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Legislation

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⁽¹⁾ Text with EEA relevance.

EN

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⁽¹⁾ Text with EEA relevance.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2020/1816

of 17 July 2020

supplementing Regulation (EU) 2016/1011 of the European Parliament and of the Council as regards the explanation in the benchmark statement of how environmental, social and governance factors are reflected in each benchmark provided and published

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/1011 of the European Parliament and of the Council of 8 June 2016 on indices used as benchmarks in financial instruments and financial contracts or to measure the performance of investment funds and amending Directives 2008/48/EC and 2014/17/EU and Regulation (EU) No 596/2014 ⁽¹⁾, and in particular Article 27 (2b) thereof,

Whereas:

- (1) The Paris Agreement adopted under the United Nations Framework Convention on Climate Change, approved by the Union on 5 October 2016 ⁽²⁾ (the 'Paris Agreement'), aims to strengthen the response to climate change, among other means by making investment flows consistent with a pathway towards low greenhouse gas emissions and climate-resilient development.
- (2) On 11 December 2019, the Commission adopted its Communication to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions 'The European Green Deal' ⁽³⁾. That European Green Deal represents a new growth strategy that aims to transform the Union into a fair and prosperous society, with a modern, resource-efficient and competitive economy where there are no net emissions of greenhouse gases in 2050 and where economic growth is decoupled from resource use. The implementation of the European Green Deal requires that investors are offered clear, long-term signals to avoid stranded assets and to raise sustainable finance.
- (3) Regulation (EU) 2016/1011 requires benchmark administrators to explain in the benchmark statement how environmental, social and governance ('ESG') factors are reflected in each benchmark or family of benchmarks provided and published.
- (4) Different ways of explaining how ESG factors are reflected would lead to a lack of comparability between benchmarks and a lack of clarity as to the scope and objectives of the ESG factors. It is therefore necessary to specify the content of that explanation and to lay down a template to be used.

⁽¹⁾ OJ L 171, 29.6.2016, p. 1.

⁽²⁾ Council Decision (EU) 2016/1841 of 5 October 2016 on the conclusion, on behalf of the European Union, of the Paris Agreement adopted under the United Nations Framework Convention on Climate Change (OJ L 282, 19.10.2016, p. 1).

⁽³⁾ COM(2019) 640 final.

- (5) In order to better adapt the information for investors, the requirement to explain how ESG factors are reflected in each benchmark or family of benchmarks provided and published should take into account the underlying assets on which benchmarks are based. This Regulation should not apply to benchmarks which do not have underlying assets that have an impact on climate change such as interest rate benchmarks and foreign exchange benchmarks.
- (6) The explanation on how ESG factors are reflected should display the corresponding score of the relevant ESG factors vis-à-vis the benchmark, at an aggregated weighted average value. Such score should not be disclosed for each constituent of the benchmarks. Where relevant and appropriate, benchmark administrators should be able to provide additional ESG information.
- (7) Due to their characteristics and objectives, specific disclosure requirements should be set out for EU Climate Transition Benchmarks and EU Paris-aligned Benchmarks, and for significant bond and equity benchmarks.
- (8) In order to provide benchmark users with accurate and up-to-date information, benchmark administrators should update the information provided to reflect any changes made to the benchmark statement, and should indicate the reason and the dates at which the information was updated,

HAS ADOPTED THIS REGULATION:

Article 1

Definitions

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

- (a) 'equity' means listed shares;
- (b) 'fixed income' means listed debt securities, other than those issued by a sovereign issuer;
- (c) 'sovereign debt' means debt securities issued by a sovereign issuer.

Article 2

Explanation of how ESG factors are reflected in each benchmark or family of benchmarks

1. Benchmark administrators shall explain in the benchmark statement, using the template laid down in Annex I, how the environmental, social and governance (ESG) factors listed in Annex II are reflected in each benchmark or family of benchmarks they provide and publish.

The requirement set out in the first subparagraph shall not apply to interest rate and foreign exchange benchmarks.

2. The explanation referred to in paragraph 1 shall include the score of the ESG factors vis-à-vis the corresponding benchmark and family of benchmark, at an aggregated weighted average value.

3. For individual benchmarks, benchmark administrators may, rather than providing all the information required by the template laid down in Annex I to this Regulation, replace that information by a hyperlink included in the benchmark statement, to a website that contains all that information.

4. Where benchmarks blend different underlying assets, benchmark administrators shall explain how ESG factors are reflected for each of the underlying assets.

5. Benchmark administrators shall include in the explanation provided a reference to the sources of data and standards used for the ESG factors disclosed.
6. Benchmark administrators that disclose additional ESG factors in accordance with Article 1(4) of Commission Delegated Regulation (EU) 2020/1817 ⁽⁴⁾ shall include the score of those additional ESG factors.

Article 3

Update of the explanation provided

Benchmark administrators shall update the explanation provided whenever significant changes relating to the ESG factors occur and in any case on an annual basis. They shall state the reasons for the update.

Article 4

Entry into force and application

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, 17 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁴⁾ Commission Delegated Regulation (EU) 2020/1817 of 17 July 2020 supplementing Regulation (EU) 2016/1011 of the European Parliament and of the Council as regards the minimum content of the explanation on how environmental, social and governance factors are reflected in the benchmark methodology (See page 12 of this Official Journal).

ANNEX I

**TEMPLATE FOR EXPLAINING HOW ENVIRONMENTAL, SOCIAL AND GOVERNANCE (ESG)
FACTORS ARE REFLECTED IN THE BENCHMARK STATEMENT**

**EXPLANATION OF HOW ESG FACTORS ARE REFLECTED IN THE
BENCHMARK STATEMENT**

SECTION 1 – CONSIDERATION OF ESG FACTORS

Item 1. Name of the benchmark administrator.	
Item 2. Type of benchmark or family of benchmarks. <i>Choose the relevant underlying asset from the list provided in Annex II.</i>	
Item 3. Name of the benchmark or family of benchmarks.	
Item 4. Are there in the portfolio of the benchmark administrator any EU Climate Transition Benchmarks, EU Paris-aligned Benchmarks, benchmarks that pursue ESG objectives or benchmarks that take into account ESG factors?	☐ Yes ☐ No
Item 5. Does the benchmark or family of benchmarks pursue ESG objectives?	☐ Yes ☐ No
Item 6. Where the response to Item 5 is positive, provide below the details (score) in relation to the ESG factors listed in Annex II for each family of benchmarks at aggregated level. The ESG factors shall be disclosed at an aggregated weighted average value at the level of the family of benchmarks.	
(a) List of combined ESG factors:	Details on each factor:
(b) List of environmental factors:	Details on each factor:
(c) List of social factors:	Details on each factor:
(d) List of governance factors:	Details on each factor:
Item 7. Where the response to Item 5 is positive, provide below the details (score) for each benchmark, in relation to the ESG factors listed in Annex II, depending on the relevant underlying asset concerned. Alternatively, all of this information may be provided in the form of a hyperlink to a website of the benchmark administrator included in the benchmark statement. The information on the website shall be easily available and accessible. Benchmark administrators shall ensure that information published on their website remains available for five years. The score of the ESG factors shall not be disclosed for each constituent of the benchmark, but shall be disclosed at an aggregated weighted average value of the benchmark.	
(a) List of combined ESG factors:	Details on each factor:
(b) List of environmental factors:	Details on each factor:
(c) List of social factors:	Details on each factor:
(d) List of governance factors:	Details on each factor:
Hyperlink to the information on ESG factors for each benchmark:	

Item 8. Data and standards used

- | | |
|---|--|
| <p>(a) Description of data sources used to provide information on the ESG factors in the benchmark statement.
<i>Describe how the data used to provide information on the ESG factors in the benchmark statement are sourced and whether, and to what extent, data are estimated or reported.</i></p> | |
| <p>(b) Reference standards.
<i>List the supporting standards used for the reporting under item 6 and/or item 7.</i></p> | |

SECTION 2 – ADDITIONAL DISCLOSURE REQUIREMENTS FOR EU CLIMATE TRANSITION AND EU PARIS-ALIGNED BENCHMARKS

Item 9. Where a benchmark is labelled as ‘EU Climate Transition Benchmark’ or ‘EU Paris-aligned Benchmark’, benchmark administrators shall also disclose the following information:

- | | |
|---|--|
| <p>(a) forward-looking year-on-year decarbonisation trajectory;</p> | |
| <p>(b) degree to which the IPCC decarbonisation trajectory (1,5 °C with no or limited overshoot) has been achieved on average per year since creation;</p> | |
| <p>(c) overlap between those benchmarks and their investable universe, as defined in Article 1, point (e), of Commission Delegated Regulation (EU) 2020/1818 ⁽¹⁾, using the active share at asset level.</p> | |

SECTION 3 – DISCLOSURE OF THE ALIGNMENT WITH THE OBJECTIVES OF THE PARIS AGREEMENT

Item 10. By the date of application of this Regulation, for significant equity and bond benchmarks, EU Climate Transition Benchmarks and EU Paris-aligned Benchmarks, benchmark administrators shall also disclose the following information. By 31 December 2021, benchmark administrators shall, for each benchmark or, where applicable, each family of benchmarks, disclose the following information:

- | | |
|--|---|
| <p>(a) Does the benchmark align with the target of reducing carbon emissions or the attainment of the objectives of the Paris Agreement;</p> | <p>☐ Yes ☐ No</p> |
| <p>(b) the temperature scenario, in accordance with international standards, used for the alignment with the target of reducing GHG emissions or attaining of the objectives of the Paris Agreement;</p> | |
| <p>(c) the name of the provider of the temperature scenario used for the alignment with the target of reducing GHG emissions or the attainment of the objectives of the Paris Agreement;</p> | |

⁽¹⁾ Commission Delegated Regulation (EU) 2020/1818 of 17 July 2020 supplementing Regulation (EU) 2016/1011 of the European Parliament and of the Council as regards the minimum standards for EU Climate Transition Benchmarks and EU Paris-aligned Benchmarks (See page 17 of this Official Journal).

(d) the methodology used for the measurement of the alignment with the temperature scenario;	
(e) the hyperlink to the website of the temperature scenario used.	
Date on which information has last been updated and reason for the update:	

ANNEX II

ENVIRONMENTAL, SOCIAL AND GOVERNANCE (ESG) FACTORS TO BE CONSIDERED BY UNDELYING ASSETS OF THE BENCHMARK

Section 1

EQUITY

ESG FACTORS	DISCLOSURES
Combined ESG factors	Weighted average ESG rating of the benchmark (voluntary).
	Overall ESG rating of top ten benchmark constituents by weighting in the benchmark (voluntary).
Environmental	Weighted average environmental rating of the benchmark (voluntary). Exposure of the benchmark portfolio to renewable energy as measured by capital expenditures (CapEx) in those activities (as a share of total CapEx by energy companies included in the portfolio) (voluntary). Exposure of the benchmark portfolio to climate-related physical risks, measuring the effects of extreme weather events on companies' operations and production or on the different stages of the supply chain (based on issuer exposure) (voluntary). Degree of exposure of the portfolio to the sectors listed in Sections A to H and Section L of Annex I to Regulation (EC) No 1893/2006 of the European Parliament and of the Council ⁽¹⁾ as a percentage of the total weight in the portfolio. Greenhouse gas (GHG) intensity of the benchmark. Percentage of GHG emissions reported versus estimated. Exposure of the benchmark portfolio to companies the activities of which fall under Divisions 05 to 09, 19 and 20 of Annex I to Regulation (EC) No 1893/2006. Exposure of the benchmark portfolio to activities included in the environmental goods and services sector, as defined in Article 2, point (5) of Regulation (EU) No 691/2011 of the European Parliament and of the Council ⁽²⁾.
Social	Weighted average social rating of the benchmark (voluntary). International treaties and conventions, United Nations principles or, where applicable, national law used in order to determine what constitutes a 'controversial weapon'. Weighted average percentage of benchmark constituents in the controversial weapons sector. Weighted average percentage of benchmark constituents in the tobacco sector. Number of benchmark constituents subject to social violations (absolute number and relative divided by all benchmark constituents), as referred to in international treaties and conventions, United Nations principles and, where applicable, national law. Exposure of the benchmark portfolio to companies without due diligence policies on issues addressed by the fundamental International Labor Organisation Conventions 1 to 8.

⁽¹⁾ Regulation (EC) No 1893/2006 of the European Parliament and of the Council of 20 December 2006 establishing the statistical classification of economic activities NACE Revision 2 and amending Council Regulation (EEC) No 3037/90 as well as certain EC Regulations on specific statistical domains (OJ L 393, 30.12.2006, p. 1).

⁽²⁾ Regulation (EU) No 691/2011 of the European Parliament and of the Council of 6 July 2011 on European environmental economic accounts (OJ L 192, 22.7.2011, p. 1).

ESG FACTORS	DISCLOSURES
	Weighted average gender pay gap. Weighted average ratio of female to male board members. Weighted average ratio of accidents, injuries, fatalities. Numbers of convictions and amount of fines for violations of anti-corruption and anti-bribery laws.
Governance	Weighted average governance rating of the benchmark (voluntary). Weighted average percentage of board members who are independent. Weighted average percentage of female board members.

Section 2

FIXED INCOME

ESG FACTORS	DISCLOSURES
Combined ESG factors	Weighted average ESG rating of the benchmark (voluntary). Overall ESG rating of top ten benchmark constituents by weighting in the benchmark (voluntary).
Environmental	Weighted average environmental rating of the benchmark (voluntary). Exposure of the benchmark portfolio to renewable energy as measured by capital expenditures (CapEx) in those activities (as a share of total CapEx by energy companies included in the portfolio) (voluntary). Exposure of the benchmark portfolio to climate-related physical risks, measuring the effects of extreme weather events on companies' operations and production or on the different stages of the supply chain (based on issuer exposure) (voluntary). Degree of exposure of the portfolio to the sectors listed in Sections A to H and Section L of Annex I to Regulation (EC) No 1893/2006 as a percentage of the total weight in the portfolio. GHG intensity of the benchmark. Percentage of reported versus estimated emissions. Exposure of the benchmark portfolio to companies the activities of which fall under Divisions 05 to 09, 19 and 20 of Annex I to Regulation (EC) No 1893/2006. Percentage of green bonds in the benchmark portfolio.
Social	Weighted average social rating of the benchmark (voluntary). International treaties and conventions, United Nations principles or, where applicable, national law used in order to determine what constitutes a 'controversial weapon'. Weighted average percentage of benchmark constituents in the controversial weapons sector. Weighted average percentage of benchmark constituents in the tobacco sector.

ESG FACTORS	DISCLOSURES
	Number of benchmark constituents subject to social violations (absolute number and relative divided by all benchmark constituents), as referred to in international treaties and conventions, United Nations principles or, where applicable, national law. Exposure of the benchmark portfolio to companies without due diligence policies on issues addressed by Conventions 1 to 8 of the International Labour Organisation. Weighted average gender pay gap. Weighted average ratio of female to male board members. Weighted average ratio of accidents, injuries, fatalities. Numbers of convictions and amount of fines for violations of anti-corruption and anti-bribery laws.
Governance	Weighted average governance rating of the benchmark (voluntary).

Section 3

SOVEREIGN DEBT

ESG FACTORS	DISCLOSURES
Combined ESG factors	Weighted average ESG rating of the benchmark (voluntary). Overall ESG rating of top ten benchmark constituents by weighting in the benchmark (voluntary). The percentage of underlying fund management companies signed up to international standards.
Environmental	Weighted average environmental rating of the benchmark (voluntary). Exposure of the benchmark portfolio to climate-related physical risks, measuring the effects of extreme weather events on companies' operations and production or on the different stages of the supply chain (based on issuer exposure) (voluntary). Top ten and bottom ten constituents by exposure to climate-related physical risks (voluntary). GHG intensity of the benchmark. Percentage of reported versus estimated emissions. Percentage of green bonds in the benchmark portfolio.
Social	Weighted average social rating of the benchmark (voluntary). Number of benchmark constituents subject to social violations (absolute number and relative number divided by all benchmark constituents), as referred to in international treaties and conventions, United Nations principles and, where applicable, national law. Average human rights performance of the issuers (including a quantitative indicator and the methodology used to calculate it). Average income inequality score, measuring the distribution of income and economic inequality among the participants in a particular economy (including a quantitative indicator and the methodology used to calculate it).

ESG FACTORS	DISCLOSURES
	Average freedom of expression score measuring the extent to which political and civil society organizations can operate freely (including a quantitative indicator and the methodology used to calculate it).
Governance	Weighted average governance rating of the benchmark (voluntary). Average corruption score measuring the perceived level of public sector corruption (including a quantitative indicator and the methodology used to calculate it). Average political stability score, measuring the likelihood that the current regime will be overthrown by the use of force (including a quantitative indicator and the methodology used to calculate it). Average rule of law score, based on the absence of corruption, respect for fundamental rights, and the state of civil and criminal justice (including a quantitative indicator and the methodology used to calculate it).

Section 4

COMMODITY

ESG FACTORS	DISCLOSURES
Environmental	Degree of exposure of the underlying commodities to climate-related physical risks, measuring the effects of extreme weather events on companies' operation and production or on the different stages of the supply chain (low, moderate or high) (voluntary). The methodology used to calculate the climate-related physical risks (voluntary). Degree of exposure of the underlying commodities to climate-transition risks, measuring the financial impacts resulting from the effects of the implementation of a low-carbon strategies (low, moderate or high)
Social	Degree of exposure of the underlying commodities to social risks (low, moderate or high).
Governance	Degree of exposure of the underlying commodities to governance risks (low, moderate or high). Average rule of law score, based on the absence of corruption, respect for fundamental rights and the state of civil and criminal justice (including a quantitative indicator and the methodology used to calculate it).

Section 5

OTHER

ESG FACTORS	DISCLOSURES
Combined ESG factors	Weighted average ESG rating of the benchmark (voluntary).
Environmental	Weighted average environmental rating of the benchmark (voluntary). Degree of exposure of the portfolio to climate-related opportunities, measuring investment opportunities related to climate change, innovating new investment solutions, as percentage of total weight in portfolio (voluntary).

ESG FACTORS	DISCLOSURES
	GHG intensity of the benchmark. Degree of exposure of the portfolio to the sectors listed in Sections A to H and Section L of Annex I to Regulation (EC) No 1893/2006 as percentage of total weight in the portfolio.
Social	Weighted average social rating for the benchmark (voluntary). International treaties and conventions, United Nations principles or, where applicable, national law used in order to determine what constitutes a 'controversial weapon'. Weighted average percentage of benchmark constituents in the controversial weapons sector. Weighted average percentage of benchmark constituents in the tobacco sector.
Governance	Weighted average governance rating of the benchmark (voluntary). Percentage of underlying funds with stewardship policies in place, including measures for the planning and management of resources.

