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KOMİSYON UYGULAMA YÖNETMELİĞİ (AB 2025/973)

23 Mayıs 2025

Organik üretimde belirli ürün ve maddelerin kullanımına izin veren ve bunların listelerini oluşturan Uygulama Yönetmeliği (AB) 2021/1165'i değiştirmek ve düzeltmek

(EEA ile ilgili metin)

AVRUPA KOMİSYONU,

Avrupa Birliği'nin İşleyişine İlişkin Antlaşma'yı dikkate alarak,

Avrupa Parlamentosu ve Konseyinin 30 Mayıs 2018 tarihli, organik ürünlerin üretimi ve etiketlenmesine ilişkin ve 834/2007 sayılı Konsey Tüzüğü'nü (1) yürürlükten kaldıran 2018/848 sayılı Tüzüğü ve özellikle bu Tüzüğü'nün 24(9) maddesi dikkate alınarak,

Zira:

(1) (AB) 2018/848 sayılı Tüzüğü'nün 45(2) maddesi, Komisyona, Birlik içinde piyasaya sürülecek olan, üçüncü ülkelerden ve Birliğin en dış bölgelerinden kaynaklanan organik ürünlerdeki ürün ve maddelerin kullanımına ilişkin özel izinler verme yetkisi vermektedir. (AB) 2021/1165 sayılı Komisyon Uygulama Tüzüğü'nün (2) 10. maddesi, bu tür izinlerin verilmesine ilişkin prosedürü, ancak yalnızca üçüncü ülkelerle ilgili olarak belirlemektedir. Bu nedenle, Birliğin en dış bölgelerinden kaynaklanan organik ürünlerdeki ürün ve maddelerin kullanımına ilişkin özel izinlerin verilmesine ilişkin prosedürün sağlanması gerekmektedir. Netlik sağlamak amacıyla, Birliğin en dış bölgelerinde izin verilen ürün ve maddelerin listesi, mevcut olduğunda, (AB) 2021/1165 sayılı Uygulama Tüzüğü'nün Ek VI'sına eklenmelidir.

(2) Komisyon Uygulama Tüzüğü (AB) 540/2011 (3), lavandulil senecioat (4), potasyum hidrojen karbonat (5), düz zincirli lepidopteran feromonları (asetatlar) (6), koyun yağı (7) ve kuvars kumu (8) aktif maddelerinin yeniden değerlendirilmesinin ardından değiştirilmiştir. Bu değişiklikleri yansıtmak amacıyla, potasyum girişleri

(1) OJ L 150, 14.6.2018, p. 1, ELI: <http://data.europa.eu/eli/reg/2018/848/oj>.

(2) Commission Implementing Regulation (EU) 2021/1165 of 15 July 2021 authorising certain products and substances for use in organic production and establishing their lists (OJ L 253, 16.7.2021, p. 13, ELI: http://data.europa.eu/eli/reg_impl/2021/1165/oj).

(3) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj).

(4) Commission Implementing Regulation (EU) 2020/646 of 13 May 2020 approving the active substance Lavandulyl senecioate as a low-risk substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L 151, 14.5.2020, p. 3, ELI: http://data.europa.eu/eli/reg_impl/2020/646/oj).

(5) Commission Implementing Regulation (EU) 2021/1452 of 3 September 2021 renewing the approval of the active substance potassium hydrogen carbonate as a low-risk substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 313, 6.9.2021, p. 30, ELI: http://data.europa.eu/eli/reg_impl/2021/1452/oj).

(6) Commission Implementing Regulation (EU) 2022/1251 of 19 July 2022 renewing the approval of the active substances Straight Chain Lepidopteran Pheromones (acetates) as low-risk active substances, and Straight Chain Lepidopteran Pheromones (aldehydes and alcohols) in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 191, 20.7.2022, p. 35, ELI: http://data.europa.eu/eli/reg_impl/2022/1251/oj).

(7) Commission Implementing Regulation (EU) 2022/1474 of 6 September 2022 renewing the approval of the low-risk active substance sheep fat in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 232, 7.9.2022, p. 3, ELI: http://data.europa.eu/eli/reg_impl/2022/1474/oj).

(8) Commission Implementing Regulation (EU) 2023/1488 of 6 July 2023 renewing the approval of the low-risk active substance quartz sand in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L 183, 20.7.2023, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2023/1488/oj).

Hidrojen karbonat, koyun yağı ve kuvars kumu, (AB) 2021/1165 sayılı Uygulama Tüzüğü'nün Ek I'inin 4. maddesinden çıkarılmalı ve lavandulil senecioat, potasyum hidrojen karbonat, düz zincirli lepidopteran feromonları (asetatlar), koyun yağı ve kuvars kumu maddeleri, düşük riskli aktif maddeleri listeleyen söz konusu Ek'in 2. maddesine eklenmelidir.

(3) (AB) 2018/848 sayılı Tüzüğün 24(7) maddesinde öngörülen prosedüre uygun olarak, Üye Devletler, belirli maddelere ilişkin dosyaları, bunların yetkilendirilmesi ve (AB) 2021/1165 sayılı Uygulama Tüzüğü'nün I, II, III ve V numaralı Eklerine dahil edilmesi nedeniyle diğer Üye Devletlere ve Komisyona sunmuştur. Bu dosyalar, Organik Üretim Teknik Tavsiye Uzman Grubu ("EGTOP") ve Komisyon tarafından incelenmiştir.

(4) (AB) 2022/1251 sayılı Uygulama Tüzüğü'nde ve yarı kimyasallar hakkındaki rehber belgede (9) yer alan düz zincirli lepidopteran feromonlarının yakın tarihli değerlendirmesine dayanarak, feromonlar ve diğer yarı kimyasallar, aktif veya pasif olsun, tuzaklar veya dağıtıcılar aracılığıyla uygulanmaktadır. Ayrıca, (AB) 2018/848 sayılı Tüzüğün 24(3) maddesinin (c)(ii) bendi, mahsulün yenilebilir kısımlarına doğrudan uygulanabilecek ürünlerin niteliğine ilişkin kısıtlamalar getirmekte olup, yarı kimyasallar söz konusu olduğunda, tuzaklar ve dağıtıcılar, söz konusu Tüzüğün Ek II'sinin Bölüm I, madde 1.10.3 uyarınca mahsulle teması önleyecektir. Bu nedenle, (AB) 2021/1165 sayılı Uygulama Tüzüğü'nün Ek I'inin 4. maddesindeki "feromonlar ve diğer yarı kimyasallar" tablosunda yer alan feromonların ve diğer yarı kimyasalların yalnızca tuzaklarda ve dağıtıcılarda kullanılması gerektiği koşulunun kaldırılması uygundur.

(5) (AB) 2021/1165 sayılı Uygulama Tüzüğü'nün Ek II'si uyarınca, bitkisel ürünler ve yan ürünler organik üretimde gübre olarak, aynı zamanda söz konusu Ek kapsamında toprak düzenleyici ve besin maddesi olarak da kullanılabilir. Bu nedenle, "gübreler için bitkisel ürünler ve yan ürünler" girişi açıklığa kavuşturulmalı ve buna göre uyarlanmalıdır.

