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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

Information on the date of signature and provisional application of the Agreement in the form of an Exchange of Letters between the European Union and the Islamic Republic of Mauritania on an extension to the Protocol setting out the fishing opportunities and financial contribution provided for in the Fisheries Partnership Agreement between the European Community and the Islamic Republic of Mauritania, expiring on 15 November 2019

The European Union and the Islamic Republic of Mauritania signed on 13 November 2019, in Brussels, the Agreement in the form of an Exchange of Letters between the European Union and the Islamic Republic of Mauritania on an extension to the Protocol setting out the fishing opportunities and financial contribution provided for in the Fisheries Partnership Agreement between the European Community and the Islamic Republic of Mauritania, expiring on 15 November 2019.

The Agreement accordingly applies provisionally from 16 November 2019 pursuant to point 6 thereof.

Information on the date of signature and provisional application of the Protocol on the implementation of the Agreement on a sustainable fisheries partnership between the European Union and the Republic of Senegal

The European Union and the Republic of Senegal signed on 18 November 2019, in Brussels, the Protocol on the implementation of the Agreement on a sustainable fisheries partnership between the European Union and the Republic of Senegal.

The Protocol accordingly applies provisionally from 18 November 2019 pursuant to Article 16 thereof.

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1964

of 26 November 2019

concerning the authorisation of L-lysine base, liquid, L-lysine monohydrochloride, liquid, L-lysine monohydrochloride, technically pure, and L-lysine sulphate as feed additives for all animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 82/471/EEC ⁽²⁾.
- (2) Concentrated liquid L-lysine (base), concentrated liquid L-lysine monohydrochloride, L-lysine monohydrochloride, technically pure, and L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* were authorised without a time limit pursuant to Directive 82/471/EEC by Commission Directive 88/485/EEC ⁽³⁾. These feed additives were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, applications were submitted for the re-evaluation of concentrated liquid L-lysine (base), concentrated liquid L-lysine monohydrochloride, L-lysine monohydrochloride, technically pure, and L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* as feed additives for all animal species. Applications were also submitted for the authorisation of concentrated liquid L-lysine (base), concentrated liquid L-lysine monohydrochloride, L-lysine monohydrochloride, technically pure, and L-lysine sulphate for all animal species in accordance with Article 7 of Regulation (EC) No 1831/2003. The applications were accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (4) The applications concern the authorisation of concentrated liquid L-lysine (base), concentrated liquid L-lysine monohydrochloride, L-lysine monohydrochloride, technically pure, and L-lysine sulphate as feed additives for all animal species, to be classified in the additive category 'nutritional additives'.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition (OJ L 213, 21.7.1982, p. 8).

⁽³⁾ Commission Directive 88/485/EEC of 26 July 1988 amending the Annex to Council Directive 82/471/EEC concerning certain products used in animal nutrition (OJ L 239, 30.8.1988, p. 36).

- (5) The European Food Safety Authority ('the Authority') concluded in its opinions of 11 September 2013 ⁽⁴⁾, 28 October 2014 ⁽⁵⁾, 10 March 2015 ⁽⁶⁾, 16 June 2015 ⁽⁷⁾, 2 December 2015 ⁽⁸⁾, 19 April 2016 ⁽⁹⁾, 28 November 2018 ⁽¹⁰⁾, ⁽¹¹⁾ and 3 April 2019 ⁽¹²⁾ that, under the proposed conditions of use, concentrated liquid L-lysine (base) produced by *Escherichia coli* FERM BP-10941, *Escherichia coli* FERM BP-11355, *Corynebacterium glutamicum* KCCM 11117P, *Corynebacterium glutamicum* NRRL B-50547, *Corynebacterium glutamicum* NRRL B-50775 and *Corynebacterium glutamicum* KCCM 10227, concentrated liquid L-lysine monohydrochloride produced by *Escherichia coli* FERM BP-10941 and *Escherichia coli* FERM BP-11355, L-lysine monohydrochloride, technically pure, produced by *Escherichia coli* FERM BP-10941, *Escherichia coli* FERM BP-11355, *Escherichia coli* CGMCC 3705, *Escherichia coli* CGMCC 7.57, *Corynebacterium glutamicum* NRRL B-50547, *Corynebacterium glutamicum* NRRL B-50775, *Corynebacterium glutamicum* KCCM 11117P and *Corynebacterium glutamicum* KCCM 10227 and L-lysine sulphate produced by *Corynebacterium glutamicum* KCCM 10227 and *Corynebacterium glutamicum* DSM 24990 do not have an adverse effect on animal health, consumer safety or the environment. The safety of the additives produced by genetically modified microorganism, in particular by *Corynebacterium glutamicum* NRRL B-50547, is subject to the condition that the manufacturing process is performed ensuring that no recombinant DNA of the production strain is present in the final product. The Authority also stated that the four forms of L-lysine should be considered hazardous for the users of the additives, in particular upon inhalation. Some of the forms should also be considered to be mildly irritant to eyes or corrosive to skin and eyes. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additives. The Authority also concluded that the additives are an efficacious source of the amino-acid L-lysine for all animal species and that in order to be as efficacious in ruminants as in non-ruminant species, the additives should be protected against degradation in the rumen. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additives in feed and water submitted by the Reference Laboratory set up by Article 21 of Regulation (EC) No 1831/2003.
- (6) The names 'concentrated liquid L-lysine (base)' and 'concentrated liquid L-lysine monohydrochloride' should be changed to 'L-lysine base, liquid' and 'L-lysine monohydrochloride, liquid' as the minimum content of L-lysine of those additives is only 50 % and 22 % respectively.
- (7) The assessment of concentrated liquid L-lysine (base), concentrated liquid L-lysine monohydrochloride, L-lysine monohydrochloride, technically pure, and L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* spp or *Escherichia coli* spp as mentioned in recital (5) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of these substances should be authorised as specified in the Annex to this Regulation.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for concentrated liquid L-lysine (base), concentrated liquid L-lysine monohydrochloride, L-lysine monohydrochloride, technically pure, and L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum*, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substances specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', are authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

⁽⁴⁾ EFSA Journal 2013;11(10):3365.

⁽⁵⁾ EFSA Journal 2014;12(11):3895.

⁽⁶⁾ EFSA Journal 2015;13(3):4052.

⁽⁷⁾ EFSA Journal 2015;13(7):4156.

⁽⁸⁾ EFSA Journal 2016;14(3):4346.

⁽⁹⁾ EFSA Journal 2016;14(5):4471.

⁽¹⁰⁾ EFSA Journal 2019;17(1):5532.

⁽¹¹⁾ EFSA Journal 2019;17(1):5537.

⁽¹²⁾ EFSA Journal 2019;17(5):5697.

*Article 2***Transitional measures**

1. Concentrated liquid L-lysine (base), concentrated liquid L-lysine monohydrochloride, L-lysine monohydrochloride, technically pure, and L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* authorised by Commission Directive 88/485/EEC and premixtures containing them may be placed on the market until 18 June 2020 in accordance with the rules applicable before 18 December 2019 and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 18 December 2020 in accordance with the rules applicable before 18 December 2019 may be placed on the market and used until the existing stocks are exhausted if they are intended for food producing animals.
3. Feed materials and compound feed containing the substances referred to in paragraph 1 which are produced and labelled before 18 December 2021 in accordance with the rules applicable before 18 December 2019 may be placed on the market and used until the existing stocks are exhausted if they are intended for non-food producing animals.

*Article 3***Entry into force**

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

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

Done at Brussels, 26 November 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method.	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg additive/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: amino acids, their salts and analogues.									
3c320	-	L-lysine base, liquid	<i>Additive composition:</i> Aqueous solution of L-lysine with a minimum of 50 % L-lysine. <i>Characterisation of the active substance:</i> L-lysine produced by fermentation with <i>Escherichia coli</i> FERM BP-10941 or <i>Escherichia coli</i> FERM BP-11355 or <i>Corynebacterium glutamicum</i> KCCM 11117P or <i>Corynebacterium glutamicum</i> NRRL B-50547 or <i>Corynebacterium glutamicum</i> NRRL B-50775 or <i>Corynebacterium glutamicum</i> KCCM 10227. Chemical formula: $\text{NH}_2\text{-(CH}_2\text{)}_4\text{-CH(NH}_2\text{)-COOH}$ CAS Number: 56-87-1 <i>Analytical methods</i> ⁽¹⁾: For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS/FLD) – EN ISO 17180.	All species	-	-	-	1. The lysine content shall be indicated on the labelling of the additive. 2. L-lysine base, liquid, may be placed on the market and used as an additive consisting of a preparation. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation and for the skin and eyes. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing, skin and eye protection. 4. The additive can be also used via water for drinking. 5. Declarations to be made on the labelling of the additive and premixtures: 'The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.'	18.12.2029

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method.	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg additive/kg of complete feed with a moisture content of 12 %			
			For the quantification of lysine in premixtures, compound feed and feed materials: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F). For the quantification of lysine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD); or — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS).						
3c321	-	L-lysine monohydrochloride, liquid	<i>Additive composition:</i> Aqueous solution of L-lysine monohydrochloride with a minimum of 22 % L-lysine and a maximum moisture content of 66 % (minimum of 58 % L-lysine in the dry matter). <i>Characterisation of the active substance:</i> L-lysine monohydrochloride produced by fermentation with <i>Escherichia coli</i> FERM BP-10941 or <i>Escherichia coli</i> FERM BP-11355. Chemical formula: NH ₂ -(CH ₂) ₄ -CH(NH ₂)-COOH CAS Number: 657-27-2 <i>Analytical methods (1):</i>	All species	-	-	-	1. The lysine content shall be indicated on the labelling of the additive. 2. L-lysine monohydrochloride, liquid, may be placed on the market and used as an additive consisting of a preparation. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation and for eyes. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing and eye protection.	18.12.2029

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method.	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg additive/kg of complete feed with a moisture content of 12 %			
			For the identification of L-lysine monohydrochloride in the feed additive: — Food Chemical Codex ‘L-lysine monohydrochloride monograph’ For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS/FLD) – EN ISO 17180. For the quantification of lysine in premixtures, compound feed and feed materials: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F).					4. Declarations to be made on the labelling of the additive and premixtures: ‘The supplementation with L-lysine should take into account all essential and conditional essential amino acids in order to avoid imbalances.’	

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method.	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg additive/kg of complete feed with a moisture content of 12 %			
3c322		L-lysine monohydrochloride, technically pure	<i>Additive composition:</i> Powder of L-lysine monohydrochloride with a minimum of 78 % L-lysine and a maximum moisture content of 1,5 %. <i>Characterisation of the active substance:</i> L-lysine monohydrochloride produced by fermentation with <i>Escherichia coli</i> FERM BP-10941 or <i>Escherichia coli</i> FERM BP-11355 or <i>Escherichia coli</i> CGMCC 3705 or <i>Escherichia coli</i> CGMCC 7.57 or <i>Corynebacterium glutamicum</i> NRRL B-50547 or <i>Corynebacterium glutamicum</i> NRRL B-50775 or <i>Corynebacterium glutamicum</i> KCCM 11117P or <i>Corynebacterium glutamicum</i> KCCM 10227. Chemical formula: $\text{NH}_2\text{-(CH}_2\text{)}_4\text{-CH(NH}_2\text{)-COOH}$ CAS Number: 657-27-2 <i>Analytical methods</i> ⁽¹⁾: For the identification of L-lysine monohydrochloride in the feed additive: — Food Chemical Codex 'L-lysine monohydrochloride monograph' For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS/FLD) — EN ISO 17180.	All species	-	-	-	1. The lysine content shall be indicated on the labelling of the additive. 2. L-lysine monohydrochloride, technically pure, may be placed on the market and used as an additive consisting of a preparation. 3. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600 IU endotoxins/m³ air ⁽²⁾. 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection. 5. The additive can be also used via water for drinking. 6. Declarations to be made on the labelling of the additive and premixtures: 'The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.'	18.12.2029

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method.	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg additive/kg of complete feed with a moisture content of 12 %			
			For the quantification of lysine in premixtures, compound feed and feed materials: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F). For the quantification of lysine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD); or — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS).						
3c324		L-lysine sulphate	<i>Additive composition:</i> Granulate with a minimum L-lysine content of 52 % and a maximum content of 24 % sulphate. <i>Characterisation of the active substance:</i> L-lysine sulphate produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 10227 or <i>Corynebacterium glutamicum</i> DSM 24990. Chemical formula: C ₁₂ H ₂₈ N ₄ O ₄ •H ₂ SO ₄ /[NH ₂ -(CH ₂) ₄ -CH(NH ₂)-COOH] ₂ SO ₄ CAS number: 60343-69-3 <i>Analytical methods</i> ⁽¹⁾ : For the quantification of lysine in the feed additive and premixtures containing more than 10 % lysine:	All species	-	-	10 000	1. The L-lysine content shall be indicated on the labelling of the additive. 2. L-lysine sulphate may be placed on the market and used as an additive consisting of a preparation. 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation. Where those risks cannot be eliminated or reduced to a minimum level by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	18.12.2029

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method.	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg additive/kg of complete feed with a moisture content of 12 %			
			— ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS/FLD) – EN ISO 17180 For the identification of sulphate in the feed additive: — European Pharmacopoeia Monograph 20301 For the quantification of lysine in premixtures, compound feed and feed materials: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-UV) – Commission Regulation (EC) No 152/2009.					4. Declarations to be made on the labelling of the additive and premixtures: 'The supplementation with L-lysine should take into account all essential and conditional essential amino acids in order to avoid imbalances.'	

