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#### COVER NOTE

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Delegations will find attached document C(2019) 2055 final.

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EUROPEAN COMMISSION

> Brussels, 13.3.2019 C(2019) 2055 final

# COMMISSION DELEGATED REGULATION (EU) .../...

## of 13.3.2019

supplementing Directive (EU) 2018/2001 as regards the determination of high indirect land-use change-risk feedstock for which a significant expansion of the production area into land with high carbon stock is observed and the certification of low indirect landuse change-risk biofuels, bioliquids and biomass fuels

## EXPLANATORY MEMORANDUM

## 1. CONTEXT OF THE DELEGATED ACT

The recast Renewable Energy Directive<sup>1</sup> ("the "Directive") introduces a new approach to address emissions from indirect land-use change ("ILUC") associated to the production of biofuels, bioliquids and biomass fuels.

ILUC emissions can occur when pasture or agricultural land previously destined for food and feed markets is diverted to the production of fuels from biomass. The food and feed demand will still need to be satisfied either through intensification of current production or by bringing non-agricultural land into production elsewhere. In the latter case, ILUC (conversion of non-agricultural land into agricultural land to produce food or feed) can lead to the release of GHG emissions<sup>2</sup>, especially when it affects land with high carbon stock such as forests, wetlands and peat land. These GHG emissions can be significant and could negate some or all of the GHG emission savings of individual biofuels.

In order to address this issue, the Directive sets national limits, which will gradually decrease to zero by 2030, for high ILUC-risk biofuels, bioliquids and biomass fuels produced from food or feed crops for which a significant expansion of the production area into land with high carbon stock is observed. These limits will affect the amount of these fuels that can be counted when calculating the overall national share of renewables and the share of renewables in transport. Therefore, Member States will still be able to import and use fuels affected by the limits, but they will not be able to consider them as renewable energy and therefore they will not be able either to count them for their renewable targets.

The Directive introduces an exemption from these limits for biofuels, bioliquids and biomass fuels certified as low ILUC-risk.

In order to implement this new approach, this delegated act sets out specific criteria both for:

- 1. determining the high ILUC-risk feedstock for which a significant expansion of the production area into land with high carbon stock is observed; and
- 2. certifying low ILUC-risk biofuels, bioliquids and biomass fuels.

The delegated act is also due to accompany a report on the status of production expansion of relevant food and feed crops worldwide. The report provides information that Member States can use in conjunction with the criteria set out in the delegated act in order to identify high ILUC-risk biofuels, bioliquids and biomass fuels from and certify low ILUC-risk biofuels, bioliquids and biomass fuels from and certify low ILUC-risk biofuels, bioliquids and biomass fuels.

# 2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In light of the short timeframe between entry into force of the Directive (24 December 2018) and the deadline set in Article 26(2) to adopt the delegated act, this could not be supported by an impact assessment, despite the political importance of the file. The report on the status of

<sup>&</sup>lt;sup>1</sup> Directive (EU) 2018/2001 of the European Parliament and of the Council of 11 December 2018 on the promotion of the use of energy from renewable sources.

<sup>&</sup>lt;sup>2</sup> The  $CO_2$  stored in trees and soil is released when forests are cut down and peatlands are drained.

<sup>&</sup>lt;sup>3</sup> The report will shortly be published in the following webpage: <u>https://ec.europa.eu/energy/en/topics/renewable-energy/biofuels/sustainability-criteria</u>

production expansion of relevant food and feed crops worldwide nevertheless carries out a thourough literature review and analysis of the available scientific evidence on ILUC and production expansion of relevant food and feed crops worldwide. The related information allows for an in-depth assessment and comparison of the existing options in order for the Commission to deliver on the empowerment set out in Article 26(2) of the Directive.

Moreover, the delegated act draws on the results of several consultation exercises undertaken by the Commission in the context of the implementation of Article 26(2) of the Directive, including *inter alia*, two workshops with experts and stakeholders organised on 19 November 2018 and 5 March 2019 to facilitate the involvement of stakeholders and engaging leading scientists in the field and a meeting with the expert group set up to receive feedback from Member States' experts.

