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Contents

[1] Text with EEA relevance.

EN

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

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

Corrigenda

[1] Text with EEA relevance.

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION (EU) 2017/1567

of 8 June 2017

on the signing, on behalf of the Union and of the Member States, and provisional application of the Protocol to the Partnership and Cooperation Agreement establishing a partnership between the European Communities and their Member States, of the one part, and the Republic of Uzbekistan, of the other part, to take account of the accession of the Republic of Croatia to the European Union

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91, Article 100(2) and Articles 207 and 209, in conjunction with Article 218(5) thereof,

Having regard to the Act of Accession of Croatia, and in particular Article 6(2) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) In accordance with Article 6(2) of the Act of Accession of Croatia, the accession of Croatia to the Partnership and Cooperation Agreement establishing a partnership between the European Communities and their Member States, of the one part, and the Republic of Uzbekistan, of the other part [1] ('the Agreement') is to be agreed by means of a protocol to the Agreement. In accordance with Article 6(2) of the Act of Accession, a simplified procedure is to apply to such accession, whereby a protocol is to be concluded by the Council, acting unanimously on behalf of the Member States, and by the third countries concerned.

(2) On 14 September 2012, the Council authorised the Commission to open negotiations with Uzbekistan for the adaptation of the Agreement. Negotiations for a protocol to the agreement ('the Protocol') were successfully concluded by exchange of *notes verbales*.

(3) As regards matters falling within the competence of the European Atomic Energy Community, the signature of the Protocol is subject to a separate procedure.

(4) Therefore, the Protocol should be signed on behalf of the Union and of the Member States, and should, in order to ensure its efficient application, be applied on a provisional basis, pending the completion of the procedures necessary for its entry into force,

HAS ADOPTED THIS DECISION:

Article 1

The signing on behalf of the Union and of the Member States of the Protocol to the Partnership and Cooperation Agreement establishing a partnership between the European Communities and their Member States, of the one part, and the Republic of Uzbekistan, of the other part, to take account of the accession of the Republic of Croatia to the European Union, is hereby authorised, subject to the conclusion of the said Protocol.

The text of the Protocol is attached to this Decision.

[1] Council and Commission Decision 1999/593/EC, ECSC, Euratom of 31 May 1999 on the conclusion of the Partnership and Cooperation Agreement establishing a partnership between the European Communities and their Member States, of the one part, and the Republic of Uzbekistan, of the other part (OJ L 229, 31.8.1999, p. 1).

Article 2

The President of the Council is hereby authorised to designate the person(s) empowered to sign the Protocol on behalf of the Union and of the Member States.

Article 3

The Protocol shall be applied provisionally, in accordance with Article 4(3) thereof, as from 1 July 2013, pending the completion of the procedures necessary for its entry into force.

Article 4

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

Done at Luxembourg, 8 June 2017.

For the Council
The President
K. SIMSON

PROTOCOL

to the Partnership and Cooperation Agreement establishing a partnership between the European Communities and their Member States, of the one part, and the Republic of Uzbekistan, of the other part, to take account of the accession of the Republic of Croatia to the European Union

THE KINGDOM OF BELGIUM,

THE REPUBLIC OF BULGARIA,

THE CZECH REPUBLIC,

THE KINGDOM OF DENMARK,

THE FEDERAL REPUBLIC OF GERMANY,

THE REPUBLIC OF ESTONIA,

IRELAND,

THE HELLENIC REPUBLIC,

THE KINGDOM OF SPAIN,

THE FRENCH REPUBLIC,

THE REPUBLIC OF CROATIA,

THE ITALIAN REPUBLIC,

THE REPUBLIC OF CYPRUS,

THE REPUBLIC OF LATVIA,

THE REPUBLIC OF LITHUANIA,

THE GRAND DUCHY OF LUXEMBOURG,

HUNGARY,

THE REPUBLIC OF MALTA,

THE KINGDOM OF THE NETHERLANDS,

THE REPUBLIC OF AUSTRIA,

THE REPUBLIC OF POLAND,

THE PORTUGUESE REPUBLIC,

ROMANIA,

THE REPUBLIC OF SLOVENIA,

THE SLOVAK REPUBLIC,

THE REPUBLIC OF FINLAND,

THE KINGDOM OF SWEDEN,

THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND

Contracting Parties to the Treaty on European Union, the Treaty on the Functioning of the European Union and the Treaty establishing the European Atomic Energy Community, hereinafter referred to as the 'Member States',

THE EUROPEAN UNION, hereinafter referered to as the 'Union', and

THE EUROPEAN ATOMIC ENERGY COMMUNITY

of the one part,

AND

THE REPUBLIC OF UZBEKISTAN

of the other part,

hereinafter referred to together as 'the Parties',

WHEREAS the Partnership and Cooperation Agreement establishing a partnership between the European Communities and their Member States, of the one part, and the Republic of Uzbekistan, of the other part, hereinafter referred to as 'the Agreement', was signed in Florence on 21 June 1996,

WHEREAS the Treaty of the Accession of the Republic of Croatia to the European Union was signed in Brussels on 9 December 2011,

WHEREAS, pursuant to Article 6(2) of the Act concerning the conditions of accession of the Republic of Croatia and the adjustments to the Treaty on European Union, the Treaty on the Functioning of the European Union and the Treaty establishing the European Atomic Energy Community, its accession to the Agreement is to be agreed by the conclusion of a protocol to the Agreement,

TAKING INTO ACCOUNT the accession of the Republic of Croatia to the Union and to the European Atomic Energy Community on 1 July 2013,

HAVE AGREED AS FOLLOWS:

Article 1

The Republic of Croatia shall accede to the Partnership and Cooperation Agreement establishing a partnership between the European Communities and their Member States, of the one part, and the Republic of Uzbekistan, of the other part, signed in Florence on 21 June 1996. The Republic of Croatia shall also adopt and take note of, in the same manner as the other Member States, the texts of the Agreement and of the Joint Declarations, Declarations and Exchanges of Letters annexed to the Final Act signed on the same date, as well as the Protocols signed in 2004, 2008 and 2011, which are integral parts of the Agreement.

Article 2

In due time after the signature of this Protocol, the Union shall communicate the text of the Agreement in the Croatian language to the Member States and to the Republic of Uzbekistan. Subject to the entry into force of this Protocol, the text referred to in the first sentence of this Article shall become authentic under the same conditions as Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish, Swedish and Uzbek texts of the Agreement.

Article 3

This Protocol shall form an integral part of the Agreement.

Article 4

1. This Protocol shall be approved by the Parties, in accordance with their own procedures, and the Parties shall notify one another of the completion of the procedures necessary for that purpose.

2. This Protocol shall enter into force on the first day of the month following the month during which the last notification provided for in paragraph 1 has been carried out.

3. Pending its entry into force, this Protocol shall apply provisionally with effect from 1 July 2013.

Article 5

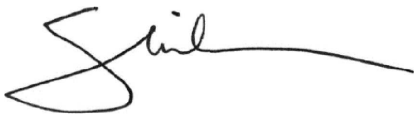
This Protocol shall be drawn up in duplicate in the Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish, Swedish and Uzbek languages, each text being equally authentic.

IN WITNESS WHEREOF, the undersigned Plenipotentiaries, duly empowered to this effect, have signed this Protocol.

Съставено в Брюксел на седемнадесети юли през две хиляди и седемнадесета година.
Hecho en Bruselas, el diecisiete de julio de dos mil diecisiete.
V Bruselu dne sedmnáctého července dva tisíce sedmnáct.
Udfærdiget i Bruxelles den syttende juli to tusind og sytten.
Geschehen zu Brüssel am siebzehnten Juli zweitausendsiebzehn.
Kahe tuhande seitsmeteistkümnenda aasta juulikuu seitsmeteistkümnendal päeval Brüsselis.
Έγινε στις Βρυξέλλες, στις δεκαεπτά Ιουλίου δύο χιλιάδες δεκαεπτά.
Done at Brussels on the seventeenth day of July in the year two thousand and seventeen.
Fait à Bruxelles, le dix-sept juillet deux mille dix-sept.
Sastavljeno u Bruxellesu sedamnaestog srpnja godine dvije tisuće sedamnaeste.
Fatto a Bruxelles, addì diciassette luglio duemiladiciassette.
Briselē, divi tūkstoši septiņpadsmitā gada septiņpadsmitajā jūlijā.
Priimta du tūkstančiai septynioliktų metų liepos septynioliktą dieną Briuselyje.
Kelt Brüsszelben, a kétezer-tizenhetedik év július havának tizenhetedik napján.
Magħmul fi Brussell, fis-sbatax-il jum ta' Lulju fis-sena elfejn u sbatax.
Gedaan te Brussel, zeventien juli tweeduizend zeventien.
Sporządzono w Brukseli dnia siedemnastego lipca roku dwa tysiące siedemnastego.
Feito em Bruxelas, em dezassete de julho de dois mil e dezassete.
Întocmit la Bruxelles la șaptesprezece iulie două mii șaptesprezece.
V Bruseli sedemnásteho júla dvetisícsedemnásť.
V Bruslju, dne sedemnajstega julija leta dva tisoč sedemnajst.
Tehty Brysselissä seitsemäntenätoista päivänä heinäkuuta vuonna kaksituhattaseitsemäntoista.
Som skedde i Bryssel den sjuttonde juli år tjugohundrasjutton.
Брюссель шаҳрида икки минг ўн еттинчи йилнинг ўн еттинчи июль санасида имзоланди.

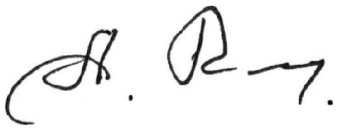
За Европейския съюз
Por la Unión Europea
Za Evropskou unii
For Den Europæiske Union
Für die Europäische Union
Euroopa Liidu nimel
Για την Ευρωπαϊκή Ένωση
For the European Union
Pour l'Union européenne
Za Europsku uniju
Per l'Unione europea
Eiropas Savienības vārdā –
Europos Sąjungos vardu
Az Európai Unió részéről
Għall-Unjoni Ewropea
Voor de Europese Unie
W imieniu Unii Europejskiej
Pela União Europeia
Pentru Uniunea Europeană
Za Európsku úniu
Za Evropsko unijo
Euroopan unionin puolesta
För Europeiska unionen
Европа Иттифоки номидан

За държавите-членки
Por los Estados miembros
Za členské státy
For medlemsstaterne
Für die Mitgliedstaaten
Liikmesriikide nimel
Για τα κράτη μέλη
For the Member States
Pour les États membres
Za države članice
Per gli Stati membri
Dalībvalstu vārdā –
Valstybių narių vardu
A tagállamok részéről
Għall-Istati Membri
Voor de lidstaten
W imieniu Państw Członkowskich
Pelos Estados-Membros
Pentru statele membre
Za členské štáty
Za države članice
Jäsenvaltioiden puolesta
För medlemsstaterna
Аъзо давлатлар номидан



За Европейската общност за атомна енергия
Por la Comunidad Europea de la Energía Atómica
Za Evropské společenství pro atomovou energii
For Det Europæiske Atomenergifællesskab
Für die Europäische Atomgemeinschaft
Euroopa Aatomienergiaühenduse nimel
Για την Ευρωπαϊκή Κοινότητα Ατομικής Ενέργειας
For the European Atomic Energy Community
Pour la Communauté européenne de l'énergie atomique
Za Europsku zajednicu za atomsku energiju
Per la Comunità europea dell'energia atomica
Eiropas Atomenerģijas Kopienas vārdā –
Europos atominės energijos bendrijos vardu
Az Európai Atomenergia-közösség részéről
F'isem il-Komunità Ewropea tal-Enerġija Atomika
Voor de Europese Gemeenschap voor Atoomenergie
W imieniu Europejskiej Wspólnoty Energii Atomowej
Pela Comunidade Europeia da Energia Atómica
Pentru Comunitatea Europeană a Energiei Atomice
Za Európske spoločenstvo pre atómovú energiu
Za Evropsko skupnost za atomsko energtjo
Euroopan atomienergiajärjestön puolesta
För Europeiska atomenergigemenskapen
Европа Атом Энергияси Ҳамжамияти номидан

За Република Узбекистан
Por la República de Uzbekistán
Za Republiku Uzbekistán
For Republikken Usbekistan
Für die Republik Usbekistan
Usbekistani Vabariigi nimel
Για τη Δημοκρατία του Ουζμπεκιστάν
For the Republic of Uzbekistan
Pour la République d'Ouzbékistan
Za Republiku Uzbekistan
Per la Repubblica dell'Uzbekistan
Uzbekistānas Republikas vārdā –
Uzbekistano Respublikos vardu
Az Üzbeg Köztársaság részéről
Għar-Repubblika tal-Użbekistan
Voor de Republiek Oezbekistan
W imieniu Republiki Uzbekistanu
Pela República do Usbequistão
Pentru Republica Uzbekistan
Za Uzbeckú republiku
Za Republiko Uzbekistan
Uzbekistanin tasavallan puolesta
För Republiken Uzbekistan
Ўзбекистон Республикаси номидан



Information relating to the entry into force of the Protocol to the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and Bosnia and Herzegovina, of the other part, to take account of the accession of the Republic of Croatia to the European Union

As the procedures necessary for the entry into force of the abovementioned Protocol have been completed on 7 September 2017, this Protocol enters into force on 1 October 2017, in accordance with its Article 8(1).

Notice concerning the provisional application of the Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part

The Comprehensive Economic and Trade Agreement (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part [1], signed in Brussels on 30 October 2016, shall, pursuant to its Article 30.7.3, be provisionally applied as from 21 September 2017. By virtue of Article 1(1) of the Council Decision of 28 October 2016 on the provisional application of the Agreement, the EU does apply provisionally the Agreement, pending the completion of the procedures for its conclusion, subject to the following points:

(a) only the following provisions of Chapter Eight of the Agreement (Investment) shall be provisionally applied, and only in so far as foreign direct investment is concerned:

— Articles 8.1 to 8.8,

— Article 8.13,

— Article 8.15, with the exception of paragraph 3 thereof, and

— Article 8.16;

(b) the following provisions of Chapter Thirteen of the Agreement (Financial Services) shall not be provisionally applied in so far as they concern portfolio investment, protection of investment or the resolution of investment disputes between investors and States:

— Paragraphs 3 and 4 of Article 13.2,

— Article 13.3 and Article 13.4,

— Article 13.9, and

— Article 13.21;

(c) the following provisions of the Agreement shall not be provisionally applied:

— Article 20.12,

— Article 27.3 and Article 27.4, to the extent that those Articles apply to administrative proceedings, review and appeal at Member State level,

— Paragraph 7 of Article 28.7;

(d) the provisional application of Chapters 22, 23 and 24 of the Agreement shall respect the allocation of competences between the Union and the Member States.

[1] OJ L 11, 14.1.2017, p. 23.

REGULATIONS

COUNCIL IMPLEMENTING REGULATION (EU) 2017/1568

of 15 September 2017

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

THE COUNCIL OF THE EUROPEAN UNION,

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

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

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

Whereas:

(1) On 30 August 2017, the Council adopted Regulation (EU) 2017/1509.

(2) On 11 September 2017 the United Nations Security Council adopted Resolution 2375 (2017), which added 1 person and 3 entities to the list of persons and entities subject to restrictive measures.

