



Glyphosate AIR 2022

Pre-submission call - AGG



GTF2 Representation on the call



Name	Company
[REDACTED]	Syngenta
[REDACTED]	Agria
[REDACTED]	Agria
[REDACTED]	Nufarm
[REDACTED]	Brokden
[REDACTED]	Helm Ag
[REDACTED]	
[REDACTED]	Ciech
[REDACTED] *	Sinon
[REDACTED]	UPL
[REDACTED]	Bayer
[REDACTED]	Bayer
[REDACTED]	Bayer
[REDACTED]	Albaugh

- [REDACTED]; POSTMON
- [REDACTED]; Knoell Germany GmbH

* Representing Sinon; employed by Exponent

Remit of the teleconference



Agenda

- ❖ Introduction of GTF2 and AGG
- ❖ Align on high level procedural and practical aspects of the upcoming evaluation
- ❖ The Representative GAP
- ❖ Transparency
- ❖ Scope the pre-submission meetings
- ❖ Literature review
- ❖ What can the Task Force do to facilitate the process?

Task Force

Membership – 2019



Confirmed

Associate members

Board

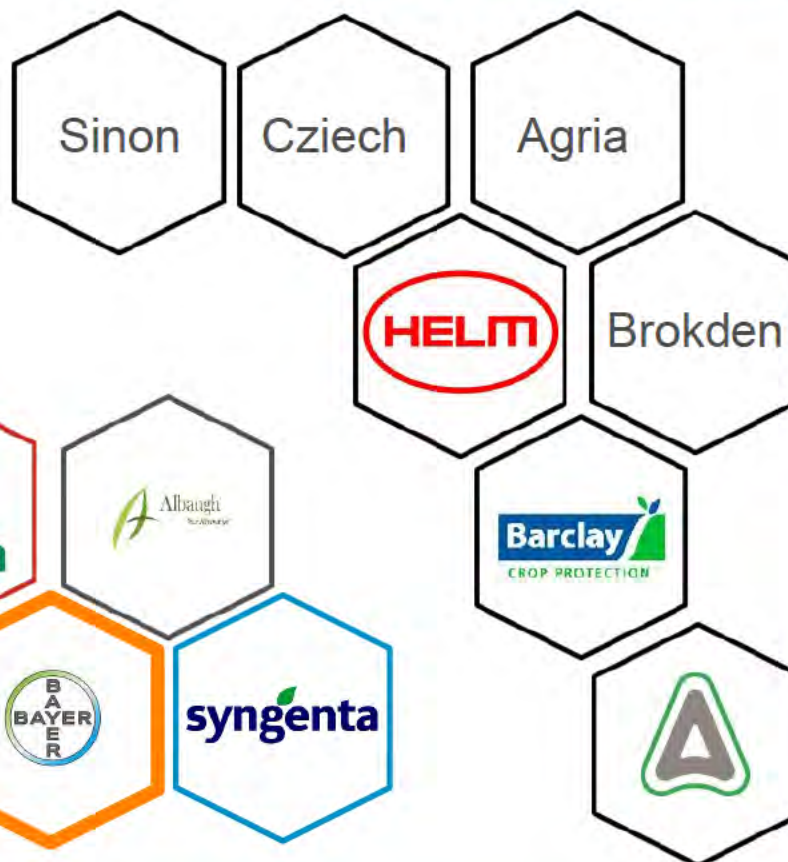
- Data package
- Representatives
- Decision vote

