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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COUNCIL IMPLEMENTING REGULATION (EU) 2018/1115

of 10 August 2018

implementing Article 20(1) of Regulation (EU) 2015/735 concerning restrictive measures in respect of the situation in South Sudan

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EU) 2015/735 of 7 May 2015 concerning restrictive measures in respect of the situation in South Sudan, and repealing Regulation (EU) No 748/2014 ⁽¹⁾, and in particular Article 20(1) thereof,

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

Whereas:

- (1) On 7 May 2015, the Council adopted Regulation (EU) 2015/735.
- (2) On 13 July 2018, the United Nations Security Council adopted Resolution 2428 (2018) which notably adds two persons to the list of persons and entities subject to restrictive measures. These persons should therefore be added to Annex I to Regulation (EU) 2015/735. Since these two persons were already designated under Annex II to Regulation (EU) 2015/735, they should therefore be removed from Annex II to Regulation (EU) 2015/735 in order that they be designated under Annex I.
- (3) Annex I and II to Regulation (EU) 2015/735 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) 2015/735 is hereby amended as set out in Annex I to this Regulation.

Article 2

Annex II to Regulation (EU) 2015/735 is hereby amended as set out in Annex II to this Regulation.

*Article 3*This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.⁽¹⁾ OJ L 117, 8.5.2015, p. 13.

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

Done at Brussels, 10 August 2018.

For the Council

The President

G. BLÜMEL

ANNEX I

The following persons are added to the list set out in Annex I to Regulation (EU) 2015/735:

7. Malek REUBEN RIAK RENGU (alias: a) Malek Ruben)

Title: Lieutenant General

Designation: a) Deputy Chief of General Staff for Logistics; b) Deputy Chief of Defence Staff and Inspector General of the Army

Date of birth: 1 Jan. 1960

Place of birth: Yei, South Sudan

Nationality: South Sudan

Date of UN designation: 13 July 2018

Other information: As SPLA Deputy Chief of Staff for Logistics, Riak was one of the senior officials of the Government of South Sudan who planned and oversaw an offensive in Unity state in 2015 that resulted in widespread destruction and large population displacement.

Information from the narrative summary of reasons for listing provided by the Sanctions Committee:

Malek Ruben Riak was listed on 13 July 2018 pursuant to paragraphs 6, 7 (a), and 8 of resolution 2206 (2015), as reaffirmed in resolution 2418 (2018), for “actions or policies that threaten the peace, security or stability of South Sudan”; “Actions or policies that have the purpose or effect of expanding or extending the conflict in South Sudan ...,” and as a leader “of any entity, including any South Sudanese government, opposition, militia, or other group, that has, or whose members have, engaged in any of the activities described in paragraphs 6 and 7,” and pursuant to paragraph 14 (e) of this resolution for “planning, directing, or committing acts involving sexual and gender-based violence in South Sudan”.

According to the report by the Panel of Experts on South Sudan in January 2016 (S/2016/70), Riak was one of a group of senior security officials who planned a Unity state offensive against the SPLM-IO beginning in January 2015, and subsequently oversaw its execution from late April 2015 onwards. The Government of South Sudan began arming Bul Nuer youth in early 2015 to facilitate their participation in the offensive. Most Bul Nuer youth already had access to AK-pattern automatic rifles, but ammunition was critical to sustaining their operations. The Panel of Experts reported evidence, including testimony from military sources, that ammunition was supplied to youth groups by SPLA headquarters specifically for the offensive. Riak was the SPLA Deputy Chief of Staff for Logistics at the time. The offensive resulted in systematic destruction of villages and infrastructure, the forced displacement of the local population, the indiscriminate killing and torturing of civilians, the widespread use of sexual violence, including against the elderly and children, the abduction and recruitment of children as soldiers, and large population displacement. Following the destruction of much of the southern and central parts of the state, numerous media and humanitarian organisations, as well as the United Nations Mission in South Sudan (UNMISS) published reports about the scale of the abuses that were perpetrated.

8. Paul MALONG AWAN (alias: a) Paul Malong Awan Anei, b) Paul Malong, c) Bol Malong)

Title: General

Designation: a) Former Chief of Staff of the Sudan People's Liberation Army (SPLA), b) Former Governor, Northern Bahr el-Ghazal State

Date of birth: a) 1962, b) 4 Dec. 1960, c) 12 Apr. 1960

Place of birth: Malualkon, South Sudan

Nationality: a) South Sudan, b) Uganda

Passport no: a) South Sudan number S00004370, b) South Sudan number D00001369, c) Sudan number 003606, d) Sudan number 00606, e) Sudan number B002606

Date of UN designation: 13 July 2018

Other information: As Chief of General Staff of the SPLA, Malong expanded or extended the conflict in South Sudan through breaches of the Cessation of Hostilities Agreement and breaches of the 2015 Agreement on the Resolution of the Conflict in South Sudan (ARCSS). He reportedly directed efforts to kill opposition leader Riek Machar. He ordered SPLA units to prevent the transport of humanitarian supplies. Under Malong's leadership, the SPLA attacked civilians,

schools and hospitals; forced the displacement of civilians; carried out enforced disappearances; arbitrarily detained civilians; and conducted acts of torture, and rape. He mobilised the Mathiang Anyoor Dinka tribal militia, which uses child soldiers. Under his leadership, the SPLA restricted UNMISS, the Joint Monitoring and Evaluation Commission (JMEC), and CTSAMM access to sites to investigate and document abuses.

Information from the narrative summary of reasons for listing provided by the Sanctions Committee:

Paul Malong Awan was listed on 13 July 2018 pursuant to paragraphs 6, 7 (a), 7 (b), 7 (c), 7 (d), 7 (f), and 8 of resolution 2206 (2015), as reaffirmed in resolution 2418 (2018), for “actions or policies that have the purpose or effect of expanding or extending the conflict in South Sudan or obstructing reconciliation or peace talks or processes, including breaches of the Cessation of Hostilities Agreement”; “actions or policies that threaten transitional agreements or undermine the political process in South Sudan”; “the targeting of civilians, including women and children, through the commission of acts of violence (including killing, maiming, torture, or rape or other sexual violence), abduction, enforced disappearance, forced displacement, or attacks on schools, hospitals, religious sites, or locations where civilians are seeking refuge, or through conduct that would constitute a serious abuse or violation of human rights or a violation of international humanitarian law”; “planning, directing, or committing acts that violate applicable international human rights law or international humanitarian law, or acts that constitute human rights abuses, in South Sudan”; “The use or recruitment of children by armed groups or armed forces in the context of the armed conflict in South Sudan”; “the obstruction of the activities of international peacekeeping, diplomatic, or humanitarian missions in South Sudan, including IGAD’s Monitoring and Verification Mechanism or of the delivery or distribution of, or access to, humanitarian assistance”; and as a leader “of any entity, including any South Sudanese government, opposition, militia, or other group, that has, or whose members have, engaged in any of the activities described in paragraphs 6 and 7”.

Malong served as Chief of General Staff of the SPLA from April 23, 2014, to May 2017. In his former position as the Chief of General Staff, he expanded or extended the conflict in South Sudan through breaches of the Cessation of Hostilities Agreement and breaches of the 2015 Agreement on the Resolution of the Conflict in South Sudan (ARCSS). As of early August 2016, Malong reportedly directed efforts to kill South Sudanese opposition leader Riek Machar. Malong, knowingly countermanding President Salva Kiir’s orders, ordered the 10 July 2016 tank, helicopter gunship, and infantry assaults on Machar’s residence and the Sudan Peoples’ Liberation Movement in Opposition (SPLM-IO)’s “Jebel” base. Malong personally oversaw efforts from SPLA headquarters to intercept Machar. As of early August 2016, Malong wanted the SPLA to attack Machar’s suspected position immediately and informed SPLA commanders that Machar was not to be taken alive. In addition, in early 2016 information indicates that Malong ordered SPLA units to prevent the transport of humanitarian supplies across the Nile River, where tens of thousands of civilians were facing hunger, claiming that food aid would be diverted from civilians to militia groups. As a result of Malong’s orders, food supplies were blocked from crossing the Nile for at least two weeks.

Throughout his tenure as Chief of General Staff of the SPLA, Malong has been responsible for the SPLA and its allied forces’ perpetration of serious abuses including attacks on civilians, forced displacement, enforced disappearances, arbitrary detentions, torture, and rape. Under Malong’s leadership, the SPLA launched attacks directed against the civilian population and intentionally killed unarmed and fleeing civilians. In the Yei area alone, the UN documented 114 killings of civilians by the SPLA and its allied forces between July 2016 and January 2017. The SPLA intentionally attacked schools and hospitals. In April 2017, Malong allegedly ordered the SPLA to clear all people, including civilians from the area around Wau. Malong reportedly did not discourage the killing of civilians by the SPLA troops, and persons suspected of hiding rebels were considered legitimate targets.

According to a 15 October 2014 African Union Commission of Inquiry on South Sudan report, Malong was responsible for the mass mobilisation of Mathiang Anyoor Dinka tribal militia, which Ceasefire and Transitional Security Arrangements Monitoring Mechanism (CTSAMM) documented use child soldiers.

Under Malong’s leadership of the SPLA, the government forces regularly restricted United Nations Mission in South Sudan (UNMISS), Joint Monitoring and Evaluation Commission (JMEC), and CTSAMM’s access when they tried to investigate and document abuses. For example, on April 5, 2017, a joint UN and CTSAMM patrol tried to access Pajok but was turned back by SPLA soldiers.’

ANNEX II

The entries for the persons mentioned below are deleted in Annex II to Regulation (EU) 2015/735:

- 1. Paul Malong;
 - 3. Malek Reuben Riak.
-

COUNCIL REGULATION (EU) 2018/1116**of 10 August 2018****amending Regulation (EU) 2015/735 concerning restrictive measures in respect of the situation in South Sudan**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 215 thereof,

Having regard to Council Decision (CFSP) 2015/740 of 7 May 2015 concerning restrictive measures in view of the situation in South Sudan and repealing Decision 2014/449/CFSP ⁽¹⁾,

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

Whereas:

- (1) Council Regulation (EU) 2015/735 ⁽²⁾ gives effect to measures provided for in Decision (CFSP) 2015/740.
- (2) On 13 July 2018, the United Nations Security Council (UNSC) adopted Resolution 2428 (2018), in which it expressed deep concern at the failures of South Sudan's leaders to bring an end to the country's hostilities, condemned the continued and flagrant violations of the Agreement on the Resolution of the Conflict in the Republic of South Sudan of 17 August 2015, the Agreement on Cessation of Hostilities, Protection of Civilians and Humanitarian Access of 21 December 2017, and the Khartoum Declaration of 27 June 2018, and reinforced the restrictive measures towards South Sudan imposed by UNSC Resolution 2206 (2015).
- (3) Amongst others, the UNSC amends the exemptions to the arms embargo and related technical and financial assistance and amends the designation criteria for the persons and entities subject to the asset freeze.
- (4) Council Decision (CFSP) 2018/1125 ⁽³⁾ amended Decision (CFSP) 2015/740 in order to give effect to the measures imposed by UNSC Resolution 2428 (2018).
- (5) These measures fall within the scope of the Treaty and, therefore, notably with a view to ensuring their uniform application in all Member States, regulatory action at the level of the Union is necessary.
- (6) Regulation (EU) 2015/735 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) 2015/735 is amended as follows:

- (1) Article 2 is replaced by the following:

'Article 2

It shall be prohibited to provide:

- (1) technical assistance, brokering services or other services related to military activities or to the provision, manufacture, maintenance and use of arms and related materiel of all types, including weapons and ammunition, military vehicles and equipment, paramilitary equipment, and spare parts therefor, directly or indirectly to any natural or legal person, entity or body in, or for use in South Sudan;
- (2) financing or financial assistance related to military activities, including in particular grants, loans and export credit insurance, as well as insurance and reinsurance, for any sale, supply, transfer or export of arms and related materiel, or for the provision of related technical assistance, brokering services or other services directly or indirectly to any natural or legal person, entity or body in, or for use in South Sudan;

⁽¹⁾ OJ L 117, 8.5.2015, p. 52.

⁽²⁾ Council Regulation (EU) 2015/735 of 7 May 2015 concerning restrictive measures in respect of the situation in South Sudan, and repealing Regulation (EU) No 748/2014 (OJ L 117, 8.5.2015, p. 13).

⁽³⁾ Council Decision (CFSP) 2018/1125 of 10 August 2018 amending Decision (CFSP) 2015/740 concerning restrictive measures in view of the situation in South Sudan (see page 48 of this Official Journal).

