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# Effect models in regulatory risk assessment of plant protection products

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Andreas Focks, Thomas G. Preuss, Simon Heine

DG SANTE FOCUS version control stakeholder group meeting

Piacenza, September 2<sup>nd</sup> 2019

# Available official standards/references for effect modelling

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- EFSA SO Good modelling practice (2014; doi:10.2903/j.efsa.2014.3589)
- EFSA SO TKTD models for aquatic organisms (2018; doi:10.2903/j.efsa.2018.5377)
- EFSA SO BEEHAVE model (2015; doi:10.2903/j.efsa.2015.4125)
- SETAC MODELLink (workshop publications series; <https://setac.onlinelibrary.wiley.com/doi/10.1002/ieam.1704>)
- OECD Statistical analysis of biotests
- OECD Guidance for PBTK models

# Consideration of available effect models

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## EFSA SO TKTD Models

- **GUTS**
- DEB
- Simple algae model
- **Lemna**
- Myriophyllum

## • MS evaluation:

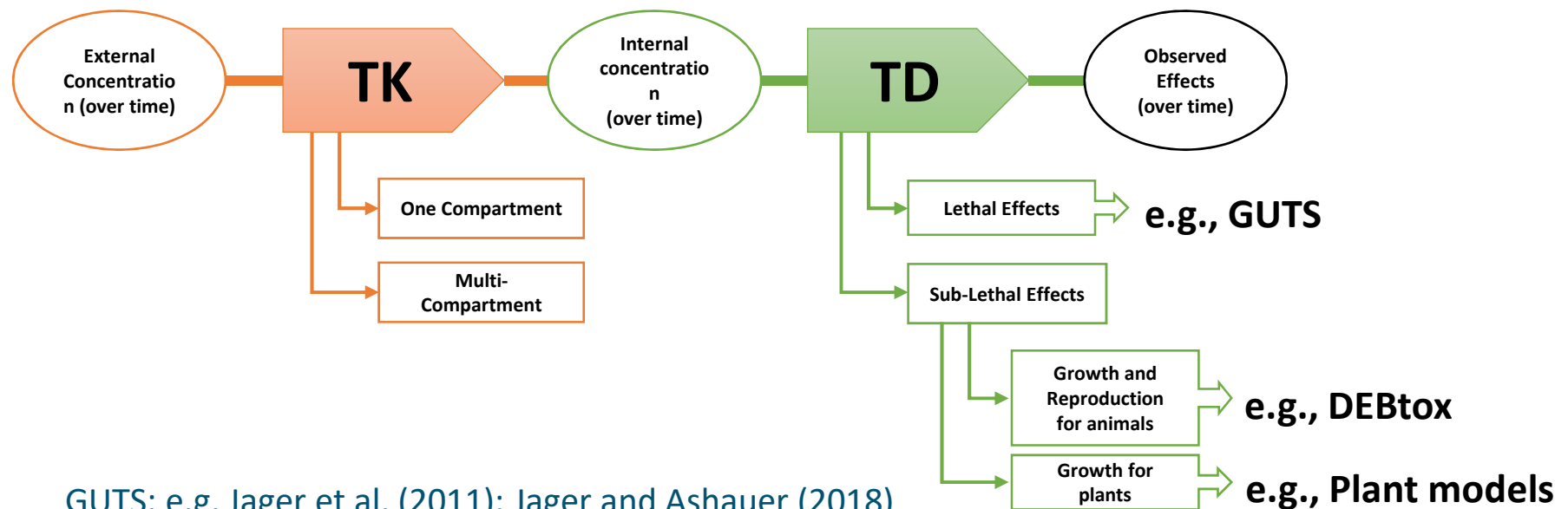
- *eVole/POLARIS* (small mammals; Ctgb and UBA)
- IDamP (*Daphnia*; UBA)
- IBM *Chaoborus* (Aq. invertebrates; UBA)

## EFSA SO *BEEHAVE*

**(Conceptual model considered fit-for-purpose by EFSA)**

*(Ongoing evaluation of model applications, feedback expected)*

# TKTD models - principles



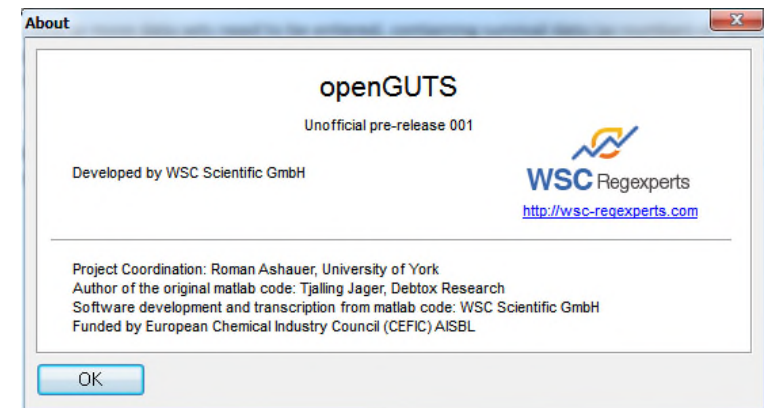
GUTS: e.g. Jager et al. (2011); Jager and Ashauer (2018)

DEBtox: e.g. Billoir et al. (2008); Jager and Zimmer (2012)

Plant models: e.g. Schmitt et al. (2013), Heine et al. (2014; 2015; 2016).

# Software implementation for GUTS

- EFSA SO on TKTD models contains comprehensive and specific evaluation criteria for GUTS implementations
- R-package [morse](http://pbil.univ-lyon1.fr/software/mosaic/) and related web-interface as part of [MOSAIC](http://pbil.univ-lyon1.fr/software/mosaic/) is available (<http://pbil.univ-lyon1.fr/software/mosaic/>)
- Standalone software (openGUTS) implementation in beta-testing phase
- First experiences of authority reviews of GUTS modelling expected soon
- Scenarios (and PEC time series) can be used from FOCUS surface water



# Software implementation for Lemna

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- First software implementation: R code attached *Lemna* publication (Schmitt et al., 2013; doi.org/10.1016/j.ecolmodel.2013.01.017).
- Some research organisations and companies have implemented own *Lemna* models that are based on the original publication, e.g. [MoLePo by Fraunhofer IME](#)
- Since August 2018 an open *Lemna* working group under the SETAC interest group effect modelling, which works on an aligned Lemna model version based on the original work of Schmitt et al. 2013.
- The aim of the group is an aligned, standard R code of the *Lemna* model that is ideally used for any future model application (adding user interface).

# Status of regulatory pesticide fate models

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From the FOCUS website:

- *FOCUS has set up a Version Control Workgroup as a standing body to ensure that version control is maintained. This group ensures that the usefulness of the scenarios as a standardised form of assessment is maintained over time, whilst also ensuring that any bugs are identified and removed and that the scenarios are updated to reflect scientific progress.*

# Status of regulatory pesticide effect models

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## Effect models:

- GUTS and Lemna model evaluated and found suitable for risk assessment (EFSA TKTD SO); R and Windows software implementations are, or become soon, available. Testing software implementations can follow the checklist laid down in the EFSA TKTD SO. Other TKTD models might follow in the coming years.
- Population models: currently, first evaluations of specific population models (Polaris, eVole, BEEHAVE) are done by single MS. Way forward requires to i) check possibilities to mutually adopt such MS-level evaluations or to find alternative mechanisms and ii) define ecological and landscape scenarios.

# Differences in status of fate and effect model evaluations

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- For some TKTD (e.g. algae) and all population models, scenarios need to be developed, a process which has been achieved a long time ago for fate models.
- When effect models will be accepted and scenarios will have been defined, it still will be required to calibrate and to check/validate effect models per species/compound based on experimental data.

# Version control for effect models in pesticide risk assessment?

- Having a structure equivalent to FOCUS fate model version control for effect models is attractive and would improve process of effect model applications in regulatory pesticide risk assessment
- Current discussion in the SETAC interest group Effect Modelling
- Possible format for version control for effect models need to be discussed and agreed; can it be under the FOCUS / DG Sante umbrella?
- How to organise such activities with the best available people and how to find resources?

# Implications for fate modelling

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- In future, alignment of exposure and effect assessment at the scale of protection goals will be needed (environmental scenarios)
- Fate modelling will need to deliver information on scales and resolutions appropriate for different biological groups from water flea up to fish; extension of fate models and adaptation of existing scenarios will be needed