Associate

- No/little data
- Volunteers
- Consulted

Lead Registrant

- Point of contact



Board members



Task Force

Membership – 2019 vs 2012

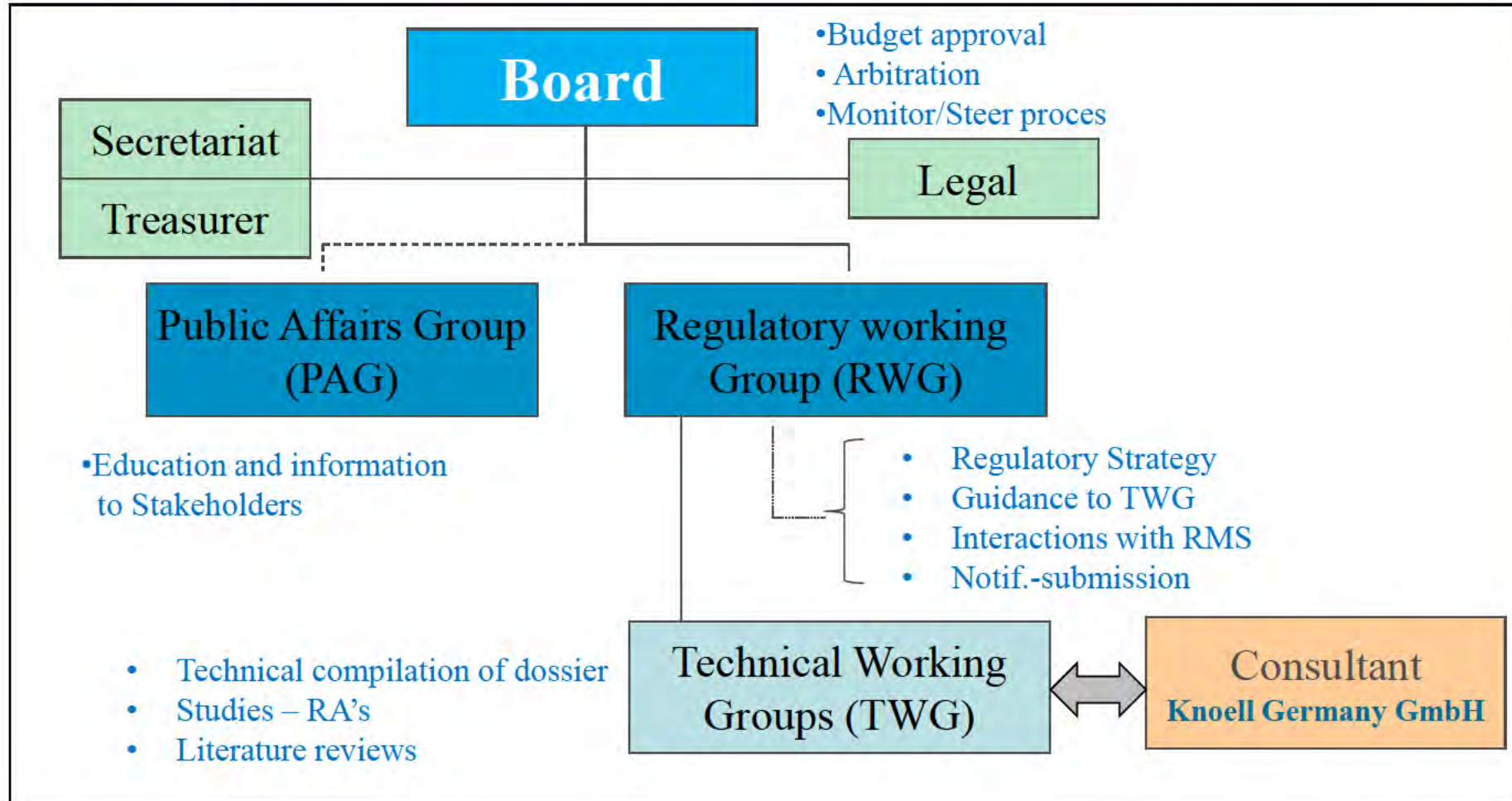


2019	2012
Adama Agan Ltd	Feinchemie Schwebda GmbH
Agria SA	Agria SA
Albaugh Europe SARL	Albaugh UK Limited
Arysta Lifescience SAS	Arysta Lifescience SAS
Barclay Chemicals Manufacturing	Barclay Chemicals Manufacturing
Bayer Agriculture bvba	Monsanto Europe SA
Brokden SLU	Brokden SLU
Ciech Sarzyna SA	Pinus TKI
Helm AG	Helm AG
Nufarm GmbH & Co KG	Nufarm GmbH & Co KG
Sinon Corporation	Sinon Corporation
Syngenta Crop protection AG	Syngenta Limited
	Cheminova AS
	Agrotrade GmbH
	Agrichem BV
	Bros Polka
	Dow Agrosciences LCC
	Excel Industries
	Industrias Afrasa SA
	ROTAM Agrochemical Europe Ltd
	Saptec Agro SA
	Société Financier de Potarlier
	United Phosphorus Limited

Task Force



Bundeling data packages, expertise sharing cost



Task Force (GTF2)



Contact

❖ Chairman of the Board : [REDACTED] (BCS- Brussels)

[REDACTED]

❖ Secretary of the Board : [REDACTED] (POSTMON- UK)