(3) Annex XIII to Regulation (EU) 2017/1509 should therefore be amended accordingly,

HAS ADOPTED THIS REGULTION:

Article 1

Annex XIII to Regulation (EU) 2017/1509 shall be amended as set out in the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 15 September 2017.

For the Council
The President
M. MAASIKAS

([1]) OJ L 224, 31.8.2017, p. 1.

ANNEX

The persons and entities listed below shall be added to the list of persons and entities subject to restrictive measures set out in Annex XIII to Regulation (EU) 2017/1509.

(a) **Natural persons**

	Name	Alias	Identifiers	Date of UN designation	Statement of Reasons
63.	Pak Yon Sik		Nationality: DPRK YOB: 1950	11.9.2017	Member of the Workers' Party of Korea Central Military Commission, which is responsible for the development and implementation of the Workers' Party of Korea military policies, commands and controls the DPRK's military, and helps direct the country's military defence industries.

(b) **Legal persons, entities and bodies**

	Name	Alias	Location	Date of UN designation	Other information
51.	Central Military Commission of the Worker's Party of Korea (CMC)		Pyongyang, DPRK	11.9.2017	The Central Military Commission is responsible for the development and implementation of the Workers' Party of Korea's military policies, commands and controls the DPRK's military, and directs the country's military defence industries in coordination with the State Affairs Commission.
52.	Organization and Guidance Department (OGD)		DPRK	11.9.2017	The Organization and Guidance Department is a very powerful body of the Worker's Party of Korea. It directs key personnel appointments for the Workers' Party of Korea, the DPRK's military, and the DPRK's government administration. It also purports to control the political affairs of all of the DPRK and is instrumental in implementing the DPRK's censorship policies.
53.	Propaganda and Agitation Department (PAD)		Pyongyang, DPRK	11.9.2017	The Propaganda and Agitation Department has full control over the media, which it uses as a tool to control the public on behalf of the DPRK leadership. The Propaganda and Agitation Department also engages in or is responsible for censorship by the Government of the DPRK, including newspaper and broadcast censorship.

COMMISSION DELEGATED REGULATION (EU) 2017/1569

of 23 May 2017

supplementing Regulation (EU) No 536/2014 of the European Parliament and of the Council by specifying principles of and guidelines for good manufacturing practice for investigational medicinal products for human use and arrangements for inspections

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC [1], and in particular Article 63(1) thereof,

Whereas:

(1) The good manufacturing practice for investigational medicinal products for human use ensures that there is consistency between batches of the same investigational medicinal product used in the same or different clinical trials, and that changes during the development of an investigational medicinal product are adequately documented and justified. The manufacturing of investigational medicinal products presents additional challenges comparing to the manufacturing of authorised medicinal products because there are no fixed routines, there is a variety of clinical trial designs and consequently packaging designs. Those challenges are due to the need, often, of randomisation and to disguise the identity of the investigational medicinal products for the purpose of clinical trial (blinding). The toxicity, potency and sensitising potential of investigational medicinal products for human use may not be fully understood at the time of the trial, and the need to minimise all risks of cross-contamination is therefore of even greater importance than for authorised medicinal products. Because of this complexity, the manufacturing operations should be subject to a highly effective pharmaceutical quality system.

(2) Good manufacturing practice as regards both medicinal products authorised to be placed on the market and investigational medicinal products are based on the same principles. The same manufacturing sites will often manufacture both investigational and medicinal products authorised to be placed on the market. For that reason the principles and guidelines of good manufacturing practice for investigational medicinal products for human use should be aligned as much as possible with those applicable to medicinal products for human use.

(3) In accordance with Article 61(5) of Regulation (EU) No 536/2014 certain processes do not require the authorisation referred to in Article 61(1) of that Regulation. In line with Article 63(2) of Regulation (EU) No 536/2014 good manufacturing practice for investigational medicinal products does not apply to those processes.

(4) For the manufacturer to be able to comply with good manufacturing practice for investigational medicinal products, cooperation between the manufacturer and the sponsor is necessary. Likewise, for the sponsor to comply with the requirements of Regulation (EU) No 536/2014 cooperation with the manufacturer is necessary. Where the manufacturer and the sponsor are different legal entities, the obligations of the manufacturer and sponsor vis-à-vis each other should be specified in a technical agreement between them. Such an agreement should provide for the sharing of inspection reports and exchange of information on quality issues.

(5) Investigational medicinal products imported into the Union should be manufactured by applying quality standards at least equivalent to those in the Union. For this reason, only products manufactured by a third country manufacturer that is entitled or authorised to do so in accordance with the laws of the country where the manufacturer is located, should be allowed to be imported into the Union.

(6) All manufacturers should operate an effective quality assurance system of their manufacturing or import operations. Such a system in order to be effective requires the implementation of a pharmaceutical quality

[1] OJ L 158, 27.5.2014, p. 1.

system. Good documentation constitutes an essential part of a quality assurance system. The documentation system of manufacturers shall enable the history of the manufacture of each batch and any changes introduced during the development of an investigational medicinal product to be traced.

(7) Principles and guidelines of good manufacturing practice for investigational medicinal products should be set out in relation to quality management, personnel, premises, equipment, documentation, production, quality control, outsourced operations, complaints and recall, and self-inspections.

(8) It is appropriate to require a product specification file which brings together and contain all of the essential reference documents to ensure that investigational medicinal products are manufactured according to good manufacturing practice for investigational medicinal products and the clinical trial authorisation.

(9) Due to the special characteristics of advanced therapy investigational medicinal products, the provisions on good manufacturing practice should be adapted to those products in accordance with a risk-based approach. As regards the advanced therapy medicinal products marketed in the Union, Article 5 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council [1] provides for such adaptation. The Commission guidelines referred to in Article 5 of Regulation (EC) No 1394/2007 should also set out the requirements on good manufacturing practice applicable to advanced therapy investigational medicinal products.

(10) In order to ensure conformity with the principles and guidelines of good manufacturing practice for investigational medicinal products, provisions on inspections by the competent authorities of the Member States should be established. Member States should not be obliged to inspect third country manufacturers of investigational medicinal products routinely. The need for such inspections should be established according to a risk-based approach but third country manufacturers should be inspected at least if there is a suspicion that the investigational medicinal products are not manufactured by applying quality standards at least equivalent to those applicable in the Union.

(11) Inspectors should consider the Commission guidelines on good manufacturing practice for investigational medicinal products for human use. To achieve and maintain mutual recognition of inspection findings in the Union and facilitate the cooperation of the Member States, commonly recognised standards on the conduct of inspections on good manufacturing practice for investigational medicinal products in the form of procedures should be developed. The Commission guidelines and these procedures should be maintained and regularly updated, according to technical and scientific developments.

(12) During inspections of a site the inspectors should check whether a site respects good manufacturing practice as regards both investigational medicinal products and medicinal products authorised to be placed on the market. For that reason, and in order to ensure the effective supervision, procedures and powers to carry out inspections to verify that good manufacturing practice for investigational medicinal products for human use is followed should be aligned as much as possible to those for medicinal products for human use.

(13) To ensure that inspections are effective, inspectors should be appropriately empowered.

(14) Member States should be able to take action in case of non-compliance with good manufacturing practice for investigational medicinal products for human use.

(15) The competent authorities should be required to set up quality systems to ensure that the inspection procedures are observed and consistently monitored. A well-functioning quality system should comprise an organisational structure, clear processes and procedures, including standard operating procedures to be followed by inspectors when performing their tasks, clearly defined details of the inspectors' duties and responsibilities and ongoing training requirements, as well as adequate resources and mechanisms which aim to eliminate non-compliance.

(16) This Regulation should apply from the same date as Commission Directive (EU) 2017/1572 [2],

[1] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).

[2] Commission Directive (EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use (See page 44 of this Official Journal).

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation specifies the principles and guidelines of good manufacturing practice for investigational medicinal products for human use the manufacture or import of which requires an authorisation as referred to in Article 61(1) of Regulation (EU) No 536/2014 and lays down arrangements for inspections of manufacturers in relation to compliance with good manufacturing practice in accordance with Article 63(4) of that Regulation.

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) 'manufacturer' means any person engaged in activities for which an authorisation is required in accordance with Article 61(1) of Regulation (EU) No 536/2014;

(2) 'third country manufacturer' means any person established in a third country and engaged in manufacturing operations in that third country;

(3) 'product specification file' means a reference file containing, or referring to files containing, all the information necessary to draft detailed written instructions on processing, packaging, quality control, testing and batch release of an investigational medicinal product and to perform batch certification;

(4) 'validation' means action of proving, in accordance with the principles of good manufacturing practice, that any procedure, process, equipment, material, activity or system actually leads to the expected results.

CHAPTER II

GOOD MANUFACTURING PRACTICE

Article 3

Conformity with good manufacturing practice

1. The manufacturer shall ensure that manufacturing operations are carried out in accordance with good manufacturing practice for investigational medicinal products specified in this Regulation and subject to an authorisation as referred to in Article 61(1) of Regulation (EU) No 536/2014.

2. When importing an investigational medicinal products, the holder of the authorisation referred to in Article 61(1) of Regulation (EU) No 536/2014 shall ensure that the products have been manufactured by applying quality standards at least equivalent to those laid down by this Regulation and in Regulation (EU) No 536/2014, and that the third country manufacturer is authorised or entitled to in accordance with the laws of that country to manufacture that investigational medicinal products in that third country.

Article 4

Compliance with clinical trial authorisation

1. The manufacturer shall ensure that all manufacturing operations for investigational medicinal products are carried out in accordance with the documentation and information provided by the sponsor pursuant to Article 25 of Regulation (EU) No 536/2014 and as authorised in accordance with the procedure laid down in Chapter II, or if documentation and information was subsequently amended, in Chapter III of abovementioned Regulation (EU) No 536/2014.

2. The manufacturer shall regularly review his manufacturing methods in the light of scientific and technical progress and experience gained by the sponsor during the development of the investigational medicinal product.

The manufacturer shall inform the sponsor of his reviews of the manufacturing methods.

Where, following a review, an amendment to the clinical trial authorisation is necessary, the application for the amendment shall be submitted in accordance with Article 16 of Regulation (EU) No 536/2014 where the change to the clinical trial is a substantial modification or the amendment shall be carried out in accordance with Article 81(9) of that Regulation where the change to the clinical trial is not a substantial modification.

Article 5

Pharmaceutical quality system

1. The manufacturer shall establish, implement and maintain effective organised arrangements to ensure that the investigational medicinal products are of the quality required for their intended use. Those arrangements shall include the establishment of a good manufacturing practice and a quality control.

2. Senior management and personnel from different departments shall participate in the establishment of the pharmaceutical quality system.

Article 6

Personnel

1. At each manufacturing site, the manufacturer shall have a sufficient number of competent and appropriately qualified personnel at his disposal to ensure that the investigational medicinal products are of the quality required for their intended use.

2. The duties of managerial and supervisory staff, including the qualified persons, responsible for implementing and operating good manufacturing practice shall be set out in their job descriptions. Their hierarchical relationships shall be set out in an organisation chart. The organisation chart and the job descriptions shall be approved in accordance with the manufacturer's internal procedures.

3. The staff referred to in paragraph 2 shall be given sufficient authority to discharge their responsibility correctly.

4. The personnel shall receive initial and ongoing training covering in particular the following areas:

(a) the theory and application of the concept of pharmaceutical quality;

(b) good manufacturing practice.

The manufacturer shall verify the effectiveness of the training.

5. The manufacturer shall establish hygiene programmes, including procedures relating to health, hygiene practice and clothing of personnel. The programmes shall be adapted to the manufacturing operations to be carried out. The manufacturer shall ensure that the programmes are observed.

Article 7

Premises and equipment

1. The manufacturer shall ensure that premises and manufacturing equipment are located, designed, constructed, adapted and maintained to suit the intended operations.

2. The manufacturer shall ensure that the premises and manufacturing equipment are laid out, designed and operated in such a way as to minimise risk of error and permit effective cleaning and maintenance in order to avoid contamination, cross contamination and any other adverse effect on the quality of the investigational medicinal product.

3. The manufacturer shall ensure that those premises and equipment to be used for manufacturing operations which are critical to the quality of the investigational medicinal products are subjected to appropriate qualification and validation.

Article 8

Documentation

1. The manufacturer shall establish and maintain a documentation system recording the following, where appropriate having regard to the activities undertaken:

(a) specifications;

(b) manufacturing formulae;

(c) processing and packaging instructions;

(d) procedures and protocols, including procedures for general manufacturing operations and conditions;

(e) records, in particular covering the various manufacturing operations performed and batch records;

(f) technical agreements;

(g) certificates of analysis;

The documents specific to any investigational medicinal product shall be consistent with the product specification file as relevant.

2. The documentation system shall ensure the data quality and integrity. Documents shall be clear, free from error and kept up to date.

3. The manufacturer shall retain the product specification file and batch documentation for at least five years after the completion or discontinuation of the last clinical trial in which the batch was used.

4. When documentation is stored using electronic, photographic or other data processing systems, the manufacturer shall first validate the systems to ensure that the data will be appropriately stored during the period of storage laid down in paragraph 3. Data stored by those systems shall be made readily available in readable form.

5. The electronically stored data shall be protected against unlawful access, loss or damage of data by techniques such as duplication, back-up and transfer onto another storage system. Audit trails, meaning records of all relevant changes and deletions in those data, shall be maintained.

6. The documentation shall be provided to competent authority upon request.

Article 9

Production

1. The manufacturer shall carry out production operations in accordance with pre-established instructions and procedures.

The manufacturer shall ensure that adequate and sufficient resources are made available for the in-process controls and that all process deviations and product defects are documented and thoroughly investigated.

2. The manufacturer shall take appropriate technical or organisational measures to avoid cross contamination and unintentional mixing of substances. Particular attention shall be paid to the handling of investigational medicinal products during and after any blinding operation.

3. The manufacturing process shall be validated in its entirety, as far as is appropriate, taking into account the stage of product development.

The manufacturer shall identify the process steps that ensure the safety of the subject, such as sterilisation, and the reliability and robustness of the clinical trial data generated in the clinical trial. Those critical process steps shall be validated and regularly re-validated.

All steps in the design and development of the manufacturing process shall be fully documented.

Article 10

Quality control

1. The manufacturer shall establish and maintain a quality control system under the authority of a person who has the requisite qualifications and is independent of production.

That person shall have access to one or more quality control laboratories appropriately staffed and equipped to carry out the examination and testing of starting materials and packaging materials and the testing of intermediate and finished investigational medicinal products.

2. The manufacturer shall ensure that the quality control laboratories comply with information provided in the application dossier, referred to in Article 25(1) of Regulation (EU) No 536/2014, as authorised by Member States.

3. When investigational medicinal products are imported from third countries, analytical control in the Union shall not be mandatory.

4. During the final control of the finished investigational medicinal product, and before its release by the manufacturer, the manufacturer shall take into account:

(a) analytical results;

(b) production conditions;

(c) the results of in-process controls;

(d) the examination of the manufacturing documents;

(e) the conformity of the product with its specifications;

(f) conformity of the product with the clinical trial authorisation;

(g) examination of the final finished packaging.

Article 11

Retention of samples used for quality control

1. The manufacturer shall retain sufficient samples of each batch of bulk formulated product, of key packaging components used for each finished investigational medicinal product batch and of each batch of finished investigational medicinal product for at least two years after the completion or discontinuation of the last clinical trial in which the batch was used.

