

Official Journal of the European Union

L 240



English edition

Legislation

Volume 61

25 September 2018

Contents

II *Non-legislative acts*

INTERNATIONAL AGREEMENTS

- ★ Notice concerning the entry into force of the Agreement in the form of an Exchange of Letters between the European Union and New Zealand pursuant to Article XXIV:6 and Article XXVIII of the General Agreement on Tariffs and Trade (GATT) 1994 relating to the modification of concessions in the schedule of the Republic of Croatia in the course of its accession to the European Union 1

REGULATIONS

- ★ Council Implementing Regulation (EU) 2018/1284 of 24 September 2018 implementing Regulation (EU) 2017/1509 concerning restrictive measures against the Democratic People's Republic of Korea 2
- ★ Council Implementing Regulation (EU) 2018/1285 of 24 September 2018 implementing Article 21(5) of Regulation (EU) 2016/44 concerning restrictive measures in view of the situation in Libya 4
- ★ Commission Implementing Regulation (EU) 2018/1286 of 24 September 2018 amending Council Regulation (EC) No 1210/2003 concerning certain specific restrictions on economic and financial relations with Iraq 8
- ★ Commission Implementing Regulation (EU) 2018/1287 of 24 September 2018 granting a Union authorisation for the biocidal product family Quat-Chem's iodine based products ⁽¹⁾ 10
- ★ Commission Implementing Regulation (EU) 2018/1288 of 24 September 2018 granting a Union authorisation for the biocidal product family Prodhynet's iodine based products ⁽¹⁾ 35

⁽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

- ★ Council Implementing Decision (CFSP) 2018/1289 of 24 September 2018 implementing Decision (CFSP) 2016/849 concerning restrictive measures against the Democratic People's Republic of Korea 61
- ★ Council Implementing Decision (CFSP) 2018/1290 of 24 September 2018 implementing Decision (CFSP) 2015/1333 concerning restrictive measures in view of the situation in Libya 63

RULES OF PROCEDURE

- ★ Amendments to the Rules of Procedure of the General Court 67
- ★ Amendments to the Rules of Procedure of the General Court 68
- ★ Decision of the General Court of 11 July 2018 on the lodging and service of procedural documents by means of e-Curia 72

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

Notice concerning the entry into force of the Agreement in the form of an Exchange of Letters between the European Union and New Zealand pursuant to Article XXIV:6 and Article XXVIII of the General Agreement on Tariffs and Trade (GATT) 1994 relating to the modification of concessions in the schedule of the Republic of Croatia in the course of its accession to the European Union

The Agreement in the form of an Exchange of Letters between the European Union and New Zealand pursuant to Article XXIV:6 and Article XXVIII of the General Agreement on Tariffs and Trade (GATT) 1994 relating to the modification of concessions in the schedule of the Republic of Croatia in the course of its accession to the European Union ⁽¹⁾, signed in Brussels on 13 March 2018, will enter into force on 1 October 2018.

⁽¹⁾ OJ L 185, 23.7.2018, p. 3.

REGULATIONS

COUNCIL IMPLEMENTING REGULATION (EU) 2018/1284

of 24 September 2018

implementing Regulation (EU) 2017/1509 concerning restrictive measures against the Democratic People's Republic of Korea

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EU) 2017/1509 of 30 August 2017 concerning restrictive measures against the Democratic People's Republic of Korea and repealing Regulation (EC) No 329/2007 ⁽¹⁾, and in particular Article 47(5) thereof,

Having regard to the proposal of the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 30 August 2017 the Council adopted Regulation (EU) 2017/1509.
- (2) On 14 September 2018 the United Nations Security Council ('UNSC') Committee established pursuant to UNSC Resolution 1718 (2006) amended the listing of one vessel subject to restrictive measures.
- (3) Annex XIV to Regulation (EU) 2017/1509 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XIV to Regulation (EU) 2017/1509 is amended as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the date 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, 24 September 2018.

For the Council

The President

J. BOGNER-STRAUSS

⁽¹⁾ OJ L 224, 31.8.2017, p. 1.

ANNEX

In Annex XIV to Regulation (EU) 2017/1509, entry 32 under the heading 'B. Vessels which are prohibited entry into ports' is replaced by the following:

'32. **Name:** WAN HENG 11

Additional information

IMO: 8791667

M/V WAN HENG 11 engaged in a ship-to-ship transfer, likely for oil, with M/V RYE SONG GANG 1 on 13 February 2018.

Wan Heng 11, formerly a Belize-flagged vessel, is now operating as a DPRK-flagged vessel named the KUMJINGANG3 or Kum Jin Gang 3.'

COUNCIL IMPLEMENTING REGULATION (EU) 2018/1285
of 24 September 2018
implementing Article 21(5) of Regulation (EU) 2016/44 concerning restrictive measures in view of
the situation in Libya

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EU) 2016/44 of 18 January 2016 concerning restrictive measures in view of the situation in Libya and repealing Regulation (EU) No 204/2011 ⁽¹⁾, and in particular Article 21(5) thereof,

Having regard to the proposal of the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 18 January 2016 the Council adopted Regulation (EU) 2016/44.
- (2) On 17 September 2018 the United Nations Security Council ('UNSC') Committee established pursuant to UNSC Resolution 1970 (2011) amended the listings of five persons subject to restrictive measures.
- (3) Annex II to Regulation (EU) 2016/44 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EU) 2016/44 is amended as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the date 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, 24 September 2018.

For the Council
The President
J. BOGNER-STRAUSS

⁽¹⁾ OJ L 12, 19.1.2016, p. 1.

ANNEX

1) In Annex II to Regulation (EU) 2016/44, entry 21 is replaced by the following:

‘21. Name: 1: ERMIA 2: ALEM 3: na 4: na

Title: na **Designation:** Leader of a transnational trafficking network **DOB:** Approximately 1980 **POB:** Eritrea **Good quality a.k.a.:** Ermias Ghermay, Guro **Low quality a.k.a.:** a) Ermias Ghermay b) Ermias Ghirmay **Nationality:** Eritrea **Passport no:** na **National identification no:** na **Address:** (Known address: Tripoli, Tarig sure no. 51, likely moved to Sabratha in 2015.) **Listed on:** 7 June 2018 **Other information:** Listed pursuant to paragraphs 15 and 17 of resolution 1970 (Travel Ban, Asset Freeze)

Listed pursuant to paragraph 22(a) of resolution 1970 (2011); paragraph 4(a) of resolution 2174 (2014); paragraph 11(a) of resolution 2213 (2015).

Additional information

Ermias Alem is extensively documented by multiple reliable sources, including criminal investigations, identifying him as one of the most important sub-Saharan actors involved in the illicit trafficking of migrants in Libya. Ermias Alem is a leader of a transnational network responsible for trafficking and smuggling tens of thousands of migrants, mainly from the Horn of Africa to the coast of Libya and onwards to destination countries in Europe and the United States. He has armed men at his disposal, as well as warehouses and detention camps where serious human rights abuses are reportedly being committed against migrants. He works in close cooperation with Libyan smuggling networks like that of Mustafa, and he is considered their ‘Eastern supply chain’. His network stretches from Sudan to the coast of Libya and to Europe (Italy, France, Germany, the Netherlands, Sweden, the United Kingdom) and the United States. Alem controls private detention camps around the Libyan northwest coast where migrants are detained, and where serious abuses against migrants have taken place. From these camps, migrants are transported to Sabratha or Zawiya. In recent years, Alem has organised countless perilous journeys across the sea, exposing migrants (including numerous minors) to the risk of death. The Court of Palermo (Italy) issued arrest warrants in 2015 against Ermias Alem in relation to the smuggling of thousands of migrants under inhumane circumstances, including the shipwrecking on 13 October 2013 near Lampedusa in which 266 people died.’

2) In Annex II to Regulation (EU) 2016/44, entry 22 is replaced by the following:

‘22. Name: 1: FITIWI 2: ABDELRAZAK 3: na 4: na

Title: na **Designation:** Leader of a transnational trafficking network **DOB:** Approximately (30-35 years old) **POB:** Massaua, Eritrea **Good quality a.k.a.:** Abdurazak, Abdelrazak, Abdulrazak, Abdrazak **Low quality a.k.a.:** Fitwi Esmail Abdelrazak **Nationality:** Eritrea **Passport no:** na **National identification no:** na **Address:** na **Listed on:** 7 June 2018 **Other information:** Listed pursuant to paragraphs 15 and 17 of resolution 1970 (Travel Ban, Asset Freeze)

Listed pursuant to paragraph 22(a) of resolution 1970 (2011); paragraph 4(a) of resolution 2174 (2014); paragraph 11(a) of resolution 2213 (2015).

