Non-legislative acts

INTERNATIONAL AGREEMENTS

* Council Decision (EU) 2017/2182 of 20 November 2017 on the signing, on behalf of the European Union, of an Agreement in the form of an Exchange of Letters between the European Union and the Kingdom of Norway concerning additional trade preferences in agricultural products ................................................................. 1

REGULATIONS

* Commission Implementing Regulation (EU) 2017/2183 of 21 November 2017 approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications (‘Arancia del Gargano’ (PGI)) ................................................................. 3

* Commission Implementing Regulation (EU) 2017/2184 of 22 November 2017 amending Regulation (EC) No 1484/95 as regards fixing representative prices in the poultry meat and egg sectors and for egg albumin ........................................................................................................ 4


Commission Implementing Regulation (EU) 2017/2186 of 23 November 2017 on the minimum selling price for skimmed milk powder for the fourteenth partial invitation to tender within the tendering procedure opened by Implementing Regulation (EU) 2016/2080 ..................................................... 18

(1) Text with EEA relevance.
II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION (EU) 2017/2182
of 20 November 2017

on the signing, on behalf of the European Union, of an Agreement in the form of an Exchange of Letters between the European Union and the Kingdom of Norway concerning additional trade preferences in agricultural products

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first subparagraph of Article 207(4), in conjunction with Article 218(5) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) Article 19 of the Agreement on the European Economic Area (the EEA Agreement) provides that the Contracting Parties undertake to continue their efforts with a view to achieving progressive liberalisation of agricultural trade.

(2) On 18 November 2014, the Council authorised the Commission to open negotiations with Norway with a view to achieving greater liberalisation of bilateral trade in agricultural products under Article 19 of the EEA Agreement. The negotiations were successfully concluded and an Agreement in the form of an Exchange of Letters between the European Union and the Kingdom of Norway concerning additional trade preferences in agricultural products (the Agreement) was initialled on 5 April 2017.

(3) The Agreement should be signed on behalf of the Union, subject to its conclusion,

HAS ADOPTED THIS DECISION:

Article 1

The signing on behalf of the Union of the Agreement in the form of an Exchange of Letters between the European Union and the Kingdom of Norway concerning additional trade preferences in agricultural products is hereby authorised, subject to the conclusion of the said Agreement (1).

Article 2

The President of the Council is hereby authorised to designate the person(s) empowered to sign the Agreement on behalf of the Union.

(1) The text of the Agreement will be published in the Official Journal together with the decision on its conclusion.
Article 3

This Decision shall enter into force on the date of its adoption.


For the Council

The President

M. MAASIKAS
REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2183

of 21 November 2017

approving non-minor amendments to the specification for a name entered in the register of protected designations of origin and protected geographical indications (‘Arancia del Gargano’ (PGI))

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs (1), and in particular Article 52(2) thereof,

Whereas:

(1) Pursuant to the first subparagraph of Article 53(1) of Regulation (EU) No 1151/2012, the Commission examined Italy’s application for the approval of amendments to the specification for the protected geographical indication ‘Arancia del Gargano’, registered under Commission Regulation (EC) No 1017/2007 (2).

(2) Since the amendments in question are not minor within the meaning of Article 53(2) of Regulation (EU) No 1151/2012, the Commission published the amendment application in the Official Journal of the European Union (3) as required by Article 50(2)(a) of that Regulation.

(3) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the amendments to the specification should be approved,

HAS ADOPTED THIS REGULATION:

Article 1

The amendments to the specification published in the Official Journal of the European Union regarding the name ‘Arancia del Gargano’ (PGI) are hereby approved.

Article 2

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

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


For the Commission,

On behalf of the President,

Phil HOGAN

Member of the Commission

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2184
of 22 November 2017
amending Regulation (EC) No 1484/95 as regards fixing representative prices in the poultrymeat and egg sectors and for egg albumin

THE EUROPEAN COMMISSION,

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


Having regard to Regulation (EU) No 510/2014 of the European Parliament and of the Council of 16 April 2014 laying down the trade arrangements applicable to certain goods resulting from the processing of agricultural products and repealing Council Regulations (EC) No 1216/2009 and (EC) No 614/2009 (2), and in particular Article 5(6)(a) thereof,

Whereas:

(1) Commission Regulation (EC) No 1484/95 (3) lays down detailed rules for implementing the system of additional import duties and fixes representative prices in the poultrymeat and egg sectors and for egg albumin.

