**DOSSIER CONCERNING THE REQUEST TO AMEND ANNEXES III
TO COMMISSION IMPLEMENTING REGULATION 1165/2021[[1]](#footnote-1)**

**concerning feed materials, additives/processing aids and certain substances used in animal**

**nutrition referred to in Regulation (EU) No 848/2018[[2]](#footnote-2), Article 24(1)(c) and (d) to be evaluated for use in EU organic production**

Article 24 (7) of Regulation (EU) No 848/2018:

*"Where a Member State considers that a product or substance should be added to or withdrawn from the lists of authorised products and substances referred to in paragraphs 1 and 2, or that the specifications of use referred to in the production rules should be amended, it shall ensure that a dossier giving the reasons for the inclusion, withdrawal or other amendments is officially sent to the Commission and to the other Member States and is made publicly available, subject to Union and national legislation on data protection. The Commission shall publish any requests referred to in this paragraph."*

### General information on the request

|  |  |
| --- | --- |
| Nature of the request | 🞏 Inclusion🞏 Deletion 🞏 Change of disposition |
| Request introduced by | [Member State]Contact e-mail:  |
| Date |  |

Please indicate if the material provided is confidential

### Requested inclusion/deletion/amendment

|  |  |
| --- | --- |
| Name of additive / substance | Primary use/conditions |
|  |  |

### Status

Authorization in general agriculture or food processing

|  |
| --- |
| Historic use |
| Regulatory status (EU, national, others) (including expiry dates of authorisation if applicable) |

### Identification [[3]](#footnote-3)

|  |
| --- |
| Common name |
| Name(s) of active substance  |
| Other names |
| Trade names |
| CAS[[4]](#footnote-4) No.  |
| IUPAC[[5]](#footnote-5) Name  |
| E.C Additive Identification No  |
| Other code(s)  |

### Aspects related to the relevance and priority of the request

|  |
| --- |
| Geographical relevance (Member States, regions, …) |
| Socio-economic relevance (acreage, turnover, number of stakeholders affected, … ) |
| Sectors affected |
| Stakeholder engagement/consultation in dossier preparation |
| Market presence: availability (quantity / quality) and origin (local / imported) |
| Aspects of international harmonization / market distortion |
| A (possible) authorization leads to amendment(s) in the respective Annex[[6]](#footnote-6) |
| Other aspects justifying high priority, such as• relevance for the development of a new organic production sector,• addressing of a newly upcoming problem in production or a quarantine organism,• addressing a recent development in agricultural policies,• addressing a new trend in consumer preferences/nutritional habits or new developments in food technology,• addressing a declared goal of organic farming. |

### Characterisation [[7]](#footnote-7)

|  |
| --- |
| Chemical formula/composition of active substance  |
| Concentration of active substance |
| If preparation, other components  |
| Physical properties |
| Origin, inputs and production method of the active substance |
| Method(s) of analysis |

### Specification of use

|  |
| --- |
| Material/additive category |
| Material/additive functional group |
| Species groups |
| Minimum or maximum rate according to species group (if appropriate) |
| Method of application |

### Reasons for the inclusion, withdrawal or amendments,

Specifiy in which Annex the inclusion , withdrawal or amendments is requested

 III A (feed material) 🞏 III B (feed additives and processing aids) 🞏

|  |
| --- |
| Explain the need for the proposed feed material or additive change |
| What alternative solutions are currently authorised or possible? |
| Is there any traditional use or precedents in organic production? |

### Consistency with objectives and principles of organic production

Please use the check list in Annex A to this dossier to indicate consistency with objectives and principles of organic production, as well as criteria and general rules, laid down in Council Regulation (EU) No 848/2018 Title II and Title III as applicable.

### Impact

|  |
| --- |
| Environment |
| Animal health and welfare |
| Human health |
| Food quality and authenticity  |

### Other aspects

|  |
| --- |
| Various aspects, further remarks |

### Annexes

### References

**Annex A**

**CHECKLIST FOR CONSISTENCY**

**with objectives and principles of organic production with reference to specific articles in the organic regulations**

|  |  |  |  |
| --- | --- | --- | --- |
| **Criterion** | **Specific articles in Regulation (EU) 848/2018**  | **Yes/No/Not applicable** | **Brief qualification** |
| Exclude the use of GMOs and products produced from or by GMOs | Art. 3(58)(59)(60); Art. 5(f)(3); Art. 11; Art. 30(4) |  |  |
| Is it a synthetic amino acid ? | Annex II part II 1.4.1 (f) |  |  |
| Is it a growth promoter? | Annex II part II 1.4.1 (f) |  |  |
| Aim at producing a wide variety of foods and other agricultural products……goods produced by the uses of processes that do not harm the environment, human health, plant health or animal health and welfare.  | Art. 5 (d) |  |  |
| Aim at producing products of high quality | Art. 5 (d) |  |  |
| Is it natural (not chemically synthesised)? | Art. 5(g)(ii) |  |  |
| Their use is necessary for sustained production and essential for its intended use, and general and specific criteria has been evaluated | Art. 24(3)(a) |  |  |
| Does it have nutritional value? | Annex II Part II 1.4.1(b) Part III 3.1.3.1 (a) |  |  |
| Is it a natural milk replacer? | Annex II Part II 1.4.1(g)  |  |  |
| Is it of agricultural origin? | Art. 24 (3)(e)(iv) |  |  |
| Is it produced organically?  | Art. 24 (3)(e)(iii) and(iv) |  |  |
| Is it land-based/using natural internal resources? | Art. 5 (c) and (f) |  |  |
| Is it aquaculture which complies with the principle of sustainable fisheries/using natural internal resources? | Art. 5 (f)(ii) and AnnexII Part III 3.1.3.3 (c) and (d); 3.1.3.4 (c) (i) and (ii) |  |  |
| The recycling of wastes and by-products of plant and animal origin as input in plant and livestock production | Art. 5 (c) |  |  |
| Is it produced internally (primarily from the holding where animals are kept or from other holding in the same region? | Art. 5 (f) |  |  |
| Does it affect the permanent access to pasture ? | Art. 5 (l); Annex II Part II 1.4.1(e) |  |  |
| Does it restrict the use of additives and processing aids? | Art. 8 (b)  |  |  |
| Is it species appropriate? | Art. 4(e) and 5(j) |  |  |
| Does it have negative environmental impacts? | Art. 24 (5) |  |  |
| Does it have negative animal health/welfare impacts? | Art. 24 (3)(e)(i) |  |  |
| Does it have negative human health impacts? | Art. 5 (d) |  |  |
| Does it involve ‘misleading’ substances/processes? | Art. 7 (c) and Art. 8 (c) |  |  |
| Products and substances to be withdrawn or their use amended/ limited  | Art. 24(7) |  |  |
| Others: please specify |  |  |  |

1. [EUR-Lex - 32021R1165 - EN - EUR-Lex (europa.eu)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R1165) [↑](#footnote-ref-1)
2. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0848&from=EN [↑](#footnote-ref-2)
3. To be filled in only when applicable [↑](#footnote-ref-3)
4. Chemical Abstracts Systematic Names [↑](#footnote-ref-4)
5. International Union of Pure & Applied Chemistry [↑](#footnote-ref-5)
6. It should be carefully analysed whether the specific use of a substance is already (impicitly) authorized or not. This is to avoid the following conclusion: "The Group considers that the use of … is in line with the objectives, criteria and principles of the organic regulation. There is no need for amendment of the specific conditions of Annex …" [↑](#footnote-ref-6)
7. To be filled in only when applicable [↑](#footnote-ref-7)