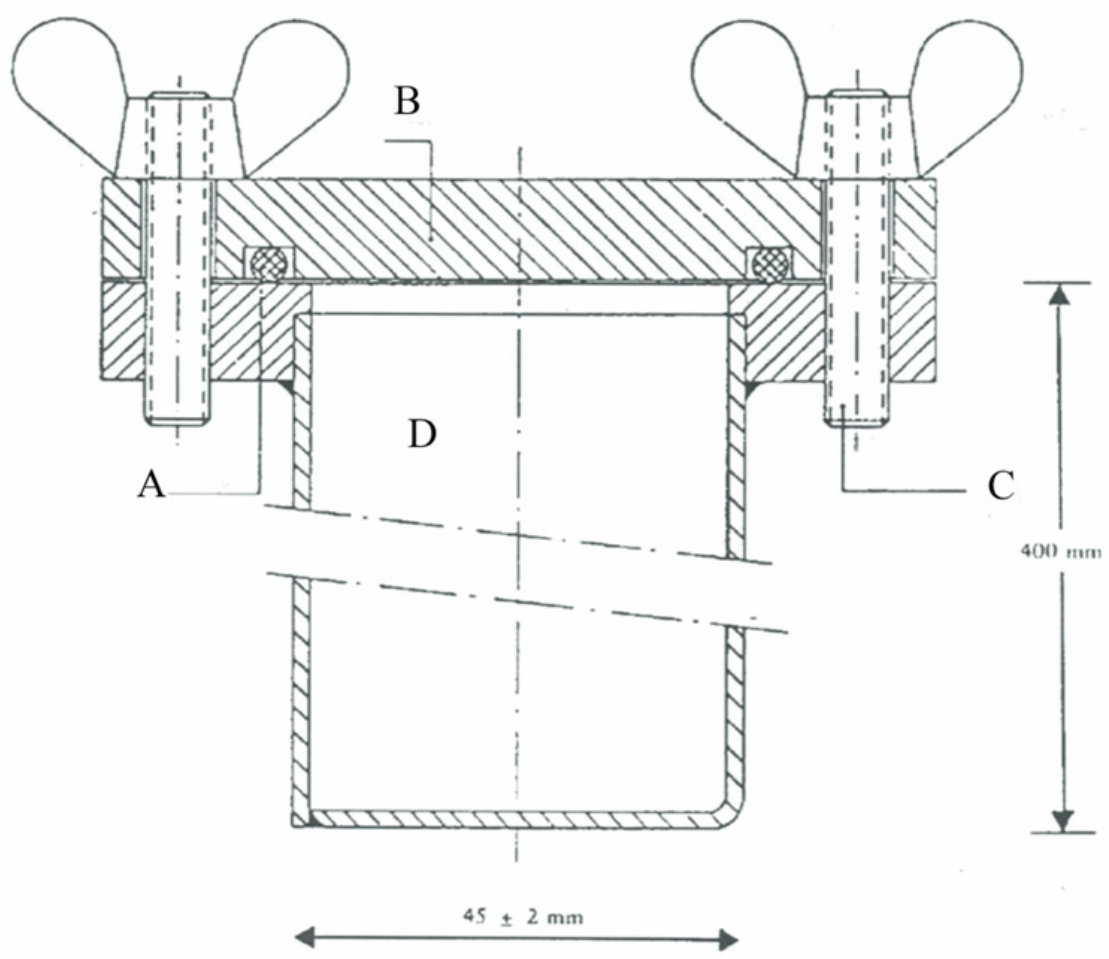
Method 2

(a) Suitable oven, thermostated in a temperature range of 20 °C to 51 °C with a minimum heating and cooling rate of 10 °C/h.

(b) Suitable airtight plastics boxes or bags provided with a suitable temperature recording device in the centre of the sample or a stainless steel box as described in point (b) of method 1 of point 4.3.2. Once filled, the outside thickness of the box or bag shall be maximum 45 mm.

4.3.3. Procedure

Place a quantity of fertilisers sufficient for the detonation resistance test into the boxes or bags and close them. Place the stainless steel boxes in the water bath (method 1) or the boxes or bags in the oven (method 2). Heat the water or oven to 51 °C and measure the temperature in the centre of the fertiliser. One hour after the temperature at the centre has reached 50 °C start cooling. One hour after the temperature at the centre has reached 25 °C start heating for the second cycle. In the case of two water baths or ovens, transfer the boxes or bags to the other bath or oven after each heating/cooling period.
Figure 1



A : O-ring
B : Cover
C : Bolt
D : Box

4.4. Detonation resistance test referred to in point 5 under PFC 1(C)(I)(a)(i-ii)(A) in Annex I

4.4.1. Description

4.4.1.1. The test shall be carried out on a representative sample of the EU fertilising product. Before being tested for resistance to detonation, the whole mass of the sample is to be thermally cycled five times in accordance with point 4.3.

