

COMMUNICATION FROM THE COMMISSION

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

(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 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.

² OJ No L396, 30.12.2006. Website : <http://echa.europa.eu/>

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) physicochemical 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 labeling 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.

**AUTHORITIES IN THE MEMBER STATES CONCERNED WITH THE REGISTRATION OF
NEW EC FERTILISERS**

Austria	Belgium	Cyprus	Czech Republic	Denmark
<p>Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH Bereich Landwirtschaft</p> <p>Spargeldstrasse 191 Postfach 400 A-1226 WIEN AUSTRIA</p> <p>Tel: + 43 50 555 34110 Fax: + 43 50 555 33233</p> <p>e-mail: franz.wernitznig@ages.at</p> <p>Web:</p>	<p>SPF Public Health, Food Chain Safety and Environment General Directorate Animals, Plants And Food Pesticide and fertiliser services Eurostation Bloc II, 7^{eme} étage Place Victor Horta 40, boîte 10 B-1060 BRUXELLES BELGIUM</p> <p>Tel: + 32 2 524.72.61 Fax: + 32 2 524.72.99</p> <p>e-mail: fytowe@health.fgov.be</p> <p>Web: https://portal.health.fgov.be</p>	<p>Ministry of Agriculture, Natural Resources and Environment Department of Agriculture Land and Water use Section</p> <p>CY-1412 NICOSIA CYPRUS</p> <p>Tel: + 357 22 305476 Fax: + 357 22 305494</p> <p>e-mail: doagrg@da.moa.gov.cy soilwater@da.moa.gov.cy</p> <p>Web: www.moa.gov.cy/da</p>	<p>Central Institute for Supervising and Testing in Agriculture</p> <p>ÚKZÚZ Hroznová 2 CZ-656 06 BRNO CZECH REPUBLIC</p> <p>Tel: + 420 569 430 438 Fax: + 420 569 430 412</p> <p>e-mail: pavel.cermak@ukzuz.cz</p> <p>Web: www.ukzuz.cz</p>	<p>Ministry of Food, Agriculture and Fisheries Plantedirektoratet</p> <p>Skovbrynet 20 DK-2800 LYNGBY DENMARK</p> <p>Tel: + 45 45 26 37 88 Or + 45 45 26 36 00</p> <p>Fax: + 45 45 26 36 10</p> <p>e-mail: mcl@pdir.dk or sfg@pdir.dk</p> <p>Web:</p>
			<p>Ministry of Agriculture of the Czech Republic Plant production department</p> <p>T•šnov 17 CZ-117 05 PRAHA 1 CZECH REPUBLIC</p> <p>Tel: + 420 221 812 071 Fax: + 420 221 812 705</p> <p>e-mail: budnakova@mze.cz</p> <p>Web: www.mze.cz</p>	

Estonia	Finland	France	Germany	Greece
<p>Plant Production Inspectorate</p> <p>Teaduse 2, EE-75501 SAKUESTONIA</p> <p>Tel: + 372 6712 651 Fax: + 372 6712 604</p> <p>e-mail: katrin.laud@plant.agri.ee</p> <p>Web: http://www.plant.agri.ee/</p>	<p>Ministry of Agriculture and Forestry</p> <p>P.O. Box 30 FI-00023 Government HELSINKI FINLAND</p> <p>Tel: + 358 9 160 88 073 Fax: + 358 9 160 24 43</p> <p>e-mail: pirjo.salminen@mmm.fi</p> <p>Web:</p>	<p>Ministère de l'Agriculture et de la Pêche - Direction Générale de l'Alimentation sous Direction de la Qualité et de la Protection des Végétaux - Bureau des Produits Antiparasitaires et des Matières Fertilisantes</p> <p>251 rue du Vaugirard F-75732 PARIS CEDEX 15 FRANCE</p> <p>Tel: + 33 1 49 55 81 41 Fax: + 33 1 49 55 59 49</p> <p>e-mail: mfsc.sdqpv.dgal@agriculture.gouv.fr</p> <p>Web: www.service-public.fr</p>	<p>Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft Referat 516A</p> <p>Postfach 14 02 70 D-53107 BONN GERMANY</p> <p>Tel: + 49 22 81 529 38 84 Fax: + 49 22 81 529 55 38 89</p> <p>e-mail: 516A@bmvvel.bund.de</p> <p>Web:</p>	<p>Ministry of Rural Development and Food Directorate General for plant production Directorate of inputs. Department D</p> <p>2, Archarnon Street GR-101 76 ATHENS GREECE</p> <p>Tel: + 30 210 2124106 Fax: + 30 210 2124137</p> <p>e-mail: ax2u207@minagric.gr</p> <p>Web: http://www.minagric.gr/en/index.html</p>
<p>Ministry of Agriculture of Estonia</p> <p>39/41 Lai St EE-15056 TALLINN ESTONIA</p> <p>Tel: + 372 62 565 07 Fax: + 372 62 562 00</p> <p>e-mail: renata.tsaturjan@agri.ee</p> <p>Web: http://www.agri.ee/</p>		<p>Direction générale de la concurrence, de la consommation et de la répression des fraudes</p> <p>Boulevard Vincent Auriol, 59 F-75703 PARIS CEDEX 13 FRANCE</p> <p>Tel: + 33 1 44 97 31 54 Fax: + 33 1 44 97 05 27</p> <p>e-mail: roselyne.roy@dgccrf.finances.gouv.fr</p> <p>Web: http://www.finances.gouv.fr/index.html</p>		<p>Ministry of finances. General Chemical State Laboratory Division of raw Materials and industrial Products. 16 An. Tsoha str. P.C. 115 21 ATHENS Greece</p> <p>Tel. + 30 210 6479264,-265 Fax.: + 30 210 6441648</p> <p>e-mail: gxx-industrial@ath.forthnet.gr</p> <p>Web: www.gcsf.gr</p>

