EU plans on harmonised registration of yield enhancers

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CEUREG Forum XVII

Budapest, 14-15 October 2013.

Scope of this presentation

- Fertilisers - Fertilising materials -Yield enhancers

- The main types in the future EU legislation
  - Inorganic fertilisers
  - Organic fertilisers
  - Soil improvers
  - Growing media
  - Biosimulants

Content of the presentation

- History of EC fertilisers legislation
- Present situation
- The need of harmonisation
- Process of harmonisation
- Opened questions

(Some details are derived from Commmission presentations)

History of EC fertilisers legislation

Till 1976 – national legislation for all categories

Between 1976 and 2003

- **18 (EEC) directives concerning EC fertilisers**
- **harmonisation duty of MSs in their national legislation**

Since 2003 to present day

- **uniform structure from 18 directives into Regulation 2003/2003/EC– EC fertilisers**
- **regulation level – mandatory application**

Present situation

EC fertilisers

- **Regulation 2003/2003/EC**
- **A fertiliser belonging to a type of fertilisers listed in Annex I and complying with the conditions laid down in this Regulation, may be designated ‘EC fertiliser’**
- **Fertilisers that are marked ‘EC fertiliser’ in accordance with this Regulation shall circulate freely within the EU (EEA relevance)**

Other products

- **National legislations**
- **Mutual recognition (Regulation 764/2008/EC)**

The need of harmonisation

- Only part of the mineral fertilisers are harmonised at EU level, other fertilisers and other fertilising materials are not
- Reluctance of authorities and economic operators to use the mutual recognition scheme for ‘national fertilisers’
- There are no rules for the limit of contaminants
- Very lengthy procedure for the introduction of new fertiliser types which encourages innovation

What to do?

Commission realised difficulties and mandated to measure and evaluate the problems :

2010. Evaluation of Regulation 2003/2003/EC on Fertilisers (Strategy & Evaluation Service)

2011. Study on options to fully harmonise the EU legislation on fertilising materials, including technical feasibility, environmental, economic and social impacts (450 pages)

(Arcadia International, BIPRO GmbH, VAN DIJK Management Consulting)

The aim of harmonisation

- To harmonise legislation for all fertilising materials
- To guarantee the safety (e.g. human health and environmental protection) of fertilising materials placed on the market
- To ensure agronomic efficacy and the ability of farmers to rely on the quality and nutrient content of the product bought
- To reduce the administrative burden for authorities and for industry, to pre-empt problems with current mutual recognition procedure
- To reduce compliance costs

Structure of the study

- Advising the Commission „policy options” for revised EU legislation
- Evaluating the effectiveness, technical feasibility and policy acceptance of the policy options
- Reviewing existing national fertilising material laws and standards
- Assessing the relationships and possible synergies in safety assessment with relevant existing and forthcoming EU legislation
- Advising the Commission in establishing essential safety and agronomic requirements for all types of fertilising materials

Option 1 : baseline option

The present regulatory framework remains unchanged :

- **Regulation 2003/2003 /EC on EC fertilisers**
- **National legislations for non harmonized area + Regulation 764/2008/EC on mutual recognition**

Option 2 : Existing Legal Framework replaced by related policies

Regulation 2003/2003 /EC would be repealed and replaced by relevant provisions and procedures :

- **For inorganic fertilisers REACH, CLP** :
  - Obligations for manufacturers and importers to register chemical substances
  - Chemical Safety Report
- **For Organic Fertilisers based on organic wastes** :
  - Directive 86/278/EEC (sewage sludge) : prevent harmful effects on soil, vegetation, animal and humans
  - Regulation 1069/2009/EC (animal by-products) : health rules linked to safety of food chain (sanitary reasons)

Option 3 : Voluntary Commitment by Industry

Industry would agree :

- **to establish voluntarily quality procedures and standards for all fertilisers, including also the presence of contaminants and / or infections materials**

- **based on good manufacturing practices, self-control activities**

Option 4 : Full harmonisation based on current Regulation

- Fertiliser types laid down in the annex to future regulation with all technical details (minimum nutrient content, description of manufacturing procedures)
- Maximum limit values for contaminants and specific technical requirements for additives
- Data requirements and clearer procedures (in respect of the deadlines !) for approval
- Two ways
  - all types in one regulation
  - different regulations for each types

Option 5 : listing authorised ingredients and additives

- Annex containing permitted ingredients and additives
- Limit values for contaminants and other specific technical details – in the legal text
- Further details developed in EN standards
- Regularly adapting the list to technical progress

Option 6 : New Approach

- To specify general essential requirements with regard to safety, agronomic and other specific technical issues
- To guarantee safe and efficient fertilisers or additives
- All further details – in necessary also individual types – would be developed in EN standards
- Manufacturers are responsible for ensuring that products placed on the market are in conformity to criterias.
- Conformity assesments are carried out by notified bodies.

Option 7

- harmonisation of the fertilisers market by using the most appropriate option for each fertilising material categories pending their characteristics
- it is also possible that for different categories of fertilisers, different options could be chosen, e.g. option 6 for growing media, but rather option 5 for organic fertilisers.
- but only one policy approach per fertilising material category
- a framework legislation links the different legal instruments and defines the fertilising material categories.

COMPARISON OF THE OPTIONS

- Identification of the relevant economic, social and environmental impacts;
- Contribution of the different policy options to the general and specific objectives (effectiveness);
- Technical feasibility, political acceptance and timing of the policy options;
- Assessment of administrative costs for authorities and industry;
- Overall cost-effectiveness assessment.