From these consultations, there is a consensus on the need to use the most recent data and to allow for future changes to be taken into account, *e.g.* at the review for 2023. There was however a split between those firmly calling to take regional differences into account and other favouring a global approach. Regarding the low ILUC-risk certification, most stakeholders underlined the need to ensure transparency and avoid fraud through the certification system. Furthermore, participants generally considered it important to ensure that the measures adopted to produce low-ILUC risk feedstock are additional, that is, go beyond business as usual.

The draft delegated act was published for public feedback on the Better Regulation Portal from 8 February to 8 March 2019. The report on the status of production expansion of relevant food and feed crops worldwide was also published on DG Energy website on 14 March.

The numerous contributions received in the context of the public feedback allowed to gather views from the entire spectrum of stakeholders concerned. The Commission was expressly prompted to reconsider the scope of the certifiable additional feedstock and of the main exceptions set out in Article 5 in the context of low ILUC-risk fuels certification. In particular, the exemptions from the financial additionality criteria applied to biofuels produced on unused land and by small holders were widely criticised in so far as they could create potential loopholes to the high ILUC-risk category and consequently lead to ILUC risks. Several comments also addressed the need to include the correct productivity factors for each species of crops in order to have a formula in Article 3 which is more fit-for-purpose and easier to use to determine which feedstock fall into the high ILUC-risk category.

As result of the feedback received, the general reference to unused land was deleted from Article 5, in order to only limit the relevant exception to the limited categories of abandoned or severely degraded land. The definition of small holders was also modified, in order to exclude potential abuses from corporations controlling a number of small producers; and the additional production to be certified will be calculated on the basis of a dynamic yield baseline, which more closely capture the actual production increases beyond business-asusual. The formula was also revisited in order to include productivity factors for each category of crops.

Finally, several recitals were redrafted in order to clarify that (i) the global approach with respect to each particular feedstock is the best approach to tackle the objectives set out in the Directive rather than a country-based approach; (ii) certifiable low ILUC-risk fuels in any case would refer to increases in production going beyond the business-as-usual scenario; (iii)

the specific criterion of financial additionality to be proven in case of measures to increase feedstock productivity is inspired by the well-established Clean Development Mechanism developed under the Kyoto protocol; (iv) the exemption for small farmers from proving financial additionality is based on the recognition of their greater potential versus large producers in terms of achievable productivity gains; (v) the amortisation of the investments in new production plays an important role in defining the time limit for taking into account the additional measures; and (vi) the Commission will further specify and harmonise rules on low ILUC-risk certification by virtue of the adoption of implementing acts.

## 3. LEGAL ELEMENTS OF THE DELEGATED ACT

The delegated act is adopted pursuant to Article 26(2) of the Directive, which empowers the Commission to do so in order to set out the criteria for certification of low indirect land-use change-risk bioliquids and biomass fuels and to determine the high indirect land-use change-risk feedstock for which a significant expansion of the production area into land with high-carbon stock is observed. The delegated act is based on the best available scientific data and accompanies a report on the status of worldwide production expansion of the relevant food and feed crops.

The delegated act lays down the key elements included in the relevant empowerment, in particular:

- (a) criteria for determining the high indirect land-use change-risk feedstock for which a significant expansion of the production area into land with high carbon stock is observed<sup>4</sup>;
- (b) general criteria for certification of low indirect land-use change-risk biofuels, bioliquids and biomass fuels;
- (c) specific criteria for additionality measures;
- (d) auditing and verification requirements for certification of low indirect land-use change-risk biofuels, bioliquids and biomass fuels.

<sup>&</sup>lt;sup>4</sup> The significance of the expansion is determined through the application of a formula factoring in GHG emissions savings achieved by biofuels produced from certain feedstock cultivated on land with high carbon stock as well as GHG emissions indirectly caused by the very same biofuels, as explained in the report on the status of production expansion of relevant food and feed crops worldwide.

