

GRG AGG PRE-SUBMISSION MEETING



Monheim, 4 June 2020

GRG Participants

- [REDACTED] (knoell consult)
 - [REDACTED] (Bayer, global regulatory manager glyphosate)
 - [REDACTED] (Bayer, chair of GRG regulatory working group)
 - [REDACTED] (Nufarm, European regulatory lead)
 - [REDACTED] (Nufarm, regulatory)
 - [REDACTED] (Syngenta, regulatory)
 - [REDACTED] (Albaugh, regulatory)
 - [REDACTED] (Ciech, regulatory)
 - [REDACTED] (Ciech, regulatory)
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Topics

- Company specific confidential information (document J)
 - Updated Application document – ongoing studies
 - Public literature articles in the dossier
 - Studies currently not accessible for GRG
 - Redaction of summary dossier
 - Submission of dossier on USB hard drives
 - Proof of payment of submission fees to ANSES
 - Admissibility timeline
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Company specific confidential information (document J)

GRG would like to share some recent developments regarding company specific confidential information

- **AFRASA:**

- The specifications of the 5 sources of AFRASA will be part of the **joint document J** included in the “AIR5 dossier” submitted by knoell to AGG in June 2020
- In the same AIR5 dossier, the **interim company-specific document J** (individual AFRASA document) will be also included. Due to the COVID-19 circumstances, AFRASA’s operational facilities in their home and production countries were affected, and therefore it was not possible to keep the timelines of the running studies (company specific sources of technical material) and to finalize them in time. Part of the supporting information will be slightly delayed.
- Plan is to **complete the AFRASA specific document J** during admissibility check, to deliver the updated dossier in July 2020

- **ALBAUGH:**

- The specifications of the sources of ALBAUGH will be part of the **joint document J** included in the “AIR5 dossier” submitted by knoell to AGG in June 2020
- In the same AIR5 dossier, the **interim company-specific document J** (individual ALBAUGH document) will be also included. Due to technical problems it was not possible to keep the timeline of one study (company specific source of technical material) and to finalize it in time. Part of the supporting information will be slightly delayed.
- Plan is to **complete the ALBAUGH specific document J** during admissibility check, to deliver the updated dossier in July 2020

Question to AGG:

- Any comments?

Company specific confidential information (document J)

GRG would like to share some recent developments regarding company specific confidential information

- **CIECH:**

- CIECH informed GRG that they will not submit any company specific information for technical material sources
- **No CIECH specific document J** will be included in the submitted dossier

Question to AGG:

- Any comments?

Updated Application document – ongoing studies

- Updated Application document was submitted to AGG on 19 May 2020
- Updated Application document is also included in **document F** of the to-be-submitted dossier
- The Application document includes **currently still ongoing and planned** GRG studies in support of the renewal evaluation
- Currently **5 studies are targeted for finalization in July 2020** and thus available for submission during the admissibility check period (see next page for details)

Question to AGG:

- Would submission of any finalized study report during admissibility check period be acceptable for AGG and would AGG consider these final study reports in their assessment?

Updated Application document – ongoing studies

KCA 7.1.2.1.2	NN [REDACTED]	May Jul 2020	Rate of degradation of AMPA in acidic soils incubated under aerobic conditions. AMPA – Rate of Degradation of Aminomethylphosphonic Acid (AMPA) in Aerobic Soil	To meet requirements of Commission implementing regulation (EU) 2017/2324.	DP
KCA 7.2.2.2	[REDACTED]	Jul 2020	Characterization of the material in unidentified peak from study CRO-2019-0268. Glyphosate - Aerobic Mineralisation of [¹⁴ C]Glyphosate in Surface Water	The confirmatory method showed the presence of a peak that exceeded levels requiring further characterization in the original study. [REDACTED] April 2020: "Glyphosate – Aerobic Mineralisation of [¹⁴ C] Glyphosate in Surface Water". Efforts to characterize were undertaken in the original study, but time did not permit adequate characterization.	
KCA 8.2.6	NN	Jul 2020	Algae study (freshwater green) with the metabolite AMPA	Data requirement for active substance according to EC Regulation 283/2013 to support risk assessment for algal species.	DP
KCP 10.4.2.1	NN	Jul 2020	<i>Folsomia candida</i> with the representative formulation MON52276	Data requirement for active substance according to EC Regulation 284/2013 to support risk assessment for sublethal effects to additional soil organisms.	DP
KCP 10.4.2.1	NN	Jul 2020	<i>Hypoaspis aculeifer</i> study with the representative formulation MON52276	Data requirement for active substance according to EC Regulation 284/2013 to support risk assessment for sublethal effects to additional soil organisms.	DP

Public literature articles in the dossier

- **3 articles and 1 translation of public literature articles** could not be obtained in-time to include into dossier (evaluated as non-relevant), due to COVID-19 impact on library operations
- Plan is to include these articles during admissibility check in the dossier