(¹) Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

(²) Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2018;16(10):5458); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1965**of 26 November 2019****concerning the authorisation of sodium molybdate dihydrate as feed additive for sheep****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) Sodium molybdate was authorised without a time limit as a feed additive for all animal species in accordance with Directive 70/524/EEC. This substance was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of sodium molybdate dihydrate as a feed additive for sheep.
- (4) The applicant requested sodium molybdate dihydrate to be classified in the additive category 'nutritional additives'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 23 January 2019 ⁽³⁾ that, under the proposed conditions of use, sodium molybdate dihydrate does not have adverse effects on animal health, consumer safety or the environment. It also concluded that the additive is considered as a skin and eye irritant. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. Moreover, the Authority concluded that molybdenum supplementation in sheep feed with sodium molybdate dihydrate is considered effective in order to guarantee an adequate balance with copper, when the copper to molybdenum ratio in the diet is in the range 3-10. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Article 21 of Regulation (EC) No 1831/2003.
- (6) The assessment of sodium molybdate dihydrate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied.
- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the substance sodium molybdate dihydrate, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

⁽³⁾ EFSA Journal 2019;17(2):5606.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'compounds of trace elements', is authorised as feed additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Transitional measures

1. Sodium molybdate dihydrate and premixtures containing that substance, which are produced and labelled before 18 June 2020 in accordance with the rules applicable before 18 December 2019 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing sodium molybdate dihydrate which are produced and labelled before 18 December 2020 in accordance with the rules applicable before 18 December 2019 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Feed materials and compound feed containing sodium molybdate dihydrate which are produced and labelled before 18 December 2021 in accordance with the rules applicable before 18 December 2019 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 3

Entry into force

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

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

Done at Brussels, 26 November 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Content of element (Mo) in mg/kg of complete feed with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
3b701	-	Sodium molybdate dihydrate	<i>Additive composition:</i> Sodium molybdate dihydrate as a powder with a minimum content of 37 % molybdenum. <i>Characterisation of the active substance:</i> Chemical formula: Na₂MoO₄ · 2 H₂O CAS number: 10102-40-6 <i>Analytical methods</i> ⁽¹⁾: For the quantification of total molybdenum in the feed additive, premixtures, feed materials and compound feed: — EN 15510: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP- AES) For the quantification of total sodium in the feed additive: — EN 15510: Inductively Coupled Plasma — Atomic Emission Spectrometry (ICP- AES); or — EN ISO 6869: Atomic Absorption Spectrometry (AAS)	Sheep	-	-	2,5 (total)	1. The additive shall be incorporated into feed in the form of a premixture. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address the potential risks by dermal or eyes contact. Where risks cannot be reduced to an acceptable level by those procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment. 3. The labelling of the additive and premixtures shall indicate the following: ‘Molybdenum supplementation in sheep feed shall result in a Cu:Mo ratio in the diet in the range of 3-10, in order to guarantee an adequate balance with copper’.	18.12.2029

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/eurl/feed-additives/evaluation-reports>

COMMISSION REGULATION (EU) 2019/1966
of 27 November 2019
amending and correcting Annexes II, III and V to Regulation (EC) No 1223/2009 of the European
Parliament and of the Council on cosmetic products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products ⁽¹⁾, and in particular Article 15(1) and the fourth subparagraph of Article 15(2) thereof,

Whereas:

- (1) Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽²⁾ provides for a harmonised classification of substances as carcinogenic, mutagenic or toxic for reproduction (CMR) based on a scientific assessment by the Risk Assessment Committee of the European Chemicals Agency. The substances are classified as CMR substances of category 1A, CMR substances of category 1B or CMR substances of category 2 depending on the level of evidence of their CMR properties.
- (2) Article 15 of Regulation (EC) No 1223/2009 provides that substances which have been classified as CMR substances of category 1A, category 1B or category 2 under Part 3 of Annex VI to Regulation (EC) No 1272/2008 (CMR substances) are prohibited from use in cosmetic products. A CMR substance may however be used in cosmetic products where the conditions laid down in the second sentence of Article 15(1) or in the second subparagraph of Article 15(2) of Regulation (EC) No 1223/2009 are fulfilled.
- (3) In order to uniformly implement the prohibition of CMR substances within the internal market, to ensure legal certainty, in particular for economic operators and national competent authorities and to ensure a high level of protection of human health, all CMR substances should be included in the list of prohibited substances in Annex II to Regulation (EC) No 1223/2009 and, where relevant, deleted from the lists of restricted or authorised substances in Annexes III and V to that Regulation. Where the conditions laid down in the second sentence of Article 15(1) or the second subparagraph of Article 15(2) of Regulation (EC) No 1223/2009 are fulfilled, the lists of restricted or authorised substances in Annexes III and V to that Regulation should be amended accordingly.
- (4) All substances which were classified as CMR substances pursuant to Regulation (EC) No 1272/2008 as at 1 December 2018, when Commission Regulation (EU) 2017/776 ⁽³⁾ became applicable, were intended to be covered by Commission Regulation (EU) 2019/831 ⁽⁴⁾. This Regulation covers the substances classified as CMR substances by Commission Regulation (EU) 2018/1480 ⁽⁵⁾, which will apply from 1 May 2020.

⁽¹⁾ OJ L 342, 22.12.2009, p. 59.

⁽²⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

⁽³⁾ Commission Regulation (EU) 2017/776 of 4 May 2017 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 116, 5.5.2017, p. 1).

⁽⁴⁾ Commission Regulation (EU) 2019/831 of 22 May 2019 amending Annexes II, III and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 137, 23.5.2019, p. 29).

⁽⁵⁾ Commission Regulation (EU) 2018/1480 of 4 October 2018 amending for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2017/776 (OJ L 251, 5.10.2018, p. 1).

- (5) With regard to the substance 2-hydroxy-benzoic acid, with the International Nomenclature of Cosmetic Ingredients (INCI) name Salicylic acid, which has been classified as a CMR substance of category 2, a request for the application of the second sentence of Article 15(1) of Regulation (EC) No 1223/2009 has been submitted and it has been established that the condition provided for in that provision is fulfilled.
- (6) Salicylic acid and its salts are currently listed in entry 3 of Annex V to Regulation (EC) No 1223/2009 as preservatives allowed in cosmetic products in a concentration of up to 0,5 % (acid).
- (7) Salicylic acid is also listed in entry 98 of Annex III to Regulation (EC) No 1223/2009 as a restricted substance only allowed, when used for purposes other than preservative, in rinse-off hair products in a concentration of up to 3,0 % and in other products in a concentration of up to 2,0 %.
- (8) In accordance with the second sentence of Article 15(1) of Regulation (EC) No 1223/2009, a substance classified as a CMR substance of category 2 may be used in cosmetic products where the substance has been evaluated by the Scientific Committee on Consumer Safety (SCCS) and found safe for use in such products.
- (9) On 21 December 2018, the SCCS issued a scientific opinion on Salicylic acid ⁽⁶⁾ ('the SCCS opinion') which concluded that, on the basis of the available data, the substance is safe for consumers when used as a preservative in cosmetic products in a concentration of up to 0,5 % (acid) considering its current restrictions in place. The SCCS opinion is not applicable to any oral products, nor to sprayable products that could lead to exposure of the consumer's lungs by inhalation.
- (10) The SCCS also concluded that Salicylic acid is safe when used for purposes other than preservative in a concentration of up to 3,0 % for rinse-off hair products and up to 2,0 % for other products, considering its current restrictions in place, except for body lotion, eye shadow, mascara, eyeliner, lipstick and roll-on deodorant applications. The SCCS opinion is not applicable to any oral products, nor to sprayable products that could lead to exposure of the consumer's lungs by inhalation.
- (11) Finally, the SCCS concluded that Salicylic acid is an eye irritant with the potential to cause serious damage to the eyes and pointed out that specific tests are currently on-going to assess whether salicylic acid has endocrine disrupting properties and that depending the outcome of these tests, the potential endocrine disrupting properties of salicylic acid in cosmetics may need to be considered.
- (12) In light of the classification of Salicylic acid as a CMR substance of category 2 and as an eye irritant which may cause serious eye damage and of the SCCS opinion, the substance should be authorised as a preservative in cosmetic products in a concentration of up to 0,5 % (acid), considering its current restrictions, except for oral products and for applications that may lead to exposure of the end-user's lungs by inhalation. It should also be authorised, with regard to non-preservative use, in rinse-off hair products in a concentration of up to 3,0 % and in other products except for body lotion, eye shadow, mascara, eyeliner, lipstick and roll-on deodorant applications, in a concentration of up to 2,0 %. It should not, in any case, be authorised in applications that may lead to exposure of the end-user's lungs by inhalation. Considering the conclusion of the SCCS that Salicylic acid is an eye irritant, the current restriction and condition stating that the substance is not to be used in products for children under 3 years of age, except for shampoos, should be modified so that they cover all products for children under 3 years of age. The restrictions set out in Annex III to Regulation (EC) No 1223/2009 and the conditions set out in Annex V to that Regulation should be adapted accordingly.
- (13) With regard to all other substances than Salicylic acid which were classified as CMR substances pursuant to Regulation (EC) No 1272/2008 by Regulation (EU) 2018/1480, no request for use in cosmetic products by way of exception has been submitted. None of those substances are currently restricted or authorised in Annexes III or V to Regulation (EC) No 1223/2009. Four of those substances are currently listed in Annex II to that Regulation. The substances that are not already listed in Annex II to Regulation (EC) No 1223/2009 should be added to the list of substances prohibited in cosmetic products in that Annex.

⁽⁶⁾ SCCS/1601/18, http://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_223.pdf

- (14) The substance 8-hydroxyquinoline; quinolin-8-ol, with the INCI name Oxyquinoline, has been classified as a CMR substance of category 1B by Regulation (EU) 2017/776 while its sulphate form, the substance Bis(8-hydroxyquinolinium) sulphate, with the INCI name Oxyquinoline sulphate, has not been classified as a CMR substance. Both substances were listed in entry 395 of Annex II to Regulation (EC) No 1223/2009 at the time when the classification of Oxyquinoline as a CMR substance started to apply and were prohibited for use in cosmetic products except under the conditions laid down in entry 51 of Annex III to that Regulation. Having being classified as a CMR substance, Oxyquinoline should have been removed from entry 51 of Annex III to Regulation (EC) No 1223/2009. By Regulation (EU) 2019/831, entry 51 was however erroneously deleted in its entirety, including the reference to that entry in entry 395 of Annex II to Regulation (EC) No 1223/2009. In order to correctly reflect the prohibition of Oxyquinoline in cosmetic products on the basis of its classification as a CMR substance, entry 51 should be re-introduced for Oxyquinoline sulphate in Annex III to Regulation (EC) No 1223/2009 and entry 395 in Annex II to that Regulation should be adapted accordingly.
- (15) The substance methyl-phenylene diamine, with the INCI name Diaminotoluene, has been added to the list of prohibited substances in Annex II to Regulation (EC) No 1223/2009 by Regulation (EU) 2019/831 as entry 1507. However, that entry does not correspond to a specific substance but to a group of substances among which only 4-methyl-m-phenylene diamine and 2-methyl-m-phenylene diamine, the mixture and the reaction mass of those two substances have been classified as CMR substances under Regulation (EC) No 1272/2008. Among those CMR substances, 4-methyl-m-phenylenediamine, 2-methyl-m-phenylenediamine and mixture of those two substances are already listed as entries 364, 413 and 1144 in Annex II to Regulation (EC) No 1223/2009 while the substance reaction mass of 4-methyl-m-phenylenediamine and 2-methyl-m-phenylenediamine has not yet been banned for use in cosmetics. Therefore, entry 1507 in Annex II to Regulation (EC) No 1223/2009 should be amended and cover only that substance. Since the CMR substances 4-methyl-m-phenylenediamine and 2-methyl-m-phenylenediamine as well as the mixture and the reaction mass of those substances are also part of the wider group of restricted substances listed as entry 9 of Annex III to Regulation (EC) No 1223/2009, the corresponding entries in Annex II, including entry 1507 as amended, should have been excluded from entry 9. Therefore, entry 9 of Annex III to Regulation (EC) No 1223/2009 should be adapted accordingly.
- (16) Moreover, 19 substances or groups of substances classified as CMR substances by Commission Regulation (EU) 2016/1179 ⁽⁷⁾, which became applicable on 1 March 2018, have by error not been included in Regulation (EU) 2019/831, despite the fact that no request for use in cosmetic products has been submitted for those substances or groups of substances. None of those substances or groups of substances are currently restricted or authorised in Annexes III or V to Regulation (EC) No 1223/2009. 18 of those substances or groups of substances are currently not listed in Annex II to Regulation (EC) No 1223/2009 and should therefore be included in the list of substances prohibited in cosmetic products in that Annex II. One of the substances, i.e. disodium octaborate anhydrous, belongs to the group of substances already listed as entry 1396 in Annex II to Regulation (EC) No 1223/2009 and should be included in that entry. Entry 1396 should therefore be adapted accordingly.
- (17) Regulation (EC) No 1223/2009 should therefore be amended and corrected accordingly.
- (18) The amendments to Regulation (EC) No 1223/2009 are based on the classifications of the relevant substances as CMR substances by Regulation (EU) 2018/1480 and should therefore apply from the same date as those classifications.
- (19) In order to avoid any discontinuity and legal uncertainty for economic operators, the correction of the error introduced by Regulation (EU) 2019/831 with regard to the substance Oxyquinoline sulphate should apply retroactively from the date of entry into force of that Regulation.
- (20) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

⁽⁷⁾ Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 195, 20.7.2016, p. 11).

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II, III and V to Regulation (EC) No 1223/2009 are amended in accordance with Annex I to this Regulation.

Article 2

Annexes II and III to Regulation (EC) No 1223/2009 are corrected in accordance with Annex II to this Regulation.

Article 3

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

Article 1 shall apply from 1 May 2020.

Points (1)(a) and (2)(b) of Annex II shall apply from 11 June 2019.

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

Done at Brussels, 27 November 2019.

For the Commission
The President
Jean-Claude JUNCKER

(1) Annex II to Regulation (EC) No 1223/2009 is amended as follows:

The following entries are added:

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
1612	Phosmet (ISO); S-[(1,3-dioxo-1,3-dihydro-2H-isoindol-2-yl)methyl]-O,O-dimethyl phosphorodithioate; O,O-dimethyl-S-phthalimidomethyl phosphorodithioate	732-11-6	211-987-4
1613	Potassium permanganate	7722-64-7	231-760-3
1614	2-Benzyl-2-dimethylamino-4'-morpholinobutyrophenone	119313-12-1	404-360-3
1615	Quizalofop-p-tefuryl (ISO); (+/-) tetrahydrofurfuryl (R)-2-[4-(6-chloroquinoxalin-2-yloxy)phenoxy]propionate	200509-41-7	414-200-4
1616	Propiconazole (ISO); (2RS,4RS;2RS,4SR)-1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole	60207-90-1	262-104-4
1617	Pinoxaden (ISO); 8-(2,6-diethyl-4-methylphenyl)-7-oxo-1,2,4,5-tetrahydro-7H-pyrazolo[1,2-d][1,4,5]oxadiazepin-9-yl 2,2-dimethylpropanoate	243973-20-8	635-361-9
1618	Tetramethrin (ISO); (1,3-dioxo-1,3,4,5,6,7-hexahydro-2H-isoindol-2-yl)methyl 2,2-dimethyl-3-(2-methylprop-1-en-1-yl)cyclopropanecarboxylate	7696-12-0	231-711-6
1619	(1,3,4,5,6,7-Hexahydro-1,3-dioxo-2H-isoindol-2-yl)methyl (1R-trans)-2,2-dimethyl-3-(2-methylprop-1-en-1-yl)cyclopropanecarboxylate	1166-46-7	214-619-0
1620	Spirodiclofen (ISO); 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutyrate	148477-71-8	604-636-5
1621	Reaction mass of 1-[2-(2-aminobutoxy)ethoxy]but-2-ylamine and 1-([2-(2-aminobutoxy)ethoxy]methyl]propoxy) but-2-ylamine	897393-42-9	447-920-2
1622	1-Vinylimidazole	1072-63-5	214-012-0
1623	Amisulbrom (ISO) 3-(3-bromo-6-fluoro-2-methylindol-1-ylsulfonyl)-N,N-dimethyl-1H-1,2,4-triazole-1-sulfonamide	348635-87-0	672-776-4'

(2) Annex III to Regulation (EC) No 1223/2009 is amended as follows:

Entry 98 is replaced by the following:

'98	Benzoic acid, 2-hydroxy- (1)	Salicylic acid	69-72-7	200-712-3	(a) Rinse-off hair products (b) Other products except body lotion, eye shadow, mascara, eyeliner, lipstick, roll-on deodorant	(a) 3,0 % (b) 2,0 %	Not to be used in preparations for children under 3 years of age. Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. Not to be used in oral products. For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.	Not to be used for children under 3 years of age (2)
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(1) For use as a preservative see Annex V, No 3.

