



**EUROPEAN COMMISSION**  
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL  
Chemicals, Metals, Forest-based & Textile Industries  
**Chemicals**

**Version 4**

**12 April 2011**

**QUESTIONS AND AGREED ANSWERS**  
**CONCERNING THE IMPLEMENTATION OF REGULATION (EC) No 2003/2003**  
**RELATING TO FERTILISERS**

## Table of contents

1. INTRODUCTION.....	3
2. TESTING OF AMMONIUM NITRATE FERTILISERS UNDER ARTICLE 27 .....	3
3. CLARIFICATION OF THE DEFINITION OF “MANUFACTURER” .....	4
4. ACCREDITATION OF LABORATORIES UNDER ANNEX V.....	4
5. DECLARATIONS OF THE SOLUBILITY OF THE P <sub>2</sub> O <sub>5</sub> CONTENT OF PHOSPHATE FERTILISERS .....	5
6. LABELLING REQUIREMENT FOR MIXTURES OF MICRONUTRIENTS .....	5

## 1. INTRODUCTION

This document gathers some questions and agreed answers concerning the interpretation of Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers.

The answers were discussed and agreed between the Commission services and the representatives from the Member States in the Working Group on Fertilisers. It attempts to provide guidance to both Member States and economic operators.

These answers represent the opinion of the Commission services but may not necessarily represent the opinion of the Commission. This guidance document does not constitute any formal commitment on behalf of the Commission. Only the European Court of Justice can give an authoritative interpretation of Community legislation.

This guidance document will be regularly updated and published on the website of the European Commission.

## 2. TESTING OF AMMONIUM NITRATE FERTILISERS UNDER ARTICLE 27

**Question:** Article 27 requires the importer/manufacture to submit results of the test of resistance to detonation to the competent authority of the Member State five days before the fertiliser is imported or placed on the market. Thereafter the manufacturer shall continue to guarantee that all supplies of the fertiliser are capable of passing the detonation test. The question has arisen of how long such test results should be considered valid, and how can a manufacturer guarantee that his product is in compliance?

**Answer:** No period of validity for test results is foreseen in the Regulation. This is the result of a decision taken by the Council Working Party during the co-decision procedure where, after debate, it was decided that it would not be appropriate to specify one single period of validity for the test results.

Member States should therefore decide on a case-by-case basis how long test results should remain valid. They should take such a decision based on their confidence in the ability of the manufacturer/importer to continue supplying fertiliser to the specification of the sample that passed the test. The level of confidence should, however, be based on objective criteria, and excessive testing should be avoided.

For example, a manufacturer who produces fertiliser in a plant that is capable of delivering a reproducible product, and for which there is adequate quality control and record-keeping, might be considered by the Member States, after inspection of the plant, to provide the necessary guarantee through his plant records. On the other hand, an importer who receives supplies from a variety of manufacturing plants that are not accessible to inspection by the Member State might be required to provide test results for each shipment.

### 3. CLARIFICATION OF THE DEFINITION OF “MANUFACTURER”

**Question:** According to Article 2(x), the term “manufacturer” means the natural or legal person placing the fertiliser on the market. The definition goes on referring to producers, importers, packagers and distributors. The question has arisen whether this definition could apply to an operator changing the label of a national fertiliser into an “EC fertiliser” standard labelling.

**Answer:** the important act for the purpose of the fertilisers Regulation is to place an “EC fertiliser” on the market, in other words, to supply it to the market. By changing the reference of the label into “EC-type” fertiliser, the operator becomes the person placing the EC fertiliser on the market, and therefore, the manufacturer.

Article 7 (1) states that the manufacturer shall provide EC fertilisers with the identification markings listed in Article 9. As one of the markings listed in Article 9 is the words “EC fertilisers”, the operator becomes the manufacturer by changing the national label into an EC fertiliser labelling.

When a person is supplying an “EC fertiliser” to the market, his name or trade name and his address should appear on the label. If another person is marketing the same product to the national market, without the designation “EC fertiliser”, this person is not subject to the rights and obligations that derive from the Fertiliser Regulation and must comply instead with national legislation.

In Regulation (EC) No 2003/2003, manufacturers are directly responsible for the conformity of the EC fertilisers with the provisions of this Regulation. By making the claim that the EC fertiliser conforms to all the requirements of the Regulation, the person changing the national label may infringe some of its provisions (for example, the tolerances of Annex II, which a distributor is probably not in position to know). In that case, he may be subject to the penalties referred to in Article 36.

