

**Guide to the compilation of a technical file on applications to designate fertilizers 'EC fertilizer'
pursuant to Regulation (EC) No 2003/2003**

(2005/C 250/02)

(Text with EEA relevance)

INTRODUCTORY NOTE

This guide is intended to help applicants wishing to register a new fertilizer for inclusion in the list of designated EC fertilizers.

Although the guide is not binding, the information requested will be required in order to avoid delays in the examination of the application.

Addresses of the services in the Member States to which applications should be sent are also included.

The Member State will subsequently transmit the application to the appropriate Commission working party for examination.

This document has been prepared in cooperation with experts representing:

- (1) the authorities concerned in the Member States,
- (2) companies in the 'European Fertilizer Manufacturers' Association' (EFMA),
- (3) the European Committee for Standardization (CEN) TC 260.

1. OBJECTIVE

The aim of this document is to set out as closely as possible the information needed by the Commission's Working Party on Fertilizers to enable it to evaluate the requests for entries in Annex I to Regulation (EC) No 2003/2003 ⁽¹⁾ and, in the light thereof, eventually designate them as 'EC fertilizer'.

It is therefore a guide for any person (manufacturer or his representative) who wishes to submit a fertilizer or type of fertilizer for designation as 'EC fertilizer'.

This information file is the result of the implementation of Article 14 of the Regulation (EC) No 2003/2003 which stipulates that:

- (a) it provides nutrients in an effective manner;
- (b) relevant sampling, analysis, and if required, test methods are being provided.
- (c) under normal conditions of use it does not adversely affect human, animal, or plant health, or the environment.

⁽¹⁾ OJ L 304, 21.11.2003, p. 1.

Practice has shown that applications have been processed more rapidly if they were presented in the form of a technical file containing all of the information required to assess the above requirements.

Consequently, this working paper is not hard-and-fast but could be amended to bring it into line with the experience gained within the Working Party and with advances in scientific and technical knowledge about fertilizers.

2. CONTENTS OF THE TECHNICAL FILE

The file must contain at least five separate chapters:

- information on effects on health, environment and safety,
- agronomic data,
- details of the methods of analysis and the results,
- a proposal for inclusion in Annex I to Regulation (EC) No 2003/2003,
- any other relevant information.

3. DESCRIPTION OF THE INFORMATION REQUIRED IN EACH CHAPTER

3.1. Information on health, the environment and safety

3.1.1. Safety data sheet

Draw up a safety data sheet containing the headings listed in Directive 91/155/EEC of 5 March 1991 ⁽²⁾ as modified by Directive 93/112/EEC of 10 December 1993 ⁽³⁾ and by Directive 2001/58/EC of 27 July 2001 ⁽⁴⁾ in accordance with the explanatory notes given in the Annex to that Directive.

Although it is not obligatory for every fertilizer under existing Community legislation- the safety data sheet is an excellent source of information, even if in some cases certain headings do not apply to the fertilizer product proposed.

3.1.2. Additional information

In addition, state undesirable substances and chemical or biological agents which have or may have an effect on human or animal health or the environment, as far as is known.

⁽²⁾ OJ L 76, 22. 3. 1991, p. 35.

⁽³⁾ OJ L 314, 16. 12. 1993.

⁽⁴⁾ OJ L 212, 7.8.2001, p. 24.

3.2. Agronomic data

3.2.1. Main effect and secondary effects

Describe the main effect obtained by application of the product under the conditions of use advocated and state the active ingredient(s) responsible for the effect claimed. Explain how the nutrient(s) in the product is/are made available to the crop. The secondary effects must be identified, characterized and explained as far as possible.

Although a scientific explanation of the action of the product is desirable, it is not necessary provided that positive and reproducible results are obtained under the conditions of use advocated.

3.2.2. Method of use of the product

In general, provide all the information necessary to enable effective use of the product.

This is a matter of describing the conditions of use of the finished product according to good agricultural practice.

Crops: It is not desirable to indicate 'all crops', but rather to select crops for which the effectiveness of the product has been demonstrated.

Application rates: Indicate the amount required to obtain the main effect on the crop concerned. It must be expressed both as a quantity of the finished product as marketed and a quantity (quantities) of the corresponding nutrient(s).

The application rate must be indicated according to agricultural practice, e.g. in kilogram of product per hectare per year. If the product is applied several times to the same crop, indicate the rate per application and the number of applications. In the case of products diluted before use, indicate the volume of diluent required.

Method of application: Specify whether the product is to be applied directly to the soil or to the plant (leaves, fruit, xylem or roots). Indicate the methods of application, e.g. broadcast or localized application, by spraying, injection, sprinkling, trickling, dusting, flowing solution, etc. Specify the calendar periods for application or the plant development stages (phenological stages) for which application is effective.

Special conditions of use: This involves supplementing the information on the use of the product, e.g. types of soils and their nutrient status, climatic and growing conditions. Describe the situations in which the use of the product is prohibited or not recommended, possible mixes, prohibited mixes, etc.

3.2.3. Efficacy

Give clear (comprehensible) information demonstrating the efficacy of the product when used under the conditions described.

If necessary, supply an experimental schedule to show the main effect, together with detailed results of trials on yield and/or crop quality. Include any relevant analyses of the soil and flora to show the nutrient levels in the crop, the type of soil and the basic agronomic data.

If the test results have been published, provide a photocopy of the publication in a Community language, if appropriate.

3.3. Details of the methods of analysis and results

Indicate the methods used to analyze the product: EC, ISO, CEN, AOAC methods, national methods, etc. EC methods have to be used except if not appropriate.

A report of the results of the various analyses carried out on the product by a laboratory approved for fertilizer analysis should also be added as supplementary information. If non-standard 'in-house' methods are used for some of the analyses, provide an annex giving full details, including a description of the method used to prepare the samples. The use of these not standardized methods has to be justified.

3.4. Proposal for inclusion in Annex I to Regulation (EC) No 2003/2003

Draw up a proposed entry based on the presentation adopted in Annex I to Regulation (EC) No 2003/2003 and the subsequent amendments thereto indicate their type designation and provide information in the appropriate columns.

3.5. Other information

Add any other information considered to be relevant and not covered in the previous chapters. As full a bibliography as possible will complete this chapter.

4. PROCEDURE FOR LODGING OF THE FILE

Any person (manufacturer or his representative) wishing to have a fertilizer designated as an 'EC fertilizer' must submit the above technical file to the Member State authorities.

The Member State concerned will then act as rapporteur for the file to the Working Party on Fertilizers of the Commission of the European Communities.

In the light of the conclusions of the Working Party on Fertilizers, the Commission will draft a proposal to adapt Annex I to Regulation (EC) No 2003/2003 which will be submitted to the Committee referred to in Article 32 of the above Regulation for an opinion, in accordance with the procedure laid down in Article 5 and 7 of Decision 1999/468/EC.

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