COMMISSION DELEGATED REGULATION (EU) 2020/1817**of 17 July 2020****supplementing Regulation (EU) 2016/1011 of the European Parliament and of the Council as regards the minimum content of the explanation on how environmental, social and governance factors are reflected in the benchmark methodology****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/1011 of the European Parliament and of the Council of 8 June 2016 on indices used as benchmarks in financial instruments and financial contracts or to measure the performance of investment funds and amending Directives 2008/48/EC and 2014/17/EU and Regulation (EU) No 596/2014⁽¹⁾, and in particular Article 13(2a) thereof,

Whereas:

- (1) The Paris Agreement adopted under the United Nations Framework Convention on Climate Change, approved by the Union on 5 October 2016⁽²⁾ (the 'Paris Agreement'), aims to strengthen the response to climate change, among other means by making investment flows consistent with a pathway towards low greenhouse gas emissions and climate-resilient development.
- (2) On 11 December 2019, the Commission adopted its Communication to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions 'The European Green Deal'⁽³⁾. The European Green Deal represents a new growth strategy that aims to transform the Union into a fair and prosperous society, with a modern, resource-efficient and competitive economy where there are no net emissions of greenhouse gases in 2050 and where economic growth is decoupled from resource use. The implementation of the European Green Deal requires that investors are offered clear, long-term signals to avoid stranded assets and to raise sustainable finance.
- (3) Regulation (EU) 2016/1011 requires benchmark administrators to explain how for each benchmark provided and published the key elements of the benchmark methodology reflect environmental, social and governance ('ESG') factors.
- (4) Different ways of explaining for each benchmark or family of benchmarks how the key elements of the benchmark methodology reflect ESG factors, would lead to a lack of comparability between benchmarks and a lack of clarity as to the scope and objectives of the ESG factors. It is therefore necessary to set out the minimum content of such explanations as well as a template to be used.
- (5) In order to better adapt the information for investors, the requirement to explain how the key elements of the methodology reflect ESG factors for each benchmark or family of benchmarks provided and published should take into account the underlying assets on which benchmarks are based. This Regulation should not apply to benchmarks which do not have underlying assets that have an impact on climate change such as interest rate benchmarks and foreign exchange benchmarks. In accordance with Article 19 of Regulation (EU) 2016/1011, this Regulation should not apply to commodity benchmarks.
- (6) The explanation on how key elements of the benchmark methodology reflect ESG factors should be made at an aggregated weighted average value, and should not be disclosed for each constituent of the benchmarks. Where relevant and appropriate, benchmark administrators should be able to provide additional ESG information.

⁽¹⁾ OJ L 171, 29.6.2016, p. 1.

⁽²⁾ Council Decision (EU) 2016/1841 of 5 October 2016 on the conclusion, on behalf of the European Union, of the Paris Agreement adopted under the United Nations Framework Convention on Climate Change (OJ L 282, 19.10.2016, p. 1).

⁽³⁾ COM(2019) 640 final.

- (7) In order to provide benchmark users with accurate and up-to-date information, benchmark administrators should update the information provided in the template to reflect any changes made to the methodology, and should indicate the reason and the dates at which the information was updated.
- (8) In order to provide investors with maximum transparency, benchmark administrators should clearly state whether they do or do not pursue ESG objectives,

HAS ADOPTED THIS REGULATION:

Article 1

Explanation on how ESG factors are reflected in the benchmark methodology

1. Benchmark administrators shall explain, using the template laid down in the Annex to this Regulation, which of the environmental, social and governance (ESG) factors referred to in Annex II to Commission Delegated Regulation (EU) 2020/1816 ⁽⁴⁾ they have taken into account when designing their benchmark methodology. They shall also explain how those factors are reflected in the key elements of that methodology, including for the selection of underlying assets, weighting factors, metrics and proxies.

The requirement set out in the first subparagraph shall not apply to commodity benchmarks.

2. For individual benchmarks, benchmark administrators may, rather than providing all the information required by the template laid down in the Annex to this Regulation, replace that information by a hyperlink in the explanation provided, to a website that contains all that information.

3. Where benchmarks blend different types underlying assets, benchmark administrators shall explain how ESG factors are reflected for each of the relevant underlying asset.

4. Benchmark administrators may include in the explanation provided additional ESG factors and related information.

5. Benchmark administrators shall clearly state in the explanation provided whether they do or do not pursue ESG objectives.

6. Benchmark administrators shall include in the explanation provided a reference to the sources of data and standards used for each ESG factor disclosed.

Article 2

Update of the explanation provided

Benchmark administrators shall update the explanation provided whenever the benchmark methodology is changed, and in any case on an annual basis. They shall state the reasons for the update.

⁽⁴⁾ Commission Delegated Regulation (EU) 2020/1816 of 17 July 2020 supplementing Regulation (EU) 2016/1011 of the European Parliament and of the Council as regards the explanation in the benchmark statement of how environmental, social and governance factors are reflected in each benchmark provided and published (See page 1 of this Official Journal).

*Article 3***Entry into force and application**

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, 17 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

**TEMPLATE FOR EXPLAINING HOW THE KEY ELEMENTS OF THE BENCHMARK
METHODOLOGY REFLECT ENVIRONMENTAL, SOCIAL AND GOVERNANCE (ESG) FACTORS**

EXPLANATION OF HOW ESG FACTORS ARE REFLECTED IN THE KEY ELEMENTS OF THE BENCHMARK METHODOLOGY

Item 1. Name of the benchmark administrator.	
Item 2. Type of benchmark or family of benchmarks. <i>Choose the relevant underlying asset from the list provided in Annex II to Commission Delegated Regulation (EU) 2020/1816.</i>	
Item 3. Name of the benchmark or family of benchmarks.	
Item 4. Does the benchmark methodology for the benchmark or family of benchmarks take into account ESG factors?	☐ Yes ☐ No

Item 5. Where the response to Item 4 is positive, please list below, for each family of benchmarks, those ESG factors that are taken into account in the benchmark methodology, taking into account the ESG factors listed in Annex II to Delegated Regulation (EU) 2020/1816.

Please explain how those ESG factors are used for the selection, weighting or exclusion of underlying assets.

The ESG factors shall be disclosed at an aggregated weighted average value at the level of the family of benchmarks.

(a) List of environmental factors considered:	Selection, weighting or exclusion:
(b) List of social factors considered:	Selection, weighting or exclusion:
(c) List of governance factors considered:	Selection, weighting or exclusion:

Item 6. Where the response to Item 4 is positive, please list below, for each benchmark, those ESG factors that are taken into account in the benchmark methodology, taking into account the ESG factors listed in Annex II to Delegated Regulation (EU) 2020/1816, depending on the relevant underlying asset concerned.

Please explain how those ESG factors are used for the selection, weighting or exclusion of underlying assets.

The ESG factors shall not be disclosed for each constituent of the benchmark, but shall be disclosed at an aggregated weighted average value of the benchmark.

Alternatively, all of this information may be provided in the form of a hyperlink to a website of the benchmark administrator included in this explanation. The information on the website shall be easily available and accessible. Benchmark administrators shall ensure that information published on their website remains available for five years.

(a) List of environmental factors considered:	Selection, weighting or exclusion:
(b) List of social factors considered:	Selection, weighting or exclusion:
(c) List of governance factors considered:	Selection, weighting or exclusion:
Hyperlink to the information on ESG factors for each benchmark:	

Item 7. Data and standards used

(a) Data input.	
(i) Describe whether the data are reported, modelled or sourced internally or externally.	
(ii) Where the data are reported, modelled or sourced externally, please name the third party data provider.	

(b) Verification and quality of data. <i>Describe how data are verified and how the quality of those data is ensured.</i>	
(c) Reference standards <i>Describe the international standards used in the benchmark methodology.</i>	
Date on which information has been last updated and reason for the update:	

COMMISSION DELEGATED REGULATION (EU) 2020/1818**of 17 July 2020****supplementing Regulation (EU) 2016/1011 of the European Parliament and of the Council as regards minimum standards for EU Climate Transition Benchmarks and EU Paris-aligned Benchmarks**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/1011 of the European Parliament and of the Council of 8 June 2016 on indices used as benchmarks in financial instruments and financial contracts or to measure the performance of investment funds and amending Directives 2008/48/EC and 2014/17/EU and Regulation (EU) No 596/2014 ⁽¹⁾, and in particular Article 19a(2) thereof,

Whereas:

- (1) The Paris Agreement, adopted under the United Nations Framework Convention on Climate Change approved by the Union on 5 October 2016 ⁽²⁾ (the 'Paris Agreement'), aims to strengthen the response to climate change, among other means by making investment flows consistent with a pathway towards low greenhouse gas emissions and climate-resilient development.
- (2) On 11 December 2019, the Commission adopted its Communication to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions 'The European Green Deal' ⁽³⁾. The European Green Deal represents a new growth strategy that aims to transform the Union into a fair and prosperous society, with a modern, resource-efficient and competitive economy where there are no net emissions of greenhouse gases in 2050 and where economic growth is decoupled from resource use. The implementation of the European Green Deal requires that investors are offered clear, long-term signals to avoid stranded assets and to raise sustainable finance.
- (3) Regulation (EU) 2016/1011 establishes EU Climate Transition Benchmarks and EU Paris-aligned Benchmarks. The methodology of those benchmarks is based on the commitments laid down in the Paris Agreement. It is necessary to specify the minimum standards applicable to both types of benchmarks. EU Climate Transition Benchmarks and EU Paris-aligned Benchmarks pursue similar objectives but vary in their level of ambition. Most of the minimum standards should therefore be common to both types of benchmarks, but the thresholds should vary depending on the type of benchmark.
- (4) There are currently not enough data to assess the carbon footprint resulting from decisions made by sovereign entities. Sovereign-based issuances should therefore not be eligible constituents of EU Climate Transition Benchmarks and EU Paris-aligned Benchmarks.
- (5) Because the methodology of EU Climate Transition Benchmarks and EU Paris-aligned Benchmarks is based on the commitments laid down in the Paris Agreement, it is necessary to use the 1,5 °C scenario, with no or limited overshoot, referred to in the Special Report on Global Warming of 1,5 °C from the Intergovernmental Panel on Climate Change (IPCC) ⁽⁴⁾ ('IPCC scenario'). That IPCC scenario is in line with the Commission's objective to reach net zero greenhouse gas (GHG) emissions by 2050, set out in the European Green Deal. To be in line with the IPCC scenario, investments should be reallocated from fossil-fuels dependent activities to green or renewable activities and the climate impact of those investments should improve year after year.

⁽¹⁾ OJ L 171, 29.6.2016, p. 1.

⁽²⁾ Council Decision (EU) 2016/1841 of 5 October 2016 on the conclusion, on behalf of the European Union, of the Paris Agreement adopted under the United Nations Framework Convention on Climate Change (OJ L 282, 19.10.2016, p. 1).

⁽³⁾ COM(2019) 640 final.

⁽⁴⁾ IPCC, 2018: Global Warming of 1.5 °C. An IPCC Special Report on the impacts of global warming of 1.5 °C above pre-industrial levels and related global greenhouse gas emission pathways, in the context of strengthening the global response to the threat of climate change, sustainable development, and efforts to eradicate poverty.

- (6) The sectors listed in Sections A to H and Section L of Annex I to Regulation (EC) No 1893/2006 of the European Parliament and of the Council ⁽⁹⁾, including the oil, gas, mining and transportation sectors, are sectors that highly contribute to climate change. To ensure that EU Climate Transition Benchmarks and EU Paris-aligned Benchmarks provide a realistic image of the real economy, including of sectors that should actively reduce GHG emissions to make the objectives of the Paris Agreement attainable, the exposure of those benchmarks to those sectors should not be less than the exposure of their underlying investable universe. That requirement should, however, only apply to EU Climate Transition Benchmarks and EU Paris-aligned Benchmarks that are equity benchmarks, to ensure that equity investors who support the objectives of the Paris Agreement maintain their influence, via engagement and voting, on the transition of the company towards more sustainable activities.
- (7) The calculation of GHG emissions should be comparable and consistent. It is therefore necessary to lay down rules about how often those calculations should be updated and, where applicable, about the currency to be used.
- (8) A decarbonisation based only on Scope 1 and Scope 2 GHG emissions could lead to counterintuitive results. It should therefore be clarified that the minimum standards for EU Climate Transition Benchmarks and EU Paris-aligned Benchmarks should not only consider direct emissions from companies, but also emissions assessed on a life-cycle basis and thus including Scope 3 GHG emissions. However, due to the insufficient quality of data currently available for Scope 3 GHG emissions, it is necessary to set out an appropriate phase-in timeline and to allow for the use of fossil fuel reserves for a limited period of time. That phase-in timeline should be based on the list of economic activities set out in Regulation (EC) No 1893/2006.
- (9) Benchmark administrators should have the possibility to overweight companies based on the decarbonisation objectives set by those companies. Specific rules relating to decarbonisation targets reported by individual companies should therefore be set out.
- (10) EU Climate Transition Benchmarks and EU Paris-aligned Benchmarks should demonstrate their ability to decarbonize themselves from one year to the other. That minimum decarbonisation trajectory should be calculated using the IPCC scenario. Furthermore, in order to prevent greenwashing, conditions for the deviation from the decarbonisation trajectory and for the right to continue to label a benchmark as an EU Climate Transition Benchmark or as an EU Paris-aligned Benchmark should be specified.
- (11) The main parameter to calculate the decarbonisation trajectory should be the GHG intensity, because that parameter ensures comparability across sectors and is not biased for or against a particular sector. To calculate the GHG intensity, the market capitalisation of the concerned company is necessary. However, where benchmarks apply to fixed-income corporate instruments, the market capitalisation might not be available for companies that do not have equity securities listed. It should therefore be laid down that where EU Climate Transition Benchmarks or EU Paris-aligned Benchmarks apply to fixed-income corporate instruments, benchmark administrators should be allowed to use GHG emissions calculated on an absolute basis, rather than on the basis of GHG intensity.
- (12) To ensure comparability and consistency of GHG emission data, rules on how to calculate changes in GHG intensity or absolute GHG emissions should be laid down.
- (13) Attaining the objectives of the Paris Agreement requires that both EU Climate Transition Benchmarks and EU Paris-aligned Benchmarks have a baseline percentage reduction in exposure to GHG intensive assets compared to their parent benchmarks or underlying investment universes. However, that percentage reduction should be more significant for EU Paris-aligned Benchmarks, which, by design, are more ambitious than EU Climate Transition Benchmarks.

⁽⁹⁾ Regulation (EC) No 1893/2006 of the European Parliament and of the Council of 20 December 2006 establishing the statistical classification of economic activities NACE Revision 2 and amending Council Regulation (EEC) No 3037/90 as well as certain EC Regulations on specific statistical domains (OJ L 393, 30.12.2006, p. 1).

- (14) EU Paris-aligned Benchmarks should not contribute to the promotion of investments in financial instruments issued by companies that violate global standards such as the United Nations Global Compact (UNGC) Principles. It is therefore necessary to lay down specific exclusion criteria that are based on climate-related or other environmental, social and governance (ESG) considerations. EU Climate Transition benchmarks should comply with those exclusion criteria by 31 December 2022, in accordance with the timeline set out in Regulation (EU) 2016/1011.
- (15) In order to support a decrease in the use of polluting energy sources and a proper transition to renewable ones, it is also appropriate that companies that derive more than a set percentage of their revenues from coal, oil or gas are excluded from the EU Paris-aligned Benchmarks. The changes in the share of those energy sources out of the global primary energy supply from 2020 to 2050, as expected in the IPCC scenario, should be taken into account to set out those specific exclusions. In particular, according to table 2.6 of the Special Report on Global Warming of 1,5 °C from the IPCC, between 2020 and 2050, the use of coal is expected to drop between 57 % and 99 % and the use of oil between 9 % and 93 %, while the use of gas is expected to go up by 85 % or to drop by 88 %. Gas can be used during the transition to a low carbon economy, in particular as a replacement for coal, which explains its wider expected range of evolution, although the expected median decrease of its use is 40 %. For the same reason, it is necessary to exclude companies that derive more than a set percentage of their revenues from electricity generation activities.
- (16) To ensure transparency about the methodology used for the EU Climate Transition Benchmarks and EU Paris-aligned Benchmarks, it is appropriate to lay down rules about the necessary disclosures pertaining to the decarbonisation trajectory and the data sources for both categories of benchmarks. For the same reason, it is appropriate to lay down disclosure requirements for benchmark administrators that use estimations for GHG emissions data, whether or not provided by external data providers.
- (17) In order to support the harmonisation of the methodology for EU Climate Transition Benchmarks and EU Paris-aligned Benchmarks, it is appropriate to lay down rules about the quality and accuracy of data sources,

HAS ADOPTED THIS REGULATION:

CHAPTER I

DEFINITIONS

Article 1

Definitions

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

- (a) 'greenhouse gas (GHG) emissions' means greenhouse gas emissions as defined in Article 3, point (1), of Regulation (EU) 2018/842 of the European Parliament and of the Council ⁽⁶⁾;
- (b) 'absolute greenhouse gas (GHG) emissions' means tonnes of CO₂ equivalent, as defined in Article 2, point (7), of Regulation (EU) No 517/2014 of the European Parliament and of the Council ⁽⁷⁾;
- (c) 'greenhouse gas (GHG) intensity' means absolute GHG emissions divided by millions of euros in enterprise value including cash;

⁽⁶⁾ Regulation (EU) 2018/842 of the European Parliament and of the Council of 30 May 2018 on binding annual greenhouse gas emission reductions by Member States from 2021 to 2030 contributing to climate action to meet commitments under the Paris Agreement and amending Regulation (EU) No 525/2013 (OJ L 156, 19.6.2018, p. 26).

⁽⁷⁾ Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 (OJ L 150, 20.5.2014, p. 195).

- (d) 'enterprise value including cash' or 'EVIC' means the sum, at fiscal year-end, of the market capitalisation of ordinary shares, the market capitalization of preferred shares, and the book value of total debt and non-controlling interests, without the deduction of cash or cash equivalents;
- (e) 'investable universe' means the set of all investable instruments in a given asset class or group of asset classes;
- (f) 'base year' means the first of a series of years in a benchmark.

