



Brussels, 4 June 2014

ENTR/F2

MINUTES OF THE FERTILISER WORKING GROUP MEETING

17 March 2014

Participants: Representatives of competent authorities for fertilisers of AT, BE, BG, CZ, DK, EE, EL, FI, FR, DE, HU, HR, IE, IT, LV, LT, LU, NL, PL, PT, RO, SK, ES, UK, NO, CH, TK

Representatives from the following companies or organisations: AEFA, AIF, AIC, Arcadia, Assofertilizzanti, BELFORM, CEN, Dabeer, EBA, ECOFI, EBIC, EFBA, EEB, EFIA, EPAGMA, EUROSLAG, Eurofema, Elkem As Solar, Fertilizers Europe, FOMA, IBMA, IFOAM, IMA, IVA, UNIFA.

Chair: European Commission, DG Enterprise & Industry, Unit F2, Chemicals Industry,

1. ADOPTION OF THE DRAFT AGENDA

The competent Commission service (hereinafter 'COM') announced the creation of a new EU consortium on organic and organo-mineral fertilisers. The new organisation will be presented under AOB. COM also explained that one MS requested the inclusion of an agenda point on the sustainable use of phosphorus. As this would deserve the involvement of other Commission services, it was agreed with the concerned MS that the discussion should be postponed to the next meeting.

2. ADOPTION OF THE DRAFT MINUTES OF THE LAST MEETING OF THE FERTILISERS WORKING GROUP ON 02.12.2013

Some MS suggested some modifications in writing before the meeting. All the comments have been duly taken into account.

A NGO and two Member States remarked that the draft minutes do no longer make reference to country names or stakeholder federations. This renders difficult the possibility to shape alliances and asked whether the names of the contributors could be reinstated.

COM explained that the main reason for anonymising the minutes is that such document is made public under transparency rules. The intention is therefore to avoid that experts are publically exposed via the minutes of the meetings. In addition, the minutes of other Commission expert meetings are commonly shorter than the minutes of the FWG. In the future, the minutes of the FWG meetings will be shorter..

Based on these amendments and explanations, the minutes were adopted.

3. PROPOSALS FOR NEW ANNEX I ENTRIES:

- a) General discussion on the application for the registration of **glucoheptonic acid** in the list of authorised complexing agents

A company presented an application for the registration of glucoheptonic acid as authorised complexing agent in Table E.3.2 for foliar and/or fertigation applications. The product is registered as complexing agent in the national fertiliser law of the MS supporting the request. The product has been pre-registered in REACH and has not been found to present any risks for the environment or human health and has proven agronomic efficacy.

COM indicated that under the CLP inventory, the commercial form sodium glucoheptonate (Na GHA) is classified as skin and eye irritant category by other companies.

The company clarified that CLP inventory is a compendium of classification notifications of different companies, but not necessary the final harmonized classification. When the notifications were done, REACH did not require the acquisition of endpoint data to justify the classification. So, companies sent old classifications, which in the most cases were not sustained by real data. The company stated that sodium glucoheptonate is a structural surrogate of sodium gluconate, which is not classified and is exempted from REACH. Pursuant to the company, the classification skin/eye irrit.cat 2 proposed by other companies make sense if they refer to the aqueous solution of sodium glucoheptonate, because if more than 0,5% of sodium hydroxide remains in the aqueous solution, the product should be classified as Skin/Eye irrit. 2. However, it stated that this classification does not apply to the solid form of Na GHA, because sodium hydroxide remains in the mother liquor during precipitation.

COM asked the company to confirm the above statement in writing. MSs did not express opposition to the inclusion of that substance in Table E.3.2.

- b) Follow-up discussion on the application for the registration of **Synthetic Wollastonite** in Section G.3 of Annex I.

The applicant recalled that the product is a by-product of the silicon metallurgy where quartz (the source of Si) is smelted a high temperature with calcium oxide to remove impurities such as boron. It stated that no traces of heavy metal can be found in the end-product. COM indicated that the description of the type designation was reconsidered to allow access to the type by other manufacturers while excluding clearly other metallurgic process which may not lead to a similar level of purity.

Two MSs mentioned that this request opens a new area for the Fertiliser regulation, as uncertainties about the heavy metal content in products from competitors would remain. Moreover, in their view, the tonnage (10.000 t/year) is considered relatively modest, and

therefore the product is not expected to be largely traded. Other MSs, on the contrary, found that the request perfectly meet the criteria for eligibility.

COM concluded that the new proposal for inclusion matches the remarks expressed by participants during the last FWG meeting. In its view, the argument regarding the tonnage was not valid, as this is up to the producer to decide whether its product can compete with other products present on the internal market. COM therefore indicated that it would prepare an amendment to the Annexes for discussion at the FWG in December. The references to trade names in column 5 should be removed.