4.4.1.2. The EU fertilising product shall be subjected to the detonation resistance test in a horizontal steel tube under the following conditions (the details of the materials are in point 4.4.3):

(a) seamless steel tube:

(i) Tube length: 1 000 mm at least,

(ii) Nominal external diameter: 114 mm at least,

(iii) Nominal wall thickness: 5 mm at least,

(b) booster: the type and mass of the booster chosen shall be such as to maximise the detonation pressure applied to the sample in order to determine its susceptibility to the transmission of detonation,

(c) temperature of the sample: 15 °C to 25 °C,

(d) witness lead cylinders for detecting detonation: 50 mm diameter and 100 mm height,

(e) placed at 150 mm intervals and supporting the tube horizontally.

NOTE: The test is to be carried out twice. The test is deemed conclusive if in both tests one or more of the supporting lead cylinders is crushed by less than 5 %.

4.4.2. Principle

The test sample is confined in a steel tube and subjected to detonation shock from an explosive booster charge. Propagation of the detonation is determined from the degree of crushing of lead cylinders on which the tube rests horizontally during the test.

4.4.3. Materials

(a) Plastic explosive containing 83 % to 86 % penthrite

— density: 1 500 kg/m^3 to 1 600 kg/m^3
— detonation velocity: 7 300 m/s to 7 700 m/s
— mass: (500 ± 1) g;

or any other plastic explosive with similar detonation characteristics.

(b) Seven lengths of flexible detonating cord with non-metallic sleeve

— filling mass: 11 g/m to 13 g/m
— length of each cord: (400 ± 2) mm.

(c) Compressed pellet of secondary explosive, recessed to receive detonator

— explosive: hexogen/wax 95/5 or similar secondary explosive, with or without added graphite
— density: 1 500 kg/m^3 to 1 600 kg/m^3
— diameter: 19 mm to 21 mm
— height: 19 mm to 23 mm
— mass of the compressed pellet: maximum 10 g
— central recess to receive detonator: maximal diameter 7,0 to 7,3 mm, depth about 12 mm. In case of detonators with large diameters, the diameter of the recess shall be slightly larger (e.g. 0,5 mm) than the diameter of the detonator.

(d) Seamless steel tube as specified in ISO 65 – 1981 – Heavy Series, with nominal dimensions DN 100 (4")

— outside diameter: 113,1 mm to 115,0 mm
— wall thickness: 5,0 mm to 6,5 mm
— length: 1 005 ± 2 mm.

(e) Bottom plate

— material: steel of good weldable quality
— dimensions: 160 mm × 160 mm
— thickness: 5 mm to 6 mm.

(f) Six lead cylinders
- diameter: 50 ± 1 mm
- height: 100 mm to 101 mm
- materials: soft lead, at least 99,5 % purity.

(g) Steel block
- length: at least 1 000 mm
- width: at least 150 mm
- height: at least 150 mm (alternatively a stack of several beams can be used to achieve this height)
- Mass: at least 300 kg if there is no firm base for the steel block.

(h) Plastic or cardboard cylinder for booster charge
- wall thickness: 1,5 mm to 2,5 mm
- diameter: 92 mm to 96 mm
- height: 64 mm to 67 mm.

(i) Detonator (electric or non-electric) with initiation force 8 to 10

(j) Wooden or plastic disc
- diameter: 92 mm to 96 mm. Diameter to be matched to the internal diameter of the plastic or cardboard cylinder (point (h))
- thickness: 20 mm.

(k) Wooden or plastic rod of same dimensions as detonator (point (i))

(l) Small split pins (maximum length 20 mm)

(m) Split pins (length about 20 mm)

4.4.4. Procedure

4.4.4.1. Preparation of booster charge for insertion into steel tube

Depending on the availability of equipment, the explosive can be initiated in the booster charge either
- by seven-point simultaneous initiation as referred to in point 4.4.4.1.1, or
- by central initiation by a compressed pellet as referred to in point 4.4.4.1.2.

4.4.4.1.1. Seven-point simultaneous initiation

The booster charge prepared for use is shown in Figure 2.

4.4.4.1.1.1. Drill holes in the wooden or plastic disc (point (j) under point 4.4.3) parallel to the axis of the disc through the centre and through six points symmetrically distributed around a concentric circle 55 mm in diameter. The diameter of the holes shall be 6 mm to 7 mm (see Section A-B in Figure 2), depending on the diameter of the detonating cord used (point (b) under point 4.4.3).

4.4.4.1.1.2. Cut seven lengths of flexible detonating cord (point (b) under point 4.4.3) each 400 mm long, avoiding any loss of explosive at each end by making a clean cut and immediately sealing the end with adhesive. Push each of the seven lengths through each of the seven holes in the wooden or plastic disc (point (j) under point 4.4.3) until their ends project a few centimetres on the other side of the disc. Then insert a small split pin (point (l) under point 4.4.3) transversally into the textile sleeve of each length of cord

5 mm to 6 mm from the end and apply adhesive around the outside of the lengths of cord in a band 2 cm wide adjacent to the pin. Finally, pull the long piece of each cord to bring the pin into contact with the wooden or plastic disc.

4.4.4.1.1.3. Shape the plastic explosive (point (a) under point 4.4.3) to form a cylinder 92 mm to 96 mm in diameter, depending on the diameter of the cylinder (point (h) under point 4.4.3). Stand this cylinder upright on a level surface and insert the shaped explosive. Then insert the wooden or plastic disc[(1)] carrying the seven lengths of detonating cord into the top of the cylinder and press it down onto the explosive. Adjust the height of the cylinder (64 mm to 67 mm) so that its top edge does not extend beyond the level of the wood or plastic. Finally, fix the cylinder to the wooden or plastic disc for instance with staples or small nails, around its entire circumference.

