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Legislation

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Contents

[1] Text with EEA relevance.

EN

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

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

DECISIONS

[1] Text with EEA relevance.

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION (EU) 2018/1257

of 18 September 2018

on the signing, on behalf of the European Union, of the Agreement to Prevent Unregulated High Seas Fisheries in the Central Arctic Ocean

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43, in conjunction with Article 218(5) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) The Union is exclusively competent, under the common fisheries policy, to adopt measures for the conservation of marine biological resources and to enter into agreements with third countries and international organisations in this respect.

(2) Pursuant to Council Decisions 98/392/EC ([1]) and 98/414/EC ([2]), the Union is a contracting party to the United Nations Convention on the Law of the Sea of 10 December 1982 ('the Convention') and to the Agreement on the implementation of the provisions of the United Nations Convention on the Law of the Sea of 10 December 1982, relating to the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks ('the Fish Stocks Agreement'). Both the Convention and the Fish Stocks Agreement require States to cooperate in conserving and managing the living resources of the sea. The Agreement to Prevent Unregulated High Seas Fisheries in the Central Arctic Ocean ('the Agreement') fulfils this obligation.

(3) Regulation (EU) No 1380/2013 of the European Parliament and of the Council ([3]) provides that the Union is to conduct its external fisheries relations in accordance with its international obligations and policy objectives, as well as the objectives and principles set out in Articles 2 and 3 of that Regulation, in order to ensure sustainable exploitation, management and conservation of marine biological resources and the marine environment. The Agreement is consistent with those objectives.

(4) On 31 March 2016, the Council authorised the Commission to negotiate, on behalf of the Union, an international agreement to prevent unregulated high seas fisheries in the central Arctic Ocean. Those negotiations were successfully concluded on 30 November 2017.

(5) Becoming a party to the Agreement will promote consistency in the Union's conservation approach across oceans and reinforce its commitment to the long-term conservation and sustainable use of marine biological resources globally.

([1]) Council Decision 98/392/EC of 23 March 1998 concerning the conclusion by the European Community of the United Nations Convention of 10 December 1982 on the Law of the Sea and the Agreement of 28 July 1994 relating to the implementation of Part XI thereof (OJ L 179, 23.6.1998, p. 1).

([2]) Council Decision 98/414/EC of 8 June 1998 on the ratification by the European Community of the Agreement for the implementing of the provisions of the United Nations Convention on the Law of the Sea of 10 December 1982 relating to the conservation and management of straddling stocks and highly migratory fish stocks (OJ L 189, 3.7.1998, p. 14).

([3]) Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC (OJ L 354, 28.12.2013, p. 22).

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

HAS ADOPTED THIS DECISION:

Article 1

The signing on behalf of the Union of the Agreement to Prevent Unregulated High Seas Fisheries in the Central Arctic Ocean ('the Agreement') is hereby authorised, subject to the conclusion of the said Agreement ([1]).

Article 2

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

Article 3

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

Done at Brussels, 18 September 2018.

For the Council
The President
G. BLÜMEL

([1]) The text of the Agreement will be published together with the decision on its conclusion.

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1258

of 18 September 2018

granting a Union authorisation for the biocidal product family Ecolab Iodine PT3 Family

(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 44(5) thereof,

Whereas:

(1) On 23 July 2015, Ecolab Deutschland GmbH submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named Ecolab Iodine PT3 Family ('the product family') of product-type 3, as described in Annex V to that Regulation. The Netherlands agreed that their competent authority referred to in Article 43(1) of Regulation (EU) No 528/2012 evaluate this application. The application was recorded under the case number BC-VG018734-32 in the Register for Biocidal Products ('the Register').

(2) The biocidal product family contains iodine, including polyvinylpyrrolidone iodine, as active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012. Taking into account the intrinsic properties of the active substance, once the scientific criteria for the determination of endocrine-disrupting properties set out in Commission Delegated Regulation (EU) 2017/2100 ([2]) will become applicable, the Commission will consider the need to review the approval of iodine, including polyvinylpyrrolidone iodine, in accordance with Article 15 of Regulation (EU) No 528/2012. Depending on the outcome of that review, the Commission will then consider whether the Union authorisations for products containing the active substance have to be reviewed in accordance with Article 48 of Regulation (EU) No 528/2012.

(3) On 6 June 2017, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, the assessment report and the conclusions of its evaluation to the European Chemicals Agency ('the Agency').

(4) On 12 January 2018, the Agency submitted to the Commission an opinion ([3]), including the draft summary of the biocidal product characteristics ('SPC') and the final assessment report on the product family in accordance with Article 44(3) of Regulation (EU) No 528/2012. The opinion concluded that the product family falls within the definition of 'biocidal product family' laid down in Article 3(1)(s) of Regulation (EU) No 528/2012, that it was found eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that subject to compliance with the draft SPC, the product family meets the conditions laid down in Article 19(1) and (6) of that Regulation.

(5) On 26 February 2018, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.

(6) The Commission concurs with the opinion of the Agency and considers therefore appropriate to grant a Union authorisation for the biocidal product family, and to record the SPC and the assessment report on the product family in the Register in accordance with Article 71(6) of Regulation (EU) No 528/2012.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) Commission delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).
([3]) ECHA opinion of 12 December 2017 on the Union authorisation of Ecolab Iodine PT3 Family (ECHA/BPC/177/2017).

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation is granted to Ecolab Deutschland GmbH for the biocidal product family Ecolab Iodine PT3 Family with authorisation number EU-0018398-0000.

The Union authorisation is valid from 11 October 2018 until 30 September 2028.

The Union authorisation is subject to compliance with the SPC set out in the Annex.

Article 2

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

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

Done at Brussels, 18 September 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Summary of product characteristics for a biocidal product family

Ecolab Iodine PT3 Family

Product type 3 — Veterinary hygiene (Disinfectants)

Authorisation number: EU-0018398-0000

R4BP asset number: EU-0018398-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	Ecolab Iodine PT3 Family

1.2. Product type(s)

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

1.3. Authorisation holder

Name and address of the authorisation holder	Name	Ecolab Deutschland GmbH
	Address	Ecolab-Allee 1, 40789 Monheim, Germany
Authorisation number	EU-0018398-0000	
R4BP asset number	EU-0018398-0000	
Date of the authorisation	11 October 2018	
Expiry date of the authorisation	30 September 2028	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	Ecolab Europe GmbH
Address of manufacturer	Richtistrasse 7, 8304 Walliselen Switzerland
Location of manufacturing sites	Ecolab Baglan, ECOLAB CONTAMINATION CONTROL BRUNEL WAY, BAGLAN ENERGY PARK, NEATH, SA11 2GA South Wales United Kingdom Ecolab Leeds, LOTHERTON WAY, GARFORTH, LEEDS LS25 2JY Leeds United Kingdom Ecolab Rovigo, Viale del Lavoro 10, 45100 Rovigo Italy Ecolab Biebesheim Nalco Deutschland Manufacturing GmbH und Co.KG, Justus-von-Liebig-Str. 11 D-64584 Biebesheim Germany Ecolab NETHERLANDS BV, NL01ECOLAB, BRUGWAL 11 3432NZ NIEUWEGEIN Netherlands

	Ecolab Weavergate, ECOLAB WEAVERGATE PLANT WINNINGTON AVENUE, NORTHWICH CHESHIRE CW8 3AA NORTHWICH United Kingdom
	Ecolab Mullingar, Forest Park, Mullingar Ind. Estate, Mullingar, Co. Zone C Westmeath Ireland
	Ecolab Maribor, Ecolab d.o.o.,Vajngerlova 4 2000 Maribor Slovenia
	Ecolab Rozzano, VIA GRANDI 9/11 20089 ROZZANO Italy
	Ecolab B.V.B.A, Havenlaan: 4 3980 Tessenderlo Belgium
	Ecolab CELRA, Nalco Española Manufacturing, SLU C/Tramuntana s/n, Polígono Industrial de Celrà 17460 CELRÀ Spain
	Ecolab Chalons Ecolab production France SAS, BP509 Avenue de Général Patton 51006 Châlons-en-Champagne France
	Ecolab Mandra, 25km Old National Road Athens Mandra, oo Attica Greece
	NALCO FINLAND MANUFACTURING OY, Kivikummuntie 1 FIN-07955 Tesjoki Finland

1.5. **Manufacturer(s) of the active substance(s)**

Active substance	Polyvinylpyrrolidone iodine
Name of manufacturer	ISP Chemicals LLC, Affiliate of Ashland Inc.
Address of manufacturer	455 N. MAIN ST. (HWY 95) KY 42029 CALVERT CITY United States
Location of manufacturing sites	455 N. MAIN ST. (HWY 95) KY 42029 CALVERT CITY United States

Active substance	Iodine
Name of manufacturer	ACF Minera S.A.
Address of manufacturer	San Martín No 499 00 Iquique Chile
Location of manufacturing sites	Lagunas mine 00 Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	SQM S.A.
Address of manufacturer	Los Militares 4290 Piso 4 Santiago Chile
Location of manufacturing sites	Nueva Victoria plant 00 Pedro de Valdivia Chile

Active substance	Iodine
Name of manufacturer	Cosayach Nitratos S.A.
Address of manufacturer	Amunategui 178 00 Santiago Chile
Location of manufacturing sites	S.C.M. Cosayach Cala Cala 00 Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	Nihon Tennen Gas Development Co., Ltd/ Kanto Natural Gas Development Co., Ltd
Address of manufacturer	661 Mobara Chiba 297-8550 Mobara City Japan
Location of manufacturing sites	Chiba Plant, 2508 Minami-Hinata, Shirako-Machi, Chosei-Gun 299-4205 Chiba Japan

2. **PRODUCT FAMILY COMPOSITION AND FORMULATION**

2.1. **Qualitative and quantitative information on the composition of the family**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1	3
Iodine		Active substance	7553-56-2	231-442-4	0,11	0,33

2.2. **Type(s) of formulation**

Formulation(s)	AL — Any other liquid

PART II

SECOND INFORMATION LEVEL — META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 1 identifier**

Identifier	meta SPC 1

1.2. **Suffix to the authorisation number**

Number	1-1

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 1 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 1**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1	1
Iodine		Active substance	7553-56-2	231-442-4	0,11	0,11

2.2. **Type(s) of formulation of the meta SPC 1**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	
Precautionary statements	

4. AUTHORISED USE(S) OF THE META SPC 1

4.1. **Use description**

Table 1. Use # 1 – Teat dips for post-milking disinfection

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Enveloped viruses
Field(s) of use	Indoor Post-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep)
Application method(s)	Manual dipping using a dip cup - 3-10 ml (dipping) 1-3 post-milking disinfections per day
Application rate(s) and frequency	3-10 ml (dipping) Post-milking application 1x - 3x per day (apply after every milking). Per milking event 3-10 ml of product are needed (animals with four teats).
Category(ies) of users	Professional
Pack sizes and packaging material	container, Plastic: HDPE, 0,5-1 000 l

4.1.1. *Use-specific instructions for use*

See general directions for use of meta SPC 1

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 1

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 1

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use of meta SPC 1

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 1

5. GENERAL DIRECTIONS FOR USE [1] OF THE META SPC 1

5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

Product to be applied post-milking by use of a dipping cup.

The products must be brought to temperatures above 20 °C before use.

Apply product on the whole teat and do not wipe it. Keep the animals standing for 5 min. Before the next milking, carefully clean the teats.

The use of a dosing pump for filling the product into the application equipment is recommended.

5.2. **Risk mitigation measures**

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.

Skin: Health injuries are not known or expected under normal use.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer If legally allowed.

5.4. **Instructions for safe disposal of the product and its packaging**

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

[1] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC1.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Store between 5 °C and 25 °C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 24 months

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Ioklar Super Dip D				
Authorisation number	EU-0018398-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1
Iodine		Active substance	7553-56-2	231-442-4	0,11

7.2. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	IoKlar Superdip				
Authorisation number	EU-0018398-0002 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1
Iodine		Active substance	7553-56-2	231-442-4	0,11

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 2 identifier**

Identifier	meta SPC 2

1.2. **Suffix to the authorisation number**

Number	1-2

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 2 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 2**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1,35	1,35
Iodine		Active substance	7553-56-2	231-442-4	0,15	0,15

2.2. **Type(s) of formulation of the meta SPC 2**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	
Precautionary statements	

4. AUTHORISED USE(S) OF THE META SPC 2

4.1. **Use description**

Table 2. Use # 1 – Teat dips for post-milking disinfection

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Enveloped viruses
Field(s) of use	Indoor Post-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep)
Application method(s)	Manual dipping using a dip cup
Application rate(s) and frequency	Post-milking application 1x - 3x per day (apply after every milking). Per milking event 3-10 ml of product are needed (animals with four teats).
Category(ies) of users	Professional
Pack sizes and packaging material	0,5 l – 1 000 l HDPE container

4.1.1. *Use-specific instructions for use*

See general directions for use of meta SPC 2

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 2

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 2

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use of meta SPC 2

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 2

5. GENERAL DIRECTIONS FOR USE ([1]) OF THE META SPC 2

5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

The products must be brought to temperatures above 20 °C before use.

Product to be applied post-milking by use of a dipping cup.

Apply product on the whole teat and do not wipe it. Keep the animals standing for 5 min. Before the next milking, carefully clean the teats.

The use of a dosing pump for filling the product into the application equipment is recommended.

5.2. **Risk mitigation measures**

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.

Skin: Health injuries are not known or expected under normal use.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

([1]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC2.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer If legally allowed.

5.4. **Instructions for safe disposal of the product and its packaging**

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Store between 5 °C and 25 °C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 24 months

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Io-Shield D IoShield MEPA Barrier D BARIOPROTECT MS Cow Udder BLOCK Iodocop EXTRA				
Authorisation number	EU-0018398-0003 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1,35
Iodine		Active substance	7553-56-2	231-442-4	0,15

7.2. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	IoDark Iodocop EXTRA GREEN Mammizan Protect MS Cow Udder BLACK				
Authorisation number	EU-0018398-0004 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1,35
Iodine		Active substance	7553-56-2	231-442-4	0,15

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 3 identifier**

Identifier	meta SPC 3

1.2. **Suffix to the authorisation number**

Number	1-3

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 3 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 3**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		2,45	2,45
Iodine		Active substance	7553-56-2	231-442-4	0,27	0,27

2.2. **Type(s) of formulation of the meta SPC 3**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	Harmful to aquatic life with long lasting effects.
Precautionary statements	Avoid release to the environment.

4. AUTHORISED USE(S) OF THE META SPC 3

4.1. **Use description**

Table 3. Use # 1 – Teat dips or sprays for post-milking disinfection

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Enveloped viruses
Field(s) of use	Indoor Post-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep)

Application method(s)	Dipping or spraying: Manual dipping using a dip cup or Manual spraying using a trigger sprayer or Manual spraying using an electronic sprayer or Automated spraying by robot.
Application rate(s) and frequency	Post-milking application 1x – 3x per day Per milking event 3-10 ml (dipping) to 10-15 ml (spraying) of product are needed (animals with four teats).
Category(ies) of users	Professional
Pack sizes and packaging material	0,5 l – 1 000 l HDPE container

4.1.1. *Use-specific instructions for use*

Product to be applied by dipping or spraying on teats of milk-producing animals post-milking, using manual or automatic equipment. Post-milking: Apply product on the whole teat and do not wipe it. Keep the animals standing for 5 min. Before the next milking, carefully clean the teats.

See also general instructions for use of meta SPC 3.

4.1.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

See also general risk mitigation measures of meta SPC 3.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 3

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use of meta SPC 3

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 3

4.2. **Use description**

Table 4. Use # 2 – Teat dips or sprays for pre-milking disinfection

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Pre-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep)
Application method(s)	Dipping or spraying: Manual dipping using a dip cup or Manual spraying using a trigger sprayer or Manual spraying using an electronic sprayer.

Application rate(s) and frequency	Pre-milking application 1x – 3x per day Per milking event 3-10 ml (dipping) to 10-15 ml (spraying) of product are needed (animals with four teats).
Category(ies) of users	Professional
Pack sizes and packaging material	0,5 l – 1 000 l HDPE container

4.2.1. *Use-specific instructions for use*

Product to be applied by dipping or spraying on teats of milk-producing animals pre-milking, using manual equipment.

Pre-milking: Clean teats by wiping with cloth before disinfection. Apply product on the whole teats and leave it for 1 min. Then wipe with a single use paper or a towel.

See also general instructions for use of meta SPC3.

4.2.2. *Use-specific risk mitigation measures*

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for post-milking disinfection.

See also general risk mitigation measures of meta SPC3.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 3

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use of meta SPC 3

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 3

5. GENERAL DIRECTIONS FOR USE [1] OF THE META SPC 3

5.1. **Instructions for use**

See use-specific instructions for each use.

Always read the label or leaflet before use and follow all the instructions provided.

The products must be brought to temperatures above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended

5.2. **Risk mitigation measures**

See use-specific risk mitigation measures for each use.

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) for spraying application.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.

Skin: Health injuries are not known or expected under normal use.

[1] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC3.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer If legally allowed.

5.4. **Instructions for safe disposal of the product and its packaging**

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Store between 5 °C and 25 °C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 24 months

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	IoKlar Multi MEPA Iospray Plus D ASTRI-IO DESINTEC MH-Iodine S				
Authorisation number	EU-0018398-0005 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		2,45
Iodine		Active substance	7553-56-2	231-442-4	0,27

META SPC 4

1. META SPC 4 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 4 identifier**

Identifier	meta SPC 4

1.2. **Suffix to the authorisation number**

Number	1-4

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 4 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 4**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1	1
Iodine		Active substance	7553-56-2	231-442-4	0,11	0,11

2.2. **Type(s) of formulation of the meta SPC 4**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

Hazard statements	
Precautionary statements	

4. AUTHORISED USE(S) OF THE META SPC 4

4.1. **Use description**

Table 5. Use # 1 – Teat dips or sprays for post-milking disinfection

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Enveloped viruses
Field(s) of use	Indoor Post-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep)

Application method(s)	Dipping or spraying: Manual dipping using a dip cup or Manual spraying using a trigger sprayer or Manual spraying using an electronic sprayer or Automated spraying by robot.
Application rate(s) and frequency	Post-milking application 1x - 3x per day. Per milking event 3-10 ml (dipping) to 10-15 ml (spraying) of product are needed (animals with four teats).
Category(ies) of users	Professional
Pack sizes and packaging material	0,5 l – 1 000 l HDPE container

4.1.1. *Use-specific instructions for use*

See general directions for use of meta SPC 4

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 4

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 4

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use of meta SPC 4

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 4

5. GENERAL DIRECTIONS FOR USE [1] OF THE META SPC 4

5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

The products must be brought to temperatures above 20 °C before use.

Product to be applied by dipping or spraying on teats of milk-producing animals post-milking using manual or automatic equipment.

Apply product on the whole teat and do not wipe it. Keep the animals standing for 5 min. Before the next milking, carefully clean the teats.

The use of a dosing pump for filling the product into the application equipment is recommended.

5.2. **Risk mitigation measures**

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) for spraying application.

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

[1] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC4.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.

Skin: Health injuries are not known or expected under normal use.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer If legally allowed.