4. PLANT BIOSTIMULANT AND AGRONOMIC FERTILISER ADDITIVES: PRESENTATION OF A STUDY PERFORMED BY AN EXTERNAL CONSULTANT

Firstly, the consultant explained the methodology used to prepare the report. Seven Member States and 4 non-EU countries were analysed to understand how plant biostimulant and agronomic fertiliser additives (hereinafter fertilising additives) are currently regulated. The study also examined different existing EU regulatory systems, to see what could be learned from the experience with other products. The study then concluded by proposing a regulatory framework including data requirements and administrative procedure as an option for the future, revised Fertilisers Regulation.

Several Member States expressed concerns about the similarity of plant biostimulants with plant protection products, in particular if the definition will cover products that act on crop quality. The efficacy and safety of such products (in particular microorganisms) is also a source of concerns and one MS mentioned that such products are currently subject to national prior authorisation procedures. In some cases a dual authorisation is granted for products that have stimulating and protecting actions on crops. For those Member States, it would be necessary to have a closer look at the proposed definition for plant biostimulants to avoid any overlap with PPP.

For the bio pesticide sector, claims should be underpinned and the future legislation should put in place mechanisms that would allow public authorities to verify they are true. All participants were of the opinion that back door legislation should be avoided at any cost.

In general, the Register approach was well supported as a tool to verify the agronomic efficacy and safety of products claimed by producers. However one MS warned about the possible cost impacts of such registration system in particular for products that are on the market for many years and that have been proven to be efficient and safe. In its view, a lighter approach than the register should be proposed in this case.

COM asked why the market for plant biostimulants is limited to a few Member States only.

The EU plant biostimulant federation explained that other Member States than the ones mentioned in the report are also currently regulating plant biostimulants. In its view, the diverging rules among Member States create barriers to trade. It stated that, as for other products, the mutual recognition regulation has not provided the necessary level playing field to allow the free circulation of national plant biostimulant in the Union.

The consultant presented its proposed new definition of a plant biostimulant, which reads as follows:

A plant biostimulant is any substance or microorganism, in the form in which it is supplied to the user, applied to plants, seeds or the root environment with the intention to stimulate natural processes of plants benefiting nutrient use efficiency and/or tolerance to abiotic stress, regardless of its nutrients content, or any combination of such substances and/or microorganisms intended for this use.

The biostimulant industry reacted by mentioning that the elimination of crop quality claims from the scope would have negative impacts on the EU industry. In its view, it is generally well recognized that the PPP definition is too large (the PPPR covers pesticides but also growth regulators with the exception of nutrients). It stated that crop quality claims can be verified at any time when the product is on the market via the EU register. As the new definition deviates significantly from the one on which industry could agree earlier on, it will send a written comment to the COM.

COM mentioned that it would be particularly sensitive to cumulative costs that may be not directly related to safety concerns, but driven by commercial interests. Costs of registration may have negative impacts on SMEs if requirements are set too high. On the other hand, restricting the definition to only a few products would also not have a positive consequence for the industry that would have to continue registering their products under the PPPR.

Several MSs found that the inclusion of microorganisms that have action on the root environment (i.e. by fixing N and therefore increase N stock in plants) is a positive element of the new definition.

The consultant mentioned that it would be sometimes difficult to differentiate the effects on plants from those on soils. For example humic acid acts on soils (chelating effect) but interacts also with cell membranes (hormone like effect).

The consultant presented its proposed, new definition of an agronomic fertiliser additive, which reads as follows:

An agronomic fertiliser additive is any substance or microorganism, in the form in which it is supplied to the user, added to a fertiliser, soil improver, growing medium with the intention to improve the agronomic efficacy of the final product and/or to modify the environmental fate of the nutrients released by the fertilisers, or any combination of such substances and/or microorganisms intended for this use.

The consultant explained that such products would aim at determining the environmental fate of nutrients in the soil reservoir and/or to help translocation of such nutrients to the plants.

COM remarked that the case of *Azobacter* mentioned above could also perfectly fit to the proposed definition.

A national fertilizer federation asked how the additives currently regulated by the Fertilisers Regulation will be covered in the future. COM answered that exemptions from registration duties should be examined in more details at the next meeting.

COM concluded that although plant biostimulants are an interesting group of products for the future of the EU agriculture, they can have very heterogeneous actions on plants which lead to unclear risk profiles. The definition proposed by the consultant should be revised in particular as regard crop quality claims. A discussion will be on the agenda of the next FWG meeting.