4.4.4.1.1.4. Group the free ends of the seven lengths of detonating cord around the circumference of the wooden or plastic rod (point (k) under point 4.4.3) so that their ends are all level in a plane perpendicular to the rod. Secure them in a bundle around the rod by means of adhesive tape[(2)].

4.4.4.1.2. Central initiation by a compressed pellet

The booster charge prepared for use is shown in Figure 3.

4.4.4.1.2.1. Preparing a compressed pellet

Taking the necessary safety precautions, place maximum 10 g of a secondary explosive (point (c) under point 4.4.3) in a mould with an inside diameter of 19 mm to 21 mm and compress to the correct shape and density (the ratio of diameter: height should be roughly 1:1). In the centre of the bottom of the mould there is a peg, 12 mm in height and 7,0 mm to 7,3 mm in diameter (depending on the diameter of the detonator used), which forms a cylindrical recess in the compressed cartridge for subsequent insertion of the detonator.

4.4.4.1.2.2. Preparing the booster charge

Place the explosive (point (a) under point 4.4.3) into the cylinder (point (h) under point 4.4.3) standing upright on a level surface, then press it down with a wooden or plastic die to give the explosive a cylindrical shape with a central recess. Insert the compressed pellet into this recess. Cover the cylindrically shaped explosive containing the compressed pellet with a wooden or plastic disc (point (j) under point 4.4.3) having a central hole 7,0 mm to 7,3 mm in diameter for insertion of a detonator. Fix the wooden or plastic disc and the cylinder together with a cross of adhesive tape. Ensure that the hole drilled in the disc and the recess in the compressed pellet are coaxial by inserting the wooden or plastic rod (point (k) under point 4.4.3).

4.4.4.2. Preparing steel tubes for the detonation tests

At one end of the steel tube (point (d) under point 4.4.3), drill two diametrically opposed holes 4 mm in diameter perpendicularly through the side wall at a distance of 4 mm from the edge. Butt weld the bottom plate (point (e) under point 4.4.3) to the opposite end of the tube, completely filling the right angle between the bottom plate and the wall of the tube with weld metal around the entire circumference of the tube.

4.4.4.3. Filling and charging the steel tube

See Figures 2 and 3.

4.4.4.3.1. The test sample, the steel tube and the booster charge shall be conditioned to temperatures of (20 ± 5) °C. About 20 kg of the test sample should be available for two detonation resistance tests.

4.4.4.3.2.1. Place the tube upright with its square bottom plate resting on a firm, flat surface, preferably concrete. Fill the tube to about one-third of its height with the test sample and drop it 10 cm vertically onto the flat surface five times to compact the prills or granules as densely as possible in the tube. To accelerate compaction, vibrate the tube by striking the side wall with a 750 g to 1 000 g hammer between drops for a total of 10 times.

4.4.4.3.2.2. Repeat this charging method with another portion of the test sample. Finally, a further addition shall be made such that, after compaction by raising and dropping the tube 10 times and a total of 20 intermittent hammer blows, the charge fills the tube to a distance of 70 mm from its orifice.

4.4.4.3.2.3. The filling height of the sample shall be adjusted in the steel tube so that the booster charge (referred to in point 4.4.4.1.1 or 4.4.4.1.2) to be inserted later will be in close contact with the sample over its entire surface.

4.4.4.3.3. Insert the booster charge into the tube so that it is in contact with the sample; the top surface of the wooden or plastic disc shall be 6 mm below the end of the tube. Ensure essential close contact between explosive and test sample by taking out the booster charge and adding or removing small quantities of sample. As shown in Figures 2 and 3, split pins should be inserted through the holes near the open end of the tube and their legs opened flat against the tube.

4.4.4.4. Positioning of the steel tube and lead cylinders (see Figure 4)

4.4.4.4.1. Number the bases of the lead cylinders (point (f) under point 4.4.3) 1, 2, 3, 4, 5 and 6. Make six marks 150 mm apart along a line on a steel block (point 4.4.3(g)) lying on a horizontal base, with each mark at least 75 mm from any edge of the block. Place a lead cylinder upright on each of these marks, with the base of each cylinder centred on its mark (see Figure 4).

4.4.4.4.2. Lay the steel tube prepared according to point 4.4.4.3 horizontally on the lead cylinders so that the axis of the tube is parallel to the centre line of the lead cylinders and the welded end of the tube extends 50 mm beyond lead cylinder No 6. To prevent the tube from rolling, insert small wooden or plastic wedges between the tops of the lead cylinders and the tube wall (one on each side) or place a cross of wood between the tube and the steel block or stack of beams. (see Figure 4).

Note: Make sure that the tube is in contact with all six lead cylinders; a slight curvature of the tube surface can be compensated for by rotating the tube about its longitudinal axis; if any of the lead cylinders is too tall, tap the cylinder in question carefully with a hammer until it is the required height.

4.4.4.5. Preparation for detonation

4.4.4.5.1. Set up the apparatus as described in point 4.4.4.4 in a bunker or suitably prepared underground site or suitable location. Ensure that the temperature of the steel tube is kept at (20 ± 5) °C before detonation.