(6) EGTOP'un seralar (10) ve gübreler (11) ile ilgili tavsiyelerine dayanarak, (AB) 2021/1165 sayılı Uygulama Tüzüğü'nün Ek II'sindeki taş unu, kil ve kil mineralleri ile ilgili giriş, başka ürünler eklenerek değiştirilmelidir. Ayrıca, taş unu, kil ve kil mineralleri filizlenmiş tohum üretiminde inert ortam olarak kullanılabilirdiğinden, bu kullanım, (AB) 2018/848 sayılı Tüzüğün Ek II'sinin Bölüm I, 1.3(a) maddesinde belirtilen özel koşullara uygun olarak söz konusu girişe dahil edilmelidir.

(7) EGTOP'un seralar ve gübreler hakkındaki önerilerine (12) dayanarak, karbondioksitin karada kapalı sistemlerde yosun üretimi için suyun zenginleştirilmesinde besin maddesi olarak kullanılmasına izin verilmeli ve suyun herhangi bir şekilde kirlenmesini önlemek için bu madde gıda sınıfında olmalıdır. Ayrıca, EGTOP organik sera üretiminde karbondioksit kullanımını değerlendirmiş ve olumlu sonuç vermiştir (13). Bu nedenle, Uygulama Yönetmeliği (AB) 2021/1165'in Ek II'sine karbondioksit için bir madde eklenmesi uygundur.

(9) European Commission: Directorate-General for Health and Food Safety, 'Guidance document on semiochemical active substances and plant protection products', SANTE/12815/2014 rev. 11, January 2024, https://food.ec.europa.eu/document/download/ae787d28-356b-4e42-8c15-89ed8c91faf2_en?filename=pesticides_ppp_app-proc_guide_doss_semiochemicals_202401.pdf.

(10) EGTOP, 'Final report on Greenhouses', 19 June 2016, https://agriculture.ec.europa.eu/document/download/7ae7f682-cf88-4c1e-8686-afd5617ec7ae_en?filename=final-report-etop-greenhouse-production.pdf.

(11) EGTOP, 'Final report on Plant Protection (X) and Fertilisers (VII)', 3 May 2024, https://agriculture.ec.europa.eu/document/download/57c18571-67ba-4e28-b9df-139f2ac36b91_en?filename=egtop-report-ppp-10_and_fertilisers-7_en.pdf.

(12) EGTOP, 'Final report on Greenhouses', 19 June 2016, https://agriculture.ec.europa.eu/document/download/7ae7f682-cf88-4c1e-8686-afd5617ec7ae_en?filename=final-report-etop-greenhouse-production.pdf; EGTOP, 'Final report on Fertilisers (VI) and Plant Protection Products (VIII)', 28 August 2023, https://agriculture.ec.europa.eu/document/download/a4561074-266c-40dd-881b-c27f150e3d8a_en?filename=egtop-report-fertilisers-vi-and-ppp-viii_en.pdf.

(13) EGTOP, 'Final report on Greenhouses', 19 June 2016, https://agriculture.ec.europa.eu/document/download/7ae7f682-cf88-4c1e-8686-afd5617ec7ae_en?filename=final-report-etop-greenhouse-production.pdf.

(8) EGTOP'un gübrelerle ilgili tavsiyelerine (14) dayanarak, kalsiyum asetat kullanımına yalnızca seralardaki sebzelerde ve elma ağaçlarında kalsiyum eksikliği önlemek için yaprakтан uygulama için izin verilmelidir. Bu tavsiyelere dayanarak, organik üretimde kalsiyum fosfat kullanımına da yalnızca kanalizasyon çamuru külünden elde edildiğinde ve yalnızca Avrupa Parlamentosu ve Konseyinin (AB) 2019/1009 sayılı Tüzüğü'nün (15) gerekliliklerine uygun ürünlerde bulunduğu izin verilmelidir. Bu nedenle, (AB) 2021/1165 sayılı Uygulama Tüzüğü'nün Ek II'si buna göre değiştirilmelidir.

(9) EGTOP'un gübrelerle ilgili tavsiyelerine (16) dayanarak, (AB) 2018/848 sayılı Tüzüğün Ek II'sinin Bölüm I, madde 1.3(a) uyarınca, filizlenmiş tohumların üretiminde herhangi bir gübre, toprak düzenleyici veya diğer besin maddesi eklenmeden bitki lifli matlarının inert bir ortam olarak kullanılmasına izin verilmelidir. Ayrıca, sunulan dosyaya dayanarak, bu tür bitkisel lifli paspasların hiçbir katkı maddesi veya bağlayıcı kullanılmadan yalnızca mekanik olarak üretilmesinin ve kullanılan bitkisel lifin organik kökenli olmasının şart koşulması uygundur. Bu nedenle, (AB) 2021/1165 sayılı Uygulama Tüzüğü'nün Ek II'si buna göre değiştirilmelidir.

(10) EGTOP'un gübrelerle ilgili tavsiyelerine (17) dayanarak, kalsiyum ve magnezyum glukonat kullanımına, yalnızca mikrobiyal fermentasyon yoluyla ve sıkı sınırlar dahilinde elde edilmesi koşuluyla izin verilmelidir. Bu nedenle, (AB) 2021/1165 sayılı Uygulama Yönetmeliği'nin Ek II'si buna göre değiştirilmelidir.

(11) (AB) 2021/1165 sayılı Uygulama Yönetmeliği'nin Ek III'ü, belirli beslenme amaçlarına yönelik yem olarak 'kalsiyum klorür' ve 'propilen glikol' (yem malzemeleri) ile 'demir dekstran %10'un (besin katkı maddesi) kullanımına izin vermektedir. İlgili maddelerin doğru anlaşılmasını sağlamak için bu kullanıma ilişkin özel koşullar ve sınırlar açıklığa kavuşturulmalıdır. Özellikle, Avrupa Parlamentosu ve Konseyi'nin (EC) 767/2009 sayılı Tüzüğü'nde (18) yer alan 'belirli beslenme amaçlı yem' tanımına ve (AB) 2020/354 sayılı Komisyon Tüzüğü (19) kapsamındaki bu maddelerin belirli beslenme amacına atıfta bulunulmalıdır.

(12) EGTOP'un yemle ilgili tavsiyelerine (20) (21) dayanarak, Trichoderma viride ve Aspergillus oryzae'den elde edilen tek hücreli proteinler ve Bacillus subtilis'ten elde edilen protein açısından zengin ürünler, tüm hayvanlar için yemlerde yem katkı maddesi olarak kullanılan lesitinler ve işleme yardımcılarını olarak kullanılan etanol ve papain onaylanmalıdır. Bu nedenle, (AB) 2021/1165 sayılı Uygulama Tüzüğü'nün Ek III'ü buna göre değiştirilmelidir.