CHAPTER II

MINIMUM STANDARDS FOR THE DESIGN OF THE BENCHMARK METHODOLOGY

SECTION 1

MINIMUM STANDARDS COMMON FOR EU CLIMATE TRANSITION BENCHMARKS AND EU PARIS-ALIGNED BENCHMARKS

Article 2

Reference temperature scenario

Administrators of EU Climate Transition Benchmarks and administrators of EU Paris-aligned Benchmarks shall use the 1,5 °C scenario, with no or limited overshoot, referred to in the Special Report on Global Warming of 1,5 °C from the Intergovernmental Panel on Climate Change (IPCC) as the reference temperature scenario to design the methodology to construct those benchmarks.

Article 3

Equity allocation constraint

EU Climate Transition Benchmarks and EU Paris-aligned Benchmarks that are based on equity securities admitted to a public market in the Union or in another jurisdiction, shall have an aggregated exposure to the sectors listed in Sections A to H and Section L of Annex I to Regulation (EC) No 1893/2006 that is at least equivalent to the aggregated exposure of the underlying investable universe to those sectors.

Article 4

Calculation of GHG intensity or absolute GHG emissions

1. Administrators of EU Climate Transition Benchmarks and administrators of EU Paris-aligned Benchmarks shall calculate the GHG intensity or, where applicable, the absolute GHG emissions of those benchmarks using the same currency for all of their underlying assets.
2. Administrators of EU Climate Transition Benchmarks and administrators of EU Paris-aligned Benchmarks shall recalculate the GHG intensity and the absolute GHG emissions of those benchmarks on a yearly basis.

Article 5

Phase-in of Scope 3 GHG emissions data in the benchmark methodology

1. The benchmark methodology for EU Climate Transition Benchmarks or EU Paris-aligned Benchmarks shall include Scope 3 GHG emissions data in the following way:
 - (a) As of 23 December 2020, Scope 3 GHG emissions data for at least the energy and mining sectors referred to in Divisions 05 to 09 and 19 and 20 of Annex I to Regulation (EC) No 1893/2006;
 - (b) within two years from 23 December 2020, Scope 3 GHG emissions data for at least the transportation, construction, buildings, materials and industrial sectors referred to in Divisions 10 to 18, 21 to 33, 41, 42 and 43, 49 to 53 and Division 81 of Annex I to Regulation (EC) No 1893/2006;

- (c) within four years from 23 December 2020, Scope 3 GHG emissions data for all other sectors referred to in Annex I to Regulation (EC) No 1893/2006.

2. For the purposes of paragraph 1, point (a), from 23 December 2020 to 31 December 2021, administrators of EU Climate Transition Benchmarks and administrators of EU Paris-aligned Benchmarks may use fossil fuel reserves, where they demonstrate that they cannot calculate nor estimate Scope 3 GHG emissions data.

Article 6

Companies setting and publishing GHG emission reduction targets

Administrators of EU Climate Transition Benchmarks and administrators of EU Paris-aligned Benchmarks may increase in those benchmarks the weight of the issuers of the constituent securities that set and publish GHG emission reduction targets, where the following conditions are fulfilled:

- (a) the issuers of the constituent securities publish consistently and accurately their Scope 1, 2 and 3 GHG emissions;
- (b) the issuers of the constituent securities have reduced their GHG intensity or, where applicable, their absolute GHG emissions, including Scope 1, 2 and 3 GHG emissions, by an average of at least 7 % per annum for at least three consecutive years.

For the purposes of the first subparagraph, Scope 3 GHG emissions shall be construed in accordance with the phase-in implementation period set out in Article 5.

Article 7

Setting a decarbonisation trajectory

1. The decarbonisation trajectory for EU Climate Transition Benchmarks and EU Paris-aligned Benchmarks shall have the following targets:

- (a) for equity securities admitted to a public market in the Union or in another jurisdiction, at least 7 % reduction of GHG intensity on average per annum;
- (b) for debt securities other than those issued by a sovereign issuer, where the issuer of those debt securities has equity securities admitted to a public market in the Union or in another jurisdiction, at least 7 % reduction of GHG intensity on average per annum or at least 7 % reduction of absolute GHG emissions on average per annum;
- (c) for debt securities other than those issued by a sovereign issuer, where the issuer of those debt securities does not have equity securities admitted to a public market in the Union or in another jurisdiction, at least 7 % reduction of absolute GHG emissions on average per annum.

2. The targets referred to in paragraph 1 shall be calculated geometrically, which shall mean that the annual minimum 7 % reduction of GHG intensity or of absolute GHG emissions for year 'n' shall be calculated based on the GHG intensity or absolute GHG emissions for the year n-1, in a geometric progression from the base year.

3. Where the average EVIC of the constituent securities of the benchmark has increased or decreased during the last calendar year, the EVIC of each constituent shall be adjusted by dividing it by an enterprise value inflation adjustment factor. That enterprise value inflation adjustment factor shall be calculated by dividing the average EVIC of the benchmark constituents at the end of a calendar year by the average EVIC of the benchmark constituents at the end of the previous calendar year.

4. Administrators of EU Climate Transition Benchmarks and administrators of EU Paris-aligned Benchmarks shall, for each year in which the targets laid down in paragraph 1 are not achieved, compensate for those missed targets by upwardly adjusting the targets in their decarbonisation trajectory for the following year.

5. Administrators of EU Climate Transition Benchmarks and administrators of EU Paris-aligned Benchmarks shall no longer be able to label their benchmarks as such where:

- (a) the targets laid down in paragraph 1 are not achieved in a given year and the target miss is not compensated in the following year; or
- (b) the targets laid down in paragraph 1 are not achieved on three occasions in any consecutive 10-year period.

Benchmark administrators may relabel a benchmark as an EU Climate Transition Benchmark or as an EU Paris-aligned Benchmark where that benchmark meets the decarbonisation trajectory target for two consecutive years following the loss of the label, unless that benchmark lost that label twice.

Article 8

Change in GHG intensity and absolute GHG emissions

1. The change in GHG intensity or absolute GHG emissions shall be calculated as the percentage change between, on the one hand, the weighted average GHG intensity or absolute GHG emissions of all constituents of the EU Climate Transition Benchmark or the EU Paris-aligned Benchmark at the end of year 'n' and, on the other hand, the weighted average GHG intensity or absolute GHG emissions of all constituents of the benchmarks at the end of year n-1.
2. Benchmark administrators shall use a new base year whenever significant changes in the calculation methodology of GHG intensity or absolute GHG emissions occur.

For the purposes of the first subparagraph, a new base year shall mean the year against which the decarbonisation trajectory referred to in Article 7 is calculated.

The selection of a new base year shall be without prejudice to the rules laid down in Article 7(5).

SECTION 2

MINIMUM STANDARDS FOR EU CLIMATE TRANSITION BENCHMARKS

Article 9

Baseline reduction of GHG intensity or absolute GHG emissions for EU Climate Transition Benchmarks

The GHG intensity or, where applicable, absolute GHG emissions for EU Climate Transition Benchmarks, including Scope 1, 2 and 3 GHG emissions, shall be at least 30 % lower than the GHG intensity or absolute GHG emissions of the investable universe.

For the purposes of the first subparagraph, Scope 3 GHG emissions shall be construed in accordance with the phase-in implementation period set out in Article 5.

Article 10

Exclusions for EU Climate Transition Benchmarks

1. Administrators of EU Climate Transition Benchmarks shall disclose in their methodology whether and how they exclude companies.
2. By 31 December 2022, administrators of EU Climate Transition Benchmarks shall comply with the requirements set out in Article 12(1), points (a), (b) and (c), and Article 12(2).

SECTION 3

MINIMUM STANDARDS FOR EU PARIS-ALIGNED BENCHMARKS

Article 11

Baseline reduction of GHG intensity or absolute GHG emissions for EU Paris-aligned Benchmarks

The GHG intensity or, where applicable, absolute GHG emissions for EU Paris-aligned Benchmarks, including Scope 1, 2 and 3 GHG emissions, shall be at least 50 % lower than the GHG intensity or absolute GHG emissions of the investable universe.

For the purposes of the first subparagraph, Scope 3 GHG emissions shall be construed in accordance with the phase-in implementation period set out in Article 5.

Article 12

Exclusions for EU Paris-aligned Benchmarks

1. Administrators of EU Paris-aligned Benchmarks shall exclude all of the following companies from those benchmarks:
 - (a) companies involved in any activities related to controversial weapons;
 - (b) companies involved in the cultivation and production of tobacco;
 - (c) companies that benchmark administrators find in violation of the United Nations Global Compact (UNGC) principles or the Organisation for Economic Cooperation and Development (OECD) Guidelines for Multinational Enterprises;
 - (d) companies that derive 1 % or more of their revenues from exploration, mining, extraction, distribution or refining of hard coal and lignite;
 - (e) companies that derive 10 % or more of their revenues from the exploration, extraction, distribution or refining of oil fuels;
 - (f) companies that derive 50 % or more of their revenues from the exploration, extraction, manufacturing or distribution of gaseous fuels;
 - (g) companies that derive 50 % or more of their revenues from electricity generation with a GHG intensity of more than 100 g CO₂ e/kWh.

For the purposes of point (a), controversial weapons shall mean controversial weapons as referred to in international treaties and conventions, United Nations principles and, where applicable, national legislation.

2. Administrators of EU Paris-aligned Benchmarks shall exclude from those benchmarks any companies that are found or estimated by them or by external data providers to significantly harm one or more of the environmental objectives referred to in Article 9 of Regulation (EU) 2020/852 of the European Parliament and of the Council ^(*), in accordance with the rules on estimations laid down in Article 13(2) of this Regulation.

3. Administrators of EU Paris-aligned Benchmarks shall disclose in their benchmark methodology any additional exclusion criteria they use and which are based on climate-related or other environmental, social and governance (ESG) factors.

^(*) Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088 (OJ L 198, 22.6.2020, p. 13).

CHAPTER III

TRANSPARENCY AND ACCURACY

Article 13

Transparency requirements for estimations

1. In addition to the requirements laid down in Annex III to Regulation (EU) 2016/1011, administrators of EU Climate Transition Benchmarks and administrators of EU Paris-aligned Benchmarks shall comply with the following requirements:

- (a) administrators of EU Climate Transition Benchmarks and administrators of EU Paris-aligned Benchmarks that use estimations that are not based on data provided by an external data provider, shall formalise, document and make public the methodology upon which such estimations are based, including:
 - (i) the approach that they have used to calculate GHG emissions, and the main assumptions and the precautionary principles underlying those estimations;
 - (ii) the research methodology to estimate missing, unreported, or underreported GHG emissions;
 - (iii) the external data sets used in the estimation of missing, unreported or underreported GHG emissions;
- (b) administrators of EU Climate Transition Benchmarks and administrators of EU Paris-aligned Benchmarks that use estimations that are based on data provided by an external data provider shall formalise, document and make public all of the following information:
 - (i) the name and contact details of the data provider;
 - (ii) the methodology used and the main assumptions and precautionary principles, where available;
 - (iii) a hyperlink to the website of the data provider, and to the relevant methodology used, where available.

2. For the purposes of Article 12(2), administrators of EU Paris-aligned Benchmarks shall comply with the following requirements:

- (a) administrators of EU Paris-aligned Benchmarks that use estimations that are not based on data provided by an external data provider shall formalise, document and make public the methodology upon which such estimations are based, including:
 - (i) the approach and research methodology that they have used, and the main assumptions and precautionary principles underlying those estimations;
 - (ii) the external data sets used in the estimation;
- (b) administrators of EU Paris-aligned Benchmarks that use estimations that are based on data provided by an external data provider shall formalise, document and make public all of the following information:
 - (i) the name and contact details of the data provider;
 - (ii) the methodology used and the main assumptions and precautionary principles, where available;
 - (iii) a hyperlink to the website of the data provider, and to the relevant methodology used, where available.

Article 14

Disclosure of the decarbonisation trajectory

Administrators of EU Climate Transition Benchmarks and administrators of EU Paris-aligned Benchmarks shall formalise, document and make public the decarbonisation trajectories of those benchmarks, the base year used for the determination of those decarbonisation trajectories, and where the targets laid down in the decarbonisation trajectory are not met, the reasons for that failure and the steps that they will take to reach the adjusted target referred to in Article 7(4).

*Article 15***Accuracy of the data sources**

1. Administrators of EU Climate Transition Benchmarks and administrators of EU Paris-aligned Benchmarks shall ensure that data on Scope 1, 2 and 3 GHG emissions are accurate, in accordance with global or European standards, such as the Product Environmental Footprint (PEF), the Organisation Environmental Footprint (OEF) methods ⁽⁹⁾, the Corporate Value Chain (Scope 3) Accounting and Reporting Standard ⁽¹⁰⁾, the EN ISO 14064 or the EN ISO 14069.
2. For the purposes of paragraph 1, administrators of EU Climate Transition Benchmarks and administrators of EU Paris-aligned Benchmarks shall disclose in their methodology the standard used.
3. Administrators of EU Climate Transition Benchmarks and administrators of EU Paris-aligned Benchmarks shall ensure the comparability and quality of GHG emissions data.

CHAPTER IV

FINAL PROVISIONS*Article 16***Entry into force and application**

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, 17 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁹⁾ Commission Recommendation 2013/179/EU of 9 April 2013 on the use of common methods to measure and communicate the life cycle environmental performance of products and organisations (OJ L 124, 4.5.2013, p. 1).

⁽¹⁰⁾ Value Chain (Scope 3) Accounting and Reporting Standard (September 2011), supplement to the GHG Protocol Corporate Accounting and Reporting Standard.

COMMISSION REGULATION (EU) 2020/1819

of 2 December 2020

**amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council
as regards the use of colours in salmon substitutes**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives ⁽¹⁾, and in particular Article 10(3) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food and their conditions of use.
- (2) That list may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008 of the European Parliament and of the Council ⁽²⁾, either on the initiative of the Commission or following an application.
- (3) Pursuant to Annex II to Regulation (EC) No 1333/2008, as amended by Commission Regulation (EU) No 232/2012 ⁽³⁾, Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124) are currently authorised as food additives in food category 09.2 'Processed fish and fishery products including molluscs and crustaceans', both at a maximum level of 200 mg/kg, for use only in salmon substitutes based on the fish species *Theragra chalcogramma* and *Pollachius virens*. On 15 July 2014 and 23 September 2009, the Authority issued opinions establishing the acceptable daily intake (ADI) for Sunset Yellow FCF/Orange Yellow S (E 110) ⁽⁴⁾ at 4 mg/kg bw/day and the ADI for Ponceau 4R, Cochineal Red A (E 124) ⁽⁵⁾ at 0,7 mg/kg bw/day. On its opinions of 15 July 2014 and of 21 April 2015 ⁽⁶⁾, the Authority concluded that none of the exposure estimates for those additives exceeded their respective ADI for any population group.
- (4) On 4 February 2019, an application was submitted for the modification of the conditions of use of Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124) contained in food category 09.2 'Processed fish and fishery products including molluscs and crustaceans', to authorise the use of those substances in salmon substitutes based on the fish species *Clupea harengus*. The application requires the current maximum level of 200 mg/kg, however, it clarifies that the actual use levels are much lower ranging between one and two tenths of the maximum level for both substances. The application was made available to the Member States pursuant to Article 4 of Regulation (EC) No 1331/2008.
- (5) Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124), when used as colours, impart the desired stable shade, improve organoleptic properties and make salmon substitutes based on the fish species *Clupea harengus* more visually appealing.
- (6) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission has to seek the opinion of the European Food Safety Authority ('the Authority') in order to update the Union list of food additives set out in Annex II to Regulation (EC) No 1333/2008, except where the update in question is not liable to have an effect on human health.

⁽¹⁾ OJ L 354, 31.12.2008, p. 16.⁽²⁾ Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1).⁽³⁾ Commission Regulation (EU) No 232/2012 of 16 March 2012 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the conditions of use and the use levels for Quinoline Yellow (E 104), Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124) (OJ L 78, 17.3.2012, p. 1).⁽⁴⁾ EFSA Journal 2014;12(7):3765.⁽⁵⁾ EFSA Journal 2009; 7(11):1328.⁽⁶⁾ EFSA Journal 2015;13(4):4073.

