

NEWSLETTER

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A CLOSE VIEW ON THE DRAFT FERTILISING PRODUCTS REGULATION

SPECIAL EDITION

Dear Subscribers,

This edition of the Newsletter comprises a detailed report of the first official draft of the possible future Regulation of the European Parliament and of the Council laying down rules on the making available on the market of CE-marked fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 (COM (2016) 157 final), including organic and waste-based fertilisers as well as “biostimulants”. The draft Regulation for CE-marked fertilising products is part of the EU’s Circular Economy package to accomplish a more sustainable economy, and shall apply from 01 January 2018 onwards.

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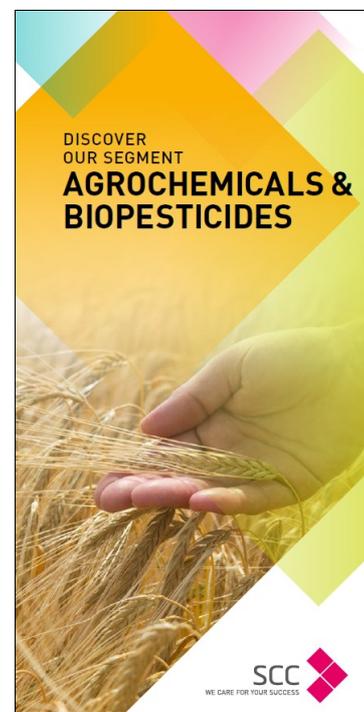
Furthermore, we appreciate your feedback and comments regarding the SCC Newsletter. Please drop us an e-mail at newsletter@scc-gmbh.de



Dr. Friedbert Pistel

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AGROCHEMICALS & BIOPESTICIDES



Draft Fertilising Products Regulation published by European Commission

The European Commission has published the first draft of the **Regulation of the European Parliament and of the Council laying down rules on the making available on the market of CE marked fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 (COM(2016) 157 final)** including organic and waste-based fertilisers as well as “biostimulants”. The draft Regulation for CE-marked fertilising products* is part of the Circular Economy package of the EU to accomplish a more sustainable economy and shall apply from 01 January 2018 onwards.

The existing Fertiliser Regulation 2003/2003¹ considers only conventional inorganic fertilisers, designated as “EC fertiliser”. There was a pronounced need for revision, inclusion of new innovative types of fertilisers and a better protection of the environment which have already been discussed since 2010. In 2015 stakeholders have been consulted and an impact assessment has shown that, due to strict national fertiliser legislations, mutual recognition is not sufficient for free movement of fertilisers not falling in the scope of the existing fertiliser Regulation 2003/2003. Thus, the new legislation shall provide more flexibility, administrative simplification and possibilities to bring safe and innovative products onto the market.

One innovative product type, not covered by the existing Regulation 2003/2003 are the so-called plant biostimulants. In a press release of March 18th, 2016, the European Biostimulants Industry Council (EBIC) “broadly welcomes the publication of this long-awaited draft Regulation, and the extent to which it recognizes biostimulants as a valuable and innovative tool for farmers.” President Giuseppe Natale calls the new regulatory framework a key step to a more integrated and efficient agricultural model and a brighter future of the industry sector.²

*Conformity marking under general principles of Regulation 765/2008

CE-marked fertilising products and Product Function Categories (PFC) under the new upcoming Regulation

In the scope of the new draft Regulation, a **fertilising product is defined as a substance, mixture, micro-organism or any other material, applied or intended to be applied, either on its own or mixed with another material, on plants or their rhizosphere for the purpose of providing plants with nutrient or improving their nutrition efficiency.**

For the sake of clarity and to address each particular kind of fertilising product, separate categories based on the function of the product will be specified in the upcoming Fertiliser Regulation. The designated “**Product Function Categories**” (PFC) encompass:

- fertilisers, both organic and inorganic
- liming materials
- soil improvers
- growing media
- agronomic additives
- fertilising product blends
- plant biostimulants.

To address the specificity of each category of fertilising product, the particular subcategory is ruled by individual safety and quality requirements. Within this scope, products of blended fertilising products will belong to all individual categories of its components.

Micro-organisms, allowed to be part of a PFC, will be listed in a **positive list** in the Annex of the upcoming Regulation.

Example 1: PFC Fertiliser

Conventional, inorganic fertilisers, solely considered by the existing Regulation 2003/2003, are mostly extracted from mines or chemically produced in line only with a linear economy model. The production process for inorganic fertilisers is very often both, energy consuming and CO₂-intensive. Additionally, only about 50 % of the fertilisers currently on the market fall under the scope of the existing European Regulation 2003/2003. Thus, currently it is very difficult for innovative fertilising products, often containing **nutrients or organic matter recycled from bio-waste or other secondary raw materials**, to be marketed in the EU. In addition, promising technical progress was made in the field of recycling of waste, such as **phosphorus recycling from sewage sludge** as well as fertilising product production from **animal by-products**.