(2) Solely for products which might be used for children under 3 years of age.'

(3) Annex V to Regulation (EC) No 1223/2009 is amended as follows:

Entry 3 is replaced by the following:

Reference number	Substance Identification				Conditions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
'3	Salicylic acid (1) and its salts	Salicylic acid Calcium salicylate, magnesium salicylate, MEA- salicylate, sodium salicylate, potassium salicylate, TEA-salicylate	69-72-7 824-35-1, 18917-89-0, 59866-70-5, 54-21-7, 578-36-9, 2174-16-5	200-712-3 212-525-4, 242-669-3, 261-963-2, 200-198-0, 209-421-6, 218-531-3		0,5 % (acid) 0,5 % (acid)	Not to be used in products for children under 3 years of age. Not to be used in oral products. Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. Not to be used in products for children under 3 years of age, except for shampoos.	Not to be used for children under 3 years of age (2) Not to be used for children under 3 years of age (3)

(1) For uses other than preservative, see Annex III, No 98.

(2) Solely for products which might be used for children under 3 years of age

(3) Solely for products which might be used for children under 3 years of age and which remain in prolonged contact with the skin.'

(1) Annex II to Regulation (EC) No 1223/2009 is corrected as follows:

(a) entry 395 is replaced by the following:

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
'395	Hydroxy-8-quinoline and its sulphate bis(8-hydroxyquinolinium) sulphate, except for the uses of the sulphate provided for in entry 51 of Annex III	148-24-3 134-31-6	205-711-1 205-137-1'

(b) entry 1396 is replaced by the following:

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
'1396	Borates, tetraborates, octaborates and boric acid salts and esters, including: Disodium octaborate anhydrous [1] Disodium octaborate tetrahydrate [2] 2-Aminoethanol, monoester with boric acid [3] 2-Hydroxypropyl ammonium dihydrogen orthoborate [4] Potassium borate, boric acid potassium salt [5] Trioctyldodecyl borate [6] Zinc borate [7] Sodium borate, disodium tetraborate anhydrous; boric acid, sodium salt [8] Tetraboron disodium heptaoxide, hydrate [9] Orthoboric acid, sodium salt [10] Disodium tetraborate decahydrate; borax decahydrate [11] Disodium tetraborate pentahydrate; borax pentahydrate [12]	12008-41-2 [1] 12280-03-4 [2] 10377-81-8 [3] 68003-13-4 [4] 12712-38-8 [5] - [6] 1332-07-6 [7] 1330-43-4 [8] 12267-73-1 [9] 13840-56-7 [10] 1303-96-4 [11] 12179-04-3 [12]	234-541-0 [1] 234-541-0 [2] 233-829-3 [3] 268-109-8 [4] 603-184-6 [5] - [6] 215-566-6 [7] 215-540-4 [8] 235-541-3 [9] 237-560-2 [10] 215-540-4 [11] 215-540-4 [12]'

(c) entry 1507 is replaced by the following:

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
'1507	Diaminotoluene, methyl-phenylenediamine, technical product-reaction mass of [4-methyl-m-phenylenediamine and 2-methyl-m-phenylenediamine]	—	—

(d) the following entries are added:

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
'1624	Pirimicarb (ISO); 2-(dimethylamino)-5,6-dimethylpyrimidin-4-yl dimethylcarbamate	23103-98-2	245-430-1
1625	1,2-Dichloropropane; propylene dichloride	78-87-5	201-152-2
1626	Phenol, dodecyl-, branched [1] Phenol, 2-dodecyl-, branched [2] Phenol, 3-dodecyl-, branched [3] Phenol, 4-dodecyl-, branched [4] Phenol, (tetrapropenyl) derivatives [5]	121158-58-5 [1] 1801269-80-6 [2] 1801269-77-1 [3] 210555-94-5 [4] 74499-35-7 [5]	310-154-3 [1] — [2] — [3] 640-104-9 [4] 616-100-8 [5]
1627	Coumatetralyl (ISO); 4- hydroxy-3-(1,2,3,4-tetrahydro-1-naphthyl) coumarin	5836-29-3	227-424-0
1628	Difenacoum (ISO); 3-(3- biphenyl-4-yl-1,2,3,4- tetrahydro-1-naphthyl)- 4-hydroxycoumarin	56073-07-5	259-978-4
1629	Brodifacoum (ISO); 4-hydroxy-3-(3-(4'-bromo-4-biphenyl)-1,2,3,4-tetrahydro-1-naphthyl)coumarin	56073-10-0	259-980-5
1630	Flocoumafen (ISO); reaction mass of: cis-4- hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1-naphthyl)coumarin and trans-4-hydroxy-3-(1,2,3,4-tetrahydro-3-(4-(4-trifluoromethylbenzyloxy)phenyl)-1-naphthyl)coumarin	90035-08-8	421-960-0
1631	Acetochlor (ISO); 2- chloro-N-(ethoxymethyl)-N-(2-ethyl-6-methylphenyl)acetamide	34256-82-1	251-899-3

Reference number	Substance identification		
	Chemical name/INN	CAS number	EC number
a	b	c	d
1632	e-Glass microfibres of representative composition	-	-
1633	Glass microfibres of representative composition	-	-
1634	Bromadiolone (ISO); 3- [3-(4'-bromobiphenyl- 4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy- 2H-chromen-2-one	28772-56-7	249-205-9
1635	Difethialone (ISO); 3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydronaphthalen-1-yl]- 4-hydroxy-2H-1-benzothio-pyran-2-one	104653-34-1	600-594-7
1636	Perfluorononan-1-oic acid [1] and its sodium [2] and ammonium [3] salts	375-95-1 [1] 21049-39-8 [2] 4149-60-4 [3]	206-801-3 [1] - [2] - [3]
1637	Dicyclohexyl phthalate	84-61-7	201-545-9
1638	3,7-Dimethylocta-2,6- dienenitrile	5146-66-7	225-918-0
1639	Bupirimate (ISO); 5-butyl-2-ethylamino-6- methylpyrimidin-4-yl dimethylsulfamate	41483-43-6	255-391-2
1640	Triflumizole (ISO); (1E)-N-[4-chloro-2-(trifluoromethyl) phenyl]-1- (1H-imidazol-1-yl)-2- propoxyethanimine	68694-11-1	604-708-8
1641	tert-Butyl hydroperoxide	75-91-2	200-915-7'

(2) Annex III to Regulation (EC) No 1223/2009 is corrected as follows:

(a) entry 9 is replaced by the following:

Ref No.	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/ INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
9	Methylphenylenediamines, their N- substituted derivatives and their salts (1), with the exception of the substance listed under reference numbers 9 a and 9 b of this Annex and the substances listed under reference numbers 364, 413, 1144, 1310, 1313 and 1507 of Annex II				Hair dye substance in oxidative hair dye products		(a) General use (b) Professional use For (a) and (b): After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 5 % calculated as free base	(a) To be printed on the label: The mixing ratio. '⚠ Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if: — you have a rash on your face or sensitive, irritated and damaged scalp, — you have ever experienced any reaction after colouring your hair, — you have experienced a reaction to a temporary 'black henna' tattoo in the past. Contains phenylenediamines (toluenediamines). Do not use to dye eyelashes or eyebrows.' (b) To be printed on the label: The mixing ratio.

Ref No.	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/ INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
								'For professional use only. Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary "black henna" tattoos may increase your risk of allergy. Do not colour your hair if: — you have a rash on your face or sensitive, irritated and damaged scalp, — you have ever experienced any reaction after colouring your hair, — you have experienced a reaction to a temporary "black henna" tattoo in the past. Contains phenylenediamines (toluenediamines). Wear suitable gloves.'

(b) the following entry is added:

Reference number	Substance identification				Restrictions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
'51	Bis(8-hydroxyquinolinium) sulphate	Oxyqui-noline sulphate	134-31-6	205-137-1	Stabilizer for hydrogen peroxide in rinse-off hair products Stabilizer for hydrogen peroxide in leave-on hair products	(0,3 % as base) (0,03 % as base)		

DECISIONS

COUNCIL DECISION (EU) 2019/1967

of 25 November 2019

appointing an alternate member, proposed by the Italian Republic, of the Committee of the Regions

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to the proposal of the Italian Government,

Whereas:

- (1) On 26 January 2015, 5 February 2015 and 23 June 2015, the Council adopted Decisions (EU) 2015/116 ⁽¹⁾, (EU) 2015/190 ⁽²⁾ and (EU) 2015/994 ⁽³⁾ appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020.
- (2) An alternate member's seat on the Committee of the Regions has become vacant following the end of the term of office of Mr Vito SANTARSIERO,

HAS ADOPTED THIS DECISION:

Article 1

The following is hereby appointed as an alternate member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2020:

— Mr Vito BARDI, *Presidente della Regione Basilicata*.

Article 2

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

Done at Brussels, 25 November 2019.

For the Council

The President

F. MOGHERINI

⁽¹⁾ Council Decision (EU) 2015/116 of 26 January 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 20, 27.1.2015, p. 42).

⁽²⁾ Council Decision (EU) 2015/190 of 5 February 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 31, 7.2.2015, p. 25).

⁽³⁾ Council Decision (EU) 2015/994 of 23 June 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 159, 25.6.2015, p. 70).

COMMISSION DECISION (EU) 2019/1968**of 2 August 2019****on the measure SA.21445 - C42/2006 implemented by the Republic of Italy to remunerate Poste Italiane for the current accounts deposited with the Italian Treasury***(notified under document C(2019) 5649)***(Only the Italian text is authentic)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first subparagraph of Article 108(2) thereof,

Having regard to the Agreement on the European Economic Area, and in particular Article 62(1)(a) thereof,

Having called on interested parties to submit their comments pursuant to the provision(s) cited above ⁽¹⁾ and having regard to their comments,

Whereas:

1. PROCEDURE

- (1) By letter dated 30 December 2005, the Associazione Bancaria Italiana ('ABI' or 'the complainant') submitted a complaint to the Commission regarding various measures benefiting the banking activities of Poste Italiane SpA ('Poste Italiane' or 'PI'). Notably, the Commission was informed that, pursuant to an agreement between the Italian Republic ('Italy') and PI, Italy would remunerate the funds collected in PI's postal current accounts and deposited with the Italian Treasury ('Treasury') with an interest rate of around 4 %, while PI would remunerate postal current accounts at a rate of around 1 % (the 'measure'). The spread between the deposit rate (i.e. the interest rate PI pays to the postal current account holders) and the loan rates (i.e. the interest rate PI receives from the Treasury for the funds deposited with the latter) would be higher than the relevant 'market' spread, thus constituting State aid in the view of the complainant.
- (2) By letter dated 7 February 2006, the Commission submitted a series of questions to Italy relating to the remunerations paid on postal current accounts. Italy replied to those questions in a letter dated 21 April 2006. A meeting with Italy and PI took place on 30 March 2006.
- (3) By letter dated 26 September 2006, the Commission informed Italy that it had decided to initiate the procedure laid down in Article 108(3) of the Treaty on the Functioning of the European Union ('TFEU') in respect of the measure. The Commission invited interested parties to submit their comments on the measure. ⁽²⁾
- (4) By decision of 16 July 2008 ⁽³⁾ ('the 2008 Decision'), the Commission concluded that the remuneration granted by Italy amounted to State aid that is incompatible with the internal market, and ordered its immediate recovery.

⁽¹⁾ GU C 290 del 29.11.2006, pag. 8

⁽²⁾ See footnote 1.

⁽³⁾ Commission Decision 2009/178/EC of 16 July 2008 on a State aid scheme implemented by Italy to remunerate current accounts held by Poste Italiane with the State Treasury (C 42/06 (ex NN 52/06)) (OJ L 64, 10.3.2009, p. 4).

- (5) On 4 December 2008, PI lodged an action before the General Court seeking the annulment of the 2008 Decision.
- (6) By ruling of 13 September 2013 in case T-525/08 ⁽⁴⁾, the General Court annulled the 2008 Decision ('the 2013 ruling').
- (7) On 30 October 2014, a call for tender was published on the Commission's website ⁽⁵⁾ to carry out a report analysing and comparing the yields of possible investments of the funds collected by PI through the offer of postal current accounts for the period 2005-2007.
- (8) On 19 December 2014, the contract was awarded to the University of Perugia. The report was concluded in November 2015.

2. DETAILED DESCRIPTION OF THE MEASURE AND THE BENEFICIARY

2.1. Poste Italiane

- (9) PI is the universal postal service provider in Italy, which fulfils a service of general economic interest, i.e. the universal postal service obligation ⁽⁶⁾, according to the second Postal Directive ⁽⁷⁾ and the regulations on the universal postal service. Financial services are presently not included within the remit of the service of general economic interest PI is entrusted with.
- (10) Besides providing core postal services, PI offers integrated products, as well as communication, logistic and financial services all over Italy.
- (11) PI's banking activities are operated through a fully integrated division called BancoPosta.
- (12) Between 2005 and 2007, PI's main shareholder was Italy with a 65 % stake while Cassa Depositi e Prestiti ('CDP') was PI's minority shareholder with a 35 % stake. CDP was part of the Public Administration until it was transformed into a limited company in late 2003. Since 2003, even with the transfer of 30 % of CDP's share capital to 65 banking foundations ⁽⁸⁾, CDP remains under the control of Italy. PI was also under the control of Italy at the time the measure was implemented.

2.2. The measure

- (13) The measure under assessment concerns the remuneration of the funds Poste Italiane collected on postal current accounts and deposited with the Treasury in the three years 2005-2007.
- (14) The obligation to deposit funds with the Treasury ('the Obligation') ⁽⁹⁾ was laid down in Law No 266 of 23 December 2005 ⁽¹⁰⁾ ('the 2005 Law'), while the remuneration was granted by means of a convention between Italy and PI, adopted on 23 February 2006 ('the Convention').

⁽⁴⁾ Judgment of the General Court in case T-525/08, *Poste Italiane SpA v Commission*, ECLI:EU:T:2013:481.