Ad hoc Working groups

- Since 2012 four ad hoc working groups
- Starting points of suggestions were based on national legislation and relevant existing and forthcoming EU legislation
- Meetings in 2012
  - WG 1 four times
  - WG 2 three times
  - WG 3 three times
  - WG 4 three times

WG 1 Objectives

- General frame of legislation and general requirements

- Definitions of different product types

- Define the difference between fertilisers and PPPs

- Differentiation between products destined to professional and private users.

- Potential need for a negative list of input material

WG 2 Objectives

- If necessary, define criteria for nutrient content, product composition and agronomic efficacy/product types

- Define production method and composition of products

- Define analythical methods

WG 3 Objectives

Define limit values for **contaminants**, **pathogens**, and **other risk factors**

- Draw up a **list of contaminants** based on EU and national legislations: chemical and biological contaminants
- Define **limit values** for contaminants
- Define **analythical methods** of contaminants
- Reflect on how information on contaminants should be mentioned on the **product label**
- Determine whether the concentration of contaminants should be **expressed** as:
  - a percentage related to nutrient content
  - a percentage related to total matter or dry matter

WG 4 Objectives

Labelling requirements for different product types

- Compulsory label elements (active ingredients, contaminants, usage)
- Optional label elements

Important: labels should be as simple as possible and provide relevant information to farmers

Compliance check

- Analytical methods
- Traceability
- Time-frame for record-keeping

Present results of WGs

topics already covered depending on the product type

- definition,
- min. nutrient content, forms of nutrients, other positive parameters (e.g. neutralisation value)
- min-max organic matter content
- list of non-nutrient metals (As, Cd, Cr VI, Hg, Ni, Pb) and human pathogens (Enterococcus, Escherichia coli, Salmonella)
- labelling requirements

still to be commented:

- contaminants: 3 "classes" of maximum limits depending on the 3 ranges of application rates?
- origin of components (waste, animal, plant)
- draft End-of-waste criteria as a basis for organic contaminants? (PAH, PCB, PCDD/F)

Opening questions
Topics not fully covered

- Fertilisers additives (improve agronomic efficacy or physical performance)
- Biostimulants
- Rules for mixtures
- Dual use
- Review of list of contaminants
- Relationship with other regulatory frameworks
- Manure (processed, raw)
- Negative list of prohibited ingredients
- Positive list of usable ingredients
- End-of-waste criteria (update on EU EoW + status of national EoW)

Dual use

- **Borderline cases :**
  - **fertilisers/Plant Protection Products (PPP);**
  - **plant biostimulant/PPP**

- **Special clause: in case of products with dual function, the final product should be subject to the most stringent regulatory framework.**

Borderline cases - decision

Yield enhancer has to be registered

EC fertiliser

Iron sulphate?

PPP

It depends on the purpose and labelling

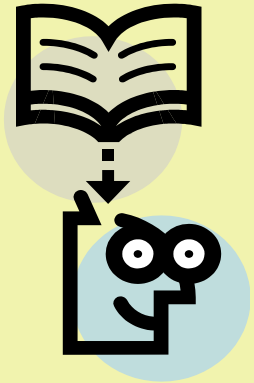
Other borderline cases: copper and iron salts, sulfur, calcium cyanamid, phosphites, plant biostimulants

Commission – DG SANCO: scope of borderlines – not legally binding

Expectations

- To establish a functioning internal market by ensuring the free circulation of all categories of fertilising materials on the whole EU territory.
- To support the competitiveness of the EU fertilising materials industry while providing for a high level of health, safety, environmental and consumer protection, through safe and efficient products.

Thank you for your attention



Structure of Regulation 2003/2003/EC

ANNEX I List of types of EC fertilisers

- Type designation,
- Data on method of production and essential ingredients
- Minimum content of nutrients (percentage by weight)
- Data on the expression of nutrients
- Other requirements
- Other data on the type designation
- Nutrient content to be declared
- Forms and solubilities of the nutrients
- Other criteria

Structure of Regulation 2003/2003/EC

- ANNEX II Tolerances
- Annex III Technical provisions for Ammonium Nitrate Fertilisers of High Nitrogen Content
- ANNEX IV Methods of Sampling and Analysis
- ANNEX V
  - List of documents to compile a technical file for a new type of fertilisers to be added to annex I of this regulation.
  - Standards of accreditation concerning the laboratories for checking compliance of EC fertilisers with the requirements of this regulation and its annexes

Direct and indirect links of current EU legislations to risk management of fertilising materials

- Regulation (EC) No 1907/2006 (REACH)
- Regulation 1272/2008 (CLP)
- Waste Framework Directive 2008/98/EC
- Directive 86/278/EEC (Sewage Sludge)
- Regulation (EC) No 1069/2009 (Animal by-products)
- Regulation (EC) No 66/2010 (Ecolabel)
- Council Regulation (EEC) No 315/1993 (Contaminants in food)
- Regulation (EC) No1881/2006 (maximum levels for certain contaminants in foodstuffs)
- Council Regulation (EC) No. 834/2007 (organic production)
- Regulation (EC) No 1107/2009 (Plant Protection Products)
- Water Framework Directive 2000/60/EC
- Directive 1999/31/EC (Landfill Directive)
- Directive 91/676/EEC (Nitrate Directive)

Harmonisation of biostimulants

- **Plant biostimulant** means a material which contains substance(s) and/or microorganisms whose function when applied to plants or the rhizosphere is to stimulate natural processes to benefit nutrient uptake, nutrient efficiency, tolerance to abiotic stress, and/or crop quality, independently of its nutrient content
- **harmonisation is difficult**, one of the most variable group (oils , plant extracts, microorganisms)

- **2011 EBIC (European Biostimulant Industry Consortium)**