Environmental Fate / Modelling

[redacted],
knoell Germany

[redacted], Nufarm Europe Ltd.

General considerations – revisiting existing data

- For revisiting existing data, EFSA administrative guidance* will be followed
- All studies referred to in the two available Monographs (glyphosate & glyphosate trimesium) and the RAR (2015) are considered as the fundamental data set
- All existing studies will be assessed against current guidelines and requirements
- All studies that are considered still acceptable will be summarized in the dossier (full OECD)
- For studies considered not acceptable anymore, a substantiated justification will be presented in the dossier and a shortened summary using the table provided to the GTF by the AGG
- Information from publications/literature search might add to the information from studies

* EFSA technical report: Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances, approved: 27 March 2019, doi:10.2903/sp.efsa.2019.EN-1612

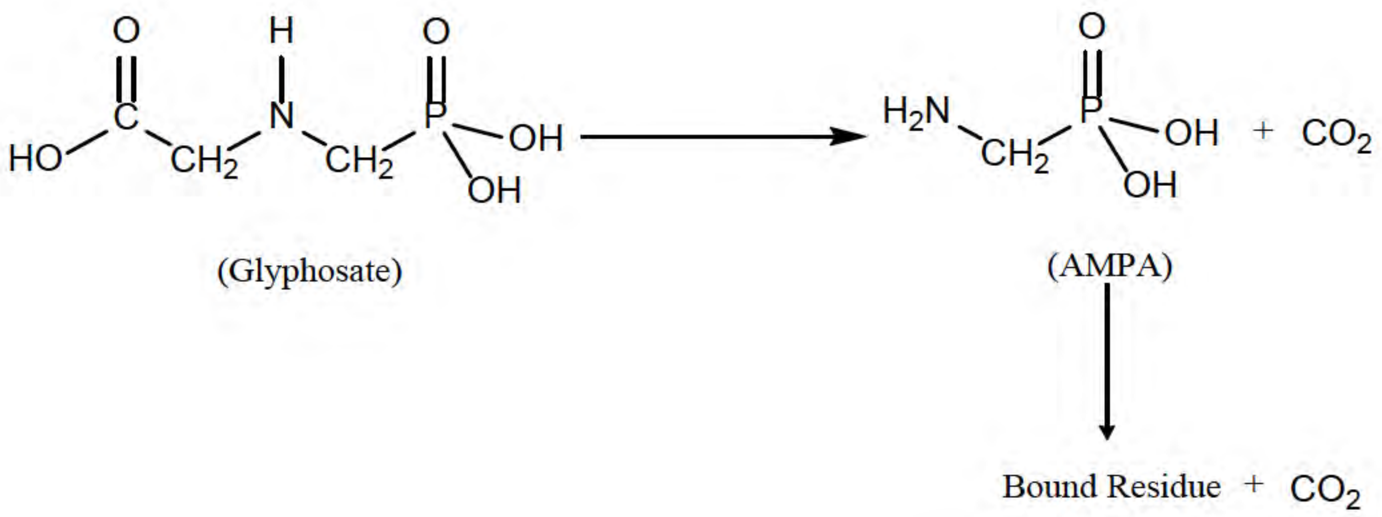
Degradation in soil - laboratory

Overview on existing experimental studies in RAR

Study type	Studies in Monographs that were NOT listed in RAR	Studies in RAR	Studies to be revisited in AIR5	Comment
Aerobic degradation in soil	2	18	20	
Anaerobic degradation in soil	(1)	5	5	Study in Trimesium Monograph only relevant for anion; not to be considered for AIR5
Soil photolysis	-	6	6	Five existing studies up to now never evaluated in detail

Metabolic pathway in soil

Existing data



Degradation in soil - laboratory

Active substance – Data according to existing LoE

Soil type	pH (H_2O)	T (°C) / soil moisture	DT_{50} (d)	DT_{90} (d)	Method of calculation	Modelling DT_{50} (d) 20°C, pF2	Method of calculation
Gartenacker, loam	7.1	20/ pF2.5	7.86	56.29	DFOP	16.0	DT_{90} FOMC/ 3.32
Arrow, sandy loam	6.5	20/ 40% MWHC	37.75	1661	FOMC	159.6	DFOP slow phase
Soil B, sandy loam	6.7	25/ 75% of 1/3 bar	1.2	20.8	FOMC	6.6	DT_{90} FOMC/ 3.32
Les Evouettes, Silt Loam	6.1	20/ 40% MWHC	8.55	83.92	DFOP	93.3	DT_{90} FOMC/ 3.32
Maasdjik, sandy loam	**7.5**	20/ 1/3 bar	4.61	62.00	DFOP	15.2	DT_{90} FOMC/ 3.32
Drusenheim, loam	7.4	20/ pF2.5	2.06	15.38	DFOP	4.2	DT_{90} FOMC/ 3.32
Pappelacker, loamy sand	7.0	20/ pF2.5	3.94	43.45	FOMC	12.0	DT_{90} FOMC/ 3.32
18-Acres, clay loam	**5.7**	20/ pF2.5	**67.72**	471.4	DFOP	**160.5**	DFOP slow phase
Speyer 2.3, Loamy Sand	6.9	20/40% MWHC	5.78	21.99	DFOP	7.2	DT_{90} FOMC/ 3.32
Speyer 2.1, sand	6.5	20/ 45% MWHC	8.3	51.3	DFOP	19.5	DT_{90} FOMC/ 3.32
Speyer 2.2, loamy sand	6.2	20/ 45% MWHC	18.7	428	FOMC	72.2	DFOP slow phase
Speyer 2.3, loamy sand	6.9	20/ 45% MWHC	2.70	13.03	DFOP	3.76	DT_{90} FOMC/ 3.32
Dupo, silt loam	7.3	25/ 75% FC	**1.01**	9.31	FOMC	**3.70**	DT_{90} FOMC/ 3.32
Speyer 2.2, loamy sand	6.0	20/ 40% MWHC	43.53	144.61	SFO	40.6	SFO
Speyer 2.1, sand	6.9	20/ 40% MWHC	11.11	144.25	FOMC	43.06	DT_{90} FOMC/ 3.32

bold: minimum & maximum values

Degradation in soil - laboratory

Active substance

Actions planned so far by GTF2

- Degradation kinetics will be updated according to FOCUS guidance using latest software versions
- For aerobic soil degradation studies, potential of pH dependency of $DegT_{50}$ will be assessed using the German Input Decision Tool
- pH range of soils tested for soil studies based on pH (water)

Question to AGG

- Recovery <90% as strict criterion to eliminate a single data point?
- Microbial biomass <1% of OC as strict criterion to eliminate experiment?
- Criterion to fulfill pH range of soils ($CaCl_2$ or water)?

Degradation in soil - laboratory

Metabolite AMPA – Data according to existing LoE

Soil type	pH (H_2O)	T (°C) / % soil moisture	DT_{50} (d)	DT_{90} (d)	Method of calculation	Modelling DT_{50} (d) 20°C pF2/10kPa	f. f. ($k_{par} \rightarrow k_{met}$)	Method of calculation
Gartenacker, loam	7.1	20/ pF2.5	120.07	398.9	DFOP (par) – SFO (met)	119.9	**0.1817**	FOMC (par) – SFO (met)
Soil B, sandy loam	6.7	25/ 75% of 1/3 bar	99.1	329	FOMC (par) – SFO (met)	106.2	0.2646	FOMC (par) – SFO (met)
Les Evouettes, Silt Loam	6.1	20/ 40% MWHC	**300.71**	998.9	DFOP (par) – SFO (met)	**300.9**	0.3618	FOMC (par) – SFO (met)
Drusenheim, loam	7.4	20/ pF2.5	**38.98**	129.5	DFOP (par) – SFO (met)	36.8	0.2578	FOMC (par) – SFO (met)
Pappelacker, loamy sand	7.0	20/ pF2.5	126.57	420.5	FOMC (par) – SFO (met)	116.3	0.1835	FOMC (par) – SFO (met)
18-Acres, clay loam	**5.7**	20/ pF2.5	No DT_{50} available				0.2169	FOMC (par) – SFO (met)
Speyer 2.3, loamy sand	6.9	20/ 40% MWHC	77.50	257.43	DFOP (par) – SFO (met)	70.92	0.3435	FOMC (par) – SFO (met)
Speyer 2.1, sand	6.5	20/ 45% MWHC	No DT_{50} available				0.520	DFOP (par) – SFO (met)
Speyer 2.2, loamy sand	6.2	20/ 45% MWHC	No DT_{50} available				**0.6076**	FOMC (par) – SFO (met)
Speyer 2.3, loamy sand	6.9	20/ 45% MWHC	41.87	139.10	DFOP (par) – SFO (met)	42.14	0.4283	FOMC (par) – SFO (met)
Dupo, silt loam	**7.3**	25/ 75% FC	48.32	160.5	FOMC (par) – SFO (met)	**30.5**	0.3637	FOMC (par) – SFO (met)
Speyer 2.1, sand	6.9	20/ 40% MWHC	230.7	766	FOMC (par) – SFO (met)	230.7	0.5851	FOMC (par) – SFO (met)

bold: minimum & maximum values

Degradation in soil - laboratory

Metabolite AMPA

New data from GTF2

- New degradation study to be submitted to address EFSA request:
  "…to investigate the degradation rate of major metabolite AMPA in soils with pHs in the acidic range…"
- Soil characteristics:

Soil	Origin	Texture (USDA)	pH ($CaCl_2$)	pH (H_2O)*	TOC [%]
Warsop	UK	loamy sand	3.9	4.6	1.76

*Calculated with German Input Decision Tool

- Extraction performed with rather harsh solvent (1N NaOH), which is worst-case with regard to soil degradation
- DT_{50} = 326 d, DT_{90} = 1080 days (SFO); same range as existing data
- Study is considered acceptable to address data gap. The low pH and harsh extraction method represent worst-case conditions with regard to soil degradation of AMPA.

Question to AGG

- Position of AGG regarding acceptance of AMPA soil degradation study?

Degradation in soil – field data

Overview on existing experimental studies in RAR

Study type	Studies in Monographs that were NOT listed in RAR	Studies in RAR	Studies to be revisited in AIR5	Comment
Terrestrial field dissipation	3+1	5	8+1	1 study in Monograph overview study of US soils; some studies not in field (e.g. forestry, leaf litter)

Degradation in soil – field data

Active substance – Data according to existing LoE

Location	Soil type	Application rate (kg a.s/ha)	pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	Method of calculation
Diegten, Switzerland	Sandy clay	3.53	7.1	0-30	6.1	116.1	DFOP
Menslage, Germany	Sandy loam	3.67	**4.7**	0-30	**5.7**	200.8	DFOP
Buchen, Germany*	Loamy sand	5.20	6.4	0-30	**40.9**	187.3	DFOP
Kleinzecher, Germany*	Sandy loam	5.7	7.0	0-30	38.3	**386.6**	DFOP
Unzhurst, Germany*	Loam	4.8	6.7	0-30	27.7	122.3	DFOP
Rohrbach, Germany*	Silt loam	5.0	**8.5**	0-30	20.1	**66.9**	SFO
Herrngiersdorf, Germany*	Clay loam	4.6	8.0	0-30	33.7	111.9	SFO
Wang-Inzkofen, Germany*	Silt loam	4.8	7.2	0-30	17.8	165.5	FOMC

* Glyphosate-trimesium as test substance

bold: minimum & maximum values

Degradation in soil – field data

Metabolite AMPA – Data according to existing LoE

Location	Soil type	pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	Formation fraction (ff)	Method of calculation
Kleinzecher, Germany*	Sandy loam	7.0	0-30	514.9	>1000	0.508	DFOP-SFO
Unzhurst, Germany*	Loam	**6.7**	0-30	**633.1**	>1000	**0.332**	DFOP-SFO
Rohrbach, Germany*	Silt loam	**8.5**	0-30	374.9	>1000	n.d.	SFO (decline fit)
Herrngiersdorf, Germany*	Clay loam	8.0	0-30	288.4	958.1	n.d.	SFO (decline fit)
Wang-Inzkofen, Germany*	Silt loam	7.2	0-30	**283.6**	942.3	**0.547**	FOMC-SFO

* Glyphosate-trimesium as test substance

bold: minimum & maximum values

Degradation in soil – field data

Actions planned so far by GTF2

- Degradation kinetics will be evaluated/updated for persistence and modelling endpoints according to FOCUS and EFSA guidance (2014) using latest software versions
- Field studies from **US/Canada**:
  - Evaluated and accepted, in principle, in Monograph
  - For AIR2, evaluation of degradation kinetics submitted
  - In RAR not accepted as regions not considered representative for Europe
  - Studies will be re-evaluated for AIR5 → Ecoregion crosswalk-approach with OECD ENASGIPS tool → decision on validity/presentation of details in dossier will be made

Question to AGG

- Position of AGG regarding the suggested handling of existing field data from US/Canada?

Adsorption to soil

Overview on existing adsorption/desorption studies in RAR

Study type	Studies in Monographs that were NOT listed in RAR	Studies in RAR	Studies to be revisited in AIR5	Comment
Parent adsorption/ desorption	8	6	14	Existing studies not evaluated in detail in AIR2 but endpoints included in LoEP. Study in Trimesium Monograph only relevant for anion; not to be considered for AIR5 Studies will be evaluated according EFSA OECD 106 evaluators checklist*.
AMPA adsorption/ desorption	1 (+1)	4	5	

* Outcome of the pesticides peer review meeting on the OECD 106 evaluators checklist, EFSA technical report, 07 November 2017, doi:10.2903/sp.efsa.2017.EN-1326

Adsorption to soil

Active substance – Data according to existing LoE

Soil Type	OC %	Soil pH (H_2O)	K_d (mL/g)	Koc (mL/g)	K_f (mL/g)	Kfoc/Kdoc (mL/g)	1/n
Drummer, silty clay loam	1.45	6.5	-	-	324.0	22300	0.92
Dupo, silt loam	0.87	7.4	-	-	33.0	3800	0.80
Spinks, loamy sand	1.10	**5.2**	-	-	660.0	**60000**	1.16
Greenan sand, sand	0.80	5.7	263	32838	-	32838	1.00
Auchincruive, sand loam	1.60	7.1	811	50660	-	50660	1.00
Headley Hall, sandy clay loam	1.40	7.8	50	3598	-	3598	1.00
Californian sandy soil, loamy sand	0.60	8.3	5	884	-	**884**	1.00
Les Evouettes II, silt loam	1.40	6.1	48	3404	-	3404	1.00
Darnconner sediment, loam (Sediment)	**3.00**	7.1	510	17010	-	17010	1.00
Lilly Field, sand	**0.29**	5.7	-	-	64.0	22000	0.75
Visalia, sandy loam	0.58	**8.4**	-	-	9.4	1600	0.72
Wisborough Green, silty clay loam	2.26	5.7	-	-	470.0	21000	0.93
Champaign, silty clay loam	2.15	6.2	-	-	700.0	33000	0.94
18 Acres, sandy loam	1.80	7.4	-	-	90.0	5000	0.76
Speyer 2.1, sand	0.62	6.5	-	-	29.5	4762	0.84
Speyer 2.2, loamy sand	2.32	6.2	-	-	71.7	3091	0.84
Speyer 2.3, loamy sand	1.22	6.9	-	-	37.7	3092	0.84
Soil 2.1, sand	0.70	5.9	66.4	9486	-	9486	1.00
Soil 2.3, loamy sand	1.34	6.3	76.5	5709	-	5709	1.00
Soil F3, sandy loam	1.20	7.3	54.4	4533	-	4533	1.00

bold: minimum & maximum values

Adsorption to soil

Active substance - evaluation according to EFSA's OECD 106 evaluators checklist (Preliminary results - study from Monograph not evaluated yet)