5.4. **Instructions for safe disposal of the product and its packaging**

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Store between 5 °C and 25 °C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 24 months

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Veloucid Spray D VelouCid Spray MEPA Soft Spray D ASTRI-UC SAC WINTERSPRAY

Authorisation number	EU-0018398-0006 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1
Iodine		Active substance	7553-56-2	231-442-4	0,11

META SPC 5

1. META SPC 5 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 5 identifier**

Identifier	meta SPC 5

1.2. **Suffix to the authorisation number**

Number	1-5

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 5 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 5**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1	1
Iodine		Active substance	7553-56-2	231-442-4	0,11	0,11

2.2. **Type(s) of formulation of the meta SPC 5**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

Hazard statements	
Precautionary statements	

4. AUTHORISED USE(S) OF THE META SPC 5

4.1. **Use description**

Table 6. Use # 1 – Teat dips for post-milking disinfection

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—

Target organism(s) (including development stage)	Bacteria Yeasts Enveloped viruses
Field(s) of use	Indoor Post-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep)
Application method(s)	Dipping Manual dipping using a dip cup.
Application rate(s) and frequency	Post-milking application 1x – 3x per day Per milking event 3-10 ml of product are needed (animals with four teats).
Category(ies) of users	Professional
Pack sizes and packaging material	0,5 l – 1 000 l HDPE container

4.1.1. *Use-specific instructions for use*

See general directions for use of meta SPC 5

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 5

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 5

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use of meta SPC 5

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 5

5. GENERAL DIRECTIONS FOR USE ([1]) OF THE META SPC 5

5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

The products must be brought to temperatures above 20 °C before use.

Product to be applied post-milking by use of a dipping cup.

Apply product on the whole teat and do not wipe it. Keep the animals standing for 5 min. Before the next milking, carefully clean the teats.

The use of a dosing pump for filling the product into the application equipment is recommended.

5.2. **Risk mitigation measures**

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

([1]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC5.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.

Skin: Health injuries are not known or expected under normal use.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer If legally allowed.

5.4. **Instructions for safe disposal of the product and its packaging**

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Store between 5 °C and 25 °C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 18 months

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Veloucid D VelouCid MEPA Care D Cremadip MS Cow Udder SEPIA

Authorisation number	EU-0018398-0007 1-5				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1
Iodine		Active substance	7553-56-2	231-442-4	0,11

META SPC 6

1. META SPC 6 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 6 identifier**

Identifier	meta SPC 6

1.2. **Suffix to the authorisation number**

Number	1-6

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 6 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 6**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1,35	1,35
Iodine		Active substance	7553-56-2	231-442-4	0,15	0,15

2.2. **Type(s) of formulation of the meta SPC 6**

Formulation	AL — Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6

Hazard statements	
Precautionary statements	

4. AUTHORISED USE(S) OF THE META SPC 6

4.1. **Use description**

Table 7. Use # 1 – Teat dips or sprays for post-milking disinfection

Product Type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—

Target organism(s) (including development stage)	Bacteria Yeasts Enveloped viruses
Field(s) of use	Indoor Post-milking disinfection of teats of milk-producing animals (cows, buffaloes, goats, sheep)
Application method(s)	Dipping or spraying: Manual dipping using a dip cup or Manual spraying using a trigger sprayer or Manual spraying using an electronic sprayer or Automated spraying by robot.
Application rate(s) and frequency	Post-milking application 1x – 3x per day Per milking event 3-10 ml (dipping) to 10-15 ml (spraying) of product are needed (animals with four teats).
Category(ies) of users	Professional
Pack sizes and packaging material	0,5 l – 1 000 l HDPE container

4.1.1. *Use-specific instructions for use*

See general directions for use of meta SPC 6

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 6

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 6

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use of meta SPC 6

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 6

5. GENERAL DIRECTIONS FOR USE ([1]) OF THE META SPC 6

5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

The products must be brought to temperatures above 20 °C before use.

Product to be applied by dipping or spraying post-milking using manual or automatic equipment.

Apply product on the whole teat and do not wipe it. Keep the animals standing for 5 min. Before the next milking, carefully clean the teats.

The use of a dosing pump for filling the product into the application equipment is recommended.

([1]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC6.

5.2. **Risk mitigation measures**

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) for spraying application

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Potential Health Effects

Eyes: Health injuries are not known or expected under normal use.

Skin: Health injuries are not known or expected under normal use.

Ingestion: Health injuries are not known or expected under normal use.

Inhalation: Health injuries are not known or expected under normal use.

Chronic Exposure: Health injuries are not known or expected under normal use.

First Aid Measures:

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. In case of inhalation of decomposition products in a fire, symptoms may be delayed. Get medical attention if symptoms occur.

Skin contact: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Environmental emergency measures: Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer If legally allowed.

5.4. **Instructions for safe disposal of the product and its packaging**

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Store between 5 °C and 25 °C and away from direct sunlight. Keep out of reach of children. Keep container tightly closed. Store in the original containers.

Shelf life: 24 months

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	MEPA Barrier Spray D IoShield Spray QUARESS-Barrier				
Authorisation number	EU-0018398-0008 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active substance	25655-41-8		1,35
Iodine		Active substance	7553-56-2	231-442-4	0,15

COMMISSION REGULATION (EU) 2018/1259

of 20 September 2018

amending Regulation (EU) No 873/2012 on transitional measures concerning the Union list of flavourings and source materials set out in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards the extension of the transition period of Article 4 concerning the flavouring 'grill flavour concentrate (vegetable)' FL No 21.002

(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 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC ([1]), and in particular Article 25(3) thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings ([2]), and in particular Article 7(5) thereof,

Whereas:

(1) Regulation (EC) No 1334/2008 lays down a Union list of flavourings and source materials approved for use in and on foods and their conditions of use.

(2) Commission Implementing Regulation (EU) No 872/2012 ([3]) adopted the list of flavouring substances and introduced that list in Part A of Annex I to Regulation (EC) No 1334/2008.

(3) Implementing Regulation (EU) No 872/2012 also introduced parts B ('Flavouring preparations'), C ('Thermal process flavourings'), D ('Flavour precursors'), E ('Other flavourings') and F ('Source materials') in Annex I to Regulation (EC) No 1334/2008. Parts B to F of that Annex correspond to the categories of flavourings and source materials referred to in Article 9(b) to (f) of Regulation (EC) No 1334/2008. Parts B to F contain no entries.

(4) Commission Regulation (EU) No 873/2012 ([4]) laid down a number of transitional measures at the time of establishing the Union list of flavourings for the first time.

(5) Regulation (EU) No 873/2012 laid down the deadline of 22 October 2015 for the submission of applications for flavourings and source materials referred to in Article 9(b) to (f) of Regulation (EC) No 1334/2008 under Regulation (EC) No 1331/2008. It also laid down a transitional period for the foods to which these flavourings were added, pending the evaluation of the submitted applications by the European Food Safety Authority ('the Authority').

(6) In accordance with Article 3 of Regulation (EU) No 873/2012 an application for authorisation of the flavouring 'grill flavour concentrate (vegetable)' (FL No 21.002) belonging to the category referred to in Article 9(e), 'other flavourings', was submitted on 20 October 2015.

(7) On 5 October 2017, the Authority requested the applicant to submit additional scientific information and toxicological studies by 5 August 2018. The applicant informed the Commission and the Authority that the requested studies are being carried out in order to submit the requested information by the deadline.

(8) For reasons of legal certainty, in the absence of a submission of the requested information by the deadline set, Article 3(4) of Regulation (EC) No 1331/2008 should be applied with a view to ending the common procedure for updating the Community list.

([1]) OJ L 354, 31.12.2008, p. 34.
([2]) OJ L 354, 31.12.2008, p. 1.
([3]) Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC (OJ L 267, 2.10.2012, p. 1).
([4]) Commission Regulation (EU) No 873/2012 of 1 October 2012 on transitional measures concerning the Union list of flavourings and source materials set out in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council (OJ L 267, 2.10.2012, p. 162).

(9) In accordance with the objectives of Regulation (EC) No 1334/2008, in order to ensure legal certainty concerning the foods to which the flavouring 'grill flavour concentrate (vegetable)' (FL No 21.002) is added until the evaluation by the Authority is completed, it is appropriate to temporarily extend the transitional period established in Article 4 of Regulation (EU) No 873/2012 for this application.

(10) 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

1. In Article 4 of Regulation (EU) No 873/2012, a new paragraph 2 is added:

'2. Foods containing the flavouring "grill flavour concentrate (vegetable)" (FL No 21.002) belonging to the category "other flavourings" which are lawfully placed on the market or labelled prior to 22 April 2020 may be marketed until their date of minimum durability or use-by-date. If the information requested by the European Food Safety Authority is not provided by 5 August 2018, the application procedure shall be brought to an end in accordance with Article 3(4) of Regulation (EC) No 1331/2008.'

2. The original paragraph of Article 4 is numbered as paragraph 1.

Article 2

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

It shall be applicable from 23 April 2018.

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

Done at Brussels, 20 September 2018.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1260

of 20 September 2018

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances pyridaben, quinmerac and zinc phosphide

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ([1]), and in particular the first paragraph of Article 17 thereof,

Whereas:

(1) Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([2]) sets out the active substances deemed to have been approved under Regulation (EC) No 1107/2009.

(2) The active substances pyridaben, quinmerac and zinc phosphide are included in part A of the Annex to Implementing Regulation (EU) No 540/2011.

(3) The approval periods of the substances pyridaben, quinmerac and zinc phosphide will expire on 30 April 2021.

(4) Applications for the renewal of the approval of the active substances included in this Regulation were submitted in accordance with Commission Implementing Regulation (EU) No 844/2012 ([3]). However, the approval of those substances is likely to expire for reasons beyond the control of the applicant before a decision has been taken on the renewal of their approval. It is therefore necessary to extend their approval periods in accordance with Article 17 of Regulation (EC) No 1107/2009.

(5) In view of the time and resources necessary for completing the assessment of applications for renewal of approvals of large number of active substances the approvals of which are expiring between 2019 and 2021, Commission Implementing Decision C(2016) 6104 ([4]) established a work programme grouping together similar active substances and setting priorities on the basis of safety concerns for human and animal health or the environment as provided for in Article 18 of Regulation (EC) No 1107/2009.

(6) As the active substances included in this Regulation do not fall in the prioritised categories of Implementing Decision C(2016) 6104, their approval period should be extended by either two or three years, taking into account the current date of expiry, the fact that in accordance with Article 6(3) of Implementing Regulation (EU) No 844/2012 the supplementary dossier for an active substance is to be submitted no later than 30 months before expiry of the approval, the need to ensure a balanced distribution of responsibilities and work among Member States acting as rapporteurs and co-rapporteurs and the available resources necessary for assessment and decision-making. It is therefore appropriate to extend the approval period for the active substance pyridaben by two years, and to extend the approval periods of the active substances quinmerac and zinc phosphide by three years.

(7) In view of the aim of the first paragraph of Article 17 of Regulation (EC) No 1107/2009, as regards cases where no supplementary dossier in accordance with Implementing Regulation (EU) No 844/2012 is submitted no later than 30 months before the respective expiry date laid down in the Annex to this Regulation, the Commission will set the expiry date at the same date as before this Regulation or at the earliest date thereafter.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).
([3]) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).
([4]) Commission Implementing Decision of 28 September 2016 on the establishment of a work programme for the assessment of applications for the renewal of approvals of active substances expiring in 2019, 2020 and 2021 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council (OJ C 357, 29.9.2016, p. 9).

(8) In view of the aim of the first paragraph of Article 17 of Regulation (EC) No 1107/2009, as regards cases where the Commission will adopt a Regulation providing that the approval of an active substance referred to in the Annex to this Regulation is not renewed because the approval criteria are not satisfied, the Commission will set the expiry date at the same date as before this Regulation or at the date of the entry into force of the Regulation providing that the approval of the active substance is not renewed, whichever date is later. As regards cases where the Commission will adopt a Regulation providing for the renewal of an active substance referred to in the Annex to this Regulation, the Commission will endeavour to set, as appropriate under the circumstances, the earliest possible application date.

(9) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(10) 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

Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 20 September 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in the sixth column, expiration of approval, of row 311, Quinmerac, the date is replaced by '30 April 2024';

(2) in the sixth column, expiration of approval, of row 313, Pyridaben, the date is replaced by '30 April 2023';

(3) in the sixth column, expiration of approval, of row 314, Zinc phosphide, the date is replaced by '30 April 2024'.

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1261

of 20 September 2018

granting a Union authorisation for the biocidal product family Hypred's iodine based products

(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 44(5) thereof,

Whereas:

(1) On 16 July 2015, Hypred SAS submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named Hypred's iodine based products ('the product family') of product-type 3, as defined in Annex V to that Regulation. The Netherlands agreed that their competent authority referred to in Article 43(1) of Regulation (EU) No 528/2012 evaluate this application. The application was recorded under the case number BC-LC018584-49 in the Register for Biocidal Products ('the Register').

(2) The biocidal product family contains iodine as active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012. Taking into account the intrinsic properties of the active substance, once the scientific criteria for the determination of endocrine-disrupting properties set out in Commission Delegated Regulation (EU) 2017/2100 ([2]) will become applicable, the Commission will consider the need to review the approval of iodine, including polyvinylpyrrolidone iodine, in accordance with Article 15 of Regulation (EU) No 528/2012. Depending on the outcome of that review, the Commission will then consider whether the Union authorisations for products containing the active substance have to be reviewed in accordance with Article 48 of Regulation (EU) No 528/2012.

(3) On 6 June 2017 the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, the assessment report and the conclusions of its evaluation to the European Chemicals Agency ('the Agency').

(4) On 12 January 2018, the Agency submitted to the Commission an opinion ([3]), including the draft summary of the biocidal product characteristics (hereinafter 'SPC') and the final product assessment report on the product family in accordance with Article 44(3) of Regulation (EU) No 528/2012. The opinion concluded that the product family falls within the definition of 'biocidal product family' laid down in Article 3(1)(s) of Regulation (EU) No 528/2012, that it was found eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that, subject to compliance with the draft SPC, the product family meets the conditions laid down in Article 19(1) and (6) of that Regulation.

(5) On 26 February 2018, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.

(6) The Commission concurs with the opinion of the Agency and considers therefore appropriate to grant a Union authorisation for the biocidal product family, and to record the SPC and the product assessment report on the product family in the Register in accordance with Article 71(6) of Regulation (EU) No 528/2012.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) Commission delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).
([3]) ECHA opinion of 12 December 2017 on the Union authorisation of Hypred's iodine based products (ECHA/BPC/178/2017).

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation is granted to Hypred SAS for the biocidal product family Hypred's iodine based products with authorisation number EU-0018397-0000.

The Union authorisation is valid from 11 October 2018 until 30 September 2028.

The Union authorisation is subject to compliance with the SPC set out in the Annex.

Article 2

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

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

Done at Brussels, 20 September 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Summary of product characteristics for a biocidal product family

HYPRED's iodine based products

Product type 3 — Veterinary hygiene (Disinfectants)

Authorisation number: EU-0018397-0000

R4BP asset number: EU-0018397-0000

PART I

FIRST INFORMATION LEVEL

1. **ADMINISTRATIVE INFORMATION**

1.1. **Family name**

Name	HYPRED's iodine based products

1.2. **Product type(s)**

Product type(s)	PT03 - Veterinary hygiene (Disinfectants)

1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	Hypred SAS
	Address	55, Boulevard Jules Verger - BP10180 35803 DINARD Cedex France
Authorisation number	EU-0018397-0000	
R4BP asset number	EU-0018397-0000	
Date of the authorisation	11 October 2018	
Expiry date of the authorisation	30 September 2028	

1.4. **Manufacturer(s) of the biocidal products**

Name of manufacturer	HYPRED SAS
Address of manufacturer	55, Boulevard Jules Verger - BP10180 35803 DINARD France
Location of manufacturing sites	HYPRED SAS - 55, Boulevard Jules Verger - BP10180 35803 DINARD France HYPRED POLSKA SP. Z O.O. NIEPRUSZEWO, KASZTANOWA 4 64320 Buk Poland HYPRED IBERICA S.L Pol. Ind. Arazuri-Orcoyen C/C nº 32 31160 Orcoyen – NAVARRA Spain HYPRED GmbH Marie-Curie-Straße 23 53332 Bornheim – Sechtem Germany HYPRED Italia s.r.l. Strada Montodine-Gombito Loc. Cà Nova 26010 Ripalta Arpina CR Italy

1.5. **Manufacturer(s) of the active substance(s)**

Active substance	Iodine
Name of manufacturer	COSAYACH: SCM Cía. Cosayach Minera Negreiros, Rut. N°96.625.710-5
Address of manufacturer	Terrenos de Elena S/N Terrenos de Elena S/N Huara, Región de Tarapacá Chile
Location of manufacturing sites	Mined at: S.C.M. Cía. Minera Negreiros, S.C.M. Cosayach Soledad. Refined at: S.C.M. Cía. Minera Negreiros. Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	ACF MINERA SA
Address of manufacturer	San Martín 499 Iquique Chile
Location of manufacturing sites	Faena Lagunas KM. 1.722 Ruta A-5, Pozo Almonte Chile

Active substance	Iodine
Name of manufacturer	SOCIEDAD QUIMICA y MINERA SA
Address of manufacturer	Los Militares 4290 SANTIAGO DE CHILE Chile
Location of manufacturing sites	Pedro de Valdivia (PV) Route B 180 Antofagasta Chile Nueva Victoria (NV) Route 5 North, Km 1925 Pozo Almonte Chile

2. **PRODUCT FAMILY COMPOSITION AND FORMULATION**

2.1. **Qualitative and quantitative information on the composition of the family**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active substance	7553-56-2	231-442-4	0,25	2,5
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		2,697	24,199

2.2. **Type(s) of formulation**

Formulation(s)	AL - Any other liquid SL - Soluble concentrate

PART II

SECOND INFORMATION LEVEL - META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 1 identifier**

Identifier	meta SPC 1: Dipping products - ready to use

1.2. **Suffix to the authorisation number**

Number	1-1

1.3. **Product type(s)**

Product type(s)	PT03 - Veterinary hygiene (Disinfectants)

2. META SPC 1 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 1**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active substance	7553-56-2	231-442-4	0,25	0,49
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		2,697	4,993

2.2. **Type(s) of formulation of the meta SPC 1**

Formulation	AL - Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Causes serious eye irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep out of reach of children. Wash hands thoroughly after handling. Wear protective gloves. Wear protective clothing. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

4. AUTHORISED USE(S) OF THE META SPC 1

4.1. **Use description**

Table 1. Use # 1 – Manual or automated dipping after milking

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Algae
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping after milking
Application method(s)	Dipping - Manual or automated disinfection of teats by dipping after milking. Dipping cup or automated dipping machine.
Application rate(s) and frequency	— cows and buffaloes (3 to 10 ml: 5 ml recommended) — sheep (1,5 to 5 ml: 1,5 ml recommended) — goats (2,5 to 6 ml: 2,5 ml recommended) Frequency: 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1 000 L

4.1.1. *Use-specific instructions for use*

See general directions for use of meta SPC 1

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 1

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 1

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

None: See general directions for use of meta SPC 1

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 1

5. GENERAL DIRECTIONS FOR USE [1] OF THE META SPC 1

5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Fill the dipping cup manually or automatically with the ready to use product.