(2) Regular monitoring of the data used to determine representative prices for poultrymeat and egg products and for egg albumin shows that the representative import prices for certain products should be amended to take account of variations in price according to origin.

(3) Regulation (EC) No 1484/95 should therefore be amended accordingly.

(4) Given the need to ensure that this measure applies as soon as possible after the updated data have been made available, this Regulation should enter into force on the day of its publication,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 1484/95 is replaced by the text set out in the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 22 November 2017.

For the Commission,

On behalf of the President,

Jerzy PLEWA

Director-General

Directorate-General for Agriculture and Rural Development
ANNEX

'ANNEX I

<table>
<thead>
<tr>
<th>CN code</th>
<th>Description</th>
<th>Representative price (EUR/100 kg)</th>
<th>Security under Article 3 (EUR/100 kg)</th>
<th>Origin (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0207 12 10</td>
<td>Fowls of the species Gallus domesticus, not cut in pieces, presented as &quot;70% chickens&quot;, frozen</td>
<td>113.2</td>
<td>0</td>
<td>AR</td>
</tr>
<tr>
<td>0207 12 90</td>
<td>Fowls of the species Gallus domesticus, not cut in pieces, presented as &quot;65% chickens&quot;, frozen</td>
<td>119.3</td>
<td>0</td>
<td>AR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>126.0</td>
<td>0</td>
<td>BR</td>
</tr>
<tr>
<td>0207 14 10</td>
<td>Fowls of the species Gallus domesticus, boneless cuts, frozen</td>
<td>236.5</td>
<td>19</td>
<td>AR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>216.9</td>
<td>25</td>
<td>BR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>303.0</td>
<td>0</td>
<td>CL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>237.5</td>
<td>19</td>
<td>TH</td>
</tr>
<tr>
<td>0207 27 10</td>
<td>Turkeys, boneless cuts, frozen</td>
<td>331.4</td>
<td>0</td>
<td>BR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>346.9</td>
<td>0</td>
<td>CL</td>
</tr>
<tr>
<td>0408 91 80</td>
<td>Eggs, not in shell, dried</td>
<td>343.3</td>
<td>0</td>
<td>AR</td>
</tr>
<tr>
<td>1602 32 11</td>
<td>Preparations of fowls of the species Gallus domesticus, uncooked</td>
<td>195.6</td>
<td>27</td>
<td>BR</td>
</tr>
</tbody>
</table>

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2185
of 23 November 2017


(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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


Whereas:

(1) Conformity assessment of medical devices under Regulation (EU) 2017/745 and Regulation (EU) 2017/746 may require involvement of conformity assessment bodies. Only conformity assessment bodies that have been designated under Regulation (EU) 2017/745 or Regulation (EU) 2017/746 may carry out such assessment and only for the activities related to the types of devices concerned. In order to enable specifying the scope of the designation of conformity assessment bodies notified under Regulation (EU) 2017/745 or Regulation (EU) 2017/746 it is necessary to draw up list of codes and corresponding types of devices.

(2) The lists of codes and corresponding types of devices should take into account various device types which can be characterised by design and intended purpose, manufacturing processes and technologies used, such as sterilisation and the use of nanomaterials. The lists of codes should provide for a multi-dimensional typology of devices which ensures that conformity assessment bodies designated as notified bodies are fully competent for the devices they are required to assess.

(3) In accordance with Article 42(3) of Regulation (EU) 2017/745 and Article 38(3) of Regulation (EU) 2017/746, when notifying the Commission and the other Member States of the conformity assessment bodies they have designated Member States are to clearly specify, using the codes, the scope of the designation indicating the conformity assessment activities and the types of devices which the notified body is authorised to assess. In order to facilitate such notification and the assessment of the application for designation referred to in Article 38 of Regulation (EU) 2017/745 and Article 34 of Regulation (EU) 2017/746, conformity assessment bodies should use the lists of codes and corresponding types of devices set out in this Regulation when applying for designation.

(4) Experience shows that conformity assessment bodies applying for designation in the field of in vitro diagnostic medical devices also apply for designation for medical devices under Regulation (EU) 2017/745. It is therefore appropriate, for reasons of user-friendliness, to include the lists of codes for Regulation (EU) 2017/745 and for Regulation (EU) 2017/746 in one Implementing Regulation.

