**DOSSIER CONCERNING THE REQUEST TO AMEND ANNEX V   
TO COMMISSION IMPLEMENTING REGULATION 1165/2021[[1]](#footnote-2)**

**Certain products and substances for use in production of processed organic food, yeast and yeast products and wine: additives, processing aids, etc. as referred to in Regulation (EU) No 848/2018[[2]](#footnote-3), Article 24(2)(a), (c) and (d) or certain techniques authorised in the processing of food as referred to in Article 16 (3) of Regulation (EU) No 848/2018, 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*"Where a Member State considers that a product or substance should be added to, or withdrawn from the list referred to in paragraphs 1 and 2, or that the specifications of use mentioned in production rules should be amended, it shall ensure that a dossier giving the reasons for the inclusion, withdrawal or amendments is sent officially to the Commission and to the Member States and is made publicly available, subject to Union and national legislation on data protection."*

Article 16 (3) of Regulation (EU) No 848/2018:

*“ The Commission may adopt implementing acts laying down the techniques authorised in the processing of food products”.*

### General information on the request

|  |  |
| --- | --- |
| Nature of the request | 🞏 Inclusion  🞏 Deletion  🞏 Change of disposition  🞏 Substance  🞏 Product  🞏 Technique |
| 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 / technique | 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) |
| Organic regulatory status (EU, Codex Alimentarius, USA, national, others); |
| Private standards; |

### Identification[[3]](#footnote-4)

Identification of substance, terminology, synonyms

|  |
| --- |
| Chemical name(s) |
| Other names |
| Trade name |
| CAS code (Chemical Abstracts Systematic Names) |
| Other code(s) |

### Description of the technique[[4]](#footnote-5)

International name of the technique

|  |
| --- |
| Purpose and function |
| Patent |
| Technological need / Alternatives to obtain the same result |
| Full description (including schemes and technical illustrations of the process from beginning to end) |
| 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[[5]](#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. |

### Basic topological data (ADI level) [[6]](#footnote-7)

|  |
| --- |
| ADI level; |
| Date of JECFA /SCF evaluation; |
| Short summary; |

### Origin and production of the substance [[7]](#footnote-8)

|  |
| --- |
| Active ingredients; |
| Possible carriers; |
| Origin of raw materials (including aspects of mining/harvesting them), production methods; |

### Technology

|  |
| --- |
| Application in food and or during food processing; |
| Intended use; |
| Technological function in food; |
| Used in food products in general; |

### Consistency with objectives and principles of organic production

Please use the check list in part A of this Annex to indicate consistency with objectives and principles of organic production, as well as criteria and general rules, laid down in Council Regulation (EC) 834/2007 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 |

### References

### Annexes

### Annex A

### CHECKLIST FOR CONSISTENCY

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

**the organic regulation**

| **Criteria** | **Specific articles in Reg. 848/2018** | **Fulfilled?**  **Yes / no / not applicable** | **Detailed qualification** |
| --- | --- | --- | --- |
| Not a GMO and not produced from or by GMOs | Art. 3(58)(59)(60);  Art. 5(f)(3); Art. 11; Art. 30(4) |  |  |
| Alternatives authorized are not available; (not available in sufficient quantities or qualities on the market/advantages and disadvantages | Art 24 (4) (a) |  |  |
| Only in case of essential technological need or for particular nutritional purposes;  Without having recourse to them, it would be impossible to produce or preserve the food or to fulfil given dietary requirements | Art 7 (b)  Art 24 (4) (b) |  |  |
| The substances and processing methods do not misleading regarding the true nature of the product | Art 7 (c) |  |  |
| The products and substances are to be found in nature and may have undergone only mechanical, physical, biological, enzymatic or microbial processes. (natural or naturally-derived substances;) | Art 24(4)(c)  Art 5 (g) (ii) |  |  |
| Strict limitation of the use of chemically synthesized inputs to exceptional cases | Art 24 (5) |  |  |
| Aim at producing products of high quality. | Art. 5(d) |  |  |
| Helps to produce a wide variety of foods that respond to consumers’ demand | Art. 5(d) |  |  |
| 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-2)
2. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0848&from=EN [↑](#footnote-ref-3)
3. To be filled in only when applicable [↑](#footnote-ref-4)
4. To be filled in only when applicable [↑](#footnote-ref-5)
5. 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)
6. To be filled in only when applicable [↑](#footnote-ref-7)
7. To be filled in only when applicable [↑](#footnote-ref-8)