(14) EGTOP, 'Final report on Plant Protection (X) and Fertilisers (VII)', 3 May 2024, https://agriculture.ec.europa.eu/document/download/57c18571-67ba-4e28-b9df-139f2ac36b91_en?filename=egtop-report-ppp-10_and_fertilisers-7_en.pdf.

(15) Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1, ELI: <http://data.europa.eu/eli/reg/2019/1009/oj>).

(16) EGTOP, 'Final report on Fertilisers (VI) and Plant Protection Products (VIII)', 28 August 2023, https://agriculture.ec.europa.eu/document/download/a4561074-266c-40dd-881b-c27f150e3d8a_en?filename=egtop-report-fertilisers-vi-and-ppp-viii_en.pdf.

(17) EGTOP, 'Final report on Plant Protection (X) and Fertilisers (VII)', 3 May 2024, https://agriculture.ec.europa.eu/document/download/57c18571-67ba-4e28-b9df-139f2ac36b91_en?filename=egtop-report-ppp-10_and_fertilisers-7_en.pdf.

(18) Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (OJ L 229 1.9.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/767/oj>).

(19) Commission Regulation (EU) 2020/354 of 4 March 2020 establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC (OJ L 67, 5.3.2020, p. 1, ELI: <http://data.europa.eu/eli/reg/2020/354/oj>).

(20) EGTOP, 'Final report on Feed (VII) and Pet Food (II)', 16 March 2023, https://agriculture.ec.europa.eu/document/download/46e56928-5332-4ae5-919e-c5c108422537_en?filename=egtop-report-feed-vii-and-petfood-ii_en.pdf.

(21) EGTOP, 'Final report on Feed (VIII) and Food (IX)', 1 July 2024, https://agriculture.ec.europa.eu/document/download/88317fd1-c9d2-4dca-bbc3-64521f806d09_en?filename=egtop-report-feed-viii_and_food-ix_en.pdf.

(13) Komisyon Tüzüğü (EC) No 2277/2003 (22), kalsiyum stearatın organik üretimde yem katkı maddesi olarak kullanılmasına izin vermiştir. Ancak, Komisyon Tüzüğü (EU) No 892/2010 (23), kalsiyum stearatın yem katkı maddesi olmayan ürünler arasında listelendiğini belirtmiştir. Sonuç olarak, 2012 yılında, Komisyon Uygulama Tüzüğü (EU) No 505/2012 (25) ile Komisyon Tüzüğü (EC) No 889/2008 (24)'teki izin verilen yem katkı maddeleri listesinden çıkarılmıştır. Kalsiyum stearat, şu anda, Komisyon Tüzüğü (EU) No 68/2013'ün (26) Ek'inin C Kısımı, 13. madde, 13.6.4 numaralı tablosunda listelenen yem maddeleri kapsamındadır. Bu nedenle kalsiyum stearat, organik üretim için yem maddesi olarak izin verilmelidir. Uygulama Yönetmeliği (AB) 2021/1165'in Ek III'ü buna göre değiştirilmelidir.

(14) (AB) 2021/1165 sayılı Uygulama Yönetmeliği'nin Ek III'ünün B Kısımı, 1(a) maddesinde, yem katkı maddeleri Avrupa gıda katkı maddesi numarası (E numarası) ile tanımlanmaktadır. Avrupa Parlamentosu ve Konseyi'nin 1831/2003 sayılı (EC) Yönetmeliği'ne (27) uygun olarak, yem katkı maddeleri fonksiyonel gruplarına göre tanımlanmalıdır. Tutarlılık sağlamak amacıyla, yem katkı maddeleri ayrıca (AB) 2021/1165 sayılı Uygulama Yönetmeliği'ndeki fonksiyonel grup kodlarıyla da tanımlanmalıdır. Bu nedenle, (AB) 2021/1165 sayılı Uygulama Yönetmeliği'nin Ek III'ü buna göre değiştirilmelidir.

(15) EGTOP, kalsiyum propiyonat'ın koruyucu ve belirli beslenme amaçlı yem olarak kullanımına ilişkin tavsiyelerinde²⁰, kalsiyum klorürün belirli beslenme amaçlı kullanılabileceği ve kalsiyum propiyonat'ın koruyucu olarak kullanılmaması gerektiği gerekçesiyle, kalsiyum propiyonat'ın yem katkı maddesi olarak eklenmesini önermemiştir. Ancak kalsiyum propiyonat, kalsiyum klorürden daha yavaş emilir ve yalnızca kalsiyum klorür kullanıldığında tahriş edici etkileri önler. (AB) 2020/354 sayılı Yönetmeliğin Ek B Kısım '60' maddesindeki tabloda, kalsiyum propiyonat belirli beslenme amaçlı yem olarak listelenmiştir. Komisyon Uygulama Yönetmeliği (AB) 2022/415 (28) uyarınca, kalsiyum propiyonat bir yem katkı maddesidir. Bu nedenle, yalnızca belirli beslenme amaçlı yem olarak kullanılması koşuluyla, (AB) 2021/1165 sayılı Yönetmeliğin Ek III'ünde yetkili bir yem katkı maddesi olarak listelenmelidir.

(22) Commission Regulation (EC) No 2277/2003 of 22 December 2003 amending Annexes I and II to Council Regulation (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs (OJ L 336, 23.12.2003, p. 68, ELI: <http://data.europa.eu/eli/reg/2003/2277/oj>).

(23) Commission Regulation (EU) No 892/2010 of 8 October 2010 on the status of certain products with regard to feed additives within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council (OJ L 266, 9.10.2010, p. 6, ELI: <http://data.europa.eu/eli/reg/2010/892/oj>).

(24) Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (OJ L 250, 18.9.2008, p. 1, ELI: <http://data.europa.eu/eli/reg/2008/889/oj>).

(25) Commission Implementing Regulation (EU) No 505/2012 of 14 June 2012 amending and correcting Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (OJ L 154, 15.6.2012, p. 12, ELI: http://data.europa.eu/eli/reg_impl/2012/505/oj).

(26) Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials (OJ L 29, 30.1.2013, p. 1, ELI: <http://data.europa.eu/eli/reg/2013/68/oj>).

(27) Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>).

(28) Commission Implementing Regulation (EU) 2022/415 of 11 March 2022 concerning the authorisation of malic acid, citric acid produced by *Aspergillus niger* DSM 25794 or CGMCC 4513/CGMCC 5751 or CICC 40347/CGMCC 5343, sorbic acid and potassium sorbate, acetic acid, sodium diacetate and calcium acetate, propionic acid, sodium propionate, calcium propionate and ammonium propionate, formic acid, sodium formate, calcium formate and ammonium formate, and lactic acid produced by *Bacillus coagulans* (LMG S-26145 or DSM 23965), or *Bacillus smithii* (LMG S-27890) or *Bacillus subtilis* (LMG S-27889) and calcium lactate as feed additives for certain animal species (OJ L 85, 14.3.2022, p. 6, ELI: http://data.europa.eu/eli/reg_impl/2022/415/oj).