Samples of starting materials, other than solvents, gases or water, used in the manufacturing process shall be retained by the manufacturer for at least two years after the release of the investigational medicinal product. However, this period may be shortened where the period of stability of the starting material, as indicated in the relevant specification, is shorter.

In all cases samples shall be maintained by the manufacturer at the disposal of the competent authority.

2. Upon application of the manufacturer, the competent authority may grant a derogation from paragraph 1 in relation to the sampling and retention of starting material and for certain products manufactured individually or in small quantities, or when their storage could raise special problems.

Article 12

Responsibilities of the qualified person

1. The qualified person referred to in Article 61(2)(b) of Regulation (EU) No 536/2014 shall be responsible for the following:

(a) where investigational medicinal products are manufactured in the Member State concerned, verifying that each production batch has been manufactured and checked in compliance with the requirements of good manufacturing practice for investigational medicinal products laid down in this Regulation and the information provided pursuant to Article 25 of Regulation (EU) No 536/2014, taking into account the guidelines referred to in Article 63(1) of that Regulation;

(b) where investigational medicinal products are manufactured in a third country, verifying that each production batch has been manufactured and checked in accordance with quality standards at least equivalent to those laid down in this Regulation and the information provided pursuant to Article 25 of Regulation (EU) No 536/2014 taking into account the guidelines referred to in Article 63(1) of that Regulation.

The qualified person shall certify in a register or equivalent document provided for that purpose that each production batch complies with the requirements laid down in paragraph 1.

2. The register or equivalent document shall be kept up to date as operations are carried out and shall remain at the disposal of the competent authority for at least five years after the completion of or the formal discontinuation of the last clinical trial in which the product batch was used.

Article 13

Outsourced operations

1. Where a manufacturing operation or operation linked thereto is outsourced, the outsourcing shall be the subject of a written contract.

2. The contract shall clearly lay down the responsibilities of each party. It shall lay down an obligation for the party to whom the operations are outsourced to follow good manufacturing practice and set out the manner in which the qualified person responsible for certifying each batch is to discharge his responsibilities.

3. The party to whom the operations are outsourced shall not subcontract any of the operations entrusted to him under the contract without written consent from the contract giver.

4. The party to whom the operations are outsourced shall comply with the principles and guidelines of good manufacturing practice applicable to the operations concerned and shall submit to inspections carried out by the competent authority pursuant to Article 63(4) of Regulation (EU) No 536/2014.

Article 14

Complaints, product recall and emergency unblinding

1. The manufacturer shall, in cooperation with the sponsor, implement a system for recording and reviewing complaints together with an effective system for recalling investigational medicinal products which have already entered the distribution network promptly and at any time. The manufacturer shall record and investigate any complaint concerning a defect and shall inform the sponsor and the competent authority of the Member States concerned of any defect that could result in a recall or abnormal restriction on supply.

All trial sites shall be identified and, in so far as possible, the countries of destination shall be indicated.

In the case of an authorised investigational medicinal product, the manufacturer shall, in cooperation with the sponsor, inform the marketing authorisation holder of any defect that could be related to that product.

2. Where blinding of investigational medicinal products is required by the protocol of a clinical trial, the manufacturer in conjunction with the sponsor shall implement a procedure for the rapid unblinding of blinded products, where this is necessary for a prompt recall as referred to in paragraph 1. The manufacturer shall ensure that the procedure discloses the identity of the blinded product only in so far as it is necessary.

Article 15

Self-inspection by the manufacturer

The manufacturer shall conduct regular inspections as part of the pharmaceutical quality system in order to monitor the implementation and respect of good manufacturing practice. He shall take any necessary corrective action and to put in place any necessary preventive measures.

The manufacturer shall maintain records of all such inspections and any corrective action or preventive measures subsequently taken.

Article 16

Advanced therapy investigational medicinal products

The good manufacturing principles shall be adapted to the specific characteristics of the advanced therapy medicinal products when used as investigational medicinal products. Investigational medicinal products, which are at the same time advanced therapy medicinal products, shall be manufactured in accordance with the guidelines referred to in Article 5 of Regulation (EC) No 1394/2007.

CHAPTER III

INSPECTIONS

Article 17

Supervision by inspection

1. By means of regular inspections as referred to in Article 63(4) of Regulation (EU) No 536/2014 the Member State shall ensure that holders of an authorisation as referred to in Article 61(1) of that Regulation comply with the principles of good manufacturing practice laid down in this Regulation and takes into account the guidelines referred in second subparagraph of Article 63(1) of Regulation (EU) No 536/2014.

2. Without prejudice to any arrangements which may have been concluded between the Union and third countries, a competent authority may require a third country manufacturer to submit to an inspection as referred to in Article 63(4) of Regulation (EU) No 536/2014 and this Regulation. This Regulation applies *mutatis mutandis* to such inspections in third countries.

3. Member States shall carry out inspections of third country manufacturers to ensure that investigational medicinal products imported into the Union are manufactured by applying quality standards at least equivalent to those laid down in the Union.

The Member States are not obliged to routinely inspect third country manufacturers of investigational medicinal products. The necessity of such inspections shall be based on an assessment of risk, but shall take place at least if the Member States have grounds for suspecting that the quality standards applied to the manufacture of the investigational medicinal products imported into the Union are lower than those laid down in this Regulation and in the guidelines referred to in the second subparagraph of Article 63(1) of Regulation (EU) No 536/2014.

4. Inspections may, if necessary, be unannounced.

5. Following an inspection, an inspection report shall be drawn up by the inspector. Before the report is adopted by competent authority, the manufacturer shall be afforded an opportunity to submit comments in relation to the findings of the report.

6. Where the findings of the final report show that the manufacturer complies with the good manufacturing practice for investigational medicinal products, the competent authority shall within a period of 90 days of the inspection issue a certificate of good manufacturing practice to the manufacturer.

7. The competent authority shall enter the certificate of good manufacturing practice which they issue into the Union database referred to in Article 111(6) of Directive 2001/83/EC of the European Parliament and of the Council ([1]).

8. Where the outcome of the inspection is that the manufacturer does not comply with good manufacturing practice for investigational medicinal products, the competent authority shall enter this information into the Union database referred to in Article 111(6) of Directive 2001/83/EC.

9. The competent authority shall, upon receipt of reasoned request, send the inspection reports referred to in paragraph 5 electronically to the competent authorities of other Member States or to the European Medicines Agency ('the Agency').

10. The competent authority shall enter the information relating to the authorisation referred to in Article 61(1) of Regulation (EU) No 536/2014 in the Union database referred to in Article 111(6) of Directive 2001/83/EC.

Article 18

Cooperation and coordination of inspections

The competent authorities shall cooperate with each other and with the Agency in relation to inspections. They shall share information with the Agency on both inspections planned and conducted.

Article 19

Recognition of inspection conclusions

1. The conclusions reached in the inspection report referred to in Article 17(5) shall be valid throughout the Union.

However, in exceptional cases, where a competent authority is unable, for reasons relating to public health, to recognise the conclusions reached following an inspection under Article 63(4) of Regulation (EU) No 536/2014, that competent authority shall forthwith inform the Commission and the Agency. The Agency shall inform the other competent authorities concerned.

2. When the Commission is informed in accordance with the second subparagraph of paragraph 1, it may, after consulting the competent authority which was unable to accept the report, request the inspector who performed the inspection to perform a new inspection. The inspector may be accompanied by two inspectors from other competent authorities which are not parties to the disagreement.

([1]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

Article 20

Empowerments of the inspectors

1. The competent authority shall provide inspectors with suitable means of their identification.

2. Inspectors shall be empowered to:

(a) enter and inspect the premises of the manufacturer and quality control laboratories having carried out checks pursuant to Article 10 for the manufacturer;

(b) take samples, including for independent tests to be carried out by an Official Medicines Control Laboratory or a laboratory designated for that purpose by the Member State, and

(c) examine any documents relating to the object of inspection, make copies of records or printed documents, print electronic records and take photographs of the premises and equipment of the manufacturer.

Article 21

Competence and obligations of the inspectors

1. The competent authority shall ensure that the inspectors possess adequate qualifications, experience and knowledge. In particular, the inspectors shall have the following:

(a) experience and knowledge of the inspection process;

(b) the ability to make professional judgements as to the compliance with the requirements of good manufacturing practice;

(c) ability to apply the principles of quality risk management;

(d) knowledge of current technologies relevant for inspections;

(e) knowledge of the current technologies for the manufacture of the investigational medicinal products.

2. Information acquired as a result of inspections shall remain confidential.

3. The competent authorities shall ensure that inspectors receive the training necessary to maintain or improve their skills. Their training needs shall be assessed regularly by the persons appointed for that task.

4. The competent authority shall document the qualifications, training and experience of each inspector. Those records shall be kept up to date.

Article 22

Quality system

1. The competent authorities shall establish, implement and comply with a properly designed quality system for their inspectors. The quality system shall be updated as appropriate.

2. Each inspector shall be informed of the standard operating procedures and of his duties, responsibilities and ongoing training requirements. Those procedures shall be kept up to date.

Article 23

Impartiality of inspectors

The competent authority shall ensure that inspectors are free of any undue influence that could affect their impartiality and judgment.

Inspectors shall be independent, in particular, of:

(a) the sponsor;

(b) the management and personnel of the clinical trial site;

(c) the investigators involved in the clinical trials where the investigational medicinal products manufactured by the inspected manufacturer are used;

(d) the persons financing the clinical trial in which the investigational medicinal product is used;

(e) the manufacturer.

Inspectors shall make an annual declaration of their financial interests in the parties inspected or other links to them. The competent authority shall take the declaration into consideration when assigning inspectors to specific inspections.

Article 24

Access to premises

The manufacturer shall allow inspectors access to his premises and documentation at all times.

Article 25

Suspension or revocation of manufacturing authorisation

If an inspection reveals that the holder of an authorisation as referred to in Article 61(1) of Regulation (EU) No 536/2014 fails to comply with good manufacturing practice as set out in Union law, the competent authority may, with regard to this manufacturer, suspend manufacture or imports from third countries of investigational medicinal products for human use, or suspend or revoke the authorisation for a category of preparations or all preparation.

CHAPTER IV

FINAL PROVISIONS

Article 26

Transitional provision

The Member States may continue to apply national transposition measures adopted under Commission Directive 2003/94/EC ([1]) to the manufacture of investigational medicinal products used in clinical trials governed by Directive 2001/20/EC of the European Parliament and of the Council ([2]) in accordance with the transitional provisions laid down in Article 98 of Regulation (EU) No 536/2014.

Article 27

Entry into force

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

It shall apply from six months after the date of publication in the *Official Journal of the European Union* of the notice referred to in Article 82(3) of Regulation (EU) No 536/2014 or 1 April 2018, whichever is the later.

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

Done at Brussels, 23 May 2017.

For the Commission
The President
Jean-Claude JUNCKER

([1]) Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (OJ L 262, 14.10.2003, p. 22).
([2]) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1570

of 15 September 2017

amending Implementing Regulation (EU) 2017/366 and Implementing Regulation (EU) 2017/367 imposing definitive countervailing and anti-dumping duties on imports of crystalline silicon photovoltaic modules and key components (i.e. cells) originating in or consigned from the People's Republic of China and repealing Implementing Decision 2013/707/EU confirming the acceptance of an undertaking offered in connection with the anti-dumping and anti-subsidy proceedings concerning imports of crystalline silicon photovoltaic modules and key components (i.e. cells) originating in or consigned from the People's Republic of China for the period of application of definitive measures

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]) ('the basic anti-dumping Regulation'), and in particular Article 11(3) and Article 8(9) thereof,

Having regard to Regulation (EU) 2016/1037 of the European Parliament and of the Council of 8 June 2016 on protection against subsidised imports from countries not members of the European Union ([2]) ('the basic anti-subsidy Regulation'), and in particular Article 19 and Article 13(9) thereof,

Whereas:

1. PROCEDURE

1.1. Measures in force

(1) By Regulation (EU) No 1238/2013 ([3]) the Council imposed a definitive anti-dumping duty on imports of crystalline silicon photovoltaic modules and key components (i.e. cells) originating in or consigned from the People's Republic of China (or 'PRC') (the original anti-dumping investigation). The measures took the form of an *ad valorem* duty ranging between 27,3 % and 64,9 %.

(2) By Regulation (EU) No 1239/2013 ([4]), the Council imposed definitive countervailing duties up to 11,5 % on imports of crystalline silicon photovoltaic modules and key components (i.e. cells) originating in or consigned from the People's Republic of China (the original anti-subsidy investigation).

(3) The China Chamber of Commerce for Import and Export of Machinery and Electronic Products ('CCCME') submitted, on behalf of a group of exporting producers, a price undertaking to the Commission. By Decision 2013/423/EU ([5]), the Commission accepted that price undertaking with regard to the provisional anti-dumping duty. Following the notification of an amended version of the price undertaking by a group of exporting producers together with the CCCME, the Commission confirmed by Implementing Decision 2013/707/EU ([6]) the

([1]) OJ L 176, 30.6.2016, p. 21.
([2]) OJ L 176, 30.6.2016, p. 55.
([3]) Council Implementing Regulation (EU) No 1238/2013 of 2 December 2013 imposing a definitive anti-dumping duty and collecting definitively the provisional duty imposed on imports of crystalline silicon photovoltaic modules and key components (i.e. cells) originating in or consigned from the People's Republic of China (OJ L 325, 5.12.2013, p. 1).
([4]) Council Implementing Regulation (EU) No 1239/2013 of 2 December 2013 imposing a definitive countervailing duty on imports of crystalline silicon photovoltaic modules and key components (i.e. cells) originating in or consigned from the People's Republic of China (OJ L 325, 5.12.2013, p. 66).
([5]) Commission Decision 2013/423/EU of 2 August 2013 accepting an undertaking offered in connection with the anti-dumping proceeding concerning imports of crystalline silicon photovoltaic modules and key components (i.e. cells and wafers) originating in or consigned from the People's Republic of China (OJ L 209, 3.8.2013, p. 26).
([6]) Commission Implementing Decision 2013/707/EU of 4 December 2013 confirming the acceptance of an undertaking offered in connection with the anti-dumping and anti-subsidy proceedings concerning imports of crystalline silicon photovoltaic modules and key components (i.e. cells) originating in or consigned from the People's Republic of China for the period of application of definitive measures (OJ L 325, 5.12.2013, p. 214).

acceptance of the price undertaking as amended for the period of application of anti-dumping and countervailing definitive measures. The Commission also adopted a Decision clarifying the implementation of the undertaking ([7]) and 11 Regulations withdrawing the acceptance of the undertaking for several exporting producers ([8]).

(4) By Implementing Regulation (EU) 2016/12 ([9]), following a partial interim review limited in scope to the benchmark used as a reference for the price adaption mechanism set out in the above undertaking, the Commission terminated the partial interim review without amending the measures.

(5) By Implementing Regulations (EU) 2016/185 ([10]) and (EU) 2016/184 ([11]), the Commission extended the definitive anti-dumping and countervailing duties on imports of crystalline silicon photovoltaic modules and key components (i.e. cells) originating in or consigned from the People's Republic of China to imports of crystalline silicon photovoltaic modules and key components (i.e. cells) consigned from Malaysia and Taiwan with the exception of a number of genuine producers.