(5) As of 26 November 2017, conformity assessment bodies may submit an application for designation as a notified body under Regulation (EU) 2017/745 and Regulation (EU) 2017/746. In order to enable the conformity assessment bodies to use the codes laid down in this Regulation in the application for designation, this Regulation should enter into force on the day following that of its publication in the Official Journal of the European Union.

HAS ADOPTED THIS REGULATION:

Article 1

List of codes

1. The list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745 is set out in Annex I to this Regulation.

2. The list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of in vitro diagnostic medical devices under Regulation (EU) 2017/746 is set out in Annex II to this Regulation.

Article 2

Application for designation

Conformity assessment bodies shall use the lists of codes and corresponding types of devices set out in Annexes I and II to this Regulation when specifying the types of devices in the application for designation referred to in Article 38 of Regulation (EU) 2017/745 and Article 34 of Regulation (EU) 2017/746.

Article 3

Entry into force

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

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

Done at Brussels, 23 November 2017.

For the Commission

The President

Jean-Claude JUNCKER
**ANNEX I**

The list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of medical devices under Regulation (EU) 2017/745

I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE

A. Active devices

1. Active implantable devices

<table>
<thead>
<tr>
<th>MDA CODE</th>
<th>Active implantable devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDA 0101</td>
<td>Active implantable devices for stimulation/inhibition/monitoring</td>
</tr>
<tr>
<td>MDA 0102</td>
<td>Active implantable devices delivering drugs or other substances</td>
</tr>
<tr>
<td>MDA 0103</td>
<td>Active implantable devices supporting or replacing organ functions</td>
</tr>
<tr>
<td>MDA 0104</td>
<td>Active implantable devices utilising radiation and other active implantable devices</td>
</tr>
</tbody>
</table>

2. Active non-implantable devices for imaging, monitoring and/or diagnosis

<table>
<thead>
<tr>
<th>MDA CODE</th>
<th>Active non-implantable devices for imaging, monitoring and/or diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDA 0201</td>
<td>Active non-implantable imaging devices utilising ionizing radiation</td>
</tr>
<tr>
<td>MDA 0202</td>
<td>Active non-implantable imaging devices utilising non-ionizing radiation</td>
</tr>
<tr>
<td>MDA 0203</td>
<td>Active non-implantable devices for monitoring of vital physiological parameters</td>
</tr>
<tr>
<td>MDA 0204</td>
<td>Other active non-implantable devices for monitoring and/or diagnosis</td>
</tr>
</tbody>
</table>

3. Active non-implantable therapeutic devices and general active non-implantable devices

<table>
<thead>
<tr>
<th>MDA CODE</th>
<th>Active non-implantable therapeutic devices and general active non-implantable devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDA 0301</td>
<td>Active non-implantable devices utilising ionizing radiation</td>
</tr>
<tr>
<td>MDA 0302</td>
<td>Active non-implantable devices utilising non-ionizing radiation</td>
</tr>
<tr>
<td>MDA 0303</td>
<td>Active non-implantable devices utilising hyperthermia/hypothermia</td>
</tr>
<tr>
<td>MDA 0304</td>
<td>Active non-implantable devices for shock-wave therapy (lithotripsy)</td>
</tr>
<tr>
<td>MDA 0305</td>
<td>Active non-implantable devices for stimulation or inhibition</td>
</tr>
<tr>
<td>MDA 0306</td>
<td>Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis</td>
</tr>
<tr>
<td>MDA 0307</td>
<td>Active non-implantable respiratory devices</td>
</tr>
<tr>
<td>MDA 0308</td>
<td>Active non-implantable devices for wound and skin care</td>
</tr>
<tr>
<td>MDA 0309</td>
<td>Active non-implantable ophthalmologic devices</td>
</tr>
<tr>
<td>MDA 0310</td>
<td>Active non-implantable devices for ear, nose and throat</td>
</tr>
<tr>
<td>MDA CODE</td>
<td>Active non-implantable therapeutic devices and general active non-implantable devices</td>
</tr>
<tr>
<td>----------</td>
<td>-------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>MDA 0311</td>
<td>Active non-implantable dental devices</td>
</tr>
<tr>
<td>MDA 0312</td>
<td>Other active non-implantable surgical devices</td>
</tr>
<tr>
<td>MDA 0313</td>
<td>Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport</td>
</tr>
<tr>
<td>MDA 0314</td>
<td>Active non-implantable devices for processing and preservation of human cells, tissues or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)</td>
</tr>
<tr>
<td>MDA 0315</td>
<td>Software</td>
</tr>
<tr>
<td>MDA 0316</td>
<td>Medical gas supply systems and parts thereof</td>
</tr>
<tr>
<td>MDA 0317</td>
<td>Active non-implantable devices for cleaning, disinfection and sterilisation</td>
</tr>
<tr>
<td>MDA 0318</td>
<td>Other active non-implantable devices</td>
</tr>
</tbody>
</table>

