Tarım Mevzuatı Değişiklikleri

1. Gıda katkı maddeleri, gıda enzimleri ve gıda aromaları için ortak yetkilendirme prosedürünün oluşturulması hakkında 1333/2008 sayılı AP ve Konsey Tüzüğü'nün II sayılı Eki'ni tadil eden 2022/1023 sayılı Komisyon Tüzüğü, AB Resmi Gazetesi'nin 28 Haziran 2022 tarihli ve L 170 sayılı nüshasında yayımlanmıştır.

2. Bazı üye ülkelerde bulaşıcı kuş gribine karşı alınan acil korunma önlemlerine dair 2021/641 sayılı Komisyon Uygulama Kararı'nı tadil eden 2022/1021 sayılı Komisyon Uygulama Kararı, AB Resmi Gazetesi'nin 28 Haziran 2022 tarihli ve L 170 sayılı nüshasında yayımlanmıştır.

3. AB gübreleme ürünlerinde yan ürünlerin kullanımına dair "agronomik verimlilik" ve güvenlik kriterlerinin belirlenmesine ilişkin 2019/1009 sayılı AP ve Konsey Tüzüğü'nü tamamlayan 2022/973 sayılı Komisyon Tüzüğü, AB Resmi Gazetesi'nin 24 Haziran 2022 tarihli ve L 167 sayılı nüshasında yayımlanmıştır.

4. "Cidre du Perche/Perche" adlı ürünün AB'de coğrafi işaretli ürün olarak tescil edilmesine dair 2022/974 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 24 Haziran 2022 tarihli ve L 167 sayılı nüshasında yayımlanmıştır.

5. Bazı hayvanlar ve hayvansal ürünlerin Birliğe girişi için onaylanmış üçüncü ülkeler listeleri hakkında 2021/404 sayılı Komisyon Uygulama Tüzüğü'nün V ve XIV sayılı Ekleri'ni tadil eden 2022/976 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 24 Haziran 2022 tarihli ve L 167 sayılı nüshasında yayımlanmıştır.

6. Şeker sektöründe ilave ithalat gümrük verilerine dair 75/2013 sayılı Komisyon Uygulama Tüzüğü'nü tadil eden 2022/980 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 24 Haziran 2022 tarihli ve L 167 sayılı nüshasında yayımlanmıştır.

7. Alkollü içeceklerin tanımlanması, tarifi, sunumu, etiketlenmesi ve coğrafi işaretlerin korunmasına ilişkin 2019/787 sayılı AP ve Konsey Tüzüğü'ne uygun olarak "Hohenloher Birnenbrand / Hohenloher Birnenwasser" adlı ürünün coğrafi işaret olarak tescil edilmesine dair 2022/888 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 7 Haziran 2022 tarihli ve L 154 sayılı nüshasında yayımlanmıştır.

8. Bolivya'da tahıl tohumu ürünleri ile yağ ve lif bitkisi tohum ürünleri üzerinde gerçekleştirilen saha denetimlerinin denkliği ve başvuru süreleri hakkında 2003/17 sayılı Konsey Kararı'nı tadil eden 2022/871 sayılı AP ve Konsey Kararı, AB Resmi Gazetesi'nin 3 Haziran 2022 tarihli ve L 152 sayılı nüshasında yayımlanmıştır.

9. İtalya'da Afrika domuz vebası ile ilgili bazı geçici acil önlemlere dair 2022/875 sayılı Komisyon Uygulama Kararı, AB Resmi Gazetesi'nin 3 Haziran 2022 tarihli ve L 152 sayılı nüshasında yayımlanmıştır.

10. Gıdalara vitamin ve minerallerin ve bazı diğer maddelerin eklenmesi hakkında 1925/2006 sayılı AP ve Konsey Tüzüğü'nün III sayılı Eki'ni tadil eden 2022/860 sayılı Komisyon Tüzüğü, AB Resmi Gazetesi'nin 2 Haziran 2022 tarihli ve L 151 sayılı nüshasında yayımlanmıştır.

11. Üye ülkelerin talepleri doğrultusunda okullarda dağıtılan meyve ve sebzeler ile süt ürünlerine dair 1 Ağustos 2022-31 Temmuz 2023 dönemi için Birlik yardımlarının tahsisine dair 2017/39 sayılı Komisyon Uygulama Tüzüğü'ne dair sağlanan istisna hakkında 2022/861

sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 2 Haziran 2022 tarihli ve L 151 sayılı nüshasında yayımlanmıştır.

12. Afrika domuz vebası için özel kontrol önlemlerinin belirlenmesi hakkında 2021/605 sayılı Komisyon Uygulama Tüzüğü'nün I sayılı Eki'ni tadil eden 2022/889, 2022/852 ve 2022/743 sayılı Komisyon Uygulama Tüzükleri, AB Resmi Gazetesi'nin L 154, L 150 ve L 137 sayılı nüshalarında yayımlanmıştır.

13. Honduras, Meksika, Sri Lanka ve Tayland menşeli "Momordica charantia L." meyveleri ile ilgili olarak 2018/2019 ve 2019/2072 sayılı Komisyon Uygulama Tüzükleri'ni tadil eden 2022/853 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 1 Haziran 2022 tarihli ve L 150 sayılı nüshasında yayımlanmıştır.

14. Almanya'daki Afrika domuz vebası ile ilgili belirli geçici acil önlemlere dair 2022/857 sayılı Komisyon Uygulama Kararı, AB Resmi Gazetesi'nin 1 Haziran 2022 tarihli ve L 150 sayılı nüshasında yayımlanmıştır.

15. 2001/82 sayılı Direktif veya 726/2004 sayılı Tüzük uyarınca ruhsatlandırılmış veya kayıtlı veteriner tıbbi ürünlerin ambalajlanması ve etiketlenmesi için geçiş kurallarını belirleyen 2022/839 sayılı AP ve Konsey Tüzüğü, AB Resmi Gazetesi'nin 31 Mayıs 2022 tarihli ve L 148 sayılı nüshasında yayımlanmıştır.

16. Tarım ürünleri piyasasına dair ortak kuralların oluşturulması hakkında 1308/2013 sayılı AP ve Konsey Tüzüğü'ne uygun olarak bazı ürünlerin korunmasına ilişkin 2022/841 ve 2022/842 sayılı Komisyon Uygulama Tüzükleri, AB Resmi Gazetesi'nin 31 Mayıs 2022 tarihli ve L 148 sayılı nüshasında yayımlanmıştır.

17. "Colli Berici" adlı coğrafi işaretli ürünlerde yapılan değişikliklere dair 2022/843 sayılı Komisyon Uygulama Tüzükleri, AB Resmi Gazetesi'nin 31 Mayıs 2022 tarihli ve L 148 sayılı nüshasında yayımlanmıştır.

18. Bazı hayvanlar ve hayvansal ürünlerin Birliğe girişi için onaylanmış üçüncü ülkeler listeleri hakkında 2021/404 sayılı Komisyon Uygulama Tüzüğü'nün V ve XIV sayılı Ekleri'ni tadil eden 2022/845, 2022/792 ve 2022/742 sayılı Komisyon Uygulama Tüzükleri, AB Resmi Gazetesi'nin L 148, L 141 ve L 137 sayılı nüshalarında yayımlanmıştır.

19. Atlantik Orkinoslarının Korunmasına İlişkin Uluslararası Sözleşme ve Kuzeybatı Atlantik Balıkçılığında Gelecekteki Çok Taraflı İşbirliği Sözleşmesi hakkında 1380/2013 sayılı AP ve Konsey Tüzüğü'ne uygun olarak Birliğin uluslararası yükümlülüklerinin uygulanmasına ilişkin 2015/98 sayılı Tüzüğü tadil eden 2022/824 sayılı Komisyon Tüzüğü, AB Resmi Gazetesi'nin 30 Mayıs 2022 tarihli ve L 147 sayılı nüshasında yayımlanmıştır.

20. Balıkçılık kaynaklarının korunması ve deniz ekosistemlerinin teknik önlemler yoluyla korunmasına dair 2019/1241 sayılı AP ve Konsey Tüzüğü'nü tadil eden 2022/826 sayılı Komisyon Tüzüğü, AB Resmi Gazetesi'nin 30 Mayıs 2022 tarihli ve L 147 sayılı nüshasında yayımlanmıştır.

21. "Dell'Emilia/Emilia" ve "Agneau du Périgord" adlı coğrafi işaretli ürünlerde yapılan değişikliklere dair 2022/812 ve 2022/761 sayılı Komisyon Uygulama Tüzükleri, AB Resmi Gazetesi'nin L 146 ve L 139 sayılı nüshalarında yayımlanmıştır.

22. Bitki koruma ürünlerinin onaylanmış aktif madde listesine dair 540/2011 sayılı Komisyon Uygulama Tüzüğü'nü tadil eden 2022/814 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 25 Mayıs 2022 tarihli ve L 146 sayılı nüshasında yayımlanmıştır.

23. Bazı üye ülkelerde bulaşıcı kuş gribine karşı alınan acil korunma önlemlerine dair 2021/641 sayılı Komisyon Uygulama Kararı'nı tadil eden 2022/817 sayılı Komisyon Uygulama Kararı, AB Resmi Gazetesi'nin 25 Mayıs 2022 tarihli ve L 146 sayılı nüshasında yayımlanmıştır.

24. 2021 mali yılı için Avrupa Tarımsal Garanti Fonu (EAGF) hakkında 2022/818, 2022/819, 2022/820 ve 2022/821 sayılı Komisyon Uygulama Kararları, AB Resmi Gazetesi'nin 25 Mayıs 2022 tarihli ve L 146 sayılı nüshasında yayımlanmıştır.

25. Onaylanmış aktif maddelerin listesine dair 540/2011 sayılı Komisyon Uygulama Tüzüğü'nü tadil eden 2022/808, 2022/800, 2022/801 ve 2022/782 sayılı Komisyon Uygulama Tüzükleri, AB Resmi Gazetesi'nin L 145, L 143 ve L 140 sayılı nüshalarında yayımlanmıştır.

26. Yemlerde inorganik arsenik varlığının izlenmesine ilişkin Komisyon Tavsiyesi, AB Resmi Gazetesi'nin 23 Mayıs 2022 tarihli ve C 206 sayılı nüshasında yayımlanmıştır.

27. "Cancoillotte" adlı ürünün AB'de coğrafi işaretli ürün olarak tescil edilmesine dair 2022/787 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 20 Mayıs 2022 tarihli ve L 141 sayılı nüshasında yayımlanmıştır.

28. Hububat, yağlı tohum ve pirinç stok seviyelerinin bildirilmesine dair 2017/1185 sayılı Komisyon Uygulama Tüzüğü'nü tadil eden 2022/791 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 20 Mayıs 2022 tarihli ve L 141 sayılı nüshasında yayımlanmıştır.

29. Genetiği değiştirilmiş gıda ve yemlere dair 1829/2003 sayılı AP ve Konsey Tüzüğü'ne uygun olarak bazı ürünlerin piyasaya sunulmasına dair 2022/797 ve 2022/798 sayılı Komisyon Uygulama Kararları, AB Resmi Gazetesi'nin 20 Mayıs 2022 tarihli ve L 141 sayılı nüshasında yayımlanmıştır.

30. Bazı organik ürünlerin ithalatı ve ihracatında resmi kontrollere dair 2021/2306 sayılı Komisyon Tüzüğü'nde yapılan düzeltme, AB Resmi Gazetesi'nin 19 Mayıs 2022 tarihli ve L 140 sayılı nüshasında yayımlanmıştır.

31. Bitki koruma ürünlerinin piyasaya arzı hakkında 1107/2009 sayılı AP ve Konsey Tüzüğü'ne uygun olarak belirli maddelerin onayına dair 2022/751 ve 2022/740 sayılı Komisyon Uygulama Tüzükleri, AB Resmi Gazetesi'nin L 138 ve L 137 sayılı nüshalarında yayımlanmıştır.

32. Azami pestisit kalıntı seviyelerine uyumu sağlamak için 2023, 2024 ve 2025 yılları için Birliğin koordineli çok yıllı kontrol programına dair 2021/601 sayılı Komisyon Uygulama Tüzüğü'nü yürürlükten kaldıran 2022/741 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 16 Mayıs 2022 tarihli ve L 137 sayılı nüshasında yayımlanmıştır.

33. Bazı üye ülkelerde yüksek derecede kuş gribi salgınlarıyla ilgili acil durum önlemlerine dair 2021/641 sayılı Komisyon Uygulama Kararı'nı tadil eden 2022/745 sayılı Komisyon Uygulama Kararı, AB Resmi Gazetesi'nin 16 Mayıs 2022 tarihli ve L 137 sayılı nüshasında yayımlanmıştır.

34. İtalya’da Afrika domuz gribi ile ilgili bazı acil koruma önlemlerine dair 2022/746 sayılı Komisyon Uygulama Kararı, AB Resmi Gazetesi'nin 16 Mayıs 2022 tarihli ve L 137 sayılı nüshasında yayımlanmıştır.

35. “Giresun Tombul Fındığı”nın AB’de coğrafi işaret (tescilli menşe adı - PDO) olarak tescil edilmesine ilişkin 2022/939 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi’nin 20 Haziran 2022 tarihli ve L 164 sayılı nüshasında yayımlanmıştır.

36. Bazı yeni gıdaların piyasaya sunulmasına dair 2017/2470 sayılı Komisyon Uygulama Tüzüğü’nü tadil eden 2022/965 ve 2022/966 sayılı Komisyon Uygulama Tüzükleri, AB Resmi Gazetesi’nin 22 Haziran 2022 tarihli ve L 166 sayılı nüshasında yayımlanmıştır.

37. Kuzey Denizi’nde deniz çevresinin korunması için balıkçılık koruma önlemlerinin oluşturulmasına dair 2017/118 sayılı Komisyon Tüzüğü’nü tadil eden 2022/952 sayılı Komisyon Tüzüğü, AB Resmi Gazetesi'nin 21 Haziran 2022 tarihli ve L 165 sayılı nüshasında yayımlanmıştır.

38. “Epanomi”, “Taleggio”, “Monte Etna”, “Radicchio di Verona”, “Arroz del Delta del Ebro/Arros del Delta de l’Ebre” ve “Jumilla” adlı coğrafi işaretli ürünlerde yapılan değişikliklere dair 2022/953, 2022/955, 2022/956, 2022/957, 2022/942 ve 2022/916 sayılı Komisyon Uygulama Tüzükleri, AB Resmi Gazetesi’nin L 165, L 164 ve L 159 sayılı nüshalarında yayımlanmıştır.