- (7) Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124) are authorised for use in a wide variety of foods. The most recent exposure assessments carried out by the Authority, as referred to in recital 3, confirmed that the overall exposure is well below their ADI even in the most conservative regulatory maximum levels scenario. The authorised uses in salmon substitutes based on *Theragra chalcogramma* and *Pollachius virens* were included in those exposure estimates. Since salmon substitutes based on *Clupea harengus* are intended as an alternative to salmon substitutes based on *Theragra chalcogramma* and *Pollachius virens*, the consumption of salmon substitutes by consumers should not significantly change. Furthermore, the use levels for Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124) needed to achieve the desired effect in salmon substitutes based on *Clupea harengus* are substantially lower than the authorised maximum levels. Therefore, it is not expected that the proposed use will have a significant impact on the overall exposure of consumers to those food additives, which therefore should remain below the ADI.
- (8) The entries for Group II, Group III and Lycopene (E 160d) in food category 09.2 'Processed fish and fishery products including molluscs and crustaceans' currently only refer to 'salmon substitutes'. In order to provide clarity and legal certainty as regards this expression, the wording of those entries should be amended to indicate that the authorised use concerns 'salmon substitutes' based on the fish species *Theragra chalcogramma*, *Pollachius virens* or *Clupea harengus*.
- (9) Therefore, it is appropriate to amend food category 09.2 'Processed fish and fishery products including molluscs and crustaceans' in Part E of Annex II to Regulation (EC) No 1333/2008 to authorise the use of Sunset Yellow FCF/Orange Yellow S (E 110) and Ponceau 4R, Cochineal Red A (E 124) in salmon substitutes based on the fish species *Clupea harengus* and to list in the entries for Group II, Group III and Lycopene (E 160d), the fish species on which 'salmon substitutes' may be based.
- (10) Annex II to Regulation (EC) No 1333/2008 should therefore be amended accordingly.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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

Done at Brussels, 2 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Part E of Annex II to Regulation (EC) No 1333/2008, regarding food category 09.2 'Processed fish and fishery products including molluscs and crustaceans' is amended as follows:

(1) the entries for Group II and Group III are replaced by the following:

	'Group II	Colours at <i>quantum satis</i>	<i>quantum satis</i>		only surimi and similar products and salmon substitutes based on <i>Theragra chalcogramma</i> , <i>Pollachius virens</i> and <i>Clupea harengus</i>
	Group III	Colours with combined maximum limit	500	(84)	only surimi and similar products and salmon substitutes based on <i>Theragra chalcogramma</i> , <i>Pollachius virens</i> and <i>Clupea harengus</i>

(2) the entry for Sunset Yellow FCF/Orange Yellow S (E 110) is replaced by the following:

	'E 110	Sunset Yellow FCF/Orange Yellow S	200	(63)	only salmon substitutes based on <i>Theragra chalcogramma</i> , <i>Pollachius virens</i> and <i>Clupea harengus</i>
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(3) the entry for Ponceau 4R, Cochineal Red A (E 124) is replaced by the following:

	'E 124	Ponceau 4R, Cochineal Red A	200	(63)	only salmon substitutes based on <i>Theragra chalcogramma</i> , <i>Pollachius virens</i> and <i>Clupea harengus</i>
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(4) the first entry for Lycopene (E 160d) is replaced by the following:

	'E 160d	Lycopene	10		only salmon substitutes based on <i>Theragra chalcogramma</i> , <i>Pollachius virens</i> and <i>Clupea harengus</i>
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COMMISSION IMPLEMENTING REGULATION (EU) 2020/1820

of 2 December 2020

authorising the placing on the market of dried *Euglena gracilis* as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ establishing a Union list of authorised novel foods was adopted.
- (3) On 20 December 2018, the company Kemin Foods L.C. ('the applicant') introduced an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place dried whole cell *Euglena gracilis* on the Union market as a novel food. The application requested for dried whole cell *Euglena gracilis* to be used as a novel food in a number of food categories for the general population as follows: breakfast, granola and protein bars; yoghurt; yoghurt beverages; fruit juices, smoothies and nectars, vegetable juices; fruit-flavoured drinks; meal replacement beverages. The applicant also requested for dried whole cell *Euglena gracilis* to be used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ⁽³⁾, excluding food supplements for infants, and in total diet replacement for weight control as defined by Regulation (EU) No 609/2013 of the European Parliament and of the Council ⁽⁴⁾, excluding total diet replacement for weight control for infants.
- (4) The applicant also made a request to the Commission for the protection of proprietary data for a number of studies submitted in support of the application namely, *in vitro* fermentation studies ⁽⁵⁾, bacterial reverse mutation test ⁽⁶⁾, *in vivo* micronucleus test ⁽⁷⁾, acute toxicity study in rats ⁽⁸⁾, 14-day dietary toxicity/palatability study in rats ⁽⁹⁾, 90-day dietary toxicity study in rats ⁽¹⁰⁾.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

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

⁽³⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

⁽⁴⁾ Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

⁽⁵⁾ Prebiotic effects of algal meal and algal-glucan. Examination of growth profile of probiotic bacteria in the presence algal meal and algal glucan. Kemin Corporation, 2016 (unpublished).

⁽⁶⁾ Dried algae (*Euglena gracilis*). Bacterial Reverse Mutation Test (Ames Test). Product Safety Labs, 2015a (unpublished).

⁽⁷⁾ Dried algae (*Euglena gracilis*). Mammalian Erythrocyte Micronucleus Test (Peripheral Blood, Flow Cytometry – Mouse). Product Safety Labs, 2015b (unpublished).

⁽⁸⁾ Algamune™ Algae Meal: Oral Toxicity Procedure In Rats. Product Safety Labs, 2014 (unpublished).

⁽⁹⁾ Dried algae (*Euglena gracilis*). A 14-day dietary toxicity/palatability study in rats. Product Safety Labs, 2015c (unpublished).

⁽¹⁰⁾ Dried algae (*Euglena gracilis*). A 90-day dietary study in rats. Product Safety Labs, 2015d (unpublished).

- (5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('Authority') on 13 May 2019, asking it to provide a scientific opinion by carrying out an assessment for dried *Euglena gracilis* as a novel food.
- (6) On 25 March 2020, the Authority adopted the scientific opinion on the "Safety of dried whole cell *Euglena gracilis* as a novel food pursuant to Regulation (EU) 2015/2283" ⁽¹¹⁾. That opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (7) In that opinion, the Authority concluded that dried *Euglena gracilis* is safe at the proposed uses and use levels. Therefore, the opinion of the Authority gives sufficient grounds to establish that dried *Euglena gracilis* under the specific conditions of use complies with Article 12(1) of Regulation (EU) 2015/2283.
- (8) In accordance with Commission Delegated Regulation (EU) 2017/1798 ⁽¹²⁾ total diet replacement for weight control are foods intended for healthy overweight or obese adults who intend to achieve weight reduction. Therefore, dried *Euglena gracilis* may be authorised for use in total diet replacement for weight control only for adults, excluding infants, children and adolescents.
- (9) In its opinion, the Authority considered that the data from the 90-day dietary toxicity study in rats served as a basis to establish the safety of the novel food. Therefore, it is considered that the conclusions on the safety of dried *Euglena gracilis* could not have been reached without the data from the unpublished report of that study.
- (10) The Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over the 90-day dietary toxicity study in rats, and to clarify its claim to an exclusive right of reference to that study, as referred to in Article 26(2)(b) of Regulation (EU) 2015/2283.
- (11) The applicant declared that, at the time of the submission of the application, it held proprietary and exclusive right of reference to that study under national law, and that therefore third parties cannot lawfully access or use that study or refer to that data.
- (12) The Commission assessed all the information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the 90-day dietary toxicity study in rats contained in the applicant's file should not be used by the Authority for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation. Accordingly, the placing on the market within the Union of dried *Euglena gracilis* should be restricted to the applicant for that period.
- (13) However, restricting the authorisation of dried *Euglena gracilis* and of the reference to the study contained in the applicant's file for the sole use of the applicant, does not prevent other applicants from applying for an authorisation to place on the market the same novel food provided that, their application is based on legally obtained information supporting such authorisation under Regulation (EU) 2015/2283.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

1. Dried *Euglena gracilis* as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

⁽¹¹⁾ EFSA Journal 2020;18(5):6100.

⁽¹²⁾ Commission Delegated Regulation (EU) 2017/1798 of 2 June 2017 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for total diet replacement for weight control (OJ L 259, 7.10.2017, p. 2).

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

— Company: Kemin Foods L.C.,

— Address: 2100 Maury Street Des Moines, IA 50317, USA,

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

3. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

Article 2

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

Article 3

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

Article 4

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

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

Done at Brussels, 2 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

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

(1) in Table 1 (Authorised novel foods), the following entry is inserted:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
'Dried <i>Euglena gracilis</i>	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'dried biomass of <i>Euglena gracilis</i> algae'. The labelling of food supplements containing dried <i>Euglena gracilis</i> shall bear a statement that those food supplements should not be consumed by infants/children under 3 years of age/children under 10 years of age/children and adolescents under 18 years of age (*).		Authorised on 23 December 2020. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: Kemin Foods L.C., 2100 Maury Street Des Moines, IA 50317, USA. During the period of data protection, the novel food is authorised for placing on the market within the Union only by Kemin Foods L.C. unless a subsequent applicant obtains authorisation for that novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Kemin Foods L.C. End date of the data protection: 23 December 2025.'
	Breakfast cereal bars, granola bars and protein bars	630 mg/100 g			
	Yoghurt	150 mg/100 g			
	Yoghurt Beverages	95 mg/100 g			
	Fruit and vegetable juices, nectars, fruit/vegetable blend beverages	120 mg/100 g			
	Fruit-Flavoured Drinks	40 mg/100 g			
	Meal replacement beverages	75 mg/100 g			
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants	100 mg/day for young children 150 mg/day for children from 3 to 9 years of age 225 mg/day for children from 10 years of age and adolescents (to 17 years of age) 375 mg/day for adults			
	Total diet replacement for weight control as defined by Regulation (EU) No 609/2013	190 mg/meal			

(*) Depending on the age group the food supplement is intended for.

(2) in Table 2 (Specifications), the following entry is inserted:

Authorised Novel Food	Specification
'Dried <i>Euglena gracilis</i>	Description/Definition: The novel food is dried whole cell <i>Euglena</i>, which is the dried biomass of the microalga <i>Euglena gracilis</i>. The novel food is produced by fermentation followed by filtration and a heat-killing step of the microalga to ensure the absence of viable <i>Euglena gracilis</i> cells in the novel food. Characteristics/Composition: Total carbohydrates: ≤ 75 % β-glucan: > 50 % Protein: ≥ 15 % Fat: ≤ 15 % Ash: ≤ 10 % Moisture: ≤ 6 % Heavy metals: Lead: $\leq 0,5$ mg/kg Cadmium: $\leq 0,5$ mg/kg Mercury: $\leq 0,05$ mg/kg Arsenic: $\leq 0,02$ mg/kg Microbiological criteria: Aerobic plate count: $\leq 10\,000$ CFU/g Coliforms: ≤ 100 MPN/g Yeast and mould: ≤ 500 CFU/g <i>Escherichia coli</i>: Absence in 10 g <i>Staphylococcus aureus</i>: Absence in 10 g <i>Salmonella</i>: Absence in 25 g <i>Listeria monocytogenes</i>: Absence in 25 g CFU: colony forming units. MPN: most probable number'

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1821**of 2 December 2020****authorising the placing on the market of an extract from *Panax notoginseng* and *Astragalus membranaceus* as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ establishing a Union list of authorised novel foods was adopted.
- (3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to submit a draft implementing act authorising the placing on the Union market of a novel food and on the update of the Union list.
- (4) On 7 June 2018, the company NuLiv Science ('the applicant') introduced an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place an extract from *Panax notoginseng* and *Astragalus membranaceus* on the Union market as a novel food. The applicant requested for an extract from *Panax notoginseng* and *Astragalus membranaceus* to be used as a novel food in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ⁽³⁾ for the general adult population, excluding food supplements for pregnant women. The applicant also made a request to the Commission for the protection of proprietary data submitted in the application.
- (5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('Authority') on 22 October 2018, asking it to provide a scientific opinion by carrying out an assessment for an extract from *Panax notoginseng* and *Astragalus membranaceus* as a novel food.
- (6) On 24 March 2020, the Authority adopted the scientific opinion on the 'Safety of a botanical extract derived from *Panax notoginseng* and *Astragalus membranaceus* (AstraGin™) as a novel food pursuant to Regulation (EU) 2015/2283' ⁽⁴⁾. That opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (7) In its opinion, the Authority concluded that an extract from *Panax notoginseng* and *Astragalus membranaceus* is safe at an intake level of 0,5 mg/kg bw per day which corresponds to a maximum intake of 35 mg/day for the target population, i.e. adults excluding pregnant women.
- (8) The opinion of the Authority gives sufficient grounds to establish that extract from *Panax notoginseng* and *Astragalus membranaceus* under the assessed conditions of use complies with Article 12(1) of Regulation (EU) 2015/2283.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

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

⁽³⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

⁽⁴⁾ EFSA Journal 2020;18(5):6099.

- (9) In its opinion the Authority considered that the toxicological data from the repeated dose 28-day oral gavage toxicity study with AstraGin™ in rats ⁽⁵⁾, the bacterial reverse mutation test (Ames test) for AstraGin™ ⁽⁶⁾, the 90-days repeated dose oral toxicity study of Astragin® in Wistar rats ⁽⁷⁾, the Panax notoginseng proprietary extract: *in vitro* micronucleus test in CHO-K1 cells ⁽⁸⁾, and the Astragalus membranaceus extract: *in vitro* micronucleus test in CHO-K1 cells ⁽⁹⁾ served as a basis to establish the safety of the novel food. Therefore, it is considered that the conclusions on the safety of extract from *Panax notoginseng* and *Astragalus membranaceus* could not have been reached without the data from the unpublished reports of those studies.
- (10) Following the Authority's opinion, the Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over the repeated dose 28-day oral gavage toxicity study with AstraGin™ in rats, the bacterial reverse mutation test (Ames test) for AstraGin™, the 90-days repeated dose oral toxicity study of Astragin® in Wistar rats, the Panax notoginseng proprietary extract: *in vitro* micronucleus test in CHO-K1 cells, and the Astragalus membranaceus extract: *in vitro* micronucleus test in CHO-K1 cells, and to clarify their claim to an exclusive right of reference to that data, as referred to in Article 26(2)(b) of Regulation (EU) 2015/2283.
- (11) The applicant declared that, at the time of the submission of the application, they held proprietary and exclusive right of reference to those studies, and that therefore third parties cannot lawfully access or use those studies or refer to that data.
- (12) The Commission assessed all the information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the toxicological data from the studies contained in the applicant's file which served as a basis for the Authority to establish the safety of the novel food and to reach its conclusions on the safety of extract from *Panax notoginseng* and *Astragalus membranaceus*, and without which the novel food could not have been assessed by the Authority, should not be used by the Authority for the benefit of any subsequent applicant for a period of five years from the date of entry into force of this Regulation. Accordingly, the placing on the market within the Union of an extract from *Panax notoginseng* and *Astragalus membranaceus* should be restricted to the applicant for that period.
- (13) However, restricting the authorisation of extract from *Panax notoginseng* and *Astragalus membranaceus* and of the reference to the studies contained in the applicant's file for the sole use of the applicant, does not prevent other applicants from applying for an authorisation to place on the market the same novel food provided that, their application is based on legally obtained information supporting such authorisation under Regulation (EU) 2015/2283.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

1. Extract from *Panax notoginseng* and *Astragalus membranaceus* as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

⁽⁵⁾ Pasics Szakonyiné I, 2011 (unpublished study report). Repeated dose 28-day oral gavage toxicity study with AstraGin™ in rats. Study No: 413.407.3084. Toxi-Coop Zrt., Hungary.

⁽⁶⁾ Zin HM, 2016 (unpublished study report). Bacterial reverse mutation test (Ames test) for AstraGin™. Study code: GLP/J165/2016/48). Environmental Technology Research Centre (ETRC). Shah Alam, Selangor, Malaysia.

⁽⁷⁾ Upadhyaya S and Wang R, 2017 (unpublished study report). 90-days repeated dose oral toxicity study of Astragin® in Wistar rats. 161101/NVS/PC. July 2017. 319pp. Vedic Life Sciences Pvt, Ltd. Mumbai, India.

⁽⁸⁾ Vedic Lifesciences, 2019a (unpublished study report). Panax notoginseng proprietary extract: *in vitro* micronucleus test in CHO-K1 cells. Study Nr. 190503/NL/PC. Mumbai, India.

⁽⁹⁾ Vedic Lifesciences, 2019b (unpublished study report). Astragalus membranaceus extract: *in vitro* micronucleus test in CHO-K1 cells. Study Nr. 190502/NL/PC. Mumbai, India.

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

- Company: NuLiv Science,
- Address: 1050 W. Central Ave., Building C, Brea, CA 92821, USA,

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

3. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

Article 2

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

Article 3

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

Article 4

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

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

Done at Brussels, 2 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

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

(1) in Table 1 (Authorised novel foods), the following entry is inserted:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection
'Extract from <i>Panax notoginseng</i> and <i>Astragalus membranaceus</i>	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Extract from <i>Panax notoginseng</i> and <i>Astragalus membranaceus</i> '		Authorised on 23 December 2020. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: NuLiv Science, 1050 W. Central Ave., Building C, Brea, CA 92821, USA. During the period of data protection, the novel food is authorised for placing on the market within the Union only by NuLiv Science, unless a subsequent applicant obtains authorisation for that novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of NuLiv Science. End date of the data protection: 23 December 2025.'
	Food supplements as defined in Directive 2002/46/EC for the general adult population, excluding food supplements for pregnant women	35 mg/day	The labelling of food supplements containing extract from <i>Panax notoginseng</i> and <i>Astragalus membranaceus</i> shall bear a statement that those food supplements should not be consumed by the population under 18 years of age and by pregnant women.		

(2) in Table 2 (Specifications), the following entry is inserted:

Authorised Novel Food	Specification
'Extract from <i>Panax notoginseng</i> and <i>Astragalus membranaceus</i>	Description/Definition: The novel food contains two extracts. One is an ethanol extract of the roots of <i>Astragalus membranaceus</i> (Fisch.) Bunge. The other is a hot water extract of the roots of <i>Panax notoginseng</i> (Burkill) F.H. Chen that is further concentrated using absorption on a resin and subsequent elution with 60 % ethanol. At the end of the manufacturing process both extracts are mixed (45–47,5 % of each extract) with maltodextrin (5–10 %). Characteristics/Composition: Total saponins: 1,5-5 % Ginsenoside Rb1: 0,1-0,5 % Astragaloside I: 0,01-0,1 % Carbohydrates: ≥ 90 % Protein: ≤ 4,5 % Ash: ≤ 1 % Moisture: ≤ 5 % Fat: ≤ 1,5 %

	Heavy metals: Arsenic: ≤ 0,3 mg/kg Microbiological criteria: Total plate count: ≤ 5 000 CFU/g Total yeast and mould count: ≤ 500 CFU/g Enterobacteriaceae: < 10 CFU/g <i>Escherichia coli</i>: Absence in 25 g <i>Salmonella</i>: Absence in 375 g <i>Staphylococcus aureus</i>: Absence in 25 g CFU: colony forming units'
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COMMISSION IMPLEMENTING REGULATION (EU) 2020/1822**of 2 December 2020****authorising the placing on the market of chromium-containing yeast (*Yarrowia lipolytica*) biomass as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ establishing a Union list of authorised novel foods was adopted.
- (3) Commission Implementing Regulation (EU) 2019/760 ⁽³⁾ authorised, in accordance with Regulation (EU) 2015/2283, the placing on the market of *Yarrowia lipolytica* yeast biomass as a novel food to be used in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ⁽⁴⁾, excluding food supplements for infants and young children.
- (4) On 22 August 2018, the company Skotan S.A. ('the applicant') introduced an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place chromium-enriched biomass of the yeast *Yarrowia lipolytica* on the Union market as a novel food. The applicant requested for chromium-enriched biomass of the yeast *Yarrowia lipolytica* to be used as a novel food in food supplements, excluding food supplements for infants and young children. The maximum use levels proposed by the applicant are 2 g per day for children from 3 to 9 years of age, and 4 g per day for adolescents and adults.
- (5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('Authority') on 18 February 2019, asking it to provide a scientific opinion by carrying out an assessment for chromium-containing yeast (*Yarrowia lipolytica*) biomass as a novel food.
- (6) On 23 January 2020, the Authority adopted its scientific opinion 'Safety of chromium-enriched biomass of *Yarrowia lipolytica* as a novel food pursuant to Regulation (EU) 2015/2283' ⁽⁵⁾. That opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (7) In its opinion, the Authority concluded that chromium-containing yeast (*Yarrowia lipolytica*) biomass is safe under the proposed uses and use levels, when used in food supplements intended for the general population above 3 years of age.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

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

⁽³⁾ Commission Implementing Regulation (EU) 2019/760 of 13 May 2019 authorising the placing on the market of *Yarrowia lipolytica* yeast biomass as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470 (OJ L 125, 14.5.2019, p. 13).

