



European Biostimulants Industry Council

Date:	16 November 2021
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Status:	Final
Distribution:	Public
Classification:	Public

## POSITION PAPER

# Options for modifying the Fertilising Products Regulation to recognise the plant biostimulant function of phosphite/phosphonates

### Summary

Paragraph 6, of Part II of Annex I of Regulation (EU) 2019/1009 (the EU Fertilising Products Regulation-FPR) states “Phosphonates shall not be intentionally added to any EU fertilising product. Unintentional presence of phosphonates shall not exceed 0,5 % by mass.” This language was added by the Council during Trilateral negotiations and appears to be in response to an issue that emerged in 2014 when Germany asked the European Commission to clarify whether phosphonates could be included in EC fertilisers.

This language prevents plant biostimulants containing phosphite/phosphonate from being placed on the EU Single Market under this legislation, despite compelling and growing evidence of the scientific justification for phosphites having more than one plant biostimulant function under certain use cases. The ban would prevent farmers from having an economic, effective, and safe tool that helps improve the use efficiency of nutrients. Several Member States have aligned their national rules with this position and stated that they won’t allow fertilising products under national rules that cannot be placed on the market under the FPR or interpreted guidance from the Commission in 2015 to ban the use of phosphite in any fertilising products.

However, there is compelling science today that certain phosphite products (taking into account use cases) provide plant biostimulant effects improving nutrient use efficiency. Moreover, the use of phosphites in fertilising products is considered safe for both humans and the environment; furthermore, these substances have a long history worldwide of safe application in agricultural products with different functions.

This position paper considers the possible amendments that could allow plant biostimulants containing phosphites/phosphonates to be placed on the EU market under Regulation (EU) 2019/1009. As outlined below, the simplest way to amend the FPR would be to restrict the use of phosphonates in EU Fertilising Products to PFC 6 Plant Biostimulants and the blends containing them.

### Background

In January 2015, the Commission gave its legal opinion on the issue and noted “The note refers merely to the regulatory situation under the existing legislation, and does neither take into account, nor prejudice, any future legislative proposal of the Commission in the field of fertilisers or plant protection products (hereinafter 'PPPs').” The EU Fertilising Products Regulation (FPR) was subsequently adopted in 2019. In the FPR, each **product function category** has specific requirements for its function based on intended use and claims made for products in that category.

With regard to products containing phosphonate on the market at the time, the 2015 Commission memo stated, “In view of current [i.e. January 2015] knowledge of the mode of action of potassium phosphonates (in particular its fungicidal properties, as well as the hitherto weak evidence of any significant nutritional effect for plants), [protecting plants from harmful organisms] is presumed to be the intended use of any product consisting solely of, or intentionally incorporating, that substance.

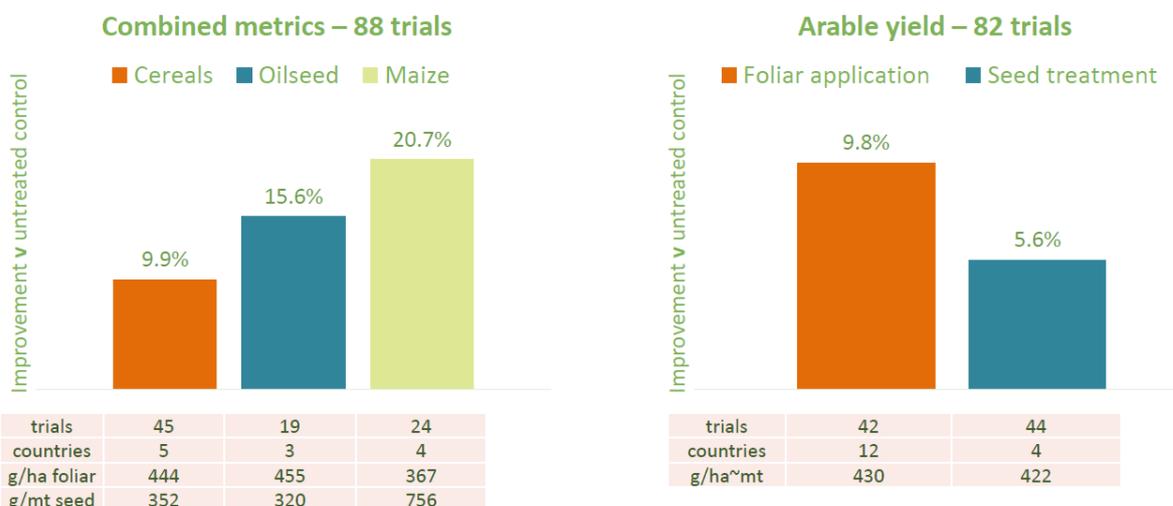
Since then, compelling evidence has been compiled by researchers, notably at Nottingham University (UK) and Christian Albrechts-Universität (Kiel, Germany) that phosphite/phosphonate provides at least two plant biostimulant effects (i.e. changes that the product brings about in the plant or the soil/rhizosphere compared to a control without reference to a specific legal framework) related to enhanced root growth and nutrient use efficiency. This research was presented at a [workshop organised by EBIC on 18 June 2021](#).

