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

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Introduction

• Exposure scenarios:

- Operators: persons involved in the mixing/loading and application of a PPP
- Workers: persons who enter an area or handle crop previously treated with a PPP
- Bystanders: persons who are located within or directly adjacent to the area where PPP application is taking place or has recently been completed.

Table 29 Current Worker Exposure Models and Databases used for Regulatory Exposure Assessments

No	Model/Database	Year	Territory	Originators data source indicated	Scenarios
1	EUROPOEM	2002	Europe	Representatives from industry, regulatory authorities (data source), and research institutes (data source) + (data source open literature)	Re-entry worker field crops and greenhouse
2	BBA model		Germany	Regulatory authority and Industry	Re-entry field crops
3	SeedTropex		France, UK	Industry (data source)	Fork lift truck driver, Farmer sowing treated seed
4	EPA (U. S. Environmental Protection Agency), 2000. Agricultural Transfer Coefficients. Policy No. 003.1. (2000.)	2000		Data supporting this review is not available to regulatory authorities in the EU.	Standard values for transfer coefficients
5	Review on the decline of foliar dislodgeable residues of PPP in greenhouses	2004	France		Dislodgeable foliar residue levels

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DE = DFR x TC x T

DE (Potential dermal exposure)

- DFR (Dislodgeable foliar residue) = amount of residue on foliage which can be dislodged during re-entry tasks
- TC (Transfer coefficient) = transfer of residues from the plant surface to clothes or skin of worker; is measure of intensity and duration of contact
- T (Time) = duration of work task







EUROPOEM II

- Developed in Europe by representatives for industry, regulatory authorities and research institutes
- Estimates dermal exposure for worker in a crop previously treated with PPP
- Scenarios: re-entry in field crops and greenhouse
- Can be used as conservative, first tier approach
- Step 1: Residue decline not taken into account







EUROPOEM II DE = DFR x TC x T

- DFR: default of 3 µg/cm² (conservative)
- TC
- Vegetables: 2,500 cm2/hr
- Fruits (from trees): 4,500 cm2/hr
- Strawberries: 3,000 cm2/hr
- Ornamentals: 5,000 cm2/hr

Based on single layer of clothes, bare hands





Conclusion

- Rather conservative model
- Lack of transparency regarding data







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Exposure models: bystander

- Three approaches:
- Direct contact airborne spray
- Exposure to spray drift fallout
- Exposure to air residues





Table 34 Current Bystander and Resident Exposure Models and Databases used for Regulatory Exposure Assessments

No	Model/Database	Year	Territory	Originators data source indicated	Scenarios
1	EUROPOEM	2002	Europe	Representatives from industry, regulatory authorities, and research institutes (data source)/academia (data source open literature)	Bystander
2	UK	1980s- 2007	UK	Regulatory Authority (data source)	Bystander drift
3	RIVM Resident model	2006	NL	RIVM (data source open literature)	Residents children and adults – amenity grass and home lawns
4	Guidance for exposure and risk evaluation for bystanders and residents exposed to plant protection products during and after application		DE	Various	Bystander, and residents, droplet and vapour drift, adults and children
5	UK		UK	Regulatory authority (California EPA)	Resident vapour drift
6	USA EPA have used the proprietary database AgDrift coupled with Standard Operating Procedures for Residential Exposure (Turf Scenario) to assess pesticide drift onto lawns situated ten feed from the treated area.		USA		Bystander – children exposure to drift fallout

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Exposure models: bystander

EUROPOEM II

- Exposure to spray drift
- Based on UK spray drift trials en DE spray drift fallout trials
- 95th percentile
- Only estimated for outdoor applications





X





Exposure models - bystander

UK and German approach

- Spray drift
- Volatilisation (for (semi-)volatiles)
- Contaminated surfaces (e.g. playing children)

Bystander and resident





X

Exposure models - bystander

NL lawn model

- Contaminated surfaces (i.e. exposure on to treated gras/turf)









Conclusion

- Limited databases
- UK and DE data from 80s, not updated to modern techniques
- New EU development: BREAM (Bystander and Residential Exposure Assessment Model)







References

German model:

http://www.bvl.bund.de/EN/04_PlantProtectionProducts/11_Applic ants/02_AuthorisationProcedure/06_Toxicology/PlantProtectionPr oducts_toxicol_node.html

• UK POEM:

http://www.pesticides.gov.uk/guidance/industries/pesticides/topics /pesticide-approvals/pesticides-registration/applicantguide/updates/updates-to-the-uk-poem-operator-exposure-model

• NL model, NL greenhouse, EUROPOEM: <u>www.ctgb.nl</u> click on "full text and Guidance documents" under "Regulation placing of ppp on the market"





Background information

- EFSA Guidance on the assessment of exposure for operators, workers, residents and bystanders in risk assessment for plant protection products <u>http://www.efsa.europa.eu/en/efsajournal/doc/1501.pdf</u>
- EFSA Project to assess current approaches and knowledge with a view to develop a Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents.

http://www.efsa.europa.eu/en/scdocs/doc/26e.pdf