(3) technical assistance, financing or financial assistance or brokering services related to the provision of armed mercenary personnel in South Sudan or for use in South Sudan.’;

(2) Article 3 is replaced by the following:

‘Article 3

The prohibitions referred to in Article 2 shall not apply to the provision of financing and financial assistance, technical assistance and brokering services related to:

- (a) arms and related materiel, intended solely for the support of or use by UN personnel, including the United Nations Mission in the Republic of South Sudan (UNMISS) and the United Nations Interim Security Force for Abyei (UNISFA);
- (b) protective clothing, including flak jackets and military helmets, temporarily exported to South Sudan by UN personnel, representatives of the media and humanitarian and development workers and associated personnel, for their personal use only.’;

(3) Article 4 is replaced by the following:

‘Article 4

1. By way of derogation from Article 2, the competent authorities may authorise the provision of financing and financial assistance, technical assistance and brokering services related to:

- (a) non-lethal military equipment intended solely for humanitarian or protective use, provided that the Member State has notified the Sanctions Committee in advance in accordance with the requirements laid down in paragraph 6 of UNSCR 2428 (2018);
- (b) arms and related materiel temporarily exported to South Sudan by the forces of a State which is taking action, in accordance with international law, solely and directly to facilitate the protection or evacuation of its nationals and those for whom it has consular responsibility in South Sudan, provided that the Member State notifies the Sanctions Committee in accordance with the requirements laid down in paragraph 6 of UNSCR 2428 (2018);
- (c) arms and related materiel, to or in support of the African Union Regional Task Force intended solely for regional operations to counter the Lord’s Resistance Army, provided that the Member State had notified the Sanctions Committee in advance in accordance with the requirements laid down in paragraph 6 of UNSCR 2428 (2018);
- (d) arms and related materiel solely in support of the implementation of the terms of the peace agreement, provided that the Member State has obtained the advance approval of the Sanctions Committee in accordance with the requirements laid down in paragraph 6 of UNSCR 2428 (2018);
- (e) other sales or supply of arms and related materiel, or provision of assistance or personnel, provided that the Member State has obtained the advance approval of the Sanctions Committee in accordance with the requirements laid down in paragraph 6 of UNSCR 2428 (2018).

2. The Member State concerned shall notify the other Member States and the Commission of any authorisation granted pursuant to paragraph 1.’;

(4) in Article 5, paragraph 1 is replaced by the following:

‘1. All funds and economic resources belonging to, owned, held or controlled by any natural or legal person, entity or body as listed in Annex I shall be frozen. Annex I shall include natural or legal persons, entities and bodies identified by the Committee of the UN Security Council established pursuant to paragraph 16 of UNSCR 2206 (2015) (‘Sanctions Committee’) as responsible for or complicit in, or having engaged in, directly or indirectly, actions or policies that threaten the peace, security or stability of South Sudan, in accordance with paragraphs 6, 7, 8 and 12 of UNSCR 2206 (2015) and paragraph 14 of UNSCR 2428 (2018).’.

Article 2

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

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

Done at Brussels, 10 August 2018.

For the Council

The President

G. BLÜMEL

COUNCIL IMPLEMENTING REGULATION (EU) 2018/1117
of 10 August 2018
implementing Regulation (EU) No 401/2013 concerning restrictive measures in respect of
Myanmar/Burma

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the Council Regulation (EU) No 401/2013 concerning restrictive measures in respect of Myanmar/Burma and repealing Regulation (EC) No 194/2008 ⁽¹⁾, and in particular Article 4i thereof,

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

Whereas:

- (1) On 2 May 2013, the Council adopted Regulation (EU) No 401/2013.
- (2) On 25 June 2018, the Council adopted Implementing Regulation (EU) 2018/898 ⁽²⁾, which added seven persons to the list of natural and legal persons, entities and bodies subject to restrictive measures in Annex IV to Regulation (EU) No 401/2013.
- (3) Updated information has been received for several listings.
- (4) Annex IV to Regulation (EU) No 401/2013 should be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex IV to Regulation (EU) No 401/2013 is amended as set out in the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 10 August 2018.

For the Council
The President
G. BLÜMEL

⁽¹⁾ OJ L 121, 3.5.2013, p. 1.

⁽²⁾ Council Implementing Regulation (EU) 2018/898 of 25 June 2018 implementing Regulation (EU) No 401/2013 concerning restrictive measures in respect of Myanmar/Burma (OJ L 160 I, 25.6. 2018, p. 1).

ANNEX

Entries 1, 3, 4 and 5 in the list of persons and entities set out in Annex IV to Regulation (EU) No 401/2013 are replaced by the following entries:

	Name	Identifying information	Reasons	Date of listing
1.	Aung Kyaw Zaw	Date of birth: 20 August 1961 Passport No: DM000826 Date of issue: 22 November 2011 Date of expiry: 21 November 2021 Military identification number: BC 17444	Lieutenant General Aung Kyaw Zaw was the Commander of the Bureau of Special Operations No. 3 of the Myanmar Armed Forces (Tatmadaw) from August 2015 to the end of 2017. The Bureau of Special Operations No. 3 oversaw the Western Command and, in that context, Lieutenant General Aung Kyaw Zaw is responsible for the atrocities and serious human rights violations committed against the Rohingya population in Rakhine State by the Western Command during that period. These include unlawful killings, sexual violence and the systematic burning of Rohingya houses and buildings.	25.6.2018
3.	Than Oo	Date of birth: 12 October 1973 Military identification number: BC 25723	Brigadier General Than Oo is the Commander of the 99th Light Infantry Division of the Myanmar Armed Forces (Tatmadaw). In that context, he is responsible for the atrocities and serious human rights violations committed against the Rohingya population in Rakhine State in the second half of 2017 by the 99th Light Infantry Division. These include unlawful killings, sexual violence and the systematic burning of Rohingya houses and buildings.	25.6.2018
4.	Aung Aung	Military identification number: BC 23750	Brigadier General Aung Aung is the Commander of the 33rd Light Infantry Division of the Myanmar Armed Forces (Tatmadaw). In that context, he is responsible for the atrocities and serious human rights violations committed against the Rohingya population in Rakhine State in the second half of 2017 by the 33rd Light Infantry Division. These include unlawful killings, sexual violence and the systematic burning of Rohingya houses and buildings.	25.6.2018
5.	Khin Maung Soe		Brigadier General Khin Maung Soe is the Commander of the Military Operation Command 15, also sometimes known as the 15th Light Infantry Division, of the Myanmar Armed Forces (Tatmadaw), under which Infantry Battalion No. 564 falls. In that context, he is responsible for the atrocities and serious human rights violations committed against the Rohingya population in Rakhine State in the second half of 2017 by the Military Operation Command 15, in particular by Infantry Battalion No. 564. These include unlawful killings, sexual violence and the systematic burning of Rohingya houses and buildings.	25.6.2018'

COMMISSION DELEGATED REGULATION (EU) 2018/1118**of 7 June 2018****amending Delegated Regulation (EU) 2015/2446 as regards the conditions for a reduction of the level of the comprehensive guarantee and the guarantee waiver**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code ⁽¹⁾, and in particular Article 99 (c) thereof,

Whereas:

- (1) Article 95(1) of the Regulation (EU) No 952/2013 lays down the conditions that must be satisfied by an economic operator to be authorised to provide a comprehensive guarantee to secure the payment of the customs debt and of other charges. Article 95(2) of the Regulation (EU) No 952/2013 lays down further criteria, which the economic operators must fulfil in order to be authorised to provide such a comprehensive guarantee with a reduced amount or to have a guarantee waiver in relation to customs debts and other charges which may be incurred. One of those criteria is the criterion of financial solvency ⁽²⁾. This criterion is deemed to be proven where the applicant has good financial standing, which enables him to fulfil his commitments with due regard to the characteristics of the type of business activity concerned.
- (2) In the context of an application for the reduction of the comprehensive guarantee or for a guarantee waiver, customs administrations need to assess if the applicant has the capacity of paying the amount of the customs debt and of other charges should this become necessary.
- (3) Article 84 of Commission Delegated Regulation (EU) 2015/2446 ⁽³⁾ lays down the conditions to be fulfilled by an economic operator in order to be authorised to use a comprehensive guarantee with a reduced amount or a guarantee waiver. In addition to the other conditions established on the basis of the criterion on financial solvency, it requires the applicant to demonstrate that he has sufficient financial resources to meet his obligations in relation to the amount of the customs debt and of other charges which may be incurred and which are not covered by the guarantee. However, practical experience from the implementation of Regulation (EU) No 952/2013 and of Delegated Regulation (EU) 2015/2446 shows that this condition is too restrictive as it is interpreted as limited to having the necessary liquidity available. Liquidity does not always represent the sole capacity of an economic operator to pay the amount of customs debt or other charges which is not covered by the guarantee. Other elements such as assets easily convertible could also be taken into account. Therefore it is necessary to take the liquidity element out as a stand-alone condition and provide for clarification so that the assessment of the capacity of the operator to meet his obligations to pay the amount of the customs debt and of other charges not covered by the guarantee is integrated in the assessment of the financial standing of the applicant.
- (4) At the same time and in order to ensure uniform application of these rules, it is necessary to clarify that the assessment of the condition on 'sufficient financial standing' in relation to the capacity of the economic operator to pay the amount of the customs debt and of other charges that may be incurred and that are not covered by the guarantee is specific to the evaluation of the applications for a comprehensive guarantee with a reduced amount or a guarantee waiver (simplification). This is necessary to define the limits of this assessment in the framework of the comprehensive guarantees with all levels of reduction.
- (5) In situations where the reference amount established in accordance with Article 155 of the Commission Implementing Regulation (EU) 2015/2447 ⁽⁴⁾ would be disproportionate in relation to the amounts of the potential customs debts which are likely to be incurred, it is necessary to foresee the possibility for the customs authorities to take into account the risk of incurrence of the customs debt, at their discretion, in order to decide on the level of reduction.

⁽¹⁾ OJ L 269, 10.10.2013, p. 1.

⁽²⁾ Article 39(c) of Regulation (EU) No 952/2013.

⁽³⁾ Commission Delegated Regulation (EU) 2015/2446 of 28 July 2015 supplementing Regulation (EU) No 952/2013 of the European Parliament and of the Council as regards detailed rules concerning certain provisions of the Union Customs Code (OJ L 343, 29.12.2015, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015 laying down detailed rules for implementing certain provisions of Regulation (EU) No 952/2013 of the European Parliament and of the Council laying down the Union Customs Code (OJ L 343, 29.12.2015, p. 558).

- (6) It is necessary to clarify as well that AEOs should not be subject to duplication of assessment procedures in accordance with Article 38(5) of Regulation (EU) No 952/2013 while it remains possible for customs authorities, before granting specific simplifications AEOs may wish to benefit from, to check compliance with the specific requirements for that simplification,

HAS ADOPTED THIS REGULATION:

Article 1

Article 84 of Delegated Regulation (EU) 2015/2446 is amended as follows:

- (1) in paragraph 1, point (f) is deleted;
- (2) in paragraph 2, point (g) is deleted;
- (3) in paragraph 3, point (l) is deleted;
- (4) the following paragraphs 3a and 3b are inserted:

‘3a. When verifying if the applicant has sufficient financial standing for the purpose of granting of an authorisation to use a comprehensive guarantee with a reduced amount or a guarantee waiver as required by paragraphs 1(e), 2(f) and 3(k), the customs authorities shall take into account the ability of the applicant to fulfil his obligations of paying his customs debts and other charges which may be incurred, not covered by that guarantee.

If justified, the customs authorities may take into account the risk of incurrence of those customs debts and of other charges having regard to the type and volume of the customs related business activities of the applicant and to the type of goods for which the guarantee is required.

3b. When the condition on sufficient financial standing has already been assessed as a modality for the application of the criterion referred to in Article 39(c) of the Code, the customs authorities shall verify only if the financial standing of the applicant justifies the granting of an authorisation to use a comprehensive guarantee with a reduced amount or a guarantee waiver.’;

- (5) paragraph 4 is replaced by the following paragraph:

‘4. Where the applicant has been established for less than three years, the fulfilment of the conditions laid down in points (d) and (e) of paragraph 1, in points (e) and (f) of paragraph 2 and in points (j) and (k) of paragraph 3 shall be checked on the basis of available records and information.’.

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, 7 June 2018.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION REGULATION (EU) 2018/1119
of 31 July 2018
amending Regulation (EU) No 1178/2011 as regards declared training organisations

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC ⁽¹⁾, and in particular Article 7(6) thereof,

Whereas:

- (1) In accordance with the requirements laid down in Annex VII (Part-ORA) to Commission Regulation (EU) No 1178/2011 ⁽²⁾, pilot training organisations need to set up and maintain a management system, including compliance monitoring, and a safety management system. The overall organisation, its processes, procedures and activities need to be set out in detailed documentation (manuals).
- (2) Annex VII (Part-ORA) constitutes an appropriate legal framework for certifying organisations providing training for the purpose of obtaining commercial pilot licences. However, the requirements laid down therein are unnecessarily burdensome and not proportionate for organisations which only provide training for the purpose of obtaining non-commercial pilot licences and specific ratings, privileges and certificates, taking account of the costs incurred, the nature and scale of their activities and the risks and benefits for aviation safety. As noted in the European Aviation Safety Agency's General Aviation Road Map ⁽³⁾, a simpler system should therefore be developed for those organisations.
- (3) For those reasons, those organisations should be made subject to a set of specific requirements and not be subject to a requirement of prior approval by the competent authority. Instead, they should be allowed to declare to the competent authority that they comply with those requirements applicable to them.
- (4) The specific requirements for such declared training organisations (DTOs) should include simplified safety procedures so as to take account of both the lower risk environment in which non-commercial pilots operate and the need for competent authorities to exercise appropriate oversight. In the interest of safety, rules on the submission of training programmes to the competent authority together with the declaration, record keeping, compliance monitoring through an annual internal review, and the appointment of DTO representatives in charge of safety policy, should also be provided for.
- (5) For the same reasons, the rules on the oversight and enforcement in respect of DTOs by the competent authorities, laid down in Annex VI (Part-ARA) to Regulation (EU) No 1178/2011, should be amended as well, so as to ensure that they are proportionate, sufficiently flexible, founded on a risk-based approach and consistent with the specific requirements for DTOs.
- (6) It is appropriate to also amend certain other provisions of Regulation (EU) No 1178/2011 on pilot training organisations, in particular to provide clarification, delete transitional provisions which are no longer relevant and amend Annex I (Part-FCL) to that Regulation so that it refers to both approved and declared training organisations.
- (7) Additional time should be provided for the implementation of the measures on upset prevention and recovery training.
- (8) In accordance with Article 19(1) of Regulation (EC) No 216/2008, the European Aviation Safety Agency submitted draft implementing rules to the Commission in Opinion No 11/2016.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 65 of Regulation (EC) No 216/2008,

⁽¹⁾ OJ L 79, 19.3.2008, p. 1.