[redacted] 1986	• No complete material balance (recovery: approx. 70% AR), possibly due to loss of CO_2 • No parental mass balance established, chromatographic analysis of adsorption supernatants only • Glyphosate reported to be not stable in supernatant (≤ 59% test item)
[redacted] 1992	• No parental mass balance established (adsorbed amounts 50-99%) • Only $CaCl_2$ supernatants analysed (no extraction step performed) • 1 test concentration, only
[redacted] 1993	• Parental mass balance <90% due to formation of NER • No pre-equilibration performed • 1 test concentration, only
[redacted], 1996	• Degradation >10% in supernatant and soil extracts (for respective fraction) • Chromatographic analysis performed for "individual replicate samples" only • Results of parental mass balance not given in detail → check for systemic errors cannot be performed due to missing f-factor
[redacted], 1996	• Stability of test item not demonstrated • Extraction steps performed but no results of chromatographic analysis presented • Chromatographic results only of second desorption step shown, residues in soil after desorption >10% • Results of parental mass balance not given in detail → check for systemic errors cannot be performed due to missing f-factor
[redacted], 2001	• Invalidated during AIR2: "On balance the experts considered that the results of the Van Noorloos & Slangen experiments should be excluded from the dataset as the longer batch equilibrium time (compared to other investigations or investigations where soils were sterilised) meant that degradation of glyphosate that occurred during the study resulted in lower confidence in these data"

Preliminary conclusion: evaluation showed potential major deficiencies for all studies

Adsorption to soil

Active substance

Actions planned so far by GTF2

- New adsorption data according to OECD 106 guideline:
  - ^{14}C-labelled test substance including check for stability during the test
  - 10 test soils to address potential pH dependency
  - Determination of adsorption Freundlich isotherms in definitive phase dependent on results of preliminary phase
  - pH dependency of adsorption coefficients will be assessed using the German Input Decision Tool

Question to AGG

- Position of AGG regarding existing studies and the proposed new study design?

Adsorption to soil

Metabolite AMPA – Data according to existing LoE

Soil Type	OC %	Soil pH (H_2O)	K_d (mL/g)	Koc (mL/g)	K_f (mL/g)	Kfoc/Kdoc (mL/g)	1/n
SLI Soil #1, clay loam	2.09	7.7	-	-	77.1	3640	0.79
SLI Soil #4, sand	1.33	7.4	-	-	15.7	1160	0.75
SLI Soil #5, clay loam	0.93	7.6	-	-	53.9	5650	0.79
SLI Soil #9, loamy sand	1.57	6.3	-	-	110.0	6920	0.77
SLI Soil #11, sand	0.29	**4.6**	-	-	73.0	24800	0.79
Lilly Field, sand	**0.29**	5.7	-	-	133.0	**45900**	0.86
Visalia, sandy loam	0.58	**8.4**	-	-	10.0	1720	0.78
Wisborough Green, silty clay loam	2.26	5.7	-	-	509.0	22500	0.91
Champaign, silty clay loam	2.15	6.2	-	-	237.0	11100	0.86
18 Acres, sandy loam	1.80	7.4	-	-	74.2	4130	0.84
Schwalbach, silt loam	1.59	6.1	-	-	137.4	8642	0.98
Hofheim, silt loam	1.24	6.1	-	-	87.9	7089	0.92
Bergen-Enkheim, silty clay	2.25	8.3	-	-	33.9	1507	0.91
Soil 2.1, sand	0.90	5.8	-	-	16.7	1861	0.6650
Soil 2.2, loamy sand	2.30	6.2	-	-	189.7	8248	0.5506
Soil 3A, sandy silty loam	**2.60**	7.6	-	-	29.1	**1119**	0.67109

bold: minimum & maximum values

Adsorption to soil

Metabolite AMPA - evaluation according to EFSA's OECD 106 evaluators checklist

[redacted], 1996	• Detailed results of parental mass balance not reported (exact value of f-factor cannot be given) • Recovery of AMPA in aqueous supernatants ($CaCl_2$ solution) and soil extracts generally stated as > 90% • Parental mass balance possibly < 90% if sum of NER and degraded AMPA would have exceeded 10%
[redacted], 2003	• No complete parental mass balance (< 90%) • Extraction method not exhaustive resulting in formation of NER > 10% which are considered as degradation products

Adsorption to soil (2)

Metabolite AMPA - evaluation according to EFSA's OECD 106 evaluators checklist

[redacted], 1993	• Results of **SLI Soil #4 and #5 are considered valid** following evaluation according to evaluators checklist
	• Three soils (SLI Soil #1, #9 and #11) showed insufficient material balances as well as parental mass balances <90%
	• SLI Soil #2 was excluded during previous evaluation **due to high OC content** of 18.7%
	• Note: Limit of detection/quantification not given in the report. However, the analytical method (LSC) is considered reliable due to the following reasons:
	  • radioactivity in an aliquot (5 mL) of lowest test concentration > 500 Bq which is 100 fold higher than a average instrumental LOD of 5 Bq.
	  • Assuming a theoretical conservative efficiency of 30% results in a background of approx. 280 dpm which is 200 fold lower than then lowest test concentration of 0.0394 mg/L (equivalent to approx. 90000 dpm per aliquot).

[redacted], 2002	• Results of **soils 2.1 and 2.2 are considered valid** • Soil 3A showed high K_{fE}/K_f value of 1.6 indicating systemic errors • Note: For soil 2.1 the parental mass balance was established at a soil:solution ratio of 1:50 while the definite test was performed at a soil:solution ratio of 1:25. The effect of this difference on stability of test item is considered as negligible.

Adsorption to soil

Metabolite AMPA

Evaluation by GTF2

- Suggestion of endpoints considered for AIR5 dossier
- Overall four data sets/soils regarded as valid for use in risk assessment:

Soil Type	OC %	Soil pH (H_2O)	K_f (mL/g)	Kfoc/Kdoc (mL/g)	1/n
SLI Soil #4, sand	1.33	7.4	15.7	1160	0.75
SLI Soil #5, clay loam	0.93	7.6	53.9	5650	0.79
Soil 2.1, sand	0.90	5.8	16.7	1861	0.6650
Soil 2.2, loamy sand	2.30	6.2	189.7	8248	0.5506

- pH dependency of adsorption coefficients will be assessed using the German Input Decision Tool

Question to AGG

- Does AGG consider the remaining experiments as sufficient for risk assessment?

Degradation in water

Overview on existing experimental studies in RAR

Study type	Studies in Monographs that were NOT listed in RAR	Studies in RAR	Studies to be revisited in AIR5	Comment
Hydrolysis	7	3	10	Glyphosate concluded to be stable
Aqueous photolysis	1	4+2	7	Considered as supplemental information, no experimental study required, partly presented with physical-chemical properties in RAR
Water/sediment	6	8	14	

Degradation in water (chemical and photochemical degradation)

Active substance & metabolite AMPA

- Existing studies on hydrolysis and photolysis in sterile aqueous buffer included in RAR regarded as acceptable and reliable
- Glyphosate and AMPA are considered stable to hydrolysis
- For Glyphosate, molar (decadic) absorption coefficient (ε) <10 L × mol^{-1}× cm^{-1} at a wavelength (λ) ≥295 nm, thus experimental study on aqueous photolysis formally not required
- In one experimental aqueous photolysis study, DT_{50} of glyphosate was 33 d (pH 5), 69 d (pH 7) and 77 d (pH 9); AMPA was detected at levels of 16% (pH 5), 11.6% (pH 7) and 6.5% (pH 9)
- AMPA is considered stable to direct aqueous photolysis
- Experimental aqueous photolysis studies are considered as supplemental information

Question to AGG

- Position of AGG regarding the role of experimental aqueous photolysis studies?

Degradation in water/sediment systems

Active substance & metabolite AMPA

Existing data & actions planned so far by GTF2

- Glyphosate is low to highly persistent under conditions of test (based on RAR), $DT_{50,\text{whole system}}$ = 13.82 to >301 days (SFO)
- Major metabolites (based on RAR):
  - Water phase: AMPA (max. 15.7% AR after 14 d)
    HMPA (max. 9.9% AR after 61 d)
  - Sediment: AMPA (max. 18.7 % AR after 58 d)
- AMPA is moderately to highly persistent (based on RAR), $DT_{50,\text{whole system}}$ = 57.61 to 455.72 days (SFO)
- Degradation kinetics will be updated according to FOCUS guidance using latest software version

Further existing studies

Active substance

- **Column leaching** studies will be presented as supplemental information
- Glyphosate is not **ready biodegradable**, only studies conducted according to OECD guidelines 301 (ready biodegradability) or 302B (Inherent Biodegradability: Zahn-Wellens/ EVPA Test) will be presented in dossier
- Route and rate of degradation in **air**:
  - Volatilisation studies will be presented as supplemental information
  - Calculation of atmospheric half-life will be updated using latest software

Question to AGG

- Any comments from AGG on column leaching and behavior in air?

