



Moving towards a simpler EU biostimulant registration regime

By Lars Huber



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The topic of the future of the crop protection industry often incorporates the vision of a crop protection toolbox incorporating biopesticides and biostimulants in addition to conventional active ingredients. But the industry seeks the simplification of the registration process for biologicals.

The European Commission is in the process of extending the scope of ais that may be considered as “low-risk” substances, in a bid to boost approvals of biological and naturally occurring pesticides. But Regulation 2003/2003 relating to fertilisers only focuses on inorganic (mineral) fertilisers. There are 28 national fertiliser regulations which, to a varying extent, offer the possibility for registration of biostimulants or biostimulant-like products. In addition, in certain countries, the national plant protection laws cover at least come type of biostimulants, for instance, in Germany.

A vote of the European Parliament on a new EU fertiliser Regulation, which will also cover biostimulants, is foreseen for September 2017 with a possible applicability in 2019. It is expected to expand the scope and also include organic fertilisers, soil improvers and biostimulants. As the progress to bring this new piece of legislation to life has been delayed and stopped several times already, it is likely that these target dates will be postponed again, making it unclear when biostimulants can be marketed on an EU-wide basis and what will be the expense in time and money for the manufacturer.

The current proposal of the new fertiliser Regulation allocates biostimulants a special Product Function Category (PFC 6), defining them as: “certain substances, mixtures and micro-organisms, commonly referred to as plant biostimulants, [which] are not as such nutrients, but nevertheless stimulate plants’ nutrition

processes. Where such products aim solely at improving the plants' nutrient use efficiency, tolerance to abiotic stress, or crop quality traits, they are by nature more similar to fertilising products than to most categories of plant protection products. Such products should therefore be eligible for CE marking (Conformity marking under general principles of Regulation 765/2008) under this (the new) Regulation and excluded from the scope of [agrochemical registration] Regulation 1107/2009".

Whereas there seems to be a common understanding of the basic definition for biostimulants, several topics regarding their registration are currently under discussion. As for fertilisers, thresholds for heavy metals are being debated. Also, a shelf-life proposal of at least six months for microbial biostimulants, as proposed by the Council, is to be removed. For non-microbial biostimulants, there is no differentiation foreseen between organic and inorganic components, which would be a clear and highly welcomed simplification compared with the current situation. There are discussions ongoing on the accepted extraction methods for non-processed or mechanically processed plants, plant parts or plant extracts [Component Material Category (CMC) 2], which is to be extended from water extraction only. It is emphasised that only processing methods will be allowed that will not affect the chemical nature of the substance. For micro-organisms (CMC 6), a positive list is being compiled and there will be a mechanism to amend the list, with individual quality criteria still to be addressed. Various discussions on these lists and how to amend them are ongoing. Due to the complexity of that issue, a new expert group on microbial biostimulants has to be launched and will include participation by the European Food Safety Authority (EFSA), other experts and industry. Micro-organism identification will be at the strain level. The prioritisation criterion for such amendments to the list will be the market potential for a proposed micro-organism.

An issue not currently addressed in the draft Regulation is that of maximum residue limits (MRLs) for biostimulants. Requirement for implementation of MRLs is an authorisation system, which is not

foreseen for biostimulants according to the draft of the upcoming Regulation.

A grave concern for industry is the still unsolved question of data protection. No data protection provisions are foreseen in the new Regulation. Data protection could only be awarded under the EU Registration, Evaluation and Authorisation of Chemicals (REACH) Regulation. A possible blueprint to address this issue could be the handling of medical devices Class 1, which are also handled under a CE system.

According to the draft Regulation, "products with one or more functions, one of which is covered by the scope of Regulation (EC) No 1107/2009, are plant protection products covered by the scope of that Regulation". This regulatory differentiation of substances and products with more than one function does not mirror the scientific conditions. As several substances clearly show effectiveness against abiotic as well as biotic stresses, it remains to be seen if feasible possibilities will arise to include "abiotic" functions under the framework of Regulation 1107/2009 if not under the framework of the future fertiliser regulation. In view of the farmer's toolbox, the loss of valuable functions of substances "only" due to regulatory and legislative obstacles seems very unfortunate.

As already indicated, when the new legislative framework for biostimulants at EU level will come into force is uncertain. As biostimulants are already an acknowledged tool in parts of the agricultural practice, several national authorities have adapted their national legislation in the recent past to cover this gap and make more biostimulating substances available to their farmers. For example, in Spain, the national fertiliser regulation (Real Decreto 506/2013) was amended to include products containing micro-organisms that increase the availability of nutrients for plants. The French

Decree No. 2016-532 of April 27th 2016 on the procedure for national authorisation of natural biostimulant substances was published on April 30th 2016. Natural biostimulant substances are authorised without further procedures provided they fulfil certain conditions related to effects on human and animal health or the environment, the origin of the substance (e.g. plant, animal or mineral origin), or the manufacturing process.

This "non-harmonisation" is in line also with the draft of the new EU fertiliser regulation that stipulates that "contrary to most other product harmonisation measures in Union legislation, Regulation (EC) No 2003/2003 does not prevent non-harmonised fertilisers from being made available on the internal market in accordance with national law". It is foreseen that this possibility should remain. In liaison with the adaptations of the national fertiliser laws regarding biostimulants as described above, the upkeep of national biostimulant registrations even after implementation of the EU framework, increase the importance of national registrations for biostimulants regarding business strategies for registration and rollout of new biostimulant products in EU.

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