⁽²⁾ Commission Regulation (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 311, 25.11.2011, p. 1).

⁽³⁾ <http://www.easa.europa.eu/easa-and-you/general-aviation>

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) No 1178/2011 is amended as follows:

(1) in Article 2, the following definitions are added:

- ‘(14) “acceptable means of compliance (AMC)” means non-binding standards adopted by the Agency to illustrate means to establish compliance with Regulation (EC) No 216/2008 and its implementing rules;
- (15) “alternative means of compliance (AltMoC)” means those means that propose an alternative to an existing AMC or those that propose new means to establish compliance with Regulation (EC) No 216/2008 and its implementing rules for which no associated AMC have been adopted by the Agency;
- (16) “approved training organisation (ATO)” means an organisation which is entitled to provide training to pilots on the basis of an approval issued in accordance with the first subparagraph of Article 10a(1);
- (17) “basic instrument training device (BITD)” means a ground-based training device for the training of pilots representing the student pilot’s station of a class of aeroplanes, which may use screen-based instrument panels and spring-loaded flight controls, and providing a training platform for at least the procedural aspects of instrument flight;
- (18) “certification specifications (CS)” mean technical standards adopted by the Agency indicating means to be used by an organisation for the purpose of certification;
- (19) “flight instructor (FI)” means an instructor with the privileges to provide training, in accordance with Subpart J of Annex I (Part-FCL), in an aircraft;
- (20) “flight simulation training device (FSTD)” means a device for the training of pilots which is:
 - (a) in the case of aeroplanes, a full flight simulator (FFS), a flight training device (FTD), a flight and navigation procedures trainer (FNPT) or a basic instrument training device (BITD);
 - (b) in the case of helicopters, a full flight simulator (FFS), a flight training device (FTD) or a flight and navigation procedures trainer (FNPT);
- (21) “FSTD qualification” means the level of technical ability of an FSTD as specified in the certification specifications relating to the FSTD in question;
- (22) “principal place of business” of an organisation means the head office or registered office of the organisation within which the principal financial functions and operational control of the activities referred to in this Regulation are exercised;
- (23) “qualification test guide (QTG)” means a document established to demonstrate that the performance and handling qualities of an FSTD represent those of the aircraft, class of aeroplane or type of helicopter, simulated within prescribed limits and that all applicable requirements have been met. The QTG includes both the data of the aircraft, class of aeroplane or type of helicopter and FSTD data used to support the validation;
- (24) “declared training organisation (DTO)” means an organisation which is entitled to provide training to pilots on the basis of a declaration made in accordance with the second subparagraph of Article 10a(1);
- (25) “DTO training programme” means a document established by a DTO, describing in detail the training course provided by that DTO.’;

(2) Article 10a is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. Organisations shall, in accordance with Article 7(3) of Regulation (EC) No 216/2008, be entitled to provide training to pilots involved in the operation of aircraft referred to in Article 4(1)(b) and (c) of Regulation (EC) No 216/2008 only where those organisations have been issued by the competent authority with an approval confirming that they comply with the essential requirements set out in Annex III to Regulation (EC) No 216/2008 and with the requirements of Annex VII to this Regulation.

However, by derogation from Article 7(3) of Regulation (EC) No 216/2008 and the first subparagraph of this paragraph, organisations shall be entitled to provide the training referred to in point DTO.GEN.110 of Annex VIII to this Regulation without such approval where they have made a declaration to the competent authority in accordance with the requirements laid down in point DTO.GEN.115 of that Annex and, where so required pursuant to point DTO.GEN.230(c) of that Annex, the competent authority has approved the training programme.’;

(b) paragraph 3 is replaced by the following:

‘3. JAR-compliant training organisations shall be allowed to provide training for a Part-FCL private pilot licence (PPL), for the associated ratings included in the registration and for a light aircraft pilot licence (LAPL) until 8 April 2019 without complying with the provisions of Annex VII and Annex VIII, provided that they were registered before 8 April 2015.’;

(3) Article 12 is amended as follows:

(a) paragraph 2a is replaced by the following:

‘2a. By way of derogation from paragraph 1, Member States may decide not to apply until 8 April 2020:

(1) the provisions of Annex I related to pilot licenses for sailplanes and balloons;

(2) the provisions of Annexes VII and VIII to a training organisation providing training only for a national licence that is eligible in accordance with Article 4(3) of Regulation (EU) No 1178/2011, for conversion into a Part-FCL light aircraft pilot licence (LAPL) for sailplanes or balloons, a Part-FCL sailplane pilot licence (SPL) or a Part-FCL balloon pilot licence (BPL);

(3) the provisions of Subpart B of Annex I.’;

(b) a new paragraph 8 is added as follows:

‘8. By way of derogation from paragraph 1, point FCL.315.A, the second sentence of paragraph (a) of point FCL.410.A and paragraph (c) of point FCL.725.A of Annex I (Part-FCL) shall apply from 8 April 2019.’;

(4) Annex I is amended in accordance with Annex I to this Regulation;

(5) Annex VI is amended in accordance with Annex II to this Regulation;

(6) Annex VII is amended in accordance with Annex III to this Regulation;

(7) Annex VIII is added as set out in Annex IV to this Regulation.

Article 2

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

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

Done at Brussels, 31 July 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Annex I to Regulation (EU) No 1178/2011 (Part-FCL) is amended as follows:

- (1) in point FCL.010, the definition of 'Basic Instrument Training Device' is deleted.
- (2) point FCL.025 is amended as follows:
 - (a) in point (a), point (2) and (3) are replaced by the following:

'(2) Applicants shall only take the theoretical knowledge examination when recommended by the declared training organisation (DTO) or the approved training organisation (ATO) responsible for their training, once they have completed the appropriate elements of the training course of theoretical knowledge instruction to a satisfactory standard.

(3) The recommendation by a DTO or an ATO shall be valid for 12 months. If the applicant has failed to attempt at least one theoretical knowledge examination paper within this period of validity, the need for further training shall be determined by the DTO or the ATO, based on the needs of the applicant.'
 - (b) point (b) is amended as follows:
 - (i) in the first paragraph, point (3) is replaced by the following:

'(3) If an applicant has failed to pass one of the theoretical knowledge examination papers within four attempts, or has failed to pass all papers within either six sittings or the period mentioned in point (2), the applicant shall retake the complete set of examination papers.

Before retaking the theoretical knowledge examinations, the applicant shall undertake further training at a DTO or an ATO. The extent and scope of the training needed shall be determined by the DTO or the ATO, based on the needs of the applicant.'
 - (ii) the second paragraph is deleted;
- (3) point FCL.115 is replaced by the following:

'FCL.115 LAPL — Training course

- (a) Applicants for an LAPL shall complete a training course at a DTO or an ATO.
 - (b) The course shall include theoretical knowledge and flight instruction appropriate to the privileges of the LAPL applied for.
 - (c) Theoretical knowledge instruction and flight instruction may be completed at a DTO or at an ATO different from the one where applicants have commenced their training.'
- (4) in point FCL.110.A, points (b) and (c) are replaced by the following:
- '(b) Specific requirements for applicants holding an LAPL(S) or an SPL with TMG extension. Applicants for an LAPL(A) holding an LAPL(S) or an SPL with TMG extension shall have completed at least 21 hours of flight time on TMGs after the endorsement of the TMG extension and complied with the requirements of point FCL.135.A(a) on aeroplanes.
- (c) Crediting. Applicants with prior experience as PIC may be credited towards the requirements of point (a).
- The amount of credit shall be decided by the DTO or the ATO where the pilot undergoes the training course, on the basis of a pre-entry flight test, but shall in any case:
- (1) not exceed the total flight time as PIC;
 - (2) not exceed 50 % of the hours required in point (a);
 - (3) not include the requirements of point (a)(2).'
- (5) in point FCL.110.H, point (b) is replaced by the following:
- '(b) Crediting. Applicants with prior experience as PIC may be credited towards the requirements of point (a).
- The amount of credit shall be decided by the DTO or the ATO where the pilot undergoes the training course, on the basis of a pre-entry flight test, but shall in any case:
- (1) not exceed the total flight time as PIC;
 - (2) not exceed 50 % of the hours required in point (a);
 - (3) not include the requirements of point (a)(2).'

(6) in point FCL.110.S, point (c) is replaced by following:

‘(c) Crediting. Applicants with prior experience as PIC may be credited towards the requirements of point (a).

The amount of credit shall be decided by the DTO or the ATO where the pilot undergoes the training course, on the basis of a pre-entry flight test, but shall in any case:

- (1) not exceed the total flight time as PIC;
- (2) not exceed 50 % of the hours required in point (a);
- (3) not include the requirements of points (2), (3) and (4) of point (a).’;

(7) in point FCL.135.S, the introductory phrase is replaced by following:

‘The privileges of an LAPL(S) shall be extended to a TMG when the pilot has completed, at a DTO or at an ATO, at least:’;

(8) in point FCL.110.B, point (b) is replaced by the following:

‘(b) Crediting. Applicants with prior experience as PIC on balloons may be credited towards the requirements of point (a).

The amount of credit shall be decided by the DTO or the ATO where the pilot undergoes the training course, on the basis of a pre-entry flight test, but shall in any case:

- (1) not exceed the total flight time as PIC on balloons;
- (2) not exceed 50 % of the hours required in point (a);
- (3) not include the requirements of points (2) and (3) of point (a).’;

(9) in point FCL.135.B, the introductory phrase is replaced by following:

‘The privileges of the LAPL(B) shall be limited to the class of balloons in which the skill test was taken. This limitation may be removed when the pilot has completed in the other class, at a DTO or at an ATO, at least:’;

(10) point FCL.210 is replaced by the following:

‘FCL.210 Training course

(a) Applicants for a BPL, SPL or PPL shall complete a training course at a DTO or at an ATO.

(b) The course shall include theoretical knowledge and flight instruction appropriate to the privileges of the BPL, SPL or PPL applied for.

(c) Theoretical knowledge instruction and flight instruction may be completed at a DTO or at an ATO different from the one where applicants have commenced their training.’;

(11) in point FCL.210.A, points (b) and (c) are replaced by the following:

‘(b) Specific requirements for applicants holding an LAPL(A). Applicants for a PPL(A) holding an LAPL(A) shall have completed at least 15 hours of flight time on aeroplanes after the issue of the LAPL(A), of which at least 10 shall be flight instruction completed in a training course at a DTO or at an ATO. That training course shall include at least four hours of supervised solo flight time, including at least two hours of solo cross-country flight time with at least one cross-country flight of at least 270 km (150 NM), during which full stop landings at two aerodromes different from the aerodrome of departure shall be made.

(c) Specific requirements for applicants holding an LAPL(S) or an SPL with a TMG extension. Applicants for a PPL(A) holding an LAPL(S) or an SPL with a TMG extension shall have completed:

- (1) at least 24 hours of flight time on TMG after the endorsement of the TMG extension; and
- (2) at least 15 hours of flight instruction in aeroplanes in a training course at a DTO or at an ATO, including at least the requirements of point (a)(2).’;

(12) in point FCL.210.H, point (b) is replaced by the following:

‘(b) Specific requirements for an applicant holding an LAPL(H). Applicants for a PPL(H) holding an LAPL(H) shall complete a training course at a DTO or at an ATO. That training course shall include at least five hours of dual flight instruction time and at least one supervised solo cross-country flight of at least 185 km (100 NM), with full stop landings at two aerodromes different from the aerodrome of departure.’;

(13) in point FCL.725, point (a) is replaced by the following:

‘(a) Training course. An applicant for a class or type rating shall complete a training course at an ATO. An applicant for a non-high-performance single-engine piston class rating, a TMG class rating or a single-engine type rating for helicopters referred to in point DTO.GEN.110(a)(2)(c) of Annex VIII (Part-DTO) may complete the training course at a DTO. The type rating training course shall include the mandatory training elements for the relevant type as defined in the operational suitability data established in accordance with Annex I (Part-21) to Commission Regulation (EU) No 748/2012.’;

(14) in point FCL.740, point (b) is replaced by the following:

‘(b) Renewal. If a class or type rating has expired, the applicant shall take the following steps:

(1) pass a proficiency check in accordance with Appendix 9 to this Annex;

(2) prior to the proficiency check referred to in point (1), take refresher training at an ATO, where necessary to reach the level of proficiency to safely operate the relevant class or type of aircraft. However, the applicant may take the training:

(i) at a DTO or at an ATO, where the expired rating was a non-high-performance single-engine piston class rating, a TMG class rating or a single-engine type rating for helicopters referred to in point DTO.GEN.110(a)(2)(c) of Annex VIII (Part-DTO);

(ii) at a DTO, at an ATO or with an instructor, where the rating expired for no more than three years and the rating was a non-high-performance single-engine piston class rating or a TMG class rating.’;

(15) in point FCL.800(b)(2), the introductory phrase is replaced by the following:

‘(2) a training course at a DTO or at an ATO, including.’;

(16) point FCL.805 is amended as follows:

(a) in point (b)(2), the introductory phrase is replaced by the following:

‘(2) a training course at a DTO or at an ATO, including.’;

