

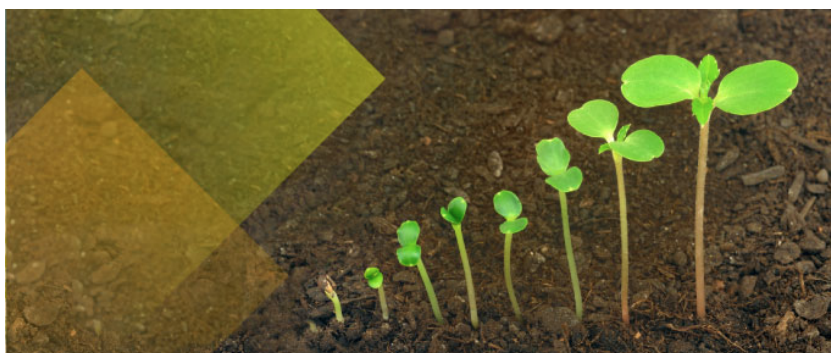
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[Fertilisers and Biostimulants](#)



## Fertilisers and Biostimulants

EC fertilisers and other fertilisers and fertiliser-related products in the EU



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### Fertilisers, biostimulants and plant aids

#### 'EC fertilisers' according to Regulation 2003/2003

On a European level REGULATION (EC) No 2003/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 October 2003 regulates the bringing onto the market of so called "EC fertilisers". Products of inorganic origin, fulfilling certain criteria, stipulated in Regulation 2003/2003 such as minimum content of **nutrients** and certain tolerances can be brought onto the market as "EC fertiliser" without an authorisation, approval or registration process. Since entry into force of Regulation 2003/2003 the Regulation was amended several times. ANNEX I of the Regulation, the list of types of **EC fertilisers**, was for example amended by COMMISSION REGULATION (EC) No 076/2004 of 3 December 2004 adapting for the first time Annex I of Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers (EDDHA and triple superphosphate), COMMISSION REGULATION (EU) No 137/2011 of 16 February 2011 amending Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers for the purposes of adapting Annexes I and IV thereto to technical progress or COMMISSION REGULATION (EU) No 1257/2014 of 24 November 2014 amending Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers for the purposes of adapting Annexes I and IV.

The Methods of Sampling and Analysis laid down in ANNEX IV of Regulation 2003/2003, the tolerances, given in ANNEX II or the Technical provisions for Ammonium Nitrate Fertilisers of High Nitrogen Content given in ANNEX III were also constantly adapted to the technical progress for example by COMMISSION REGULATION (EC) No 1020/2009 of 28 October 2009 amending Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers for the purposes of adapting Annexes I, III, IV and V thereto to technical progress, COMMISSION REGULATION (EU) No 137/2011 of 16 February 2011 amending Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers for the purposes of adapting Annexes I and IV thereto to technical progress or COMMISSION REGULATION (EU) No 463/2013 of 17 May 2013 amending Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers for the purposes of adapting Annexes I, II

and IV thereto to technical progress.

For checking compliance of **EC fertilisers** with the requirements of Regulation 2003/2003, studies have to be provided by approved laboratories which must meet the standards given in section B of Annex V of this Regulation. If a new type of **EC fertilisers** is to be introduced, a technical file has to be lodged together with the proposal with one of the authorities in the member states concerned with the registration of new **EC fertilisers**. Guidance for the compilation of such a technical file is given in the COMMUNICATION FROM THE COMMISSION (Guide to the compilation of a technical file on application to designate a fertiliser as '**EC fertiliser**').

### Fertilisers other than 'EC fertilisers'

Fertilisers and fertiliser-related products not fulfilling the criteria given in Regulation 2003/2003 have to be registered under national provisions of the European Member States. National provisions can differ widely between member states. Based on the **THE TREATY ON THE FUNCTIONING OF THE EUROPEAN UNION (TFEU; 2012/C 326/01)** and the single market strategy (COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS - Upgrading the Single Market: more opportunities for people and business; COM(2015) 550 final) the principle of the **free movement of goods** according to Articles 34 to 36 of the **TFEU** have to be respected also regarding these fertilisers and fertiliser-related products. Therefore, the **mutual recognition** principle for nationally registered products also applies for this non harmonised legislation of fertilisers and fertiliser-related products not to be designated '**EC fertiliser**'. Based on REGULATION (EC) No 764/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC for fertilisers and **growing media** guidance regarding the **mutual recognition** principle is given in Guidance document - The application of the **Mutual Recognition** Regulation to fertilisers and **growing media** of 14th February 2011.

To further harmonise EU legislation on fertilisers and fertiliser-related products, Commission intends to revise Regulation (EC) No 2003/2003 and extend its scope beyond fertilisers solely based on inorganic materials. This is especially true for a new product type, the so called **biostimulants**.

### Biostimulants

Products falling under this type fertiliser-related products are known under different terms worldwide such as **plant aid**, **plant strengthener** or **plant helping substance**. At the moment all these products have to be approved, authorised, registered or notified under national plant protection or fertiliser regulatory frameworks. Requirements differ and range from direct access to the market (not regulated), notification of the product to be placed on the market as "other fertilisers" without supportive data, notification with supportive data (e.g. efficacy), notification with supportive data, assessment of data and authorisation/listing in a positive list of "other fertilisers".

To harmonise the European market for these products and product type the current commercial, legislative and regulatory situation was analysed in various studies such as Arcadia study on 'A Legal Framework for Plant **Biostimulants** and **Agronomic Fertiliser Additives** in the EU' (Contract n° 255/PP/ENT/IMA/13/1112420), Ecorys study 'Ex ante evaluation of competitiveness impacts of the European Commission's policy proposal Review of Regulation (EC) no 2003/2003 relating to fertilisers', du Jardin (2012: 'The science of plant **biostimulants** – a bibliographic analysis'; Contract 30-CE0455515/00-96), the 'Study on options to fully harmonise the EU legislation on fertilising materials including technical feasibility, environmental, economic and social impacts (Contract number 30-CE-0392420/00-18) or the 'Evaluation of Regulation (EC) 2003/2003 relating to Fertilisers' by CSES. Inter alia based on these studies, in October 2015 Commission published a roadmap in the 'Revision of the Fertilisers Regulation (EC) No 2003/2003'.

One of the main issues in the discussion regarding the development of a new fertiliser regulation was a

general definition of “**biostimulant**” to be included in the new fertiliser regulation such as “a **biostimulant** is a substance in a fertilising product which, independent of its **nutrient** content, stimulates plant biological processes, thus improving **nutrient use efficacy**, tolerance to **abiotic stress** or crop quality traits” or a microorganism (not PPP) in a fertilising product”. In addition to the development of a harmonised definition, concepts for the registration process and the regulatory procedure are currently formed. This includes discussions on possible positive lists for ingredients based on “commodity” plant **biostimulants** already on the market with functionality and safety being “under control” or the provisions for so called “**Dual-use products**”, that is substances and products falling under plant protection as well as fertiliser regulatory frameworks.

Please refer to SCC's home page (<http://www.scc-gmbh.de/business-units/agrochemicals-biopesticides>) for more information about available services relating to Fertilisers and Biostimulants

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