⁽⁵⁾ http://ec.europa.eu/competition/calls/tenders_closed.html, ref COMP/2014/017.

⁽⁶⁾ The universal service comprises the conveyance of items of correspondence and addressed printed matter weighing up to 2 kg and postal packages of up to 20 kg; as well as a service of registered items and service of insured items.

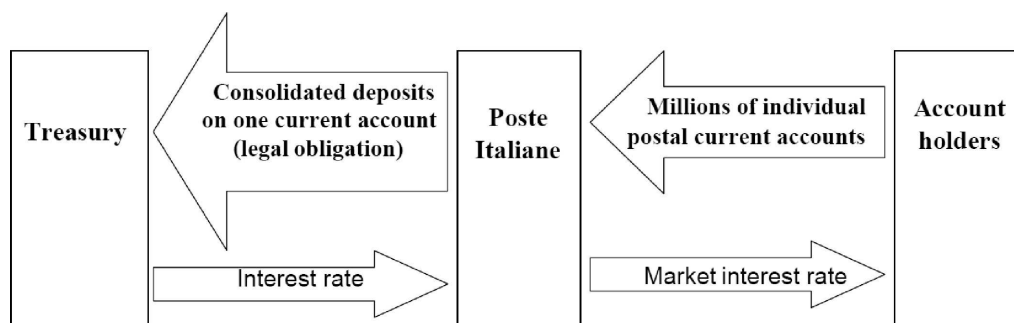
⁽⁷⁾ Directive 2002/39/EC of the European Parliament and of the Council of 10 June 2002 amending Directive 97/67/EC with regard to the further opening to completion of Community postal services (OJ L 176, 5.7.2002, p. 21).

⁽⁸⁾ According to Article 5 of Law Decree No 269 of 30 September 2003 and the Conversion Law No 326 of 24 November 2003, CDP shares are assigned to Italy. Moreover, bank foundations and other public or private entities can only hold, in aggregate, minority shares of CDP capital.

⁽⁹⁾ The postal current account service has been essentially governed by a law of 1917, published in G.U. 219 of 6 September 1917, modified by Decree 822 of 22 November 1945, published in GU 12 of 15 January 1946. Until 2003, the law established notably that the funds collected on postal current accounts are deposited with a CDP's account bearing an interest rate equal to the rate received CDP on its financing activity less 15 hundredth of a percentage point. Following a decree of 5 December 2003, the Treasury replaced CDP.

⁽¹⁰⁾ Published in G.U. 302 of 29 December 2005, 'supplemento ordinario' 211.

- (15) Following a decree on 5 December 2003 ⁽¹¹⁾, the relationship between PI and the Treasury can be described by the following chart:



- (16) The 2005 Law provided that the financial interests paid to PI for the deposits with the Treasury were to be defined between Italy and PI according to market parameters.
- (17) Following the 2005 Law, the Convention defined the concrete mechanisms for establishing the interest rates for a three-year period; it entered into force on 4 April 2006 ⁽¹²⁾ with retroactive effect as of 1 January 2005. The yearly interest rate was essentially calculated as the weighted average of the yield of Italian Government bonds ⁽¹³⁾ at 30 years (80 %), and at 10 years (10 %), and of twelve-month Treasury bills ⁽¹⁴⁾ (10 %). The yearly rates of the government securities and of Treasury bonds used as reference in the Convention were obtained on the basis of the simple average of the 24 quotation values noted on the 1st and 15th of each month by MTS SpA (the company providing wholesale electronic trading of Italian Government bonds and other fixed term securities). Hence, the provision concerning the resetting of the parameters every 15 days determined the floating nature of the indexation. Furthermore, in case of significant changes in the rates curve (for instance a change in the relation between long and short term rates), PI could revise the calculation scheme. The Convention could be revoked by either party at the end of each year with 6-months prior notice.
- (18) The interest rate in the years 2005, 2006 and 2007 amounted to 3,9 %, 4,25 % and 4,7 %, respectively.
- (19) By virtue of Law No 296 of 27 December 2006 ('the 2006 Law') ⁽¹⁵⁾, Italy modified the 2005 Law. The 2006 Law defined a new investment framework: the requirement that PI deposit the funds collected on current postal accounts belonging to private customers (i.e. not belonging to the Public Administration) was abolished and those funds had to be invested by PI in Euro area Government bonds ⁽¹⁶⁾. Pursuant to the 2006 Law, the new investment framework was gradually implemented during the course of 2007 and completed by the end of that year.

2.3. The 2008 Decision

- (20) In the 2008 Decision, the Commission concluded that the measure under assessment, (i.e. the remuneration granted by the Treasury to PI under the Convention) amounted to State aid that is incompatible with the internal market, and ordered its immediate and effective recovery.

2.3.1. Prudent private borrower

- (21) To establish the existence of an advantage within the meaning of Article 107(1) TFEU in the 2008 Decision, the Commission compared the interest rate paid by the Treasury to PI pursuant to the Convention ('the Convention's rate') and the interest rate that a prudent private borrower would have paid on the market in a similar situation ('rate granted to the prudent private borrower').

⁽¹¹⁾ Published in G.U. 288 of 12 December 2003.

⁽¹²⁾ A ministerial decree of 3 April 2006 approved the implementation of the Convention.

⁽¹³⁾ BTP: Buoni del Tesoro Poliennali.

⁽¹⁴⁾ BOT: Buoni ordinari del Tesoro.

⁽¹⁵⁾ Published in G.U. 299 of 27 December 2006.

⁽¹⁶⁾ According to Italy, the amount of funds collected on postal accounts belonging to private customers represents around 70-75 % of the total amount of funds collected on postal accounts.

- (22) As explained in recital 119 of the 2008 Decision, in defining the remuneration of deposits, a prudent private borrower would have essentially considered the following elements:
- (a) the gross amount of the deposited funds;
 - (b) the stability of the deposited funds;
 - (c) the average duration/maturity and the changes in the deposited funds; and
 - (d) the financial risk borne.
- (23) Regarding the gross amounts of the deposited funds, the Commission considered in the 2008 Decision that it totalled EUR 35 billion, which is a significant amount of money from a single lender. However, the Commission noted that the deposit by PI to the Treasury represents only 2,8 % of the outstanding amount of Government securities as of the end of 2005. In addition, the Italian Government bonds' issuance had been oversubscribed during that period. Therefore, there was no indication of a shortage of funds on the market and that PI' deposit was instrumental to overcome such a shortfall (recital 124 of the 2008 Decision).
- (24) Regarding the stability of the deposited funds, the Commission considered that 10 % of the deposits on current postal accounts could be considered volatile and 90 % could be considered stable (recital 133 of the 2008 Decision).
- (25) Regarding the average duration/maturity of the deposits, the Commission distinguished between active fund management, which would have been possible in the absence of the Convention, and passive fund management, resulting from the Obligation. A prudent private borrower should have expected that the Obligation would have been changed within a maximum of five years, and would have taken that into account when determining the loan rate. In an active fund management framework, the Commission stated that the average maturity of the global amount of funds collected on postal accounts was slightly less than five years. Accordingly, a prudent private borrower should have based the market remuneration of the stable part of the deposits on the yield of a five-year bond (instead of the 10 or 30 years yield, as required by the Convention). Concerning the volatile part of the deposits, a prudent private borrower would have based the remuneration on three-month Treasury bills (instead of the 12-month Treasury bills, as required by the Convention).
- (26) Regarding the financial risks related to the deposits from postal current accounts, the Commission noted that the liquidity risk was fully borne by the borrower (i.e. the Treasury) and not by PI. Under the Convention, if depositors withdrew their money from the postal current accounts, the Treasury would have to provide PI with the required funds for the same amount.
- (27) The Commission concluded (recital 178 of the 2008 Decision) that the Convention rate exceeded the rate granted to the prudent private borrower by 1,09 % in 2005, 0,65 % in 2006 and 0,47 % in 2007. The Commission therefore concluded that the measure constituted State Aid within the meaning of Article 107(1) TFEU.

2.3.2. *Analyses of investment policies by PI in the absence of the Obligation*

- (28) *Ad abundatiam*, the Commission looked, in its assessment, at the alternative investment possibilities suggested by Italy as available to PI in the absence of the Obligation, notably the investments made by PI with the funds collected through its insurance activities, Poste Vita SpA, and alternative active fund management strategies. In this context, the Commission analysed whether these alternative investments would have provided PI with similar or higher yields than the one set by the Convention.
- (29) The Commission concluded that these alternative investments would have not provided PI with similar or higher yields than the one set by the Convention, from a risk/return perspective.

2.4. **Annulment of the 2008 Decision: the 2013 ruling**

- (30) By means of the 2013 ruling, the General Court annulled the 2008 Decision.

- (31) The General Court held that the existence of a positive difference between the Convention's rate and the rate granted to the prudent private borrower was not sufficient to demonstrate an advantage for PI.
- (32) The General Court observed that the rate granted to the prudent private borrower had been estimated by the Commission based on the four parameters described in recital 22 of the present decision. Under these circumstances, the General Court concluded that the rate granted to the prudent private borrower did not constitute a market rate ⁽¹⁷⁾.
- (33) The General Court noted that even if the rate granted to the prudent private borrower was not at the level of the market rate, PI would benefit from an advantage only if the Convention's rate was higher than the return PI could have reasonably achieved in the absence of the Obligation.
- (34) The General Court determined that the Commission could not conclude that the measure benefitted PI without actively demonstrating that, in the absence of the Obligation, PI could not have gotten a higher return by investing the deposits from the postal current accounts as compared to the Convention's rate.
- (35) The General Court concluded that the Commission had made a manifest error in the 2008 Decision by concluding that the measure was advantageous for PI based on the positive difference between the Convention's rate and the rate granted to the prudent private borrower.
- (36) The General Court considered the reasons put forward by the Commission to contest the relevance of the elements presented by Italy as not sufficiently substantiated.
- (37) The General Court also noted that the Commission had assessed, *ad abundatiam*, the returns achieved by the investments made by PI with the funds collected through its insurance activities and returns generated in the framework of an active fund management strategy, and had concluded that such alternative investments strategies would not have generated interest rates similar to or higher than that set by the Convention over the relevant period, from a risk/return perspective.
- (38) The General Court assessed whether the Commission's conclusion, based on its assessment of the alternative investments strategies proposed by Italy, that the measure constituted State aid was correct.
- (39) The General Court held that the management fees related to postal current accounts and insurance products were not relevant to the comparison of the returns generated by the Convention's rate and the alternative investment strategies. Consequently, the Court held that the Commission had been wrong to deduct those fees, and that the comparison between the Convention's rate and the returns 'netted' of those management fees related to insurance products was not relevant to the assessment of whether the measure constituted State aid.
- (40) Regarding the active fund management strategy, the General Court stated that the Commission could not make a meaningful comparison between the Convention's rate and the return of the active fund management strategy by focusing on a limited period of three years, which was not representative of the returns achieved by active fund management strategy.
- (41) Moreover, the General Court held that the fact that capital gains are an important parameter of active fund management strategies and should therefore not be omitted from an analysis of the measure's compatibility with the internal market. The Commission had argued that capital gains should be omitted from the analysis, as they could have not been foreseen *ex-ante*, and, as a result, returns generated by an active fund management strategy after deducting those capital gains were lower than the Convention's rate or the rate granted to the prudent private borrower.
- (42) The General Court held that the fact that the returns generated by the active funds management strategy, after deducting capital gains, was lower than the Convention's rate was not relevant to establishing the existence of an advantage within the meaning of Article 107(1) TFEU.

⁽¹⁷⁾ 2013 ruling, paragraph 65 'la Commission a uniquement examiné le niveau de rémunération que le Trésor aurait pu demander unilatéralement compte tenu de quatre paramètres, à savoir la masse des fonds déposés, la stabilité de ces fonds, la durée moyenne du dépôt des fonds et les risques financiers supportés. Dans ces conditions, le taux de l'emprunteur privé, défini aux considérants 119 à 180 de la décision attaquée, ne constitue pas véritablement un «taux de marché»'.

- (43) The General Court held that the Commission's conclusion in the 2008 Decision that, in the absence of the Obligation, PI would not have been able to achieve returns equal to or higher than the Convention's rate, was based on erroneous or incorrect information.
- (44) The General Court therefore annulled the 2008 Decision. The 2013 ruling was not appealed.

3. COMMENTS FROM INTERESTED PARTIES

3.1. Comments from ABI

- (45) In its letter of 27 December 2006, ABI submitted the following comments:
- (a) ABI indicated that the funds deposited with the Treasury represented a debt to be paid by the Treasury the year following the deposit. As the Commission argued in the opening decision, ⁽¹⁸⁾ the Treasury, and not PI, would cover the liquidity risk associated with the deposited funds. This would mean that, in case of decrease of the deposited amounts from one year to the next, the Treasury should both remunerate PI at the rate fixed by the Convention and reimburse PI for the difference in the deposited amounts.
 - (b) According to ABI, the nature of the funds collected on the Treasury account is short term. Moreover, these funds are used to finance ordinary budget needs.
 - (c) Moreover, on the basis of the ministerial decree of 5 December 2003 (see recital 15), CDP opened two current accounts with the Treasury, bearing a variable interest rate equal to the simple average of the gross 6-month interest rate of Treasury bills and the Rendistato interest rate ⁽¹⁹⁾.
 - (d) Finally, in order to assess whether the PI's remuneration for the funds deposited with the Treasury constitutes State aid, the interest rate allocated to PI should have been compared to the interest rate of short-term (12-month) Treasury bills. In January 2005, the rate of a 12-month Treasury bill was 2,21 %, which implies that the PI's remuneration would be overestimated by 1,69 %.

3.2. Comments from Italy

- (46) In its letters of 31 October 2006, 29 December 2006, 16 February 2007, 30 March 2007, 2 April 2007, 1 June 2007, 27 November 2007, 29 February 2008, 7 March 2008, and 23 April 2008, Italy submitted several arguments.
- (47) First, Italy recalled that the 2005 Law and the Convention specified that the financial interest paid to PI had to be set according to market parameters. No advantage was derived from that interest, according to Italy.

3.2.1. *Variation in the amounts deposited with postal current accounts*

- (48) Second, Italy argued that postal current accounts should only be compared to banking current accounts as of 2001, when the new product 'Conto BancoPosta' was launched. Before 2001, the amounts deposited with the Treasury varied, for example there was a significant reduction in the current accounts' deposits in the late 1990s, in particular between 1996 and 1997, which resulted from the adoption of Law No 662 of 23 December 1996, which imposed the closure of the accounts used by the Treasury to pay State pensions. This closure led to a reduction in deposits of approximately EUR 11 billion (as of 1 January 1997). According to Italy, it is difficult to identify the exact cause for such variations, due to exogenous political factors and the fact that PI was a public institution at that time. After the transformation of PI into a public company in 1998, the amounts deposited with the Treasury grew regularly and steadily.