New environmental fate studies planned for AIR5

- Experimental studies:
  - Rate of degradation in aerobic soil: metabolite AMPA, 1 acidic soil (final)
  - Adsorption to soil: Glyphosate (scheduled)
  - Aerobic mineralisation in surface water (OECD 309) (ongoing)
- Calculation/simulation studies
  - Updated kinetic evaluations for studies on soil laboratory degradation, field dissipation & water/sediment systems
  - Updated calculation of atmospheric half-life

Potential effects of water treatment

Active substance

- No guidance available at EU level
- Theoretical assessment planned to be based on:
  - Available literature data
  - Estimation of concentration at drinking water abstraction points based on PEC modelling

Question to AGG

- Any comments from AGG ?

[redacted]
BAYER AG
Crop Science

Environmental Monitoring

Introduction

Aim: Undertake a comprehensive review of public monitoring datasets, building on and expanding the 2015/2016 review, to better understand and address potential risks to the environment and human health.

Approach: Build on the 2015/2016 review through:

- Considering an additional (non-relevant) metabolite HMPA
- Considering additional compartments of Air, Soil and Sediment
- Expanding the dataset to include new data/datasets and recent years
- Harmonising the dataset to facilitate comparable and additional analyses

Where potential risks to various compartments are indicated by the monitoring data, seek to understand their regulatory significance and the factors driving them. Identify risk mitigation and communication strategies to promote continued improvement in environmental quality.

Public Monitoring Datasets

Review of datasets 2015/2016 ([redacted], 2015/2016)

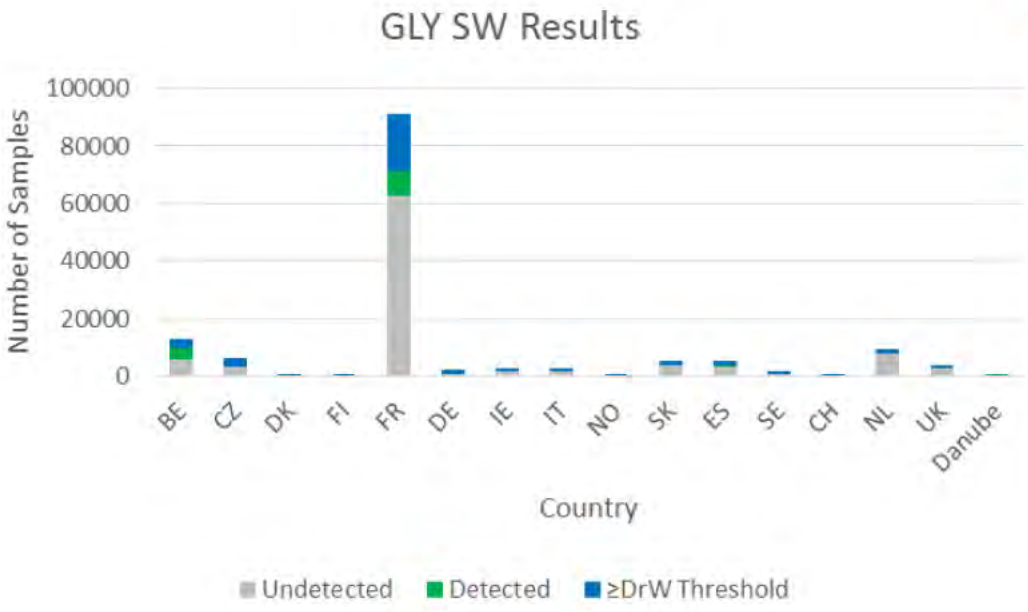
- Previous evaluations considered: Surface Water (SW), Ground Water (GW), Drinking Water (DrW)

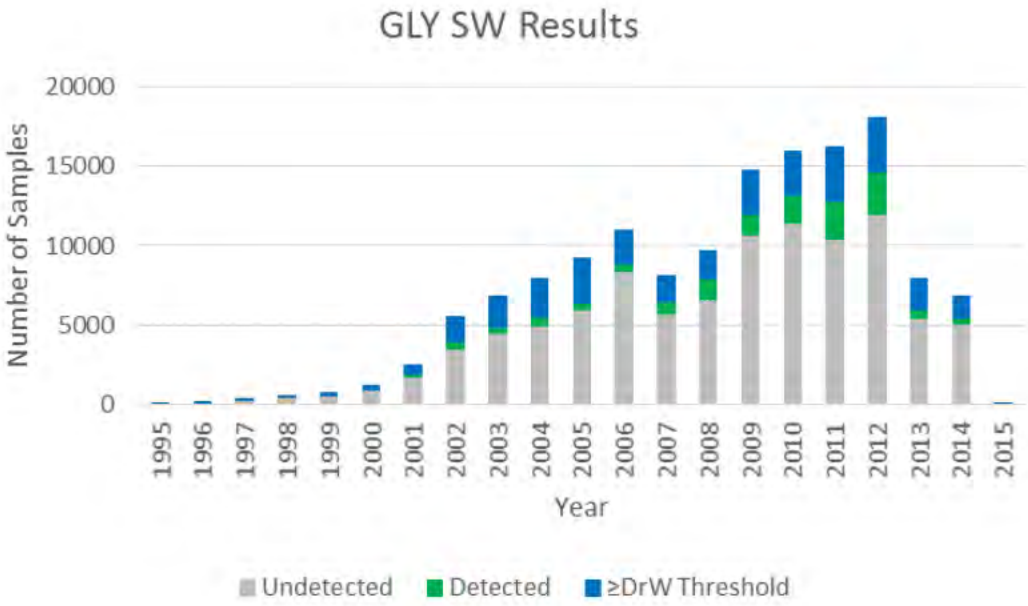
- SW/GW
  - Monitoring data for 16 (SW) / 15 (GW) MS (some MS analysed for GLY or AMPA only)
  - Confirmation received that no monitoring data for GLY or AMPA was collected in 11 MS
- DrW
  - Monitoring data for 11 MS
  - No monitoring collected in 2 MS based on risk assessment
  - Confirmation received that no monitoring data for GLY or AMPA was collected in 3 MS

Public Monitoring Datasets - SW

Review of datasets ([redacted] 2016)

- 16 MS plus Danube Basin with data
  - GLY ~143 000 samples (1993 – 2015)
  - AMPA ~115 000 samples (1997– 2015)
- Detection rate
  - GLY ~30.8 %; AMPA ~ 49.8 %
- Exceedance rate (0.1 µg/L, not RAC)
  - GLY ~ 21.5 %; AMPA ~ 41.5 %
- GLY/AMPA frequently detected
  - Concentrations highly variable and often >0.1 µg/L; Exceedance of SW RAC unlikely
  - AMPA concentrations typically higher owing to other sources of AMPA