39. “Akta Granna Polkagrisar”, “Maranho da Serta”, “Spreewalder Gurkensülze” ve “Lenticchia di Onano” adlı ürünlerin AB’de coğrafi işaretli ürün olarak tescil edilmesine dair 2022/958, 2022/940, 2022/924 ve 2022/897 sayılı Komisyon Uygulama Tüzükleri, AB Resmi Gazetesi’nin L 165, L 164, L 160 ve L 156 sayılı nüshalarında yayımlanmıştır.

40. Bitki zararlılarına karşı koruyucu önlemler hakkında “Capsicum (L.)”, “Citrus L.”, “Citrus sinensis Pers.”, “Prunus persica (L.) Batsch” ve “Punica granatum L” meyvelerinin Birliğe girişi için gerekliliklere dair 2019/2072 sayılı Komisyon Uygulama Tüzüğü’nün VII sayılı Eki’ni tadil eden 2022/959 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 21 Haziran 2022 tarihli ve L 165 sayılı nüshasında yayımlanmıştır.

41. “Tetrahydrocurcuminoids” maddelerinin yeni bir gıda olarak piyasaya sunulmasına izin verilmesine ilişkin 2017/2470 sayılı Komisyon Uygulama Tüzüğü’nü tadil eden 2022/961 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 21 Haziran 2022 tarihli ve L 165 sayılı nüshasında yayımlanmıştır.

42. Bazı üye ülkelerde bulaşıcı kuş gribine karşı alınan acil korunma önlemlerine dair 2021/641 sayılı Komisyon Uygulama Kararı’nı tadil eden 2022/963 ve 2022/898 sayılı Komisyon Uygulama Kararları, AB Resmi Gazetesi’nin L 165 ve L 156 sayılı nüshalarında yayımlanmıştır.

42. “Sopa da Pedra de Almeirim” adlı ürünün AB’de geleneksel özellikli ürün olarak tescil edilmesine dair 2022/941 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 20 Haziran 2022 tarihli ve L 164 sayılı nüshasında yayımlanmıştır.

43. Afrika domuz vebası için özel kontrol önlemlerinin belirlenmesi hakkında 2021/605 sayılı

Komisyon Uygulama Tüzüğü'nün I sayılı Eki'ni tadil eden 2022/946 ve 2022/917 sayılı Komisyon Uygulama Tüzükleri, AB Resmi Gazetesi'nin L 164 ve L 159 sayılı nüshalarında yayımlanmıştır.

44. Gıdalardaki kirleticilere ilişkin resmi kontrollerin uygulanmasına ilişkin kurallar hakkında 2017/625 sayılı AP ve Konsey Tüzüğü'nü tamamlayan 2022/931 sayılı Komisyon Tüzüğü, AB Resmi Gazetesi'nin 17 Haziran 2022 tarihli ve L 162 sayılı nüshasında yayımlanmıştır.

45. Gıdalarda bulaşanlara ilişkin resmi kontrollerin gerçekleştirilmesi için tek tip pratik düzenlemeler, çok yıllı ulusal kontrol planlarının özel ek içerikleri ve bunların hazırlanması için özel düzenlemeler hakkında 2022/932 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 17 Haziran 2022 tarihli ve L 162 sayılı nüshasında yayımlanmıştır.

46. AB'de yabani kuşlarda H5N1 alt tipinin yüksek derecede patojenik kuş gribi ile ilgili belirli koruma önlemlerine dair 2006/563 sayılı Komisyon Kararı'nı yürürlükten kaldıran 2022/937 sayılı Komisyon Uygulama Kararı, AB Resmi Gazetesi'nin 17 Haziran 2022 tarihli ve L 162 sayılı nüshasında yayımlanmıştır.

47. Belirli türlerin organik heterojen materyalinden bitki üreme materyalinin üretimi ve pazarlanması hakkında 2021/1189 sayılı Komisyon Tüzüğü'nün bazı dil versiyonlarını düzelten 2022/923 sayılı Komisyon Tüzüğü, AB Resmi Gazetesi'nin 15 Haziran 2022 tarihli ve L 160 sayılı nüshasında yayımlanmıştır.

48. Suda yaşayan hayvanların listelenen hastalıkları ve bu listelenen hastalıkların yayılması için önemli bir risk oluşturan türler ve tür gruplarının listesi hakkında 2018/1882 sayılı Komisyon Uygulama Tüzüğü'nün Eki'ni tadil eden 2022/925 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 15 Haziran 2022 tarihli ve L 160 sayılı nüshasında yayımlanmıştır.

49. İtalya ve Almanya'da Afrika domuz gribiyle ilgili bazı acil durum önlemlerine dair 2022/920 ve 2022/921 sayılı Komisyon Uygulama Kararları, AB Resmi Gazetesi'nin 14 Haziran 2022 tarihli ve L 159 sayılı nüshasında yayımlanmıştır.

50. Bazı hayvanlar ve hayvansal ürünlerin Birliğe girişi için onaylanmış üçüncü ülkeler listeleri hakkında 2021/404 sayılı Komisyon Uygulama Tüzüğü'nün V ve XIV sayılı Ekleri'ni tadil eden 2022/914 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 13 Haziran 2022 tarihli ve L 158 sayılı nüshasında yayımlanmıştır.

51. Tarımsal bitki türlerinin ve sebze türlerinin belirli çeşitlerinin incelenmesine ilişkin protokollere dair 2003/91 ve 2003/90 sayılı Direktifleri tadil eden 2022/905 sayılı Komisyon Uygulama Direktifi, AB Resmi Gazetesi'nin 10 Haziran 2022 tarihli ve L 157 sayılı nüshasında yayımlanmıştır.

52. Avrupa Tarımsal Garanti Fonu (EAGF) ve Avrupa Kırsal Kalkınma Tarım Fonu (EAFRD) kapsamında yapılan belirli harcamaların finanse edilmesine dair 2022/908 ve 2022/909 sayılı Komisyon Uygulama Kararları, AB Resmi Gazetesi'nin 10 Haziran 2022 tarihli ve L 157 sayılı nüshasında yayımlanmıştır. 20. Organik ürünlerin ithalatında üçüncü ülkeler listeleri ve kontrol otoriteleri ile kontrol organları listelerine dair 2021/2325 sayılı Komisyon Uygulama Tüzüğü'nde yapılan düzeltme, AB Resmi Gazetesi'nin 9 Haziran 2022 tarihli ve L 156 sayılı nüshasında yayımlanmıştır.

53. OTP Stratejik Planlarının içeriğinin sunumu ve güvenli bilgi alışverişi için elektronik sisteme dair 2021/2115 sayılı AP ve Konsey Tüzüğü'ne uygun olarak kuralları belirleyen 2021/2289 sayılı Komisyon Uygulama Tüzüğü'nde yapılan düzeltme, AB Resmi Gazetesi'nin 9 Haziran 2022 tarihli ve L 156 sayılı nüshasında yayımlanmıştır.

54. Korunan menşe adları, coğrafi işaretler ve garanti edilen geleneksel özellikler ve belirli kaynak bulma kuralları, usul kuralları ve ilave geçiş kuralları ile ilgili olarak Birlik sembollerinin oluşturulması hakkında 664/2014 sayılı Komisyon Tüzüğü'nü tadil eden 2022/891 sayılı Komisyon Tüzüğü, AB Resmi Gazetesi'nin 8 Haziran 2022 tarihli ve L 155 sayılı nüshasında yayımlanmıştır.

55. Tarım ürünleri ve gıda maddeleri için kalite planları hakkında 1151/2012 AP ve Konsey Tüzüğü'ne uygun kuralları belirleyen 668/2014 sayılı Komisyon Uygulama Tüzüğü'nü tadil eden 2022/892 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 8 Haziran 2022 tarihli ve L 155 sayılı nüshasında yayımlanmıştır.

56. İç pazarla uyumlu balıkçılık ve su ürünlerinin üretimi, işlenmesi ve pazarlanmasında faaliyet gösteren işletmelere belirli yardım kategorilerini belirleyen Komisyon Tüzüğü taslağının onaylanmasına dair Komisyon Bildirimi, AB Resmi Gazetesi'nin 6 Mayıs 2022 tarihli ve C 185 sayılı nüshasındayayımlanmıştır.

57. Üçüncü ülkelerden yapılan şerbetçiotu ithalatına dair 1295/2008 sayılı Komisyon Tüzüğü'nü tadil eden 2022/700 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 5 Mayıs 2022 tarihli ve L131 sayılı nüshasında yayımlanmıştır.

58. Romanya'da at enfeksiyöz anemisine karşı koruyucu önlemlere ilişkin 2010/346 sayılı Komisyon Kararı'nı tadil eden 2022/701 sayılı Komisyon Uygulama Kararı, AB Resmi Gazetesi'nin 5 Mayıs 2022 tarihli ve L 131 sayılı nüshasında yayımlanmıştır.

59. Suların tarımsal kaynaklardan gelen nitratlara karşı korunmasına ilişkin 91/676 sayılı Konsey Tüzüğü'ne uygun olarak İrlanda tarafından talep edilen derogasyon hakkında 2022/696 sayılı Komisyon Uygulama Kararı, AB Resmi Gazetesi'nin 3 Mayıs 2022 tarihli ve L 129 sayılı nüshasında yayımlanmıştır.

60. 2022 yılına dair Birlik ve Birlik dışı bazı sularda AB balıkçı gemileri için geçerli olan belirli balık stokları ve balık stoku grupları için balıkçılık fırsatlarının belirlenmesine dair 2022/109 sayılı Konsey Tüzüğü'nü tadil eden 2022/681 sayılı Konsey Tüzüğü, AB Resmi Gazetesi'nin 29 Nisan 2022 tarihli ve L 126 sayılı nüshasında yayımlanmıştır.

61. Gıda maddelerinde elementlerin ve işleme kirleticilerinin seviyelerinin kontrolüne dair 333/2007 sayılı Komisyon Tüzüğü'nü tadil eden 2022/685 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 29 Nisan 2022 tarihli ve L 126 sayılı nüshasında yayımlanmıştır.

62. Bitki koruma ürünlerinin piyasaya sunulmasıyla ilgili olarak aktif maddelerin onay şartlarına dair 2015/1295 ve 540/2011 sayılı Komisyon Uygulama Tüzükleri'ni tadil eden 2022/686 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 29 Nisan 2022 tarihli ve L 126 sayılı nüshasında yayımlanmıştır.

63. Bazı tarım ürünlerinin AB'ye girişinde Birleşik Krallık için bitki sağlığı sertifikasının gerekli olmadığına dair 2020/178 sayılı Komisyon Uygulama Tüzüğü'nü tadil eden 2022/680

sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 28 Nisan 2022 tarihli ve L 125 sayılı nüshasında yayımlanmıştır.

64. Bazı hayvanlar, hayvansal kökenli ürünler ve germinal ürünler üzerinde yetkili otoriteler tarafından gerçekleştirilen resmi kontrollere ilişkin özel kurallara dair 2017/625 sayılı AP ve Konsey Tüzüğü'nü tamamlayan 2022/671 sayılı Komisyon Tüzüğü, AB Resmi Gazetesi'nin 25 Nisan 2022 tarihli ve L 122 sayılı nüshasında yayımlanmıştır.

65. Yeni gıdalara dair 2017/2470 sayılı Komisyon Uygulama Tüzüğü'nü tadil eden 2022/684, 2022/672 ve 2022/673 sayılı Komisyon Uygulama Tüzükleri, AB Resmi Gazetesi'nin L 126 ve L 122 sayılı nüshalarında yayımlanmıştır.

66. Gıda katkı maddelerinin özellikleri hakkında 231/2012 sayılı Komisyon Tüzüğü'nü tadil eden 2022/650 sayılı Komisyon Tüzüğü, AB Resmi Gazetesi'nin 21 Nisan 2022 tarihli ve L 119 sayılı nüshasında yayımlanmıştır.

67. "Phyllosticta citricarpa" zararlısının Birlik topraklarına girmesini ve yayılmasını önlemek için Arjantin, Brezilya, Güney Afrika, Uruguay ve Zimbabve menşeli belirli meyvelerle ilgili geçici önlemlere dair 2022/632 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 19 Nisan 2022 tarihli ve L 117 sayılı nüshasında yayımlanmıştır.

68. Hayvansal kaynaklı gıda maddelerinde maksimum kalıntı limitine göre bazı maddelerin sınıflandırılması hakkında 37/2010 sayılı Komisyon Tüzüğü'nü tadil eden 2022/634 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 19 Nisan 2022 tarihli ve L 117 sayılı nüshasında yayımlanmıştır.

69. Balık ve tuzdaki maksimum cıva seviyeleri hakkında 1881/2006 sayılı Komisyon Tüzüğü'nü tadil eden 2022/617 sayılı Komisyon Tüzüğü, AB Resmi Gazetesi'nin 13 Nisan 2022 tarihli ve L 115 sayılı nüshasında yayımlanmıştır.

70. Afrika domuz vebası için özel kontrol önlemlerinin belirlenmesi hakkında 2021/605 sayılı Komisyon Uygulama Tüzüğü'nün I sayılı Eki'ni tadil eden 2022/705, 2022/491 ve 2022/587 sayılı Komisyon Uygulama Tüzükleri, AB Resmi Gazetesi'nin L 132, L 112 ve L 100 sayılı nüshalarında yayımlanmıştır.

71. Bazı hayvanlar ve hayvansal ürünlerin Birliğe girişi için onaylanmış üçüncü ülkeler listeleri hakkında 2021/404 sayılı Komisyon Uygulama Tüzüğü'nün V ve XIV sayılı Eki'ni tadil eden 2022/704, 2022/678, 2022/649, 2022/588 ve 2022/528 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin L 132, L 124, L 119, L 112 ve L 105 sayılı nüshalarında yayımlanmıştır.

72. Hayvan beslemede kullanılan yem katkı maddelerine ilişkin 1831/2003 sayılı AP ve Konsey Tüzüğü bağlamında bazı yem katkı maddelerinin onayı hakkında 2022/702, 2022/703, 2022/593, 2022/633, 2022/652, 2022/653, 2022/654, 2022/565 ve 2022/538 sayılı Komisyon Uygulama Tüzükleri, AB Resmi Gazetesi'nin L 132, L 114, L 119, L 117, L 109 ve L 106 sayılı nüshalarında yayımlanmıştır.