3.2.2. *Nature of the Convention*

- (49) Italy stated that the Convention between the Treasury and PI regulated their financial relationship in a transparent way. On the one hand, the Convention had a three-year duration and was not unlimited in time; on the other hand, the Convention foresaw the possibility for either party to revoke the contract if market conditions no longer guaranteed the consistency of the mechanism of calculating the remuneration of the deposit.

⁽¹⁸⁾ See footnote 1.

⁽¹⁹⁾ Since 1 October 1995, Rendistato comprises the average gross yield on Government bonds subject to taxation and with a residual maturity of more than one year. (Source: Bank of Italy).

- (50) According to Italy, the choice of a floating interest rate for the Convention helped to ensure conformity with a market-conform rate. In particular, the floating interest rate represented a fair rate for the Treasury because it entailed costs for the Treasury in line with the cost of alternative financing sources, e.g. medium/long term debt.
- (51) Italy states that, since 2007, PI has adopted a conservative approach to its active funds management, which differs from that of the Convention, because it allows PI to build a portfolio based on an asset allocation in line with the company's objectives and financial strategy.

3.2.3. *Changes to the legal obligation to deposit funds with the Treasury*

- (52) Italy informed the Commission that the law requiring PI to deposit with the Treasury the funds collected on the postal current accounts was repealed in December 2006, by the 2006 Law. According to this law, the funds collected on the postal current accounts of private customers were invested by PI in Euro area Government bonds (see recital 19). The new law was designed to provide PI with greater financial autonomy.

3.2.4. *Stability of the funds collected on postal current accounts*

- (53) In support of its position on the stability of the deposited funds, Italy submitted the results of two models: the internal statistical models elaborated by PI and the model elaborated by PI and the consulting company [...], aimed at identifying the prudential trend of funds collected on postal current accounts.
- (54) The internal models were based on the analysis of the daily deviation of the amounts of funds collected on postal current accounts and the average amounts, using only the historical trends of the current accounts. The models show a growing trend in the amounts deposited with the Treasury (funds collected on accounts of private customers represent around 75 % of the total funds collected on postal current accounts). The stable part of the deposits shows a growing trend and represents 90 % of the total average deposit (from 85 % in 2002 to 92 % in 2006). Likewise, the internal models establish a volatile part of deposits, which has fallen to about 10 %.
- (55) The [...] model, which Italy considers to be very conservative, demonstrated that the duration of the total number of postal current accounts was different from the duration of a single postal current account. If some customers had indeed decided to close their accounts from one day to the next, the effect on the total amounts of funds collected by PI were marginal because of the high number of customers, the fact that the average deposit on those accounts was low and that new customers' deposits essentially replaced leaving customers' deposits.
- (56) The type of prudential model developed by [...] was used by several Italian banks in the context of their active management of liquidity, at the time of the Convention, in order to determine the duration of their current accounts, and then to mirror that duration in a corresponding investment portfolio as part of their assets/liabilities management ('ALM'). That prudential model was used by PI to identify the duration of the funds collected on postal current accounts (owned by private persons ⁽²⁰⁾) during the period 2005-2006, when PI was obliged to deposit all the funds with the Treasury (passive management of liquidity), and for the period beyond 1 January 2007, where the funds collected on postal current accounts of private customers are invested by PI in Euro area Government bonds (active management of liquidity).

⁽²⁰⁾ In 2006, the postal current accounts owned by private persons (i.e. excluded the public administration) amounted to [...], of which [...] belonged to retail customers and [...] to undertakings.

3.2.4.1. Passive fund management

- (57) According to Italy, within the context of passive management of PI's liquidity, the [...] model sought to quantify the duration of the stable and volatile parts of the deposits identified by the internal models on the basis of the historical volatility of postal current accounts and on the probabilistic behaviour of the accounts holders. One model specification ⁽²¹⁾ indicated that approximately two-thirds of the funds had a very long duration and one-third had a duration varying from 0 to 10 years. Consequently, the corresponding investment portfolio would have had an average life of 4,1 years and a Macaulay duration ⁽²²⁾ of 3,2 years. In an alternative model specification ⁽²³⁾, the corresponding investment portfolio will have an average life of 4,9 years and a Macaulay duration of 3,8 years ⁽²⁴⁾.

3.2.4.2. Active fund management

- (58) According to Italy, within the context of active management of PI's liquidity, the [...] model supported PI in the definition of the optimal asset allocation. Based on very prudential hypotheses, it indicated that it was reasonable for PI to adopt an asset allocation with a 4 to 5-year average life.

3.2.5. Costs of postal current accounts

- (59) Regarding the costs relating to the collection and deposit of funds stemming from the postal current accounts of PI customers, Italy indicates that PI's analytical accounting system allows for determining the costs of the activity of PI as a whole, and not by product. Italy stated that PI's margins were lower than the corresponding margins in the banking sector.

3.2.6. Consistency between the Convention's remuneration and the Treasury's financing cost

- (60) Italy stated that the Convention allowed PI to be remunerated on the basis of the yields of the Treasury bonds, the main funding instrument available to Italy.
- (61) In particular, the Convention allowed PI to be remunerated on the basis of long term rates, which were in line with the horizon of the funds collected on the postal current accounts. The Convention also protected the Treasury against adverse market conditions, by allowing it to revoke the Convention it had become inconsistent with the cost of alternative financing sources.
- (62) On the basis of a comparison between the rate foreseen by the Convention and the Treasury's financing costs, Italy submitted that the cost of medium/long term funding of the Treasury was in line with the rate set by the Convention.
- (63) Moreover, (i) the rate of remuneration set in the Convention is indexed to parameters linked to Italy's public debt (government securities) that constitute the most appropriate reference for the Treasury's financing costs; (ii) the stability of the funding, as verified through statistical models and the Obligation imposed on PI make the investment permanent for the most part (without considering specific safety measures – such as the possibility of early withdrawal, the three-year term of the relationship – that protect the Treasury from unforeseen changes in the market); (iii) the liquidity risk assumed by the Treasury is limited in consideration of the proven stability of the postal funding, having indexed 10 % of such funding to short-term parameters.
- (64) Regarding the long term element of the loan rate (90 %, composed of (i) the 10 % linked to the yield of 10-year Italian Government bonds, and ii) by the 80 % linked to the yield of 30-year Italian Government bonds), Italy considered that the Obligation was different from an obligation to directly invest in Italian Government bonds, where Italian Government bonds could be freely chosen and freely manageable.

⁽²¹⁾ The VaR model, using a 10-year cut-off point.

⁽²²⁾ The Macaulay duration is the weighted average time until cash flows are received, where the weight of each cash flow is determined by dividing the present value of the cash flow by the sum of the present value of all cash flows. It is measured in years.

⁽²³⁾ The linear depreciation model, using a 10-year cut-off point

⁽²⁴⁾ In the letters sent by Italy, the terms duration and average life are often used interchangeably, although they can refer to different concepts. This does not have any impact on the assessment carried on in this Decision.

3.2.7. Market conformity of the remuneration granted to PI for the postal current accounts deposited with the Treasury

- (65) The loan rate was market-conform because the funds deposited with the Treasury had a long-term duration. This was due to the fact that the Obligation was not limited in time and due to the stability of the funds collected on the postal current accounts of PI's customers and deposited with the Treasury. In addition, Italy considered that the Obligation precluded PI from applying active, and potentially more advantageous, management of the funding. In the absence of the Obligation, Italy contends that PI could have invested 10 % of its liquidity in short-term bonds and 90 % in long-term bonds.
- (66) Regarding the market conformity of the interest rate paid to PI, Italy provided the opinion of the auditors of PI and comfort letters by private banks and consultants. PI's auditors stated that because of their characteristics and growth rates, the funds collected on postal current accounts were stable. Private banks and consultants ⁽²⁵⁾ agreed that the returns achieved by PI on the funds collected on current postal accounts and deposited with the Treasury were similar to market returns achievable by PI by implementing appropriate investment and risk management strategies.

3.2.7.1. Comparison with the returns achieved on Poste Vita products

- (67) Italy considers that the remuneration obtained by PI on the funds deposited with the Treasury was in line with the remuneration obtained by Poste Vita on its invested funds. Italy contends that life insurance policies are products that can be considered comparable to postal current accounts and that the average interest rate on the invested proceeds of those products (e.g. *Posta Più*) was 4,68 % during the period 2002-2006, which corresponds to the Convention rate (4,55 %).
- (68) Italy considers that postal current accounts and life insurance policies were comparable financial products because postal accounts were short-term products but *de facto* they were similar to medium term financial instruments, with minimum guaranteed capital and return.

3.2.7.2. Comparison with La Banque Postale

- (69) According to Italy, *La Banque Postale's* (France) ALM strategy was based on the same kind of statistical model used by PI, during the period under assessment.
- (70) That statistical model identifies the stable and volatile funds collected on postal current accounts. The stable funds are invested in OECD-zone bonds and the volatile funds in short-term instruments bonds. On the basis of this model, in 2005 the return on the investment of *La Banque Postale's* current accounts was 4,4 % (vs. 3,9 % foreseen by the Convention).
- (71) More specifically, the example of *La Banque Postale* demonstrated that it is possible to have higher returns on investment than those set by the Convention by using prudential ALM of an average duration of 5 years.

3.2.7.3. Comparison with other alternative investment strategies (active management of funds)

- (72) In order to demonstrate that the remuneration set by the Convention did not grant any advantage to PI, Italy provided the Commission with a study conducted by [...]
- (73) The [...] Study developed the following analysis:
- (a) The remuneration paid by the Treasury to PI on the deposits could be deemed to be fair because:
- (1) The expected duration of such deposit base, net of a component theoretically more volatile, is extremely long and virtually infinite.
 - (2) The features of such deposit base are transferred to the Treasury by law.
 - (3) The indexation paid by the Treasury is based on 12-month Treasury bills for 10 % (the most volatile component), on 10-year Italian Government bonds for 10 % (the component which under more conservative assumptions could potentially decrease over time), and on 30-year Italian Government bonds for 80 %.
 - (4) The Obligation underpins the permanent nature of the relationship between PI and the Treasury.

⁽²⁵⁾ Letter of [...], letter of [...], letter of [...], letter of [...], letter of [...].

- (5) The constraints on PI as depositor incorporated implicit costs and burdens:
- (a) The deposit at the Treasury cannot be considered a short term 'risk free' asset in light of PI's permanent obligation to deposit funds with the Treasury.
 - (b) The impossibility for PI to enter into active fund management strategies (the quantitative analysis conducted by [...]) is aimed at establishing the relevant resulting costs).
- (b) A comparison of PI's interest margin with the comparable private sector banks' interest margin revealed that the cost for PI's deposits from retail customers is in line with the cost of retail depositors of private sector banks. In addition, the interest margin achieved by private sector banks on the deposits component of their funding is significantly higher than PI's, which in [...]'s view represents proof that no State aid was granted to PI.
- (c) A comparison of PI's asset liability tenor mismatch with its private sector peers revealed that PI's deposit base has a 'virtually infinite' duration component conservatively estimated to at least 60,8 % of the total. Pursuant to the Convention, PI uses the proceeds of its deposit base to fund a long-term asset such as the deposit with the Treasury. To ascertain the behaviour of private sector banks, the financials of banks specialised in funding the public sector (such as Dexia, Depfa, etc.) were analysed. Such banks show similar patterns. In fact, public sector banks fund themselves for approximately 50 % on the medium to long term, and the remainder on repos with the ECB or interbank deposits, while investing their total funding in illiquid public sector assets issued by governments or local authorities, usually with maturities from 10 to 50 years.
- (d) A quantitative analysis aimed at proving the benefit of an active asset management based on PI's investment in a portfolio of European Government bonds starting March 2007. The analysis is grounded in two elements, the first based on the analysis of potential past performance, the second on a future evolution:
- (1) [...] retrospectively applied fund management strategies to PI's deposit portfolio, one involving a similar duration as the portfolio of the [...] study in the Value-at-risk (VaR) specification (referred to as the 'benchmark portfolio') and another (referred to as a 'tactical strategy') using the same criteria and investment constraints currently adopted by PI. The latter strategy is based on an automatic quantitative model. The return obtained over the last 10 years under the tactical strategy would have exceeded the Convention return over the same period by approximately 1,62 % per annum (without taking into consideration transaction costs, however). The return obtained over the two-year period 2005-2006 (2,45 %) would have been lower than the Convention return (4,14 %).
 - (2) Looking at the future, [...] identified certain fund management solutions that PI could implement to obtain incremental returns on the passive investment in Government bonds without adding significant incremental risks. As evidence of such strategies, the [...] Study provides the following detailed description:
 - (a) Strategies based on the sale of purchase option on Government bonds, which would achieve an extra yield in 2008 of [...];
 - (b) Construction of a synthetic sovereign Euro zone bond, which would achieve an extra yield in 2008 of [...];
 - (c) Management of a portion of existing capital gains achieved on the portfolio, which would achieve an extra yield in 2008 of [...]; and
 - (d) Bonds switch in the portfolio, which would achieve an extra yield in 2008 of [...].
- (74) As for the comparison between Treasury deposit's remuneration and the remuneration offered by active management fund strategies, Italy explained that such a comparison had to be made over a significant time horizon – 10 years – in order to take into account a full economic cycle. This was the reason why [...] compared the Convention return against the returns from alternative strategies over a 10-year period and not over a shorter period. Therefore, when interest rates grow, fixed rate portfolios tend to under-perform compared to floating rate portfolios, whereas the opposite occurred in the case of decreasing interest rates.

