Glyphosate AIR 2022

Procedural Pre- Submission Meeting with AGG

Brussels September 27th, 2019

GTF2 AIR 5 Project Team here today

Regulatory Affairs

- [redacted] (knoell) - Regulatory Project Manager
- [redacted] (Helm)
- [redacted] (POSTMON) – Secretary of the GTF2 board
- [redacted] (Nufarm)
- [redacted] (Bayer)
- [redacted] (Bayer) - GTF2 Regulatory Working Group chair
- [redacted] (Bayer France)
- [redacted] (Bayer / legacy Monsanto France/Netherlands)

List of abbreviations

GTF2 – Glyphosate Task Force for 2020 renewal submission

TF – Task Force

AGG - Assessment Group on Glyphosate

CBI – Confidential Business information

PSM – Pre Submission Meeting

LRR – Literature review report

GFL – General Food Law

* – changed after slides were provided to AGG

Meeting Agenda – Procedural Pre-Submission Meeting

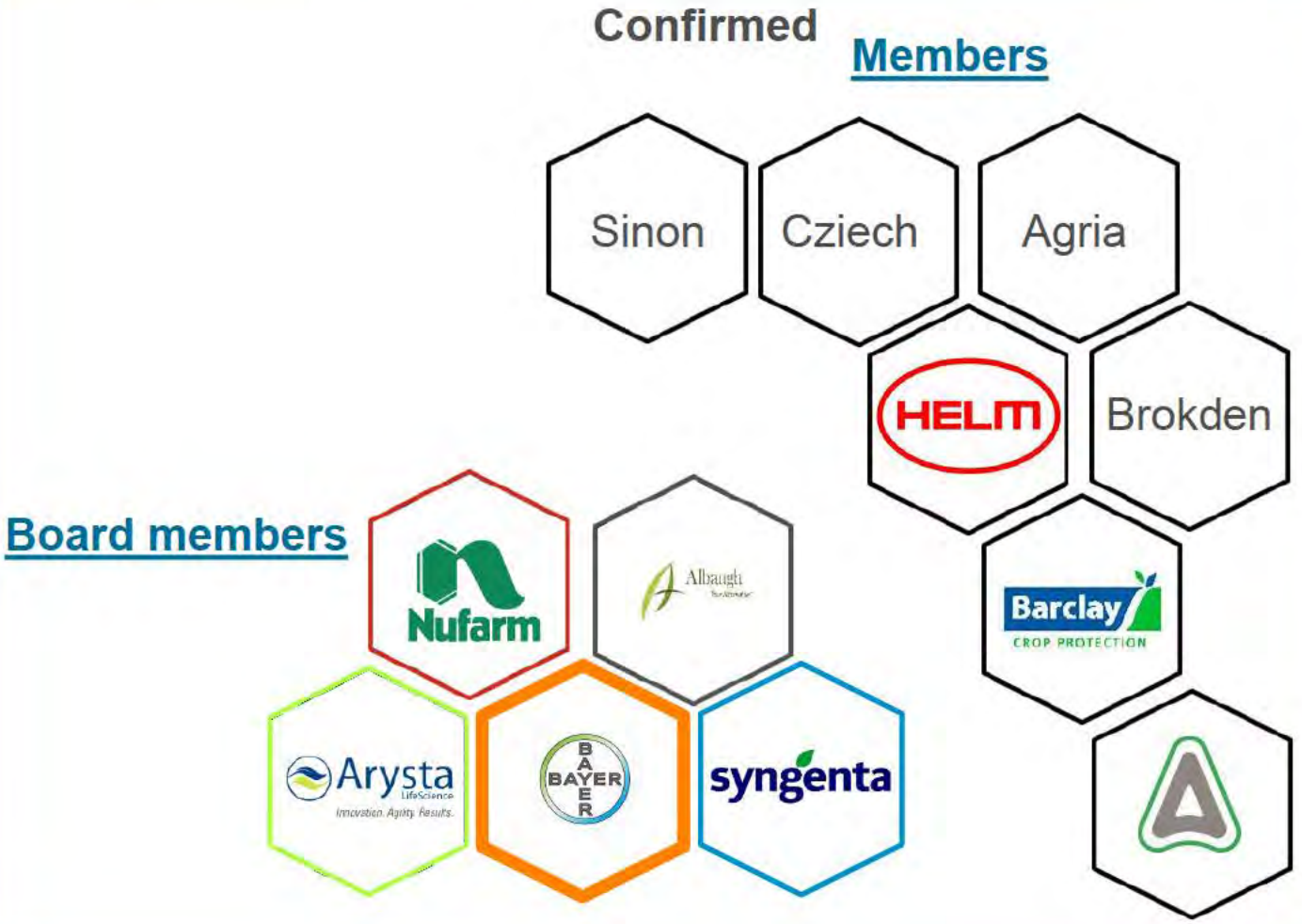
GTF 2

1. GTF2 AIR 5 set up
2. GTF2 single contact point for AGG
3. Work-sharing in AGG during AIR 5: authority responsibility for evaluation per dossier section
4. Submissions of SANCO Dossier / Application Document: Turbo check / Pre-check feedback
5. Regulatory Guidance docs related to: dossier structure, content, format for AIR5 submission
6. Discussion of the definition of full dossier: data package
7. Reference to studies of non GTF2 members (vertebrates studies/non-vertebrates studies)
8. Public literature search: timelines
9. CLH Dossier: background, structure, timelines
10. GAP: proposed representative uses
11. Transparency/General Food Law/Redaction