Additional information

Fitiwi Abdelrazak is a leader of a transnational network responsible for trafficking and smuggling tens of thousands of migrants, mainly from the Horn of Africa to the coast of Libya and onwards to destination countries in Europe and the United States. Fitiwi Abdelrazak has been identified in open sources and in several criminal investigations as one of the top-level actors responsible for the exploitation and abuse of a large number of migrants in Libya. Abdelrazak has extensive contacts within Libyan smuggling networks and has accumulated immense wealth through the illicit trafficking of migrants. He has armed men at his disposal, as well as warehouses and detention camps where serious human rights abuses are being committed. His network is composed of cells reaching from Sudan, Libya, Italy and onwards to destination countries for migrants. Migrants in his camps are also bought from other parties, such as other local detention facilities. From these camps, migrants are transported to the Libyan coast. Abdelrazak has organised countless perilous maritime journeys, exposing migrants (including minors) to the risk of death. Abdelrazak is linked to at least two shipwrecks with fatal consequences between April 2014 and July 2014.’

3) In Annex II to Regulation (EU) 2016/44, entry 23 is replaced by the following:

‘23. Name: 1: AHMAD 2: OUMAR 3: IMHAMAD 4: AL-FITOURI

Title: na **Designation:** Commander of the Anas al-Dabbashi militia, Leader of a transnational trafficking network **DOB:** 7 May 1988 **POB:** (possibly Sabratha, Talil neighbourhood) **Good quality a.k.a.:** na **Low quality a.k.a.:** a) Al-Dabachi b) Al Ammu c) The Uncle d) Al-Ahwal e) Al Dabbashi **Nationality:** Libya **Passport no:** na **National identification no:** na **Address:** a) Garabulli, Libya b) Zawiya, Libya **Listed on:** 7 June 2018 **Other information:** Listed pursuant to paragraphs 15 and 17 of resolution 1970 (Travel Ban, Asset Freeze)

Listed pursuant to paragraph 22(a) of resolution 1970 (2011); paragraph 4(a) of resolution 2174 (2014); paragraph 11(a) of resolution 2213 (2015). INTERPOL-UN Security Council Special Notice web link: <https://www.interpol.int/en/notice/search/un/>

Additional information

Ahmad Imhamad is the commander of the Anas al-Dabbashi militia, formerly operating in the coastal area between Sabratha and Melita. Imhamad is a significant leader in illicit activities related to the trafficking of migrants. The al-Dabbashi clan and militia also cultivate relationships with terrorist and violent extremist groups. Imhamad is currently active around Zawiya, after violent clashes broke out with other militia and rivaling smuggling organisations around the coastal area in October 2017, resulting in over 30 deaths including civilians. In response to his ouster, Ahmad Imhamad on 4 December 2017 publicly vowed to return to Sabratha with weapons and force. There is extensive evidence that Imhamad's militia has been directly involved in the illicit trafficking and smuggling of migrants, and that his militia controls departure areas for migrants, camps, safe houses and boats. There is information that supports the conclusion that Imhamad has exposed migrants (including minors) to brutal conditions and sometimes fatal circumstances on land and at sea. After violent clashes between Imhamad's militia and other militia in Sabratha, thousands of migrants were found (many in serious condition), most of them held in centres of the Martyrs Anas al-Dabbashi brigade and al-Ghul militia. The al-Dabbashi clan, and the connected Anas al-Dabbashi militia, have long-standing links with Islamic State in the Levante (ISIL) and its affiliates.

Several ISIL operatives have been in their ranks, including Abdallah al-Dabbashi, the ISIL 'caliph' of Sabratha. Imhamad was also allegedly involved in orchestrating the murder of Sami Khalifa al-Gharabli, who was appointed by the Sabratha municipal council to counter migrant smuggling operations in July 2017. Imhamad's activities largely contribute to the mounting violence and insecurity in western Libya and threaten peace and stability in Libya and neighbouring countries.'

4) In Annex II to Regulation (EU) 2016/44, entry 24 is replaced by the following:

‘24. Name: 1: MUS'AB 2: MUSTAFA 3: ABU AL QUASSIM 4: OMAR

Title: na **Designation:** Leader of a transnational trafficking network **DOB:** 19 Jan. 1983 **POB:** Sabratha, Libya **Good quality a.k.a.:** Mus'ab Abu Qarin **Low quality a.k.a.:** a) ABU-AL QASSIM OMAR Musab Boukrin b) The Doctor c) Al-Grein **Nationality:** Libya **Passport no:** a) 782633, issued on 31 May 2005 b) 540794, issued on 12 Jan. 2008 **National identification no:** na **Address:** na **Listed on:** 7 June 2018 **Other information:** Listed pursuant to paragraphs 15 and 17 of resolution 1970 (Travel Ban, Asset Freeze)

Listed pursuant to paragraph 22(a) of resolution 1970 (2011); paragraph 4(a) of resolution 2174 (2014); paragraph 11(a) of resolution 2213 (2015). INTERPOL-UN Security Council Special Notice web link: <https://www.interpol.int/en/notice/search/un/>

Additional information

Mus'ab Mustafa is seen as a central actor in human trafficking and migrant smuggling activities in the area of Sabratha, but also works from Zawiya and Garibulli. His transnational network covers Libya, European destinations, sub-Saharan countries for the recruitment of migrants and Arab countries for the financial sector. Reliable sources have documented his collusion in human trafficking and smuggling with Ermas Alem, who takes care of the 'Eastern supply chain' on behalf of Mustafa. There is evidence that Mustafa has cultivated relationships with other actors in the trafficking business, notably Mohammed al-Hadi (cousin and head of the al-Nasr brigade, also proposed for listing) in Zawiya. A former accomplice of Mustafa, who is now cooperating with the Libyan authorities, claims that Mustafa organised journeys over sea for 45 000 people in 2015 alone, exposing migrants (including minors) to the risk of death. Mustafa is the organiser of a journey on 18 April 2015 ending in a shipwrecking in the Sicilian Canal that caused the death of 800 people. Evidence, including from the UN Panel of Experts, documents that he is responsible for the detention of migrants under brutal conditions, including in Tripoli near the al-Wadi area and seaside resorts near Sabratha where migrants are held.

Mustafa is reported to have been close to the al-Dabbashi clan in Sabratha, until a conflict broke out over a 'protection tax'. Sources have reported that Mustafa has paid persons close to violent extremists in the Sabratha area, in exchange for the approval to smuggle migrants on behalf of violent extremist circles, that financially benefit from the exploitation of illegal immigration. Mustafa is connected to a network of smugglers composed of Salafi armed groups in Tripoli, Sebha and Kufra.'

- 5) In Annex II to Regulation (EU) 2016/44, entry 25 is replaced by the following:

'25. Name: 1: MOHAMMED 2: AL-HADI 3: AL-ARABI 4: KASHLAF

Title: na **Designation:** Commander of the Shuhada al-Nasr brigade, Head of the Petrol Refinery Guard of Zawiya's refinery **DOB:** 15 November 1988 **POB:** Zawiya, Libya **Good quality a.k.a.:** na **Low quality a.k.a.:** a) Kashlaf b) Koshlaf c) Keslaf d) al-Qasab **Nationality:** Libya **Passport no:** HR8CHGP8; Date of issue: 27 April 2015; Place of issue: Zawiya **National identification no:** a) 119880210419 b) **Personal Identification Card no:** 728498; **Date of issue:** 24 February 2007 **Address:** Zawiya, Libya **Listed on:** 7 June 2018 **Other information:** Listed pursuant to paragraphs 15 and 17 of resolution 1970 (Travel Ban, Asset Freeze)

Listed pursuant to paragraph 22(a) of resolution 1970 (2011); paragraph 4(a) of resolution 2174 (2014); paragraph 11(a) of resolution 2213 (2015).