(b) in point (c)(2), the introductory phrase is replaced by the following:

‘(2) a training course at a DTO or at an ATO, including.’;

(17) point FCL.810 is amended as follows:

(a) in point (a)(1), the introductory phrase is replaced by the following:

‘(1) If the privileges of an LAPL, an SPL or a PPL for aeroplanes, TMGs or airships are to be exercised in VFR conditions at night, applicants shall have completed a training course at a DTO or at an ATO. The course shall comprise.’;

(b) in point (b)(2), the introductory phrase is replaced by the following:

‘(2) completed a training course at a DTO or at an ATO. The course shall be completed within a period of six months and comprise.’;

(18) in point FCL.815, point (b) is replaced by the following:

‘(b) Training course. Applicants for a mountain rating shall have completed, within a period of 24 months, a course of theoretical knowledge instruction and flight training at a DTO or at an ATO. The content of the course shall be appropriate to the privileges of the mountain rating applied for.’;

(19) in point FCL.830(b)(2), the introductory phrase is replaced by the following:

‘(2) a training course at a DTO or at an ATO, including.’;

(20) point FCL.930 is replaced by the following:

FCL.930 Training course

- (a) An applicant for an instructor certificate shall have completed a course of theoretical knowledge and flight instruction at an ATO. An applicant for an instructor certificate for sailplanes or balloons may have completed a course of theoretical knowledge and flight instruction at a DTO.
- (b) In addition to the specific elements set out in this Annex (Part-FCL) for each category of instructor, the training course shall contain the elements required in point FCL.920.;

(21) in point FCL.910.FI(a), the introductory phrase is replaced by the following:

- ‘(a) An FI shall have his or her privileges limited to conducting flight instruction under the supervision of an FI for the same category of aircraft nominated by the DTO or the ATO for this purpose, in the following cases:’;

(22) in point FCL.1015, point (a) is replaced by the following:

- ‘(a) An applicant for an examiner certificate shall undertake a standardisation course which is provided by the competent authority or which is provided by an ATO and approved by the competent authority. An applicant for an examiner certificate for sailplanes or balloons may undertake a standardisation course which is provided by a DTO and approved by the competent authority.’;

(23) in point FCL.1025(b), point (2) is replaced by the following:

- ‘(2) attended, during the last year of the validity period, an examiner refresher course which is provided by the competent authority or which is provided by an ATO and approved by the competent authority. An examiner holding a certificate for sailplanes or balloons may have attended, during the last year of the validity period, an examiner refresher course which is provided by a DTO and approved by the competent authority.’
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ANNEX II

Annex VI to Regulation (EU) No 1178/2011 (Part-ARA) is amended as follows:

(1) point ARA.GEN.105 is deleted;

(2) in point ARA.GEN.200, point (c) is replaced by the following:

‘(c) The competent authority shall establish procedures for participation in a mutual exchange of all necessary information and assistance with other competent authorities concerned, including information on all findings raised, corrective follow-up actions taken pursuant to such findings and enforcement measures taken as a result of oversight of persons and organisations exercising activities in the territory of a Member State but certified by or having made declarations to the competent authority of another Member State or the Agency.’;

(3) point ARA.GEN.220 is amended as follows:

(a) in point (a), point (4) is replaced by the following:

‘(4) certification and declaration processes as well as oversight of certified and declared organisations.’;

(b) point (b) is replaced by the following:

‘(b) The competent authority shall establish and keep up-to-date a list of all organisation certificates, FSTD qualification certificates and personnel licences, certificates and attestations it issued, DTO declarations it received and the DTO training programmes it verified or approved for compliance with Annex I (Part-FCL).’;

(4) in point ARA.GEN.300(a), point (2) is replaced by following:

‘(2) continued compliance with the requirements applicable to the persons holding licences, ratings and certificates, the organisations it has certified, the holders of a FSTD qualification and the organisations from which it received a declaration.’;

(5) in point ARA.GEN.305, the following point (f) is added:

‘(f) Notwithstanding points (b), (c), and (ca), the oversight programme of DTOs shall be developed taking into account the specific nature of the organisation, the complexity of its activities and the results of past oversight activities and shall be based on the assessment of risks associated with the type of training provided. The oversight activities shall include inspections, including unannounced inspections, and may, as deemed necessary by the competent authority, include audits.’;

(6) in point ARA.GEN.330, the following point (d) is added:

‘(d) Notwithstanding points (a), (b) and (c), in the case of changes to the information contained in the declarations received from a DTO or to the training programme used by the DTO, notified to it in accordance with point DTO.GEN.116 of Annex VIII (Part-DTO), the competent authority shall act in accordance with the requirements of points ARA.DTO.105 and ARA.DTO.110, as applicable.’;

(7) point ARA.GEN.350 is amended as follows:

(a) the following point (da) is inserted:

‘(da) Notwithstanding points (a) to (d), in the case of DTOs, if during oversight or by any other means the competent authority finds evidence indicating non-compliance with the essential requirements set out in Annex III to Regulation (EC) No 216/2008 or with the requirements of Annex I (Part-FCL) and Annex VIII (Part-DTO) to this Regulation by a DTO, the competent authority shall:

(1) raise a finding, record it, communicate it in writing to the representative of the DTO and determine a reasonable period of time within which the DTO is to take the steps specified in point DTO.GEN.150 of Annex VIII (Part-DTO);

- (2) take immediate and appropriate action to limit or prohibit the training activities affected by the non-compliance until the DTO has taken the corrective action referred to in point (1), where any of the following situations occurs:
 - (i) a safety problem has been identified;
 - (ii) the DTO fails to take corrective action in accordance with point DTO.GEN.150;
 - (3) in respect of the training programmes referred to in point DTO.GEN.230(c) of Annex VIII (Part-DTO), limit, suspend or revoke the approval of the training programme;
 - (4) take any further enforcement measures necessary in order to ensure the termination of the non-compliance and, where relevant, remedy the consequences thereof.;
- (b) point (e) is replaced by the following:
- ‘(e) Without prejudice to any additional enforcement measures, when the authority of a Member State acting in accordance with point ARA.GEN.300(d) identifies any non-compliance with the essential requirements set out in Annex III to Regulation (EC) No 216/2008 or with the requirements of Annex I (Part-FCL) and Annex VIII (Part-DTO) to this Regulation by an organisation certified by, or having made a declaration to, the competent authority of another Member State or the Agency, it shall inform that competent authority of that non-compliance.’;
- (8) the following Subpart DTO is added after Subpart MED:

‘SUBPART DTO

SPECIFIC REQUIREMENTS RELATING TO DECLARED TRAINING ORGANISATIONS (DTOs)

ARA.DTO.100 Declaration to the competent authority

- (a) Upon receiving a declaration from a DTO, the competent authority shall verify that the declaration contains all the information specified in point DTO.GEN.115 of Annex VIII (Part-DTO) and acknowledge receipt of the declaration, including the assignment of an individual DTO reference number to the representative of the DTO.
- (b) If the declaration does not contain the required information, or contains information that indicates a non-compliance with the essential requirements set out in Annex III to Regulation (EC) No 216/2008 or with the requirements of Annex I (Part-FCL) and Annex VIII (Part-DTO) to this Regulation, the competent authority shall act in accordance with point ARA.GEN.350(da).

ARA.DTO.105 Changes to declarations

Upon receiving a notification of a change to the information contained in the declaration of a DTO, the competent authority shall act in accordance with point ARA.DTO.100.

ARA.DTO.110 Verification of compliance of the training programme

- (a) Upon receiving the training programme of a DTO, and any changes thereto, notified to it in accordance with point DTO.GEN.115(c) of Annex VIII (Part-DTO) or the application for approval of the training programme of a DTO submitted to it in accordance with point DTO.GEN.230(c) of that Annex, the competent authority shall verify the compliance of those training programmes with the requirements of Annex I (Part-FCL).
- (b) When satisfied that the DTO training programme, and any subsequent changes thereto, are in compliance with those requirements, the competent authority shall inform the representative of the DTO thereof in writing or, in the case referred to in point DTO.GEN.230(c) of Annex VIII (Part-DTO), approve the training programme. For such approval it shall use the form contained in Appendix VIII to this Annex (Part-ARA).
- (c) In case of any non-compliance, the competent authority shall act in accordance with point ARA.GEN.350(da) or, in the case referred to in point DTO.GEN.230(c) of Annex VIII (Part-DTO), reject the application for approval of the training programme.;

(9) the following Appendix VIII is added:

'Appendix VIII to Annex VI (Part-ARA)

Training programme approval

for a declared training organisation (DTO)

European Union (*)

Competent authority

Issuing authority:

Name of DTO:

DTO reference number:

Training programme(s) approved:

Examiner standardisation — FE(S), FIE(S), FE(B), FIE(B) (**)

Examiner refresher seminar — FE(S), FIE(S), FE(B), FIE(B) (**)

Doc reference:

Remarks:

The above-mentioned training programme(s) has (have) been verified by the above-mentioned competent authority and found to be in compliance with the requirements of Annex I (Part-FCL) to Commission Regulation (EU) No 1178/2011.

Date of issue:

Signed: [competent authority]

(*) "European Union" to be deleted for non-EU Member States.

(**) To be adjusted as applicable.

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ANNEX III

In Annex VII to Regulation (EU) No 1178/2011 (Part-ORA), the introductory phrase in point ORA.ATO.120 is replaced by the following:

‘The following records shall be kept throughout the course and for a period of three years after the completion of the training:’.

ANNEX IV

‘ANNEX VIII

REQUIREMENTS FOR DECLARED TRAINING ORGANISATIONS (DTOs)

[PART-DTO]

DTO.GEN.100 General

In accordance with the second subparagraph of Article 10a(1), this Annex (Part-DTO) sets out the requirements applicable to pilot training organisations providing the training referred to in point DTO.GEN.110 on the basis of an declaration made in accordance with point DTO.GEN.115.

DTO.GEN.105 Competent authority

For the purpose of this Annex (Part-DTO), the competent authority in respect of a DTO shall be the authority designated by the Member State on the territory of which the DTO has its principal place of business.

DTO.GEN.110 Scope of the training

(a) A DTO shall be entitled to provide the following training, provided that the DTO has submitted a declaration in accordance with point DTO.GEN.115:

(1) for aeroplanes:

- (a) theoretical knowledge instruction for LAPL(A) and PPL(A);
- (b) flight instruction for LAPL(A) and PPL(A);
- (c) training towards class rating for SEP(land), SEP(sea) and TMG;
- (d) training towards additional ratings: night, aerobatics, mountain, sailplane and banner towing;

(2) for helicopters:

- (a) theoretical knowledge instruction for LAPL(H) and PPL(H);
- (b) flight instruction for LAPL(H), PPL(H);
- (c) single-engine type rating for helicopters for which the maximum certified seat configuration does not exceed five seats;
- (d) training towards night rating;

(3) for sailplanes:

- (a) theoretical knowledge instruction for LAPL(S) and SPL;
- (b) flight instruction for LAPL(S) and SPL;
- (c) training towards extension of privileges to TMG in accordance with point FCL.135.S;
- (d) training towards additional launch methods in accordance with point FCL.130.S;
- (e) training towards additional ratings: aerobatics, sailplane towing, and sailplane cloud flying rating;
- (f) training towards flight instructor rating FI(S);
- (g) FI(S) refresher seminar.

(4) for balloons:

- (a) theoretical knowledge instruction for LAPL(B) and BPL;
- (b) flight instruction for LAPL(B) and BPL;
- (c) training towards class extension in accordance with point FCL.135.B;

- (d) training towards class or group extension in accordance with point FCL.225.B;
 - (e) training towards extension to tethered flight in accordance with point FCL.130.B;
 - (f) training towards night rating;
 - (g) training towards flight instructor rating FI(B);
 - (h) FI(B) refresher seminar.
- (b) A DTO shall be entitled to also provide the examiner courses referred to in points FCL.1015(a) and FCL.1025(b)(2) of Annex I (Part-FCL) for FE(S), FIE(S), FE(B) and FIE(B), provided that the DTO has submitted a declaration in accordance with point DTO.GEN.115 and the competent authority has approved the training programme in accordance with point DTO.GEN.230(c).

DTO.GEN.115 Declaration

- (a) Prior to providing any of the training specified in point DTO.GEN.110, an organisation intending to provide such training shall submit a declaration to the competent authority. The declaration shall contain at least the following information:
- (1) the name of the DTO;
 - (2) contact details of the DTO's principal place of business and, where applicable, the contact details of the aerodromes and the operating sites of the DTO;
 - (3) names and contact details of the following persons:
 - (i) the representative of the DTO;
 - (ii) the head of training of the DTO; and
 - (iii) all deputy heads of training, if required by point DTO.GEN.250(b)(1);
 - (4) the type of training, as specified in point DTO.GEN.110, provided at each aerodrome and/or operating site;
 - (5) a list of all aircraft and FSTDs to be used for the training, if applicable;
 - (6) the date of intended commencement of the training;
 - (7) a statement confirming that the DTO has developed a safety policy and will apply that policy during all training activities covered by the declaration, in accordance with point DTO.GEN.210(a)(1)(ii);
 - (8) a statement confirming that the DTO complies and will, during all training activities covered by the declaration, continue to comply with the essential requirements set out in Annex III to Regulation (EC) No 216/2008 and with the requirements of Annex I (Part-FCL) and Annex VIII (Part-DTO) to this Regulation.
- (b) The declaration, and any subsequent changes thereto, shall be made using the form contained in Appendix 1.
- (c) A DTO shall, together with the declaration, submit to the competent authority the training programme or programmes, which it uses or intends to use to provide the training, as well as its application for approval of the training programme or programmes where such approval is required in accordance with point DTO.GEN.230(c).
- (d) By derogation from point (c), an organisation which holds an approval issued in accordance with Subpart ATO of Annex VII (Part-ORA) may, together with the declaration, only submit the reference to the already approved training manual or manuals.