[REDACTED]

❖ Chairman of the RWG : [REDACTED] (BCS-Brussels)

❖ Coordinator of the TWG : [REDACTED] (BCS- Saint Louis)

[REDACTED]

❖ Knoell Germany GmbH rep. : [REDACTED]

[REDACTED]

Procedural topics

Back-up

Dossier technical topics-general

Back-up

Confidential data

Task Force (GTF2)



Data sharing – data generation- data ownership & access

➤ All **existing glyphosate studies** owned by the membership are included in the joint submission

- ❖ Ownership remains with original owner; access rights are granted
- ❖ Study reports are not shared – included via Consultant
- ❖ Data compensation is considered as necessary

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 libitum* globally

➤ **Confidential data** ((5-batch, sources of TGA etc) are **NOT** shared

- ❖ Included in the dossier by the Consultant
- ❖ EU reference specification is unknown to the membership

Alignment on procedural and practical aspects of the submission

Dossier & Application preparation - Evaluation



❖ Application (< December 15 2019)

- List of new studies
- Updating Statement
 - ❖ Expectations
 - ❖ Special format requirements

❖ Regulation 1141/2010 - Art 9 :Supplementary Dossier

- GTF2 intends to submit **full dossier**
 - ❖ All data (old & new) presented in line with latest requirements
 - ❖ Full weight of scientific evidence evaluated
- How to make cross reference to studies already evaluated in 1998 -2012?
 - ❖ OECD summaries vs tabular summaries

Note : Art 13 (third party submission) to be anticipated

Alignment on Procedural and Practical aspects of the submission (2)

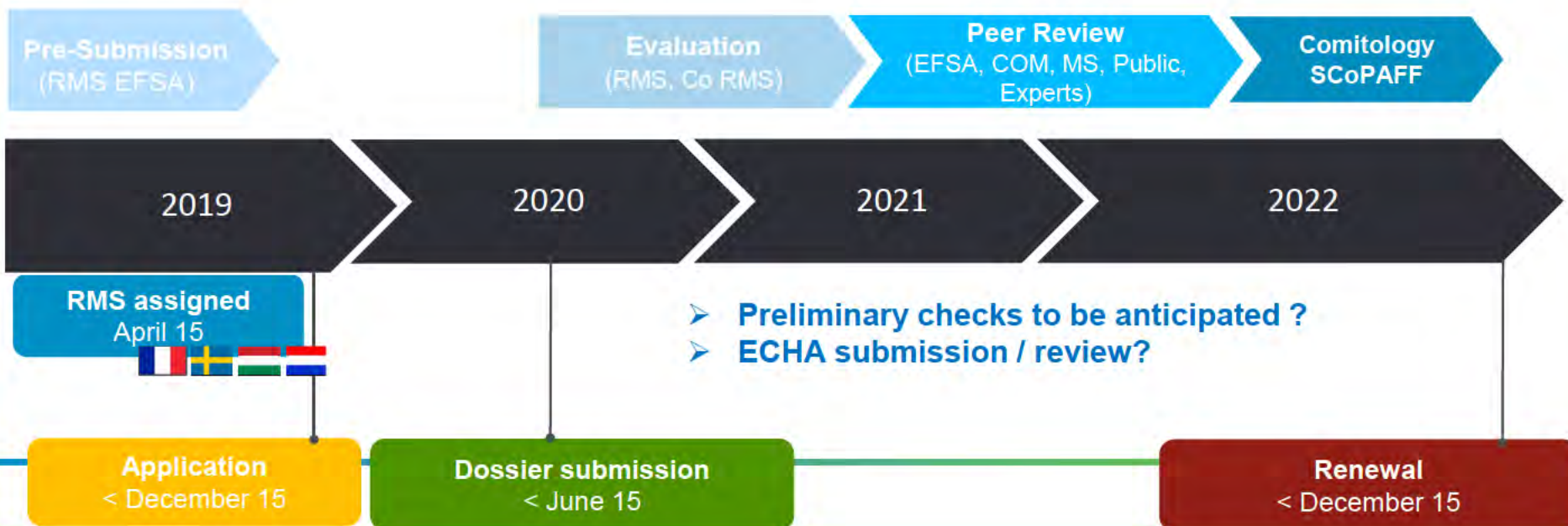


Dossier & Application preparation - Evaluation

❖ Guidance, dossier and data requirements in force at time of submission

- Will be used by GTF2 as basis for dossier preparation
- Will be used by AGG/EFSA as the basis of evaluation