Additional information

Mohammed al-Hadi is the head of the Shuhada al Nasr brigade in Zawiya, Western Libya. His militia controls the Zawiya refinery, a central hub of migrant smuggling operations. Al-Hadi also controls detention centres, including the Nasr detention centre – nominally under the control of the DCIM. As documented in various sources, the network of al-Hadi is one of the most dominant in the field of migrant smuggling and the exploitation of migrants in Libya. Al-Hadi has extensive links with the head of the local unit of the coast guard of Zawiya, al-Rahman al-Milad, whose unit intercepts boats with migrants, often of rivaling migrant smuggling networks. Migrants are then brought to detention facilities under the control of the Al Nasr militia, where they are reportedly held in critical conditions. The Panel of Experts for Libya collected evidence of migrants that were frequently beaten, while others, notably women from sub-Saharan countries and Morocco, were sold on the local market as 'sex slaves'. The Panel has also found that al-Hadi collaborates with other armed groups and has been involved in repeated violent clashes in 2016 and 2017.'

- 6) In Annex II to Regulation (EU) 2016/44, entry 26 is replaced by the following:

'26. Name: 1: ABD 2: AL-RAHMAN 3: AL-MILAD 4: na

Title: na **Designation:** Commander of the Coast Guard in Zawiya **DOB:** Approximately (29 years old) **POB:** Tripoli, Libya **Good quality a.k.a.:** na **Low quality a.k.a.:** a) Rahman Salim Milad b) al-Bija **Nationality:** Libya **Passport no:** na **National identification no:** na **Address:** Zawiya, Libya **Listed on:** 7 June 2018 **Other information:** Listed pursuant to paragraphs 15 and 17 of resolution 1970 (Travel Ban, Asset Freeze)

Listed pursuant to paragraph 22(a) of resolution 1970 (2011); paragraph 4(a) of resolution 2174 (2014); paragraph 11(a) of resolution 2213 (2015).

Additional information

Abd al Rahman al-Milad heads the regional unit of the Coast Guard in Zawiya that is consistently linked with violence against migrants and other human smugglers. The UN Panel of Experts claims that Milad, and other coastguard members, are directly involved in the sinking of migrant boats using firearms. Al-Milad collaborates with other migrant smugglers such as Mohammed al-Hadi (also proposed for listing) who, sources suggest, is providing protection to him to carry out illicit operations related to the trafficking and smuggling of migrants. Several witnesses in criminal investigations have stated they were picked up at sea by armed men on a Coast Guard ship called Tallil (used by al-Milad) and taken to the al-Nasr detention centre, where they are reportedly held in brutal conditions and subjected to beatings.'

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1286**of 24 September 2018****amending Council Regulation (EC) No 1210/2003 concerning certain specific restrictions on economic and financial relations with Iraq**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1210/2003 of 7 July 2003 concerning certain specific restrictions on economic and financial relations with Iraq and repealing Regulation (EC) No 2465/96 ⁽¹⁾, and in particular Article 11(b) thereof,

Whereas:

- (1) Annex III to Regulation (EC) No 1210/2003 lists public bodies, corporations and agencies and natural and legal persons, bodies and entities of the previous government of Iraq covered by the freezing of funds and economic resources that were located outside Iraq on the date of 22 May 2003 under that Regulation.
- (2) On 19 September 2018, the Sanctions Committee of the United Nations Security Council decided to remove two entries from the list of persons or entities to whom the freezing of funds and economic resources should apply.
- (3) Annex III to Regulation (EC) No 1210/2003 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EC) No 1210/2003 is amended as set out in the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 24 September 2018.

For the Commission,

On behalf of the President,

Head of the Service for Foreign Policy Instruments

⁽¹⁾ OJ L 169, 8.7.2003, p. 6.

ANNEX

In Annex III to Regulation (EC) No 1210/2003, the following entries are deleted:

- ‘116. STATE COMPANY FOR ELECTRICAL INDUSTRIES (alias (a) STATE ENTERPRISE FOR ELECTRICAL INDUSTRIES, (b) STATE ENTERPRISE FOR ELECTRICAL INDUSTRIES/ELECTRICAL LAMPS, (c) STATE ENTERPRISE FOR GENERATION AND TRANSMISSION OF ELECTRICITY). Addresses: (a) P.O. Box 1118, Waziria, Baghdad, Iraq; (b) P.O. Box 9145, Al-Kadhmiyah, Al-Taji, Baghdad, Iraq; (c) 4/356 Al Masbah Building, P.O. Box 1098, Baghdad, Iraq.’
- ‘134. STATE ENTERPRISE FOR DRUG INDUSTRIES (alias STATE COMPANY FOR DRUG PRODUCTS). Address: P.O. Box 271, Samara, Iraq.’
-

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1287
of 24 September 2018
granting a Union authorisation for the biocidal product family Quat-Chem'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 24 July 2015, Quatchem Ltd submitted to the European Chemicals Agency ('the Agency') an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 and Article 4 of Commission Implementing Regulation (EU) No 414/2013 ⁽²⁾ for authorisation of a same biocidal product family, as referred to in Article 1 of Regulation (EU) No 414/2013, named Quat-chem's iodine based products ('the same product family') of product-type 3, as described in Annex V to Regulation (EU) No 528/2012. The application for the same product family was recorded under the case number BC-YN018814-15 in the Register for Biocidal Products ('the Register'). The application also indicated the application number of the related reference product family (Hypred's iodine based products), recorded in the Register under the case number BC-LC018584-49.
- (2) The same 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 ⁽³⁾ will become applicable, the Commission will consider the need to review of 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 biocidal products containing the active substance have to be reviewed in accordance with Article 48 of Regulation (EU) No 528/2012.
- (3) On 26 January 2018, the Agency submitted to the Commission an opinion ⁽⁴⁾, including the draft summary of the biocidal product characteristics (hereinafter 'SPC'), in accordance with Article 6(2) of Regulation (EU) No 414/2013. The opinion concluded that the same product family falls within the definition of 'biocidal product family' laid down in Article 3(1)(s) of Regulation (EU) No 528/2012, that the proposed differences between the same product family and the related reference biocidal product family are limited to information which can be the subject of an administrative change in accordance with Implementing Regulation (EU) No 354/2013 ⁽⁵⁾, and that based on the assessment of the abovementioned related reference product family and subject to compliance with the draft SPC, the same product family meets the conditions laid down in Article 19(1) and (6) of Regulation (EU) No 528/2012.
- (4) On 13 March 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.
- (5) The Commission concurs with the opinion of the Agency and considers therefore appropriate to grant a Union authorisation for the same product family, and to record the SPC in the Register in accordance with Article 71(6) of that Regulation.
- (6) 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 Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 125, 7.5.2013, p. 4).

⁽³⁾ 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).

⁽⁴⁾ ECHA opinion of 25 January 2018 on the Union authorisation of the same biocidal product family QUAT-CHEM's iodine based products (UBP-C-1177989-01-00/F).

⁽⁵⁾ Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4).

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation is granted to Quatchem Ltd for the same biocidal product family Quat-chem's iodine based products with authorisation number EU-0018496-0000.

The Union authorisation is valid from 15 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, 24 September 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Summary of product characteristics for a biocidal product family

QUAT-CHEM's iodine based products

Product type 3 — Veterinary hygiene (Disinfectants)

Authorisation number: EU-0018496-0000

R4BP asset number: EU-0018496-0000

PART I

FIRST INFORMATION LEVEL**1. ADMINISTRATIVE INFORMATION****1.1. Family name**

Name	QUAT-CHEM'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	Quatchem Ltd
	Address	4 Dodgson Street, OL16 5SJ, Rochdale, United Kingdom
Authorisation number	EU-0018496-0000	
R4BP asset number	EU-0018496-0000	
Date of the authorisation	15 October 2018	
Expiry date of the authorisation	30 September 2028	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	QUAT-CHEM LTD
Address of manufacturer	Charter House 33 - Greek Street SK3 8AX Stockport United Kingdom
Location of manufacturing sites	QUAT-CHEM LTD - Charter House 33 - Greek Street SK3 8AX Stockport United Kingdom

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 SPCs

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 directions for use 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.

⁽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.

5.2. 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.

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)	Teatsan 2500 IODO GUARD 2500				
Authorisation number	EU-0018496-0001 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

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)
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.

