**New Approach applied to the revised Fertilisers Regulation**

**Obligations of economic operators**

Fertilisers Working Group – 17 March 2014

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**OUTLINE of the presentation**

1. Introduction to the New Approach

2. Obligations of economic operators
   - 2.1. Manufacturers
   - 2.2. Importers
   - 2.3. Distributors

3. Conformity assessment procedures
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Scope of New Approach in the revised Fertilisers Regulation

• Fertilising materials:
  – Fertilisers: organic, inorganic, organo-mineral fertilisers
  – Liming materials
  – Soil improvers: organic and other soil improvers
  – Growing media

• All fertilising materials shall be concerned

   FULL HARMONISATION of the fertilising materials market at EU level
Quick-step to the New Approach

- Products placed on the market must conform to **essential safety and quality requirements** defined in an Annex to the Regulation
- **Harmonised standards** developed by CEN provide a **presumption** of conformity
- Compliant products are "**CE marked**" and may **circulate freely** within the EU

**ECONOMIC OPERATORS:**

- Other obligations before the placing on the market:
  - Compliant labelling and safety information
  - Traceability of product
  - Importers/distributors: check that they deal with compliant products only

**EU declaration of conformity and CE marking for compliant fertilising materials**

**Quality assurance by economic operators (incl. safety)**

**Free movement of fertilising materials within the EU**

**Market surveillance at national level**

**Union market surveillance and safeguard procedure**

**COM control on national measures**

**NATIONAL MARKET SURVEILLANCE AUTHORITIES:**

- If risk to health/safety suspected: evaluation of fertilising material;
- If non-compliant fertilising material: information to COM and MS and corrective measures with economic operators;
- Provisional measures against non-compliant economic operators where applicable
Key actors of the New Approach

- Economic operators
  - Manufacturers
  - Importers
  - Distributors
- Notified bodies
- National competent authorities

Focus on economic operators:
Decision 768/2008/EC on a common framework for the marketing of products

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General obligations of economic operators

**Manufacturer**
Shall design and manufacture products in accordance with the essential requirements
Shall draw up the EU declaration of conformity

**Importer**
Shall place only compliant products on the European market
Shall keep technical documentation

**Distributor**
Shall act with due care in relation to the applicable requirements

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Manufacturers - definition

- "A natural or legal person who manufactures a fertilising material or has a material designed or manufactured, and markets that material under his name or trademark."
- The obligations of manufacturers apply where an economic operator markets fertilising material under its own name or trademark
- The obligations of manufacturers applies to any person who changes a fertilising material to the point that different essential requirements will become applicable, or substantially modifies a fertilising material with a view to placing it on the market
**Importers - definition**

- "A natural or legal person established within the Union who places a fertilising material from a third country on the Union market."

**Distributors - definition**

- "A natural or legal person in the supply chain other than the manufacturer or the importer who makes a fertilising materials available on the market."

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### Types of economic operators

#### Typical business models

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<th>Type</th>
<th>Description</th>
<th>Product cycles</th>
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<tbody>
<tr>
<td>1 EU Production</td>
<td>Product developed, produced, and sold entirely within the EU</td>
<td>Manufacturer</td>
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<tr>
<td>2 Developed &amp; Domestic</td>
<td>Product developed and sold within the EU by an EU operator but produced outside EU</td>
<td>Manufacturer</td>
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<tr>
<td>3 3rd party &amp; domestic (no product alteration)</td>
<td>Unaltered product developed by supplier and sold within the EU by EU operator</td>
<td>Manufacturer</td>
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<tr>
<td>4 3rd party &amp; domestic (product alteration)</td>
<td>Supplier product specifically modified for/by an EU operator and sold within the EU</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>5 Direct Import</td>
<td>Product developed by non-EU operator sold outside EU for direct import by EU operator</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>6 Manufacturers Authorized Representative in EU</td>
<td>Product sold by contracted representative of a non-EU operator to hold technical file</td>
<td>Manufacturer</td>
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<tr>
<td>7 Retail own brand product</td>
<td>Product developed exclusively for EU sold and bought outside the EU</td>
<td>Manufacturer</td>
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2.1. General obligations of manufacturers

