



EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Chemicals, Metals, Forest-based & Textile Industries
Chemicals

Brussels, 16th December 2008
M/418 EN Rev. 2

AMENDMENT TO:
STANDARDIZATION MANDATE M/335
ASSIGNED TO CEN CONCERNING THE MODERNISATION OF THE
METHODS OF ANALYSIS OF FERTILIZERS

(1) BACKGROUNDS

This extension of the standardisation Mandate M/335 falls within the framework of the following legal act:

- Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers.

In order to avoid any improper use of the term “EC fertiliser” Member States are required to check not only the content of such fertilisers, but also the compliance of fertilisers with the requirements of this legal act.

The fact that the analytical methods mentioned in these legal acts have not been adapted to technical progress since 1975 has a consequence in practice that many of these methods are obsolete and can therefore constitute an obstacle to the efficiency of the controls that Member States are required to perform. Moreover some new types of fertilisers have been introduced in national markets and are now deemed to become “EC fertilisers”. Therefore, competent authorities require, whenever possible, the development of robust and flexible standardized methods adapted to the control of any straight or compound “EC fertiliser” by national approved laboratories.

As it is necessary also to facilitate the future adaptation to technical progress of these analytical methods, their updated version delivered by CEN will not be annexed to community law but will exist in the form of separate standards to which the community law will refer.

The Commission intends to propose amendments to the above-mentioned legal act in order to ensure that CEN standards can be considered as official methods of analysis to be used as reference for official controls.

The establishment of European standards for methods of analysis is of utmost importance to guarantee a uniform application and control of the European legislation in all Member States. Standardized methods of analysis are an indispensable element in guaranteeing a high level of quality and safety of EC fertilisers.

(2) BODIES TO BE ASSOCIATED

A request for the introduction of a new fertiliser type in the Annex I of Regulation (EC) N° 2003/2003 can be proposed by industry. Industry and CEN will cooperate to prepare a validated European Standard for the determination of this new product in straight or compound fertilisers. Items described under points c, d and e of the present mandate are concerned.

(3) JUSTIFICATION FOR AMENDMENT

In its Article 2, Mandate M/335 highlights that the Commission invites CEN to update and adapt to technical progress methods of analysis in order to be able to control in an efficient and modernised way the compliance with the provisions of Community legislation in the field of fertilisers for:

- All the methods of analysis described in the Annexes II, III and IV of Regulation (EC) 2003/2003 on fertilisers.
- Any other new methods of analysis in the field governed by the Community legislation on fertilisers if these are added to the list annexed to the present mandate by the Commission, after consultation of the Member States within the Standards and Technical Regulations Committee.

During a working group meeting on fertilisers (24.03.2006), the Member States requested a revision of the current mandate to include new items in the project planning of Annex I to Mandate M/335.

(4) NEW ELEMENTS TO BE ADDED IN THE ANNEX I OF MANDATE M/335

Regarding the previous elements, the current Mandate M/335 is to be extended to the following issues:

a) Tolerances on analytical methods

The Working Group on fertilisers requested an extension of the Mandate M/335 which covers the set-up of standards for analytical methods, to include tolerances as mentioned in Appendix II of Regulation (EC)2003/2003 for the fertilisers listed in Appendix IV. Ring testing of the various methods of analysis has shown that in a substantial number of cases the tolerances for nutrient content specified in Annex II of the Fertiliser Regulation are smaller than can be measured by the test methods as revised by CEN. Tolerances levels are meant to cover variations in manufacturing, sampling and analysis as well. To address this problem, CEN will suggest new tolerances values wherever required and these will be taken up in a future adaptation of the Regulation.

The concern was expressed by the Fertiliser Working Group that the tolerances should not be relaxed more than is strictly necessary in order to make the tolerances compatible with the accuracy of the analysis methods.

b) Instrumental methods for the determination of heavy metals in EC fertilisers

During the Fertiliser Working Group Meeting of 23.10.2006, Member States were concerned about the presence of excessive amounts of heavy metals in some inorganic fertilisers. A reliable instrumental analytic method is needed for the determination of

heavy metals in fertilisers similar to that already requested for the determination of Cadmium under Mandate M/335. Another objective should be to check the reliability of the present sampling methods in the context of traces analysis.

c) Analysis method for IDHA and lignosulphonates (chelating agents)

During the meeting of the Working Group on Fertilisers in October 2006, some Member States requested the validation of analysis methods for the determination of micro-nutrients chelated by D,L aspartic-N-(1,2-dicarboxyethyl)acid and for the determination of micro-nutrients complexed by lignosulphonates in “EC fertilisers” straight or compound. The setting of tolerances is also requested for both products.

