

## II

(Non-legislative acts)

## DECISIONS

**COMMISSION IMPLEMENTING DECISION (EU) 2021/800**

**of 17 May 2021**

**amending Decision 2011/163/EU on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC**

(notified under document C(2021) 3291)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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 <sup>(1)</sup>, and in particular the fourth subparagraph of Article 29(1) and Article 29(2) thereof,

Whereas:

- (1) Article 29(1) of Directive 96/23/EC requires that third countries from which Member States are authorised to import animals and animal products covered by that Directive submit residue monitoring plans providing required guarantees ('the plans'). These guarantees must have an effect at least equivalent to those provided for in that Directive and must, in particular, meet the requirements of Article 4 of that Directive and specify the particulars laid down in Article 7 of that Directive and meet the requirements of Article 11(2) of Directive 96/22/EC. The plans should cover at least the groups of residues and substances listed in Annex I to the Directive 96/23.
- (2) Commission Decision 2011/163/EU <sup>(2)</sup> approves the plans submitted by certain third countries concerning animals and animal products, which are listed in the Annex to that Decision.
- (3) Animal casings may contain residues of pharmacologically active substances. Such residues have been found in casings imported into the Union and reported in the Rapid Alert System for Food and Feed since 2015 from some third countries and have concerned prohibited substances with an antimicrobial activity. Those residues may be present in casings due to the administration of antimicrobials to prevent their bacterial spoilage. Therefore, the Commission should ensure the chemical safety of casings by requiring that animal casings enter into the Union only from third countries listed in the Annex to Decision 2011/163/EU, which have provided the required guarantees for this commodity in their approved residue monitoring plans. Article 2(1) of Decision 2011/163/EU should be amended accordingly.

<sup>(1)</sup> OJ L 125, 23.5.1996, p. 10.

<sup>(2)</sup> 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).

- (4) Third countries authorised for the entry into the Union of certain meat products and treated stomachs, bladders and intestines for human consumption in accordance with Regulation (EU) 2017/625 <sup>(3)</sup> are listed in Commission Implementing Regulation (EU) 2021/404 <sup>(4)</sup>. Third countries authorised for the entry into the Union of certain meat products in accordance with Regulation (EU) 2016/429 <sup>(5)</sup> are listed in Commission Implementing Regulation (EU) 2021/405 <sup>(6)</sup>.
- (5) In order to minimise trade disruptions, all of the third countries currently authorised for entry into the Union of meat products in Implementing Regulations (EU) 2021/404 and (EU) 2021/405 and which are already listed in the Annex to Decision 2011/163/EU should also be listed for in that Annex for animal casings, as they have already provided sufficient guarantees related to the residues surveillance. In addition, with casings, the risk arises not from the treatment of the animal but from adulteration of the product to prevent bacterial spoilage.
- (6) In addition, those third countries, which have successfully completed the questionnaire related to animal and public health with a view to be included in Implementing Regulations (EU) 2021/404 and (EU) 2021/405, should also be listed for casings in the Annex to Decision 2011/163/EU, provided that they have submitted to the Commission a specific residues monitoring plan for animal casings and that plan has been approved by the Commission.
- (7) A definitive list of countries complying with the requirements of Directive 96/23/EC, related to the absence of prohibited substances with an antimicrobial activity in casings, will be established by the Commission after the full evaluation of the residue monitoring plans presented by all third countries exporting casings to the Union, and before the end of the transitional period expiring on 20 October 2021.
- (8) While Australia has no approved residues monitoring plan for eggs, it has provided guarantees to use only eggs, originating either from Member States or from third countries which are approved to export such products to the Union, to be included in composite products to be exported to the EU. An entry for Australia regarding eggs with the appropriate footnote should therefore be added to the list.
- (9) While India has no approved residues monitoring plan for poultry products and dairy products, it has provided guarantees to use only dairy products, originating either from Member States or from third countries, which are approved to export such products to the Union, to be included in composite products to be exported to the EU. An entry for India regarding dairy products with the appropriate footnote should therefore be added to the list.
- (10) While New Zealand has no approved residues monitoring plan for porcine species, poultry products, eggs and rabbit, it has provided guarantees to use only pork products, poultry products, eggs and rabbit, to be included in composite products to be exported to the EU, originating either from Member States or from third countries, which are approved to export such products to the Union. An entry for New Zealand regarding porcine species, poultry products, eggs and rabbit with the appropriate footnote should therefore be added to the list.