GTF2 AIR 5 set up and single contact point for AGG during AIR 5

GTF2 Task Force

Membership – 2019



Board Members

- Data package
- Representatives
- Decision vote

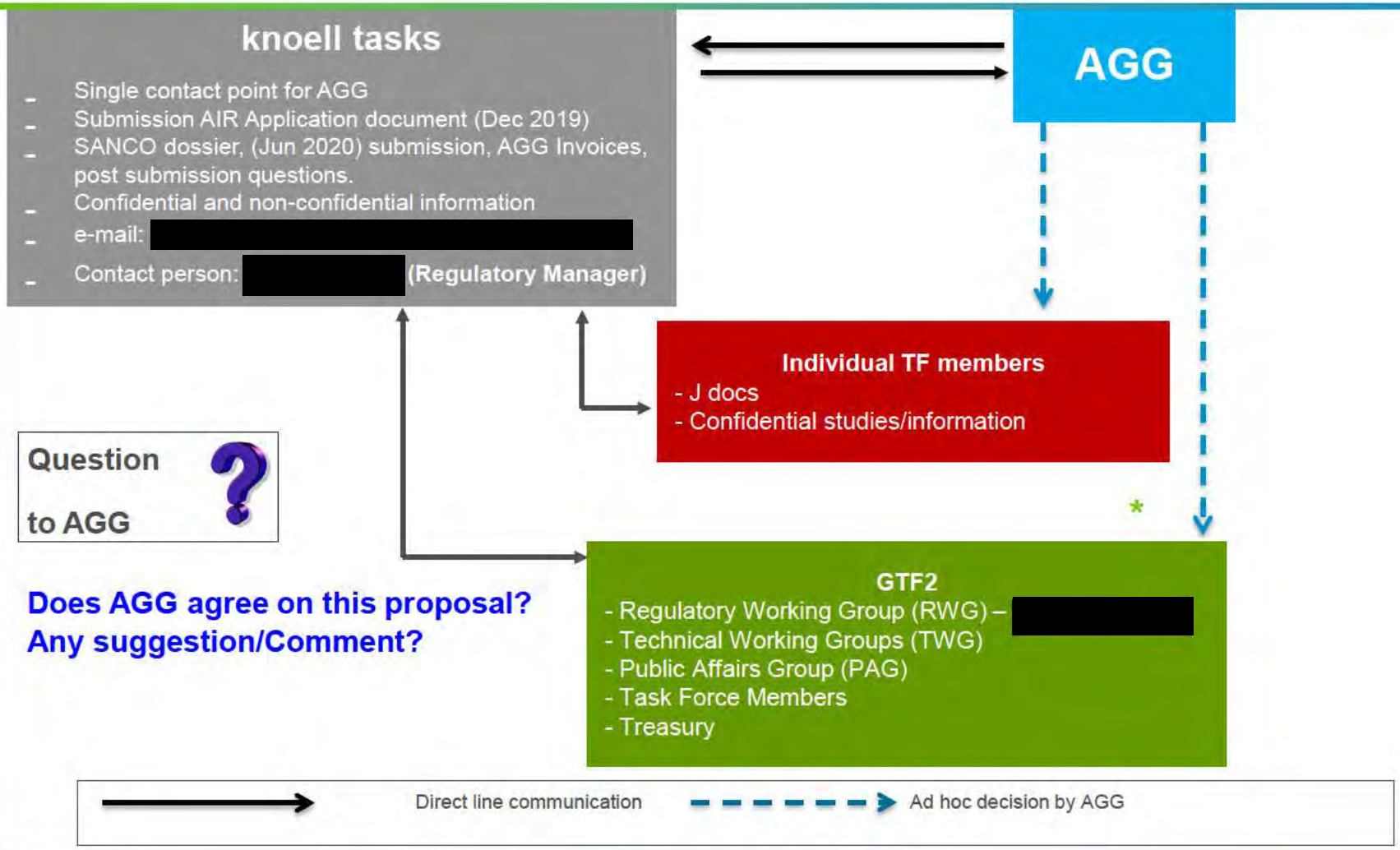
Members

- No/little data
- Voluntairs
- Consulted

Lead Registrant

- Bayer

GTF2 Task Force support by knoell as single contact point for AGG



GTF 2

Work Sharing during AIR 5 within AGG team

Guidance Documents for Preparation of the AIR 5 Application Document - Format of Submission

GTF 2

Question to AGG

- Each AGG member will receive the AIR 5 dossier in Caddy format.
- Is there any paper version needed by any of the AGG member?
- Can the AGG explain the planned structure of the technical evaluation team for the different dossier sections? Country/technical section evaluation?
- The CBI forms to be signed by the 4 AGG members?
- Is there any centralized contact person for the AGG?

GTF 2

Application document for AIR 5 and pre-check

Guidance Documents for Preparation of the AIR 5 Application Document - Format of Submission

GTF 2

- The AIR 5 application document is in line with:
  - Regulation (EU) No 844/2012
  - SANCO/2012/11251 rev. 5 (22 Mar 2019).

Question to AGG

Any comment from the AGG?

Application Document – Representative formulation

- Plant protection product MON 52276
  - The representative formulations supporting the renewal of the active substance glyphosate is MON 52276, a soluble concentrate (SL) containing 360 g/L glyphosate as isopropylammonium salt (486 g/L).
  - This formulation is registered in Europe and will also be the representative chemical product supporting the joint GTF2 AIR 5 dossier for the renewal dossier. **The composition of this formulation has not changed in comparison to the AIR 2 submission**.
