



*FOCUS Surface Water  
Repair activity:  
First impressions from a  
user's point of view*



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***on behalf of the ECPA FOCUS  
SW Repair ad-hoc group***

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# Agenda

- // Introduction
- // Key Aspects for Discussion
  - // Need for a robust Pesticide Application Timer
  - // Need for a crop model to link environment and agronomy
  - // Need for flexible guidance to evaluate multi-year results
- // Summary and Conclusions



# *Introduction*

# General Thoughts on the “Repair” Action

- // Draft report of the EFSA working group is short and targeted to the mandate, with well-documented approaches and decisions
- // Beyond extension to 20 assessment years: models and scenarios improved, transparency of guidance increased, errors corrected, regulatory developments in other areas (groundwater, soil) considered
  - // impressive work to deliver such complex task within very short timeframe
- // Extensive testing is necessary to understand impact of model and guidance changes on the strongly event-driven aquatic PEC values
  - // no comprehensive testing was possible in the timeframe of the mandate ... and in the time available to prepare this talk
  - // further input from stakeholders should be possible after revised software tools become available

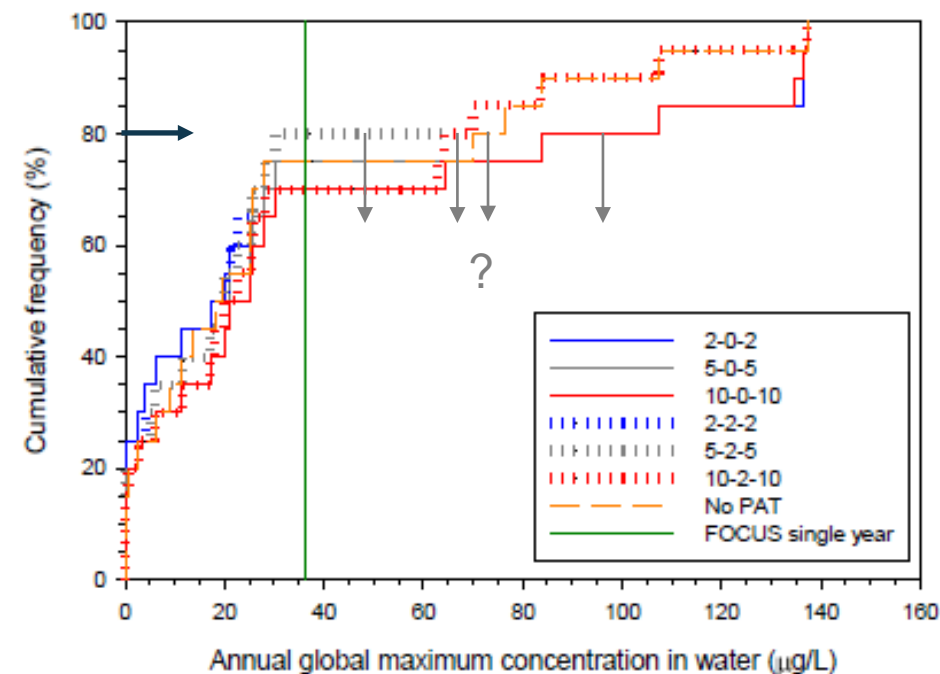


# *Key Aspects for Discussion*

## *Need for a robust PAT*

# Pesticide Application Timer (PAT)

- // Current PAT in FOCUS SW has dual purpose:
  - // ensure that application is followed by significant rainfall (> 10 mm of rain in the next 10 days)
  - // ensure that application is not done during wet periods (< 2 mm of rain each day in a 5-day period around the application date)
- // Introducing a 20-year assessment period, the EFSA working group proposes to drop the PAT completely
  - // based on limited example runs (one scenario, one crop) the impact on PEC<sub>sw</sub> values is assumed to be minor
  - // But: even if the impact is small in most cases, large (unintended) impacts for some combinations of crop, scenario, use pattern and compound are possible



Distribution of annual max. PEC<sub>sw</sub> values (scenario R1, FOCUS dummy G) for different PAT designs (source: Fig 24 of FOCUS SW Repair draft report, modified)



# Pesticide Application Timer (PAT)

- // Decision to keep, adapt or remove the PAT should be based on the objective to get protective but realistic results
  - // **Remove 1<sup>st</sup> PAT rule?** 20-year assessment conceptually ensures that dry and wet periods after application are covered in a realistic way
  - // **Simplify 2<sup>nd</sup> PAT rule?** Current rule possibly too restrictive for agronomic reality, partly requires significant relaxation to find suitable application dates that respect the GAP
  - // **Remove 2<sup>nd</sup> PAT rule?** Applications may be made under agronomically unrealistic conditions
- // “Simplified PAT” from German surface water model GERDA may be a good compromise:
  - // no applications on rainy days (>2 mm) or under very wet conditions (>10 mm on the day before)
  - // assumes accurate weather forecast only for day of application
  - // reasonably reflects farming practice, e.g. to ensure trafficability of the field or to avoid early wash-off losses of applied product
  - // simple rules make it easy to find suitable application dates





# Pesticide Application Timer (PAT)

// Comparison of PEC<sub>sw</sub> values calculated with the current FOCUS-PAT, the simplified PAT according to GERDA, and without PAT (all values in µg/L)