73. Bazı gıda ve bitki ürünlerinin içerisinde veya üzerinde kabul edilen azami kalıntı seviyelerinin belirlenmesine dair 396/2005 sayılı AP ve Konsey Tüzüğü'nü tadil eden 2022/566 sayılı Komisyon Tüzüğü, AB Resmi Gazetesi'nin 8 Nisan 2022 tarihli ve L 109 sayılı nüshasında yayımlanmıştır.

74. Bulaşıcı hayvan hastalıkları ve hayvan sağlığı kurallarına dair üçüncü ülkelerden gelen saman sevkiyatları yoluyla şap hastalığının Avrupa Birliği'ne girmesini önlemek için acil önlemlere dair 2022/575 sayılı Komisyon Uygulama Kararı, AB Resmi Gazetesi'nin 8 Nisan 2022 tarihli ve L 109 sayılı nüshasında yayımlanmıştır.

75. AB-Birleşik Krallık Geri Çekilme Anlaşması kapsamında balıkçılık sertifikalarına dair yetkili otoriteler listesi, AB Resmi Gazetesi'nin 8 Nisan 2022 tarihli ve C 154 sayılı nüshasında yayımlanmıştır.

76. Genetiği değiştirilmiş gıda ve yemlere dair 1829/2003 sayılı AP ve Konsey Tüzüğü'ne uygun olarak onayların yenilenmesi hakkında 2022/560, 2022/529, 2022/530 ve 2022/531 sayılı Komisyon Uygulama Kararları, AB Resmi Gazetesi'nin L 108 ve L 105 sayılı nüshalarında yayımlanmıştır.

77. Patates ve türev ürünlerde glikoalkaloidlerin varlığının izlenmesine dair 2022/561 sayılı Komisyon Tavsiyesi, AB Resmi Gazetesi'nin 7 Nisan 2022 tarihli ve L 108 sayılı nüshasında yayımlanmıştır.

78. Akdeniz ve Karadeniz'de geçerli olan belirli balık stokları ve balık stoku grupları için 2022 yılına dair balıkçılık fırsatlarının belirlenmesi hakkında 202/110 sayılı Konsey Tüzüğü'nde yapılan düzeltme, AB Resmi Gazetesi'nin 7 Nisan 2022 tarihli ve L 108 sayılı nüshasında yayımlanmıştır.

79. Gıdalarda "Alternaria" toksinlerinin varlığının izlenmesine dair 2022/553 sayılı Komisyon Tavsiyesi, AB Resmi Gazetesi'nin 6 Nisan 2022 tarihli ve L 107 sayılı nüshasında yayımlanmıştır.

80. "Carne de Avila", "Carne Mertolenga", "Nocciola Romana" ve "Rashera" adlı coğrafi işaretli ürünlerde yapılan değişikliklere dair 2022/536 ve 2022/487 sayılı Komisyon Uygulama Tüzükleri, AB Resmi Gazetesi'nin L 106 ve L 100 sayılı nüshalarında yayımlanmıştır.

81. Limon özü preparatının tüm hayvan türleri için yem katkı maddesi olarak yetkilendirilmesine dair 2022/537 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 5 Nisan 2022 tarihli ve L 106 sayılı nüshasında yayımlanmıştır.

82. AB'de coğrafi işaretli ürünlerin korunmasına dair 2019/787 sayılı AP ve Konsey Tüzüğü kapsamında uluslararası coğrafi işaretli ürünlerin listesinin oluşturulması ve anılan listeye İtalya'dan "Bolgheri", Fransa'dan "Val de Loire" ve "Pays d'Oc", Yunanistan'dan "Santorini" ve "Tsipouro of Tyrnavos" ve Bulgaristan'dan "Muscatova rakya/Muscatova rakya" ve "Yambolska grozdova rakya/Grozdova rakya ot Yambol" isimli ürünlerin eklenmesine dair 2022/540 ve 2022/541 sayılı Komisyon Uygulama Kararları, AB Resmi Gazetesi'nin 5 Nisan 2022 tarihli ve L 106 sayılı nüshasında yayımlanmıştır.

83. Birlik ve Birlik dışı sularda 2022 yılında AB balıkçı gemileri için belirli balık stokları ve balık stoku grupları için balıkçılık fırsatlarının belirlenmesine dair 2022/109 sayılı Konsey Tüzüğü'nü tadil eden 2022/515 sayılı Konsey Tüzüğü, AB Resmi Gazetesi'nin 1 Nisan 2022 tarihli ve L 104 sayılı nüshasında yayımlanmıştır.

84. Su ürünleri yetiştiriciliğinde yabancı ve yerel olarak bulunmayan türlerin kullanımı hakkında 708/2007 sayılı Konsey Tüzüğü'nün IV sayılı Eki'ni tadil eden 2022/516 sayılı

Komisyon Tüzüğü, AB Resmi Gazetesi'nin 1 Nisan 2022 tarihli ve L 104 sayılı nüshasında yayımlanmıştır.

85. Protein hidrolizatlarından üretilen bebek ve devam formülleri için protein gereksinimlerine dair 2016/127 sayılı Komisyon Tüzüğü'nü tadil eden 2022/519 sayılı Komisyon Tüzüğü, AB Resmi Gazetesi'nin 1 Nisan 2022 tarihli ve L 104 sayılı nüshasında yayımlanmıştır.

86. Bazı üye ülkelerde bulaşıcı kuş gribine karşı alınan acil korunma önlemlerine dair 2021/641 sayılı Komisyon Uygulama Kararı'nı tadil eden 2022/690, 2022/623 ve 2022/522 sayılı Komisyon Uygulama Kararı, AB Resmi Gazetesi'nin L 128, L 115 ve L 104 sayılı nüshalarında yayımlanmıştır.

87. "Vincisgrassi alla maceratese" adlı ürünün AB'de geleneksel işaretli ürün olarak tescil edilmesine dair 2022/509 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 31 Mart 2022 tarihli ve L 103 sayılı nüshasında yayımlanmıştır.

88. Bitki koruma ürünlerinin onaylanmış aktif madde listesine dair 540/2011 sayılı Komisyon Uygulama Tüzüğü'nü tadil eden 2022/698, 2022/501, 2022/496 ve 2022/489 sayılı Komisyon Uygulama Tüzükleri, AB Resmi Gazetesi'nin L 130, L 102, L 101 ve L 100 sayılı nüshalarında yayımlanmıştır.

89. Gıdalarda kullanılan duman aroma verici birincil ürünlerin Birlik listesine dair 1321/2013 sayılı Komisyon Uygulama Tüzüğü'nü tadil eden 2022/502 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 30 Mart 2022 tarihli ve L 102 sayılı nüshasında yayımlanmıştır.

90. Kara hayvanlarının Birliğe girişi ve AB içinde hareketleri için belirli model hayvan sağlığı sertifikalarına dair 2021/403 sayılı Komisyon Uygulama Tüzüğü'nü tadil eden 2022/497 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 29 Mart 2022 tarihli ve L 101 sayılı nüshasında yayımlanmıştır.

91. Türkiye menşeli "Juglans regia L.", "Nerium oleander L." ve "Robinia pseudoacacia L." İsimli bitkilerin Birliğe getirilmesine yönelik bitki sağlığı önlemlerine dair 2018/2019 sayılı Komisyon Uygulama Tüzüğü'nü tadil eden 2022/490 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 28 Mart 2022 tarihli ve L 100 sayılı nüshasında yayımlanmıştır.

92. Gıdalarda furan ve alkilfuranların varlığının izlenmesi hakkında 2022/495 sayılı Komisyon Tavsiyesi, AB Resmi Gazetesi'nin 28 Mart 2022 tarihli ve L 100 sayılı nüshasında yayımlanmıştır.

93. AB gübreleme ürünlerinde bileşen malzeme kategorisi olarak geri kazanılmış yüksek saflıkta malzemelere dair 2019/1009 sayılı AP ve Konsey Tüzüğü'nün II, III ve IV sayılı Ekleri'ni tadil eden 2022/1171 sayılı Komisyon Tüzüğü, AB Resmi Gazetesi'nin 8 Temmuz 2022 tarihli ve L 183 sayılı nüshasında yayımlanmıştır.

94. Ortak tarım politikasının finansmanı, yönetimi ve izlenmesi hakkında ortak tarım politikasının entegre yönetimi ve kontrol sistemine dair 2021/2116 sayılı AP ve Konsey Tüzüğü'nü tamamlayan 2022/1172 ve 2022/1173 sayılı Komisyon Tüzükleri, AB Resmi Gazetesi'nin 8 Temmuz 2022 tarihli ve L 183 sayılı nüshasında yayımlanmıştır.

95. Üye ülkelerin Ortak Tarım Politikası (OTP), Avrupa Tarımsal Garanti Fonu (EAGF) ve Avrupa Kırsal Kalkınma Tarım Fonu (EAFRD) stratejik planlarının desteklenmesine dair kuralları belirleyen 2021/2115 sayılı AP ve Konsey Tüzüğü'nde yapılan düzeltme, AB Resmi Gazetesi'nin 7 Temmuz 2022 tarihli ve L 181 sayılı nüshasında yayımlanmıştır.

96. Yeni gıdaların Birlik listesine dair 2017/2470 sayılı Komisyon Uygulama Tüzüğü'nü tadil eden 2022/1160 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 6 Temmuz 2022 tarihli ve L 179 sayılı nüshasında yayımlanmıştır.

97. Ortak tarım politikası çerçevesinde destek programları kapsamında çiftçilere doğrudan ödemeler için kurallar oluşturulmasına dair 1307/2013 sayılı AP ve Konsey Tüzüğü kapsamında 2022 yılı için belirli doğrudan destek programlarına uygulanabilecek bütçe tavanlarının belirlenmesine ilişkin 2022/1161 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 6 Temmuz 2022 tarihli ve L 179 sayılı nüshasında yayımlanmıştır.

98. Gıda amaçlı yetiştirilen hayvanlar ile insan tüketimine yönelik belirli ürün sevkiyatlarının Birliğe girişine ilişkin gereklilikler hakkında 2017/625 sayılı AP ve Konsey Tüzüğü'nü tamamlayan Komisyon Tüzüğü taslağı ekte sunulmaktadır.

99. "Queso de Acehuche" adlı ürünün AB'de coğrafi işaretli ürün olarak tescil edilmesine dair 2022/1106 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 5 Temmuz 2022 tarihli ve L 178 sayılı nüshasında yayımlanmıştır.

100. Yem malzemeleri kataloğuna dair 68/2013 sayılı Komisyon Tüzüğü'nü tadil eden 2022/1104 sayılı Komisyon Tüzüğü, AB Resmi Gazetesi'nin 4 Temmuz 2022 tarihli ve L 177 sayılı nüshasında yayımlanmıştır.

101. 2022 yılı için AB ve AB dışı bazı sularda Birlik balıkçı gemileri için geçerli olan belirli balık stokları ve balık stoku grupları için balıkçılık fırsatlarının belirlenmesine dair 2022/109 sayılı Konsey Tüzüğü'nü tadil eden 2022/1091 sayılı Konsey Tüzüğü, AB Resmi Gazetesi'nin 1 Temmuz 2022 tarihli ve L 176 sayılı nüshasında yayımlanmıştır.

102. Genetiği değiştirilmiş gıda ve yemlerin piyasaya sunulmasına dair 2022/1094 sayılı Komisyon Uygulama Kararı, AB Resmi Gazetesi'nin 1 Temmuz 2022 tarihli ve L 176 sayılı nüshasında yayımlanmıştır.

103. Hayvan sağlığı alanında bazı AB mevzuatının geçerliliğinin yitirilmesinin resmi olarak tanınması hakkında Komisyon Bildirimi, AB Resmi Gazetesi'nin 1 Temmuz 2022 tarihli ve C 252 sayılı nüshasında yayımlanmıştır.

104. Gıda katkı maddeleri, gıda enzimleri ve gıda aromaları için ortak yetkilendirme prosedürünün oluşturulması hakkında 1333/2008 sayılı AP ve Konsey Tüzüğü'nün II sayılı Eki'ni tadil eden 2022/1037 ve 2022/1038 sayılı Komisyon Tüzükleri, AB Resmi Gazetesi'nin 30 Haziran 2022 tarihli ve L 173 sayılı nüshasında yayımlanmıştır.

105. Bazı hayvanlar ve hayvansal ürünlerin Birliğe girişi için onaylanmış üçüncü ülkeler listeleri hakkında 2021/404 sayılı Komisyon Uygulama Tüzüğü'nün V ve XIV sayılı Ekleri'ni tadil eden 2022/1040 sayılı Komisyon Uygulama Tüzüğü, AB Resmi Gazetesi'nin 30 Haziran 2022 tarihli ve L 173 sayılı nüshasında yayımlanmıştır.

Ek:
1- PART-2022-218927V3
2- PART-2022-218925V3

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COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of food-producing animals and certain goods intended for human consumption

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) 2017/625 of the European Parliament and of the Council[1] lays down rules for the performance of official controls and other control activities by the competent authorities of the Member States, in particular to ensure that consignments of animals and goods from third countries comply with the requirements for entry into the European Union.

Article 126(1) of Regulation (EU) 2017/625 empowers the Commission to lay down the conditions that animals and goods entering the Union from third countries are to respect, to ensure that they comply with the relevant requirements established by the Union legislation or with requirements recognised to be equivalent thereto.

Commission Delegated Regulation (EU) 2019/625[2] supplements the requirements for entry into the EU in accordance with Article 126(1) of Regulation (EU) 2017/625 as regards the identification of food-producing animals and certain goods subject to the inclusion of the country or region thereof or the establishment in a list and to the issuance of official certificates or presentation of a private attestation, and the specific conditions for entry in the Union for those animals and those goods.

It is necessary to further supplement Regulation (EU) 2017/625 by establishing additional conditions for the entry into the Union of animals and goods, to ensure that, upon the controls of food-producing animals and animal products from third countries intended for the entry into the Union, those food-producing animals and those animal products comply with restriction and requirements at least equivalent to, respectively, the restrictions on the use of veterinary medicinal products ('VMP') laid down in Union legislation and to the requirements on contaminants and residues of VMP and pesticides in food-producing animals and goods laid down in Union legislation by means of risk-based control plans.

The purpose of this Delegated Regulation is to lay down all supplementary requirements for the entry into the Union of animals and goods from third countries, in accordance with Article 126(1) of Regulation (EU) 2017/625, in a single Delegated Regulation, thus merging the restrictions on the use of VMP and the requirements on contaminants and residues of VMP and pesticides with the requirements provided for in Delegated Regulation (EU) 2019/625, which is to be repealed.