- (75) According to Italy, over a 10-year period, investment portfolios based on floating rates can be compared to investment portfolios based on fixed rates, because of the compensation of capital gains and capital losses. Over a 10-year period, in fact, returns of fixed-rate portfolios tend to be in line with returns of floating-rate portfolios. Active funds management clearly provides better returns than passive ('parametric') investments such as the Convention (e.g. the return of the 5-year duration benchmark used by [...] is in line with the Convention return, the duration of which is much longer)
- (76) Furthermore, according to Italy, the Commission should distinguish between short term and long-term risk. Whereas it is true that the value of fixed-rate securities with a duration of 10 years can vary a lot in the short term, over the entire 10-year period fixed-rate bonds give a very reliable (because fixed) rate of return. All in all, over a 10-year period, returns of fixed-rate portfolios would tend to be in line with returns of floating-rate portfolios, the latter in fact being more risky (because subject to yearly changes in interest return).
- (77) Moreover, true alternative investment strategies that are flexible and can be based on all possible financial instruments offered by the market, offer a higher possibility of better results than passive investments such as the Convention.
- (78) In addition, Italy underlined that, at the moment of the conclusion of the Convention with the Treasury, the future trend of interest rates was unknown. The choice to use floating parameters for the Convention was economically rational, according to Italy, because it was fair to the two parties: PI and the Treasury. The option to revise the Convention after three years and to cancel it every year allowed any of the two parties to withdraw from the agreement in case the remuneration had become unfair or inconsistent, due to evolving market interest rates.
- (79) The [...] Study also shows that the Obligation generated opportunity costs and risks for PI by limiting the spectrum of its investment option. The deposit with the Treasury was exclusively linked to the credit risk of Italy, preventing PI from seeking diversified investment opportunity within the European Government bond market. Moreover, such credit risk was compounded by the liquidity risk due to the long-term nature of the deposit tenor without early redemption rights.
- (80) Italy justifies the comparability of the Convention mechanism (based on variable interest rates) with the quantitative models used by [...] aimed at proving the benefit of an active asset management (based on fix interest rates) by stating that it is usual practice for market operators trading in bonds and for PI since 2007 to foresee fix interest rate investments. They also contend that the comparison between the Convention mechanism and the quantitative models used by RBS has to be analysed in the light of the comparison between passive and active management of funds rather than between two remuneration mechanisms based on fixed and floating interest rates.
- (81) Finally, Italy argues that the Convention mechanism based on short-term remuneration for the volatile component of the funds deposited with the Treasury adequately estimates the real liquidity risk borne by the Treasury.

3.2.8. *Remarks to ABI's comments*

- (82) According to Italy, the rate on the deposit with the Treasury could not be a short-term rate (e.g. interest rate of 12-month Treasury bills) because of the stability of the deposits.
- (83) Italy indicated that, using (as done by ABI) 2005 as a reference year, resulted in an inappropriate analysis because 2005 was the year when interest rates on short-term Treasury bills were at their lowest.
- (84) Regarding the comparison made by ABI with the remuneration obtained by CDP on its liquidity deposited with the Treasury (remuneration equal to a floating six-month rate calculated as the simple arithmetic average of the gross yield on six-month Treasury bills and the monthly Rendistato index), Italy contends that CDP cannot be compared to PI since it is a different company in terms of structure, activities, business' objectives, operations, organisation and investment policies. Italy also contends that, since the monthly Rendistato index represents a medium/long-term rate, ABI contradicts itself in considering that PI's liquidity deposited with the Treasury should be remunerated according to short-term parameters.

- (85) Italy also argues that the uniqueness of its Treasury deposits made it difficult to identify one single substitutive instrument. However, because of the stability of postal current accounts, the deposit of these funds with the Treasury could be compared to the funds collected by means of long-term bonds for the most part. The stability of the postal current accounts made a comparison with short term (12-month) Treasury bills irrelevant.

4. ASSESSMENT OF THE MEASURE

4.1. Existence of aid

- (86) In order to ascertain whether a measure constitutes aid within the meaning of Article 107(1) TFEU, the Commission has to determine (i) whether the measure is granted by the State or through State resources; (ii) whether the measure provides an economic advantage; (iii) whether the measure is capable of distorting competition by selectively favouring certain undertakings or the production of certain goods; and finally, (iv) whether the measure affects trade between Member States. All of these conditions must be met in order for a measure to constitute State aid within the meaning of Article 107(1) TFEU.
- (87) By means of the 2013 ruling, the General Court annulled the 2008 Decision. Notably, the Court considered that the Commission had made a manifest error by concluding that the measure constituted State aid, based on the positive difference between the rate of the Convention and the rate granted to the prudent private borrower. In order to demonstrate that the measure indeed provides such an economic advantage, the Commission should have clearly demonstrated that, in the absence of the Obligation, PI could not have reasonably got a return higher than or equal to the Convention's rate by investing the deposits from the postal current accounts in the market.
- (88) Accordingly, this assessment addresses whether an economic advantage was provided, failing which the measure would not amount to State aid within the meaning of Article 107(1) TFEU.
- (89) The Commission considers that the comparison between the Convention and the alternative investments available to PI in the absence of the Obligation should take properly into account the investments' risk and their interactions with the risks arising from PI's liabilities (i.e. the aggregate customers' deposits), from an integrated asset/liability management perspective. The comparison should then be carried out either between the return available under the Convention and the return of investments holding a risk level similar to the one of the Convention, or between risk-adjusted returns.
- (90) The Commission also recalls that the analysis of the possible advantage granted by the Convention to PI has to be made *ex ante*. The estimation of the returns available under the alternative investments should be made in accordance with the information available to the parties at the moment the Convention was passed.
- (91) The Commission first reviewed the comparisons submitted by Italy, as summarised in Section 3.2.7. Italy claimed that the alternative investments, which could have been available to PI in the absence of the Obligation, offered similar or higher returns than the Convention and that this demonstrated that the Convention did not entail any advantage for PI. The Commission found that these proposed alternative investments are not proven to be comparable to the Convention from a risk perspective. As a result, they cannot form a basis for the assessment described by the General Court, as they do not allow for a meaningful conclusion on whether PI benefitted under the Convention.
- In the comparative analysis of PI's insurance activities (see recitals 67-68), Italy claims but does not prove that the life insurance policies are comparable to postal current accounts and that the risks of the investments, made on the back of these products, are comparable to the risks associated with the Convention.

- In the comparative analysis of *La Banque Postale*'s investment strategy (see recitals 69-71), Italy does not prove that the liability profile of *La Banque Postale* matches that of PI or that the investment profile of *La Banque Postale* is similar to PI's investment profile under the Convention.
 - In the comparative analysis of other investment strategies, as presented in the [...] study (see recitals 72-81), PI's liability profile is taken properly into account in accordance with the assessment performed by [...] (see recitals 53-58), and a synthetic measure of risk, i.e. the volatility of the returns, is presented. However, the Commission noted that the proposed alternative investments bear a different level of risk than that of the Convention and that, therefore, the return of these alternative investments – if not risk-adjusted – cannot be compared with the return available under the Convention.
- (92) In addition, Italy claimed that the absence of any *ex-ante* advantage for PI resulted from the option – available to both PI and the State – to cancel the Convention each year, in case the remuneration had become unfair (see recital 78). However, the Commission considered that this option did not exclude a potential advantage for PI. The option did not cover the first year and there was no obligation for Italy to exercise it, even if it would have been convenient to do so, in the following years.
- (93) Based on the above, the Commission concludes that the arguments brought forward by Italy are not sufficient to draw a meaningful conclusion on whether or not the Convention provided an advantage for PI. The Commission then applied the assessment described by the General Court in this case. To this aim, the Commission estimated the expected returns/risks offered by a comprehensive set of alternative investment strategies, available in the absence of the Obligation. For technical support on these issues, the Commission selected the University of Perugia via a tender process, whose experts produced a report in November 2015 ('the Experts' Report').

4.2. Summary of the Experts' Report

- (94) The Experts' Report examines the investment made by PI under the Obligation, whose return is governed by the Convention, and potential alternative market investment strategies, which could have been considered by PI in the absence of the Obligation for the period 2005-2007 for the funds collected through postal current accounts. The Report also estimates the respective risk-return profiles using only information available to PI at the time of the investment.
- (95) The Experts' Report simulates how PIs liabilities (i.e. deposits) are expected to evolve over time. As those liabilities are claims of depositors, PI can only invest what depositors do not withdraw. As a consequence, the experts estimate so-called liability patterns ('LP') which model the amount of funds expected to be available to PI over a certain time period, which PI can therefore invest. For that estimation, the Experts' Report distinguishes the stable components of the liabilities from the volatile components. Only the stable components can be invested in short or long term maturity assets according to the estimated LP.
- (96) The Experts' Report considers two liability patterns — LP1 and LP2 — which differ in how the stable component of the deposits is treated (i.e. the part that is not withdrawn during the next 30 years under the modelling assumptions). In both scenarios, the Experts' Report assumes that the total amount of the collected funds will decrease in time because of the withdrawal of the current account deposits. LP1 allocates outflows with a modelled maturity of more than 30 years proportionally over a period of 30 years. LP2 allocates all outflows with a modelled maturity of more than 30 years to the outflow at year 30. Under the assumptions of the Experts' Report, the difference is significant as roughly 60 % of all deposits have a modelled outflow dates beyond 30 years. On that basis, under LP1, outflows occur regularly between one and 30 years, whereas under LP2, only 40 % of outflows occur between one and 30 years and 60 % occur at year 30 only.

- (97) With respect to the question on which of the two liability patterns would present a more appropriate assumption, the Experts' Report argues that the less conservative liability pattern LP2 is more appropriate. To support this conclusion, the Experts' Report submits that PI is different from a typical commercial bank to the extent that (i) PI was not subject to the prudential regulation applicable for banks and thus to the requirement of higher capital level for longer-term investments; and that (ii) PI is not exposed to the same risk of massive withdrawals and liquidity crisis as a typical bank, because PI is considered by a large part of the investors to be the same as Italy. The Experts' Report argues that this perception is consistent with the expectation that, in case of a liquidity crisis, Italy would be forced to finance any insolvency position of PI to avoid a contagion effect leading to a deterioration of credit standing of the entire stock of public debt.
- (98) The Commission notes that the Experts' Report suggests that the funds deposited by PI on the Treasury account were *de facto* not short-term in nature. A short-term horizon of the funds was suggested by ABI, which claimed that the remuneration of the Treasury deposit should have corresponded to its short-term nature (see recital 45). At the same time, the Commission recalls that the long-term nature of the funds deposited by PI with the Treasury, as assessed in the Experts' Report, is not sufficient to determine the absence of State aid. Pursuant to the assessment required under the 2013 ruling, a meaningful comparison of the returns/risk both under the Obligation and free of the Obligation is necessary to effectively determine whether the measure gave PI an advantage.
- (99) Accordingly, the Experts' Report constructs a dynamic interest rate model that allows for the calculation of prices of bonds based on the model of the interest rate yield curve at any point in the future. The Report considers three interest rate scenarios: stationary (stable), increasing and decreasing interest rates, compared to the yield curve prevailing at the time of the Convention.
- (100) The Experts' Report then examines the risk-return characteristics of the actual investment that PI undertook under the Obligation and whose return is governed by the Convention. Here, the risk — which is entirely due to changes in the interest rate that has an impact on the bond prices used to calculate the appropriate remuneration rate under the Convention — is very low. In fact, the risk level is 0,11 %, 0,17 % and 0,06 % under the stationary, increasing and decreasing rate scenarios, respectively.
- (101) Regarding the available investment strategies, PI was allowed to invest only in Euro area investment grade bonds at the time of investment. Correspondingly, the experts consider strategies based on Italian Government bonds of different maturities and a strategy using Euro area Government bonds for the comparison.
- (102) When examining the available investment strategies, the Experts' Report considers two main risks: the risk resulting from a gap between the maturities of PI's assets (the Italian Government bonds) and its liabilities (the deposits), and the risk of a sovereign default by Italy.
- (103) The gap or mismatch between the maturities of assets and liabilities creates liquidity risk (i.e. the risk that PI does not have sufficient liquid means to meet withdrawal requests by depositors at a given point in time). That liquidity risk is limited, however, when the assets (i.e. Italian Government bonds) are easy to sell. If PI had to sell those bonds prior to their maturity, the market price would be driven by the prevailing interest rate at the time, thereby making PI vulnerable to interest rate risk, leading to potential capital gains or losses. This risk is explicitly modelled in the Experts' Report.
- (104) Regarding the risk of a sovereign default, the Experts' Report points out that PI also bears the sovereign risk of default by Italy under the Convention. Therefore, the Experts' Report considers that the use of Italian Government bonds in the model allows for the same sovereign risk in both strategies and presents a like-for-like comparison without explicit modelling.
- (105) The Experts' Report analyses five different strategies:
- The first investment strategy is a buy-and-hold strategy. Under this strategy, PI purchases Italian Government bonds and holds them until maturity. The Experts' Report assumes that such bonds are available for all maturities (i.e. for any time period) and priced according to the modelled yield curve. Given that appropriate bonds can be purchased to match precisely the maturity of assets, the strategy leads to a perfect match between the maturity of assets and liabilities so that there is no interest rate risk at all in this strategy.

- The second strategy is similar to the first but removes the assumption that bonds are available for any time period. Now, PI does bear some interest rate risk because there are deposit outflows expected for times where no bond is available in the market to cover them. Therefore, PI might be forced to invest in some bonds with a longer maturity and sell them prior to their maturity to cover expected deposit outflows, which leads to some risk of capital gains or losses.
 - The third strategy is another buy-and-hold strategy but introduces a voluntary strategic maturity gap between the maturity of the bonds and the deposits. Here, the maturity gap is generated by PI investing in assets with a maturity longer than the expected deposit outflows. Therefore, PI accepts the interest rate risk related to having to sell the underlying bond in order to cover the corresponding deposit claim at the time when such a claim arises in return for a higher yield on bonds with a longer maturity.
 - The fourth strategy is a dynamic trading strategy where PI dynamically buys and sells bonds. In particular, PI invests all the funds collected under the postal current account in a bond of a given maturity — considered are five, ten or 20 years — sells it after 15 days and reinvests the proceeds in another bond with again the same maturity (i.e. the newly bought bond matures 15 days after the sold one). Given that outflows of deposits are considered only at the end of a given year, the amount invested in any given year is considered constant with respect to outflows and fluctuates only with respect to changes in the interest rate. Therefore, the resulting annual rates of return of this strategy are independent of the liability pattern.
 - As a fifth strategy, the study also considers PI to invest entirely in a long term Euro area Government bonds index. This index includes Euro area Government bonds (and not only Italian Government bonds) of maturities longer than 10 years. This strategy departs from the framework of the previous strategies since the underlying credit risk is not just on Italian Government bonds but a mix of Euro area Government bonds. Additional modelling assumptions are made to cover that additional risk. Again, outflows of deposits are only considered at the end of a given year, making the annual returns independent of the liability pattern.
- (106) The five investment strategies are simulated in the Experts' Report. For all strategies except the Euro area Government bond strategy, the risk-return profile is estimated under the three different interest rate scenarios: stationary, increasing and decreasing rates.
- (107) Finally, the Experts' Report examines what investment strategy PI implemented when the funds were released from the Obligation in 2007. The Report demonstrates that the funds were invested in five-year Euro area Government bonds and they again provide the risk-return of such an investment on the basis of their model. The Experts' Report concludes that the strategy was suboptimal as it leads to a lower return with higher risk (0,65 %) than what could have been achieved by following one of the alternative investment strategies.
- (108) Having estimated risk-return profiles for all investment strategies, the experts then use portfolio pricing theory to determine whether the investment that PI had to undertake under the Obligation and whose return was governed by the Convention in fact provided an economic advantage to PI (i.e. whether the return received under the Convention taking into account the risk of the investment was higher than achievable returns at equivalent risk levels in alternative investments).
- (109) To that effect, the Experts' Report combined the risk-return characteristics of all available alternative investments into a single investment function expressing the achievable market return as a function of the risk taken. If the risk-return characteristics of the Convention were to lie above that function (i.e. if under the Convention, PI were to achieve a higher return for equivalent risk than available in the market) then one would have to conclude that there had been an advantage.
- (110) On the basis of these considerations, the report concludes that only using the conservative liability pattern LP1 and only under the expectation of increasing interest rates, the Convention provided PI with a higher return. In that scenario, taking into account the fact that PI was later ready to accept a risk of 0,65 %, the advantage would amount to only 0,29 percentage points. Under LP2, no advantage would be provided in any interest rate scenario.