⁽⁴⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

⁽⁵⁾ EFSA Journal 2020;18(3):6005.

- (8) The opinion of the Authority gives sufficient grounds to establish that chromium-containing yeast (*Yarrowia lipolytica*) biomass under the proposed conditions of use complies with Article 12(1) of Regulation (EU) 2015/2283.
- (9) Regulation (EU) 2017/2470 should be therefore amended accordingly.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

- 1. Chromium-containing yeast (*Yarrowia lipolytica*) biomass as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.
- 2. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex.

Article 2

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

Article 3

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

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

Done at Brussels, 2 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

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

(1) in Table 1 (Authorised novel foods), the following entry is inserted:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements
'Chromium-containing yeast (<i>Yarrowia lipolytica</i>) biomass	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be "chromium-containing yeast (<i>Yarrowia lipolytica</i>) biomass" The labelling of food supplements containing chromium-containing yeast (<i>Yarrowia lipolytica</i>) biomass shall bear a statement that the food supplements should not be consumed by infants and young children (children under 3 years of age)/children from 3 to 9 years of age (*).	
	Food supplements as defined in Directive 2002/46/EC, excluding food supplements for infants and young children	2 g/day for children from 3 to 9 years of age, resulting in 46 µg of chromium per day 4 g/day for children from 10 years of age, adolescents and adults, resulting in 92 µg of chromium per day		

(*) Depending on the age group the food supplement is intended for.'

(2) in Table 2 (Specifications), the following entry is inserted:

Authorised Novel Food	Specification
'Chromium-containing yeast (<i>Yarrowia lipolytica</i>) biomass	Description/Definition: The novel food is the dried and heat-killed chromium-containing biomass of the yeast <i>Yarrowia lipolytica</i>. The novel food is produced by fermentation in the presence of chromium chloride followed by a number of purification steps and a heat-killing step of the yeast to ensure the absence of viable <i>Yarrowia lipolytica</i> cells in the novel food. Characteristics/Composition: Total chromium: 18–23 µg/g Chromium (VI): < 10 µg/kg (i.e. limit of detection) Protein: 40–50 g/100 g Dietary fibre: 24–32 g/100 g Sugars: < 2 g/100 g

Fat: 6–12 g/100 g

Total ash: ≤ 15 %

Water: ≤ 5 %

Dry matter: ≥ 95 %

Heavy metals:

Lead: ≤ 3,0 mg/kg

Cadmium: ≤ 1,0 mg/kg

Mercury: ≤ 0,1 mg/kg

Microbiological criteria:

Total aerobic microbial count: ≤ 5 × 10³ CFU/g

Total yeast and mould count: ≤ 10² CFU/g

Viable *Yarrowia lipolytica* cells (*): < 10 CFU/g (i.e. limit of detection)

Coliforms: ≤ 10 CFU/g

Salmonella spp.: Absence in 25 g

CFU: colony forming units

(*) Applicable at all stages after the heat-treatment step to guarantee the absence of viable *Yarrowia lipolytica* cells and to be first tested immediately after the heat-treatment step. Measures have to be in place to prevent cross-contamination with viable *Yarrowia lipolytica* cells during packaging and/or storage of the novel food.'

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1823**of 2 December 2020****amending Regulation (EU) No 234/2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings****(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 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings ⁽¹⁾, and in particular Article 9(1) thereof,

Whereas:

- (1) Regulation (EC) No 1331/2008 lays down procedural arrangements for updating the lists of substances the marketing of which is authorised in the Union pursuant to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ⁽²⁾, Regulation (EC) No 1332/2008 of the European Parliament and of the Council ⁽³⁾ and Regulation (EC) No 1334/2008 of the European Parliament and of the Council ⁽⁴⁾ ('the sectoral food laws').
- (2) Commission Regulation (EU) No 234/2011 ⁽⁵⁾ lays down provisions regarding the content, drafting and presentation of applications to update the Union lists under each sectoral food law. That Regulation provides for detailed arrangements for checking the validity of applications for food additives, food enzymes and food flavourings and the type of information that should be included in the opinion of the European Food Safety Authority ('the Authority').
- (3) Regulation (EU) 2019/1381 of the European Parliament and the Council ⁽⁶⁾ amended Regulation (EC) No 178/2002 ⁽⁷⁾ and Regulation (EC) No 1331/2008. Those amendments are aimed at strengthening the transparency and the sustainability of the EU risk assessment in all areas of the food chain where the Authority delivers a scientific risk assessment, including in the area of food additives, food enzymes and food flavourings.
- (4) As regards the placing on the market of food additives, food enzymes and food flavourings and ingredients with flavouring properties for use in and on foods, the amendments to Regulation (EC) No 178/2002 introduced new provisions concerning, amongst other issues: general pre-submission advice by the staff of the Authority at the request of a potential applicant and the obligation to notify studies commissioned or carried out by business operators to support an application and the consequences of non-compliance with that obligation. It also introduced provisions on the public disclosure, by the Authority, of all scientific data, studies and other information

⁽¹⁾ OJ L 354, 31.12.2008, p. 1.

⁽²⁾ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

⁽³⁾ Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p. 7).

⁽⁴⁾ Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).

⁽⁵⁾ Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 64, 11.3.2011, p. 15).

⁽⁶⁾ Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and the sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (OJ L 231, 6.9.2019, p. 1).

⁽⁷⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

supporting applications with the exception of confidential information, early on in the risk assessment process, followed up by a consultation of third parties. The amendments also set out specific procedural requirements for the submission of confidentiality requests and the assessment thereof by the Authority in relation to the information submitted by an applicant, where the Commission requests the opinion of the Authority.

- (5) Regulation (EU) 2019/1381 also amended Regulation (EC) No 1331/2008 to include provisions ensuring consistency with the adaptations of Regulation (EC) No 178/2002 and taking into account sectoral specificities with respect to confidential information.
- (6) Given the scope and application of all those amendments, Regulation (EU) No 234/2011 should be adjusted to accommodate the changes as regards the content, drafting and presentation of applications to update the Union lists under each sectoral food law, the arrangements for checking the validity of applications and the information to be included in the opinions of the Authority. In particular, Regulation (EU) No 234/2011 should make reference to the standard data formats and require that applications provide information demonstrating compliance with the notification requirement laid down in Article 32b of Regulation (EC) No 178/2002. It should also clarify that the assessment of compliance with the notification requirement forms part of the verification of the validity of an application.
- (7) Furthermore, taking into account the fact that the Authority is responsible for managing the database of studies in accordance with Article 32b of Regulation (EC) No 178/2002, it should also be made possible for the Commission to consult the Authority as part of the verification of the validity of applications to ascertain that the application fulfils the relevant requirements that are laid down in that Article.
- (8) Where public consultations are performed during the risk assessment in accordance with Article 32c(2) of Regulation (EC) No 178/2002, the opinion of the Authority should also include the results of those consultations, in line with the transparency requirements to which the Authority is subject.
- (9) This Regulation should apply from 27 March 2021 and to applications submitted as of that date, which is the date of application of Regulation (EU) 2019/1381.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) No 234/2011

Regulation (EU) No 234/2011 is amended as follows:

(1) Article 2 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. The application referred to in Article 1 shall consist of the following:

- (a) a letter;
- (b) a technical dossier;
- (c) a detailed summary and a public summary of the dossier.’;

(b) paragraph 3 is replaced by the following:

‘3. The technical dossier referred to in paragraph 1(b) shall contain:

- (a) the administrative data as provided for in Article 4;
- (b) the data required for risk assessment as provided for in Articles 5, 6, 8 and 10 and information concerning the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002; and
- (c) the data required for risk management as provided for in Articles 7, 9 and 11 and information concerning the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002.’;

(c) paragraph 6 is replaced by the following:

‘6. The summary of the dossier referred to in paragraph 1(c) shall include a reasoned statement that the use of the product complies with the conditions laid down in:

- (a) Article 6 of Regulation (EC) No 1332/2008; or
- (b) Articles 6, 7 and 8 of Regulation (EC) No 1333/2008; or
- (c) Article 4 of Regulation (EC) No 1334/2008.

The public summary of the dossier shall not contain any information subject to a request for confidential treatment pursuant to Article 12 of Regulation (EC) No 1331/2008 and 39a of Regulation (EC) No 178/2002.’;

(2) Article 3, paragraph 1 is replaced by the following

‘1. Prior to the adoption of standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002, the application shall be submitted through the electronic submission system provided by the Commission, in an electronic format allowing for the downloading, printing and searching of documents. After the adoption of standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002, the application shall be submitted through the electronic submission system provided by the Commission in accordance with those standard data formats. The applicant shall take into account the practical guidance on the submission of applications made available by the Commission (Directorate-General for Health and Food Safety (*) website).

(*) https://ec.europa.eu/food/safety_en;

(3) Article 4 is amended as follows:

(a) point (m) is replaced by the following:

‘(m) where the applicant submits, in accordance with Article 12 of Regulation (EC) No 1331/2008, a request to treat as confidential certain parts of the information of the dossier, including supplementary information, a list of the parts to be treated as confidential, accompanied by verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree;’

(b) point (n) is added:

‘(n) a list of the studies submitted to support the application, including information demonstrating compliance with Article 32b of Regulation (EC) No 178/2002.’;

(4) Article 12 is replaced by the following:

‘Article 12

Procedures

1. On receipt of an application the Commission shall, without delay, verify whether the food additive, food enzyme or flavouring falls within the scope of the appropriate sectoral food law, whether the application contains all the elements required under Chapter II and whether it fulfils the requirements set out in Article 32b of Regulation (EC) No 178/2002.

2. The Commission may consult the Authority on the suitability of the data for risk assessment in accordance with the scientific opinions on data requirements for the evaluation of substance applications and on whether the application fulfils the requirements set out in Article 32b of Regulation (EC) No 178/2002. The Authority shall provide the Commission with its views within 30 working days.

3. If the application is considered valid by the Commission, the evaluation period referred to in Article 5(1) of Regulation (EC) No 1331/2008 shall begin on the date of receipt of the Authority’s reply referred to in paragraph 2 of this Article.

However, in accordance with point (a) of the second subparagraph of Article 17(4) of Regulation (EC) No 1332/2008, in the case of establishment of the Union list of food enzymes, Article 5(1) of Regulation (EC) No 1331/2008 shall not apply.

4. In case of an application to update the Union list of food additives, food enzymes or flavourings, the Commission may request additional information from the applicant on matters regarding the validity of the application and inform the applicant of the period within which that information has to be provided. In the case of applications submitted in compliance with Article 17(2) of Regulation (EC) No 1332/2008, the Commission shall determine that period together with the applicant.

5. The application shall be considered not valid if:

- (a) it does not fall within the appropriate sectoral food law,
- (b) it does not contain all the elements required under Chapter II,
- (c) it does not comply with Article 32b of Regulation (EC) No 178/2002 or,
- (d) the Authority considers that the data for risk assessment are not suitable.

In such a case, the Commission shall inform the applicant, the Member States and the Authority indicating the reasons why the application is considered not valid.

6. By way of derogation from paragraph 5 and without prejudice to Article 32b(4) and (5) of Regulation (EC) No 178/2002, an application may be considered as valid even if it does not contain all the elements required under Chapter II, provided that the applicant has submitted appropriate justification for each missing element.;

(5) in Article 13(1), the following point (g) is added:

‘(g) the results of consultations performed during the risk assessment process in accordance with Article 32c(2) of Regulation (EC) No 178/2002.’;

(6) the Annex is replaced by the Annex to this Regulation.

Article 2

Entry into force and 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 27 March 2021 and to applications submitted to the Commission from that date.

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

Done at Brussels, 2 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

'ANNEX

MODEL LETTER ACCOMPANYING AN APPLICATION FOR THE AUTHORISATION OF FOOD ADDITIVES

EUROPEAN COMMISSION

Directorate-General

Directorate

Unit

Date:

Subject: **Application for the authorisation of a food additive in accordance with Regulation (EC) No 1331/2008**

- ☐ Application for the authorisation of a new food additive
- ☐ Application for the modification of the conditions of use of an already authorised food additive
- ☐ Application for the modification of the specifications of an already authorised food additive

(Please indicate clearly by ticking one of the boxes).

The Applicant(s) and/or his/her Representative(s) in the European Union.

(name, address, ...)

.....

.....

.....

submit(s) the present application for the authorisation of (a) food additive(s).

Food additive name:

.....

ELINCS or EINECS number (if attributed):

CAS No (if applicable):

Functional class(es) of food additives (*):

(list)

.....

Food categories and required levels:

Food category	Normal use level	Maximum proposed use level

Yours sincerely,

Signature:

Enclosures:

- ☐ Complete dossier
- ☐ Public summary of the dossier (non-confidential)
- ☐ Detailed summary of the dossier
- ☐ List of the parts of the dossier requested to be treated as confidential, accompanied by verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree

- ☐ List of studies and all information concerning the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002
- ☐ Copy of administrative data of applicant(s)

MODEL LETTER ACCOMPANYING AN APPLICATION FOR THE AUTHORISATION OF FOOD ENZYMES

EUROPEAN COMMISSION

Directorate-General

Directorate

Unit

Date:

Subject: **Application for the authorisation of a food enzyme in accordance with Regulation (EC) No 1331/2008**

- ☐ Application for the authorisation of a new food enzyme
- ☐ Application for the modification of the conditions of use of an already authorised food enzyme
- ☐ Application for the modification of the specifications of an already authorised food enzyme

(Please indicate clearly by ticking one of the boxes)

The Applicant(s) and/or his/their Representative(s) in the European Union

(name, address, ...)

.....

.....

submit(s) the present application for the authorisation of (a) food enzyme(s).

Food enzyme name:

.....

Enzyme Classification Number of Enzyme Commission of the IUBMB:

Source material:

.....

.....

Name	Specifications	Foods	Conditions of use	Restrictions on the sale of the food enzyme to the final consumer	Specific requirement in respect of labelling of food

Yours sincerely,

Signature:

Enclosures:

- ☐ Complete dossier
- ☐ Public summary of the dossier (non-confidential)
- ☐ Detailed summary of the dossier
- ☐ List of the parts of the dossier requested to be treated as confidential, accompanied by verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree
- ☐ List of studies and all information concerning the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002
- ☐ Copy of administrative data of applicant(s)

MODEL LETTER ACCOMPANYING AN APPLICATION FOR THE AUTHORISATION OF FOOD FLAVOURINGS

EUROPEAN COMMISSION

Directorate-General

Directorate

Unit

Date:

Subject: **Application for the authorisation of a food flavouring in accordance with Regulation (EC)
No 1331/2008**

- ☐ Application for the authorisation of a new flavouring substance
- ☐ Application for the authorisation of a new flavouring preparation
- ☐ Application for the authorisation of a new flavour precursor
- ☐ Application for the authorisation of a new thermal process flavouring
- ☐ Application for the authorisation of a new other flavouring
- ☐ Application for the authorisation of a new source material
- ☐ Application for the modification of the conditions of use of an already authorised food flavouring
- ☐ Application for the modification of the specifications of an already authorised food flavouring

(Please indicate clearly by ticking one of the boxes)

The Applicant(s) and/or his/their Representative(s) in the European Union

(name, address, ...)

.....

.....

submit(s) the present application for the authorisation of (a) food flavouring(s).

Name of the flavouring or source material:

.....

FL-, CAS-, JECFA-, CoE-number (if attributed):

Organoleptic properties of the flavouring:

.....

Food categories and required levels:

Food category	Normal use level	Maximum proposed use level

Yours sincerely,

Signature:

Enclosures:

- ☐ Complete dossier
- ☐ Public summary of the dossier (non-confidential)
- ☐ Detailed summary of the dossier
- ☐ List of the parts of the dossier requested to be treated as confidential, accompanied by verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree

- ☐ List of studies and all information concerning the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002
- ☐ Copy of administrative data of applicant(s)

(*) The functional classes of food additives in foods and of food additives in food additives and food enzymes are listed in Annex I to Regulation (EC) No 1333/2008. If the additive does not belong to one of the mentioned classes, a new functional class name and definition can be proposed.

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1824**of 2 December 2020****amending Implementing Regulation (EU) 2017/2468 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 20 and Article 35(3) thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 lays down rules for the placing on the market and use of novel foods in the Union.
- (2) Commission Implementing Regulation (EU) 2017/2468 ⁽²⁾ lays down administrative and scientific requirements concerning traditional foods from third countries.
- (3) Regulation (EU) 2019/1381 of the European Parliament and the Council ⁽³⁾ amended Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽⁴⁾ and Regulation (EU) 2015/2283. Those amendments are aimed at strengthening the transparency and the sustainability of the EU risk assessment in all areas of the food chain where the European Food Safety Authority ('the Authority') delivers a scientific risk assessment, including in the area of traditional foods from third countries.
- (4) As regards the placing on the market of traditional foods from third countries, the amendments to Regulation (EC) No 178/2002 introduced new provisions concerning, amongst other issues: general pre-submission advice by the staff of the Authority at the request of a potential applicant or notifier and the obligation to notify studies commissioned or carried out by business operators to support an application or notification and the consequences of non-compliance with that obligation. It also introduced provisions on the public disclosure by the Authority of all scientific data, studies and other information supporting applications, with the exception of confidential information, early on in the risk assessment process, followed up by a consultation of third parties. The amendments also set out specific procedural requirements for the submission of confidentiality requests and the assessment thereof by the Authority in relation to the information submitted by an applicant, where the Commission requests the opinion of the Authority.
- (5) Regulation (EU) 2019/1381 also amended Regulation (EU) 2015/2283 to provide for the public disclosure by the Authority of notifications where it submits duly reasoned safety objections as well as to include provisions ensuring consistency with the adaptations of Regulation (EC) No 178/2002 and taking into account sectoral specificities with respect to confidential information.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 55).

⁽³⁾ Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (OJ L 231, 6.9.2019, p. 1).