Author	Year	Title
Boscardin J. et al.	2014	Relationship between ant communities and environmental quality in <i>Eucalyptus grandis</i> submitted to different weedy species control in the south of Brazil. (original in Portuguese language)
Burstyn I. et al.	2017	Visualizing the heterogeneity of effects in the analysis of associations of multiple myeloma with glyphosate use. Comments on Sorahan, T. Multiple myeloma and glyphosate use: A re-analysis of us agricultural health study (AHS) data.
Marusca T.	2017	Oversowing or resowing of subalpine grassland appointed after the dynamics of floristic composition.
Shimina V. S. et al.	2010	Effect of Herbicide Excel Mera-71 (Glyphosate) Treatment on Seed Germination and Early Seedling Growth of Black Gram (<i>Vigna mungo</i> , Hepper.) var. T-9.

Question to AGG:

- Is this acceptable? Any comments?

Studies currently not accessible for GRG

- A small number of studies is currently not accessible for GRG:
 - **46 studies from companies no longer existing on the market**
 - **19 studies from GRG companies**
- GRG activities
 - Letter to German BVL (RMS 2012 renewal submission) to ask for availability of these studies
 - **BVL advice to file “request for administrative assistance (Art. 39 of Regulation (EC) No. 1107/2009)” so that AGG can get access to these studies**
 - **Document B:** List of currently inaccessible studies
- Information on those unavailable studies has been summarised based on the 2000 monograph documents and is included in the present AIR5 dossier (Category 4a/b)
- All unavailable studies have been superseded by current regulatory studies submitted in the AIR5 dossier.

Question to AGG:

- Would this approach work for AGG? Any comments?

Redaction of summary dossier

- Correspondence between GRG and EFSA / AGG / DG SANTE regarding transparency and redaction of personal information
- GRG position:
 - **GRG is applying the principles of the General Data Protection Regulation (GDPR) (EU) 2016/679** for
 - sanitization of all dossier documents and study reports that can be accessed via our GRG website
 - sanitization of the 2020 renewal dossier documents that will be provided to regulatory authorities during the renewal process
 - to protect personal data and confidential business information in line with applicable data privacy provisions.

Question to AGG:

- Any comments?

Submission of dossier on USB hard drives

- AGG confirmed that dossier submission on USB hard drives is acceptable
- Any fall-back planning necessary?

Question to AGG:

- Any comments?

Proof of payment of submission fees to ANSES and KEMI

- Communication from **ANSES** (27 May 2020)
 - Payment of submission fees in advance of submission
 - Include proof of bank transfer in dossier
- Invoice from **KEMI** received on 19 May 2020 for 2nd instalment
 - Payment of SEK 2,500,000 on 26 May 2020 by Bayer on behalf of GRG
 - Submission of proof of bank transfer required?
- Proposal from GRG:
 - To include the proof of payment to ANSES in the submission letter sent to ANSES, that is accompanying the dossier submission

Question to AGG:

- Is the proposal to include the proof of payment to ANSES in the submission letter sent to ANSES acceptable?
- Is the submission of proof of bank transfer required for KEMI?

AGG Evaluation Fees (in EURO)

	General	Application (December 2019)	AGG Organizational Cost / PSMs	Dossier Submission (June 2020)	6 Months after Dossier Submission (December 2020)	Draft RAR Submission to EFSA (Q3 2021)	Peer Review (Q3 2021)	End of Peer Review (Q4 2021)	SUM
Sweden	~ 635,000 (actual costs will be charged, amount not used will be reimbursed) 92 hourly cost	47,126		45% at date of submission of dossier ~ 285,750	45% ~ 285,750				~ 510,000 (~ 635,000 max)
Netherlands	140 hourly cost	12,875	Secretariat ~ 60,000 ICT AGG ~ 20,000	After intake of dossier costs of evaluation are estimated and charged before start of evaluation. (Signal will be given when 80% of estimated hours is spent) ~ 150,000		Final payment in case initially estimated amount is exceeded	At the start of peer review. (Signal will be given when 80% of estimated hours is spent) ~ 75,000	Final payment in case initially estimated amount is exceeded	~ 225,000 ~ 92,875
France	200,000 (fixed fee for the whole process)			200,000					200,000
Hungary	75,000 (for the whole process)		Travel costs for face to face meeting 5,000 – 10,000			75,000			80,000 – 85,000
									SUM 1,107,875 – 1,237,875

No ECHA submission fee

Admissibility timeline

- GRG's understanding is that AGG will take **one month for admissibility check** (based on pre-submission meeting discussions)
- Can we plan with receiving the decision on admissibility of the application / list of additional requests by **15 July 2020**?

Question to AGG:

- Can AGG confirm our understanding of the timeline?

THANK YOU!



**Glyphosate
Renewal Group**