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<sup>(3)</sup> 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 (OJ L 95, 7.4.2017, p. 1).

<sup>(4)</sup> 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 the Council (OJ L 114, 31.3.2021, p. 1).

<sup>(5)</sup> Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1).

<sup>(6)</sup> 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).

- (11) While Philippines has no approved residues monitoring plan for dairy products, and eggs, it has provided guarantees to use only dairy products and eggs, originating either from Member States or from third countries, which are approved to export such products to the Union, to be included in composite products to be exported to the EU. An entry for Philippines regarding dairy products, and eggs with the appropriate footnote should therefore be added to the list.
- (12) While Singapore has no approved residues monitoring plan for eggs, it has provided guarantees to use only eggs originating either from Member States or from third countries, which are approved to export such products to the Union, to be included in composite products to be exported to the EU. An entry for Singapore regarding eggs with the appropriate footnote should therefore be added to the list.
- (13) While Thailand has no approved residues monitoring plan for bovine species, porcine species, dairy products, and eggs, it has provided guarantees to use only bovine, dairy products, and eggs, originating either from Member States or from third countries, which are approved to export such products to the Union, to be included in composite products to be exported to the EU. An entry for Thailand regarding bovine species, dairy products, and eggs with the appropriate footnote should therefore be added to the list.
- (14) While South Korea has no approved residues monitoring plan for dairy products, eggs, and honey, it has provided guarantees to use only dairy products, eggs, and honey, originating either from Member States or from third countries, which are approved to export such products to the Union, to be included in composite products to be exported to the EU. An entry for South Korea regarding dairy products, eggs, and honey with the appropriate footnote should therefore be added to the list.
- (15) Decision 2011/163/EU should therefore be amended accordingly.
- (16) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

#### *Article 1*

For the purpose of this Decision, the definitions laid down in Article 2 of Commission Delegated Regulation (EU) 2020/692 <sup>(7)</sup> apply.

#### *Article 2*

Article 2(1) of Decision 2011/163/EU is replaced by the following:

‘1. With the exception of raw material used for the production of casings, third countries using raw material imported from other third countries approved for production of food of animal origin in accordance with this Decision or from Member States to be exported to the Union and which are unable to provide a residue monitoring plan equivalent to that required by Article 7 of Directive 96/23/EC for such raw material shall complement the plan with the following statement: “The competent authority of [third country] ensures that animal products for human consumption exported to the European Union, in particular products produced from raw material imported into [third country], shall only come from establishments listed in accordance with Article 5 of Commission Delegated Regulation (EU) 2019/625 <sup>(\*)</sup> and having reliable procedures in place to guarantee that raw material of animal origin used in such food originates only from Member States of the European Union or third countries listed for the respective raw material in the Annex to Decision 2011/163/EU without a restrictive footnote as provided for in Article 2(2) of the Decision.”.

For the production of casings intended for export to the Union, third countries may use raw material imported from other third countries, which are authorised for the entry into the Union of fresh meat, or of certain meat products and treated stomachs, bladders and intestines in Implementing Regulations (EU) 2021/404 and (EU) 2021/405.

<sup>(7)</sup> 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 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).

The third country intending to export casings to the Union shall be listed in Implementing Regulations (EU) 2021/404 and (EU) 2021/405 for casings, as well as in the Annex to Decision 2011/163/EU (for casings). In addition, the establishments from which the casings are to be exported to the Union shall be listed in accordance with Article 5 of Delegated Regulation (EU) 2019/625.