⁽⁴⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

- (6) Given the scope and application of all those amendments, Implementing Regulation (EU) 2017/2468 should be adjusted to accommodate the changes as regards the content, drafting and presentation of notifications and applications referred to in Articles 14 and 16 of Regulation (EU) 2015/2283, the arrangements for verifying the validity of notifications and applications and the information to be included in the opinion of the Authority. In particular, Implementing Regulation (EU) 2017/2468 should make reference to the standard data formats and require that applications provide information demonstrating compliance with the notification requirement laid down in Article 32b of Regulation (EC) No 178/2002. It should also clarify that the assessment of compliance with the notification requirement forms part of the verification of the validity of an application.
- (7) Furthermore, taking into account the fact that the Authority is responsible for managing the database of studies in accordance with Article 32b of Regulation (EC) No 178/2002, it should be made possible for the Commission to consult the Authority as part of the verification of the validity of notifications and applications, in particular with a view to ascertaining that the notification or application fulfils the relevant requirements that are laid down in that Article.
- (8) Where public consultations are performed during the risk assessment in accordance with Article 32c(2) of Regulation (EC) No 178/2002, the opinion of the Authority should also include the results of those consultations in line with the transparency requirements to which the Authority is subject.
- (9) This Regulation should apply from 27 March 2021 and to notifications and applications submitted as of that date, which is the date of application of Regulation (EU) 2019/1381.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Implementing Regulation (EU) 2017/2468

Implementing Regulation (EU) 2017/2468 is amended as follows:

- (1) Article 3 is amended as follows:

- (a) paragraph 1 is replaced by the following:

‘1. A notification shall consist of the following:

- (a) a cover letter;
- (b) a technical dossier;
- (c) a summary of the dossier.

Prior to the adoption of standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002, the notification shall be submitted through the electronic submission system provided by the Commission, in an electronic format allowing for the downloading, printing and searching of documents. After the adoption of standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002, the notification shall be submitted through the electronic submission system provided by the Commission in accordance with those standard data formats.’;

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

‘5. The summary of the dossier referred to in paragraph 1(c) shall provide evidence that the use of a traditional food from a third country complies with the conditions laid down in Article 7 of Regulation (EU) 2015/2283. The summary of the dossier shall not contain any information subject to a request for confidential treatment pursuant to Article 23 of Regulation (EU) 2015/2283 and Article 39a of Regulation (EC) No 178/2002.’;

- (2) Article 4 is amended as follows:

- (a) paragraph 1 is replaced by the following:

‘1. An application shall consist of the following:

- (a) a cover letter;
- (b) a technical dossier;
- (c) a summary of the dossier.

(d) duly reasoned safety objections referred to in Article 15(2) of Regulation (EU) 2015/2283;

(e) the applicant's response to duly reasoned safety objections.

Prior to the adoption of standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002, the application shall be submitted through the electronic submission system provided by the Commission, in an electronic format allowing for the downloading, printing and searching of documents. After the adoption of standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002, the application shall be submitted through the electronic submission system provided by the Commission in accordance with those standard data formats.';

(b) paragraph 5 is replaced by the following:

'5. The summary of the dossier referred to in paragraph 1(c) shall provide evidence that the use of a traditional food from a third country complies with the conditions laid down in Article 7 of Regulation (EU) 2015/2283. The summary of the dossier shall not contain any information subject to a request for confidential treatment pursuant to Article 23 of Regulation (EU) 2015/2283 and Article 39a of Regulation (EC) No 178/2002.';

(3) Article 5 is amended as follows:

(a) point (e) is replaced by the following:

'(e) where the applicant submits, in accordance with Article 23 of Regulation (EU) 2015/2283, a request to treat as confidential certain parts of the information of the dossier, including supplementary information, a list of the parts to be treated as confidential accompanied by verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree;';

(b) point (f) is added:

'(f) a list of the studies submitted to support the notification or application, including information demonstrating compliance with Article 32b of Regulation (EC) No 178/2002.';

(4) Article 7 is replaced by the following:

'Article 7

Verification of the validity of a notification

1. On receipt of a notification of a traditional food from a third country, the Commission shall, without delay, verify whether the food concerned falls within the scope of Regulation (EU) 2015/2283 and whether the notification fulfils the requirements set out in Articles 3, 5 and 6 of this Regulation and in Article 32b of Regulation (EC) No 178/2002.
2. The Commission may consult the Member States and the Authority on whether the notification fulfils the requirements referred to in paragraph 1. The Member States and the Authority shall provide the Commission with their views within a period of 30 working days.
3. The Commission may request additional information from the applicant as regards the validity of the notification and inform the applicant of the period within which that information has to be provided.
4. By way of derogation from paragraph 1 of this Article and without prejudice to Article 14 of Regulation (EU) 2015/2283 and to Article 32b(4) and (5) of Regulation (EC) No 178/2002, a notification may be considered valid even if it does not contain all the elements required under Articles 3, 5 and 6 of this Regulation, provided that the applicant has submitted appropriate justification for each missing element.
5. The Commission shall inform the applicant, the Member States and the Authority whether the notification is considered valid or not. Where the notification is not considered valid, the Commission shall indicate the reasons for that finding.';

(5) Article 8 is replaced by the following:

'Article 8

Verification of the validity of an application

1. On receipt of an application for the authorisation of a traditional food from a third country the Commission shall, without delay, verify whether the application fulfils the requirements of Articles 4 to 6 of this Regulation and of Article 32b of Regulation (EC) No 178/2002.

2. The Commission may consult the Authority on whether the application fulfils the requirements referred to in paragraph 1. The Authority shall provide the Commission with its views within a period of 30 working days.
 3. The Commission may request additional information from the applicant on matters regarding the validity of the application and inform the applicant of the period within which that information has to be provided.
 4. By way of derogation from paragraph 1 of this Article and without prejudice to Article 16 of Regulation (EU) 2015/2283 and to Article 32b(4) and (5) of Regulation (EC) No 178/2002, an application may be considered valid even if it does not contain all the elements required under Articles 4 to 6 of this Regulation, provided that the applicant has submitted appropriate justification for each missing element.
 5. The Commission shall inform the applicant, the Member States and the Authority whether the application is considered valid or not. Where the application is not considered valid, the Commission shall indicate the reasons for that finding.’;
- (6) Article 10 is amended as follows:
- point (e) is added:
- ‘(e) the results of consultations performed during the risk assessment process in accordance with Article 32c(2) of Regulation (EC) No 178/2002.’;
- (7) Annexes I and II are replaced in accordance with the Annex to this Regulation;
- (8) Annex III is deleted.

Article 2

Entry into force and 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 27 March 2021 and to notifications and applications submitted to the Commission from that date.

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

Done at Brussels, 2 December 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annexes I and II to Regulation (EU) 2017/2468 are replaced as follows:

(1) Annex I is replaced by the following:

‘ANNEX I

**TEMPLATE COVER LETTER ACCOMPANYING A NOTIFICATION OF A TRADITIONAL FOOD
FROM A THIRD COUNTRY IN ACCORDANCE WITH ARTICLE 14 OF REGULATION (EU)
2015/2283**

EUROPEAN COMMISSION

Directorate-General

Directorate

Unit

Date: ...

Subject: Notification of a traditional food from a third country in accordance with Regulation (EU) 2015/2283

(Please indicate clearly by ticking one of the boxes)

- ☐ Notification for an authorisation of a new traditional food.
- ☐ Notification for adding, removing or changing the conditions of use of an already authorised traditional food. Please provide a reference to that notification.
- ☐ Notification for adding, removing or changing the specifications of an already authorised traditional food. Please provide a reference to that notification.
- ☐ Notification for adding, removing or changing additional labelling requirements of an already authorised traditional food. Please provide a reference to that notification.
- ☐ Notification for adding, removing or changing the post-market monitoring requirements of an already authorised traditional food. Please provide a reference to that notification.

The Applicant(s) or their Representative(s) in the Union

(name(s), address(es)....)

...

...

...

submit(s) this notification in order to update the Union list on novel foods.

Identity of the traditional food:

...

...

Confidentiality. Where appropriate, state whether the application includes confidential data in accordance with Article 23 of Regulation (EU) 2015/2283

- ☐ Yes
- ☐ No

Food categories, conditions of use and labelling requirements

Food category	Specific conditions of use	Additional specific labelling requirement
-		

Yours sincerely,

Signature ...

Enclosures:

- ☐ Complete technical dossier
- ☐ Summary of the dossier (non-confidential)
- ☐ List of the parts of the dossier requested to be treated as confidential, accompanied by verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree
- ☐ Copy of administrative data of applicant(s)
- ☐ List of studies and all information concerning the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002'

(2) Annex II is replaced by the following:

'ANNEX II

**TEMPLATE COVER LETTER ACCOMPANYING AN APPLICATION FOR THE AUTHORISATION OF
A TRADITIONAL FOOD FROM A THIRD COUNTRY IN ACCORDANCE WITH ARTICLE 16 OF
REGULATION (EU) 2015/2283**

EUROPEAN COMMISSION

Directorate-General

Directorate

Unit

Date: ...

Subject: Application for the authorisation of a traditional food from a third country in accordance with Article 16 of Regulation (EU) 2015/2283

The Applicant(s) or their Representative(s) within the European Union

(name(s), address(es)....)

...

...

...

submit(s) this application in order to update the Union list on novel foods.

Identity of the traditional food:

...

...

Confidentiality. Where appropriate, state whether the application includes confidential data in accordance with Article 23 of Regulation (EU) 2015/2283

- ☐ Yes
☐ No

Food categories, conditions of use and labelling requirements

Food category	Specific conditions of use	Additional specific labelling requirement

Yours sincerely,

Signature ...

Enclosures:

- ☐ Complete application
☐ Summary of the application (non-confidential)
☐ List of the parts of the application requested to be treated as confidential, accompanied by verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree
☐ Documented data relating to the duly reasoned safety objections
☐ Copy of administrative data of applicant(s)
☐ List of studies and all information concerning the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002'

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1825**of 2 December 2020****amending Articles 7 and 8 of Implementing Regulation (EU) 2019/2072 as regards temporary measures for the introduction into, or movement within, the Union territory of certain plants, plant products or other objects**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants ⁽¹⁾, and in particular Articles 40(2) and 41(2) thereof,

Whereas:

- (1) Article 7 of Commission Implementing Regulation (EU) 2019/2072 ⁽²⁾, in conjunction with Annex VI of that Regulation, provides for a list of plants, plant products and other objects whose introduction into the Union territory is prohibited, together with the third countries, groups of third countries or specific areas of third countries to which the prohibition applies, as referred to in Article 40(2) of Regulation (EU) 2016/2031.
- (2) Article 8(1) of Implementing Regulation (EU) 2019/2072, in conjunction with Annex VII of that Regulation, provides for a list of plants, plant products and other objects, originating from third countries, and the corresponding special requirements for their introduction into the Union territory, as referred to in Article 41(2) of Regulation (EU) 2016/2031.
- (3) Moreover, Article 8(2) of Implementing Regulation (EU) 2019/2072, in conjunction with Annex VIII of that Regulation, provides for a list of plants, plant products and other objects, originating in the Union territory, and the corresponding special requirements for their movement within the Union territory, as referred to in Article 41(2) of Regulation (EU) 2016/2031.
- (4) Since the adoption of Implementing Regulation (EU) 2019/2072, it has become clear that, in certain exceptional cases, certain implementing acts, setting out temporary prohibitions or special requirements for the introduction into, or movement within, the Union territory of certain plants, plant products or other objects, need to be adopted pursuant to Articles 28(1), 30(1), 40(2), (41)2, 42(3), 42(4) or 49(1) of Regulation (EU) 2016/2031 to address specific phytosanitary risks, which have not been sufficiently assessed. That will allow the phytosanitary risks addressed through those prohibitions or special requirements to be further assessed in order to determine their phytosanitary status.
- (5) Therefore, Articles 7 and 8 of Implementing Regulation (EU) 2019/2072 should provide that the respective prohibitions or special requirements are to apply without prejudice to those acts.
- (6) Implementing Regulation (EU) 2019/2072 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,

⁽¹⁾ Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC (OJ L 317, 23.11.2016, p. 4).

⁽²⁾ Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019 (OJ L 319, 10.12.2019, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Amendment of Implementing Regulation (EU) 2019/2072

Implementing Regulation (EU) 2019/2072 is amended as follows:

(1) in Article 7, the following subparagraph is added:

‘The first paragraph shall apply without prejudice to any other acts setting out prohibitions, having a temporary character, adopted pursuant to Articles 40(2), 42(3) or 49(1) of Regulation (EU) 2016/2031, and concerning the introduction into the Union territory of certain plants, plant products or other objects to address particular phytosanitary risks which are not yet fully assessed.’;

(2) Article 8 is amended as follows:

(a) in paragraph 1, the following subparagraph is added:

‘The first subparagraph shall apply without prejudice to any other acts setting out special requirements, having a temporary character, adopted pursuant to Articles 41(2), 42(4) or 49(1) of Regulation (EU) 2016/2031, and concerning the introduction into the Union territory of certain plants, plant products or other objects to address particular phytosanitary risks which are not yet fully assessed.’;

(b) in paragraph 2, the following subparagraph is added:

‘The first subparagraph shall apply without prejudice to any other acts setting out special requirements, having a temporary character, adopted pursuant to Articles 28(1), 30(1), 41(2), 42(4) or 49(1) of Regulation (EU) 2016/2031, and concerning the movement within the Union territory of certain plants, plant products or other objects to address particular phytosanitary risks which are not yet fully assessed.’.

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, 2 December 2020.

For the Commission

The President

Ursula VON DER LEYEN

DECISIONS

POLITICAL AND SECURITY COMMITTEE DECISION (CFSP) 2020/1826

of 1 December 2020

on the appointment of the EU Force Commander for the European Union military operation to contribute to the deterrence, prevention and repression of acts of piracy and armed robbery off the Somali coast (Atalanta) and repealing Decision (CFSP) 2020/895 (ATALANTA/3/2020)

THE POLITICAL AND SECURITY COMMITTEE,

Having regard to the Treaty on European Union, and in particular Article 38 thereof,

Having regard to Council Joint Action 2008/851/CFSP of 10 November 2008 on a European Union military operation to contribute to the deterrence, prevention and repression of acts of piracy and armed robbery off the Somali coast ⁽¹⁾, and in particular Article 6(1) thereof,

Whereas:

- (1) Pursuant to Article 6(1) of Joint Action 2008/851/CFSP, the Council authorised the Political and Security Committee to take the relevant decisions on the appointment of the EU Force Commander for the European Union military operation to contribute to the deterrence, prevention and repression of acts of piracy and armed robbery off the Somali coast ('Atalanta').
- (2) On 25 June 2020, the Political and Security Committee adopted Decision (CFSP) 2020/895 ⁽²⁾ appointing Rear Admiral Riccardo MARCHIÒ as EU Force Commander for Atalanta.
- (3) The EU Operation Commander has recommended the appointment of Captain Diogo ARROTEIA as the new EU Force Commander for Atalanta as from 3 December 2020.
- (4) On 22 October 2020, the EU Military Committee supported that recommendation.
- (5) Decision (CFSP) 2020/895 should therefore be repealed.
- (6) In accordance with Article 5 of Protocol No 22 on the position of Denmark, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, Denmark does not participate in the elaboration and the implementation of decisions and actions of the Union which have defence implications,

HAS ADOPTED THIS DECISION:

Article 1

Captain Diogo ARROTEIA is hereby appointed EU Force Commander for the European Union military operation to contribute to the deterrence, prevention and repression of acts of piracy and armed robbery off the Somali coast (Atalanta) as from 3 December 2020.

Article 2

Decision (CFSP) 2020/895 (ATALANTA/2/2020) is repealed.

⁽¹⁾ OJ L 301, 12.11.2008, p. 33.

⁽²⁾ Political and Security Committee Decision (CFSP) 2020/895 of 25 June 2020 on the appointment of the EU Force Commander for the European Union military operation to contribute to the deterrence, prevention and repression of acts of piracy and armed robbery off the Somali coast (Atalanta) and repealing Decision (CFSP) 2020/401 (ATALANTA/2/2020) (OJ L 206, 30.6.2020, p. 63).

Article 3

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

It shall apply from 3 December 2020.

Done at Brussels, 1 December 2020.

For the Political and Security Committee

The Chairperson

S. FROM-EMMESBERGER

COMMISSION DECISION (EU) 2020/1827**of 26 May 2020****on the measures SA.39990 – (2016/C) (ex 2016/NN) (ex 2014/FC) (ex 2014/CP) – implemented by Belgium for Ducatt NV***(notified under document C(2020) 3287)***(Only the Dutch and French texts are authentic)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION

Having regard to the Treaty on the Functioning of the European Union, and in particular the first subparagraph of Article 108(2) thereof,

Having regard to the Agreement on the European Economic Area, and in particular Article 62(1)(a) thereof,

Having called on interested parties to submit their comments pursuant to the provisions cited above ⁽¹⁾, and having regard to their comments,

Whereas:

1. PROCEDURE

- (1) On 28 November 2014, the Commission received a formal complaint submitted by the German glass producer GMB Glasmanufaktur Brandenburg GmbH ('GMB') and its parent company Interfloat Corporation ('Interfloat Group'), registered in Liechtenstein (together 'the complainant'). The complainant alleged that its direct competitor Ducatt NV ('Ducatt') had received unlawful State aid that was incompatible with the internal market from the Flemish Region, Belgium.
- (2) By letter dated 19 May 2016, the Commission informed Belgium that it had decided to initiate the procedure laid down in the first subparagraph of Article 108(2) of the Treaty on the Functioning of the European Union ('TFEU') in respect of the alleged State aid granted to Ducatt ('the Opening Decision').
- (3) The Opening Decision was published in the *Official Journal of the European Union* ⁽²⁾. The Commission invited interested parties to submit their comments on the measures described in the Opening Decision.
- (4) The Belgian authorities submitted their comments on the Opening Decision on 20 June 2016 ⁽³⁾ and 19 July 2016.
- (5) The Commission received comments from the complainant on 17 June 2016, 18 August 2016, 13 September 2016 and 6 October 2016. It forwarded them to the Belgian authorities, which commented on them by letter dated 23 January 2017.
- (6) The Commission requested additional information from Belgium on 30 January 2017, which was submitted by the Belgian authorities on 27 March 2017.
- (7) On 14 June 2017, the Belgian authorities informed the Commission of the bankruptcy of Ducatt as of 20 May 2017, following which the Commission met the representatives of Belgium on 23 June 2017.
- (8) On 5 July 2017, the Commission met the complainant and its legal representatives.
- (9) On 10 July 2017, the Belgian authorities submitted additional information to the Commission, which the latter had requested at the meeting on 23 June 2017.
- (10) The Commission requested further information from Belgium on 20 November 2017, 22 June 2018 and 31 January 2020. The Belgian authorities responded on 15 December 2017, 27 August 2018, 4 March and 12 May 2020.

