

To all accredited and applicant certification bodies, PRD scheme
To the associations of conformity assessment bodies

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SUBJECT **Certification and Inspection Department**

**Technical circular DC N° 17/2023 – Provisions for the
accreditation of Conformity Assessment Bodies of fertilising
products of the EU, according to Regulation (EU) 2019/1009.**

Introduction

Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 establishes rules on the making available on the market of EU fertilising products with the CE marking.

With this Regulation, Regulation (EC) n. 1069/2009 establishing health regulations relating to by-products of animal origin and derived products not intended for human consumption, and Regulation (EC) n. 1107/2009 concerning the placing of plant protection products on the market, as well as Regulation (EC) n. 2003/2003 relating to fertilizers.

As established by Decision (EC) 768/2008, relating to a common framework for the marketing of products, the checks necessary to affix the CE marking can, in certain cases, be performed by Conformity Assessment Bodies notified to the European Commission, after accreditation in accordance with Regulation (EC) 765/2008.

The main objective of this Regulation is therefore to harmonize the rules concerning both fertilizers derived from recycled and organic products, and those composed of inorganic materials deriving from extraction or chemical processes, which already had their own regulations. This harmonization will therefore be able to encourage its use, with positive environmental effects in terms of sustainable and circular economy and reduction of purchases of fertilizers from non-EU countries.

Regulation (EU) 1009/2019, which is applicable from 16 July 2022, is structured in 53 articles divided into 8 chapters which concern:

- CHAPTER I: General provisions;
- CHAPTER II: Obligations of economic operators;
- CHAPTER III: Conformity of EU fertilising products;
- CHAPTER IV: Notification of conformity assessment bodies;

- CHAPTER V: Union market surveillance, control of EU fertilising products entering the union market and union safeguard procedure;
- CHAPTER VI: Delegated powers and committee procedures;
- CHAPTER VII: Amendments;
- CHAPTER VIII: Transitional and final provisions.

The Regulation contains 5 Annexes:

- Annex I: Product Function Categories (PFCs) of EU fertilising products;
- Annex II: Component Material Categories (CMCs);
- Annex III: Labelling requirements;
- Annex IV: Conformity assessment procedures;
- Annex V: EU Declaration of conformity.

Annex IV relating to conformity assessment procedures provides for the use of 5 modules in line with the provisions of decision 768 of 2008:

- Module A: Internal production control;
- Module A1: Internal production control combined with official product tests;
- Module B: The relevant EU exam;
- Module C: Conformity based on internal production control;
- Module D1: Quality assurance of the production process.

The following articles of the Regulation are also highlighted:

- art.21 which provides for the possibility of accrediting Conformity Assessment Bodies, which remains a choice of the national States;
- art. 24, containing the requirements which such bodies shall fulfil;
- art. 27 which provides that the application for notification - presented by the Conformity Assessment Body which intends to carry out the verifications for the purpose of placing the CE marking on fertilizers - must also include the accreditation certificate;
- art. 28 which indicates the provisions relating to the notification procedure of the Conformity Assessment Bodies by the Notification Authority;
- art. 29, paragraph 2, regarding publication by the Commission of the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified.

On 7 January 2023, the Ministerial Decree of 11 November 2022 entitled "Designation of the national notification authority and establishment of the national register of conformity assessment bodies for EU fertilising products" was published in the Official Gazette of the Italian Republic.

This Ministerial Decree identifies the Ministry of Agriculture, Food Sovereignty and Forests - Departments of European and International Policies and Rural Development - General Directorate of Rural Development - DISR V.

The control activities for maintaining the accreditation of the Bodies authorized to carry out conformity assessment activities for EU fertilising products, in application of art. 21, paragraph 2 of Regulation (EU) 2019/1009, are entrusted to ACCREDIA, as the sole national accreditation body designated pursuant to the ministerial decree of 22 December 2009.

Accreditation, as required by EU Regulation 2019/1009, is a prerequisite for obtaining notification and, in accordance with document EA 2/17 M:2020 and the Ministerial Decree of 11 November 2022, ACCREDIA issues the following accreditations:

- module A1 → UNI CEI EN ISO/IEC 17065:2012;
- module B → UNI CEI EN ISO/IEC 17065:2012;
- module D1 → UNI CEI EN ISO/IEC 17065:2012;

Accreditation process

The audits necessary for the issuance of the certification must be carried out by accredited certification bodies according to the standard UNI CEI EN ISO/IEC 17065:2012.

Various cases may occur, based on the ACCREDIA accreditations already held by the Certification Body that applies for accreditation or extension.

If the CB already has accreditations issued by other Accreditation Bodies, an assessment must be carried out on a case-by-case basis, according to the applicable EA/IAF MLA agreements.

The requirements of RG-01 and RG-01-03 for the granting of accreditation and extension remain unchanged and the provisions contained in the Technical Document DT-01-DC will also apply for the assessment activities by ACCREDIA.

A	CB already accredited for the scheme ISO/IEC 17065:2012	<ul style="list-style-type: none"> • Document review of 1 day (to be performed if possible, at the CB's premises). • Assessment of 1 day at the CB's head office. • <u>Following positive outcome of the document review and the assessment at the CB's head office, the accreditation or extension file will be presented to the relevant Sector Accreditation Committee for deliberation.</u> • 1 witnessed assessment of 1 day for each module requested and for which the CAB was authorized on the occasion of the first assessment activity performed by the Body as a Notified Body.
B	CB not yet accredited to ISO/IEC 17065:2012, but accredited for other accreditation schemes	<ul style="list-style-type: none"> • Document review of 1 day (to be performed if possible, at the CB's premises). • Assessment of 2 days at the CB's head office. • <u>Following positive outcome of the document review and the assessment at the CB head office, the accreditation or extension file will be presented to the relevant Sector Accreditation Committee for deliberation.</u>

		<ul style="list-style-type: none"> 1 witnessed assessment of 1 day for each module requested and for which the CAB was authorized on the occasion of the first assessment activity performed by the Body as a Notified Body.
C	CB not yet accredited in any scheme	<ul style="list-style-type: none"> Document review of 1 day. Assessment of 4 days at the CB's head office. <u>Following positive outcome of the document review and the assessment at the CB head office, the accreditation or extension file will be presented to the relevant Sector Accreditation Committee for deliberation.</u> 1 witnessed assessment of 1 day for each module requested and for which the CAB was authorized on the occasion of the first assessment activity performed by the Body as a Notified Body.

The above accreditation/extension process was included in the agreement signed between ACCREDIA and the Ministry of Agriculture to comply with the provisions of article 7 of the Ministerial Decree of 11 November 2022, which was published on 7 January 2023.

Documentation to be presented to ACCREDIA for the document review

The Certification Body must complete and send to ACCREDIA the application modules DA-00 and DA-04, accompanied by the required documentation, both in the case of accreditation and of extension.

Maintenance of accreditation

For the maintenance of accreditation, throughout the accreditation cycle, except for particular situations (e.g.: management of complaints and feedbacks, changes to the certification scheme, changes in the structure of the Body...), in addition to the provisions of the Accreditation Regulations for on-site surveillance audits, at least 1 witnessed assessment shall be performed every year in accordance with Regulation (EU) 2019/1009.

With kind regards

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