anses
agence nationale de sécurité sanitaire
alimentation, environnement, travail

Connaître, évaluer, protéger

**Direction d'évaluation**
**des produits réglementés**

**Glyphosate Renewal Group**

**(par email)**

**Unité de Coordination**
**des Intrants du Végétal**

**Objet :** Notification de renouvellement d'approbation du glyphosate

Maisons-Alfort, le 9 janvier 2019

**Dossier suivi par :**
AGG France

**E- mail :**
AGG-France@anses.fr

**N. Réf. : 2019-6550**

Madame, Monsieur,

L'Anses, autorité compétente membre du groupe pour l'évaluation du glyphosate, a reçu le 13 décembre 2019 votre demande en vue du renouvellement du glyphosate.

Nous avons identifié des éléments manquants ou imprécis, nécessitant une mise à jour de votre demande. Ces éléments sont listés à l'annexe 1 de la présente.

Nous vous demandons de nous transmettre au plus tard d'ici le **23 janvier 2020** une notification révisée, contenant les éléments manquants spécifiés à l'annexe 1, accompagnés, lorsque cela est nécessaire, d'explications supplémentaires.

Pour votre information, le caractère nécessaire des nouvelles études qui seront soumises n'a pas été évalué à ce stade. Il en est de même pour les revendications de protection des données.

Je vous prie de croire, Madame, Monsieur, en l'assurance de ma considération distinguée.

*Traduction de courtoisie/English version*

***Result of the AGG's check of your application for renewal of the approval of Glyphosate under Commission Implementing Regulation (EU) No 844/2012***

*Anses, being the competent authority of France which is one of the Members of the Assessment Group on Glyphosate (AGG), received on the 13th of December 2019 your application for renewal of the approval of Glyphosate.*
*We have found that some elements are missing or unclear and that your application therefore needs to be updated. These elements are listed in the Appendix 1 to this letter.*

*We ask you to submit at the latest by **23rd of January 2020** a revised application including the missing elements and, where appropriate, clarifications, as specified in the Appendix 1 to this letter.*
*For your information, we did at this stage not consider whether each one of the new studies intended to be submitted will eventually be considered as necessary for the evaluation. Also, we do not consider the claims for data protection.*

*Yours sincerely,*

Pour l'AGG-France,

## Appendix 1: Elements that should be addressed in a revised application.

| Points to check | Glyphosate Renewal Group |
|---|---|
| **Date of receipt** | |
| Application received before deadline 15 December 2019? | Yes |
| **Format and contents of the application according to Article 2 of Regulation (EU) No 844/2012** | |
| Format as set out in the Annex of Regulation (EU) No 844/2012 used? | 1. Information concerning the applicant: Yes<br>Please note that an update of the application (i.e. additional information regarding possible new members of the Glyphosate Renewal Group) is not allowed once a decision on the admissibility has been made. This information should be provided in the dossier to be submitted before 15 June 2020.<br><br>2. Information to facilitate identification: **No. The applicant should ensure that the chemical names (IUPAC and ISO), CAS No and EC No are up-to-date.**<br>There are doubts whether the correct IUPAC and ISO names are used in all cases. Furthermore, for the glyphosate potassium salt an old CAS number is given and EC numbers are available for glyphosate potassium salt, glyphosate ammonium and glyphosate dimethylammonium salt.<br><br>3. New information: Lists 3.1 and 3.2 provided: Yes.<br>**List 3.3 (timetable) provided: No. The applicant should update the application with expected dates for finalisation of any new and ongoing studies (currently only stated as "pending").**<br>In pre-submission meetings AGG was already informed that only two of the on-going studies will be finalised after June 2020 but the application provides information not only for the AGG but also for EFSA, Commission and others, so expected dates for finalisation of new studies should be provided.<br>Preferably, list 3.1 is an overall list with lists 3.2 and 3.3 being subsets of list 3.1.<br><br>4. **Signature: No, the application has not been signed. The applicant must send a signed version.**<br>It seems that an error has occurred since the text "The applicant confirms that the above information submitted included in the application is correct" has been inserted at the very end of the application (after the Appendix 1). The text should be moved above the date and signature of the person competent to act for the applicant.<br><br>5. **Chapter 5 of the Appendix 1 to the application (identified areas for which detailed re-evaluation is needed in dossier from notifier and in evaluation by RMS/co-RMS): No, the chapter should be removed.**<br>On page 18 it seems that text is missing after the following sentence "The dossier supporting the approval renewal and its evaluation will/should focus on the main following areas:". However, as chapter 5 is not part of the formats as set out in Regulation (EU) No 844/2012 and SANCO/2012/11251 rev.5 (22 March 2019) and as it is not for the applicant to identify areas for which detailed re-evaluation is needed, the applicant is requested to remove this chapter from the application. |
| New information listed that applicant intends to submit demonstrating that such information is necessary in accordance with the first subparagraph of Article 15(2) of 1107/2009? | • New information listed: N**o. The applicant may need to update the new information based on the comments below:**<br>- It is noted that no new studies for the representative product (KCP studies) are listed. Is this correct? Please note that some studies referred to as KCA studies mention the representative product MON 52276 and may have to be listed as a KCP study.<br>- Under KCA 4.1.2 it is not clear whether a single study will be submitted. Please clarify and, if applicable, list all studies intended to be submitted.<br>- In several entries (i.e. KCA 5.8.3, KCA 6.7, KCA 8.1.5, 8.2.3) an assessment is mentioned to be submitted. Please note that if new studies underlie these assessments, these should be listed. |

| Points to check | Glyphosate Renewal Group |
|---|---|
| | - It is noted that no study/assessment of impact on biodiversity through the food chains are listed. With reference to the concern specified in the Commission implementing regulation (EU) 2017/2324, the AGG expects that the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions will be addressed in the dossier.<br><br>• Justifications: **No (not all). The applicant should update the justifications based on the comments below:**<br>- Where it is currently only stated "Data requirement" the applicant should provide more specific justifications.<br>- The applicant should specify general wording as "current guidance documents".<br>- New studies listed under KCA 2.4 to 2.9 should be further justified as neither the data requirements nor the guidance documents were amended.<br>- Please note that the studies KCA 5.4.1 and KCA 6.3. are available (according to applicant's remarks), but are listed as "pending". Author and date of study are to be provided.<br>- For the vertebrate study intended to be submitted under KCA 8.1.2, the applicant should provide further clarification to justify why this study can be performed with respect to Article 62 of Reg. (EC) 1107/2009 and Directive 2010/63. |
| Separate list of any new studies involving vertebrate studies? | Yes<br>See above for further justification of the study intended to be submitted. |
| **Claims for confidentiality and data protection claims according to Article 1 of Regulation (EU) No 844/2012** | |
| Claims for confidentiality submitted? | Yes<br>AGG can agree to the claims for confidentiality. |
| Claims for data protections submitted? | Yes<br>It should be noted that data protection can only be claimed for studies and not for rationale. |
| Other remarks | It is noted that on page 11 of the application reference is only made to Commission Implementing Regulation (EU) 2016/1313 whilst the most recent regulation is Commission Implementing Regulation (EU) 2017/2324. Please also include the latter regulation. |