[1] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

[2] Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (OJ L 131, 17.5.2019, p. 18).

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Member States' experts were consulted within the Commission Expert Groups on Residues of Veterinary Medicines[3] and on Food Hygiene and Control of Food of Animal Origin[4], which met on the subject on 15 July 2022 and on 15 February 2022, respectively.

In addition, stakeholders' organisations were consulted through the Advisory Group on the Food Chain and Animal and Plant Health.

Third countries were informed by notification to the World Trade Organisation within the framework of the Agreement on the Application of Sanitary and Phytosanitary Measures.

Finally, before adopting this Delegated Regulation, the Commission conducted open and transparent public consultations in accordance with the procedures laid down in the Inter-institutional Agreement on Better Law-Making[5].

This Delegated Regulation maintains the current requirements for the entry of animals and animal products from third countries into the EU and to guarantee the third countries' commitment to ensure that those animals and animal products comply with restrictions and requirements at least equivalent to the Union restrictions on the use of VMP and to the Union requirements on contaminants and residues of VMP and pesticides in food-producing animals and goods.

As the Delegated Regulation is maintaining the current requirements, no impact assessment has been carried out.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The legal basis for the Delegated Regulation is Article 126(1) and (2) of Regulation (EU) 2017/625.

3 Reference E03595 in the Register of Commission Expert Groups and other similar entities.
4 Reference E03522 in the Register of Commission Expert Groups and other similar entities.
5 http://ec.europa.eu/smart-regulation/better_regulation/documents/iia_blm_final_en.pdf.

COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of food-producing animals and certain goods intended for human consumption

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/625 of the European Parliament and the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)[1], and in particular Article 126(1) thereof,

Whereas:

(1) Regulation (EU) 2017/625 lays down rules for the performance of official controls and other official activities by the competent authorities of the Member States, in particular to ensure compliance, by consignments of animals and goods from third countries or regions thereof intended for human consumption, upon entry into the Union, with Union legislation on food and feed safety.

(2) Regulation (EU) 2017/625 empowers the Commission to adopt delegated acts to supplement the conditions laid down in that Regulation for the entry into Union of food-producing animals and certain goods. Those conditions may include additional requirements, namely the possibility of allowing the entry of animals and goods only from third countries that appear on lists drawn up by the Commission for that purpose. These additional requirements include guarantees of compliance with:

– measures to monitor substances and groups of residues in animals and goods intended for human consumption, in accordance with Council Directive 96/23/EC[2] and the provisions provided for in Council Directive 96/22/EC[3];

[1] OJ L 95, 7.4.2017, p. 1.

[2] Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

– the rules for the prevention, control and eradication of transmissible spongiform encephalopathies in live animals and products of animal origin, in accordance with Regulation (EC) No 999/2001 of the European Parliament and of the Council[4];

– the general principles and requirements governing food in general and food safety in particular at Union and national level, in accordance with Regulation (EC) No 178/2002 of the European Parliament and of the Council[5];

– the general rules for food business operators on the hygiene of foodstuffs, in accordance with Regulation (EC) No 852/2004 of the European Parliament and of the Council[6];

– the specific rules on the hygiene of food of animal origin for food business operators, in accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council[7];

– the specific rules on official controls performed, and for actions taken, by the competent authorities on the production of certain animals and products of animal origin intended for human consumption, in accordance with Commission Delegated Regulation (EU) 2019/624[8] and Commission Implementing Regulation (EU) 2019/627[9].

(3) Commission Delegated Regulation (EU) 2019/625[10] laid down such additional requirements and applies since 14 December 2019. It does not cover the requirements already laid down in Directive 96/23/EC.

(4) At present, third countries from which animals and products of animal origin are authorised for the entry into the Union as regards the Union rules on public health are included and kept on lists drawn on the basis of various requirements, including the existence of a control plan setting out guarantees on the monitoring of certain groups

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3 Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ L125, 23.5.1996, p. 3)

4 Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

5 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

6 Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

7 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).

8 Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 131, 17.5.2019, p. 1).

9 Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51).

10 Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (OJ L 131, 17.5.2019, p. 18).

of residues and substances, in accordance with the requirements of Directive 96/23/EC.

(5) Regulation (EU) 2017/625 repealed Directive 96/23/EC with effect from 14 December 2019 and provided for the transitional application, until 14 December 2022, of certain provisions of that Directive.

(6) The introduction of additional requirements to ensure compliance with the measures for monitoring substances and groups of residues in animals and goods intended for human consumption laid down in Directive 96/23/EC should be combined with the additional requirements already laid down in Delegated Regulation (EU) 2019/625.

(7) It is thus appropriate to lay down all these additional requirements in one single Delegated Regulation, thereby simplifying their interpretation and application and enhancing transparency for third countries.

(8) Regulation (EC) No 853/2004 lays down requirements for food business operators importing products of animal origin into the Union. Accordingly, the additional requirements laid down in this Regulation for official controls should be consistent with those already laid down in Regulation (EC) No 853/2004.

(9) When laying down requirements for the entry into the Union of consignments of certain animals and good intended for human consumption, reference should be made to the Combined Nomenclature codes set out in Council Regulation (EEC) No 2658/87[11], to identify these goods and animals clearly.

(10) Consignments of certain animals and goods intended for human consumption should only be allowed to enter the Union, based on a risk analysis, where the third countries or regions thereof from which these animals and goods originate can ensure compliance with the requirements on the safety of those animals and goods and those third countries or regions thereof are included, in accordance with Article 127(2) of Regulation (EU) 2017/625, in the lists laid down in Commission Implementing Regulation (EU) 2021/405[12].

(11) In addition to the requirements laid down in Article 127(3) of Regulation (EU) 2017/625, specific requirements should be laid down for certain animals and goods intended for human consumption, to ensure that third countries or regions thereof provide guarantees on the efficiency of official controls on food safety as regards those animals and goods. Third countries or regions thereof should only appear on the lists laid down in Implementing Regulation (EU) 2021/405, after having provided evidence and guarantees that the animals and goods originating in them comply with the Union requirements on food safety laid down in Regulations (EC) No 999/2001, (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004, (EU) 2017/625, Delegated Regulation (EU) 2019/624 and Implementing Regulation (EU) 2019/627, or with requirements recognised to be equivalent thereto.

(12) Under Article 127(3) of Regulation (EU) 2017/625, the Commission may subject the decision to include third countries in lists laid down in Implementing Regulation (EU) 2021/405 to the provision, by those third countries, of appropriate evidence and

[11] Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

[12] Commission Implementing Regulation (EU) 2021/405 of 24 March 2021 laying down the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 114, 31.3.2021, p. 118).

guarantees of compliance with the Union requirements on the use of pharmacologically active substances in food-producing animals and of the compliance of consignments of products of animal origin and composite products intended to enter into the Union with the maximum residue limits of pharmacologically active substances, maximum residue levels of pesticides and maximum levels of contaminants established in Union legislation. This ensures that those food-producing animals, products of animal origin and composite products offer a same level of health protection to that provided for by the Union legislation on food and food safety.

(13) To ensure that same level of health protection, evidence and guarantees have to be provided by submitting a control plan that meets certain requirements, provided for in this Regulation and to ensure continuous compliance with those requirements, updated control plans should be submitted to the Commission on a yearly basis.

(14) However, third countries may also be included in the list laid down in Annex -I to Implementing Regulation (EU) 2021/405 if they provide appropriate evidence and guarantees that the food-producing animals and products of animal origin, including those used in composite products entering the Union, originate in a Member State or a third country included in a list of third countries with approved control plans for those food-producing animals, products of animal origin and composite products. Information on the procedures in place to ensure the traceability and to guarantee the origin of the concerned food-producing animals or products of animal origin should be provided to benefit from that derogation.

(15) Union legislation lays down rules on the use of pharmacologically active substances and establishes limits for their residues in edible products of animal origin arising from such use. Food-producing animals, products of animal origin and composite products should only enter the Union from third countries ensuring that controls on the use of pharmacologically active substances and the residues thereof in animal products are at least equivalent to those of the Union control plans included in the multi-annual national control plans referred to in Commission Delegated Regulation 2022/x[13] (C(2022)4400) and Commission Implementing Regulation 2022/xx[14] (C(2022)4401). The rules laid down in Commission Implementing Regulation (EU) 2021/808[15] should apply to the official controls on those substances and residues.

(16) The use, in food-producing animals in the Union, of beta-agonists and substances that have a hormonal or thyrostatic action is prohibited under Council Directive 96/22/EC[16]. Similarly, Commission Regulation (EU) No 37/2010[17] list in Table 2 of

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13 Commission Delegated Regulation (EU) 2022/xx of … (C(2022)4400) supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with specific requirements for the performance of official controls on the use of pharmacologically active substances authorised as veterinary medicinal products or as feed additives and on the use of prohibited or unauthorised pharmacologically active substances and residues thereof (OJ L …, … , p. …).

14 Commission Implementing Regulation (EU) 2022/xx of … (C(2022)4401) on uniform practical arrangements of multi-annual national control plans (MANCPs) and annual reports by Member States on the performance of official controls on the use of pharmacologically active substances authorised as veterinary medicinal products or as feed additives and of prohibited or unauthorised pharmacologically active substances and residues thereof (OJ L …, … , p. …).

15 Commission Implementing Regulation (EU) 2021/808 of 22 March 2021 on the performance of analytical methods for residues of pharmacologically active substances used in food-producing animals and on the interpretation of results as well as on the methods to be used for sampling and repealing Decisions 2002/657/EC and 98/179/EC (OJ L 180, 21.5.2021, p. 84).

16 Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ L 125, 23.5.1996, p. 3).

the Annex to that Regulation pharmacologically active substances, that are prohibited for use in the Union. . Guarantees that food-producing animals, products of animal origin and composite products intended for entry into the Union comply with these provisions has to be provided.

(17) Regulation (EC) No 396/2005 of the European Parliament and of the Council[18] lays down a coordinated control programme of the Union on the maximum residue levels of pesticides in or on food and feed of plant and animal origin, with a view to assessing consumer exposure and the application of legislation in the EU. This Union control programme forms an integral part of the multiannual national control programmes for pesticides residues that Member States are to establish. Food-producing animals, products of animal origin and composite products should only enter the Union from third countries, which ensure that controls on pesticide residues are carried out according to the same stringent criteria as those imposed on Member States through the multiannual national control programmes for pesticide residues set out in Commission Implementing Regulation (EU) 2021/1355[19]. It should thus be ensured that evidence is provided through statistically representative sampling that the products intended for entry into the Union comply with Union legislation on pesticide residues.

(18) Commission Delegated Regulation (EU) 2022/931[20] and Commission Implementing Regulation (EU) 2022/932[21] provide for the establishment and the content of risk-based control plans on contaminants in food. Food of animal origin and composite products should only enter the Union from third countries, which ensure that controls on contaminants are carried out to provide evidence that food of animal origin and composite products intended for the entry into the Union comply with EU legislation on contaminants.

(19) Commission Decision 2011/163/EU[22] sets out, in accordance with Directive 96/23/EC, a list of third countries authorised for the entry of certain animal species or products of animal origin into the Union.

(20) Following the repeal of Directive 96/23/EC, Commission Implementing Regulation (EU) 2022/xxxxx[23] replaced Decision 2011/163/EU in its entirety.

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17 Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

18 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).

19 Commission Implementing Regulation (EU) 2021/1355 of 12 August 2021 on multiannual national control programmes for pesticides residues to be established by Member States (OJ L 291, 13.8.2021, p. 120).

20 Commission Delegated Regulation (EU) 2022/931 of 23 March 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council by laying down rules for the performance of official controls as regards contaminants in food (OJ L162, 17.6.2022, p. 7).

21 Commission Implementing Regulation (EU) 2022/932 of 9 June 2022 on uniform practical arrangements for the performance of official controls as regards contaminants in food, on specific additional content of multi-annual national control plans and specific additional arrangements for their preparation (OJ L162, 17.6.2022, p. 13).

22 Commission Decision 2011/163/EU of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC (OJ L 70, 17.3.2011, p. 40).

23 Commission Implementing Regulation (EU) 2022/xxxxx of … [ISC/2022/02577] amending Implementing Regulation (EU) 2021/405 as regards the list of third countries with an approved control plan on the use of pharmacologically active substances, the maximum residue limits of

(21) Consignments of certain goods intended for human consumption should only be allowed to enter the Union where those goods are dispatched from, and obtained or prepared in, establishments which appear on the list drawn up and kept up to date in accordance with Article 127(3), point (e)(ii), of Regulation (EU) 2017/625. In addition, in order to ensure compliance with Union food hygiene rules, or with rules recognised to be at least equivalent thereto, it is appropriate to provide that, when drawing up and updating that list, the third country should provide additional guarantees to those provided for in Article 127(3), points (e)(i) and (iv), of Regulation (EU) 2017/625.

(22) The lists of establishments referred to in Article 127(3), point (e)(i), of Regulation (EU) 2017/625 should be made available to the public to ensure transparency for food business operators and consumers. To strengthen such transparency, Member States should only allow the entry of consignments of animals and goods where the official certificates required for such consignments under the relevant Union rules are issued by the competent authorities of the third country after the publication of those lists.

(23) It is not necessary to lay down such listing requirements as regards goods intended for transit, since those goods represent a low risk from a food safety perspective and are not placed on the market within the Union. Moreover, such requirements should not apply to establishments carrying out only primary production activities, transport operations, storage of products of animal origin not requiring temperature-controlled storage conditions or production of highly refined products referred to in Section XVI of Annex III to Regulation (EC) No 853/2004.

(24) Commission Regulation (EU) No 210/2013[24] requires establishments producing sprouts to be approved by the competent authorities in accordance with Article 6 of Regulation (EC) No 852/2004. In order to ensure compliance with Union food hygiene rules, or with rules recognised to be at least equivalent thereto, sprouts should only be allowed entry into the Union if they are produced in establishments, which appear on lists drawn up and updated in accordance with this Regulation.

(25) In order to ensure compliance with Union food hygiene rules, or with rules recognised to be at least equivalent thereto, products from establishments manufacturing fresh meat, minced meat, meat preparations, meat products, mechanically separated meat and raw materials intended for the production of gelatine and collagen should only be allowed entry into the Union if those establishments appear on lists drawn up and updated in accordance with Article 127(3), point (e)(ii), of Regulation (EU) 2017/625. In addition, the raw materials these products are manufactured from should come from establishments (slaughterhouses, game-handling establishments, cutting plants and establishments handling fishery products) appearing on lists drawn up and updated in accordance with Article 127(3), point (e)(ii), of Regulation (EU) 2017/625.