(16) EGTOP, demir(II) fumaratın belirli beslenme amaçlarına yönelik bir yem olarak kullanımına ilişkin tavsiyelerinde (29), 2021/1165 sayılı Uygulama Tüzüğü'nde demir(II) fumaratın dahil edilmesini önermemiştir; çünkü söz konusu Uygulama Tüzüğü'nde yetkilendirilen demir dekstranın demir eksikliği için en etkili ürün olduğunu düşünmüştür. Ancak demir dekstran ve demir(II) fumarat alternatif değildir; ancak farklı halleri nedeniyle her ikisine de ihtiyaç duyulmaktadır; demir dekstran sıvı, demir(II) fumarat ise katıdır. Bu nedenle demir(II) fumarat, 2021/1165 sayılı Uygulama Tüzüğü'nün Ek III'ünde yem katkı maddesi olarak listelenmelidir.

(17) İşlenmiş organik gıda üretiminde kullanılan gıda katkı maddeleri ve gıda işleme yardımcıları, (AB) 2021/1165 sayılı Uygulama Tüzüğü'nün Ek V'inin A Kısımında iki ayrı bölümde listelenmiştir. Bir ürünün gıda katkı maddesi veya işleme yardımcısı olarak kullanımı, Avrupa Parlamentosu ve Konseyinin (EC) 1333/2008 sayılı Tüzüğü'nün 3(2) maddesindeki gıda katkı maddesi ve işleme yardımcısı tanımlarına uygun olarak belirlenecektir (30). Son ürünlerdeki teknolojik işlevlerine bağlı olarak, işleme yardımcısı olarak sınıflandırılan bazı ürünler gıda katkı maddesi olarak sınıflandırılmalı ve bazı diğer ürünler kullanımlarına göre gıda katkı maddesi ve gıda işleme yardımcısı olarak sınıflandırılmalıdır. Netlik sağlamak amacıyla, (AB) 2021/1165 sayılı Uygulama Tüzüğü'nün Ek V'inin A Kısım, A1 ve A2 bölümlerinde yer alan gıda katkı maddeleri ve gıda işleme yardımcıları listeleri bu nedenle tek bir listede birleştirilmeli ve gıda katkı maddesi olarak da kullanılabilen işleme yardımcıları için daha özel koşullar belirlenmelidir.

(18) Birleştirilmiş listede, katkı maddesi "kalsiyum karbonat"ın renklendirme veya kalsiyum zenginleştirme amacıyla kullanılmaması gerektiği yönündeki özel koşul, (AB) 2018/848 sayılı Yönetmeliğin Ek II'sinin IV. Kısım, 2.2.2(c), (d) ve (f) maddelerinde belirtilen kurallar zaten bu koşulu içerdiğinden silinmelidir.

(19) EGTOP'un gıda ile ilgili tavsiyelerine (31) dayanarak, tamponlu sirke, (AB) 2021/1165 sayılı Uygulama Yönetmeliğinin Ek V'inin A Kısımında yer alan yetkili gıda katkı maddeleri ve işleme yardımcıları listesine gıda katkı maddesi olarak dahil edilmelidir.

(20) Uygulama Tüzüğü (AB) 2021/1165'in Ek V'inin A Kısımında yer alan yetkili gıda katkı maddeleri ve işleme yardımcıları listesinde, sodyum nitrit ve potasyum nitrat için maksimum seviyeler, Avrupa Gıda Güvenliği Otoritesi (32) tarafından belirlenen Kabul Edilebilir Günlük Alım Miktarları (ADI) doğrultusunda nitrit iyonu ve nitrat iyonu olarak ifade edilmelidir. Bu amaçla, sodyum nitrit ile nitrit iyonu arasında 0,67'lik ve sodyum nitrat ile nitrat iyonu arasında 0,73'lük bir dönüşüm faktörü uygulanmalıdır.

(21) (AB) 2021/1165 sayılı Uygulama Tüzüğü'nün Ek V'inin A Kısım, A1 bölümünde, gellan zımkı, 1 Ocak 2026'dan itibaren organik üretim kurallarına uygun olarak üretilecek yetkili bir gıda katkı maddesi olarak listelenmiştir. Gellan zımkı üretimi, mikroorganizma için belirli ve tutarlı hammadde niteliklerinin korunmasına bağlıdır. Şimdiye kadar, organik tarımsal hammaddeler kullanılarak gellan zımkı üretme girişimleri başarısız olmuştur. Gellan zımkı, organik işlenmiş gıdalarda katkı maddesi olarak kullanılır. Organik işlenmiş gıda üretiminin aksamamasını önlemek için, organik üretimde organik olmayan gellan zımkının kullanımına izin verilmeye devam edilmelidir. Bu durum, (AB) 2021/1165 sayılı Uygulama Tüzüğü'nün Ek V'inin A Kısımındaki yetkili gıda katkı maddeleri ve işleme yardımcılarının birleştirilmiş listesindeki gellan zımkı girişine yansıtılmalıdır.

(29) EGTOP, 'Final report on Feed (VII) and Pet Food (II)', 16 March 2023, https://agriculture.ec.europa.eu/document/download/46e56928-5332-4ae5-919e-c5c108422537_en?filename=egtop-report-feed-vii-and-petfood-ii_en.pdf.

(30) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16, ELI: <http://data.europa.eu/eli/reg/2008/1333/oj>).

(31) EGTOP, 'Final report on Feed (VIII) and Food (IX)', 1 July 2024, https://agriculture.ec.europa.eu/document/download/88317fd1-c9d2-4dca-bbc3-64521f806d09_en?filename=egtop-report-feed-viii_and_food-ix_en.pdf.

(32) EFSA, *Re-evaluation of potassium nitrite (E 249) and sodium nitrite (E 250) as food additives*, EFSA Journal 2017;15(6):4786, <https://doi.org/10.2903/j.efsa.2017.4786>.

(22) (AB) 2021/1165 sayılı Uygulama Tüzüğü'nün Ek V'inin A Kısımı, A1 bölümünde, jelatin üretiminin Avrupa Parlamentosu ve Konseyi'nin (EC) 853/2004 sayılı Tüzüğü'nde (33) belirtilen jelatin üretim kurallarına uygun olması koşuluyla jelatin üretiminde hidroklorik asit, hidrojen peroksit ve amonyum hidroksit kullanımına izin verilmektedir. (AB) 2021/1165 sayılı Uygulama Tüzüğü'nün Ek V'inin A Kısımında yer alan yetkili gıda katkı maddeleri ve işleme yardımcılarının birleştirilmiş listesinde bu özel koşulun tekrarlanmasına gerek yoktur.

