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II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2018/1461

of 28 September 2018

amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the use of Low-substituted hydroxypropyl cellulose (L-HPC) in food supplements

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ⁽¹⁾, and in particular Articles 10(3) and 14 thereof,Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings ⁽²⁾, and in particular Article 7(5) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food and their conditions of use.
- (2) Only food additives included in the Union list in Annex II to Regulation (EC) No 1333/2008 may be placed on the market as such and used in foods under the conditions of use specified therein.
- (3) Commission Regulation (EU) No 231/2012 ⁽³⁾ lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (4) The Union list and the specifications may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.
- (5) On 21 October 2016 an application was submitted for the authorisation of the use of low-substituted hydroxypropyl cellulose (L-HPC) as a food additive in food supplements in tablet form falling under the food category 17.1 'Food supplements supplied in a solid form' in Part E of Annex II to Regulation (EC) No 1333/2008. The application was subsequently made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (6) The European Food Safety Authority evaluated the safety of L-HPC as a food additive and in its opinion ⁽⁴⁾ of 20 January 2018 concluded that there was no safety concern from the proposed use in food supplements in solid form (tablet), at a maximum use level of 20 000 mg/kg and a typical use level of 10 000 mg/kg.

⁽¹⁾ OJ L 354, 31.12.2008, p. 16.⁽²⁾ OJ L 354, 31.12.2008, p. 1.⁽³⁾ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).⁽⁴⁾ EFSA Journal 2018;16(1):5062.

- (7) Low-substituted hydroxypropyl cellulose (L-HPC) is water insoluble cellulose that facilitates the manufacturing of solid food supplements in tablet form due to its good compressibility and binding properties. Being insoluble in water, it absorbs water while increasing in volume. The increased volume makes the tablet disintegrating rapidly providing a fast release of the nutrients in the stomach.
- (8) It is therefore appropriate to include low-substituted hydroxypropyl cellulose (L-HPC) in the Union list of food additives and to assign E 463a as E-number to that additive to enable its authorisation as a glazing agent in food supplements in solid form (tablet) at a maximum use level of 20 000 mg/kg.
- (9) The specifications for low-substituted hydroxypropyl cellulose (L-HPC) (E 463a) should be included in Regulation (EU) No 231/2012 when it is included in the Union list of food additives laid down in Annex II to Regulation (EC) No 1333/2008 for the first time.
- (10) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with Annex I to this Regulation.

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

Article 3

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

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

Done at Brussels, 28 September 2018.

For the Commission
The President
Jean-Claude JUNKER

ANNEX I

Annex II to Regulation (EC) No 1333/2008 is amended as follows:

- (1) in Part B, point 3 'Additives other than colours and sweeteners', the following new entry E 463a for Low-substituted hydroxypropyl cellulose (L-HPC) is inserted after the entry for E 463 Hydroxypropyl cellulose:

'E 463a	Low-substituted hydroxypropyl cellulose (L-HPC)
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- (2) in Part E, in food category 17.1 'Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms', the following new entry for Low-substituted hydroxypropyl cellulose (L-HPC) is inserted after the entry for E 459 Beta-cyclodextrin:

'E 463a	Low-substituted hydroxypropyl cellulose (L-HPC)	20 000	only food supplements in tablet form'
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ANNEX II

In the Annex to Regulation (EU) No 231/2012 the following entry for E 463a (Low-substituted hydroxypropyl cellulose (L-HPC)) is inserted after the entry for E 463 (Hydroxypropyl cellulose):

E 463a LOW-SUBSTITUTED HYDROXYPROPYL CELLULOSE (L-HPC)

Synonyms	Cellulose hydroxypropyl ether, low substituted
Definition	L-HPC is a low-substituted poly (hydroxypropyl) ether of cellulose. L-HPC is manufactured by partial etherification of the anhydroglucose units of pure cellulose (wood pulp) with propylene oxide/hydroxypropyl groups. The resulting product is then purified, dried and milled to yield low-substituted hydroxypropyl cellulose. L-HPC contains not less than 5,0 % and not more than 16,0 % of hydroxypropoxy groups, calculated on the dried basis. L-HPC differs from hydroxypropyl cellulose (E 463) with respect to the degree of molar substitution with hydroxypropoxy groups of the glucose ring unit (0,2 for L-HPC vs 3,5 for E 463) of the cellulose backbone.
IUPAC name	Cellulose, 2-hydroxypropyl ether (low substituted)
CAS number	9004-64-2
Einecs number	
Chemical name	Hydroxypropyl ether of cellulose, low-substituted
Chemical formula	The polymers contain substituted anhydroglucose units with the following general formula: $\text{C}_6\text{H}_7\text{O}_2(\text{OR}_1)(\text{OR}_2)(\text{OR}_3)$ where R_1, R_2, R_3 each may be one of the following: — H — $\text{CH}_2\text{CHOHCH}_3$ — $\text{CH}_2\text{CHO}(\text{CH}_2\text{CHOHCH}_3)\text{CH}_3$ — $\text{CH}_2\text{CHO}[\text{CH}_2\text{CHO}(\text{CH}_2\text{CHOHCH}_3)\text{CH}_3]\text{CH}_3$
Molecular weight	From about 30 000 to 150 000 g/mol
Assay	The average number of hydroxypropoxy groups ($-\text{OCH}_2\text{CHOHCH}_3$) corresponds to 0,2 hydroxypropyl groups per anhydroglucose unit on the anhydrous basis
Particle size	by laser diffraction method — Not less than 45 µm (not more than 1 % in weight of particles of less than 45 µm) and not more than 65 µm by size-exclusion chromatography (SEC) — Average (D50) particle size between 47,3 µm and 50,3 µm; D90 value (90 % below given value) between 126,2 µm and 138 µm
Description	Slightly hygroscopic white or slightly yellowish or greyish odourless and tasteless, granular or fibrous powder
Identification	Passes test
Solubility	Insoluble in water; swelling in water. It dissolves in a solution of 10 % sodium hydroxide producing a viscous solution.

Assay	Determination of the degree of molar substitution by gas chromatography
pH	Not less than 5,0 and not more than 7,5 (1 % colloidal suspension)
Purity	
Loss on drying	Not more than 5,0 % (105 °C, 1 hour)
Residue on ignition	Not more than 0,8 % determined at 800 °C ± 25 °C
Propylene chlorohydrins	Not more than 0,1 mg/kg (on an anhydrous basis) (gas chromatography–mass spectrometry (GC–MS))
Arsenic	Not more than 2 mg/kg
Lead	Not more than 1 mg/kg
Mercury	Not more than 0,5 mg/kg
Cadmium	Not more than 0,15 mg/kg'

COMMISSION REGULATION (EU) 2018/1462**of 28 September 2018****amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards specifications for certain sorbitan esters (E 491 Sorbitan monostearate, E 492 Sorbitan tristearate and E 495 Sorbitan monopalmitate)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ⁽¹⁾, and in particular Article 14 thereof,

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

Whereas:

- (1) Commission Regulation (EU) No 231/2012 ⁽³⁾ lays down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008.
- (2) Those specifications may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008, either on the initiative of the Commission or following an application.
- (3) On 14 October 2014 an application was submitted for the amendment of specifications concerning the food additives sorbitan monostearate (E 491), sorbitan tristearate (E 492) and sorbitan monopalmitate (E 495). The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (4) The current Union specifications lay down a range of congealing temperatures (an identification parameter) for sorbitan monostearate (E 491), sorbitan tristearate (E 492) and sorbitan monopalmitate (E 495).
- (5) The applicant requests that the reference to the congealing range as an identification method of sorbitan monostearate (E 491), sorbitan tristearate (E 492) and sorbitan monopalmitate (E 495) in the Union specifications be removed as it is not an optimal method for identification due to a lack of a clear and common methodology.
- (6) In its opinion of 5 May 2017 ⁽⁴⁾ the European Food Safety Authority ('the Authority') concluded that the amendment to the specifications as regards the removal of the parameter 'congealing range' for identification of sorbitan monostearate (E 491), sorbitan tristearate (E 492) and sorbitan monopalmitate (E 495) as proposed by the applicant would not give rise to a safety concern.
- (7) The Authority also concluded that the removal of the congealing range from the Union specifications would result in less characterisation of the various sorbitan esters of saturated fatty acids, and that this identification parameter could be replaced by another one. The Authority noted that out of all analytical methods available, gas chromatography analysis appears to deliver the most accurate and reliable results and is fit for purposes of food controls.
- (8) Consequently, it is appropriate to amend the Union specifications regarding the removal of the 'congealing range' as an identification parameter for the food additives sorbitan monostearate (E 491), sorbitan tristearate (E 492) and sorbitan monopalmitate (E 495) and to replace it by 'Identification test — by acid value, iodine value, gas chromatography'.

⁽¹⁾ OJ L 354, 31.12.2008, p. 16.

⁽²⁾ OJ L 354, 31.12.2008, p. 1.

⁽³⁾ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

⁽⁴⁾ EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to food), 2017. Scientific Opinion on the re-evaluation of sorbitan monostearate (E 491), sorbitan tristearate (E 492), sorbitan monolaurate (E 493), sorbitan monooleate (E 494) and sorbitan monopalmitate (E 495) when used as food additives. EFSA Journal 2017;15(5):4788, 56 pp. <https://doi.org/10.2903/j.efsa.2017.4788>.

- (9) The Annex to Regulation (EU) No 231/2012 should therefore be amended accordingly.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 231/2012 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 28 September 2018.

For the Commission
The President
Jean-Claude JUNKER

ANNEX

The Annex to Regulation (EU) No 231/2012 is amended as follows:

- (1) In the entry for the food additive E 491 Sorbitan monostearate, the specification as regards 'congealing range' is replaced by the following:

'Identification test	by acid value, iodine value (not more than 4), gas chromatography'
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- (2) In the entry for the food additive E 492 Sorbitan tristearate, the specification as regards 'congealing range' is replaced by the following:

'Identification test	by acid value, iodine value (not more than 4), gas chromatography'
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- (3) In the entry for the food additive E 495 Sorbitan monopalmitate, the specification as regards 'congealing range' is replaced by the following:

'Identification test	by acid value, iodine value (not more than 4), gas chromatography'
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DECISIONS

COUNCIL IMPLEMENTING DECISION (EU) 2018/1463

of 28 September 2018

on subjecting the new psychoactive substances N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]cyclopropanecarboxamide (cyclopropylfentanyl) and 2-methoxy-N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (methoxyacetyl fentanyl) to control measures

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Decision 2005/387/JHA of 10 May 2005 on information exchange, risk-assessment and control of new psychoactive substances ⁽¹⁾, and in particular Article 8(3) thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Parliament ⁽²⁾,

Whereas:

- (1) In accordance with Article 6 of Decision 2005/387/JHA, risk assessment reports on the new psychoactive substances N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]cyclopropanecarboxamide ('cyclopropylfentanyl') and 2-methoxy-N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide ('methoxyacetyl fentanyl') were drawn up by a special session of the extended Scientific Committee of the European Monitoring Centre for Drugs and Drug Addiction on 21 March 2018, and were submitted to the Commission and to the Council on 23 March 2018.
- (2) Cyclopropylfentanyl and methoxyacetyl fentanyl are synthetic opioids and are structurally related to fentanyl, a controlled substance widely used in medicine as an adjunct to general anaesthesia during surgery and for pain management. Cyclopropylfentanyl is also structurally related to butyrfentanyl, another internationally controlled substance. Methoxyacetyl fentanyl is also structurally related to ocfentanil ⁽³⁾ and acetyl fentanyl, which are both internationally controlled substances.
- (3) Cyclopropylfentanyl has been available in the Union since at least June 2017. It has been detected in six Member States, which reported 140 seizures in total between June 2017 and January 2018. In general, detections are likely to be under-reported since cyclopropylfentanyl is not routinely screened for. In most cases, cyclopropylfentanyl was seized as powder, but it has also been seized, to a lesser extent, as a liquid and as tablets. The detected quantities are relatively small. However, they should be seen within the context of the high potency that is typical of the fentanils.
- (4) 77 deaths have been reported by two Member States where exposure to cyclopropylfentanyl was confirmed. The deaths occurred within a short time period, i.e. between June and December 2017. In most of the cases, other drugs were also detected with cyclopropylfentanyl. In the case of at least 74 of those deaths, cyclopropylfentanyl was the cause of death or is likely to have contributed to the death. No acute intoxications with confirmed exposure to cyclopropylfentanyl were reported. It is likely that naloxone works as an antidote to poisoning caused by cyclopropylfentanyl. Both non-fatal intoxications and deaths caused by cyclopropylfentanyl are likely to be under-detected and under-reported, as cyclopropylfentanyl is not routinely screened for. Accidental exposure to cyclopropylfentanyl may pose a risk to family and friends of the user, law enforcement, emergency personnel, medical and forensic laboratory personnel, as well as to those in custodial settings and postal services.

⁽¹⁾ OJ L 127, 20.5.2005, p. 32.

⁽²⁾ Opinion of 11 September 2018 (not yet published in the Official Journal).

⁽³⁾ The 61st session of the Commission on Narcotic Drugs in March 2018 decided to schedule Ocfentanil in Schedule I of the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol.

- (5) There is no direct evidence showing the involvement of organised crime in the manufacture, distribution, trafficking and supply of cyclopropylfentanyl within the Union. However, given the fact that it has been detected in a heroin sample and in fake medicines, the involvement of organised crime cannot be excluded. The available information suggests that cyclopropylfentanyl is produced by chemical companies based in China, but the capability to manufacture fentanils may also exist within the Union.
- (6) Cyclopropylfentanyl appears to be sold online in small and wholesale amounts, under the guise of a research chemical or as a legal replacement to illicit opioids, mainly as a powder or as a solution in ready-to-use nasal sprays. In addition, information from seizures shows that cyclopropylfentanyl has also been used to make fake tablets of popular benzodiazepine and analgesic medicines. Information from seizures suggests that cyclopropylfentanyl can have also been sold on the illicit opioid market as methoxyacetylfentanyl, as heroin and in mixtures with other opioids such as heroin. Due to this, users may not be aware that they are using a fentanyl.
- (7) Methoxyacetylfentanyl has been available in the Union since at least November 2016. It has been detected in 11 Member States, which reported 44 seizures in total between June and December 2017. In general, detections are likely to be under-reported since methoxyacetylfentanyl is not routinely screened for. In most cases, methoxyacetylfentanyl was seized as powder or as a liquid, but it has also been seized, to a lesser extent, as tablets. The detected quantities are relatively small. However, they should be seen within the context of the high potency that is typical of the fentanils.
- (8) 13 deaths have been reported by four Member States where exposure to methoxyacetylfentanyl was confirmed. In all cases, other drugs were also detected with methoxyacetylfentanyl. In the case of at least seven of those deaths, methoxyacetylfentanyl was the cause of death or was likely to have contributed to the death. Two cases of acute intoxication with confirmed exposure to methoxyacetylfentanyl were reported. It is likely that naloxone works as an antidote to poisoning caused by methoxyacetylfentanyl. Both non-fatal intoxications and deaths caused by methoxyacetylfentanyl are likely to be under-detected and under-reported, as methoxyacetylfentanyl is not routinely screened for. Accidental exposure to methoxyacetylfentanyl may pose a risk to family and friends of users, law enforcement, emergency personnel, medical and forensic laboratory personnel, as well as to those in custodial settings and postal services.
- (9) There is no information to suggest the involvement of organised crime in the manufacture, distribution, trafficking and supply of methoxyacetylfentanyl within the Union. The available information suggests that methoxyacetylfentanyl is produced by chemical companies in China, but the capability to manufacture fentanils may also exist within the Union.
- (10) Methoxyacetylfentanyl appears to be sold online in small and wholesale amounts, under the guise of a research chemical or as a legal replacement to illicit opioids, as powder or as a solution in ready-to-use nasal sprays. Information from seizures suggests that methoxyacetylfentanyl may have also been sold on the illicit opioid market, where it is sold as or is used to make fake opioid analgesics and benzodiazepine. Due to this, users may not be aware that they are using a fentanyl.
- (11) Cyclopropylfentanyl and methoxyacetylfentanyl have no recognised human or veterinary medical use in the Union nor, it appears, elsewhere. There are no indications that they may be used for any other purpose aside from as an analytical reference standard and in scientific research.
- (12) The risk assessment reports reveal that many of the questions related to cyclopropylfentanyl and methoxyacetylfentanyl that are posed by the lack of data on the risks to individual health, risks to public health, and social risks, could be answered through further research. However, the available evidence and information on the health and social risks that cyclopropylfentanyl and methoxyacetylfentanyl pose, given also their similarities with fentanyl, provide sufficient grounds for subjecting cyclopropylfentanyl and methoxyacetylfentanyl to control measures across the Union.
- (13) Cyclopropylfentanyl and methoxyacetylfentanyl are not listed for control under the 1961 United Nations Single Convention on Narcotic Drugs or under the 1971 United Nations Convention on Psychotropic Substances. They are not currently under assessment by the United Nations system.
- (14) Given that eight Member States control cyclopropylfentanyl and nine Member States control methoxyacetylfentanyl under national drug control legislation, and that five Member States control cyclopropylfentanyl and methoxyacetylfentanyl under other legislation, subjecting cyclopropylfentanyl and methoxyacetylfentanyl to control measures across the Union would help avoid the emergence of obstacles in cross-border law enforcement and judicial cooperation, and would help protect from the risks that their availability and use poses.

- (15) Decision 2005/387/JHA confers implementing powers upon the Council with a view to giving a quick and expertise-based response at Union level to the emergence of new psychoactive substances detected and reported by the Member States, by subjecting those substances to control measures across the Union. As the conditions and procedure for triggering the exercise of such implementing powers have been met, an implementing decision should be adopted in order to subject cyclopropylfentanyl and methoxyacetylfentanyl to control measures across the Union.
- (16) Denmark is bound by Decision 2005/387/JHA and is therefore taking part in the adoption and application of this Decision, which implements Decision 2005/387/JHA.
- (17) Ireland is bound by Decision 2005/387/JHA and is therefore taking part in the adoption and application of this Decision, which implements Decision 2005/387/JHA.
- (18) The United Kingdom is not bound by Decision 2005/387/JHA and is therefore not taking part in the adoption and application of this Decision and is not bound by it or subject to its application,

HAS ADOPTED THIS DECISION:

Article 1

The new psychoactive substances *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]cyclopropanecarboxamide ('cyclopropylfentanyl') and 2-methoxy-*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]acetamide ('methoxyacetylfentanyl') shall be subjected to control measures across the Union.

Article 2

By 29 September 2019, Member States shall take the necessary measures, in accordance with their national law, to subject cyclopropylfentanyl and methoxyacetylfentanyl to control measures and criminal penalties, as provided for under their legislation, in compliance with their obligations under the 1961 United Nations Single Convention on Narcotic Drugs or under the 1971 United Nations Convention on Psychotropic Substances.

Article 3

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

This Decision shall apply in accordance with the Treaties.

Done at Brussels, 28 September 2018.

For the Council
The President
M. SCHRAMBÖCK

COUNCIL DECISION (EU) 2018/1464**of 28 September 2018**

on the position to be adopted on behalf of the European Union in the CETA Committee on Trade and Sustainable Development, established by the Comprehensive Economic and Trade Agreement between Canada, of the one part, and the European Union and its Member States, of the other part, as regards the establishment of lists of individuals willing to serve as panellists under Chapter Twenty-Three and Chapter Twenty-Four of the Agreement

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first subparagraph of Article 207(4), in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) Council Decision (EU) 2017/37 ⁽¹⁾ provides for the signing on behalf of the European Union 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 Agreement'). The Agreement was signed on 30 October 2016.
- (2) Council Decision (EU) 2017/38 ⁽²⁾ provides for provisional application of parts of the Agreement, including the establishment of the CETA Joint Committee and specialised committees. Those parts of the Agreement have been provisionally applied since 21 September 2017.
- (3) Pursuant to Article 26.2.1(g) of the Agreement, the CETA Committee on Trade and Sustainable Development has been established.
- (4) In accordance with Articles 23.10 and 24.15 of the Agreement, the CETA Committee on Trade and Sustainable Development, during its first meeting, is to adopt a decision establishing lists of individuals willing and able to serve as panellists under Chapter Twenty-Three (Trade and Labour) and Chapter Twenty-Four (Trade and Environment) of the Agreement.
- (5) It is therefore appropriate to establish the position to be adopted on the Union's behalf in the CETA Committee on Trade and Sustainable Development on the basis of the attached draft Decision establishing lists of individuals willing to serve as panellists under Chapter Twenty-Three and Chapter Twenty-Four of the Agreement,

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted on behalf of the Union in the first meeting of the CETA Committee on Trade and Sustainable Development, established by 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, as regards the establishment of the lists of individuals willing to serve as panellists under Chapter Twenty-Three and Chapter Twenty-Four of the Agreement, shall be based on the draft decision of the CETA Committee on Trade and Sustainable Development attached to this Decision.

⁽¹⁾ Council Decision (EU) 2017/37 of 28 October 2016 on the signing on behalf of the European Union 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 (OJ L 11, 14.1.2017, p. 1).

⁽²⁾ Council Decision (EU) 2017/38 of 28 October 2016 on 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 (OJ L 11, 14.1.2017, p. 1080).

Article 2

This Decision is addressed to the Commission.

Done at Brussels, 28 September 2018.

For the Council
The President
M. SCHRAMBÖCK

DRAFT

**DECISION No [X/2018] OF THE CETA COMMITTEE ON TRADE AND SUSTAINABLE
DEVELOPMENT**

of xxx

**establishing lists of individuals willing to serve as panellists under Chapter 23 and Chapter 24 of
the Agreement**

THE CETA COMMITTEE ON TRADE AND SUSTAINABLE DEVELOPMENT,

Having regard to 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, and in particular paragraphs 6 and 7 of Article 23.10 and paragraphs 6 and 7 of Article 24.15 thereof,

Whereas:

- (1) In accordance with Article 30.7.3 of the Agreement, parts of the Agreement have been applied provisionally since 21 September 2017.
- (2) Pursuant to paragraph 6 of Article 23.10 of the Agreement, the CETA Committee on Trade and Sustainable Development is to establish a list of at least nine individuals who are willing and able to serve as panellists with regard to matters arising under Chapter 23 (Trade and Labour) and who, pursuant to paragraph 7, have specialised knowledge or expertise in labour law, other issues addressed in Chapter 23, or in the resolution of disputes arising under international agreements.
- (3) Pursuant to paragraph 6 of Article 24.15 of the Agreement, the CETA Committee on Trade and Sustainable Development is to establish a list of at least nine individuals who are willing and able to serve as panellists with regard to matters arising under Chapter 24 (Trade and Environment) and who, pursuant to paragraph 7, have specialised knowledge or expertise in environmental law, issues addressed in Chapter 24, or in the resolution of disputes arising under international agreements.
- (4) Pursuant to paragraph 6 of Article 23.10 and paragraph 6 of Article 24.15, each list shall consist of at least three individuals named by each Party and at least three individuals named by the Parties who are not nationals of either Party and who are willing and able to serve as chairperson of a Panel of Experts,

HAS DECIDED AS FOLLOWS:

1. The lists of individuals willing to serve as panellists as set out in the Annex are hereby established.
2. This Decision takes effect on the date of its adoption by the CETA Committee on Trade and Sustainable Development.

For the CETA COMMITTEE ON TRADE AND SUSTAINABLE DEVELOPMENT

For the EU

For Canada

ANNEX

LIST OF INDIVIDUALS WILLING TO SERVE AS PANELLISTS WITH REGARD TO MATTERS ARISING UNDER CHAPTER 23 (TRADE AND LABOUR) OF THE AGREEMENT**Individuals with specialised knowledge or expertise in labour law, other issues addressed in Chapter 23, or in the resolution of disputes arising under international agreements:**

Individuals named by Canada:

Kevin Banks

Adelle Blackett

Carol Nelder-Corvari

Individuals named by the European Union:

Jorge Cardona

Eddy Laurijssen

Karin Lukas

Chairpersons (non-nationals of the Parties):

Janice Bellace

Kathleen Claussen

Christian Häberli

Jill Murray

Patrick Pearsall

Ross Wilson

LIST OF INDIVIDUALS WILLING TO SERVE AS PANELLISTS WITH REGARD TO MATTERS ARISING UNDER CHAPTER 24 (TRADE AND ENVIRONMENT) OF THE AGREEMENT**Individuals with specialised knowledge or expertise in environmental law, issues addressed in Chapter 24, or in the resolution of disputes arising under international agreements:**

Individuals named by Canada:

Anne Daniel

Armand de Mestral

Elaine Feldman

Matthew Kronby

Brendan McGivern

Individuals named by the European Union:

Laurence Boisson de Chazournes

Hélène Ruiz Fabri

Geert Van Calster

Chairpersons (non-nationals of the Parties):

Arthur Edmond Appleton

James Bacchus

Nathalie Bernasconi-Osterwalder

Christian Häberli

COUNCIL DECISION (CFSP) 2018/1465
of 28 September 2018
amending Decision (CFSP) 2015/1333 concerning restrictive measures in view of the situation in
Libya

THE COUNCIL OF THE EUROPEAN UNION,

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

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

Whereas:

- (1) On 31 July 2015 the Council adopted Decision (CFSP) 2015/1333 ⁽¹⁾.
- (2) On 21 March 2018 the Council adopted Decision (CFSP) 2018/476 ⁽²⁾.
- (3) In view of the continuing instability and gravity of the situation in Libya, the Council has decided that the restrictive measures concerning three persons should be extended for a further period of six months.
- (4) Decision (CFSP) 2015/1333 should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

In Article 17 of Decision (CFSP) 2015/1333, paragraphs 3 and 4 are replaced by the following:

- ‘3. The measures referred to in Article 8(2) shall apply with regard to entries 14, 15 and 16 in Annex II until 2 April 2019.
4. The measures referred to in Article 9(2) shall apply with regard to entries 19, 20 and 21 in Annex IV until 2 April 2019.’.

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, 28 September 2018.

For the Council
The President
M. SCHRAMBÖCK

⁽¹⁾ Council Decision (CFSP) 2015/1333 of 31 July 2015 concerning restrictive measures in view of the situation in Libya, and repealing Decision 2011/137/CFSP (OJ L 206, 1.8.2015, p. 34).

⁽²⁾ Council Decision (CFSP) 2018/476 of 21 March 2018 amending Decision (CFSP) 2015/1333 concerning restrictive measures in view of the situation in Libya (OJ L 79, 22.3.2018, p. 30).

EUROPEAN SECURITIES AND MARKETS AUTHORITY DECISION (EU) 2018/1466**of 21 September 2018****renewing and amending the temporary prohibition in Decision (EU) 2018/795 on the marketing, distribution or sale of binary options to retail clients**

THE EUROPEAN SECURITIES AND MARKETS AUTHORITY BOARD OF SUPERVISORS,

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

Having regard to Regulation (EU) No 1095/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Securities and Markets Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/77/EC ⁽¹⁾, and in particular Articles 9(5), 43(2) and 44(1) thereof,

Having regard to Regulation (EU) No 600/2014 of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Regulation (EU) No 648/2012 ⁽²⁾, and in particular Article 40 thereof,

Having regard to Commission Delegated Regulation (EU) 2017/567 of 18 May 2016 supplementing Regulation (EU) No 600/2014 of the European Parliament and of the Council with regard to definitions, transparency, portfolio compression and supervisory measures on product intervention and positions ⁽³⁾, and in particular Article 19 thereof,

Whereas:

1. By Decision (EU) 2018/795 ⁽⁴⁾, the European Securities and Markets Authority (ESMA) prohibited the marketing, distribution or sale of binary options to retail clients with effect from 2 July 2018 for a period of three months.
2. In accordance with Article 40(6) of Regulation (EU) No 600/2014, ESMA must review a temporary product intervention measure at appropriate intervals and at least every three months.
3. ESMA's review of the prohibition on binary options has been informed by, inter alia, a survey amongst national competent authorities ⁽⁵⁾ (NCAs) on the practical application and impact of the product intervention measure as well as additional information provided by NCAs and stakeholders.
4. NCAs detected only limited examples of non-compliance with the ESMA product intervention measures. Furthermore, no new authorisations have been provided to firms that market, distribute or sell binary options since the announcement of the agreed measures on 27 March 2018.
5. NCAs reported a slight increase in the number of clients treated as professional clients on request over the month of July 2018 in comparison with July 2017. However, the number of professional clients on request is relatively small in comparison to the previous number of retail clients of providers of binary options. ESMA is aware that some third-country firms are actively approaching Union clients. However, without authorisation or registration in the Union, these firms are only allowed to offer services to clients established or situated in the Union at the client's own exclusive initiative. ESMA is also aware that firms are starting to provide other speculative investment products. ESMA will continue to monitor the offer of these other products to determine whether any other Union measures are appropriate.

⁽¹⁾ OJ L 331, 15.12.2010, p. 84.

⁽²⁾ OJ L 173, 12.6.2014, p. 84.

⁽³⁾ OJ L 87, 31.3.2017, p. 90.

⁽⁴⁾ European Securities and Markets Authority Decision (EU) 2018/795 of 22 May 2018 to temporarily prohibit the marketing, distribution or sale of binary options to retail clients in the Union in accordance with Article 40 of Regulation (EU) No 600/2014 of the European Parliament and of the Council (OJ L 136, 1.6.2018, p. 31).

⁽⁵⁾ 20 NCAs have responded: Cyprus Securities and Exchange Commission (CY—CySEC), Comisión Nacional del Mercado de Valores (ES — CNMV), Autoriteit Financiële Markten (NL—AFM), Czech National Bank (CZ — CNB), Financial Market Authority (AT — FMA), Finnish Financial Supervisory Authority (FI — FSA), Comissão do Mercado de Valores Mobiliários (PT — CMVM), Malta Financial Services Authority (MT — MFSA), Financial Supervisory Authority (IS — FME), Financial Services and Markets Authority (BE — FSMA), Commissione Nazionale per le Società e la Borsa (IT — Consob), Financial Supervision Commission (BG — FSC), Bundesanstalt für Finanzdienstleistungsaufsicht (DE — BaFin), Autorité des Marchés Financiers (FR — AMF), Magyar Nemzeti Bank (HU — MNB), Financial Conduct Authority (UK— FCA), Commission de Surveillance du Secteur Financier (LU — CSSF), Romanian Financial Supervisory Authority (RO — FSA), Agencija za trg vrednostnih papirjev (SL — SMA), Central Bank of Ireland (IE — CBI).

6. During the review period, ESMA did not obtain evidence contradicting its overall finding of a significant investor protection concern identified in Decision (EU) 2018/795. ESMA has therefore concluded that the significant investor protection concern identified in Decision (EU) 2018/795 would persist if its decision to prohibit the marketing, distribution or sale of binary options to retail clients is not renewed.
7. Since the adoption of that Decision, the applicable existing regulatory requirements under Union law have not changed and continue not to address the threat identified by ESMA. Furthermore, NCAs have not taken action to address the threat or the actions taken do not adequately address the threat. In particular, since the adoption of the Decision, no NCA has adopted its own national product intervention measure under Article 42 of Regulation (EU) No 600/2014 ⁽¹⁾.
8. The renewal of the prohibition set out in Decision (EU) 2018/795 does not have a detrimental effect on the efficiency of financial markets or on investors that is disproportionate to the benefits of the action and does not create a risk of regulatory arbitrage for the same reasons set out in that Decision.
9. If the temporary prohibition is not renewed, ESMA considers it is likely that binary options will again be offered to retail clients and that the same or similar products will return to the market that gave rise to the consumer detriment identified in Decision (EU) 2018/795.
10. In view of these reasons, taken together with the reasons set out in Decision (EU) 2018/795, ESMA has decided to renew the prohibition for a further three-month period to address the significant investor protection concern.
11. In renewing the prohibition, ESMA has taken care to examine whether there is any new evidence relating to specific products within the scope of its measure that should be exempted in the renewed period of application due to their specific features not giving rise to the significant investor protection concern set out in Decision (EU) 2018/795.
12. In this respect, ESMA obtained new information relating to binary options that are sufficiently long-term, are accompanied by a prospectus and are fully hedged by the provider or another entity in the provider's group, are unlikely to give rise to the significant investor protection concern identified in Decision (EU) 2018/795. An example of this kind of binary option is an inline warrant that cumulatively meets these conditions.
13. While the degree of complexity of this specific type of binary option is comparable to that of binary options generally, the minimum term requirement ameliorates the negative effects of complexity and opacity for investors. Investors can more reasonably take an informed view of the market over a period of 90 days or longer from the date when the product was first issued than over the very brief terms characteristic of the wider binary options market that existed prior to the application of Decision (EU) 2018/795. A term of 90 days or longer reduces the scope for frequently-repeated speculative trades that worsen losses and are associated with addictive behaviour.
14. A particular feature of binary options acting as a significant driver of potential detrimental consequences and exacerbating the disparity between returns for investors and the risk of loss is the conflict of interest that exists between many providers of binary options and their clients. However, some firms provide binary options that are fully hedged against market risk throughout their terms. Where such hedging activity relates to the provision of a binary option and is carried out by the provider or by another entity in the provider's group, and if no profit or loss is made on the binary option by any of the group entities other than previously disclosed commissions, transaction fees and related charges, the conflict of interest between the provider and client is significantly reduced. In particular, the net profit derived from the binary option is not substantially determined by whether it pays out or not. Hedged providers are not incentivised to misreport underlying prices or to speculate against the client.
15. Evidence received by ESMA suggests that hedged business models are consistent with binary options offerings with sufficiently long terms, in contrast to unhedged business models characterised by short term offerings. NCAs ⁽²⁾ supervising markets in which long term securitised binary options are provided by hedged

⁽¹⁾ On 4 June 2018, a competent authority of an EEA EFTA State, NO-Finanstilsynet, adopted national product intervention measures that have the same terms and dates of application of ESMA's measures. Furthermore, on 5 July 2018, the Financial Supervisory Authority of Iceland published that it considers the marketing, distribution or sale of binary options to be contrary to proper and sound business procedures and practices in securities trading according to its national law (Article 5 of Act No 108/2007 on Securities Transactions).

⁽²⁾ DE-BaFIN, [FR-AMF (awaiting confirmation)]

providers have confirmed that in respect of such products they have identified no reported cases of significant detriment to individual retail clients. Furthermore, BaFIN has not received any investor complaints in relation to inline warrants.

16. Additionally, and in this context, the requirement that binary options made available to retail investors must be accompanied by a prospectus approved in accordance with Directive 2003/71/EC of the European Parliament and the Council ⁽¹⁾ is intended to ensure a minimum level of transparency around these longer-term products. It ensures that in relation to the marketing, distribution or sale of these products to retail clients, prescribed information on the provider, including its business model and financial statements, and the risks and characteristics of the product, is made available to investors. Furthermore, the prospectus is subject to the scrutiny of the relevant NCA.
17. There is also no product-specific evidence that the marketing and distribution activities in relation to sufficiently long-term binary options with a prospectus and fully hedged by the provider or another entity in the provider's group consist of aggressive marketing practices and misleading communications techniques.
18. While the existence of any one of the criteria alone would not be sufficient to tackle the risk of investor detriment, ESMA has received new evidence during the renewal period that a binary option that benefits from the cumulative effect of an approved prospectus, a sufficiently long term and full hedging by the provider or its group entity is unlikely to give rise to the significant investor protection concern identified in Decision (EU) 2018/795. Accordingly, binary options that fulfill all these three criteria should be explicitly excluded from the scope of the renewal of ESMA's temporary product intervention measure.
19. ESMA will continue to keep these products under review and will act as necessary. In particular, ESMA has considered the risk that the exclusion may be used by a binary option provider to offer products with comparable features to those that raise significant investor protection concerns, for example, by issuing products that incentivise short duration trading behavior by setting the barrier close to the underlying market price at issuance. ESMA and NCAs will monitor whether any new distribution trends develop and will pay particular attention to products that, despite their long terms, are designed to incentivise such short duration trading behavior.
20. During its review, ESMA also obtained information on existing products that at the end of the term have one of two predetermined pay-outs, neither of which is less than the initial investment. The pay-out for this type of binary option could be the higher or the lower one, but in both circumstances the investor would not lose money compared to its total investment in the product. Decision (EU) 2018/795 targets products with the risk that investors face substantial losses in relation to their total investment in the product. Therefore, for reasons of legal certainty, this renewal should explicitly exclude products whose payoff structure does not put the investor's capital at risk.
21. As the proposed measures may, to a limited extent, relate to agricultural commodities derivatives, ESMA has consulted the public bodies competent for the oversight, administration and regulation of physical agricultural markets under Council Regulation (EC) No 1234/2007 ⁽²⁾. None of those bodies has raised any objections to the proposed renewal of the measures.
22. ESMA has notified NCAs of the proposed renewal Decision,

HAS ADOPTED THIS DECISION:

Article 1

Temporary prohibition on binary options in respect of retail clients

1. The marketing, distribution or sale to retail clients of binary options is prohibited.

⁽¹⁾ Directive 2003/71/EC of the European Parliament and of the Council of 4 November 2003 on the prospectus to be published when securities are offered to the public or admitted to trading and amending Directive 2001/34/EC (OJ L 345, 31.12.2003, p. 64).

⁽²⁾ Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) (OJ L 299, 16.11.2007, p. 1).

2. For the purposes of paragraph 1, irrespective of whether it is traded on a trading venue, a binary option is a derivative that meets the following conditions:
- (a) it must be settled in cash or may be settled in cash at the option of one of the parties other than by reason of default or other termination event;
 - (b) it only provides for payment at its close-out or expiry;
 - (c) its payment is limited to:
 - (i) a predetermined fixed amount or zero if the underlying of the derivative meets one or more predetermined conditions; and
 - (ii) a predetermined fixed amount or zero if the underlying of the derivative does not meet one or more predetermined conditions.
3. The prohibition in paragraph 1 does not apply to:
- (a) a binary option for which the lower of the two predetermined fixed amounts is at least equal to the total payment made by a retail client for the binary option, including any commission, transaction fees and other related costs;
 - (b) a binary option that meets the following conditions:
 - (i) the term from issuance to maturity is at least 90 calendar days;
 - (ii) a prospectus drawn up and approved in accordance with Directive 2003/71/EC is available to the public; and
 - (iii) the binary option does not expose the provider to market risk throughout the term of the binary option and the provider or any of its group entities do not make a profit or loss from the binary option, other than previously disclosed commission, transaction fees or other related charges.

Article 2

Prohibition of participating in circumvention activities

It shall be prohibited to participate, knowingly and intentionally, in activities the object or effect of which is to circumvent the requirements in Article 1, including by acting as a substitute for the binary option provider.

Article 3

Entry into force and application

1. This Decision enters into force on the day following that of its publication in the *Official Journal of the European Union*.
2. This Decision shall apply from 2 October 2018 for a period of 3 months.

Done at Paris, 21 September 2018.

For the Board of Supervisors
Steven MAIJLOOR
The Chair

