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QUESTIONS AND AGREED ANSWERS

CONCERNING THE IMPLEMENTATION OF REGULATION (EC) No 2003/2003

RELATING TO FERTILISERS

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1. INTRODUCTION

This document gathers some questions and agreed answers concerning the interpretation of Regulation (EC) No 003/2003 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 Fertiliser 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 of 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 4th 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 P₂O₅ CONTENT OF PHOSPHATE FERTILISERS

Question: Regulation (EC) No 2003/2003 requires the P₂O₅ 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 MICRO-NUTRIENTS

Question: Commission Regulation (EU) No 137/2011 introduced two mixed micro-nutrient 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 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 micro-nutrient fertilisers as soon as possible in a future ATP while retaining the original objective of introducing a specific type 'mixture of micro-nutrients' 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.

7. RULES ON MICRO-NUTRIENT CHELATE, MICRO-NUTRIENT SOLUTION AND MICRO-NUTRIENT COMPLEX

Question: The rules on micro-nutrients have been amended in Commission Regulation (EC) No 137/2011 and Commission Regulation (EC) No 223/2012 in view of the harmonisation of their requirements. Could the Commission clarify the new rules by describing the labelling of such micro-nutrient fertiliser types?

Answer: To illustrate the different labelling provisions, copper is taken as an example:

a) Copper chelate (type 3d)

Mandatory labelling:

Copper chelate

Water-soluble Copper (Cu): 6%

Copper (Cu) chelated by (o,o) EDDHA: 3%

Copper (Cu) chelated by EDTA: 2%

If a product contains a chelating agent that does not chelate at least 1% of the water-soluble copper (e.g. 0.8% EDDHSA), the name of this chelating agent cannot appear in the label. However, the sum of the chelated form can optionally be declared.

Optional labelling:

Total copper (Cu) chelated by authorised chelating agents: 5.8% (i.e. in our example: 3%+2%+0.8%)

b) Copper fertiliser solution (type 3f)

The former product diluted in water would give:

Mandatory labelling:

Copper fertiliser solution

Mineral anions present: sulphate and chloride

Authorised chelating agents: (o,o) EDDHA, EDTA

Water-soluble copper (Cu): 3%

Copper (Cu) chelated by (o,o) EDDHA: 1.5%

Copper (Cu) chelated by EDTA: 1%

Optional labelling:

Total copper (Cu) chelated by authorised chelating agents: 2.9%

c) Copper complex (type 3i)

Mandatory labelling:

Copper complex

Lignosulphonate

Water-soluble copper (Cu): 5% (*at least*)

Copper (Cu) complexed: 4% (*at least*)

Authorised complexing agent: LS

8. SOLUTIONS OF MICRO-NUTRIENT FERTILISER

Question: Data on method of production of micro-nutrient solutions allow the use of micro-nutrient salts and/or micro-nutrient chelate or micro-nutrient complex. A clarification is needed to explain which combinations of such fertiliser types are allowed.

Answer: For copper fertiliser solution, the following combinations would be permitted:

Copper salts, or

Copper chelates, or

Copper complex, or

Copper salts and copper chelates, or

Copper salts and one copper complex.

The current analytical methods do not allow the combination of micro-nutrient salts, micro-nutrient chelates and micro-nutrient complex(es).

9. EXAMPLE OF LABELLING FOR MIXTURES OF MICRO-NUTRIENTS

Question: Commission Regulation (EC) No 223/2012 clarified the rules for mixtures of fertilisers in a revised Table E.2.4 by referring directly to the Articles of the Fertiliser Regulation. Could the Commission clarify the labelling requirements by giving an example of labelling for such micro-nutrient fertiliser?