(23) EGTOP, maya bazlı besin maddeleri hakkındaki tavsiyelerinde (34), mineraller, vitaminler ve amino asitlere karşılık gelen besin maddelerinin maya üretimini desteklemek için gerekli fermantasyon aktivatörleri olduğunu doğrulamıştır. Ancak EGTOP, sentetik besin maddelerinin kullanımının organik üretim ilkeleriyle uyumlu olmadığı sonucuna varmıştır. Bu nedenle EGTOP, maya üretimini desteklemek amacıyla yalnızca maya özütü veya otolizattan elde edilen besin maddelerinin, kuru madde ağırlığına göre hesaplanan ilgili substratın %5'ine kadar sınırlı miktarda kullanılmasına izin verilmesini önermiştir. Bu nedenle, maya özütü veya otolizattan elde edilen besin maddelerinden oluşan fermantasyon aktivatörleri, substratın %5'i sınırında olmak üzere, (AB) 2021/1165 sayılı Uygulama Tüzüğü'nün Ek V'inin C Bölümü'nde yetkili ürünler olarak listelenmelidir.

(24) (AB) 2018/848 sayılı Tüzüğün Ek II'sinin VI. Kısım, 3.4. maddesi uyarınca, bir Üye Devlet, organik şarap üretiminde asitlik düzenleyici olarak maya ve laktik asit bakterilerinin kullanımına izin verilmesi için bir dosya sunmuştur. (AB) 2021/1165 sayılı Uygulama Tüzüğü'nün Ek V'inin D Kısımı uyarınca, şarap üretimi için mayalar ve laktik asit bakterileri fermantasyon ajanı olarak izin verilmiştir. Bu fermantasyon ajanları ayrıca asitlik düzenleyici özellikler de göstermektedir. Bu fermantasyon ajanları, organik şarap üretimi için halihazırda izin verilen diğer asitlik düzenleyicilere uygun alternatifler olduğundan, asitlik düzenleyici olarak kullanımlarına izin verilmeli ve (AB) 2021/1165 sayılı Uygulama Tüzüğü'nün Ek V'inin D Kısımı buna göre değiştirilmelidir.

(25) EGTOP'un bitki koruma ürünlerine ilişkin tavsiyelerine (35) dayanarak, ananasta çiçek açması için etilen kullanımı ve genetiği değiştirilmiş organizmalardan kaynaklanmayan mikroorganizmaların organik ürünlerde kullanılması, üçüncü ülkelerde bitki koruma ürünlerinde bulunan aktif maddeler olarak organik üretimde kullanılmasına izin verilmelidir. Bu nedenle, bu maddelerin ve kullanımlarına ilişkin özel koşulların ve sınırların, (AB) 2021/1165 sayılı Uygulama Tüzüğü'nün Ek VI'sına dahil edilmesi uygundur.

(26) Temel madde olan "Magnezyum hidrojen metasilikat silikat minerali (Talk E 553b)", (AB) 2021/1165 sayılı Uygulama Yönetmeliği'nin Ek I'inin 1. maddesindeki tabloda listelenmiştir. Ancak, "özel koşullar ve sınırlar" sütununda belirtilen özel koşul, söz konusu temel maddenin kullanımına ilişkin ek bir kısıtlama değildir. Bu nedenle, bu hata düzeltilmelidir.

(27) Bu nedenle, (AB) 2021/1165 sayılı Uygulama Yönetmeliği düzeltilmeli ve uygun şekilde düzeltilmelidir.

(28) Bu Yönetmelikte öngörülen önlemler, Organik Üretim Komitesi'nin görüşüne uygundur.

(33) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55, ELI: <http://data.europa.eu/eli/reg/2004/853/oj>).

(34) EGTOP, 'Final report on Food (X)', 31 January 2025, https://agriculture.ec.europa.eu/document/download/c4cef8da-34a4-48f7-9f5d-2c97f86f2a15_en?filename=egtop-report-food-x_en.pdf.

(35) EGTOP, 'Final report on Fertilisers (VI) and Plant Protection Products (VIII)', 28 August 2023, https://agriculture.ec.europa.eu/document/download/a4561074-266c-40dd-881b-c27f150e3d8a_en?filename=egtop-report-fertilisers-vi-and-ppp-viii_en.pdf; EGTOP, 'Final report on Plant Protection (IX)', 14 December 2023, https://agriculture.ec.europa.eu/document/download/5a183a99-2e86-4add-a0ae-27fc519e5c11_en?filename=egtop-report-ppp-ix_en.pdf.

BU DÜZENLEMİYİ KABUL ETMİŞTİR:

Madde 1

Amendments to Implementing Regulation (EU) 2021/1165

Implementing Regulation (EU) 2021/1165 is amended as follows:

- (1) The following Article 10a is inserted:

'Article 10a

Procedure to grant specific authorisation for the use of products and substances in the outermost regions of the Union

1. Where a Member State considers that a product or substance should be granted a specific authorisation for use in an outermost region of the Union due to the specific conditions set out in Article 45(2) of Regulation (EU) 2018/848, it may request the Commission to carry out an assessment. For that purpose, it shall notify the Commission of a dossier describing the product or substance concerned, giving the reasons for such specific authorisation due to the specific conditions set out in Article 45(2) of Regulation (EU) 2018/848 and explaining why the products and substances authorised under this Regulation are not adequate to be used due to the specific conditions in the outermost region concerned. It shall ensure that the dossier is fit to be made publicly available subject to Union and national legislation of the Member States on data protection.

2. The Commission shall publish any requests referred to in paragraph 1.

3. The Commission shall analyse the dossier referred to in paragraph 1. The Commission shall authorise the product or substance in the light of the specific conditions referred to in the dossier only if its analysis concludes, as a whole that:

- (a) such specific authorisation is justified in the outermost region concerned;
- (b) the product or substance described in the dossier complies with the principles laid down in Chapter II, the criteria set out in Article 24(3) and the condition set out in Article 24(5) of Regulation (EU) 2018/848; and
- (c) the use of the product or substance is in accordance with the relevant provisions of Union law, in particular, for active substances contained in plant protection products, with Regulation (EC) No 396/2005.

The authorised product or substance shall be included in Annex VI to this Regulation.

4. When the 2-year period referred to in Article 45(2) of Regulation (EU) 2018/848 expires, the authorisation shall be automatically renewed for another period of 2 years, provided that no new elements are available and no Member State or control authority or control body recognised under Article 46(1) of Regulation (EU) 2018/848 has objected, justifying that the conclusion by the Commission referred to in paragraph 3 needs to be reassessed.;

- (2) Annex I is amended in accordance with Annex I to this Regulation;
- (3) Annex II is amended in accordance with Annex II to this Regulation;
- (4) Annex III is amended in accordance with Annex III to this Regulation;
- (5) Annex V is amended in accordance with Annex IV to this Regulation;
- (6) Annex VI is replaced by the text set out in Annex V to this Regulation.

*Article 2***Correction of Implementing Regulation (EU) 2021/1165**

In the table in point 1 of Annex I to Implementing Regulation (EU) 2021/1165, the entry '19C' is replaced by the following:

'19C	14807-96-6	Magnesium hydrogen metasilicate silicate mineral (Talc E 553b)	
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*Article 3***Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Brüksel'de tamamlandı, 23 Mayıs 2025.

