



Council of the
European Union

Brussels, 11 July 2014
(OR. en)

7305/14

AGRILEG 151

COVER NOTE

From:	European Commission
date of receipt:	9 July 2014
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union

No. Cion doc.:	D032665/03
Subject:	COMMISSION REGULATION (EU) No .../. of XXX amending Regulation (EU) No 283/2013 as regards the transitional measures applying to procedures concerning plant protection products (Text with EEA relevance)

Delegations will find attached document D032665/03.

Encl.: D032665/03



Brussels, **XXX**
SANCO/10422/2014 Rev. 1
(POOL/E3/2014/10422/10422R1-
EN.doc) D032665/03
[...](2014) **XXX** draft

COMMISSION REGULATION (EU) No .../..

of **XXX**

**amending Regulation (EU) No 283/2013 as regards the transitional measures applying to
procedures concerning plant protection products**

(Text with EEA relevance)

COMMISSION REGULATION (EU) No .../..

of **XXX**

amending Regulation (EU) No 283/2013 as regards the transitional measures applying to procedures concerning plant protection products

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC¹, and in particular Article 78(1)(b) thereof,

Whereas:

- (1) Commission Regulation (EU) No 283/2013² repealed Commission Regulation (EU) No 544/2011³ and laid down new data requirements for active substances.
- (2) In order to permit Member States and the interested parties to prepare themselves to meet those new requirements, Regulation (EU) No 283/2013 sets transitional measures concerning both submission of data for applications for the approval, renewal of approval or amendment to the approval of active substances and submission of data for applications for authorisation, renewal of authorisation or amendment to the authorisation of plant protection products.
- (3) In order to allow, in certain cases, the submission of data concerning the active substances in applications for authorisation or for amendment of the authorisation of plant protection products in accordance with the data requirements in force at the time of their approval or renewal, the transitional measures as regards procedures concerning the authorisation of plant protection products should be amended. The reason for such change is to prevent the occurrence of disparities in the assessment of data generated in accordance with the new data requirements by Member States belonging to different zones and, accordingly, to preserve a uniform and harmonized approach to the assessment of those data through their evaluation at Union level.

¹ OJ L 309, 24.11.2009, p. 1.

² Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 3.4.2013, p. 1).

³ Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances (OJ L 155, 11.6.2011, p. 1).

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

HAS ADOPTED THIS REGULATION:

Article 1

Article 4(1) of Regulation (EU) No 283/2013 is replaced by the following:

- ‘1. In case of applications for authorisation, as referred to in Article 28 of Regulation (EC) No 1107/2009, which concern plant protection products containing one or more active substances for which the dossiers have been submitted in compliance with Article 3 or for which the approval has not been renewed in accordance with Article 14 of Regulation (EC) No 1107/2009 and in accordance with Commission Implementing Regulation (EU) No 844/2012⁴, Regulation (EU) No 544/2011 shall continue to apply to the submission of data concerning this(these) active substance(s).’

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,

For the Commission
The President
José Manuel BARROSO

⁴ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).