Scenario	Mitigation	Substance	FOCUS PAT, annual max. single year	FOCUS PAT, 80 <sup>th</sup> %ile annual max. 20 years	No PAT, 80 <sup>th</sup> %ile annual max. 20 years	GERDA PAT, 80 <sup>th</sup> %ile annual max. 20 years
R1: maize post-em 04 Jun	Step 3	dummy B	16.4	16.9	19.2	22.3
R1: winter barley post-em 15 Oct	Step 3	dummy B	38.7	37.3	28.6	32.6
R1: winter barley post-em 16 Oct	Step 3	dummy B	38.7	40.0	33.8	32.9
R2: weed control in grapes 04 Oct	Step 4 no drift	dummy B	4.2	5.4	4.5	4.5
R2: maize pre-em 28 Apr	Step 4 no drift	dummy H	11.8	20.3	22.4	18.7
R3: winter cereals pre-em 01 Dec	Step 3	dummy H	49.1	35.9	36.4	35.5
R4: winter cereals pre-em 05 Nov	Step 3	dummy B	4.2	46.7	62.1	51.2





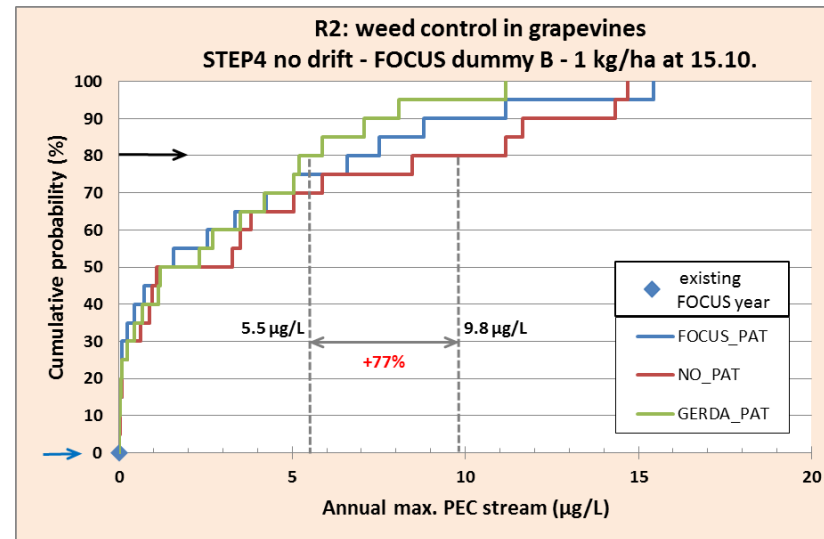
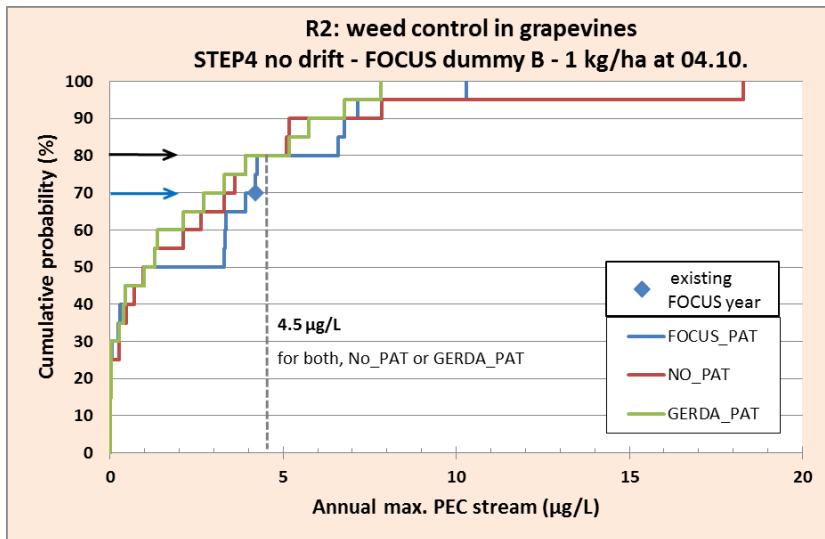
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R4: winter cereals pre-em 05 Nov	Step 3	dummy B	4.2	46.7	62.1	51.2
R1: summer OSR post-em 02 Apr	Step 3	dummy B	4.2	7.5	42.1	10.7
R1: summer OSR post-em 02 Apr	Step 4 no drift	dummy B	2.1	7.5	41.2	10.7
R1: maize post-em 07 Jun	Step 3	dummy B	16.4	17.5	26.8	16.0
R1: maize post-em 27 Jun	Step 3	dummy B	36.7	15.1	42.0	22.7
R2: bulb vegetables post-em 28 Feb	Step 3	dummy B	8.9	10.0	25.7	11.5
R2: potato post-em 02 Apr	Step 4 no drift	dummy B	9.0	10.9	22.1	14.7
R4: spring cereals post-em 19 May	Step 3	dummy B	4.2	14.1	30.5	22.0

# Pesticide Application Timer (PAT)

- // Multi-year PECsw values can be much higher without PAT than with the current PAT
  - // this is even true based on the 80<sup>th</sup> percentile annual maximum values
- // With the GERDA PAT, multi-year PECsw values are generally similar to those based on current PAT
  - // simple rules that shift applications away from unrealistically wet conditions
  - // sensitivity of PECsw to exact application dates reduced
  - // clearly deserves further consideration and testing in the context of FOCUS SW Repair



Distributions of annual max. PECsw values: High sensitivity to application date (04 Oct vs. 15 Oct) without PAT

# *Key Aspects for Discussion*

## *Need for a crop model*



# Crop Model to Link Environment and Agronomy

- // EFSA working group proposes fixed link between BBCH stage of application and first calendar date of the application window
  - // AppDate establishes that link for each crop and scenario, based on average growing conditions
- // however, crop development depends on the weather, and same BBCH stage occurs at different calendar dates in each of the 20 years
  - // may result in agronomically unrealistic situations, e.g. too early applications in a cold year, or application when field is not accessible with heavy machinery
  - // soil and weather conditions also influence compound behavior and PEC<sub>sw</sub> values ...
  - // ... and have an impact on ecotoxicological effects (e.g. exposure relative to life-cycle organisms)

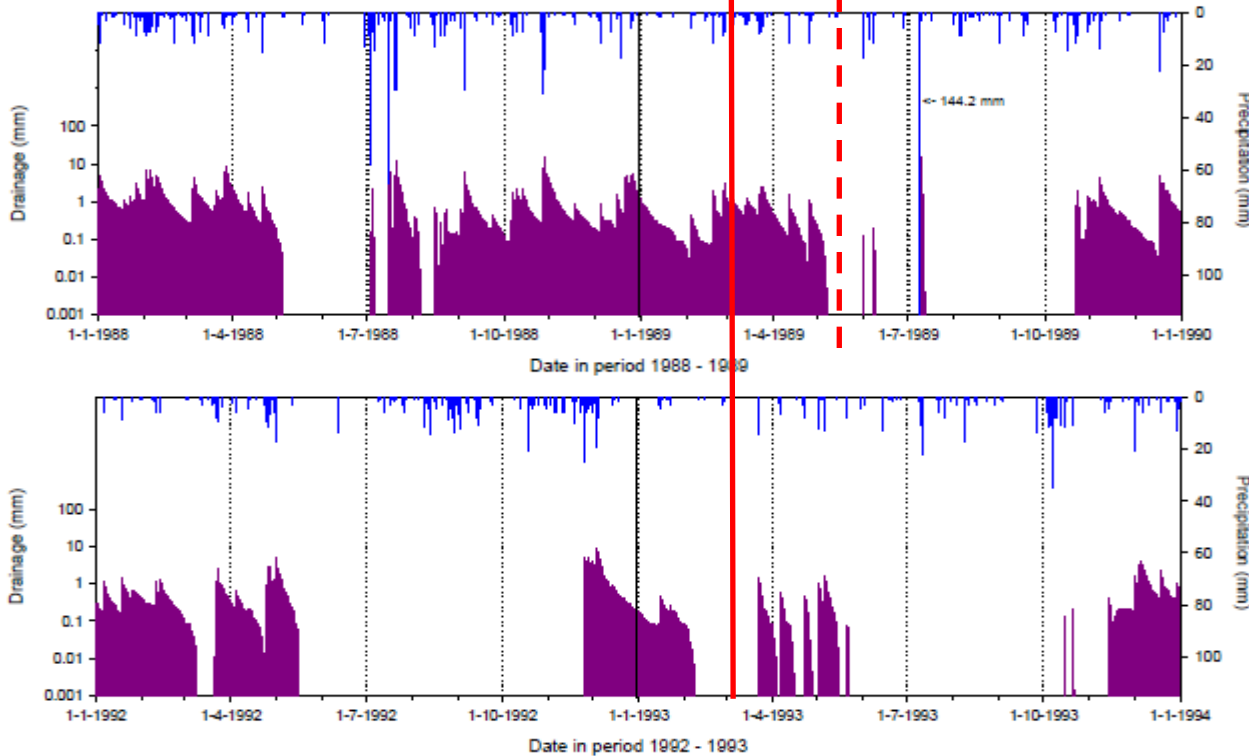
Year	BBCH	Calendar date
2009	67	15 June
2010	69	12 June
2011	67	13 May
2015	67	22 May
AppDate	67	20 June

Calendar dates of BBCH 67 (69) in winter oil seed rape, observed in four years of residue trials in the UK (source: Bayer residue trial data) vs. AppDate recommendation (source: Tab. 19 of FOCUS SW Repair draft report)

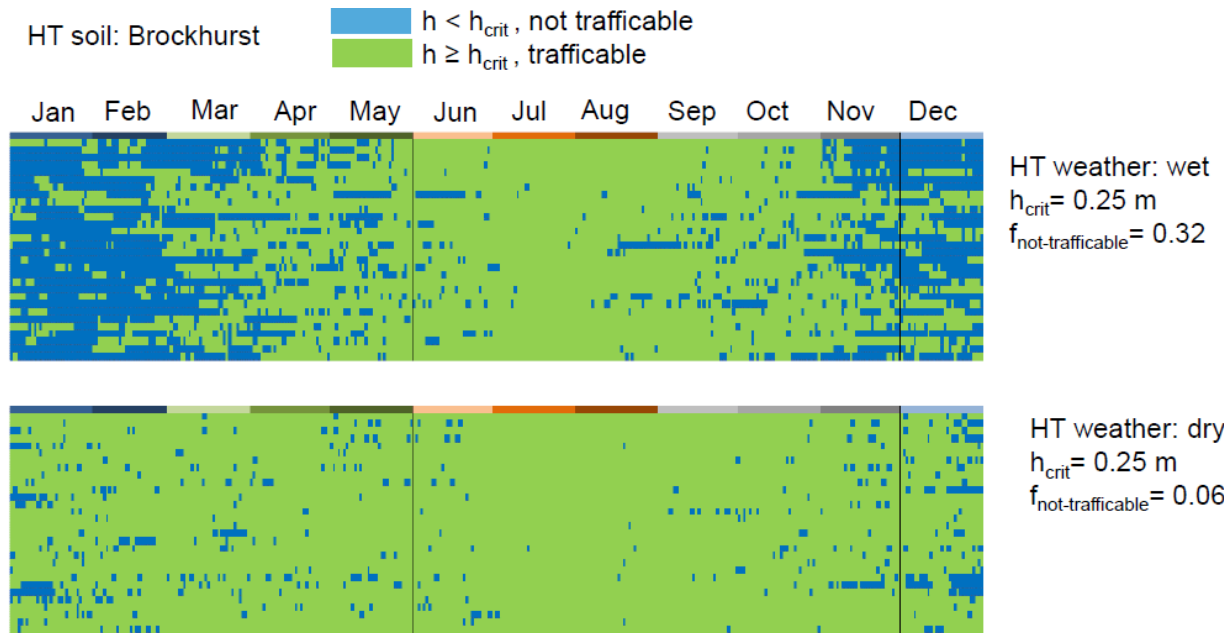
# Crop Model to Link Environment and Agronomy

// EFSA working group recommends to review options for a crop model to calculate crop development depending on weather conditions (“... especially important now that there are multi-year simulations.”)

Delay of crop development  
and of agronomic activities?



Rainfall and drainage patterns in FOCUSsw scenario D1 for two 2-year periods (source: Appendix B.1 of FOCUS SW Repair draft report)



Trafficability of heavy clay soils under UK conditions, for dry and wet years (source: Bayer analysis of UK soil and weather data)

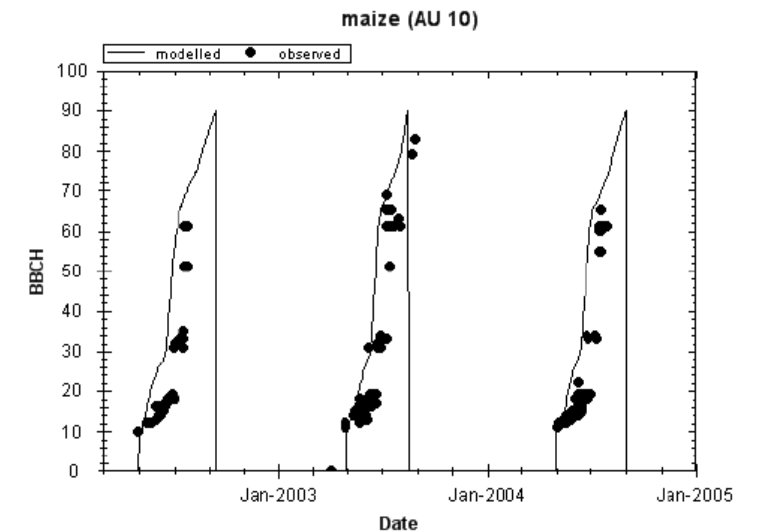
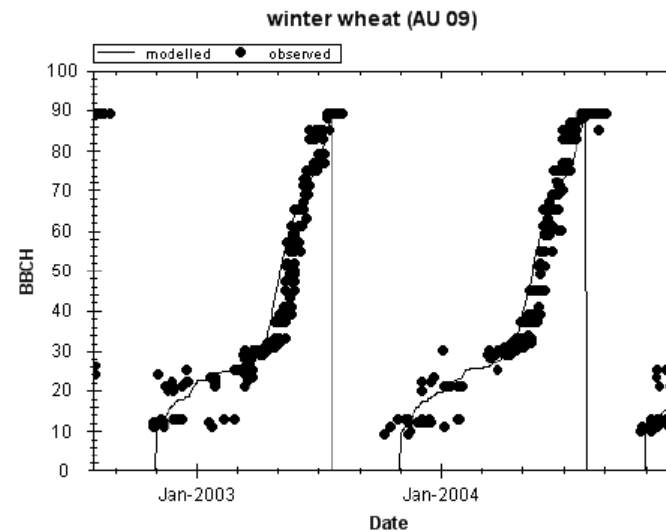
# Crop Model to Link Environment and Agronomy

- // one example is the crop model of the French leaching model FROGS:
- // development stage is a function of the (effective) temperature sum
- // crop-specific parameters are available for all major crops
- // calculated development stages can be related to BBCH stages
- // successfully validated against field data



$$D_s^{j+1} = D_s^j + \frac{T_{\text{eff}}}{T_{\text{sum},i}}$$

$$\begin{aligned} T_{\text{avg}} &\leq T_{\text{lb}} &\rightarrow T_{\text{eff}} &= 0, \\ T_{\text{lb}} &< T_{\text{avg}} < T_{\text{ub}} &\rightarrow T_{\text{eff}} &= T_{\text{avg}} - T_{\text{lb}}, \\ T_{\text{avg}} &\geq T_{\text{ub}} &\rightarrow T_{\text{eff}} &= T_{\text{ub}} - T_{\text{lb}}. \end{aligned}$$

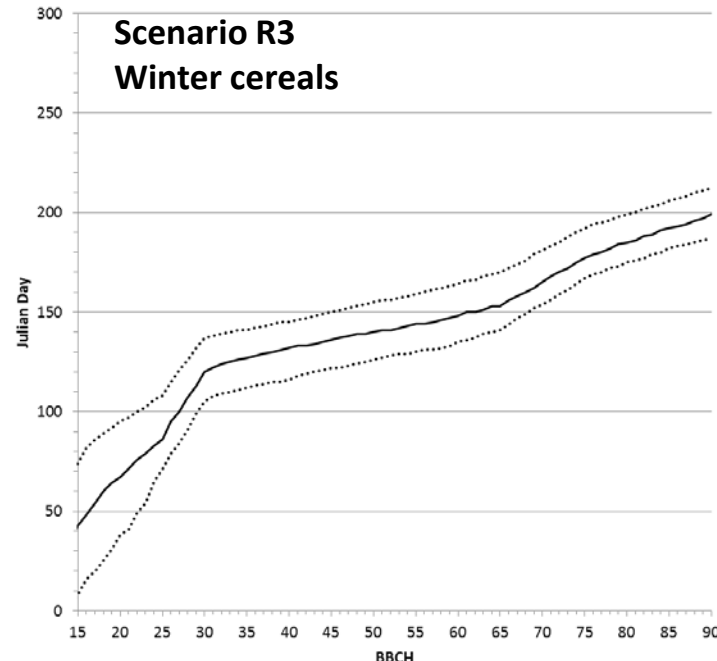
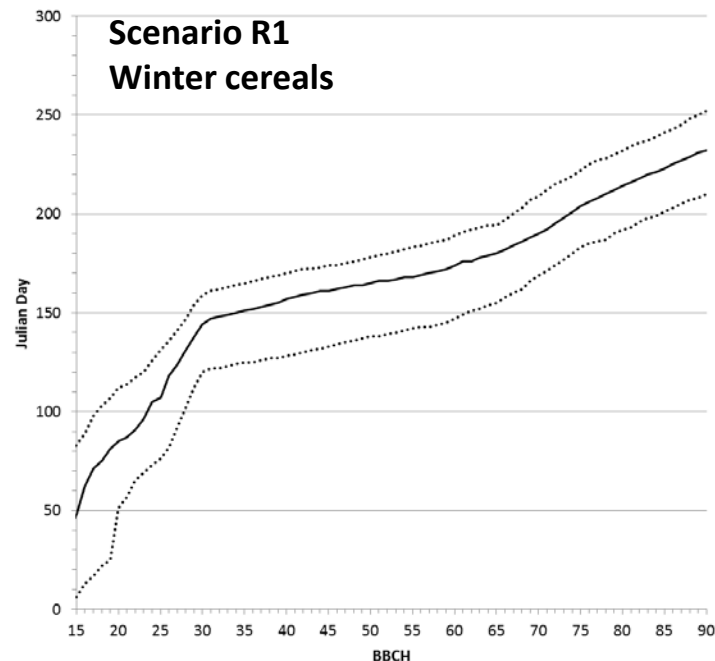


Modelled and observed calendar dates of BBCH stages of winter wheat and maize (source: FROGS report)



# Crop Model to Link Environment and Agronomy

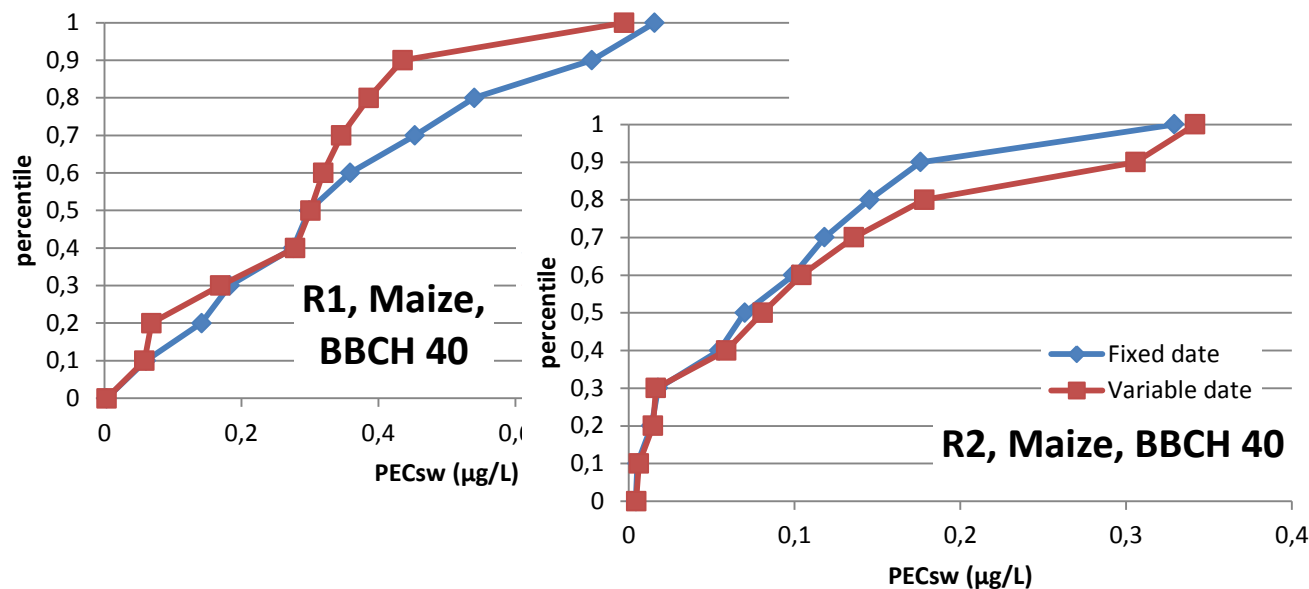
- // In a first test, the crop model of FROGS was applied to the 20-year FOCUS weather data
- // Results indicate relatively wide, but plausible range of calendar dates for each BBCH stage, e.g.
  - // winter cereals, scenario R1: approx. 40 day range
  - // winter cereals, scenario R3: approx. 30 day range



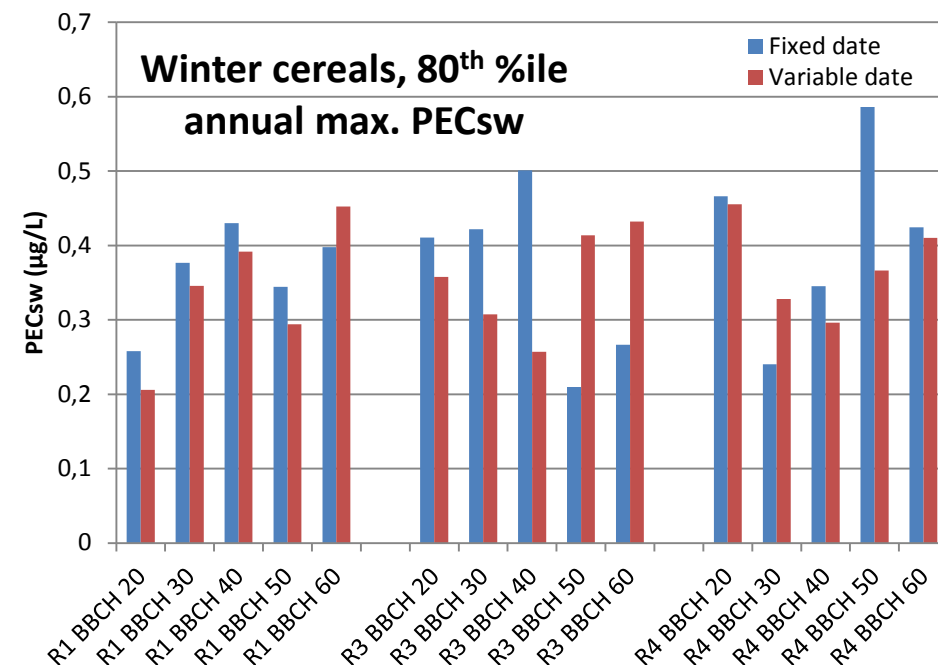
Calendar dates of BBCH stages of winter cereals as predicted by the FROGS crop model: Minimum, median and maximum for the 20 years of FOCUS weather data.

# Crop Model to Link Environment and Agronomy

- // Impact on PECsw investigated for ELINKSulfuron ( $DT_{50}$  24 days, Koc 43 L/kg, 15 g/ha)
- // impact of crop model appears to be random, but is sometimes significant
- // crop model clearly would add realism and objectivity to the selection of application dates



Distribution of annual maximum PECsw values, assuming application at different BBCH stages; application dates calculated with the FROGS crop model; “fixed” = application at the median date, “variable” = application date dependent on weather data of each year



80<sup>th</sup> %ile annual maximum PECsw values, for different run-off scenarios and BBCH stages; application dates calculated with the FROGS crop model

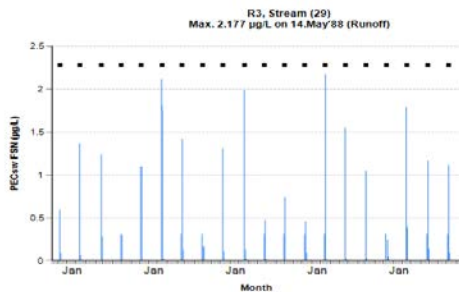


# *Key Aspects for Discussion*

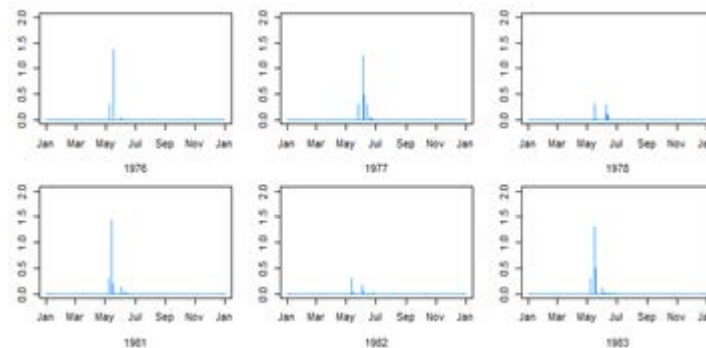
*Need for guidance on  
data evaluation*

# Guidance to Evaluate Multi-Year Results

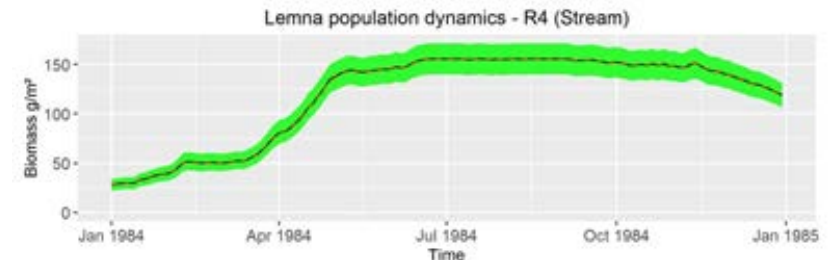
- // EFSA working group remains vague regarding evaluation and use of multi-year exposure calculations
  - // understandable because of mandate, time pressure and risk assessor role of EFSA
  - // still critical because complex exposure data may be produced without guidance how to use them in risk assessments
- // Detailed, multi-year exposure time series with clearly improved quality and reliability should not just be used to extract a single PEC value
  - // readily available higher-tier options should be presented in sufficient detail in the report, e.g.



Tier 1: Select appropriate overall percentile of predicted exposure



Tier 2: Derive appropriate worst case exposure patterns full time series



Tier 3: Run effect model with full time series and base RA on predicted effects

# Guidance to Evaluate Multi-Year Results

- // Tier 1: 80<sup>th</sup> percentile of the 20 maximum annual concentrations seems a good choice
- // in line with risk assessment principles defined for groundwater

FOCUS Groundwater:

**80<sup>th</sup>** spatial %ile (soil & climate)  
 + **80<sup>th</sup>** temporal %ile (of annual max.)  
 ≈ **90<sup>th</sup>** %ile overall



FOCUS SW, 20 year calculation:

**80<sup>th</sup>** spatial %ile (soil & climate)  
 + **80<sup>th</sup>** temporal %ile (of annual max.)  
 ≈ **90<sup>th</sup>** %ile overall

	FOCUS SW spatial vulnerability %ile
D1	82.4
D2	98.8
D3	91.5
D4	38.0
D5	80.5
D6	78.3
R1	72.6
R2	98.1
R3	83.1
R4	77.2
Median	<b>81.5</b>

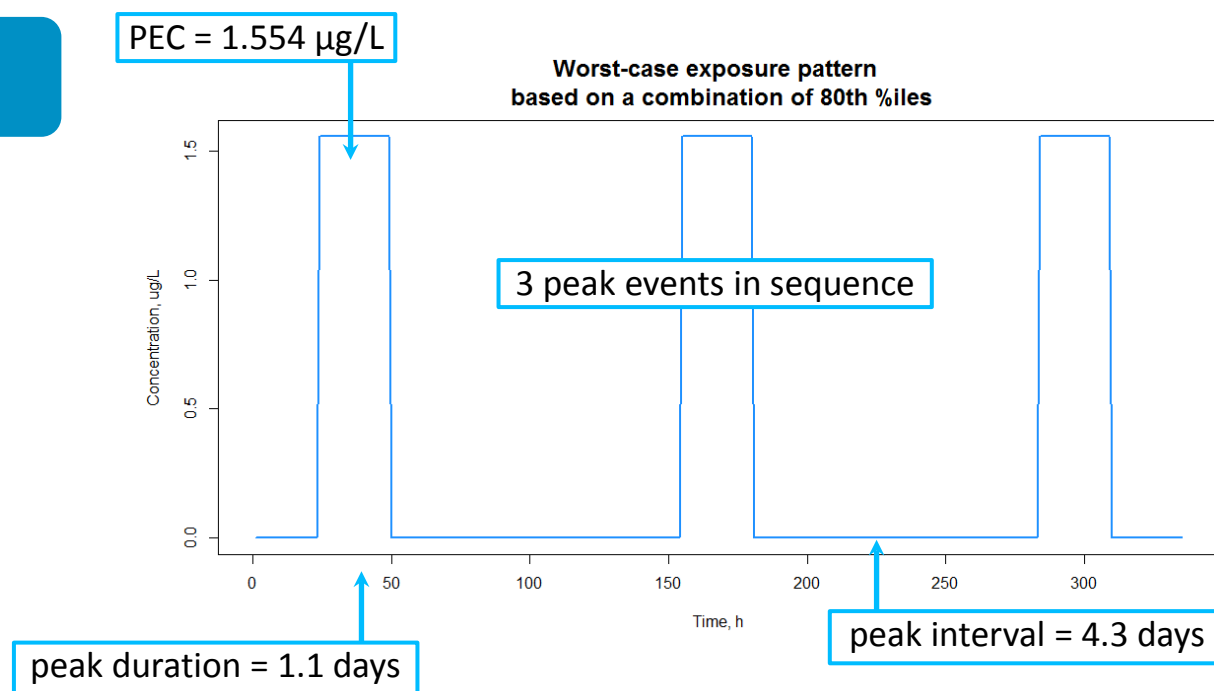
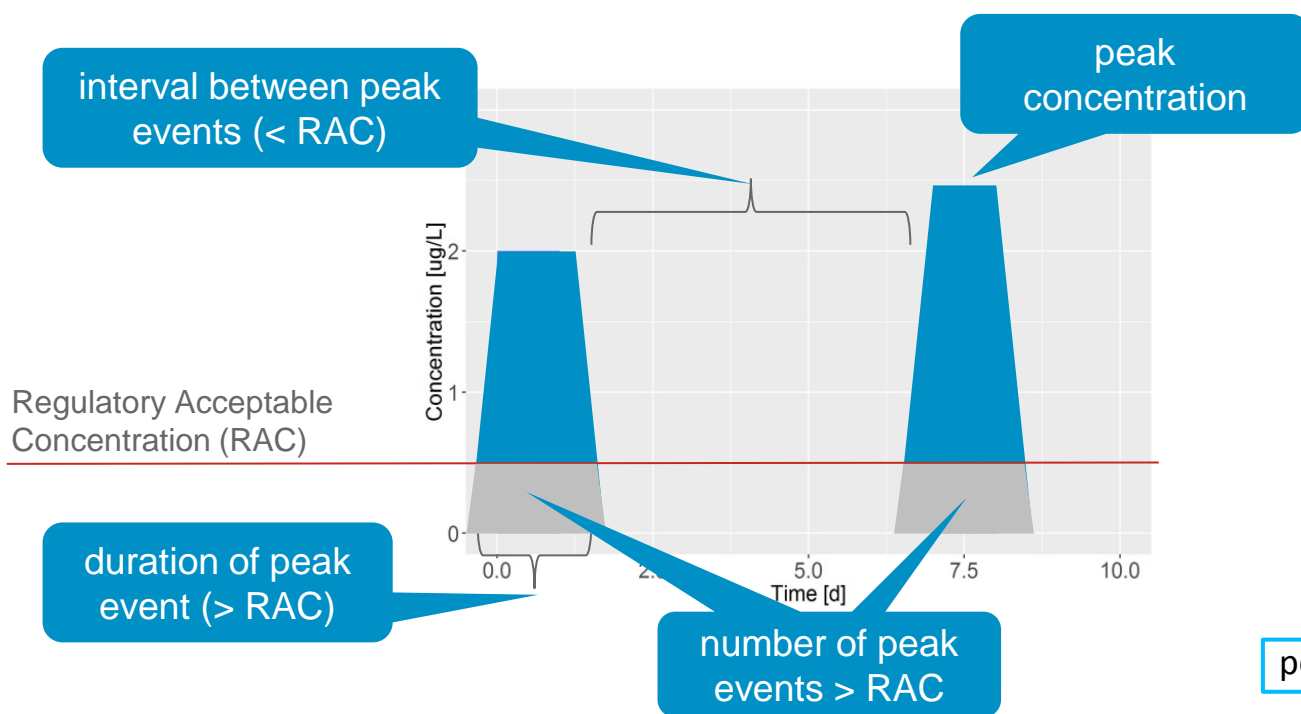
**+ 80<sup>th</sup> %ile  
annual PEC<sub>max</sub>**

	20 year overall vulnerability %ile *
D1	89.0
D2	99.1
D3	94.6
D4	55.9
D5	87.8
D6	86.3
R1	82.6
R2	98.7
R3	89.4
R4	85.6
Median	<b>88.4</b>

\* assuming similar variability of spatial and temporal components

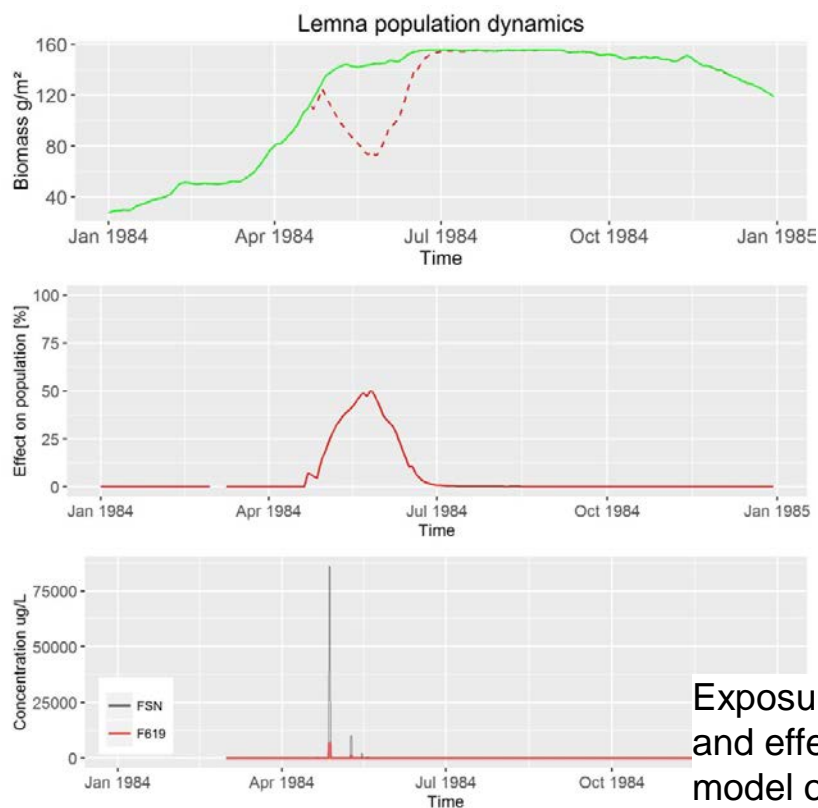
# Guidance to Evaluate Multi-Year Results

- // Tier 2: ELINK report provides good basis to construct worst case exposure patterns for risk assessment
- // Exposure Pattern Analysis Tool (EPAT) available for analysis of multi-year time series
- // allows to link complex exposure patterns to empirical Tier 2C risk assessment according to EFSA Aquatic Guidance Document



# Guidance to Evaluate Multi-Year Results

- // Tier 3: Use of complete 20-year exposure pattern to predict effects with an appropriate TK/TD or population model avoids selection of individual exposure concentrations or patterns
- // risk assessment can be directly based on extent and duration of predicted effects
- // fits nicely with recently published EFSA Scientific Opinion on TKTD Effect Models



Exposure pattern of a sulfonylurea herbicide (bottom) and effect on Lemna (top), calculated with the Lemna model of Schmitt et al. (2013)

## SCIENTIFIC OPINION

ADOPTED: 27 June 2018

doi: 10.2903/j.efsa.2018.5377

**Scientific Opinion on the state of the art of Toxicokinetic/Toxicodynamic (TKTD) effect models for regulatory risk assessment of pesticides for aquatic organisms**

*"The GUTS model and the Lemna model are considered ready to be used in risk assessment."*



# *Summary and Conclusions*



# Summary and Conclusions

- // EFSA working group did impressive job to deliver an good draft proposal in a very short timeframe
- // Several proposals need more extensive testing to clarify their impact; once the revised FOCUS modelling tools become available, a second round of commenting may be useful
- // A simplified PAT could ensure robust PEC calculations and prevent agronomically unrealistic situations; the PAT implemented in GERDA may be a good candidate
- // A crop model would clearly add realism and objectivity to the selection of multi-year application dates; the crop model implemented in FROGS may be a good candidate
- // More detailed recommendations for evaluating multi-year exposure data is essential, including options beyond single percentiles, e.g. pattern analysis and effect models (=> EFSA TK/TD Scientific Opinion)
- // Further comments will be provided by ECPA in the framework of the ongoing consultation ...



# Many thanks to the colleagues who made this talk possible !

## // ECPA FOCUS SW Repair ad-hoc group

Andrew Eatherall, Corteva

Lucas Garcia, BASF

Michael-Xiao Huang, FMC

Dale Mason, Syngenta

David Patterson, TSGE

Gregor Spickermann, Adama



## // Additional input from many other colleagues, with special thanks to

Beate Erzgräber, BASF

Klaus Hammel, Bayer







# *Thank You !*



**Questions?**  
**Comments?**  
**Ideas?**