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.

⁽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.

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)	Teat Guard 2500 IODO SPRAY 2500				
Authorisation number	EU-0018496-0002 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

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 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	<p>Causes serious eye damage.</p> <p>May cause damage to organs (thyroid) through prolonged or repeated exposure oral.</p> <p>Toxic to aquatic life with long lasting effects.</p> <p>May be corrosive to metals.</p>
Precautionary statements	<p>Keep out of reach of children.</p> <p>Do not breathe mist.</p> <p>Do not breathe vapours.</p> <p>Do not breathe spray.</p> <p>Wash hands thoroughly after handling.</p> <p>Wear protective gloves.</p> <p>Wear protective clothing.</p> <p>Wear eye protection.</p> <p>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>Immediately call a poison center / doctor.</p> <p>Get medical advice/attention if you feel unwell.</p> <p>Dispose of contents to in accordance with local/ regional/ national/ international regulations. Dispose of container to in accordance with local/ regional/ national/ international regulations.</p> <p>Keep only in original container.</p> <p>Absorb spillage to prevent material damage.</p>

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)	<p>Bacteria</p> <p>Yeasts</p>
Field(s) of use	<p>Indoor</p> <p>Disinfection of teats of milk producing animals by dipping, foaming or spraying before milking</p>

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 100ml) 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 100ml) 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 SPC3

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 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.

⁽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.

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)	Teat Guard Concentrate 1:4 IODO GUARD CONCENTRATE 1:4				
Authorisation number	EU-0018496-0003 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*

None: see directions for use 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.

⁽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.

5.2. 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.

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)	Teatsan 5000 IODO GUARD 5000				
Authorisation number	EU-0018496-0004 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.

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.

⁽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.

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)	Teat Guard 5500 IODO SPRAY 5500				
Authorisation number	EU-0018496-0005 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) 2018/1288
of 24 September 2018
granting a Union authorisation for the biocidal product family Prodhynet'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 3 August 2015, Prodhynet SA submitted to the European Chemicals Agency ('the Agency') an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 and Article 4 of Commission Implementing Regulation (EU) No 414/2013 ⁽²⁾ for authorisation of a same biocidal product family, as referred to in Article 1 of Regulation (EU) No 414/2013, named Prodhynet's iodine based products ('the same product family') of product-type 3, as described in Annex V to Regulation (EU) No 528/2012. The application for the same product family was recorded under the case number BC-YK019030-42 in the Register for Biocidal Products ('the Register'). The application also indicated the application number of the related reference product family (Hypred's iodine based products), recorded in the Register under the case number BC-LC018584-49.
- (2) The same 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 ⁽³⁾ 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 biocidal products containing the active substance have to be reviewed in accordance with Article 48 of Regulation (EU) No 528/2012.
- (3) On 26 January 2018, the Agency submitted to the Commission an opinion ⁽⁴⁾, including the draft summary of the biocidal product characteristics ('SPC'), in accordance with Article 6(2) of Regulation (EU) No 414/2013. The opinion concluded that the same product family falls within the definition of 'biocidal product family' laid down in Article 3(1)(s) of Regulation (EU) No 528/2012, that the proposed differences between the same product family and the related reference biocidal product family are limited to information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 ⁽⁵⁾, and that based on the assessment of the above-mentioned related reference product family and subject to compliance with the draft SPC, the same product family meets the conditions laid down in Article 19(1) and (6) of Regulation (EU) No 528/2012.
- (4) On 6 March 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.
- (5) The Commission concurs with the opinion of the Agency and considers therefore appropriate to grant a Union authorisation for the same product family, and to record the SPC in the Register in accordance with Article 71(6) of that Regulation.
- (6) 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 Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 125, 7.5.2013, p. 4).

⁽³⁾ 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).

⁽⁴⁾ ECHA opinion of 25 January 2018 on the Union authorisation of the same biocidal product family PRODHYNETS iodine based products (UBP-C-1177988-02-00/F).

⁽⁵⁾ Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4).

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation is granted to Prodhynet SA for the same biocidal product family Prodhynet's iodine based products with authorisation number EU-0018497-0000.

The Union authorisation is valid from 15 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, 24 September 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Summary of product characteristics for a biocidal product family

PRODHYNET's iodine based products

Product type 3 - Veterinary hygiene (Disinfectants)

Authorisation number: EU-0018497-0000

R4BP asset number: EU-0018497-0000

PART I

FIRST INFORMATION LEVEL**1. ADMINISTRATIVE INFORMATION****1.1. Family name**

Name	PRODHYNET'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	PRODHYNET SA
	Address	11 Avenue des châtelets, 22440, PLOUFRAGAN, France
Authorisation number	EU-0018497-0000	
R4BP asset number	EU-0018497-0000	
Date of the authorisation	15 October 2018	
Expiry date of the authorisation	30 September 2028	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	PRODHYNET SA
Address of manufacturer	11, Avenue des Châtelets 22440 PLOUFRAGAN France
Location of manufacturing sites	PRODHYNET SA - 11, Avenue des Châtelets 22440 PLOUFRAGAN France

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 directions for use 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)

⁽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.

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.

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)	IODO EP25 IODOGEL PRO TI-N
Authorisation number	EU-0018497-0001 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

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.

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.

⁽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.

— 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)	IODO FL25 PRO ROBO I-N				
Authorisation number	EU-0018497-0002 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

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 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	<p>Causes serious eye damage.</p> <p>May cause damage to organs (thyroid) through prolonged or repeated exposure oral.</p> <p>Toxic to aquatic life with long lasting effects.</p> <p>May be corrosive to metals.</p>
Precautionary statements	<p>Keep out of reach of children.</p> <p>Do not breathe mist.</p> <p>Do not breathe vapours.</p> <p>Do not breathe spray.</p> <p>Wash hands thoroughly after handling.</p> <p>Wear protective gloves.</p> <p>Wear protective clothing.</p> <p>Wear eye protection.</p> <p>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.</p> <p>Immediately call a poison center/doctor.</p> <p>Get medical advice/attention if you feel unwell.</p> <p>Dispose of contents to in accordance with local/ regional/ national/ international regulations. Dispose of container to in accordance with local/ regional/ national/ international regulations.</p> <p>Keep only in original container.</p> <p>Absorb spillage to prevent material damage.</p>

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 3ml 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, yeastical and algacidal 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.

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.

⁽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.

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)	PRMX IODOSE				
Authorisation number	EU-0018497-0003 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.

⁽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.

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.

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)	AGRI IODE EPAIS S HYGIA IODE EPAIS S IODE EPAIS NETAIODE EPAIS S TREMPAGE EPAIS IODE S IODO EP50 ADIEL IODE EPAIS LATI IODE PRO TI PROXA IODE EPAIS S BREIZH-IODE EPAIS S BRETAIODE EPAIS DR16 PLUSAIOD EPAIS HELIO FIRST EP TECNO FIRST LACTOIODE EPAIS MAG IODE EPAIS S				
Authorisation number	EU-0018497-0004 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.

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 SPC5.

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)	AGRI IODE FLUIDE HYGIA IODE FLUIDE IODE FLUIDE IOSPRAY FLUIDE PULVE IODE IODO FL55 IODOLIN ADIEL IODE FLUIDE BOVI IODE SPRAY PRO ROBO I PROXA IODE FLUIDE HELIODE FLUIDE TECNO FLUIDE DR15 GANAIODE FLUIDE PLUSAIOD PROTECTION FLUIDE IODE BREIZH-IODE FLUIDE BRETAIODE LQ IODE NET FLUIDE LACTOIODE FLUIDE MAG IODE FLUIDE NETAIODE FLUIDE NETAIODE				
Authorisation number	EU-0018497-0005 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

DECISIONS

COUNCIL IMPLEMENTING DECISION (CFSP) 2018/1289

of 24 September 2018

implementing Decision (CFSP) 2016/849 concerning restrictive measures against the Democratic People's Republic of Korea

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 31(2) thereof,

Having regard to Council Decision (CFSP) 2016/849 of 27 May 2016 concerning restrictive measures against the Democratic People's Republic of Korea and repealing Decision 2013/183/CFSP ⁽¹⁾, and in particular Article 33(1) thereof,

Having regard to the proposal of the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 27 May 2016 the Council adopted Decision (CFSP) 2016/849.
- (2) On 14 September 2018 the United Nations Security Council ('UNSC') Committee established pursuant to UNSC Resolution 1718 (2006) amended the listing of one vessel subject to restrictive measures.
- (3) Annex IV to Decision (CFSP) 2016/849 should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Annex IV to Decision (CFSP) 2016/849 is amended as set out in the Annex to this Decision.