❖ Timelines



Representative GAP



Demonstrating a safe and acceptable use concept

Setting the representative GAP : 2012

Major uses
(80% of volumes
sprayed)

No refined
application rates

No mitigation

No specific uses
under pressure at
that time

Crop	Pest	Growth stage	#	interval	Water	Dose rate	PHI	comment
All crops	Emerged annual perennial and biennial weeds	Pre-planting of the crop	1-2	21d	100-400L	0,36-2,16	N/A	Spring & autumn after harvest (including stubble and seed bed preparation); max 4,32 kg/ha in any 12 month period across use categories
All crops	Emerged annual perennial and biennial weeds	Post-planting pre- emergence of the crop	1		100-400L	0,36-1,08	N/A	
Cereals (pre-harvest) Dessication + weed control	Emerged annual perennial and biennial weeds	Crop maturity <30% grain moisture	1		100-400L	0,72-2,16	7	max 4,32 kg/ha in any 12 month period across use categories
Oil seeds pre-harvest Dessication + weed control	Emerged annual perennial and biennial weeds	Crop maturity <30% grain moisture	1		100-400L	0,72-2,16	14	
Orchard crops, vines	Emerged annual perennial and biennial weeds	Post emergence of weeds	1-3	28d	100-400L	0,72-2,88	N/A	Stone and pome fruit, olives Applications made around the trunk of trees; seasonal application not to exceed 4,32 kg/ha;
Orchard crops, vines Spot treatment	Emerged annual perennial and biennial weeds	Post emergen,ce of weeds	1 1-3	 28d	 0-400	 0,72-2,88 0,96-2,88	 N/A	Stone and pome fruit, olives Applications made around the trunk of trees; seasonal application not to exceed 4,32 kg/ha; 0L water = undiluted product

Representative GAP



Demonstrating a safe and acceptable use concept (2)

Setting the representative GAP : 2020



- Representing ~ 80% of volumes sprayed in the EU
- Exclude uses associated with (highest) residue levels
- MRLs = LOQ
- Exclude lawn & garden uses
- Annual weeds
- Biennial perennial weeds in early vs advanced GS
- Efficacy
- WRM
- More targetted and refined application approach (sustainability)
- Drift reducing nozzles
- Banded applications
- PPE?



Representative GAP



Demonstrating a safe and acceptable use concept (3)

Setting the representative GAP : 2020 versus 2012

Crop	Pest	Growth stage	#	interval	Water	Dose rate	PHI	comment
All crops	Emerged annual perrenial and biennial weeds	Pre-planting of the crop	1-2	21d	100-400L	0,36-2,16	N/A	Spring & autumn after harvest (including stubble and seed bed preparation); max 4,32 kg/ha in any 12 month period accross use categories
All crops	Emerged annual perrenial and biennial weeds	Post-planting pre-emergence of the crop	1		100-400L	0,36-1,08	N/A	
Cereals (pre-harvest) Dessication + weed control	Emerged annual perrenial and biennial weeds	Crop maturity <30% grain moisture	1		100-400L	0,72-2,16	7	max 4,32 kg/ha in any 12 month period accross use categories
Oil seeds pre-harvest Dessication + weed control	Emerged annual perrenial and biennial weeds	Crop maturity <30% grain moisture	1		100-400L	0,72-2,16	14	
Orchard crops, vines	Emerged annual perrenial and biennial weeds	Post emergence of weeds	1-3	28d	100-400L	0,72-2,88	N/A	Stone and pome fruit, olives Applications made around the trunk of trees; seasonal application not to exceed 4,32 kg/ha;
Orchard crops, vines Spot treatment	Emerged annual perrenial and biennial weeds	Post emergen,ce of weeds	1		0-400	0,72-2,88	N/A	Stone and pome fruit, olives Applications made around the trunk of trees; seasonal application not to exceed 4,32 kg/ha; 0L water = undiluted product
			1-3	28d		0,96-2,88		