(\*) 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).<sup>1</sup>

*Article 3*

The Annex to Decision 2011/163/EU is replaced by the text set out in the Annex to this Decision.

*Article 4*

This Decision is addressed to the Member States.

Done at Brussels, 17 May 2021.

*For the Commission*  
Stella KYRIAKIDES  
*Member of the Commission*

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## ANNEX

## 'ANNEX

Code ISO2	Country (1)	Bovine	Ovine/caprine	Porcine	Equine	Poultry	Aqua-culture	Milk	Eggs	Rabbit	Wild game	Farmed game	Honey	Casings
AD	Andorra	X	X	X (4)	X								X	
AE	United Arab Emirates						X (4)	X (2)						
AL	Albania		X				X (2)		X					X
AM	Armenia						X						X	
AR	Argentina	X	X		X	X	X	X	X	X	X	X	X	X
AU	Australia	X	X		X		X	X	X 4bis		X	X	X	X
BA	Bosnia and Herzegovina	X	X	X		X	X (2)	X	X				X	
BD	Bangladesh						X							
BF	Burkina Faso												X	
BJ	Benin												X	
BN	Brunei						X							
BR	Brazil	X			X	X	X						X	X
BW	Botswana	X												
BY	Belarus				X (2)		X	X	X				X	X
BZ	Belize						X							
CA	Canada	X	X	X	X	X	X	X	X	X	X	X	X	X
CH	Switzerland	X	X	X	X	X	X	X	X	X	X	X	X	X
CL	Chile	X	X	X		X	X	X			X		X	X
CM	Cameroon												X	
CN	China					X	X		X	X			X	X
CO	Colombia						X	X	X (4)					X
CR	Costa Rica						X							

Code ISO2	Country (1)	Bovine	Ovine/caprine	Porcine	Equine	Poultry	Aqua-culture	Milk	Eggs	Rabbit	Wild game	Farmed game	Honey	Casings
CU	Cuba						X						X	
DO	Dominican Republic												X	
EC	Ecuador						X							
ET	Ethiopia												X	
FK	Falkland Islands	X	X (13)				X (2)							
FO	Faroes						X (2)							
GB	Great Britain	X	X	X	X	X	X	X	X	X	X	X	X	X
GE	Georgia												X	
GG	Guernsey	X						X						
GH	Ghana												X	
GL	Greenland		X									X		
GT	Guatemala						X (11)						X	
HN	Honduras						X							
ID	Indonesia						X							
IL	Israel (7)					X	X	X	X				X	
IM	Isle of Man	X	X	X			X	X					X	
IN	India					X 4bis	X	X 4bis	X				X	X
IR	Iran						X (11)							X
JE	Jersey	X						X						
JM	Jamaica												X	
JP	Japan	X		X		X	X	X	X					X
KE	Kenya						X							
KR	South Korea					X	X	X 4bis	X 4bis				X 4bis	
LBN	Lebanon													X

Code ISO2	Country (1)	Bovine	Ovine/caprine	Porcine	Equine	Poultry	Aqua-culture	Milk	Eggs	Rabbit	Wild game	Farmed game	Honey	Casings
LK	Sri Lanka						X							
MA	Morocco					X	X (9)							X
MD	Moldova					X	X (9)	X	X				X	
ME	Montenegro	X	X (13)	X		X	X (9)	X	X				X	
MG	Madagascar						X						X	
MK	North Macedonia	X	X	X		X	X	X	X		X		X	
MM	Myanmar						X						X	
MU	Mauritius						X						X (4)	
MX	Mexico						X		X				X	X
MY	Malaysia					X (4)	X							
MZ	Mozambique						X (11)							
NA	Namibia	X	X (13)								X			
NC	New Caledonia						X (11)					X	X	
NI	Nicaragua						X (11)						X	
NG	Nigeria						X (11)							
NZ	New Zealand	X	X	X 4bis	X	X 4bis	X	X	X 4bis	X 4bis	X	X	X	X
OM	Oman						X (9)							
PA	Panama						X							
PK	Pakistan													X
PE	Peru						X							
PH	Philippines						X	X 4bis	X 4bis					
PM	Saint Pierre and Miquelon					X								
PN	Pitcairn Islands												X	
PY	Paraguay	X												X