A two step approach is required for the determination of micro-nutrients complexed by lignosulphonates. A first method of analysis will determine the complexed micro-nutrients total content and the complexed fraction of each micro-nutrient irrespective to the complexing agents. A second method of analysis will specifically identify lignosulphonates in micro-nutrient complexes. A similar methodology was used for the determination of micro-nutrients chelated by chelating agents (EN 13366 and EN 13368-1 and 2).

These new products, proposed by industry, will be considered for inclusion as “EC fertiliser” in Annex I provided CEN can afford a reliable European Standard.

d) Analysis method for nitrification inhibitors

During the meeting of the Working Group on Fertilisers in October 2006, Member States raised the question of the reliability of the existing methods for the detection of nitrification inhibitors in “EC fertilisers” straight or compound. Especially the determination of 1H-1,2,4-triazole (TZ) and the determination of 3-methylpyrazole (MP) were of concern. Member States asked for the validation of the existing methods as well as for tolerances for both products.

A similar work is currently on going under Mandate M/335 in CEN on DCD nitrification inhibitor.

These new products, proposed by industry, will be considered for inclusion as “EC fertilisers” in Annex I provided CEN can afford a reliable European Standard.

e) Determination of calcium formate

During the meeting in March 2007, the Working Group on fertilisers requested CEN to develop a European Standard for the determination of calcium and formate ion in “EC fertilisers” straight or compound. In the case of calcium determination, any possible interference with other cations should be avoided. The setting of tolerances is also required for calcium and formate ion.

This new fertiliser type, proposed by industry, will be considered for inclusion as “EC fertiliser” in Annex I provided CEN can afford a reliable European Standard.

CEN shall provide the Commission within 4 months after the acceptance of this standard mandate with a work program to be carried out.

DESCRIPTION OF THE MANDATED WORK:

CEN is requested to provide the deliverables in accordance with the modification of the original annex of Mandate M/335 as contained in the annex to this mandate amendment and within the time schedule stated.

The mandated work should be carried out in conjunction with other work being undertaken by CEN, with a view to preventing duplication and finding synergies with similarly developed methods and approaches that may be able to make use of the same validation and presentation of test results. In particular, the project HORIZONTAL should be considered in this regard as appropriate.

Project	Time estimation/remarks	Revision / Ring tests
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ANNEX

Mandated work programme covered by the present amendment (5 pages)

Project	Time estimation/remarks	Revision / Ring tests
<p><u>Tolerances</u> <u>Introduction of new tolerances as mentioned in Appendix II in accordance with the actual methods of analysis</u></p>	<p><u>Approval of new work item WI 00260111:</u> <u>Title:</u> "Review of tolerances referring to Annex II of the Regulation (EC) 2003/2003 relating to fertilisers" <u>Deliverable:</u> Technical Specification CEN/TS <u>Timing:</u> Approval of BT Resolution +48 months (Revision of TS every 3 years taking into account the statistical data of the methods which have been established and validated)</p>	<p>Tolerance figures have to follow the time table of the ring tests of the methods. They shall be based on the results of ring testing and the various methods of determination. Therefore it is an ongoing issue. For future items it should be the last step of method validation (proposal of tolerances).</p>