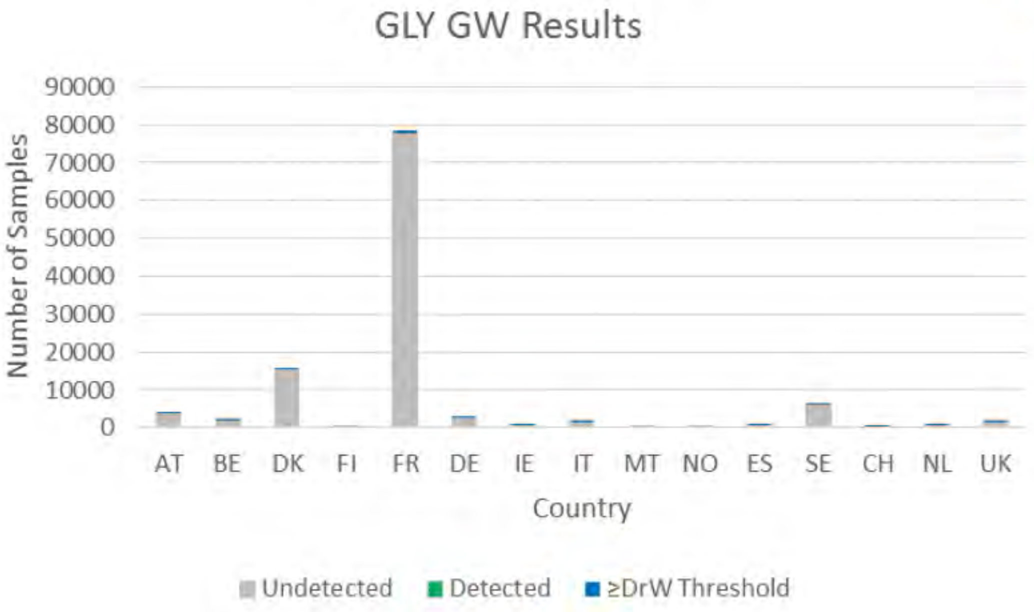


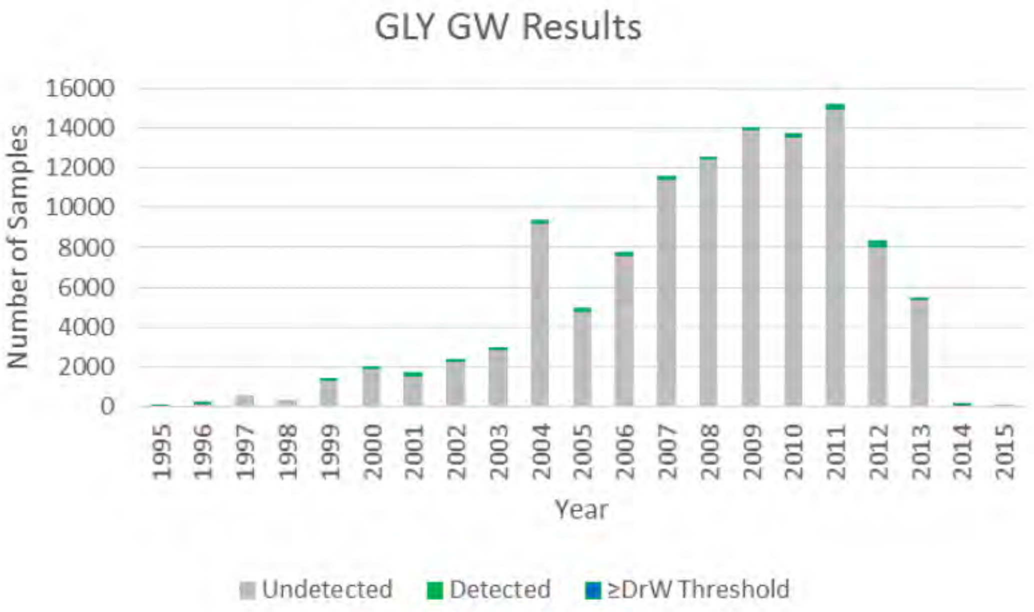


Public Monitoring Datasets - GW

Review of datasets ([redacted], 2016)

- 15 MS with data
  - GLY ~114 000 samples (1990 – 2015)
  - AMPA ~105 000 samples (1990 – 2013)
- Detection rate
  - GLY ~1.3 %; AMPA ~2.1 %
- Exceedance rate (0.1 µg/L)
  - GLY ~0.63 %; AMPA ~0.75 %
- GLY/AMPA rarely found in GW
  - Isolated not systematic detections
  - Associated shallow GW; direct SW influence
  - Some MS reduced/stopped monitoring as low risk

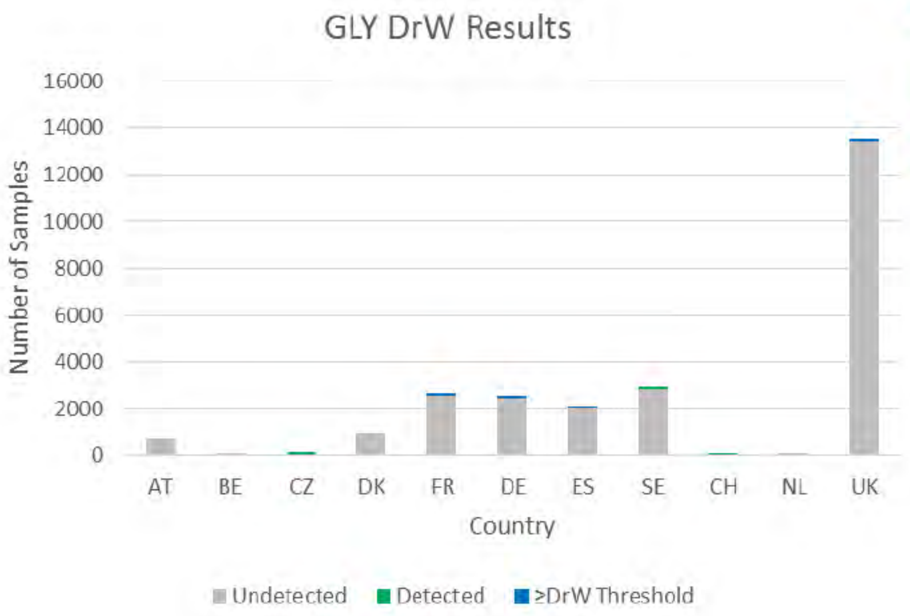


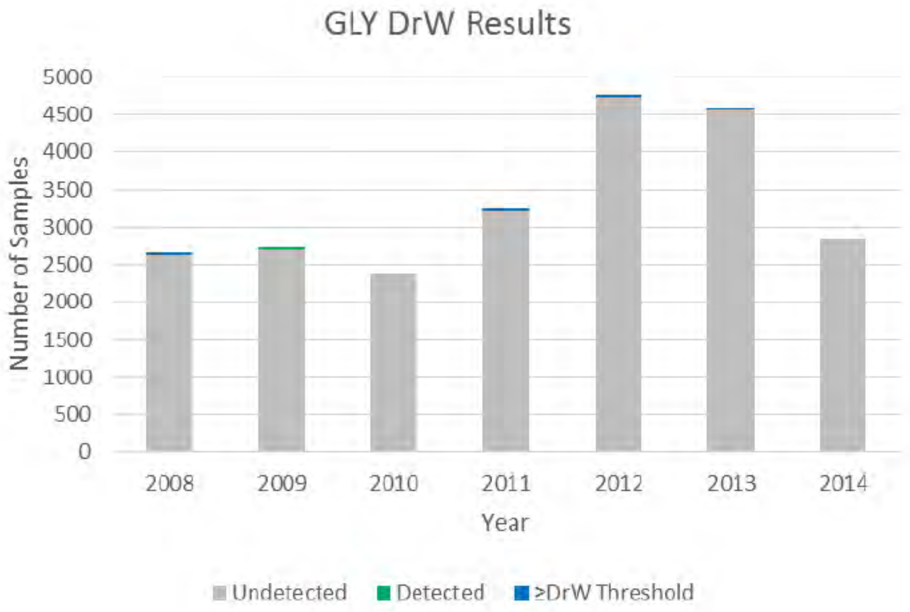


Public Monitoring Datasets - DrW

Review of datasets ([redacted], 2015)

- 11 MS with data
  - GLY ~25 000 samples (2008 – 2015)
  - AMPA ~6 500 samples (2008 – 2015)
- Detection rate
  - GLY ~0.11 %
  - AMPA ~0.39 %
- Exceedance rate (0.1 µg/L)
  - GLY ~0.09 %
  - AMPA ~0.22 %
- Small number of isolated detections and exceedances
  - Detections often associated with small supplies





