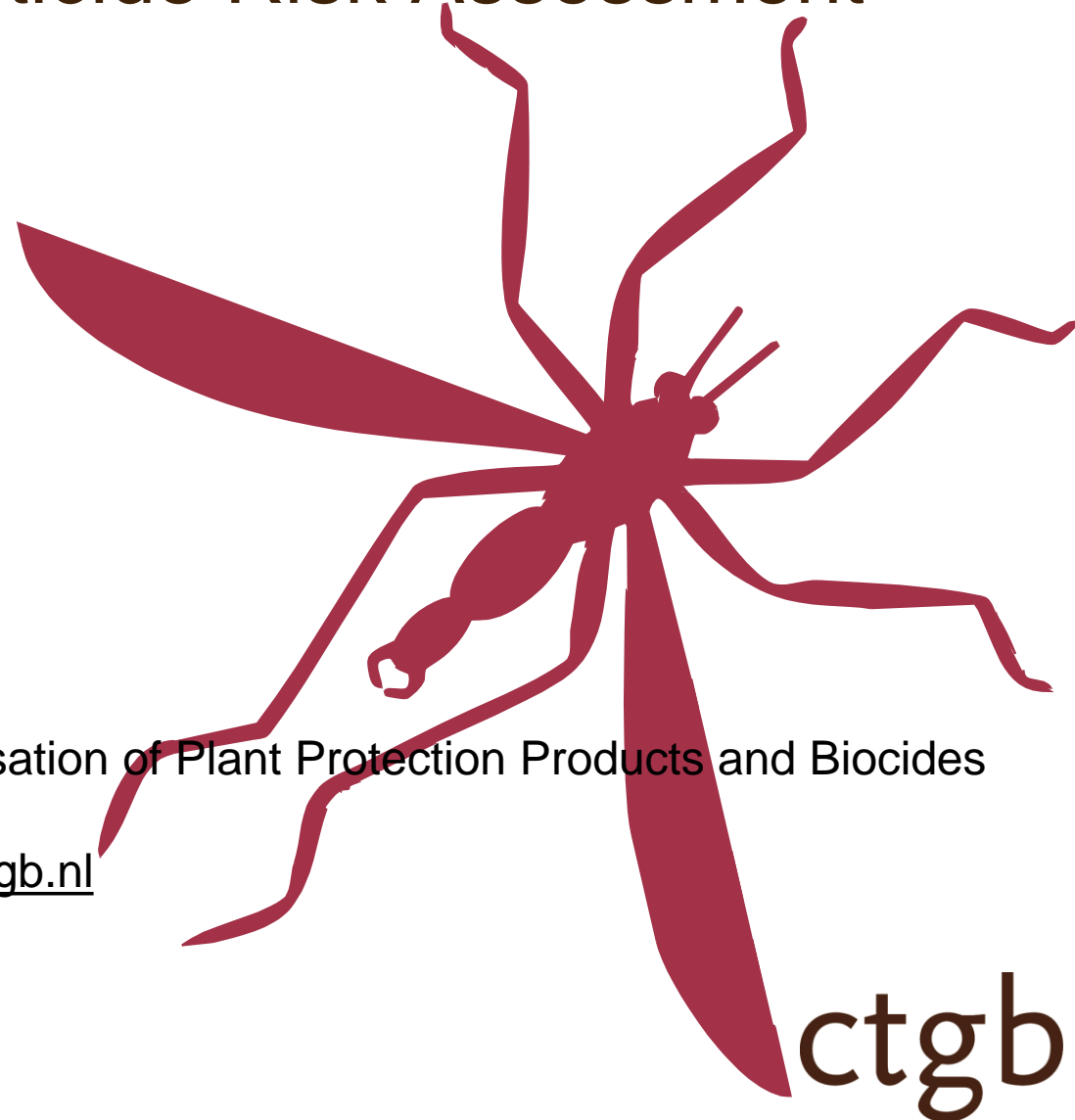
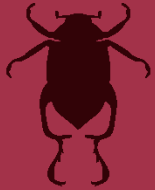