### B. Non-active devices

#### 1. Non-active implants and long term surgically invasive devices

<table>
<thead>
<tr>
<th>MDN CODE</th>
<th>Non-active implants and long term surgically invasive devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDN 1101</td>
<td>Non-active cardiovascular, vascular and neurovascular implants</td>
</tr>
<tr>
<td>MDN 1102</td>
<td>Non-active osteo- and orthopaedic implants</td>
</tr>
<tr>
<td>MDN 1103</td>
<td>Non-active dental implants and dental materials</td>
</tr>
<tr>
<td>MDN 1104</td>
<td>Non-active soft tissue and other implants</td>
</tr>
</tbody>
</table>

#### 2. Non-active non-implantable devices

<table>
<thead>
<tr>
<th>MDN CODE</th>
<th>Non-active non-implantable devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDN 1201</td>
<td>Non-active non-implantable devices for anaesthesia, emergency and intensive care</td>
</tr>
<tr>
<td>MDN 1202</td>
<td>Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis</td>
</tr>
<tr>
<td>MDN 1203</td>
<td>Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools</td>
</tr>
<tr>
<td>MDN 1204</td>
<td>Non-active non-implantable devices for wound and skin care</td>
</tr>
<tr>
<td>MDN 1205</td>
<td>Non-active non-implantable orthopaedic and rehabilitation devices</td>
</tr>
<tr>
<td>MDN 1206</td>
<td>Non-active non-implantable ophthalmologic devices</td>
</tr>
<tr>
<td>MDN 1207</td>
<td>Non-active non-implantable diagnostic devices</td>
</tr>
<tr>
<td>MDN 1208</td>
<td>Non-active non-implantable instruments</td>
</tr>
</tbody>
</table>
II. HORIZONTAL CODES

1. Devices with specific characteristics

<table>
<thead>
<tr>
<th>MDS CODE</th>
<th>Devices with specific characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDS 1001</td>
<td>Devices incorporating medicinal substances</td>
</tr>
<tr>
<td>MDS 1002</td>
<td>Devices manufactured utilising tissues or cells of human origin, or their derivatives</td>
</tr>
<tr>
<td>MDS 1003</td>
<td>Devices manufactured utilising tissues or cells of animal origin, or their derivatives</td>
</tr>
<tr>
<td>MDS 1004</td>
<td>Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)</td>
</tr>
<tr>
<td>MDS 1005</td>
<td>Devices in sterile condition</td>
</tr>
<tr>
<td>MDS 1006</td>
<td>Reusable surgical instruments</td>
</tr>
<tr>
<td>MDS 1007</td>
<td>Devices incorporating or consisting of nanomaterial</td>
</tr>
<tr>
<td>MDS 1008</td>
<td>Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body</td>
</tr>
<tr>
<td>MDS 1009</td>
<td>Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices</td>
</tr>
<tr>
<td>MDS 1010</td>
<td>Devices with a measuring function</td>
</tr>
<tr>
<td>MDS 1011</td>
<td>Devices in systems or procedure packs</td>
</tr>
<tr>
<td>MDS 1012</td>
<td>Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745</td>
</tr>
<tr>
<td>MDS 1013</td>
<td>Class III custom-made implantable devices</td>
</tr>
<tr>
<td>MDS 1014</td>
<td>Devices incorporating as an integral part an in vitro diagnostic device</td>
</tr>
</tbody>
</table>