Note: Detonation can cause steel fragments to be projected with high kinetic energy, therefore, firing shall be carried out at a suitable distance from dwellings or thoroughfares.

4.4.4.5.2. If the booster charge with seven-point initiation is used, ensure that the detonation cords are stretched out as described in the footnote to point 4.4.4.1.1.4 and arranged as horizontally as possible.

4.4.4.5.3. Finally, remove the wooden or plastic rod and replace with the detonator. Do not carry out firing until the danger zone has been evacuated and the test personnel have taken cover.

4.4.4.5.4. Detonate the explosive.

4.4.4.6.1. Allow sufficient time for the fumes (gaseous and sometimes toxic decomposition products such as nitrous gases) to disperse, then collect the lead cylinders and measure their heights with a Vernier caliper.

4.4.4.6.2. Record for each of the marked lead cylinders, the degree of crushing expressed as a percentage of the original height of 100 mm. If the cylinders are crushed obliquely, record the highest and the lowest values and calculate the average.

4.4.4.7. Detonation velocity measurement can also be performed.

4.4.4.8. Two detonation tests per sample are to be carried out.

4.4.5. Test report

Values for the following parameters are to be given in the test report for each of the detonation resistance tests:

— the values actually measured for the outside diameter of the steel tube and for the wall thickness,

— the Brinell hardness of the steel tube,

— the temperature of the tube and the sample shortly before firing,

— the packing density (kg/m^3) of the sample in the steel tube,

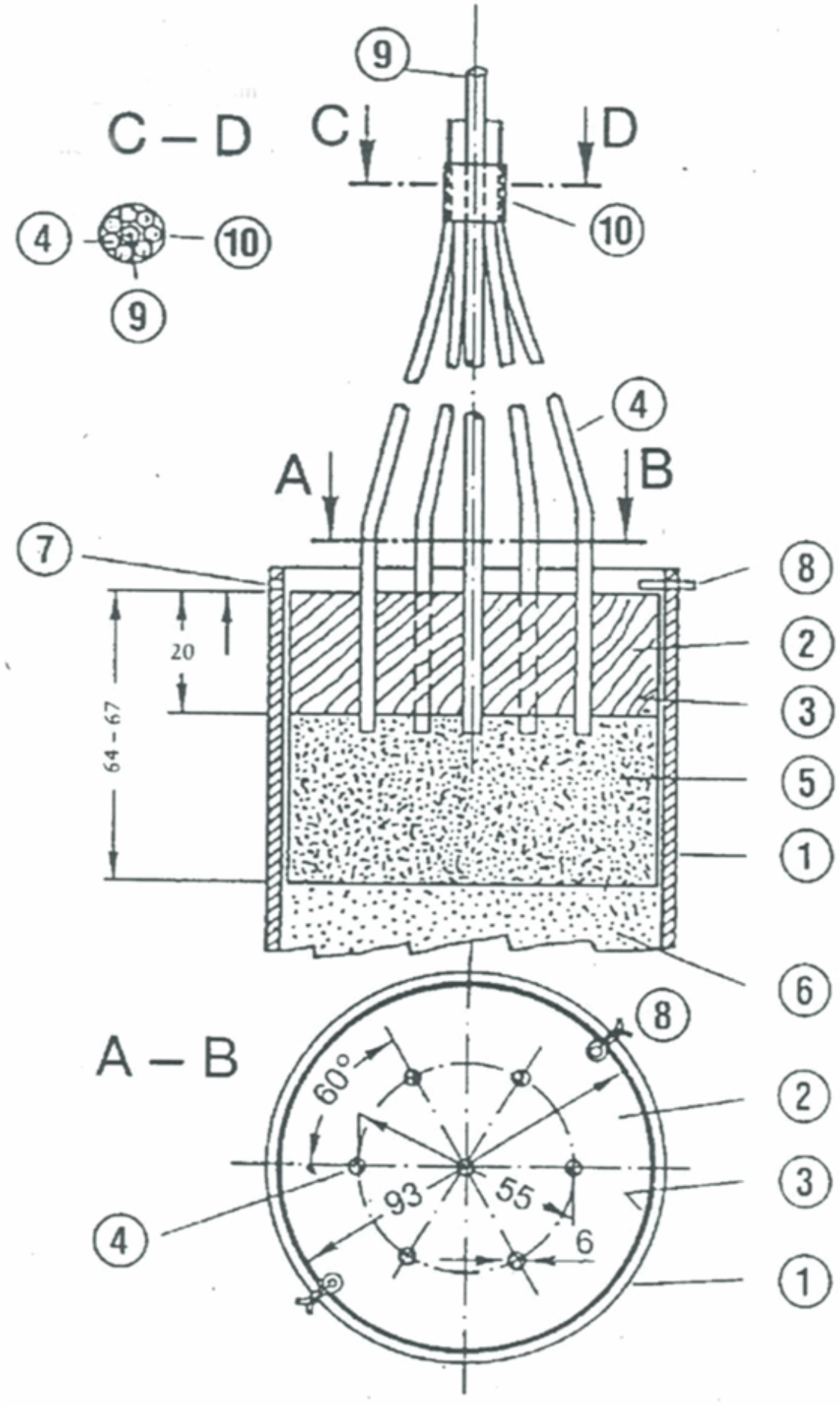
— the height of each lead cylinder after firing, specifying the corresponding cylinder number,

— method of initiation employed for the booster charge.