Research by the Universities of Nottingham and Kiel has shown that the use of phosphite as a plant biostimulant has a dramatic effect on the uptake and efficient use of nitrogen, saving up to 40kg/ha from leaching or volatilisation. At current nitrogen prices this translates to an average of EUR 13.50/ha, a significant saving from such a low-cost input as well as a benefit to the environment.

The Nottingham research focuses on the interdependent physiological effects of root development, nutrient use efficiency, and tolerance to abiotic stress and the underlying mode of action. For their part, researchers in Kiel are looking at root growth, nutrient use efficiency, and yield, as well as the underlying mode of action. Each university studies a different mode of action for the plant biostimulant function of phosphites. Nottingham researchers identified the role of Cis-Zeatin (a type of cytokinin) while their German counterparts looked at gene expression and the effects on a range of phytohormones. Each university has published a white paper summarizing their work, is in the process of publishing their studies in peer-reviewed journals, and recently presented their findings to policymakers at a workshop held by EBIC on 18 June 2021. [View a summary of the workshop and download the white papers](#).

While the science seems clear that certain products containing phosphites/phosphonates have functions that fall under Product Function Category (PFC) 6 (Plant Biostimulants) of the Fertilising Products Regulation, Paragraph 6, of Part II of Annex I of that regulation would need to be amended before such products could access the Single Market.

Allowing the use of phosphite-based plant biostimulants could make an important contribution to the objectives of the Farm to Fork Strategy related to reducing fertiliser applications through improved nutrient use efficiency. Data from trials conducted by the members of the [Phosphite Biostimulant Stewardship Group \(PBSG\)](#) across four years, 13 countries, and eight different crops demonstrate the agronomic benefits of using phosphite as a plant biostimulant: with 178 individual trials analysed, the aggregated data show improvements across all metrics, including root weight, tissue analysis and crop yield. As mentioned above, these effects, together with the modes of action studied by the Universities of Nottingham and Kiel, improve nutrient-use efficiency significantly with economic benefits for farmers and environmental benefits.



Source: Phosphite Biostimulant Stewardship Group (PBSG)

Following the discussions in 2014 and 2015, we understand that some member states are concerned about potential exceedances of MRLs set for phosphonates. Unlike, fertilizer applications (which are generally in much higher quantities), it is possible to manage plant biostimulant applications in ways that respect MRLs where they have been set to reflect actual use and even respect MRLs set at quantification levels in most cases. In a June 2016 letter and on several occasions since, EBIC shared data with the European Commission from 8 GLP studies and 31 non-GLP monitoring studies the industry has undertaken the levels were well below the presumed safety level of 75 mg/kg indicated by EFSA in its 2013 opinion on phosphonate<sup>1</sup>.

Furthermore, the exceedances that might occur (in cases of poor management) are unlikely to create any risk for human, animal or environmental health. Under Regulation EC 1278/2008, there are no harmonised human health classifications relevant to consumer risk assessment for potassium phosphite, nor is there an ecotoxicological classification. EFSA concluded that it is a low-risk substance for the aquatic environment, honeybees, non-target arthropods, earthworms & other soil macro-organisms, soil micro-organisms and non-target terrestrial plants after 6 applications of potassium phosphite as a vine fungicide (rate equivalent to 2.016 kg phosphonic acid/ha) with a 60 day PHI at rate of 12 kg phosphonic acid/ha per year; by comparison, plant biostimulant uses are between 5 and 12 times lower. Phosphonate is considered so safe in jurisdictions such as the United States that it is not even subject to the US equivalent of MRLs.

On June 29, 2015, scientific consultancy LSR associates presented consumer risk assessments using the EFSA PRIMo acute chronic RA model rev 2.0 to DG SANTE illustrating the impacts of raising the MRLs on key plant biostimulant crops to 30 mg/kg or 60 mg/kg. The highest exposure diet under both scenarios showed safe use. EBIC can make this information available to regulators.

<sup>1</sup> European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance disodium phosphonate. EFSA Journal 2013;11(5):3213. [50 pp.] doi:10.2903/j.efsa.2013.3213. Available online: [www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal)

## EBIC's proposals for how to amend Paragraph 6, of Part II of Annex I of the FPR

EBIC's preferred option is to modify paragraph 6 so that phosphites/phosphonates could only be incorporated into plant biostimulants: "Phosphonates shall not be intentionally added to any EU fertilising product, **except for PFC 6 Plant Biostimulants and the PFC 7 Blends that contain those PFC 6 phosphite plant biostimulants are found.** Unintentional presence of **phosphonates in any PFC 1, 2, 3, 4, or 5 fertilising product** shall not exceed 0,5 % by mass."