2. Devices for which specific technologies or processes are used

<table>
<thead>
<tr>
<th>MDT CODE</th>
<th>Devices for which specific technologies or processes are used</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDT 2001</td>
<td>Devices manufactured using metal processing</td>
</tr>
<tr>
<td>MDT 2002</td>
<td>Devices manufactured using plastic processing</td>
</tr>
<tr>
<td>MDT 2003</td>
<td>Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)</td>
</tr>
<tr>
<td>MDT 2004</td>
<td>Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)</td>
</tr>
<tr>
<td>MDT 2005</td>
<td>Devices manufactured using biotechnology</td>
</tr>
<tr>
<td>MDT 2006</td>
<td>Devices manufactured using chemical processing</td>
</tr>
<tr>
<td>MDT 2007</td>
<td>Devices which require knowledge regarding the production of pharmaceuticals</td>
</tr>
<tr>
<td>MDT 2008</td>
<td>Devices manufactured in clean rooms and associated controlled environments</td>
</tr>
<tr>
<td>MDT 2009</td>
<td>Devices manufactured using processing of materials of human, animal, or microbial origin</td>
</tr>
<tr>
<td>MDT 2010</td>
<td>Devices manufactured using electronic components including communication devices</td>
</tr>
<tr>
<td>MDT 2011</td>
<td>Devices which require packaging, including labelling</td>
</tr>
<tr>
<td>MDT 2012</td>
<td>Devices which require installation, refurbishment</td>
</tr>
<tr>
<td>MDT 2013</td>
<td>Devices which have undergone reprocessing</td>
</tr>
</tbody>
</table>
ANNEX II

The list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies in the field of in vitro diagnostic medical devices under Regulation (EU) 2017/746

I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE

1. Devices intended to be used for blood grouping

<table>
<thead>
<tr>
<th>IVR CODE</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVR 0101</td>
<td>Devices intended to determine markers of the ABO system [A (ABO1), B (ABO2), AB (ABO3)]</td>
</tr>
<tr>
<td>IVR 0102</td>
<td>Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]</td>
</tr>
<tr>
<td>IVR 0103</td>
<td>Devices intended to determine markers of the Kell system [Kel1 (K)]</td>
</tr>
<tr>
<td>IVR 0104</td>
<td>Devices intended to determine markers of the Kidd system [JK1 (Jka), JK2 (Jkb)]</td>
</tr>
<tr>
<td>IVR 0105</td>
<td>Devices intended to determine markers of the Duffy system [FY1 (Fya), FY2 (Fyb)]</td>
</tr>
<tr>
<td>IVR 0106</td>
<td>Other devices intended to be used for blood grouping</td>
</tr>
</tbody>
</table>

2. Devices intended to be used for tissue typing

<table>
<thead>
<tr>
<th>IVR CODE</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVR 0201</td>
<td>Devices intended to be used for tissue typing (HLA A, B, DR) to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration</td>
</tr>
<tr>
<td>IVR 0202</td>
<td>Other devices intended to be used for tissue typing</td>
</tr>
</tbody>
</table>

3. Devices intended to be used for markers of cancer and non-malignant tumours

<table>
<thead>
<tr>
<th>IVR CODE</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVR 0301</td>
<td>Devices intended to be used in screening, diagnosis, staging or monitoring of cancer</td>
</tr>
<tr>
<td>IVR 0302</td>
<td>Other devices intended to be used for markers of cancer and non-malignant tumours</td>
</tr>
</tbody>
</table>

4. Devices intended to be used for human genetic testing

<table>
<thead>
<tr>
<th>IVR CODE</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVR 0401</td>
<td>Devices intended to be used in screening/confirmation of congenital/inherited disorders</td>
</tr>
</tbody>
</table>
5. Devices intended to be used to determine markers of infections/immune status

<table>
<thead>
<tr>
<th>IVR CODE</th>
<th>Devices intended to be used for the screening, confirmation, identification of infectious agents or determination of immune status</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVR 0501</td>
<td>Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents</td>
</tr>
<tr>
<td>IVR 0502</td>
<td>Devices intended to be used to detect the presence of, or exposure to transmissible agents in blood, blood components, cells, tissues or organs, or in any of their derivatives, to assess their suitability for transfusion, transplantation or cell administration</td>
</tr>
<tr>
<td>IVR 0503</td>
<td>Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents</td>
</tr>
<tr>
<td>IVR 0504</td>
<td>Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging</td>
</tr>
<tr>
<td>IVR 0505</td>
<td>Devices intended to be used to grow/isolate/identify and handle infectious agents</td>
</tr>
<tr>
<td>IVR 0506</td>
<td>Other devices intended to be used to determine markers of infections/immune status</td>
</tr>
</tbody>
</table>