Apply by dipping manually or automatically on animal's teats on the full length of the teat after milking.

— cows and buffaloes (3 to 10 ml: 5 ml recommended)

— sheep (1,5 to 5 ml: 1,5 ml recommended)

— goats (2,5 to 6 ml: 2,5 ml recommended)

Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

Where necessary, repeat the application after each milking.

Clean the application equipment regularly with warm water.

5.2. **Risk mitigation measures**

Wear eye protection.

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID INSTRUCTIONS

— In the event of inhalation: Bring to fresh air.

— In the event of contact with the skin: Wash with water.

— In the event of contact with the eyes:

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

— In the event of ingestion: Rinse mouth. Do NOT induce vomiting. Get medical advice.

Refer to the safety data sheet available for professional user: it contains an emergency phone number.

Large spillage: Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

5.4. **Instructions for safe disposal of the product and its packaging**

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

[1] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC1.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Shelf life: 2 years in HDPE

Do not store at a temperature higher than 30 °C.

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Dip-io 2500 JOD DIP IODERM PSP DERMINO FR Iododip IODEX EXTRA Iodystrong DERMIODE INO IODE EPAIS INO STAR + IODACTIV 2500 IODIUM BX2500 Usual Iod Post ASiRAL Dip Coat IODOCAN EXTRA UDDER PLUS PRIMADIODE CERTIODE EPAIS IODIPACK GEL HELIO IODE EPAIS VAGEL GELAPIS ACTIV IOSAPIS GEL ZENCARE FLASH REPROGEL DERMADINE + KRONI Jod Dipp 2500 WÜBBELMANN JOD DIP Iodine Cleaner&Sanitizer MUNGIFILM ZEP FS FILMIODINE NIPPLE NP
Authorisation number	EU-0018397-0001 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	0,25
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		2,697

7.2. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Dip-io YB MAX INO Io Dip MAX JOD DIP YB MAX IodoDip YB MAX Iodium Dip YB MAX JodyDip YB MAX Delta IoDip YB MAX
Authorisation number	EU-0018397-0002 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	0,49
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		4,993

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 2 identifier**

Identifier	meta SPC 2: Dipping, foaming, spraying products - Ready to use

1.2. **Suffix to the authorisation number**

Number	1-2

1.3. **Product type(s)**

Product type(s)	PT03 - Veterinary hygiene (Disinfectants)

2. META SPC 2 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 2**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active substance	7553-56-2	231-442-4	0,25	0,49
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		2,697	4,69

2.2. **Type(s) of formulation of the meta SPC 2**

Formulation	AL - Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	Causes serious eye irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep out of reach of children. Wash hands thoroughly after handling. Wear protective gloves. Wear protective clothing. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

4. AUTHORISED USE(S) OF THE META SPC 2

4.1. **Use description**

Table 2. Use # 1 – Manual or automated dipping, foaming or spraying before milking

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking
Application method(s)	Dipping, foaming or spraying before milking - Manual or automated disinfection of teats by dipping, foaming or spraying before milking Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	— cows and buffaloes (3 to 10 ml: 5 to 8 ml recommended) — sheep (1,5 to 5 ml: 1,5 to 3 ml recommended) — goats (2,5 to 6 ml: 2,5 to 4 ml recommended) Frequency: 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1 000 L

4.1.1. *Use-specific instructions for use*

Eliminate all visible dirt before applying the product.

Manual or automatic dipping/foaming/spraying on animal's teats on the full length of the teat before milking.

Let the product act at least one minute.

Use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general instructions for use of meta SPC 2.

4.1.2. *Use-specific risk mitigation measures*

For manual dipping/foaming application: Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/eye protection.

For manual spraying applications wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing/eye protection.

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for post-milking disinfection.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 2

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use of meta SPC 2

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 2

4.2. **Use description**

Table 3. Use # 2 – Manual or automated dipping, foaming or spraying after milking

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Algae
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking
Application method(s)	Dipping, foaming, spraying after milking - Manual or automated disinfection of teats by dipping, foaming or spraying after milking Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine

Application rate(s) and frequency	— cows and buffaloes (3 to 10 ml: 5 to 8 ml recommended) — sheep (1,5 to 5 ml: 1,5 to 3 ml recommended) — goats (2,5 to 6 ml: 2,5 to 4 ml recommended) Frequency: 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1 000 L

4.2.1. *Use-specific instructions for use*

Manual or automatic dipping/foaming/spraying on animal's teats on the full length of the teat after milking.

Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general instructions for use of meta SPC 2.

4.2.2. *Use-specific risk mitigation measures*

For manual spraying applications wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing/eye protection.

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 2

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use of meta SPC 2

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 2

5. GENERAL DIRECTIONS FOR USE [1] OF THE META SPC 2

5.1. **Instructions for use**

See use-specific instructions for each use.

Always read the label or leaflet before use and follow all the instructions provided.

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended. Fill the dipping/foaming cup/sprayer manually or automatically with the ready to use product.

[1] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC2.

Where necessary repeat the application at each milking

Clean the application equipment regularly with warm water.

5.2. **Risk mitigation measures**

See use-specific risk mitigation measures for each use.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID INSTRUCTIONS

— In the event of inhalation: Bring to fresh air.

— In the event of contact with the skin: Wash with water.

— In the event of contact with the eyes:

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

— In the event of ingestion: Rinse mouth. Do NOT induce vomiting. Get medical advice.

Refer to the safety data sheet available for professional user: it contains an emergency phone number.

Large spillage: Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

5.4. **Instructions for safe disposal of the product and its packaging**

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Shelf life: 2 years in HDPE

Do not store at a temperature higher than 30 °C.

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Liq-io 2500 JOD SPRAY IODINE 3000 RTU IODEX 2500 Usual Iod Liquid Iodoliquid Iodospray DESINTEAT IODYSPRAY

	RBT 2500 IODY'FLASH INO IODE SPRAY IODYPRO 2500 IODYPRO BL2500 Robot Liq-io 25 ADF iDip+ ASiRAL Dip Spray J IODIPACK HELIO IODE LIQUIDE POLY-IODE CERTIODE LIQUIDE IOSAPIS FLUID GELAPIS ROBOT ZENCARE SPRAY HELIO IODE SPRAY + IODIP + KRONI Jod Spray 2500 WÜBBELMANN JOD LIQUID
Authorisation number	EU-0018397-0003 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	0,25
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		2,697

7.2. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Liq-io YB MAX INO Io Liquid Max Iodoliquid YB MAX Iodospray YB MAX Desinteat YB MAX Iodium Spray YB MAX JodySpray YB MAX Delta IoSpray YB MAX
Authorisation number	EU-0018397-0004 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	0,49
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		4,69

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 3 identifier**

Identifier	meta SPC 3: Dipping, foaming, spraying concentrated products

1.2. **Suffix to the authorisation number**

Number	1-3

1.3. **Product type(s)**

Product type(s)	PT03 - Veterinary hygiene (Disinfectants)

2. META SPC 3 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 3**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active substance	7553-56-2	231-442-4	2,5	2,5
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		24,199	24,199

2.2. **Type(s) of formulation of the meta SPC 3**

Formulation	SL - Soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	Causes serious eye damage. May cause damage to organs (thyroid) through prolonged or repeated exposure oral. Toxic to aquatic life with long lasting effects. May be corrosive to metals.
Precautionary statements	Keep out of reach of children. Do not breathe mist. Do not breathe vapours. Do not breathe spray. Wash hands thoroughly after handling. Wear protective gloves. Wear protective clothing. Wear eye protection.

	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor. Get medical advice/attention if you feel unwell. Dispose of contents to in accordance with local/regional/national/international regulations. Dispose of container to in accordance with local/regional/national/international regulations. Keep only in original container. Absorb spillage to prevent material damage.

4. AUTHORISED USE(S) OF THE META SPC 3

4.1. **Use description**

Table 4. Use # 1 – Manual or automated dipping, foaming or spraying before milking

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking
Application method(s)	Dipping, foaming, spraying - Manual or automated disinfection of teats by dipping, foaming or spraying before milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	A dilution at 10 % (v/v) should be prepared Application rate for the diluted product: — cows and buffaloes (3 to 10 ml: 5 to 8 ml recommended) — sheep (1,5 to 5 ml: 1,5 to 3 ml recommended) — goats (2,5 to 6 ml: 2,5 to 4 ml recommended) Frequency: 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1 000 L

4.1.1. *Use-specific instructions for use*

Prepare a dilution at 10 % (v/v: 10 ml product, add water up to 100 ml) for bactericidal and yeasticidal activity.

Fill the dipping/foaming cup/sprayer manually or automatically with the prepared dilution.

Eliminate all visible dirt before applying the product.

Manual or automatic dipping/foaming/spraying on animal's teats on the full length of the teat before milking.

Let the product act at least one minute.

Use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general directions for use of meta SPC 3.

4.1.2. *Use-specific risk mitigation measures*

For manual spraying applications wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing/eye protection.

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for post-milking disinfection.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 3

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use of meta SPC 3

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 3

4.2. **Use description**

Table 5. Use # 2 – Manual or automated dipping, foaming or spraying after milking

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Algae Viruses
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking
Application method(s)	Dipping, foaming, spraying - Manual or automated disinfection of teats by dipping, foaming or spraying after milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	For disinfection of bacteria, yeasts and algae a dilution at 10 % (v/v: 10 ml product, add water up to 100 ml) should be prepared. For disinfection of viruses a dilution at 20 % (v/v: 20 ml product, add water up to 100 ml) should be prepared

	Application rate for the diluted product: — cows and buffaloes (3 to 10 ml: 5 to 8 ml recommended) — sheep (1,5 to 5 ml: 1,5 to 3 ml recommended) — goats (2,5 to 6 ml: 2,5 to 4 ml recommended) Frequency: 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1 000 L

4.2.1. *Use-specific instructions for use*

Prepare a dilution at 10 % (v/v: 10 ml product, add water up to 100 ml) for bactericidal, yeasticidal and algaecidal activity or 20 % (v/v: 20 ml product, add water up to 100 ml) in case virucidal activity is also needed.

Fill the dipping/foaming cup/sprayer manually or automatically with the prepared dilution.

Manual or automatic dipping/foaming/spraying on animal's teats on the full length of the teat after milking.

Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general directions for use of meta SPC 3.

4.2.2. *Use-specific risk mitigation measures*

For manual spraying applications wear chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing/eye protection.

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 3

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use of meta SPC 3

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 3

5. GENERAL DIRECTIONS FOR USE [1] OF THE META SPC 3

5.1. **Instructions for use**

See use-specific instructions for each use.

Always read the label or leaflet before use and follow all the instructions provided.

[1] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC3.

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended. Fill the dipping/foaming cup/sprayer manually or automatically with the prepared dilution.

Where necessary, repeat the application at each milking

Clean the application equipment regularly with warm water.

5.2. **Risk mitigation measures**

See use-specific risk mitigation measures for each use.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

In case of faintness, get medical advice/attention. Show this safety data sheet to the doctor.

FIRST AID INSTRUCTIONS

— In the event of inhalation: Bring to fresh air.

— In the event of contact with the skin: Wash with water.

— In the event of contact with the eyes: Rinse at once with a soft stream of water for at least 15 minutes, eyes wide open.

  Remove contact lenses if present and easy to do. Continue rinsing.

  Immediately call a POISON CENTER or doctor/physician.

— In the event of ingestion: Rinse mouth. Do NOT induce vomiting. Get medical advice.

Refer to the safety data sheet available for professional user: it contains an emergency phone number.

Large spillage: Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

5.4. **Instructions for safe disposal of the product and its packaging**

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Shelf life: 2 years in HDPE

Do not store at a temperature higher than 30 °C.

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Liq-io concentrate INO Jod Konzentrat Usual Iod Concent

	Iodoconcentrat D 10 IODINE D 5 IODINE Liq-io C INO IODE C D 4 IODINE ADF iDip+ concentrate Mammizan Concentré
Authorisation number	EU-0018397-0005 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	2,5
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		24,199

META SPC 4

1. META SPC 4 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 4 identifier**

Identifier	meta SPC 4: Dipping products reaching virucidal activity – Ready to use

1.2. **Suffix to the authorisation number**

Number	1-4

1.3. **Product type(s)**

Product type(s)	PT03 - Veterinary hygiene (Disinfectants)

2. META SPC 4 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 4**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active substance	7553-56-2	231-442-4	0,5	0,5
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		4,993	4,993

2.2. **Type(s) of formulation of the meta SPC 4**

Formulation	AL - Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

Hazard statements	Causes serious eye irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep out of reach of children. Wash hands thoroughly after handling. Wear protective gloves. Wear protective clothing. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

4. AUTHORISED USE(S) OF THE META SPC 4

4.1. **Use description**

Table 6. Use # 1 – Manual or automated dipping after milking

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Algae Viruses
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping after milking
Application method(s)	Dipping - Manual or automated disinfection of teats by dipping after milking. Dipping cup or automated dipping machine.
Application rate(s) and frequency	— cows and buffaloes (3 to 10 ml: 5 ml recommended) — sheep (1,5 to 5 ml: 1,5 ml recommended) — goats (2,5 to 6 ml: 2,5 ml recommended) Frequency: 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1 000 L

4.1.1. *Use-specific instructions for use*

See general directions for use of meta SPC 4

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 4

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 4

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use of meta SPC 4

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 4

5. GENERAL DIRECTIONS FOR USE ([1]) OF THE META SPC 4

5.1. **Instructions for use**

Always read the label or leaflet before use and follow all the instructions provided.

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended. Fill the dipping cup manually or automatically with the ready to use product.

Apply by dipping manually or automatically on animal's teats on the full length of the teat after milking.

— cows and buffaloes (3 to 10 ml: 5 ml recommended)

— sheep (1,5 to 5 ml: 1,5 ml recommended)

— goats (2,5 to 6 ml: 2,5 ml recommended)

Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

Where necessary, repeat the application after each milking.

Clean the application equipment regularly with warm water.

5.2. **Risk mitigation measures**

Wear eye protection.

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

FIRST AID INSTRUCTIONS

— In the event of inhalation: Bring to fresh air.

— In the event of contact with the skin: Wash with water.

([1]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC4.

— In the event of contact with the eyes:

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

— In the event of ingestion: Rinse mouth. Do NOT induce vomiting. Get medical advice.

Refer to the safety data sheet available for professional user: it contains an emergency phone number.

Large spillage: Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

5.4. **Instructions for safe disposal of the product and its packaging**

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Shelf life: 2 years in HDPE

Do not store at a temperature higher than 30 °C.

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Dip-io 5000 IODIUM TX INO JOD 50 DIP Usual Iod Post + IODIUM PRO DIP IODERM PSP + IODEX EXTRA + Iododip + IODYSTRONG PLUS INO TREMP INO STAR IODACTIV 5000 DERMINO IODERM 5000 IODIUM BX5000 HOEVE-PLUS DIP TREMPASEPT IODE DERMADINE MAMMO-DERM KRONI Jod Dipp 5000
Authorisation number	EU-0018397-0006 1-4

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	0,5
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		4,993

META SPC 5

1. META SPC 5 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 5 identifier**

Identifier	meta SPC 5: Dipping, foaming, spraying products 5 500 ppm – Ready to use

1.2. **Suffix to the authorisation number**

Number	1-5

1.3. **Product type(s)**

Product type(s)	PT03 - Veterinary hygiene (Disinfectants)

2. META SPC 5 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 5**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active substance	7553-56-2	231-442-4	0,55	0,55
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		4,69	4,69

2.2. **Type(s) of formulation of the meta SPC 5**

Formulation	AL - Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

Hazard statements	Causes serious eye irritation. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep out of reach of children. Wash hands thoroughly after handling. Wear protective gloves.

	Wear protective clothing. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

4. AUTHORISED USE(S) OF THE META SPC 5

4.1. **Use description**

Table 7. Use # 1 – Manual or automated dipping, foaming or spraying before milking

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking
Application method(s)	Dipping, foaming, spraying - Manual or automated disinfection of teats by dipping, foaming or spraying before milking Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine
Application rate(s) and frequency	— cows and buffaloes (3 to 10 ml: 5 to 8 ml recommended) — sheep (1,5 to 5 ml: 1,5 to 3 ml recommended) — goats (2,5 to 6 ml: 2,5 to 4 ml recommended) Frequency: 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1 000 L

4.1.1. *Use-specific instructions for use*

Fill the dipping/foaming cup/sprayer manually or automatically with the ready to use product.

Eliminate all visible dirt before applying the product.

Manual or automatic dipping/foaming/spraying on animal's teats on the full length of the teat before milking.

Let the product act at least one minute.

Use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general instructions for use of meta SPC5.

4.1.2. *Use-specific risk mitigation measures*

For manual dipping/foaming application: Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/eye protection.

For manual spraying applications wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing/eye protection.

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for post-milking disinfection.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 5

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use of meta SPC 5

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 5

4.2. **Use description**

Table 8. Use # 2 – Manual or automated dipping, foaming or spraying after milking

Product Type	PT03 - Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Algae Viruses
Field(s) of use	Indoor Disinfection of teats of milk producing animals by dipping, foaming or spraying after milking
Application method(s)	Dipping, foaming, spraying - Manual or automated disinfection of teats by dipping, foaming or spraying after milking. Dipping cup, foaming cup, teat sprayer, automated dipping machine, automated foaming machine or automated spraying machine.
Application rate(s) and frequency	— cows and buffaloes (3 to 10 ml: 5 to 8 ml recommended) — sheep (1,5 to 5 ml: 1,5 to 3 ml recommended) — goats (2,5 to 6 ml: 2,5 to 4 ml recommended) Frequency: 2 to 3 times per day
Category(ies) of users	Professional
Pack sizes and packaging material	HDPE JERRYCAN 5, 10, 22 L HDPE DRUM 60, 120, 220 L HDPE CONTAINER 1 000 L

4.2.1. *Use-specific instructions for use*

Fill the dipping/foaming cup/sprayer manually or automatically with the ready to use product.

Manual or automatic dipping/foaming/spraying on animal's teats on the full length of the teat after milking.

Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).

At the next milking, use the teat cleaning and wiping method systematically before attaching the milking cluster.

See also general instructions for use of meta SPC 5.

4.2.2. *Use-specific risk mitigation measures*

For manual spraying applications wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information)/protective clothing/eye protection.

In case a combination of pre- and post-milking disinfection is necessary, using another biocidal product not containing iodine has to be considered for pre-milking disinfection.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use of meta SPC 5

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use of meta SPC 5

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use of meta SPC 5

5. GENERAL DIRECTIONS FOR USE [1] OF THE META SPC 5

5.1. **Instructions for use**

See use-specific instructions for each use.

Always read the label or leaflet before use and follow all the instructions provided.

The product must be brought to a temperature above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

Where necessary repeat the application at each milking.

Clean the application equipment regularly with warm water.

5.2. **Risk mitigation measures**

See use-specific risk mitigation measures for each use.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

Take the contaminated clothes and shoes off immediately. Wash them before wearing them again.

[1] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC5.