DTO.GEN.116 Notification of changes and cessation of training activities

A DTO shall notify the competent authority without undue delay of the following:

- (a) any changes to the information contained in the declaration specified in point DTO.GEN.115(a) and to the training programme or programmes or the approved training manual or manuals referred to in points DTO.GEN.115(c) and (d) respectively;
- (b) the cessation of some or all training activities covered by the declaration.

DTO.GEN.135 Termination of entitlement to provide training

A DTO shall no longer be entitled to provide some or all of the training specified in its declaration on the basis of that declaration, where one of the following occurs:

- (a) the DTO has notified the competent authority of the cessation of some or all of the training activities covered by the declaration in accordance with point DTO.GEN.116(b);
- (b) the DTO has not provided the training for more than 36 consecutive months.

DTO.GEN.140 Access

For the purpose of determining whether a DTO is acting in compliance with its declaration, the DTO shall grant access at any time to any facility, aircraft, document, records, data, procedures or any other material relevant to its training activities covered by the declaration, to any person authorised by the competent authority

DTO.GEN.150 Findings

After the competent authority has communicated a finding to a DTO in accordance with point ARA.GEN.350(da)(1), the DTO shall take the following steps within the time period determined by the competent authority:

- (a) identify the root cause of the non-compliance;
- (b) take the necessary corrective action to terminate the non-compliance and, where relevant, remedy the consequences thereof;
- (c) inform the competent authority about the corrective action it has taken.

DTO.GEN.155 Reaction to a safety problem

As a reaction to a safety problem, a DTO shall implement:

- (a) the safety measures mandated by the competent authority in accordance with point ARA.GEN.135(c);
- (b) the relevant mandatory safety information issued by the Agency, including airworthiness directives.

DTO.GEN.210 Personnel requirements

- (a) A DTO shall designate:

(1) a representative, who shall be responsible and duly authorised to do at least the following:

- (i) ensure compliance of the DTO and its activities with the applicable requirements and with its declaration;
- (ii) develop and establish a safety policy which ensures that the DTO's activities are carried out safely, ensure that the DTO adheres to that safety policy and take the necessary measures in order to achieve the objectives of that safety policy;
- (iii) promote safety within the DTO;
- (iv) ensure the availability of sufficient resources within the DTO so that the activities referred to in points (i), (ii) and (iii) can be carried out in an effective manner.

(2) a head of training, who shall be responsible and qualified to ensure at least the following:

- (i) that the training provided complies with the requirements of Annex I (Part-FCL) and with the DTO's training programme;
- (ii) the satisfactory integration of flight training in an aircraft or a flight simulation training device (FSTD) and theoretical knowledge instruction;
- (iii) the supervision of the progress of students;
- (iv) in the case referred to in point DTO.GEN.250(b), the supervision of the deputy head or heads of training.

- (b) A DTO may designate a single person as its representative and its head of training.

- (c) A DTO shall not designate a person as its representative or its head of training if there are objective indications that he or she cannot be trusted to carry out the tasks listed in point (a) in a manner which safeguards and furthers aviation safety. The fact that a person has been subject to an enforcement measure taken in accordance with point ARA.GEN.355 in the past three years shall be deemed to constitute such an objective indication, unless that person can demonstrate that the finding leading to that measure, by reason of its nature, scale or impact on aviation safety, is not such as to indicate that he or she cannot be trusted to carry out those tasks in that manner.
- (d) A DTO shall ensure that its theoretical knowledge instructors have either of the following qualifications:
 - (1) practical background in aviation in the areas relevant for the training provided and have undergone a course of training instructional techniques;
 - (2) previous experience in giving theoretical knowledge instruction and an appropriate theoretical background in the subject on which they will provide theoretical knowledge instruction.
- (e) Flight instructors and flight simulation training instructors shall hold the qualifications required by Annex I (Part-FCL) for the type of training they are providing.

DTO.GEN.215 Facility requirements

A DTO shall have facilities in place allowing the performance and management of all its activities in accordance with the essential requirements of Annex III to Regulation (EC) No 216/2008 and with the requirements of this Annex (Part-DTO).

DTO.GEN.220 Record-keeping

- (a) A DTO shall keep for each individual student the following records throughout the training course and for three years after completion of the last training session:
 - (1) details of ground, flight and simulated flight training;
 - (2) information on individual progress;
 - (3) information on the licences and associated ratings relevant to the training provided, including expiry dates of ratings and medical certificates.
- (b) A DTO shall keep the report on the annual internal review and the activity report referred to in point DTO.GEN.270(a) and (b) respectively for three years from the date at which the DTO established those reports.
- (c) A DTO shall keep its training programme for three years from the date at which it provided the last training course in accordance with that programme.
- (d) A DTO shall, in accordance with the applicable law on the protection of personal data, store the records referred to in point (a) in a manner that ensures protection by appropriate tools and protocols and take the necessary measures to restrict the access to those records to persons who are duly authorised to access them.

DTO.GEN.230 DTO training programme

- (a) A DTO shall establish a training programme for each of the trainings specified in point DTO.GEN.110 which the DTO provides.
- (b) The training programmes shall comply with the requirements of Annex I (Part-FCL).
- (c) A DTO shall be entitled to provide the training referred to in point DTO.GEN.110(b) only where its training programme for that training, and any changes thereto, have been issued by the competent authority, upon application by the DTO, with an approval confirming that the training programme and any changes comply with the requirements of Annex I (Part-FCL), in accordance with point ARA.DTO.110. A DTO shall apply for such approval through the submission of its declaration in accordance with point DTO.GEN.115.
- (d) Point (c) shall not apply to an organisation also holding an approval issued in accordance with Subpart ATO of Annex VII (Part-ORA) that includes privileges for that training.

DTO.GEN.240 Training aircraft and FSTDs

- (a) A DTO shall use an adequate fleet of training aircraft or FSTDs appropriate to the training it provides.
- (b) A DTO shall establish and keep up-to-date a list of all aircraft, including their registration marks, used for the training it provides.

DTO.GEN.250 Aerodromes and operating sites

- (a) When providing flight training on an aircraft, a DTO shall only use aerodromes or operating sites that have the appropriate facilities and characteristics to allow training of the relevant manoeuvres, taking into account the training provided and the category and type of aircraft used.
- (b) When a DTO uses more than one aerodrome to provide any of the training specified in point DTO.GEN.110(a)(1) and (2), it shall:
 - (1) for each additional aerodrome, designate a deputy head of training, who shall be responsible for the tasks referred to in point DTO.GEN.210(a)(2)(i) to (iii) on that aerodrome; and
 - (2) ensure the availability of sufficient resources to safely operate on all aerodromes, in compliance with the requirements of this Annex (Part-DTO).

DTO.GEN.260 Theoretical knowledge instruction

- (a) When providing theoretical knowledge instruction, a DTO may use on-site instruction or distance learning.
- (b) A DTO shall monitor and record the progress of any student undergoing theoretical knowledge instruction.

DTO.GEN.270 Annual internal review and annual activity report

A DTO shall take the following steps:

- (a) conduct an annual internal review of the tasks and responsibilities specified in point DTO.GEN.210 and establish a report on that review;
 - (b) establish an annual activity report;
 - (c) submit the report on the annual internal review and the annual activity report to the competent authority by the date determined by the competent authority.
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Appendix 1 to Annex VIII (Part-DTO)

DECLARATION

pursuant to Commission Regulation (EU) No 1178/2011

☐ Initial declaration☐ Notification of changes ⁽¹⁾ – DTO reference number:

1.	Declared training organisation (DTO) Name:
2.	Place(s) of business Contact details (address, phone, email) of the DTO's principal place of business:
3.	Personnel Name and contact details (address, phone, email) of the DTO's representative: Name and contact details (address, phone, email) of the DTO's head of training and, if applicable, of the DTO's deputy head(s) of training:
4.	Training scope List of all training provided: List of all training programmes used to provide the training (documents to be attached to this declaration) or, in the case referred to in point DTO.GEN.230(d) of Annex VIII (Part-DTO) to Regulation (EU) No 1178/2011, the reference to all approved training manuals used to provide the training:
5.	Training aircraft and FSTDs List of aircraft used for the training: List of qualified FSTDs used for the training (if applicable, including letter code as indicated on the qualification certificate):
6.	Aerodrome(s) and the operating site(s) Contact details (address, phone, email) of all aerodromes and operating sites used by the DTO to provide the training:
7.	Date of intended commencement of training:
8.	Application for approval of examiner standardisation courses and refresher seminars (if applicable) ☐ The DTO hereby applies for approval of the above-mentioned training programme(s) for examiner courses for sailplanes or balloons in accordance with points DTO.GEN.110(b) and DTO.GEN.230(c) of Annex VIII (Part-DTO) to Regulation (EU) No 1178/2011.
9.	Statements The DTO has developed a safety policy in accordance with Annex VIII (Part-DTO) of Regulation (EU) No 1178/2011, and in particular with point DTO.GEN.210(a)(1)(ii) thereof, and will apply that policy during all training activities covered by the declaration. The DTO complies and will, during all training activities covered by the declaration, continue to comply with the essential requirements set out in Annex III to Regulation (EC) No 216/2008 and with the requirements of Annex I (Part-FCL) and Annex VIII (Part-DTO) to Regulation (EU) No 1178/2011.

We confirm that all information contained in this declaration, including its annexes (if applicable), is complete and correct.

Name, date and signature of the representative of the DTO

Name, date and signature of the head of training of the DTO

⁽¹⁾ In the case of changes, only point 1 and those fields containing changes need to be completed.'

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1120**of 10 August 2018****amending Annex I to Regulation (EU) No 605/2010 as regards the list of third countries or parts thereof from which the introduction into the European Union of consignments of raw milk, dairy products, colostrum and colostrum-based products is authorised****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption ⁽¹⁾, and in particular the introductory phrase of Article 8, the first subparagraph of point (1) and point (4) of Article 8 and Article 9(4) thereof,

Having regard to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption ⁽²⁾, and in particular Article 11(1) thereof,

Whereas:

- (1) Commission Regulation (EU) No 605/2010 ⁽³⁾ lays down the public and animal health conditions and certification requirements for the introduction into the Union of consignments of raw milk, dairy products, colostrum and colostrum-based products and the list of third countries from which the introduction into the Union of such consignments is authorised.
- (2) Annex I to Regulation (EU) No 605/2010 sets out a list of third countries or parts thereof authorised for the introduction into the Union of consignments of raw milk, dairy products, colostrum and colostrum-based products and indicates the type of treatment required for such commodities.
- (3) Bosnia and Herzegovina is already listed in Annex I to Regulation (EU) No 605/2010 and is authorised for export to the Union of milk and milk products which have undergone treatment 'C'.
- (4) Bosnia and Herzegovina made a request to the Commission for an authorisation to export milk, dairy products, colostrum and colostrum-based products to the Union which have undergone a less stringent treatment. From the animal health perspective, Bosnia and Herzegovina is a third country listed by the World Organisation for Animal Health as being free of foot-and-mouth disease (FMD) without a required vaccination policy and therefore fulfils the Union animal health import requirements.
- (5) The Commission has carried out veterinary controls in Bosnia and Herzegovina. The results of such controls have shown certain shortcomings, in particular as regards public health issues in the establishments. The competent authorities in Bosnia and Herzegovina are in the process of addressing those shortcomings.
- (6) However, based on the favourable animal health situation as regards foot-and-mouth disease in Bosnia and Herzegovina, it is appropriate to place Bosnia and Herzegovina in column A of Annex I to Regulation (EU) No 605/2010. This addition to column A of Annex I should be without prejudice to obligations arising from other provisions of Union legislation concerning imports into, and placing on the market within, the Union of products of animal origin, in particular those relating to the listing of establishments under Article 12 of Regulation (EC) No 854/2004.
- (7) Regulation (EU) No 605/2010 should therefore be amended accordingly.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 18, 23.1.2003, p. 11.

⁽²⁾ OJ L 139, 30.4.2004, p. 206.

⁽³⁾ Commission Regulation (EU) No 605/2010 of 2 July 2010 laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk, dairy products, colostrum and colostrum-based products intended for human consumption (OJ L 175, 10.7.2010, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

In the table set out in Annex I to Regulation (EU) No 605/2010, the entry for Bosnia and Herzegovina is replaced by the following:

'BA	Bosnia and Herzegovina	+	+	+
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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, 10 August 2018.