⁽¹⁾ OJ C 369, 7.10.2016, p. 27.

⁽²⁾ See footnote 1.

⁽³⁾ At the meeting with the Commission of 20 June 2016.

- (11) The Commission also requested further information from the receivers of the Ducatt bankruptcy on 18 July 2017, 25 July 2017, 7 and 9 March 2018, 16 May 2018 and 28 January 2019. The receivers replied on 22 July 2017, 6 March 2018, 9 March 2018, 30 March 2018, 30 May 2018 and 29 January 2019.
- (12) The Commission also engaged in the following correspondence with the complainant: it received letters from the complainant on 3 April 2018, 2 April 2019 and 26 January 2020, to which it replied respectively on 24 April 2018, 6 May 2019 and 10 February 2020. The Commission also had two telephone conversations with the complainant on 26 July 2018 and 27 March 2019.
- (13) On 26 March 2020, the Commission received a letter from the complainant with a formal request to act pursuant to Article 265(2) TFEU.

2. BACKGROUND

2.1. The beneficiary

- (14) Ducatt is a spin-off from Emgo NV ('Emgo'), a 50/50 joint venture between Philips and Osram, which was established in 1966 as a producer of glass bulbs for the production of incandescent lamps and glass tubes for the production of fluorescent lamps. Ducatt was established in November 2010 by the (then) Innovation Manager at Emgo (via Vercundus BVBA) and the (then) Finance & Accounting Manager at Emgo (via ArsiCO BVBA).
- (15) Due to changes in European Union legislation, prohibiting the sale of incandescent lamps from 1 September 2009, Emgo's glass bulb business was split off and merged with Ducatt in January 2011 with the aim of safeguarding jobs and its know-how in the glass manufacturing sector. Ducatt's management aimed to enter the market for glass for solar panels and invested heavily as of 2011 in the necessary machinery.
- (16) In addition to the two founding companies, Vercundus BVBA and ArsiCO BVBA, Ducatt is or has been co-owned to various degrees by the following legal entities: Limburgse Reconversie Maatschappij ('LRM'), Participatie Maatschappij Vlaanderen ('PMV'), Capricorn Cleantech Fund ('CCF'), Quest for Growth ('QFG'), Belfius, VF Capital ('VFC'), VMF and Aro. In addition, parts of the shares of the company were, for some time, held by a natural person, namely [...]*.

2.2. The complaint

- (17) The complainant is a producer of glass for solar panels and a direct competitor of the alleged aid beneficiary Ducatt. The complainant alleges that Ducatt received around EUR 70 million of unlawful State aid incompatible with the internal market from the State-owned bank Belfius and LRM and PMV, which are two investment companies owned by the Flemish Region.
- (18) According to the complainant, the alleged aid took the form of loans granted and capital increases performed at non-market conditions dating back to Ducatt's establishment in 2011. They were used to set up the company and start up its production and continuously to cover its losses.

3. DESCRIPTION OF THE MEASURES AND CONTENT OF THE OPENING DECISION

- (19) The Commission opened the formal investigation procedure to assess whether the following measures in favour of Ducatt constituted State aid within the meaning of Article 107(1) TFEU and, if so, if they were compatible with the internal market.

3.1. Capital increases

- (20) The Opening Decision expressed doubts as to whether the following capital increases subscribed by LRM and PMV amounting to EUR [...] were granted on market terms:
 - (a) EUR [...] from a capital increase on 28 February 2014 by LRM (EUR [...]) and PMV (EUR [...]);
 - (b) EUR [...] from a capital increase on 4 July 2014 by LRM (EUR [...]) and PMV (EUR [...]);

* Confidential.

- (c) EUR [...] of loans which were subsequently converted into equity:
- (i) EUR [...] of loans (interest of [...] %) granted on 21 December 2012 by LRM (EUR [...]) and PMV (EUR [...]) which were converted into equity with interest on 5 December 2013 ('loan 4');
 - (ii) EUR [...] of loans (interest of [...] %) granted on 27 September 2013 by LRM (EUR [...]) and PMV (EUR [...]) which were converted into equity on 13 December 2013 ('loan 5');
 - (iii) EUR [...] of loans (interest of [...] %) granted on 28 November 2013 by LRM which were converted into equity on 28 February 2014 ('loan 6');
 - (iv) EUR [...] of loans (interest of [...] %) granted on 16 December 2013 by LRM (EUR [...]) and PMV (EUR [...]) which were converted into equity on 28 February 2014 ('loan 7');
 - (v) EUR [...] from the EUR [...] bridging loan granted in mid-September 2015 by LRM (part of 'loan 13');
- (d) EUR [...] due to stock warrants, exercised on:
- (i) EUR [...] on 30 September 2014 by LRM (EUR [...]) and PMV (EUR [...]);
 - (ii) EUR [...] on 27 October 2014 by LRM (EUR [...]) and PMV (EUR [...]);
 - (iii) EUR [...] on 28 November 2014 by LRM;
 - (iv) EUR [...] on 28 January 2015 by LRM.

3.2. Loans

- (21) The Opening Decision expressed doubts as to whether, in addition to the loans converted to equity as stated in recital (20) above, the following loans granted by LRM and PMV amounting to EUR [...] were granted on market terms:
- (a) EUR [...] bridging loan on 10 and 19 February 2014 by LRM repaid on 28 February 2014 ('loan 8' and 'loan 9');
 - (b) EUR [...] loan on 16 May 2014 by LRM (EUR [...]) and PMV (EUR [...]) ('loan 10');
 - (c) EUR [...] loan on 29 April 2015 by LRM ('loan 11');
 - (d) EUR [...] bridging loan granted during July and August 2015 by LRM ('loan 12');
 - (e) EUR [...] bridging loan granted in the middle of September 2015 by LRM (part of 'loan 13').

3.3. Recapitalisation round of November 2015

- (22) The Opening Decision furthermore expressed doubts as to whether the capital increase and restructuring of shareholder loans of November 2015 were carried out on market terms. This included, on the one hand, the capital increase subscribed by LRM in cash of EUR [...] (beside the conversion of EUR [...] from loan 13) and, on the other hand, the takeover of the outstanding parts of loan 10 from other parties by LRM, as well as the write-off of parts of the principals and interest of loans 10, 11 and 12 by LRM.

4. BANKRUPTCY OF THE BENEFICIARY

- (23) On 11 May 2017, the insolvency of Solarworld, Ducatt's main customer, sales to which generated approximately 30 % of Ducatt's revenues, was made public.
- (24) Subsequently, on 20 May 2017, the board of Ducatt decided to initiate the bankruptcy procedure for Ducatt. Ducatt was declared bankrupt as of 20 May 2017 by the bankruptcy order issued by the Commercial Court of Hasselt on 23 May 2017, which also appointed three bankruptcy receivers.

4.1. Cessation of business activity and disposal of beneficiary's assets

- (25) In July 2017, all business activity at Ducatt had definitively ceased after the termination of the contracts of all its employees and the halting of production ⁽⁴⁾.
- (26) In August 2017, after no bids for the sale of Ducatt's business as a going concern were received, the bankruptcy receivers sold Ducatt's non-production-related assets (furniture, computers, spare parts, transport equipment, inventory, packaging materials, cleaning machines, etc.) via an online auction to a number of different buyers.
- (27) Ducatt's main production-related assets were leased by Ducatt from third parties, which repossessed these production assets as a result of Ducatt's bankruptcy. In particular, the premises and part of the machinery (production hall with the glass furnace, offices and logistics premises) were repossessed by the lease company LRM Lease NV, whereas the glass treatment lines (for glass coming out of the glass furnace) were repossessed by the lease companies ING Equipment Lease, KBC Lease and ES Finance.
- (28) Based on information provided by Belgium, the production premises and offices are currently empty, whereas parts of the logistics premises are rented out to various logistics companies as storage space. The plan is to tear the production hall down along with the offices, to redevelop the underlying land and to keep the premises currently rented out to logistics companies. The glass furnace has been removed from the production hall and has been dismantled, with the stone parts of the furnace having been sold via an online auction to the highest bidders, and other components of the furnace having been scrapped after failed attempts to sell them via an online auction.

4.2. Balance of assets and liabilities of the beneficiary and its liquidation

- (29) Belgium has shown that the liabilities of Ducatt in bankruptcy amount to around EUR 33,8 million, of which Ducatt's liabilities to preferential creditors (mostly personnel, social security, banks and leasing companies) amount to EUR 14,3 million, whereas the assets of Ducatt in bankruptcy amount to around EUR 3,6 million.
- (30) Furthermore, in the event that the Commission found that unlawful State aid that was incompatible with the internal market had been granted to Ducatt by Belgium and ordered the recovery of such State aid, Belgium's claim for the recovery of State aid in Ducatt's bankruptcy procedure would not be preferential under Belgian insolvency laws. Since the assets are, by far, insufficient to repay the preferential creditors, there is no realistic chance of non-preferential claims being satisfied, even partially.
- (31) Ducatt's inevitable liquidation is delayed only by a number of legal procedures pending, which are related to claims from creditors and from some of its employees. The outcome of these procedures will not change the fact that preferential claims exceed Ducatt's assets.

5. CONCLUSION

- (32) The Commission notes that, according to Articles 107 and 108 TFEU, the powers of the Commission are designed to avoid the granting of aid incompatible with the internal market. As far as recovery is concerned, the Court has consistently held that the Commission's power to order Member States to recover aid regarded by the Commission as being incompatible with the internal market is designed to re-establish the situation prior to granting of State aid that is incompatible with the internal market ⁽⁵⁾.
- (33) In other words, one of the goals of State aid control is to prevent the granting of unlawful or incompatible State aid. The other goal is to ensure that the situation prior to the distortion of competition caused by State aid incompatible with the internal market is restored.
- (34) In the present case, no aid can be granted any longer to Ducatt. A decision declaring that the measures already granted constitute State aid incompatible with the internal market and ordering their recovery would, in any event, not result in a recovery (such recovery being manifestly impossible), and would not have any influence on the payment of the claims of other creditors.

⁽⁴⁾ Owing to the specific characteristics of the functioning of the glass furnace, it could not be switched off immediately and had to undergo a gradual cooling-down procedure, which required the involvement of part of the staff. That is why certain members of Ducatt's staff were employed until the cooling-down was completed in early July.

⁽⁵⁾ Judgment of the Court of 14 September 1994 in Joined Cases C-278/92, C-279/92 and C-280/92 *Spain v Commission*, ECLI:EU:C:1994:325, para 75.

- (35) More precisely, the Commission notes that Ducatt's business activity has definitively ceased due to (i) the termination of all contracts with Ducatt's employees, who are now mostly employed by other employers; (ii) the dismantling of Ducatt's production facilities and the sale of all non-production-related assets of Ducatt to a number of different buyers.
- (36) Furthermore, the Commission notes that Ducatt's main production asset, the glass furnace repossessed by LRM Lease, has been dismantled and therefore may not be offered to any market operator anymore, whereas the premises repossessed by LRM Lease have not been used for purposes related to Ducatt's business activity. Finally, the Commission notes that the glass treatment lines are owned by private undertakings, independent of Ducatt and the Flemish Region, the business strategy of which is to lease the assets and not to conduct any production activity comparable to that of Ducatt. For the above reasons, the Commission considers that any chance of another undertaking continuing Ducatt's business activity can be ruled out.
- (37) The Commission further notes that a recovery order would not have any impact on the payment of the State aid claims, nor of any other claim. Under Belgian bankruptcy law, the claim for recovery of State aid in the event of a negative Commission decision involving recovery would be registered as a non-preferential creditor claim in the schedule of liabilities of Ducatt. The preferential claims by Ducatt's creditors in the bankruptcy proceedings significantly exceed the amount of Ducatt's assets in bankruptcy. Therefore, even if the Commission were to find that Ducatt had received illegal and incompatible State aid, the recovery based on such a decision would be impossible and would not influence the outcome of the reimbursement of the claims of the non-preferential creditors of Ducatt in any way.
- (38) The sole rationale for Ducatt's continued existence, without any business activity, is to await the outcome of several pending legal procedures related to claims from creditors and former employees. Once these procedures have been terminated, Ducatt will be inevitably liquidated and removed from the company register.
- (39) Under these circumstances, a Commission decision on the qualification of the measures in question as incompatible aid would have no practical effect, and the formal investigation procedure initiated under the first subparagraph of Article 108(2) TFEU in respect of the measures in question no longer serves any purpose,

HAS ADOPTED THIS DECISION:

Article 1

The proceeding initiated under the first subparagraph of Article 108(2) TFEU on 19 May 2016 in respect of Ducatt NV is hereby terminated.

Article 2

This Decision is addressed to the Kingdom of Belgium.

Done at Brussels, 26 May 2020.

For the Commission
Margrethe VESTAGER
Executive Vice-President

CORRIGENDA

Corrigendum to Council Implementing Regulation (EU) 2020/1536 of 22 October 2020 of implementing Regulation (EU) 2019/796 concerning restrictive measures against cyber-attacks threatening the Union or its Member States

(Official Journal of the European Union L 351 I of 22 October 2020)

On the cover, in the table of contents, and on page 1, in the title:

for: 'Council Implementing Regulation (EU) 2020/1536 of 22 October 2020 of implementing Regulation (EU) 2019/796 concerning restrictive measures against cyber-attacks threatening the Union or its Member States',

read: 'Council Implementing Regulation (EU) 2020/1536 of 22 October 2020 implementing Regulation (EU) 2019/796 concerning restrictive measures against cyber-attacks threatening the Union or its Member States'.

Corrigendum to Council Decision (EU) 2020/1410 of 25 September 2020 on the position to be taken, on behalf of the European Union, in the 66th session of the Harmonized System Committee of the World Customs Organization in relation to the envisaged adoption of Classification opinions, classification decisions, amendments to the Harmonized System Explanatory Notes or other advice on the interpretation of the Harmonized System, and of recommendations to secure uniformity in the interpretation of the Harmonized System under the Harmonized System Convention

(Official Journal of the European Union L 327 of 8 October 2020)

The Annex should read:

'ANNEX

IV. REPORT OF THE SCIENTIFIC SUB-COMMITTEE: Doc. NS0456Eb (SSC/35 - report)

(1) Matters for decision (doc. NC2708Ea)

- (a) Annexes A/1 and C/1 – Classification of new INN products (List 120). The Union shall approve the 125 classifications (HS 2017 Edition) and the three consequential reclassifications (HS 2022 Edition) recommended by the Scientific Sub-Committee.
- (b) Annexes A/2 and C/2 – Classification of new INN products (List 121). The Union shall approve the 143 classifications (HS 2017 Edition) and the 15 consequential reclassifications (HS 2022 Edition) recommended by the Scientific Sub-Committee.
- (c) Annexes A/3 and C/3 – Possible reclassification of certain INN products consequential upon the Article 16 Recommendation of 23 June 2019. The Union shall approve the consequential (HS 2022 Edition) reclassifications of the 143 INN products agreed to by the Scientific Sub-Committee.
- (d) Annexes B/1 and C/6 – Decisions taken by the HS Committee at its 63rd and 64th Sessions and the WCO Council at its 133rd/134th Sessions, affecting the work of the Scientific Sub-Committee. The Union shall approve the reclassifications of “zilucoplan” and “etryptamine” agreed by the Scientific Sub-Committee, in subheadings 2 933,79 and 2 939,80, respectively.

The Union shall agree to all proposed classifications as they are in line with the current classification policy in the Union.

(2) Possible amendment of the Explanatory Notes to Chapter 29 in respect to the list of narcotic drugs, psychotropic substances and precursors Doc. NC2738Ea

The Union shall agree to the proposal to amend the HSEN to Chapter 29, in line with the advice of the Scientific Sub-Committee.

V. REPORT OF THE HS REVIEW SUB-COMMITTEE (Doc. NR1403E)

(1) Matters for decision (Doc. NC2709Ea)

- (a) Annexes D/6 and G/11 – Possible amendment to the Explanatory Note to heading 85.24 (HS 2022)
- (b) Annexes D/7 and G/12 – Possible amendments to the HS 2022 Explanatory Notes in respect of 3D printers
- (c) Annexes E/14 and G/19 – Amendment to the Explanatory Notes to heading 70.19 in respect of glass fibres (HS 2022)
- (d) Annexes E/1 to E/6, E/8 to E/13, E/15 to E/18, E/20, E/23 and G/1 to G/6, G/8, G/13 to G/18, G/21, G/22, G/24, G/27 – Possible amendment to the Explanatory Note to Sections I, II, III, IV, V, VI, VII, VIII, IX, X, XI, XII, XIII, XIV, XV, XVI, XVII, XVIII, XX and XXI.
- (e) Annexes E/23 and G/27 – Amendments to the Explanatory Notes to Chapter 97 in respect of certain cultural articles (HS 2022)
- (f) Annexes E/24 and G/28 – Amendments to the Explanatory Notes (GIRs)

The Union shall agree to all proposed amendments in the documents as they reflect the current classification policy in the Union.

- (2) Classification in HS 2022 of certain disposable or rechargeable personal electric vaporisers (Request by the Secretariat) Doc. NC2710Eb

The Union would classify product 1 in subheading 8 543,70 in the HS2017 and in subheading 8 543,40 in the HS2022. Product 2 shall be classified in heading 24.04 in the HS2022 using GIR 3(b), based on the essential character conferred by the e-liquid.

- (3) Classification in HS 2022 of certain collections and collectors' pieces of numismatic interest (Request by the Secretariat) Doc. NC2711Ea

The Union shall express the need for additional information on the products to determine classification.

The Union shall not agree with the proposal for amending the HSEN, pending clarification and guidance on how to differentiate between the new subheadings under heading 97.05.

- (4) Classification in HS 2022 of cartridges for 3D printers (Request by the Secretariat) Doc. NC2712Ea

The Union would classify the products in Chapter 39 according to the constituent material, in line with the ruling of the Court of Justice of the European Union in Case C-276/00. Additional information is needed to classify the products at subheading level. The proposed amendment to the HSEN shall not be supported, as the current practice in the Union is not to classify printer cartridges as parts of printers.

- (5) Classification in HS 2022 of a sheet lamination machine for additive manufacturing doc. NC2744Ea

The Union would classify the product in heading 84.85 (option II).