<p><u>Determination of heavy metals in fertilisers</u></p> <p><u>Four instrumental methods for the determination of the following heavy metals in “EC fertilisers” (Arsenic, Chromium VI, Lead, Mercury, Nickel). A similar standardized method already exists for the determination of Cd in “EC fertilisers”.</u></p> <ol style="list-style-type: none"> 1) Determination of mercury content in “EC fertilisers” 2) Determination of lead and nickel in “EC fertilisers” 3) Determination of chromium VI content in “EC fertilisers” 4) Determination of arsenic content in “EC fertilisers” 	<p>Approval of 4 new work items:</p> <p><u>Title:</u></p> <ol style="list-style-type: none"> 1) WI 00260110 “Fertilizers – Determination of the mercury content” 2) WI 00260109 “Fertilizers – Determination of the lead and nickel content” 3) WI 00260108 “Fertilizers – Determination of the chromium VI content” 4) WI 00260107 “Fertilizers – Determination of the arsenic content” <p><u>Four Deliverables:</u> 2-step-procedure</p> <ol style="list-style-type: none"> 1st step CEN/TS 2nd step EN <p><u>Timing:</u> TS: Approval of BT Resolution + 36 months EN: Approval of BT Resolution + 51 months</p> <p>Analytical methods based on the information available. Final adjustment on the number of heavy metals to analyse could be necessary after input of the sub-group on heavy metals. Inclusion in a new extension of M/335 is being actively considered.</p>	<p>Ring tests are required since very high expertise is necessary.</p>
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Project	Time estimation/remarks	Revision / Ring tests
<p><u>Nitrification inhibitor</u></p> <p><u>Determination of 1H – 1,2,4 – triazole for solid “EC fertilisers”</u></p> <p>Check if, in combination with DCD in the ratio (DCD:TZ) (10:1), both components can be easily detected.</p> <p>DCD determination using pr EN 15360: “determination of dicyandiamide – Method using HPLC”</p>	<p>Requested by Member States during the WG meeting on 23.10.06</p> <p>Approval of a new work item: WI 00260105</p> <p><u>Title:</u> "Fertilizers – Determination of 1H, 2,4 – triazole (TZ) using high performance liquid chromatography (HPLC)"</p> <p><u>Deliverable:</u> EN</p> <p><u>Timing:</u> Approval of BT Resolution + 36 months</p>	
<p><u>Determination of 3-methylpyrazole for liquid “EC fertilisers” in the ratio (2:1) in “EC fertilisers”</u></p> <p>Check if, in combination with 1H – 1,2,4-triazole in the ratio (TZ:MP) (2:1), both components can be easily detected.</p>	<p>Requested by Member States during the WG meeting on 23.10.06</p> <p>Approval of a new work item: WI 00260106</p> <p><u>Title:</u> "Fertilizers – Determination of 3-methylpyrazole (MP) using high performance liquid chromatography (HPLC)"</p> <p><u>Deliverable:</u> EN</p> <p><u>Timing:</u> Approval of BT Resolution + 36 months</p>	

Project	Time estimation/remarks	Revision / Ring tests
<p><u>Chelating agents</u></p> <p>Determination of micronutrients chelated by <u>D,L aspartic-N-(1,2-dicarboxyethyl)acid (IDHA) in “EC fertilisers”</u></p>	<p>Requested by Member States during the WG meeting on 23.10.06</p> <p>Approval of a new work item: WI 00260103</p> <p><u>Title:</u> "Fertilizers – Determination of micronutrients chelated by D,L aspartic-N-(1,2-dicarboxyethyl)acid in fertilisers"</p> <p><u>Deliverable:</u> EN</p> <p><u>Timing:</u> Approval of BT Resolution + 36 months</p>	
<p><u>Complexing agents</u></p> <p>1) A two step approach is required to determine the content of micro-nutrients complexed by lignosulphonates in “EC fertilisers”.</p> <p>- a general method to determine the complexed micro-nutrients content and the complexed fraction of micro-nutrients</p> <p>- a specific method to identify lignosulphonates in micro-nutrients complexes</p>	<p>Requested by Member States during the WG meeting on 23.10.06</p> <p>Approval of a new work item: WI 00260104</p> <p><u>Titles:</u></p> <p>"Fertilizers – Determination of the complexed micro-nutrients content and of the complexed fraction of micro-nutrients"</p> <p>"Fertilizers – Identification of lignosulphonates in micro-nutrient complexes"</p> <p><u>Deliverable:</u> EN</p> <p><u>Timing:</u> Approval of BT Resolution + 36 months</p>	

Project	Time estimation/remarks	Revision / Ring tests
<p><u>Calcium formate</u></p> <p>Determination of calcium and formate in “EC fertilisers”</p> <p><u>Detection of calcium should not be inhibited or distorted by the presence of other cations</u></p>	<p>Requested by Member States during the WG meeting on 13.03.2007</p> <p>Approval of a new work item : WI 00260112</p> <p><u>Title: “Fertilizers – Determination of calcium and formate in EC fertilisers”</u></p> <p>Deliverable: EN</p> <p>Timing: Approval of BT Resolution + 36 months</p>	