(26) Consignments of live bivalve molluscs, echinoderms, tunicates and marine gastropods should only be allowed entry into the Union from production areas in third countries or regions thereof that appear on lists drawn up and updated in accordance with Article 127(3), point (e)(ii), of Regulation (EU) 2017/625 in order to ensure compliance with the applicable specific requirements for these products laid down in

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pharmacologically active substances and pesticides and the maximum levels of contaminants, and repealing Commission Decision 2011/163/EU (OJ L …, … , p. …).

[24] Commission Regulation (EU) No 210/2013 of 11 March 2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) No 852/2004 of the European Parliament and of the Council (OJ L 68, 12.3.2013, p. 24).

Regulation (EC) No 853/2004 and Implementing Regulation (EU) 2019/627, or with rules recognised to be at least equivalent thereto. The publication of those lists should ensure transparency for food business operators and consumers as regards the production areas from which live bivalve molluscs, echinoderms, tunicates and marine gastropods are allowed to enter the Union.

(27) Consignments of fishery products should only be allowed to enter the Union where those consignments are dispatched from, obtained or prepared in an on-land establishment, reefer, factory or freezer vessels flying the flag of a third country that appears on lists drawn up and updated in accordance with Article 127(3), point (e)(ii), of Regulation (EU) 2017/625 in order to ensure compliance with Union requirements, in particular with the specific requirements for fishery products laid down in Regulation (EC) No 853/2004 and Implementing Regulation (EU) 2019/627, or with rules recognised to be at least equivalent thereto. The publication of such lists should ensure transparency for food business operators and consumers as regards the vessels whose fishery products may enter the Union.

(28) The risk associated with composite products depends on the type of ingredients thereof and on the conditions of storage of those ingredients. Requirements on the consignments of composite products should therefore be laid down, to ensure that the composite products presenting a risk are exported from countries authorised for entry into the Union pursuant to Implementing Regulation (EU) 2021/405. Composite products presenting a risk are those that contain processed products of animal origin, for which specific requirements are laid down in Annex III to Regulation (EC) No 853/2004, or for which a residue-monitoring plan is required.

(29) Given the number of notifications received in the Rapid Alert System for Food and Feed established by Regulation (EC) No 178/2002, the consignments of certain animals and goods intended to be placed on the market for human consumption present an enhanced risk of non-compliance with Union requirements on food safety. The consignments of such animals and goods should therefore be subject to individual certification for each consignment prior to the entry into the Union. That certification also contributes to reminding food business operators and the competent authorities of third countries or regions thereof of the relevant Union requirements. Commission Implementing Regulation (EU) 2020/2235[25] lays down model animal health and/or official certificates for that purpose. Consignments for such animals and goods for which the Union is not the final destination should be accompanied by animal health certificates or official certificates with animal health attestation, whilst public health attestation for those animals and goods is not needed, since they will not be placed on the market in the Union. As regards certain composite products, which present a low risk, private attestation by the importing food business operator should replace the certification to ensure a proportionate, risk-based approach.

(30) Shelf-stable composite products representing a negligible risk, such as those where the only animal product present in the final composite product are food improvement

[25] Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1).

agents, namely vitamin D3, food additives, food enzymes or food flavourings, should be exempted from the controls at the borders and from the private attestation requirements.

(31) Delegated Regulation (EU) 2019/625 should therefore be repealed and replaced by this Regulation,

(32) As Annexes I, II, III and IV to Directive 96/23/EC cease to apply on 14 December 2022, this Regulation should apply from 15 December 2022.

HAS ADOPTED THIS REGULATION:

CHAPTER I: Scope and definitions

Article 1
Subject matter and scope

1. This Regulation supplements Regulation (EU) 2017/625 as regards the requirements for the entry in the Union of consignments of food-producing animals and certain goods intended for human consumption from third countries or regions thereof in order to ensure that they comply with the applicable requirements established by the rules referred to in Article 1(2), point (a), of Regulation (EU) 2017/625 or with requirements recognised to be at least equivalent thereto.

2. The requirements referred to in paragraph 1 cover:

   (a) the identification of food-producing animals and certain goods intended for human consumption subject to the following requirements for entry into the Union:

      (i) the requirement that those food-producing animals and certain goods intended for human consumption shall come from a third country or region thereof listed in accordance with Article 126(2), point (a), of Regulation (EU) 2017/625;

      (ii) the requirement that those food-producing animals and certain goods intended for human consumption be dispatched from, and obtained or prepared in, establishments which comply with applicable requirements referred to in Article 126(1) of Regulation (EU) 2017/625, or with requirements recognised to be at least equivalent thereto, and which appear on lists drawn up and updated in accordance with Article 127(3), points (e)(ii) and (iii), of Regulation (EU) 2017/625;

      (iii) the requirement that each consignment of food-producing animals and certain goods intended for human consumption be accompanied, by an official certificate, or official attestation or any other evidence of compliance with the rules referred to in Article 1(2), point (a), of Regulation (EU) 2017/625, such a as private attestation, in accordance with Article 126(2), point (c), of Regulation (EU) 2017/625;

   (b) requirements for the entry into the Union of food-producing animals and certain goods intended for human consumption from a third country or region thereof, listed in accordance with Article 127(2) of Regulation (EU) 2017/625;

   (c) requirements that consignments of food-producing animals and certain goods intended for human consumption from third countries be dispatched from, and obtained or prepared in, establishments which comply with the applicable

requirements referred to in Article 126(1) of Regulation (EU) 2017/625, or with requirements recognised to be at least equivalent thereto, and which appear on lists drawn up and updated in accordance with Article 127(3), points (e)(ii)and (iii) of Regulation (EU) 2017/625;

(d) requirements for the entry into the Union for placing on the market of the specific following commodities in addition to the requirements laid down in accordance with Article 126 of Regulation (EU) 2017/625:

(i) fresh meat, minced meat, meat preparations, meat products, mechanically separated meat and raw materials intended for the production of gelatine and collagen;

(ii) live bivalve molluscs, echinoderms, tunicates and marine gastropods;

(iii) fishery products;

(iv) composite products;

(e) additional requirements for the official certificates, official attestations and private attestations that shall accompany food-producing animals and certain goods intended for human consumption for entry into the Union;

(f) requirements for the use of pharmacologically active substances in food-producing animals and the residues thereof and for the levels of contaminants and pesticide residues in products of animal origin and composite products, where those food-producing animals, products of animal origin and composite products enter the Union from third countries and are intended to be placed on the market of the Union, and those requirements are necessary to ensure that such food-producing animals, products of animal origin and composite products provide a level of human health protection equivalent to that provided by the relevant Union rules on food safety;

(g) the requirement that food-producing animals, products of animal origin and composite products shall only enter the Union from third countries that provide evidence and guarantees of compliance with the requirements set out in this Regulation by submitting a control plan.

3. This Regulation shall not apply to:

(a) Animals and goods not intended for human consumption, however when the destination of the animals and goods has not been decided at entry into the Union, this Regulation applies;

(b) Animals and goods intended for human consumption only for transit through the Union without being placed on the market.

(c) Goods intended for human consumption for the purpose of samples for product analysis and quality testing without being placed on the market.

Article 2
Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) ‘entering the Union’ or ‘entry into the Union’ means entering the Union or entry into the Union as defined in Article 3, point (40), of Regulation (EU) 2017/625;

(2) ‘consignment’ means consignment as defined in Article 3, point (37), of Regulation (EU) 2017/625;

(3) ‘animals’ means animals as defined in Article 3, point (9), of Regulation (EU) 2017/625;

(4) ‘goods’ means goods as defined in Article 3, point (11), of Regulation (EU) 2017/625;

(5) ‘equivalent’ means equivalent as defined in Article 2(1), point (e), of Regulation (EC) No 852/2004;

(6) ‘establishment’ means an establishment as defined in Article 2(1), point (c), of Regulation (EC) No 852/2004;

(7) ‘official certificate’ means official certificate as defined in Article 3, point (27) to Regulation (EU) 2017/625;

(8) ‘official attestation’ means official attestation as defined in Article 3, point (28) to Regulation (EU) 2017/625;

(9) ‘private attestation’ means an attestation signed by the importing food business operator;

(10) ‘placing on the market’ means placing on the market as defined in Article 3, point (8), of Regulation (EC) No 178/2002;

(11) ‘fresh meat’ means fresh meat as defined in point 1.10 of Annex I to Regulation (EC) No 853/2004;

(12) ‘minced meat’ means minced meat as defined in point 1.13 of Annex I to Regulation (EC) No 853/2004;

(13) ‘meat preparations’ means meat preparations as defined in point 1.15 of Annex I to Regulation (EC) No 853/2004;

(14) ‘meat products’ means meat products as defined in point 7.1 of Annex I to Regulation (EC) No 853/2004;

(15) ‘mechanically separated meat’ means mechanically separated meat as defined in point 1.14 of Annex I to Regulation (EC) No 853/2004;

(16) ‘gelatine’ means gelatine as defined in point 7.7 of Annex I to Regulation (EC) No 853/2004;

(17) ‘collagen’ means collagen as defined in point 7.8 of Annex I to Regulation (EC) No 853/2004;

(18) ‘bivalve molluscs’ means bivalve molluscs as defined in point 2.1 of Annex I to Regulation (EC) No 853/2004;

(19) ‘fishery products’ means fishery products as defined in point 3.1 of Annex I to Regulation (EC) No 853/2004;

(20) ‘composite product’ means food containing both products of plant origin and processed products of animal origin;

(21) ‘pharmacologically active substance’ means pharmacologically active substance as defined in Article 2, point (a), of Delegated Regulation (EU) 2019/2090[26];

(22) ‘contaminant’ means contaminant as defined in Article 1(1), second subparagraph, of Council Regulation (EEC) No 315/93[27];

(23) ‘pesticide residues’ means pesticide residues as defined in Article 3(2), point (c), of Regulation 396/2005;

(24) ‘product of animal origin’ means product of animal origin as defined in point 8.1 of Annex I to Regulation (EC) No 853/2004;

(25) ‘control plan’ means control plan as defined in Article 3, point (8) of Regulation (EU) 2017/625 for the areas on the use of pharmacologically active substances and their residues, contaminants and pesticide residues in food-producing animals, products of animal origin and composite products;

(26) ‘insects’ means food consisting of, isolated from or produced from insects or their parts including any life stadia of insects intended for human consumption which are, when applicable, authorised in accordance with Regulation (EU) 2015/2283[28] and included in the Union list of novel foods established by Commission Implementing Regulation (EU) 2017/2470[29] (‘the Union list of novel foods’);

(27) ‘transit’ means transit as defined in Article 3, point (44), of Regulation (EU) 2017/625;

(28) ‘reptile meat’ means the edible parts, either unprocessed or processed, derived from farmed reptiles, belonging to the species *Alligator mississippiensis, Crocodylus johnstoni, Crocodylus niloticus, Crocodylus porosus, Timon Lepidus, Python reticulatus, Python molurus bivittatus* or *Pelodiscus sinensis*, which are, when applicable, authorised in accordance with Regulation (EU) 2015/2283 of the European Parliament of the Council and included in the Union list of novel foods;

(29) ‘snails’ means snails as defined in point 6.2 of Annex I to Regulation (EC) No 853/2004 and any other species of snails of the family of *Helicidae, Hygromiidae* or *Sphincterochilidae*, intended for human consumption;

(30) ‘food’ means food as defined in Article 2 of Regulation (EC) No 178/2002;

(31) ‘feed’ or ‘feedingstuff’ means feed or feedingstuff as defined in Article 3, point (4) to Regulation (EC) No 178/2002;

(32) ‘audit’ means audit as defined in Article 3, point (30), of Regulation (EU) 2017/625;

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[26] Commission Delegated Regulation (EU) 2019/2090 of 19 June 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and Council regarding cases of suspected or established non-compliance with Union rules applicable to the use or residues of pharmacologically active substances authorised in veterinary medicinal products or as feed additives or with Union rules applicable to the use or residues of prohibited or unauthorised pharmacologically active substances (OJ L 317, 9.12.2019, p. 28).

[27] Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 307, 13.2.1993, p. 1).

[28] Regulation (EU) 2015/2283 of the European Parliament of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

[29] Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel food (OJ L 351, 30.12.2017, p. 72).

(33) ‘competent authorities’ means competent authorities as defined in Article 3, point (3), of Regulation (EU) 2017/625;

(34) ‘sprouts’ means sprouts as defined in Article 2, point (a), of Commission Implementing Regulation (EU) No 208/2013[30];

(35) ‘primary production’ means primary production as defined in Article 3, point (17), of Regulation (EC) No 178/2002;

(36) ‘slaughterhouse’ means slaughterhouse as defined in point 1.16 of Annex I to Regulation (EC) No 853/2004;

(37) ‘game-handling establishment’ means game-handling establishment as defined in point 1.18 of Annex I to Regulation (EC) No 853/2004;

(38) ‘cutting plant’ means cutting plant as defined in point 1.17 of Annex I to Regulation (EC) No 853/2004;

(39) ‘production area’ means production area as defined in point 2.5 of Annex I to Regulation (EC) No 853/2004;

(40) ‘factory vessel’ means factory vessel as defined in point 3.2 of Annex I to Regulation (EC) No 853/2004;

(41) ‘freezer vessel’ means freezer vessel as defined in point 3.3 of Annex I to Regulation (EC) No 853/2004;

(42) ‘reefer vessel’ means a vessel equipped to store and transport palletised or loose cargo (bulk) goods in temperature-controlled holds or chambers;

(43) ‘dairy products’ means dairy products as defined in point 7.2 of Annex I to Regulation (EC) No 853/2004;

(44) ‘egg products’ means egg products as defined in point 7.3 of Annex I to Regulation (EC) No 853/2004;

(45) ‘food business operator’ means a food business operator as defined in Article 3, point (3), of Regulation (EC) No 178/2002.

(46) ‘operator’ means operator as defined in Article 3, point (29), of Regulation (EU) 2017/625;

(47) ‘border control post’ means border control post as defined in Article 3, point (38) to Regulation (EU) 2017/625;

[30] Commission Implementing Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts (OJ L 68, 12.3.2013, p. 16).

