

From:
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To:
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Importance: High

Dear

After the publication of the Roadmap for the New Fertilizer regulation (attached), and the new options envisaged by DG Grow (optional harmonization of a combination between two options, the list of ingredient and an adaptation of the "New Legislative Framework"), we have published a new short position paper (attached, dated 3 November 2015) to express our comments and recommendations.

I also attach our original official position paper, published at the end of the procedure initiated by DG Grow (dated 31 August 2014), more detailed but referring to the proposal made at that time: a full harmonization using strictly the "New Legislative Framework".

Please share with your colleagues involved, and I will come back to you by end of next week.

Have a good day

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3 November 2015

NEW FERTILIZER REGULATION

POSITION OF FERTILIZERS EUROPE

ON THE

ROADMAP FOR THE REVISION OF THE FERTILIZERS REGULATION (EC) N° 2003/2003

OCTOBER 2015

As outlined in previous position papers, Fertilizers Europe supports a fertilizer regulation which guarantees that fertilizers available on the market:

- ✓ provide a **true agronomic** function, i.e. provide nutrients to plants in a plant-available form,
- ✓ are **adequately labelled** as to allow European farmers to make the best choice for their cropping system and make the best use of the products, and
- ✓ **do not** generate a **negative impact** on health or the environment.

We note that the revision of the Fertilizer Regulation will be now included in the EU Commissions' "**Circular Economy Package**".

We understand also that the revision will be most likely based on a combination of **option 3** (Positive ingredient list) and **option 5** (New Legislative Framework adapted to the potential risks of categories of products), and that these options would be applied under an OPTIONAL HARMONIZATION, as described in the **Roadmap** of October 2015.

Below our preliminary comments on these options:

1) Concerning the **Positive INGREDIENT LIST** of the **inorganic fertilizer** category:

- a. The **initial regulation** should contain a list of known and uncontested fertilizer ingredients which would be to a large extent built on the existing fertilizer regulation (EC) 2003/2003, and on the main products currently registered at national level.
- b. The eligible fertilizer **ingredients should be defined** according to their:
 - production process,
 - chemical formula (if available),
 - inherent properties,
 - nutrient content,
 - nutrient form and availability for plants.
- c. Before **new fertilizer ingredients** can be added to the positive list of eligible ingredients for fertilizer production, they should be assessed by **JRC, CEN** or other official certification body.

- d. For the production of an **inorganic fertilizer** the manufacturer is free to combine ingredients, following the compatibility rules for mixtures to ensure safety aspects. The final product should however comply with the ESSENTIAL REQUIREMENTS of the category, and especially the minimum nutrient content, the nutrient forms and an organic carbon content below 1%.

2) Concerning the ESSENTIAL REQUIREMENTS of the **inorganic fertilizer** category:

a. Nutrient forms:

Positive lists of the nutrient forms allowed for nitrogenous and phosphorus fertilizers should be defined:

- i. A positive list of forms is a very efficient way to support the compliance of fertilizer products, at the same time with the safety concerns and with ensuring a fertilizing function.
- ii. Nutrient forms currently allowed for inorganic fertilizers are:
 1. **Nitrogen forms**: ammoniacal N, nitric N, ureic N, N from urea formaldehyde, N from Isobutylidene diurea, N from crotonylidene diurea.
 2. **Phosphorus form**: phosphatic P.
- iii. A new nitrogenous or phosphorus inorganic form should pass an **EU type examination** to be included in the existing list by delegated act.

b. For inorganic phosphorus fertilizers:

A minimum solubility level should be fixed for each of the solubility types, to avoid that plant-unavailable phosphorus materials are put on the market as "fertilizer", to the detriment of farmers and the environment.

The **types and minimum solubility levels** qualifying a phosphorus material as fertilizer are:

- Water solubility minimum level of **40%** of total P
- Solubility in neutral ammonium citrate minimum level of **75%** of total P
- For soft rock only, solubility in formic acid minimum level of **55%** of total P

P content and solubility will be labelled only when above one of the minimum solubility levels

c. Labelling:

Labelling must be mandatory, extensive and controls by competent authorities should be carried out. All parameters related to agronomic function (nutrient content, nutrient form and solubility) must be clearly labelled on any fertilizer sold. Certain key definitions necessary to be labelled for better application by farmers, like **complex fertilizers** and **blended fertilizers**, must be clearly defined in the core text of the regulation.

3) Concerning the OPTIONAL HARMONIZATION:

We support this variant of implementation which facilitates a quick implementation of the new regulation. Moreover, national producers interested to have their products on the EU wide **Internal Market** should ensure and demonstrate the compliance of their products with the harmonized ESSENTIAL REQUIREMENTS of the relevant category.

To conclude we would like to highlight that **the inorganic fertilizer industry is constantly innovating and performing research** to produce products that better match the needs of the plant, such as: urease inhibitors and other additives that contribute to a better control of the release of nutrients.

31/08/2014

NEW FERTILIZER REGULATION

POSITION OF FERTILIZERS EUROPE

ON

THE “RESULTS OF THE TECHNICAL WORKING GROUPS FOR THE REVISION OF THE FERTILIZER REGULATION”,
PRESENTATION AND COMMENTS MADE BY DG ENTERPRISE ON 19/11/2012,
AND ON THE PRESENTATIONS AND COMMENTS MADE BY DG ENTERPRISE ON 17/03/2014 AND 2/06/2014

INTRODUCTORY STATEMENT

FERTILIZERS EUROPE is supporting a fertilizer regulation where all products put on the market provide a true agronomic function, are well defined and controllable and do not generate a negative impact on health or the environment.

In that respect, Fertilizers Europe is of the opinion that the existing legislation (Regulation EC 2003/2003) has proven to be a good piece of legislation with many positive aspects. Especially the precise product definition as provided by the “type designation” has helped to guaranty the agronomic value of the products and to address safety concerns.

Fertilizers Europe takes note of the wish of DG Enterprise to opt for a fully harmonized legislation on plant nutrients based on the “New Approach principles”, inducing the abandonment of the “type designation”.

In this context, Fertilizers Europe strongly underlines the new legislation must ensure that only products which have a true agronomic function providing nutrients can be put on the market as a fertilizer.

It is also vital that safety concerns can be adequately handled within the framework of a more horizontal legislation.

Finally, European farmers must be provided with all the information necessary for optimum choice and best use of these products.

Fertilizers Europe is striving to have the quality of inorganic fertilizers duly differentiated, valued and communicated to the market through product standards and appropriate labelling.

We wish in this document to express our position on the future regulation, and more specifically for the sub category inorganic fertilizers.

1) INSIDE THE TEXT OF THE NEW REGULATION:

⇒ In the core text of the New Regulation - Definitions:

During the preparatory phase, in 2012, significant efforts and time have been dedicated to defining product categories, sub-categories, products and product mixtures. We would like to stress the following points:

- **Inorganic fertilizer:** Fertilizers Europe supports the definition proposed by DG Enterprise in the FWG meeting of 19 November 2012. This definition reads as follows:

“Inorganic fertiliser” means a fertiliser without organic material other than those defined as additives. By convention, products such as urea and its condensation products, chelated and complexed micronutrients are recognised as inorganic fertilisers.

- **Mixtures:** Fertilizers Europe considers that a product resulting from mixing ingredients issued from different categories or sub-categories is a mixture and should be labelled as such. All ingredients of the mixture should comply with quality and safety requirements of their respective categories or sub-categories.

- Fertilizers Europe considers essential to differentiate **“Complex fertilizers”** and **“Blended fertilizers”**:

“Complex fertilizers” are obtained by chemical reaction, and/or by solution, and/or in its solid state by granulation or compaction. The resulting characteristic is that, for solid fertilizers, each granule has exactly the same composition, whether it contains one or several nutrients.

“Blended fertilizers” are obtained by dry mixing of several fertilizers, with no chemical reaction.

This differentiation is justified for three important reasons:

- **Quality:** The homogeneity of all granules of complex fertilizers offers a more even spreading of their nutrient content, without physical segregation between the nutrients as each granule contains all nutrients in their declared composition.
- **Safety:** For blended fertilizers based on ammonium nitrate, the possible segregation of input materials during transport and storage may generate safety risks linked to segregated AN.
- **Security:** For fertilizers based on ammonium nitrate, complex fertilizers make it more difficult to separate AN for malicious misuse.

⇒ In the Annexes of the new regulation:

We think that we should keep the following minimum quality requirements, as presented by DG Enterprise in its status report of 19 November 2012, a report which was referred to in the 17 March 2014 and 2 June 2014 meetings of the Fertilizer Working Group:

○ Essential QUALITY requirements for inorganic fertilizers:

▪ Minimum nutrient content for each primary nutrient.

Fertilizers Europe proposes that the following minimum levels are set for inorganic fertilizers in solid form, as also proposed by a majority of Member States in 2012:

- 3% for total N
- 3% for total P (expressed as P_2O_5), fulfilling solubility criteria (see Annex 2)
- 3% for total K (expressed as K_2O)

▪ Nutrient forms:

A list of the nutrient forms allowed for nitrogenous and phosphorous fertilizers should be defined:

- Nutrient forms currently allowed for inorganic fertilizers:
 - **Nitrogen forms:** ammoniacal N, nitric N, ureic N, N from urea formaldehyde, N from Isobutylidene diurea, N from crotonylidene diurea.
 - **Phosphorus form:** phosphatic P.
The list of known forms is very limited and stable overtime (three additions during last 100 years).
- A new nitrogenous or phosphorous inorganic form should pass an **EU type examination** and be included in the existing list by delegated act.
- A positive list of forms is a very efficient way to support the compliance of fertilizer products, at the same time with the safety concerns and with ensuring a fertilizing function.