Hungary	Ireland	Italy	Latvia	Lituania
<p>Central Agricultural Office, Directorate of Plant Protection, Soil Conservation and Agri-environment</p> <p>Budaörsi út 141-145. H – 1118 Budapest HUNGARY</p> <p>Tel: + 36 1 301 10 00 Fax: + 36 1 246 29 60</p> <p>e-mail: ntai@ntai.ontsz.hu</p> <p>Web : www.ontsz.hu</p>	<p>Department of Agriculture, Food and Rural Development</p> <p>Agriculture House Kildare Street IE-DUBLIN 2 IRELAND</p> <p>Tel: + 353 1 607 26 03 Fax: + 353 1 661 626</p> <p>e-mail: jim.fleming@agriculture.gov.ie</p> <p>Web :</p>	<p>Ministero delle politiche agricole e forestali Dipartimento della qualità dei prodotti agroalimentari e dei servizi Direzione Generale per la Qualità dei prodotti agroalimentari e la tutela del consumatore</p> <p>Via XX Settembre, 20 I-00187 ROMA ITALIA</p> <p>Tel: + 39 06 466 55 020 Fax: + 39 06 481 97 14</p> <p>e-mail: qualprod-tutconsum@politicheagricole.it</p> <p>Web :</p>	<p>State Plant Protection Service</p> <p>Republikas laukums 2, RIGA, LV-1981 LATVIA</p> <p>Tel: + 371 7027309 Fax: + 371 7027302</p> <p>e-mail: Skaidrite.rulle@vaad.gov.lv</p> <p>Web :</p>	<p>Ministry of Economy, Industry and Business Department, Product Technical Regulation Division Gedimino ave.38/2 LT-01104 Vilnius LITHUANIA</p> <p>Tel: + 370 5 2626810 Fax: + 370 5 2623974</p> <p>e-mail :</p> <p>Web :</p>
		<p>Ministero delle Politiche Agricole e Forestali <i>Ispettorato centrale repressione frodi</i></p> <p>Via XX Settembre, 20 I-00187 ROMA ITALIA</p> <p>Tel: + 39 06 474 38 82 Fax: + 39 06 488 10 41</p> <p>e-mail :</p> <p>Web: http://www.politicheagricole.it/</p>		

Luxembourg	Malta	Poland	Portugal	Slovakia
<p>Ministère de l'agriculture ASTA Laboratoire de contrôle et d'essais</p> <p>BP 75 L-9001 ETTTELBRUCK LUXEMBOURG</p> <p>Tel : + 35 2 8100 81 212 Fax : + 35 2 8100 81 333</p> <p>e-mail : rene.meyers@asta.etat.lu</p> <p>Web :</p>	<p>Foodstuffs, Chemicals & Cosmetics Directorate, Malta Standards Authority</p> <p>2nd Floor, Evans Buildings, Merchants Street, MT - Valletta VLT 03 MALTA</p> <p>Tel: + 356 21255546 Fax: + 356 21242420</p> <p>e-mail: martin.seychell@msa.org.mt</p> <p>Web :</p>	<p>Ministerstwo Gospodarki Pracy i Polityki Społecznej Departament Polityki Przemysłowej</p> <p>Pl. Trzech Krzyży 3/5 PL - 00-507 WARSZAWA POLAND</p> <p>Tel: + 48 22 693 56 35 Fax: + 48 22 693 40 32</p> <p>e-mail : krysen@mg.gov.pl renzna@mg.gov.pl</p> <p>Web : http://www.mgpips.gov.pl</p>	<p>Ministério da Economia e da Inovação Direção-Geral das Actividades Económicas 1069-041 LISBOA PORTUGAL</p> <p>Tel: + 351 21 791 91 00 Fax: + 351 21 796 51 58</p> <p>e-mail: margarida.belo@dgae.min-economia.pt</p> <p>Web : http://www.dgae.min-economia.pt</p>	<p>Ústredný kontrolný a skúšobný ústav poľnohospodársky Oddelenie registrácie hnojív</p> <p>Matuškova 21 SK - 833 16 BRATISLAVA SLOVAKIA</p> <p>Tel: + 421 2 547 758 22 <i>xt.202</i> Fax: + 421 2 546 512 03</p> <p>e-mail: z.brana@uksup.sk</p> <p>Web :</p>
		<p>Ministerstwo Rolnictwa i Rozwoju Wsi, Departament Hodowli i Ochrony Roślin</p> <p>Wspólna 30, PL - 00-930 WARSZAWA POLAND</p> <p>Tel: + 48 22 623 21 04 Fax: + 48 22 628 87 84</p> <p>e-mail : kinga.roslan@minrol.gov.pl tj@iung.pulawy.pl</p> <p>Web: http://www.minrol.gov.pl/</p>		

