efsa
European Food Safety Authority

anses
French agency for food, environmental and occupational health & safety

# Occupational exposure to pesticides

## Challenges for research, evaluation and prevention

Conference

28&29

OCTOBER 2014

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# Agricultural Operator Exposure Model (AOEM)

**Sabine Martin**

Federal Institute for Risk Assessment

Occupational exposure to pesticides
Challenges for research, evaluation and prevention

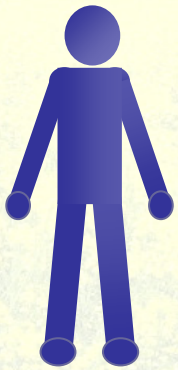
28&29 OCTOBER 2014

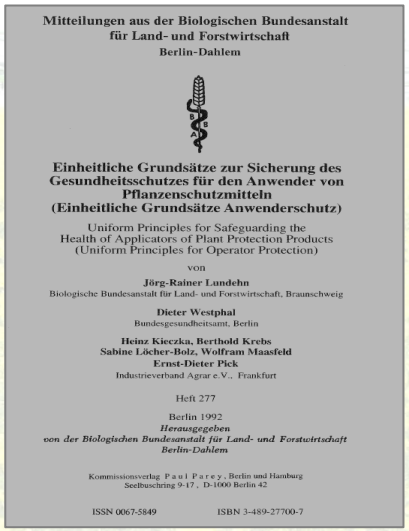
# Introduction

## Current situation:

- different models used in risk assessment for PPPs
- mainly based on data for outdated equipment and practices


Exposure




Mitteilungen aus der Biologischen Bundesanstalt
für Land- und Forstwirtschaft
Berlin-Dahlem

Einheitliche Grundsätze zur Sicherung des Gesundheitsschutzes für den Anwender von Pflanzenschutzmitteln
(Einheitliche Grundsätze Anwenderschutz)

Uniform Principles for Safeguarding the Health of Applicators of Plant Protection Products
(Uniform Principles for Operator Protection)

von

Jörg-Rainer Lundehn
Biologische Bundesanstalt für Land- und Forstwirtschaft, Braunschweig

Dieter Westphal
Bundesgesundheitsamt, Berlin

Heinz Kieczka, Berthold Krebs
Sabine Löcher-Bolz, Wolfram Maasfeld
Ernst-Dieter Pick
Industrieverband Agrar e.V., Frankfurt

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*Berlin-Dahlem*

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Seelbuschring 9-17, D-1000 Berlin 42

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⇨ no harmonised risk assessment in EU-MS

# Scope of the new Model

**Development of a new, harmonised operator exposure model for current outdoor application types, particularly:**

- Field crop applications (tractor mounted/trailed, hand held)
- High crop applications (tractor mounted/trailed, hand held).

→ appropriate deterministic model for regular exposure estimations in authorisation procedures,

→ based on new values from valid exposure studies according to the present scientific knowledge

Project group

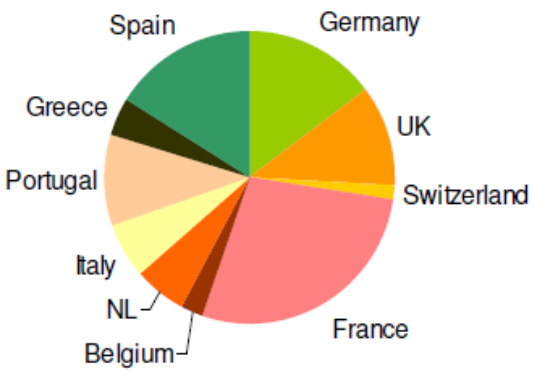
- ANSES (French Agency for Food, Environmental and Occupational Health & Safety)
- BfR (Federal Institute for Risk Assessment)
- BVL (Federal Office of Consumer Protection and Food Safety)
- HSE (Health and Safety Executive)
- JKI (Federal Research Centre for Cultivated Plants) and
- ECPA (European Crop Protection Association) observed by EFSA and TNO