The European Court of First Instance has previously recognized, in other context, that a distinction must be made between the information content of the label and the language used to present that information (case C- 33/97). According to this ruling, an accurate translation does not change the information content and such a translation is therefore not considered to be a change to the labelling. Within the meaning of the Fertiliser Regulation, a person who affixes an accurate translation to a package would therefore not be considered to be a manufacturer. An inaccurate translation which changes the information content of the label would however constitute a change to the labelling, and the person who does this assumes the responsibilities of a manufacturer.

### 4. ACCREDITATION OF LABORATORIES UNDER ANNEX V

**Question:** Annex V.B.1 lays down that laboratories authorized to provide services for checking the compliance of EC fertilisers shall be accredited in accordance with EN ISO/IEC 17025, for at least one of the methods of Annex IV. Does this mean that a laboratory accredited for just one method can be authorized to perform all methods of Annex IV?

**Answer:** No. The laboratory must be accredited for each of the analysis methods that are actually used in official controls.

From the requirements for laboratories given in Article 30 of the Regulation as well as in Annex V, it is clear that the laboratories must meet four conditions before a Member State can make valid use the test results to check the compliance of EC fertilisers in order to enforce the legislation. Those conditions are: competence, accreditation, approval and notification.

According to Article 30, laboratories first have to be competent to carry out the necessary services for checking compliance of EC fertilisers, and they have to prove that competence through EN ISO/IEC 17025 accreditation. The Member State may then approve the laboratory and notify the Commission.

It would not seem plausible that a MS could make use in court of test results from an approved laboratory unless the analysis method that was used was included in the quality manual that is needed for accreditation, otherwise the laboratory could not demonstrate its competence.

The mention of “at least one of the techniques of Annex IV” in the Annex V text therefore does not absolve the MS or the laboratory concerned from being accredited for other test methods. Rather, the reverse is true: it means that it is a prerequisite for a test method to be included in the accreditation before the test results may be used in official controls.

EN ISO/IEC 17025 accreditation is a general standard for any testing laboratory and has no particular requirements for testing of fertilisers. Changes introduced in the 4<sup>th</sup> ATP of the Fertiliser Regulation (i.e. the words underlined in the question) ensure that there is a link to the testing of fertilisers. The new wording alerted manufacturers and Member States to the fact that the laboratories must be accredited for specific test methods, i.e. that in order to conform to the requirements of the Regulation the relevant test method must be included in the quality manual that is needed for accreditation of the laboratory.

## **5. DECLARATIONS OF THE SOLUBILITY OF THE P<sub>2</sub>O<sub>5</sub> CONTENT OF PHOSPHATE FERTILISERS**

**Question:** Regulation (EC) No 2003/2003 requires the P<sub>2</sub>O<sub>5</sub> content in NP and NPK fertilisers to be declared in accordance with the solubility in various media, for example: (1) in water, (2) in neutral ammonium citrate, and (3) in neutral ammonium citrate and in water. Whereas there are methods specifically designated in Annex IV to determine solubility (1) and (2), namely Method 3.1.6 and Method 3.1.4 respectively, there is no method specifically designated to determine solubility (3). How should the solubility in neutral ammonium citrate and in water be determined?

**Answer:** Method 3.1.4 should be used to determine solubility (3). The water content of the neutral ammonium citrate solution is sufficient to extract the phosphate that is soluble in neutral ammonium citrate and in water. Solubilities (2) and (3) are therefore identical and differ only in name.

## **6. LABELLING REQUIREMENT FOR MIXTURES OF MICRONUTRIENTS**

**Question:** Commission Regulation (EU) No 137/2011 introduced two mixed micronutrient fertiliser types with labelling provisions that go beyond the requirements of Articles 6(6) and 23(2) of the Regulation (EC) No 2003/2003. Which labelling rules should be applied?

**Answer:** Either set of rules may be used.

The existing rules contained in Article 6, 9 and 23 were not repealed when the more detailed rules were introduced by Regulation 137/2011. The new rules in Table E.2.4 essentially reproduce the existing rules as set out in Articles 6, 9 and 23, but also require some additional labelling information on the mineral anions present and the micro-nutrient water-soluble content. Fertilisers that comply with the new rules therefore automatically comply with the pre-existing rules as well. However, the new rules have not replaced the old rules. Consequently, fertilisers that comply with the rules on labelling that are set out in the articles of the Fertiliser Regulation do not need relabeling, despite the entry into effect of the new rules on 9 March 2011.

The Commission will try to improve the coherence of the labelling rules for mixed micronutrient fertilisers as soon as possible in a future ATP while retaining the original objective of introducing a specific type 'mixture of micronutrients' in Annex I to make this fertiliser type fully compliant with the requirements of Article 3 of the Regulation. Once the new legislation is adopted, this entry in the FAQ document will be deleted.