FIRST AID INSTRUCTIONS

— In the event of inhalation: Bring to fresh air.

— In the event of contact with the skin: Wash with water.

— In the event of contact with the eyes:

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice/attention.

— In the event of ingestion: Rinse mouth. Do NOT induce vomiting. Get medical advice.

Refer to the safety data sheet available for professional user: it contains an emergency phone number.

Large spillage: Mark out, dyke up with an inert absorbant and pump in an emergency tank. Keep in suitable, properly labelled and closed containers for disposal. Never return spills in original containers for re-use.

5.4. **Instructions for safe disposal of the product and its packaging**

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

The paper towels used for removing the product and drying the teats are disposed in the normal and domestic waste.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Shelf life: 2 years in HDPE

Do not store at a temperature higher than 30 °C.

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	Liq-io 5500 IODYPRO INO JOD 50 Liquid Usual Iod Liquid + IODIUM PRO SPRAY IODEX Iodoliquid + Iodospray Plus DESINTEAT PLUS ROBOSPRAY IODE INOTRAYON IODYPRO 5500 Robot Liq-io 55 IODYPRO BL5500 ADF iDip+ 5500 HOEVE-JODIUM SPRAY

	GRUPAIODE IODOCAN JOFO JODI PLUS K-AGRO PRODIP ID IODIP HELIO IODE SPRAY MAMMO-JOD KRONI Jod Spray 5500 MUNGI-IOD LELY QUARESS-Iodine
Authorisation number	EU-0018397-0007 1-5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active substance	7553-56-2	231-442-4	0,55
Alcohols, C12-14, ethoxylated (11 mol EO average molar ratio)	Poly(oxy-1,2-ethanediyl), -C12-14-(even numbered)-alkyl-hydroxy	Non active substance	68439-50-9		4,69

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1262

of 20 September 2018

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-methylcyclopropene, beta-cyfluthrin, chlorothalonil, chlorotoluron, clomazone, cypermethrin, daminozide, deltamethrin, dimethenamid-p, diuron, fludioxonil, flufenacet, flurtamone, fosthiazate, indoxacarb, MCPA, MCPB, prosulfocarb, thiophanate-methyl and tribenuron

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ([1]), and in particular the first paragraph of Article 17 thereof,

Whereas:

(1) Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([2]) sets out the active substances deemed to have been approved under Regulation (EC) No 1107/2009.

(2) The approval periods of the active substances 1-methylcyclopropene, beta-cyfluthrin, chlorothalonil, chlorotoluron, cypermethrin, daminozide, deltamethrin, dimethenamid-p, flufenacet, flurtamone, fosthiazate, indoxacarb, MCPA, MCPB, thiophanate-methyl and tribenuron were last extended by Commission Implementing Regulation (EU) 2017/1511 ([3]). The approval periods of those substances will expire on 31 October 2018.

(3) The approval period of the active substance diuron will expire on 30 September 2018.

(4) The approval periods of the active substances clomazone, fludioxonil and prosulfocarb will expire on 31 October 2018.

(5) Applications for the renewal of the approval of those substances were submitted in accordance with Commission Implementing Regulation (EU) No 844/2012 ([4]).

(6) Due to the fact that the assessment of those substances has been delayed for reasons beyond the control of the applicants, the approvals of those active substances are likely to expire before a decision has been taken on their renewal. It is therefore necessary to extend their approval periods.

(7) In view of the aim of the first paragraph of Article 17 of Regulation (EC) No 1107/2009, as regards cases where the Commission will adopt a Regulation providing that the approval of an active substance referred to in the Annex to this Regulation is not renewed because the approval criteria are not satisfied, the Commission will set the expiry date at the same date as before this Regulation or at the date of the entry into force of the Regulation providing that the approval of the active substance is not renewed, whichever date is later. As regards cases where the Commission will adopt a Regulation providing for the renewal of an active substance referred to in the Annex to this Regulation, the Commission will endeavour to set, as appropriate under the circumstances, the earliest possible application date.

(8) Taking into account that the approval of the active substance diuron expires on 30 September 2018, this Regulation should enter into force as soon as possible.

(9) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

([3]) Commission Implementing Regulation (EU) 2017/1511 of 30 August 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-methylcyclopropene, beta-cyfluthrin, chlorothalonil, chlorotoluron, cypermethrin, daminozide, deltamethrin, dimethenamid-p, flufenacet, flurtamone, forchlorfenuron, fosthiazate, indoxacarb, iprodione, MCPA, MCPB, silthiofam, thiophanate-methyl and tribenuron (OJ L 224, 31.8.2017, p. 115).

([4]) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

(10) 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

Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the third 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, 20 September 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in the sixth column, expiration of approval, of row 40, Deltamethrin, the date is replaced by '31 October 2019';

(2) in the sixth column, expiration of approval, of row 48, Beta-cyfluthrin, the date is replaced by '31 October 2019';

(3) in the sixth column, expiration of approval, of row 64, Flurtamone, the date is replaced by '31 October 2019';

(4) in the sixth column, expiration of approval, of row 65, Flufenacet, the date is replaced by '31 October 2019';

(5) in the sixth column, expiration of approval, of row 67, Dimethenamid-p, the date is replaced by '31 October 2019';

(6) in the sixth column, expiration of approval, of row 69, Fosthiazate, the date is replaced by '31 October 2019';

(7) in the sixth column, expiration of approval, of row 101, Chlorothalonil, the date is replaced by '31 October 2019';

(8) in the sixth column, expiration of approval, of row 102, Chlorotoluron, the date is replaced by '31 October 2019';

(9) in the sixth column, expiration of approval, of row 103, Cypermethrin, the date is replaced by '31 October 2019';

(10) in the sixth column, expiration of approval, of row 104, Daminozide, the date is replaced by '31 October 2019';

(11) in the sixth column, expiration of approval, of row 105, Thiophanate-methyl, the date is replaced by '31 October 2019';

(12) in the sixth column, expiration of approval, of row 106, Tribenuron, the date is replaced by '31 October 2019';

(13) in the sixth column, expiration of approval, of row 107, MCPA, the date is replaced by '31 October 2019';

(14) in the sixth column, expiration of approval, of row 108, MCPB, the date is replaced by '31 October 2019';

(15) in the sixth column, expiration of approval, of row 117, 1-methylcyclopropene, the date is replaced by '31 October 2019';

(16) in the sixth column, expiration of approval, of row 119, Indoxacarb, the date is replaced by '31 October 2019';

(17) in the sixth column, expiration of approval, of row 160, Prosulfocarb, the date is replaced by '31 October 2019';

(18) in the sixth column, expiration of approval, of row 161, Fludioxonil, the date is replaced by '31 October 2019';

(19) in the sixth column, expiration of approval, of row 162, Clomazone, the date is replaced by '31 October 2019';

(20) in the sixth column, expiration of approval, of row 192, Diuron, the date is replaced by '30 September 2019'.

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1263

of 20 September 2018

establishing the forms for the submission of information by parcel delivery service providers pursuant to Regulation (EU) 2018/644 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 Regulation (EU) 2018/644 of the European Parliament and of the Council of 18 April 2018 on cross-border parcel delivery services ([1]), and in particular Article 4(4) thereof,

Whereas:

(1) Regulation (EU) 2018/644 lays down specific provisions to foster better cross-border parcel delivery services in addition to those laid down in Directive 97/67/EC of the European Parliament and of the Council ([2]). Those provisions concern in particular regulatory oversight related to parcel delivery services and the transparency of tariffs for certain cross-border parcel delivery services.

(2) Regulation (EU) 2018/644 requires that parcel delivery service providers submit to national regulatory authority of the Member State in which they are established information about themselves using a form established by the Commission.

(3) Article 4(1) of Regulation (EU) 2018/644 requires submitting information about parcel delivery service provider only once and that they inform the national regulatory authority of any change to that information within 30 days. Article 4(3) of Regulation (EU) 2018/644 requires submitting information about the activities of the parcel delivery service provider every year. It is therefore appropriate to establish two separate forms for submission of that information.

(4) In order to avoid the double counting of parcels, parcel delivery service providers should, when providing information on the number and turnover of parcels handled over the previous calendar year, indicate whether the parcel delivery services are contracted with the sender or handled on behalf of another parcel delivery service provider. The submission should also include information on whether the parcels are sent to or received from destinations within or outside the Union, as this will have an impact on the steps in the postal delivery chain that are undertaken by that provider.

(5) Given that the requested information is to be processed by the national regulatory authorities of the Member States and in view of the expertise of those authorities, the forms have been drawn up in close cooperation with the European Regulators Group for Postal Services.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 21 of Directive 97/67/EC,

HAS ADOPTED THIS REGULATION:

Article 1

The forms for the submission of the information referred to in paragraphs 1 and 3 of Article 4 of Regulation (EU) 2018/644 are set out in Annexes I and II to this Regulation.

Article 2

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

([1]) OJ L 112, 2.5.2018, p. 19.
([2]) Directive 97/67/EC of the European Parliament and of the Council of 15 December 1997 on common rules for the development of the internal market of Community postal services and the improvement of quality of services (OJ L 15, 21.1.1998, p. 14).

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

Done at Brussels, 20 September 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Form for the submission of information referred to in Article 4(1) of Regulation (EU) 2018/644 [1]						
Table 1. Information on the parcel delivery service provider.						
Name						
Legal status and form						
Registration number in a trade or similar register						
VAT identification number						
Address of establishment						
If applicable, name of the group or a franchised network of parcel delivery service providers to which the parcel delivery service provider belongs.						
Date of submission						
Table 2. Contact details of a contact person.						
First name and last name						
Function						
Email address						
Phone number						
Table 3. Characteristics of the parcel delivery services offered [2]**.**						
Steps in the postal delivery chain						
clearance	**sorting**	**transport**	**distribution**	**Within the scope of USO** [3]	**Outside the scope of USO**	**Notes/remarks**
Table 4. Detailed description of the parcel delivery services offered [4]**.**						
Table 5. General terms and conditions for parcel delivery services [5]**.**						
Link(s):						

(1) In accordance with Article 4(5) of Regulation (EU) 2018/644 the national regulatory authorities may impose information requirements additional to those referred to in Article 4(1) of that Regulation. The requirement to submit the information referred to in Article 4(1) of Regulation (EU) 2018/644 is subject to paragraphs 6 and 7 of Article 4 of that Regulation.
(2) Tick the boxes corresponding to services offered. Do not tick the box if the service is offered by a subcontractor.
(3) Universal service obligation.
(4) Provide this information where possible and indicate whether added value is offered.
(5) Attach a copy of the relevant documents in an Annex to this form. Provide also details of complaints procedures for users and any potential limitations of liability. If the relevant documents are available online, provide the link(s).

ANNEX II

Form for the submission of information referred to in Article 4(3) of Regulation (EU) 2018/644 (1)	
Name of parcel delivery service provider	
Registration number in a trade or similar register	
Date of submission (2)	
Name of contact person	
Year for which information is submitted	

Table 1. Number (3) **of parcels handled over the previous calendar year and annual turnover in parcel delivery services for the previous calendar** (4) **year in the Member State in which the parcel delivery service provider is established** (5)**.**

Table 1.1. Domestic parcel delivery services

	Unit	**Contracted with the sender**	**Handled on behalf of another provider**	**Remarks**
Number of parcels (6)				
Turnover in parcel delivery services (7)				

Table 1.2. Incoming cross-border parcel delivery services (intra and extra Union/European Economic Area (EEA))

	Unit	**contracted with the sender**	**handled on behalf of another provider**	**Remarks**
Total number of incoming parcels (1)				
of which number of parcels incoming from INTRA Union/EEA (1)				
of which number of parcels incoming from EXTRA Union/EEA (1)				
Turnover in incoming parcels delivery services (2)				
of which turnover of parcels delivery service incoming from INTRA Union/EEA (2)				
of which turnover of parcels delivery service incoming from EXTRA Union/EEA (2)				

Table 1.3. Outgoing cross-border parcel delivery services (intra and extra Union/EEA)

	Unit	**contracted with the sender**	**handled on behalf of another provider**	**Remarks**
Number of parcels (1)				
of which number of parcels outgoing to INTRA Union/EEA (1)				

of which number of parcels outgoing to EXTRA Union/EEA (1)				
Total turnover from outgoing parcels delivery services (2)				
of which turnover of parcels delivery service outgoing to INTRA Union/EEA (2)				
of which turnover of parcels delivery service outgoing to EXTRA Union/EEA (2)				

Table 2. Number of persons working for the parcel delivery service provider over the previous calendar year involved in the provision of parcel delivery services in the Member State in which the provider is established.

	30/06/20XX	**31/12/20XX**	**Remarks**
Full-time			
Part-time			
Temporary employees			
Self-employed			
TOTAL			

Table 3. Information concerning characteristics of parcel delivery services provided by subcontractors of parcel delivery service providers (8)

	Name of subcontractor	**clearance**	**sorting**	**transport**	**distribution**	**Remarks**
Total number of subcontractors (9)						
Subcontractor 1 (10)						
Subcontractor 2 (5)						
Subcontractor 3 (5)						
Subcontractor 4 (5)						
Subcontractor 5 (5)						

Table 4. Names of subcontractors of parcel delivery service providers ([11])		
Numbering of subcontractors	**Name of subcontractor**	**Remarks**
(…) ([12])	**(…)**	

Table 5. Any publicly accessible price list applicable on January 1 of each calendar year for parcel delivery services ([13]).	
List attached as Annex …. **Link(s):**	

([1]) In accordance with Article 4(5) of Regulation (EU) 2018/644 the national regulatory authorities may impose information requirements additional to those referred to in Article 4(3) of that Regulation. Requirement to submit the information referred to in Article 4(3) of Regulation (EU) 2018/644 is subject to paragraphs 6 and 7 of Article 4 of that Regulation.
([2]) In accordance with Article 4(3), the form is to be submitted by 30 June of each calendar year.
([3]) Include items generated by activities related both to standard parcels and to shipments of goods handled in the letter post mail stream.
([4]) Where the information provided is based on estimation, describe the basis of it.
([5]) Provide information on actual parcel delivery services provided from an establishment in a Member State from the previous calendar year (mentioned above as 'year for which information is submitted').
([6]) Indicate in thousand ('000).
([7]) Indicate in thousands of national currency, VAT excluded.
([8]) Provide an estimate of the number of subcontractors that provide any of the services in the postal delivery chain.
([9]) State the number of subcontractors involved in each relevant step (the sum might exceed the total number of subcontractors as some of the subcontractors may provide services at several steps).
([10]) Provide the names of the five largest subcontractors and indicate which steps of the delivery chain they provide.
([11]) Provide information on subcontractors over the previous calendar year.
([12]) Provide information either directly in the table or attach a document to this form listing the subcontracors.
([13]) Attach the list to this form and, if the list is available online, provide the link(s).

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1264

of 20 September 2018

renewing the approval of the active substance pethoxamid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ([1]) and in particular Article 20(1) thereof,

Whereas:

(1) Commission Directive 2006/41/EC ([2]) included pethoxamid as an active substance in Annex I to Council Directive 91/414/EEC ([3]).

(2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([4]).

(3) The approval of the active substance pethoxamid, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 January 2019.

(4) An application for the renewal of the approval of pethoxamid was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ([5]) within the time period provided for in that Article.

(5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.

(6) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 31 August 2016.

(7) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.

(8) On 30 August 2017 the Authority communicated to the Commission its conclusion ([6]) on whether pethoxamid can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft renewal report for pethoxamid to the Standing Committee on Plants, Animals, Food and Feed on 6 October 2017.

(9) The applicant was given the opportunity to submit comments on the draft renewal report.

(10) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance pethoxamid that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Directive 2006/41/EC of 7 July 2006 amending Council Directive 91/414/EEC to include clothianidin and pethoxamid as active substances (OJ L 187, 8.7.2006, p. 24).

([3]) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

([4]) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

([5]) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

([6]) EFSA Journal 2017;15(9):4981 [22 pp.] Available online: www.efsa.europa.eu.

(11) It is therefore appropriate to renew the approval of pethoxamid.

(12) The risk assessment for the renewal of the approval of pethoxamid is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing pethoxamid may be authorised. It is therefore appropriate to remove the restriction for use only as an herbicide.

(13) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions. It is, in particular, appropriate to require further confirmatory information.

(14) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(15) Commission Implementing Regulation (EU) 2018/84 [1] extended the expiry date of pethoxamid to 31 January 2019 in order to allow the renewal process to be completed before the expiry of the approval of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply from 1 December 2018.

(16) 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

Renewal of the approval of the active substance

The approval of the active substance pethoxamid is renewed as set out in Annex I.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and date of application

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

It shall apply from 1 December 2018.

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

Done at Brussels, 20 September 2018.

For the Commission
The President
Jean-Claude JUNCKER

[1] Commission Implementing Regulation (EU) 2018/84 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances chlorpyrifos, chlorpyrifos-methyl, clothianidin, copper compounds, dimoxystrobin, mancozeb, mecoprop-p, metiram, oxamyl, pethoxamid, propiconazole, propineb, propyzamide, pyraclostrobin and zoxamide (OJ L 16, 20.1.2018, p. 8).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity [1]	Date of approval	Expiration of approval	Specific provisions
Pethoxamid CAS No 106700-29-2 CIPAC No 665	2-chloro-N-(2-ethoxyethyl)-N-(2-methyl-1-phenylprop-1-enyl) acetamide	≥ 940 g/kg Impurities: Toluene: max 3 g/kg.	1 December 2018	30 November 2033	PART A Use shall be limited to one application every two years in the same field at a maximum dose of 1 200 g active substance per hectare. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on pethoxamid, and in particular Appendices I and II thereto, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the risk of groundwater metabolites when pethoxamid is applied in regions with vulnerable soil and/or climatic conditions; — the risk to aquatic organisms and earthworms; — the risk to consumers from residues in the succeeding crops or in case of crop failure. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. the relevance of the metabolites that may occur in groundwater, taking into account any relevant classification for pethoxamid in accordance with Regulation (EC) No 1272/2008 of the Parliament and of the Council [2], in particular as carcinogen category 2; 2. the effect of water treatment processes on the nature of residues present in drinking water; 3. the endocrine disrupting potential of pethoxamid as regards the thyroid modality/pathway as a minimum providing mechanistic data to clarify whether there is a thyroid endocrine disrupting mode of action. The applicant shall submit the information requested under point 1 within one year after the publication of the opinion adopted by the Committee for Risk Assessment of the European Chemicals Agency in accordance with Article 37(4) Regulation (EC) No 1272/2008 of the European Parliament and of the Council with respect to pethoxamid and the information requested.

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
					The applicant shall submit the information requested under point 2 within two years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission. The applicant shall submit the information requested under point 3 by 10 November 2020 in accordance with Commission Regulation (EU) 2018/605 (3) amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties and the joint guidance document to identify endocrine disrupting substances as adopted by EFSA and ECHA.