Regarding the data requirements and the registration process, COM explained that it is currently envisaging having the procedure managed by an EU agency. As regard safety, data requirements could be organized in a tiered approach. In Tier 1, companies could be required to provide identification and tox and ecotox data on the submitted substances/commercial preparations in order to assess hazards. If hazards are identified under tier1, companies would have to carry out an exposure assessment based on the recommended conditions of use, under tier 2. A full risk assessment under tier 3 would have to be performed if tier 2 shows actual exposure levels close to some order of magnitude to the lowest levels where hazardous effects could be observed. In this case risks could be real and would need to be mitigated by modifying the conditions of application, for instance.

Data submitted under Tier 2 and 3 would be covered by data protection. Unless a joint submission is organized by several companies, only the company that submitted the data for registration would be authorized to place the substance on the market.

The different registration steps envisaged were explained in details. Completeness and compliance checks would be managed by the agency. At any moment, data submitted by applicants as well as their conclusions regarding the safety and/or the efficacy of products may be subject to re-examination by volunteering MS which may lead to the withdrawal of product from the market. COM will continue discussion with the EU agency to ensure that the costs entailed by the preparation of data and the registration procedure will remain affordable for companies. It proposed to carry out test-runs on existing files and called upon the participation of some experienced MS which could send real dossiers to ECHA in order to test the feasibility of the proposed procedures.

A follow-up discussion will be organised at the next Fertilisers Working Group in June about all these aspects.

5. REVISION OF THE FERTILISERS REGULATION: ORIENTATION DEBATE

- a) How to demonstrate compliance with the essential requirements? Role of harmonised standards?

COM presented a quick-step on the New Legislative Framework (NLF) for fertilising materials. The regulatory technique establishes the following principles:

- Legislative harmonisation would require the set-up of essential requirements for products placed on the market;
- The use of harmonised standards developed by CEN would provide a presumption of conformity of products with the essential requirements;
- Compliant products are CE marked and may circulate freely on the internal market.

- b) Roles and obligations of economic operators

Definitions of manufacturers, importers, distributors were presented, as well as their expected roles under the NLF. COM also explained that in order to get the CE mark, producers would have to verify whether their products comply with the essential requirements applicable to the relevant fertiliser category and identify the corresponding

conformity assessment procedure for conformity assessment. There would be two choices. Products deriving from natural raw materials and for which the composition is repeatable would be self-certified by producers. Products deriving from waste streams or by-products from the agro-food industry would be subject to a more tightly regulatory approach involving the intervention of a third party certifying the conformity of the products to the essential requirements.

After the presentation, the members of the FWG had the following comments:

The definitions for manufacturers and importers seems different compared to the current regulatory framework where importer as considered as manufacturer. What would be the legal consequences?

COM explained that, according to Article 2(x) of the NLF Decision, 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 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 composition or the identification marking of the product, the operator becomes the manufacturer. This would be further highlighted in the revised Fertilisers Regulation by differentiating the role of importers and distributors.

On industrial by-products, there were general concerns about third party certification for by-products deriving from the agro-food industry which in general provide good quality materials for the manufacture of fertilisers. An industry federation suggested introducing a legal provision in the proposal which would allow producers using such products to move from third party certification to self certification when they can demonstrate that their raw materials are safe.

COM answered that third party certification has been recommended in the EU EoW on biodegradable waste which includes by-products from the agro-food industry as permissible material for the production of compost and digestate. The current position of COM is to follow that approach. There might be a large variability in the quality of and treatment of such by-products derived from the agro-food industry. Cost reduction could be envisaged by reducing the number of authorised input materials and therefore the list of contaminants that need to be controlled and the frequency of controls by third party over time. A sufficient transitional period for manufacturers to adapt to the new rules would have to be granted.

On waste, one MS explained that some raw materials may have different level of quality. Therefore the future provisions should clearly identify which waste material would *not* be allowed for the manufacture of fertilising materials.

COM expressed its opinion that the revised Fertilisers Regulation should take account of the recommendation by DG JRC concerning these End of Waste criteria, which contain a list of authorised biodegradable wastes that could be used as input materials for the manufacture of compost or digestate. If needed, this list could be complemented by a negative list of materials that are considered as outside the scope of the revised regulation. For example, raw sewage sludge within the meaning of the Sewage Sludge Directive should be excluded from the scope.

Another industry federation requested clarification on the procedure to certify groups of products.

COM explained that, similarly to the Biocidal Products Regulation, products presenting the same level of safety and efficacy could be grouped into one family of products under the NLF.

Notified bodies would verify that the whole product family complies with the relevant safety and agronomic requirements, by verifying the compliance of sample materials. If during the examination of samples, a product failed to meet the essential safety or agronomic requirements, the whole family would be deemed to fail. This would allow a reduction of the costs of certification for SMEs without reducing the level of protection of human health or the environment.

Member States questioned the quality of the controls of notified bodies and how this could be ensured across the Union. An NGO asked whether data submitted to notified bodies would be available to consumer and/or environmental organisations.