Introduction on Pesticide Risk Assessment



Janhendrik Krook

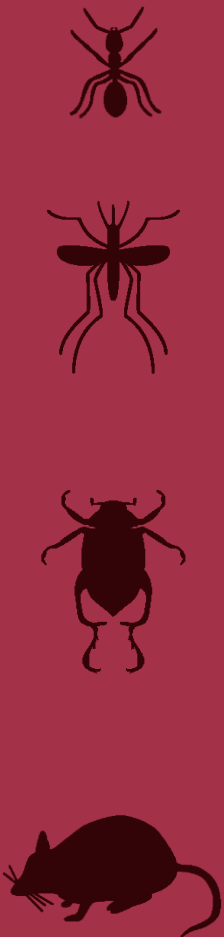
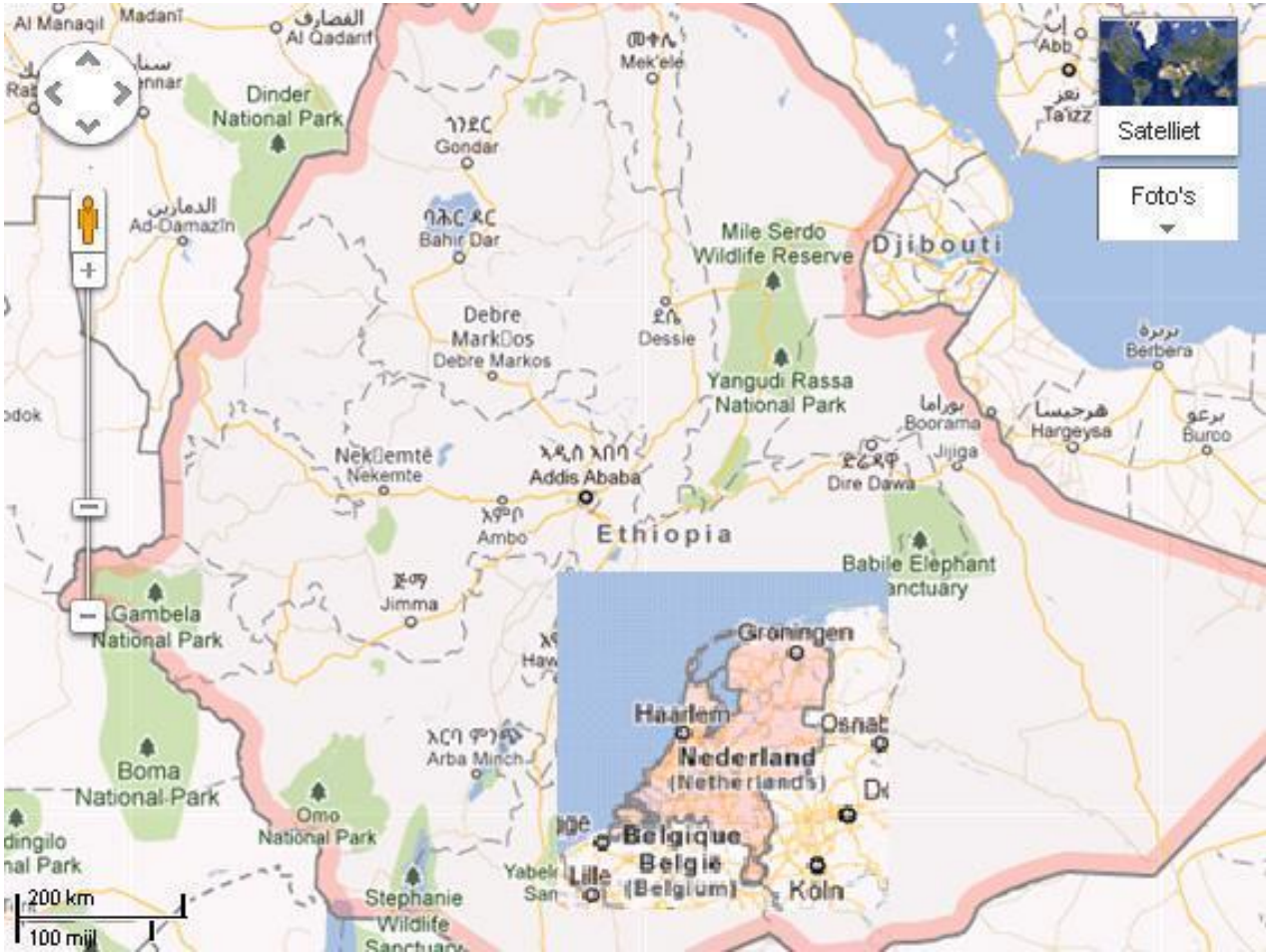
Board for the Authorisation of Plant Protection Products and Biocides
(Ctgb)

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May 2012

ctgb

Orientation & distance



Workshop PRRP Residues Program overview



Monday: introduction on residue evaluation



Tuesday: food basket, risk assessment & practical exercises



Wednesday: Evaluating bodies, MRLs, GAPs, applicability for Ethiopia

Thursday: other dossier requirements, AOB, summary, next steps



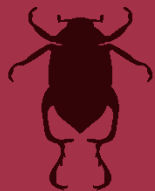
Plant Protection Products Legal Aspects



PPP = Formulations which protect plants or products of crop origin like:

Insecticides, herbicides, fungicides, compounds influencing metabolism of plants, growth regulators (e.g. plant hormones) and protection of supplies

Plant Protection Products Legal Aspects



Prerequisites

- No direct or indirect harmful effects on human or animal health via drinking water, food, feed or any other way
- no direct or indirect harmful effects on environment
- No unnecessary repeats of tests on vertebrates (EU: human volunteer testing not allowed at all)

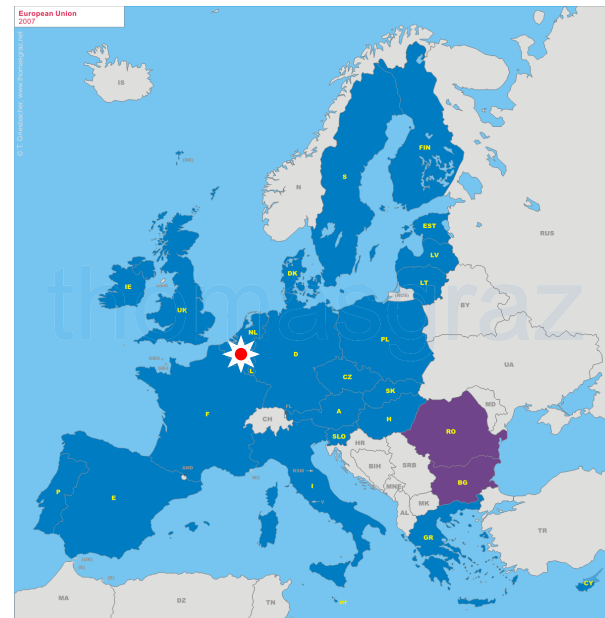


Pesticide composition

- One or more active substances
 - full evaluation of all aspects within pesticide regulations
- other formulants
 - evaluation within other regulations like 'REACH' (usually)
- Complete formulation
 - limited toxicological evaluation (operator and ecotoxicology risk assessment)
- Residues: in general only active substances are evaluated and other formulants are expected to be less toxic
- Residue: active substance and/or one or more of its metabolites

European situation

- Communautary legislation, prepared by European commission and controlled by European parliament
- National legislation: prepared by the national administration and controlled by national parliaments





Pesticide, EU risk assessment



Active substance(s)

Evaluation by EU (EFSA and MS) for inclusion in a positive list

- RMS writes Draft Assessment Report (DAR)
- MSs comment on DAR of RMS
- MSs participate in (expert) meetings
- Advise government on national position in Standing committee



National authorisations

Evaluation of active substance and plant protection product, detailed risk assessment for specific national applications.





Risk assessment aspects



Aspects

- Efficacy
- Human toxicology: **Residues** and operator exposure
- Ecotoxicology
- Fate en behaviour in environment
- Physical-chemical properties and analytical methods



Plant protection products Risk assessment

*Risk Assessment in basic is a simple method,
based on two values:*

1. Health-based acceptable exposure level
(reference doses)
2. calculated exposure from diet and residue
level

Exposure \leq Acceptable Exposure Level





Essential knowledge

- Toxicological profile (Marloes Busschers, April 2012) for setting Reference values
- Population(s) exposed
- Exposure scenario
 - Duration
 - Level of exposure



Acceptable exposure levels



Can have several definitions

For Risk assessment of pesticides the following Acceptable Exposure levels are important:

ADI: Acceptable Daily Intake
(by daily consumption, whole lifetime)

ARfD: Acute Reference Dose
(accidental high consumption)

(AOEL: Acceptable operator exposure level)



Exposure assessment



Tiered approach:

Basis

- dietary intake data (food basket)
- residue levels in crop



Refinement by use of processing data:

- Food basket: whole apple or juice, whole orange or peeling, etc
- residue level: MRL, mean level, etc.





Exposure assessment



How to define 'consumers'?

- Mean population?
- Children and adults?
- Different tribes with different culinary habits?



Example

United Kingdom: 13 diets

Netherlands: 2 diets

WHO: 1 diet per region





Important Ethiopian food crops

- Maize/teff?
- Oilseeds?
- Potato?
- Peas?
-?



Which model to select?

- Existing WHO models on food basket?
- Own Ethiopian diets requiring research, data or based on general knowledge



Open points to discuss this week



- Where to find reference values
- How to define a diet
- How to define sub populations
- How to set or find MRLs
- How to perform a risk assessment
- Ethiopia and export of fruits and vegetables