(1) Further details on identity and specification of active substance are provided in the renewal report.
(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) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

ANNEX II

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 122 on pethoxamid is deleted;

(2) in Part B, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
'127	Pethoxamid CAS No 106700-29-2 CIPAC No 665	2-chloro-N-(2-ethoxyethyl)-N-(2-methyl-1-phenylprop-1-enyl) acetamide	≥ 940 g/kg Impurities: Toluene: max 3 g/kg.	1 December 2018	30 November 2033	PART A Use shall be limited to one application every two years in the same field at a maximum dose of 1 200 g active substance per hectare. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on pethoxamid, and in particular Appendices I and II thereto, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the risk of groundwater metabolites when pethoxamid is applied in regions with vulnerable soil and/or climatic conditions; — the risk to aquatic organisms and earthworms; — the risk to consumers from residues in the succeeding crops or in case of crop failure. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. the relevance of the metabolites that may occur in groundwater, taking into account any relevant classification for pethoxamid in accordance with Regulation (EC) No 1272/2008 of the Parliament and of the Council (2), in particular as carcinogen category 2;

No	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
						2. the effect of water treatment processes on the nature of residues present in drinking water; 3. the endocrine disrupting potential of pethoxamid as regards the thyroid modality/pathway as a minimum providing mechanistic data to clarify whether there is a thyroid endocrine disrupting mode of action. The applicant shall submit the information requested under point 1 within one year after the publication of the opinion adopted by the Committee for Risk Assessment of the European Chemicals Agency in accordance with Article 37(4) Regulation (EC) No 1272/2008 of the European Parliament and of the Council with respect to pethoxamid and the information requested. The applicant shall submit the information requested under point 2 within two years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission. The applicant shall submit the information requested under point 3 by 10 November 2020 in accordance with Commission Regulation (EU) 2018/605 (3) amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties and the joint guidance document to identify endocrine disrupting substances as adopted by EFSA and ECHA.'

(1) Further details on identity and specification of active substance are provided in the renewal report.
(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) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1265

of 20 September 2018

approving the active substance fenpicoxamid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ([1]), and in particular Article 13(2) thereof,

Whereas:

(1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009 the United Kingdom received on 2 December 2014 an application from Dow AgroScience GmbH for the approval of the active substance fenpicoxamid.

(2) In accordance with Article 9(3) of that Regulation, the United Kingdom, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') on 13 January 2015 of the admissibility of the application.

(3) On 13 October 2016 the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(4) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of Regulation (EC) No 1107/2009, it requested that the applicant supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the format of an updated draft assessment report on 31 July 2017.

(5) On 22 December 2017 the Authority communicated to the applicant, the Member States and the Commission its conclusion ([2]) on whether the active substance fenpicoxamid can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority made its conclusion available to the public.

(6) On 23 March 2018 the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for fenpicoxamid and a draft Regulation providing that fenpicoxamid is approved.

(7) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, and in particular the uses which were examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(8) It is therefore appropriate to approve fenpicoxamid.

(9) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions. In particular, it is appropriate to require further confirmatory information.

(10) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ([3]) should be amended accordingly.

(11) 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 309, 24.11.2009, p. 1.
([2]) EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance fenpicoxamid (XDE-777). EFSA Journal 2018;16(1):5146, 27 pp. https://doi.org/10.2903/j.efsa.2018.5146.
([3]) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Approval of active substance

The active substance fenpicoxamid, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

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, 20 September 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Fenpicoxamid CAS No: 517875-34-2 CIPAC No: 991	(3*S*,6*S*,7*R*,8*R*)-8-benzyl-3-{3-[(isobutyryloxy) methoxy]-4-methoxy-pyridine-2-carboxamido}-6-methyl-4,9-dioxo-1,5-dioxonan-7-yl isobutyrate	≥ 750 g/kg	11 October 2018	11 October 2028	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenpicoxamid, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the impact of processing on the consumer risk assessment, — the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: 1. the technical specification of the active substance as manufactured (based on commercial scale production) and the compliance of the toxicity batches with the confirmed technical specification; 2. the effect of water treatment processes on the nature of residues present in drinking water; 3. the endocrine disrupting potential of fenpicoxamid as regards the thyroid modality/pathway, providing in particular mechanistic data to clarify according to Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 (2), whether the effects observed in the studies submitted for approval are or are not related to a thyroid endocrine disrupting mode of action. The applicant shall submit to the Commission, the Member States and the Authority the information referred to in point 1 by 11 October 2019, in point 2 within 2 years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission and in point 3 by 10 November 2020.

(1) Further details on identity and specification of active substance are provided in the review report.
(2) Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

ANNEX II

In Part B of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
'126	Fenpicoxamid CAS No: 517875-34-2 CIPAC No: 991	(3*S*,6*S*,7*R*,8*R*)-8-benzyl-3-{3-[(isobutyryloxy)methoxy]-4-methoxypyridine-2-carboxamido}-6-methyl-4,9-dioxo-1,5-dioxonan-7-yl isobutyrate	≥ 750 g/kg	11 October 2018	11 October 2028	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenpicoxamid, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the impact of processing on the consumer risk assessment, — the risk to aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: 1. the technical specification of the active substance as manufactured (based on commercial scale production) and the compliance of the toxicity batches with the confirmed technical specification; 2. the effect of water treatment processes on the nature of residues present in drinking water; 3. the endocrine disrupting potential of fenpicoxamid as regards the thyroid modality/pathway, providing in particular mechanistic data to clarify according to Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 (2), whether the effects observed in the studies submitted for approval are or are not related to a thyroid endocrine disrupting mode of action. The applicant shall submit to the Commission, the Member States and the Authority the information referred to in point 1 by 11 October 2019, in point 2 within 2 years of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater being made public by the Commission and in point 3 by 10 November 2020.'

(1) Further details on identity and specification of active substance are provided in the review report.
(2) Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. (OJ L 101, 20.4.2018, p. 33).

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1266

of 20 September 2018

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-decanol, 6-benzyladenine, aluminium sulfate, azadirachtin, bupirimate, carboxin, clethodim, cycloxydim, dazomet, diclofop, dithianon, dodine, fenazaquin, fluometuron, flutriafol, hexythiazox, hymexazol, indolylbutyric acid, isoxaben, lime sulphur, metaldehyde, paclobutrazol, pencycuron, sintofen, tau-fluvalinate and tebufenozide

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ([1]), and in particular the first paragraph of Article 17 thereof,

Whereas:

(1) Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([2]) sets out the active substances deemed to have been approved under Regulation (EC) No 1107/2009.

(2) Applications for the renewal of the approval of 1-decanol, 6-benzyladenine, aluminium sulfate, azadirachtin, bupirimate, carboxin, clethodim, cycloxydim, dazomet, diclofop, dithianon, dodine, fenazaquin, fluometuron, flutriafol, hexythiazox, hymexazol, indolylbutyric acid, isoxaben, lime sulphur, metaldehyde, paclobutrazol, pencycuron, sintofen, tau-fluvalinate and tebufenozide were submitted in accordance with Commission Implementing Regulation (EU) No 844/2012 ([3]). However, the approval of those substances is likely to expire for reasons beyond the control of the applicant before a decision has been taken on the renewal of their approval. It is therefore necessary to extend their approval periods in accordance with Article 17 of Regulation (EC) No 1107/2009.

(3) In view of the time and resources necessary for completing the assessment of applications for renewal of approval of a large number of active substances the approvals of which are expiring between 2019 and 2021, Commission Implementing Decision C(2016) 6104 ([4]) established a work programme grouping together similar active substances and setting priorities on the basis of safety concerns for human and animal health or the environment as provided for in Article 18 of Regulation (EC) No 1107/2009.

(4) As the active substances 1-decanol, 6-benzyladenine, aluminium sulfate, azadirachtin, bupirimate, carboxin, clethodim, cycloxydim, dazomet, diclofop, dithianon, dodine, fenazaquin, fluometuron, flutriafol, hexythiazox, hymexazol, indolylbutyric acid, isoxaben, lime sulphur, metaldehyde, paclobutrazol, pencycuron, sintofen, tau-fluvalinate and tebufenozide do not fall in the prioritised categories of Implementing Decision C(2016) 6104, their approval period should be extended by either two or three years, taking into account the current date of expiry, the fact that in accordance with Article 6(3) of Implementing Regulation (EU) No 844/2012 the supplementary dossier for an active substance is to be submitted no later than 30 months before expiry of the approval, the need to ensure a balanced distribution of responsibilities and work among Member States acting as rapporteurs and co-rapporteurs and the available resources necessary for assessment and decision-making.

(5) It is therefore appropriate to extend the approval period for the active substances carboxin, clethodim, cycloxydim, dazomet, diclofop, fenazaquin, hymexazol, indolylbutyric acid, metaldehyde, and paclobutrazol by two years, and the approval period of the active substances 1-decanol, 6-benzyladenine, aluminium sulfate, azadirachtin, bupirimate, dithianon, dodine, fluometuron, flutriafol, hexythiazox, isoxaben, lime sulphur, pencycuron, sintofen, tau-fluvalinate and tebufenozide by three years.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).
([3]) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).
([4]) Commission Implementing Decision of 28 September 2016 on the establishment of a work programme for the assessment of applications for the renewal of approvals of active substances expiring in 2019, 2020 and 2021 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council (OJ C 357, 29.9.2016, p. 9).

(6) Where no supplementary dossier in accordance with Implementing Regulation (EU) No 844/2012 is submitted no later than 30 months before the respective expiry date laid down in the Annex to this Regulation, the expiry date should remain the same as before this Regulation or it should be set at the earliest date thereafter.

(7) Where the Commission will adopt a Regulation providing that the approval of an active substance referred to in the Annex to this Regulation is not renewed because the approval criteria are not satisfied, the Commission will set the expiry date at the same date as before this Regulation or at the date of the entry into force of the Regulation providing that the approval of the active substance is not renewed, whichever date is later. As regards cases where the Commission will adopt a Regulation providing for the renewal of an active substance referred to in the Annex to this Regulation, the Commission will endeavour to set, as appropriate under the circumstances, the earliest possible application date.

(8) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(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

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 20 September 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in the sixth column, expiration of approval, of row 316, Cycloxydim, the date is replaced by '31 May 2023';

(2) in the sixth column, expiration of approval, of row 317, 6-Benzyladenine, the date is replaced by '31 May 2024';

(3) in the sixth column, expiration of approval, of row 322, Hymexazol, the date is replaced by '31 May 2023';

(4) in the sixth column, expiration of approval, of row 323, Dodine, the date is replaced by '31 May 2024';

(5) in the sixth column, expiration of approval, of row 326, Indolylbutyric acid, the date is replaced by '31 May 2023';

(6) in the sixth column, expiration of approval, of row 328, Tau-fluvalinate, the date is replaced by '31 May 2024';

(7) in the sixth column, expiration of approval, of row 329, Clethodim, the date is replaced by '31 May 2023';

(8) in the sixth column, expiration of approval, of row 330, Bupirimate, the date is replaced by '31 May 2024';

(9) in the sixth column, expiration of approval, of row 333, 1-decanol, the date is replaced by '31 May 2024';

(10) in the sixth column, expiration of approval, of row 334, Isoxaben, the date is replaced by '31 May 2024';

(11) in the sixth column, expiration of approval, of row 335, Fluometuron, the date is replaced by '31 May 2024';

(12) in the sixth column, expiration of approval, of row 337, Carboxin, the date is replaced by '31 May 2023';

(13) in the sixth column, expiration of approval, of row 339, Dazomet, the date is replaced by '31 May 2023';

(14) in the sixth column, expiration of approval, of row 340, Metaldehyde, the date is replaced by '31 May 2023';

(15) in the sixth column, expiration of approval, of row 341, Sintofen, the date is replaced by '31 May 2024';

(16) in the sixth column, expiration of approval, of row 342, Fenazaquin, the date is replaced by '31 May 2023';

(17) in the sixth column, expiration of approval, of row 343, Azadirachtin, the date is replaced by '31 May 2024';

(18) in the sixth column, expiration of approval, of row 344, Diclofop, the date is replaced by '31 May 2023';

(19) in the sixth column, expiration of approval, of row 345, Lime sulphur, the date is replaced by '31 May 2024';

(20) in the sixth column, expiration of approval, of row 346, Aluminium sulfate, the date is replaced by '31 May 2024';

(21) in the sixth column, expiration of approval, of row 348, Paclobutrazol, the date is replaced by '31 May 2023';

(22) in the sixth column, expiration of approval, of row 349, Pencycuron, the date is replaced by '31 May 2024';

(23) in the sixth column, expiration of approval, of row 350, Tebufenozide, the date is replaced by '31 May 2024';

(24) in the sixth column, expiration of approval, of row 351, Dithianon, the date is replaced by '31 May 2024';

(25) in the sixth column, expiration of approval, of row 352, Hexythiazox, the date is replaced by '31 May 2024';

(26) in the sixth column, expiration of approval, of row 353, Flutriafol, the date is replaced by '31 May 2024'.

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1267

of 20 September 2018

on the minimum selling price for skimmed milk powder for the 24th partial invitation to tender within the tendering procedure opened by Implementing Regulation (EU) 2016/2080

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]),

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

Whereas:

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

(2) In the light of the tenders received for the 24th partial invitation to tender, a minimum selling price should be fixed.

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

HAS ADOPTED THIS REGULATION:

Article 1

For the 24th partial invitation to tender for the selling of skimmed milk powder within the tendering procedure opened by Implementing Regulation (EU) 2016/2080, in respect of which the period during which tenders were to be submitted ended on 18 September 2018, the minimum selling price shall be 123 EUR/100 kg.

Article 2

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

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

Done at Brussels, 20 September 2018.

For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-General
Directorate-General for Agriculture and Rural Development

([1]) OJ L 347, 20.12.2013, p. 671.
([2]) OJ L 206, 30.7.2016, p. 71.
([3]) Commission Implementing Regulation (EU) 2016/2080 of 25 November 2016 opening the sale of skimmed milk powder by a tendering procedure (OJ L 321, 29.11.2016, p. 45).

DECISIONS

COUNCIL DECISION (EU) 2018/1268

of 18 September 2018

appointing a member, proposed by the Kingdom of Sweden, 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 Swedish 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) A member's seat on the Committee of the Regions has become vacant following the end of the term of office of Mr Martin ANDREASSON,

HAS ADOPTED THIS DECISION:

Article 1

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

— Mr Alexander WENDT, *Ledamot i landstingsfullmäktige, Blekinge läns landsting*.

Article 2

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

Done at Brussels, 18 September 2018.

For the Council
The President
G. BLÜMEL

([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).

COUNCIL DECISION (EU) 2018/1269

of 18 September 2018

amending Decision 1999/70/EC concerning the external auditors of the national central banks, as regards the external auditors of Banka Slovenije

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to Protocol No 4 on the Statute of the European System of Central Banks and of the European Central Bank, annexed to the Treaty on European Union and the Treaty on the Functioning of the European Union, and in particular Article 27.1 thereof,

Having regard to the Recommendation of the European Central Bank of 6 July 2018 to the Council of the European Union on the external auditors of Banka Slovenije (ECB/2018/18) ([1]),

Whereas:

(1) The accounts of the European Central Bank (ECB) and the national central banks of the Member States whose currency is the euro are to be audited by independent external auditors recommended by the Governing Council of the ECB and approved by the Council of the European Union.

(2) The mandate of Banka Slovenije's current external auditors expired following the audit for the financial year 2017. It is therefore necessary to appoint external auditors from the financial year 2018.

(3) Banka Slovenije has selected Ernst & Young revizija, poslovno svetovanje, d.o.o. as its external auditors for the financial years 2018 to 2020.

(4) The Governing Council of the ECB recommended that Ernst & Young revizija, poslovno svetovanje, d.o.o. be appointed as the external auditors of Banka Slovenije for the financial years 2018 to 2020.

(5) Following the recommendation of the Governing Council of the ECB, Council Decision 1999/70/EC ([2]) should be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

In Article 1 of Decision 1999/70/EC, paragraph 13 is replaced by the following:

'13. Ernst & Young revizija, poslovno svetovanje, d.o.o. are hereby approved as the external auditors of Banka Slovenije for the financial years 2018 to 2020.'.

Article 2

This Decision shall take effect on the day of its notification.

Article 3

This Decision is addressed to the ECB.

Done at Brussels, 18 September 2018.

For the Council
The President
G. BLÜMEL

([1]) OJ C 260, 24.7.2018, p. 1.
([2]) Council Decision 1999/70/EC of 25 January 1999 concerning the external auditors of the national central banks (OJ L 22, 29.1.1999, p. 69).

COUNCIL DECISION (EU) 2018/1270

of 18 September 2018

appointing a member, proposed by the Republic of Lithuania, 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 Lithuanian 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) A member's seat on the Committee of the Regions has become vacant following the end of the term of office of Mr Andrius KUPČINSKAS,

HAS ADOPTED THIS DECISION:

Article 1

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

— Mr Vytenis TOMKUS, *Member of Kaišiadorys District Municipal Council.*

Article 2

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

Done at Brussels, 18 September 2018.

For the Council
The President
G. BLÜMEL

([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).

COUNCIL DECISION (EU) 2018/1271

of 18 September 2018

appointing a member, proposed by the Federal Republic of Germany, 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 German 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) A member's seat on the Committee of the Regions has become vacant following the end of the term of office of Dr Beate MERK,

HAS ADOPTED THIS DECISION:

Article 1

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

— Mr Georg EISENREICH, *Staatsminister (Freistaat Bayern)*.

Article 2

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

Done at Brussels, 18 September 2018.

For the Council
The President
G. BLÜMEL

([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).

COUNCIL DECISION (EU) 2018/1272

of 18 September 2018

appointing a 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. On the basis of different mandates, Mr Mauro D'ATTIS was re-appointed as a member, respectively, on 21 April 2016 by Council Decision (EU) 2016/643 ([4]), on 17 October 2016 by Council Decision (EU) 2016/1860 ([5]), and on 14 September 2017 by Council Decision (EU) 2017/1753 ([6]).

(2) A member's seat on the Committee of the Regions has become vacant following the end of the term of office of Mr Mauro D'ATTIS,

HAS ADOPTED THIS DECISION:

Article 1

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

— Mr Salvatore Domenico Antonio POGLIESE, *Sindaco del Comune di Catania*.

Article 2

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

Done at Brussels, 18 September 2018.

For the Council
The President
G. BLÜMEL

([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).
([4]) Council Decision (EU) 2016/643 of 21 April 2016 appointing a member, proposed by the Italian Republic, of the Committee of the Regions (OJ L 108, 23.4.2016, p. 35).
([5]) Council Decision (EU) 2016/1860 of 17 October 2016 appointing two members and an alternate member, proposed by the Italian Republic, of the Committee of the Regions. (OJ L 284, 20.10.2016, p. 31).
([6]) Council Decision (EU) 2017/1753 of 14 September 2017 appointing a member and an alternate member, proposed by the Italian Republic, of the Committee of the Regions. (OJ L 246, 26.9.2017, p. 5).

COUNCIL DECISION (EU, Euratom) 2018/1273

of 18 September 2018

appointing a member, proposed by the Republic of Poland, of the European Economic and Social Committee

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 302 thereof,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 106a thereof,

Having regard to the proposal of the Polish Government,

Having regard to the opinion of the European Commission,

Whereas:

(1) On 18 September 2015 and 1 October 2015, the Council adopted Decisions (EU, Euratom) 2015/1600 ([1]) and (EU, Euratom) 2015/1790 ([2]) appointing the members of the European Economic and Social Committee for the period from 21 September 2015 to 20 September 2020.