Public Monitoring - Update

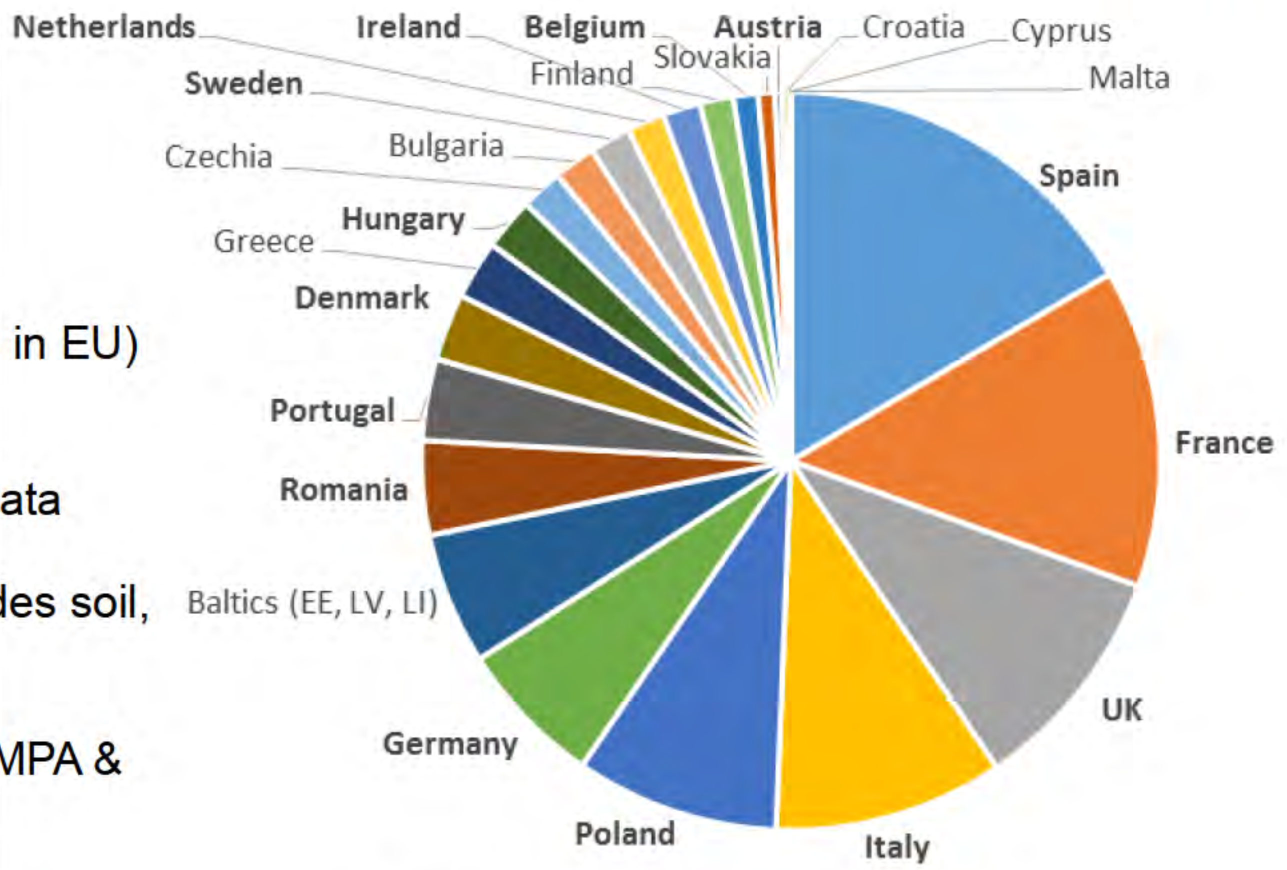
Review of readily accessible datasets 2019

- Estimated GLY applications and pedoclimatic factors used to inform data sourcing activity
  - NZ ~12%; CZ ~37%; SZ ~51%
- Requesting data from MS with
  - Significant GLY applications (MS in bold ~82% in EU)
    - NZ ~6%; CZ ~42%; SZ ~52%
  - Readily available and substantive monitoring data

Project scope: mainly GW, SW, DrW but also includes soil, sediment and air (where available)

Substances: GLY and (non-relevant) metabolites AMPA & HMPA

Time period: 1995 (where available) – 2018 but focus on most recent years 2012 - 2018



Estimated application amounts of GLY in 2018

Public Monitoring - Update

Review of readily accessible datasets 2019

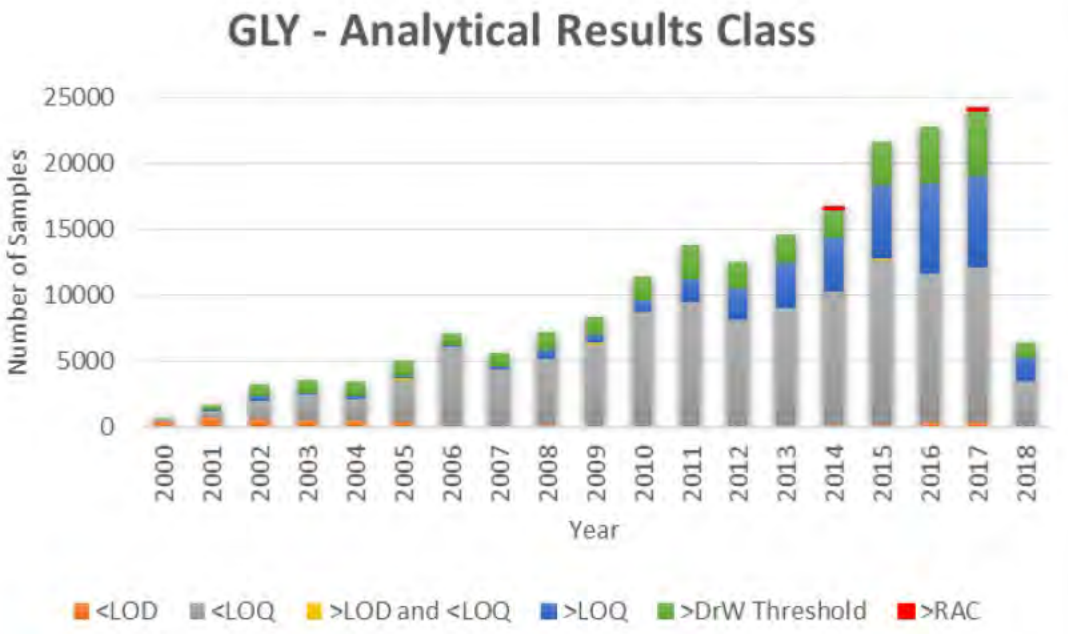
- Collation of raw data on a consistent basis to promote standardised analysis across each MS
- Focus on the exceedances and attempt to contextualise these further
  - Recommend comparing surface water detects against RAC instead of DrW threshold 0.1 µg/L; separate assessment of DrW is being undertaken
  - AIR2: GLY RAC - 100 µg/L; AMPA RAC - 1200 µg/L; HMPA RAC - 1000 µg/L
- Assessment of spatial and temporal distribution
  - Spatial: are data clustered?
  - Temporal: exceedance rate and duration (associated with detections)
- Assess potential drivers for the exceedance to inform regulatory relevance and mitigation options
  - Climate, catchment composition, urban contributions, proximity to surface water bodies
- Detailed elucidation of a limited number of sites
  - Detailed site and monitoring data assessment; Including other pollutants, e.g. nitrate

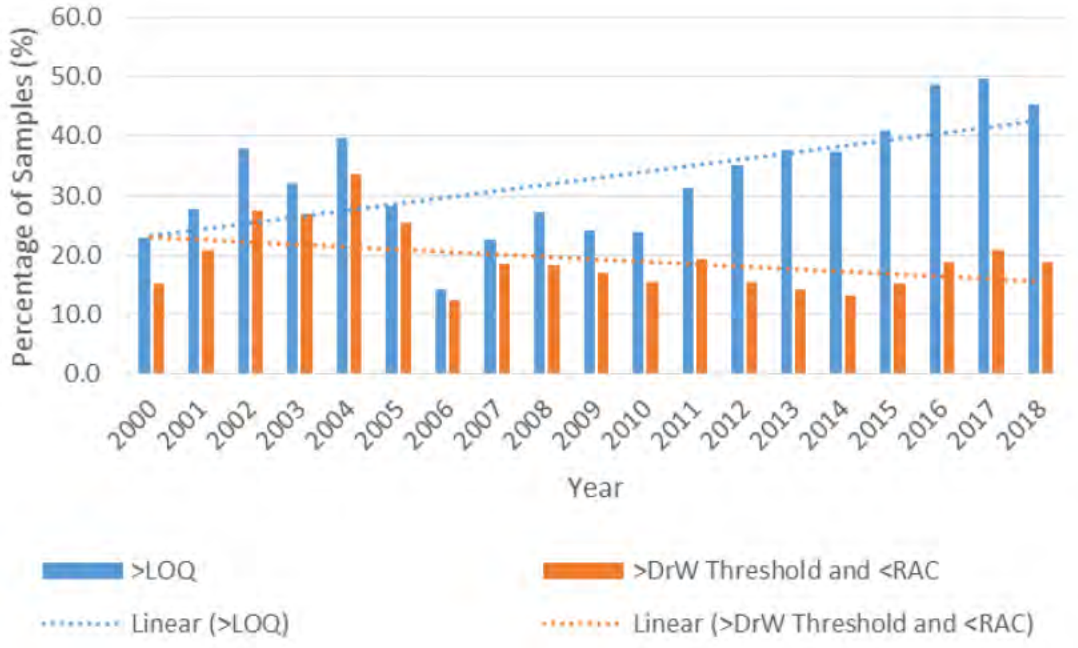
Public Monitoring - Update

France SW example – Selected Preliminary Results

France SW used as an example owing to readily available and comprehensive online datasets:

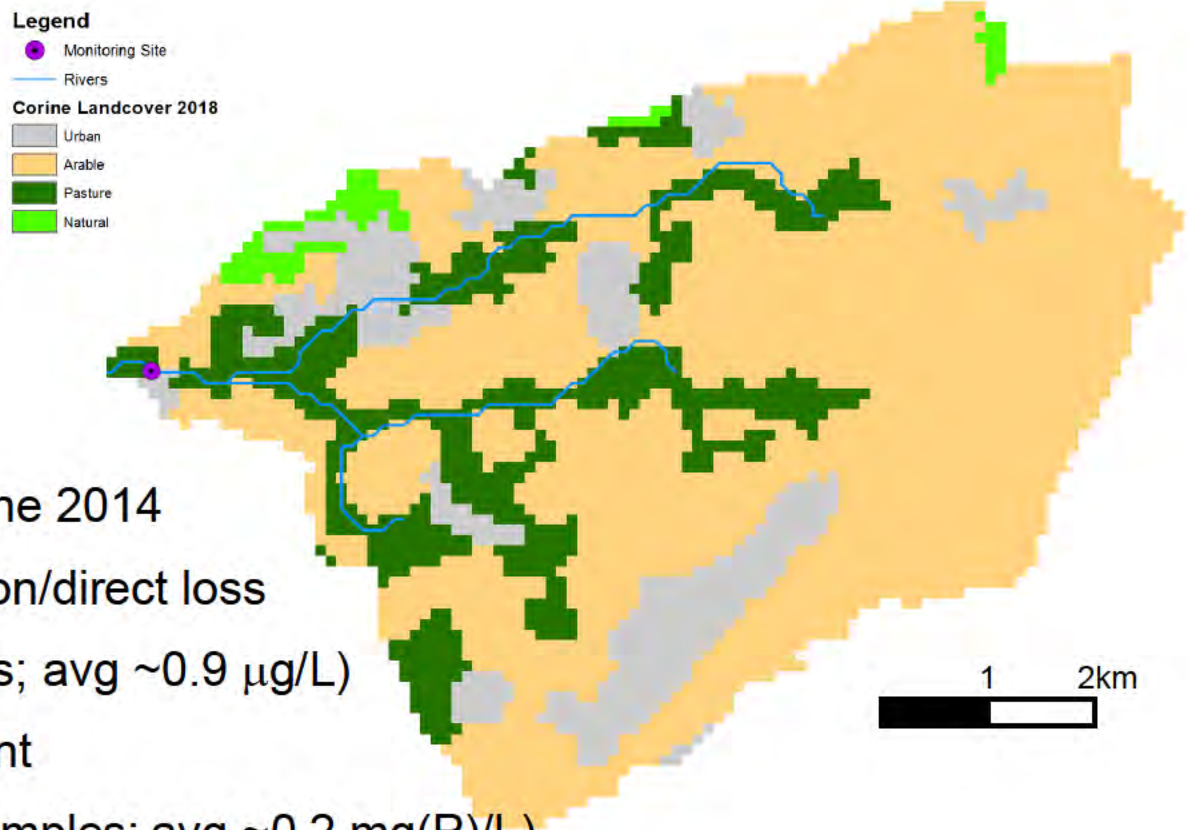
- Increased sampling effort and improving LOQs driving increased detections (>LOQ)
- Exceedances of 0.1 μg/L as a percentage of total samples appears relatively stable over the last decade at ~17%
- Only 2 exceedances of the SW RAC of 100 μg/L (AIR2) at 2 separate sites in 18 year timeframe and ~191 000 samples
  - Months of exceedance: May and June
  - Both sites have mixed catchments with possible urban and agricultural sources





Public Monitoring - Update

France SW example – Selected Preliminary Results



Station – Le Ruisseau de verny a pommerieux
(Data source: Naïades eaufrance)

- Measured GLY concentration of 558 µg/L on 5 June 2014
  - GLY to AMPA ratio suggests a recent application/direct loss
    - AMPA conc. of 4.35 µg/L (max of 17 samples; avg ~0.9 µg/L)
  - Other agricultural pollutants suggest runoff event
    - Total Phosphorus 0.5 mg(P)/L (max of 17 samples; avg ~0.2 mg(P)/L)
    - Fluroxypyr 0.91 µg/L (max of 17 samples; avg ~0.08 µg/L)
  - Weather data not suggesting a major runoff event on the day
    - MARS 25km gridded weather dataset indicates no rain on day but 10 mm the day before
  - Next largest GLY concentration is 1.1 µg/L (17 samples; avg 0.23 µg/L)

- Interpretation – Potential point source pollution event

Public Monitoring - Update

RAC Exceedance Evaluation and Interpretation – Regulatory Significance

Public environmental monitoring datasets, collected to meet a wide range of regulatory investigation and reporting requirements, e.g. Water Framework Directive, are a valuable source of information complementing GLP studies and peer reviewed literature datasets.

- Data collected for other purposes: require careful interpretation and contextualisation to ensure the regulatory significance of any potential exceedance of the threshold values are understood
  - Example: Schmidt *et al*. (2005) evaluate the regulatory significance of GW exceedances following removal of samples from unsuitable wells or results derived using inappropriate analytical techniques
  - In addition, AMPA may arise from aminopolyphosphonate used in detergents and as a cooling water additive (Horth, 2016)
- This understanding can be used to assess risk mitigation and communication strategies to further promote safe use of products containing GLY
  - Example: A 5-year (2014-2018) GLY mitigation project (Seuntjens *et al*., 2019) demonstrates how targeted communication can encourage farmers to adopt best practice and promote the use of mitigation measures, e.g. vegetated buffer strips, reducing point source contributions and overall concentrations of GLY in SW

Public Monitoring

Summary

Actions planned so far by GTF

- Update and expand the public monitoring data review for recent years – taken a sales and regulatory zone approach
  - GLY and (non-relevant) metabolites AMPA & HMPA
  - Compartments: SW, GW, DrW, Air, Soil and Sediment
  - Data requests directed to Govt. Agencies in MS: ongoing at present
- Consider exceedances of the Regulatory Acceptable Concentrations for each compartment:
  - e.g. 100 µg/L for SW rather than the drinking water threshold of 0.1 µg/L which will be applied to DrW and GW datasets;
- Explore exceedances to understand the drivers of the exposure, their regulatory significance and appropriate local risk mitigation/communication options for product authorization in individual member states

Question to RMS

- Does the approach presented meet regulatory needs?

[redacted],
knoell Germany

Modelling approach

[Subject to adaptations]

Representative GAP

Crop and/or situation (a)	MS Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation: Type (d-f)	Formulation: Conc. a.s. (i)	Application: method kind (f-h)	Application: Growth Stages & season (j)	Application: number min-max (k)	Application: Interval between application min-max	Application rate per treatment: L/ha product min-max (l)	Application rate per treatment: Water L/ha min-max	Application rate per treatment: kg a.s./ha min-max (l)	PHI (days) (m)	Remarks
Root & tuber vegetables Bulb vegetables Fruiting vegetables Brassica Leafy vegetables Stem vegetables Sugar beet	EU	MON 52276	F	*Emerged weeds*	SL	360 g/L	Spray	Pre-sowing, crop pre-emergence / pre-planting, pre-transplanting.	1-3	21	2	100-400	0.72	-	Renovation / change of land use applications. Broadcast tractor mounted application (to 100% of the field). Use 75% drift reducing nozzles. Maximum application rate of 2.16 kg as/ha glyphosate in any 12 months period across all use types.

* GAP under discussion. Provisional GAP presented here.