CHAPTER II: Conditions for the entry into the Union as regards third countries of origin or regions thereof

Article 3

Food-producing animals and goods which are required to come from third countries or regions thereof included in the list referred to in Article 126(2), point (a), of Regulation (EU) 2017/625

Consignments of the following food-producing animals and goods intended for human consumption shall enter the Union only from a third country or region thereof included in the list for those animals and goods laid down in Implementing Regulation (EU) 2021/405:

(a) products of animal origin, including reptile meat and dead whole insects, parts of insects or processed insects, intended for human consumption, for which the following codes have been laid down in Part Two of Annex I to Regulation (EEC) No 2658/87:

  (i) CN codes in Chapters 2 to 5, 15, 16 or 29; or

  (ii) HS headings 0901, 1702, 2105, 2106, 2301, 3001, 3002, 3302, 3501, 3502, 3503, 3504, 3507, 3913, 3926, 4101, 4102, 4103 or 9602;

(b) live insects, other than bees, referred to by the CN code 0106 49 00 of Part Two of Annex I to Regulation (EEC) No 2658/87;

(c) live snails, other than sea snails, referred to by the CN code 0307 60 00 of Part Two of Annex I to Regulation (EEC) No 2658/87;

(d) pollen flour falling under the CN code ex 1212 99 95 of Part Two of Annex I to Regulation (EEC) No 2658/87.

Article 4

Additional requirements for the entry into the Union of food-producing animals and goods from a third country or region thereof

In addition to the requirements laid down in Article 127(3) of Regulation (EU) 2017/625, the Commission shall only decide on the inclusion of third countries or regions thereof in the list referred to in Article 126(2), point (a), of that Regulation if the following requirements are recognised by the Commission as being at least equivalent to the relevant requirements in the Union for the food-producing animals and goods referred to in Article 3 of this Regulation:

(a) the legislation of the third country on:

  (i) the production of food of animal origin;

  (ii) the use of veterinary medicinal products, including rules on their prohibition or authorisation, their distribution, their placing on the market and the rules covering administration and inspection;

  (iii) the preparation and use of feed, including the procedures for using additives and the preparation and use of medicated feedingstuffs, as well as the hygiene quality of the raw materials used for preparing feedingstuffs and of the final product;

(b) the hygiene conditions of production, manufacture, handling, storage and dispatch currently applied to products of animal origin destined for the Union;

(c) any experience of marketing of the products of animal origin from the third country and the results of any official controls on entry in the Union;

(d) when available, the results of audits carried out by the Commission in the third country related to other food-producing animals and goods for which the third country is already listed in accordance with Article 127(2) of Regulation (EU) 2017/625, in particular the results of the assessment of the competent authorities in the third country audited, and the action that the competent authorities have taken in the light of any recommendations addressed to them following such audits by the Commission;

(e) the existence, implementation and communication of a zoonoses control programme approved by the Commission when applicable;

(f) the third country's requirements as regards pharmaceutical active substances, pesticides and contaminants, in accordance with Article 5.

Article 5

Additional requirements for the entry into the Union of food-producing animals, products of animal origin and composite products, as regards pharmacologically active substances and residues thereof, contaminants and pesticide residues

1. In addition to the requirements laid down in Regulation (EU) 2017/625, consignments of food-producing animals, products of animal origin and composite products, shall enter the Union only from a third country that has in place a control plan setting out guarantees as regards compliance with:

   (a) the Union requirements on the use of pharmacologically active substances, the maximum residue limits of pharmacologically active substances, maximum residue levels of pesticides and maximum levels of contaminants established in the Union; and

   (b) the additional requirements specified in Articles 8 to 12 of this Regulation.

2. In addition to the requirements laid down in Article 127(3) of Regulation (EU) 2017/625, the Commission shall decide on the inclusion of a third country in the list referred to in Article 126(2), point (a), of that Regulation only if that third country provides evidence and guarantees of compliance with the requirements laid down in paragraph 1, together with the information listed in Part II of Annex I to this Regulation, in the request for inclusion in the list of third countries which that third country is to submit under Article 127(2) of Regulation (EU) 2017/625.

3. After having approved the inclusion of the third country in the list of authorised third countries, the Commission shall ensure, in accordance with Article 127(3) of Regulation (EU) 2017/625, that the third country continues to comply with the requirements laid down in paragraph 1 of this Article.

4. For the purposes of paragraph 3, the Commission shall take into account the updated evidence and guarantees of compliance with the requirements laid down in paragraph 1, which includes information on the third country's control plan set out in Annex I, submitted by that third country by 31 March of each year.

Article 6

Inclusion of a third country in a list of third countries that comply with Union

requirements on pharmacologically active substances and residues thereof, contaminants and pesticide residues

In addition to the conditions laid down in Regulation (EU) 2017/625, consignments of food-producing animals, products of animal origin and composite products, shall enter the Union only from a third country that complies with the requirements provided for in Article 5(1) and is included in the list of third countries approved for the entry into the Union of the concerned food-producing animals or products of animal origin for human consumption, set out in Annex -I to Implementing Regulation (EU) 2021/405.

Article 7

Derogation from the requirements for the entry into the Union of food-producing animals, products of animal origin and composite products

1. By way of derogation from Article 6, consignments of food-producing animals, products of animal origin and composite products may enter the Union from third countries that do not have an approved control plan but ensure that the food-producing animals and products of animal origin, including those used as ingredients in the composite products entering the Union, originate in a Member State or a third country included in the list set out in Annex -I to Implementing Regulation (EU) 2021/405 as regards those food-producing animals or products of animal origin.

2. In addition to the requirements laid down in Article 127(3) of Regulation (EU) 2017/625, the Commission shall decide on the inclusion of a third country in the list referred to in Article 126(2), point (a), of that Regulation only if the competent authority of that third country provides the Commission with evidence and guarantees of compliance with the requirements laid down in paragraph 1. Such evidence and guarantees shall consist of information on the procedures in place in that third country to guarantee the traceability and origin of those food-producing animals and those products of animal origin..

3. Where a third country is included, in accordance with paragraphs (1) and (2), in the list of authorised third countries for specific food-producing animals or products of animal origin, the entry for this country shall be associated with the following note:

   (a) 'Third country, only entering the Union specific food-producing animals or products of animal origin – as such or as ingredients of composite products –, which originate: (a) from other third countries authorised for the entry into the Union of such food-producing animals or such products of animal origin, or (b) from Member States, in accordance with Article 7 of Commission Delegated Regulation (EU) 2022/… [*Publications Office: please insert in the text the number of this Regulation*].'

   [or, for third countries that are not allowed to be listed with note (a) because of non-compliance with animal health requirements,]

   (b) 'Third country, only entering the Union composite products containing processed products of animal origin, which originate: (a) from other third countries authorised for the entry into the Union of such food-producing animals or products of animal origin, or (b) from Member States, in accordance with Article 7 of Commission Delegated Regulation (EU) 2022/… (*Publications Office please insert in the text the number of this Regulation*).'

4. For the production of casings intended for export to the Union, third countries may use raw material of animal origin imported from other third countries or regions

thereof which are authorised for the entry into the Union of fresh meat, or of certain meat products and treated stomachs, bladders and intestines, and which are listed in the relevant lists of such fresh meat and meat products of Implementing Regulations (EU) 2021/404[31] or 2021/405 and are listed in Annex -I to Implementing Regulation (EU) 2021/405 for casings. In addition, the establishments from which the casings are to be exported to the Union shall be listed in accordance with Article 13(1) of this Regulation.

5. After having approved the inclusion of the third country in the lists of authorised third countries referred to in this Article, the Commission shall ensure, in accordance with Article 127(3) of Regulation (EU) 2017/625, that the third country continues to comply with the requirements laid down in paragraph 1 of this Article.

CHAPTER III: Conditions for the entry into the Union as regards the use of pharmacologically active substances and residues thereof, contaminants and pesticide residues

Article 8

Requirements as regards the use of pharmacologically active substances in food-producing animals and of residues of those substances in products of animal origin for human consumption and composite products

1. Food-producing animals, products of animal origin and composite products shall only enter the Union from third countries which provide guarantees that the controls on the use of pharmacologically active substances referred to in Annex I to Commission Delegated Regulation 2022/x (C(2022)4400) [and the residues of those substances are at least equivalent to those required for the multiannual national control plans of Member States, as referred to in Article 4 of Implementing Regulation 2022/xx (C(2022)4401).

2. Where a third country authorises the use in food-producing animals of pharmacologically active substances which are not authorised for such animals in the Union, food-producing animals, products of animal origin and composite products shall only enter the Union insofar as that third country provides guarantees that no residues of those substances are present in those animals and products. The methods of analysis used to demonstrate the absence of such residues shall comply with the requirements laid down in Annex I to Implementing Regulation (EU) 2021/808 or with requirements equivalent thereto.

Article 9

Requirements as regards the prohibition of certain substances

1. Food-producing animals, products of animal origin and composite products shall only enter the Union from third countries which provide guarantees of compliance

[31] Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and of the Council (OJ L 114, 31.3.2021, p. 1).

with the prohibition of the use of beta-agonists and any stilbene, thyrostatic, oestrogenic, androgenic and gestagenic substances in farm animals laid down in Directive 96/22/EC, and with the prohibition of the use of the substances listed in Table 2 of the Annex to Regulation (EU) No 37/2010.

2. Food-producing animals, products of animal origin and composite products from third countries that authorise the use of the substances referred to in paragraph 1 in food-producing animals or do not have rules on the use of those substances shall only enter the Union insofar as those third countries provide guarantees that:

(a) they have set up a segregated production system to ensure that food-producing animals, products of animal origin and composite products intended for entry into the Union are not treated with the substances referred to in paragraph 1, and

(b) they have set up an appropriate animal identification and traceability system, as well as a system for the control of the distribution of the substances referred to in paragraph 1 and for the record keeping of the administration of veterinary medicinal products.

Article 10

Requirements as regards residues of pesticides in food of animal origin and composite products

Products of animal origin and composite products shall only enter the Union from third countries which provide guarantees that representative controls on pesticide residues are performed in order to demonstrate that those products comply with the maximum residue levels laid down in Regulation (EC) No 396/2005. Those guarantees shall be at least equivalent to those provided for by the multiannual national control programmes for pesticide residues referred to in Implementing Regulation 2021/1355.

Article 11

Requirements as regards contaminants in food of animal origin and composite products

Products of animal origin and composite products shall only enter the Union from third countries which provide guarantees that those products comply with the maximum tolerances for contaminants established on the basis of Regulation (EEC) No 315/93. Those guarantees shall be at least equivalent to those provided for by the multiannual national control plans established in accordance with Delegated Regulation 2022/931 and Implementing Regulation 2022/932

Article 12

Application of Article 5 to 11

1. The requirements referred to in Articles 5 to 11 shall apply to the entry into the Union of the following food-producing animals, products of animal origin and composite products:

(a) live animals for which Combined Nomenclature codes (‘CN codes’) have been laid down in Part Two, Chapter 1, of Annex I to Regulation (EEC) No 2658/87, where those animals are food-producing animals;

(b) products of animal origin, for which CN codes have been laid down in Part Two, Chapters 2 to 5, 15 and 16, of Annex I to Regulation (EEC) No 2658/87, and for which Harmonised System subheadings (‘HS subheadings’) have been laid down under headings 0901, 3501, 3502 and 3504;

(c) dead whole insects, parts of insects or processed insects; and

(d) composite products for which CN codes have been laid down in Part Two, Chapters 15 to 22, of Annex I to Regulation (EEC) No 2658/87.

2. However, the requirements referred to in Articles 5 to 11 shall not apply to gelatine referred to in Section XIV of Annex III to Regulation (EC) 853/2004, raw materials for the production of gelatine referred to in Section XIV, Chapter I, point 1 of that Regulation, collagen referred to in Section XV of that Regulation, raw materials for the production of collagen referred to in Section XV, Chapter I, points 1 of that Regulation, and highly refined products referred to in Section XVI, point 1, of that Regulation.

CHAPTER IV: Conditions for the entry into the Union as regards establishments

Article 13

Requirements for establishments

1. Consignments of the following goods shall only enter the Union where those consignments are dispatched from, and obtained or prepared in, establishments that appear on lists drawn up and kept up-to-date in accordance with Article 127(3), points (e)(ii) and (iii), of Regulation (EU) 2017/625:

(a) products of animal origin, for which requirements are laid down in Annex III to Regulation (EC) No 853/2004, and for which the following codes have been laid down in Part Two of Annex I to Regulation (EEC) No 2658/87:

(i) CN codes in Chapters 2 to 5, 15 or 16; or

(ii) HS subheadings 1702, 2105, 2106, 2301, 2932, 3001, 3002, 3501, 3502, 3503, 3504, 4101, 4102 or 4103;

(b) sprouts falling under the following HS subheadings: 0704 90, 0706 90, 0708 10, 0708 20, 0708 90 or 1214 90 of Part Two of Annex I to Regulation (EEC) No 2658/87.

2. Establishments referred to in paragraph 1 of this Article may be placed on the lists referred to in Article 127(3), point (e), of Regulation (EU) 2017/625 only if, in addition to the guarantees laid down in Article 127(3), points (e)(ii) and (iv), of Regulation (EU) 2017/625, the third country where the establishments are located provides the following guarantees:

(a) such establishments, together with any establishments handling raw material of animal origin used in the manufacture of the products of animal origin referred to in paragraph 1(a), comply with applicable requirements referred to in Article 126(1) of Regulation (EU) 2017/625, in particular those of Regulation (EC) No 853/2004, or with requirements recognised to be at least equivalent thereto;

(b) such establishments, where appropriate, only handle raw materials of animal origin that come from third countries with an approved residue monitoring plan for that product category in accordance with Delegated Regulation (EU)

2022/xxxx (C(2022) 4400) and Implementing Regulation (EU) 2022/xxx (C(2022) 4401 or from Member States;

(c) it has real powers to stop such establishments from exporting to the Union in the event that the establishments fail to meet the relevant Union requirements or requirements recognised to be at least equivalent thereto.

3. The Commission shall provide the Member States with any new and updated lists that it receives from the competent authorities of the third country in accordance with Article 127(3), point (e)(iii), of Regulation (EU) 2017/625 and shall publish such lists on its website.

4. Member States shall only allow the entry into the Union of the consignments referred to in paragraph 1 provided that the official certificates which are required to accompany such consignments pursuant to the applicable Union rules are issued by the competent authorities of the third country starting with the date of publication, by the Commission, of the establishment in the lists referred to in paragraph 1.