Representative GAP



Crop	Pest	Growth stage	#	interval	Water	Dose rate (kg/ha)	PHI	comment
1 All crops	Emerged annual weeds	Pre-planting of the crop	1-2	21d	100-400L	0,72- 1,08	N/A	Broadcast tractor mounted application (treatment to 100% of field) ;Spring & autumn after harvest (including stubble and seed bed preparation); 75% drift reducing nozzles
2a All crops	Emerged perennial and biennial weeds Weeds in early development stage (BBCH 13-21)	Pre-planting of the crop	1-2	21d	100-400L	1,08 – 1,44	N/A	Broadcast tractor mounted application (treatment to 100% of field) ; Spring & autumn after harvest (including stubble and seed bed preparation); 75% drift reducing nozzles
2b All crops	Emerged perennial and biennial weeds Weeds in advanced development stage > BBCH 21)	Pre-planting of the crop	1	-	100-400L	1,44 - 2,16	N/A	Broadcast tractor mounted application (treatment to 100% of field) ; Spring & autumn after harvest (including stubble and seed bed preparation); 75% drift reducing nozzles

Crop	Pest	Growth stage	#	interval	Water	Dose rate (kg/ha)	PHI	comment
3 All crops	Emerged annual weeds	post planting / pre-crop emergence	1	-	100-400L	0,72-1,08	N/A	Broadcast tractor mounted application ; treatment 100% field 75% drift reducing nozzles
4 All crops	Emerged perennial and biennial weeds	post planting / pre-crop emergence	1	-	100-400L	1,08 – 1,44	N/A	Broadcast tractor mounted application; treatment 100% field 75% drift reducing nozzles

Refinements

'All crops'



- ❖ *“All seeded and transplanted crops including but not restricted to root & tuber vegetables, bulb vegetables, stem vegetables (fruit vegetables, brassica vegetables, leaf vegetables and fresh herbs, legume vegetables), pulses, oil seeds, potatoes, cereals, sugar & fodder beets; before planting fruit crops, ornamentals, trees, nursery plants etc.”*
- ❖ **Maximum annual application** rate per treated area : **2.88 kg/ha**
 - allows for instance combinations of :
 - pre-plant/pre-emergence annual weed treatment + perennial/biennial advanced development stage treatment
 - pre-plant/pre-emergence 2 applications targeting perennial/biennial early development stage
 - 1 Pre-plant pre-emergence + 1 post-plant pre-emergence application

In line with realistic and labeled treatment regimes



Representative GAP



Demonstrating a safe and acceptable use concept (4)

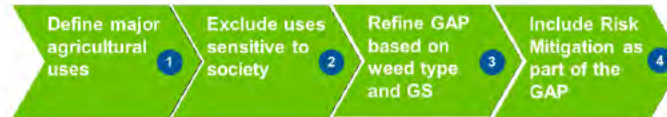


Crop	Pest	Growth stage	#	interval	Water	Dose rate (kg/orchard ha)	PHI	comment
5 Orchard crops, vines	Emerged annual weeds	Post emergence of weeds	1-3	28d	100-400L	0,36- 0,54	N/A	Stone and pome fruit, olives Applications made around the trunk of trees – bands between tree rows left green (dose rate = 0,72 -1,08 kg band ha treated orchard area = 50 %) Ground-directed - Shielded (drift) sprayer
6 Orchard crops, vines	Emerged perennial and biennial weeds Weeds in early development stage (BBCH 13-21)	Post emergence of weeds	1-3	28d	100-400L	0,54-0,72	N/A	Stone and pome fruit, olives Applications made around the trunk of trees (dose rate = 1,08-1,44 kg band ha treated orchard area = 50 %) ; Ground-directed - Shielded (drift) sprayer
7 Orchard crops, vines	Emerged perennial and biennial weeds Weeds in advanced development stage > BBCH 21)	Post emergence of weeds	1-2	21d	100-400L	0,72-1,08	N/A	Stone and pome fruit, olives Applications made around the trunk of trees (dose rate = 1,44-2,16 kg band ha treated orchard area = 50 %) Ground-directed - Shielded (drift) sprayer

Representative GAP



Demonstrating a safe and acceptable use concept (5)