4.3. The Commission's assessment of the Experts' Report

- (111) The Commission finds some scenarios more plausible than others with respect to specific assumptions or interpretations made in the Experts' Report. In particular, the Commission disagrees with the use of liability pattern LP2.
- (112) The Commission notes that the experts' report is only using information available prior to the conclusion of the Convention, as requested in the 2013 ruling, with the exception of the reference to the 0,65 % risk level accepted by PI after the end of the Obligation. The Commission disagrees with the use of 0,65 % as the appropriate risk level to estimate the expected return in the absence of the Obligation.
- (113) First, the choice of the liability pattern has an important impact on the expected return of different investment strategies. As stated in recitals 96-97, there are significant differences with respect to the assumptions about deposit outflows that follow from the choice of LP1 or LP2. The average duration of PI's deposits — i.e. the weighted average time of keeping those deposits available — varies significantly between roughly nine and fourteen years, respectively, under LP1 and LP2.
- (114) The Commission notes that the durations under both LP1 and LP2 exceed the maximum duration of five years recommended by the European Banking Authority ('EBA') to model non-maturing liabilities such as deposits.
- (115) The Commission has assessed the question of the average duration of PI's deposits to be used for the assessment required under the 2013 ruling. It considers that LP2 seems significantly over-optimistic with respect to the average expected retention of customer deposits. However, PI's customer deposits' duration may in practice exceed the five years recommended by EBA, as proposed by the Experts' Report. In its assessment, the Commission has balanced the following considerations:
- (a) EBA recommendations of a deposit's duration of five years were only issued in 2015, as the regulatory requirements in terms of liquidity management had been reinforced.
 - (b) Under the current EBA recommendations, if the deposit-taking institution can demonstrate that it has accurately modelled its deposit repricing profile ⁽²⁶⁾, a higher duration could be deemed appropriate.
 - (c) As also claimed by Italy (see recitals 53-56), the profile of customers of postal banks could be considered more stable than that of customers of typical commercial banks. In fact, postal banks may attract customers with average or less than average incomes and an older age, who tend to be less rate-sensitive. As a result, PI's deposit duration could be expected to exceed the five years recommended by EBA.
 - (d) At the same time, the Commission considers that the arguments made in the Experts' Report and set out in recitals 96-97 are not sufficient to justify a preference for LP2 over LP1. The Experts' Report claims that LP2 could be justified, in this specific case, given that PI was not subject to the prudential regulation applicable for banks, and that PI's image perceived by large part of the investors is the same as Italy. However, the Commission considers that:
 - (1) the absence of regulatory capital requirements for PI does not affect *per se* its depositors' behaviour, and certainly not in the sense of increasing the horizon of their deposits with PI;
 - (2) the depositors cannot be expected to consider PI's risk profile the same as Italy. In fact, assuming that Italy would be forced to finance any insolvency position of PI, as suggested in the Experts' Report, would imply the existence of State aid in the form of an implicit guarantee.
- (116) On the basis of the above, the Commission accepts LP1 as a realistic assumption for determining the prudent investment strategy that PI would have pursued in the absence of the Obligation during the relevant period.
- (117) Further, the Commission recalls that the Experts' Report stated that the expected Convention's rate is higher than the expected return of alternative investment strategies, only under the increasing rate scenario, by 0,29 percentage points (see recital 110). However, those 0,29 percentage points had been calculated by comparing the expected market return at a risk level of 0,65 %, while the return under the Convention showed a risk level of 0,17 % under the increasing rate scenario.

⁽²⁶⁾ <https://www.eba.europa.eu/documents/10180/1084098/EBA-GL-2015-08+GL+on+the+management+of+interest+rate+risk+.pdf>

- (118) The Commission does not find any justifiable reason to compare returns at different risk levels, in particular because the applied risk level of 0,65 % had been calculated in the Experts' Report by considering the investment strategy that PI eventually implemented after the Obligation had been revoked (see recital 104). Such a consideration does not seem suitable for use in a methodology which should take into account only information which was available on an *ex-ante* perspective.
- (119) Therefore, the risk level used to calculate the achievable market return for comparison with the rate under the Convention should be the same as the risk of the Convention, i.e. 0,11 %, 0,17 % and 0,06 % under the stationary, increasing and decreasing rate scenarios, respectively.
- (120) On that basis, the Commission notes that for LP1, the expected advantage under the Convention in the increasing rate scenario would therefore be approximately 0,5 percentage points, rather than 0,29 percentage points. For stationary and decreasing rates, achievable market returns would continue to be greater than the return under the Convention, by roughly 0,15 percentage points for stationary rates and 0,4 percentage points for decreasing rates.

4.4. Conclusion

- (121) The expected rate under the Convention is lower than the expected return of alternative investment strategies, in a stationary rate scenario, at similar risk levels, in the absence of the Obligation. As a result, the rate under the Convention did not entail an immediate advantage for PI.
- (122) The Commission has no element to assume that PI or Italy could reasonably have expected a specific rate trend at the time when the Convention was concluded. Accordingly, applying the same probability to the three rate scenarios (i.e. decreasing, stationary and increasing rates), the expected rate under the Convention is marginally lower than the expected return of alternative investment strategies, at similar risk levels, in the absence of the Obligation. As a result, the Convention did not provide an advantage for PI.
- (123) On that basis, the Commission concludes that the evidence is not sufficient to prove that PI benefitted from an advantage under the Convention,

HAS ADOPTED THIS DECISION:

Article 1

The remuneration paid by the public authorities of the Italian Republic to Poste Italiane pursuant to Law No 266 of 23 December 2005 and the Convention in the years 2005-2007 does not constitute aid within the meaning of Article 107(1) of the Treaty on the Functioning of the European Union.

Article 2

This Decision is addressed to the Republic of Italy.

Done at Brussels, 2 August 2019.

For the Commission
Margrethe VESTAGER
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2019/1969
of 26 November 2019
postponing the expiry date of approval of IPBC for use in biocidal products of product-type 8
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

- (1) The active substance IPBC was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ⁽²⁾ for use in biocidal products of product-type 8, and pursuant to Article 86 of Regulation (EU) No 528/2012 is therefore considered approved under that Regulation subject to the specifications and conditions set out in Annex I to that Directive.
- (2) The approval of IPBC for use in biocidal products of product-type 8 will expire on 30 June 2020. On 20 December 2018, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of IPBC.
- (3) On 11 April 2019, the evaluating competent authority of Denmark informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of Regulation (EU) No 528/2012, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.
- (4) The evaluating competent authority may, as appropriate, request the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of that Regulation. In such case, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.
- (5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.
- (6) Consequently, for reasons beyond the control of the applicant, the approval of IPBC for use in biocidal products of product-type 8 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of approval of IPBC for use in biocidal products of product-type 8 for a period of time sufficient to enable the examination of the application. Considering the time-limits for the evaluation by the evaluating competent authority and for the preparation and submission of the opinion by the Agency, it is appropriate to postpone the expiry date of approval to 31 December 2022.
- (7) Except for the expiry date of the approval, IPBC remains approved for use in biocidal products of product-type 8 subject to the specifications and conditions set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of approval of IPBC for use in biocidal products of product-type 8 is postponed to 31 December 2022.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

Article 2

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, 26 November 2019.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION IMPLEMENTING DECISION (EU) 2019/1970**of 26 November 2019**

amending Annex II to Decision 93/52/EEC as regards the officially brucellosis (*B. melitensis*)-free status and Annex II to Decision 2003/467/EC as regards the officially brucellosis-free status of certain regions of Spain and Annexes I and II to Decision 2008/185/EC as regards the free status and the approval of the eradication programmes for Aujeszky's disease for certain regions of Italy

(notified under document C(2019) 8378)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals ⁽¹⁾, and in particular Section II of Chapter 1 of Annex A thereto,

Having regard to Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine ⁽²⁾, and in particular Articles 9(2), 10(2) and paragraph 7 of Annex A.II thereof,

Whereas:

- (1) Directive 91/68/EEC establishes the animal health conditions governing trade in the Union in ovine and caprine animals. It lays down the conditions whereby Member States or regions thereof may be recognised as officially free of brucellosis (*B. melitensis*) as regards ovine and caprine herds.
- (2) Commission Decision 93/52/EEC ⁽³⁾ provides that the regions of the Member States listed in Annex II thereto are recognised as officially free of brucellosis (*B. melitensis*) as regards ovine and caprine herds, in accordance with the conditions laid down in Directive 91/68/EEC.
- (3) Spain has submitted to the Commission documentation demonstrating compliance for the Autonomous Community of Murcia, the Province of Toledo of the Autonomous Community of Castilla-La Mancha and the Provinces of Huelva, Sevilla and Cordoba of the Autonomous Community of Andalusia with the conditions laid down in Directive 91/68/EEC in order to be recognised as officially free of brucellosis (*B. melitensis*) as regards ovine and caprine herds.
- (4) Following the evaluation of that supporting documentation, the Autonomous Community of Murcia, the Province of Toledo of the Autonomous Community of Castilla-La Mancha and the Provinces of Huelva, Sevilla and Cordoba of the Autonomous Community of Andalusia should be recognised as officially free of brucellosis (*B. melitensis*) as regards ovine and caprine herds.
- (5) Annex II to Decision 93/52/EEC should therefore be amended accordingly.
- (6) Directive 64/432/EEC applies to trade within the Union in bovine and porcine animals. It lays down the conditions whereby a Member State or a region thereof may be declared officially brucellosis-free as regards bovine herds.
- (7) Article 2 of Commission Decision 2003/467/EC ⁽⁴⁾ provides that regions of Member States listed in Chapter 2 of Annex II thereto are declared officially brucellosis-free as regards bovine herds.

⁽¹⁾ OJ L 46, 19.2.1991, p. 19.

⁽²⁾ OJ P 121, 29.7.1964, p. 1977/64.

⁽³⁾ Commission Decision 93/52/EEC of 21 December 1992 recording the compliance by certain Member States or regions with the requirements relating to brucellosis (*B. melitensis*) and according them the status of a Member State or region officially free of the disease (OJ L 13, 21.1.1993, p. 14).

⁽⁴⁾ Commission Decision 2003/467/EC of 23 June 2003 establishing the official tuberculosis, brucellosis, and enzootic-bovine-leukosis-free status of certain Member States and regions of Member States as regards bovine herds (OJ L 156 25.6.2003, p. 74).

- (8) Spain has submitted to the Commission documentation demonstrating compliance for the Autonomous Community of Aragon and the Province of Leon of the Autonomous Community of Castilla Y Leon with the conditions laid down in Directive 64/432/EEC in order to be recognised as officially brucellosis-free regions as regards bovine herds.
- (9) Following the evaluation of that supporting documentation, the Autonomous Community of Aragon and the Province of Leon of the Autonomous Community of Castilla Y Leon should be recognised as officially free of brucellosis as regards bovine herds.
- (10) Annex II to Decision 2003/467/EC should therefore be amended accordingly.
- (11) Article 10 of Directive 64/432/EEC provides that where a Member State considers that its territory or part thereof is free of Aujeszky's disease, it should present appropriate supporting documentation to the Commission. It also provides that additional guarantees may be required for intra-Union trade in porcine animals.
- (12) Article 9 of Directive 64/432/EEC provides that a Member State, which has a compulsory national control programme for Aujeszky's disease for part of its territory, may submit its programme to the Commission for approval. It also provides that additional guarantees may be required for intra-Union trade in porcine animals.
- (13) Commission Decision 2008/185/EC ^(*) lays down additional guarantees for movements of pigs between Member States. Those guarantees are linked to the classification of the Member States or regions thereof according to their disease status for Aujeszky's disease.
- (14) Annex I to Decision 2008/185/EC lists the Member States or regions thereof free of Aujeszky's disease.
- (15) Italy has submitted to the Commission documentation demonstrating compliance for the Region of Friuli Venezia Giulia with the conditions laid down in Decision 2008/185/EC in order to be recognised as free of Aujeszky's disease.
- (16) Following the evaluation of that supporting documentation, the Region of Friuli Venezia Giulia should be recognised as free of Aujeszky's disease.
- (17) Annex I to Decision 2008/185/EC should therefore be amended accordingly.
- (18) Annex II to Decision 2008/185/EC lists the Member States or regions thereof where approved national control programmes for the eradication of Aujeszky's disease are in place.
- (19) Italy has submitted to the Commission supporting documentation for the approval of its control programmes for the eradication of Aujeszky's disease for the regions of Piemonte and Umbria and for these regions to be duly listed in Annex II to Decision 2008/185/EC.
- (20) Following the evaluation of that supporting documentation, the control programmes for the eradication of Aujeszky's disease for the regions of Piemonte and Umbria should be approved.
- (21) Annex II to Decision 2008/185/EC should therefore be amended accordingly.
- (22) 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

Annex II to Decision 93/52/EEC is amended in accordance with Annex I to this Decision.

^(*) Commission Decision 2008/185/EC of 21 February 2008 on additional guarantees in intra-Community trade of pigs relating to Aujeszky's disease and criteria to provide information on this disease (OJ L 59, 4.3.2008, p. 19).

Article 2

Annex II to Decision 2003/467/EC is amended in accordance with Annex II to this Decision.

Article 3

Annexes I and II to Decision 2008/185/EC are replaced by the text set out in Annex III to this Decision.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 26 November 2019.