Slovenia	Spain	Sweden	The Netherlands	United Kingdom
<p>Mrs.Darja KROPIVŠEK Ministry of Agriculture, Forestry and Food Phytosanitary Administration of RS</p> <p>Einspielerjeva 6, SI-1000 Ljubljana SLOVENIA</p> <p>Tel: + 386 1 3094 432 Fax: + 386 1 3094 335</p> <p>e-mail: furs.mkgp@gov.si; darja.kropivsek@gov.si</p> <p>Web :</p>	<p>Registro de Productos Fertilizantes Dirección General de Agricultura Ministerio de Agricultura, Pesca y Alimentación</p> <p>C/ Alfonso XII, 62 3ª planta MADRID 28014 SPAIN</p> <p>Tel: + 34 91 3474086 Fax: + 34 91 3474087</p> <p>e-mail:</p> <p>Web : http://www.mapya.es</p>	<p>The Swedish Board of Agriculture Plant nutrient division</p> <p>S-551 82 JÖNKÖPING SWEDEN</p> <p>Tel: + 46 36 15 50 00</p> <p>e-mail : vaxtnaring@sjv.se</p> <p>Web : www.sjv.se</p>	<p>Ministerie van Landbouw, Natuur en Voedsel kwaliteit Directie Landbouw Cluster Milieu en Mestbeleid</p> <p>Postbus 20401 NL-2500 EK Den Haag NEDERLAND</p> <p>Tel: + 31 70 378 42 50 Fax: + 31 70 378 61 61</p> <p>e-mail : infotiek@minlnv.nl</p> <p>Web : http://www.minlnv.nl</p>	<p>Department for Environment, Food & Rural Affairs (DEFRA)</p> <p>Nutrient Management Unit Area 5c, 9 Millbank c/o 17 Smith Square London SW1P3JR UNITED KINGDOM</p> <p>Tel: + 44 20 7238 6756 Fax: + 44 20 7238 3082</p> <p>e-mail:</p> <p>Web : http://www.defra.gov.uk</p>
				<p>Ministry of Agriculture, Fisheries and Food Rural and Marine Environment Division</p> <p>Ergon House 17, Smith Square UK - London SW1 P3JR UNITED KINGDOM</p> <p>Tel: + 44 20 72 38 67 70 Fax: + 44 20 72 38 67 00</p> <p>e-mail :</p> <p>Web: http://www.maff.gov.uk/</p>

**AUTHORITIES IN EFTA MEMBER STATES CONCERNED WITH THE REGISTRATION OF
NEW EC FERTILISERS**

Iceland	Liechtenstein	Norway	Switzerland
<p>Adfangaeftirlit Feed, Seed and Fertilizer Inspectorate</p> <p>RALA-building, Keldnaholt IS – 112 REYKJAVIK ICELAND</p> <p>Tel: + 354 591 1590 Fax: + 354 591 1591</p> <p>e-mail: oli@adfangaefirlit.is</p> <p>Web :</p>	<p>Office for Environmental Protection Postfach 684 LI - FL 9490 Vaduz LIECHTENSTEIN</p> <p>Tel: + 423 2366194 Fax: + 423 2366199</p> <p>e-mail: manfred.frick@aus.llv.li</p> <p>Web :</p>	<p>Norwegian Food Safety Authority National Registration Section</p> <p>P.O. Box 383 N-2381 Brumunddal NORWAY</p> <p>Tel: + 47 64 94 44 00 Fax: + 47 64 94 44 10</p> <p>e-mail: marianne.johansen@mattilsynet.no</p> <p>Web : http://www.mattilsynet.no</p>	<p>Office Fédéral de l'Agriculture Division moyens de production Mattenhofstrasse 5 CH - 3003 Bern SWITZERLAND</p> <p>Tel: + 41 31 322 25 50 Fax: + 41 31 322 26 34</p> <p>e-mail: markus.hardegger@blw.admin.ch</p> <p>Web :</p>