

CONTRIBUTION TO CEG-FP DISCUSSIONS

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There is compelling science today that certain phosphite (inorganic phosphonate salts) products -- defined by the function under specific use cases -- provide plant biostimulant functions: improving nutrient use efficiency and tolerance to abiotic stress. To reflect this new science, the European Commission submitted a proposal to the Expert Group on Fertilising Products (CEG-FP) in October 2022 suggesting an amendment to the Fertilising Products Regulation to make it possible to place such plant biostimulants on the market as EU Fertilising Products.

The Commission's proposal was discussed in the Expert Group on Fertilising Products and was subsequently discussed by the Standing Committee on Plants, Animals, Food, and Feed (SCoPAFF) since phosphonate would therefore be recognised as a multiple-use component. **This document contains EBIC's suggestions for improving the draft amendment to address various concerns, notably by narrowing the scope of the amendment and suggesting several labelling requirements and a stewardship approach to MRLs, where applicable.**

Response to Commission proposal to amend FPR to allow phosphonate in plant biostimulants

The Commission's proposal as submitted to its Expert Group on Fertilising Products in October 2022

Point 6 in Part II of Annex I to the FPR	Proposed amendment in track changes
Phosphonates shall not be intentionally added to any EU fertilising product. Unintentional presence of phosphonates shall not exceed 0,5 % by mass.	Phosphonates shall not be intentionally added to any EU fertilising product belonging to PFCs 1 to 5. Unintentional presence of phosphonates in any EU fertilising product shall not exceed 0,5 % by mass.
Point 3 in Part I of Annex III to the FPR	Proposal to add the following sentence
Where the EU fertilising product contains a component material which, if placed on the market as food or feed, would have been subject to maximum residue limits established pursuant to Regulation (EC) No 470/2009 or Regulation (EU) No 1831/2003 of the European Parliament and of the Council (38), maximum residue levels set in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council (39), or maximum levels established pursuant to Council Regulation (EEC) No 315/93 (40) or Directive 2002/32/EC of the European Parliament and of the Council (41), and that component material contains a substance in exceedance of (one of) the corresponding limit value(s), the maximum concentration of that substance in the EU fertilising product shall be indicated, together with a warning that the EU fertilising product must not be used in such a manner as to risk leading to the exceedance of that limit in food or feed.	Where an EU fertilising product belonging to PFC 6 contains intentionally added phosphonates, the content of phosphonates shall be indicated, together with the same warning.

Based on the compelling science that certain phosphite products (defined by the function under specific use cases) provide plant biostimulant functions, the Commission proposed in October 2022 to amend the Fertilising Products Regulation as pictured to the left. However, phosphites are inorganic salts of a much larger group “phosphonates,” which also includes organic compounds. The inorganic and organic compounds exhibit different characteristics. We therefore focus our proposal on the narrower group of Inorganic salts (phosphites).

Concerns expressed during consultations with Member States

The concerns expressed by Member States can be summarised by the following points:



Misuse of products containing multiple-use components (specifically concerns about off-label use for unauthorised pesticide applications);



Farmers unintentionally exceeding Maximum Residue Levels (MRLs);



Environmental impacts, especially related to persistence.

Rephrasing the proposed amendment to address some concerns

EBIC's Project Team on Phosphites has considered each of the concerns seriously and discussed at length what could be done to address these concerns while still allowing farmers to access a useful tool to improve nutrient use efficiency (especially nitrogen) and to help plants tolerate abiotic stress.

As a result of our deliberations, we believe that the proposed amendment by the Commission is worded too broadly.

The term “phosphonate” includes two groups of substances with quite different properties: organic phosphonates characterised by C-P bonds and inorganic phosphonates where the phosphorus is bound exclusively with O-P bonds. Phosphite biostimulants, such as potassium phosphite and ammonium phosphites, are inorganic phosphonates and more specifically inorganic salts. To dispel any misperceptions that we are advocating for organic phosphonates to be eligible for EU Fertilising Products, **we suggest modifying the wording for the EU Fertilising Products Regulation to accommodate phosphite plant biostimulants as follows** (the red text indicates what is different from the Commission’s proposal):

Phosphonates shall not be intentionally added to any EU fertilising product, **except for inorganic phosphonate salts [phosphites], which may be used in PFCs 6 and 7**. Unintentional presence of phosphonates in any EU fertilising product shall not exceed 0,5 % by mass.