4.4.6. Evaluation of test results

If, in each firing, the crushing of at least one lead cylinder is less than 5 %, the test shall be considered conclusive and it shall be considered that the sample presented is resistant to detonation.

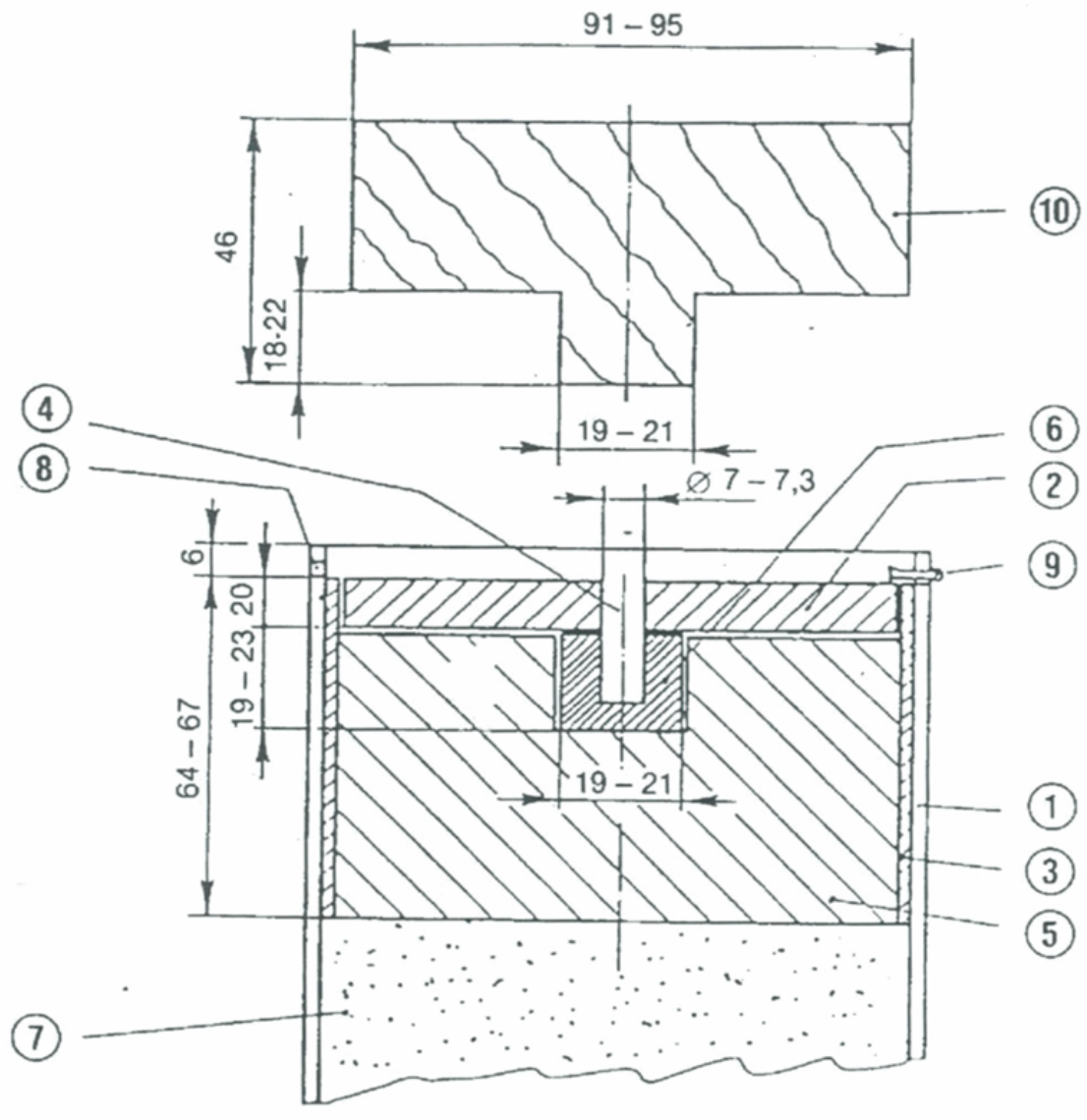
4.4.7. The test report shall form part of the technical documentation.
Figure 2


C – D
C
D
9
10
4
9
A
B
7
8
2
3
5
1
20
64 - 67
6
A – B
60°
93
55
6

Booster charge with seven-point initiation

1	:	Steel tube
2	:	Wooden or plastic disc with seven holes
3	:	Plastic or cardboard cylinder
4	:	Detonating cords
5	:	Plastic explosive
6	:	Test sample
7	:	4 mm hole drilled to receive split pin
8	:	Split pin
9	:	Wooden or plastic rod surrounded by 4
10	:	Adhesive tape for securing 4 around 9