(6) By Implementing Regulation (EU) 2017/367 ([12]) the Commission extended the definitive anti-dumping duty on imports of crystalline silicon photovoltaic modules and key components (i.e. cells) originating in or consigned from the People's Republic of China following an expiry review pursuant to Article 11(2) of the basic anti-dumping Regulation and terminated the partial interim review investigation pursuant to Article 11(3) of the basic anti-dumping Regulation ('expiry review anti-dumping investigation').

(7) By Implementing Regulation (EU) 2017/366 ([13]) the Commission extended a definitive countervailing duty on imports of crystalline silicon photovoltaic modules and key components (i.e. cells) originating in or consigned from the People's Republic of China following an expiry review pursuant to Article 18(2) of the basic anti-subsidy Regulation and terminated the partial interim review investigation pursuant to Article 19(3) of the basic anti-subsidy Regulation (expiry review anti-subsidy investigation) (the expiry review anti-dumping investigation and the expiry review anti-subsidy investigation are hereinafter commonly referred as 'expiry review investigations').

(8) By Implementing Decision (EU) 2017/615 ([14]), the Commission accepted the proposal from the exporting producers to maintain the minimum import price ('MIP') at the level applicable in March 2017.

([7]) Commission Implementing Decision 2014/657/EU of 10 September 2014 accepting a proposal by a group of exporting producers together with the China Chamber of Commerce for Import and Export of Machinery and Electronic Products for clarifications concerning the implementation of the undertaking referred to in Implementing Decision 2013/707/EU (OJ L 270, 11.9.2014, p. 6).

([8]) Commission Implementing Regulations (EU) 2015/866 (OJ L 139, 5.6.2015, p. 30), (EU) 2015/1403 (OJ L 218, 19.8.2015, p. 1), (EU) 2015/2018 (OJ L 295, 12.11.2015, p. 23), (EU) 2016/115 (OJ L 23, 29.1.2016, p. 47), (EU) 2016/1045 (OJ L 170, 29.6.2016, p. 5), (EU) 2016/1382 (OJ L 222, 17.8.2016, p. 10), (EU) 2016/1402 (OJ L 228, 23.8.2016, p. 16), (EU) 2016/1998 (OJ L 308, 16.11.2016, p. 8), (EU) 2016/2146 (OJ L 333, 8.12.2016, p. 4), (EU) 2017/454 (OJ L 71, 16.3.2017, p. 5), (EU) 2017/941 (OJ L 142, 2.6.2017, p. 43) withdrawing the acceptance of the undertaking for several exporting producers.

([9]) Commission Implementing Regulation (EU) 2016/12 of 6 January 2016 terminating the partial interim review of the anti-dumping and countervailing measures applicable to imports of crystalline silicon photovoltaic modules and key components (i.e. cells) originating in or consigned from the People's Republic of China (OJ L 4, 7.1.2016, p. 1).

([10]) Commission Implementing Regulation (EU) 2016/185 of 11 February 2016 extending the definitive anti-dumping duty imposed by Council Regulation (EU) No 1238/2013 on imports of crystalline silicon photovoltaic modules and key components (i.e. cells) originating in or consigned from the People's Republic of China to imports of crystalline silicon photovoltaic modules and key components (i.e. cells) consigned from Malaysia and Taiwan, whether declared as originating in Malaysia and in Taiwan or not (OJ L 37, 12.2.2016, p. 76).

([11]) Commission Implementing Regulation (EU) 2016/184 of 11 February 2016 extending the definitive countervailing duty imposed by Council Implementing Regulation (EU) No 1239/2013 on imports of crystalline silicon photovoltaic modules and key components (i.e. cells) originating in or consigned from the People's Republic of China to imports of crystalline silicon photovoltaic modules and key components (i.e. cells) consigned from Malaysia and Taiwan, whether declared as originating in Malaysia and in Taiwan or not (OJ L 37, 12.2.2016, p. 56).

([12]) Commission Implementing Regulation (EU) 2017/367 of 1 March 2017 imposing a definitive anti-dumping duty on imports of crystalline silicon photovoltaic modules and key components (i.e. cells) originating in or consigned from the People's Republic of China following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council and terminating the partial interim review investigation pursuant to Article 11(3) of Regulation (EU) 2016/1036 (OJ L 56, 3.3.2017, p. 131).

([13]) Commission Implementing Regulation (EU) 2017/366 of 1 March 2017 imposing definitive countervailing duties on imports of crystalline silicon photovoltaic modules and key components (i.e. cells) originating in or consigned from the People's Republic of China following an expiry review pursuant to Article 18(2) of Regulation (EU) 2016/1037 of the European Parliament and of the Council and terminating the partial interim review investigation pursuant to Article 19(3) of Regulation (EU) 2016/1037 (OJ L 56, 3.3.2017, p. 1).

([14]) Commission Implementing Decision (EU) 2017/615 of 30 March 2017 accepting a proposal by a group of exporting producers together with the China Chamber of Commerce for Import and Export of Machinery and Electronic Products concerning the implementation of the undertaking referred to in Implementing Decision 2013/707/EU (OJ L 86, 31.3.2017, p. 14).

1.2. **Initiation of a partial interim review**

(9) On 3 March 2017 the Commission initiated *ex officio* this partial interim review limited to the form of the measures pursuant to Article 11(3) of the basic anti-dumping Regulation and Article 19 of the basic anti-subsidy Regulation ([15]) ('the Notice of Initiation'). The Commission's intention to initiate this review was announced in the Union Interest chapter of the two expiry review regulations as a means to strike the right balance between the diverging interests that the expiry review investigations had found to exist on the solar market for the remaining period of the measures' duration ([16]).

1.3. **Interested parties**

(10) In the Notice of Initiation, the Commission invited interested parties to contact it in order to participate in the investigation. In addition, the Commission informed the CCCME, known exporting producers in the PRC and the PRC authorities of the investigations and invited them to participate.

(11) Interested parties had an opportunity to comment on the initiation of the investigation and to request a hearing with the Commission and/or the Hearing Officer in trade proceedings.

1.4. **Disclosure**

(12) On 19 July 2017, the Commission disclosed to all interested parties the essential facts and considerations of the investigation and invited them to comment within 14 days. The Commission received replies, within the deadline, from 20 interested parties, namely the association of the Union producers, seven Union producers, two associations of users, four upstream and downstream interested parties in the Union, four Chinese exporting producers, the CCCME and the Government of the PRC. Subsequently, the Commission sent an additional disclosure document to all interested parties and invited them to comment. This redisclosure was limited to only two elements of the methodology for establishing the MIP and a provision regarding the entry into force of this regulation.

2. **FINDINGS OF THE INVESTIGATION**

(13) The Commission sent a request for information on 21 March 2017 to more than 100 interested parties. It received replies from 26 interested parties: two Union producers; five European upstream and downstream companies as well as three associations; the CCCME; the Government of the PRC; 13 exporting producers and one Malaysian exporting producer.

2.1. **Variable duty under the form of a minimum import price**

(14) The current form of the measures is an *ad valorem* anti-dumping duty set out in Article 1 of Implementing Regulation (EU) 2017/367 and *ad valorem* countervailing duty set out in Article 1 of Implementing Regulation (EU) 2017/366. A price undertaking was offered by a group of cooperating exporting producers together with the CCCME and accepted by the Commission. One of the core elements of the undertaking is the MIP which is subject to a quarterly adjustment mechanism. Under the price undertaking accepted by the Commission, the MIP for the modules and cells is adjusted quarterly by reference to international spot prices of modules including Chinese prices as reported by the Bloomberg database. The undertaking was initially accepted from more than 120 companies/company groups. In the meantime, the Commission withdrew its acceptance of the undertaking for 14 companies. Twelve of these were found to have breached the undertaking while the remaining two companies had business models that made it impracticable to monitor their compliance with the undertaking. In addition, 15 other Chinese companies voluntarily withdrew from the undertaking ([17]).

([15]) Notice of Initiation of a partial interim review of the anti-dumping and countervailing measures applicable to imports of crystalline silicon photovoltaic modules and key components (i.e. cells) originating in or consigned from the People's Republic of China (OJ C 67, 3.3.2017, p. 16).
([16]) See recitals (256), (336), (364) and (369) of Regulation (EU) 2017/367.
([17]) See footnote 8.

(15) When reviewing the interests of unrelated importers and non-vertically integrated Union module manufactures in the expiry review investigations, the Commission received complaints about the heavy administrative burden put on them, while the Union producers complained about ongoing circumvention ([18]). For instance, both the CCCME and the exporting producers have to submit monthly and quarterly reports to the Commission for the monitoring of the undertaking. These reports have been essential to verify that the annual level is not exceeded and to carry out a first analysis whether the reported sales transactions comply with the MIP.

(16) All the interested parties who replied to the request for information considered that a variable duty in the form of a MIP ('variable duty MIP') is a more appropriate form of measures than the previous *ad valorem* duty coupled with the price undertaking ('undertaking MIP'). In particular the interested parties considered that a variable duty MIP will be more transparent, predictable and enforceable. The interested parties considered that a variable duty MIP would reduce the administrative burden and costs for the importers. Some of the interested parties encouraged the Commission to ensure that the new form of the measures does not impose significant restrictions on the Union companies in terms of their business deals with manufacturers worldwide. In their view, these restrictions resulted in significant risks, liabilities, expensive due diligence and delays for the Union importers. The same parties also claimed that the existing cap on volumes of imports contained in the undertaking should be removed as it added further administrative burden and did not serve any purpose as the imports were anyway significantly below it.

(17) The Commission accepted these points. It considered that the measures should take the form of a variable duty MIP. The variable duty MIP means that eligible ([19]) imports with a declared value at, or above, the MIP would not be subject to duties and customs authorities will levy duties immediately if the product is imported at a price below the MIP. The variable duty MIP will alleviate the administrative burden on the exporting producers, the importers and the Commission as the monthly reporting by the CCCME and the quarterly reporting to the Commission by all the exporting producers will no longer be necessary. In addition, the level of the variable duty MIP will be published. This will provide transparency and enable a better enforcement of the measures.

(18) The Commission also agreed with the interested parties that the variable duty MIP should not be accompanied by a list of additional restrictions and caps. Indeed, the exports have always been well below the annual level. It will be up to the Union customs authorities to verify if the companies involved did not enter into any cross compensation agreements and other arrangements circumventing the MIP.

2.2. **Distinction between mono-crystalline and multi-crystalline products**

(19) Several interested parties companies, including the Union producers, considered that there should be separate variable duty MIP for different product types. Most of the interested parties also considered that the best differentiation is based on technology i.e. mono-crystalline vs multi-crystalline (sometimes also called poly-crystalline) products. Mono-crystalline and multi-crystalline products are priced differently and the main price indexes such as PV Insights and Energy Trend PV quote separate prices for mono- and multi-crystalline cells and modules. Mono-crystalline products are consistently more expensive as they have higher output per area of space. According to the price quotes by PV Insights ([20]), between 1 January 2014 and 31 March 2017 the average price difference between mono-crystalline and multi-crystalline modules was EUR 0,047/W and between multi-crystalline and mono-crystalline cells was EUR 0,040/W.

(20) The distinction between mono-crystalline and multi-crystalline products also fits into the reasoning brought forward in the expiry review investigations to strike an appropriate balance between competing interests. On the one hand, it will better protect the Union industry, which is increasingly focusing on manufacturing high-end mono-crystalline products for the rooftop sector. On the other hand, such a distinction will serve better the

([18]) See recitals (253), (336) and (369) of Implementing Regulation (EU) 2017/367.
([19]) On eligibility see Section 3 of this Regulation.
([20]) Converted at the ECB's average monthly exchange rate from USD into EUR.

interests of unrelated importers and engineering, procurement and construction companies (EPCs) active in the utility-scale sector, which need access to cheap commodity type multi-crystalline modules to be able to compete with other renewable energy sources in technology neutral tenders.

(21) Mono-crystalline and multi-crystalline cells can be easily distinguished by customs authorities. Multi-crystalline cells are made of multi-crystalline silicon (multi-Si) consisting of small crystals. Mono-crystalline cells are made of mono-crystalline silicon (mono-Si), a continuous crystal. Mono- and multi-crystalline cells are never combined in one device, therefore there are no modules that are made with both mono- and multi-crystalline cells. Multi-crystalline modules are made exclusively of multi-crystalline cells; and mono-crystalline modules are made exclusively of mono-crystalline cells. Mono-crystalline products have higher efficiency of converting sunlight into electrical current, which results in a higher output per area of space. Mono-crystalline products can be identified from multi-crystalline products by physical inspection. The multi-crystalline cell is perfectly rectangular. A mono-crystalline cell, by contrast, has its four corners cut off.

(22) Therefore, the Commission considered that there should be separate MIPs for mono-crystalline and multi-crystalline cells and modules and each of the four product types should have its own TARIC code.

2.3. **Gradual decrease of the variable duty MIP**

(23) Under the current price undertaking accepted by the Commission, the MIP for modules and cells is adjusted quarterly by reference to international spot prices of modules, including Chinese prices, as reported by the Bloomberg database (also called Bloomberg or BNEF spot prices index). When accepting the undertaking, the Commission considered that this price reflected the non-injurious price and ensured sufficient supply of the Union with the product under consideration ([21]).

(24) In the expiry review investigations the Commission became aware that throughout most of 2016 the undertaking MIP adjustment mechanism did not follow global price decreases, and hence no longer reflected the non-injurious price, as established in the original investigation.

(25) In addition the previous adjustment system had cut European cell users (i.e. non-vertically integrated module makers) and module users (i.e. individuals and companies purchasing solar systems) off global efficiency gains ([22]).

(26) Indeed, the evidence provided by the interested parties confirmed that the undertaking MIP stopped following the decreasing global price trend during 2016. Even if at the beginning of 2017 the MIP got significantly decreased, there was still a significant gap between the MIP and the global prices ([23]).

(27) Therefore the Commission investigated whether there was another benchmark, which would better reflect the non-injurious price level as established in the original investigation and global cost and price decreases.

(28) One Union producer and an association of the Union producers claimed that the new MIP adaptation mechanism should be based on the solar industry learning rate. The evidence provided by all interested parties confirmed that the cost of production in the solar industry has been continuously falling, which is reflected in the learning rates of the solar industry. However, several other interested parties commented extensively why the solar industry learning rates are not suitable as a benchmark for a MIP adaptation mechanism. First, the parties claimed that the studies which report learning rates estimate these rates over long periods of time. Therefore they do not

([21]) See recitals (3) to (9) of Decision 2013/423/EU.
([22]) See recitals (256), (336) and (370) of Implementing Regulation (EU) 2017/367.
([23]) For instance average spot prices reported by PV Insights in 2nd quarter 2017 were EUR 0,3/W for multi modules and EUR 0,35/W for mono modules; EUR 0,18/W for multi cells and EUR 0,21/W for mono cells. All prices were converted from USD into EUR at the ECB's average exchange rate applicable in each relevant month. This compares to the current non-injurious minimum price established under the price undertaking for cells (EUR 0,23/W) and modules (EUR 0,46/W).

reflect short term dynamics in the market. In addition, the time period under consideration has a significant impact on the results. For example, the latest International Technology Roadmap for Photovoltaic ('ITRPV') reports the rate of 22,5 % over 40 years ([24]) and a rate of 39 % over the last 10 years ([25]). The interested parties also claimed that the primary aim of the learning rates is not to forecast the development of prices in the near future. For instance, the ITRPV's learning rate is part of the project whose aim it is to inform suppliers and customers about anticipated technology trends and to stimulate discussion on required improvements and standards.