# Quality Criteria for Exposure Studies

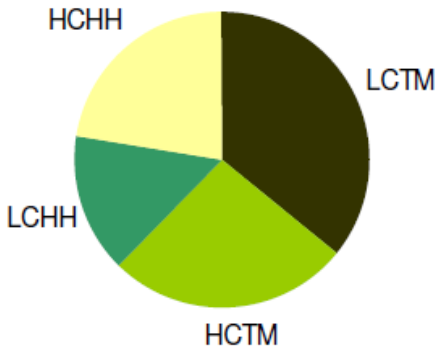
- Compliance with OECD Series No. 9
- Trained operators working in accordance with Good Agricultural Practice
- Data recording and observations according to current scientific knowledge
- Compliance with GLP
- Consistent field recovery
- Suitable data measurements
- Whole body dosimetry for dermal exposure
- Appropriate inhalation fraction samplers for inhalation exposure
- Representative application methods and application techniques

# Database

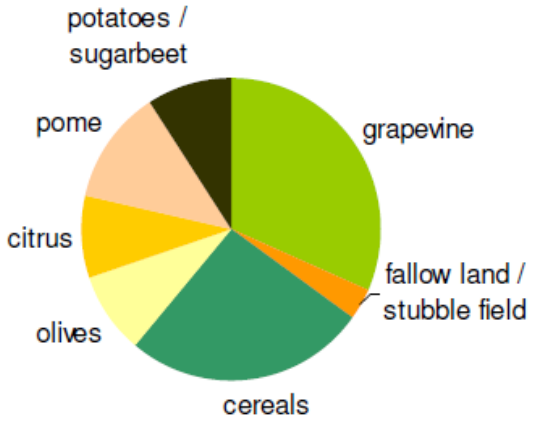
**Countries**



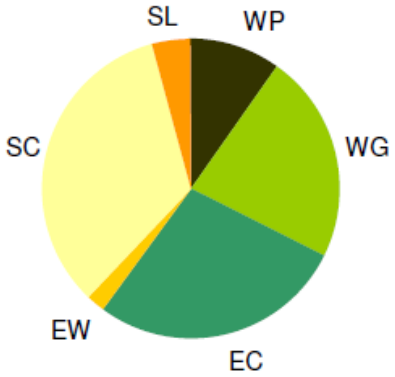

**Application types**




**Crops**




**Formulation types**



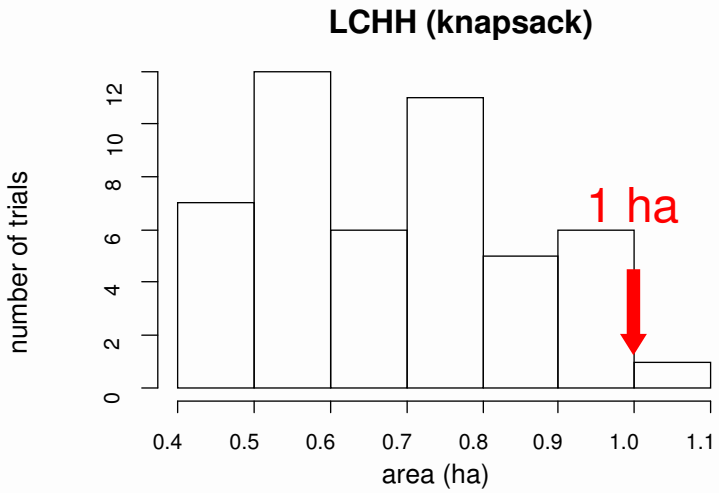

LC – Low crops,
HC – High crops,
TM – Tractor mounted/- trailed,