• Design and manufacture of fertilising materials according to essential safety and quality requirements
• Carry out the conformity assessment procedure or have it carried out
• Upon request, provide all information on the safety/compliance of products made available on market:
  – Drawing up and keeping available the technical documentation
  – EU declaration of conformity and affix CE marking
2.1. General obligations of manufacturers (2)

• **Labelling** and **traceability** of products:
  – Elements allowing product identification
  – Elements allowing economic operator identification

• **Ensure the safety & quality** of products placed on the market:
  – Sample testing required when risk suspected;
  – Instruction and safety information on product;
  – **Take corrective measures** in case of a non-compliant product;
  – Quality assurance of product made available on market;
  – Immediate information of competent authorities if risky product on market

Authorised Representatives

• Act on **behalf of the manufacturer** in relation to **specific tasks** (keeping the papers and provide information to public authorities), on the basis of a **written mandate**

• Shall not:
  – Draw up technical documentation
  – Ensure that the fertilising materials have been designed and manufactured in accordance with the essential requirements

• Can be:
  – Swedish company with an authorised representative in IT
Steps for manufacturers*
Manufacturing "orientation"

Identification of fertilising materials sub-categories and corresponding essential requirements

Essential requirements include:
• Minimum nutrient content;
• Maximum contaminant content;
• Values to be declared;
• ... etc.

Manufacturing of product
outside Regulation scope

Making available on the market

* Without prejudice to the obligations of manufacturers stemming from other applicable EU legislation

Steps for manufacturers* (2)
The conformity check obligations

Manufacturing of product

Conformity assessment procedure

• Choice of EU-type examination module
• Self-certification by manufacturer

EU declaration of conformity, and CE marking by manufacturer for compliant fertilising materials

* Without prejudice to the obligations of manufacturers stemming from other applicable EU legislation
Steps for manufacturers *(3)
Labelling and traceability obligations

- Compliant labelling and safety information
- Traceability of product

Importers/distributors: check that the manufacturer complied with its obligations

Steps for manufacturers *(4)
Post-marketing obligations

- Quality assurance
- Take corrective measures if applicable

* Without prejudice to the obligations of manufacturers stemming from other applicable EU legislation
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2.2. Obligations of importers

• Place **only compliant fertilising material on the market:**
  – Technical documentation drawn up, conformity assessment procedure carried out and CE marking present;
  – Safety information and instructions on label;
  – Information of manufacturer and market surveillance authorities if fertilising material presents a risk

• Storage and transport conditions in line with the **essential safety and quality requirements**

• Complete the **labelling** (name, trade name, address...)

2.2. Obligations of importers (2)

• **Take corrective measures** to bring fertilising materials made available on the market into conformity (withdrawal/recall)

• **Cooperation with authorities:**
  – Provide EU declaration of conformity if required
  – Sample testing if required when risk suspected
  – Provide competent authorities with all information requested
  – Immediate information of authorities if fertilising material made available presents a risk

• **Identification** of manufacturer/distributor
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2.3. Obligations of distributors

- **Act in due care** of the requirements of the regulation
  - CE marking and required documentation
  - Safety information and instructions on label;
  - Compliant labelling (obligation of manufacturer/importer)
  - Not making available on the market non-compliant products
  - Information of manufacturer/importer and market surveillance authorities if fertilising material presents a risk

- Storage and transport conditions in line with the **essential safety and quality requirements**
2.3. Obligations of distributors (2)

- **Make sure corrective measures are taken** to bring fertilising materials made available on the market into conformity (withdrawal/recall)

- **Cooperation with authorities:**
  - Provide competent authorities with all information requested
  - Immediate information of authorities if fertilising material made available presents a risk

- **Identification** of manufacturer/importer
How to get CE marking?

• Be the **manufacturer** of the product
• Identify the **categories of fertilising material** at stake
• Have a fertilising material **complying with the essential safety and quality requirements applicable to that fertilisers categories**
• Identify the corresponding **choice of modules** for the conformity assessment

Conformity assessment procedure

2 main possibilities

• **Self-certification**: self-assessment by manufacturer that the material meets the fertilisers category’s essential requirements
• **EU-type examination** (assessment by notified body): choice between 4 modules to check conformity to fertilisers type:
  – Internal production control
  – Internal production control + supervised product testing
  – Quality assurance of the production process
  – Product quality assurance
Conformity assessment procedure
SELF-CERTIFICATION