Representative GAP (2)

Crop and/or situation (a)	MS Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	Growth Stages & season (j)	number min-max (k)	Interval between application min-max	L/ha product min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Root & tuber vegetables Bulb vegetables Fruiting vegetables Brassica Leafy vegetables Stem vegetables Sugar beet	EU	MON 52276	F	*Emerged weeds*	SL	360 g/L	Spray	Post-harvest, pre-sowing / pre-planting.	1-3	21	2-6	100-400	0.72-2.16	-	Application to existing row cropland after harvest for removal of remaining crop / stubble and for control of actively growing annual weed. Broadcast tractor mounted application (to 100% of the field). Use 75% drift reducing nozzles. Maximum application rate of 2.16 kg as/ha glyphosate in any 12 months period across all use types.

* GAP under discussion. Provisional GAP presented here.

Representative GAP (3)

Crop and/or situation (a)	MS Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation Type (d-f)	Formulation Conc. a.s. (i)	Application method kind (f-h)	Application Growth Stages & season (j)	Application number min-max (k)	Application Interval between application min-max	Application rate per treatment L/ha product min-max (l)	Application rate per treatment Water L/ha min-max	Application rate per treatment kg a.s./ha min-max (l)	PHI (days) (m)	Remarks
Top fruit plantations (including citrus, tree nuts, pome fruit, stone fruit, kiwi and banana)	EU	MON 52276	F	*Emerged weeds*	SL	360 g/L	Spray	Post-emergence of weeds	1-3	21 days	2-4	100-400	0.72-1.44	7	Avoid crop contamination during treatment. Maximum application rate of 2.88 kg as/ha glyphosate in any 12 months period Applications are performed in the rows below the trees or as spot treatments. The rate refers to the treated area only which represents not more than 50% of the total orchard area. The application rate with reference to the total orchard or vineyard surface area is not more than 50% of the stated dose rate.
Grape plantations (table and wine grape)	EU	MON 52276	F	*Emerged weeds*	SL	360 g/L	Spray	Post-emergence of weeds	1-3	21 days	2-4	100-400	0.72-1.44	7	

* GAP under discussion. Provisional GAP presented here.

PEC calculations

Risk envelope approach

- For PEC calculations, risk envelope approach is suggested
- If feasible, worst-case modelling scenarios will be defined based on a single application at the maximum seasonal application rate of 2.16 or 2.88 kg a.s./ha, respectively; split application would be considered if necessary to demonstrate safe use
- Interception is zero for all uses
- Spring and autumn application will be considered separately
- Crops are selected to be representative for the annual field crops, orchards and vines, respectively, and to cover all relevant FOCUS locations

Question to AGG

- Does AGG agree with this approach?
- Does AGG see necessity to consider the split application in Tier 1 simulations?

PECsoil calculations

Relevance of new EFSA guidance

- New guidance document published:
  "*EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil*"
- However: Modelling tools to be used <u>still not finalized</u> and published
- Current approach: If new modelling tools will become available in sufficient time before submission (by end of January, 2020), new guidance will be followed. Otherwise, PECsoil calculations will be performed according to existing FOCUS guideline.

Question to AGG

- Does AGG agree with this approach?

PECsoil calculations

Proposed risk envelope

Crop	Annual crops	Perennial crops
Application rate (g a.s./ha)	2160[a]	2880[a,b]
Number of applications (-) / interval (d)	1/ -	1/ -
Crop interception (%)	0	0
Depth of soil layer (relevant for plateau concentration) (cm)	20 cm (tillage)	5 cm (no tillage)
Model used for calculation	ESCAPE 2.0	

[a] Split applications are covered by considering the maximum seasonal load as a single application.
[b] For PEC_{soil} calculations 100% area treated are considered to account for localised effects of direct spraying to soil.

Question to AGG

// Does AGG agree with proposed scenarios?

// Does AGG see necessity to consider the split application in Tier 1 simulations?

PECgw calculations

Proposed risk envelope

Crop	Field crops	Top fruit	Grapes
FOCUS$_{gw}$ crop	Carrots, potatoes, onions, tomatoes, cabbage, sugar beet	Apples[b]/ pome/stone fruit[c], citrus	Vines
Application rate (g a.s./ha)	2160[a]	2880[a,d]	2880[a,d]
Number of applications (-) / interval (d)	1/ -	1/-	1/-
Relative application date	Pre-planting or post-harvest	First emergence of weeds, spring & pre-harvest application	First emergence of weeds, spring & pre-harvest application
Application method	Ground spray	Ground spray	Ground spray
Crop interception (%)	0	0	0
Frequency of application	Annual	Annual	Annual
Models used for calculation	FOCUS PEARL 4.4.4, FOCUS PELMO 5.5.3, FOCUS MACRO 5.5.4		

Question to AGG

- Does AGG agree with proposed scenarios?
- Does AGG see necessity to consider the split application in Tier 1 simulations?

[a] Split applications are covered by considering the maximum seasonal load as a single application.
[b] Model crop used in FOCUS PEARL/ PELMO
[c] Model crop used in FOCUS MACRO
[d] The full area is assumed to be treated. If safe use cannot be demonstrated, refined calculations with 50% area can be considered.

PECsw calculations

Proposed risk envelope FOCUS Steps 1-2

Crop	Field crops	Top fruit	Grapes
$FOCUS_{sw}$ crop	Bulb vegetables[a]	Grass/alfalfa[b]	
Application rate (g a.s./ha)	2160[c]	1440[d]	
Number of applications (-) / interval (d)	1/ -	2/ 21	
Application period / region	Mar-May, Jun-Sep, Oct-Dec/ NEU, SEU		
Interception class (relevant for STEP 2)	No interception		
Application method	Ground spray		
Models used for calculation	STEPS 1-2 in FOCUS 3.2		

Question to AGG ?

- Does AGG agree with proposed scenarios?
- Does AGG see necessity to consider the split application in Tier 1 simulations?

[a] All arable crops have the same mass loadings *via* drainage, runoff and drift in FOCUS STEPS 1-2, hence only bulb vegetables needs to be considered for spring and autumn uses in the modelling.

[b] Since treatment is spraying to weeds at tree base, a surrogate crop is chosen with a representative drift rate. The standard drift rate for arable crops is conservative with respect to shielded mechanical and handheld sprayers.

[c] Split applications are covered by considering the maximum seasonal load as a single application.

[d] Full area is assumed to be treated. If safe use cannot be demonstrated, refined calculations with 50% area can be considered for runoff/drainage entry pathways, while the full load would still apply to spray drift entry.

PECsw calculations

Proposed risk envelope FOCUS Step 3

Crop	Field crops		Top fruit	Grapes
$FOCUS_{sw}$ crop	Root vegetables, potatoes, bulb vegetables, fruiting vegetables, leafy vegetables, sugar beet		Pome/stone fruit, citrus	Vines
Use type	Change of land use	Existing row cropland		
Application rate (g a.s./ha)	720[b]	2160[a,b]	1440[c]	1440[c]
Number of applications (-) / interval (d)	3/ 21	1/ -	2/ 21	2/ 21
Relative application date	Pre-planting or post-harvest		First emergence of weeds, spring & pre-harvest application	First emergence of weeds, spring & pre-harvest application
Application method	Ground spray		Ground spray[d]	Ground spray[d]
Interception	None		None[e]	None[e]
Models used for calculation	FOCUS SPIN 2.2, FOCUS SWASH 5.3 (FOCUS PRZM 4.3.1, FOCUS MACRO 5.5.4, FOCUS TOXSWA 5.5.3)			

Question to AGG

- Does AGG agree with proposed scenarios?
- Does AGG see necessity to consider the split application in Tier 1 simulations?

[a] Split applications are covered by considering the maximum seasonal load as a single application.
[b] If safe use cannot be demonstrated, refined Step 3 calculations would be conducted considering lower drift rates appropriate for 75% drift reducing nozzles according to the GAP.
[c] Full area is assumed to be treated. If safe use cannot be demonstrated, 50% area would be considered for runoff/drainage entry pathways, while the full load would still apply to spray drift entry.
[d] The default application method for pome/stone fruit & citrus at FOCUS Step 3 is 'air blast'. Since treatment is spraying to weeds at tree base/between rows, drift rate for ground spray to arable crops is considered representative .
[e] The interception rate will be adapted to reflect downward spraying to weeds at tree base. As a conservative approach, no foliar interception is assumed.

Thank you!