Komisyon Başkanı

Ursula VON DER LEYEN

ANNEX I

Annex I to Implementing Regulation (EU) 2021/1165 is amended as follows:

(1) in point 2, the table is amended as follows:

(a) the following entry is inserted between the entries '16D' and '20D':

'19D	23960-07-8	Lavandulyl senecioate'	
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(b) the following entries are added after the entry for other low risk substances from plant or animal origin *:

'32D	298-14-6	Potassium hydrogen carbonate	
38D		Straight chain lepidopteran pheromones (acetates)	
39D	98999-15-6	Sheep fat	use as repellent by smell'
44D	14808-60-7 and 7631-86-9	Quartz sand Silicon dioxide	

(2) in point 4, the table is amended as follows:

(a) the entries '244A', '247A', '249A' and '255A and others' are deleted;

(b) the following entry is inserted between the entries '47B' and '10E':

'153B and others		Pheromones and other semiochemicals'	
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ANNEX II

Annex II to Implementing Regulation (EU) 2021/1165 is amended as follows:

- (1) in the table, the entry 'products and by-products of plant origin for fertilisers' is replaced by the following:

'Products and by-products of plant origin	e.g., oilseed cake meal, cocoa husks, malt culms'
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- (2) in the table, the entry 'stone meal, clays and clay minerals' is replaced by the following:

'Stone meal, sand of natural origin, clays and clay minerals	e.g., perlite, sand and vermiculite, including when heat treated, perlite, sand and vermiculite, including when heat treated, may also be used for sprouted seeds production as an inert medium as referred to in Part I, point 1.3(a), of Annex II to Regulation (EU) 2018/848'
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- (3) in the table, the following entries are added after the entry 'selenium salts':

'Carbon dioxide	use for enrichment of water for algae production on land in closed systems; in this case, carbon dioxide shall be of food grade when available, carbon dioxide shall be obtained as a by-product of other processes or from renewable sources pursuant to Directive (EU) 2018/2001 of the European Parliament and of the Council (*) may also be used in greenhouse production
Calcium acetate	only for foliar application on vegetables in greenhouses and on apple trees to prevent deficiency in calcium obtained from calcium carbonate of natural origin
Calcium phosphate	only when derived from sewage sludge ash only products complying with the requirements of Regulation (EU) 2019/1009
Plant fibre mats	plant-based fibres, such as hemp fibre, flax fibre, coconut fibre with no addition of any fertiliser, soil conditioner or nutrient nor additives or binders, only mechanically manufactured only for sprouted seeds production as an inert medium referred to in Part I, point 1.3(a), of Annex II to Regulation (EU) 2018/848 when available, materials from organic production shall be used
Calcium and magnesium gluconate	derived from microbial fermentation

(*) Directive (EU) 2018/2001 of the European Parliament and of the Council of 11 December 2018 on the promotion of the use of energy from renewable sources (OJ L 328, 21.12.2018, p. 82, ELI: <http://data.europa.eu/eli/dir/2018/2001/oj>).

ANNEX III

Annex III to Implementing Regulation (EU) 2021/1165 is amended as follows:

(1) Part A is amended as follows:

(a) in point (1), in the table, the entry '11.1.6' is replaced by the following:

'11.1.6	Calcium chloride	may only be used as "feed intended for particular nutritional purposes" defined in Article 3(2), point (o), of Regulation (EC) No 767/2009 for the reduction of the risk of milk fever and subclinical hypocalcaemia in accordance with Part B, table entry "60", of the Annex to Commission Regulation (EU) 2020/354 (*), including bolus formulation calcium chloride when purified from naturally occurring brine, if available only for dairy cows in need and for a limited period
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(*) Commission Regulation (EU) 2020/354 of 4 March 2020 establishing a list of intended uses of feed intended for particular nutritional purposes and repealing Directive 2008/38/EC (OJ L 67, 5.3.2020, p. 1, ELI: <http://data.europa.eu/eli/reg/2020/354/oj>).

(b) in point (2), the table is amended as follows:

(i) the following entries are inserted between the entries '12.1.5' and '12.1.12':

'ex 12.1.9	Single cell proteins from <i>Trichoderma viride</i> and <i>Aspergillus oryzae</i>	only from non-GM strain and culture media not obtained from substrates with synthetic nitrogen sources obtained from substrates coming from organic production when used for ruminants and other herbivores when used, antifoaming agents shall be authorised for organic production
12.1.10	Products from <i>Bacillus subtilis</i> rich in protein	only from non-GM strain and culture media not obtained from substrates with synthetic nitrogen sources obtained from substrates coming from organic production when used for ruminants and other herbivores when used, antifoaming agents shall be authorised for organic production'

(ii) the following entry is inserted between the entries '12.1.12' and '13.11.1':

'ex 13.6.4	Calcium stearate'	
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(iii) the entry '13.11.1' is replaced by the following:

'13.11.1	Propylene glycol; [1,2-propanediol]; [propane-1,2-diol]	may only be used as "feed intended for particular nutritional purposes" defined in Article 3(2), point (o), of Regulation (EC) No 767/2009 for the reduction of the risk of ketosis in accordance with Part B, table entry "61", of the Annex to Regulation (EU) 2020/354, including bolus formulation only for dairy cows, ewes and goats in need and for a limited period'
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(2) Part B is amended as follows:

(a) in point (1)(a), the table is replaced by the following:

'ID number or functional group	Name	Specific conditions and limits
1a200	Sorbic acid	
1k236	Formic acid	
1k237i	Sodium formate	
1a260	Acetic acid	
1a270 1a270i	Lactic acids	
1k280	Propionic acid	
1a282	Calcium propionate	may only be used as "feed intended for particular nutritional purposes" defined in Article 3(2), point (o), of Regulation (EC) No 767/2009 for the reduction of the risk of milk fever and subclinical hypocalcaemia in accordance with Part B, table entry "60", of the Annex to Regulation (EU) 2020/354, including bolus formulation only for dairy cows in need and for a limited period'
1a330	Citric acid	

(b) in point (1)(c), in the table, the entry '1c322, 1c322i' is replaced by the following:

'1c322, 1c322i	Lecithins	derived from organic raw material from 1 January 2027, only from organic production'
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(c) in point (3)(b), the table is amended as follows:

(i) the following entry is inserted between the entries '3b104' and '3b107':

'3b105	Iron(II) fumarate	may only be used as "feed intended for particular nutritional purposes" defined in Article 3(2), point (o), of Regulation (EC) No 767/2009 for compensation of insufficient iron availability after birth in accordance with Part B, table entry "64", of the Annex to Regulation (EU) 2020/354 only for suckling piglets in need and for a limited period'
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(ii) the entry '3b110' is replaced by the following:

'3b110	Iron dextran 10 %	may only be used as "feed intended for particular nutritional purposes" defined in Article 3(2), point (o), of Regulation (EC) No 767/2009 for compensation of insufficient iron availability after birth in accordance with Part B, table entry "64", of the Annex to Regulation (EU) 2020/354 growing medium for the fermentation process for dextran shall be of non-GMO origin only for suckling piglets in need and for a limited period'
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(d) the following point is added:

'(5) PROCESSING AIDS

For processing aids as defined in Article 2(2), point (h), of Regulation (EC) No 1831/2003, the specific conditions and limits set out in the following table shall apply.