Crop	Pest	Growth stage	#	interval	Water	Dose rate (kg/orchard ha)	PHI	comment
8 Orchard crops, vines Spot treatment	Emerged annual weeds	Post emergence of weeds	1-3	28d	100-400	0,36-0,54	N/A	Stone and pome fruit, olives Applications made around the trunk of trees – bands between tree rows left green (dose rate = 0,72 -1,08 kg band ha treated orchard area = 50 %) Ground-directed - Shielded (drift) sprayer Knapsack applicator (tbc)
9 Orchard crops, vines Spot treatment	Emerged perennial and biennial weeds Weeds in early development stage	Post emergence of weeds	1-3	28d	100-400	0,54-0,72	N/A	Stone and pome fruit, olives Applications made around the trunk of trees (dose rate = 1,08-1,44 kg band ha treated orchard area = 50 %) ; Ground-directed - Shielded (drift) sprayer Knapsack applicator(tbc)
10 Orchard crops, vines Spot treatment	Emerged perennial and biennial weeds Weeds in advanced development stage	Post emergence of weeds	1-2	21d	100-400	0,72-1,08	N/A	Stone and pome fruit, olives Applications made around the trunk of trees (dose rate = 1,44-2,16 kg band ha treated orchard area = 50 %) Ground-directed - Shielded (drift) sprayer Knapsack applicator(tbc)

Transparency

Society urges for full transparency – GTF2 acts upon it!



GTF2 commits to pursue renewal ambitions in full transparency

- Pro-active application of new **transparency provisions in the revised GFL**
 - ❖ Register of studies – Consultation of third parties
 - ❖ Publication of study reports after completeness check
- Publication of all **communication** between GTF2 and AGG – EFSA – COM and other formal stakeholders in the renewal process
 - ❖ Letters
 - ❖ Minutes of meetings
- Publication of **safety studies** leading to 2017 renewal
- **Exploring other options as a Task Force**

Transparency



Notification of Studies

➤ GFL; Art 32b, Notification of studies

- EFSA to establish a database of studies **commissioned** or **carried out** to support applications
- Applicants must “...*notify, **without delay**...the title and the scope of the study, the laboratory or testing facility carrying out the study, and the starting and planned completion dates of any study commissioned or carried out by them to support an application ...*”

➤ GFL; Art 32c, Consultation of third parties

Public consultation on intended studies:

- EFSA holds public consultation on intended studies
- Based on comments received EFSA provides advice to Applicants on content of renewal application, as well as design of studies

Transparency

Notification of Studies - Adapted from ECPA format proposal (Excel spreadsheet)



Ongoing studies

Identified areas for which detailed re-evaluation is needed in dossier from applicant and in evaluation by RMS/Co-RMS.	Related data point	Dossier section	Study title (if available) / otherwise study purpose	Justification	Guideline or guidance document	GLP	CRO	Envisaged dates of study conducts	Vertebrate study	Confidentiality claims*	Notifier comment
Identity / specification of TGA1	Doc. J	Identity of the active substance Analytical methods	Analytical characterization of five batches of XY Method validations	New five batch analysis representing current commercial production	EU 283/2013 SANCO/3030/09 SANCO/10567/2003 (Equivalence of TGA1)					Yes	Public discussion only makes sense regarding already registered minimum purity and relevant impurities
Relevance of metabolites, Residue definition for MRL setting and RA	MCA 5.1.1	Absorption, distribution, metabolism and excretion after exposure by oral route	Investigation of bioavailability for parent and metabolites	Changed policy on evaluation of metabolites	Method B.36 Toxicokinetics (Annex to Regulation (EC) No 440/2008). OECD Test Guideline 417: Toxicokinetics				yes		
	MCA 5.8	Mammalian toxicology - crop and livestock metabolites	Genotoxicity, acute and subchronic toxicity studies for crop and livestock metabolites	Changed policy on evaluation of metabolites					yes		
	MCA 6.2	Metabolism in target crops	Metabolism in rice	Extension of uses	OECD Test Guideline 501: Metabolism in crops						
	MCA 6.2	Metabolism in livestock	Metabolism in fish (oral dosing)	New EU guideline	SANCO/11187/2013				yes		
	MCA 6.7	Residue definition for MRL setting and RA		Changed policy on evaluation of metabolites; international harmonization	OECD (2006). Guidance Document on the Definition of Residues. Environment, Health and Safety Publications. Series on Testing and Assessment No. 83 and Series on Pesticides No. 31						Subsequent to MCA 5.1.1, 5.8 and 6.2

New existing studies

Dossier section / data point	Areas where today's requirements are not longer met by existing data	Study title (if available)	Justification	Guidelines	CRO	Date of issue	GLP	Vertebrate	Notifier comment
MCA 4.1	Residue Analytical Methods in crops	Validation of methods in crop matrices and processed fractions	Available studies not in accordance with today's requirements	SANCO/3029/99 rev.4; OECD (2007). Guidance Document on Pesticide Residue Analytical Methods. Environment, Health and Safety Publications. Series on Testing and Assessment No. 72 and Series on Pesticides No. 39.	EUROFINS	June 15 2015	EUROFINS	June 15 2015	

Transparency



Notification of Studies – How? – When?

