An Roinn Talmhaíochta,
Bia agus Mara
Department of Agriculture,
Food and the Marine

Procedure for the appointment of a Notified Body under Regulation (EU) 2019/1009 on EU Fertilising Products

March 2021

Procedure for the appointment of a Notified Body under Regulation (EU) No 2019/1009

1 Introduction

This document sets out the procedures applicable in Ireland for the assessment and notification of bodies, and the subsequent monitoring of such bodies, seeking authorization to carry out conformity assessment tasks in accordance with the requirements of Regulation (EU) 2019/1009 lays down rules on the making available on the market of EU fertilising products. Regulation (EU) No 2019/1009 repeals Regulation (EC) No 2003/2003[1] and amends Regulation (EC) No 1069/2009[2] and Regulation (EC) No 1107/2009[3].

2 Fertiliser Products Regulation (FPR)

The Fertiliser Products Regulation (FPR) lays down harmonised rules for the making available on the market of EU fertilising products. It repeals Regulation (EC) No 2003/2003 and will apply in Ireland from 16th July 2022. The main aims for the FPR include the following:

- It opens the single market for fertilising products which are not currently covered by harmonisation rules, such as organic and organo-mineral fertilisers, soil improvers, inhibitors, plant biostimulants, growing media or blends.
- It introduces CE marking of fertiliser for the first time
- The FPR harmonises EU rules for products derived from recycled or organic materials and by-products, and provides rules to recover nutrients from such materials for fertilising purposes
- It lays down common rules on safety, quality and labelling requirements for fertilising products and introduces limits for contaminants for the first time.
- Contrary to most other product harmonisation Regulations in the EU and taking into account the principles of better regulation and subsidiarity, the Regulation maintains optional harmonisation and does not prevent non-harmonised fertilisers from being made available on the internal market in accordance with national law and the general free movement rules. Compliance with harmonised rules therefore remain optional and are only required for fertiliser products which are CE marked.

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[1] Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers (OJ L 304, 21.11.2003, p. 1).

[2] Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

3 Conformity of EU Fertilising Products and Notified Bodies

The Fertiliser Products Regulation puts in place a conformity assessment system to provide for quality assurance for EU fertiliser products that are available on the market. The new system will ensure that testing the conformity of EU fertilising products is performed in a reliable and reproducible manner.

Conformity assessment of EU fertilising products with the requirements laid down in the FPR must be carried out under the applicable conformity assessment procedure in accordance with Annex IV of the Regulation. There are 4 different conformity assessment procedure modules and the applicability of these modules to EU fertilising products will depend on the product function category (PFC) to which the fertiliser product belongs and to the category of the component materials (CMC) used to produce them.

Apart from the internal production control modules (Modules A and C), the other three conformity assessment modules require the intervention of notified bodies, namely; (i) internal production control plus supervised product testing (module A1), (ii) EU-type examination (module B) and (iii) quality assurance of the production process (module D1).

Notified bodies are designated by Member States and a list of all official notified bodies under the Fertiliser Products Regulation is available on the NANDO database of notified bodies. For a third party body in Ireland to become a notified body under the Fertiliser Products Regulation, it must be a legal entity established under Irish law and it must be assessed and notified by the Irish notifying authority.

4 Irish Notifying Authority

The Department of Agriculture, Food and the Marine (DAFM) is the notifying authority under the Fertiliser Products Regulation in Ireland. The Irish National Accreditation Board (INAB) will undertake the accreditation and monitoring of notified bodies for the purposes of the Regulation in Ireland.

5 Application Process for Notification

Applications for Notified Body status under Regulation (EU) No 2019/1009 should be made to the Department of Agriculture, Food and the Marine using the Application Form in Appendix 1. Prospective Notified Bodies must seek accreditation from INAB before the Department can make an assessment as the Notifying Authority. Once INAB has decided on the accreditation application, the Department will then consider the merits of the applicant as a candidate for Notified Body status. No formal application from a prospective Notified Body will be accepted without being accompanied by the appropriate accreditation from INAB.