COM explained that notified bodies are competing between each other, and therefore companies could perfectly choose a notified body in another Member State. This possibility calls for the verification of the competence of the notified bodies via EU accreditation system. The Commission also highlighted that products imported from non-EU countries will be under the responsibility of importers located within the EU. At international level, cooperation between accreditation bodies takes place within the International Accreditation Forum and within the International Laboratory Accreditation Cooperation. Access to information held by notified bodies has to be discussed with competent services of the Commission.

As regards the quality of products placed on the market, an industry federation recalled its views that the NLF is not the appropriate regulatory tool to ensure the quality of fertilisers marketed in the EU.

COM answered that there is an increasing need for customized products that best fit the requirements of farmers and growers. The NLF is considered as the best regulatory approach to ensure producers the necessary flexibility to produce tailor-made products. COM reiterated its plea for an integrated EU fertiliser market which calls for generic essential safety and agronomic criteria that would cover the broad range of products currently being on the market and regulated by national rules.

One Member State asked whether the COM envisaged the full harmonisation of the Fertiliser market, or whether some national requirement for example on testing of ammonium nitrate could continue to fall under the competence of Member States. One MS called for harmonised rules in this regard as well.

COM replied that it intends to propose as far as possible full harmonisation of the EU fertiliser market to allow products to circulate freely on the market without recourse to sometimes cumbersome mutual recognition. The NLF is considered as the most effective approach for products currently regulated at national level, as producers would not be required to register the products at EU level before placing them on the market.

No period of validity for test results is indeed foreseen in the current fertilisers 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. If necessary, the Commission proposal could also proposed harmonised rules for the frequency of testing of AN fertilisers.

c) Essential safety requirements for the different product categories

COM recalled the general objectives of the essential safety requirements:

- Ensure a high level of safety for the products placed on the market by setting generic limit values for contaminants that are likely to be present in most fertilising materials, taking into account their application rates
- Limit values should be based on sound scientific evidence and peer-review assessment. Risk based limit values are envisaged in the longer term when science will allow such study
- Allow flexibility in the modification of the list of contaminants or their limit values based on new scientific evidence
- Facilitate the placing on the market of products that satisfy these requirements (and other obligations)

COM displayed the lists of contaminants that are envisaged for the Commission proposal. Apart from some reactions from industry as regards the comparability of the proposed limit value for cadmium in inorganic fertiliser and soil improvers, the proposed limit values were generally well accepted, except by the organic fertiliser industry which questioned the pertinence of some parameters. COM indicated that some EN Standards would have to be developed or adapted for the determination of certain contaminants or physical impurities in the fertilising materials which are not yet covered at EU level.

d) Essential quality requirements for the different product categories

COM indicated that it intends to put less emphasis on agronomic efficacy than on safety in the revised Fertiliser Regulation. The role of ensuring efficacy could be assumed by the industry itself, or by other EU legal instrument such as the CAP or existing EU environmental law on the protection of groundwater and surface water in relation with nitrate for example. COM also recalled the role of effective market surveillance in making sure that whatever has been claimed by producers, this is justified. The future legislation should not defend the concept of agronomic efficiency but should ensure a minimum quality of products.

COM explained that, in its view, any disruption of the market should be avoided as far as possible on the grounds of efficacy criteria. The minimum limit values should be therefore proposed with the aim to cover as much as possible well introduced products, including those for the hobby market. It would be always possible to place products with a higher content in nutrients, and to declare via labelling the actual content in nutrients. Other added value of the fertilising materials could be detailed in a technical document if necessary (e.g. parameters for spreading the product). One MS mentioned, however, that

a low content in nutrients would mean that more contaminants are brought to the soils, as a higher application rate would be required to satisfy plant nutrition needs.

An industry federation explained that the minimum limit values for micronutrient are too high compared to the limit values proposed for primary and secondary nutrient fertilisers. In its view, the current limit values of Tables E.2.2 for horticulture should therefore continue to apply.

An EU federation promised to submit other quality criteria to differentiate organic fertilisers from soil improvers taking into account their different levels of application.

COM is calling the participants and the EU federation of producers of organic fertilising materials to revise the essential quality criteria for organo-mineral fertilisers in order to insist on the genuine added value of such product compared to mixtures of organic and inorganic fertilisers. The criteria proposed so far define only their composition in terms of nutrient content but organo-mineral fertilisers provide apparently more functions, among others by influencing the release patterns of nutrients in the environment and this claim should be verifiable by an efficient and reliable analytical method. The stability of the product should be ensured to allow controls on the market.

A follow-up discussion will be organised at the next Fertilisers Working Group in June about all these aspects.

6. AOB

A new European consortium covering organic, organo-mineral fertilisers and organic soil improvers has been set up. The organisation presented its main objectives.

Next meeting: 2 June 2014