Answer: The following table shows an example of labelling for mixtures of micro-nutrient fertiliser. A reference to the Articles of the Fertiliser Regulation is given in column 2 for information. As the current methods of analysis do not allow identifying which fraction of micro-nutrient is complexed by a specific complexing agent, the

labelling should bear the percentage of micro-nutrient complexed and the name of the complexing agent(s).

| | |
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| EC FERTILISER | Art 9(a), 1st bullet |
| Mixture of micronutrients Boron (B) (sodium), Cobalt (Co) (sulphate), Copper (Cu) (oxide, chloride), Iron (Fe) (sulphate) | Art 23(2) Each micronutrient present is followed by the name(s) of its counter-ion(s). |
| Water-soluble Boron (B) 1% Total Copper (Cu) 3% Water-soluble Copper (Cu) 1.6% Copper (Cu) chelated by EDTA 0.6% Water-soluble Cobalt (Co) 0.02% Water-soluble Iron (Fe) 2% Iron (Fe) chelated by [o,o] EDDHA 0.5% Iron (Fe) complexed 0.5% Complexing agent: LS | Art 6(6) i Art 6(6) ii Art 6(6) last para Art 9(1) (a), 6,7 bullet |
| « To be used only where there is a recognised need. Do not exceed the appropriate dose rate » | Art 23(5) |

10. CLARIFICATION ON THE USE OF SEVERAL UREA CONDENSATES IN THE PRODUCTION OF COMPOUND FERTILISERS

Question: Tables B.1.2, B.2.2 and B.3.2 of Annex I to Regulation (EC) No 2003/2003 allow the use of crotonylidene diurea (CDU) **or** isobutylidene diurea (IBDU) **or** urea formaldehyde (UF) in the manufacture of NPK, NP and NK EC fertilisers. The wording ‘**or**’ has proven not to be without ambiguity. Two conflicting interpretations can be made: either that a cumulative presence of the 3 substances is allowed or that only an individual use of those substances is allowed.

Answer: The use of different combinations of CDU, IBDU and UF is acceptable. An inclusive interpretation of ‘or’ should be made to allow for the cumulative presence of the three substances in a given urea condensate. Those substances all have the same agronomic objective (slow release of nitrogen). Furthermore, EN 15705 (method B) allows the determination of the presence of IBDU, CDU and UF in compound fertilisers so that each substance can be individually detected in commercial products.

11. NUMBERS INDICATING THE PHOSPHORUS CONTENT IN COMPOUND FERTILISERS

Question: According to Article 19.2.ii of Regulation (EC) No 2003/2003, the type designation of compound fertilisers shall be followed by numbers indicating the primary

nutrient content. A question has been raised on how the phosphorus solubility has to be expressed in products free from Thomas slag, calcined phosphate, aluminium-calcium phosphate, partially solubilised rock phosphate and soft ground rock phosphate (Types B.1.1.1, B.2.1.1 and B.4.1 of Annex I). It appears that some producers have marketed such EC fertilisers by declaring the phosphorus content as the sum of the phosphorus soluble in neutral ammonium citrate and in water plus the phosphorus soluble in mineral acid only. Is that practice allowed under the rules of Regulation (EC) No 2003/2003?

Answer: Fertiliser producers can use different sources of phosphorus in the manufacture of NPK fertilisers. They can either use water soluble phosphates (monoammonium phosphate, diammonium phosphate, TSP, SSP) or choose to use sources that are hardly soluble in water (rock phosphate, partially solubilised rock phosphate...).

The first case corresponds to products complying with types B.1.1.1, B.2.1.1 and B.4.1 in which case the Fertilisers Regulation specifies that the quantity of phosphorus P soluble in mineral acids only must be less than 2% and cannot be declared.

It follows that under a correct application of Regulation (EC) No 2003/2003, the only forms of phosphorus that can be declared for products corresponding to entries B.1.1.1, B.2.1.1 and B.4.1 of Annex I are the following:

- (1) Water-soluble P_2O_5 ;
 - (2) P_2O_5 soluble in ammonium citrate;
 - (3) P_2O_5 soluble in neutral ammonium citrate and in water;
- depending on the actual content of water-soluble P_2O_5

Therefore, the number indicating the phosphorus content after the type designation for compound fertilisers free from Thomas slag, calcinated phosphate, aluminium-calcium phosphate, partially solubilised rock phosphate and soft ground phosphate has to be expressed as the solubility in neutral ammonium citrate and in water or as the solubility in neutral ammonium citrate.