Name	Specific conditions and limits
Ethanol	to be used only as extraction solvent for the production of protein meals and only when protein meals from mechanical extraction are not available in sufficient quantities only from fermentation if available only from organic production if available
Papain	only for the production of flavouring innards for the manufacture of pet food that are defined in point 18 of Annex I to Regulation (EU) No 142/2011 provided that the enzyme is inactivated during the process and therefore is not present as such in the resulting flavouring innards and does not have any technological effect on the product from 1 January 2027, only from organic raw material'

ANNEX IV

Annex V to Implementing Regulation (EU) 2021/1165 is amended as follows:

(1) Part A is replaced by the following:

‘PART A

Authorised food additives and processing aids referred to in Article 24(2), point (a), of Regulation (EU) 2018/848, including carriers and other substances used in the same way and with the same purpose as processing aids

The organic foodstuffs to which food additives may be added are within the limit of authorisations given in accordance with Regulation (EC) No 1333/2008.

The specific conditions and limits set out in the table below shall apply in addition to the conditions of the authorisations under Regulation (EC) No 1333/2008.

The use as food additives or as processing aids shall be attributed on a case-by-case basis in accordance with Regulation (EC) No 1333/2008 and national legislation on processing aids.

For the purpose of the calculation of the percentages referred to in Article 30(5) of Regulation (EU) 2018/848, food additives marked with an asterisk in the column “E-number or EINECS, or both” shall be calculated as ingredients of agricultural origin.

E-number or EINECS (*), or both	Name	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits	
		Use as an additive	Use as a processing aid
E 153	Vegetable carbon	edible cheese rind of ashy goat cheese	
		Morbier cheese	
E 160b(i)*	Annatto bixin	Red Leicester cheese	
		Double Gloucester cheese	
		Cheddar	
		Mimolette cheese	
E 160b(ii)*	Annatto norbixin	Red Leicester cheese	
		Double Gloucester cheese	
		Cheddar	
		Mimolette cheese	
E 170/207-439-9 and 215-279-6	Calcium carbonate	products of plant and animal origin	products of plant origin
E 220	Sulphur dioxide	fruit wines (wine made from fruits other than grapes, including cider and perry) and mead with and without added sugar 100 mg/l (maximum levels available from all sources, expressed as SO ₂ in mg/l)	
E 223	Sodium metabisulphite	crustaceans	

E-number or Einescs (*), or both	Name	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits	
		Use as an additive	Use as a processing aid
E 224	Potassium metabisulphite	fruit wines (wine made from fruits other than grapes, including cider and perry) and mead with and without added sugar 100 mg/l (maximum levels available from all sources, expressed as SO ₂ in mg/l)	
E 250	Sodium nitrite	meat products may only be used, if it has been demonstrated to the satisfaction of the competent authority that no technological alternative, giving the same guarantees and/or allowing to maintain the specific features of the product, is available not in combination with E252 maximum amount that may be added during the manufacturing expressed as NO ₂ ion: 50 mg/kg maximum residual amount from all sources for the product ready for marketing throughout the shelf life of the product expressed as NO ₂ ion: 30 mg/kg	
E252	Potassium nitrate	meat products may only be used, if it has been demonstrated to the satisfaction of the competent authority that no technological alternative, giving the same guarantees and/or allowing to maintain the specific features of the product, is available not in combination with E250 maximum amount that may be added during the manufacturing expressed as NO ₃ ion: 55 mg/kg maximum residual amount from all sources for the product ready for marketing throughout the shelf life of the product expressed as NO ₃ ion: 35 mg/kg	
E 267*	Buffered vinegar	products of plant and animal origin only from organic production	
E 270/200-018-0	Lactic acid	products of plant and animal origin	cheese for the regulation of pH of the brine bath in cheese production

E-number or Einescs (*), or both	Name	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits	
		Use as an additive	Use as a processing aid
E 290/204-696-9	Carbon dioxide	products of plant and animal origin	products of plant and animal origin
E 296	Malic acid	products of plant origin	
E 300	Ascorbic acid	products of plant origin meat products (category 08,3 (**)) and meat preparations (category 08,2 (**)) to which other ingredients than additives or salt have been added	
E 301	Sodium ascorbate	meat products may only be used in connection with nitrates and nitrites	
E 306*	Tocopherol-rich extract	products of plant and animal origin only as antioxidant	
E 322*	Lecithins	products of plant and animal origin only from organic production	
E 325	Sodium lactate	products of plant origin	
		milk-based products	
		meat products	
E 330/201-069-1	Citric acid	products of plant and animal origin	products of plant and animal origin
E 331	Sodium citrates	products of plant and animal origin	
E 333	Calcium citrates	products of plant origin	
E 334	Tartaric acid (L(+)-)	products of plant origin mead	
E 335*	Sodium tartrates	products of plant origin from 1 January 2027, only from organic production	
E 336*	Potassium tartrates	products of plant origin from 1 January 2027, only from organic production	
E 337*	Potassium sodium tartrate	products of plant origin from 1 January 2027, only from organic production	

E-number or Einescs (*), or both	Name	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits	
		Use as an additive	Use as a processing aid
E 341(i)	Monocalcium phosphate	self-raising flour only as raising agent	
E 392*	Extracts of rosemary	products of plant and animal origin only from organic production	
E 400	Alginic acid	products of plant origin	
		milk products	
E 401	Sodium alginate	products of plant origin	
		milk products	
		sausages based on meat	
E 402	Potassium alginate	products of plant origin	
		milk-based products	
E 406	Agar	products of plant origin	
		milk-based products	
		meat products	
E 407	Carrageenan	products of plant origin	
		milk-based products	
E 410*	Locust bean gum	products of plant and animal origin only from organic production	
E 412*	Guar gum	products of plant and animal origin only from organic production	
E 414*	Arabic gum	products of plant and animal origin only from organic production	
E 415	Xanthan gum	products of plant and animal origin	
E 417*	Tara gum	products of plant and animal origin only from organic production only as thickener	

E-number or Einescs (*), or both	Name	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits	
		Use as an additive	Use as a processing aid
E 418*	Gellan gum	products of plant and animal origin from organic production, if available only high-acyl form	
E 422*	Glycerol	plant extracts and flavourings only from plant origin only from organic production as solvent and carrier as humectant in gel capsules as surface coating of tablets	
E 440(i)*	Pectin	products of plant origin	
		milk-based products	
E 460/232-674-9	Cellulose	gelatine	gelatine
			products of plant origin
E 464	Hydroxypropyl methyl cellulose	products of plant and animal origin only as encapsulation material for capsules	
E 500/207-838-8, 205-633-8, 208-580-9	Sodium carbonates	products of plant and animal origin	products of plant and animal origin
E 501/209-529-3, 206-059-0	Potassium carbonates	products of plant origin	grapes only as drying agent to produce dried grapes
E 503	Ammonium carbonates	products of plant origin	
E 504	Magnesium carbonates	products of plant origin	
E 509/233-140-8	Calcium chloride	products of plant origin only to induce coagulation	products of plant origin only as clarifying/ flocculating agent
		milk-based products only as stabiliser	
		sausages based on meat only to induce coagulation to form casing	