  - The chemical product MON 52276 has been already peer reviewed during the previous AIR 2 process at EU level.

Question to AGG

Any comment or question from the AGG?

Application Document – New studies

- Additional studies for the AIR 5: The GTF2 to the best of its knowledge at the time of application for renewal, expects that the technical dossier supporting the renewal of glyphosate will include **different new non-vertebrate studies and pieces of information for the different dossier sections**.
- New Studies are listed (slides 41 to 47)

Question to AGG

Any comment from the AGG?

Pre-check of AIR 5 application document - Timelines

GTF 2

Question to AGG

- **Does the AGG see any benefit in submitting the AIR 5 Application Document for a pre-check before the final deadline? If yes,**
  - Timelines proposal:
    - ✓ Submission of final version to AGG by 4th Nov 2019
    - ✓ To receive feedback comments from AGG by 20th Nov 2019
    - ✓ **Deadline for final submission to AGG by 15th Dec 2019**

GTF 2

SANCO Dossier for AIR 5, data package and pre-check

Guidance Documents for Preparation of AIR 5 SANCO Dossier – Format of Submission

GTF 2

Question to AGG

Confirmation that only guidance is applied that entered into force at the time of submission and that during the evaluation procedure no changing guidance documents / data requirements will be applied? *

The SANCO CA/CP dossier will be prepared considering:

a) SANCO 10181 rev 5: Guidance document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to regulation no 283/2013 and regulation No 284/2013

b) The LCA and LCP reference list tables are based on the table in SANCO/12580/2012-rev. 4 (22 March 2019).

