



Brussels, XXX
SANTE/11469/2018
[...] (2018) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

amending Implementing Regulation (EU) No 686/2012 as regards the nomination of rapporteur Member States and co-rapporteur Member States for the active substances glyphosate, **Buiten reikwijdte verzoek**

and

amending Implementing Regulation (EU) No 844/2012 as regards the possibility that a group of Member States assumes jointly the role of the Rapporteur Member State

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

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(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 19, thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) No 686/2012² allocates the evaluation of active substances to a rapporteur Member State and to a co-rapporteur Member State for the purposes of the renewal procedure. Since the evaluations of the active substances glyphosate, **Buiten reikwijdte verzoek** have not yet been allocated to a Member State or to a co-rapporteur Member State and their approval expires between 1 January 2022 and 31 December 2024, it is appropriate to proceed to such allocation.
- (2) That allocation should be made in such a way that a balance is achieved as regards the distribution of the responsibilities and the work between Member States.
- (3) In exceptional cases, the expected workload and the complexity related to the evaluation of a specific active substance might exceed the capacities of a single Member State as a rapporteur. In these cases, the expected high workload, the particular sensitivity and complexity of the scientific assessment of the dossier for a specific substance warrants a broader repartition of the workload and a pooling of expertise of several Member States may be warranted by either designating one Member State as rapporteur, seconded by several co-rapporteur Member States, or a group of Member States acting jointly as Rapporteur Member State. It should therefore be clarified that, in such cases the latter case, it is possible that the role of the rapporteur Member States can be assumed jointly by a group of Member States. In this case, an appointment of a co-rapporteur Member State would appear redundant and

¹ OJ L 309, 24.11.2009, p. 1.

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

should therefore be omitted. Accordingly, where several Member States perform jointly the role as rapporteur Member State, they should agree on the modalities of the work organisation. This may include the involvement of a structure that supports and facilitates their cooperation and functions as the single interlocutor, on behalf of the group of Member States acting as rapporteur Member State, with the applicant.

~~(4)~~ Against this background, the evaluation of the active substance glyphosate should be allocated to a group of Member States acting jointly as rapporteur Member State.

~~(5)~~(4) **Buiten reikwijdte verzoek**

~~(6)~~(5) In agreement with the Member States concerned, it is also considered necessary to **Buiten reikwijdte verzoek**

~~(7)~~(6) Implementing Regulation (EU) No 686/2012 should therefore be amended accordingly.

~~(8)~~(7) Commission Implementing Regulation (EU) No 844/2012³ provides for the implementation of the renewal procedure for active substances as provided for in Regulation (EC) No 1107/2009.

~~(9)~~(8) This Commission Implementing Regulation provides for the handling of applications and the subsequently submitted supplementary dossier and its assessment by one Member State as **R**apporteur Member State supported by one Member State acting as co-rapporteur Member State. However, the procedural modalities should be clarified for the exceptional cases referred to above, where, the evaluation is allocated to a group of Member States acting jointly as rapporteur Member States in accordance with Regulation (EU) No 686/2012. This group should jointly assume the role given to the rapporteur Member State and the co-rapporteur Member State by Regulation (EU) No 844/2012.

~~(10)~~(9) The possibilities to **request-require** fees and charges in accordance with Article 74 of Regulation (EC) No 1107/2009 should also be clarified for the renewal procedure.

~~(11)~~(10) Implementing Regulation (EU) No 844/2012 should therefore be amended accordingly.

~~(12)~~(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

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

³ 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 of 21 October 2009 concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p.26).

Met opmerkingen ^{5.1.2.0 W}: Since this is only presented as a possibility, I would prefer to keep the text as it was proposed by the Commission.

Met opmerkingen ^{5.1.2.0 W} Suggestion ^{Buiten reikwijdte verzoek}

Met opmerkingen ^{5.1.2.0 W} ^{Buiten reikwijdte verzoek}

Met opmerkingen ^{5.1.2.0 W} The drafted Article 2(4) states "required".

- (1) Article 1 is replaced by the following: 'For the purposes of the renewal procedure, the evaluation of each active substance set out in the first column of the Annex is allocated either to a rapporteur Member State, as set out in the second column of that Annex, and to a one or more a co-rapporteur Member States, as set out in the third column of that Annex, or to a group of Member States acting jointly as Rapporteur Member State, as set out in the fourth column of that Annex. In the latter case, no co-rapporteur is appointed.'
- (2) The Annex is amended in accordance with the Annex to this Regulation.

Article 2

Implementing Regulation (EU) No 844/2012 is amended as follows:

- (1) Article 1 subparagraph 1. is replaced by 'Without prejudice to the fourth subparagraph, an application for the renewal of an approval of an active substance shall be submitted by a producer of the active substance to the rapporteur Member State, as set out in the second column of the Annex to Commission Implementing Regulation (EU) No 686/2012 and to the co-rapporteur Member State or co-rapporteur Member States as set out in the third column of that Annex, or to each of the Member States in a group of Member States acting jointly as Rapporteur Member State, no later than three years before the expiry of the approval'.
- (2) The following new subparagraphs are inserted after the third subparagraph of Article 1 1. 'Where a group of Member States jointly assumes the role of the Rapporteur Member State as set out in the fourth column of the Annex to Commission Implementing Regulation (EU) No 686/2012, no co-rapporteur Member State shall be appointed. In this case, all references to 'the rapporteur Member State' and 'the co-rapporteur Member State' in this Regulation shall be deemed to be references to 'the group of rapporteur Member States'.

Prior to the expiry of the deadline for submission of the application, the Member States forming acting jointly the group of Rapporteur Member States as rapporteur Member State shall agree on the repartition of the all tasks and workload, and agree as to which of the Member States shall receive and handle any communication on behalf of this group with the applicant, the Authority, the Commission, and other Member States provided for by this Regulation. They may entrust an existing body or create a specific body to support and facilitate the organisation of their work and to act, on their joint behalf, as a single contact point with the applicant, and inform the applicant thereof, and agree as to which of the Member States shall receive and handle any communication on behalf of this group with the applicant, the Authority, the Commission, and other Member States provided for by this Regulation. This Member State shall also in consultation with the other Member States forming part of the group of rapporteur Member States assess any confidentiality requests and carry out the application check pursuant to Article 3 and the completeness check of the supplementary dossier pursuant to Article 8. The applicant fulfils his obligations by submitting all required information to this designated Member State.

All Member States forming part of the group of rapporteur Member States shall endeavour to reach consensus during the evaluation.'

- (3) Point (h) of Article 11 1. is replaced by 'the points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur Member State, where relevant, and or, where applicable, the points where there is no agreement

Met opmerkingen ^{5.1.2.a Woo} : **5.1.2.a Woo**
 prefers the previous draft from the Commission and has therefore inserted this text here.

Met opmerkingen ^{5.1.2.a Woo} : Yes, we have to be very clear how to deal with communication, but the regulation is not the suitable document. Therefore, I have deleted the text proposed by ^{5.1.2.a Woo} The yellow marked text is the text proposed by the Commission and that is strongly preferred by ^{5.1.2.a Woo} The details will be in the governance model and, if needed, in a separate document with more details on responsibilities and practical issues, see my e-mail sent on 21 December.

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between several Member States forming a group of rapporteur Member States, where relevant.'

- (4) A new Article 13a 'Fees and charges' is inserted after Article 13 and before Article 14: 'Member States may require payment of fees and charges in accordance with Article 74 of Regulation (EC) No 1107/2009 to recover the costs associated with any work they carry out within the scope of this Regulation.'

Article ~~3~~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
Jean-Claude JUNCKER*