The application to the Department must be accompanied by the following:

- Proof of the applicant's legal establishment in Ireland
- A description of the conformity assessment activities, the conformity assessment procedure module(s) and those EU fertilising products for which the applicant wishes to be notified and claims to be competent for
- An accreditation certificate and schedule, issued by INAB, attesting that the applicant meets the requirements laid down in Article 24 of Regulation (EU) No 2019/1009. The scope of accreditation should match the scope of notification being sought
- A current Tax Clearance Certificate
- Proof of insurance cover

Any further assessment of a prospective Notified Body can be decided on a case by case basis. Such additional assessment criteria may take into account advice from competent authorities, market surveillance authorities or other Member States.

As applications are subject to Ministerial approval, once the Minister is satisfied that the applicant, within the scope identified, is fit for notification for the purpose of Regulation 2019/1009, correspondence will issue outlining details of notification, stipulating the scope of notification and the conditions for operating as a Notified Body. Such conditions may include, but are not limited to, the following:

- Agreement to comply with the operational obligations of Notified Bodies as outlined in Article 32 of the FPR and to carry out conformity assessment activities for which it is notified
- Agreement to comply with the information obligations of Notified Bodies (see Section 8)
- Agreement to participate in co-ordination activities at both Irish and European levels, including the work and activities of the coordinating group of Notified Bodies (see Section 8)
- The requirement for surveillance, annually, or at whatever intervals are thought appropriate by the Department, and
- The requirement for a full reassessment, every 5 years, or at whatever intervals are thought appropriate by the Department.

Following receipt of acceptance on the conditions of notification, the Department will notify the European Commission and the other Member States by publishing details on NANDO (the information system developed and managed by the European Commission).

A two week period is allowed for the European Commission or other Member States to raise an objection to the proposed notification. At the end of the two week period and subject to no objections being raised, the applicant will be considered a Notified Body for the FPR, and will be issued with a unique notified body number to be used as the official identification of that notified body.

6 Accreditation

Bodies seeking to be notified for the purpose of Regulation (EU) 2019/1009 must apply to INAB for accreditation.

INAB will undertake an assessment of the applicant against the relevant harmonised European accreditation standard(s) to ensure that the applicant complies with the requirements of Article 24 of Regulation (EU) 2019/1009 and has the necessary product knowledge and capability to carry out the proposed conformity assessment activities. The scope of accreditation (and notification) will be determined by reference to the types of EU fertilising products and component materials and the proposed conformity assessment activities as specified in the application. All applicants will need to be able to demonstrate their professional ability and a necessary level of understanding of Regulation (EU) 2019/1009 with respect to the harmonised standards for EU fertilising products and conformity assessment procedures.

Applications for accreditation should be submitted directly to INAB and full details of the accreditation process are available from the INAB website at www.inab.ie

Simultaneous to the submission of its application for accreditation to INAB, the applicant should also send a copy to the Department (as the notifying authority).

Once INAB has completed its assessment and accreditation, it will issue an accreditation certificate and schedule to the prospective Notified Body. The applicant should then submit this certificate and schedule as part of the application for notified body status to the Department.

7 Monitoring of Notified Bodies

Reassessment and surveillance will be carried out by INAB in line with usual accreditation practice. A report on all reassessment and surveillance must be sent to the Department by the Notified Body. This report must be accompanied by all relevant documentation. INAB will advise the Department of the outcome of each annual surveillance, 5 yearly reassessment and any other necessary monitoring in the intervening period and any implications for notification.

The Department may request further information about the reassessment and surveillance activities, as required.

8 Information Obligations

Notified Bodies must agree to keep the Notifying Authority informed of the following:

- Any refusal, restriction, suspension or withdrawal of the conformity of a product issued

under the scope of notification
- Any circumstances affecting the scope of and conditions for the notification
- On request, of all activities performed both within and outside the scope of the notification, including subcontracted tasks and cross border activities
- Any requests for information received from market surveillance authorities

Notified Bodies must agree to provide relevant information relating to conformity assessment and inspection results to other Notified Bodies carrying out activities on the same product.

Notified Bodies will be requested to agree to participate, either directly or by a designated representative, in the work of a coordinating group of Notified Bodies established under the Regulation.

9 Insurance

In accordance with Article 24(9) of Regulation (EU) 2019/1009 and Article 17(9) of Decision 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products, all applicants will be required to demonstrate that they have adequate public and professional indemnity insurance for the activities they wish to carry out. Evidence of this should be submitted to the Department at the point at which an application to be notified is made. Applicants will be required to show that indemnity insurance is kept up to date for the period covering the appointment as a Notified Body.