(2) A member's seat on the European Economic and Social Committee has become vacant following the passing away of Mr Franciszek BOBROWSKI,

HAS ADOPTED THIS DECISION:

Article 1

Mr Dariusz Mirosław POTYRAŁA, *President of the Trade Unions of Miners/All-Poland Alliance of Trade Unions*, is hereby appointed as a member of the European Economic and Social Committee for the remainder of the current term of office, which runs until 20 September 2020.

Article 2

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

Done at Brussels, 18 September 2018.

For the Council
The President
G. BLÜMEL

([1]) Council Decision (EU, Euratom) 2015/1600 of 18 September 2015 appointing the members of the European Economic and Social Committee for the period from 21 September 2015 to 20 September 2020 (OJ L 248, 24.9.2015, p. 53).
([2]) Council Decision (EU, Euratom) 2015/1790 of 1 October 2015 appointing the members of the European Economic and Social Committee for the period from 21 September 2015 to 20 September 2020 (OJ L 260, 7.10.2015, p. 23).

COUNCIL DECISION (EU, Euratom) 2018/1274

of 18 September 2018

appointing a member, proposed by the Kingdom of Denmark, of the European Economic and Social Committee

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 302 thereof,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 106a thereof,

Having regard to the proposal of the Danish Government,

Having regard to the opinion of the European Commission,

Whereas:

(1) On 18 September 2015 and 1 October 2015, the Council adopted Decisions (EU, Euratom) 2015/1600 ([1]) and (EU, Euratom) 2015/1790 ([2]) appointing the members of the European Economic and Social Committee for the period from 21 September 2015 to 20 September 2020.

(2) A member's seat on the European Economic and Social Committee has become vacant following the end of the mandate of Ms Dorthe ANDERSEN,

HAS ADOPTED THIS DECISION:

Article 1

Mr Nils TRAMPE, *Director Social Affairs in the Confederation of Danish Employers (DA)*, is hereby appointed as a member of the European Economic and Social Committee for the remainder of the current term of office, which runs until 20 September 2020.

Article 2

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

Done at Brussels, 18 September 2018.

For the Council
The President
G. BLÜMEL

([1]) Council Decision (EU, Euratom) 2015/1600 of 18 September 2015 appointing the members of the European Economic and Social Committee for the period from 21 September 2015 to 20 September 2020 (OJ L 248, 24.9.2015, p. 53).
([2]) Council Decision (EU, Euratom) 2015/1790 of 1 October 2015 appointing the members of the European Economic and Social Committee for the period from 21 September 2015 to 20 September 2020 (OJ L 260, 7.10.2015, p. 23).

COUNCIL DECISION (EU) 2018/1275

of 18 September 2018

appointing the members of the selection panel provided for in Article 14(3) of Regulation (EU) 2017/1939

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office ('the EPPO') [1], and in particular Article 14(3) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) Pursuant to Article 14(3) of Regulation (EU) 2017/1939, a selection panel is to be set up in order to draw up a shortlist of qualified candidates for the position of European Chief Prosecutor and to provide a reasoned opinion on the qualifications of candidates for European Prosecutors.

(2) Regulation (EU) 2017/1939 provides that the European Parliament and the Council appoint the European Chief Prosecutor, by common accord, from a shortlist of qualified candidates drawn up by the selection panel.

(3) Regulation (EU) 2017/1939 also provides that the Council appoints each European Prosecutor from amongst three candidates nominated by each Member State after having received a reasoned opinion from the selection panel.

(4) The selection panel is to review the applications for the position of European Chief Prosecutor and for the positions of European Prosecutors with regard to the requirements set out in Articles 14(2) and 16(1) of Regulation (EU) 2017/1939, respectively, including whether the candidates' independence is beyond doubt.

(5) The selection panel is to comprise 12 persons chosen from among former members of the Court of Justice and the Court of Auditors, former national members of Eurojust, members of national supreme courts, high-level prosecutors and lawyers of recognised competence.

(6) One of the panel members is to be proposed by the European Parliament. On 31 May 2018, the European Parliament nominated Mr Antonio MURA as the panel member to be proposed by it.

(7) The Commission took into account the need for geographical balance, gender balance and due representation of the legal systems of the Member States participating in the EPPO for the membership in the selection panel.

(8) Among the eleven persons, namely, six men and five women, proposed by the Commission, there is one former member of the Court of Justice, one former member of the Court of Auditors, one former national member of Eurojust, five high-level prosecutors, two members of national supreme courts and one lawyer of recognised competence.

(9) Article 14(3) of Regulation (EU) 2017/1939 provides that the Council is to adopt a decision appointing the members of the panel on a proposal from the Commission.

(10) The members of the selection panel should therefore be appointed,

HAS ADOPTED THIS DECISION:

Article 1

For the period of four years from 9 October 2018, the following persons shall be appointed members of the panel provided for in Article 14(3) of Regulation (EU) 2017/1939:

Mr Peter FRANK

Ms Ulrike HABERL-SCHWARZ

[1] OJ L 283, 31.10.2017, p. 1.

Mr Theodoros IOANNIDES

Ms Saale LAOS

Mr Jean-Claude MARIN

Mr Ján MAZÁK

Ms María de los Ángeles GARRIDO LORENZO

Mr Marin MRČELA

Mr Antonio MURA

Mr Vítor Manuel DA SILVA CALDEIRA

Ms Martine SOLOVIEFF

Ms Raija TOIVIAINEN.

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, 18 September 2018.

For the Council
The President
G. BLÜMEL

COMMISSION DECISION (EU) 2018/1276

of 22 February 2018

on SA.31149 (2012/C) — Germany

Alleged State aid to Ryanair

(notified under document C(2018) 1034)

(Only the German 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 provisions cited above ([1]) and having regard to their comments,

Whereas:

1. PROCEDURE

(1) By letter dated 10 July 2007 ('the 2007 Opening Decision'), the Commission informed Germany of its decision to initiate the procedure provided for in Article 108(2) of the Treaty with regard to the financing of Lübeck airport, the financial relations between Hansestadt Lübeck and Infratil Limited ('Infratil'), and the airport's financial relations with the airline Ryanair. The formal investigation procedure was registered under the case number SA.21877 (C 24/2007). A Corrigendum of the 2007 Opening Decision was adopted on 24 October 2007.

(2) The 2007 Opening Decision was published in the *Official Journal of the European Union* on 29 November 2007 ([2]). The Corrigendum was published on 7 December 2007 ([3]). The Commission invited interested parties to submit their comments on the measures in question within one month of the publication date.

(3) On 28 January 2009, Schutzgemeinschaft gegen Fluglärm Lübeck und Umgebung eV ('SGF') ([4]) sent a complaint regarding case SA.21877, registered under the case number SA.27585.

(4) On 22 June 2010 and 30 June 2010, SGF submitted a further complaint, alleging that further unlawful State aid had been granted by Germany in favour of Flughafen Lübeck GmbH ('FLG') and Infratil. This complaint was registered under the case number SA.31149.

(5) By letter dated 22 February 2012 ('the 2012 Opening Decision'), the Commission informed Germany of its decision to initiate the procedure provided for in Article 108(2) of the Treaty with regard to alleged State aid to FLG, Infratil, Ryanair, and other airlines using Lübeck airport ([5]).

(6) The 2012 Opening Decision was published in the *Official Journal of the European Union* on 10 August 2012 ([6]). The Commission invited interested parties to submit their comments on the measures in question within one month of the publication date.

([1]) OJ C 241, 10.8.2012, p. 56.
([2]) OJ C 287, 29.11.2007, p. 27.
([3]) OJ C 295, 7.12.2007, p. 29.
([4]) SGF is a non-governmental organisation registered under the rules of Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment and amending with regard to public participation and access to justice Council Directives 85/337/EEC and 96/61/EC (OJ L 156, 25.6.2003, p. 17).
([5]) Prior to the opening, the measures were investigated in cases CP 31/2009 (SA.27585) and CP 162/2010 (SA.31149).
([6]) Commission Decision of 22 February 2012 on State aid SA.27585 and SA.31149 (2012/C) (ex NN/2011, ex CP 31/2009 and CP 162/2010) Alleged State aid to Lübeck airport, Infratil and airlines using the airport (Ryanair, Wizz Air and Others) — Germany — Invitation to submit comments pursuant to Article 108(2) of the Treaty (OJ C 241, 10.8.2012, p. 56).

(7) The Commission joined the procedures SA.21877, SA.27585 and SA.31149 in 2014.

(8) On 7 February 2017, the Commission adopted a final decision in cases SA.21877 and SA.27585, as well as in case SA.31149 ([1]). As to the potential State aid in favour of Ryanair, that Commission Decision only assessed an agreement concluded between the airport operator and Ryanair in 2000. It indicated that, at the date of the Decision, the Commission did not have sufficient information in its file to assess whether later agreements, in particular those concluded in 2010, constituted State aid in favour of Ryanair. Those agreements therefore would be assessed in a separate decision ([2]).

(9) A request for information concerning two side letters concluded between FLG and Ryanair in 2010 and an Oxera report of 6 February 2015 ([3]) was sent to Germany on 27 July 2017. Germany requested an extension of the deadline to reply which the Commission granted on 2 August 2017. The requested information was provided on 20 September 2017.

(10) On 22 September 2017, a request for information was sent to Ryanair and forwarded to Germany. Subsequently, information was submitted by Ryanair and Oxera on 6 October 2017. On 24 October 2017, the Commission forwarded the documents received from Ryanair to Germany, inviting Germany to comment.

(11) The Commission refers to recitals 1 to 61 of Decision (EU) 2017/2336 as regards the procedure in cases SA.21877, SA.27585 and SA.31149.

2. DETAILED DESCRIPTION OF THE MEASURES

2.1. Background of the investigation and context of the measures

2.1.1. *Airport facts and passenger development*

(12) Lübeck airport is situated approximately 73 kilometres from the City of Hamburg, in Schleswig-Holstein, Germany.

(13) The airport itself defines its catchment area as the metropolitan areas of the City of Hamburg and Öresund (Greater Copenhagen/Malmö).

(14) According to a market study carried out by the airport in 2009 ([4]), the majority of the (outbound) passengers at Lübeck airport came from Hamburg (namely 47,20 %). Hamburg airport is located 78 kilometres from Lübeck airport, about 65 minutes travelling time by car.

(15) Until 2000, Lübeck was an airport depending on aviation revenues generated by charter flights and general aviation. In 2000, the airport changed its business model to an airport for low-cost carriers where revenues are generated through a combination of aviation and non-aviation activities. From that date, the vast majority of the flights at Lübeck airport were undertaken by Ryanair which operated about 90 % of the traffic in 2010.

(16) Lübeck airport was originally operated by FLG, which was a limited liability company, with Hansestadt Lübeck as its sole shareholder. It was first privatised in 2005 but then bought back by Hansestadt Lübeck in 2009. A public vote of the citizens of Hansestadt Lübeck ensured the survival of the airport in April 2010, approving further investments for the airport until a new private investor would enter the company. A new private investor was found in 2012. The ownership of the airport has changed several times in recent years.

(17) The passenger traffic at the airport increased from 48 652 passengers in 1999 to 697 559 passengers in 2009. It gradually declined afterwards contrary to the expectations of the airport, which had expected passenger numbers to increase to 2,2 million by 2015.

([1]) Commission Decision (EU) 2017/2336 of 7 February 2017, SA.21877 (C 24/2007), SA.27585 (2012/C) and SA.31149 (2012/C) — Germany — Alleged State aid to Flughafen Lübeck GmbH, Infratil Limited, Ryanair and other airlines using the airport (OJ L 339, 19.12.2017, p. 1).
([2]) See recital 186 of Decision (EU) 2017/2336.
([3]) Oxera report, Economic Market Ecomomy Operator Principle (MEOP) Assessment: Lübeck airport, 6 February 2015.
([4]) *Take-Off Konzept — Flughafen Lübeck GmbH*, 21 December 2009, p. 23.

(18) At the date of this decision, no airline is operating from Lübeck airport. Neither scheduled nor charter flights are on offer.

2.1.2. *The 2000 Agreement*

(19) FLG signed an Air Services Agreement ('ASA') with Ryanair in May 2000 ('the 2000 Agreement') that specified the airport charges payable by Ryanair as well as the marketing support payable by the airport. The 2000 Agreement was scheduled to start on 1 June 2000 and to continue until 31 May 2010.

(20) For the route to Stansted, the agreement included the following costs and revenues:

Table 1

Costs and revenues involved in the 2000 Agreement from FLG's perspective

	< 18 turnarounds per week	≥ 18 turnarounds per week
FLG costs:		
Marketing support — costs per arriving passenger	EUR […] (*)	EUR […]
	Until 31 May 2005	From 1 June 2005
FLG income:		
Ryanair payable fees per plane	EUR […]	EUR […]
Ryanair payable fees per arriving passenger	EUR […]	EUR […]
Ryanair net payable fees per arriving passenger (fees minus marketing support)	*EUR […]*	*EUR […]*
Other:		
Fee on turnover per ticket sold by FLG	[…]	[…]
Commission on turnover rental car booked by FLG	*[…]*	*[…]*
Security fee (paid by Ryanair to appropriate government body)	EUR […]	EUR […]

(*) Confidential information.

2.2. **Potential State aid granted by the airport operator FLG to Ryanair**

(21) In March and October 2010, Ryanair and FLG signed two side letters to the 2000 Agreement mentioned above (collectively, 'the 2010 Agreements' or 'the 2010 Side Letters').

(22) The first side letter signed on 29 March 2010 ('Side Letter No 1') covered the period from 28 March 2010 until 30 October 2010. It constitutes a prolongation of the 2000 Agreement, which would have ended in May 2010, and introduced a new marketing fee of EUR […] per passenger to be paid by FLG in return for a temporary marketing event organised by Ryanair. This new marketing fee had to be paid in addition to the marketing fee specified in the 2000 Agreement of EUR […] per passenger (below 18 turnarounds per week) or EUR […] per

passenger (above 18 turnarounds per week). Since more than 18 turnarounds per week were carried out by Ryanair, a total of EUR […] was to be paid by FLG to Ryanair for the duration of the agreement. As all other conditions from the 2000 Agreement were maintained, passenger service fees per departing passenger to be paid to FLG amounted to EUR […] and ramp handling charges per turnaround amounted to EUR […].

(23) On 31 October 2010, after the end of the contract period of Side Letter No 1, a second side letter was signed ('Side Letter No 2'). Side Letter No 2 did not maintain the conditions of Side Letter No 1, but returned to the schedule of marketing payments as stated in the 2000 Agreement, extending its terms for three years until 1 November 2013.

(24) On the day that Side Letter No 1 was entered into, namely on 29 March 2010, FLG also signed a marketing services agreement with Airport Marketing Services Limited ('AMS'), a fully-owned subsidiary of Ryanair. That marketing services agreement covered the period from 29 March 2010 to 30 October 2010 and set out the advertising services to be provided by AMS on the website www.ryanair.com, in return for a sum of EUR […] to be paid by FLG.

2.3. **Scope of the investigation**

(25) The 2000 Agreement between FLG and Ryanair was part of Decision (EU) 2017/2336. Therefore, this Decision is limited to Side Letter No 1 and Side Letter No 2 concluded in 2010.

2.4. **Grounds for initiating the procedure**

(26) The Commission was concerned that the 2010 Agreements conferred a selective advantage to Ryanair and therefore constituted State aid within the meaning of Article 107 of the Treaty.

3. **COMMENTS FROM GERMANY**

(27) Germany took the view that the 2010 Agreements did not distort or threaten to distort competition and did not affect trade between Member States, since Lübeck airport was a small regional airport and since it was not in competition with Hamburg airport and other airports.

(28) As regards Side Letter No 1, Germany submitted that it was in line with market conditions and did not entail an advantage for Ryanair. Germany argued with reference to the *Helaba I* case ([1]), that there was no advantage when other operators of regional airports offered Ryanair similar conditions. Germany further argued that this was proven by Ryanair's comparator analysis.

(29) Germany argued that low-cost carriers, such as Ryanair and Wizz Air, have fewer demands with regards to ground handling services and infrastructure services. Firstly, at Lübeck airport fewer check-in counters were needed because check-in with Ryanair is available to passengers online. Secondly, there were no passenger buses. Thirdly, since walking distances are shorter at Lübeck airport, the time for Ryanair airplanes on the ground was shorter. Fourthly, there were no transfer flights and fewer pieces of luggage per person, which meant that there did not have to be facilities for such purposes. Fifthly and finally, since the flight crew often took charge of cleaning in the airplane, there was less demand for ground cleaning services.

(30) As regards Side Letter No 2, Germany pointed out that this agreement was an extension, without substantial changes, of the 2000 Agreement. Germany took the view that the 2000 Agreement complied with the Market Economy Operator test.

(31) Furthermore, Germany is of the opinion that the alleged advantages in favour of Ryanair could not be imputed to the State based on the ruling in *Stardust Marine* ([2]). According to Germany, FLG acted with autonomy and without any exertion of influence by the State. Germany stated that FLG was not integrated into the structures of the public administration. In addition, Germany stated that the supervision by the public authorities of the management of FLG was limited to aviation and public remit matters and did not include business management activities.

([1]) Judgment of the General Court of 3 March 2010, *Bundesverband deutscher Banken v Commission* ('Helaba I'), T-163/05, ECLI:EU:T:2010:59.
([2]) Judgment of the Court of Justice of 16 May 2002, *France v Commission* ('Stardust Marine'), C-482/99, ECLI:EU:C:2002:294.

4. COMMENTS FROM INTERESTED PARTIES

4.1. Flughafen Lübeck GmbH

(32) FLG stated that the measures were not imputable to Germany, since the agreements were negotiated by it autonomously.

4.2. Ryanair

(33) Ryanair argued that the 2010 Agreements were not imputable to the State.

(34) Furthermore, Ryanair argued that there was no selectivity, since the 2010 Agreements were merely short side letters extending the duration of the existing arrangements under the 2000 Agreement. The only new element was a commercially negotiated adjustment to the marketing support.

(35) Ryanair stated that the contract with FLG was entered into on the basis of economic considerations. Lübeck airport was seen as a viable secondary airport to Hamburg airport and Lübeck itself was regarded as a valuable cultural destination. Even though Ryanair could not offer a business plan to substantiate its decision to start services at Lübeck airport, Ryanair emphasised that such a business plan was not generally required for a private sector investor. Ryanair explained that its services from Lübeck airport were discontinued because of commercial considerations, including cost increases and a yield lower than anticipated (as a consequence of economic recession).

(36) Ryanair stated that regional airports in the Union are in a difficult market position. Therefore, airport revenues from both aeronautical and non-aeronautical activities had to be taken into consideration, which is referred to as the 'single-till approach'. Since contracts with Ryanair typically promise a large number of passengers, such business relations often help to raise the airport's recognisability and to attract other airlines as well as retail outlets and other service providers. In addition, Ryanair stated that there was strong evidence that the increased number of passengers would lead to a rise in non-aeronautical revenues.