c) Practical guidance for Applicants and Member States for preparing Dossiers and Assessment Reports (DAR/RAR)- 2018.

d) Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances EFSA Admin GD 27 Mar 2019

e) EC Working Document on Evidence Needed to Identify POP, PBT and vPvB Properties for pesticides, September 2012 – across technical sections

Data sharing – data generation – data ownership & access

- All **existing glyphosate studies** owned by the members are **considered*** in the joint submission
  - ✓ Ownership remains with original owner; access rights are granted
  - ✓ Study reports are not shared – included via consultant (knoell)

All members are provided the right to refer to all studies in the data package in the context of the EU AIR and any product (re) authorization in the EEA.

- **New glyphosate studies** are jointly developed/sponsored and co-owned.
  - These studies can be used *ad libidum* globally.
- **Confidential data** (5-batch, sources of TGA etc) are **NOT** shared
  - Included in the dossier by knoell (GTF2 consultant)
  - EU reference specification is unknown to the GTF2 member companies

* List of not included studies (e.g. from countries outside EU, EU data requirement related) will be submitted in the AIR 5 dossier

Specifications at EU level – AIR 5

The specification of purity of the active substance in g/kg approved at AIR 2:

≥ 950 g/kg
Impurities:
Formaldehyde, less than 1 g/kg
N*-Nitroso-glyphosate, less than 1 mg/kg

The active substance's minimum purity **to be supported during the AIR 5 process remains at 950 g glyphosate acid/kg** (**EU*** reference specification), as previously approved at EU level.

The sources of technical glyphosate will be documented and evaluated in company specific confidential parts of the renewal dossier.

Reference specifications

- **Feedback pending from AGG regarding EU specifications (Minutes: Point 3)**
- During AIR2, in the J Docs prepared of all technical sources, the so-called "**umbrella specification**", which covered impurity profiles for all sources, was included.
- After finalization of AIR2 process, a **EU* reference specification** was finalized by RMS and made available to knoell (Individual company specification - which is confidential to each individual TF member). Together with it, EFSA-requested updates regarding tox assessment on certain impurities levels will be elaborated (already communicated individually to each TF member by knoell in Q3 / 2019).
- In the AIR 5 dossier, **change / addition of sources** instead of holding previously defended sources is being considered by some GTF members→ knoell will check the technical equivalence of all the sources against "reference specification" on behalf of each member to make sure they the meet reference specification.
- **knoell will perform a "technical equivalence check" on behalf of the GTF.**

Question to AGG

Does AGG agree on this proposal?

The fundamental data set

GTF 2

What is the fundamental data set to be included in the AIR 5 dossier?

Submission	Regulatory process
1. **1998 submission**	Under Directive 91/414 - Monograph
2. **AIR 2 submission in 2012**	Dossier submitted under Directive 91/414 (data requirements) and evaluation/approval under EC Reg 1107/2009

The fundamental data set

GTF 2

Glyphosate is a unique active substance with a large and robust data package - repeated for many data requirement points.

The set of studies is large and extensive.

Data package for the AIR 5 submission:

1. **List of information, tests and studies relied upon RAR, Volume 2 from 15 Dec 2017**: "List of information, tests and studies which are considered as relied upon by the RMS for the evaluation with a view to renew the active substance approval" **(*)**
   → *The list of studies "relied upon" comprised a combination of studies from the two existing regulatory processes (see previous slide).*
2. **New AIR 5 studies, not previously submitted during the AIR 2 process.**

The fundamental data set

What is the fundamental data set to be included in the AIR 5 dossier?

GTF 2

Data package		OECD summaries
1. **1998 submission studies**	AIR 2 Dossier OR RAR available study summaries of all acceptable (relied upon) listed studies **(* see Slide 21)** to be included in the AIR dossier. The overview of **"key studies"** *(representative data package from the "List of studies to relied upon)* will be presented for discussion per technical dossier sections to the AGG team (Technical PSMs Oct 2019).	For the "key studies" **a full robust OECD summary format** will be prepared/updated for the AIR dossier
2. **AIR 2 (2012) studies**		
3. **New AIR 5 studies**	Studies generated after the AIR 2 (2012) submission, regardless whether they have already been submitted and evaluated by the RMS or any other country.	**Full robust OECD summary to be submitted**

Question to AGG

Does AGG agree on this approach across all dossier sections?