Such cover must extend to the whole of the European Union, the EEA, or, if the applicant intends to carry out work outside these areas, world-wide. The Department will not in relation to any case or circumstance cover a notified body's liability.

10 Appeals Procedure

Any prospective Notified Body may appeal a decision of the Minister, acting as a Notifying Authority. The Irish legislation transposing Regulation (EU) 2019/1009 will allow an appeal to the Minister and the Minister will then set up an appeals panel of between 3 and 5 people to decide on the merits of such an appeal.

An Roinn Talmhaíochta,
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Department of Agriculture,
Food and the Marine

Appendix 1

APPLICATION FOR NOTIFICATION

1. Please complete the details in the following tables and post to Feedingstuffs, Fertiliser, Grain and Poultry Division, Department of Agriculture, Food & the Marine, Administration Building, Youngs Cross, Celbridge, Co Kildare, or email to FeedEnquiries@agriculture.gov.ie

Table 1

Company Name	
Address	
Telephone	
Website	
Contact Name	
Title	
Telephone	
Email	

2. Please describe in Table 2 the conformity assessment activities, the conformity assessment procedure module(s) and the EU fertilising products for which the applicant wishes to be notified and claims to be competent for.

(Details of EU fertilising products and the applicable conformity assessment procedures within the meaning of Regulation (EU) 2019/1009 is included in appendix 3)

Table 2

Conformity Assessment Activities and Procedure Modules	**Fertiliser Products (PFCs) and Component Materials (CMCs)** **Please list**
Internal production control plus supervised product testing (module A1)	
EU-type examination (module B)	
Quality assurance of the production process (module D1).	

3. Please attach proof of the company's legal status in Ireland. (Complete questionnaire at Appendix 2 to assist)

4. Provide a copy of the accreditation certificate and schedule to Feedingstuffs, Fertiliser, Grain and Poultry Division, Department of Agriculture, Food & the Marine, Administration Building, Youngs Cross, Celbridge, Co Kildare

☐ I confirm that the information I have provided is correct.

Signed :

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Dated :

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Appendix 2

COMPANY ESTABLISHMENT IN IRELAND QUESTIONNAIRE

Company Details:	
Phone:	
Email:	

Please provide answers to the following questions:	
1. Is your company established in Ireland?	YES / NO
2. Does your company have premises in Ireland?	YES / NO
3. What activities relating to this appointment will take place in Ireland?	(Provide Details)
4. What activities relating to this appointment will take place in another State?	(Provide Details)
5. Is your company a subsidiary of a company established outside Ireland?	YES / NO
6. If so, can you give details of the contractual relationship between the two companies, including details of where the Head Office is established?	

7. Will the company established in Ireland be responsible for all aspects of conformity assessment?	YES /NO
8. If not, please detail which aspects will be the responsibility of the company established in Ireland and which aspects will be the responsibility of a company, or companies, outside Ireland?	
9. Please give details of the degree of technical competence available in the Irish company.	
10. Please also give full details of the level of activities that the Irish company will engage in	
11. Please give full details of what aspects of the business is relocating to Ireland?	
12. Will your company outsource any of the operations pertinent to your business?	YES / NO
13. If so where will the operations be outsourced and how will this outsourcing be managed by the Irish company?	
14. How many members of senior management will be located in Ireland?	

15. How many current members of staff will be located in Ireland?	
16. Will employees be permanently based in Ireland, seconded to Ireland or employed on a contract for services basis?	YES / NO (Please give a full breakdown)
17. Does your company currently provide assessment services in Ireland?	
18. Can you provide documentary proof that your company is incorporated in Ireland?	YES / NO (Enclose documents)
19. Will the Irish company's board meetings take place in Ireland?	YES / NO
20. Will other key meetings take place in Ireland?	YES / NO (Please give details)

Signed :

_____

Dated :

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Please return all completed documents to Feedingstuffs, Fertiliser, Grain and Poultry Division, Department of Agriculture, Food & the Marine, Administration Building, Youngs Cross, Celbridge, Co Kildare