(37) Ryanair argued that, from a Market Economy Operator viewpoint, any commercial offer would normally be an improvement over the existing situation, as long as it expected marginal benefits to exceed its marginal costs. Furthermore, Ryanair argued that it had to be considered that Ryanair has significantly reduced needs compared to other airlines given its business model and operational efficiency.

(38) Ryanair conducted a comparison between airports of comparable size and situation as Lübeck airport. Comparator airports are Bournemouth Airport, Grenoble Airport, Knock Airport, Maastricht Airport, Nîmes Airport and Prestwick Airport. A comparison of charges paid by Ryanair at the comparator airports showed that costs paid by Ryanair at Lübeck airport were higher in general than the average level at the comparator airports on both a per-passenger and a per-turnaround basis.

(39) Ryanair submitted two Oxera reports evaluating the expected profitability of the 2010 Side Letters ([1]). Both reports were based on a business plan, drawn up by Lübeck airport in 2010 prior to signing the 2010 Side Letters. The reports indicate that, under reasonable assumptions at the time when the 2010 Side Letters were signed, the agreements were both expected to be sufficiently profitable and an airport behaving in the manner of a Market Economy Operator would have been likely to offer similar terms. According to Oxera, this would even be the case if the marketing services agreement with AMS were to be considered jointly with the 2010 Side Letters and the costs but not the AMS-related revenues were included.

(40) With regards to the marketing services agreement with AMS, Ryanair argued that such agreements are mutually beneficial due to the popularity of Ryanair's website and the consequent increases in international recognition, brand building and passengers, which was substantiated by another Oxera report of 26 September 2014.

([1]) Oxera report, Economic MEOP Assessment: Lübeck airport, 6 February 2015; Oxera report, Response to the European Commission's request, 6 October 2017.

4.3. **Air Berlin**

(41) Air Berlin stated that the routes offered by Ryanair from Lübeck airport were in direct competition with those offered by Air Berlin at Hamburg airport. In particular, the destinations of London, Milan and Barcelona were concerned, since both airlines had them in their portfolio.

(42) Air Berlin argued that the purpose of Ryanair's marketing strategy was to poach potential clients of, amongst others, Air Berlin. Due to the low prices of Ryanair, customers moved from Hamburg to Lübeck airport. Air Berlin claims that as a result of the State aid, Air Berlin suffered substantial economic losses. Air Berlin had to discontinue some of its flights due to the parallel offer by Ryanair at Lübeck airport. In addition, Air Berlin stated that it found it difficult to open new destinations from Hamburg airport as long as similar destinations were offered by Ryanair from Lübeck airport at excessively low prices.

(43) Additionally, Air Berlin stated that the agreement with Ryanair was imputable to Germany. According to the articles of association of FLG, the supervisory board had to give its approval for charges resulting from the use of the airport (paragraph 12 of the articles of association). Four of the six members of the supervisory board were elected by Hansestadt Lübeck. Therefore, Air Berlin concluded that Hansestadt Lübeck could be held responsible.

(44) According to Air Berlin, a further point of concern was the marketing services agreement between AMS and FLG, since the benefits from 'marketing support' appear to be unrelated to the actual marketing expenditures incurred by Ryanair.

5. **COMMENTS OF GERMANY ON THIRD PARTIES' SUBMISSIONS**

5.1. **Comments on Ryanair's submissions**

(45) According to Germany, Ryanair's submissions reveal that airport Lübeck acted in accordance with the Market Economy Operator principle.

(46) Germany particularly highlights the usefulness of Ryanair's approach of proving the market conformity of the agreements through a profitability analysis and a comparator analysis.

(47) According to Germany, the 2010 Side Letters were not imputable to the State since they were autonomously negotiated and entered into by FLG, without interference of Hansestadt Lübeck. Furthermore, with regard to Side Letter No 2, Germany pointed out that it merely constituted an extension of the 2000 Agreement, without containing any material change. Therefore, all arguments put forward in relation to the 2000 Agreement were relevant.

(48) Germany stated that it does not understand why the marketing services agreement between FLG and AMS was included in the State aid investigation, since FLG did not spend any public funds in the framework of this agreement. The costs laid down in the marketing services agreement with AMS were covered by private sources, as the money came from the *Industrie- und Handelskammer Lübeck*, a representation of private companies in Lübeck. Moreover, Germany commented that the marketing services agreement with AMS could be regarded as conforming to market standards. This is supported by the observation that FLG was charged with lower costs than other airports with a similar agreement. What is more, the marketing agreement in question was based on the promise of Ryanair to expand its flight portfolio by two destinations.

(49) Another point added by Germany is the function of Lübeck airport as a back-up airport for Hamburg airport and as a necessary transport infrastructure for northern Germany.

5.2. **Comments on Air Berlin's submissions**

(50) According to Germany, Air Berlin would have been granted the same advantages as Ryanair if it had fulfilled the same criteria concerning passenger numbers and flight frequency. Instead, Air Berlin refused any offer for negotiations with FLG, since it never intended to take up services at Lübeck airport. Air Berlin never objected to the conditions under which Ryanair operated at Hamburg airport. In addition, several airlines had complained (amongst others to the Commission) that Air Berlin had been benefitting from substantial State aid by the United Arabic Emirates. Therefore, it cannot present itself as a victim vis-à-vis its main competitor Ryanair.

(51) Germany disagreed with Air Berlin's comments concerning the existence of competition between Lübeck airport and Hamburg airport. In particular, Germany referred to the fact that Hamburg had 70 times as many passengers as Lübeck airport in 2000. The absence of complaints by other airports showed that there was no competition between the two airports.

(52) Furthermore, Germany rejected Air Berlin's argument that there was an economic advantage for Ryanair. Germany stated that Air Berlin used inaccurate calculations and that the only test relevant for assessing whether an airport-airline agreement was market conform was the Market Economy Operator principle.

6. **ASSESSMENT OF THE MEASURES**

(53) Article 107(1) of the Treaty provides that any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, in so far as it affects trade between Member States, be incompatible with the internal market.

(54) The criteria laid down in Article 107(1) of the Treaty are cumulative. Therefore, in order to determine whether a measure constitutes State aid, the following conditions have to be fulfilled:

— the beneficiary is an undertaking,

— the measure confers an advantage,

— the advantage is granted through State resources,

— the advantage is selective, and

— the measure distorts or threatens to distort competition and is liable to affect trade between Member States.

6.1. **Economic activity and notion of undertaking**

(55) The concept of an undertaking covers any entity engaged in an economic activity, regardless of its legal status and the way in which it is financed. Any activity consisting in offering goods or services on a given market is an economic activity.

(56) Since Ryanair is a private company that provides air transport services for remuneration with the aim of making profits, Ryanair is an undertaking that is engaged in an economic activity. It is therefore an undertaking within the meaning of Article 107(1) of the Treaty.

6.2. **Economic advantage**

(57) An advantage within the meaning of Article 107(1) of the Treaty is any economic benefit which an undertaking could not have obtained under normal market conditions, that is to say in the absence of State intervention ([1]).

(58) Where an airport has public resources at its disposal, aid to an airline can, in principle, be excluded where the relationship between the airport and the airline is carried out in line with normal market conditions. This so-called 'Market Economy Operator test' ('MEO test') follows the basic concept that the behaviour of public authorities should be compared to that of similar private economic operators under normal market conditions to determine whether an agreement grants an advantage to its counterpart ([2]).

6.2.1. *Preliminary remarks with regard to the MEO test*

(59) In accordance with point 53 of the 2014 Aviation Guidelines ([3]), the existence of aid to an airline using a particular airport can, in principle, be excluded if the price charged for the airport services corresponds to the market price ('first approach' — comparison with the market price). A second approach is to demonstrate through an *ex ante* analysis — that is to say, an analysis founded on information available when the aid is granted and on developments foreseeable at the time — that the arrangement will lead to a positive incremental profit contribution for the airport and is part of an overall strategy leading to profitability at least in the long term ('second apporach' — *ex ante* profitability analysis) ([4]).

([1]) See for example Judgment of the Court of Justice of 11 July 1996, *Syndicat français de l'Express international (SFEI) and Others v La Poste and Others*, C-39/94, ECLI:EU:C:1996:285, paragraph 60.
([2]) Ibid.
([3]) Communication from the Commission — Guidelines on State aid to airports and airlines (OJ C 99, 4.4.2014, p. 3).
([4]) See point 53 of the 2014 Aviation Guidelines.

(60) As regards the first approach, the Commission does not consider that, at the present time, an appropriate benchmark can be identified to establish a true market price for services provided by airports ([1]). It therefore considers an *ex ante* incremental profitability analysis to be the most relevant approach for the assessment of arrangements concluded by airports with individual airlines.

(61) It should be noted that, in general, the application of the MEO principle based on an average price on other similar markets may prove helpful if such a price can be reasonably identified or deduced from other market indicators. However, this method is of limited relevance for airport services, as the structure of costs and revenues tends to differ greatly from one airport to another. This is because costs and revenues depend on how developed an airport is, the number of airlines which use the airport, its capacity in terms of passenger traffic, the state of the infrastructure and related investments, the regulatory framework which can vary from one Member State to another, and any debts or obligations entered into by the airport in the past ([2]).

(62) Moreover, the liberalisation of the air transport market complicates any purely comparative analysis. As can be seen in this case, commercial practices between airports and airlines are not always based exclusively on a published schedule of charges. Rather, these commercial relations vary to a great extent. They include sharing risks with regard to passenger traffic and any related commercial and financial liability, standard incentive schemes and changing the spread of risks over the term of agreements. Consequently, one transaction cannot really be compared with another based on a turnaround price or price per passenger.

(63) In addition, benchmarking is not an appropriate method to establish market prices if the available benchmarks have not been defined with regard to market considerations or the existing prices are significantly distorted by public interventions. Such distortions appear to be present in the aviation industry, for reasons explained in points 57 to 59 of the 2014 Aviation Guidelines:

'Publicly owned airports have traditionally been considered by public authorities as infrastructures for facilitating local development and not as undertakings operating in accordance with market rules. Those airports' prices consequently tend not to be determined with regard to market considerations and in particular sound *ex ante* profitability prospects, but essentially having regard to social or regional considerations.

Even if some airports are privately owned or managed without social or regional considerations, the prices charged by those airports can be strongly influenced by the prices charged by the majority of publicly subsidised airports as the latter prices are taken into account by airlines during their negotiations with the privately owned or managed airports.

In those circumstances, the Commission has strong doubts that at the present time, an appropriate benchmark can be identified to establish a true market price for services provided by airports. This situation may change or evolve in the future […]'.

(64) Moreover, as the Union courts have recalled, benchmarking by reference to the sector concerned is merely one analytical tool amongst others to determine if a beneficiary has received an economic advantage which it would not have obtained in normal market conditions ([3]). As such, while the Commission may use that approach, it is not obliged to do so where, as in this case, it would be inappropriate.

(65) Ryanair essentially argued that the MEO test can be applied based on a comparison with the commercial arrangements of other European airports. In particular, it compared charges paid by Ryanair at Bournemouth, Grenoble, Knock, Maastricht, Nîmes and Prestwick airports with the charges paid by Ryanair under the agreements at Lübeck airport. However, this comparison study did not assess whether the sample of benchmark airports fulfilled all the criteria spelled out in the 2014 Aviation Guidelines, as it only assessed traffic volumes, type of airport traffic and prosperity of the surrounding area ([4]).

([1]) See point 59 of the 2014 Aviation Guidelines.
([2]) See recitals 88 and 89 of Commission Decision 2011/60/EU of 27 January 2010 on State aid C 12/08 (ex NN 74/07) — Slovakia — Agreement between Bratislava Airport and Ryanair (OJ L 27, 1.2.2011, p. 24).
([3]) See, as regards benchmarking by reference to profitability (as opposed to pricing) in the sector, judgment of the General Court of 3 July 2014, *Kingdom of Spain and Others v Commission*, joined cases T-319/12 and T-321/12, ECLI:EU:T:2014:604, paragraph 44.
([4]) For further criteria to be assessed, see point 60 of the 2014 Aviation Guidelines.

(66) In recital 296 of its 2012 Opening Decision, the Commission compared the charges laid down in the 2010 Side Letters with the charges at Hamburg airport, which led to doubts as to the market conformity of the charges laid down in the 2010 Side Letters. The Commission notes that traffic volume in Lübeck was much lower than in Hamburg airport. In fact, Hamburg was the airport with the most traffic in northern Germany. Hamburg was used for all segments of air transport, whereas Lübeck was specialised in low-cost carriers which required fewer check-in counters and facilities for transfer passengers, no passenger buses, less baggage-handling personnel and facilities, less cleaning personnel, and allowed for a shorter turnaround time. Consequently, Hamburg airport was not sufficiently comparable to Lübeck airport.

(67) In the light of those considerations, the Commission takes the view that the approach generally recommended in the 2014 Aviation Guidelines for applying the MEO test to relationships between airports and airlines, namely the *ex ante* incremental profitability analysis, must be applied to this case ([1]).

6.2.2. *Timeframe of the assessment*

(68) The Commission considers that the appropriate timeframe for assessing the profitability of arrangements between airports and airlines is typically the time horizon of the agreement itself. As airlines are able to adapt their operations in a short timeframe and as the specific contents of possible future agreements usually cannot be predicted, a private airport operator would usually not assume that the specific terms of an agreement will continue beyond its agreed duration ([2]).

(69) The 2010 Side Letters were not concluded at the same time but more than six months apart from each other, and they cover different periods of time. Furthermore, their content differs in so far as only Side Letter No 1 contains an additional marketing payment of considerable size connected to a temporary marketing event.

(70) The Commission therefore considers that the agreements exist independently from each other and that the profitabiliy of each side letter needs to be assessed separately, over its agreed duration ([3]).

(71) The Court of Justice declared in the *Stardust Marine* judgment that, '[…] in order to examine whether or not the State has adopted the conduct of a prudent investor operating in a market economy, it is necessary to place oneself in the context of the period during which the financial support measures were taken in order to assess the economic rationality of the State's conduct, and thus to refrain from any assessment based on a later situation ([4]).'

(72) For the purpose of assessing the agreements in question, both the existence and the amount of possible aid in the agreements therefore have to be assessed in the light of the situation prevailing at the time they were signed and, more specifically, in the light of the information available and developments foreseeable at the time.

6.2.3. *Assessment of Side Letter No 1*

(73) According to the *Charleroi* judgment ([5]), when assessing the measures in question, the Commission has to take into account all the relevant features of the measures and their context. It needs to be established whether, when setting up an arrangement with an airline, the airport is capable of covering all the costs stemming from the arrangement, over the duration of the arrangement, with a reasonable profit margin on the basis of sound medium-term prospects ([6]).

([1]) See points 61 and 63 of the 2014 Aviation Guidelines.
([2]) See for example Commission Decision (EU) 2015/1227 of 23 July 2014 on State aid SA.22614 (C 53/07) implemented by France in favour of the Chamber of Commerce and Industry of Pau-Béarn, Ryanair, Airport Marketing Services and Transavia (OJ L 201, 30.7.2015, p. 109).
([3]) See also judgment of the General Court of 15 September 1998, *BP Chemicals Limited v Commission ('BP Chemicals')*, T-11/95, ECLI:EU:T:1998:199, paragraphs 170 and 171; Recitals 14 to 33 of Commission Decision of 19 December 2012 on State aid SA.35378 (2012/N) — Germany — Financing of Berlin Brandenburg Airport (OJ C 36, 8.2.2013, p. 10).
([4]) Judgment of the Court of Justice of 16 May 2002, *France v Commission* ('Stardust Marine'), C-482/99, ECLI:EU:C:2002:294, paragraph 71.
([5]) Judgment of the General Court of 17 December 2008, *Ryanair Ltd v Commission* ('Charleroi'), T-196/04, ECLI:EU:T:2008:585, paragraph 59.
([6]) See point 63 of the 2014 Aviation Guidelines.

(74) This is to be measured by the difference between the incremental revenues expected to be generated by the agreement and the incremental costs expected to be incurred as a result of the agreement, the resulting cash flows being discounted with an appropriate discount rate.

(75) This approach is justified by the fact that an airport operator may have an objective interest in concluding a transaction with an airline, regardless of any comparison with the conditions offered to airlines by other airport operators, or even with the conditions offered by the same airport operator to other airlines.

(76) The Commission also notes in this context that price differentiation is a standard business practice. Such differentiated pricing policies should, however, be commercially justified.

(77) When assessing the incremental profitability of the agreement, it is appropriate to take only into account the incremental costs and revenues generated over the duration of the agreement, that is to say from 28 March to 30 October 2010.

(78) In line with this approach, Oxera provided an *ex ante* calculation of the incremental profitability of the 2010 Side Letters ([1]). In its calculations, Oxera takes into account all incremental traffic, and all costs and revenues relating to Ryanair's operation at Lübeck airport. As the 2000 Agreement would have ended in May 2010, the Commission finds this to be sound.

(79) The Oxera analysis is based on the terms of the agreements between FLG and Ryanair, actual financial data of FLG, as well as *ex ante* projections from a business plan submitted by Germany, drawn up by FLG on 10 March 2010 ([2]). This business plan covers the *ex ante* passenger numbers as well as the expected costs and revenues of Lübeck airport for the period 2010 to 2015. The business plan was originally prepared in December 2009 and then later revised by adjusting the traffic scenario from the original plan downwards and by adding two additional scenarios. Oxera's analysis of incremental costs and revenues is based on the data of this revised version of the business plan dated 10 March 2010, as it was drawn up closer to the date of signing the 2010 Agreements.

(80) The plan distinguishes between three scenarios:

— Best case: the assumption is that traffic will increase significantly over the period due to the expectation that Ryanair will establish a base at the airport. Consequently, the plan assumes an increase of non-aeronautical revenues and an expansion of non-aeronautical services,

— Middle case: it is assumed that business will continue as before, namely in line with the data available for 2010, the year of the business plan, and

— Worst case: it is assumed that the airport will close by 2012, with passenger numbers declining during 2010 and 2011.

(81) While in the best-case scenario, the passenger numbers increase from […] in 2010 to […] in 2013 and lead to a corresponding increase of revenues, the passenger numbers stagnate in the middle-case scenario at […], in line with the expected numbers for 2010. In the worst-case scenario, the passenger numbers drop rapidly in 2011 and any airport operations cease in 2012.

(82) For the purpose of analysing the 2010 Agreements, Oxera found it not appropriate to adopt the worst-case projections of the business plan, as this scenario assumed that the public vote of the citizens of Hansestadt Lübeck in 2010 would decide in favour of closing the airport. Considering the positive outcome of the public vote ensuring further investments for the airport on 25 April 2010 (see recital 16) only one month after concluding Side Letter No 1, the Commission finds the assumption reasonable that both parties expected the airport to continue operations ([3]). To ensure that the approach is conservative, Oxera based its analysis primarily on FLG's projections for the middle-case scenario.

([1]) Oxera report, Economic MEOP Assessment: Lübeck airport, 6 February 2015; Oxera report, Response to the European Commission's request, 6 October 2017.
([2]) *Flughafen Lübeck — Fortschreibung des Takeoff-Konzepts inkl. Business- und Investitionsplanung*, 10 March 2010.
([3]) See *Take-Off Konzept — Flughafen Lübeck GmbH* of 21 December 2009. This assumption is also in line with a letter submitted by Ryanair addressed to FLG in 2009, stating different commitments of Ryanair with regard to a future cooperation.