HH – Hand held

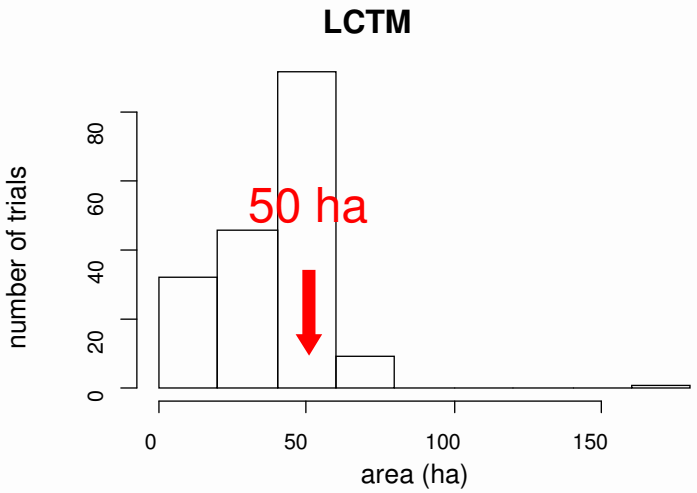
# Database

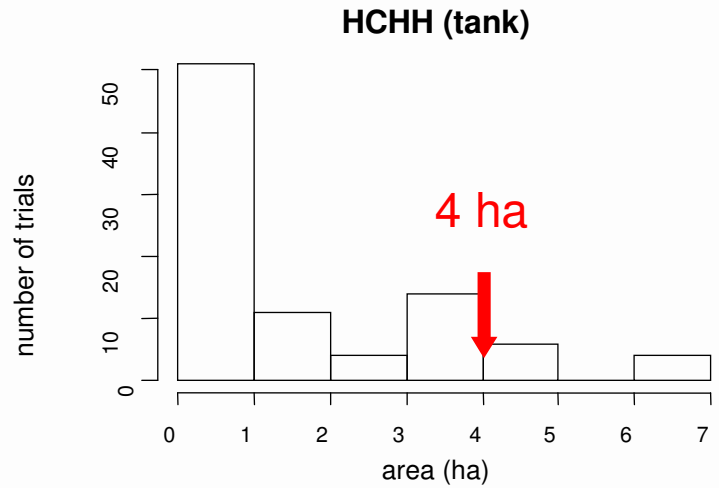
Number of mixing/loading and application data available for model development

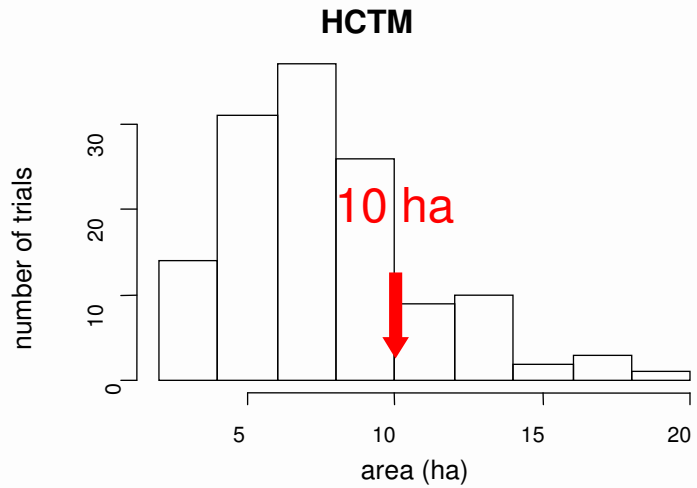
| | Inhalation | Total hands | Protected hands | Total body | Protected body | Head |
|---|---|---|---|---|---|---|
| **Mixing/Loading** | | | | | | |
| **Tank** | 161 | 206 | 229 | 130 | 129 | 129 |
| **Knapsack** | 40 | 49 | 49 | 40 | 40 | 40 |
| **Total** | 201 | 255 | 278 | 170 | 169 | 169 |
| **Application** | | | | | | |
| **LCTM** | 66 | 85 | 74 | 46 | 45 | 46 |
| **HCTM** | 83 | 97 | 92 | 72 | 72 | 71 |
| **LCHH** | 39 | 48 | 20 | 39 | 39 | 39 |
| **HCHH** | 90 | 90 | 90 | 90 | 90 | 90 |
| **Total** | 278 | 320 | 276 | 247 | 246 | 246 |