The fundamental data set

GTF 2

Previously submitted studies

But not valid / not reliable

→ In a tabular form along with a substantiated justification

Except for studies considered important as supplementary information

List of not included studies

e.g. from countries outside EU, EU data requirement related

→ Studies can be requested by AGG if considered relevant

Question to AGG

Does AGG agree on this approach across all dossier sections?

Pre-check of AIR 5 SANCO Dossier - Timelines

GTF 2

Pre-check of AIR 5 SANCO Dossier by AGG

- **Feedback pending from AGG (Minutes: Point 7)**

- The "Completeness check" (30 days after submission) is a defined regulatory step during any AIR process, and in case of any missing data applicant will have 30 days ("Stop of the clock") to provide any data to the AGG (RMS).

Question to AGG 

Does AGG agree on this?

GTF 2

General Literature Review Report (search) according to Art. 8.5 EC Regulation 1107/2009 and EFSA Guidance document 2092/2011

Guidance Documents for Preparation of the LRR

GTF 2

The Literature review Report will be prepared considering:

a) EFSA 2092: Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/20091 - EFSA Journal 2011;9(2):2092

b) Practical guidance for Applicants and Member States for preparing Dossiers and Assessment Reports (DAR/RAR). *Appendix: Template for the submission peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009*. 2018

   i. No Klimisch evaluation will be performed during the preparation of the LRR*

   ii. Detailed relevance/reliability criteria set up per technical section

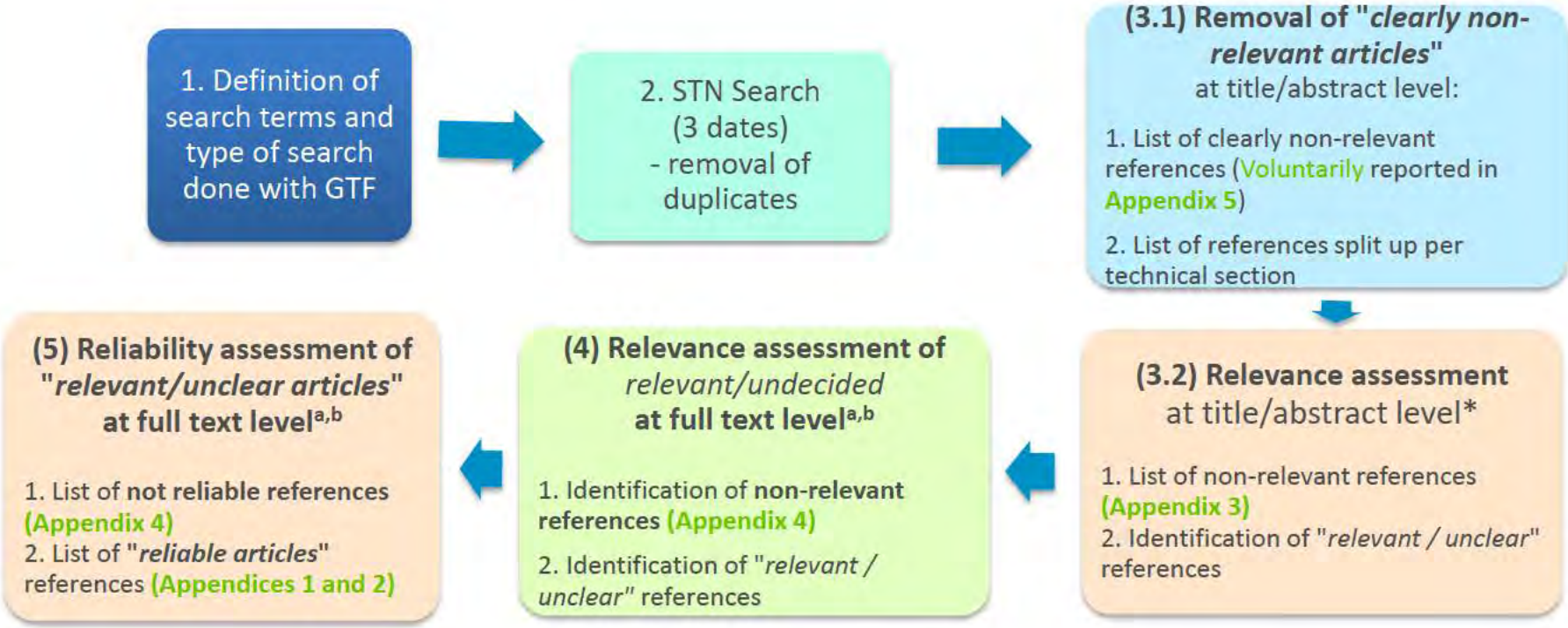
c) Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances EFSA Admin GD 27 Mar 2019