For the Commission

The President

Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1121**of 10 August 2018****amending Commission Implementing Regulation (EU) 2015/1518 imposing a definitive anti-dumping duty on imports of biodiesel originating in the United States of America following an expiry review pursuant to Article 11(2) of Council Regulation (EC) No 1225/2009**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/1036 of the European Parliament and of the Council of 8 June 2016 on protection against dumped imports from countries not members of the European Union ⁽¹⁾,

Having regard to Commission Implementing Regulation (EU) 2015/1518 of 14 September 2015 imposing a definitive anti-dumping duty on imports of biodiesel originating in the United States of America following an expiry review pursuant to Article 11(2) of Council Regulation (EC) No 1225/2009 ⁽²⁾, and in particular Article 1(6) thereof,

Whereas:

A. MEASURES IN FORCE

- (1) By Council Regulation (EC) No 599/2009 of 7 July 2009 ⁽³⁾, the Council imposed a definitive anti-dumping duty on imports of biodiesel originating in the United States of America ('USA').
- (2) In the original investigation, a large number of exporting producers from the USA made themselves known. As a result, the Commission selected a sample of American exporting producers to be investigated.
- (3) The Council imposed individual duty rates on imports of biodiesel originating in the USA ranging from EUR 0 to 198 per tonne net on the sampled companies, and a weighted average duty of EUR 115,6 per tonne net on other cooperating companies not included in the sample. In addition, a duty rate of EUR 172,2 per tonne net was imposed on imports of biodiesel from all other American companies.
- (4) Following an expiry review based on Article 11(2) of Regulation (EC) No 1225/2009, the original measures were prolonged for five years by Implementing Regulation (EU) 2015/1518.
- (5) Commission Implementing Regulation (EU) 2017/1598 ⁽⁴⁾ amended Implementing Regulation (EU) 2015/1518 to include Article 1(6) allowing exporting producers to request a new exporting producer treatment.
- (6) Article 1(6) of Implementing Regulation (EU) 2015/1518 states that the Commission may amend Annex I, in order to attribute the duty applicable to cooperating producers not included in the sample, namely EUR 115,6 per tonne net, where any party from the USA provides sufficient evidence to the Commission that:
 - (a) it did not export biodiesel originating in the USA during the period of investigation (1 April 2007-31 March 2008);
 - (b) it is not related to an exporter or producer subject to the measures imposed by that Regulation; and
 - (c) it has either actually exported the goods concerned or has entered into an irrevocable contractual obligation to export a significant quantity to the Union after the end of the period of investigation.

⁽¹⁾ OJ L 176, 30.6.2016, p. 21.

⁽²⁾ Commission Implementing Regulation (EU) 2015/1518 of 14 September 2015 imposing a definitive anti-dumping duty on imports of biodiesel originating in the United States of America following an expiry review pursuant to Article 11(2) of Council Regulation (EC) No 1225/2009 (OJ L 239, 15.9.2015, p. 69).

⁽³⁾ Council Regulation (EC) No 599/2009 of 7 July 2009 imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of biodiesel originating in the United States of America (OJ L 179, 10.7.2009, p. 26).

⁽⁴⁾ Commission Implementing Regulation (EU) 2017/1598 of 22 September 2017 amending Commission Implementing Regulation (EU) 2015/1518 imposing a definitive anti-dumping duty on imports of biodiesel originating in the United States of America following an expiry review pursuant to Article 11(2) of Council Regulation (EC) No 1225/2009 (OJ L 245, 23.9.2017, p. 1)

B. REQUESTS FOR NEW EXPORTING PRODUCER TREATMENT

- (7) Following the publication of Implementing Regulation (EU) 2015/1518, an American company, Organic Technologies ('the applicant'), came forward claiming that it met all three criteria set out in recital 6 and should be granted new exporting producer treatment. The applicant provided information and supporting evidence in response to a questionnaire from the Commission. After an initial analysis of the questionnaire response, the Commission sent the applicant a letter requesting further information. The applicant responded.
- (8) As for criterion (a), the applicant claimed that it existed during the original investigation period. It also claimed that it started to produce biodiesel in 2009, that is, after the original investigation period. The Commission verified the sales ledgers provided by the applicant. The applicant showed that it started production of biodiesel in 2009 and the first sales outside of the USA took place only in 2016. Therefore, the Commission accepted that the applicant did not export biodiesel to the Union during the original investigation period. Hence, the applicant complies with criterion (a).
- (9) With regard to the criterion (b), namely that the applicant is not related to an exporter or producer subject to anti-dumping measures imposed by Implementing Regulation (EU) 2015/1518, the Commission established, on the basis of the documents submitted by the applicant, that the applicant does not have any related companies which are subject to the measures. Therefore, the applicant complies with criterion (b).
- (10) With regard to the criterion (c), the Commission also established that the applicant had entered into an irrevocable contractual obligation to export a significant quantity of the product concerned to the Union in 2018. In that respect, the applicant provided a sales contract for the delivery of the product concerned in 2018, which satisfied this criterion. Therefore, the applicant complies with criterion (c).
- (11) Consequently, the Commission concluded that the applicant meets the three criteria to be considered as a new exporting producer. Therefore, its name should be added to the list of cooperating companies not included in the sample in Annex I to Implementing Regulation (EU) 2015/1518.
- (12) Therefore, Commission Implementing Regulation (EU) 2015/1518 should be amended accordingly.
- (13) The Commission informed the applicant and the Union industry of these findings and gave an opportunity to comment. The Commission received no comments.
- (14) This Regulation is in accordance with the opinion of the Committee established by Article 15(1) of Regulation (EU) 2016/1036,

HAS ADOPTED THIS REGULATION:

Article 1

In Annex I to Commission Implementing Regulation (EU) 2015/1518 the following company shall be added to the list of exporting producers from the United States of America:

Company name	City	TARIC additional code
'Organic Technologies	Coshocton (Ohio)	C482'

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, 10 August 2018.

For the Commission

The President

Jean-Claude JUNKER

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1122**of 10 August 2018****authorising the placing on the market of pyrroloquinoline quinone disodium salt as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 12 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283 the Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ was adopted, which establishes a Union list of authorised novel foods.
- (3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a novel food and on updating the Union list.
- (4) On 6 December 2012, the company Mitsubishi Gas Chemical Company, Inc. ('the Applicant') made a request to the competent authority of Ireland to place pyrroloquinoline quinone disodium salt produced from the bacterium *Hyphomicrobium denitrificans*, on the Union market as a novel food ingredient within the meaning of point (c) of Article 1(2) of Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽³⁾. The application requests for pyrroloquinoline quinone disodium salt to be used in food supplements for the general adult population, excluding pregnant and lactating women.
- (5) Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 concerning novel foods and novel food ingredients, and for which the final decision has not been taken before 1 January 2018 shall be treated as an application submitted under Regulation (EU) 2015/2283.
- (6) While the request for placing pyrroloquinoline quinone disodium salt on the market as a novel food within the Union was submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97, the application also meets the requirements laid down in Regulation (EU) 2015/2283.
- (7) On 8 July 2016, the competent authority of Ireland issued its initial assessment report. In that report, it came to the conclusion that an additional assessment is required for pyrroloquinoline quinone disodium salt with regards to its safety following long-term consumption at the levels proposed in the application, in accordance with Article 6(3) of Regulation (EC) No 258/97.
- (8) On 2 August 2016, the Commission forwarded the initial assessment report to the other Member States. The Member States within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97 agreed with the initial assessment report of Ireland.
- (9) In view of the initial assessment report conclusions issued by Ireland, to which the other Member States agreed, on 13 October 2016, the Commission consulted the European Food Safety Authority ('the Authority') asking it to carry out an additional assessment for pyrroloquinoline quinone disodium salt as a novel food ingredient in accordance with Regulation (EC) No 258/97.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

⁽³⁾ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

- (10) On 24 October 2017, the Authority adopted ‘Scientific Opinion on the safety of pyrroloquinoline quinone disodium salt as a novel food pursuant to Regulation (EC) No 258/97’ ⁽¹⁾. This opinion, although elaborated and adopted by the Authority under Regulation (EC) No 258/97 is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (11) That opinion gives sufficient grounds to establish that pyrroloquinoline quinone disodium salt in the proposed uses and use levels when used as an ingredient in food supplements, complies with Article 12(1) of Regulation (EU) 2015/2283.
- (12) On 24 January 2018, the Applicant made a request to the Commission for protection of proprietary data for a number of studies submitted in support of the application namely, a bacterial reverse mutation test study ⁽²⁾, an *in vitro* chromosomal aberration test in human blood lymphocytes study ⁽³⁾, an *in vitro* chromosomal aberration test in Chinese hamster lung fibroblasts study ⁽⁴⁾, an *in vivo* micronucleus test study ⁽⁵⁾, a 14-day oral toxicity and a 90-day oral toxicity studies ⁽⁶⁾, and a 28-day renal toxicity study ⁽⁷⁾.
- (13) On 18 February 2018, the Authority considered ⁽⁸⁾ that in elaborating its opinion on pyrroloquinoline quinone disodium salt as a novel food, the data from the bacterial reverse mutation test and from the *in vivo* micronucleus test studies served as basis to alleviate concerns with respect to the potential genotoxicity of pyrroloquinoline quinone disodium salt, and the 14-day oral, the 28-day renal toxicity, and the 90-day oral toxicity studies served as a basis to assess the toxicity profile of pyrroloquinoline quinone disodium salt and to establish the related No Observed Adverse Effect Level (NOAEL). Therefore, it is considered that the conclusions on the safety of pyrroloquinoline quinone disodium salt, could not have been reached without the data from the unpublished reports of these studies.
- (14) Following the receipt of the Authority’s opinion, the Commission requested the Applicant to further clarify the justification provided with regard to their proprietary claim over the study reports, which were unpublished at the time the application was made, and to clarify their claim to an exclusive right of reference to those studies, as referred to in Article 26(2)(a)(b) of Regulation (EU) 2015/2283.
- (15) The Applicant has also declared that, at the time the application was submitted, they held proprietary or exclusive rights of reference to the studies under national law and that therefore third parties could not lawfully access or use those studies. The Commission assessed all the information provided by the Applicant and considered that the Applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283.
- (16) Accordingly, as provided for under Article 26(2) of Regulation (EU) 2015/2283, the bacterial reverse mutation test, the *in vivo* micronucleus test studies, the 14-day oral toxicity, the 28-day renal toxicity, and the 90-day oral toxicity studies contained in the Applicant’s file should not be used by the Authority for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation. As a consequence, the placing on the market within the Union of the novel food authorised by this Regulation should be restricted to the Applicant for a period of five years.
- (17) However, restricting the authorisation of this novel food and of the reference to the studies contained in the Applicant’s file for the sole use of the Applicant does not prevent other applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting the authorisation under this Regulation.
- (18) Taking into account of the intended use in food supplements for the general adult population, and the fact that the request for authorisation excludes pregnant and lactating women, food supplements containing pyrroloquinoline quinone disodium salt should be appropriately labelled.
- (19) Directive 2002/46/EC of the European Parliament and of the Council ⁽⁹⁾ lays down requirements on food supplements. The use of pyrroloquinoline quinone disodium salt should be authorised without prejudice to that Directive.

⁽¹⁾ EFSA Journal 2017; 15(11):5058.

⁽²⁾ Mitsubishi Gas Chemical Company Inc., 2005b (unpublished report).

⁽³⁾ Mitsubishi Gas Chemical Company Inc., 2008b (unpublished report).

⁽⁴⁾ Mitsubishi Gas Chemical Company Inc., 2006d (unpublished report).

⁽⁵⁾ Mitsubishi Gas Chemical Company Inc., 2006c (unpublished report).

⁽⁶⁾ Mitsubishi Gas Chemical Company Inc., 2005a (unpublished report).

⁽⁷⁾ Mitsubishi Gas Chemical Company Inc., 2006b (unpublished report).

⁽⁸⁾ EFSA Scientific Panel on Dietetic Products, Nutrition and Allergies, Minutes of the 83rd Plenary held on 7-8 February 2018 and agreed on 18 February 2018.

⁽⁹⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

- (20) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

1. Pyrroloquinoline quinone disodium salt as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

2. For a period of five years from the date of entry into force of this Regulation only the initial Applicant:

Company: Mitsubishi Gas Chemical Company, Inc.

Address: Mitsubishi Building 5-2 Marunouchi 2-chome, Chiyoda-ku, Tokyo 100-8324, Japan

is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for the novel food without reference to the data protected pursuant to Article 2 of this Regulation or with the agreement of Mitsubishi Gas Chemical Company, Inc.

3. The entry in the Union list referred to in the first paragraph shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

4. The authorisation provided for in this Article shall be without prejudice to the provisions of Directive 2002/46/EC.

Article 2

The studies contained in the application file on the basis of which the novel food referred to in Article 1 has been assessed by the Authority, claimed by the applicant as proprietary and without which the data protection could not have been authorised, shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of Mitsubishi Gas Chemical Company, Inc.

Article 3

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 4

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, 10 August 2018.