# Database

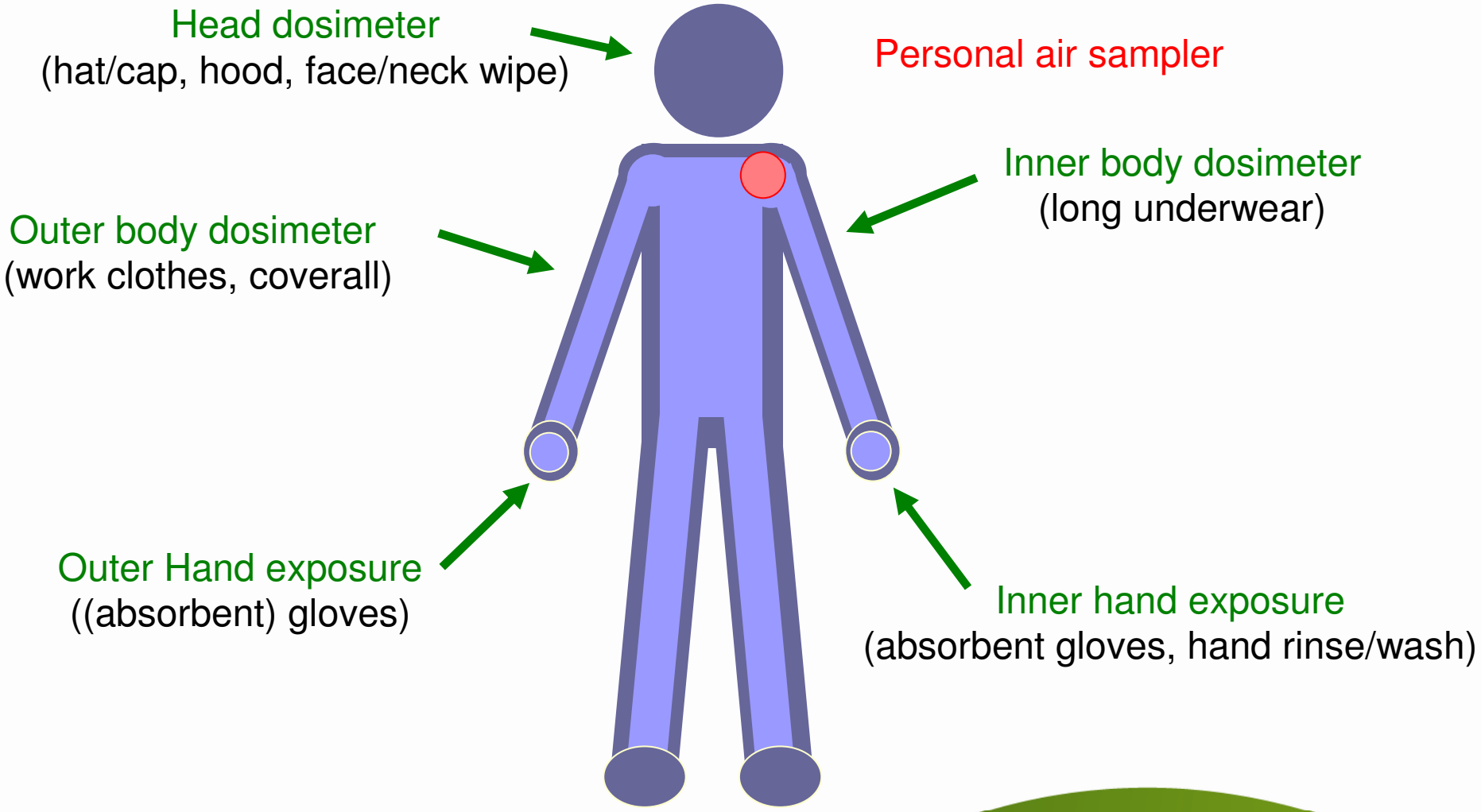

LCHH (knapsack)
number of trials
0
2
4
6
8
10
12
1 ha
0.4
0.5
0.6
0.7
0.8
0.9
1.0
1.1
area (ha)


LCTM
number of trials
0
20
40
60
80
50 ha
0
50
100
150
area (ha)


HCHH (tank)
number of trials
0
10
20
30
40
50
4 ha
0
1
2
3
4
5
6
7
area (ha)


HCTM
number of trials
0
10
20
30
10 ha
5
10
15
20
area (ha)

# Types of Dosimeters



# Exposure Variables

Potential body exposure:
sum of deposits on outer and inner body dosimeters

Protected body exposure:
deposits on inner body dosimeters (below one layer of clothing)

Potential hand exposure:
sum of deposits on protective gloves and hands

Protected hand exposure:
deposits on protected hands (inner gloves, hand rinse/wash)

Head exposure:
deposit on the head dosimeter corrected for the whole head

Inhalation exposure:
amount collected by air sampling corrected for respiratory rate

# Statistical Analysis

| ML scenarios | | Application scenarios | | Model scenarios |
|---|---|---|---|---|
| Tank ML | + | LCTM A<br>HCTM A<br>LCHH A (knapsack sprayer)<br>HCHH A (tank sprayer) | = | LCTM<br>HCTM<br>LCHH tank<br>HCHH tank |
| Knapsack ML | + | LCHH A (knapsack sprayer)<br>HCHH A (tank sprayer) | = | LCHH knapsack<br>HCHH knapsack |

$$E_O = DE_{OML(H)} + DE_{OML(B)} + DE_{OML(C)} + IE_{OML} + DE_{OA(H)} + DE_{OA(B)} + DE_{OA(C)} + IE_{OA}$$

$$SDE = (D \times (PPE) \times DA) / BW \quad SIE = (I \times (PPE) \times IA) / BW$$