Article 2

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

Done at Brussels, 24 September 2018.

For the Council

The President

J. BOGNER-STRAUSS

⁽¹⁾ OJ L 141, 28.5.2016, p. 79.

ANNEX

- (1) In Annex IV to Decision (CFSP) 2016/849, entry 11 under the heading 'A. Deflagged vessels', is replaced by the following:

'11. **Name:** WAN HENG 11

Additional information

IMO: 8791667

M/V WAN HENG 11 engaged in a ship-to-ship transfer, likely for oil, with M/V RYE SONG GANG 1 on 13 February 2018.

Wan Heng 11, formerly a Belize-flagged vessel, is now operating as a DPRK-flagged vessel named the KUMJINGANG3 or Kum Jin Gang 3.'

- (2) In Annex IV to Decision (CFSP) 2016/849, entry 32 under the heading 'D. Vessels which are prohibited entry into ports', is replaced by the following:

'32. **Name:** WAN HENG 11

Additional information

IMO: 8791667

M/V WAN HENG 11 engaged in a ship-to-ship transfer, likely for oil, with M/V RYE SONG GANG 1 on 13 February 2018.

Wan Heng 11, formerly a Belize-flagged vessel, is now operating as a DPRK-flagged vessel named the KUMJINGANG3 or Kum Jin Gang 3.'

COUNCIL IMPLEMENTING DECISION (CFSP) 2018/1290
of 24 September 2018
implementing Decision (CFSP) 2015/1333 concerning restrictive measures in view of the situation
in Libya

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 31(2) thereof,

Having regard to Council Decision (CFSP) 2015/1333 of 31 July 2015 concerning restrictive measures in view of the situation in Libya, and repealing Decision 2011/137/CFSP ⁽¹⁾, and in particular Article 12(1) thereof,

Having regard to the proposal of the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 31 July 2015 the Council adopted Decision (CFSP) 2015/1333.
- (2) On 17 September 2018 the United Nations Security Council ('UNSC') Committee established pursuant to UNSC Resolution 1970 (2011) amended the listings of five persons subject to restrictive measures.
- (3) Annexes I and III to Decision (CFSP) 2015/1333 should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Annexes I and III to Decision (CFSP) 2015/1333 are amended as set out in the Annex to this Decision.

Article 2

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

Done at Brussels, 24 September 2018.

For the Council
The President
J. BOGNER-STRAUSS

⁽¹⁾ OJ L 206, 1.8.2015, p. 34.

ANNEX

(1) In Annex I and Annex III to Decision (CFSP) 2015/1333, entry 21 is replaced by the following:

‘21. Name: 1: ERMIAS 2: ALEM 3: na 4: na

Title: na **Designation:** Leader of a transnational trafficking network **DOB:** Approximately 1980 **POB:** Eritrea **Good quality a.k.a.:** Ermias Ghermay, Guro **Low quality a.k.a.:** a) Ermies Ghermay b) Ermias Ghirmay **Nationality:** Eritrea **Passport no:** na **National identification no:** na **Address:** (Known address: Tripoli, Tarig sure no. 51, likely moved to Sabratha in 2015.) **Listed on:** 7 June 2018 **Other information:** Listed pursuant to paragraphs 15 and 17 of resolution 1970 (Travel Ban, Asset Freeze)

Listed pursuant to paragraph 22(a) of resolution 1970 (2011); paragraph 4(a) of resolution 2174 (2014); paragraph 11(a) of resolution 2213 (2015).

Additional information

Ermias Alem is extensively documented by multiple reliable sources, including criminal investigations, identifying him as one of the most important sub-Saharan actors involved in the illicit trafficking of migrants in Libya. Ermias Alem is a leader of a transnational network responsible for trafficking and smuggling tens of thousands of migrants, mainly from the Horn of Africa to the coast of Libya and onwards to destination countries in Europe and the United States. He has armed men at his disposal, as well as warehouses and detention camps where serious human rights abuses are reportedly being committed against migrants. He works in close cooperation with Libyan smuggling networks like that of Mustafa, and he is considered their “Eastern supply chain”. His network stretches from Sudan to the coast of Libya and to Europe (Italy, France, Germany, the Netherlands, Sweden, the United Kingdom) and the United States. Alem controls private detention camps around the Libyan northwest coast where migrants are detained, and where serious abuses against migrants have taken place. From these camps, migrants are transported to Sabratha or Zawiya. In recent years, Alem has organised countless perilous journeys across the sea, exposing migrants (including numerous minors) to the risk of death. The Court of Palermo (Italy) issued arrest warrants in 2015 against Ermias Alem in relation to the smuggling of thousands of migrants under inhumane circumstances, including the shipwrecking on 13 October 2013 near Lampedusa in which 266 people died.’

(2) In Annex I and Annex III to Decision (CFSP) 2015/1333, entry 22 is replaced by the following:

‘22. Name: 1: FITIWI 2: ABDELRAZAK 3: na 4: na

Title: na **Designation:** Leader of a transnational trafficking network **DOB:** Approximately (30-35 years old) **POB:** Massaua, Eritrea **Good quality a.k.a.:** Abdurezak, Abdelrazaq, Abdulrazak, Abdrazzak **Low quality a.k.a.:** Fitwi Esmail Abdelrazak **Nationality:** Eritrea **Passport no:** na **National identification no:** na **Address:** na **Listed on:** 7 June 2018 **Other information:** Listed pursuant to paragraphs 15 and 17 of resolution 1970 (Travel Ban, Asset Freeze)

Listed pursuant to paragraph 22(a) of resolution 1970 (2011); paragraph 4(a) of resolution 2174 (2014); paragraph 11(a) of resolution 2213 (2015).

Additional information

Fitiwi Abdelrazak is a leader of a transnational network responsible for trafficking and smuggling tens of thousands of migrants, mainly from the Horn of Africa to the coast of Libya and onwards to destination countries in Europe and the United States. Fitiwi Abdelrazak has been identified in open sources and in several criminal investigations as one of the top-level actors responsible for the exploitation and abuse of a large number of migrants in Libya. Abdelrazak has extensive contacts within Libyan smuggling networks and has accumulated immense wealth through the illicit trafficking of migrants. He has armed men at his disposal, as well as warehouses and detention camps where serious human rights abuses are being committed. His network is composed of cells reaching from Sudan, Libya, Italy and onwards to destination countries for migrants. Migrants in his camps are also bought from other parties, such as other local detention facilities. From these camps, migrants are transported to the Libyan coast. Abdelrazak has organised countless perilous maritime journeys, exposing migrants (including minors) to the risk of death. Abdelrazak is linked to at least two shipwrecks with fatal consequences between April 2014 and July 2014.’