For the Commission
The President
Jean-Claude JUNCKER

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) the following last column is added in Table 1 (Authorised novel foods):

'Data Protection'

(2) The following entry is inserted in Table 1 (Authorised novel foods) in alphabetical order:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
Pyrroloquinoline quinone disodium salt	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "Pyrroloquinoline quinone disodium salt". Food supplements containing Pyrroloquinoline quinone disodium salt shall bear the following statement: This food supplement should be consumed by adults only excluding pregnant and lactating women		Authorised on 2 September 2018. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Mitsubishi Gas Chemical Company, Inc., Mitsubishi Building 5-2 Marunouchi 2-chome, Chiyoda-ku, Tokyo 100-8324, Japan. During the period of data protection the novel food Pyrroloquinoline quinone disodium salt is authorised for placing on the market within the Union only by Mitsubishi Gas Chemical Company, Inc., unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Mitsubishi Gas Chemical Company, Inc. End date of the data protection: 2 september 2023'
	Food Supplements as defined in Directive 2002/46/EC intended for the adult population, excluding pregnant and lactating women	20 mg/day			

(3) The following entry is inserted in Table 2 (Specifications) in alphabetical order:

Authorised Novel Food	Specification
Pyrroloquinoline quinone disodium salt	Definition: Chemical name: disodium 9-carboxy-4,5-dioxo-1H-pyrrolo[5,4-f]quinoline-2,7-dicarboxylate Chemical formula: C ₁₄ H ₄ N ₂ Na ₂ O ₈ CAS No: 122628-50-6 Molecular weight: 374,17 Da

Authorised Novel Food	Specification
	Description Pyrroloquinoline quinone disodium salt is a reddish-brown powder produced by the non-genetically modified bacterium <i>Hyphomicrobium denitrificans</i> strain CK-275. Characteristics/Composition Appearance: Reddish-brown powder Purity: $\geq 99,0 \%$ (dry weight) UV absorbance (A322/A259): $0,56 \pm 0,03$ UV absorbance (A233/A259): $0,90 \pm 0,09$ Moisture: $\leq 12,0 \%$ Residual Solvent Ethanol: $\leq 0,05 \%$ Heavy metals Lead: $< 3 \text{ mg/kg}$ Arsenic: $< 2 \text{ mg/kg}$ Microbiological criteria: Total viable cell count: $\leq 300 \text{ CFU/g}$ Mould/yeast: $\leq 12 \text{ CFU/g}$ Coliforms: absent in 1 g <i>Hyphomicrobium denitrificans</i>: $\leq 25 \text{ CFU/g}$ CFU: Colony Forming Units'

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1123**of 10 August 2018****authorising the placing on the market of 1-methylnicotinamide chloride as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 12 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283 the Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ was adopted, which establishes a Union list of authorised novel foods.
- (3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a novel food and on updating the Union list.
- (4) On 18 September 2013, the company Pharmena SA ('the Applicant') made a request to the competent authority of the United Kingdom to place synthetic 1-methylnicotinamide chloride on the Union market as a novel food ingredient within the meaning of point (c) of Article 1(2) of Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽³⁾. The application requests for 1-methylnicotinamide chloride to be used in food supplements for the general adult population, excluding pregnant and lactating women.
- (5) Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 and for which the final decision has not been taken before 1 January 2018, shall be treated as an application submitted under Regulation (EU) 2015/2283.
- (6) While the request for placing 1-methylnicotinamide chloride on the market as a novel food within the Union was submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97, the application also meets the requirements laid down in Regulation (EU) 2015/2283.
- (7) On 26 November 2015, the competent authority of the United Kingdom issued its initial assessment report. In that report, it came to the conclusion that 1-methylnicotinamide chloride meets the criteria for novel food ingredient set out in Article 3(1) of Regulation (EC) No 258/97.
- (8) On 11 December 2015, the Commission forwarded the initial assessment report to the other Member States. Reasoned objections were raised by other Member States within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97 with regard to the safety and tolerance of 1-methylnicotinamide chloride, and in particular on the effects on consumer health of the long-term intake of 1-MNA, especially when taking into account the intake of niacin from the diet, including food supplements.
- (9) In view of the objections raised by the other Member States, on 11 August 2016, the Commission consulted the European Food Safety Authority ('the Authority') asking it to carry out an additional assessment for 1-methylnicotinamide chloride as novel food ingredient in accordance with Regulation (EC) No 258/97

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

⁽³⁾ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

- (10) On 20 September 2017, the Authority adopted ‘Scientific Opinion on the safety of 1-methylnicotinamide chloride as a novel food pursuant to Regulation (EC) No 258/97’ ⁽¹⁾. This opinion, although elaborated and adopted by EFSA under Regulation (EC) No 258/97 is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (11) That opinion gives sufficient grounds to establish that 1-methylnicotinamide chloride in the proposed uses and use levels when used as an ingredient in food supplements, complies with Article 12(1) of Regulation (EU) 2015/2283.
- (12) On 25 January 2018, the Applicant made a request to the Commission for protection of proprietary data for a number of studies submitted in support of the application namely, the methods of analysis ⁽²⁾, an animal toxicity and pharmacokinetic study ⁽³⁾, a human pharmacokinetic study ⁽⁴⁾, an *in vitro* micronucleus test with human lymphocytes study ⁽⁵⁾, a human lipid metabolism study ⁽⁶⁾, a 90-day sub chronic oral toxicity study ⁽⁷⁾, and a single dose human bioavailability study ⁽⁸⁾.
- (13) On 18 February 2018, the Authority considered that in elaborating its opinion on 1-methylnicotinamide chloride as a novel food, the methods of analysis served as the basis to assess the specifications and the composition of 1-methylnicotinamide, the *in vitro* micronucleus test study with human lymphocytes served as the basis to conclude that there were no concerns with respect to the genotoxicity of 1-methylnicotinamide chloride, and the 90-day oral toxicity study served as the basis to establish a reference point and to assess whether the margin of exposure in relation to the proposed maximum intake of 1-methylnicotinamide chloride by humans is sufficient.
- (14) Following the receipt of the Authority’s opinion, the Commission requested the Applicant to further clarify the justification provided with regard to their proprietary claim over the studies, which were unpublished at the time the application was submitted, and to clarify their claim to an exclusive right of reference to those studies, as referred to in Article 26(2)(a)(b) of Regulation (EU) 2015/2283.
- (15) The Applicant has also declared that, at the time the application was submitted, they held proprietary or exclusive rights of reference to the studies under national law and that therefore third parties could not lawfully access or use those studies. The Commission assessed all the information provided by the Applicant and considered that the Applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283.
- (16) Accordingly, as provided for under Article 26(2) of Regulation (EU) 2015/2283, the methods of analysis of 1-methylnicotinamide chloride, the *in vitro* micronucleus test with human lymphocytes study, and the 90-day sub chronic oral toxicity study contained in the Applicant’s file should not be used by the Authority for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation. As a consequence, the placing on the market within the Union of the novel food authorised by this Regulation should be restricted to the Applicant for a period of five years.
- (17) However, restricting the authorisation of this novel food and of the reference to the studies contained in the Applicant’s file for the sole use of the Applicant, does not prevent other applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information available outside the Applicant’s file supporting the authorisation under this Regulation.
- (18) Taking into account of the intended use in food supplements for the general adult population, and the fact that the request for authorisation excludes pregnant and lactating women, food supplements containing 1-methylnicotinamide chloride should be appropriately labelled.
- (19) Directive 2002/46/EC of the European Parliament and of the Council ⁽⁹⁾ lays down requirements on food supplements. The use of 1-methylnicotinamide chloride should be authorised without prejudice to that Directive.
- (20) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ EFSA Journal 2017; 15(10):5001.

⁽²⁾ Unpublished internal company report.

⁽³⁾ Przybyła M., 2013, unpublished report.

⁽⁴⁾ Proskin, H.M., 2008, unpublished report.

⁽⁵⁾ Stepnik M., 2012, unpublished report.

⁽⁶⁾ Cossette M., 2009, unpublished report.

⁽⁷⁾ Ford J.A., 2014, unpublished study.

⁽⁸⁾ Dessouki E., 2013, unpublished study.

⁽⁹⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

HAS ADOPTED THIS REGULATION:

Article 1

1. 1-methylnicotinamide chloride as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

2. For a period of five years from the date of entry into force of this Regulation only the initial Applicant:

Company: Pharmena SA

Address: ul. Wolczanska 178, 90 530 Lodz, Poland

is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for the novel food without reference to the data protected pursuant to Article 2 of this Regulation or with the agreement of Pharmena SA.

3. The entry in the Union list referred to in the first paragraph shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

4. The authorisation provided for in this Article shall be without prejudice to the provisions of Directive 2002/46/EC.

Article 2

The studies contained in the application file on the basis of which the novel food referred to in Article 1 has been assessed by the Authority, claimed by the applicant as proprietary and without which the data protection could not have been authorised, shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of Pharmena SA.

Article 3

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 4

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, 10 August 2018.

For the Commission
The President
Jean-Claude JUNCKER

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) the following last column is added in Table 1 (Authorised novel foods):

'Data Protection'

(2) The following entry is inserted in Table 1 (Authorised novel foods) in alphabetical order:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
'1-Methylnicotinamide chloride'	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "1- Methylnicotinamide chloride". Food supplements containing 1-Methylnicotinamide shall bear the following statement: This food supplement should be consumed by adults only excluding pregnant and lactating women		Authorised on 2 September 2018. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Pharmena SA, Wolczanska 178, 90 530 Lodz, Poland. During the period of data protection the novel food 1-methylnicotinamide chloride is authorised for placing on the market within the Union only by Pharmena S.A. unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Pharmena S.A. End date of the data protection: 2 September 2023'.
	Food Supplements as defined in Directive 2002/46/EC for the adult population excluding pregnant and lactating women	58 mg/day			

(3) The following entry is inserted in Table 2 (Specifications) in alphabetical order:

Authorised Novel Food	Specification
'1-Methylnicotinamide chloride'	Definition: Chemical name: 3-carbamoyl-1-methyl-pyridinium chloride Chemical formula: C ₇ H ₉ N ₂ OCl CAS No: 1005-24-9 Molecular weight: 172,61 Da

Authorised Novel Food	Specification
	Description 1-Methylnicotinamide chloride is white or off-white, crystalline solid produced by a chemical synthesis process. Characteristics/Composition Appearance: White – off-white, crystalline solid Purity: $\geq 98,5 \%$ Trigonelline: $\leq 0,05 \%$ Nicotinic Acid: $\leq 0,10 \%$ Nicotinamide: $\leq 0,10 \%$ Largest unknown impurity: $\leq 0,05 \%$ Sum of unknown impurities: $\leq 0,20 \%$ Sum of all impurities: $\leq 0,50 \%$ Solubility: soluble in water and methanol. Practically insoluble in 2-propanol and dichloromethane Moisture: $\leq 0,3 \%$ Loss on drying: $\leq 1,0 \%$ Residue on ignition: $\leq 0,1 \%$ Residual Solvents and Heavy Metals Methanol: $\leq 0,3 \%$ Heavy metals: $\leq 0,002 \%$ Microbiological criteria: Total aerobic microbial count: $\leq 100 \text{ CFU/g}$ Mould/yeast: $\leq 10 \text{ CFU/g}$ Enterobacteriaceae: absence in 1 g <i>Pseudomonas aeruginosa</i>: absence in 1 g <i>Staphylococcus aureus</i>: absent in 1 g CFU: Colony Forming Units'

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1124**of 10 August 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 7 August 2018, the Sanctions Committee of the United Nations Security Council decided to remove one entry 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, 10 August 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 entry is deleted:

‘28. DIRECTORATE GENERAL OF GEOLOGICAL SURVEY AND MINERAL INVESTIGATION. Address: P.O. Box 986, Alwiya, Al Sadoon Park Area, Baghdad, Iraq.’

DECISIONS

COUNCIL DECISION (CFSP) 2018/1125

of 10 August 2018

amending Decision (CFSP) 2015/740 concerning restrictive measures in view of the situation in South Sudan

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 29 thereof,

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

Whereas:

- (1) On 7 May 2015, the Council adopted Decision (CFSP) 2015/740 ⁽¹⁾ concerning restrictive measures in view of the situation in South Sudan.
- (2) On 13 July 2018, the United Nations Security Council adopted Resolution 2428 (2018) which notably imposes an arms embargo and adds two persons to the list of persons and entities subject to restrictive measures.
- (3) Decision (CFSP) 2015/740 should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Decision (CFSP) 2015/740 is amended as follows:

- (1) Article 1, paragraph 2, is replaced by the following:

‘2. It shall also be prohibited to:

- (a) provide, directly or indirectly, technical assistance, brokering services or other services, including the provision of armed mercenary personnel, related to military activities or related to the items referred to in paragraph 1 or related to the provision, manufacture, maintenance and use of such items, to any natural or legal person, entity or body in, or for use in, South Sudan;
- (b) provide, directly or indirectly, financing or financial assistance related to military activities or related to the items referred to in paragraph 1, including in particular grants, loans and export credit insurance, as well as insurance or reinsurance for any sale, supply, transfer or export of such items, or for the provision of related technical assistance, brokering services or other services to any natural or legal person, entity or body in, or for use in, South Sudan;
- (c) participate, knowingly and intentionally, in activities, the object or effect of which is to circumvent the measures referred to in point (a) or (b).’;

- (2) Article 2 is replaced by the following:

‘Article 2

Article 1 shall not apply to the sale, supply, transfer or export of:

- (a) arms and related materiel, as well as training and assistance, intended solely for support of or use by UN personnel, including the United Nations Mission in the Republic of South Sudan (UNMISS) and the United Nations Interim Security Force for Abyei (UNISFA);
- (b) non-lethal military equipment intended solely for humanitarian or protective use, and related technical assistance or training, as notified in advance to the Security Council Committee established pursuant to resolution 2206 (2015) (“the Committee”);
- (c) protective clothing, including flak jackets and military helmets, temporarily exported to South Sudan by UN personnel, representatives of the media and humanitarian and development workers and associated personnel, for their personal use only;

⁽¹⁾ Council Decision (CFSP) 2015/740 of 7 May 2015 concerning restrictive measures in view of the situation in South Sudan and repealing Decision 2014/449/CFSP (OJ L 117, 8.5.2015, p. 52).

- (d) arms and related materiel temporarily exported to South Sudan by the forces of a State which is taking action, in accordance with international law, solely and directly to facilitate the protection or evacuation of its nationals and those for whom it has consular responsibility in South Sudan, as notified to the Committee;
- (e) arms and related materiel, as well as technical training and assistance, to or in support of the African Union Regional Task Force intended solely for regional operations to counter the Lord's Resistance Army, as notified in advance to the Committee;
- (f) arms and related materiel, as well as technical training and assistance, solely in support of the implementation of the terms of the peace agreement, as approved in advance by the Committee;
- (g) other sales or supply of arms and related materiel, or provision of assistance or personnel, as approved in advance by the Committee.;

(3) the following Article is inserted:

'Article 2a

1. Member States shall inspect, in accordance with their national authorities and legislation and consistent with international law, all cargo to South Sudan in their territory, including seaports and airports, if they have information that provides reasonable grounds to believe that the cargo contains items whose supply, sale, transfer or export is prohibited under Article 1.