6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures

<table>
<thead>
<tr>
<th>IVR CODE</th>
<th>Devices intended to be used for a specific disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVR 0601</td>
<td>Devices intended to be used for screening/confirmation of specific disorders/impairments</td>
</tr>
<tr>
<td>IVR 0602</td>
<td>Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease</td>
</tr>
<tr>
<td>IVR 0603</td>
<td>Devices intended to be used for screening, confirmation/determination, or monitoring of allergies and intolerances</td>
</tr>
<tr>
<td>IVR 0604</td>
<td>Other devices intended to be used for a specific disease</td>
</tr>
<tr>
<td></td>
<td>Devices intended to be used to define or monitor physiological status and therapeutic measures</td>
</tr>
<tr>
<td>IVR 0605</td>
<td>Devices intended to be used for monitoring of levels of medicinal products, substances or biological components</td>
</tr>
<tr>
<td>IVR 0606</td>
<td>Devices intended to be used for non-infectious disease staging</td>
</tr>
<tr>
<td>IVR 0607</td>
<td>Devices intended to be used for detection of pregnancy or fertility testing</td>
</tr>
<tr>
<td>IVR 0608</td>
<td>Devices intended to be used for screening, determination or monitoring of physiological markers</td>
</tr>
<tr>
<td>IVR 0609</td>
<td>Other devices intended to be used to define or monitor physiological status and therapeutic measures</td>
</tr>
</tbody>
</table>
7. Devices which are controls without a quantitative or qualitative assigned value

<table>
<thead>
<tr>
<th>IVR CODE</th>
<th>Controls without a quantitative or qualitative assigned value</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVR 0701</td>
<td>Devices which are controls without a quantitative assigned value</td>
</tr>
<tr>
<td>IVR 0702</td>
<td>Devices which are controls without a qualitative assigned value</td>
</tr>
</tbody>
</table>

8. Class A devices in sterile condition

<table>
<thead>
<tr>
<th>IVR CODE</th>
<th>Class A devices in sterile condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVR 0801</td>
<td>Devices referred to in point 2.5 (rule 5), under a), of Annex VIII to Regulation (EU) 2017/746</td>
</tr>
<tr>
<td>IVR 0802</td>
<td>Instruments intended specifically to be used for in vitro diagnostic procedures referred to in point 2.5 (rule 5), under b), of Annex VIII to Regulation (EU) 2017/746</td>
</tr>
<tr>
<td>IVR 0803</td>
<td>Specimen receptacles referred to in point 2.5 (rule 5), under c), of Annex VIII to Regulation (EU) 2017/746</td>
</tr>
</tbody>
</table>

II. HORIZONTAL CODES

1. In vitro diagnostic devices with specific characteristics

<table>
<thead>
<tr>
<th>IVS CODE</th>
<th>In vitro diagnostic devices with specific characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVS 1001</td>
<td>Devices intended to be used for near-patient testing</td>
</tr>
<tr>
<td>IVS 1002</td>
<td>Devices intended to be used for self-testing</td>
</tr>
<tr>
<td>IVS 1003</td>
<td>Devices intended to be used as companion diagnostics</td>
</tr>
<tr>
<td>IVS 1004</td>
<td>Devices manufactured utilising tissues or cells of human origin, or their derivatives</td>
</tr>
<tr>
<td>IVS 1005</td>
<td>Devices in sterile condition</td>
</tr>
<tr>
<td>IVS 1006</td>
<td>Calibrators (point 1.5 of Annex VIII to Regulation (EU) 2017/746)</td>
</tr>
<tr>
<td>IVS 1007</td>
<td>Control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes (point 1.6 of Annex VIII to Regulation (EU) 2017/746)</td>
</tr>
<tr>
<td>IVS 1008</td>
<td>Instruments, equipment, systems or apparatus</td>
</tr>
<tr>
<td>IVS 1009</td>
<td>Software that are devices in themselves including software apps, software for data analysis, and for defining or monitoring therapeutic measures</td>
</tr>
<tr>
<td>IVS 1010</td>
<td>Devices incorporating software/utilising software/controlled by software</td>
</tr>
</tbody>
</table>