Code ISO2	Country <sup>(1)</sup>	Bovine	Ovine/caprine	Porcine	Equine	Poultry	Aqua-culture	Milk	Eggs	Rabbit	Wild game	Farmed game	Honey	Casings
RS	Serbia <sup>(5)</sup>	X	X	X	X <sup>(3)</sup>	X	X	X	X		X		X	X
RU	Russia	X	X	X		X		X	X			X <sup>(6)</sup>	X	X
RW	Rwanda												X	
SA	Saudi Arabia						X							
SG	Singapore	X <sup>(4)</sup>	X <sup>(4)</sup>	X <sup>(4)</sup>	X <sup>(8)</sup>	X <sup>(4)</sup>	X	X <sup>(4)</sup>	X <sup>4bis</sup>		X <sup>(8)</sup>	X <sup>(8)</sup>		
SL	Sierra Leone												X	
SM	San Marino	X		X <sup>(4)</sup>				X					X	
SV	El Salvador												X	
SZ	Eswatini	X												
TG	Togo												X	
TH	Thailand	X <sup>4bis</sup>		X <sup>4bis</sup>		X	X	X <sup>4bis</sup>	X <sup>4bis</sup>				X	
TN	Tunisia						X <sup>(9)</sup>				X			X
TR	Turkey					X	X	X	X				X	X
TW	Taiwan						X		X				X	
TZ	Tanzania						X <sup>(11)</sup>						X	
UA	Ukraine	X		X		X	X <sup>(9)</sup>	X	X	X			X	X
UG	Uganda						X						X	
US	United States	X	X <sup>(12)</sup>	X		X	X	X	X	X	X	X	X	X
UY	Uruguay	X	X		X		X	X			X		X	X
VE	Venezuela						X							
VN	Vietnam						X						X	
XK	Kosovo <sup>(14)</sup>					X <sup>(4)</sup>								
ZA	South Africa										X	X <sup>(10)</sup>		
ZM	Zambia												X	



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- (<sup>1</sup>) The table contains a list of countries and territories. It is not limited to countries recognised by the EU.
- (<sup>2</sup>) Camel milk only.
- (<sup>3</sup>) Export to the Union of live equidae for slaughter (food producing animals only).
- (<sup>4</sup>) Third countries using only raw material either from Member States or from other third countries approved for imports of such raw material to the Union, in accordance with Article 2.
- <sup>4bis</sup> Third countries using only raw material either from Member States or from other third countries approved for imports of such raw material to the Union, in accordance with Article 2, with the purpose to be used only for the preparation of composite products to be exported to the EU.
- (<sup>5</sup>) Not including Kosovo.
- (<sup>6</sup>) Reindeer only.
- (<sup>7</sup>) Hereafter understood as the State of Israel, excluding the territories under Israeli administration since June 1967, namely the Golan Heights, the Gaza Strip, East Jerusalem and the rest of the West Bank.
- (<sup>8</sup>) Only for commodities of fresh meat originating from New Zealand, destined to the Union and being unloaded, reloaded and transited with or without storage through Singapore.
- (<sup>9</sup>) Excluding crustaceans.
- (<sup>10</sup>) Ratites only.
- (<sup>11</sup>) Excluding finfish.
- (<sup>12</sup>) Caprine species only.
- (<sup>13</sup>) Ovine species only.
- (<sup>14</sup>) This designation is without prejudice to positions on status, and is in line with UNSC 1244 and the ICJ Opinion on the Kosovo Declaration of Independence.’
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