12. ORGANIC MATTER IN EC FERTILISERS

Question: Can a product belong to one of the EC fertiliser types listed in Section B or C.2 (i.e., type B.1.1, B.1.2, B.2.1, B.2.2, B.3.1, B.3.2, B.4, C.2.1, C.2.2, C.2.3, C.2.4, C.2.5, C.2.6, C.2.7, or C.2.8; hereinafter the 'compound fertiliser types') ,of Annex I to Regulation (EC) No 2003/2003 (hereinafter 'the Fertilisers Regulation'), if organic matter of animal or vegetable origin is added to the product?

Answer: A product cannot belong to one of the compound fertiliser types, if organic nutrients of animal or vegetable origin have been added to the product. This follows from the "Data on method for production" specified for each of the compound fertiliser types.

In theory, if an organic matter would be entirely free of any plant nutrient, a product could belong to one of the compound fertiliser types even if that organic matter had been added to the product.¹ However, this scenario is highly unlikely, since organic matter will always contain traces of plant nutrients.

¹ The Spanish language version of the Fertilisers Regulation gives an indication to the contrary. However, most – if not all – the other language versions support the view taken in this document, and must therefore be seen as prevailing.

Therefore, the Commission services competent for fertilisers conclude, that a product *cannot* belong to one of the compound fertiliser types if organic matter of animal or vegetable origin has been added to the product.

13. PHOSPHONATES IN FERTILISERS

Question: Potassium phosphonates (potassium phosphonate and disodium phosphonate) are recognised as active substance according to Regulation (EC) No 1107/2009. Annex I to the Fertilisers Regulation does not contain any type designation for monopotassium phosphonate but phosphonate are often found as source of phosphorus in compound fertilisers. Several Member States have expressed concerns that phosphonates do not have fertiliser action but rather fungicidal properties and but can lead to residues that can have consequences as regards the compliance of plant commodities with food law. Can phosphonates be added to fertilisers and be labelled as EC fertilisers?

Answer: The Commission Units responsible for regulation of fertilisers and PPPs note, that any product, which consists of, or contains potassium phosphonates, and is intended for one of the uses listed in Article 2(1) of the PPPR (i.e., e.g., protecting plants from harmful organisms), is considered as a PPP and hence requires an authorisation. In view of current knowledge of the mode of action of potassium phosphonates (in particular its fungicidal properties, as well as the hitherto weak evidence of any significant nutritional effect for plants), this is presumed to be the intended use of any product consisting solely of, or intentionally incorporating, that substance.

In consequence, any product which consists of or intentionally incorporates potassium phosphonates can only be placed on the market and used if authorised for that specific use under the PPPR, unless it can be proven that the product is intended to be used solely for purposes *other* than those listed in Article 2(1) of the PPPR (i.e., e.g., other uses than that of protecting plants through the fungicidal properties of that active substance), which would be for the company placing the product on the market to demonstrate.

PPPR authorisation requirements would apply also in a case, where that product (be it a substance or a mixture) was marketed as a fertiliser, either based on compliance with any national rules, or as an EC fertiliser based on compliance with one of the type designations in Annex I to Regulation (EC) No 2003/2003. Label claims or user instructions related to the use of that mixture for the sake of its fertilising properties may not contradict the requirements contained in the PPPR authorisation.

As indicated in a letter of 1 September 2014, addressed to stakeholders by the Commission Unit responsible for regulation of PPPs, regardless of the legal status of products containing phosphonates, phosphonate residues fall within the scope of Regulation (EC) No 396/2005. It is therefore the responsibility of food business operators to find solutions to ensure compliance with the Maximum Residues Levels (MRLs) at 2 mg/kg, which will be applicable again from 1 January 2016. Producers of the concerned food products should thus consider discontinuing the use of such products and investigate the use of alternative fertilisers that do not lead to non-compliances with the EU MRLs.