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission

ANNEX I

In Annex II to Decision 93/52/EEC, the entry for Spain is replaced by the following:

'In Spain:

- Autonomous Community of Aragon,
 - Autonomous Community of Andalusia: Provinces of Cadiz, Cordoba, Huelva and Sevilla,
 - Autonomous Community of Asturias,
 - Autonomous Community of the Balearic Islands,
 - Autonomous Community of the Canary Islands,
 - Autonomous Community of Cantabria,
 - Autonomous Community of Castilla-La Mancha,
 - Autonomous Community of Castilla y León,
 - Autonomous Community of Catalonia,
 - Autonomous Community of Extremadura,
 - Autonomous Community of Galicia,
 - Autonomous Community of La Rioja,
 - Autonomous Community of Madrid,
 - Autonomous Community of Murcia,
 - Autonomous Community of Navarra,
 - Autonomous Community of Pais Vasco,
 - Autonomous Community of Valencia.'
-

ANNEX II

In Chapter 2 of Annex II to Decision 2003/467/EC, the entry for Spain is replaced by the following:

'In Spain:

- Autonomous Community of Andalusia: Provinces of Almeria, Granada and Jaen,
 - Autonomous Community of Aragon,
 - Autonomous Community of Asturias,
 - Autonomous Community of the Balearic Islands,
 - Autonomous Community of the Canary Islands,
 - Autonomous Community of Castilla-La Mancha,
 - Autonomous Community of Castilla y León: Provinces of Burgos, León, Soria, Valladolid and Zamora,
 - Autonomous Community of Cataluña,
 - Autonomous Community of Galicia,
 - Autonomous Community of La Rioja,
 - Autonomous Community of Madrid,
 - Autonomous Community of Murcia,
 - Autonomous Community of Navarra,
 - Autonomous Community of Pais Vasco,
 - Autonomous Community of Valencia.'
-

ANNEX III

'ANNEX I

Member States or regions thereof free of Aujeszky's disease and where vaccination is prohibited

ISO code	Member State	Regions
BE	Belgium	All regions
CZ	Czechia	All regions
DK	Denmark	All regions
DE	Germany	All regions
IE	Ireland	All regions
FR	France	The departments of Ain, Aisne, Allier, Alpes-de-Haute-Provence, Alpes-Maritimes, Ardèche, Ardennes, Ariège, Aube, Aude, Aveyron, Bas-Rhin, Bouches-du-Rhône, Calvados, Cantal, Charente, Charente-Maritime, Cher, Corrèze, Côte-d'Or, Côtes-d'Armor, Creuse, Deux-Sèvres, Dordogne, Doubs, Drôme, Essonne, Eure, Eure-et-Loir, Finistère, Gard, Gers, Gironde, Hautes-Alpes, Hauts-de-Seine, Haute-Garonne, Haute-Loire, Haute-Marne, Hautes-Pyrénées, Haut-Rhin, Haute-Saône, Haute-Savoie, Haute-Vienne, Hérault, Indre, Ille-et-Vilaine, Indre-et-Loire, Isère, Jura, Landes, Loire, Loire-Atlantique, Loir-et-Cher, Loiret, Lot, Lot-et-Garonne, Lozère, Maine-et-Loire, Manche, Marne, Mayenne, Meurthe-et-Moselle, Meuse, Morbihan, Moselle, Nièvre, Nord, Oise, Orne, Paris, Pas-de-Calais, Pyrénées-Atlantiques, Pyrénées-Orientales, Puy-de-Dôme, Réunion, Rhône, Sarthe, Saône-et-Loire, Savoie, Seine-et-Marne, Seine-Maritime, Seine-Saint-Denis, Somme, Tarn, Tarn-et-Garonne, Territoire de Belfort, Val-de-Marne, Val-d'Oise, Var, Vaucluse, Vendée, Vienne, Vosges, Yonne, Yvelines
IT	Italy	Autonomous Province of Bolzano Region Friuli Venezia Giulia
CY	Cyprus	All regions
LU	Luxembourg	All regions
HU	Hungary	All regions
NL	Netherlands	All regions
AT	Austria	All regions
PL	Poland	Voivodship podlaskie the following powiaty: augustowski, białostocki, Białystok, bielski, hajnowski, moniecki, sejneński, siemiatycki, sokółski, suwalski, Suwałki
SI	Slovenia	All regions
SK	Slovakia	All regions
FI	Finland	All regions
SE	Sweden	All regions
UK	United Kingdom	All regions

ANNEX II

Member States or regions thereof where approved national control programmes for the eradication of Aujeszky's disease are in place

ISO code	Member State	Regions
ES	Spain	All regions
IT	Italy	Region Emilia-Romagna Region Lombardia Region Piemonte Region Umbria Region Veneto
LT	Lithuania	All regions
PL	Poland	Voivodship dolnośląskie: all powiaty; Voivodship kujawsko-pomorskie: all powiaty; Voivodship lubelskie: all powiaty; Voivodship lubuskie: all powiaty; Voivodship łódzkie: all powiaty; Voivodship małopolskie: all powiaty; Voivodship mazowieckie: all powiaty; Voivodship opolskie: all powiaty; Voivodship podkarpackie: all powiaty; Voivodship podlaskie the following powiaty: grajewski, kolneński, łomżyński, Łomża, wysokomazowiecki, zambrowski. Voivodship pomorskie: all powiaty; Voivodship śląskie: all powiaty; Voivodship świętokrzyskie: all powiaty; Voivodship warmińsko-mazurskie: all powiaty; Voivodship wielkopolskie: all powiaty; Voivodship zachodniopomorskie: all powiaty.

COMMISSION IMPLEMENTING DECISION (EU) 2019/1971**of 26 November 2019****on recognition of the ‘Universal Feed Assurance Scheme’ for demonstrating compliance with the sustainability criteria under Directives 98/70/EC and 2009/28/EC of the European Parliament and of the Council**

THE EUROPEAN COMMISSION,

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

Having regard to Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC ⁽¹⁾, and in particular the second subparagraph of Article 7c(4) thereof,

Having regard to Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC ⁽²⁾, and in particular the second subparagraph of Article 18(4) thereof,

Whereas:

- (1) Articles 7b and 7c of, and Annex IV to, Directive 98/70/EC and Articles 17 and 18 of, and Annex V to, Directive 2009/28/EC lay down similar sustainability criteria for biofuels and bioliquids, and similar procedures for verifying that biofuels and bioliquids comply with those criteria.
- (2) Where biofuels and bioliquids are to be taken into account for the purposes referred to in Article 17(1)(a), (b) and (c) of Directive 2009/28/EC, Member States should require economic operators to show that biofuels and bioliquids comply with the sustainability criteria set out in Article 17(2) to (5) of that Directive.
- (3) The Commission may decide that voluntary national or international schemes setting standards for the production of biomass products contain accurate data for the purposes of Article 17(2) of Directive 2009/28/EC, and/or demonstrate that consignments of biofuel or bioliquid comply with the sustainability criteria set out in Article 17(3), (4) and (5), and/or that no materials have been intentionally modified or discarded so that the consignment or part thereof would fall under Annex IX. Where an economic operator provides proof or data obtained in accordance with a voluntary scheme that has been recognised by the Commission, to the extent covered by the recognition decision, a Member State should not require the supplier to provide further evidence of compliance with the sustainability criteria.
- (4) The request for recognition that the ‘Universal Feed Assurance Scheme’ demonstrates that consignments of biofuel comply with the sustainability criteria set out in Directives 98/70/EC and 2009/28/EC was submitted to the Commission on 14 June 2019. The scheme that is based in Confederation House, East of England Showground, Peterborough, PE2 6XE, United Kingdom, cover feed ingredients and compound feeds as well as combinable crops. This scheme covers the trading, transport and storage stages of agricultural feedstock from farm gate to first processor and, for the other stages, relies on other voluntary schemes recognised by the Commission. As such, it is the responsibility of the ‘Universal Feed Assurance Scheme’ to ensure that the recognition issued by the Commission on those schemes with which it jointly operates remains valid during the length of cooperation. The recognised scheme should be made available at the transparency platform established under Directive 2009/28/EC.
- (5) In assessing the ‘Universal Feed Assurance Scheme’, the Commission found that it covers adequately the sustainability criteria set out in Directives 98/70/EC and 2009/28/EC, except Article 7b(2) of Directive 98/70/EC and Article 17(2) of Directive 2009/28/EC. It does, however, provide accurate data on elements that are required by economic operators downstream the chain of custody to demonstrate compliance with Article 7b(2) of Directive 98/70/EC and Article 17(2) of Directive 2009/28/EC and applies a mass balance methodology in line with the requirements of Article 7c(1) of Directive 98/70/EC and Article 18(1) of Directive 2009/28/EC.

⁽¹⁾ OJ L 350, 28.12.1998, p. 58.

⁽²⁾ OJ L 140, 5.6.2009, p. 16.

- (6) The assessment of the 'Universal Feed Assurance Scheme' found that it meets adequate standards of reliability, transparency and independent auditing and also complies with the methodological requirements set out in Annex IV to Directive 98/70/EC and in Annex V to Directive 2009/28/EC.
- (7) The measures provided for in this Decision are in accordance with the opinion of the Committee on the Sustainability of Biofuels and Bioliquids,

HAS ADOPTED THIS DECISION:

Article 1

The 'Universal Feed Assurance Scheme' ('the scheme'), submitted for recognition to the Commission on 14 June 2019, demonstrates that consignments of biofuels and bioliquids produced in accordance with the standards for the production of biofuels and bioliquids set in the scheme comply with the sustainability criteria laid down in Article 7b(3), (4) and (5) of Directive 98/70/EC and Article 17(3), (4) and (5) of Directive 2009/28/EC.

The scheme also contains accurate data for the purposes of Article 17(2) of Directive 2009/28/EC and Article 7b(2) of Directive 98/70/EC in as far as it ensures that all relevant information from economic operators upstream the chain of custody is transferred to the economic operators downstream the chain of custody.

Article 2

In the event that the contents of the scheme, as submitted for recognition to the Commission on 14 June 2019, change in a way that might affect the basis of this Decision, such changes shall be notified to the Commission without delay. The Commission shall assess the notified changes with a view to establishing whether the scheme still adequately covers the sustainability criteria for which it is recognised.

Article 3

The Commission may repeal this Decision *inter alia* under the following circumstances:

- (a) if it has been clearly demonstrated that the scheme has not implemented elements considered to be important for this Decision or if severe and structural breach of those elements has taken place;
- (b) if the scheme fails to submit annual reports to the Commission pursuant to Article 7c(6) of Directive 98/70/EC and Article 18(6) of Directive 2009/28/EC;
- (c) if the scheme fails to implement standards of independent auditing specified in implementing acts referred to in the third subparagraph of Article 7c(5) of Directive 98/70/EC and the third subparagraph of Article 18(5) of Directive 2009/28/EC or improvements to other elements of the scheme considered to be important for a continued recognition.

Article 4

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

It shall apply until 30 June 2021.

Done at Brussels, 26 November 2019.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION IMPLEMENTING DECISION (EU) 2019/1972**of 26 November 2019****amending Implementing Decision 2013/764/EU concerning animal health control measures relating to classical swine fever in certain Member States***(notified under document C(2019) 8396)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market ⁽¹⁾, and in particular Article 9(4) thereof,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary checks applicable in intra-Union trade in certain live animals and products with a view to the completion of the internal market ⁽²⁾, and in particular Article 10(4) thereof,

Whereas:

- (1) Commission Implementing Decision 2013/764/EU ⁽³⁾ lays down animal health control measures in relation to classical swine fever in certain Member States. Those measures include prohibitions on the dispatch of consignments of domestic pigs and pig products from certain areas. The animal health control measures laid down in that Implementing Decision apply in parallel to those laid down in Council Directive 2001/89/EC ⁽⁴⁾ and are intended to combat the spread of classical swine fever particularly at Union level.
- (2) Implementing Decision 2013/764/EU also provides for derogations from the prohibition on the dispatch of live pigs from certain areas, subject to compliance with a number of conditions.
- (3) The period of application of the measures provided for in Implementing Decision 2013/764/EU should take account of the epidemiology of classical swine fever and also of the efficacy of the animal health measures applied by the Member States listed in the Annex to Implementing Decision 2013/764/EU with Union legislation. Therefore, given the current epidemiological situation in the Union and in neighbouring third countries and the efforts required to combat that disease, while at the same time not imposing unnecessary restrictions on trade, the period of application of Implementing Decision 2013/764/EU should be extended.
- (4) As it is important to have continuity of measures against classical swine fever at Union level in light of the current epidemic of that disease, the extension of the period of application of Implementing Decision 2013/764/EU should take into account that Regulation (EU) 2016/429 of the European Parliament and of the Council ⁽⁵⁾, which provides for safeguard measures in the event of animal diseases, applies from 21 April 2021.
- (5) In addition, taking into account the effectiveness of the overall measures applied in Croatia in accordance with Directive 2001/89/EC, the surveillance and the measures in place as presented to the Standing Committee on Plants, Animals, Food and Feed, all areas in Croatia currently listed in the Annex to Implementing Decision 2013/764/EU, should now be delisted from that Annex, in view of the favourable epidemiological situation of the disease in that Member State.
- (6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 395, 30.12.1989, p. 13.

⁽²⁾ OJ L 224, 18.8.1990, p. 29.

⁽³⁾ Commission Implementing Decision 2013/764/EU of 13 December 2013 concerning animal health control measures relating to classical swine fever in certain Member States (OJ L 338, 17.12.2013, p. 102).

⁽⁴⁾ Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever (OJ L 316, 1.12.2001, p. 5).

⁽⁵⁾ 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).

HAS ADOPTED THIS DECISION:

Article 1

Implementing Decision 2013/764/EU is amended as follows:

In Article 10, the date ‘31 December 2019’ is replaced by ‘21 April 2021’.

Article 2

Point 2 of the Annex to Implementing Decision 2013/764/EU is deleted.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 26 November 2019.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2019/1973**of 27 November 2019****not approving silver copper zeolite as an existing active substance for use in biocidal products of product-types 2 and 7****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular the third subparagraph of Article 89 (1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014 ⁽²⁾ establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes silver copper zeolite (EC No: n.a., CAS No: 130328-19-7).
- (2) Silver copper zeolite has been evaluated for use in products of product-type 2, disinfectants and algacides not intended for direct application to humans or animals, and of product-type 7, film preservatives, as described in Annex V to Regulation (EU) No 528/2012.
- (3) Sweden was designated as a rapporteur Member State and its competent authority submitted the assessment reports together with its conclusions to the European Chemicals Agency on 12 June 2017.
- (4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency ⁽³⁾ were adopted on 17 October 2018 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (5) According to those opinions, biocidal products of product-types 2 and 7 containing silver copper zeolite may not be expected to meet the criteria laid down in Article 19(1)(b) of Regulation (EU) No 528/2012 as sufficient efficacy has not been demonstrated.
- (6) Taking into account the opinions of the European Chemicals Agency, it is not appropriate to approve silver copper zeolite for use in biocidal products of product-types 2 and 7, as the conditions laid down in Article 4(1) of Regulation (EU) No 528/2012 are not satisfied.
- (7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

Silver copper zeolite (EC No: n.a., CAS No: 130328-19-7) is not approved as an active substance for use in biocidal products of product-types 2 and 7.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

⁽³⁾ Biocidal Products Committee (BPC) opinion on the application for approval of the active substance Silver copper zeolite, Product type: 2, ECHA/BPC/210/2018, adopted on 17 October 2018; Biocidal Products Committee (BPC) opinion on the application for approval of the active substance Silver copper zeolite, Product type: 7, ECHA/BPC/213/2018, adopted on 17 October 2018.

Article 2

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, 27 November 2019.

For the Commission
The President
Jean-Claude JUNCKER

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