Appendix 3

CONFORMITY ASSESSMENT PROCEDURES FOR FERTILISING PRODUCTS WITHIN THE MEANING OF REGULATION (EU) 2019/1009

Products	Applicable procedures	Articles/Annexes	Procedures' applicability limitations
Fertilising products as specified in PFC 1 to 4 composed solely of materials covered by one or more of the following CMCs: CMC 1 (except inhibitors as specified in CMC 1 point 4), CMC 4, CMC 6, CMC 7, CMC 8, CMC 11.	Internal Production Control (Module A),	Articles 13, 14(2)-(3), 15, 16 Annex IV, Part I, point 1 Annex IV, Part II, Module A Annex V	Except for ammonium nitrate fertilisers of high nitrogen content as specified in PFC 1 (C)(I)(a)(i-ii)(A)
	EU-type examination (module B) followed by conformity to type based on internal production control (module C), or	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 3 Annex IV, Part II, Module B+C Annex V	
	Quality assurance of the production process (module D1)	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 4 Annex IV, Part II, Module D1 Annex V	
Fertilising product blends as specified in PFC 7	Internal Production Control (Module A),	Articles 13, 14(2)-(3), 15, 16 Annex IV, Part I, point 1 Annex IV, Part II, Module A Annex V	Except for fertilising product blends containing 28% or more by mass of nitrogen (N) from a fertilising product as specified in PFC 1 (C)(I)(a)(i-ii)(A)
	EU-type examination (module B) followed by conformity to type based on internal production control (module C), or	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 3 Annex IV, Part II, Module B+C Annex V	
	Quality assurance of the production process (module D1)	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 4 Annex IV, Part II, Module D1 Annex V	

Ammonium nitrate fertilisers of high nitrogen content as specified in PFC 1 (C)(I)(a)(i-ii)(A)	Internal production control plus supervised product testing (module A1)	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 2 Annex IV, Part II, Module A1 Annex V	
Fertilising product blends as specified in PFC 7 containing 28% or more by mass of nitrogen (N) from a fertilising product as specified in PFC 1 (C)(I)(a)(i-ii)(A)	Internal production control plus supervised product testing (module A1)	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 2 Annex IV, Part II, Module A1 Annex V	
Fertilising products as specified in PFC 1 to 4 containing materials covered by one or more of the following CMCs: CMC 2, CMC 9, CMC 10.	EU-type examination (module B) followed by conformity to type based on internal production control (module C), or	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 3 Annex IV, Part II, Module B+C Annex V	Except for a) ammonium nitrate fertilisers of high nitrogen content as specified in PFC 1 (C)(I)(a)(i-ii)(A) and b) fertilising products containing materials covered by CMC 3 or CMC 5
	Quality assurance of the production process (module D1)	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 4 Annex IV, Part II, Module D1 Annex V	Except for ammonium nitrate fertilisers of high nitrogen content as specified in PFC 1 (C)(I)(a)(i-ii)(A)
Inhibitors as specified in PFC 5 or Fertilising products containing inhibitors as specified in CMC 1, point 4	EU-type examination (module B) followed by conformity to type based on internal production control (module C), or	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 3 Annex IV, Part II, Module B+C Annex V	Except for a) ammonium nitrate fertilisers of high nitrogen content as specified in PFC 1 (C)(I)(a)(i-ii)(A) and b) fertilising products containing materials covered by CMC 3 or CMC 5
	Quality assurance of the production process (module D1)	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 4 Annex IV, Part II, Module D1 Annex V	Except ammonium nitrate fertilisers of high nitrogen content as specified in PFC 1 (C)(I)(a)(i-ii)(A)

Plant biostimulants as specified in PFC 6	EU-type examination (module B) followed by conformity to type based on internal production control (module C), or	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 3 Annex IV, Part II, Module B+C Annex V	Except products containing materials covered by CMC 3 or CMC 5
	Quality assurance of the production process (module D1)	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 4 Annex IV, Part II, Module D1 Annex V	
Fertilising products as specified in PFCs 1 to 6 containing materials covered by at least one of the following CMCs: CMC 3, CMC 5	Quality assurance of the production process (module D1)	Articles 13, 14(2)-(3), 15, 16, 20-36 Annex IV, Part I, point 4 Annex IV, Part II, Module D1 Annex V	Except ammonium nitrate fertilisers of high nitrogen content as specified in PFC 1 (C)(I)(a)(i-ii)(A)