(29) Finally, the learning curve rate indicates the decrease in prices for each doubling of global cumulative module shipments ([26]). Forecasting the demand is by its very nature characterised by significant uncertainty. As one of the interested parties pointed out: 'It is important to note that forecasts of future demand and growth are only educated guesses and highly dependent on factors such as the trade policies in place in different markets, changes to support schemes and changes to the regulatory framework governing solar PV in each market'. For these reasons there are several forecasts of the evolution of the global demand, which are produced by several organisations.

(30) The Commission accepted these arguments and noted the following. If the Commission had decided to use the learning rate for the MIP adaptation mechanism, it would have needed to assess which of these two rates would be more suitable to forecast the evolution of the cost decline in the solar sector over the next 18 months. Making such an assessment would have introduced a significant element of complexity. Furthermore, the learning curve rate indicates the decrease in prices for each doubling of global cumulative module shipments ([27]). Most of the forecasts made available to the Commission predict that the cumulative solar module shipments could double in about 2020 or 2021. Therefore, as the precise prediction is impossible, the Commission would be obliged to make an educated guess and choose a precise date when the cumulative shipments will double between 1 January 2020 and 31 December 2021, which entails a high degree of uncertainty. Finally, the Commission noted that none of the downstream and upstream companies who replied to the request for information uses the solar industry learning rates to forecast the evolution of prices.

(31) Therefore, the Commission concluded that using the solar industry learning rates to adapt the MIP would introduce considerable uncertainties, which would render any precise predictions on price developments impossible. Therefore, the Commission decided to rely on another benchmark, which is based on more recent, transparent and reliable data.

(32) Most of the interested parties claimed that the new adjustment mechanism should be based on the price quotes by Taiwanese market intelligence agency PV Insights. Only Solar World, the largest European producer, considered PV Insights unreliable. PV Insights was also considered to be the most widely used by the interested parties. Several parties pointed out that the prices quoted by PV Insights and its price development trends were in line with the prices and trends quoted by another index trusted by the industry, i.e. Energy Trend PV (run by another market intelligence also based in Taiwan). By contrast, the prices quoted by the index used at present, i.e. Bloomberg database were subject to much more volatility and around December 2015 Bloomberg spot prices index started following a different trend from PV Insights and Energy Trend PV. The Bloomberg database is based on voluntary price quote submissions, which means that it has captured only a very small part of the market.

(33) The Commission requested the ITRPV to provide more information on the solar prices that they used to calculate the solar industry learning rate. The ITRPV provided the price data and indicated that they currently use two sources — PV Insights and Energy Trend PV. Before the end of 2016, ITRPV had used a wider basket of prices, including Bloomberg spot prices index. Given that PV Insights is one of the two sources used by the ITRPV and that the prices quoted by PV Insights and Energy Trend PV have been broadly in line with each other, the level and evolution of prices that the ITRPV used to calculate the learning rate have been closely in line with the data reported by PV Insights, especially since the end of 2016.

([24]) International Technology Roadmap for Photovoltaic (ITRPV): Results 2017, Eighth Edition, March 2017, p. 6.
([25]) International Technology Roadmap for Photovoltaic (ITRPV): Results 2017, Eighth Edition, March 2017, p. 44.
([26]) Global cumulative shipments are broadly equivalent to global cumulative demand. The former measures the amount of modules sold by manufactures, the latter measures the amount of modules that were installed by users and started generating power. After a certain time lag the one should be equal the other, except for a small percentage of modules that got broken in transit.
([27]) Global cumulative shipments are broadly equivalent to global cumulative demand. The former measures the amount of modules sold by manufactures; the latter measures the amount of modules that were installed by users and started generating power. After a certain time lag the one should be equal the other, except for a small percentage of modules that got broken in transit.

(34) The Commission devised a decreasing MIP system based on the PV Insights data, which was considered the most reliable and the most widely used by the solar industry. The starting point of this decreasing MIP system is based on the current non-injurious minimum price established under the price undertaking for cells (EUR 0,23/W) and modules (EUR 0,46/W). These prices, however, do not distinguish between the multi- and mono- products, which the new mechanism will do. The Commission found a price difference over a 3-year period between mono- and multi- cells and modules ([28]). The average of this price difference was evenly split between mono- and multi- cells and modules to establish the current non-injurious price for each product type i.e. EUR 0,210/W and EUR 0,437/W for multi-crystalline cells and modules, respectively and EUR 0,250/W and EUR 0,483/W for mono-crystalline cells and modules. These price will gradually converge towards the current prices reported by PV Insights ([29]), i.e. EUR 0,18/W and EUR 0,3/W for multi-crystalline cells and modules, respectively, and EUR 0,21/W and EUR 0,35/W for mono-crystalline cells and modules.

(35) This adaptation mechanism will result in MIPs which by September 2018 will be at the level of global prices in the first quarter of 2017 (the latest available global prices for the whole quarter of the year). As the prices have been going aggressively down over the last three years, the margins of the key manufactures shrank considerably ([30]). Therefore, the Commission expected that such an aggressive drop in prices could not be sustained for much longer and the prices in September 2018 would not be significantly lower, and hence still offering some residual protection to the Union industry.

(36) Accordingly, the mechanism allows the convergence towards world market prices in a relatively short timeframe. First, this ensures a return to the non-injurious price level as established in the original investigation. Second, this is in line with the findings in the expiry review investigations concerning the balance of interests under the Union interest test ([31]). It has furthermore the advantage of reflecting better the more recent technological developments and the price saving potential for consumers, which ensures that the users in the Union will no longer be cut off from the global efficiency gains. At the same time this mechanism provides adequate protection for the Union industry to adapt to increased competitive pressure once the measures lapse.

(37) Following disclosure the Commission received many comments on the level of the variable duty MIP. The Union cell and module makers and their association claimed that the global market prices did not reflect the non-injurious level of prices as they are driven by the dumping of massive Chinese overcapacities. Therefore, the variable duty MIP based on the global price benchmark would be too low. They reiterated their claim that, instead, the MIP should be based on the long-term solar industry learning rate. However, when accepting the undertaking in July 2013, the Commission had already considered that international spot prices of modules, including Chinese prices, reflected the non-injurious price ([32]). Moreover, in the interim review terminated by Implementing Regulation (EU) 2016/12, the Commission concluded that the price benchmark including an increasing share of Chinese companies fulfilled its objective as set out in the measures in force ([33]). The Commission therefore rejected this claim.

(38) The Union cell and module makers and their association also claimed that PV Insights is currently under investigation by the Taiwan Fair Trade Commission, Taiwan's national competition authority, following a complaint by the Taiwanese solar manufactures association. This investigation was opened on the basis of the claims that PV Insights index was dominated or even manipulated by Chinese price quotes and that the index's price level is below the cost of production in Taiwan. For them, relying on PV Insights would thus not be appropriate.

(39) The Commission recalled that the downstream and upstream industries had considered PV Insights the most reliable index in their daily business. PV Insights was also one of the key price benchmarks for the ITRPV reports when estimating the solar industry learning rate. Until now the upstream and downstream industry did not cast any doubt on the reliability of the PV Insights index. Finally, the Taiwanese authorities have not yet made

([28]) See recital 19.
([29]) The average of prices reported by PV Insights in the first quarter of 2017 for each product type.
([30]) Bloomberg New Energy Finance, Q1 2017 Global PV Market Outlook, p. 14 and Bloomberg New Energy Finance, May 2017 PV Index Supply, Shipments and Prices, p. 12
([31]) See recitals (256), (336) and (370) of Implementing Regulation (EU) 2017/367.
([32]) See recitals (3) to (9) of Decision 2013/423/EU.
([33]) See recital 41 of Implementing Regulation (EU) 2016/12.

definitive findings on the allegations. The Commission will monitor the developments of the Taiwan Fair Trade Commission and will consider any action necessary in view of potential findings. At this stage, the Commission therefore rejected this claim.

(40) The upstream and downstream European interested parties as well the Government of the PRC and the CCCME took issue with several aspects of the new MIP decrease.

(41) First, these parties considered that the starting MIP was too high. They claimed that for mono-products the new variable duty MIP would be even higher than the previous undertaking MIP. Setting the variable duty MIP at an even higher level would, in their view, be in contradiction with the findings of the review investigation that the undertaking MIP was set too high relative to the non-injurious price. Consequently it would need to be brought down to the appropriate level. Some parties also claimed that the MIP applicable in the first quarter of 2017 was not an appropriate starting point for the variable duty MIP as the Commission had itself found that it was out of line with the global price developments.

(42) The Commission took account of these comments and developed a new quarterly gradual decrease of the variable duty MIP. As the undertaking MIP was frozen from the second quarter of 2017 onwards, the Commission frontloaded the starting point of the gradual decrease. This starting point is set at the level of the frozen undertaking MIP decreased by the value of two quarterly adjustments that should have occurred while it was frozen, namely the second and third quarter of 2017.

(43) Second, several parties considered that the ending variable duty MIP, i.e. the one applicable at the expiry of the measures in September 2018, was also too high. They claimed that, according to the PV Insights price quotes that were available following disclosure, the global solar prices already decreased. The Commission accepted the proposition that the latest available data should be used as the most appropriate proxy for the ending quarter. Therefore, it set the final variable duty MIP at the level of prices in the latest quarter available i.e. the second quarter of 2017.

(44) These parties also claimed that the Commission's forecast that the decrease in solar prices would slow down was unfounded. However, the analysis of the PV Insights long-term price curve suggests that solar prices are cyclical — historically solar prices were dropping aggressively throughout several quarters and then stabilised or even slightly increased thereafter. During the current cycle the prices of modules have been continuously falling for a relatively long period of time, i.e. since the fourth quarter of 2015. At the same time, the cell prices that used to follow a similar trend have already stabilised or even slightly increased. The fact that the prices for the main raw material, i.e. cells, stabilised after a particularly long period of decreasing prices reinforces the Commission's forecast that the module prices would eventually stabilise too. Therefore, the claim was rejected.

(45) The non-integrated module makers also claimed that the variable duty MIP indicated in the disclosure document decreased much faster for modules than for cells, which would affect disproportionately their profit margins. The Commission pointed out that such a difference in the slope of the decrease is an unavoidable consequence of the fact that the undertaking MIP for cells was much closer to global market prices than the undertaking MIP for modules. In addition, following disclosure, the Commission decreased the variable duty starting MIP, therefore the variable duty MIP will no longer be above the undertaking MIP for mono-cells.

(46) Following redisclosure, upstream and downstream companies as well as their associations and the CCCME repeated their view that the MIP was too high even if it was adjusted further downwards, which some of them welcomed. On the other hand, the Union producers and their association reiterated that the MIP was too low and that it did not reflect the non-injurious price; that the MIP decreased disproportionally faster for modules than for cells and that PV Insights was not a reliable benchmark.

(47) The Commission observed that none of these parties brought forward new arguments on the two new elements disclosed (frontloading of the gradual decrease and use of the most recent quarterly data). Rather, they repeated their general approach on the MIP that they had already outlined post disclosure, adapted to the new levels of the quarterly MIPs. Therefore, the Commission considered that it had already addressed the essence of these claims after disclosure.

(48) Several parties also claimed that the period for comments was too short. The Commission considered that one working day was sufficient for the parties to comment, given that the disclosure was limited to only two elements of the methodology for establishing the MIP and a provision regarding the entry into force of this regulation. Therefore, the Commission rejected this claim.

(49) The gradual decrease of the variable duty MIP will be as follows:

	MIP multi-crystalline cells (EUR/Watt)	MIP mono-crystalline cells (EUR/Watt)	MIP multi-crystalline modules (EUR/Watt)	MIP mono-crystalline modules (EUR/Watt)
Frozen undertaking MIP [1]	0,21 0,23 – (0,04/2)	0,25 0,23 + (0,04/2)	0,43 0,46 – (0,047/2)	0,48 0,46 + (0,047/2)
2nd quarter 2017 hypothetical adjustment [2]	0,20	0,24	0,41	0,46
3rd quarter 2017 hypothetical adjustment [2]	0,20	0,23	0,39	0,44
From 1 October 2017 until 31 December 2017	0,19	0,23	0,37	0,42
From 1 January 2018 until 31 March 2018	0,19	0,22	0,34	0,39
From 1 April 2018 until 30 June 2018	0,19	0,22	0,32	0,37
As from 1 July 2018	0,18	0,21	0,30	0,35

[1] See recitals (19) and (34) for the methodology to split the undertaking MIP between multi- and mono-products.
[2] Hypothetical adjustment for the purpose of frontloading as explained in recital (42).

3. SCOPE OF APPLICATION OF THE VARIABLE DUTY MIP

(50) The Commission noted that the price undertaking initially covered all companies cooperating in the initial investigation. Given that that the new variable duty MIP will replace this undertaking, the Commission found it appropriate that the new MIP shall only apply to those companies that were still part of the price undertaking or withdrew voluntarily without any previous issues identified by the Commission.

(51) In return, the Commission considered that other companies should not be subject to the new MIP system, but to *ad valorem* duties in order not to undermine the effectiveness of the new form of measures. In particular, this exclusion should apply to companies for whom the Commission had withdrawn its acceptance of the undertaking for breaches of the undertaking. In these cases, the past conduct of the Chinese exporting producers at issue to have exported the product concerned below the non-injurious price or to have otherwise breached the undertaking constituted a sufficient ground for the Commission to assume that there is a considerable risk that they would equally not respect the new MIP. This would undermine the latter's effectiveness and therefore not provide the required protection against future injurious dumping. In the same vain, the companies who had voluntarily withdrawn from the undertaking in order to pre-empt the imminent withdrawal by the Commission should also not fall under the new variable duty MIP.

(52) Following disclosure, three companies that had withdrawn voluntarily from the undertaking, but were not included in the Annex VI, provided substantiated comments why they considered that they had legitimate reasons for their withdrawal. On the basis of additional evidence provided by these companies, the Commission found that they had not breached the undertaking in the past. Moreover, no Commission withdrawal of the undertaking had been imminent prior to their voluntary withdrawal. The Commission was also satisfied that their withdrawal was done for reasons that did not indicate a considerable risk that they would not respect the new MIP in the future. Therefore, the Commission included these three companies in Annex VI. In addition, it also included two more companies, for which the acceptance of the undertaking had solely been withdrawn on 'impracticability' grounds. In these cases, there was no evidence that they had sold the product concerned to the Union market below the non-injurious price.