VI. REPORT OF THE PRESESSIONAL WORKING PARTY Doc. NC2714Ea and Annexes A to T

Subject to some editorial suggestions, the Union shall adopt the text presented in Annexes A to T with the following remarks:

- (1) Amendment to the Compendium of Classification Opinions to reflect the decision to classify a product in heading 18.06 (subheading 1 806,32)

The Union shall suggest to delete the list of ingredients, not necessary for classification purposes.

- (2) Amendment to the Compendium of Classification Opinions to reflect the decision to classify two kinds of tobacco stems ("Cut rolled expanded stem tobacco (CRES)" and "Expanded tobacco stems (ETS)") in heading 24.03 (subheading 2 403,99)

The Union shall insist to keep the text "cannot be smoked directly" as it was the decisive criterion for classification.

- (3) Amendment to the Compendium of Classification Opinions to reflect the decision to classify Solid Oxide Fuel Cells (SOFC) in heading 85.01 (subheading 8 501,62)

The Union shall suggest using the product description from the boxed text of the initial working document (doc. NC2655E1b).

VII. REQUESTS FOR RE-EXAMINATION (RESERVATIONS)

- (1) Re-examination of the classification of certain dietary sip feeds (Products 1 to 5) (Request by the United States) Doc. NC2715Ea

The Union would classify the products as beverages in heading 22.02, in line with the ruling of the Court of Justice of the European Union in Case C-114/80 and Classification Opinions 2 202,99/2-4.

- (2) Re-examination of the classification of a GPS running watch with wrist-based heart rate monitor (Requests by the United States and Japan) Doc. NC2716Ea

The Union would classify the product in subheading 9 102,12 as a wrist-watch, in line with the CNEN for heading 91.02.

- (3) Re-examination of the classification of Sterilizer (Request by Ukraine) Doc. NC2717Ea

The Union would classify the product in heading 84.19, as it is a specific heading for sterilisers. The change in temperature takes place and has an important effect on the sterilising process. The apparatus does not fulfil any mechanical functions.

- (4) Re-examination of the classification of two products called “RF Generators and RF Matching Networks” (Request by South Korea) Doc. NC2718Ea, NC2745Eb, NC2747Ea

The Union would classify the products in heading 84.86 because they are identifiable machines used solely or principally for the manufacture of semiconductor devices.

VIII. FURTHER STUDIES

- (1) Classification of edible insects (Proposal by the Secretariat) Doc. NC2719Ea

The Union shall support possible transfers from both headings 02.10 and 04.10 for product 1. Product 2 could be transferred either from heading 04.10 or Chapter 16. Product 3 could be transferred from Chapter 16. Product 4 could be transferred either from Chapter 16 or 21.

- (2) Possible amendment of the Explanatory Note to heading 27.11 to clarify the classification of liquefied petroleum gas (LPG) (Proposal by the Secretariat) Doc. NC2720Ea

The Union shall support the creation of a subheading Explanatory Note to subheading 2 711,19.

- (3) Amendment of the Explanatory Notes to Rule 3 (b) to clarify the classification of sets Doc. NC2721Ea

The Union shall support keeping the *status quo* and current classification practices.

- (4) Possible amendment of the Explanatory Note to heading 91.02 Doc. NC2722Ea

The Union would prefer to wait for a definitive decision on the classification in point VII.2 before advancing with amending the HSEN.

- (5) Possible amendment of the Explanatory Note to heading 87.03 in relation to micro hybrid vehicles Doc. NC2723Ea

The Union shall support the amendment of the HSEN as it clarifies the classification of the new type of vehicles.

- (6) Classification of mild hybrid vehicles Doc. NC2724Ea

The Union would classify the product in subheading 8 703,40, as the electric motor is designed to give the vehicle a boost by supporting the engine operation.

- (7) Classification of a waxy product (Request by Ecuador) Doc. NC2725Ea

The Union would classify the product in heading 34.04, as the laboratory analysis confirmed that the product had a waxy character.

- (8) Possible amendment of the Explanatory Note to heading 95.03 (Proposal by the Union) Doc. NC2667Ea

The Union shall remain flexible to any additional editorial comments on the original EU proposal.

- (9) Possible amendment of the Explanatory Note to heading 95.05 (Proposal by the Union) Doc. NC2668Ea

The Union shall remain flexible to any additional editorial comments on the original EU proposal.

- (10) Classification of certain essential oils put up for retail sale (Request by Costa Rica) Doc. NC2672Ea

The Union would classify the product in heading 33.01. This product is a lavender essential oil containing monoterpene alcohols, thus it is not deterpenated and it is covered by heading 33.01. It is obtained by steam distillation process thus compliant with the HSEN to heading 33.01.

- (11) Classification of two floor polishers (Request by Costa Rica) Doc. NC2673Ea

The Union would classify the products in heading 84.79. Due to their technical characteristics, they are not of the kind commonly used for domestic purposes and considering Note 4 (a) to Chapter 85 they should be classified in heading 84.79.

- (12) Classification of a “Self-Propelled Articulated Boom Lift” (Request by South Korea) Doc. NC2674Ea

The Union would classify the product in heading 84.28 based on Regulation (EC) No 738/2000 for a similar product.

- (13) Classification of certain food preparations (Request by the United States) Doc. NC2676Ea, NC2742Ea

The Union shall request additional information on all four products concerned to determine classification.

Product 1: protein contents. If very high (over 85 %), heading 35.04 could be considered. Based on current information, the product could be classified in subheading 2 106,10 in line with Classification opinion 2 106,90/5.

Product 2: the Union would classify it in heading 22.02 if directly drinkable, or heading 21.06 if to be diluted before drinking.

Product 3: the Union would classify it in subheading 2 101,20, however, additional information about the caffeine content would be helpful.

Product 4: the product description is confusing, as it is not clear what the main ingredient is. If containing cocoa, it could be classified in heading 18.06, if not 19.05.

- (14) Classification of a “cutter/ripper” (Request by the Russian Federation) Doc. NC2677Ea

The Union shall note that the machine having many functions makes classification difficult to determine, and that it could be classified both in headings 84.30 and 84.32, thus in heading 84.32, using GIR 3(c).

- (15) Classification of certain new pneumatic tyres, of rubber, intended for vehicles used for the transportation of goods in construction, mining or industry (Request by the Russian Federation) Doc. NC2678Ea, NC2748Ea

The Union shall share the WCO Secretariat’s advice, and classify both products in subheading 4 011,20.

- (16) Classification of certain preparations of a kind used in animal feeding (Request by Canada) Doc. NC2679Ea, NC2743Ea

Based on the ruling of the Court of Justice of the European Union in Case C-144/15, the Union would classify the product in heading 23.09.

- (17) Classification of a product called “Tracing Light Box” (Request by Japan) Doc. NC2681Ea

The Union would classify the product in heading 94.05, as it has a multi-use function and is not equipped with any drawing instruments.

- (18) Classification of an electronic speed controller (Request by Tunisia) Doc. NC2682Ea

The Union would classify the product in heading 85.04, as suggested by the WCO Secretariat.

- (19) Possible amendment of the Explanatory Note to heading 27.10 (Proposal by Japan) Doc. NC2641Ea, NC2739Ea

The Union shall refrain to participate to discussions as the classification opinion from which this amendment stems cannot be applied in the Union due to the ruling of the Court of Justice of the European Union in Case C-330/13. It would be better to think about amending the HS in the future, and rearranging Note 2 to Chapter 27.

- (20) Possible misalignment between the English and French texts in the Explanatory Note to heading 85.01 Doc. NC2688Ea

The Union shall agree to the proposed amendment to use the French-language term “onduleur” as in other parts of the HS Nomenclature.

IX. NEW QUESTIONS

- (1) Classification of certain on-street garbage containers (Request by Tunisia) Doc. NC2726Ea

The Union would classify the products in heading 39.26 due to the larger size of the containers, not for domestic use. The Union notes that the product description should include the capacity of the containers in litres.

- (2) Classification of certain food preparations in liquid form (Request by Tunisia) Doc. NC2727Ea

The Union shall request more information concerning the contents of the products (water or juice, oily substances, other ingredients in addition to vitamins, dosage).

- (3) Classification of two products containing cannabidiol (CBD) (Request by the Secretariat) Doc. NC2728Ea

The Union shall propose to send the matter to the Scientific Sub-Committee, requesting information on (i) whether the products have enough active ingredients to give a therapeutic or prophylactic effect; and (ii) the minimum amount of CBD as active ingredient in any product to have a therapeutic or prophylactic effect.

- (4) Classification of dried fish subsequently treated with water (rehydrated dried fish) (Request by Norway) Doc. NC2729Ea

The Union could classify the product in Chapter 3, but more information is needed concerning if the flavour, texture of product were those of dried or fresh fish.

- (5) Classification of certain steam boiling generators for steam rooms (Request by Egypt) Doc. NC2730Ea

The Union would classify the products in heading 84.02 as proposed by the WCO Secretariat, in line with the heading text and HSEN to heading 84.02.

- (6) Classification of a product called "Soy bean flakes" (Request by Madagascar) Doc. NC2731Ea

The Union would classify the product in heading 23.04, similar to the product of Classification Opinion 2 304,00/1.

- (7) Classification of a 2-burner ethanol stove (Request by Kenya) Doc. NC2732Ea

The Union would classify the product in subheading 7 321,12., as ethanol fuel is in liquid form at room temperature and fits therefore with the subheading text.

- (8) Classification of an interactive kiosk for receiving complaints (Request by Egypt) Doc. NC2733Ea

The Union shall request additional information: whether the product could function and how with a USB device, or whether it can be used only via touch screen.

XI. ADDITIONAL LIST

- (1) Classification of a product called "baby corn cobs" (Request by the EU) Doc. NC2736Ea

The Union has requested a Classification Opinion.

- (2) Classification of a diesel power generating set with dual power rating (Request by Ghana) Doc. NC2737Ea

The Union would classify the product in subheading 8 502,13.

- (3) Classification of a TFT-LCD module (Request by South Korea) Doc. NC2740Ea

In line with Commission Regulation (EC) No 957/2006, Commission Implementing Regulations (EU) No 1201/2011 and No 1202/2011, and considering Note 2 (b) to Section XVI, the Union would classify the product in subheading 8 529,90.

- (4) Deletion of Classification Opinions 8 528,69/1 and 8 528,69/2 Doc. NC2741Ea

As the products are not anymore on the market, the Union shall support the deletion of those Classification Opinions.

- (5) Classification of a product called “partially defatted coconut powder” (Request from the Union) Doc. NC2746Ea

The Union has requested a Classification Opinion.’

Corrigendum to Council Decision (EU) 2020/1532 of 12 October 2020 on the position to be taken, on behalf of the European Union, in the 66th session of the Harmonized System Committee of the World Customs Organization in relation to the envisaged adoption of Classification Opinions, classification decisions, amendments to the Harmonized System Explanatory Notes or other advice on the interpretation of the Harmonized System, and of recommendations to secure uniformity in the interpretation of the Harmonized System under the Harmonized System Convention

(Official Journal of the European Union L 352 of 22 October 2020)

The Annex should read:

‘ANNEX

This Annex supplements the Annex to Decision (EU) 2020/1410.

II.2. Development of correlation tables between the 2017 and 2022 versions of the Harmonized System (Doc. NC2704, NC2749 and NC2753)

Concerning the correlation table for subheadings 4 407,13 and 4 407,14 (mixtures of S-P-F (spruce, pine and fir) and Hem-fir (Western hemlock and fir)), the Union shall support the correlations proposed by the WCO Secretariat in paragraph 20 of document NC2753.

Concerning the correlation table for subheading 4 418,83 (I beams), the Union shall support the correlations proposed by Japan in paragraph 14 of document NC2753.

Concerning the correlation table for subheading 7 019,71 (veils/thin sheets of glass fibres), the Union notes that the only transfer from HS 2017 would be from subheading 7 019,32.

Concerning the correlation table for subheadings 8 462,62 and 8 462,63 (forging machines), the Union shall support keeping all the subheadings proposed for transfer mentioned under HS 2017, including the ones in square brackets.

Concerning the correlation table for subheading 8 519,81 (telephone answering machines), the Union shall support the proposal of the WCO Secretariat in paragraph 26 of document NC2704.

Concerning the correlation table for subheading 8 539,51 (LED), the Union shall support the WCO Secretariat's conclusion in paragraph 24 of document NC2704.

Concerning the correlation table for new subheading 8 541,51 (semiconductor-based transducers), the Union notes that there is no evidence of parts classified separately in the HS 2017 version. Therefore no additional transfers are needed.

Concerning the correlation table for heading 88.06 (unmanned aircraft), the Union shall support option (i) mentioned in paragraph 25 of document NC2704.

Finally, the Union shall support the correction of some editorial errors in the draft Correlation Tables I and II, as set out in the Annex to document NC2753.

III.4. Classification in HS 2022 of certain collections and collectors' pieces of numismatic interest (Request by the Secretariat) (Doc. NC2711, NC2754)

The Union would classify the three products in the new subheading 9 705,31 in HS 2022. The Union notes that both Canada and the WCO Secretariat support the Union's proposal to delete the mention of the "coins generally known in the trade as 'ancients' or 'ancient coins'" from the second paragraph of Item (4) of new Part (A) of HSEs to heading 97.05.

III.5. Classification in HS 2022 of cartridges for 3D printers (Request by the Secretariat) (Doc. NC2712, NC2755)

The Union shall support the proposal for amending the HSEs which specifies that 3D printer cartridges with electronic components or mechanical mechanisms should be classified as parts of 3D printers.

The Union would classify products presented in both documents NC2712 and NC2755 in heading 84.85 in HS 2022 as parts of 3D printers considering the presence of electronic components for connection to a 3D printer.

III.7. Report of the 57th Session of the HS Review Sub-Committee (Doc. NR1434)

III.8. Matters for decision (Doc. NC2709)

- (a) Annexes C/4 and D/8 – Amendments to the Explanatory Notes (HS 2022) (Section VI)
- (b) Annexes C/5, D/9 and D/22 – Amendments to the Explanatory Notes (HS 2022) (Section VII)
- (c) Annexes C/8 and D/12 – Amendments to the Explanatory Notes consequential to the Article 16 Recommendation of 28 June 2019 (Section XIII)
- (d) Annexes C/13 and D/17 – Amendments to the Explanatory Notes consequential to the Article 16 Recommendation of 28 June 2019 (Section XX)
- (e) Annexes C/14 and D/18 – Possible amendments to the Explanatory Notes in respect of certain amusement park equipment (Proposal by the United States)

The Union shall agree to all proposed amendments in those documents.

- (f) Annexes C/1 and D/5 – Possible amendments to the Explanatory Notes to heading 15.09 in respect of other virgin olive oils, and heading 15.15 in respect of examples of microbial fats and oils

Concerning the HSEs to heading 15.09, the Union shall support the Union's proposal (option 2) and the new Canadian proposal (option 3). In item (D)(2), the Union shall support the use of "or" (option 2) instead of "and/or".

Concerning the HSEs to heading 15.15, the Union shall support the use of the expression "single cell organism" (option 1), and the use of "or" (option 2) instead of "and/or". In examples (a) and (b), the Union shall support the use of the expression "obtained from" (option 2).

- (g) Annexes C/3 and D/7 – Possible amendments to the Explanatory Notes in respect of "placebos" and "double-blinded clinical trial kits" in heading 30.06 (Request by Australia)

Concerning the sentence "The placebos of this heading also include [control vaccines] [controlled vaccines] [vaccines which are used as control substances and] that have been licensed for use in recognized clinical trials.", the Union shall not support adding this sentence to the text of item (12) of the HSEs to heading 30.06, as it is not clear what kind of substances are described by it. If the other Contracting Parties decide to add it, the Union shall support "vaccines which are used as control substances" (option 3), or if flexibility is needed, "control vaccines" (option 1).

Concerning the sentence "[Active ingredients to be trialled can include herbal medicinal products [for therapeutic or prophylactic uses].]", the Union shall remain flexible for adding it to the text, but shall not support an open list of examples as suggested by the United States.

- (h) Annexes C/6 and D/10 – Amendments to the Explanatory Notes Consequential to the Article 16 Recommendation of 28 June 2019 (Section IX)

The Union shall support the proposal to add Subheading Explanatory Notes to subheadings 4 412.41, 4 412.42 and 4 412.49. The Union shall request that the proposed text needs to be further analysed and improved in order to bring it in line with the current classification practices in the Union (for example, the orientation of the veneers).

- (i) Annexes C/7 and D/11 – Amendments to the Explanatory Notes consequential to the Article 16 Recommendation of 28 June 2019 (Sections XI and XII)

The Union shall support adding "paraseismic wall covering" and "geotextiles" to the list of examples of electronic textiles. In the text on "geotextiles", the Union shall support the text "a sensor made of fibres or at least being fully integrated in the fibres" (option 2) as previously suggested by the Union.

The Union shall support provisionally adopting the texts approved by the HS Review Sub-Committee.

- (j) Annexes C/12 and D/16 – Amendments to the Explanatory Notes Consequential to the Article 16 Recommendation of 28 June 2019 (Section XVII)

The Union shall support adding the reference to permanently integrated cameras in paragraph 3 of the HSEs to heading 88.06, provided that the Classification Opinion classifying a drone with an integrated camera in heading 85.25 is reviewed and aligned with HS 2022 and HSEN.

In relation to paragraph 4 of the HSEs to heading 88.06, the Union shall support the proposal by China with additional technical criteria introduced by the Union (second option).

- (k) Annexes C/15 and D/19 – Possible amendment to the Explanatory Notes to Chapter 97 in respect of certain cultural articles (Proposal by the United States)

The Union shall not support the list of items mentioned as examples, as these are very specific and limited to explain the scope of the articles to be classified under subheading 9 705,10.

The Union further notes that the definitions and examples provided would not give clarity on how to classify for example “traditional national costumes” or “old cars”.

- (l) Annexes C/16 and D/20 – Amendment to the GIR’s Explanatory Notes (HS 2022)

The Union shall support the original proposal by the WCO Secretariat (option 1, using the term “merely”, but remaining flexible for the expression “not further worked than”) and shall request to align the texts in English and French.

- III.9. Possible amendment of the Explanatory Note to heading 71.04 in relation to synthetic diamonds (Proposal by the Kimberley Process) (Doc. NC2757)

The Union shall agree to the proposed modifications to the new third paragraph to heading 71.04 and to the creation of new item (3) of the subheading Explanatory Notes to subheading 7 104,91.

- III.10. Classification of a micro-electro-mechanical systems (MEMS) element in HS 2022 (Proposal by the Secretariat)

The Union would classify the product in heading 85.41.’

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