

Disclaimer: 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. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

Amendment of Regulation 844/2012¹

Amendment to Article 1 (1) (small change to 1st subparagraph and a new (fourth) subparagraph– inserted after current subparagraph 3):

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 as set out in the third column of that Annex, no later than three years before the expiry of the approval.

When submitting an application, the applicant may, pursuant to Article 63 of Regulation (EC) No 1107/2009, request certain information to be kept confidential. In that event, the applicant shall present such parts of the application physically separated, setting out the reasons for requesting confidentiality.

At the same time, the applicant shall submit any data protection claims pursuant to Article 59 of Regulation (EC) No 1107/2009.

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’ 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 the group of Rapporteur Member States shall agree on the repartition of the tasks and workload and agree as to which of the Member States included in this group 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 Article 3. The applicant fulfils its 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.

Amendment of Article 11(1)(h):

The draft renewal assessment report shall also include the following:

- (h) the points on which the co-rapporteur Member State did not agree with the assessment by the rapporteur Member State, where relevant, **and, where applicable, the points where there is no agreement between several Member States forming a group of rapporteur Member States**, where relevant.

¹ A recital would clarify, for both regulations, that the appointment of a group of RMS will only be an exceptional option for files that are particularly complex as to workload under a qualitative and quantitative perspective.

Disclaimer: 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. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

Insertion of a new article 13(a):

Fees and Charges:

Member States may require payment of fees or 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.

Changes to Regulation 686/2012:

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

(1) In parts A, B, and C, a fourth column is inserted with the following heading: "group of Rapporteur Member States (in alphabetical order)"

ANNEX

(4) In Part C, the following entry is added following the alphabetical order:

Active substance	Rapporteur Member State	Co-rapporteur Member State	Group of Rapporteur Member States (in alphabetical order)
'Glyphosate	-	-	AA, BB, CC (...)'