With attention to this progress and new product types available, the revision of the fertiliser Regulation has been included into the **EU Action Plan for the Circular Economy**³, setting new goals for recycling and waste reduction, as well as promoting global competitiveness and economic growth.

The upcoming Regulation, once approved, shall replace Regulation 2003/2003 to harmonise the process of making fertilisers available on the EU market.

Fertilisers in compliance with the new legislation will be **CE marked under the general principles of Regulation 765/2008**⁴ **presenting requirements for marketing of CE-products**, and can move freely in the EU internal market.

For **EC fertilisers** covered by Regulation 2003/2003 the new draft Regulation will set **transitional provisions**. Designated EC fertilisers placed on the market before application of the new requirements will still be marketable, but after entry into force, all EC fertilisers must be in conformity with the CE Regulations.

Special requirements for products based on animal by-products

Regulation 1069/2009⁵, regarding animal by-products, will be amended to that extend, that a fertilising product should be excluded from the requirements of that Regulation, as soon as it no longer poses any significant risk to public or animal health (defined as the 'end point in the manufacturing chain'). Nonetheless, where a manufacturing process governed by the new upcoming fertiliser Regulation starts already before that end point has been reached, the process requirements of Regulation 1069/2009 apply together with the Regulation for CE-marked fertilising products. Animal by-products for which no such end point has been determined will be in any event excluded from the scope of the upcoming Regulation.

Example 2: PFC Plant Biostimulant

By amendment of Regulation 1107/2009⁶, concerning Plant Protection Products (PPPs), plant biostimulants will be explicitly excluded from this Regulation and will fall under the new upcoming legislation of ferti-

lisers. They are, by definition according to the upcoming fertiliser Regulation, certain **substances, mixtures and micro-organisms aiming solely at improving the plants' nutrient use efficiency, tolerance to abiotic stress, or crop quality traits independently of the product's nutrient content**. They are delimited from PPPs, which mainly focuses on substances and/or microorganisms exerting an effect on plant pests, but also those influencing plant life processes (e.g. growth regulators) distinguished from nutrients. Fertilisers and PPPs have to be differentiated according to their definition. However, the proposed PFC 'Plant Biostimulant' concerns substances and/or micro-organisms exerting an effect on plant growth in very similar ways as certain PPPs do. Thus, **products with one or more functions, one of which is covered by the scope of Regulation 1107/2009, will remain under the scope of the PPP Regulation**.

New requirements and range of the Regulation

One aim of the upcoming Regulation is to improve safety standards of fertilising products as well **lower limits for heavy metals**, especially cadmium, for each PFC. This improves food and consumer safety, along with soil protection. In accordance with new safety standards, maximum limits for impurities, such as organic or microbial contaminants, are defined. Furthermore, a new **minimum nutrient content** for each individual PFC is set, to ensure quality of CE-marked fertilising products.

In addition to the PFC, "**Categories for Component Material**" (CMC) will be included in the new Regulation. Component materials that can be contained in CE-marked fertilising products are listed in Annex II of the draft Regulation and comprise of:

- **virgin material substances and mixtures,**
- **non-processed or mechanically processed plants,**
- **plant parts or plant extracts,**
- **compost,**
- **digestates,**
- **food industry by-products,**
- **micro-organisms,**
- **agronomic additives,**
- **polymers and**
- **certain animal by-products.**

Input materials allowed to produce PFC products are defined by CMCs. For these materials specific safety requirements will apply, depending on the type (sub-category) of component material. The materials shall not include any material for which **maximum limit values** have been set in the PFC. Maximum Residue Levels will still be covered by the relevant Regulations for food and feed for each component of a PFC (**Regulation 396/2005**⁷, on maximum residue levels of pesticides; **Regulation 470/2009**⁸, as concerns residue limits of pharmacologically active substances or **Directive 2002/32/EC**⁹ on undesirable substances in animal feed).

The new Legislation will be complementary to **Regulation 1907/2006**¹⁰ concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (**REACH**), which will continue to apply to chemical substances incorporated in fertilising products.