(53) Following disclosure some exporting producers, the Government of the PRC and the CCCME also claimed that the new variable duty MIP should apply to all the Chinese exporting producers and that the exclusion of any exporter from the MIP violated in their view Article 9(5) of the basic anti-dumping Regulation and Article 15(2) of the basic anti-subsidy Regulation. The Commission recalled that it had set different duty levels for individual exporting producers, groups of other cooperating exporting producers and all other companies on non-discriminatory grounds. In addition, insofar as it concerns the variable duty MIP, the Commission has put in place a distinction between exporting producers on objective grounds only (namely, whether, on the basis of adherence to the conditions of the undertaking, the exposure to the variable duty MIP raises a considerable risk of non-compliance with the variable duty MIP). By basing itself on its investigations into the compliance with the undertaking, the Commission has thus determined that only certain companies should be subject to the variable duty MIP as they do not represent a risk of future non-compliance with the variable duty MIP. Those companies are: (i) exporting producers which respected the terms of the undertaking by exporting the product concerned to the Union at the respectively-determined non-injurious price level; and (ii) exporting producers which voluntarily withdrew from the undertaking without a view to pre-empt the imminent withdrawal of the undertaking by the Commission. Those companies should be subject to the variable duty MIP for exports of the product concerned to the Union. On the other hand, all those exporting producers which breached the undertaking, irrespective of whether such a breach has already been found to have occurred or whether such a breach will be found to have occurred in future investigations by the Commission, cannot be trusted to comply with the variable duty MIP. The respective uncapped *ad valorem* duty should, accordingly, apply to them.

(54) The Commission continues to conduct investigations concerning the compliance with the price undertaking and may open new investigations for goods that were released for free circulation while the price undertaking was still in place. For those investigations, Articles 2 and 3 of Implementing Regulations (EU) 2017/366 and (EU) 2017/367 remain the applicable law. In particular, a customs debt will be incurred at the time of acceptance of the declaration for release into free circulation: (a) whenever it is established, in respect of imports invoiced by companies subject to the undertaking, that one or more of the conditions of the undertaking was not fulfilled; or (b) when the Commission finds that the undertaking was breached in a regulation or decision which refers to particular transactions and declares the relevant undertaking invoices as invalid. The Commission further considered that an exporting producer which is found to have breached the undertaking should not benefit from the variable duty MIP, even if these findings are made after the termination of the price undertaking. In those kind of cases, the variable duty MIP should no longer be applicable. The Commission should then remove the names of the respective company(ies) from the new Annex VI and the new Annex 5 by the same legal act in which the non-compliance is established.

(55) Accordingly, the variable duty MIP will only apply to the legal entities listed in the new Annex VI to be added to Implementing Regulation (EU) 2017/367 and new Annex 5 to be added to the Implementing Regulation (EU) 2017/366.

4. **OPERATION OF THE VARIABLE DUTY MIP**

(56) Where goods from the legal entities listed in the new Annex VI to be added to Implementing Regulation (EU) 2017/367 and new Annex 5 to be added to Implementing Regulation (EU) 2017/366 are imported at a CIF Union border price equal to or above the variable duty MIP established, no duty would be payable. If such imports are made at a price below the variable duty MIP, the definitive duty should be equal to the difference between the applicable variable duty MIP and the net free-at-Union-frontier price, before duty. In no event shall the amount of the duty be higher than the combined *ad valorem* duty rates set in in Article 1(2) of Implementing Regulation (EU) 2017/367 and Article 1(2) of Implementing Regulation (EU) 2017/366. Accordingly, if imports are made at a price below the variable duty MIP, the lower of the difference between the applicable variable duty MIP and the net free-at-Union-frontier price, before duty, and the combined *ad valorem* duty rates set in in Article 1(2) of Implementing Regulation (EU) 2017/367 and Article 1(2) of Implementing Regulation (EU) 2017/366 would be payable.

(57) Implementing Decision 2013/707/EU confirming the acceptance of the undertaking, as last amended by Implementing Decision (EU) 2017/615, needs to be repealed, because the variable duty MIP will replace the current undertaking. At the same time, it is appropriate to continue the investigations concerning the compliance with the price undertaking that the Commission is currently conducting and to initiate new investigations in the future for goods that were released for free circulation while the price undertaking was still in place, where appropriate.

(58) Following disclosure some parties requested that the new MIP is published in advance, so as to give them sufficient time to prepare for the change. As no party presented any time indication in this respect, the Commission considered that two weeks' notice gives all parties concerned sufficient time in this respect. It is therefore appropriate to foresee a delay of two weeks between the publication and the entry into force of this Regulation. Following redisclosure, the CCCME commented that the variable duty MIP should enter into force without any delay. The Commission considered that the difference between the current undertaking MIP and the new variable duty MIP is substantial. Therefore, companies need two weeks to adjust to the changed market circumstances. Accordingly, the Commission rejected this claim.

(59) The Committees established by Article 15(1) of the Regulation (EU) 2016/1036 and Article 25(1) of Regulation (EU) 2016/1037 did not deliver an opinion,

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) 2017/367 is amended as follows:

(1) in Article 1, the following paragraph (2a) is inserted:

'2a. The amount of the definitive anti-dumping duty applicable to the products described in paragraph 1, currently falling under the TARIC codes listed in new paragraph 5 and produced by the named legal entities set out in Annex VI, shall be the difference between the minimum import prices fixed in the next subparagraph and the net free-at-Union-frontier price, before duty, if the latter is lower than the former. No duty shall be collected where the net free-at-Union-frontier price is equal to or higher than the corresponding minimum import price set out in the table below. In no event shall the amount of the duty be higher than the *ad valorem* duty rate set out in paragraph 2. The application of the measures for the companies mentioned in Annex VI shall be conditional upon presentation to the customs authorities of the Member States of a valid commercial invoice indicating the elements set out in Annex V.

For the purpose of the previous subparagraph, the minimum import price set out in the table below shall apply. Where it is found, following post-importation verification, that the net free-at-Union-frontier price actually paid by the first independent customer in the Union (post-importation price) is below the net free-at-Union-frontier price, before duty, as resulting from the customs declaration, and the post-importation price is lower than the minimum import price, an amount of duty equivalent to the difference between the minimum import price set out in the table below and the post-importation price shall apply, unless the application of the *ad valorem* duties set out in paragraph 2 plus the post-importation price lead to an amount (price actually paid plus *ad valorem* duty) which remains below the minimum import price set out in the table below.

The minimum import price (MIP) will decrease each quarter as set in the table below for each corresponding product type:

Period of application of the MIP	MIP multi-crystalline cells (EUR/Watt)	MIP mono-crystalline cells (EUR/Watt)	MIP multi-crystalline modules (EUR/Watt)	MIP mono-crystalline modules (EUR/Watt)
From 1 October 2017 until 31 December 2017	0,19	0,23	0,37	0,42
From 1 January 2018 until 31 March 2018	0,19	0,22	0,34	0,39
From 1 April 2018 until 30 June 2018	0,19	0,22	0,32	0,37
As from 1 July 2018	0,18	0,21	0,30	0,35

The legal entities which are neither listed in paragraph 2 nor in Annex I, Annex II or Annex VI shall be subject to the combined *ad valorem* duty rates applicable to 'all other companies' set out in paragraph 2.';

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

'4. Where any new exporting producer in the People's Republic of China provides sufficient evidence to the Commission that:

— it did not export to the Union the product described in paragraph 1 in the period between 1 July 2011 and 30 June 2012 (original investigation period),

— it is not related to any exporter or producer in the People's Republic of China which is subject to the anti-dumping measures imposed by this Regulation,

— it has actually exported to the Union the product concerned after the investigation period on which the measures are based, or it has entered into an irrevocable contractual obligation to export a significant quantity to the Union,

the Commission may amend Annex I and Annex VI by adding the new exporting producer.';

(3) in Article 1, the following paragraph 5 is inserted:

'5. Multi-crystalline (also called poly-crystalline) silicon photovoltaic modules or panels currently fall under TARIC codes 8541 40 90 51, 8541 40 90 52, 8541 40 90 53, and 8541 40 90 59. Multi-crystalline modules are made out of multi-crystalline cells.

Mono-crystalline silicon photovoltaic modules or panels currently fall under TARIC codes 8541 40 90 41, 8541 40 90 42, 8541 40 90 43, and 8541 40 90 49. Mono-crystalline modules are made out of mono-crystalline cells.

Multi-crystalline (also called poly-crystalline) cells of the type used in crystalline silicon photovoltaic modules or panels with a thickness of the cells not exceeding 400 μm currently fall under TARIC codes 8541 40 90 71, 8541 40 90 72, 8541 40 90 73 and 8541 40 90 79. Multi-crystalline cells are made of multi-crystalline silicon (multi-Si) consisting of small crystals and have a perfectly rectangular shape.

Mono-crystalline cells of the type used in crystalline silicon photovoltaic modules or panels with a thickness of the cells not exceeding 400 μm currently fall under TARIC codes 8541 40 90 61, 8541 40 90 62, 8541 40 90 63, and 8541 40 90 69. Mono-crystalline cells are made of mono-crystalline silicon (mono-Si), a continuous crystal and have their four corners cut off.';

(4) Article 2 is repealed;

(5) Article 3 is repealed.

Article 2

The Annex to this Regulation is inserted as Annex VI to Implementing Regulation (EU) 2017/367.

Article 3

Implementing Regulation (EU) 2017/366 is amended as follows:

(1) in Article 1, the following paragraph (2a) is inserted:

'2a. The amount of the definitive countervailing duty applicable to the product described in paragraph 1, currently falling under the TARIC codes listed in new paragraph 4 and produced by the named legal entities set out in in Annex 5, shall be the difference between the minimum import prices fixed in the next subparagraph and the net free-at-Union-frontier price, before duty, if the latter is lower than the former. No duty shall be collected where the net free-at-Union-frontier price is equal to or higher than the corresponding minimum import price set out in the table below. In no event shall the amount of the duty be higher than the *ad valorem* duty rate set in paragraph 2. The application of the measures for the companies mentioned in Annex 5 shall be conditional upon presentation to the customs authorities of the Member States of a valid commercial invoice indicating the elements set out in Annex 4.

For the purpose of the previous subparagraph, the minimum import price set out in the table below shall apply. Where it is found, following post-importation verification, that the net free-at-Union-frontier price actually paid by the first independent customer in the Union (post-importation price) is below the net free-at-Union-frontier price, before duty, as resulting from the customs declaration, and the post-importation price is lower than the minimum import price, an amount of duty equivalent to the difference between the minimum import price set out in the table below and the post-importation price shall apply, unless the application of the *ad valorem* duties set out in paragraph 2 plus the post-importation price lead to an amount (price actually paid plus *ad valorem* duty) which remains below the minimum import price set out in the table below.

The minimum import price (MIP) will decrease each quarter for each corresponding product type:

Period of application of the MIP	MIP multi-crystalline cells (EUR/Watt)	MIP mono-crystalline cells (EUR/Watt)	MIP multi-crystalline modules (EUR/Watt)	MIP mono-crystalline modules (EUR/Watt)
From 1 October 2017 until 31 December 2017	0,19	0,23	0,37	0,42
From 1 January 2018 until 31 March 2018	0,19	0,22	0,34	0,39
From 1 April 2018 until 30 June 2018	0,19	0,22	0,32	0,37
As from 1 July 2018	0,18	0,21	0,30	0,35

The legal entities which are neither listed in paragraph 2 nor in Annex 1 or Annex 5 shall be subject to the combined *ad valorem* duty rates applicable to 'all other companies' set out in paragraph 2.';

(2) in Article 1, the following paragraph 4 is inserted:

'4. Multi-crystalline (also called poly-crystalline) silicon photovoltaic modules or panels currently fall under TARIC codes 8541 40 90 51, 8541 40 90 52, 8541 40 90 53, and 8541 40 90 59. Multi-crystalline modules are made out of multi-crystalline cells.

Mono-crystalline silicon photovoltaic modules or panels currently fall under TARIC codes 8541 40 90 41, 8541 40 90 42, 8541 40 90 43 and 8541 40 90 49. Mono-crystalline modules are made out of mono-crystalline cells.

Multi-crystalline (also called poly-crystalline) cells of the type used in crystalline silicon photovoltaic modules or panels with a thickness of the cells not exceeding 400 μm currently fall under TARIC codes 8541 40 90 71, 8541 40 90 72, 8541 40 90 73 and 8541 40 90 79. Multi-crystalline cells are made of multi-crystalline silicon (multi-Si) consisting of small crystals and have a perfectly rectangular shape.

Mono-crystalline cells of the type used in crystalline silicon photovoltaic modules or panels with a thickness of the cells not exceeding 400 μm currently fall under TARIC codes 8541 40 90 61, 8541 40 90 62, 8541 40 90 63, and 8541 40 90 69. Mono-crystalline cells are made of mono-crystalline silicon (mono-Si), a continuous crystal and have their four corners cut off.';

(3) Article 2 is repealed;

(4) Article 3 is repealed.

Article 4

The Annex to this Regulation is inserted as Annex 5 to Implementing Regulation (EU) 2017/366.

Article 5

Implementing Decision 2013/707/EU and Implementing Decision (EU) 2017/615 are hereby repealed.

Article 6

This Regulation shall enter into force 15 days following 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, 15 September 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Annex VI to Implementing Regulation (EU) 2017/367 and Annex 5 to Implementing Regulation (EU) 2017/366 (The legal entities to which the variable duty MIP is applicable):

'Name of the company	TARIC additional code
Changzhou Trina Solar Energy Co. Ltd Trina Solar (Changzhou) Science & Technology Co. Ltd Changzhou Youze Technology Co. Ltd Trina Solar Energy (Shanghai) Co. Ltd Yancheng Trina Solar Energy Technology Co. Ltd together with their related companies in the European Union	B791
Delsolar (Wujiang) Ltd	B792
JingAo Solar Co. Ltd Shanghai JA Solar Technology Co. Ltd JA Solar Technology Yangzhou Co. Ltd Hefei JA Solar Technology Co. Ltd Shanghai JA Solar PV Technology Co. Ltd together with their related company in the Union	B794
Wuxi Suntech Power Co. Ltd Suntech Power Co. Ltd Wuxi Sunshine Power Co. Ltd Luoyang Suntech Power Co. Ltd Zhenjiang Rietech New Energy Science Technology Co. Ltd Zhenjiang Ren De New Energy Science Technology Co. Ltd together with their related companies in the Union	B796
Yingli Energy (China) Co. Ltd Baoding Tianwei Yingli New Energy Resources Co. Ltd Hainan Yingli New Energy Resources Co. Ltd Hengshui Yingli New Energy Resources Co. Ltd Tianjin Yingli New Energy Resources Co. Ltd Lixian Yingli New Energy Resources Co. Ltd Baoding Jiasheng Photovoltaic Technology Co. Ltd Beijing Tianneng Yingli New Energy Resources Co. Ltd Yingli Energy (Beijing) Co. Ltd	B797
Jiangsu Aide Solar Energy Technology Co. Ltd	B798
Anhui Chaoqun Power Co. Ltd	B800
Anji DaSol Solar Energy Science & Technology Co. Ltd	B802
Anhui Schutten Solar Energy Co. Ltd Quanjiao Jingkun Trade Co. Ltd	B801
Anhui Titan PV Co. Ltd	B803