# Statistical Analysis

## M/L task

- formulation type
- total amount a.s. used per day
- number of containers handled
- number of M/L tasks
- concentration of a.s.
- equipment (e.g. induction hopper)
- duration of M/L

## Application task

- formulation type
- total amount a.s. used per day
- concentration of a.s. in spray solution
- equipment (cabin)
- size of area treated
- spray droplet size
- cleaning
- duration of cleaning

log-linear model: $\log X = \alpha \cdot \log A + \Sigma [Fi] \qquad (0 < \alpha \leq 1)$

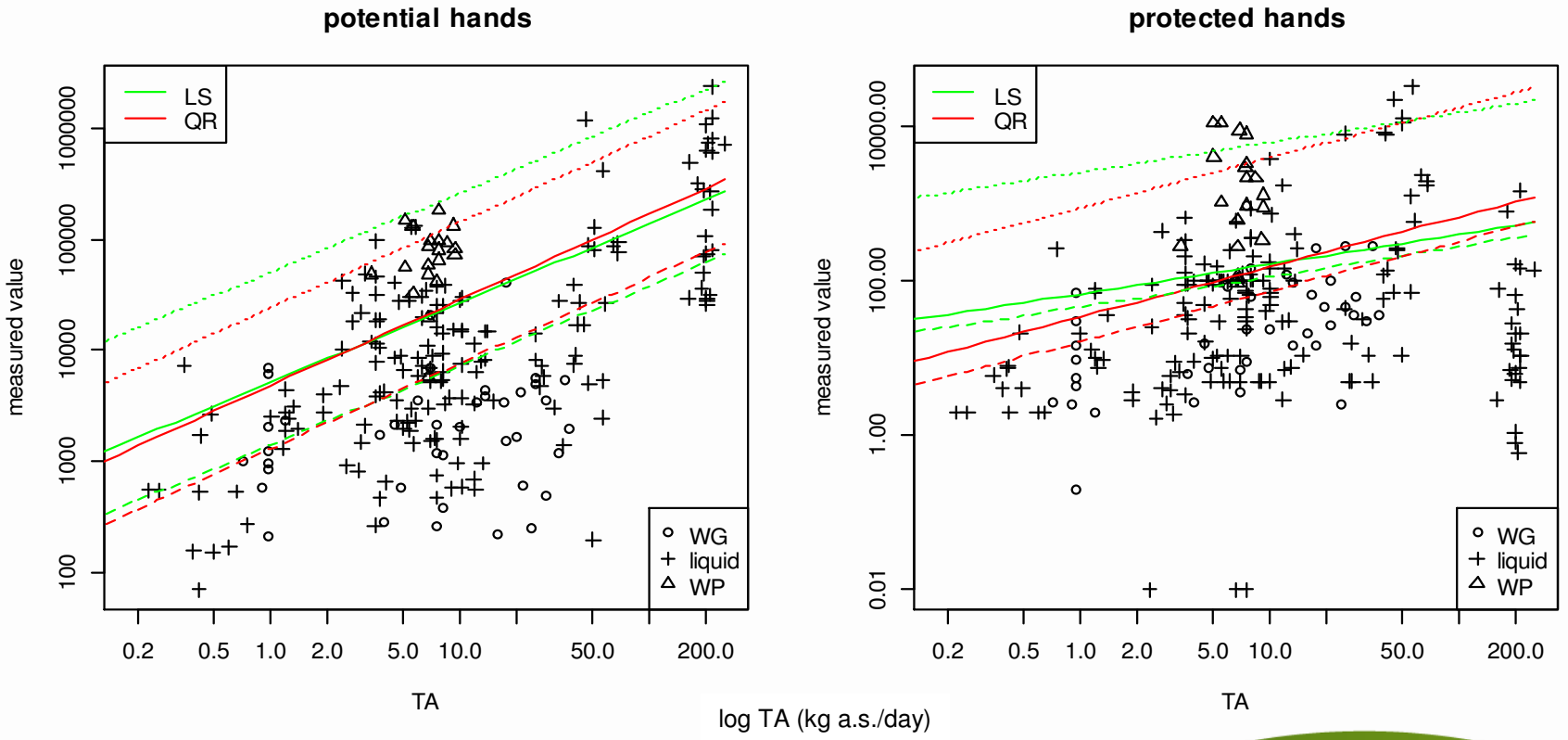
# Statistical Analysis

| | Mix./Loading | | Application | | | |
|---|---|---|---|---|---|---|
| | Tank | Knapsack | LCTM | HCTM | LCHH | HCHH |
| Factors | Total amount of a.s., Formulation type (WP, WG, liquids) | None ($75^{th}$ / $95^{th}$ perc.) | Total amount of a.s., Droplet size (coarse vs. other) | Total amount of a.s., Cabin status (cabin, vs. no cabin) | None ($75^{th}$ / $95^{th}$ ) | Total amount of a.s. |
| Subset | Face mask, (Glove rinse) | None | Herbicide application in high crops | None | None | Application in dense crops |