Article 14

Establishments not subject to the requirements of Article 13(1)

The requirements laid down in Article 13 shall not apply to establishments that only carry out the following activities:

(a) primary production;

(b) transport operations;

(c) storage of products of animal origin not requiring temperature-controlled storage conditions;

(d) production of highly refined products referred to in Section XVI of Annex III to Regulation (EC) No 853/2004 and referred to by HS subheadings 2930, 2932, 3503, 3507 or 3913 of Part Two of Annex I to Regulation (EEC) No 2658/87.

(e) Gelatine capsules referred to by subheadings 3913, 3926 or 9602 of Part Two of Annex I to Regulation (EEC) No 2658/87.

CHAPTER V: Additional requirements for the entry into the Union of certain goods intended for human consumption

Article 15

Requirements for consignments of fresh meat, minced meat, meat preparations, meat products, mechanically separated meat and raw materials intended for the production of gelatine and collagen

Consignments of the following products of animal origin shall only enter the Union if they have been manufactured from raw materials obtained in slaughterhouses, game-handling establishments, cutting plants and establishments handling fishery products, appearing on lists of establishments drawn up and kept up-to-date in accordance with Article 127(3), point (e), of Regulation (EU) 2017/625:

(a) fresh meat;

(b) minced meat;

(c) meat preparations;

(d) mechanically separated meat and meat products, excluding casings as defined in Article 2, point (45), of Commission Delegated Regulation (EU) No 2020/692[32];

(e) raw materials intended for the production of gelatine and collagen referred to respectively in Section XIV, Chapter I, point 4(a), and in section XV, Chapter I, point 4(a), of Annex III to Regulation (EC) No 853/2004.

Article 16

Requirements for consignments of live bivalve molluscs, echinoderms, tunicates and marine gastropods

1. Notwithstanding Article 14 of this Regulation, consignments of live bivalve molluscs, echinoderms, tunicates and marine gastropods for which CN codes have been laid down in heading 0307 of Part Two of Annex I to Regulation (EEC) No 2658/87 shall enter the Union only from production areas in third countries that appear on lists drawn up by the competent authorities of the third country in accordance with Article 127(3), point (e), of Regulation (EU) 2017/625 and published by the Commission.

2. The following products may enter the Union, even if harvested in areas which have not been classified by the competent authorities in the third country of production in accordance with Article 18(6) of Regulation (EU) 2017/625:

   (a) *Pectinidae*, except where data from monitoring programmes established by Article 57 of Implementing Regulation (EU) 2019/627 enable the competent authorities to classify fishing grounds as set out in Section VII, Chapter IX, point 2, of Annex III to Regulation (EC) No 853/2004;

   (b) marine gastropods that are not filter feeders and echinoderms that are not filter feeders.

Article 17

Listing of production areas

1. Before the lists referred to in Article 16(1) of this Regulation are drawn up by the competent authorities of the third country, particular account shall be taken of the guarantees that the competent authorities of the third country can give concerning compliance with the requirements of Article 52 of Implementing Regulation 2019/627 on the classification and control of production areas.

2. The Commission shall carry out an on-the-spot control visit before the lists referred to in Article 16(1) are drawn up.

3. Once lists referred to in Article 16(1) are drawn up, and when the competent authorities of the third country offer sufficient guarantees on the management and controls of production areas under their responsibility, the on-the-spot Commission control visit need not to be carried out prior to the addition of a new production area to an existing list established in accordance with Article 13.

[32] Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).

Article 18

Special requirements for fishery products

Consignments of fishery products for which CN codes have been laid down in headings 0301, 0302, 0303, 0304, 0305, 0306, 0307, 0308, 0309, 1504, 1516, 1516, 1517, 1603, 1604, 1605 or 2106 of Part Two of Annex I to Regulation (EEC) No 2658/87, shall enter the Union for placing on the market only if they have been obtained or prepared, at any stage of their production, in an on-land establishment, a factory or freezer vessel or stored in a cold-store or a reefer vessel that appears on a list drawn up and updated in accordance with Article 127(3), point (e), of Regulation (EU) 2017/625 and published by the Commission.

Article 189

Special requirements for listing vessels

1. A vessel may be included on the lists of establishments referred to in Article 127(3), point (e)(ii), of Regulation (EU) 2017/625 provided that the competent authorities of the third country whose flag the vessel is flying, and the competent authorities of another third country to which the competent authorities of the third country whose flag the vessel is flying have delegated responsibility for the inspection of the vessel concerned, provide the Commission with a joint communication stating that all of the following requirements are met:

   (a) both third countries appear on the list of third countries or regions thereof, drawn up in accordance with Article 127(3) of Regulation (EU) 2017/625, from which entry into the Union of fishery products is permitted;

   (b) all fishery products from the vessel concerned that are destined for placing on the market in the Union are landed directly in the third country to which the third country whose flag the vessel is flying has delegated responsibility for the inspection of the vessel concerned;

   (c) the delegated competent authorities have inspected the vessel and have declared that it complies with the applicable Union requirements;

   (d) the delegated competent authorities have declared that they will regularly inspect the vessel to ensure that it continues to comply with the applicable Union requirements.

2. A vessel may be included on the lists of establishments referred to in Article 127(3), point (e)(ii), of Regulation (EU) 2017/625 on the basis of a joint communication from the competent authorities of the third country whose flag the vessel is flying and from the competent authorities of a Member State, to which the competent authorities of the third country whose flag the vessel is flying have delegated responsibility for the inspection of the vessel concerned, if all of the following requirements are met:

   (a) all fishery products from the vessel concerned that are destined for placing on the market in the Union are landed directly in that Member State;

   (b) the competent authorities of that Member State have inspected the vessel and have declared that it complies with the applicable Union requirements;

   (c) the competent authorities of that Member State have declared that they will regularly inspect the vessel to ensure that it continues to comply with the applicable Union requirements.

Article 20

Requirements for consignments of composite products

1. Consignments of composite products referred to by the CN codes under headings 1517, 1518, 1601 00, 1602, 1603 00, 1604, 1605, 1702, 1704, 1806, 1901, 1902, 1904, 1905, 2001, 2004, 2005, 2008, 2101, 2103, 2104, 2105 00, 2106, 2202 or 2208 of Annex I to Regulation (EEC) No 2658/87 shall enter the Union for placing on the market only if each processed product of animal origin contained in the composite products was either produced in establishments that are located in third countries or regions thereof and authorised to export those processed products of animal origin to the Union in accordance with Article 13 of this Regulation or in establishments located in Member States.

2. Pending the establishment by the Commission of a specific list of third countries or regions thereof authorised to export composite products to the Union, consignments of composite products from third countries or regions thereof may enter the Union, subject to compliance with the following rules:

   (a) composite products referred to in paragraph 1 that need to be transported or stored under controlled temperatures shall originate from third countries or regions thereof authorised, under Article 3, to export to the Union each processed product of animal origin contained in the composite products;

   (b) composite products referred to in paragraph 1 that do not need to be transported or stored under controlled temperatures and that contain any quantity of colostrum-based products or processed meat, shall originate from third countries or regions thereof authorised, under Article 3, to export to the Union the colostrum-based products or meat products contained in the composite products;

   (c) composite products referred to in paragraph 1 that do not need to be transported or stored under controlled temperatures and that contain processed products of animal origin other than colostrum-based products or processed meat, for which requirements are laid down in Annex III to Regulation (EC) No 853/2004, shall originate from third countries or regions thereof that are authorised, under Article 3, to export meat products, dairy products, fishery products or egg products to the Union on the basis of Union animal and public health requirements and are listed at least for one of these products of animal origin.

3. The third countries or regions thereof exporting composite products to the Union shall be listed in Annex -1 to Implementing Regulation (EU) 2021/405 as having an approved control plan, in accordance with Article 6 of this Regulation, for the species or commodities from which the processed products of animal origin contained in the composite products, with the exception of collagen, gelatine and the highly refined products listed in Section XVI, point 1, of Annex III to Regulation (EC) No 853/2004, are derived.

4. Paragraphs 2 and 3 shall not apply to shelf-stable composite products that only contain processed products of animal origin or composite products that fall under the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council[33], Regulation (EC) No 1333/2008 of the European Parliament and of the

[33] Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999,

Council [34], Regulation (EC) No 1334/2008 of the European Parliament and of the Council [35], or that only contain vitamin D3.

CHAPTER VI: Conditions for the entry into the Union as regards certification and attestation

Article 21
Official certificates

1. Each consignment of the following products shall enter the Union only where the consignment is accompanied by an official certificate except in case of consignments for which the Union is not the final destination:

   (a) products of animal origin intended for human consumption, for which the following codes have been laid down in Part Two of Annex I to Regulation (EEC) No 2658/87:

      (i) CN codes in Chapters 2 to 5, 15, 16 or 29; or

      (ii) HS subheadings 0901, 1702, 2105, 2106, 2301, 3001, 3002, 3501, 3502, 3503, 3504, 3507, 3913, 3926, 4101, 4102, 4103 or 9602;

   (b) live insects referred to by the CN code 0106 49 00 of Part Two of Annex I to Regulation (EEC) No 2658/87;

   (c) sprouts and seeds intended for the production of sprouts and referred to by the following HS subheadings: 0704 90, 0706 90, 0708 10, 0708 20, 0708 90, 0712 34, 0712 35, 0712 50, 0712 60, 0713 10, 0713 33, 0712 34, 0713 39, 0713 40, 0713 90, 0910 99, 1201 10, 1201 90, 1207 50, 1207 99, 1209 10, 1209 21, 1209 91 or 1214 90 of Part Two of Annex I to Regulation (EEC) No 2658/87;

   (d) pollen flour referred to by the CN code 1212 99 95 of Part Two of Annex I to Regulation (EEC) No 2658/87;

   (e) live snails, other than sea snails, referred to by the CN code 0307 60 00 of Part Two of Annex I to Regulation (EEC) No 2658/87;

   (f) composite products referred to in Article 20(2), points (a) and (b), of this Regulation, with the exclusion of shelf-stable composite products that do not contain colostrum-based products or processed meat other than gelatine, collagen or highly refined products referred to in Section XVI of Annex III to Regulation (EC) No 853/2004.

2. When consignments of fishery products enter the Union directly from a reefer, factory or a freezer vessel flying the flag of a third country, the official certificate

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Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 on food additives (OJ L 354, 31.12.2008, p. 7).

[34] 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).

[35] Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).

referred to in Article 14(3) of Implementing Regulation (EU) 2020/2235 may be signed by the captain.

3. No official certificate is necessary for the entry into the Union of gelatine capsules covered by HS subheadings 3913, 3926 or 9602 of Part Two of Annex I to Regulation (EEC) No 2658/87, where those capsules are not derived from ruminant bones.

4. The official certificates referred to in paragraph 1 shall certify that the products comply with:

   (a) the requirements laid down in Regulations (EC) No 178/2002, (EC) No 852/2004 and (EC) No 853/2004 or provisions recognised to be equivalent to those requirements;

   (b) any specific requirements for entry into the Union set out in this Regulation.

5. The official certificates referred to in paragraph 1 may include details required in accordance with other Union legislation on public and animal health matters.

6. The official certificate for sprouts and seeds intended for the production of sprouts referred to in paragraph 1(c) shall accompany the consignment until it reaches its destination as indicated in the official certificate. In the case of splitting of the consignment, a copy of the official certificate shall accompany each part of the consignment.

7. The competent authorities of the third country of dispatch may certify consignments of products of animal origin that only require public health attestation, or consignments of sprouts, coming from another third country, if the competent authorities of the third country of dispatch can ensure compliance of the consignments with the requirements for entry into the Union laid down in this Regulation.

Article 22

Private attestation

1. A private attestation confirming that the consignments comply with the applicable requirements referred to in Article 126(2) of Regulation (EU) 2017/625, prepared and signed by the importing food business operator, shall accompany:

   (a) the consignments of the composite products referred to in Article 20(2), point (b) of this Regulation, where the composite products do not contain colostrum-based products or processed meat other than gelatine, collagen or highly refined products referred to in Section XVI of Annex III to Regulation (EC) No 853/2004; and

   (b) the consignments of the composite products referred to in Article 20(2), point (c).

2. By way of derogation from paragraph 1, for the products exempted from official controls at border control posts, in accordance with Article 48, point (h), of Regulation (EU) 2017/625, the private attestation shall accompany the products at the time of the placing on the market.

3. The private attestation referred to in paragraph 1 shall ensure the traceability of the consignment and shall include:

   (a) information regarding the consignor and consignee of the imported goods;

(b) the list of products of plant origin and processed products of animal origin contained in the composite products, indicated in descending order of weight, as recorded at the time of their use in the manufacture of the composite product;

(c) the approval number of the establishment(s) manufacturing the processed products of animal origin contained in the composite product, as provided for in Article 4(2) of Regulation (EC) No 853/2004 and indicated by the importing food business operator.

4. The private attestation referred to in paragraph 1 shall attest that:

(a) the third country or region thereof producing the composite product is listed at least for one of the following categories of products of animal origin:

(i) meat products;

(ii) dairy products or colostrum-based products;

(iii) fishery products;

(iv) egg products;

(b) the establishment producing the composite products fulfils hygiene standards recognised to be equivalent to those required by Regulation (EC) No 852/2004;

(c) the composite product does not need to be stored or transported under controlled temperature;

(d) the processed products of animal origin contained in the composite product originate from third countries or regions thereof authorised to export each processed product of animal origin to the Union, or from the Union, and are sourced from a listed establishment or listed establishments;

(e) the processed products of animal origin used in the composite product have undergone at least one of the treatments referred to in Article 163, point (a), of Delegated Regulation (EU) 2020/692, with a brief description of any processes undergone and temperatures applied to the composite product.

CHAPTER VII: Final provisions

Article 23
References

References to Article 29 of Directive 96/23/EC shall be construed as references to this Regulation.

Article 24
Repeal

Delegated Regulation (EU) 2019/625 is repealed.

References to the repealed Delegated Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex II.

Article 25

Entry into force and application

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

It shall apply from 15 December 2022.

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/11988/2017 ANNEX feedback
(POOL/G4/2017/11988/11988-EN
ANNEX.docx)
[…](2022) XXX draft

ANNEXES 1 to 2

ANNEXES

to the

Commission Delegated Regulation

supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of food-producing animals and certain goods intended for human consumption and repealing Commission Delegation Regulation (EU) 2019/625

ANNEX I

This Annex sets out the information on the control plans and updated control plans third countries are to submit for the purpose of their inclusion and maintenance in the list referred to in Article 6.