2. In vitro diagnostic devices for which specific technologies are used

<table>
<thead>
<tr>
<th>IVT CODE</th>
<th>In vitro diagnostic devices for which specific technologies are used</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVT 2001</td>
<td>In vitro diagnostic devices manufactured using metal processing</td>
</tr>
<tr>
<td>IVT 2002</td>
<td>In vitro diagnostic devices manufactured using plastic processing</td>
</tr>
</tbody>
</table>
### IVT CODE

<table>
<thead>
<tr>
<th>IVT CODE</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVT 2003</td>
<td>In vitro diagnostic devices manufactured using non-metal mineral processing (e.g. glass, ceramics)</td>
</tr>
<tr>
<td>IVT 2004</td>
<td>In vitro diagnostic devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)</td>
</tr>
<tr>
<td>IVT 2005</td>
<td>In vitro diagnostic devices manufactured using biotechnology</td>
</tr>
<tr>
<td>IVT 2006</td>
<td>In vitro diagnostic devices manufactured using chemical processing</td>
</tr>
<tr>
<td>IVT 2007</td>
<td>In vitro diagnostic devices which require knowledge regarding the production of pharmaceuticals</td>
</tr>
<tr>
<td>IVT 2008</td>
<td>In vitro diagnostic devices manufactured in clean rooms and associated controlled environments</td>
</tr>
<tr>
<td>IVT 2009</td>
<td>In vitro diagnostic devices manufactured using processing of materials of human, animal or microbial origin</td>
</tr>
<tr>
<td>IVT 2010</td>
<td>In vitro diagnostic devices manufactured using electronic components including communication devices</td>
</tr>
<tr>
<td>IVT 2011</td>
<td>In vitro diagnostic devices which require packaging, including labelling</td>
</tr>
</tbody>
</table>

### IVP CODE

<table>
<thead>
<tr>
<th>IVP CODE</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVP 3001</td>
<td>In vitro diagnostic devices which require knowledge regarding agglutination tests</td>
</tr>
<tr>
<td>IVP 3002</td>
<td>In vitro diagnostic devices which require knowledge regarding biochemistry</td>
</tr>
<tr>
<td>IVP 3003</td>
<td>In vitro diagnostic devices which require knowledge regarding chromatography</td>
</tr>
<tr>
<td>IVP 3004</td>
<td>In vitro diagnostic devices which require knowledge regarding chromosomal analysis</td>
</tr>
<tr>
<td>IVP 3005</td>
<td>In vitro diagnostic devices which require knowledge regarding coagulometry</td>
</tr>
<tr>
<td>IVP 3006</td>
<td>In vitro diagnostic devices which require knowledge regarding flow cytometry</td>
</tr>
<tr>
<td>IVP 3007</td>
<td>In vitro diagnostic devices which require knowledge regarding immunoassays</td>
</tr>
<tr>
<td>IVP 3008</td>
<td>In vitro diagnostic devices which require knowledge regarding lysis based testing</td>
</tr>
<tr>
<td>IVP 3009</td>
<td>In vitro diagnostic devices which require knowledge regarding measurement of radioactivity</td>
</tr>
<tr>
<td>IVP 3010</td>
<td>In vitro diagnostic devices which require knowledge regarding microscopy</td>
</tr>
<tr>
<td>IVP 3011</td>
<td>In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)</td>
</tr>
<tr>
<td>IVP 3012</td>
<td>In vitro diagnostic devices which require knowledge regarding physical chemistry including electrochemistry</td>
</tr>
<tr>
<td>IVP CODE</td>
<td>In vitro diagnostic devices which require specific knowledge in examination procedures</td>
</tr>
<tr>
<td>-----------</td>
<td>----------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>IVP 3013</td>
<td>In vitro diagnostic devices which require knowledge regarding spectroscopy</td>
</tr>
<tr>
<td>IVP 3014</td>
<td>In vitro diagnostic devices which require knowledge regarding tests of cell function</td>
</tr>
</tbody>
</table>

4. In vitro diagnostic devices which require specific knowledge in laboratory and clinical disciplines for the purpose of product verification