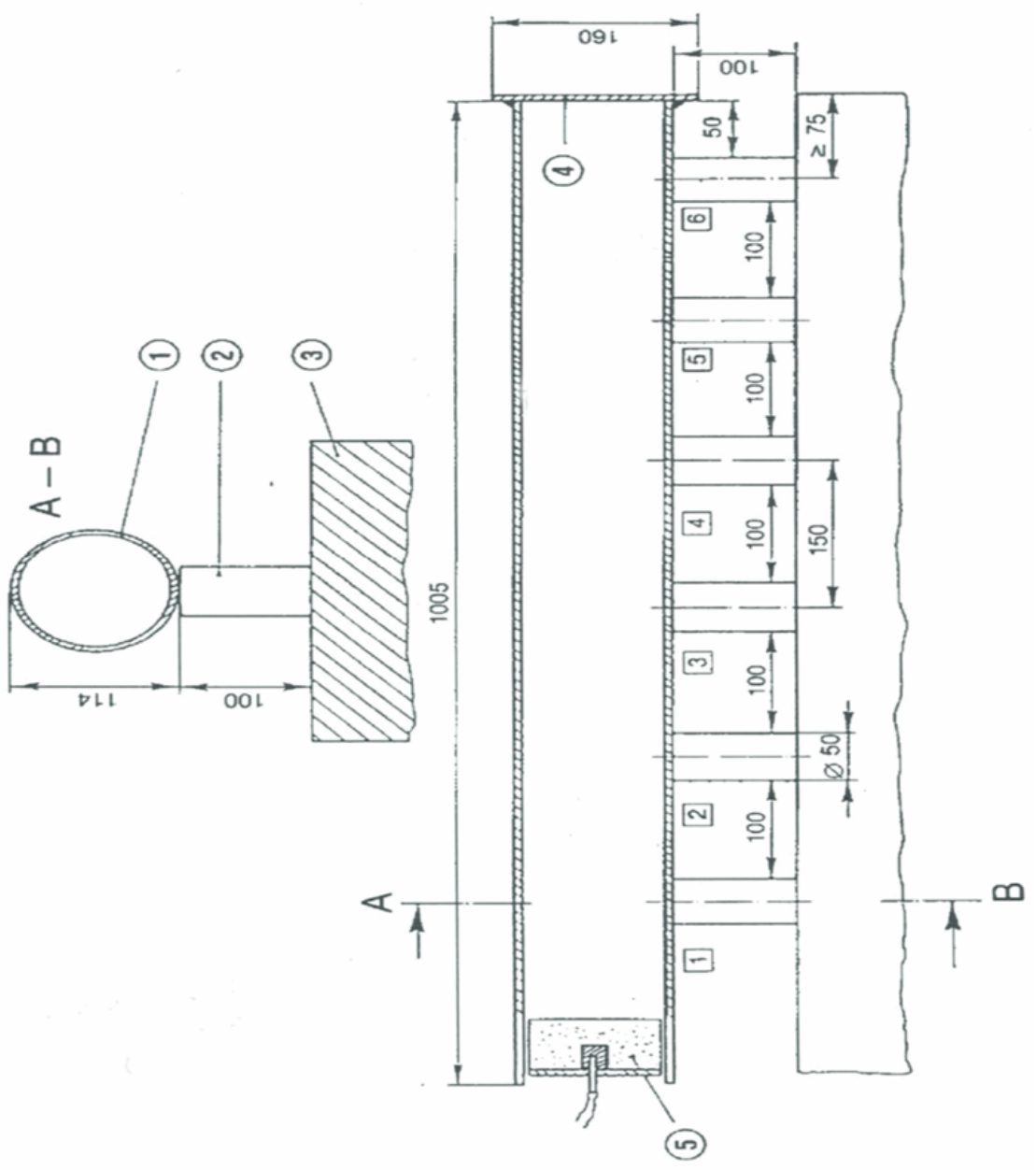
Figure 3



1	:	Steel tube
2	:	Wooden of plastic disc
3	:	Plastic or cardboard cylinder

4 : Wooden of plastic rod
5 : Plastic explosive
6 : Compressed pellet
7 : Test sample
8 : 4 mm hole drilled to receive split pin
9 : Split pin
10 : Wooden or plastic die for 5

Figure 4



Numbers in circles:

1 : Steel tube
2 : Lead cylinders

3 : Steel block or stack of beams
4 : Bottom plate
5 : Booster charge

Numbers in squares:

Lead cylinders 1 to 6

5. CE marking and EU declaration of conformity

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 4, 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.

5.2. 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.

5.3. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. Notified bodies' information and operational obligations

6.1. Each notified body shall, without undue delay, inform its notifying authority 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.

6.2. In the case referred to in point 6.1(b) the notified body shall request the manufacturer to take the necessary measures in accordance with Article 6(8).

7. Authorised representative

The manufacturer's obligations set out in points 4.4.7 and 5 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.

MODULE B – EU-TYPE EXAMINATION

1. Description of the module

1.1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an EU fertilising product and verifies and attests that the technical design of the EU fertilising product meets the requirements of this Regulation.

1.2. Assessment of the adequacy of the technical design of the EU fertilising product is carried out through examination of the technical documentation and supporting evidence, plus examination of samples, representative of the production envisaged.

2. Technical documentation

2.1. 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).

2.2. 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,

(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) 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,

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

(h) test reports,

(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,

(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, information about the maximum quantity and exact source of total chromium (Cr).