Part I

General requirements as regards the submission of control plans and updated control plans

1. The control plans third countries are to submit, together with their request for the inclusion in the list referred to in Article 6 for specific food-producing animals or products of animal origin, shall include the information specified in Part II of this Annex.

2. After a third country is included in the list referred to in point (1), for the purposes of maintenance on that list it shall submit annually updated control plans, with the information specified in Part III of this Annex.

3. Additional information to complement the control plans and updated control plans referred to in points (1) and (2) may be provided by third countries anytime.

4. The relevant guidance documents as regards contaminants, residues of veterinary medicinal products, prohibited substances and pesticides made publicly available by the Commission shall be taken into account by third countries for the submission of the control plans and updated control plans.

5. The control plans shall be sent to the Commission electronically, in the format described in the guidance documents referred to in point (4) or in another format, provided that it includes all of the information listed in Parts II and III, where applicable.

Part II [

Third country control plan – required information

The following information shall be provided:

A) Scope of the control plan

(1) List of categories of food-producing animals, products of animal origin, including those used as ingredients in composite products, covered by the control plan, including details on the species and sub-species of animals.

(2) Information on the origin of the food-producing animals and products of animal origin covered by the control plan, in particular whether they are produced, within the third country, entirely from animals or products of animal origin that originate from that country or whether they include animals or products of animal origin that originate from other third countries or Union Member States. If the food-producing animals and animal products are not produced in the third country submitting the control plan, information shall be provided on the countries of origin and the intended purpose of those animals and products of animal origin, in particular by explaining if the products of animal origin are intended for the entry into the Union as such or as ingredients of composite products intended for entry into the Union.

(3) National production data from the previous year for the animal species and animal products covered by the control plan.

(4) An explanation of whether, for the animals and products of animal origin concerned, the control plan covers the total national production or a proportion of the national production (for example, the production of certain farms/producers and the throughput of establishments intending for the entry into the Union). If only part of the national production is covered, a description of the system in place to ensure that only those animals and products of animal origin from that segregated population covered by the control plan are eligible for the Union market shall be provided.

B) Competent authorities responsible and their legal powers

(1) Contact details of the competent authorities: name and address of the central competent authority or authorities and contact point details for correspondence on the control plans (e.g., email addresses, telephone details).

(2) A description of the structure of the competent authorities, including, where relevant, the various levels of organisation (e.g. central, regional, local), the departments involved and organisational charts.

(3) A description of the role of the competent authorities involved in the implementation of the control plans, including on aspects related to the drawing up of the control plan, the coordination and supervision of the implementation of the control plan, the collection of samples, the collation and evaluation of results, the application of corrective measures, if required, that are effective, proportionate and dissuasive to stop re-occurrence, and the submission of updated control plans to the Commission.

(4) The legal basis of the control plan, including references to the specific provisions giving the competent authorities the right to enter the relevant premises, to collect samples, to carry out follow-up investigations where non-

compliant results are detected and to impose corrective actions in such cases, for example, restrictions on the movement of animals, the destruction of animals or the imposition of fines.

C) Pharmacologically active substances

(1) The requirements followed by the control plan, in particular whether such requirements are those referred to in Article 4 of Implementing Regulation (EU) 2022/xx (C(2022) 4401)[or equivalent. In the latter case, further details should be provided on how these requirements address all of the points listed under Part II, Sections C) to K), of this Annex.

(2) The list of groups of substances covered by the control plan for each animal species and products as specified in Part I of this Annex and as specified in:

(1) point A)(1) of Annex II to Delegated Regulation (EU) 2022/x (C(2022 4400)] for group A substances as referred to in Annex I to Delegated Regulation (EU) 2022/xx (C(2022) 4400

(2) point B)(1) of Annex II to Delegated Regulation (EU) 2022/x (C(2022) 4400[for group B substances as referred to in Annex I to Delegated Regulation (EU) 2022/xx (C(2022) 4400)[.

(3) For group B substances, the selection of groups covered by the control plan shall take into account the authorisation and use of such substances and the risks of residues in animals and products of animal origin intended for the entry into the Union.

(4) Within the groups of substances covered by the control plan: the list of substances and their marker residues to be analysed for the specific animal species and products in the specific matrices, including a justification for their selection based on the risk criteria set in Annex II to Delegated Regulation (EU) 2022/x (C(2022) 4400)[.

(5) The number of samples per animal species and products for each of the groups of substances covered by the control plan based on the control frequencies laid down in Annex I to Implementing Regulation (EU) 2022/xx (C(2022) 4401) [or providing equivalent guarantees. A description of the criteria for selection of sampling points and animals or animal products to be sampled based on the criteria laid down in Annex II to Delegated Regulation (EU) 2022/x (C(2022) 4400) [

(6) A description of the sampling strategy, explaining how it addresses the provisions of Annex III to Delegated Regulation (EU) 2022/x (C(2022) 4400) [

D) Pesticides

(1) The list of substances tested for in the control plan and the corresponding number of samples per category of food-producing animals and products of animal origin covered by the control programme in accordance with the requirements laid down in Implementing Regulation (EU) 2021/1355.

(2) A justification for the selection of substances covered by the control plan, in particular that the range of substances tested for is representative of the pesticides used.

(3) The controls should provide guarantees on the compliance of food of animal origin intended for entry into the Union with the maximum residue levels

referred to in Regulation (EC) No 396/2005. These guarantees should be provided for all pesticides authorised in the third country, in particular for those pesticides which are authorised in the third country, but not authorised in the Union.

(4) A justification for the selection of pesticides covered by the plan, taking into account the risks from animal feed and the environment and the pesticides for which maximum residue levels are established in the Union, as well as a justification for the number of samples planned, based on the level of confidence achieved in identifying a certain percentage of exceedance of the maximum residue levels set out in Union legislation for the animals and animal products intended for entry into the Union.

E) Contaminants

(1) The list of contaminants tested for in the control plan and the corresponding number of samples per category of food-producing animals and animal products covered by the control plan, in accordance with the requirements laid down in Delegated Regulation (EU) 2022/931 and Implementing Regulation (EU) 2022/932.

(2) A justification for the selection of contaminants covered by the control plan taking into account the risks from animal feed and the environment, as well the contaminants for which maximum limits have been set in the Union in the animal products covered by the control plan.

F) Analytical methods and laboratories

(1) The list of official laboratories or contracted laboratories, or both, involved in carrying out analyses for the control plans.

(2) The accreditation status, including the scope of accreditation, of each of the official laboratories carrying out analyses for the control plans.

(3) For each of the laboratories, a list of all the methods used in the control plan, with an indication on whether they are included or not in the scope of accreditation for the specific matrices of animal origin covered by the control plan.

(4) For each of the laboratories, a list of the methods used in the control plan, with an indication of whether they are validated in accordance with the relevant Union rules, or equivalent, or not validated, for the specific matrices covered by the control plans, specifying the standard used for validation.

(5) For each of the substances tested for in the control plan, a list of the analytical methods and regulatory standards to be used for interpreting analytical results and the performance requirements of the analytical methods, including information on:

(1) The analysed substance and marker residues;

(2) The analysed matrix;

(3) The analytical method identification (e.g. Elisa, LC-MS/MS, AAS);

(4) The analytical method type (screening or confirmatory);

(5) For the screening and confirmatory methods used, the limits of detection and limits of quantification or, if relevant, the decision limit for

confirmation (CCα) and detection capability for screening (CCß) as defined in Article 2 of Implementing Regulation (EU) 2021/808;

(6) The concentration above which a result is considered non-compliant for the purpose of the control plan. In particular, compliance with the limits set out in Union legislation should be verified and differences indicated.

G) Pharmacologically active substances authorised in veterinary medicinal products or as feed additives for use in food-producing animals and prohibitions on use in such animals

(1) The national legislation governing the placing on the market and conditions for use of veterinary medicinal products in relation to food-producing animal species covered by the control plan, including references to the relevant provisions covering the aforementioned points.

(2) The list of authorised veterinary medicinal products for the food-producing animal species covered by the control plan indicating for each product, the product name, the pharmacologically active substance(s) contained therein and target species. Those substances which are authorised in the third country but which are not authorised for such use in the Union shall be highlighted in the list. The list shall also include feed additives that are pharmacologically active, such as antibiotics, coccidiostats and histomonostats.

(3) A description of the system in place to ensure that, for each of the substances which are authorised in the third country for use in the animal species covered by the control plans, but not authorised for such use in the Union, there are no residues present at concentrations which can be reliably quantified in such animals or animal products intended for entry into the Union. Evidence shall be provided that such substances are tested for in the appropriate matrix in the control plan for the relevant animals and animal products.

(4) A statement on whether any of the substances included in Table 2 of Regulation (EU) No 37/2010 are authorised for use in the food-producing animal species covered by the control plan. If such substances are authorised, a description of the system ensuring that animals treated with such substances and products derived therefrom are not eligible for the entry into the Union shall be provided. If use of such substances in food-producing animals is prohibited in the third country, a reference to the national legal basis for that prohibition shall be provided.

(5) A confirmation that stilbene substances (i.e. stilbenes, stilbene derivatives, their salts and esters) or thyrostatic substances are not authorised for use in food-producing animal species covered by the control plan, regardless of their eligibility for entry into the Union, and a reference to the national legal basis for that prohibition.

(6) A statement on whether substances having a oestrogenic, androgenic or gestagenic action and beta-agonists are authorised for growth promotion purposes in the food-producing animal species covered by the control plans. If such substances are authorised, a detailed description of the system in place to ensure that treated animals are not eligible for the entry into the Union shall be provided. If such substances are either not authorised or are expressly prohibited, a reference to the national legal basis for the prohibition shall be provided.

H) Specific information for bovine, caprine and ovine animals and products of animal origin derived therefrom, including milk

(1) A statement on whether 17-beta oestradiol and its ester-like derivatives are authorised and used in veterinary medicinal products for any purpose in the species in question, including zootechnical or therapeutic treatments. If such substances are authorised, a description of the system ensuring that treated animals and the products derived therefrom are not eligible for the entry into the Union shall be provided. If such substances are prohibited, a reference to the national legal basis for the prohibition shall be provided.

(2) Bovine, caprine and ovine animals eligible for the entry into the Union from a third country included in the list of third countries with approved control plans referred to in Annex -I to Implementing Regulation 2021/405 shall originate in the territory of that third country, or in Union Member States, or in other third countries implementing a Union-approved control plan.

I) Specific information for honey

(1) If antimicrobial substances are authorised for the treatment or prevention of diseases in honeybees, a description of the system in place to provide guarantees that no residues are present, at concentrations which can be quantified, in honey intended for entry into the Union.

(2) Honey intended for entry into the Union from a third country included in a list of third countries with approved control plans as referred to in Annex -I to Implementing Regulation 2021/405 shall originate in the territory of that third country, or in Union Member States, or in other third countries implementing a Union-approved control plan.

J) Specific information for aquaculture

(1) If dyes are authorised for the treatment and prevention of disease at any stage of production, a description of the dyes used and the fishery products (including crustaceans) for which the treatment is authorised and of the system in place to provide guarantees that no residues are present at concentrations which can be quantified in aquaculture products intended for entry into the Union.

(2) Aquaculture products intended for the entry into the Union from a third country included in a list of third countries with approved control plans as referred to in Annex -I to Implementing Regulation 2021/405 shall originate in the territory of that third country, or in Union Member States, or in other third countries implementing a Union-approved control plan.

K) Specific information for equine animals

(1) A description of the system in place to ensure that equine animals treated with substances prohibited or not authorised in the Union for use in food-producing animals and products derived from such animals are not eligible for entry into the Union for human consumption. The following elements of such a system should be described:

(1) Identification and traceability of equine animals;

(2) Record keeping of administration of veterinary medicinal products;

(3) Records indicating all treatments with pharmacologically active substances.

(2) Where equine animals are treated with substances considered essential under Union rules, a description of the system in place to ensure that food derived from such animals is not eligible for the entry into the Union until six months have elapsed since the last treatment.

(3) Food-producing equine animals eligible for the entry into the Union shall originate from the territory of the third country, which intends to import equine animals or in other countries implementing a control plan approved by the Commission.

L) Specific information to be provided by the third countries referred to in Articles 7(1) and 7(2)

(1) A statement by the competent authority of the third country confirming that products of animal origin intended for entry into the Union as such, or as ingredients of composite products, only originate in approved third countries included in the list of third countries with approved control plans as referred to in Implementing Regulation (EU) 2021/405 for those food-producing animals or products of animal origin, and that the procedures it has in place for this purpose are sufficient to guarantee the traceability and origin of those products of animal origin.

(2) A comprehensive description, by the competent authority of the third country, of the procedures in place in the third country, to substantiate the statement referred to in point (1).

M) Specific information for casings

A description of the system in place to ensure that no antimicrobial substances, the use of which in food-producing animals is prohibited in the Union in accordance with Table 2 of the Annex to Regulation (EU) No 37/2010, are used in the treatment of casings.

Part III

Updated control plans

The following information shall be provided:

A) Changes introduced in the updated control plan

(1) Updated production data of the animals and animal products covered by the control plan and the impact on the number of planned samples.

(2) Details on any changes that have occurred since the previous annual submission of the control plan and which alter the information previously provided under Part II, Sections A) to M).

(3) In the absence of changes, a statement that no changes have occurred shall be included under Part II, Sections A) to M), when relevant.

B) Results of the implementation of the previous year's control plan

(1) The results of the implementation of the previous year’s control plan, together with the updated control plan.

(2) A justification for any discrepancies between the number of samples or the substance planned and the number of samples and/or the substances analysed.

(3) Details on results non-compliant with the Union maximum residue levels, maximum residue limits or maximum limits, including, for each of these non-compliant results, the dates of sampling, dates of availability of the analytical results, marker residues identified, concentrations measured, analytical methods used and the laboratories involved.

(4) For each of the non-compliant results, a description of the outcome of the follow-up investigations undertaken by the competent authorities, what the reason for the non-compliance was and any measures taken to prevent recurrence.

ANNEX II

Correlation table referred to in Article 24, second paragraph

Regulation (EU) 2019/625	This Regulation
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article 4	Article 4
Article 5	Article 13
Article 6	Article 14
Article 7	Article 15
Article 8	Article 16
Article 9	Article 17
Article 10	Article 18
Article 11	Article 19
Article 12	Article 20
Article 13	Article 21
Article 14	Article 22