This more precise wording could also help address certain Member State concerns over the potential environmental impacts of allowing phosphonates in fertilising products since the environmental impact of organic and inorganic phosphonates differs¹.

Additional labelling requirements to address other concerns

In addition to the sentence that the European Commission suggests adding to Point 3 in Part I of Annex III to the FPR, EBIC also proposes adding the following labelling requirements:

-  Inorganic phosphonates [phosphites] do not provide phosphorus in a plant-available nutrient form and so should not be used as a P-fertiliser.
-  Use of this product according to the manufacturer’s instructions for use has been assessed to be compliant with the maximum residue levels for food or feed set in

¹ “Potassium phosphonates are relatively stable in the soil, but are finally oxidised to phosphate. (Adams & Conrad 1953; EFSA 2012b). [EGTOP] has not identified unacceptable negative impacts on the environment.” -- Expert Group for Technical Advice on Organic Production 2014 Final Report On Plant Protection Products (II)

accordance with Regulation (EC) 396/2005 for the following crops [manufacturer to insert the relevant crop names for which data is available to make this claim].

Industry stewardship on residue compliance

Looking at biocides, veterinary medicines, and plant biostimulants, the European Commission and Member States have been discussing how to assess the risk of consumers exposed to substances for which Maximum Residue Limits have been set under Regulation (EC) 396/2005 when they come from multiple sources. In this context, the Commission has suggested that the producers of all relevant agrifood chain products should conduct appropriate residue trials to inform risk assessment taking into account multiple sources of such substances.

For crops where there may be more than one source of a substance, residue trials should consider scenarios with the highest combined dose and latest timing of application (according to manufacturer instructions) of combined product use. For plant biostimulants, the approach would be as follows:

For crops where no plant protection use of phosphonate has been approved:

the scenario would only involve the phosphite plant biostimulant use. The trial results would either confirm that exceedances are not a concern or be used to request a modification of the default MRL (subject to a satisfactory consumer risk assessment).

If a plant protection producer subsequently wanted to seek authorisation for a phosphonate-based plant protection product on that crop, they would have to do MRL trials and testing on the combined use.

Where a phosphonate-based plant protection product has already been approved for a crop, the trial scenario would include combined use of a phosphite plant biostimulant and a phosphonate plant protection product the same season. Trial results would either confirm that exceedances are not a concern or be used to request a modification of the existing MRL (subject to a satisfactory consumer risk assessment).

On 31 October 2024, a group of phosphite biostimulant manufacturers met to discuss the formation of a consortium to conduct such trials for selected crops that benefit from phosphite-based plant biostimulants, followed by a survey to determine which ones would commit to a first phase to determine the exact conditions and requirements for such trials under the Commission's proposed way forward. The interested companies are currently in talks to form a task force for the initial information-gathering phase, with the expected outcome to be residue trials if the requirements are acceptable to a critical mass.

Addressing protection of residue trial data in a conformity assessment system

Under Reg (EC) 1107/2009, companies seeking authorisation for plant protection products benefit from data protection, including for the data from the residue trials they conduct. No such provision exists under Reg (EU) 2019/1009. However, the issue can be addressed pragmatically: since Notified Bodies check that the technical documentation for a plant biostimulant product is complete, there could be a requirement that any company wanting to place an EU Fertilising Product containing inorganic phosphonate salts (phosphite) on the market must submit a letter of access to any relevant residue trial data. That would simultaneously allow the Notified Body to ensure that MRL requirements are respected without divulging intellectual property unduly.

Conclusion

By adopting the suggested changes above, we believe that phosphite biostimulants can be placed on the market under the FPR in order to enhance the farmer toolbox while addressing concerns related to safety, residue compliance, and misuse.