(3) In Annex I and Annex III to Decision (CFSP) 2015/1333, entry 23 is replaced by the following:

‘23. Name: 1: AHMAD 2: OUMAR 3: IMHAMAD 4: AL-FITOURI

Title: na **Designation:** Commander of the Anas al-Dabbashi militia, Leader of a transnational trafficking network **DOB:** 7 May 1988 **POB:** (possibly Sabratha, Talil neighbourhood) **Good quality a.k.a.:** na **Low quality a.k.a.:** a) Al-Dabachi b) Al Ammu c) The Uncle d) Al-Ahwal e) Al Dabbashi **Nationality:** Libya **Passport no.:** na **National identification no.:** na **Address:** a) Garabulli, Libya b) Zawiya, Libya **Listed on:** 7 June 2018 **Other information:** Listed pursuant to paragraphs 15 and 17 of resolution 1970 (Travel Ban, Asset Freeze)

Listed pursuant to paragraph 22(a) of resolution 1970 (2011); paragraph 4(a) of resolution 2174 (2014); paragraph 11(a) of resolution 2213 (2015). INTERPOL-UN Security Council Special Notice web link: <https://www.interpol.int/en/notice/search/un/>

Additional information

Ahmad Imhamad is the commander of the Anas al-Dabbashi militia, formerly operating in the coastal area between Sabratha and Melita. Imhamad is a significant leader in illicit activities related to the trafficking of migrants. The al-Dabbashi clan and militia also cultivate relationships with terrorist and violent extremist groups. Imhamad is currently active around Zawiya, after violent clashes broke out with other militia and rivaling smuggling organisations around the coastal area in October 2017, resulting in over 30 deaths including civilians. In response to his ouster, Ahmad Imhamad on 4 December 2017 publicly vowed to return to Sabratha with weapons and force. There is extensive evidence that Imhamad's militia has been directly involved in the illicit trafficking and smuggling of migrants, and that his militia controls departure areas for migrants, camps, safe houses and boats. There is information that supports the conclusion that Imhamad has exposed migrants (including minors) to brutal conditions and sometimes fatal circumstances on land and at sea. After violent clashes between Imhamad's militia and other militia in Sabratha, thousands of migrants were found (many in serious condition), most of them held in centres of the Martyrs Anas al-Dabbashi brigade and al-Ghul militia. The al-Dabbashi clan, and the connected Anas al-Dabbashi militia, have long-standing links with Islamic State in the Levante (ISIL) and its affiliates.

Several ISIL operatives have been in their ranks, including Abdallah al-Dabbashi, the ISIL “caliph” of Sabratha. Imhamad was also allegedly involved in orchestrating the murder of Sami Khalifa al-Gharabli, who was appointed by the Sabratha municipal council to counter migrant smuggling operations in July 2017. Imhamad's activities largely contribute to the mounting violence and insecurity in western Libya and threaten peace and stability in Libya and neighbouring countries.’

(4) In Annex I and Annex III to Decision (CFSP) 2015/1333, entry 24 is replaced by the following:

‘24. Name: 1: MUS'AB 2: MUSTAFA 3: ABU AL QUASSIM 4: OMAR

Title: na **Designation:** Leader of a transnational trafficking network **DOB:** 19 Jan. 1983 **POB:** Sabratha, Libya **Good quality a.k.a.:** Mus'ab Abu Qarin **Low quality a.k.a.:** a) ABU-AL QASSIM OMAR Musab Boukrin b) The Doctor c) Al-Grein **Nationality:** Libya **Passport no.:** a) 782633, issued on 31 May 2005 b) 540794, issued on 12 Jan. 2008 **National identification no.:** na **Address:** na **Listed on:** 7 June 2018 **Other information:** Listed pursuant to paragraphs 15 and 17 of resolution 1970 (Travel Ban, Asset Freeze)

Listed pursuant to paragraph 22(a) of resolution 1970 (2011); paragraph 4(a) of resolution 2174 (2014); paragraph 11(a) of resolution 2213 (2015). INTERPOL-UN Security Council Special Notice web link: <https://www.interpol.int/en/notice/search/un/>

Additional information

Mus'ab Mustafa is seen as a central actor in human trafficking and migrant smuggling activities in the area of Sabratha, but also works from Zawiya and Garibulli. His transnational network covers Libya, European destinations, sub-Saharan countries for the recruitment of migrants and Arab countries for the financial sector. Reliable sources have documented his collusion in human trafficking and smuggling with Ermas Alem, who takes care of the “Eastern supply chain” on behalf of Mustafa. There is evidence that Mustafa has cultivated relationships with other actors in the trafficking business, notably Mohammed al-HadiadaHh (cousin and head of the al-Nasr brigade, also proposed for listing) in Zawiya. A former accomplice of Mustafa, who is now cooperating with the Libyan authorities, claims that Mustafa organised journeys over sea for 45 000 people in 2015 alone, exposing migrants (including minors) to the risk of death. Mustafa is the organiser of a journey on 18 April 2015 ending in a shipwrecking in the Sicilian Canal that caused the death of 800 people. Evidence, including from the UN Panel of Experts, documents that he is responsible for the detention of migrants under

brutal conditions, including in Tripoli near the al-Wadi area and seaside resorts near Sabratha where migrants are held. Mustafa is reported to have been close to the al-Dabbashi clan in Sabratha, until a conflict broke out over a “protection tax”. Sources have reported that Mustafa has paid persons close to violent extremists in the Sabratha area, in exchange for the approval to smuggle migrants on behalf of violent extremist circles, that financially benefit from the exploitation of illegal immigration. Mustafa is connected to a network of smugglers composed of Salafi armed groups in Tripoli, Sebha and Kufra.’

(5) In Annex I and Annex III to Decision (CFSP) 2015/1333, entry 25 is replaced by the following:

‘25. Name: 1: MOHAMMED 2: AL-HADI 3: AL-ARABI 4: KASHLAF

Title: na **Designation:** Commander of the Shuhada al-Nasr brigade, Head of the Petrol Refinery Guard of Zawiya’s refinery **DOB:** 15 November 1988 **POB:** Zawiya, Libya **Good quality a.k.a.:** na **Low quality a.k.a.:** a) Kahlaf b) Koshlaf c) Keslaf d) al-Qasab **Nationality:** Libya **Passport no:** HR8CHGP8; Date of issue: 27 April 2015; Place of issue: Zawiya **National identification no:** a) 119880210419 b) **Personal Identification Card no:** 728498; **Date of issue:** 24 February 2007 **Address:** Zawiya, Libya **Listed on:** 7 June 2018 **Other information:** Listed pursuant to paragraphs 15 and 17 of resolution 1970 (Travel Ban, Asset Freeze)

Listed pursuant to paragraph 22(a) of resolution 1970 (2011); paragraph 4(a) of resolution 2174 (2014); paragraph 11(a) of resolution 2213 (2015).

Additional information

Mohammed al-Hadi is the head of the Shuhada al Nasr brigade in Zawiya, Western Libya. His militia controls the Zawiya refinery, a central hub of migrant smuggling operations. Al-Hadi also controls detention centres, including the Nasr detention centre – nominally under the control of the DCIM. As documented in various sources, the network of al-Hadi is one of the most dominant in the field of migrant smuggling and the exploitation of migrants in Libya. Al-Hadi has extensive links with the head of the local unit of the coast guard of Zawiya, al-Rahman al-Milad, whose unit intercepts boats with migrants, often of rivalling migrant smuggling networks. Migrants are then brought to detention facilities under the control of the Al Nasr militia, where they are reportedly held in critical conditions. The Panel of Experts for Libya collected evidence of migrants that were frequently beaten, while others, notably women from sub-Saharan countries and Morocco, were sold on the local market as “sex slaves”. The Panel has also found that al-Hadi collaborates with other armed groups and has been involved in repeated violent clashes in 2016 and 2017.’

(6) In Annex I and Annex III to Decision (CFSP) 2015/1333, entry 26 is replaced by the following:

‘26. Name: 1: ABD 2: AL-RAHMAN 3: AL-MILAD 4: na

Title: na **Designation:** Commander of the Coast Guard in Zawiya **DOB:** Approximately (29 years old) **POB:** Tripoli, Libya **Good quality a.k.a.:** na **Low quality a.k.a.:** a) Rahman Salim Milad b) al-Bija **Nationality:** Libya **Passport no:** na **National identification no:** na **Address:** Zawiya, Libya **Listed on:** 7 June 2018 **Other information:** Listed pursuant to paragraphs 15 and 17 of resolution 1970 (Travel Ban, Asset Freeze)

Listed pursuant to paragraph 22(a) of resolution 1970 (2011); paragraph 4(a) of resolution 2174 (2014); paragraph 11(a) of resolution 2213 (2015).

Additional information

Abd al Rahman al-Milad heads the regional unit of the Coast Guard in Zawiya that is consistently linked with violence against migrants and other human smugglers. The UN Panel of Experts claims that Milad, and other coastguard members, are directly involved in the sinking of migrant boats using firearms. Al-Milad collaborates with other migrant smugglers such as Mohammed al-Hadi (also proposed for listing) who, sources suggest, is providing protection to him to carry out illicit operations related to the trafficking and smuggling of migrants. Several witnesses in criminal investigations have stated they were picked up at sea by armed men on a Coast Guard ship called Tallil (used by al-Milad) and taken to the al-Nasr detention centre, where they are reportedly held in brutal conditions and subjected to beatings.’