3. Application for EU-type examination

3.1. The manufacturer shall lodge an application for EU-type examination with a single notified body of his or her choice.

3.2. The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his or her name and address as well,

(b) a written declaration that the same application has not been lodged with any other notified body,

(c) the technical documentation referred to in point 2,

(d) the samples representative of the production envisaged. The notified body may request further samples if needed for carrying out the test programme,

(e) the supporting evidence for the adequacy of the technical design solution. This 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.

4. Assessment of the adequacy of the technical design

The notified body shall:

(a) examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the EU fertilising product;

(b) verify that the sample(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;

(c) carry 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) carry 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) agree with the manufacturer on a location where the examinations and tests will be carried out.

5. Evaluation report

The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authority, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. EU-type examination certificate

6.1. Where the type meets the requirements of this Regulation that apply to the EU fertilising product concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the 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.

6.2. 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.

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

7. Changes which may affect the conformity of the EU fertilising product

7.1. The notified body 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, the notified body shall inform the manufacturer accordingly.

7.2. The manufacturer shall inform the notified body 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.

8. Notified bodies' information obligation

8.1. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of EU-type examination certificates and/or any additions thereto refused, suspended or otherwise restricted.

8.2. Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the EU-type examination certificates and/or additions thereto which it has issued.

8.3. 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 the notified body.

9. Availability of the EU-type examination certificate

9.1. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the EU-type examination certificate.

9.2. 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.

10. Authorised representative

The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9.2, provided that they are specified in the mandate.

MODULE C – CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL

1. Description of the module

Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares on his or her sole responsibility that the EU fertilising products concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Regulation that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured EU fertilising products with the approved type described in the EU-type examination certificate and with the requirements of this Regulation that apply to them.

3. CE marking and EU declaration of conformity

3.1 The manufacturer shall affix the CE marking to each individual packaging of the EU fertilising product that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Regulation or, where it is supplied without packaging, in a document accompanying the EU fertilising product.

3.2 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.

3.3. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

4. Authorised representative

The manufacturer's obligations set out in point 3 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.

MODULE D1 – QUALITY ASSURANCE OF THE PRODUCTION PROCESS

1. Description of the module

Quality assurance of the production process is the conformity assessment procedure whereby 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.

2. Technical documentation

2.1. 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).

2.2. 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, and, in relation to compost belonging to CMC 3 or digestate belonging to CMC 5, 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) 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,

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

(h) test reports,

(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,

(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, information about the maximum quantity and exact source of total chromium (Cr).

3. Availability of technical documentation

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.

4. Manufacturing

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.

5. Quality system

5.1. The manufacturer shall implement a quality system which shall ensure compliance of the EU fertilising products with the requirements of this Regulation that apply to them.

5.1.1. The quality system shall cover the quality objectives and the organisational structure with responsibilities and powers of the management with regard to product quality.

5.1.1.1. For compost belonging to CMC 3 and digestate belonging to CMC 5, as defined in Annex II, senior management of the manufacturer's organisation shall:

(a) ensure that sufficient resources (people, infrastructure, equipment) are available to create and implement the quality system;

(b) appoint a member of the organisation's management who shall be responsible for:
- ensuring that quality management processes are established, approved, implemented and maintained;
- reporting to senior management of the manufacturer on the performance of the quality management and any need for improvement;
- ensuring the promotion of awareness of customer needs and legal requirements throughout the manufacturer's organisation, and for making the personnel aware of the relevance and importance of the quality management requirements to meet the legal requirements of this Regulation;
- ensuring that each person whose duties affect the product quality is sufficiently trained and instructed; and
- ensuring the classification of the quality management documents mentioned under point 5.1.4;

(c) conduct an internal audit every year, or sooner than scheduled if triggered by any significant change that may affect the quality of the EU fertilising product; and

(d) ensure that appropriate communication processes are established within and outside the organisation and that communication take place regarding the effectiveness of the quality management.

5.1.2. The quality system shall cover the manufacturing, quality control and quality assurance techniques, processes and systematic actions.

5.1.2.1. For compost belonging to CMC 3 and digestate belonging to CMC 5, as defined in Annex II, the quality system shall ensure compliance with the composting and digestion process criteria specified in that Annex.

5.1.3. The quality system shall cover the examinations and tests to be carried out before, during and after manufacture with a specified frequency.

5.1.3.1. For compost belonging to CMC 3 and digestate belonging to CMC 5, as defined in Annex II, the examinations and tests shall comprise the following elements:

(a) The following information shall be recorded for each batch of input materials:

(i) date of delivery;

(ii) amount by weight (or estimation based on the volume and density);

(iii) identity of the input material supplier;

(iv) input material type;

(v) identification of each batch and delivery location on site. A unique identification code shall be assigned throughout the production process for quality management purposes; and

(vi) in case of refusal, the reasons for the rejection of the batch and where it was sent.

(b) Qualified staff shall carry out a visual inspection of each consignment of input materials and verify compatibility with the specifications of input materials laid down in CMC 3 and CMC 5 in Annex II.

(c) The manufacturer shall refuse any consignment of any given input material where visual inspection raises any suspicion of:

— the presence of hazardous or damageable substances for the composting or digestion process or for the quality of the final EU fertilising product, or

— incompatibility with the specifications laid down in CMC 3 and CMC 5 in Annex II, in particular by presence of plastics leading to exceedence of the limit value for macroscopic impurities.