- ❖ Applicant submits Register to EFSA after pre-submission meetings
- ❖ EFSA publishes on Website and opens for public comments

Note:

- Most studies have been completed or are ongoing
- Remit should be to inform before dossier submission
- Assess need for/suggestions for other studies

Questions

- Public comments : how long? – 30 days
- How will public comments be handled?
 - Non standard studies
 - Verification studies
- How to formally address/respond to comments/suggestions?

Transparency



Disclosure of study reports – How? – When?

➤ Art 38, Making Public

EFSA shall make public (among other things):

- “*scientific data, studies and other information supporting applications*”, (including supplementary information)
- a **summary** of advice provided at pre-submission phase
- “*without delay*” once an application has been considered admissible

- ❖ EFSA publishes full dossier (except confidential sections) on Website after completeness check and opens for public comments
- ❖ GTF will make sanitized version of dossier available

Questions

- Public comments : how long? –30 days
- How will public comments be handled?

Transparency

Disclosure of communication with authorities



- ❖ Applicant will make public all written exchanges with authorities
- ❖ RMS, EFSA, COM
- ❖ GTF transparency portal

Scope:

- Letters
- E-mails
- Minutes of meetings
- Elements submitted as part of dossier not in scope (GFL principles apply)
- Other elements?

Questions

- Agreement? Concerns?

Pre-submission meeting(s)

Scope : general



➤ Focus on technical/regulatory aspects of the dossier

- ❖ Per Section : state of play (endpoints –conclusions)
- ❖ Gaps identified by EFSA (2015)
- ❖ New studies/new assessments – *what-where-how-who-by when?*
- ❖ Representative GAP – Representative formulation
- ❖ Methodology details of handling the literature review
- ❖ Questions

➤ Practical set-up; logistics?

Pre-submission meeting(s)

Special attention to the following topics



➤ Residues in Honey-Establishing MRL in Honey

- New EFSA requirement (to follow the new Guidance on the establishment of the residue definition for dietary risk assessment“)
- Tunnel Study initiated
- Protocol and use of monitoring data need to be explained



➤ Toxicology

- Anses long term study
- Revisit the ADI and the study it is based on
- Need for phototoxicity testing
- Genotoxicity of glyphosate based formulated products
- Data presentation glyphosate genotoxicity/carcinogenicity
- ED-assessment following the “ECHA-EFSA Guidance Document “Guidance for the identification of ED in the context of Reg (EU) No 528/2012 and (EC) No 1107/2009”



➤ Eco-toxicology

- Acceptability of Vole population modelling
- Higher tier refinement studies (Vole enclosure studies)
- Endpoint selection for bird and mammalian risk assessment
- Impact on biodiversity through trophic interaction
- ED-assessment following the “ECHA-EFSA Guidance Document “Guidance for the identification of ED in the context of Reg (EU) No 528/2012 and (EC) No 1107/2009”



➤ Analytical methods

- Extractability





Literature Review (EFSA 2092 - 2011)

Complete exhaustive literature review from 2012-2020

➤ 3 Phases

- **Phase 1** : 2012-2018
- 7,000+ new articles published
- **Phase 2** : 2018 – present
- **Phase 3** : present - 2020

➤ **Relevance assessment** which articles to include (content)

- **In scope**: Articles relevant to risk assessments + articles with negative allegations/gaining popularity from activists/media

➤ OECD summaries and **reliability assessment** (criteria per section)

➤ Technical/regulatory **positioning**

➤ List of and link to recent (?) **Regulatory Evaluation Documents**

Literature Review



Part 1: Literature review from Jan 12 - Jan 18

	STN search P1 Relevant articles subject for reliability assessment	STN Search P2 (Feb 18 - Jun 19)	STN Search P3 (Jul 19- Dec 19)
Ecotox	192	tbd	tbd
E-Fate	99	tbd	tbd
Residues	4	tbd	tbd
Toxicology & Metabolism	59	tbd	tbd

354

Glyphosate AIR V



Questions

- What advice can AGG provide after this consultation and in what time frame?
- What advice/level of consultation to expect from EFSA?
- What can the Task Force do to facilitate the review?



Thank you!