# Model

## Method: Quantile Regression (75./95. percentile)

e.g. Hand exposure during mixing/loading tanks (75. percentile)



# Model

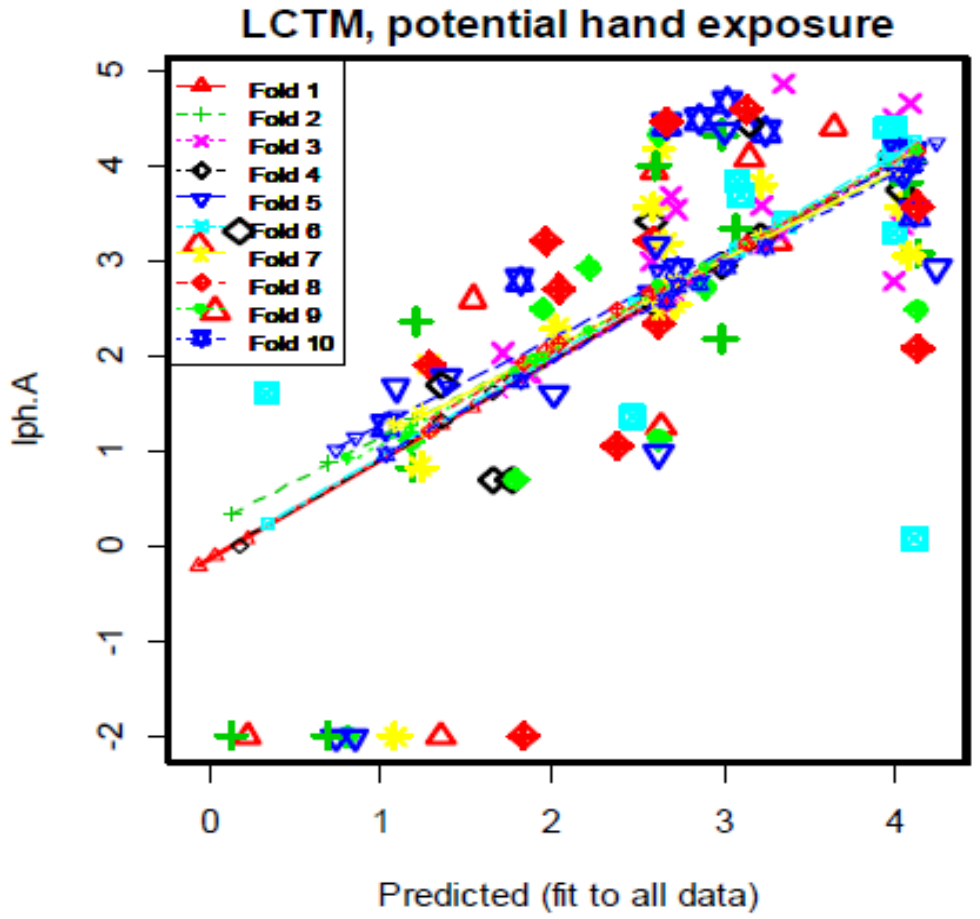
| | | |
|---|---|---|
| **Mixing/loading – tank** | potential hands | log $D_{M(H)}$ = 0.77 log TA + 0.57 [liquid] + 1.27 [WP] – 0.29 [glove wash] + 3.12 |
| | protected hands | log $D_{M(Hp)}$ = 0.65 log TA + 0.32 [liquid] + 1.74 [WP] + 1.22 |
| | total body | log $D_{M(B)}$ = 0.70 log TA + 0.46 [liquid] + 1.83 [WP] + 3.09 |
| | protected body | log $D_{M(Bp)}$ = 0.89 log TA + 0.11 [liquid] + 1.76 [WP] + 1.27 |
| | head | log $D_{M(C)}$ = log TA + 0.90 [liquid] + 1.28 [WP] + 1.79 [no face shield] - 0.98 |
| | inhalation | log $I_M$ = 0.30 log TA - 1.00 [liquid] + 1.76 [WP] + 1.57 |
| **Mixing/loading - knapsack** | potential hands | **75th percentile (above 1.5 kg a.s. linear extrapolation)** |
| | protected hands | |
| | total body | |
| | protected body | |
| | head | |
| | inhalation | |