The upcoming Regulation will not prevent the application of existing Union Legislation relating to aspects of protection of health, safety and the environment. The upcoming Regulation therefore applies without prejudice to:

- **Council Directive 86/278/EEC**¹¹, on sewage sludge
- **Council Directive 89/391/EEC**¹², regarding health of workers
- **Regulation 1272/2008**¹³, on classification, labelling and packaging of substances and mixtures
- **Commission Regulation 1881/2006**¹⁴, about contaminants in foodstuffs
- **Council Directive 2000/29/EC**¹⁵, on protective measures
- **Regulation (EU) No 98/2013**¹⁶, respecting explosives precursors
- **Regulation (EU) No 1143/2014**¹⁷, concerning invasive alien species

The upcoming Regulation will **not replace the Legislation on national basis**, which shall co-exist. Therefore, national non-harmonised fertilisers compliant to national law will stay on the market and continue to be subject to **mutual recognition**.

Envisaged registration process for products covered by the upcoming Regulation

To register a CE-marked Fertilising Product, the **registrant (applicant company or manufacturer)** will have to carry out a **conformity assessment procedure** compliant to Decision No 768/2008/EC¹⁸, on a common framework for the marketing of products. The

assessment dossier shall be in accordance with all existing EU and national regulatory frameworks for similar substances (not specified further in the draft Regulation), and shall include a relevant set of information. Hereby, applicants are encouraged to use existing data submitted in other EU regulatory contexts. Detailed rules on conformity assessment procedures are given in Annex IV of the upcoming Regulation.

The CE-marked products will **not be tested** by authorities and the conformity with the legislative requirements is the **sole responsibility of the registrant**. The application for assessment will be evaluated by an authorised Notified Body. Technical documentation, as well as the EU declaration of conformity has to be kept by the manufacturer for ten years. Information has to be submitted upon reasoned request to a responsible authority. In addition, registrants have to carry out and keep record of sample testing as well as a register of complaints.

In addition, the upcoming Regulation foresees, that CE marked fertilising products can be brought onto the market by importers and distributors having regard to certain obligations.

Importers are liable to ensure that the fertilising product is in accordance with conformity assessment. Therefore, they might carry out sample testing of such fertilising products and keep a register of complaints, if necessary. They have to keep a copy of the conformity declaration for ten years and have to ensure that the technical documentation will be available for authorities upon request. As soon as an importer distributes the fertilising product under his name or trademark or modifies an existing CE-marked product, he will be designated as the manufacturer and has to carry out the specific obligations.

The **distributor** has the obligation to verify the EU declaration of conformity and that the requirements are met. Hereby, the distributor is as well obliged to forward all necessary documentation to the responsible authority in the course of a reasoned request.

An **authorised representative** may be appointed by a written mandate by the registrant, to keep the declaration of conformity and the technical information. Furthermore, upon a reasonable request from a competent national authority, the authorised representative must forward the declaration of conformity and the technical information to the responsible authority and cooperate with any actions necessary to eliminate risk. The representative shall not carry out the obligations of drawing technical documenta-

tion or carrying out sample testing. The role of the authorised representative can be taken on by an experienced regulatory consultant and is one of the areas of responsibility of SCC.

After placing on the market of a CE-marked fertilising product, the Member States will have to designate a national authority to carry out the assessment and monitoring of notified conformity assessment bodies. The assessment body shall be an independent third-party body and has to carry out the conformity assessment activities for each kind or category of CE-marked fertilising products.

Brief assessment of open key points

The current draft of the new Fertiliser Regulation is already part of various discussions. EBIC for example emphasizes the need for refinement in key areas of the draft with attention to the long-term market conditions of biostimulants². Certain areas of concern, such as data protection issues are also discussed e.g. during the “Crops and Chemicals Europe” Conference in February (please refer to the SCC Newsletter of March 2016). In addition, possible adaptations of national rules and legislation to the new EU regulatory framework regarding marketing of non-harmonised products are further issues discussed.

References

¹ Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers

²<http://www.biostimulants.eu/2016/03/future-of-biostimulants-industry-brighter-thanks-to-fertilizer-regulation-proposal/>

³ Closing the loop - An EU action plan for the Circular Economy <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52015DC0614>

⁴ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

⁵ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)

⁶ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

⁷ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC

⁸ Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council

⁹ Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed - Council statement

¹⁰ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

¹¹ Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture

¹² Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work

¹³ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures

¹⁴ Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs

¹⁵ Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community

¹⁶ Regulation (EU) No 98/2013 of the European Parliament and of the Council of 15 January 2013 on the marketing and use of explosives precursors

¹⁷ Regulation (EU) No 1143/2014 of the European Parliament and of the Council of 22 October 2014 on the prevention and management of the introduction and spread of invasive alien species

¹⁸ Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC



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CALENDAR



Meet us at Biocides Symposium 2016 in Budapest (HU), 10 - 11 May 2016

Please meet **Dr Martina Galler**, Senior Manager Regulatory Affairs Biocides, and **Dr Rebecca Hamm**, Assistant Manager Regulatory Affairs Biocides at the Biocides Symposium 2016 in Budapest (HU). Our experts will be happy to discuss your regulatory needs with you.

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