(d) The staff shall be trained on:

— potential hazardous properties that may be associated with input materials, and

— features that allow hazardous properties and the presence of plastics to be recognised.

(e) Samples shall be taken on output materials, to verify that they comply with the component material specifications for compost and digestate laid down in CMC 3 and CMC 5 in Annex II, and that the properties of the output material do not jeopardise the EU fertilising product's compliance with the relevant requirements in Annex I.

(f) The output material samples shall be taken on a regular basis with at least the following frequency:

Annual input(tonnes)	**Samples / year**
≤ 3 000	1
3 001 – 10 000	2
10 001 – 20 000	3
20 001 – 40 000	4
40 001 – 60 000	5

60 001 – 80 000	6
80 001 – 100 000	7
100 001 – 120 000	8
120 001 – 140 000	9
140 001 – 160 000	10
160 001 – 180 000	11
> 180 000	12

(g) If any tested output material sample fails one or more of the applicable limits specified in the relevant sections of Annexes I and II, the person responsible for quality management referred to in point 5.1.1.1(b) shall:

(i) clearly identify the non-conforming output materials and their storage place,

(ii) analyse the reasons of the non-conformity and take any necessary action to avoid its repetition,

(iii) record in the quality records referred to in point 5.1.4 if reprocessing takes place, or if the output material is eliminated.

5.1.4. The quality system shall cover the manufacturer's quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

5.1.4.1. For compost belonging to CMC 3 and digestate belonging to CMC 5, as defined in Annex II, the quality records shall demonstrate effective control of input materials, production, storage and compliance of input- and output materials with the relevant requirements of this Regulation. Each document shall be legible and available at its relevant place(s) of use, and any obsolete version shall be promptly removed from all places where it is used, or at least identified as obsolete. The quality management documentation shall at least contain the following information:

(a) a title,

(b) a version number,

(c) a date of issue,

(d) the name of the person who issued it,

(e) records about the effective control of input materials,

(f) records about the effective control of the production process,

(g) records about the effective control of the output materials,

(h) records of non-conformities,

(i) reports on all accidents and incidents that occur to the site, their known or suspected causes and actions taken,

(j) records of the complaints expressed by third parties and how they have been addressed,

(k) a record of the date, type and topic of training followed by the persons responsible for the quality of the product,

(l) results of internal audit and actions taken, and

(m) results of external audit review and actions taken.

5.1.5. The quality system shall cover the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

5.1.5.1. For compost belonging to CMC 3 and digestate belonging to CMC 5, as defined in Annex II, the manufacturer shall establish an annual internal audit program in order to verify the compliance of the quality system with the following components:

(a) a procedure that defines the responsibilities and requirements for planning and conducting internal audits, establishing records and reporting results shall be established and documented. A report identifying the non-conformities to the quality scheme shall be prepared and all corrective actions shall be reported. The records of the internal audit shall be annexed to the quality management documentation;

(b) priority shall be given to non-conformities identified by external audits;

(c) each auditor shall not audit his or her own work;

(d) the management responsible for the area audited shall ensure that the necessary corrective actions are taken without undue delay;

(e) internal audit realised in the frame of another quality management system can be taken into account provided that it is completed by an audit of the requirements to this quality system.

5.1.6. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records. It shall, in particular, contain an adequate description of all the quality management elements set out in points 5.1.1 to 5.1.5.

5.2. The manufacturer shall lodge an application for assessment of his or her quality system with the notified body of his or her choice, for the EU fertilising products concerned. The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised 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 containing all the elements set out in point 5.1,

— the technical documentation referred to in point 2.

5.3.1. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.1.

5.3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

5.3.3. In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and

product technology concerned, and knowledge of the applicable requirements of this Regulation. 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 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.

5.3.4. The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

5.4. 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.

5.5.1. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

5.5.2. The notified body 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.

5.5.3. It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

6. Surveillance under the responsibility of the notified body

6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

6.2. The manufacturer shall, for assessment purposes, allow the 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.

6.3.1. The notified body 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.

6.3.2. For compost belonging to CMC 3 and digestate belonging to CMC 5, as defined in Annex II, the notified body shall take and analyse output material samples during each audit, and the audits shall be carried out with the following frequency:

(a) during the notified body'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); and

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

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

7. CE marking and EU declaration of conformity

7.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 5.2, 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.

7.2. The manufacturer shall draw up a written EU declaration of conformity for an EU fertilising product or 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 or type for which it has been drawn up.

7.3. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

8. Availability of quality system documentation

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,

— the decisions and reports of the notified body referred to in points 5.5.3, 6.3.1 and 6.4.

9. Notified bodies' information obligation

9.1. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

9.2. Each notified body shall inform the other notified bodies of quality system approvals which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of quality system approvals which it has issued.

10. Authorised representative

The manufacturer's obligations set out in points 3, 5.2, 5.5.1, 7 and 8 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.

(**1**) The diameter of the disc must always correspond to the inside diameter of the cylinder.

(**2**) NB: When the six peripheral lengths of cord are taut after assembly, the central cord must remain slightly slack.