# Model

| | | |
|---|---|---|
| **Downward spraying – vehicle mounted** | potential hands | log $D_{A(H)}$ = log TA + 0.37 [normal droplets] - 1.04 [normal equipment] + 2.84 |
| | protected hands | log $D_{A(Hp)}$ = 0.54 log TA + 1.11 [normal droplets] + 0.29 [normal equipment] - 0.23 |
| | total body | log $D_{A(B)}$ = log TA + 0.81 [normal droplets] - 1.43 [normal equipment] + 2.54 |
| | protected body | log $D_{A(Bp)}$ = log TA + 0.70 [normal droplets] - 1.09 [normal equipment] + 0.74 |
| | head | log $D_{A(C)}$ = log TA + 0.88 [normal droplets] - 0.53 [normal equipment] + 0.24 |
| | inhalation | log $I_A$ = 0.50 log TA + 0.01 [normal droplets] - 0.71 [normal equipment] + 0.72 |
| **Upward spraying – vehicle mounted** | potential hands | log $D_{A(H)}$ = 0.89 log TA + 0.28 [no cabin] + 3.12 |
| | protected hands | log $D_{A(Hp)}$ = log TA - 1.55 |
| | total body | log $D_{A(B)}$ = log TA + 0.48 [no cabin] + 3.47 |
| | protected body | log $D_{A(Bp)}$ = log TA + 0.23 [no cabin] + 1.83 |
| | head | log $D_{A(C)}$ = log TA + 1.89 [no cabin] + 1.17 |
| | inhalation | log $I_A$ = 0.57 log TA + 0.82 [no cabin] + 0.99 |
| **Downward spraying – hand-held** | potential hands | **75th percentile (above 1.5 kg a.s. linear extrapolation)** |
| | protected hands | |
| | total body | |
| | protected body | |
| | head | |
| | inhalation | |
| **Upward spraying – hand-held** | potential hands | log $D_{A(H)}$ = 0.84 log TA - 0.83 [normal culture] + 4.26 |
| | protected hands | log ($D_{A(Hp)}$ = log TA - 0.88 [normal culture] + 2.26 |
| | total body | log $D_{A(B)}$ = 0.16 log TA - 1.29 [normal culture] + 6.08 |
| | protected body | log $D_{A(Bp)}$ = - 1.64 [normal culture] + 4.65 |
| | head | log $D_{A(C)}$ = 0.32 log TA - 1.09 [normal culture] + 3.27 |
| | inhalation | log $I_A$ = 0.83 log TA - 0.26 [normal culture] + 2.17 |

# Validation

- Robustness (Cross validation)
- Prediction (MLA data)