• The "simplest case"
• **Scope?** Political choice proposed = "what we know best?":
  – Inorganic Fertilisers if not derived from industrial by-products, except ammonium nitrate fertilisers
  – Liming materials if not derived from industrial by-products
  – Growing media

Conformity assessment procedure
SELF-CERTIFICATION (2)

• **What shall be done?**
  In principle for each commercial product (grouping duly justified might be possible):
  – Analyse nutrients content and/or any required quality parameters of several product batches as well as contaminants content.
  – Based on these results consider the conformity of the fertilising materials with quality essential requirements and prepare the declaration of parameters required on the label (based on the average nutrient content values,...).
  – Fill in the EU declaration of conformity
  – Affix the CE marking
Conformity assessment procedure

SELF-CERTIFICATION (3)

• **Which information shall be kept available by the manufacturer?**

  All technical documentation, such as the composition, the origin of the feedstocks, the results of quality and safety tests + any information regarding instructions for use and safety informations+ the EU declaration of conformity

• **What shall the manufacturer do after the placing on the market?**
  
  – Regular sample testing of marketed fertilising materials
  – Register of complaints for non conforming products, or recalls and inform distributors,…
  – Inform about risks and corrective measures
  – Respond to reasoned request from a competent national authority

Conformity assessment procedure

EU-TYPE EXAMINATION

• **The "most stringent case" = "pre-marketing approval"**

• **Scope?** Political choice proposed = "what we know less", in particular, all fertilising materials derived from industrial by-products and/or waste":
  
  – Animal – by products
  – Sewage sludge processed to recover nutrients
  – Bio-degradable waste (digestate/compost)
  – By-product from the steel, agro-food industry,…

  when these feedstocks are still present/proved to be present/cannot be proved to be absent.
Conformity assessment procedure
EU-TYPE EXAMINATION (2)

• EU-type examination only, choice between:
  – Internal production control + supervised product testing
  – Quality assurance of the production process
  – Product quality assurance

• Notified bodies might reject the choice of the manufacturer and impose another "modules of certification" if it considers more appropriate (procedure to be provided in annex of the Fertilisers Regulation).

Conformity assessment procedure
EU-TYPE EXAMINATION (3)

• What shall be done?
In principle for each commercial product (grouping - duly justified might be possible):
  – Analyse nutrients content and/or any required quality parameters of several product batches as well as contaminants content.
  – Based on these results prepare a technical dossier to prove the conformity of the fertilising materials with quality essential requirements and prepare the declaration of parameters required on the label (based on the average nutrient content values,...).
  – Assessment of compliance by notified body based on info provided by the manufacturer and/or own sampling and analysis
  – Notified body fill in the declaration of conformity
  – The producers affix the CE marking
Conformity assessment procedure
EU-TYPE EXAMINATION (4)

• Which information shall be kept available by the manufacturer or could be obtained via the notified bodies?
  Similar information as for the self certification: responsibilities towards distributors...
  + Access to the information provided by the manufacturers to the notified bodies for competent authorities!

Conformity assessment procedure
EU-TYPE EXAMINATION (5)

• What shall the manufacturer do after the placing on the market?
  – Regular sample testing of marketed fertilising materials, sometimes imposed or carried out by the notified bodies
  – Register of complaints for non conforming products, or recalls and inform distributors, notified bodies
  – Inform about changes in composition (major changes, need for guidance document), in risks and corrective measures where considered necessary
  – Respond to reasoned request from a competent national authority in case of doubt concerning the product or in case of doubt concerning the serious work done by notified bodies
Conformity assessment procedure

Special case of ammonium nitrate fertilisers of high nitrogen content

• Straight or compound ammonium nitrate based fertilisers containing more than 28% by mass of nitrogen in relation to ammonium nitrate

• No choice of conformity assessment procedure: internal production control (self-assessment) with **supervised product testing for the detonation test.**
Conclusions

Revision of the Fertilisers legislation, based on the new approach, will

- Remove the remaining trade barriers on the EU market for fertilisers thanks to the full harmonisation of the market, while ensuring an appropriate level of protection of health and environment
- Be less "patronizing" the design of products than with fertilisers types
- Create less barriers, meaning also more competition
- Require more "marketing" work to defend the products and to convince farmers
- Reduce administrative costs for Member States and companies

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