(83) Table 2 shows that the revenues stemming from the Side Letter No 1 were expected to exceed the incremental costs, leading to an annual surplus of EUR […] in the scenario calculated by Oxera ([1]).

Table 2

Incremental profitability analysis of Side Letter No 1

Profitability analysis of Side Letter 1 to Airport Service Agreement between Lübeck and Ryanair		
	Note:	
	Units	
Discount rate in use	%	[…]
Growth rate	%	2,70
Contract length	years	0,6
Probability of contract renewal	%	30
AMS marketing (2 = include upper case, 1 = include base case, 0 = exclude)	n/a	0
Side Letter 1		
Side Letter 1 effective as of	Date	28.3.2010
Side Letter 1 effective until	Date	30.10.2010
Proportion of 2010 in which this rebate was effective	%	59,5
Proportion of 2010 when agreement was in force in which this rebate was effective	%	77,8
Marketing Payments		
Per Dpax marketing rebate if 17 or fewer turnarounds per week:	EUR/DPAX	[…]
Per Dpax marketing rebate if 18 or more turnarounds per week:	EUR/DPAX	[…]
Cut-off number of turnarounds per week	ATM	18,00
Marketing rebate from Side Letter 1 (EUR per DPAX)	EUR/DPAX	[…]
Ryanair turnaround annualised	ATM	1 779
Ryanair turnaround per week	ATM	34
Marketing rebate (EUR per DPAX)	EUR/DPAX	[…]
Profitability		**2010**
Ryanair DPAX	DPAX	[…]
Total DPAX	DPAX	[…]
Ryanair ATMs	ATM	1 058
Total ATMs	ATM	1 160

([1]) According to the Oxera report of 6 February 2015, the net present value of both side letters is also positive, if the projections are based on the best case scenario of the business plan.

Profitability analysis of Side Letter 1 to Airport Service Agreement between Lübeck and Ryanair		
Revenues		
Passenger security charge	EUR/DPAX	[…]
Ramp handling charges	EUR TA	[…]
Passenger service fee	EUR/DPAX	[…]
Airport security charge	EUR/DPAX	[…]
Aeronautical revenues	EUR '000s	[…]
Non-aeronautical revenues	EUR '000s	[…]
Total Revenue	EUR '000s	[…]
Costs		
OPEX	EUR '000s	[…]
Marketing	EUR '000s	[…]
AMS marketing	EUR '000s	[…]
Depreciation	EUR '000s	[…]
Total costs	EUR '000s	[…]
Net cash flow	EUR '000s	[…]
Terminal Value	EUR '000s	[…]
Total cash flows	EUR '000s	[…]
Number of years when cash flow is due	years	0,6
Discount factor	n/a	[…]
NPV	EUR '000s	[…]
NPV	EUR m	[…]

Source: Oxera report, Response to the European Commission's request, 6 October 2017

(84) As the 2010 Agreements do not stipulate a specific traffic target for Ryanair, the forecast of airport traffic stems from FLG's projections for the year 2010, as expressed in the middle-case scenario of the business plan. The proportion of Ryanair traffic at the airport is expected to remain at 91 %, which reflects the average level of the three years prior to signing Side Letter No 1. Ryanair turnarounds have been calculated, assuming 189 available seats per aircraft and a load factor of 80 %. This is in line with Ryanair's 2010 load factor, which, according to Ryanair's annual report and financial statement of 2010, was 81 to 82 % at the time. The expected incremental passenger numbers for the duration of the agreement were calculated from the envisaged number of flights and extrapolated for the duration of Side Letter No 1.

(85) Considering that the middle-case scenario of the business plan assumes no growth in passenger numbers, but bases its projections on already existing information for the year 2010, and noticing that the projected numbers are below the actual traffic numbers of the previous year 2009, the Commission finds this approach to be sound.

(86) Furthermore, the Commission notes that the sensitivity analysis performed by Oxera shows that even when using Ryanair's actual *ex post* passenger numbers, the resulting net present value remains positive at EUR […].

(87) According to Commission practice, in order to assess whether an arrangement concluded by an airport with an airline satisfies the MEO test, expected non-aeronautical revenues stemming from the airline's activities must be

taken into consideration together with airport charges, net of any rebates, marketing support or incentive schemes ('single-till approach') ([1]). Therefore, incremental revenues that a private Market Economy Operator would reasonably expect from the agreement include:

(a) aeronautical revenues from passengers and landing charges paid by Ryanair; and

(b) non-aeronautical revenues from, for example, car parking, franchise shops, or directly operated shops.

(88) Oxera takes into account the aeronautical revenues per passenger from the airport charges stipulated in Side Letter No 1 in connection with the 2000 Agreement, and multiplies them with the respective passenger numbers. In line with Commission practice, security fees have been excluded from the analysis, as they were passed on by FLG to the competent public authority ([2]). Oxera submitted that for Side Letter No 1, the airport could have expected aeronautical revenues of EUR […]. The Commission finds this result to be sound.

(89) The non-aeronautical revenues per passenger are calculated based on the middle-case scenario of FLG's business plan. In line with the projections for the year 2010, it assumes that the non-aeronautical revenues will stay at approximately […] of the aeronautical revenues ([3]). They include, for example, revenues from shops and restaurants, and revenues from parking. Oxera estimates that revenues from non-aeronautical business amount to EUR […].

(90) Regarding the calculation of incremental costs, according to Commission practice, all costs incurred by the airport in relation to the airline's activities at the airport have to be taken into account. Such incremental costs may encompass all categories of expenses or marketing costs, such as incremental personnel and equipment costs induced by the presence of the airline at the airport ([4]).

(91) According to Commission practice, costs which the airport would have to incur anyway, independently from the arrangement with the airline, should not be taken into account in the MEO test ([5]).

(92) In line with this approach, Oxera takes into account incremental operating and marketing costs.

(93) The marketing costs stem from the 2000 Agreement, which are maintained in Side Letter No 1, increased by the marketing payments during the period of validity of Side Letter No 1 between 28 March and 30 October 2010:

Table 3

Schedule of marketing payments per departing passenger in Side Letter No 1

Marketing payments per departing passenger if:	
Fewer than 18 turnarounds per week	18 or more turnarounds per week
EUR […]	EUR […]

(94) As the forecast of the number of turnarounds exceeded 18 per week, the marketing payments were based on the amount of EUR […] per departing passenger. In order to calculate total marketing payments, these marketing payments were multiplied by the respective forecasts of the number of departing Ryanair passengers. The expected incremental marketing costs for the period March to October 2010 were calculated to amount to EUR […].

([1]) See point 64 of the 2014 Aviation Guidelines.
([2]) Ibid.
([3]) The Commission notes that this result assumes an increase of non-aeronautical revenues per passenger from approximately […] of aeronautical revenues, which was taken as a basis for the 2000 Agreement, to approximately […] in 2010. The Commission finds this assumption reasonable considering the growth of business at Lübeck airport after the year 2000.
([4]) See point 64 of the 2014 Aviation Guidelines.
([5]) See point 64 of the 2014 Aviation Guidelines; Commission Decision (EU) 2015/1226 of 23 July 2014 on State aid SA.33963 (2012/C) (ex 2012/NN) implemented by France in favour of Angoulême Chamber of Commerce and Industry, SNC-Lavalin, Ryanair and Airport Marketing Services (OJ L 201, 30.7.2015, p. 48); Commission Decision (EU) 2015/1584 of 1 October 2014 on State aid SA.23098 (C 37/07) (ex NN 36/07) implemented by Italy in favour of Società di Gestione dell'Aeroporto di Alghero So.Ge.A.AL S.p.A. and various air carriers operating at Alghero airport (OJ L 250, 25.9.2015, p. 38); Commission Decision (EU) 2016/2069 of 1 October 2014 concerning measures SA.14093 (C 76/2002) implemented by Belgium in favour of Brussels South Charleroi Airport and Ryanair (OJ L 325, 30.11.2016, p. 63).

(95) Incremental operating costs were estimated on the basis of a regression analysis that identified the impact of a change in total passenger numbers on the airport's operating costs. However, as in the middle-case scenario, the annual forecast of operating costs varies from year to year but the passenger forecast does not, Oxera could not perform a regression analysis based on this scenario. Instead, Oxera calculated the incremental operating costs by using the average estimates from the best and the worst-case scenarios to ensure a conservative approach. Oxera estimated incremental operating costs of EUR […].

(96) Considering Ryanair's share of around 90 % of traffic at Lübeck airport at the time of the agreement, the Commission finds this approach to be sound.

(97) There are no depreciation costs (investment costs) included in the calculations of the incremental profitability of Side Letter No 1.

(98) For its calculations, Oxera used a discount rate of 2,24 %, which corresponds to the Commission's reference rate plus 100 basis points. The Commission considers that the discount rate of 10 % is likely to be closer to the weighted average of the costs of capital of a MEO than the reference rate plus 100 basis points. However, the Commission notes that a sensitivity check performed by Oxera shows that the net present value would still be positive at EUR […] when using a 10 % discount rate.

(99) In addition, Oxera performed a sensitivity check taking into account different scenarios, among others:

(a) Calculating with a discount rate of 10 % (NPV positive at EUR […]);

(b) Using Ryanair's actual *ex post* passenger numbers instead of the *ex ante* passenger numbers, which were assumed in the middle-case scenario of the business plan (NPV positive at EUR […]);

(c) Using the operating costs derived from FLG's actual data of the years 2000 to 2010 instead of the costs assumed in the business plan (NPV positive at EUR […]).

(100) For the MEO test, only *ex ante* estimations based on data that were known and expected at the time of the decision making are relevant. The assessment based on *ex post* data can, however, serve to support the validation of the assumptions made to determine the *ex ante* expected revenues and costs.

(101) According to Oxera, in all scenarios described above, the net present value remains positive.

(102) Furthermore, Oxera carried out a further sensitivity analysis taking into account the marketing services agreement with AMS of 29 March 2010.

(103) The Commission notes that Side Letter No 1 and the 2010 marketing services agreement between FLG and AMS were signed on the same date and have the same contractual period. AMS is a wholly-owned subsidiary of Ryanair and its directors are senior Ryanair executives. The Commission therefore considers Ryanair and AMS to constitute a single economic entity in the sense that AMS acts in accordance with the interests of Ryanair and under its control, and the profits it generates are destined for Ryanair, in the form of dividends or an increase in the value of the company. The Commission thus considers Side Letter No 1 and the 2010 marketing services agreement to be concluded between the same parties. Moreover, the 2010 marketing services agreement states that it is rooted in Ryanair's commitment to operate routes from/to Lübeck. Consequently, the Commission considers Side Letter No 1 and the 2010 marketing services agreement to be part of the same commercial transaction. The mere fact that FLG concluded the 2010 marketing services agreement with AMS and not with Ryanair cannot prevent a marketing services agreement and an airport services agreement concluded at the same time from being considered as forming a single transaction.

(104) The Commission therefore believes that the profitability of both agreements should be considered jointly.

(105) Oxera's risk analysis shows that if the payment of EUR […] agreed to by FLG under the 2010 marketing services agreement with AMS is included in the calculation, the NPV remains positive at EUR […]. The agreement with AMS has therefore only little influence on the profitability of Side Letter No 1.

(106) After an in-depth assessment of the Oxera reports, the Commission takes the view that the presented results are reasonable and that the methodology used is sound. This finding is supported by the fact that the reports are solely based on *ex ante* information available at the time of signing the agreement. Furthermore, the sensitivity analysis performed by Oxera validates the assumption of a positive net present value.

(107) The Commission therefore considers that Side Letter No 1 was likely to be profitable from an *ex ante* perspective. Similarly, as marketing measures are meant to attract more passengers, the agreement can also be considered to be part of the implementation of an overall strategy to lead to profitability at least in the long term.

6.2.4. *Assessment of Side Letter No 2*

(108) Taking into account the explanations under Section 6.2.2, a MEO would have assessed the incremental costs and revenues for the term of application of the agreement, namely from 31 October 2010 to 1 November 2013.

(109) The calculations performed by Oxera regarding Side Letter No 2 follow the same methodology as the calculations for Side Letter No 1.

(110) Table 4 shows that the revenues stemming from Side Letter No 2 were expected to exceed the costs, leading to an annual surplus of EUR […] in the scenario calculated by Oxera.

Table 4

Incremental profitability analysis of Side Letter No 2

Profitability analysis of Side Letter 2 to Airport Service Agreement between Lübeck and Ryanair		
	Note:	
	Units	
Discount rate in use	%	[…]
Growth rate	%	2,70
Contract length	years	3,0
Probability of contract renewal		30
Side Letter 2		
Side Letter 2 effective as of		31.10.2010
Contract start year	year	2010
Contract start date adjustment	%	17,0
Side Letter 2 effective until		1.11.2013
Contract end year	year	2013
Contract end date adjustment	%	83,6
Combined start date adjustment	%	76,4
Proportion of 2010 when agreement was in force	%	22,2
Marketing Payments		
Per Dpax marketing rebate if 17 or fewer turnarounds per week:	EUR/DPAX	[…]
Per Dpax marketing rebate if 18 or more turnarounds per week:	EUR/DPAX	[…]
Cut-off number of turnarounds per week	ATM	18,00

Profitability analysis of Side Letter 2 to Airport Service Agreement between Lübeck and Ryanair					
Ryanair turnaround annualised	ATM	1 779			
Ryanair turnaround per week	ATM	34			
Marketing rebate (EUR per DPAX)	EUR/DPAX	[…]			
Profitability		**2010**	**2011**	**2012**	**2013**
Date adjustment	%	22	100	100	100
Ryanair DPAX	DPAX	[…]	[…]	[…]	[…]
Total DPAX	DPAX	[…]	[…]	[…]	[…]
Ryanair ATMs	ATM	302	1 779	1 779	1 487
Total ATMs	ATM	331	1 951	1 951	1 630
Revenues					
Passenger security charge	EUR/DPAX	0	0	0	0
Ramp handling charges	EUR/TA	[…]	[…]	[…]	[…]
Passenger service fee	EUR/DPAX	[…]	[…]	[…]	[…]
Airport security charge	EUR/DPAX	0	0	0	0
Aeronautical revenues	EUR '000s	[…]	[…]	[…]	[…]
Non-aeronautical revenues	EUR '000s	[…]	[…]	[…]	[…]
Total Revenue	EUR '000s	[…]	[…]	[…]	[…]
Costs					
OPEX	EUR '000s	[…]	[…]	[…]	[…]
Marketing	EUR '000s	[…]	[…]	[…]	[…]
AMS marketing	EUR '000s	0	0	0	0
Depreciation	EUR '000s	0	[…]	[…]	[…]
Total costs	EUR '000s	[…]	[…]	[…]	[…]
Net cash flow	EUR '000s	[…]	[…]	[…]	[…]
Terminal Value	EUR '000s	0	0	0	0
Total cash flows	EUR '000s	[…]	[…]	[…]	[…]
Number of years when cash flow is due	years	0,2	1,2	2,2	3,0
Discount factor	n/a	[…]	[…]	[…]	[…]
NPV	EUR '000s	[…]			
NPV	EUR m	[…]			

Source: Oxera report, Response to the European Commission's request, 6 October 2017

(111) Oxera submitted that based on the charges stipulated in the 2000 Agreement and Side Letter No 2, the airport could have expected aeronautical revenues of a total of EUR […]. With regard to non-aeronautical revenues, Oxera again relied on the information from the middle-case scenario of FLG's business plan which predicts the revenues to remain on the 2010 level, and estimated revenues of EUR […]..

(112) Following the same approach, Oxera estimated the total incremental operating costs to be EUR […]. The calculation of the marketing costs was based on the terms of the original 2000 Agreement, multiplied by the respective forecasts of the number of departing Ryanair passengers.

(113) For the reasons mentioned in recitals 82 to 96 above, the Commission finds Oxera's approach to be sound.

(114) The Commission notes that Oxera included investment costs in the calculation of Side Letter No 2, which consist of a passenger-related proportion of the depreciation costs. The costs are estimated by means of a regression analysis of the planned investments and the expected passenger numbers according to the business plan.

(115) The Commission notes that according to the middle-case scenario of FLG's 2010 business plan, no investments were specific to Ryanair but could potentially be exploited by other airlines. This indicates that investment costs did not have to be included in the incremental costs of Side Letter No 2. In this respect, the Commission notes that Germany emphasised that FLG continuously attempted to attract other airlines and succeeded in this attempt as Wizz Air was also operating from the airport. The Commission further notes that the 2010 Agreements did not require FLG to make investments.

(116) In the light of those considerations, the Commission concludes that it is unreasonable to attribute investments made at Lübeck airport to Side Letter No 2. However, the Commission also notes that even if investment costs were attributed to the agreement, the expected NPV was still positive amounting to EUR […].

(117) Furthermore, the sensitivity analysis performed by Oxera shows a positive NPV in the following scenarios:

(a) Calculating with a discount rate of 10 % (NPV positive at EUR […]);

(b) Using Ryanair's actual *ex post* passenger numbers instead of the *ex ante* passenger numbers, which were assumed in the middle-case scenario of the business plan (NPV positive at EUR […]);

(c) Using the operating costs derived from FLG's actual data of the years 2000 to 2010 ([1]) instead of the costs assumed in the business plan (NPV positive at EUR […]);

(118) In this respect, the previous statements in recitals 98 to 101 apply also to Side Letter No 2.

(119) The Commission therefore considers that Side Letter No 2 was likely to be profitable from an *ex ante* perspective. Similarly, in view of the clearly positive contribution, the agreement can also be considered to be part of the implementation of an overall strategy to lead to profitability in the long term.

6.2.5. *Assessment result*

(120) Based on the information provided, the Commission considers that FLG could have expected a positive incremental return on the 2010 Agreements with Ryanair.

(121) Furthermore, it could be reasonably expected that Side Letter No 1 would be incrementally profitable even when taking into account the marketing services agreement with AMS.

(122) The Commission therefore considers that FLG acted as a MEO when it concluded the 2010 Agreements with Ryanair. These agreements therefore do not confer an economic advantage that Ryanair would not have obtained under normal market conditions.

([1]) According to Oxera, it was unable to obtain data from FLG that covers the period after 2010.

7. **CONCLUSION**

(123) The Commission concludes that the 2010 Side Letters do not confer an economic advantage on Ryanair. Therefore, neither Side Letter No 1 nor Side Letter No 2 constitutes State aid within the meaning of Article 107(1) of the Treaty,

HAS ADOPTED THIS DECISION:

Article 1

The Side Letter No 1 of 29 March 2010 concluded between Ryanair Ltd and Flughafen Lübeck GmbH does not constitute State aid within the meaning of Article 107(1) of the Treaty.

Article 2

The Side Letter No 2 of 31 October 2010 concluded between Ryanair Ltd and Flughafen Lübeck GmbH does not constitute State aid within the meaning of Article 107(1) of the Treaty.

Article 3

This Decision is addressed to the Federal Republic of Germany.

Done at Brussels, 22 February 2018.

For the Commission
Margrethe VESTAGER
Member of the Commission

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