### COMMISSION DELEGATED REGULATION (EU) .../...

#### of 13.3.2019

#### supplementing Directive (EU) 2018/2001 as regards the determination of high indirect land-use change-risk feedstock for which a significant expansion of the production area into land with high carbon stock is observed and the certification of low indirect landuse change-risk biofuels, bioliquids and biomass fuels

#### THE EUROPEAN COMMISSION,

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

Having regard to Directive (EU) 2018/2001 of the European Parliament and of the Council of 11 December 2018 on the promotion of the use of energy from renewable sources<sup>5</sup>, and in particular the fourth subparagraph of Article 26(2) thereof,

Whereas:

- (1) In order to address the issue of indirect land use change ('ILUC'), Directive (EU) 2018/2001 requires the Commission to adopt a delegated act to lay down provisions setting out the criteria for determining the high ILUC-risk feedstock for which a significant expansion of the production area into land with high carbon stock is observed, and for certifying low ILUC-risk biofuels, bioliquids and biomass fuels. Such provisions should accompany the report on the status of worldwide production expansion of the relevant feedstock ('report on feedstock expansion'), submitted to the European Parliament and to the Council on this date.
- (2) ILUC can occur when land previously devoted to food or feed production is converted to produce biofuels, bioliquids and biomass fuels. In that case, food and feed demand still needs to be satisfied, which may lead to the extension of agricultural land into areas with high carbon stock such as forests, wetlands and peat land, causing additional greenhouse gas emissions.
- (3) Sustainability and greenhouse gas saving criteria set out in both Directive 2009/28/EC of the European Parliament and of the Council<sup>6</sup> and Directive (EU) 2018/2001 do not account for ILUC emissions.
- (4) Directive (EU) 2015/1513 of the European Parliament and of the Council<sup>7</sup> not only acknowledged the existence of ILUC emissions, but also recognised, despite the uncertainty in calculating them, that the magnitude of greenhouse gas emissions linked to ILUC can lead to negating some or all of the greenhouse gas emissions savings of individual biofuels, as defined in that Directive, and bioliquids. Therefore, it introduced an overall limit to the amount of those fuels produced from cereal and other

<sup>&</sup>lt;sup>5</sup> OJ L 328, 21.12.2018, p. 82.

<sup>&</sup>lt;sup>6</sup> Directive 2009/28/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of the use of energy from renewable sources and amending and subsequently repealing Directives 2001/77/EC and 2003/30/EC (OJ L 140, 5.6.2009, p. 16).

<sup>&</sup>lt;sup>7</sup> Directive (EU) 2015/1513 of the European Parliament and of the Council of 9 September 2015 amending Directive 98/70/EC relating to the quality of petrol and diesel fuels and amending Directive 2009/28/EC on the promotion of the use of energy from renewable sources (OJ L 239, 15.9.2015, p. 1).

starch-rich crops, sugars and oil crops and from crops grown as main crops primarily for energy purposes on agricultural land that can be counted towards targets set out in Directive 2009/28/EC. That limit consists of a 7% maximum contribution of such fuels towards the final consumption of energy in rail and road transport in each Member State.

- (5) Directive (EU) 2018/2001 keeps the limitation on biofuels and biomass fuels produced from food and feed crops consumed in transport and strengthens it by introducing specific national limits for the total contribution of these fuels towards the Union renewable energy target for 2030. Those limits are determined by the 2020 national share of those fuels in final consumption of energy in rail and road transport in each Member State, with the possibility to increase them by one percentage point, up to a maximum of 7%.
- (6) Directive (EU) 2018/2001 also calls for a specific limit to biofuels, bioliquids and biomass fuels produced from food and feed crops with high ILUC-risk and for which a significant expansion of their feedstock production area into land with high carbon stock is observed, in the amount of their level of consumption in each Member State in 2019. Starting from 31 December 2023, their contribution should be gradually reduced to 0% by 2030 at the latest.
- (7) While it is widely acknowledged that there are risks arising from ILUC related to the use of food and feed crops for the production of fuels, scientific literature shows that the level of ILUC emissions depends on a variety of factors, including the type of feedstock used for the renewable fuel production, the level of additional demand for feedstock triggered by the use of biofuels, bioliquids and biomass fuels, and the extent to which land with high-carbon stock is protected worldwide.
- (8) Scientific literature also demonstrates that the impact of ILUC on the potential of biofuels, bioliquids and biomass fuels to achieve greenhouse gas emission savings is particularly pronounced for oil crops. Renewable fuels made from such feedstocks are therefore widely considered as having a higher ILUC-risk. This is reflected in Annex VIII, Part A of both Directive 2009/28/EC and Directive (EU) 2018/2001. The report on feedstock expansion, reflecting the latest best available scientific data on the worldwide expansion of the production area of food and feed crops into land with high carbon stock, confirms that these crops are also responsible for an overwhelming majority of the observed worldwide expansion of the production area of food and feed crops into land with high-carbon stock.
- (9) The report on feedstock expansion also highlights that the impact of the expansion of the production area of oil crops into land with high-carbon stock on the potential of biofuels, bioliquids and biomass fuels to achieve greenhouse gas emission savings depends on several factors. Among those, the absolute and relative magnitude of the land expansion since a specific reference year compared to the total production area of the relevant crop, the share of this expansion into land with high-carbon stock as well as the type of high-carbon stock area, play a crucial role in determining the significance of such expansion for the purposes of Directive (EU) 2018/2001. These factors, as well as the specific productivity factors for each group of crop, should therefore be taken into account when laying down the criteria for determining the high ILUC-risk biofuels, bioliquids and biomass fuels produced from food and feed crops for which a significant expansion of the feedstock production area into land with high-carbon stock is observed.

