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DECISIONS

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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.
II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

Information on the date of signature of the Protocol on the implementation of the Fisheries Partnership Agreement between the European Union and Côte d'Ivoire

The Protocol (1) on the implementation of the Fisheries Partnership Agreement between the European Union and the Republic of Côte d'Ivoire was signed on 1 August 2018.

The Protocol applies provisionally from 1 August 2018, date of signature, in accordance with its Article 13.

COMMISSION DECISION (EU) 2018/1103
of 7 August 2018
confirming the participation of Malta in the enhanced cooperation on the establishment of the European Public Prosecutor’s Office

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 328(1) and 331(1) thereof,

Having regard to Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor’s Office (the EPPO) (1),

Having regard to the notification by Malta of its intention to participate in the enhanced cooperation on the establishment of the EPPO by letter dated 14 June 2018,

Whereas:

(1) On 3 April 2017, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Finland, France, Germany, Greece, Lithuania, Luxembourg, Portugal, Romania, Slovakia, Slovenia and Spain notified the European Parliament, the Council and the Commission that they wished to establish enhanced cooperation regarding the setting up of the EPPO. In addition, by letters of 19 April 2017, 1 June 2017, 9 June 2017 and 22 June 2017 respectively, Latvia, Estonia, Austria and Italy indicated their wish to participate in the establishment of that enhanced cooperation.

(2) On 3 April 2017, the authorisation to proceed with enhanced cooperation referred to in Article 20(2) of the Treaty on European Union (TEU) and Article 329(1) of the Treaty on the Functioning of the European Union (TFEU) was deemed to be granted in accordance with the third subparagraph of Article 86(1) TFEU.

(3) On 12 October 2017, the Council adopted Regulation (EU) 2017/1939 implementing enhanced cooperation on the establishment of the EPPO.

(4) On 20 November 2017, Regulation (EU) 2017/1939 entered into force. The EPPO should assume its investigative and prosecutorial tasks on a date to be determined by a decision of the Commission on a proposal of the European Chief Prosecutor once the EPPO is set up, which cannot be earlier than three years after the date of entry into force of that Regulation.

(5) On 14 May 2018, the Netherlands notified the Commission of its intention to participate in the enhanced cooperation on the establishment of the EPPO.

(6) On 14 June 2018, Malta notified the Commission of its intention to participate in the enhanced cooperation on the establishment of the EPPO.

(7) Regulation (EU) 2017/1939 does not prescribe any particular conditions of participation in the enhanced cooperation on the establishment of the EPPO.

(8) In accordance with the first subparagraph of Article 120(2) of Regulation (EU) 2017/1939, the EPPO is to exercise its competence with regard to any offence within its competence committed after the date on which Regulation (EU) 2017/1939 has entered into force. For offences referred to in Articles 22 and 23 of Regulation (EU) 2017/1939 that are not already subject to the competence of the EPPO since the initial entry into force of that Regulation, the EPPO should therefore exercise its competence, as regards the territory or nationals of Malta, after the entry into force of that Regulation in Malta.

HAS ADOPTED THIS DECISION:

Article 1

The participation of Malta in the enhanced cooperation on the establishment of the EPPO is confirmed.

Article 2

Regulation (EU) 2017/1939 shall enter into force in Malta on the day of entry into force of this Decision.

Article 3

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

Done at Brussels, 7 August 2018.

For the Commission

The President

Jean-Claude JUNCKER
ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 2/JP/2018
of 17 July 2018
of the Joint Committee established under the Agreement on Mutual Recognition between the European Community and Japan [2018/1104]

Having regard to the Agreement on Mutual Recognition between the European Community and Japan (hereinafter ‘Agreement’) and in particular paragraph 3 of Article 8 thereof;

Whereas the Joint Committee is to confirm the operational product scope of the Sectoral Annex on Good Manufacturing Practice for Medicinal Products (hereinafter ‘Sectoral Annex’), established by the Sub-committee under the Sectoral Annex in its 6th Meeting;

HAS DECIDED AS FOLLOWS:

1. The new operational scope of the categories of medicinal products subject to the Sectoral Annex of this Agreement, done at Brussels on April 4, 2001 now includes the following categories:

   (1) Chemical pharmaceuticals;

   (2) Homeopathic medicinal products (as long as treated as medicinal products and subject to the GMP requirements in Japan);

   (3) Vitamins, minerals and herbal medicines (if considered as medicinal products in both Parties);

   (4) Biological pharmaceuticals (†), including immunologicals and vaccines, belonging to the following categories:

      (4.1) Medicinal products produced by cell culture utilising natural microorganisms or established cell lines;

      (4.2) Medicinal products produced by cell culture utilising recombinant microorganisms or established cell lines; and

      (4.3) Medicinal products derived from non-transgenic plants and non-transgenic animals;

   (5) Active pharmaceutical ingredients (APIs) for any of the above categories; and

   (6) Sterile products belonging to any of the above categories.

2. This Decision, done in duplicate, shall be signed by the co-chairs. The Decision shall be effective from the date of the later of these signatures.

   Signed in Tokyo, 17 July 2018.
   On behalf of Japan
   Daisuke OKABE

   On behalf of the European Community
   Ignacio IRUARRIZAGA

(†) For the purpose of the Sectoral Annex on GMP, biological pharmaceuticals include products which are not necessarily designated by the Ministry of Health, Labour and Welfare as ‘biological products’ in accordance with laws and regulations of Japan but which would be considered as biological products in the EU.