▪ Time span for nutrient release of inorganic fertilizers:

The declared nutrient content of inorganic fertilizers should be released (in the soil or in a substrate) within a maximum time limit:

- For N fertilizers: release of the declared content in up to [4 months].
- For P and K fertilizers: release of the declared content in up to [12 months].

▪ Other quality requirements for all inorganic fertilizers:

- **Maximum organic carbon content:** Without taking into account the carbon content of the fertilizers which are considered inorganic by convention

and of the additives, the maximum organic carbon content in inorganic fertilizer is [1%].

- **Phytotoxicity:** Absence of phytotoxicity should be guaranteed by setting maximum limit on any contaminant or by-product which may be harmful for the crop, such as biuret in urea which should be limited to 2.7% of the ureic N content (1.2% for a 44% ureic N content).
- **Compatibility:** Blends of fertilizers must respect the compatibility between individual components. The table given in **(Annex 1)** provide guidance for the blends of the most common components.

▪ **For inorganic phosphorus fertilizers:**

A **minimum solubility level** should be fixed for each of the solubility types, to avoid that plant-unavailable phosphorus materials are put on the market as “fertilizer”, to the detriment of farmers. **(see attached Annex 2)**

The **types of solubility** qualifying a phosphorus material as fertilizer are:

- Water solubility
- Solubility in neutral ammonium citrate
- For soft rock, solubility in formic acid.

○ **Essential SAFETY requirements for inorganic fertilizers:**

• **Safety requirements for all inorganic fertilizers:**

• **Contaminants:**

• **Heavy metals:**

- Maximum level of contaminants will be defined in proportion to the average application rate of the category. **(see Annex 3 and 4)**
- Plants cannot survive without nutrients, including phosphate. Given the unavoidable natural presence of heavy metals in phosphate rock of sedimentary origin, the setting of maximum contaminants level should not be made to the detriment of EU supply with phosphorus. The global supply of phosphorus ores is highly concentrated in a few countries, with the low level ores predominantly found in Russia.

- **Organic contaminants:** Food produced with correct use of inorganic fertilizers is safe for human consumption and thus comply with food limits for contaminants. Products issued from recycled materials should be tested on the presence of organic contaminants such as pathogens, hormones, pharmaceuticals, etc. An exception to this testing procedure can be granted when both production process and the input materials preclude the presence of organic contaminants (e.g. mono-incineration ashes).

- **Compatibility:** Blends of fertilizers must respect the compatibility between individual components, in relation with safety. The table given in **(Annex 1)** provide guidance for the blends of the most common components.

- **For inorganic nitrogen fertilizers:**

Fillers: For products based on Ammonium Nitrate (AN) and to ensure compliance with necessary safety requirements, it is necessary to limit the use of fillers to those mentioned in **Annex I.1 entry 5** of Regulation 2003/2003. Additionally safety related provisions in existing regulations (such as the 2003/2003) should be maintained and when necessary adapted.

- **For inorganic phosphorus fertilizers:**

Already listed in the “Essential QUALITY requirements”, the following requirement is an essential contribution to the safety of supply and the respect of the environment: A **minimum solubility level** should be fixed for each of the solubility types, to avoid that plant-unavailable phosphorus materials are put on the market as “inorganic fertilizer”, to the detriment of the environment, but also depleting unnecessarily very limited global P reserves. (see attached Annex 2)

- **Essential DECLARATION and LABELLING requirements:**

Full transparency towards the market is essential to ensure that farmers can make an informed choice of a fertilizer, adapted to the crop need while minimizing the impact on the environment. Labelling is in this respect a fundamental component of the fertilizer regulation.

Fertilizers Europe underlines that labelling is also an important mean to communicate product quality. We are therefore putting particular attention on this aspect, and we would like to raise the following points:

 - **Definitions related to products:**

The product related definitions guaranty farmers to buy a product of a well specified quality. It is therefore important that the following definitions are mentioned on the label:

 - The product **category** and **sub-category**.
 - If the product is a **mixture** of two or more ingredients which already belong to a defined category or sub-category of the New Regulation, the label should clearly mention that the product is a mixture of xx % of “ingredient 1” + YY % of “ingredient 2” + (etc...), the percentage of each ingredient being expressed in “product as it is”. A mixture of ingredients belonging to different categories or sub-categories **CANNOT be classified under one “main” category.**

- Information on the formulation is also important for the farmer so as to use the appropriate spreading technique: for NPK fertilizers, for example, it is important to mention whether it is a “**Complex fertilizer**” or a “**Blended fertilizer**”.
- **Tolerances:**
Fertilizers Europe proposes tolerances on declared nutrient content as presented in the attached Annex 5.
- **Essential quality requirements:**
Information should be provided on all essential quality requirements, such as:
 - **Total nutrient content**, for each nutrient.
 - **Nitrogen forms.**
 - **Phosphorus forms.**
 - **Phosphate solubility** - For each solubility type, and above the minimum solubility level, the actual solubility level will be mentioned in absolute value.
- **Essential safety requirements:**
 - Providing that the product complies with the essential safety requirements, the actual level of contaminant should **NOT be labelled**.
 - Micro-nutrients Cu and Zn should be declared if above a certain limit.

2) OUTSIDE THE TEXT OF THE NEW REGULATION

⇒ **Product standards:** (see attached Annex 6)

Fertilizers Europe considers that the **main fertilizer types** should be defined through a “**product standard**”, with the following objectives:

- **Safety and compatibility:** Underlining the importance of safety and compatibility as mentioned in the **Essential SAFETY Requirements**, this concern would be better addressed by establishing product standards. (see attached Annex 1)
- **Link with other EU regulations:** Several product types are specified in other regulations, as transport and storage (Seveso directive 2012/18/UE) for example, both at national and international levels. The best way to ensure consistency between the different legal texts concerning the definitions of these products is to establish a product standard.

- **Link with guidance documents and BAT:** Several product types are specified in many technical guidance documents used for information and training concerning safety in various environments, including for example fire brigades, as well as in official BAT Ref documents (IED Directive 2010/75/EU). The best way to ensure consistency between these technical documents concerning the definitions of these products is again to establish product standards.
- **Avoid confusing EU farmers:** For nearly 40 years EU farmers are used to certain denominations which guaranty a minimum nutrient content associated with a nutrient form, allowing them to adapt precisely the products they use to their crop needs while minimizing the impact on the environment. Product denominations such as “Urea” or “Ammonium Nitrate” (AN) correspond to very precise specifications for all EU farmers, which can be ensured only by product standard.
- **List of “product standards”:**
Additionally, Fertilizers Europe is of the opinion that these product standards should be listed for easy consultation by market actors, whether farmers, distributors or personnel in charge of safety. Therefore this list should be made available on the EU Commission website (as for the list of accredited laboratories) and regularly updated.

⇒ **Certification procedures:**

We have two important points that we want to raise in this area:

- **Self-certification:**

We welcome the possibility of self-certification for inorganic fertilizers, with the following conditions:

- Exclusion from this procedure of materials issued from waste flows and from industrial by-products or co-products. New products and products issued from waste flows, and from industrial by-products or co-products, should pass an **EU-type examination** where conformity with essential quality and safety requirements will be checked.
- However, industrial by-products or co-products which are today used as feed stock for inorganic fertilizers under the 2003/2003 should benefit from a “fast track” (simplified dossier) and, when duly justified, from the self-certification procedure.

- **Negative list:**

A negative list of the “critical materials” which are not allowed to be used as feedstock will be defined. This list will be under the responsibility of the EU Commission

⇒ **Control of compliance with the New Regulation:**

Appropriate authority structure and financial resources should be committed to the control of compliance of products on the market with the New Regulation, to ensure that Essential QUALITY and SAFETY Requirements are met by all products put on the market, whether imported or from EU production.

ANNEX 1

COMPATIBILITY TABLE OF VARIOUS SOLID INORGANIC FERTILIZERS

COMPATIBILITY OF VARIOUS SOLID INORGANIC FERTILIZERS

	Ammonium Nitrate	Calcium Ammonium Nitrate	Calcium nitrate (fertilizer grade)	Ammonium Sulphate nitrate	Potassium Nitrate / Sodium nitrate	Ammonium sulphate	Urea	Rock Phosphate	Partially acidulated rock phosphate	Single/Triple super phosphate	Monoammonium phosphate	Diammonium phosphate	Mono potassium phosphate	Potassium chloride	Potassium sulphate/magnesium sulphate (kieserite)	NPK, NP, NK (AN based)	NPK, NP, NK (Urea based)	Limestone/dolomite/calcium sulphate/calcium carbonate	Sulphur (elemental)
Ammonium Nitrate			1	2		3	NC1		4	4				5		5	NC1		NC2
Calcium Ammonium Nitrate			6			2	NC1			7				5		5	NC1		NC2
Calcium nitrate (fertilizer grade)	1	6		8	8	8	8			8	8	8	8	8	9	8	8		8
Ammonium Sulphate nitrate	2		8		2	2	NC1	10	4	7				5		5	NC1		NC2
Potassium Nitrate / Sodium nitrate			8	2		11										12	13		NC2
Ammonium sulphate	3	2	8	2	11											5			
Urea	NC1	NC1	8	NC1					14	15				16		NC1			
Rock Phosphate				10															
Partially acidulated rock phosphate	4			4			14					17							
Single/Triple super phosphate	4	7	8	7			15					17				4	14	17	
Monoammonium phosphate			8																
Diammonium phosphate			8						17	17									
Mono potassium phosphate			8																
Potassium chloride	5	5	8	5			16									5			
Potassium sulphate/magnesium sulphate (kieserite)			9																
NPK, NP, NK (AN based)	5	5	8	5	12	5	NC1			4				5			NC1		NC2
NPK, NP, NK (Urea based)	NC1	NC1	8	NC1	13					14						NC1			
Limestone/dolomite/calcium sulphate/Calcium carbonate										17									
Sulphur (elemental)	NC1	NC1	8	NC2	NC2											NC2			

	Compatible
	Limited compatibility linked to quality issues
⚠	Limited compatibility related to safety or regulatory issues
NC	Not Compatible

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FOOTNOTES FOR THE NUMBERS IN THE BOXES IN THE COMPATIBILITY TABLE

Limited Compatibility

1. Due to the hygroscopic behaviour of both products, the type of stabilisation of the ammonium nitrate grade could influence storage properties.
2. Consider the safety implications regarding detonability of the blend (AN/AS mixtures) and legislative implications.
3. Consider the safety implications regarding detonability of the blend (AN/AS mixtures), impact of free acid and organic impurities, if present, and legislative implications.
4. If free acid is present it could cause very slow decomposition of AN, affecting, for example, packaging.
5. Consider the possibility of self-sustaining decomposition and the overall level of oil coating.
6. Due to the hygroscopic behaviour of both products, the type of stabilisation of the ammonium nitrate based fertilizer could influence the storage properties.
7. Consider the moisture content of the SSP/TSP.
8. Consider the relative humidity during blending.
9. Risk of formation of gypsum.
10. No experience but this can be expected to be compatible. Confirm by test and/or analysis.
11. Consider impurities in AS and the drop in the critical relative humidity of the blend.
12. Consider the likely impact of additional nitrate.
13. Consider the possibility of ammonium phosphate/potassium nitrate reaction with urea and relative humidity during blending to avoid caking.
14. If free acid present, there is a possibility of hydrolysis of urea giving ammonia and carbon dioxide.
15. Formation of very sticky urea phosphate.
16. Potential caking problem due to moisture.
17. If free acid is present, consider the risk of a reaction e.g. neutralisation with ammonia and acid attack with carbonates.

Not Compatible

- NC1. Mixture will quickly become wet and absorb moisture resulting in formation of liquid or slurry. There could also be safety implications.
- NC2. Sulphur is combustible and can react with nitrates e.g. AN, KNO_3 and NaNO_3 .

Definitions for the inorganic fertilizer compatibility table

Name	Description	CAS number / EC number of the pure substance	Specifications for safety sensitive ingredients in the Compatibility Table
Ammonium nitrate	Chemically obtained product containing ammonium nitrate as its essential ingredient, which may contain fillers such as ground limestone, calcium sulphate, ground dolomite, magnesium sulphate, kieserite.	6484-52-2 / 229-347-8	20 % N Nitrogen expressed as nitric nitrogen and ammoniacal nitrogen, each of these two forms of nitrogen accounting for about half the nitrogen present.
Calcium ammonium nitrate			Contains only calcium carbonate (for instance limestone) and/or magnesium carbonate and calcium carbonate (for instance dolomite) in addition to ammonium nitrate. The minimum content of these carbonates must be 20 % and their purity level at least 90 %
Calcium nitrate	Chemically obtained product containing calcium nitrate as its essential ingredient and possibly ammonium nitrate	10124-37-5 / 233-332-1	
Ammonium sulphate-nitrate	Chemically obtained product containing as essential ingredients ammonium nitrate and ammonium sulphate		25 % N Nitrogen expressed as ammoniacal and nitric nitrogen. Minimum nitric nitrogen content: 5 %
Sodium nitrate	Natural or chemically obtained product containing sodium nitrate as its essential ingredient	7631-99-4 / 231-554-3	15 % N Nitrogen expressed as nitric nitrogen
Potassium nitrate	Natural or chemically obtained product containing sodium nitrate as its essential ingredient	7757-79-1 / 231-818-8	15 % N Nitrogen expressed as nitric nitrogen
Ammonium sulphate	Chemically obtained product containing ammonium sulphate as its essential ingredient	7783-20-2 / 231-984-1	20 % N
Urea	Chemically obtained product containing carbonyl diamide (carbamide) as its essential ingredient	57-13-6 / 200-315-5	44 % N Total ureic nitrogen (including biuret). Maximum biuret content: 1,2 %
Rock phosphate	Product obtained by grinding mineral phosphates and containing tricalcium phosphate and calcium carbonate as essential ingredients		
Partially solubilised rock phosphate	Product obtained by partial solubilisation of ground rock phosphate with sulphuric acid or phosphoric acid and containing no free acidity		
Single superphosphate	Product obtained by reaction of ground mineral phosphate with sulphuric acid	8011-76-5 / 232-379-5	
Triple superphosphate	Product obtained by reaction of ground mineral phosphate with phosphoric acid	65996-95-4 / 266-030-3	

Monoammonium phosphate	Product obtained by reaction of ammonia with phosphoric acid and containing monoammonium phosphate as its essential ingredient	7722-76-1 / 231-764-5	
Diammonium phosphate	Product obtained by reaction of ammonia with phosphoric acid and containing diammonium phosphate as its essential ingredient	7783-28-0 / 231-987-8	
Monopotassium phosphate	Product obtained by reaction of potassium salts with phosphoric acid and containing monopotassium phosphate as its main ingredient	7778-77-0 / 231-913-4	
Potassium chloride (Muriate of potash)	Product obtained from crude potassium salts and containing potassium chloride as its essential ingredient	7447-40-7 / 231-211-8	37 % K ₂ O
Potassium sulphate	Product obtained chemically from potassium salts and containing potassium sulphate as its essential ingredient	7778-80-5 / 231-915-5	
Sulphate of potash containing magnesium salt	Product obtained chemically from potassium salts, possibly with addition of magnesium salts, and containing potassium sulphate and magnesium sulphate as essential ingredients		
NPK, NP, NK (AN based)	Compound fertilizers containing N and P and/or K produced based on ammonium nitrate		
NPK, NP, NK (AN based)	Compound fertilizers containing N and P and/or K produced based on urea		
Limestone	Natural product containing as main ingredient calcium carbonate		
Dolomite	Natural product containing as main ingredient calcium magnesium carbonate		
Calcium sulphate	Natural or chemical product containing as main ingredient calcium sulphate	7778-18-9 / 231-900-3	
Calcium carbonate	Natural or chemical product containing as main ingredient calcium carbonate	471-34-1 / 207-439-9	
Sulphur	Elemental sulphur	7704-34-9 / 231-722-6	

ANNEX 2

THE MINIMUM SOLUBILITY LEVEL FOR PHOSPHORUS FERTILIZERS

These minimum levels are corresponding to those used in the 2003/2003 regulation (Annex I – A.2).

- ⇒ **Water solubility:** minimum level **40%** of total P
- ⇒ **Solubility in neutral ammonium citrate:** minimum level **75%** of total P
- ⇒ **Solubility in formic acid:** minimum level **55%** of total P
(only for soft rock phosphate)

In order to be recognized as a P fertilizer, the fertilizer should comply with the minimal total P content and with one of the minimum solubility levels.

The actual solubility level will be expressed in absolute value on the label.

LIMITS ON HEAVY METALS AND CONTAMINANTS IN INORGANIC FERTILIZERS

Limits on heavy metals and contaminants will be part of the essential safety requirements for inorganic fertilizers. Limits should be set as below, reflecting the agreement in Working Group 3 (December 2013).

<i>Substance</i>	<i>Max. Content</i>
Cd (for products with less than 5% P ₂ O ₅)	3 mg/kg dry matter
Cd (for products > 5% P ₂ O ₅)	60 mg/kg P ₂ O ₅
Cr VI	2 mg/kg dry matter
Hg	2 mg/kg dry matter
Ni	120 mg/kg dry matter
Pb	150 mg/kg dry matter
As	60 mg/kg dry matter

Plants cannot survive without nutrients, including phosphate. Given the unavoidable natural presence of heavy metals in phosphate rock of sedimentary origin, the setting of maximum contaminants level should not be made to the detriment of EU supply with phosphorus. The global supply of phosphorus ores is highly concentrated in a few countries, with the low level ores predominantly found in Russia (The Hague Centre for Strategic Studies, 2012; JRC 2012).

A recent study by Smolders (2013) shows that a Cd limit of 80 mg Cd/kg P₂O₅ for fertilizers results in a non-accumulation of Cd in European soils over the next 100 years. In 2006, Nziguheba and Smolders sampled 196 phosphate fertilizers in EU15. Their study shows that, whereas the average Cd content in phosphate fertilizers is 36 mg Cd/kg P₂O₅, an EU limit set at 60 mg Cd/kg P₂O₅ would exclude 30 % of the phosphate fertilizers currently available on the market.

References:

The Hague Centre for Strategic Studies. **2012**. Risk and opportunities in the global phosphate rock market- Robust strategies in times of uncertainty. N° 17/12/12.

JRC (Albino, M., Malingreau, J-P, Bock, A-K, Eva, H., Scapolo, F., Ruiz Fabra, H.). **2012**. NPK: Will there be enough plant nutrients to feed a world of 9 billion in 2050? Publications Office of the European Union. JRC70936

Smolders. **2013**. Revisiting and updating the effect of phosphorus fertilisers on cadmium accumulation in European soils. IFS Proceedings 724.

Nziguheba and Smolders. **2008**. Inputs of trace elements in agricultural soils via phosphate fertilizers in European countries. Sci Total Environ 390: 53-57

ANNEX 4

LIMITS ON HEAVY METALS IN MICRONUTRIENT FERTILIZERS

1. Introduction

At the March 2008 meeting of the Fertiliser Working Group, Fertilisers Europe (then EMFA) raised Industry concerns that the Commission's proposed limits for heavy metals in EC fertilisers would be too restrictive when applied to micronutrients as they took no account of the special features of this group of fertilisers, namely their chemical nature and low application rates. Fertilisers Europe reported that if the amendment to Regulation 2003/2003 was to be implemented in its original form it would have the effect of removing a high proportion of good quality micronutrient fertilisers from the market with serious consequences for European agriculture.

The Working Group acknowledged these concerns and requested that Fertilisers Europe report back with proposals for a revised approach to deal with this group of fertilisers. Following a series of Task Force meetings, Fertilisers Europe established a position which was presented to the FWG Meeting on 19 March 2009.

In 2012 the Commission set up four Working Groups for discussing the future New Fertilizer Regulation. This updated version of the original 2009 position paper is set out below for discussions in WG3 meetings.

2. Background

The sub-group of the Working Group on Fertilisers proposed to set maximum concentration limits for six heavy metals (arsenic, cadmium, chromium VI, lead, mercury and nickel) based on levels currently achievable by fertiliser industry good practice¹. For most types of EC fertilisers the proposed limits were considered to be acceptable. However, Industry, via Fertilisers Europe, highlighted difficulties in relation to micronutrient fertilisers which, due to their chemical nature, are inherently more likely to contain higher levels of heavy metal contaminants than other fertilisers. Fertilisers Europe also made the point that the low application rates of micronutrient fertilisers substantially reduces the potential for input of heavy metals to crop or soil from this source.

2.1 Chemistry of Micronutrients.

The very nature of micronutrient fertilisers means that the levels of heavy metals present tend to be higher in absolute concentration terms than in Primary or Secondary fertilisers. In Nature the ores or minerals containing micronutrient elements (B, Co, Cu, Fe, Mn, Mo, Zn) usually occur in association with one or more of the heavy metals listed in the proposed amendment.

For example, one of the principal ores of boron is colemanite which occurs in association with arsenic minerals (realgar and orpiment) in some of the world's main reserves in Turkey².

The main source of zinc is sphalerite [(ZnFe)S] which commonly occurs with galena (PbS). Due to its chemical similarity to zinc, cadmium occurs by isomorphous replacement in almost all zinc ores³.

Copper is widely distributed in Nature in a variety of minerals including arsenides⁴.

Molybdenum occurs chiefly as molybdenite (MoS_2) but also as molybdates such as wulfenite (PbMo_4)⁵.

It is therefore practically impossible to avoid some carry-over of heavy metal contaminants into the compounds which are used as raw materials for the production of micronutrient fertilisers, even when good quality materials are used. This fact is recognized in regulations governing other industries. For example, Commission Regulation (EU) No 574/2011⁶ which sets limits on undesirable substances in animal feed stipulates the following maximum contents for arsenic, cadmium and lead in trace element feed additives:

Feed material	Maximum content in mg/kg
Cupric carbonate	As: 50 mg/kg; Pb: 200 mg/kg
Cupric oxide	As: 100 mg/kg; Cd: 30 mg/kg;
Cupric sulphate pentahydrate	As: 50 mg/kg
Ferrous carbonate	Pb: 200 mg/kg;
Manganous oxide	As: 100 mg/kg; Cd: 30 mg/kg; Pb: 200 mg/kg
Manganous sulphate monohydrate	Cd: 30 mg/kg
Zinc oxide	As: 100 mg/kg; Cd: 30 mg/kg; Pb: 400 mg/kg

Several of the above substances could potentially be used as micronutrient fertilisers but in many cases animal feed grades would not comply with the maximum limits for heavy metals originally proposed for EC fertilisers. For example feed grade copper oxide would exceed the proposed limit for As (60 mg/kg) and feed grade zinc oxide would exceed the proposed limit for Pb (150 mg/kg).

The monograph for pharmaceutical grade zinc oxide⁷ sets limits for As, Cd and Pb of 5 ppm, 10 ppm and 50 ppm respectively, demonstrating that even the highest purity compounds of this type contain measurable amounts of heavy metal contaminants.

The fertiliser regulations of some non-European countries recognize the particular properties of micronutrients. For example, the Californian⁸ and South Australian⁹ regulations both make a distinction between micronutrient fertilisers and other types and set limits for heavy metals in micronutrient fertilisers which are generally higher than for the other types.

It is known that P fertilizers are likely to contain higher cadmium levels due to the levels that naturally occur in some phosphate rock deposits. Micronutrient fertilisers are affected in a similar way and it is Fertilisers Europe's view that this should be taken into account in the New Fertilizer Regulation.

2.2 Micronutrient Fertiliser Type Designations.

Annex I of the present Regulation 2003/2003 defines the chemical and physical form and minimum nutrient content for the various type designations of micronutrient fertilisers. Type designations include solids, solutions and suspensions. The minimum allowable nutrient content for the different types varies considerably. In some cases the minimum nutrient content defined in the regulation is very high and it is with these fertilisers in particular that the heavy metal limits originally proposed would be too restrictive.

Compliance with threshold limits for heavy metal contaminants based on absolute concentration is much more difficult to achieve with a highly concentrated micronutrient fertiliser than for a more dilute fertiliser so in effect the proposed amendment would be prejudicial against the former types.

For example, E.1.3b of the present regulation defines the requirements for a micronutrient fertiliser based on copper oxide.

This indicates a minimum Cu content of 70%. E.1.3d defines the requirements for a copper chelate which has a minimum copper content of 9%. E.1.3b therefore contains almost 8 times the amount of nutrient but would be subject to the same absolute limit for heavy metals.

A survey of commercially available agricultural grades of copper oxide has shown typical heavy metal contents to be as follows:

Pb	250 - 420ppm
Cd	10 - 80ppm
As	10 - 80ppm

Copper oxide of this quality would fail to comply with the limits set out in the original proposals and would not be allowed to be marketed as an EC fertiliser. However if the same copper oxide was used as a raw material and reacted with chelating agent to form a "copper chelate" with 9% Cu the product would most probably meet the heavy metals limits simply by virtue of the dilution effect of the manufacturing process.

The application rates of highly concentrated micronutrient fertilisers are generally lower than those for fertilisers with low nutrient content (in order to supply equivalent amounts of nutrient to the crop). Therefore in practice the actual heavy metal input from the two copper fertilisers described above would be the same. The effect of the amendment to the regulation, as originally proposed, would have been to remove concentrated micronutrient fertilisers from the market with no meaningful benefit to the consumer.

In order to take account of the wide range of nutrient concentrations of micronutrient fertilisers and avoid the problems described above, Fertilisers Europe would favour a system that set limits for heavy metals per unit (kg or %) of nutrient in the fertiliser. This approach has been adopted by other authorities around the world, for example the State of California in the USA⁸. The Californian regulations are worded as follows:

"For each percent iron, manganese or zinc, the fertilising material shall not exceed the following concentrations of non-nutrient metals: arsenic, 13ppm; cadmium, 12ppm; lead, 140ppm."

This type of approach would be fundamentally fairer as it would take into account the wide variation in nutrient contents of the micronutrient fertilisers and would not set unrealistic limits on highly concentrated micronutrient fertilisers that are used at very low application rates.

2.3 Application Rates.

By definition, micronutrients (B, Co, Cu, Fe, Mn, Mo, Zn) are required in much lower concentrations by crops than primary or secondary nutrients. Consequently the application rates for micronutrient fertilisers are much lower than the other classes of fertiliser. Typical application rates for

micronutrient fertilisers may be of the order of 1 to 10 kg per hectare per year compared with perhaps 100 to 1000kg of NKP per hectare per year. Therefore the amount of micronutrient fertiliser applied is lower by a factor of 100 or 1000 thus reducing the potential for input of heavy metals by a similar factor.

A survey of micronutrient fertiliser usage conducted for Fertilisers Europe to establish the maximum input rates for each of the nutrient elements produced the figures shown in the table below. In each case the crop with the highest demand for each nutrient was selected in order to show the highest inputs ever likely to be applied per hectare per annum (i.e. the worst case scenario).

Micronutrient	Most demanding Crop	Maximum Nutrient input
Boron	Swede	6.0 kg B per ha per annum
Cobalt	Grass (livestock)	0.1 kg Co per ha per annum
Copper	Cereals	3.0 kg Cu per ha per annum
Manganese	Sugar Beet	8.6 kg Mn per ha per annum
Molybdenum	Cauliflower	0.4 kg Mo per ha per annum
Iron	Pear	4.1 kg Fe per ha per annum
Zinc	Maize	7.0 kg Zn per ha per annum

In practice most micronutrient fertiliser inputs would be considerably lower than the above figures.

3. Proposed System for Micronutrient Fertilisers.

Fertilisers Europe recommends that the New Fertilizer Regulation should make a distinction between micronutrients and other types of fertiliser. Fertilisers Europe proposes that a different system that sets limits for heavy metals per unit nutrient in the fertiliser should be adopted for micronutrient fertilisers (using the same principle as for Cd in fertilisers containing more than 5% P₂O₅).

The table below summarizes the proposed limits for each heavy metal:

Heavy Metal	Maximum Heavy Metal Concentration per Unit Micronutrient (mg/kg B, Co, Cu, Fe, Mn, Mo, or Zn)
Arsenic (As)	1000
Cadmium (Cd)	200
Chromium VI (Cr VI)	*
Lead (Pb)	600
Mercury (Hg)	100
Nickel (Ni)	2000

* No limit has been set for Cr VI – see 3.2 below.

3.1 Scope

Fertilisers Europe envisages that this system would apply to fertilisers currently defined in Sections E1 and E2.1 of Annex I of Regulation 2003/2003, that is, fertilisers containing only one micronutrient

and solid or fluid mixtures of micronutrient. Fertilisers containing primary or secondary nutrients with micronutrients would be subject to the limits set out in the Commission's original amendment in 2008.

3.2 Chromium VI

Analysis carried out by Fertilisers Europe members on commercially available micronutrient fertilisers has identified serious shortcomings in the method proposed for determination of Cr VI. In particular it has proved impossible to determine Cr VI levels in iron-containing micronutrient fertilisers due to interference with Fe. Straight Fe micronutrient fertilisers such as FeEDTA, FeDTPA and FeEDDHA, as well as mixed micronutrient fertilisers containing Fe, represent a significant part of the micronutrient fertiliser market and without a reliable method for determining Cr VI in these products it is Fertilisers Europe's view that limit values for this metal should not be set.

3.3 Worked Examples

The following examples illustrate how Fertilisers Europe's proposed system would work in practice.

Example 1- illustrating the case of a straight B micronutrient fertiliser with relatively low nutrient content.

Boron Fertiliser based on calcium borate with 7% w/w total B (i.e. complying with Section E1.1c of Annex I).

Allowable heavy metal content in this fertiliser would be:

As: 70 mg/kg, Cd: 14 mg/kg, Pb: 42 mg/kg, Hg: 7mg/kg, Ni: 140 mg/kg.

Heavy metal input to the crop/soil based on the maximum application rate to a boron demanding crop such as swede of 6.0 kg B (i.e. worst case scenario) would be:

As: 6.0g, Cd: 1.2g, Pb: 3.6g, Hg: 0.6g, Ni: 12.0g per hectare per annum.

Example 2 – illustrating the case of a straight Cu micronutrient fertiliser with very high nutrient content.

Copper Fertiliser based on copper oxychloride with 50% w/w Cu (i.e. complying with Section E1.3g of Annex I).

Allowable heavy metal content in this fertiliser would be:

As: 500 mg/kg, Cd: 100 mg/kg, Pb: 300 mg/kg, Hg: 50mg/kg, Ni: 1000 mg/kg.

Heavy metal input to the crop/soil based on the maximum application rate to a copper demanding crop such as cereals of 3.0 kg Cu (i.e. worst case scenario) would be:

As: 3.0g, Cd: 0.6g, Pb: 1.8g, Hg: 0.3g, Ni: 6.0g per hectare per annum.

Example 3 – illustrating the case of a straight Cu micronutrient fertiliser with very low nutrient content.

Copper Fertiliser solution based on CuEDTA with 3% w/w Cu (i.e. complying with Section E1.3f of Annex I).

Allowable heavy metal content in this fertiliser would be:

As: 30 mg/kg, Cd: 6 mg/kg, Pb: 18 mg/kg, Hg: 3 mg/kg, Ni: 60 mg/kg.

Heavy metal input to the crop/soil based on the maximum application rate to a copper demanding crop such as cereals of 3.0 kg Cu (i.e. worst case scenario) would be:

As: 3.0g, Cd: 0.6g, Pb: 1.8g, Hg: 0.3g, Ni: 6.0g per hectare per annum (i.e. exactly the same as example 2)

Example 4 – illustrating the case of a straight Zn micronutrient fertiliser with very high nutrient content.

Zinc Fertiliser based on zinc oxide with 70% w/w Zn (i.e. complying with Section E1.7c of Annex I).

Allowable heavy metal content in this fertiliser would be:

As: 700 mg/kg, Cd: 140 mg/kg, Pb: 420 mg/kg, Hg: 70mg/kg, Ni: 1400 mg/kg.

Heavy metal input to the crop/soil based on the maximum application rate to a zinc demanding crop such as maize of 7.0 kg Zn (i.e. worst case scenario) would be:

As: 7.0g, Cd: 1.4g, Pb: 4.2g, Hg: 0.7g, Ni: 14.0g per hectare per annum.

Example 5 – illustrating the case of a straight Fe micronutrient fertiliser with very low nutrient content.

Iron Fertiliser solution based on FeEDTA with 2% w/w water soluble Fe (i.e. complying with Section E1.4c of Annex I).

Allowable heavy metal content in this fertiliser would be:

As: 20 mg/kg, Cd: 4 mg/kg, Pb: 12 mg/kg, Hg: 2mg/kg, Ni: 40 mg/kg.

Heavy metal input to the crop/soil based on the maximum application rate to an iron demanding crop such as pear of 4.1 kg Fe (i.e. worst case scenario) would be:

As: 4.1g, Cd: 0.8g, Pb: 2.5g, Hg: 0.4g, Ni: 8.2g per hectare per annum.

Example 6 – illustrating the case of a straight Mn micronutrient fertiliser with very high nutrient content.

Manganese Fertiliser based on manganese oxide 40% w/w Mn (i.e. complying with Section E1.5c of Annex I).

Allowable heavy metal content in this fertiliser would be:

As: 400 mg/kg, Cd: 80 mg/kg, Pb: 240 mg/kg, Hg: 40mg/kg, Ni: 800 mg/kg.

Heavy metal input to the crop/soil based on the maximum application rate to a manganese demanding crop such as sugar beet of 8.6 kg Mn (i.e. worst case scenario) would be:

As: 8.6g, Cd: 1.7g, Pb: 5.2g, Hg: 0.9g, Ni: 17.2g per hectare per annum.

Example 7 – illustrating the case of a Mixed micronutrient fertiliser.

Solid mixture based on EDTA chelates with 4% w/w Cu, 3% w/w Fe, 2.5% w/w Mn, 4% w/w Zn (i.e. complying with Section E2.1 of Annex I).

Total micronutrient content = 13.5% w/w therefore allowable heavy metal content in this fertiliser would be:

As: 135 mg/kg, Cd: 27 mg/kg, Pb: 81 mg/kg, Hg: 13.5 mg/kg, Ni: 270 mg/kg.

The above examples demonstrate the following:

- a) By relating heavy metal limits to nutrient content this system is able to accommodate the wide range of nutrient concentrations of micronutrient fertilisers. Unlike the level system originally proposed, it sets realistic limits for the most concentrated products whilst not being overly lenient when applied to lower concentration products. In some cases where the nutrient content is low (example 5) the limits are tighter than those original proposed.
- b) The proposed limits are in line with or more stringent than similar systems in use in other parts of the world (e.g. California).
- c) The actual heavy metal inputs to soil or crops due to application of micronutrient fertilisers complying with these limits would be very low.

4. Conclusion

Fertilisers Europe recommends adoption of the system described above for setting limits for heavy metals in micronutrient fertilisers.

Fertilisers Europe is supportive of the proposal to review the limits after three years or when risk analysis allows risk-based limits to be set.

References:

1. Outcome of the meeting of the Sub-Group Fertilisers of 5.11.2007 on heavy metals.
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9. South Australia Agricultural and Veterinary Products (Control of Use) Regulations 2004. Version 1.7.2005, Part 3 – Fertilisers, Division 1. P 5-6.

ANNEX 5

TOLERANCES AND LIMIT VALUES

Qualification:

Table 1 Minimum nutrient content to qualify product as inorganic fertilizer.

Inorganic fertilizer – Minimum nutrient content		
Nutrient	Minimum nutrient content on dry matter (% wt by mass) (individual value qualifies the product as an inorganic fertilizer)	
Nitrogen	3 % N	
Phosphorous	3 % P ₂ O ₅	1.3 % P
Potassium	3 % K ₂ O	2.5 % K
Calcium	4 % CaO	2.8 % Ca
Sulphur	5 % SO ₃	2 % S
Magnesium	2 % MgO	1.2 % Mg
Sodium	3 % Na ₂ O	2.2 % Na

Tolerances:

The table below gives an overview of the minimum nutrient contents and the proposal for their tolerances. In the first table tolerances are expressed for oxides, while in the second table values are expressed for elements.

Table 2 Positive and negative tolerances for inorganic fertilizers, expressed as oxides.

Nutrient	Min. nutrient content (% wt by mass)	Negative Tolerance		Positive Tolerance	
		Relative (%)	Absolute maximal (%)	Relative (%)	Absolute maximal (%)
Nitrogen	3 % N	25	1	50	2
Phosphorous	3 % P ₂ O ₅	25	1	50	2
Potassium	3 % K ₂ O	25	1	50	2
Calcium	4 % CaO	50	2	100	4
Sulphur	5 % SO ₃	50	2	100	4
Magnesium	2 % MgO	50	2	100	4
Sodium	3 % Na ₂ O	50	2	100	4

Table 3 Positive and negative tolerances for inorganic fertilizers, expressed as elements.

Nutrient	Min. nutrient content (% wt by mass)	Negative Tolerance		Positive Tolerance	
		Relative (%)	Absolute maximal (%)	Relative (%)	Absolute maximal (%)
Nitrogen	2.0 % N	25	1.0	50	2.0
Phosphorous	1.3 % P	25	0.4	50	0.8
Potassium	2.5 % K	25	0.8	50	1.6
Calcium	2.9 % Ca	50	1.4	100	2.8
Sulphur	2.0 % S	50	0.8	100	1.6
Magnesium	1.2 % Mg	50	1.2	100	2.4
Sodium	2.2 %	50	1.5	100	3.0

Following statements for clarification should be added:

- "The manufacturer shall not systematically exceed the existing minimum declaration values for the undeclared nutrients sulphur, magnesium and sodium by taking systematic advantage of tolerances given in above table".
- "Tolerances should be based on total nutrient contents, rather than for water soluble nutrients".

ANNEX 6

MINIMUM LIST OF PRODUCT STANDARDS FOR INORGANIC FERTILIZERS

This list is based on the necessity to have precise product definitions to address several safety issues (including compatibility tables) and to ensure consistency with other EU legislations.

The products of this list are defined according to their description in the type designation of the current regulation 2003/2003.

⇒ Nitrogen Fertilizers (Annex I – A.1. of 2003/2003):

- Sulphate of ammonia (Annex I – A.1.4)
- Ammonium Nitrate (Annex I – A.1.5)
- Calcium Ammonium Nitrate (Annex I – A.1.5)
- Ammonium sulphate-nitrate (Annex I – A.1.6)
- Urea (Annex I – A.1.9)
- Urea Ammonium sulphate (Annex I – A.1.18)
- Urea Ammonium Nitrate (Annex I – C.1.2)

⇒ Phosphatic fertilizers (Annex I – A.2. of 2003/2003):

- SuperPhosphates (Annex I – A.2.2a, A.2.2b and A.2.2c)
- Soft ground rock phosphate (Annex I – A.2.4)

⇒ Potassic fertilizers (Annex I – A.3. of 2003/2003):

- Muriate of Potash (Potassium chloride) - without Mg salts (Annex I –A.3.3)
- Potassium chloride - with Mg salts (Annex I –A.3.4)
- Sulphate of potash - without Mg salts (Annex I – A.3.5)
- Sulphate of potash - with Mg salts (Annex I –A.3.6)

To facilitate consultation by market actors, whether farmers, distributors or personnel in charge of safety, these product standards should be made available on the EU Commission website (as for the list of accredited laboratories) and regularly updated.



ROADMAP

TITLE OF THE INITIATIVE	Revision of the Fertilisers Regulation (EC) No 2003/2003		
LEAD DG – RESPONSIBLE UNIT	GROW – D2	DATE OF ROADMAP	October 2015

This indicative roadmap is provided for information purposes only and is subject to change. It does not prejudice the final decision of the Commission on whether this initiative will be pursued or on its final content and structure.

A. Context and problem definition

- (1) What is the political context of the initiative?
- (2) How does it relate to past and possible future initiatives, and to other EU policies?
- (3) What ex-post analysis of existing policy has been carried out? What results are relevant for this initiative?

(1) Political context

The initiative supports the Commission's agenda for jobs, growth and investment¹, by providing the right regulatory environment for investment in the real economy.

In particular, the initiative will make an important and concrete contribution to the Commission's fulfilment of its commitment to submit a new, more ambitious Circular Economy Package by the end of 2015. It will create a level playing field for all fertiliser materials and facilitate recourse to domestic, secondary raw materials.

Furthermore, the initiative supports the aim to create a deeper and fairer internal market with a strengthened industrial base², by removing existing barriers to free movement of certain innovative fertilisers and facilitating the market surveillance by Member States.

(2) Other EU policies

The initiative is related to the following policy initiatives:

- The Circular Economy Package: The Fertilisers Regulation revision aims at establishing a regulatory framework enabling production of fertilisers from recovered bio-wastes and other secondary raw materials. This would boost domestic sourcing of plant nutrients which are essential for a sustainable European agriculture, including the critical raw material phosphorus. It would also contribute to a better implementation of the waste hierarchy, by minimising landfilling or energy recovery of bio-wastes, and hence to solving related waste management problems. A shift towards fertiliser production from organic or secondary raw materials would also reduce CO₂ emissions, hence contributing towards a low carbon economy and the sustainability of the fertilisers sector.
- The Internal Market Strategy: The Fertilisers Regulation revision aims at addressing a well-known barrier to free movement on the internal market. The barrier has the form of heavy and diverging national regulatory frameworks for those fertilisers currently not covered by harmonisation legislation. While economic operators often regard the diverging national rules as a prohibitive obstacle to entering new markets, Member States regard the rules as essential for protecting the food chain and the environment. Because of those concerns relating to health and the environment, mutual recognition has proven exceptionally difficult in the field of non-harmonised fertilisers, and economic operators have asked for the possibility to get access to the entire internal market by complying with harmonised rules addressing those concerns at EU level.
- Horizon 2020: The initiative would stimulate the research activities launched under Societal Challenges 2 ("Food security, sustainable agriculture and forestry, marine and maritime and inland water research, and the Bioeconomy") and 5 ("Climate action, environment, resource efficiency and raw materials"), which aim, among other objectives, at providing innovative solutions for a more efficient and safer recovery of resources from waste, wastewater and bio-wastes, and at encouraging researchers to deliver innovative products in compliance with the market and societal needs. The *Bio*

¹ First area addressed in President Juncker's Political Guidelines for the European Commission.

² Fourth area addressed in President Juncker's Political Guidelines for the European Commission.

Based Industries Joint Undertaking has identified *i.a.* phosphorus recycling for production of fertilisers as an emerging and economically promising new value chain from (organic) waste.³ Easy access to the internal market for such fertilizers would be a pre-condition for achieving these goals and bringing results from research to the market.

(3) Ex-post analysis of existing policy

An ex-post evaluation of the Fertilisers Regulation was conducted in 2010.⁴ It concluded⁵ that the Regulation had been effective in meeting its objective of simplifying and harmonising the regulatory framework in relation to an important part of the fertiliser market.

However, the evaluation also concluded that the Regulation could be more effective in promoting innovative fertilisers, and that adjustments would also be needed to better protect the environment. Furthermore, regarding the organic fertilisers currently left out of the scope of the Regulation, the evaluation showed that neither economic operators, nor national authorities considered that mutual recognition was the most appropriate tool for ensuring free movement, since fertilisers are products for which legitimate product quality, environmental, and human health concerns can warrant stringent rules.

What are the main problems which this initiative will address?

The initiative will address two important problems:

1) Innovative fertilisers, often containing nutrients or organic matter recovered and recycled from biowaste or other secondary raw materials in line with the circular economy model, have difficulties accessing the internal market due to the existence of diverging national rules and standards.

The Fertilisers Regulation ensures free movement on the internal market of a *class* of harmonised inorganic products belonging to one of the product-types which have been approved by the Commission in comitology and are included in one of the Annexes to the Regulation. Such products are eligible to be labelled 'EC-fertilisers'. Companies wishing to market products of *other* types as EC-fertilisers must first obtain a new type-approval. Virtually all product-types currently included in the Regulation are conventional, inorganic fertilisers, typically extracted from mines or chemically produced in line with a linear economy model. Also, the chemical processes for production of for example nitrogen-based fertilisers are both very energy consuming and CO₂-intensive.

Around 50 % of the fertilisers currently on the market, however, are left out of the scope of the Regulation. This is true for a few inorganic fertilisers and for all fertilisers produced from organic materials, such as animal or other agricultural by-products, or recovered bio-waste from the food chain. Research, innovation and investment are currently developing rapidly, contributing to the circular economy by creating local jobs and by generating value from secondary, domestically sourced resources which would otherwise have been dispatched on land or disposed as landfill waste, causing unnecessary eutrophication and greenhouse gas emissions. There is also a servitization trend in the business, with increasing product customisation based on analysis of the soil where the fertiliser will be used. SMEs and other enterprises throughout Europe are increasingly interested to contribute to this development. However, for customised products containing organic fertilisers, access to the internal market is currently depending on mutual recognition, and therefore often hindered.

The problem for innovative fertilisers with the existing regulatory construction is two-fold: First, inclusion in the Regulation of types of products sourced from organic or secondary raw material is challenging. Regulators hesitate because of the relatively variable composition and characteristics of such materials. The Regulation as it stands is clearly tailored for well characterised, inorganic fertilisers from primary raw materials, and lacks the robust control mechanisms and safeguards necessary for creating trust in products from inherently variable organic or secondary material sources. Furthermore, the links with existing legislation on control of animal by-products and waste are not clear. Second, even for new, inorganic fertilisers from primary raw materials, the type-approval procedure is lengthy, and cannot keep up with the innovation cycle of the fertilisers sector.

As a result, fertilisers sourced in line with the circular economy remain non-harmonised. Many Member States have detailed, national rules and standards in place for such non-harmonised fertilisers, with environmental requirements (such as heavy metal contaminant limits) that do not apply to EC-fertilisers. Furthermore, free movement between Member States through mutual recognition has proven extremely difficult. As a result, access for fertilisers sourced from organic or secondary raw materials to the market of another Member State than that of establishment is often prohibitively expensive. The resulting lack of critical mass hampers

³ http://bbi-europe.eu/sites/default/files/documents/BBI_JU_annual_Work_plan_2014.pdf.

⁴ http://ec.europa.eu/enterprise/sectors/chemicals/files/fertilizers/final_report_2010_en.pdf

⁵ See Section 4, *Conclusions and recommendations*.

investment in this important sector of the circular economy. The problem is of particular importance for producers established in Member States with a small domestic market compared to the surplus of organic, secondary raw materials (typically manure) of which they dispose.

In summary, the playing field in the competition between those fertilisers sourced from domestic organic or secondary raw material in line with the circular economy model and those produced in line with a linear economy model is tilted in favour of the latter. This competition distortion hampers investment in the circular economy, in particular in small Member States.

The problem is aggravated by the fact that one of the main fertiliser constituents is phosphate rock, which has been identified by the Commission as a critical raw material. For phosphate fertilisers, the EU is currently highly dependent on import of phosphate rock mined outside of the EU (more than 90% of the phosphate fertilisers used in the EU are imported, mainly from Morocco, Tunisia and Russia). This while domestic waste (in particular sewage sludge) contains large amounts of phosphorus, which – if recovered in line with a circular economy model – could potentially cover about 20-30% of EU's demand of phosphate fertilisers. The related investment potential remains, however, currently largely unexploited, which is partially due to the above-mentioned difficulties to access the internal market.

2) The Fertilisers Regulation fails to address environmental concerns arising from contamination of soil, and ultimately food. A well-recognised issue is, the presence of cadmium in inorganic phosphate fertilisers. In the absence of EU limit values, some Member States have imposed unilateral cadmium limits for EC-fertilisers by virtue of Article 114 TFEU, hence creating a certain market fragmentation also in the harmonised field. The presence of contaminants in those fertilisers which are currently subject to national rules (e.g. fertilisers derived from sewage sludge) poses similar concerns.

Who will be affected by it?

The initiative will mainly affect those producers of innovative fertilisers produced from organic or secondary raw materials in line with the circular economy model, who will be able to reach a critical mass through radically facilitated access to the internal market. Such producers will benefit from the initiative in particular in those Member States which are not providing a sufficiently large home market for new types of fertilisers.

It will also affect private and public recovery operators (such as operators of waste water treatment plants, or of waste management plants producing compost or digestate) who will be able to valorise their output, and thus facilitate investments in such infrastructure.

Many national authorities will see a decreased workload when national registration or authorisation systems for fertilisers are fully or partially replaced by EU-wide control mechanisms.

Finally, farmers and other fertiliser users are likely to see an increase in the product variety offered to them, while the general public will be better protected from contamination of soil, water and food.

Is EU action justified on grounds of subsidiarity? Why can Member States not achieve the objectives of the proposed action sufficiently by themselves? Can the EU achieve the objectives better?

The first objective of the proposed action is to boost investment in production and uptake of effective, safe, innovative fertilisers produced from organic or secondary raw materials in line with the circular economy model, by helping those products reach a critical mass through access to the entire internal market. More efficient recourse to such fertilisers can offer significant environmental benefits, reduced dependency on import of critical raw materials from outside of the EU, as well as an increased variety of high quality fertilising products to farmers. The existing barriers to the free movement of such products, in the form of diverging, national regulatory frameworks, cannot be removed through Member States' unilateral actions. In particular, mutual recognition in this field has proven exceptionally difficult, and becomes an increasingly important obstacle as the interest in producing and trading high-quality fertilisers from organic or secondary raw materials tends to increase. EU action, on the other hand, could ensure the free movement of such fertilisers by establishing harmonised high quality, safety and environmental criteria.

The second objective is to address heavy-metal contamination of soil and food through fertiliser use. Since most of the fertilisers posing the greatest concern (i.e., inorganic phosphate fertilisers) are already harmonised, Member States cannot achieve this objective unilaterally. EU-wide maximum limits, on the other hand, can effectively reduce contaminants in harmonised fertilisers to safer levels.

B. Objectives of the initiative

What are the main policy objectives?

The main policy objective of the initiative is to incentivise large scale fertiliser production in the EU from domestic organic or secondary raw materials in line with the circular economy model by transforming waste into nutrients for crops. The initiative would provide a regulatory framework radically easing access to the internal market for such fertilisers, thereby levelling their playing field with that of mined or chemical fertilisers produced

in line with a linear economy model. This would contribute to the following circular economy objectives:

- It would allow valorisation of secondary raw materials, hence enabling improved use of raw materials and turning eutrophication and waste management problems into economic opportunities for public and private operators.
- It would boost investment and innovation in the circular economy, hence creating jobs in the EU.
- It would contribute to relieving the fertilisers industry from its current pressure to reduce CO₂-emissions under ETS, by allowing it to produce fertilisers from less carbon-intensive feedstock.
- It would increase resource efficiency and decrease import dependency for raw materials essential to European agriculture, in particular phosphorus.

Increased production and trade in innovative fertilisers would also diversify the fertilisers offered to farmers, potentially contributing to making food production more cost- and resource-effective.

A second policy objective is to address the current, well-recognised environmental concern stemming from cadmium contamination of fertilisers from phosphate rock, and remove the current market fragmentation to which it currently gives rise in the form of national cadmium limits. The setting of limit values, aiming at minimising the negative impact of fertiliser use on the environment and on human health, will contribute to a reduction of cadmium accumulation in soil and of cadmium contamination of food and water....

Do the objectives imply developing EU policy in new areas?

No. It will cut across the existing policy areas of internal market, protection of the environment and of consumers, and agriculture.

C. Options

(1) What are the policy options (including exemptions/adapted regimes e.g. for SMEs) being considered?

(2) What legislative or 'soft law' instruments could be considered?

(3) How do the options respect the proportionality principle?

1&2) Five different policy options have been examined in the Impact Assessment, ranging from 'no action' to various levels of regulatory reform.

- Option 1: *Status quo*: The Fertilisers Regulation remains unchanged. Since the Regulation is not well adapted to fertilisers produced from organic or secondary (*i.e.*, often relatively variable) raw materials, a large part of the fertilisers market remains non-harmonised, and in many Member States subject to national product authorisation.
- Option 2: The regulatory technique of the Fertilisers Regulation, *i.e.* type-approval, remains un-changed, and is extended to the harmonisation of fertilisers from organic raw materials and of other fertiliser-related products, such as 'plant biostimulants'. For the purpose of ensuring the safety of innovative fertilisers from waste and other secondary raw materials, limit values are introduced for heavy metals. In the interest of allowing all fertilisers to compete on a level playing field, these limit values are made applicable to all fertilisers, and hence also address existing environmental concerns with conventional fertilisers.
- Option 3: Harmonisation is extended to fertilisers from organic raw materials and to other fertiliser-related products, such as 'plant biostimulants', and achieved through approval of ingredients, leading to a positive, exhaustive list of materials eligible for intentional incorporation into a fertiliser. As under option 2, limit values are introduced for heavy metals for all fertilising materials.
- Option 4: Harmonisation is extended to fertilisers from organic raw materials and to other fertiliser-related products, such as 'plant biostimulants', and achieved through the 'New Legislative Framework', which builds on mandatory, essential quality and safety requirements and voluntary, harmonised technical standards. Under different sub-options, various levels of third party involvement in the assessment of conformity with the essential requirements apply across the board. One of the requirements is compliance with limit values for heavy metals.
- Option 5: As under option 4, harmonisation is extended to organic fertilisers and to other fertiliser-related products and achieved through the 'New Legislative Framework' with essential requirements and standards. However, third party involvement in the assessment of conformity with the essential requirements *varies* between material categories, and is highest for waste and other secondary materials with potentially variable composition. One of the requirements is compliance with limit values for heavy metals.

Product harmonisation at EU level typically covers all products with a given function. If this default option of **full harmonisation** were to be applied to options 2 to 5 described above, fertilisers *not* complying with the harmonised legislation could not be placed on the market anywhere in the EU.

However, in view of the very local nature of the market of certain fertilisers, this initiative could follow an alternative approach. Under this alternative variant, which could be applied to either of the options 2-5, national legislation in this area could continue to exist, but any fertilisers could comply with the harmonised legislation *instead*, on an *optional* basis (as is the case under *status quo* for inorganic fertilisers). Under this variant of **optional harmonisation**, operators interested to get products CE-marked for easy access to the EU-wide *internal market* would have the option of ensuring that their products comply with the harmonised requirements. However, non-harmonised products could still remain on the *national markets*, subject to any applicable national requirements maintained or introduced by Member States and mutual recognition.

3) The first objective of the initiative is that of boosting investment in production of effective, safe, innovative fertilisers produced from organic or secondary raw materials in line with the circular economy model, with the related benefits for environmental impact, reduced import dependency, and increased variability of high-quality products on offer. The initiative aims at reaching a critical mass through internal market for such products. Mutual recognition of non-harmonised fertilisers has proven extremely difficult in the past, whereas product harmonisation legislation has been an effective way of securing internal market access for inorganic fertilisers produced in line with a *linear* economy model. It is therefore concluded that product harmonisation legislation for fertilisers from organic or secondary raw materials does not go beyond what is necessary for providing the regulatory certainty required to incentivise large scale investment in the *circular* economy. This is true in particular for option 3, which keeps administrative costs at a minimum, and option 5, which leaves economic operators a maximum of flexibility to put new products on the markets without compromising on quality and safety. It is also particularly true for the variant of *optional* harmonisation, which would leave Member States free to allow non-harmonised fertilisers to on the market without depriving those economic operators seeking larger markets of the possibility to opt for the benefits of the harmonised regulatory framework. The form of a Regulation is deemed the most appropriate for harmonisation of products in a field of such technical complexity and potential impact on the food chain and the environment as fertilisers. That conclusion is supported by the fact that the existing harmonisation legislation for fertilisers also has the form of a Regulation.

Regarding the second objective, *i.e.*, addressing heavy-metal contamination of soil and food through use of fertilisers many of which are already harmonised, maximum levels in the product legislation is seen as an effective means of addressing the problem at source. The economic impacts are deemed proportionate to the objective of preventing irrevocable soil contamination affecting current and future generations of farmers and food consumers.

D. Initial assessment of impacts

What are the benefits and costs of each of the policy options?

Below, *status quo* is compared with the four other policy options described above. The cost estimations of *status quo* include public authorities' and companies' costs for ensuring compliance with the existing Fertilisers Regulation as well as with the existing national regulatory schemes.

Option 2: Type-approval

Benefits: If effective, the type-approval option could achieve the main objective of stimulating investment in and uptake of organic fertiliser production by granting access to the internal market. However, the administration of such a process would make it very slow, unavoidably delaying such access for a large number of products. A large part of the market would therefore de facto remain fragmented over many years to come.

Costs: Administrative costs of this option would be lower than *status quo* for economic operators, but could be higher than *status quo* for the public authorities involved in the type-approvals. Furthermore, the type-approval-procedure would remain incapable of keeping up with the innovation cycle of the industry, and the absence of rapid internal market access for innovative products would deter investments and hence represent an opportunity cost (albeit difficult to quantify).

Option 3: Positive ingredient list

Benefits: This option, too, could achieve the objective of stimulating investment in and uptake of organic fertiliser production by granting access to the internal market. Abolishing types-approval would significantly increase market flexibility and hence stimulate innovation, whereas agronomic efficacy and protection of health and the environment would still be ensured through the ingredient approval. Increased competition enabled by the flexibility might be expected to reduce fertiliser prices (although this has not been quantified in the assessment). Administrative costs of this option would be lower than *status quo* for economic operators as well as public authorities.

Costs: As under option 2, the approval procedure would have difficulties keeping up with the innovation cycle of the industry, although under this option this would only affect new ingredients, and not new mixtures of existing ingredients.

Option 4: NLF applying the same conformity assessment across the board

Benefits: This option, too, could achieve the objective of stimulating investment and uptake by granting access to the internal market. Abolishing types-approval would significantly increase market flexibility and hence stimulate innovation, whereas agronomic efficacy and protection of health and the environment would still be ensured through the essential requirements. Increased competition enabled by the flexibility might be expected to reduce fertiliser prices (although, also under this option, that potential price reduction has not been quantified in the assessment). For public authorities, the Impact Assessment estimates that this option will provide lower administrative costs than both *status quo* and the type-approval option.

Costs: According to the impact assessment, while the sub-options of this option with high third-party involvement in the conformity assessment would imply significantly higher administrative costs for companies than *status quo*, other sub-options would give them lower administrative costs than *status quo*. However, at the level of individual companies, it can in any event be expected that administrative costs will in certain cases be higher than under *status quo*. This would be the situation for companies currently benefitting from a type-approval, or operating in a country without any authorisation or registration scheme. Under this option, those companies would in the future have to perform a conformity assessment, or have it performed, and might have to contribute to the financing of technical standards.

Option 5: NLF adapted to the potential risks of categories of products

Benefits: The benefits in terms of internal market access and market flexibility of this option are very similar to those of option 4. The Impact Assessment estimates that this option will provide lower administrative costs for both public authorities and economic operators than *status quo*, and significantly lower administrative costs for public authorities than the type-approval option.

Costs: According to the impact assessment, this option would imply lower administrative costs than the type-approval option for economic operators. As under option 4, it can, however, be expected that administrative costs will in certain cases be higher than under *status quo* at the level of individual companies. This would be true in particular for producers of relatively variable materials requiring a high level of third-party involvement in the conformity assessment.

The variant of optional harmonisation, which can be applied to any of options 2-5 listed above, would have the advantage of affecting only economic operators with a genuine interest in getting access to the market in several Member States, in line with the principles of subsidiarity and better regulation. The potential disadvantage could be that non-harmonised products could continue raising concerns about cross-border food contamination. Furthermore, optional harmonisation could imply higher costs for national administrations than full harmonisation, since they could be expected to maintain national procedures to some extent. As it was not part of the original Impact Assessment, the below mentioned revision of that assessment covers this new variant.

Could any or all of the options have significant impacts on (i) simplification, (ii) administrative burden and (iii) on relations with other countries, (iv) implementation arrangements? And (v) could any be difficult to transpose for certain Member States?

i&ii) The NLF-options 4 and 5 have the highest potential to lead to simplification and reduction of the administrative burden. Comparing the variant of full harmonisation with that of optional harmonisation, the former is likely to provide the greatest administrative simplification for public authorities, since that variant will only require the administration of one single set of rules, whereas under the latter, many Member States could be expected to maintain national rules and procedures for mutual recognition.

iii) All options except *status quo* could have impacts on relations with third countries, as the setting of EU limit values for heavy metals could affect imports of contaminated raw materials.

iv) None of the options is expected to have significant impacts on implementation arrangements.

v) N.a., since under all options the EU legislation would take the form of a directly applicable Regulation.

(1) Will an IA be carried out for this initiative and/or possible follow-up initiatives?

(2) When will the IA work start?

(3) When will you set up the IA Steering Group and how often will it meet?

(4) What DGs will be invited?

1&2) A draft Impact Assessment report was prepared and scrutinised by the Impact Assessment Board under the former Commission. It integrates the findings of an assessment performed in 2011 on the impacts of imposing a cadmium limit on phosphate fertilisers (hereinafter the 'Cd impact assessment'). The draft Impact Assessment report is currently being revised, and the options assessed are being aligned with the options presented in this roadmap, for the purpose of ensuring compliance with the priorities of the new Commission.

Furthermore, the consistency between the Cd Impact Assessment and a recent SCHER opinion⁶ on the accumulation of Cd in soil will be analysed.

3&4) The Impact Assessment is being guided by an Inter Service Steering Group including SG, DG ENV, DG AGRI, DG SANTE, DG TRADE, DG RTD, DG TAXUD, DG JRC, DG EMPL, DG GROW, and EASME.

(1) Is any option likely to have impacts on the EU budget above € 5m?

(2) If so, will this IA serve also as an ex-ante evaluation, as required by the Financial Regulation? If not, provide information about the timing of the ex-ante evaluation.

1) No.

2) N.a.

E. Evidence base, planning of further work and consultation

(1) What information and data are already available? Will existing IA and evaluation work be used?

(2) What further information needs to be gathered, how will this be done (e.g. internally or by an external contractor), and by when?

(3) What is the timing for the procurement process & the contract for any external contracts that you are planning (e.g. for analytical studies, information gathering, etc.)?

(4) Is any particular communication or information activity foreseen? If so, what, and by when?

1) The existing draft Impact Assessment report relies largely on the abovementioned ex-post evaluation of the Fertilisers Regulation of 2010 as well as on the study carried out in 2012 on options to fully harmonise the EU legislation on fertilising materials including technical feasibility, environmental, economic and social impacts⁷. It will be revised as indicated in section D above.

Phosphorus recovery and recycling has also been addressed by FP7 research projects, the results of which have been analysed during the workshop 'Circular approaches to phosphorus: from research to deployment', held in Berlin on 4 March 2015⁸. One of the identified priorities is to revise the EU Fertiliser Regulation to extend its scope to nutrients from secondary sources (e.g. recycled phosphates) and organic sources.

2&3) The contributions to the public consultation on the Circular Economy Package with regard to this initiative are being analysed. No major further information gathering is foreseen at this stage.

4) No.

Which stakeholders & experts have been or will be consulted, how, and at what stage?

Consultation of Member States and other stakeholders has been conducted extensively throughout the preparatory phase starting in 2012, in particular in the context of the Fertilisers Working Group. The public consultation on Circular economy published in May 2015 included questions on this topic.

⁶ Scientific Committee on Health and Environmental Risks. SCHER adopted the opinion on 31 May 2015.

⁷ http://ec.europa.eu/enterprise/sectors/chemicals/files/fertilizers/final_report_23jan2012_en.pdf

⁸ The report of the workshop can be downloaded at <http://bookshop.europa.eu/en/circular-approaches-to-phosphorus/pbK10115204>