- (10) Taking into account all of the foregoing considerations, including all of the relevant scientific information and studies, the differences between the various feedstocks, the global nature of different commodities markets and the manner in which they function, the related risk of unintended or counterproductive deflection or diversion effects, the relative availability of complete data, and the periodic and frequent review of that data, as well as the relevant international obligations of the European Union, the most appropriate, objective and even-handed methodology at this stage of the regulatory process is considered to be one based on the overall worldwide position with respect to each particular feedstock, rather than an approach that would discriminate between particular countries. This represents the best achievable regulatory approach taking into account the competing but complementary objectives pursued by this regulation. Such an approach is further appropriately balanced by the possibility of low ILUC-risk certification.
- (11) In accordance with Article 26(2) of Directive (EU) 2018/2001, Member States are required to apply the criteria set out in this Regulation for determining the high indirect land-use change-risk feedstock for which a significant expansion of the production area into land with high-carbon stock is observed. They should do so on the basis of the information included in an annex, to be revised in accordance with this Regulation. The Commission should review the report on feedstock expansion regularly, to take into account the evolving circumstances and the latest available scientific evidence. The annex should be amended where appropriate.
- (12) Under certain circumstances, the ILUC impacts of biofuels, bioliquids and biomass fuels generally considered as high ILUC-risk can be avoided and the cultivation of the related feedstock can even prove to be beneficial for the relevant production areas. For such cases, it is necessary to lay down criteria to allow the identification and certification as low ILUC-risk biofuels, bioliquids and biomass fuels. Certified low ILUC-risk biofuels, bioliquids or biomass fuels should be exempted from the limit and gradual reduction set for high ILUC-risk biofuels, bioliquids and biomass fuels produced from food and feed crops, provided that they meet the relevant sustainability and greenhouse gas emissions saving criteria laid down in Article 29 of Directive (EU) 2018/2001.
- (13) Biofuels, bioliquids or biomass fuels should be considered low ILUC-risk only if the feedstock used for their production is cultivated as a result of the application of duly verifiable measures to increase productivity beyond the increases which would be already achieved in a business-as-usual scenario. In addition, these measures should ensure sustainability of feedstock in view of all requirements set in Directive 2009/28/EC or Directive (EU) 2018/2001 in relation to renewable energy targets.
- (14) As a further guarantee of the positive effects of low ILUC-risk certification, the additional feedstock to be used for low ILUC-risk fuels should be taken into account only if resulting from a limited category of measures. In particular, only measures that are financially attractive because they allow to reap the financial premium arising from such certification should be considered, in analogy with the financial additionality criteria applied under the Clean Development Mechanism of the Kyoto Protocol.
- (15) Furthermore, it is appropriate not to apply the financial additionality criterion to the additional feedstock cultivated on abandoned or severely degraded land or by independent small farm holders. This would in fact amount to an unreasonable administrative burden in light of the significant potential for productivity improvements and the barriers faced to finance the necessary investments. Therefore,

measures taken on abandoned or severely degraded land or by independent small farm holders should be exempted from proving compliance with the financial additionality criteria, without prejudice to the requirement of producing additional feedstock and complying with the sustainability criteria. In light of the statistical work carried out in several analyses, including the FAO smallholders data-portrait, holdings below 2 hectares should be considered small in this context.