Name of the company	TARIC additional code
Xi'an SunOasis (Prime) Company Limited TBEA SOLAR CO. LTD XINJIANG SANG'O SOLAR EQUIPMENT	B804
Changzhou NESL Solartech Co. Ltd	B806
Changzhou Shangyou Lianyi Electronic Co. Ltd	B807
ChangZhou EGing Photovoltaic Technology Co. Ltd	B811
CIXI CITY RIXING ELECTRONICS CO. LTD ANHUI RINENG ZHONGTIAN SEMICONDUCTOR DEVELOPMENT CO. LTD HUOSHAN KEBO ENERGY & TECHNOLOGY CO. LTD	B812
CNPV Dongying Solar Power Co. Ltd	B813
CSG PVtech Co. Ltd	B814
China Sunergy (Nanjing) Co. Ltd CEEG Nanjing Renewable Energy Co. Ltd CEEG (Shanghai) Solar Science Technology Co. Ltd China Sunergy (Yangzhou) Co. Ltd China Sunergy (Shanghai) Co. Ltd	B809
Dongfang Electric (Yixing) MAGI Solar Power Technology Co. Ltd	B816
EOPLLY New Energy Technology Co. Ltd SHANGHAI EBEST SOLAR ENERGY TECHNOLOGY CO. LTD JIANGSU EOPLLY IMPORT & EXPORT CO. LTD	B817
Zheijiang Era Solar Co. Ltd	B818
GD Solar Co. Ltd	B820
Greenway Solar-Tech (Shanghai) Co. Ltd Greenway Solar-Tech (Huaian) Co. Ltd	B821
Guodian Jintech Solar Energy Co. Ltd	B822
Hangzhou Bluesun New Material Co. Ltd	B824
Hanwha SolarOne (Qidong) Co. Ltd	B826
Hengdian Group DMEGC Magnetics Co. Ltd	B827
HENGJI PV-TECH ENERGY CO. LTD	B828
Himin Clean Energy Holdings Co. Ltd	B829
Jetion Solar (China) Co. Ltd Junfeng Solar (Jiangsu) Co. Ltd Jetion Solar (Jiangyin) Co. Ltd together with their related company in the Union	B830

Name of the company	TARIC additional code
Jiangsu Green Power PV Co. Ltd	B831
Jiangsu Hosun Solar Power Co. Ltd	B832
Jiangsu Jiasheng Photovoltaic Technology Co. Ltd	B833
Jiangsu Runda PV Co. Ltd	B834
Jiangsu Sainty Photovoltaic Systems Co. Ltd Jiangsu Sainty Machinery Imp. And Exp. Corp. Ltd	B835
Jiangsu Shunfeng Photovoltaic Technology Co. Ltd Changzhou Shunfeng Photovoltaic Materials Co. Ltd Jiangsu Shunfeng Photovoltaic Electronic Power Co. Ltd	B837
Jiangsu Sinski PV Co. Ltd	B838
Jiangsu Sunlink PV Technology Co. Ltd	B839
Jiangsu Zhongchao Solar Technology Co. Ltd	B840
Jiangxi Risun Solar Energy Co. Ltd	B841
Jiangyin Hareon Power Co. Ltd Hareon Solar Technology Co. Ltd Taicang Hareon Solar Co. Ltd Hefei Hareon Solar Technology Co. Ltd Jiangyin Xinhui Solar Energy Co. Ltd Altusvia Energy (Taicang) Co. Ltd together with their related company in the Union	B842
Jiangxi LDK Solar Hi-Tech Co. Ltd LDK Solar Hi-Tech (Nanchang) Co. Ltd LDK Solar Hi-Tech (Suzhou) Co. Ltd	B793
Jiangyin Shine Science and Technology Co. Ltd	B843
Jinzhou Yangguang Energy Co. Ltd Jinzhou Huachang Photovoltaic Technology Co. Ltd Jinzhou Jinmao Photovoltaic Technology Co. Ltd Jinzhou Rixin Silicon Materials Co. Ltd Jinzhou Youhua Silicon Materials Co. Ltd	B795
Jinko Solar Co. Ltd Jinko Solar Import and Export Co. Ltd ZHEJIANG JINKO SOLAR CO. LTD ZHEJIANG JINKO SOLAR TRADING CO. LTD together with their related companies in the Union	B845
Juli New Energy Co. Ltd	B846

Name of the company	TARIC additional code
Jumao Photonic (Xiamen) Co. Ltd	B847
King-PV Technology Co. Ltd	B848
Kinve Solar Power Co. Ltd (Maanshan)	B849
GCL System Integration Technology Co. Ltd Konca Solar Cell Co. Ltd Suzhou GCL Photovoltaic Technology Co. Ltd Jiangsu GCL Silicon Material Technology Development Co. Ltd Jiangsu Zhongneng Polysilicon Technology Development Co. Ltd GCL-Poly (Suzhou) Energy Limited GCL-Poly Solar Power System Integration (Taicang) Co. Ltd GCL SOLAR POWER (SUZHOU) LIMITED GCL Solar System (Shuzhou) Limited	B850
Lightway Green New Energy Co. Ltd Lightway Green New Energy(Zhuozhou) Co. Ltd	B851
Motech (Suzhou) Renewable Energy Co. Ltd	B852
Nanjing Daqo New Energy Co. Ltd	B853
NICE SUN PV CO. LTD LEVO SOLAR TECHNOLOGY CO. LTD	B854
Ningbo Jinshi Solar Electrical Science & Technology Co. Ltd	B857
Ningbo Komaes Solar Technology Co. Ltd	B858
Ningbo South New Energy Technology Co. Ltd	B861
Ningbo Sunbe Electric Ind Co. Ltd	B862
Ningbo Ulica Solar Science & Technology Co. Ltd	B863
Perfectenergy (Shanghai) Co. Ltd	B864
Perlight Solar Co. Ltd	B865
Sumec Hardware & Tools Co. Ltd Phono Solar Technology Co. Ltd	B866
Risen Energy Co., Ltd together with its related company in the Union	B868
SHANGHAI ALEX SOLAR ENERGY SCIENCE & TECHNOLOGY CO. LTD SHANGHAI ALEX NEW ENERGY CO. LTD	B870
Shanghai BYD Co. Ltd BYD (Shangluo) Industrial Co. Ltd	B871
Shanghai Chaori Solar Energy Science & Technology Co. Ltd	B872

Name of the company	TARIC additional code
Propsolar (Zhejiang) New Energy Technology Co. Ltd Shanghai Propsolar New Energy Co. Ltd	B873
SHANGHAI SHANGHONG ENERGY TECHNOLOGY CO. LTD	B874
SHANGHAI SOLAR ENERGY S&T CO. LTD Shanghai Shenzhou New Energy Development Co. Ltd Lianyungang Shenzhou New Energy Co. Ltd	B875
Shanghai ST Solar Co. Ltd Jiangsu ST Solar Co. Ltd	B876
Shenzhen Sacred Industry Co. Ltd	B878
Sopray Energy Co. Ltd Shanghai Sopray New Energy Co. Ltd	B881
SUN EARTH SOLAR POWER CO. LTD NINGBO SUN EARTH SOLAR POWER CO. LTD Ningbo Sun Earth Solar Energy Co. Ltd	B882
SUZHOU SHENGLONG PV-TECH CO. LTD	B883
TDG Holding Co. Ltd	B884
Tianwei New Energy Holdings Co. Ltd Tianwei New Energy (Chengdu) PV Module Co. Ltd Tianwei New Energy (Yangzhou) Co. Ltd	B885
Wenzhou Jingri Electrical and Mechanical Co. Ltd	B886
Shanghai Topsolar Green Energy Co. Ltd	B877
Shenzhen Sungold Solar Co. Ltd	B879
Wuhu Zhongfu PV Co. Ltd	B889
Wuxi Shangpin Solar Energy Science and Technology Co. Ltd	B891
Wuxi Solar Innova PV Co. Ltd	B892
Wuxi Taichang Electronic Co. Ltd China Machinery Engineering Wuxi Co.Ltd Wuxi Taichen Machinery & Equipment Co. Ltd	B893
Xi'an Huanghe Photovoltaic Technology Co. Ltd State-run Huanghe Machine-Building Factory Import and Export Corporation Shanghai Huanghe Fengjia Photovoltaic Technology Co. Ltd	B896
Xi'an LONGi Silicon Materials Corp. Wuxi LONGi Silicon Materials Co. Ltd	B897
LERRI Solar Technology (Zhejiang) Co. Ltd together with its related company in the Union	B898

Name of the company	TARIC additional code
Yuhuan Sinosola Science & Technology Co. Ltd	B900
Zhangjiagang City SEG PV Co. Ltd	B902
Zhejiang Fengsheng Electrical Co. Ltd	B903
Zhejiang Global Photovoltaic Technology Co. Ltd	B904
Zhejiang Heda Solar Technology Co. Ltd	B905
Zhejiang Jiutai New Energy Co. Ltd Zhejiang Topoint Photovoltaic Co. Ltd	B906
Zhejiang Kingdom Solar Energy Technic Co. Ltd	B907
Zhejiang Koly Energy Co. Ltd	B908
Zhejiang Mega Solar Energy Co. Ltd Zhejiang Fortune Photovoltaic Co. Ltd	B910
Zhejiang Shuqimeng Photovoltaic Technology Co. Ltd	B911
Zhejiang Shinew Photoelectronic Technology Co. Ltd	B912
Zhejiang Sunflower Light Energy Science & Technology Limited Liability Company Zhejiang Yauchong Light Energy Science & Technology Co. Ltd	B914
Zhejiang Sunrupu New Energy Co. Ltd	B915
Zhejiang Tianming Solar Technology Co. Ltd	B916
Zhejiang Trunsun Solar Co. Ltd Zhejiang Beyondsun PV Co. Ltd	B917
Zhejiang Wanxiang Solar Co. Ltd WANXIANG IMPORT & EXPORT CO LTD	B918
ZHEJIANG YUANZHONG SOLAR CO. LTD	B920
Zhongli Talesun Solar Co. Ltd together with its related company in the Union	B922’

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1571

of 15 September 2017

amending for the 277th time Council Regulation (EC) No 881/2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the ISIL (Da'esh) and Al-Qaida organisations

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 881/2002 of 27 May 2002 imposing certain specific restrictive measures directed against certain persons and entities associated with the ISIL (Da'esh) and Al-Qaida organisations [1], and in particular Article 7(1)(a) and Article 7a(5) thereof,

Whereas:

(1) Annex I to Regulation (EC) No 881/2002 lists the persons, groups and entities covered by the freezing of funds and economic resources under that Regulation.

(2) On 12 September 2017, the Sanctions Committee of the United Nations Security Council decided to remove one natural person from the list of persons, groups and entities to whom the freezing of funds and economic resources should apply. Annex I to Regulation (EC) No 881/2002 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 881/2002 is amended in accordance with 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, 15 September 2017.

For the Commission,
On behalf of the President,
Head of the Service for Foreign Policy Instruments

[1] OJ L 139, 29.5.2002, p. 9.

ANNEX

In Annex I to Council Regulation (EC) No 881/2002 under the heading 'Natural persons' the following entry is deleted:

'Zulkifli Abdul Hir (alias (a) Musa Abdul Hir, (b) Muslimin Abdulmotalib, (c) Salim Alombra, (d) Armand Escalante, (e) Normina Hashim, (f) Henri Lawi, (g) Hendri Lawi, (h) Norhana Mohamad, (i) Omar Salem, (j) Ahmad Shobirin, (k) Bin Abdul Hir Zulkifli, (l) Abdulhir Bin Hir, (m) Hassan, (n) Hogalu, (o) Hugalu, (p) Lagu, (q) Marwan (prominently known as)). Address: (a) Seksyen 17, Shah Alam, Selangor, Malaysia (previous location), (b) Maguindanao, the Philippines (as at Jan. 2015). Date of birth: (a) 5.1.1966, (b) 5.10.1966. Place of birth: Muar Johor, Malaysia. Nationality: Malaysian. Passport No: (a) A 11263265, (b) National identification No: 660105-01-5297, (c) Driver license D2161572, issued in California, USA. Other Information: (a) The Court for the Northern District of California, USA, issued a warrant of arrest for him on 1 Aug. 2007. (b) Confirmed to have died in Maguindanao, Philippines in January 2015. (c) Mother's name is Minah Binto Aogist Abd Aziz. Date of designation referred to in Article 2a (4) (b): 9.9.2003.'

DIRECTIVES

COMMISSION DIRECTIVE (EU) 2017/1572

of 15 September 2017

supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards the principles and guidelines of good manufacturing practice for medicinal products for human use

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ([1]), and in particular the first paragraph of Article 47 thereof,

Whereas:

(1) Commission Directive 2003/94/EC ([2]) applies to both medicinal products for human use and investigational medicinal products for human use.

(2) In accordance with Article 63(1) of Regulation (EU) No 536/2014 of the European Parliament and of the Council ([3]) the Commission is empowered to adopt a delegated act laying down principles of good manufacturing practice for investigational medicinal products for human use. It is therefore necessary to adapt the provisions of Directive 2003/94/EC by deleting the references to investigational medicinal products for human use.

(3) The definition of a pharmaceutical quality system and some terminology should be updated to reflect the international developments or the actual usage of that terminology of inspectors and manufacturers.

(4) All medicinal products for human use manufactured or imported into the Union, including medicinal products intended for export, should be manufactured in accordance with the principles and guidelines of good manufacturing practice. However, for the manufacturer to be able to comply with those principles and guidelines, cooperation between the manufacturer and the marketing authorisation holder, when they are different legal entities, is necessary. The obligations of the manufacturer and marketing authorisation holder vis-à-vis each other should be defined in a technical agreement between them.

(5) The manufacturer of medicinal products has to ensure that they are fit for their intended use, comply with the requirements of the marketing authorisation and do not place patients at risk due to inadequate quality. To achieve this quality objective reliably the manufacturer must implement a comprehensively designed and correctly implemented pharmaceutical quality system incorporating good manufacturing practice and quality risk management.

(6) In order to ensure conformity with the principles and guidelines of good manufacturing practice, it is necessary to lay down detailed provisions on inspections by the competent authorities and on certain obligations of manufacturer.

(7) It is necessary to ensure that all medicinal products available on the EU territory comply with the same quality standards, therefore medicinal products imported into the Union should be manufactured in accordance with standards which are at least equivalent to the good manufacturing practice standards laid down in the Union.

([1]) OJ L 311, 28.11.2001, p. 67.
([2]) Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (OJ L 262, 14.10.2003, p. 22).
([3]) Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

(8) In order to ensure the consistent application of the principles of good manufacturing practice, manufacturers of medicinal products for human use and inspectors should consider the guidelines referred to in the second paragraph of Article 47 of Directive 2001/83/EC. However, for advanced therapy medicinal products, the guideline referred in Article 5 of Regulation (EC) No 1394/2007 ([1]) should be applied. Principles and guidelines of good manufacturing practice for medicinal products for human use should be set out in relation to quality management, personnel, premises and equipment, documentation, production, quality control, outsourced operations, complaints, product recall, and self-inspections. As regards the advanced therapy medicinal products those principles and guidelines should be adapted to the specific characteristic of those products in accordance with the risk-based approach.

(9) Since many of the provisions of Directive 2003/94/EC need to be adjusted, for the sake of clarity, that Directive should be repealed.

(10) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee for Medicinal Products for Human Use,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Subject-matter

This Directive lays down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use whose manufacture or import requires the authorisation referred to in Article 40 of Directive 2001/83/EC.

Article 2

Definitions

For the purposes of this Directive, the following definitions shall apply:

(1) 'manufacturer' means any person engaged in activities for which the authorisation referred to in Article 40(1) and (3) of Directive 2001/83/EC is required;

(2) 'pharmaceutical quality system' means the total sum of the organised arrangements made with the objective of ensuring that medicinal products are of the quality required for their intended use;

(3) 'good manufacturing practice' means the part of the quality assurance which ensures that medicinal products are consistently produced, imported and controlled in accordance with the quality standards appropriate to their intended use.