<table>
<thead>
<tr>
<th>IVD CODE</th>
<th>In vitro diagnostic devices which require specific knowledge in laboratory and clinical disciplines for the purpose of product verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVD 4001</td>
<td>In vitro diagnostic devices which require knowledge regarding bacteriology</td>
</tr>
<tr>
<td>IVD 4002</td>
<td>In vitro diagnostic devices which require knowledge regarding clinical chemistry/biochemistry</td>
</tr>
<tr>
<td>IVD 4003</td>
<td>In vitro diagnostic devices which require knowledge regarding detection of transmissible agents (without organisms or viruses)</td>
</tr>
<tr>
<td>IVD 4004</td>
<td>In vitro diagnostic devices which require knowledge regarding genetics</td>
</tr>
<tr>
<td>IVD 4005</td>
<td>In vitro diagnostic devices which require knowledge regarding haematology/haemostasis, including coagulation disorders</td>
</tr>
<tr>
<td>IVD 4006</td>
<td>In vitro diagnostic devices which require knowledge regarding histocompatibility and immunogenetics</td>
</tr>
<tr>
<td>IVD 4007</td>
<td>In vitro diagnostic devices which require knowledge regarding immunohistochemistry/histology</td>
</tr>
<tr>
<td>IVD 4008</td>
<td>In vitro diagnostic devices which require knowledge regarding immunology</td>
</tr>
<tr>
<td>IVD 4009</td>
<td>In vitro diagnostic devices which require knowledge regarding molecular biology/diagnostics</td>
</tr>
<tr>
<td>IVD 4010</td>
<td>In vitro diagnostic devices which require knowledge regarding mycology</td>
</tr>
<tr>
<td>IVD 4011</td>
<td>In vitro diagnostic devices which require knowledge regarding parasitology</td>
</tr>
<tr>
<td>IVD 4012</td>
<td>In vitro diagnostic devices which require knowledge regarding virology</td>
</tr>
</tbody>
</table>
COMMISSION IMPLEMENTING REGULATION (EU) 2017/2186
of 23 November 2017

on the minimum selling price for skimmed milk powder for the fourteenth partial invitation to tender within the tendering procedure opened by Implementing Regulation (EU) 2016/2080

THE EUROPEAN COMMISSION,

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


Having regard to Commission Implementing Regulation (EU) 2016/1240 of 18 May 2016 laying down rules for the application of Regulation (EU) No 1308/2013 of the European Parliament and of the Council with regard to public intervention and aid for private storage (2), and in particular Article 32 thereof,

Whereas:

(1) Commission Implementing Regulation (EU) 2016/2080 (3) has opened the sale of skimmed milk powder by a tendering procedure.

(2) In the light of the tenders received for the fourteenth partial invitation to tender, a minimum selling price should be fixed.

(3) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

For the fourteenth partial invitation to tender for the selling of skimmed milk powder within the tendering procedure opened by Implementing Regulation (EU) 2016/2080, in respect of which the period during which tenders were to be submitted ended on 21 November 2017, the minimum selling price shall be 139,02 EUR/100 kg.

Article 2

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

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

Done at Brussels, 23 November 2017.

For the Commission,

On behalf of the President,

Jerzy BLEWA

Director-General

Directorate-General for Agriculture and Rural Development

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2017/2187
of 16 November 2017
extending the period of validity of Implementing Decision (EU) 2015/179 authorising Member States to provide for a derogation from certain provisions of Council Directive 2000/29/EC in respect of wood packaging material of conifers (Coniferales) in the form of ammunition boxes originating in the United States of America under the control of the United States Department of Defence

(notified under document C(2017) 7489)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (1), and in particular the first indent of Article 15(1) thereof,

Whereas:

(1) Commission Implementing Decision (EU) 2015/179 (2) allows Member States, by way of derogation from Article 5(1) of Directive 2000/29/EC and in conjunction with point 2 of Section I of Part A of Annex IV to that Directive, to authorise the introduction into their territory of ammunition boxes made of wood packaging material originating in the United States of America subject to certain conditions.

(2) Since the circumstances justifying that authorisation still apply and there is no new information giving cause for revision of the specific conditions, that authorisation should be extended.

(3) Based on the experience gained with the application of Implementing Decision (EU) 2015/179, and based on the information provided by the competent authority of the United States, it is appropriate to extend the authorisation for 3 years.

(4) Implementing Decision (EU) 2015/179 should therefore be amended accordingly.

(5) 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

In Article 7 of Implementing Decision (EU) 2015/179, the date ‘31 December 2017’ is replaced by ‘31 December 2020’.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 16 November 2017.

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission