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* Notice concerning the entry into force of the Agreement in the form of an Exchange of Letters between the European Union and the Swiss Confederation on the cumulation of origin between the European Union, the Swiss Confederation, the Kingdom of Norway and the Republic of Turkey in the framework of the Generalised System of Preferences .................................................. 1

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REGULATIONS

* Commission Implementing Regulation (EU) 2019/144 of 28 January 2019 concerning the authorisation of a preparation of 3-phytase produced by Komagataella pastoris (CECT 13094) as a feed additive for chickens reared for laying and minor poultry species for fattening or reared for laying or for breeding (holder of authorisation Fertinagro Biotech S.L.) (1) ....................... 8


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(1) Text with EEA relevance.

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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.
* Commission Implementing Regulation (EU) 2019/146 of 30 January 2019 amending Implementing Regulation (EU) 2015/502, concerning the authorisation of the preparation of *Saccharomyces cerevisiae*NCY R404 as a feed additive for dairy cows (1) ........................................... 12


* Commission Implementing Regulation (EU) 2019/149 of 30 January 2019 amending Implementing Regulations (EU) 2015/1108 and (EU) No 540/2011 as regards the conditions of use of vinegar as a basic substance (1) .............................................................. 20

* Commission Implementing Regulation (EU) 2019/150 of 30 January 2019 amending Implementing Regulation (EU) No 686/2012 as regards the rapporteur Member State for the evaluation of the following active substances contained in plant protection products: deltamethrin, diflufenican, epoxiconazole, fluoxastrobirin, prothioconazole and tebuconazole (1) ................................................................. 23


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(1) Text with EEA relevance.
INTERNATIONAL AGREEMENTS

Notice concerning the entry into force of the Agreement in the form of an Exchange of Letters between the European Union and the Swiss Confederation on the cumulation of origin between the European Union, the Swiss Confederation, the Kingdom of Norway and the Republic of Turkey in the framework of the Generalised System of Preferences

The Agreement in the form of an Exchange of Letters between the European Union and the Swiss Confederation on the cumulation of origin between the European Union, the Swiss Confederation, the Kingdom of Norway and the Republic of Turkey in the framework of the Generalised System of Preferences will enter into force on 1 February 2019 in accordance with point 18 of the Agreement.

Notice concerning the entry into force of the Agreement in the form of an Exchange of Letters between the European Union and the Kingdom of Norway on the cumulation of origin between the European Union, the Swiss Confederation, the Kingdom of Norway and the Republic of Turkey in the framework of the Generalised System of Preferences

The Agreement in the form of an Exchange of Letters between the European Union and the Kingdom of Norway on the cumulation of origin between the European Union, the Swiss Confederation, the Kingdom of Norway and the Republic of Turkey in the framework of the Generalised System of Preferences will enter into force on 1 February 2019 in accordance with point 18 of the Agreement.
COUNCIL DECISION (EU) 2019/143

of 28 January 2019

on the conclusion, on behalf of the Union, of the Agreement in the form of an Exchange of Letters between the European Union and the People’s Republic of China in connection with DS492 European Union — Measures affecting Tariff Concessions on Certain Poultry Meat Products

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 point (a)(v) of the second subparagraph of Article 218(6) thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament (¹),

Whereas:

(1) On 12 March 2018, the Council authorised the Commission to open negotiations on a mutually agreed solution with China in connection with the WTO dispute settlement proceedings DS492 European Union — Measures affecting Tariff Concessions on Certain Poultry Meat Products.

(2) Those negotiations have been concluded and an Agreement in the form of an Exchange of Letters between the European Union and China (the Agreement) was initialled on 18 June 2018.

(3) The agreement was signed on behalf of the Union on 30 November 2018, subject to its conclusion at a later date, in accordance with Council Decision (EU) 2018/1252 (²).

(4) The Agreement should be approved,

HAS ADOPTED THIS DECISION:

Article 1

The Agreement in the form of an Exchange of Letters between the European Union and the People’s Republic of China in connection with DS492 European Union — Measures affecting Tariff Concessions on Certain Poultry Meat Products is hereby approved on behalf of the Union.

The text of the Agreement is attached to this Decision.

Article 2

The President of the Council shall, on behalf of the Union, give the notification provided for in the Agreement. (³)


(³) The date of entry into force of the Agreement will be published in the Official Journal of the European Union by the General Secretariat of the Council.
Article 3

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

Done at Brussels, 28 January 2019.

For the Council
The President
P. DAEA
AGREEMENT


A. Letter from the European Union

Sir/Madam,

I have the honour to write to you concerning the above mentioned WTO dispute and the results of our negotiations towards a mutually agreed solution.

The European Union shall open the following Tariff Rate Quotas (TRQ) (1):

— a TRQ of 6 060 tonnes for the tariff line 1602.3929 (with specific country allocation of 6 000 tonnes to China and 60 tonnes to all others), with an in-quota duty rate of 10.9 %;

— a TRQ of 660 tonnes for the tariff line 1602.3985 (with specific country allocation of 600 tonnes to China and 60 tonnes to all others), with an in-quota duty rate of 10.9 %;

— an erga omnes TRQ of 5 000 tonnes for the tariff line 1602.3219, with an in-quota duty rate of 8 %.

The European Union and China shall notify each other of the completion of their internal procedures for the entry into force of this Agreement. The Agreement shall enter into force 14 days after the date of receipt of the latest notification. The European Union shall open the above mentioned TRQs from the date of entry into force of this Agreement.

After opening of the TRQs, the European Union and China shall notify this Agreement to the Dispute Settlement Body (DSB) as a mutually agreed solution under Article 3.6 of the DSU in relation to DS492 European Union — Measures affecting Tariff Concessions on Certain Poultry Meat Products. On this basis, China confirms that, with regard to DS492, it will neither request initiation of procedures pursuant to Article 21.5 of the DSU nor request suspension of concessions or other obligations pursuant to DSU Article 22.6, as long as the European Union is in compliance with all of its obligations under this Agreement.

I should be obliged if you would confirm that your Government is in agreement with the above.

I have the honour to propose that, if the above is acceptable to your Government, this letter and your confirmation shall together constitute an Agreement in the form of an Exchange of Letters between the European Union and the People’s Republic of China.

Please accept, Sir/Madam, the assurance of my highest consideration.

Cc. Thailand

(1) The allocation to China for the first two TRQs is in agreement with Thailand.
30-11-2018
B. Letter from China

Sir/Madam,

I have the honour to acknowledge the receipt of your letter of today’s date, which reads as follows:

‘I have the honour to write to you concerning the above mentioned WTO dispute and the results of our negotiations towards a mutually agreed solution.

The European Union shall open the following Tariff Rate Quotas (TRQ) (2):

— a TRQ of 6 060 tonnes for the tariff line 1602.3929 (with specific country allocation of 6 000 tonnes to China and 60 tonnes to all others), with an in-quota duty rate of 10.9 %;

— a TRQ of 660 tonnes for the tariff line 1602.3985 (with specific country allocation of 600 tonnes to China and 60 tonnes to all others), with an in-quota duty rate of 10.9 %;

— an erga omnes TRQ of 5 000 tonnes for the tariff line 1602.3219, with an in-quota duty rate of 8 %.

The European Union and China shall notify each other of the completion of their internal procedures for the entry into force of this Agreement. The Agreement shall enter into force 14 days after the date of receipt of the latest notification. The European Union shall open the above mentioned TRQs from the date of entry into force of this Agreement.

After opening of the TRQs, the European Union and China shall notify this agreement to the Dispute Settlement Body (DSB) as a mutually agreed solution under Article 3.6 of the DSU in relation to DS492 European Union – Measures affecting Tariff Concessions on Certain Poultry Meat Products. On this basis, China confirms that, with regard to DS492, it will neither request initiation of procedures pursuant to Article 21.5 of the DSU nor request suspension of concessions or other obligations pursuant to DSU Article 22.6, as long as the European Union is in compliance with all of its obligations under this Agreement.’

I hereby have the honour to express my Government’s agreement with the above letter.

Please accept, Sir/Madam, the assurance of my highest consideration.

(2) The allocation to China for the first two TRQs is in agreement with Thailand.
中华人民共和国代表

For the People's Republic of China

Pour la République populaire de Chine

For Folkrepubliken Kina

Za Narodnu Republiku Kinu

Pour la République populaire cinese

A Kínai Népkoztársaság részéről

Voor de Volksrepubliek China

W imieniu Chińskiej Republiki Ludowej

Pela República Popular da China

Pentru Republica Populară Chineză

Za Čínsku lidovou republiku

Za Ljudsko republiko Kitajsko

Kiinan kansantasavallan puolesta

För Folkrepubliken Kina
REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2019/144

of 28 January 2019

concerning the authorisation of a preparation of 3-phytase produced by Komagataella pastoris (CECT 13094) as a feed additive for chickens reared for laying and minor poultry species for fattening or reared for laying or for breeding (holder of authorisation Fertinagro Biotech S.L.)

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (1), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of 3-phytase produced by Komagataella pastoris (CECT 13094). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a preparation of 3-phytase produced by Komagataella pastoris (CECT 13094) as a feed additive for chickens reared for laying and minor poultry species for fattening or reared for laying or for breeding to be classified in the additive category ‘zootechnical additives’.

(4) The preparation of 3-phytase produced by Komagataella pastoris (CECT 13094) belonging to the additive category of ‘zootechnical additives’, was authorised for 10 years as a feed additive for chickens for fattening and laying hens by Commission Implementing Regulation (EU) 2017/895 (2).

(5) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 21 February 2018 (3) that, under the proposed conditions of use, 3-phytase produced by Komagataella pastoris (CECT 13094) does not have an adverse effect on animal health, human health or the environment. It has also concluded that the additive has a potential to be efficacious in improving phosphorus retention in chickens for fattening and that conclusion can be extended to chickens reared for laying. Since the mode of action can reasonably be assumed to be the same in poultry species, the Authority has extrapolated the conclusion on the efficacy to minor poultry species for fattening and reared for laying or breeding purposes. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of the 3-phytase shows that the conditions for authorisation of 3-phytase produced by Komagataella pastoris (CECT 13094), as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

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

(3) EFSA Journal 2018;16(3):5203.
HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘digestibility enhancers’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

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

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

Done at Brussels, 28 January 2019.

For the Commission
The President
Jean-Claude JUNCKER
## ANNEX

<table>
<thead>
<tr>
<th>Identification number of the additive</th>
<th>Name of the holder of authorisation</th>
<th>Additive</th>
<th>Composition, chemical formula, description, analytical method</th>
<th>Species or category of animal</th>
<th>Maximum age</th>
<th>Minimum content</th>
<th>Maximum content</th>
<th>Units of activity/kg of complete feedingstuff with a moisture content of 12 %</th>
<th>Other provisions</th>
<th>End of period of authorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>4a25</td>
<td>Fertinagro Nutrientes S.L.</td>
<td>3-phytase</td>
<td>Additive composition: Preparation of 3-phytase produced by Komagataella pastoris (CECT 13094) having a minimum activity of: 1 000 FTU (1)/ml Liquid form Characterisation of the active substance: 3-phytase (EC 3.1.3.8) produced by Komagataella pastoris (CECT 13094) Analytical method (2) For the quantification of 3-phytase activity in the feed additive: — colorimetric method based on the enzymatic reaction of phytase on the phytate For the quantification of 3-phytase activity in feedingstuffs: — colorimetric method based on the enzymatic reaction of phytase on the phytate – EN ISO 30024</td>
<td>Chickens reared for laying Minor poultry species for fattening or reared for laying or for breeding</td>
<td>—</td>
<td>500 FTU</td>
<td></td>
<td>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.</td>
<td>20 February 2029</td>
<td></td>
</tr>
</tbody>
</table>

(1) 1 FTU is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from a sodium phytate substrate at pH 5.5 and 37 °C.  
(2) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports
COMMISSION REGULATION (EU) 2019/145
of 30 January 2019

correcting the Dutch language version of Regulation (EU) No 68/2013 on the Catalogue of feed materials

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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


Whereas:

(1) The Dutch language version of Commission Regulation (EU) No 68/2013 (2) contains an error in entries 13.8.1 and 13.8.2. in Part C of the Annex as regards the reference to a constituent of a feed material to be declared. The erroneous reference to ‘moisture’ instead of ‘potassium’ affects the scope of certain obligations of the operators.

(2) The Dutch language version of Regulation (EU No 68/2013 should therefore be corrected accordingly. The other language versions are not affected.

(3) 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

(does not concern the English language)

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, 30 January 2019.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2019/146

of 30 January 2019

amending Implementing Regulation (EU) 2015/502, concerning the authorisation of the preparation of Saccharomyces cerevisiae NCYC R404 as a feed additive for dairy cows

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (1) and in particular Article 13(3) thereof,

Whereas:

(1) In accordance with Regulation (EC) No 1831/2003, the preparation of Saccharomyces cerevisiae NCYC R404, as a feed additive for dairy cows, was authorised by Commission Implementing Regulation (EU) 2015/502 (2).

(2) The holder of authorisation, Micron Bio-systems Ltd, has submitted an application in accordance with Article 13(3) of Regulation (EC) No 1831/2003 proposing to add to the authorisation the name of its representative.

(3) The holder of authorisation has submitted relevant data supporting the fact that, with effect from 30 March 2019, FeedVision BV will act as its representative for the feed additive concerned.

(4) The proposed change of the terms of the authorisation is purely administrative in nature and does not entail a fresh assessment of the additive concerned. The European Food Safety Authority was informed of the application.

(5) To allow FeedVision BV to act as the representative of the holder of the authorisation, it is necessary to change the terms of the authorisation concerned. Therefore, the name of the representative should be added in the title and in the Annex to that Regulation. The name of the holder of the authorisation was not correctly spelled in the title of Implementing Regulation (EU) 2015/502. Consequently, in the title of the Implementing Regulation the name of the holder of the authorisation should be replaced by the correct spelling.

(6) Implementing Regulation (EU) 2015/502 should, therefore, be amended accordingly.

(7) The provisions of this Regulation should apply from the date of the withdrawal of the United Kingdom from the Union.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Implementing Regulation (EU) 2015/502

Implementing Regulation (EU) 2015/502 is amended as follows:

(1) in the title, the words 'Micro Bio-System Ltd' are replaced by the words 'Micron Bio-Systems Ltd, represented by FeedVision BV';

(2) in the second column of the Annex, the words 'Micron Bio-Systems Ltd' are replaced by the words 'Micron Bio-Systems Ltd, represented by FeedVision BV'.


Article 2

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 30 March 2019.

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

Done at Brussels, 30 January 2019.

For the Commission

The President

Jean-Claude JUNCKER
COMMISSION IMPLEMENTING REGULATION (EU) 2019/147

of 30 January 2019


(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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


Whereas:

(1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009 the Netherlands received on 1 October 2014 an application from BASF Corporation for the approval of the active substance Beauveria bassiana strain PPRI 5339.

(2) In accordance with Article 9(3) of Regulation (EC) No 1107/2009, the Netherlands, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority (the Authority) on 2 June 2015 of the admissibility of the application.

(3) On 22 December 2016 the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

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

(5) On 12 March 2018 the Authority communicated to the applicant, the Member States and the Commission its conclusion (2) on whether the active substance Beauveria bassiana strain PPRI 5339 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority made its conclusion available to the public.

(6) On 24 October 2018 the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the draft review report for Beauveria bassiana strain PPRI 5339 and a draft Regulation providing that Beauveria bassiana strain PPRI 5339 is approved.

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

(8) It is therefore appropriate to approve Beauveria bassiana strain PPRI 5339.

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

In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 (1) should be amended accordingly.

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
Approval of active substance

The active substance Beauveria bassiana strain PPRI 5339, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2
Amendments to Implementing Regulation (EU) No 540/2011

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

Article 3
Entry into force

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, 30 January 2019.

For the Commission
The President
Jean-Claude JUNCKER

<table>
<thead>
<tr>
<th>Common Name, Identification Numbers</th>
<th>IUPAC Name</th>
<th>Purity (1)</th>
<th>Date of approval</th>
<th>Expiration of approval</th>
<th>Specific provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beauveria bassiana strain PPRI 5339</td>
<td>Not applicable</td>
<td>Max. level of beauvericin: 0.5 mg/kg</td>
<td>20 February 2019</td>
<td>20 February 2029</td>
<td>For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on <em>Beauveria bassiana</em> strain PPRI 5339, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the level of the metabolite beauvericin content in a shelf-life study after storage of the formulation(s) containing <em>B. bassiana</em> strain PPRI 5339; — the effects on pollinators introduced in glasshouses following exposure to formulation(s) different from the representative one supporting this approval; — the protection of operators and workers, taking into account that <em>B. bassiana</em> strain PPRI 5339 is to be considered, as any micro-organism, as a potential sensitizer. The compliance with strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 (2). Conditions of use shall include risk mitigation measures where appropriate.</td>
</tr>
</tbody>
</table>

(1) Further details on identity and specification of active substance are provided in the review report.
In Part B of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

<table>
<thead>
<tr>
<th>'131</th>
<th>Beauveria bassiana strain PPRI 5339</th>
<th>Not applicable</th>
<th>Max. level of beauvericin: 0,5 mg/kg</th>
<th>20 February 2019</th>
<th>20 February 2029</th>
</tr>
</thead>
</table>

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on *Beauveria bassiana* strain PPRI 5339, and in particular Appendices I and II thereof, shall be taken into account.

In this overall assessment Member States shall pay particular attention to:

- the level of the metabolite beauvericin content in a shelf-life study after storage of the formulation(s) containing *B. bassiana* strain PPRI 5339;
- the effects on pollinators introduced in glasshouses following exposure to formulation(s) different from the representative one supporting this approval;
- the protection of operators and workers, taking into account that *B. bassiana* strain PPRI 5339 is to be considered, as any micro-organism, as a potential sensitizer.

The compliance with strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfillment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 (*)

Conditions of use shall include risk mitigation measures where appropriate.

COMMISSION IMPLEMENTING REGULATION (EU) 2019/148

of 30 January 2019

concerning the non-approval of the active substance propanil, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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


Whereas:

(1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, on 28 December 2015, Italy received an application from UPL Europe Ltd for the approval of the active substance propanil.

(2) In accordance with Article 9(3) of that Regulation, the rapporteur Member State notified the applicant, the other Member States, the Commission and the European Food Safety Authority (the Authority) of the admissibility of the application, on 29 February 2016.

(3) For that active substance, the effects on human and animal health and the environment have been assessed, in accordance with Regulation (EC) No 1107/2009, for the uses proposed by the applicant. The rapporteur Member State submitted a draft assessment report to the Commission and the Authority on 14 July 2017.

(4) The draft assessment report was reviewed by the Member States and the Authority. The Authority presented to the Commission its conclusion on the pesticide risk assessment of the active substance propanil (2) on 6 September 2018.

(5) By letter of 14 September 2018 UPL Europe Ltd withdrew its application for the approval of propanil.

(6) Due to the withdrawal of the application, propanil should not be approved.

(7) This Regulation does not prejudice the submission of a further application for propanil pursuant to Article 7 of Regulation (EC) No 1107/2009.

(8) 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

Non-approval of active substance

The active substance propanil is not approved.

Article 2

Entry into force

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

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

Done at Brussels, 30 January 2019.

For the Commission

The President

Jean-Claude JUNCKER
COMMISSION IMPLEMENTING REGULATION (EU) 2019/149

of 30 January 2019

amending Implementing Regulations (EU) 2015/1108 and (EU) No 540/2011 as regards the conditions of use of vinegar as a basic substance

(Text with EEA relevance)

THE EUROPEAN COMMISION,

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


Whereas:


(2) In November 2016, Charbonneaux-Brabant SA submitted to the Commission an application for the extension of the use of vinegar as herbicide in accordance with Article 23(3) of Regulation (EC) No 1107/2009.

(3) The Commission asked the European Food Safety Authority (‘the Authority’) for scientific assistance. On 4 August 2017, the Authority presented to the Commission a technical report on the extension of the use of vinegar in plant protection as herbicide (4). The Commission presented the review report to the Standing Committee on Plants, Animals, Food and Feed on 23 October 2018 and the draft of this Regulation on 12 December 2018.

(4) It has appeared from the examinations made that vinegar may be expected to satisfy, in general, the requirements laid down in Article 23 of Regulation (EC) No 1107/2009, in particular with regard to the use as herbicide which was examined and detailed in the review report. Therefore the use of vinegar as herbicide should be allowed. Moreover, given the fact that a new use of vinegar is being permitted, it is acceptable to allow other possible uses of vinegar as referred to in the latest version of the review report for vinegar. It is therefore appropriate to revoke the current restriction for use only as a fungicide and a bactericide.

(5) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to respect certain conditions for use.

(6) Implementing Regulations (EU) 2015/1108 and (EU) No 540/2011 should therefore be amended accordingly.

(7) 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

Amendment to Implementing Regulation (EU) 2015/1108

Annex I to Implementing Regulation (EU) 2015/1108 is amended as set out in Annex I to this Regulation.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended as set out in Annex II to this Regulation.

Article 3

Entry into force

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

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

Done at Brussels, 30 January 2019.

*For the Commission*

*The President*

Jean-Claude JUNCKER
ANNEX I

In Annex I to Implementing Regulation (EU) 2015/1108, the entry in the fifth column ‘Specific provisions’ is replaced by the following:

‘Vinegar shall be used in accordance with the specific conditions included in the conclusions of the review report on vinegar (SANCO/12896/2014) and in particular Appendices I and II thereof.’

ANNEX II

In the Annex to Implementing Regulation (EU) No 540/2011, the entry in the sixth column ‘Specific provisions’ of row number 5, vinegar, of the table in Part C is replaced by the following:

‘Vinegar shall be used in accordance with the specific conditions included in the conclusions of the review report on vinegar (SANCO/12896/2014) and in particular Appendices I and II thereof.’
COMMISSION IMPLEMENTING REGULATION (EU) 2019/150
of 30 January 2019
amending Implementing Regulation (EU) No 686/2012 as regards the rapporteur Member State for the evaluation of the following active substances contained in plant protection products: deltamethrin, diflufenican, epoxiconazole, fluoxastrobin, prothioconazole and tebuconazole

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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


Whereas:

(1) Commission Implementing Regulation (EU) No 686/2012 (2) allocated to the United Kingdom, as rapporteur Member State, the evaluation of certain active substances contained in plant protection products.

(2) On 29 March 2017, the United Kingdom submitted the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. The Treaties will cease to apply to the United Kingdom from the date of entry into force of a withdrawal agreement or failing that, two years after that notification, i.e. from 30 March 2019, unless the European Council, in agreement with the United Kingdom, unanimously decides to extend that period.

(3) The withdrawal agreement as agreed between the negotiators contains arrangements for the application of provisions of Union law to and in the United Kingdom beyond the date the Treaties cease to apply to and in the United Kingdom. If that agreement enters into force Union legislation in the field of plant protection products will apply to and in the United Kingdom during the transition period in accordance with that agreement and will cease to apply at the end of that period. In accordance with that agreement, during the transition period the United Kingdom is not to act as leading authority for risk assessments, examinations, approvals or authorisations at the level of the Union or at the level of Member States acting jointly as referred to, amongst others, in Regulation (EC) No 1107/2009.

(4) It is therefore necessary to allocate to other Member States the evaluation of the active substances for which the United Kingdom is the rapporteur Member State and where it is expected that the European Food Safety Authority will not issue a Conclusion before 29 March 2019. The active substances concerned are deltamethrin, diflufenican, epoxiconazole, fluoxastrobin, prothioconazole and tebuconazole.

(5) That allocation should ensure a balance in the distribution of the responsibilities and the work between Member States.

(6) As the evaluation of the active substances concerned are at an advanced stage and the work to be carried out is expected to be minor, a co-rapporteur Member State should not be allocated for that evaluation.

(7) Implementing Regulation (EU) No 686/2012 should therefore be amended accordingly.

(8) This Regulation should apply from 30 March 2019.

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

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) No 686/2012 is amended in accordance with the Annex to this Regulation.

(2) Commission Implementing Regulation (EU) No 686/2012 of 26 July 2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances whose approval expires by 31 December 2018 at the latest (OJ L 200, 27.7.2012, p. 5).
Article 2

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

It shall apply from 30 March 2019.

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

Done at Brussels, 30 January 2019.

*For the Commission*

*The President*

Jean-Claude JUNCKER
ANNEX

The Annex to Implementing Regulation (EU) No 686/2012 is amended as follows:

(1) Part A is amended as follows:

(a) the entry for Deltamethrin is replaced by the following:

<table>
<thead>
<tr>
<th>Active substance</th>
<th>Rapporteur Member State</th>
<th>Co-rapporteur Member State</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Deltamethrin’</td>
<td>AT’</td>
<td></td>
</tr>
</tbody>
</table>

(b) the entry for Diflufenican is replaced by the following:

<table>
<thead>
<tr>
<th>Active substance</th>
<th>Rapporteur Member State</th>
<th>Co-rapporteur Member State</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Diflufenican’</td>
<td>CZ’</td>
<td></td>
</tr>
</tbody>
</table>

(c) the entry for Fluoxastrobin is replaced by the following:

<table>
<thead>
<tr>
<th>Active substance</th>
<th>Rapporteur Member State</th>
<th>Co-rapporteur Member State</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Fluoxastrobin’</td>
<td>DE’</td>
<td></td>
</tr>
</tbody>
</table>

(d) the entry for Prothioconazole is replaced by the following:

<table>
<thead>
<tr>
<th>Active substance</th>
<th>Rapporteur Member State</th>
<th>Co-rapporteur Member State</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Prothioconazole’</td>
<td>PL’</td>
<td></td>
</tr>
</tbody>
</table>

(2) Part B is amended as follows:

(a) the entry for Epoxiconazole is replaced by the following:

<table>
<thead>
<tr>
<th>Active substance</th>
<th>Rapporteur Member State</th>
<th>Co-rapporteur Member State</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Epoxiconazole’</td>
<td>PL’</td>
<td></td>
</tr>
</tbody>
</table>

(b) the entry for Tebuconazole is replaced by the following:

<table>
<thead>
<tr>
<th>Active substance</th>
<th>Rapporteur Member State</th>
<th>Co-rapporteur Member State</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Tebuconazole’</td>
<td>DK’</td>
<td></td>
</tr>
</tbody>
</table>
COMMISSION IMPLEMENTING REGULATION (EU) 2019/151

of 30 January 2019


(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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


Whereas:


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


(4) An application for the renewal of the approval of Clonostachys rosea strain J1446 was submitted by Verdera Oy (‘the applicant’) in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 (5) within the time period provided for in that Article.

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

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

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

(8) On 21 June 2017 the Authority communicated to the Commission its conclusion (6) on whether Clonostachys rosea strain J1446 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft renewal report for Clonostachys rosea strain J1446 to the Standing Committee on Plants, Animals, Food and Feed on 11 December 2017.

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

It has been established with respect to one or more representative uses of at least one plant protection product containing *Clonostachys rosea* strain J1446 that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to renew the approval of *Clonostachys rosea* strain J1446.

The risk assessment for the renewal of the approval of *Clonostachys rosea* strain J1446 is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing *Clonostachys rosea* strain J1446 may be authorised. It is therefore appropriate not to maintain the restriction to use only as a fungicide.

The Commission further considers that *Clonostachys rosea* strain J1446 is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. *Clonostachys rosea* strain J1446 is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009.

It is therefore appropriate to renew the approval of *Clonostachys rosea* strain J1446 as a low-risk substance.

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

In accordance with Article 20(3) of Regulation (EC) No 1107/2009, in conjunction with Article 13(4) thereof, the Annex to Implementing Regulation (EU) No 540/2011 should be amended accordingly.

Commission Implementing Regulation (EU) 2018/917 (7) extended the approval period of *Clonostachys rosea* strain J1446 to 31 July 2019 in order to allow the renewal process to be completed before the expiry date of the approval of that substance. However, given that a decision on renewal has been taken ahead of this extended expiry date, this Regulation shall apply from 1 April 2019.

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

HAS ADOPTED THIS REGULATION:

**Article 1**

**Renewal of the approval of active substance**

The approval of the active substance *Clonostachys rosea* strain J1446, as specified in Annex I, is renewed subject to the conditions laid down in that Annex.

**Article 2**

**Amendments to Implementing Regulation (EU) No 540/2011**

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

**Article 3**

**Entry into force and date of application**

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

It shall apply from 1 April 2019.

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

Done at Brussels, 30 January 2019.

For the Commission
The President
Jean-Claude JUNCKER
**ANNEX I**

<table>
<thead>
<tr>
<th>Common Name, Identification Numbers</th>
<th>IUPAC Name</th>
<th>Purity ($)</th>
<th>Date of approval</th>
<th>Expiration of approval</th>
<th>Specific provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clonostachys rosea strain J1446</td>
<td>Not applicable</td>
<td>Not applicable Glutoxin content: max. 50 µg/kg in the technical grade of the MCPA.</td>
<td>1 April 2019</td>
<td>31 March 2034</td>
<td>For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on Clonostachys rosea strain J1446, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the specification of technical material as commercially manufactured in plant protection products, including full characterisation of potential metabolites of concern; — the protection of operators and workers, taking into account that microorganisms are considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use; — the studies or information from the scientific literature recently made available in relation to antifungal susceptibility of Clonostachys rosea J1446. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer, in order to ensure the fulfilment of the limits on microbial contamination as referred to in the Working Document SANCO/12116/2012 (2). Conditions of use shall include risk mitigation measures, where appropriate.</td>
</tr>
</tbody>
</table>

($) Further details on identity and specification of active substance are provided in the review report.


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**31.1.2019**

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

(1) in Part A, entry 98 on *Gliocladium catenulatum* strain J1446 is deleted;

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

<table>
<thead>
<tr>
<th></th>
<th>Clonostachys rosea strain J1446</th>
<th>Accession number in the culture collection of the German Collection of Microorganisms and Cell Cultures (DSMZ): DSM 9212</th>
<th>Not applicable</th>
<th>Not applicable Gliotoxin content: max. 50 µg/kg in the technical grade of the MCPA.</th>
<th>1 April 2019</th>
<th>31 March 2034</th>
</tr>
</thead>
</table>

For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on *Clonostachys rosea* strain J1446, and in particular Appendices I and II thereof, shall be taken into account.

In this overall assessment Member States shall pay particular attention to:

— the specification of technical material as commercially manufactured in plant protection products, including full characterisation of potential metabolites of concern;

— the protection of operators and workers, taking into account that microorganisms are considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use;

— the studies or information from the scientific literature recently made available in relation to antifungal susceptibility of *Clonostachys rosea* J1446.

Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer, in order to ensure the fulfilment of the limits on microbial contamination as referred to in the Working Document SANCO/12116/2012 (*).

Conditions of use shall include risk mitigation measures, where appropriate.

DECISIONS

COUNCIL DECISION (EU) 2019/152
of 28 January 2019
appointing a member, proposed by the Kingdom of Belgium, of the Committee of the Regions

THE COUNCIL OF THE EUROPEAN UNION,
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,
Having regard to the proposal of the Belgian Government,
Whereas:
(2) A member’s seat on the Committee of the Regions has become vacant following the end of the mandate on the basis of which Mr Alain HUTCHINSON (Conseiller communal et échevin à Saint-Gilles) was proposed,

HAS ADOPTED THIS DECISION:

Article 1

The following is hereby appointed as a member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2020:
— Mr Alain HUTCHINSON, Commissaire pour l’Europe et l’accueil des organisations internationales (change of mandate).

Article 2

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

Done at Brussels, 28 January 2019.

For the Council

The President

P. DAEA

COUNCIL DECISION (EU) 2019/153
of 28 January 2019

appointing a member, proposed by the Italian Republic, of the Committee of the Regions

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to the proposal of the Italian Government,

Whereas:


(2) A member’s seat on the Committee of the Regions has become vacant following the end of the term of office of Mr Piero FASSINO,

HAS ADOPTED THIS DECISION:

Article 1

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

— Mr Virginio MEROLA, Sindaco del Comune di Bologna.

Article 2

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

Done at Brussels, 28 January 2019.

For the Council
The President
P. DAEA

Commission Decision (EU) 2019/154
laying down internal rules concerning the restriction of the right of access of data subjects to their medical files

The European Commission,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 249(1) thereof,

Whereas:

1. Pursuant to Article 26a of the Staff Regulations and Articles 16 and 91 of the Conditions of Employment of other servants, officials and agents have the right to acquaint themselves with their medical files, in accordance with arrangements to be laid down by the appointing authorities of the institutions.

2. Since 2004, Conclusion 221/04 of the Heads of administrations (1) has regulated access to medical files and does not allow direct access of data subject to all documents of a psychological or psychiatric nature concerning them. That general restriction does not entail a case-by-case analysis.

3. In order to comply with Regulation (EU) 2018/1725 of the European Parliament and of the Council (2), restrictions on access to such documents applied by the Commission must be proportionate and involve a case-by-case analysis.

4. While access to medical files should be granted to the fullest extent possible to data subjects, restrictions based on Article 25 of Regulation (EU) 2018/1725 may in some cases be necessary to protect the staff member's health or the legitimate interests of third parties. The medical officer, acting on behalf of the Commission, should give the reasons for any such restriction and those reasons should become part of the medical files of the staff member concerned.

5. The personal data are stored in secured physical and electronic environments preventing unlawful access or transfer of data to persons who do not have a need to know.

6. The storage periods that apply to processing of medical files are laid down in the Common Commission-level retention list for European Commission files (3).

7. The Data Protection Officer of the European Commission should carry out an independent review of the application of restrictions, with a view to ensuring compliance with this decision.

8. The European Data Protection Supervisor delivered an opinion on 10 December 2018.

9. Regulation (EU) 2018/1725 replaces Regulation (EC) No 45/2001 of the European Parliament and of the Council (4), without any transitional period, from the date on which it enters into force. The possibility to apply restrictions to certain rights was provided for in Regulation (EC) No 45/2001. In order to avoid jeopardising the data subjects' rights, this Decision should apply from the date of entry into force of Regulation (EU) 2018/1725.

HAS ADOPTED THIS DECISION:

Article 1
Subject matter and scope

1. This Decision lays down the conditions under which the Commission may restrict the application of Article 17 of Regulation (EU) 2018/1725, in accordance with Article 25(1)(h) of that Regulation.

2. This Decision applies to the access to personal medical data processed by the Commission pursuant to Articles 26a, 33, 59, 72, 73 and 78 of the Staff Regulations and Articles 1, 13 to 15 of its Annex VIII, and Articles 13, 16, 28, 32, 33, 83, 91, 95, 100, 101 and 102 of the Conditions of Employment of Other Servants.

(1) That conclusion was approved by the Heads of Administration at their 236th meeting on 19 February 2004.


Article 2
Applicable restrictions

1. Subject to Articles 3 to 5, the Commission may restrict, on a case-by-case basis, data subjects’ right to access directly personal medical data of a psychological or psychiatric nature concerning them which is processed by the Commission, where access to such data is likely to represent a risk for the data subject’s health. This restriction shall be proportionate to what is strictly necessary to protect the data subject.

2. Access to the information referred to in paragraph 1 shall be given to a doctor of the data subject’s choice.

3. In such cases, the data subject shall, upon request, be reimbursed by the Medical Service of the part of the cost of the medical consultation with the doctor who received access to the medical files that has not been reimbursed by the Joint Sickness Insurance Scheme (JSIS). The reimbursement shall not exceed the difference between the ceiling laid down in the General Implementing Provisions for the reimbursement of medical expenses (\(^{(5)}\)) and the amount reimbursed to the data subject by the Joint Sickness Insurance Scheme pursuant to those rules.

4. Such reimbursement by the Medical Service shall be subject to the condition that access has not already been granted for the same data.

5. Subject to Articles 3 to 5 of this Decision, the Commission may restrict, on a case-by-case basis and in accordance with Article 25(1)(h) of Regulation (EU) 2018/1725, data subjects’ right to access their personal medical data in its possession where the exercise of that right would adversely affect the rights and freedoms of the data subject or other data subjects.

Article 3
Right of access by data subjects

1. Where the Commission restricts, wholly or partly, the right of access to personal medical data by data subjects, as referred to in Article 17 of Regulation (EU) 2018/1725, it shall inform the data subject concerned, in writing, in its reply to the request for access without undue delay of the restriction applied and of the principal reasons therefor. The Commission will also inform the data subject of the possibility of lodging a complaint with the European Data Protection Supervisor or of seeking judicial remedy in the Court of Justice of the European Union.

2. The provision of information concerning the reasons for the restriction referred to in paragraph 1 may be deferred, omitted or denied for as long as it would undermine the purpose of the restriction.

3. The Commission shall record the reasons for the restriction in accordance with Article 5.

4. Where the right of access is wholly or partly restricted, the data subject shall exercise his or her right of access through the intermediary of the European Data Protection Supervisor, in accordance with Article 25(6), (7) and (8) of Regulation (EU) 2018/1725.

Article 4
Recording and registering of restrictions

1. The Commission shall record the reasons for any restriction applied pursuant to this Decision, including an assessment of the necessity and proportionality of the restriction, taking into account the relevant elements in Article 25(2) of Regulation (EU) 2018/1725.

To that end, the record shall state how the exercise of the right would present a risk for the data subject’s health or would adversely affect the rights and freedoms of other data subjects.

2. The record and, where applicable, the documents containing the underlying factual and legal elements shall be registered in the relevant medical file.

Article 5
Duration of restrictions

1. Restrictions referred to in Articles 2 shall continue to apply as long as the reasons justifying them remain applicable.

2. Where the reasons for a restriction no longer apply and the data subject has asked again for access to the personal medical data concerned, the Commission shall lift the restriction and provide the principal reasons for the restriction to the data subject. At the same time, the Commission shall inform the data subject of the possibility of lodging a complaint with the European Data Protection Supervisor at any time or of seeking a judicial remedy in the Court of Justice of the European Union.

**Article 6**

**Review by the Data Protection Officer of the European Commission**

1. The Data Protection Officer shall be informed, without undue delay, whenever data subjects’ rights are restricted in accordance with this Decision. Upon request, the Data Protection Officer shall be provided with access to the record and any documents containing underlying factual and legal elements.

2. The Data Protection Officer may request a review of the restriction. The Data Protection Officer shall be informed in writing of the outcome of the requested review.

**Article 7**

**Entry into force**

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

It shall apply from 11 December 2018.

Done at Brussels, 30 January 2019.

*For the Commission*

*The President*

Jean-Claude JUNCKER
EUROPEAN SECURITIES AND MARKETS AUTHORITY DECISION (EU) 2019/155

of 23 January 2019

renewing the temporary restriction on the marketing, distribution or sale of contracts for differences 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) 2018/796 (4), the European Securities and Markets Authority (ESMA) restricted the marketing, distribution or sale of contracts for differences (CFDs) to retail clients with effect from 1 August 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) By Decision (EU) 2018/1636 (5), ESMA renewed and amended the temporary restriction on the marketing, distribution or sale of CFDs to retail clients with effect from 1 November 2018 for a period of three months.

(4) ESMA’s further review of the restriction on CFDs has been informed by, inter alia, a survey among national competent authorities (6) (NCAs) on the practical application and impact of the product intervention measure as well as additional information provided by NCAs and stakeholders.

(5) NCAs detected only limited examples of non-compliance with the ESMA product intervention measure, which mainly related to the risk warnings.

(6) NCAs reported an overall decrease in the number of CFD retail client accounts, trading volume and total retail client equity over the three months from August to October 2018 (2018 period) in comparison with the same period in 2017 (2017 period). The share of profitable retail client accounts remained broadly stable when

(1) OJ L 331, 15.12.2010, p. 84.
(2) OJ L 173, 12.6.2014, p. 84.
comparing these periods. The average costs incurred by retail clients while trading CFDs, which appear to be less dependent on market conditions than the overall client outcomes, were significantly lower in the 2018 period in comparison to the 2017 period (7). Average costs in respect of active retail accounts containing CFDs on cryptocurrencies fell disproportionately in comparison to others, though such accounts continued to incur higher costs than accounts with no cryptocurrency exposure. Finally, NCAs reported a sustained decrease in the number of automatic close-outs, the number of times accounts went into negative equity and the size of negative equity balances (8).

(7) NCAs also reported an increase in the number of clients treated as professional clients on request in the 2018 period in comparison with the 2017 period. ESMA is aware that some CFD providers are advertising to retail clients the possibility of becoming professional clients on request. However, a retail client may request to be treated as a professional client when, in particular, the client submits a request in writing in accordance with all the requirements set out in the applicable legislation. Providers should ensure that they comply at all times with those requirements (9). ESMA is also aware that some third-country firms are actively approaching Union clients or that some CFD providers in the Union are marketing the possibility for retail clients to move their accounts to an intra-group third-country entity. However, without authorisation or registration in the Union, third-country firms are only allowed to offer services to clients established or situated in the Union at the client’s own exclusive initiative. Finally, ESMA is 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.

(8) Since the adoption of Decision (EU) 2018/796, ESMA did not obtain evidence contradicting its overall finding of a significant investor protection concern identified in Decision (EU) 2018/796 or Decision (EU) 2018/1636 (Decisions). ESMA has therefore concluded that the significant investor protection concern identified in the Decisions would persist if the temporary restriction on the marketing, distribution or sale of CFDs to retail clients is not renewed.

(9) Moreover, 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 Decision (EU) 2018/796, no NCA has adopted its own national product intervention measure under Article 42 of Regulation (EU) No 600/2014 (10).

(10) The renewal of the restriction 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 the Decisions.

(11) If the temporary restriction is not renewed, ESMA continues to consider it likely that CFDs will again be offered to retail clients without adequate measures to sufficiently protect them against the risks related to those products that gave rise to the consumer detriment identified in the Decisions.

(12) In view of these reasons, taken together with the reasons set out in the Decisions, ESMA has decided to renew the restriction on the same terms as those set out in Decision (EU) 2018/1636 for a further three-month period to address the significant investor protection concern.

(7) This is consistent with observed decreases in total trade volumes on which spreads and fees are typically calculated. Average client equity increased slightly among active retail client accounts, though this was a significantly smaller change in percentage terms than the decrease in total trade volumes and total exposure for these accounts.

(8) In the period from August to October 2018, the negative balance protection was applicable. However, market gapping can lead to the client initially being closed out at a price that creates negative equity, with the account then re-credited back to zero equity by the provider to meet the new requirement of negative balance protection. This was also the case for those providers that offered negative balance protection in the same period in 2017.


(10) ESMA has taken into account that: (a) 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; (b) on 6 July 2018, in Romania national law started to apply that has similar terms as ESMA’s measures.
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 (\(^{11}\)). None of those bodies has raised any objections to the proposed renewal of the measures.

ESMA has notified NCAs of the proposed renewal Decision,

HAS ADOPTED THIS DECISION

Article 1

Definitions

For the purposes of this Decision:

(a) ‘contract for differences’ or ‘CFD’ means a derivative other than an option, future, swap or forward rate agreement, the purpose of which is to give the holder a long or short exposure to fluctuations in the price, level or value of an underlying, irrespective of whether it is traded on a trading venue, and that 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) ‘excluded non-monetary benefit’ means any non-monetary benefit other than, insofar as they relate to CFDs, information and research tools;

(c) ‘initial margin’ means any payment for the purpose of entering into a CFD, excluding commission, transaction fees and any other related costs;

(d) ‘initial margin protection’ means the initial margin determined by Annex I;

(e) ‘margin close-out protection’ means the closure of one or more of a retail client’s open CFDs on terms most favourable to the client in accordance with Articles 24 and 27 of Directive 2014/65/EU when the sum of funds in the CFD trading account and the unrealised net profits of all open CFDs connected to that account falls to less than half of the total initial margin protection for all those open CFDs;

(f) ‘negative balance protection’ means the limit of a retail client’s aggregate liability for all CFDs connected to a CFD trading account with a CFD provider to the funds in that CFD trading account.

Article 2

Temporary restriction on CFDs in respect of retail clients

The marketing, distribution or sale to retail clients of CFDs is restricted to circumstances where at least all of the following conditions are met:

(a) the CFD provider requires the retail client to pay the initial margin protection;

(b) the CFD provider provides the retail client with the margin close-out protection;

(c) the CFD provider provides the retail client with the negative balance protection;

(d) the CFD provider does not directly or indirectly provide the retail client with a payment, monetary or excluded non-monetary benefit in relation to the marketing, distribution or sale of a CFD, other than the realised profits on any CFD provided; and

(e) the CFD provider does not send directly or indirectly a communication to or publish information accessible by a retail client relating to the marketing, distribution or sale of a CFD unless it includes the appropriate risk warning specified by and complying with the conditions in Annex II.

Article 3

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 2, including by acting as a substitute for the CFD provider.

Article 4

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 1 February 2019 for a period of 3 months.


For the Board of Supervisors
Steven MAJJOOR
The Chair

ANNEX I

INITIAL MARGIN PERCENTAGES BY TYPE OF UNDERLYING

(a) 3.33 % of the notional value of the CFD when the underlying currency pair is composed of any two of the following currencies: US dollar, Euro, Japanese yen, Pound sterling, Canadian dollar or Swiss franc;

(b) 5 % of the notional value of the CFD when the underlying index, currency pair or commodity is:
   (i) any of the following equity indices: Financial Times Stock Exchange 100 (FTSE 100); Cotation Assistée en Continu 40 (CAC 40); Deutsche Bourse AG German Stock Index 30 (DAX30); Dow Jones Industrial Average (DJI); Standard & Poors 500 (S&P 500); NASDAQ Composite Index (NASDAQ), NASDAQ 100 Index (NASDAQ 100); Nikkei Index (Nikkei 225); Standard & Poors/Australian Securities Exchange 200 (ASX 200); EURO STOXX 50 Index (EURO STOXX 50);
   (ii) a currency pair composed of at least one currency that is not listed in point (a) above; or
   (iii) gold;

(c) 10 % of the notional value of the CFD when the underlying commodity or equity index is a commodity or any equity index other than those listed in point (b) above;

(d) 50 % of the notional value of the CFD when the underlying is a cryptocurrency; or

(e) 20 % of the notional value of the CFD when the underlying is:
   (i) a share; or
   (ii) not otherwise listed in this Annex.
ANNEX II

RISK WARNINGS

SECTION A

Risk warning conditions

1. The risk warning shall be in a layout ensuring its prominence, in a font size at least equal to the predominant font size and in the same language as that used in the communication or published information.

2. If the communication or published information is in a durable medium or a webpage, the risk warning shall be in the format specified in Section B.

3. If the communication or published information is in a medium other than a durable medium or a webpage, the risk warning shall be in the format specified in Section C.

4. By way of derogation to paragraphs 2 and 3, if the number of characters contained in the risk warning in the format specified in Section B or C exceeds the character limit permitted in the standard terms of a third party marketing provider, the risk warning may instead be in the format specified in Section D.

5. If the risk warning in the format specified in Section D is used, the communication or published information shall also include a direct link to the webpage of the CFD provider containing the risk warning in the format specified in Section B.

6. The risk warning shall include an up-to-date provider-specific loss percentage based on a calculation of the percentage of CFD trading accounts provided to retail clients by the CFD provider that lost money. The calculation shall be performed every three months and cover the 12-month period preceding the date on which it is performed ('12-month calculation period'). For the purposes of the calculation:

(a) an individual retail client CFD trading account shall be considered to have lost money if the sum of all realised and unrealised net profits on CFDs connected to the CFD trading account during the 12-month calculation period is negative;

(b) any costs relating to the CFDs connected to the CFD trading account shall be included in the calculation, including all charges, fees and commissions;

(c) the following items shall be excluded from the calculation:

(i) any CFD trading account that did not have an open CFD connected to it within the calculation period;
(ii) any profits or losses from products other than CFDs connected to the CFD trading account;
(iii) any deposits or withdrawals of funds from the CFD trading account.

7. By way of derogation from paragraphs 2 to 6, if in the last 12-month calculation period a CFD provider has not provided an open CFD connected to a retail client CFD trading account, that CFD provider shall use the standard risk warning in the format specified in Sections E to G, as appropriate.

SECTION B

Durable medium and webpage provider-specific risk warning

CFDs are complex instruments and come with a high risk of losing money rapidly due to leverage.

[insert percentage per provider] % of retail investor accounts lose money when trading CFDs with this provider.

You should consider whether you understand how CFDs work and whether you can afford to take the high risk of losing your money.
SECTION C

Abbreviated provider-specific risk warning

[insert percentage per provider] % of retail investor accounts lose money when trading CFDs with this provider.

You should consider whether you can afford to take the high risk of losing your money.

SECTION D

Reduced character provider-specific risk warning

[insert percentage per provider] % of retail CFD accounts lose money.

SECTION E

Durable medium and webpage standard risk warning

CFDs are complex instruments and come with a high risk of losing money rapidly due to leverage.

Between 74-89% of retail investor accounts lose money when trading CFDs.

You should consider whether you understand how CFDs work and whether you can afford to take the high risk of losing your money.

SECTION F

Abbreviated standard risk warning

Between 74-89% of retail investor accounts lose money when trading CFDs.

You should consider whether you can afford to take the high risk of losing your money.

SECTION G

Reduced character standard risk warning

74-89% of retail CFD accounts lose money.
III

(Other acts)

EUROPEAN ECONOMIC AREA

EFTA SURVEILLANCE AUTHORITY DECISION

No 83/18/COL

of 26 September 2018

on state guarantees granted to Landsvirkjun for derivative contracts (Iceland) [2019/156]

THE EFTA SURVEILLANCE AUTHORITY (‘the Authority’),

Having regard to:

the Agreement on the European Economic Area (‘the EEA Agreement’), in particular to Article 61,

Protocol 26 to the EEA Agreement,

the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice (‘the Surveillance and Court Agreement’), in particular to Article 24,

Protocol 3 to the Surveillance and Court Agreement (Protocol 3), in particular to Article 7(2) of Part II,

Having called on interested parties to submit their comments (1) and having regard to their comments,

Whereas:

1. PROCEDURE

(1) On 3 May 2017, the Authority opened a formal investigation into potential state aid granted to Landsvirkjun through state guarantees for derivative contracts (‘the opening decision’) (2).

(2) By letter dated 15 September 2017 (3), Landsvirkjun submitted its comments (4). The Authority in turn submitted the comments to Iceland (5). The Authority did not receive comments from any other interested party.

(3) By letter dated 25 September 2017 (6), the Icelandic authorities submitted comments.

(4) On 23 March 2018, the Authority met with representatives of Landsvirkjun and the Icelandic authorities. Following the meeting and receiving questions from the Authority on 27 March 2018 (7), Landsvirkjun submitted additional information on 11 April 2018 (8). On 12 April 2018, the Icelandic authorities informed the Authority that it supports Landsvirkjun’s arguments and did not see the need to submit additional observations (9).


(2) Ibid.

(3) Document No 874341.

(4) At the request of Landsvirkjun dated 8 August 2017 (Document No 869480), the Authority extended the deadline to submit comments until 15 September 2017 (Document No 869479).

(5) Document No 878807.

(6) Document No 875032.

(7) Document No 905567.

(8) Document No 908632.

(9) Document No 908885.
On 6 June 2018, the Authority discussed the matter further at a meeting with the Icelandic authorities and Landsvirkjun. On 7 June 2018, Landsvirkjun sent additional information to the Authority (10). Following the meeting and receiving the additional information from Landsvirkjun, the Authority asked the Icelandic authorities for additional clarifications (11). By letter dated 29 June 2018, the Icelandic authorities sent the requested information (12).

2. DESCRIPTION OF THE MEASURE

2.1. The beneficiary: Landsvirkjun

Landsvirkjun is a public partnership company regulated by the Landsvirkjun Act (13). As of 1 January 2007, the State Treasury took over full ownership of Landsvirkjun. Landsvirkjun is owned by the state, directly by the State Treasury (99.9%) and indirectly through Eignarhlutir ehf. (0.1%), a limited liability company that is wholly owned by the State Treasury.

2.2. Derivative contracts entered into by Landsvirkjun and state guarantees

According to the Icelandic authorities (14), Landsvirkjun is exposed to foreign currency exchange (FX) and interest rate risks on its debt portfolio. Landsvirkjun uses various derivative contracts to control and manage these risks.

As explained in the opening decision, the Authority looked into the following types of derivative contracts entered into by Landsvirkjun: FX swaps, FX options and interest rate swaps (15). In the opening decision, the Authority provided a description of these derivative contracts based on the explanations of the Icelandic authorities (16).

2.3. The existing aid procedure as regards state aid granted through unlimited state guarantees

By letter dated 26 September 2006 (17), the Authority initiated the procedure on existing aid measures provided for in Article 17(2) of Part II of Protocol 3, with respect to certain measures in favour of electricity utilities in Iceland, including unlimited state guarantees to Landsvirkjun. In that letter, the Authority informed the Icelandic authorities of its preliminary view that these measures involved existing state aid incompatible with the functioning of the EEA Agreement.

The Authority concluded in its Decision No 302/09/COL (18) that the unlimited state guarantee to Landsvirkjun constituted existing state aid. In that decision, the Authority proposed that the Icelandic authorities take legislative, administrative and other measures necessary to eliminate any incompatible aid resulting from the unlimited state guarantee granted to Landsvirkjun.

By letter dated 8 August 2009 (19), the Icelandic authorities accepted the proposed measures and committed themselves to inform the Authority of the measures they would take to implement Decision No 302/09/COL. After further exchanges with the Icelandic authorities, the Authority recorded in its Decision No 159/13/COL (20) Iceland’s acceptance of the appropriate measures with regard to the existing aid scheme and closed the case.

3. GROUNDS FOR INITIATING THE FORMAL INVESTIGATION PROCEDURE

In the opening decision, the Authority presented its preliminary view on the existence of aid concerning the guarantees at stake and their potential incompatibility with the functioning of the EEA Agreement.

(10) Documents No 918376 and 918377.
(11) Documents No 917646 and 917656.
(12) Paragraph 14 of the opening decision.
(13) Paragraph 14 of the opening decision.
(15) Document No 793116.
(16) Paragraph 14 of the opening decision.
(17) Paragraph 14 of the opening decision.
(18) Document No 920923 and 920925.
(19) Paragraph 14 of the opening decision.
(20) Sections 2.3.1 to 2.3.3 of part I of the opening decision.
(21) Document No 280834.
(22) Paragraph 14 of the opening decision.
(23) Document No 527076.
(24) Decision No 159/13/COL of 24 April 2013 to close the case concerning existing aid granted to Landsvirkjun and Orkuveita Reykjavíkur through unlimited state guarantees (OJ C 237, 15.8.2013, p. 3 and EEA Supplement No 45, 15.8.2013, p. 28).
(13) According to the Authority's preliminary view, the state guarantees in question had been granted to Landsvirkjun for derivative contracts at least since 2013. The Authority explained in the opening decision that several aspects necessary for the state aid assessment of the guarantees to Landsvirkjun for derivative contracts remained unclear (21).

(14) The Authority could not rule out the existence of state aid concerning the guarantees. As regards the economic advantage, the Authority was of the preliminary view that the guarantees in question did not meet the conditions (b), (c) and (d) of point 3.2 of the state aid guidelines on state guarantees ('the Guarantee Guidelines') (22) and constituted an advantage within the meaning of the state aid rules. The Authority expressed doubts as to whether the guarantees could be declared compatible with the functioning of the EEA Agreement.

(15) Iceland and Landsvirkjun have submitted comments both as regards the derivative contracts entered into by Landsvirkjun and the state guarantees. The parts of the comments relevant for the decision are summarised in Sections 4 and 5.

4. COMMENTS BY ICELAND

4.1. General comments as regards the derivative contracts and state guarantees

(16) Referring to paragraph 20 of the opening decision (23), Iceland argues that in contrast to what was stated in the follow-up letter of the Authority of 27 June 2016, Landsvirkjun was able to enter into the hedging derivative contracts without state guarantees. The statement in the follow-up letter to the contrary is a mistake that Iceland did not identify at the time. Furthermore, the relevant legal framework does not oblige Landsvirkjun to obtain a state guarantee, in order to enter into a derivative contract. Landsvirkjun can apply every year for a guarantee for hedging derivatives up to a specific cumulative nominal value.

(17) Referring to paragraphs 20, 24, 33 and 39 of the opening decision (24), Iceland explains that the guarantees were granted by the Minister of Finance and Economic Affairs rather than the Government Debt Management ('GDM'), which is a unit within the Central Bank under Treasury and Market Operations. The GDM is entrusted with certain tasks related to state guarantees, but that is not to say that the GDM is entrusted with granting them (25).

4.2. Existence of state aid

(18) Iceland does not dispute that the state guarantees in question are imputable to the state nor that, should a selective advantage be found to exist, they are liable to distort competition and to affect trade between the Contracting Parties to the EEA Agreement.

(19) However, Iceland disputes the Authority's preliminary finding (26) that the guarantees in question could grant an advantage to Landsvirkjun.

(20) According to Iceland, the guarantees in question are guarantees of collection that do not have a specific value for Landsvirkjun. There is only a theoretical possibility of collection against the state. Iceland claims that Landsvirkjun enters into derivative contracts for hedging purposes only, i.e. to reduce Landsvirkjun's financial risk from the underlying financial transactions. This is demanded by the state as the owner as well as Landsvirkjun's risk management policy set by its Board of Directors. Iceland also argues that Landsvirkjun enters into derivative contracts without a state guarantee with terms identical to guaranteed contracts.

(21) Paragraph 24 of the opening decision.
(23) According to paragraph 20 of the opening decision, the Authority had understood the Icelandic authorities to have explained at a meeting on 31 May 2016 that Landsvirkjun would not be able to enter into the hedging derivative contracts without the state guarantee.
(24) Paragraphs 20, 24, 33 and 39 of the opening decision reflect the Authority's initial understanding that the guarantees in question were granted by the Government Debt Management.
(26) Paragraph 58 of the opening decision.
4.3. Applicability of the Icelandic legislative framework for state guarantees

(21) By reference to paragraph 65 of the opening decision (\(^{21}\)), Iceland argues the guarantees in question fell under the legislative framework that was subject to the Authority's Decision No 302/09/COL, both before and after the amendments following that decision. Iceland refers to correspondence between the Icelandic authorities and the Authority confirming that explanation.

5. COMMENTS BY LANDSVIRKJUN (\(^{22}\))

5.1. The Icelandic legal framework on state guarantees to Landsvirkjun

(22) The legislative framework, under which state guarantees are granted to Landsvirkjun, is based on the State Guarantee Act (\(^{23}\)) and the Landsvirkjun Act. Landsvirkjun was already established as a partnership under the previously applicable Act on Landsvirkjun (\(^{24}\)).

(23) According to Article 1 of the State Guarantee Act, the state can never issue a guarantee without a legal basis (\(^{25}\)). In the case of Landsvirkjun, the legal basis for state guarantees is the Landsvirkjun Act. Under the Landsvirkjun Act, before and after the existing aid procedure, the owners' guarantee is a guarantee of collection. Furthermore, the guarantees are granted by the Minister of Finance and Economic Affairs rather than the GDM.

(24) A guarantee of collection is different from the normally applicable liability rules for owners of partnership companies. Under the Act on Partnership Companies No 50/2007, the owners are liable for the partnership company's obligations on the basis of a direct, unlimited and unconditional guarantee, and thus without limitations, for all the obligations of the company.

(25) Under a guarantee of collection a creditor must exhaust all legal remedies against Landsvirkjun before proceeding against the state. In practice, this means that the creditor must prove that the debtor is insolvent, according to the general principles of Icelandic law. The creditor therefore would need to have unsuccessful distraint or formally start (or be a part of with others) the procedures set out in the Bankruptcy Act before reverting to the guarantor (\(^{26}\)). Due to the very burdensome and lengthy procedure and the requirement that all means are exhausted with respect to the company before the guarantor can be addressed, a guarantee of collection has far less value for the creditors. Landsvirkjun also refers to the Authority's previous practice in this regard (\(^{27}\)).

5.2. Landsvirkjun's use of derivative contracts

(26) As regards the derivative contracts in question that were covered by a state guarantee, these derivative contracts concerned underlying financial obligations (loans or bonds) that were entered into prior to implementing the appropriate measure under the existing aid procedure (\(^{28}\)).

(27) Landsvirkjun states that it structures its financing fully in line with standard practice throughout the OECD countries for large undertakings and derivative contracts form an integral part of risk management. Landsvirkjun enters into ISDA Master Agreements (\(^{29}\)) with counterparties, which set out standard terms that apply to all the derivative transactions entered into between those parties (\(^{30}\)).

\(^{21}\) According to paragraph 65 of the opening decision (by reference to Section 2.5 of Part I), the Authority was of the preliminarily view that the guarantees in question did not meet the terms of Iceland's amended legislative framework for state guarantees nor with the Guarantee Guidelines. In particular, Landsvirkjun did not appear to pay a premium covering the benefits it enjoys due to the guarantees; the guarantees appeared to cover more than 80 % of any outstanding obligations; and the guarantees did not appear to be linked to specific financial transactions, for a fixed maximum amount and limited in time.

\(^{22}\) The Authority notes that, as explained in Section 1, Iceland agrees with the comments submitted by Landsvirkjun.

\(^{23}\) Act No 121/1997.

\(^{24}\) Article 1 of the Act No 59/1965, as translated by Landsvirkjun: 'The Government and the City council of Reykjavík set up a power company, named Landsvirkjun. The company is an independent legal entity, which has an independent financial and accounting status. Its home and venue is in Reykjavik. Landsvirkjun is a partnership company of the state and the city of Reykjavik with each party owning half of the company. Each party is solely responsible for all liabilities of the company, but their internal liability depends on ownership ratios. Neither party may withdraw from the company without the consent of the other.'

\(^{25}\) The same was enacted in the previously applicable State Guarantee Act No 37/1961.

\(^{26}\) Documents No 874341 and 92092.


\(^{28}\) Document No 917656.

\(^{29}\) The ISDA Master Agreement is a standard document that is regularly used to govern over-the-counter derivatives transactions. The ISDA Master Agreement is published by the International Swaps and Derivatives Association (ISDA).

\(^{30}\) Document No 874341.
Landsvirkjun has financial obligations denominated in USD and other currencies, with both variable and fixed interest rates. Landsvirkjun is therefore exposed to FX and interest rate risks. Landsvirkjun hedges these risks by using derivative contracts to convert financial obligations denominated in currency other than USD (its functional currency since 2008) to USD and financial obligations with variable interest rates to fixed interest rates.

Landsvirkjun uses derivative contracts for hedging purposes only. Landsvirkjun does not enter into derivative contracts for speculative or arbitrage purposes. Limiting the use of derivative contracts to hedging purposes only has also been imposed on Landsvirkjun by its owner — the State. Landsvirkjun submitted internal documents and letters from its owner to confirm these claims.

Landsvirkjun also explains that its policy is not to use any guarantees, either private or public, for any transactions. Following the amendments to the state guarantee system, Landsvirkjun started to negotiate a renewal of the guaranteed derivative contracts, with the last state guarantee removed in July 2017. Landsvirkjun is able to and indeed does enter into derivative contracts without state guarantees. Landsvirkjun has also provided evidence showing that removing the state guarantees did not result in changes to the economic terms of the derivative contracts.

5.3. No advantage

Landsvirkjun is of the opinion that no advantage was granted through the state guarantees for the derivative contracts in question.

A hedging derivative will by definition reduce the risk exposure which should lead to a reduction of the premium paid for the guarantee linked to the underlying transaction. Landsvirkjun reiterates that the amendment of the outstanding derivative contracts to eliminate the state guarantee has not entailed any additional cost for the company. The conditions and requirements with respect to the financing of Landsvirkjun with or without a state guarantee have not changed.

Landsvirkjun has submitted two reports on the effect of the state guarantees on the derivative contracts. According to the reports, an economic advantage of the state guarantees on the derivative portfolio was non-existent.

Landsvirkjun also explains that during 2010 to 2017 its cash at hand was between USD 142 million and USD 287 million. This high cash at hand position has been held for liquidity risk purposes, i.e. as a buffer for unforeseen risk. The strong liquidity entails opportunity cost that is directly linked to the premiums currently paid to the state. Instead of holding the cash at hand, the company could have bought back bonds from the market and/or prepaid/amortized loans from their lenders. It would not only save interest, but also the [0,1-2] % guarantee fee that Landsvirkjun currently pays for the guaranteed bonds and loans.

6. PRESENCE OF STATE AID

Article 61(1) of the EEA Agreement reads as follows:

'Save as otherwise provided in this Agreement, any aid granted by EC Member States, EFTA States or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, in so far as it affects trade between Contracting Parties, be incompatible with the functioning of this Agreement.'

The qualification of a measure as aid within the meaning of this provision therefore requires the following cumulative conditions to be met: (i) the measure must be granted by the state or through state resources; (ii) it must confer an advantage on an undertaking; (iii) it must favour certain undertakings; and (iv) it must be liable to distort competition and affect trade. The Authority finds it appropriate to start its assessment with whether the guarantees for the derivative contracts in question conferred an advantage on Landsvirkjun.

(*) Document No 908632.
(†) Document No 908632.
(‡) Document No 908631.
(§) Document No 874341.
(¶) Document No 875032.
(‖) Idem.
(¶) Documents No 908633 and 920923.
(‖) Documents No 874341, 908633 and 920923.
(‴) Documents No 874344 (Zanders report, September 2017) and 874345 (Summa report, September 2017).
6.1. **Advantage**

### 6.1.1. Preliminary remarks

(37) The Authority concurs with the Icelandic authorities and Landsvirkjun that the guarantees in question fall under the Icelandic legislation on state guarantees, including the Landsvirkjun Act, which was subject to the existing aid procedure (⁴⁶).

(38) The current formal investigation initiated by the opening decision has a narrower focus than the existing aid procedure in that it only covers the application of the Landsvirkjun Act to state guarantees for certain derivative contracts.

(39) In the opening decision, the Authority questioned whether the guarantees met the conditions (b), (c) and (d) under point 3.2 (⁴⁷) of the Guarantee Guidelines that would allow ruling out the presence of aid (⁴⁸).

(40) Without prejudice to the issue of whether the conditions set out in the Guarantee Guidelines for ruling out state aid are met, as explained below and based on the information received from Iceland and Landsvirkjun in the course of the formal investigation, the Authority finds that the state guarantees in question did not result in an advantage to Landsvirkjun (⁴⁹).

### 6.1.2. Exclusion of advantage from state guarantees for the derivative contracts

(41) An advantage within the meaning of Article 61(1) of the EEA Agreement is any economic benefit which an undertaking could not have obtained under normal market conditions that is to say in the absence of the state intervention (⁵⁰). The Authority has held on several occasions that a guarantee may constitute an advantage under Article 61(1) of the EEA Agreement (⁵¹).

(42) The benefit of a guarantee is that the risk associated with the guarantee is carried by the state. Such risk-carrying by the state should normally be remunerated by an appropriate premium (⁵²). However, according to the Guarantee Guidelines, ‘if an individual guarantee or a guarantee scheme entered into by the state does not bring any advantage to an undertaking, it will not constitute state aid’ (⁵³). Points 3.2 to 3.5 of the Guarantee Guidelines set out the conditions for excluding aid in individual guarantees and guarantee schemes. According to point 3.6 of the Guarantee Guidelines, ‘a failure to comply with any one of the conditions set out in points 3.2 to 3.5 does not mean that the guarantee or guarantee scheme is automatically regarded as state aid.’

(43) After 1 January 2010, Landsvirkjun has managed to negotiate with the derivative contracts counterparties the removal of the state guarantees, with the last such guarantee removed in July 2017 (⁵⁴). As the evidence provided during the formal investigation shows, removing the state guarantees did not change the economic terms of the derivative contracts (⁵⁵).

(44) The Authority sees the fact that the counterparties were willing to remove the state guarantees without requesting better economic terms as an indication that the guarantees did not entail an advantage for Landsvirkjun.

(45) Furthermore, Landsvirkjun has not used private guarantees and from the information provided during the formal investigation, it is not possible to establish a market price for the guarantees on hedging derivatives.

(46) In order to quantify the potential advantage conferred by a guarantee (where a market price cannot be established), the Guarantee Guidelines foresee a comparison of the economic terms of a transaction with and without the guarantee (⁵⁶).

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(⁴⁶) Sections 4.3 and 5.1.
(⁴⁷) In the opening decision, the Authority did not question, and had no reason to question, that Landsvirkjun fulfilled condition (a) of point 3.2 of the Guarantee Guidelines, i.e. that the borrower must not be in financial difficulty.
(⁴⁸) Section 1.1.3 of Part II of the opening decision.
(⁴⁹) The Authority notes that this conclusion concerns the guarantees covered by the opening decision and the current decision only and is without prejudice to any other state guarantees to either Landsvirkjun or other undertakings.
(⁵¹) The Authority has found an advantage to exist, inter alia, in its Decision No 177/05/COL of 15 July 2005 concerning a state guarantee to Liechtensteinische Landesbank (not published) and Decision No 227/06/COL with regard to state aid in favour of Farice hf. (OJ L 36, 5.2.2009, p. 69 and EEA Supplement No 6, 5.2.2009, p. 9).
(⁵²) Guarantee Guidelines, point 2.1.
(⁵³) Guarantee Guidelines, point 3.1.
(⁵⁴) Document No 908632.
(⁵⁵) Section 5.2.
(⁵⁶) Guarantee Guidelines, point 4.2.
The removal of the state guarantees in question did not change the economic terms of the relevant derivative contracts. Therefore, the guarantees cannot be seen to constitute an advantage to Landsvirkjun. Further, the Authority has no indications or information at its disposal suggesting that the economic terms of the relevant derivative contracts would have been different without the state guarantees at the time when the state guarantees were actually granted. Consequently, the Authority must assume that a removal (or non-existence) of the state guarantees did not change the economic terms of the relevant derivative contracts at any given point during the lifetime of these guarantees.

The conclusion that the guarantees on the derivative contracts in question did not confer an advantage on Landsvirkjun is also supported by the reports referred to in recital 33. In particular, Zanders (a consulting firm specialising in financial services) looked, on behalf of Landsvirkjun, at a sample of derivative contracts held by Landsvirkjun and calculated the corresponding margins for those derivative contracts (57). The report showed that such margins, which ranged between [–2-2] and [10-15] basis points, were in line with the margins observed for similar derivative contracts held by companies with a comparable credit rating, which, unlike Landsvirkjun, did not benefit from a guarantee of collection. On this basis, the Zanders report concludes that, on average, there is no pricing advantage between Landsvirkjun and other companies as a result of the guarantee of collection. Accordingly, the report concludes that Landsvirkjun did not enjoy an economic benefit from such a guarantee.

A report by another consulting firm, Summa Consulting slf, noted in respect of the pricing of the hedging derivatives that, ‘considering the strong balance sheet, good liquidity position and credit quality of Landsvirkjun, it is not likely that a state guarantee or an absence thereof will have meaningful effects on the pricing of derivative contracts that Landsvirkjun enters into’ (58).

Further, Landsvirkjun used the guaranteed derivative contracts exclusively for hedging purposes, i.e. to convert its financial obligations denominated in currency other than USD (its functional currency since 2008) to USD and financial obligations with variable interest rates to fixed interest rates (59). According to the information submitted during the formal investigation, the implementation of the appropriate measures in the course of the existing aid procedure led to limiting the state guarantees to 80 % of the value of the derivative contracts in question and the guarantees on hedging derivatives were limited by a specific cumulative nominal value (60). Hence, neither Landsvirkjun nor the state as its guarantor can be said to have been exposed to unlimited liabilities from these guarantees.

Furthermore, the guarantees in question are, according to Article 1 of the Landsvirkjun Act, guarantees of collection. Under a guarantee of collection, a creditor must exhaust all legal remedies against Landsvirkjun before proceeding against the state. (61) The Authority has earlier concluded that, though not excluding the advantage, this type of guarantee comes with lesser risk (62). As shown by Landsvirkjun, in each of the years 2010 to 2017 the company's cash and cash equivalents exceeded losses recorded from the guaranteed derivatives (63). Therefore, any risks to the guarantor were reduced.

As explained in recital 36, for a measure to constitute state aid within the meaning of Article 61(1) of the EEA Agreement, all four conditions must be cumulatively fulfilled. Since the guarantees in question do not confer an advantage on Landsvirkjun, it is not necessary to carry out an assessment with regard to the other conditions.

7. CONCLUSION

On the basis of the foregoing assessment, the Authority concludes that the state guarantees to Landsvirkjun for derivative contracts for hedging Landsvirkjun’s foreign currency exchange and interest rate risks, the last of which was removed in July 2017, did not constitute state aid within the meaning of Article 61(1) of the EEA Agreement,

HAS ADOPTED THIS DECISION:

Article 1

The state guarantees to Landsvirkjun for derivative contracts for hedging Landsvirkjun’s foreign currency exchange and interest rate risks, the last of which was removed in July 2017, did not constitute state aid within the meaning of Article 61(1) of the EEA Agreement.

(57) Document No 874344.
(59) Section 5.2 and Document No 874345.
(60) Documents No 875032, 874341 and 908632.
(61) Section 5.1.
(62) Footnote 34.
(63) Document No 874345.
The formal investigation is hereby closed.

Article 2

This Decision is addressed to Iceland.

Article 3

Only the English language version of this decision is authentic.

Done at Brussels, 26 September 2018.

For the EFTA Surveillance Authority,

Bente ANGELL-HANSEN  Frank J. BÜCHEL  Hógni KRISTJÁNSSON  Carsten ZATSCHLER
President  College Member  College Member  Countersigning as Director,
Responsible College Member  Legal and Executive Affairs