### Advantages and disadvantages:

This modification would be simple to make and to enforce, while still recognizing the scientific legitimacy of plant biostimulant functions for phosphites. Market surveillance authorities would still be able to detect other products from other PFCs that contained non-permitted phosphonates. Because they are applied in smaller quantities than fertilisers, plant biostimulants can be managed in such a way that MRLs are respected. These management approaches entail following manufacturer instructions regarding amounts to be applied, timing, and target crops.

### Alternatives that EBIC did not retain and the reasons

We considered alternative ways to modify the FPR but they each entailed more disadvantages than the option that EBIC supports. In the spirit of transparency and accelerating the debate, our evaluations are outlined below.

Alternative 1: Delete the entire paragraph: "~~Phosphonates shall not be intentionally added to any EU fertilising product. Unintentional presence of phosphonates shall not exceed 0,5 % by mass.~~"

### Advantages and disadvantages of Alternative 1:

This would be the simplest change to make, but since there is currently no compelling scientific evidence that phosphites would contribute to the effects of any other PFC function, it seems unnecessary to open up the language to this extent especially given concerns about exceedances related to the application of products applied at higher rates than plant biostimulants.

### Alternative 2: Modify both Paragraph 6, of Part II of Annex I AND PFC 6 of the FPR:

- Paragraph 6: "Phosphonates shall not be intentionally added to any EU fertilising product, **except for PFC 6 Plant Biostimulants and the PFC 7 Blends that those phosphite-containing PFC 6 Plant Biostimulants are found.** Unintentional presence of **phosphonates in any PFC 1, 2, 3, 4, or 5 fertilising product** shall not exceed 0,5 % by mass."
- New paragraph in PFC 6: "Phosphonates may be incorporated in PFC Plant Biostimulants applied to the following crops [INSERT POSITIVE LIST]."

Advantages and disadvantages of Alternative 2: Alternative 2 provides the strongest assurances of respecting MRLs where they have been set to reflect authorised product use<sup>2</sup>; however, it entails **significant disadvantages**. A positive list of crops to which the products could be applied precludes the evolution of scientific knowledge about additional plant biostimulant functions and benefits that could be discovered. A positive list in the Regulation would be difficult to update when needed and would provide redundant information as crop claims must be demonstrated for PFC6 during the conformity assessment process. It also confuses the purpose of the regulation which is a product regulation, not a regulation of use.

Since phosphite plant biostimulants can be used safely, it seems counterproductive to prevent farmers from benefitting from the significant enhancements to nutrient use efficiency demonstrated from their use at a time when the EU has published ambitious targets to reduce nutrient applications through greater efficiency and the above-mentioned research demonstrates the important contribution that phosphite-based plant biostimulants can make to achieving this objective.

PFC 6 requires manufacturers to demonstrate that their products can deliver the effects that are claimed. This provision means that any phosphite-based plant biostimulant should enhance nutrient use efficiency (or provide another plant biostimulant function as defined under the FPR) when used according to the manufacturer's instructions on the crops for which it is intended. This requirement would automatically exclude phosphite-based plant biostimulants being sold with claims for crops where there is no evidence that they provide a plant biostimulant function. Thus, a positive list for crops is not needed

## Conclusion

The EU Fertilising Products Regulation is intended to modernize and improve plant nutrition management by fostering integrated nutrient management and increasing nutrient use efficiency and progress towards this objective should consider what efficiency means per application, per season, per farm, etc. The science is clear that phosphite-based plant biostimulants can be a powerful tool for farmers to improve plants' ability to take up and use nutrients well, at least on certain crops. If the 5% increase of nutrient use efficiency that has been observed by researchers at the University of Kiel were generalised across the entire EU, that would save 80,000 tonnes of nitrogen applications annually with benefits for the environment (in line with the objectives in the EU Farm to Farm Strategy) and for farmers' pockets.

Evaluations by EFSA and others have demonstrated that the level at which phosphonates are applied in plant biostimulants poses no concerns for health, safety, or the environment.

EBIC therefore suggests that Paragraph 6, of Part II of Annex I of the FPR should be amended as follows: "**Phosphonates shall not be intentionally added to any EU fertilising product, except for PFC 6 Plant Biostimulants and the PFC 7 Blends in which those phosphite-containing PFC 6 Plant Biostimulants are found. Unintentional presence of phosphonates in any PFC 1, 2, 3, 4, or 5 fertilising product shall not exceed 0,5 % by mass.**"

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<sup>2</sup> MRLs are set at default detection/quantification levels for crops where no plant protection product has been authorised. This is clearly intended to control unauthorised use rather than due to safety concerns about applications on those specific crops. In cases where a plant biostimulant use is scientifically justified and no plant protection use is authorised, it would be worth discussing – in a second time – modifying these defaults levels to reflect appropriate use while still ensuring consumer safety.