Article 3

Inspections

1. By means of the repeated inspections referred to in Article 111(1a) of Directive 2001/83/EC, the Member States shall ensure that manufacturers authorised in accordance with Article 40(1) and (3) of Directive 2001/83/EC respect the principles and guidelines of good manufacturing practice laid down by this Directive.

Member States shall also take into account the compilation, published by the Commission, of Union procedures on inspections and exchange of information.

2. For the interpretation of the principles and guidelines of good manufacturing practice, manufacturers and the competent authorities shall take into account the detailed guidelines referred to in the second paragraph of Article 47 of Directive 2001/83/EC. In the case of advanced therapy medicinal products, the guidelines on good manufacturing practice specific to advanced therapy medicinal products referred to in Article 5 of Regulation (EC) No 1394/2007 on advanced therapy medicinal products shall be taken into account.

([1]) Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).

3. Member States shall establish and implement in their inspectorates a properly designed quality system that shall be complied with by inspectorates' personnel and management. The quality system shall be updated as appropriate.

Article 4

Conformity with good manufacturing practice

1. The Member States shall ensure that the manufacturing operations are carried out by manufacturers in accordance with good manufacturing practice and with the manufacturing authorisation. This provision shall also apply to medicinal products intended only for export.

2. For medicinal products imported from third countries, the Member States shall ensure that the products have been manufactured in accordance with standards which are at least equivalent to the good manufacturing practice standards laid down in the Union and that such products have been manufactured by manufacturers duly authorised to do so.

Article 5

Compliance with marketing authorisation

1. The Member States shall ensure that all manufacturing or import operations for medicinal products subject to a marketing authorisation are carried out by manufacturers in accordance with the information provided in the application for that marketing authorisation.

2. The Member States shall oblige the manufacturer to regularly review his manufacturing methods in light of scientific and technical progress.

If a variation to the marketing authorisation dossier is necessary, the variation shall take place by the arrangements established in accordance with Article 23b of Directive 2001/83/EC.

Article 6

Pharmaceutical quality system

The Member States shall ensure that the manufacturers establish, implement and maintain an effective pharmaceutical quality system, involving the active participation of the senior management and the personnel of the different departments.

Article 7

Personnel

1. The manufacturer shall be obliged to have at each manufacturing or import site a sufficient number of competent and appropriately qualified personnel at his disposal to achieve the objective of the pharmaceutical quality system.

2. The duties of the managerial and supervisory staff, including the qualified persons referred to in Article 48 of Directive 2001/83/EC, responsible for implementing and operating good manufacturing practice, shall be defined in job descriptions. Their hierarchical relationships shall be defined in an organisation chart. Organisation charts and job descriptions shall be approved in accordance with the manufacturer's internal procedures.

3. The staff referred to in paragraph 2 shall be given sufficient authority to discharge their responsibility correctly.

4. The personnel shall receive initial and ongoing training, the effectiveness of which shall be verified, covering in particular the theory and application of the concept of quality assurance and good manufacturing practice.

5. Hygiene programmes adapted to the activities to be carried out shall be established and observed. These programmes shall, in particular, include procedures relating to health, hygiene practice and clothing of personnel.

Article 8

Premises and equipment

1. As regards the premises and manufacturing equipment the manufacturer shall be obliged to ensure that they are located, designed, constructed, adapted and maintained to suit the intended operations.

2. The Member States shall require that the premises and manufacturing equipment are laid out, designed and operated in such a way as to minimise the risk of error and to permit effective cleaning and maintenance in order to avoid contamination, cross contamination and, in general, any adverse effect on the quality of the product.

3. Premises and equipment to be used for manufacturing or import operations, which are critical to the quality of the products, shall be subjected to appropriate qualification and validation.

Article 9

Documentation

1. The manufacturer shall be obliged to establish and maintain a documentation system based upon specifications, manufacturing formulae and processing and packaging instructions, procedures and records covering the various manufacturing operations performed. The documentation system shall ensure data quality and integrity. Documents shall be clear, free from error and kept up to date. Pre-established procedures for general manufacturing operations and conditions shall be kept available, together with specific documents for the manufacture of each batch. That set of documents shall enable the history of the manufacture of each batch to be traced.

The manufacturer shall be required to retain the batch documentation for at least 1 year after the expiry date of the batches to which it relates or at least 5 years after the certification referred to in Article 51(3) of Directive 2001/83/EC, whichever is the longer period.

2. When electronic, photographic or other data processing systems are used instead of written documents, the manufacturer shall be required to first validate the systems by showing that the data will be appropriately stored during the anticipated period of storage. Data stored by those systems shall be made readily available in legible form and shall be provided to the competent authorities upon request. The electronically stored data shall be protected, by techniques such as duplication or back-up and transfer to another storage system, against unlawful access, loss or damage of data, and audit trails shall be maintained.

Article 10

Production

1. The Member States shall ensure that the manufacturers carry out the different production operations in accordance with pre-established instructions and procedures and in accordance with good manufacturing practice. Adequate and sufficient resources shall be made available by the manufacturer for the in-process controls. All process deviations and product defects shall be documented and thoroughly investigated.

2. The manufacturers shall be required to take appropriate technical and organisational measures to avoid cross contamination and mix-ups.

3. Any new manufacturing or important modification of a manufacturing process of a medicinal product shall be validated. Critical phases of manufacturing processes shall be regularly revalidated.

Article 11

Quality control

1. The manufacturer shall be obliged to establish and maintain a quality control system placed under the authority of a person who has the requisite qualifications and is independent of production.

That person shall have at his disposal, or shall have access to, one or more quality control laboratories appropriately staffed and equipped to carry out the necessary examination and testing of starting materials and packaging materials and the testing of intermediate and finished medicinal products.

2. For medicinal products, including those imported from third countries, contract laboratories may be used if authorised in accordance with Article 12 of this Directive and point (b) of Article 20 of Directive 2001/83/EC.

3. During the final control of the finished medicinal product before its release for sale or distribution, the quality control system shall take into account, in addition to analytical results, essential information such as the production conditions, the results of in-process controls, the examination of the manufacturing documents and the conformity of the product to its specifications, including the final finished pack.

4. Samples of each batch of finished medicinal product shall be retained for at least 1 year after the expiry date.

Samples of starting materials, other than solvents, gases or water, used in the manufacturing process shall be retained for at least 2 years after the release of the product. That period may be shortened if the period of stability of the material, as indicated in the relevant specification, is shorter. All those samples shall be maintained at the disposal of the competent authorities.

Other conditions may be defined, by agreement with the competent authority, for the sampling and retaining of starting materials and certain products manufactured individually or in small quantities, or when their storage could raise special problems.

Article 12

Outsourced operations

1. The Member States shall require that any manufacturing or import operation or operation linked thereto which is outsourced is the subject of a written contract.

2. The contract shall clearly define the responsibilities of each party and shall define, in particular, the observance of good manufacturing practice to be followed by the contract-acceptor and the manner in which the qualified person referred to in Article 48 of Directive 2001/83/EC responsible for certifying each batch is to discharge his responsibilities.

3. The contract-acceptor shall not subcontract any of the work entrusted to him under the contract without written authorisation from the contract-giver.

4. The contract-acceptor shall comply with the principles and guidelines of good manufacturing practice applicable to the operations concerned laid down in the Union and shall submit to inspections carried out by competent authorities pursuant to Article 111 of Directive 2001/83/EC.

Article 13

Complaints and product recall

1. The Member States shall ensure that manufacturers implement a system for recording and reviewing complaints together with an effective system for recalling, promptly and at any time, medicinal products in the distribution network. Any complaint concerning a defect shall be recorded and investigated by the manufacturer. The manufacturer shall be required to inform the competent authority and, if applicable, the marketing authorisation holder of any defect that could result in a recall or an abnormal restriction on supply and, in so far as possible, indicate the countries of destination.

2. Any recall shall be made in accordance with the requirements referred to in Article 123 of Directive 2001/83/EC.

Article 14

Self-inspection

The manufacturer shall be required to conduct repeated self-inspections as part of the pharmaceutical quality system in order to monitor the implementation and respect of good manufacturing practice and to propose any necessary corrective measures and/or preventive actions. Records shall be maintained of such self-inspections and any corrective actions subsequently taken.

Article 15

Repeal of Directive 2003/94/EC

Directive 2003/94/EC is repealed with effect from 6 months after the date of publication in the *Official Journal of the European Union* of the notice referred to in Article 82(3) of Regulation (EU) No 536/2014 or 1 April 2018, whichever is the later.

References to the repealed Directive shall be construed as references to this Directive and to Commission Delegated Regulation (EU) 2017/1569 ([1]) and read in accordance with the correlation table in the Annex.

Article 16

Transposition

1. Member States shall adopt and publish, by 31 March 2018 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 6 months after the date of publication in the *Official Journal of the European Union* of the notice referred to in Article 82(3) of Regulation (EU) No 536/2014 or 1 April 2018, whichever is the later.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 17

Entry into force

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

Article 18

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 15 September 2017.

For the Commission
The President
Jean-Claude JUNCKER

([1]) Commission Delegated Regulation (EU) 2017/1569 of 23 May 2017 supplementing Regulation (EU) No 536/2014 of the European Parliament and of the Council by specifying principles of and the guidelines for good manufacturing practice for investigational medicinal products for human use and arrangements for inspections (see page 12 of this Official Journal).

ANNEX

Correlation table

Directive 2003/94/EC	This Directive	Commission Delegated Regulation (EU) 2017/1569 supplementing Regulation (EU) No 536/2014 of the European Parliament and of the Council by specifying principles of and guidelines for good manufacturing practice for investigational medicinal products for human use and arrangements for inspections
Article 1	Article 1	Article 1
Article 2	Article 2	Article 2
Article 3	Article 3	—
Article 4	Article 4	Article 3
Article 5	Article 5	Article 4
Article 6	Article 6	Article 5(1)
Article 7	Article 7	Article 6
Article 8	Article 8	Article 7
Article 9	Article 9	Article 8
Article 10	Article 10	Article 9
Article 11	Article 11	Article 10
Article 12	Article 12	Article 13
Article 13	Article 13	Article 14
Article 14	Article 14	Article 15
Article 15	—	—
Article 16	—	—
Article 17	—	—
Article 18	—	—
Article 19	—	—

DECISIONS

COUNCIL IMPLEMENTING DECISION (CFSP) 2017/1573

of 15 September 2017

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

THE COUNCIL OF THE EUROPEAN UNION,

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

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

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

Whereas:

(1) On 27 May 2016, the Council adopted Decision (CFSP) 2016/849.

(2) On 11 September 2017, the United Nations Security Council adopted Resolution 2375 (2017), which added one person and three entities to the list of persons and entities subject to restrictive measures.

(3) Annex I to Decision (CFSP) 2016/849 should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

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

Article 2

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

Done at Brussels, 15 September 2017.

For the Council
The President
M. MAASIKAS

[1] OJ L 141, 28.5.2016, p. 79.

ANNEX

The persons and entities listed below shall be added to the list of persons and entities subject to restrictive measures set out in Annex I to Decision (CFSP) 2016/849.

A. **Persons**

	Name	Alias	Identifiers	Date of UN designation	Statement of Reasons
63.	Pak Yon Sik		Nationality: DPRK YOB: 1950	11.9.2017	Member of the Workers' Party of Korea Central Military Commission, which is responsible for the development and implementation of the Workers' Party of Korea military policies, commands and controls the DPRK's military, and helps direct the country's military defence industries.

B. **Entities**

	Name	Alias	Location	Date of UN designation	Other information
51.	Central Military Commission of the Worker's Party of Korea (CMC)		Pyongyang, DPRK	11.9.2017	The Central Military Commission is responsible for the development and implementation of the Workers' Party of Korea's military policies, commands and controls the DPRK's military, and directs the country's military defence industries in coordination with the State Affairs Commission.
52.	Organization and Guidance Department (OGD)		DPRK	11.9.2017	The Organization and Guidance Department is a very powerful body of the Worker's Party of Korea. It directs key personnel appointments for the Workers' Party of Korea, the DPRK's military, and the DPRK's government administration. It also purports to control the political affairs of all of the DPRK and is instrumental in implementing the DPRK's censorship policies.
53.	Propaganda and Agitation Department (PAD)		Pyongyang, DPRK	11.9.2017	The Propaganda and Agitation Department has full control over the media, which it uses as a tool to control the public on behalf of the DPRK leadership. The Propaganda and Agitation Department also engages in or is responsible for censorship by the Government of the DPRK, including newspaper and broadcast censorship.

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 51/2017 OF THE JOINT COMMITTEE ESTABLISHED UNDER THE AGREEMENT ON MUTUAL RECOGNITION BETWEEN THE EUROPEAN COMMUNITY AND THE UNITED STATES OF AMERICA

of 4 September 2017

related to the listing of Conformity Assessment Bodies under the Sectoral Annex for Electromagnetic Compatibility [2017/1574]

THE JOINT COMMITTEE,

Having regard to the Agreement on Mutual Recognition between the European Community and the United States of America and in particular Articles 7 and 14;

Whereas the Joint Committee is to take a decision to list a Conformity Assessment Body or Bodies under a Sectoral Annex;

HAS DECIDED AS FOLLOWS:

1. The Conformity Assessment Body in Attachment A is added to the list of Conformity Assessment Bodies under column 'EC access to the US market' in Section V of the Sectoral Annex for Electromagnetic Compatibility.

2. The specific scope of listing, in terms of products and conformity assessment procedures, of the Conformity Assessment Body indicated in Attachment A has been agreed by the Parties and will be maintained by them.

This Decision, done in duplicate, shall be signed by representatives of the Joint Committee who are authorized to act on behalf of the Parties for purposes of amending the Agreement. This Decision shall be effective from the date of the later of these signatures.

On behalf of the United States of America

James C. SANFORD

Signed in Washington DC, on 5 July 2017.

On behalf of the European Union

Ignacio IRUARRIZAGA

Signed in Brussels, on 4 September 2017.

Attachment A

EC Conformity Assessment Body added to the list of Conformity Assessment Bodies under column 'EC access to the US market' in Section V of the Sectoral Annex for Electromagnetic Compatibility

Electromagnetic Testing Services Ltd Pratts Fields, Lubberhedges Lane Stebbing, Dunmow Essex CM6 3BT UNITED KINGDOM

CORRIGENDA

Corrigendum to Council Regulation (EU) 2017/1398 of 25 July 2017 amending Regulation (EU) 2017/127 as regards certain fishing opportunities

(Official Journal of the European Union L 199 of 29 July 2017)

On page 3, recital 8:

for: 'The prohibition under that recommendation no longer applied after that the end of that period.',

read: 'The prohibition under that recommendation no longer applied after the end of that period.';

on page 3, Article 1, point 2:

for: 'Annexes IA and ID to Regulation (EU) 2017/127 are amended …',

read: 'Annexes IA, IB and ID to Regulation (EU) 2017/127 are amended …';

on page 7, the Annex, point 1(f), the opening wording:

for: '(f) the fishing opportunities table for redfish in international waters of I and II is replaced by the following:',

read: '2. In Annex IB to Regulation (EU) 2017/127, the fishing opportunities table for redfish in international waters of I and II is replaced by the following:';

on page 7, the Annex, point 2:

for: '2. In Annex ID to Regulation (EU) 2017/127 …',

read: '3. In Annex ID to Regulation (EU) 2017/127 …'.

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