2. Member States shall, upon discovery, seize and dispose of (such as through destruction, rendering inoperable, storage or transferring to a State other than the originating or destination States for disposal) items the supply, sale, transfer or export of which is prohibited under Article 1.;

(4) in Article 3(1), point (a) is replaced by the following:

'(a) designated by the Security Council or by the Committee in accordance with paragraphs 6, 7, 8 and 9 of UNSCR 2206 (2015) and with paragraph 14 of UNSCR 2428 (2018), as listed in Annex I to this Decision;';

(5) in Article 6(1), point (a) is replaced by the following:

'(a) persons and entities designated by the Security Council or by the Committee in accordance with paragraphs 6, 7, 8 and 12 of UNSCR 2206 (2015) and with paragraph 14 of UNSCR 2428 (2018), as listed in Annex I to this Decision;'.

Article 2

Annex I to Decision (CFSP) 2015/740 is hereby amended as set out in Annex I to this Decision.

Article 3

Annex II to Decision (CFSP) 2015/740 is hereby amended as set out in Annex II to this Decision.

Article 4

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

Done at Brussels, 10 August 2018.

For the Council
The President
G. BLÜMEL

ANNEX I

The following persons are added to the list set out in Annex I to Decision (CFSP) 2015/740:

7. Malek REUBEN RIAK RENGU (alias: a) Malek Ruben)

Title: Lieutenant General

Designation: a) Deputy Chief of General Staff for Logistics; b) Deputy Chief of Defence Staff and Inspector General of the Army

Date of birth: 1 Jan. 1960

Place of birth: Yei, South Sudan

Nationality: South Sudan

Date of UN designation: 13 July 2018

Other information: As SPLA Deputy Chief of Staff for Logistics, Riak was one of the senior officials of the Government of South Sudan who planned and oversaw an offensive in Unity state in 2015 that resulted in widespread destruction and large population displacement.

Information from the narrative summary of reasons for listing provided by the Sanctions Committee:

Malek Ruben Riak was listed on 13 July 2018 pursuant to paragraphs 6, 7 (a), and 8 of resolution 2206 (2015), as reaffirmed in resolution 2418 (2018), for “actions or policies that threaten the peace, security or stability of South Sudan”; “Actions or policies that have the purpose or effect of expanding or extending the conflict in South Sudan ...,” and as a leader “of any entity, including any South Sudanese government, opposition, militia, or other group, that has, or whose members have, engaged in any of the activities described in paragraphs 6 and 7,” and pursuant to paragraph 14 (e) of this resolution for “planning, directing, or committing acts involving sexual and gender-based violence in South Sudan”.

According to the report by the Panel of Experts on South Sudan in January 2016 (S/2016/70), Riak was one of a group of senior security officials who planned a Unity state offensive against the SPLM-IO beginning in January 2015, and subsequently oversaw its execution from late April 2015 onwards. The Government of South Sudan began arming Bul Nuer youth in early 2015 to facilitate their participation in the offensive. Most Bul Nuer youth already had access to AK-pattern automatic rifles, but ammunition was critical to sustaining their operations. The Panel of Experts reported evidence, including testimony from military sources, that ammunition was supplied to youth groups by SPLA headquarters specifically for the offensive. Riak was the SPLA Deputy Chief of Staff for Logistics at the time. The offensive resulted in systematic destruction of villages and infrastructure, the forced displacement of the local population, the indiscriminate killing and torturing of civilians, the widespread use of sexual violence, including against the elderly and children, the abduction and recruitment of children as soldiers, and large population displacement. Following the destruction of much of the southern and central parts of the state, numerous media and humanitarian organisations, as well as the United Nations Mission in South Sudan (UNMISS) published reports about the scale of the abuses that were perpetrated.

8. Paul MALONG AWAN (alias: a) Paul Malong Awan Anei, b) Paul Malong, c) Bol Malong)

Title: General

Designation: a) Former Chief of Staff of the Sudan People's Liberation Army (SPLA), b) Former Governor, Northern Bahr el-Ghazal State

Date of birth: a) 1962, b) 4 Dec. 1960, c) 12 Apr. 1960

Place of birth: Malualkon, South Sudan

Nationality: a) South Sudan, b) Uganda

Passport no: a) South Sudan number S00004370, b) South Sudan number D00001369, c) Sudan number 003606, d) Sudan number 00606, e) Sudan number B002606

Date of UN designation: 13 July 2018

Other information: As Chief of General Staff of the SPLA, Malong expanded or extended the conflict in South Sudan through breaches of the Cessation of Hostilities Agreement and breaches of the 2015 Agreement on the Resolution of the Conflict in South Sudan (ARCSS). He reportedly directed efforts to kill opposition leader Riek Machar. He ordered SPLA units to prevent the transport of humanitarian supplies. Under Malong's leadership, the SPLA attacked civilians,

schools and hospitals; forced the displacement of civilians; carried out enforced disappearances; arbitrarily detained civilians; and conducted acts of torture, and rape. He mobilised the Mathiang Anyoor Dinka tribal militia, which uses child soldiers. Under his leadership, the SPLA restricted UNMISS, the Joint Monitoring and Evaluation Commission (JMEC), and CTSAMM access to sites to investigate and document abuses.

Information from the narrative summary of reasons for listing provided by the Sanctions Committee:

Paul Malong Awan was listed on 13 July 2018 pursuant to paragraphs 6, 7 (a), 7 (b), 7 (c), 7 (d), 7 (f), and 8 of resolution 2206 (2015), as reaffirmed in resolution 2418 (2018), for “actions or policies that have the purpose or effect of expanding or extending the conflict in South Sudan or obstructing reconciliation or peace talks or processes, including breaches of the Cessation of Hostilities Agreement”; “actions or policies that threaten transitional agreements or undermine the political process in South Sudan”; “the targeting of civilians, including women and children, through the commission of acts of violence (including killing, maiming, torture, or rape or other sexual violence), abduction, enforced disappearance, forced displacement, or attacks on schools, hospitals, religious sites, or locations where civilians are seeking refuge, or through conduct that would constitute a serious abuse or violation of human rights or a violation of international humanitarian law”; “planning, directing, or committing acts that violate applicable international human rights law or international humanitarian law, or acts that constitute human rights abuses, in South Sudan”; “The use or recruitment of children by armed groups or armed forces in the context of the armed conflict in South Sudan”; “the obstruction of the activities of international peacekeeping, diplomatic, or humanitarian missions in South Sudan, including IGAD’s Monitoring and Verification Mechanism or of the delivery or distribution of, or access to, humanitarian assistance”; and as a leader “of any entity, including any South Sudanese government, opposition, militia, or other group, that has, or whose members have, engaged in any of the activities described in paragraphs 6 and 7”.

Malong served as Chief of General Staff of the SPLA from April 23, 2014, to May 2017. In his former position as the Chief of General Staff, he expanded or extended the conflict in South Sudan through breaches of the Cessation of Hostilities Agreement and breaches of the 2015 Agreement on the Resolution of the Conflict in South Sudan (ARCSS). As of early August 2016, Malong reportedly directed efforts to kill South Sudanese opposition leader Riek Machar. Malong, knowingly countermanding President Salva Kiir’s orders, ordered the 10 July 2016 tank, helicopter gunship, and infantry assaults on Machar’s residence and the Sudan Peoples’ Liberation Movement in Opposition (SPLM-IO)’s “Jebel” base. Malong personally oversaw efforts from SPLA headquarters to intercept Machar. As of early August 2016, Malong wanted the SPLA to attack Machar’s suspected position immediately and informed SPLA commanders that Machar was not to be taken alive. In addition, in early 2016 information indicates that Malong ordered SPLA units to prevent the transport of humanitarian supplies across the Nile River, where tens of thousands of civilians were facing hunger, claiming that food aid would be diverted from civilians to militia groups. As a result of Malong’s orders, food supplies were blocked from crossing the Nile for at least two weeks.

Throughout his tenure as Chief of General Staff of the SPLA, Malong has been responsible for the SPLA and its allied forces’ perpetration of serious abuses including attacks on civilians, forced displacement, enforced disappearances, arbitrary detentions, torture, and rape. Under Malong’s leadership, the SPLA launched attacks directed against the civilian population and intentionally killed unarmed and fleeing civilians. In the Yei area alone, the UN documented 114 killings of civilians by the SPLA and its allied forces between July 2016 and January 2017. The SPLA intentionally attacked schools and hospitals. In April 2017, Malong allegedly ordered the SPLA to clear all people, including civilians from the area around Wau. Malong reportedly did not discourage the killing of civilians by the SPLA troops, and persons suspected of hiding rebels were considered legitimate targets.

According to a 15 October 2014 African Union Commission of Inquiry on South Sudan report, Malong was responsible for the mass mobilisation of Mathiang Anyoor Dinka tribal militia, which Ceasefire and Transitional Security Arrangements Monitoring Mechanism (CTSAMM) documented use child soldiers.

Under Malong’s leadership of the SPLA, the government forces regularly restricted United Nations Mission in South Sudan (UNMISS), Joint Monitoring and Evaluation Commission (JMEC), and CTSAMM’s access when they tried to investigate and document abuses. For example, on April 5, 2017, a joint UN and CTSAMM patrol tried to access Pajok but was turned back by SPLA soldiers.’

ANNEX II

The entries for the persons mentioned below are deleted in Annex II to Decision (CFSP) 2015/740:

- 1. Paul Malong;
 - 3. Malek Reuben Riak.
-

COUNCIL DECISION (CFSP) 2018/1126
of 10 August 2018
amending Decision 2013/184/CFSP concerning restrictive measures against Myanmar/Burma

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 29 thereof,

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

Whereas:

- (1) On 22 April 2013, the Council adopted Decision 2013/184/CFSP ⁽¹⁾ concerning restrictive measures against Myanmar/Burma.
- (2) On 25 June 2018, the Council adopted Decision (CFSP) 2018/900 ⁽²⁾, which added seven persons to the list of natural and legal persons, entities and bodies subject to restrictive measures in the Annex to Decision 2013/184/CFSP.
- (3) Updated information has been received for several listings.
- (4) The Annex to Decision 2013/184/CFSP should be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision 2013/184/CFSP is amended as set out in the Annex to this Decision.

Article 2

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

Done at Brussels, 10 August 2018.

For the Council
The President
G. BLÜMEL

⁽¹⁾ Council Decision 2013/184/CFSP of 22 April 2013 concerning restrictive measures against Myanmar/Burma and repealing Decision 2010/232/CFSP (OJ L 111, 23.4.2013, p. 75).

⁽²⁾ Council Decision (CFSP) 2018/900 of 25 June 2018 amending Decision 2013/184/CFSP concerning restrictive measures against Myanmar/Burma (OJ L 160 I, 25.6.2018, p. 9).

ANNEX

Entries 1, 3, 4 and 5 in the list of persons and entities set out in the Annex to Decision 2013/184/CFSP are replaced by the following entries:

	Name	Identifying information	Reasons	Date of listing
1.	Aung Kyaw Zaw	Date of birth: 20 August 1961 Passport No: DM000826 Date of issue: 22 November 2011 Date of expiry: 21 November 2021 Military identification number: BC 17444	Lieutenant General Aung Kyaw Zaw was the Commander of the Bureau of Special Operations No. 3 of the Myanmar Armed Forces (Tatmadaw) from August 2015 to the end of 2017. The Bureau of Special Operations No. 3 oversaw the Western Command and, in that context, Lieutenant General Aung Kyaw Zaw is responsible for the atrocities and serious human rights violations committed against the Rohingya population in Rakhine State by the Western Command during that period. These include unlawful killings, sexual violence and the systematic burning of Rohingya houses and buildings.	25.6.2018
3.	Than Oo	Date of birth: 12 October 1973 Military identification number: BC 25723	Brigadier General Than Oo is the Commander of the 99th Light Infantry Division of the Myanmar Armed Forces (Tatmadaw). In that context, he is responsible for the atrocities and serious human rights violations committed against the Rohingya population in Rakhine State in the second half of 2017 by the 99th Light Infantry Division. These include unlawful killings, sexual violence and the systematic burning of Rohingya houses and buildings.	25.6.2018
4.	Aung Aung	Military identification number: BC 23750	Brigadier General Aung Aung is the Commander of the 33rd Light Infantry Division of the Myanmar Armed Forces (Tatmadaw). In that context, he is responsible for the atrocities and serious human rights violations committed against the Rohingya population in Rakhine State in the second half of 2017 by the 33rd Light Infantry Division. These include unlawful killings, sexual violence and the systematic burning of Rohingya houses and buildings.	25.6.2018
5.	Khin Maung Soe		Brigadier General Khin Maung Soe is the Commander of the Military Operation Command 15, also sometimes known as the 15th Light Infantry Division, of the Myanmar Armed Forces (Tatmadaw), under which Infantry Battalion No. 564 falls. In that context, he is responsible for the atrocities and serious human rights violations committed against the Rohingya population in Rakhine State in the second half of 2017 by the Military Operation Command 15, in particular by Infantry Battalion No. 564. These include unlawful killings, sexual violence and the systematic burning of Rohingya houses and buildings.	25.6.2018'