Question to AGG

Does AGG agree on this proposal?

General LRR Accord. EC Regulation Art. 8.5 and EFSA GD 2092/2011*

GTF 2



The reliability criteria, except for the step (3.1), was set up per technical section, and will be presented in a tabular form in the LRR document (K document for submission).
a,b: Reliability criteria set up per section: Toxicology / Residues / E-fate / Ecotoxicology (see back-up slides)

General LRR Accord. EC Regulation Art. 8.5

GTF 2

Part	Search Period	Status
Literature Search Part 1	Jan 2012 – Dec 2017	7,031 as total of hits. Finalized evaluation for relevance at title/abstract level: Relevant articles subject for reliability assessment Ecotoxicology: 41* E-Fate: 99 Residues: 4 Toxicology & metabolism: 59
Literature Search Part 2	Jan 2018 – Jun 2019	2,085 hits Ongoing evaluation for relevance at title/abstract level
	2010 – 2011 Period	1,909 Literature search for the period 2010 to 2014* was done upon request from EFSA during the AIR 2 process from 07 Aug 2014*). → see back-up slides: 50 to 62
Literature Search Part 3	Jul 2019 - Dec 2019	Pending

Question to AGG

Literature review search period before 2012?

Feedback pending from AGG (Minutes: Point 13)

* EFSA Ref D(2014) JVT/JS/mc out-9267902

General LRR Accord. EC Regulation Art. 8.5

Classification of the studies in a dossier following EFSA GD 2092/2011 on Literature Search (Point 5.4 *)

GTF 2

Studies that are clearly relevant to the risk assessment may then be considered for reliability assessment. Articles will be included in the dossier as following:

(a) Studies that provide **data for establishing or refining risk assessment parameters**. These studies should be **summarised in detail*** following the subsequent steps of the OECD Guidance documents (OECD, 2005; 2006) and should be considered for reliability (see back-up slides).

(b) Studies that are **relevant to the data requirement**, but in the opinion of the applicant provide only **supplementary information** that does not alter existing risk assessment parameters. A justification for such a decision should be provided → OECD summaries will be presented in the LRR*

(c) Studies for which relevance cannot be clearly determined. For each of these studies the applicants should provide an explanation of why the relevance of such studies could not be definitively determined → will be included in tabulated form in the LRR*

** Following the Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances EFSA Admin GD 27 Mar 2019*

Question to AGG

Does AGG agree on this approach?

General LRR Accord. EC Regulation Art. 8.5 and EFSA GD 2092/2011 on Literature Search

LRR appendixes

GTF 2

Appendix in LRR	Description
Appendix / Table 1	Relevant studies included in a dossier after detailed assessment of full-text documents for relevance: sorted by data requirement(s)
Appendix / Table 2	Relevant studies included in the dossier after detailed assessment of full-text documents for relevance: sorted by author(s)
Appendix / Table 3	Publications excluded from the risk assessment after assessment of title/abstract
Appendix / Table 4	Publications excluded from the risk assessment after detailed assessment of full-text documents
Appendix / Table 5	List of articles identified as "clearly not relevant" *

* Even when those articles would be discarded after rapid assessment, the list and description of "reason for exclusion" will be included in tabulated form in the LRR document. NOTE: The Practical Guidance EFSA 2018 states *"It is not needed to include the non-relevant publications in the dossier (thus neither in the RAR/DAR)."*

Question to AGG

Does AGG agree on this approach?