

Guide to the compilation of a technical file on application to designate a fertiliser as ‘EC fertiliser’

COMMUNICATION FROM THE COMMISSION

(Guide pursuant to Regulation (EC) No 2003/2003 relating to fertilisers with additional information relating to chelating agents, complexing agents, urease inhibitors and nitrification inhibitors)

(Text with EEA relevance)

INTRODUCTORY NOTE

This guide is intended to help applicants wishing to register a new fertiliser type for inclusion in the list of designated EC fertilisers. It is also intended to help applicants wishing to register a chelating agent, a complexing agent, a nitrification inhibitor or a urease inhibitor for inclusion in Annex I of Regulation 2003/2003. 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 Group 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 the information requirements for the technical file which will be evaluated by the Commission’s Working Group on Fertilisers in order to decide on requests for entries in Annex I to Regulation 2003/2003¹.

It is therefore a guide for any person (manufacturer or his representative) who wishes to submit a fertiliser or type of fertiliser for designation as ‘EC fertiliser’, or to submit a chelating agent, complexing agent, nitrification inhibitor or urease inhibitor for authorization for use with EC fertilisers.

¹OJ No L 304, 21.11.2003 Website: http://ec.europa.eu/enterprise/chemicals/legislation/fertilizers/index_en.htm

This information required in the technical file must show that the conditions set out in Article 14 of Regulation 2003/2003 are met: “A type of fertiliser may only be included in Annex I if:

- (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.”

Points (a) to (c) apply by analogy to chelating agents, complexing agents, nitrification inhibitor or urease inhibitors. For chelating agents or complexing agents it should be shown that the agent improves the transport of nutrients from the fertiliser to the plant so that nutrients are provided in an effective manner. For urease inhibitors and nitrification inhibitors, it should be shown that the inhibitor reduces the loss of nutrients to the environment, and that the inhibitor does not have any of the above-mentioned adverse effects.

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 Group and with advances in scientific and technical knowledge about fertilisers.

2. CONTENTS OF THE TECHNICAL FILE

The Technical File shall be written in the English language, must not exceed 40 pages and should refer to no more than 20 relevant studies in its annexes. The file must contain at least seven separate chapters:

- General information
- REACH₂ registration and hazard classification,
- 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 2003/2003,
- Any other relevant information.

The applicant should make every effort to report original data rather than results obtained from literature reviews. The applicant shall document all relevant available information.

3. DESCRIPTION OF THE INFORMATION REQUIRED IN EACH CHAPTER

3.1. General information

- (a) Member State authority acting as rapporteur
- (b) Manufacturer information
- (c) Contact person for technical file
- (d) Location of production sites
- (e) General product information

3.2. Information on health, the environment and safety

3.2.1. Safety data sheet

Give a safety data sheet in accordance with Article 31 of REACH.

Safety Data Sheet in English, French and German should be required for the registration process. Safety Data Sheets in all European languages should be made available for the Member States where the product will be marketed.

3.2.2. REACH registration data

Whenever possible³, registrants are advised to use the following information from the REACH registration:

- a) substance(s) identification and EC number(s) – when not available CAS classification will be accepted. If it is not technically possible or if it does not appear scientifically necessary to give more information on one or more of the substance identification parameter, the reasons shall be clearly stated,
- b) physico-chemical properties and hazard assessment of the substance or preparation,
- c) depending on the quantities manufactured or imported, toxicological hazard assessment of the substance(s) derived from the application of Annexes VII to XI of REACH,
- d) quantities manufactured or imported per year.

The level of detail needed to be reported depends on each situation. For key studies, it is important that as many details as necessary to describe the test protocol and justify the validity of the results are reported.

³ Registration deadlines under REACH run between 2010 and 2018 depending on the tonnage.

Toxicological and ecotoxicological tests should be carried out in compliance with the principles of good laboratory practice (GLP) provided by Directive 2004/10/EC⁴ or other international standards recognised as being equivalent by the Commission or the European Chemical Agency and with the provisions of Directive 86/609/EEC if applicable.

However, data on physicochemical properties and toxicological hazards of the substance(s) may be generated in accordance with other test methods provided that the conditions set out in Annex XI of REACH are met.

Robust study summaries from REACH (only for information from the application of Annexes VII to XI) can be used in this section of the technical file.

Information on intrinsic properties of substances may be generated by means other than tests, provided that the conditions set out in Annex XI of REACH are met. In particular for human toxicity, information shall be generated, whenever possible, by means other than vertebrate animal tests, through alternative measures like in vitro methods or qualitative or quantitative structure-activity methods ((Q)SAR) or from information from structurally related substances. Give the classification and labelling of the substance with respect to physicochemical properties, environment and human health. During the period that registration under REACH is not mandatory³, registrant are requested to provide the Working Group with equivalent information, in particular for substance(s) identification by EC number(s), physicochemical properties and hazard assessment of the substance(s) or preparation.

3.2.3. Additional information

In addition, list those constituents that have, or may have, an adverse effect on human or animal health or the environment, and their effects.

3.3. Agronomic data

3.3.1. Main effect and secondary effects

Describe the main effect obtained by application of the product under the conditions of use advocated (climate, soil, crop type) 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. In the case of chelating and complexing agents, the effects of the product on the uptake of nutrients should be described. In the case of urease and nitrification inhibitors, the effects of the product on the enzymatic inhibition should be described. 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.

⁴ http://ec.europa.eu/enterprise/chemicals/legislation/glp/index_en.htm

3.3.2. 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 kg of product per ha 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.

3.3.3. 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.

3.4. Details of the methods of analysis and results

Indicate the internationally recognized methods used to analyze the product: CEN, ISO, etc. CEN Standards are strongly recommended but not mandatory. 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.

An internationally recognized test method is needed for enforcement of the legislation. Therefore, 'in-house' methods will not be recognized as long as this method has not been evaluated and ring-tested by CEN. The cost for the development of EN Standards by CEN is for the applicant.

3.5. 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, indicating the type designation and provide information in the appropriate columns.

3.6. 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 SUBMITTING THE FILE

Any person (manufacturer or his representative) wishing to have a fertiliser, chelating agents, complexing agents, urease inhibitors and nitrification inhibitors designated as an 'EC fertiliser' must submit the above technical file to the Member State authorities, a list of which is also available at:

http://ec.europa.eu/enterprise/chemicals/legislation/fertilizers/national_en.htm

The Member State concerned will then act as rapporteur for the file to the Working Group on Fertilisers of the European Commission.

In the light of the conclusions of the Working Group on Fertilisers, the Commission will draft a proposal to adapt Annex I to Regulation 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.

Or further information please contact:

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