RULES OF PROCEDURE

AMENDMENTS TO THE RULES OF PROCEDURE OF THE GENERAL COURT

THE GENERAL COURT,

Having regard to the Treaty on the Functioning of the European Union, and in particular the fifth paragraph of Article 254 thereof,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 106a(1) thereof,

Having regard to the Protocol on the Statute of the Court of Justice of the European Union, and in particular Article 63 thereof,

Whereas implementation of the reform of the judicial architecture of the Court of Justice of the European Union resulting from Regulation (EU, Euratom) 2015/2422 of the European Parliament and of the Council of 16 December 2015 amending Protocol No 3 on the Statute of the Court of Justice of the European Union ⁽¹⁾ and from Regulation (EU, Euratom) 2016/1192 of the European Parliament and of the Council of 6 July 2016 on the transfer to the General Court of jurisdiction at first instance in disputes between the European Union and its servants ⁽²⁾ requires that the procedural rules governing the performance of the duties conferred on the Vice-President of the General Court be amended,

With the agreement of the Court of Justice,

With the approval of the Council given on 16 July 2018,

HAS ADOPTED THE FOLLOWING AMENDMENTS TO ITS RULES OF PROCEDURE:

Article 1

The Rules of Procedure of the General Court of 4 March 2015 ⁽³⁾ are hereby amended as follows:

- (1) In Article 3(3), the words ‘, the Vice-President’ are deleted.
- (2) In Article 28(2), the words ‘, the Vice-President of the General Court’ are added after ‘The Chamber seised of the case’.

Article 2

These amendments to the Rules of Procedure, authentic in the languages referred to in Article 44 of those Rules, shall be published in the *Official Journal of the European Union* and shall enter into force on the first day of the month following that of their publication.

Done at Luxembourg, 31 July 2018.

The Registrar
E. COULON

The President
M. JAEGER

⁽¹⁾ OJ L 341, 24.12.2015, p. 14.

⁽²⁾ OJ L 200, 26.7.2016, p. 137.

⁽³⁾ OJ L 105, 23.4.2015, p. 1.

AMENDMENTS TO THE RULES OF PROCEDURE OF THE GENERAL COURT

THE GENERAL COURT,

Having regard to the Treaty on the Functioning of the European Union, and in particular the fifth paragraph of Article 254 thereof,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 106a(1) thereof,

Having regard to the Protocol on the Statute of the Court of Justice of the European Union, and in particular Article 63 thereof,

Whereas the computer application 'e-Curia' has been a success and offers benefits in terms of the immediacy of paperless communication between the representatives of parties before the General Court and the General Court Registry,

Whereas it is appropriate to amend the Rules of Procedure of the General Court in order to make the use of e-Curia mandatory for the lodging of procedural documents and service effected by the General Court Registry in proceedings before the General Court,

Whereas it is appropriate to insert in the Rules of Procedure a legal basis for specifying the procedure to be followed where it is technically impossible to use e-Curia,

With the agreement of the Court of Justice,

With the approval of the Council given on 26 June 2018,

HAS ADOPTED THE FOLLOWING AMENDMENTS TO ITS RULES OF PROCEDURE:

Article 1

The Rules of Procedure of the General Court of 4 March 2015 ⁽¹⁾ are hereby amended as follows:

- (1) In Article 1(2), the full stop at the end of point (j) is replaced by a semi-colon and a point (k) is added:
'(k) 'e-Curia' means the computer application of the Court of Justice of the European Union that enables procedural documents to be lodged and served electronically.'
- (2) Article 36(2) is replaced by the following:
'2. When a procedural document has been registered, the Registrar shall make a note to that effect on the procedural document included in the file in the case and, if a party so requests, on any copy submitted for the purpose.'
- (3) In Article 42(1), the reference to 'Articles 7, 9, 11, 13, 15, 16, 18, 25, 28, 31 to 33, 41, 74 and 224' is replaced by a reference to 'Articles 7, 9, 11, 13, 15, 16, 18, 25, 28, 31 to 33, 41, 56a and 224'.
- (4) After Article 56, a new section is inserted containing a new Article 56a:

*'Section 2a***Communication with parties' representatives via e-Curia***Article 56a***e-Curia**

1. Without prejudice to the cases referred to in Article 57(2), Article 72(4), Article 80(1), Article 105(1) and (2), Article 147(6), Article 148(9) and Article 178(2) and (3), all procedural documents shall be lodged and served via e-Curia.
2. The conditions for the lodging and service of procedural documents via e-Curia shall be specified in a decision adopted by the General Court. That decision shall be published in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 105, 23.4.2015, p. 1.

3. Use of e-Curia shall require an access account to have been opened under the conditions laid down in the decision referred to in paragraph 2.

4. If a procedural document is lodged via e-Curia before the supporting documents required for validation of the access account have been produced, those supporting documents must be received in paper format at the Registry of the General Court within 10 days of the procedural document being lodged. This time limit may not be extended and Article 60 shall not apply. If the supporting documents are not received within the prescribed time limit, the Court shall declare the procedural document lodged via e-Curia to be inadmissible.

5. Where the use of e-Curia is technically impossible and without prejudice to the application of the second paragraph of Article 45 of the Statute, a procedural document may be lodged or served by any appropriate means available. The procedure to be followed in such circumstances shall be specified in the decision referred to in paragraph 2.'

(5) Article 57 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. Without prejudice to Article 80(1), Article 148(9) and Article 178(2) and (3), where the Statute or these Rules require a document to be served on a person the Registrar shall ensure that service is effected via e-Curia.;

(b) in paragraph 2, the words 'Where, for technical reasons or on account of the nature or size of the document,' are replaced by 'Where, on account of the nature of the document,' in the first sentence, and the words 'by the method referred to in paragraph 4 or by telefax' are replaced by the words 'via e-Curia' in the second and third sentences;

(c) paragraph 3 is replaced by the following:

'3. Without prejudice to Article 72(4), the Registrar shall prepare and certify the copies of documents to be served pursuant to paragraph 2.;

(d) paragraph 4 is deleted.

(6) Article 68 is amended as follows:

(a) paragraph 4 is replaced by the following:

'4. Procedural documents included in the files of the joined cases shall be served via e-Curia on the parties who request this. The President may, however, on application by a party, order that certain information from the case file which it is claimed is confidential be excluded from such service.;

b) paragraph 5 is deleted.

(7) Article 72 is amended as follows:

(a) the wording of the title 'Common rules for the lodging of procedural documents' is replaced by 'Rules for the lodging of procedural documents via e-Curia';

(b) paragraph 1 is replaced by the following:

'1. With the exception of documents lodged pursuant to Article 105(1) and (2) and Article 147(6), all procedural documents shall be lodged at the Registry via e-Curia.;

(c) the following is inserted as paragraph 4:

'4. Where, on account of its nature, an annex to a procedural document cannot be lodged via e-Curia, the relevant annex shall be sent separately by post or shall be delivered to the Registry. The annex shall be submitted together with a copy for the General Court and a copy for every other party to the proceedings. Copies shall be certified as being identical by the party lodging them.;

(d) paragraphs 4 and 5 are renumbered paragraphs 5 and 6.

(8) Article 73 is deleted.

(9) Article 74 is deleted.

(10) Article 77 is deleted.

(11) Article 80(1) is replaced by the following:

‘1. The application shall be served on the defendant via e-Curia if he has an e-Curia account. Where the defendant has no such account, the application shall be served on him in the form of a certified copy sent by registered post with a form for acknowledgement of receipt or by delivery of the copy against receipt.’

(12) In Article 81(2), the reference to Article 77 is deleted and paragraph 2 is accordingly replaced by the following:

‘2. Article 78(4) to (6) shall apply to the defence.’

(13) In Article 143(4), the reference to Article 77 is deleted and paragraph 4 is accordingly replaced by the following:

‘4. Article 78(4) to (6) and Article 139 shall apply to the application to intervene.’

(14) Article 147 is amended as follows:

(a) in paragraph 2, the sentence ‘Without prejudice to Article 74, the form must be signed by the applicant for legal aid or, if he is represented, by his lawyer.’ is deleted;

(b) paragraph 6 is replaced by the following:

‘6. Where the applicant for legal aid is not represented by a lawyer, the original of the application for legal aid shall be lodged at the Registry in paper form. The original of the application for legal aid must bear the handwritten signature of the applicant for legal aid.’