- (16) Only actual increases in productivity in existing or new projects resulting from measures that aim to achieve additional yields should be considered. Therefore, the certification period should be limited to a reasonable time and scope allowing for the full amortisation of the relevant investment and for the existence of robust procedures to monitor the effectiveness of the certification.
- (17) In order to ensure a smooth certification process for low ILUC-risk biofuels, bioliquids or biomass fuels, economic operators should be able to rely on robust and reliable certification rules. These rules should take into account the role of voluntary national or international schemes in line with the recast text of Article 30 of Directive (EU) 2018/2001, which strengthened the robustness of the verification that they are tasked to perform in comparison with the corresponding provisions set out in Directive 2009/28/EC. In addition to the national schemes recognised by the Commission in accordance to Article 30(6) of Directive (EU) 2018/2001, voluntary schemes may certify low ILUC-risk biofuels, bioliquids and biomass fuels as they do for the purpose of certifying compliance with the sustainability criteria set out in Article 29 of Directive (EU) 2018/2001.
- (18) In order to ensure that the information provided by economic operators is transparent, accurate, reliable and protected against fraud, overarching rules should be introduced on certification of low indirect land-use change-risk biofuels, bioliquids or biomass fuels providing for an adequate standard of independent auditing of the claims submitted by economic operators. Such rules, including on group certification, may be further specified and harmonised by virtue of the adoption of implementing acts in accordance with Article 30(8) of Directive (EU) 2018/2001,

HAS ADOPTED THIS REGULATION:

#### Article 1

#### Subject matter

This Regulation lays down the criteria for determining the high ILUC-risk feedstock for which a significant expansion of the production area into land with high carbon stock is observed, and for certifying low ILUC-risk biofuels, bioliquids and biomass fuels.

## Article 2

#### Definitions

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

(1) 'oil crops' means food and feed crops such as rapeseed, palm, soybeans and sunflower, that are not starch rich crops and sugar crops that are commonly used as feedstock for the production of biofuels, bioliquids and biomass fuels;

- (2) 'unused land' means areas which, for a consecutive period of at least 5 years before the start of cultivation of the feedstock used for the production of biofuels, bioliquids and biomass fuels, were neither used for the cultivation of food and feed crops, other energy crops nor any substantial amount of fodder for grazing animals;
- (3) 'abandoned land' means unused land, which was used in the past for the cultivation of food and feed crops but where the cultivation of food and feed crops was stopped due to biophysical or socioeconomic constraints;
- (4) 'severely degraded land' means land as defined in point 9 of Annex V, part C to Directive (EU) 2018/2001;
- (5) 'additionality measure' means any improvement of agricultural practices leading, in a sustainable manner, to an increase in yields of food and feed crops on land that is already used for the cultivation of food and feed crops; and any action that enables the cultivation of food and feed crops on unused land, including abandoned land, for the production of biofuels, bioliquids and biomass fuels;
- (6) 'additional feedstock' means the additional amount of a food and feed crop produced in a clearly delineated area compared to the dynamic yield baseline and that is the direct result of applying an additionality measure.
- (7) 'dynamic yield baseline' means the average yield from the delineated area where an additionality measure has been taken, calculated over the 3-year period immediately preceding the year of the application of such measure, taking into account the average yield increase observed for that feedstock over the previous decade and the yield curves over the life time in case of permanent crops, excluding yield fluctuations;
- (8) 'land with high-carbon stock' means wetlands, including peatland, and continuously forested areas within the meaning of Article 29(4)(a), (b) and (c) of Directive (EU) 2018/2001;
- (9) 'small holders' means farmers who conduct independently an agricultural activity on a holding with an agricultural area of less than 2 hectares for which they hold ownership, tenure rights or any equivalent title granting them control over land, and who are not employed by a company, except for a cooperative of which they are members with other small holders, provided that such a cooperative is not controlled by a third party;
- (10) 'permanent crops' means non-rotational crops other than permanent grassland and permanent pasture that occupy the land for five years or more and yield repeated harvests.