E-number or Einescs (*), or both	Name	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits	
		Use as an additive	Use as a processing aid
E 511/232-094-6	Magnesium chloride	products of plant origin only to induce coagulation	products of plant origin only as clarifying/ flocculating agent
E 516/231-900-3	Calcium sulphate	products of plant origin only as carrier or to induce coagulation	products of plant origin only as clarifying/ flocculating agent
E 524/215-185-5	Sodium hydroxide	surface-treated <i>Laugengebäck</i> only as surface treatment	sugar(s)
		flavourings only as acidity regulator	oil from plant origin excluding olive oil
			plant protein extracts
E 551/231-545-4	Silicon dioxide	cocoa only as anticaking agent for use in automated dispensing machines	products of plant origin
		herbs and spices in dried powdered form	
		flavourings	
		propolis	
E 553b	Talc	products of plant origin	products of plant origin
		sausages based on meat only as surface treatment	
E 901*/232-383-7	Beeswax	confectionery only from organic production only as glazing agent	products of plant origin only from organic production only as releasing agent

E-number or Einescs (*), or both	Name	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits	
		Use as an additive	Use as a processing aid
E 903*/232-399-4	Carnauba wax	confectionery only from organic production only as glazing agent	products of plant origin only from organic production only as releasing agent
		citrus fruit only from organic production only as mitigating method for mandatory extreme cold treatment of fruit against harmful organisms in accordance with Commission Implementing Regulation (EU) 2019/2072 (**)	
E 938	Argon	products of plant and animal origin	
E 939	Helium	products of plant and animal origin	
E 941/231-783-9	Nitrogen	products of plant and animal origin	products of plant and animal origin
E 948	Oxygen	products of plant and animal origin	
E 968*	Erythritol	products of plant and animal origin only from organic production without using ion exchange technology	
-/200-578-6	Ethanol		products of plant and animal origin only as solvent on crystallization primers for the production of sugar and/or extraction solvent
-/200-580-7	Acetic acid		products of plant origin from organic production, if available
			fish from organic production, if available
-/215-108-5	Bentonite		products of plant origin
			mead only as sticking agent

E-number or Eines (°), or both	Name	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits	
		Use as an additive	Use as a processing aid
-/215-137-3	Calcium hydroxide		products of plant origin
-/231-595-7	Hydrochloric acid		gelatine
			Gouda, Edam and Maasdammer cheeses, Boerenkaas, Friese and Leidse Nagelkaas only as regulation of the pH of the brine bath in the processing of cheeses
-/231-639-5	Sulphuric acid		gelatine
			sugar(s)
-/231-765-0	Hydrogen peroxide		gelatine
-/232-554-6	Gelatine		products of plant origin
-/232-555-1	Casein		products of plant origin
-/293-292-6	Isinglass		products of plant origin
-/931-328-0	Activated carbon		products of plant and animal origin
	Ammonium hydroxide		gelatine
	Diammonium phosphate		fruit wines, cider, perry and mead
	L(+)lactic acid from fermentation		plant protein extracts
	Thiamin hydrochloride		fruit wines, cider, perry and mead
	Diatomaceous earth		products of plant origin
			gelatine
	Egg white albumin		products of plant origin
	Hop extract		products of plant origin from organic production, if available only for antimicrobial purposes

E-number or Einescs (*), or both	Name	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits	
		Use as an additive	Use as a processing aid
	Hazelnut shells		products of plant origin
	Perlite		products of plant origin
			gelatine
	Pine rosin extract		products of plant origin from organic production, if available only for antimicrobial purposes
	Rice meal		products of plant origin
	Tannic acid		products of plant origin only as filtration aid
	Vegetable oils		products of plant and animal origin only from organic production only as greasing, releasing or antifoaming agent
	Vinegar		products of plant origin only from organic production
			fish only from organic production
	Water		products of plant and animal origin water intended for human consumption within the meaning of Directive (EU) 2020/2184 of the European Parliament and of the Council (****)

E-number or Einescs (*), or both	Name	Organic foodstuffs in which the additive or processing aid may be used and specific conditions and limits	
		Use as an additive	Use as a processing aid
	Wood fibre		products of plant and animal origin the source of timber shall be restricted to certified, sustainably harvested wood wood used shall not contain toxic components (post-harvest treatment, naturally occurring toxins or toxins from microorganisms)

(*) European Inventory of Existing Commercial Chemical Substances (OJ C 146, 15.6.1990, p. 4).

(**) Food categories in Part D of Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16, ELI: <http://data.europa.eu/eli/reg/2008/1333/oj>).

(***) Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019 (OJ L 319, 10.12.2019, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2019/2072/oj).

(****) Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1, ELI: <http://data.europa.eu/eli/dir/2020/2184/oj>);

(2) in Part C, in the table, the following entry is added after the entry 'vegetable oils':

'Fermentation activators	X		nutrients from yeast extract or autolysate up to 5 % of the substrate calculated in weight of dry matter'
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(3) in Part D, the table is amended as follows:

(a) the entry 'yeasts for wine production' is replaced by the following:

'Yeasts for wine production		Part A, Table 2, point 1.11 Part A, Table 2, point 9.1	for the individual yeast strains, organic if available'
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(b) the entry 'lactic acid bacteria' is replaced by the following:

'Lactic acid bacteria		Part A, Table 2, point 1.12 Part A, Table 2, point 9.2'	
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ANNEX V

‘ANNEX VI

Products and substances authorised for use in organic production in third countries and in the outermost regions of the Union pursuant to Article 45(2) of Regulation (EU) 2018/848

PART A

PRODUCTS AND SUBSTANCES AUTHORISED FOR USE IN ORGANIC PRODUCTION IN THIRD COUNTRIES

Active substances to be used in plant protection products

Active substances listed in the table below may be used in organic production in third countries, provided that they comply with the relevant third country legislation, are exempted from maximum residue levels in accordance with Codex Alimentarius guidelines CXG 97-2022 (*), are included in Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council (**), or specific maximum residue levels have been set in that Regulation. They are subject to the corresponding specific conditions and limits set out in that table.

CAS number	Name of the active substance	Specific conditions and limits
	Microorganisms including viruses, when used as biological control agents	not from GMO origin not produced by using growing media of GMO origin
74-85-1	Ethylene	for flower induction in pineapple

PART B

PRODUCTS AND SUBSTANCES AUTHORISED FOR USE IN ORGANIC PRODUCTION IN THE OUTERMOST REGIONS OF THE UNION

Active substances to be used in plant protection products

Active substances listed in the table below may be used in organic production in the outermost regions of the Union, provided that they comply with the relevant provisions of Union law and, where applicable, with national provisions based on Union law.

(*) <https://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en>.

(**) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1, ELI: <http://data.europa.eu/eli/reg/2005/396/oj>).’.