(15) Article 148(9) is replaced by the following:

‘9. Where the applicant for legal aid is not represented by a lawyer, a copy of the document to be served shall be served on him by registered post with a form for acknowledgement of receipt or by delivery of the copy against receipt. Service on other parties shall be effected as provided for in Article 80(1).’

(16) In Article 156(5), the reference to ‘Articles 76 to 78’ is replaced by a reference to ‘Articles 76 and 78’.

(17) In Article 166(2), the reference to ‘Articles 76 to 78’ is replaced by a reference to ‘Articles 76 and 78’.

18) In Article 167(1), the reference to ‘Articles 76 to 78’ is replaced by a reference to ‘Articles 76 and 78’.

(19) In Article 168(3), the reference to ‘Articles 76 to 78’ is replaced by a reference to ‘Articles 76 and 78’.

(20) In Article 169(3), the reference to ‘Articles 76 to 78’ is replaced by a reference to ‘Articles 76 and 78’.

(21) In Article 170(1), the reference to ‘Articles 76 to 78’ is replaced by a reference to ‘Articles 76 and 78’.

(22) In Article 173(5), the reference to Article 77 is deleted and paragraph 5 is accordingly replaced by the following:

‘5. Article 78(4) to (6) shall apply to the procedural document referred to in paragraph 2.’

(23) In Article 175(4), the reference to Article 77 is deleted and paragraph 4 is accordingly replaced by the following:

‘4. Article 78(4) to (6) and Article 139 shall apply to the application for replacement.’

(24) Article 177 is amended as follows:

(a) paragraph 6 is deleted;

(b) paragraph 7 is renumbered paragraph 6.

(25) Article 178 is amended as follows:

(a) paragraph 2 is replaced by the following:

‘2. The application shall be served on the defendant via e-Curia if he has an e-Curia account. Where the defendant has no such account, the application shall be served on him in the form of a certified copy sent by registered post with a form for acknowledgement of receipt or by delivery of the copy against receipt.’;

(b) paragraph 3 is replaced by the following:

‘3. The application shall be served on a party to the proceedings before the Board of Appeal via e-Curia where that party has become a party to the proceedings before the General Court in accordance with Article 173(2). If the party to the proceedings before the Board of Appeal is an institution that has an account giving access to e-Curia, service of the application shall be made by e-Curia. Otherwise, the application shall be served by registered post with a form for acknowledgement of receipt at the address given by the party concerned for the purposes of the notifications to be effected in the course of the proceedings before the Board of Appeal.’;

(c) in paragraph 4, the reference to ‘Article 177(7)’ is replaced by a reference to ‘Article 177(6)’.

(26) In Article 180(2), the reference to ‘Article 177(4) to (7)’ is replaced by a reference to ‘Article 177(4) to (6)’.

(27) Article 194 is amended as follows:

(a) paragraph 5 is deleted;

(b) paragraph 6 is renumbered paragraph 5.

(28) In Article 197(2), the reference to ‘Article 194(6)’ is replaced by a reference to ‘Article 194(5)’.

(29) In Article 199(2), the reference to ‘Article 194(3) to (6)’ is replaced by a reference to ‘Article 194(3) to (5)’.

(30) In Article 213(1), the reference to ‘Articles 51 to 58, 60 to 74, 79, 84, 87, 89, 90, 107 to 122, 124, 125, 129, 131, 142 to 162, 164, 165 and 167 to 170’ is replaced by a reference to ‘Articles 51 to 58, 60 to 72, 79, 84, 87, 89, 90, 107 to 122, 124, 125, 129, 131, 142 to 162, 164, 165 and 167 to 170’.

Article 2

These amendments to the Rules of Procedure, authentic in the languages referred to in Article 44 of these Rules, shall be published in the *Official Journal of the European Union* and shall enter into force on the first day of the third month following that of the publication in the *Official Journal of the European Union* of the decision referred to in Article 56a(2) of the Rules of Procedure.

Done at Luxembourg, 11 July 2018.

The Registrar
E. COULON

The President
M. JAEGER

DECISION OF THE GENERAL COURT
of 11 July 2018
on the lodging and service of procedural documents by means of e-Curia

THE GENERAL COURT,

Having regard to the Rules of Procedure and, in particular, Article 56a(1), (2) and (5) thereof

Whereas:

- (1) In order to take account of developments in communication technology, an information technology application has been developed to allow the lodging and service of procedural documents by electronic means.
- (2) This application, which is based on an electronic authentication system using a combination of a user identification and a password, meets the requirements of authenticity, integrity and confidentiality of documents exchanged.
- (3) Having regard to the advantages of the immediacy of paperless communication offered by this application, its use has become mandatory for the lodging and service of procedural documents in proceedings before the General Court,

HAS DECIDED AS FOLLOWS:

Article 1

The information technology application known as ‘e-Curia’, common to the constituent courts of the Court of Justice of the European Union, allows the lodging and service of procedural documents by electronic means under the conditions laid down by this Decision.

Article 2

Use of this application shall require the opening of an access account and use of a personal user identification and password.

Article 3

A procedural document shall be lodged by e-Curia where the representative’s user identification and password have been used to effect the lodging. Use of the representative’s personal user identification and password for the lodging of a procedural document shall constitute the signature of the document concerned.

Article 4

A procedural document lodged by means of e-Curia must be accompanied by the annexes referred to therein and a schedule listing such annexes.

Article 5

A procedural document shall be deemed to have been lodged for the purposes of Article 72(2) of the Rules of Procedure at the time of the representative’s validation of lodging of that document.

The relevant time shall be the time in the Grand Duchy of Luxembourg.

Article 6

Procedural documents, including judgments and orders, shall be served by e-Curia on the holders of access accounts in the cases which concern them.

The intended recipients of the documents served referred to in the preceding paragraph shall be notified by email of any document served on them by means of e-Curia.

A procedural document shall be served at the time when the intended recipient (representative or assistant) requests access to that document. In the absence of any request for access, the document shall be deemed to have been served on the expiry of the seventh day following the day on which the notification email was sent.

Where a party is represented by more than one agent or lawyer, the time to be taken into account in the reckoning of time limits shall be the time when the first request for access was made.

The relevant time shall be the time in the Grand Duchy of Luxembourg.

Article 7

Where it is technically impossible to lodge a procedural document by e-Curia, the user must notify immediately the Registry of the General Court by email (GC.Registry@curia.europa.eu) or by fax (+352 43032100), indicating:

- the type of document the user wishes to lodge,
- where appropriate, the relevant time limit for the lodging of that document,
- the nature of the technical impossibility identified, for verification by the staff of the institution if it is due to the unavailability of e-Curia.

If the representative is bound to comply with a time limit, he shall transmit a copy of the document to the Registry of the General Court by any appropriate means (lodging of a paper version or transmission by post, email or fax). That transmission must be followed by the lodging of the document by e-Curia as soon as it is again technically possible to use that application.

The General Court or the President of the General Court will if necessary give a ruling on the acceptance of a document lodged by e-Curia after the prescribed time limit, taking into consideration information provided by the party lodging that document to prove that it was technically impossible to lodge that document by e-Curia before the prescribed time limit.

Where the use of e-Curia is technically impossible and if urgency requires, the Registrar shall transmit the procedural documents by any means appropriate. That transmission must be followed by service by e-Curia as soon as it is again technically possible to use that application.

Article 8

The Registrar shall draw up the conditions of use of e-Curia and ensure that they are observed. Any use of e-Curia contrary to those conditions may result in the deactivation of the access account concerned.

The General Court shall take the necessary steps to protect e-Curia from any abuse or malicious use.

Users shall be notified by email of any action taken pursuant to this Article that prevents them from using their access account.

Article 9

This decision shall replace the decision of the General Court of 14 September 2011 on the lodging and service of procedural documents by means of e-Curia ⁽¹⁾.

Article 10

This decision shall enter into force on the first day of the third month following that of its publication in the *Official Journal of the European Union*.

Done at Luxembourg, 11 July 2018.

The Registrar
E. COULON

The President
M. JAEGER

⁽¹⁾ OJ C 289, 1.10.2011, p. 9.