## Article 3

# Criteria for determining the high indirect land-use change-risk feedstock for which a significant expansion of the production area into land with high carbon stock is observed

For the purpose of determining the high indirect land-use change-risk feedstock for which a significant expansion of the production area into land with high-carbon stock is observed, the following cumulative criteria shall apply:

(a) the average annual expansion of the global production area of the feedstock since 2008 is higher than 1% and affects more than 100,000 hectares;

(b) the share of such expansion into land with high-carbon stock is higher than 10%, in accordance with the following formula:  $x_{here} = \frac{x_f + 2.6x_p}{x_f + 2.6x_p}$ 

$$a_{hcs} = \frac{1}{PF}$$

where

 $x_{hcs}$  = share of expansion into land with high-carbon stock;

 $x_f$  = share of expansion into land referred to in Article 29(4)(b) and (c) of Directive (EU) 2018/2001;

 $x_p$  = share of expansion into land referred to in Article 29(4)(a) of Directive (EU) 2018/2001 including peatland;

PF = productivity factor.

PF shall be 1,7 for maize, 2,5 for palm oil, 3,2 for sugar beet, 2,2 for sugar cane and 1 for all other crops.

The application of the criteria in points (a) and (b) above shall be based on the information included in the Annex, as revised in accordance with Article 7.

#### Article 4

# General criteria for certification of low indirect land-use change-risk biofuels, bioliquids and biomass fuels

- 1. Biofuels, bioliquids and biomass fuels may only be certified as low indirect land-use change-risk fuels if all the following criteria are met:
  - (a) the biofuels, bioliquids and biomass fuels comply with the sustainability and greenhouse gas emissions saving criteria set out in Article 29 of Directive (EU) 2018/2001;
  - (b) the biofuels, bioliquids and biomass fuels have been produced from additional feedstock obtained through additionality measures that meet the specific criteria set out in Article 5;
  - (c) the evidence needed to identify the additional feedstock and substantiate claims regarding the production of additional feedstock is duly collected and thoroughly documented by the relevant economic operators.
- 2. The evidence in point (c) of paragraph 1 shall at least include information on the additionality measures taken to produce additional feedstock, the delineated areas on which these measures have been applied and the average yield achieved from the land where these measures have been applied over the 3-year period immediately preceding the year when the additionality measure was applied.

## Article 5

#### Additionality measures

- 1. Biofuels, bioliquids and biomass fuels may only be certified as low indirect land-use change-risk fuels if:
  - (a) the additionality measures to produce the additional feedstock meet at least one of the following conditions:

- (i) they become financially attractive or face no barrier preventing their implementation only because the biofuels, bioliquids and biomass fuels produced from the additional feedstock can be counted towards the targets for renewable energy under Directive 2009/28/EC or Directive (EU) 2018/2001;
- (ii) they allow for cultivation of food and feed crops on abandoned land or severely degraded land;
- (iii) they are applied by small holders;
- (b) the additionality measures are taken no longer than 10 years before the certification of the biofuels, bioliquids and biomass fuels as low indirect land-use change-risk fuels.

# Article 6

# Auditing and verification requirements for certification of low indirect land-use change-risk biofuels, bioliquids and biomass fuels

- 1. For the purpose of certifying low indirect land-use change-risk biofuels, bioliquids and biomass fuels, economic operators shall:
  - (a) submit reliable information substantiating their claims ensuring that all requirements set out in Articles 4 and 5 have been duly fulfilled;
  - (b) arrange for an adequate standard of independent auditing of the information submitted and an adequate level of transparency reflecting the need for public scrutiny of the auditing approach; and
  - (c) provide evidence that audits are conducted.
- 2. The auditing shall verify that information submitted by economic operators is accurate, reliable and protected against fraud.
- 3. In order to demonstrate that a consignment is to be considered as a low indirect landuse change-risk biofuel, bioliquid or biomass fuel, economic operators shall use the mass balance system set out in Article 30(1) of Directive (EU) 2018/2001. Voluntary schemes may be used to demonstrate compliance with the criteria set out in Articles 4 to 6 in accordance with Article 30 of Directive (EU) 2018/2001.

# Article 7

# Monitoring and review

The Commission shall, by 30 June 2021, review all relevant aspects of the report on feedstock expansion, in particular the data on feedstock expansion, as well as the evidence on the factors justifying the small holders provision in Article 5(1), and, if appropriate, amend this Regulation. This revised report shall be submitted to the European Parliament and the Council and become the basis for the application of the criteria set out in Article 3.

The Commission shall review thereafter the data included in the report in light of evolving circumstances and latest available scientific evidence.

# Article 8

# 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, 13.3.2019

For the Commission The President Jean-Claude JUNCKER