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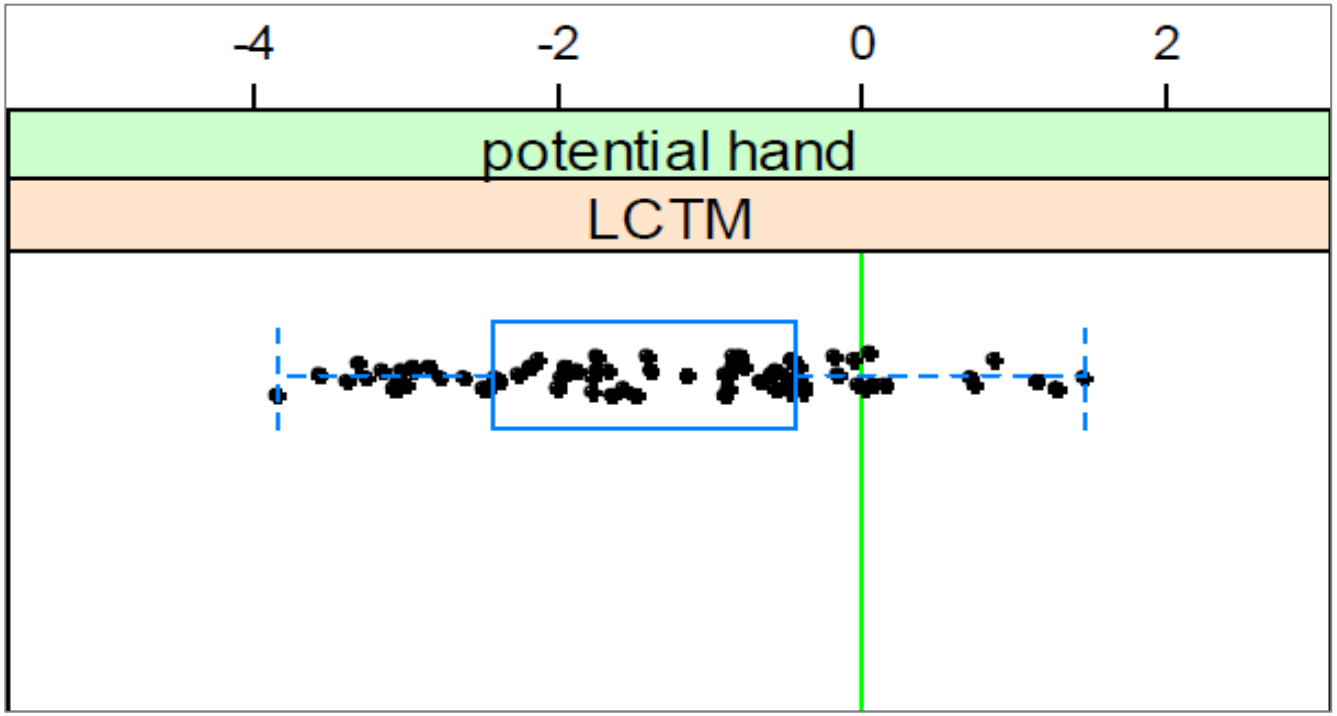
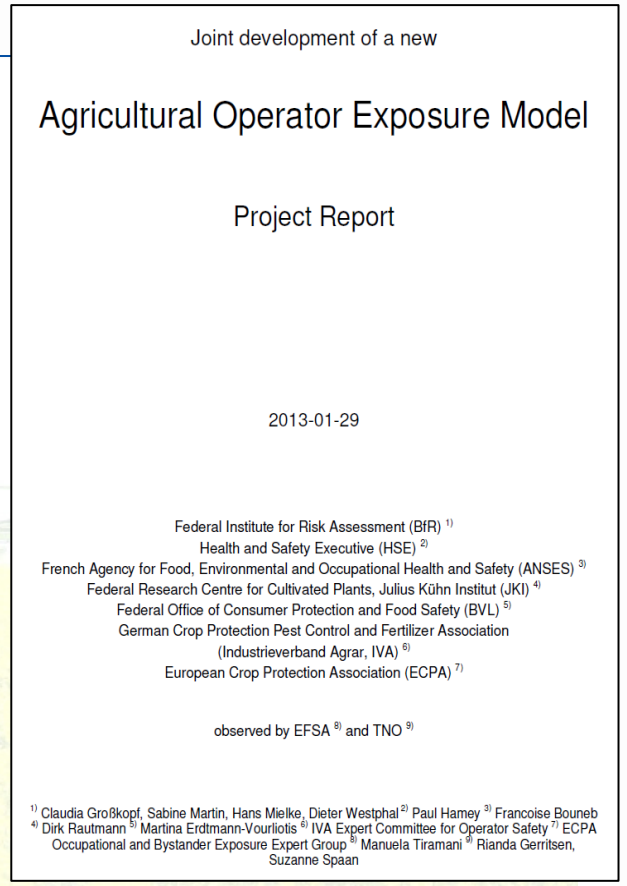


# Conclusions

- New model for typical outdoor scenarios,
- Model for risk assessment

  for zonal and national applications,
- Exposure factors selected by statistical analysis,
- Log linear model

  (quantile regression, 75$^{th}$ and 95$^{th}$ percentile),
- Validation,
- Tiered approach possible,
- Update of the model if new data become available



Joint development of a new

Agricultural Operator Exposure Model

Project Report

2013-01-29

Federal Institute for Risk Assessment (BfR) [1]
Health and Safety Executive (HSE) [2]
French Agency for Food, Environmental and Occupational Health and Safety (ANSES) [3]
Federal Research Centre for Cultivated Plants, Julius Kühn Institut (JKI) [4]
Federal Office of Consumer Protection and Food Safety (BVL) [5]
German Crop Protection Pest Control and Fertilizer Association
(Industrieverband Agrar, IVA) [6]
European Crop Protection Association (ECPA) [7]

observed by EFSA [8] and TNO [9]

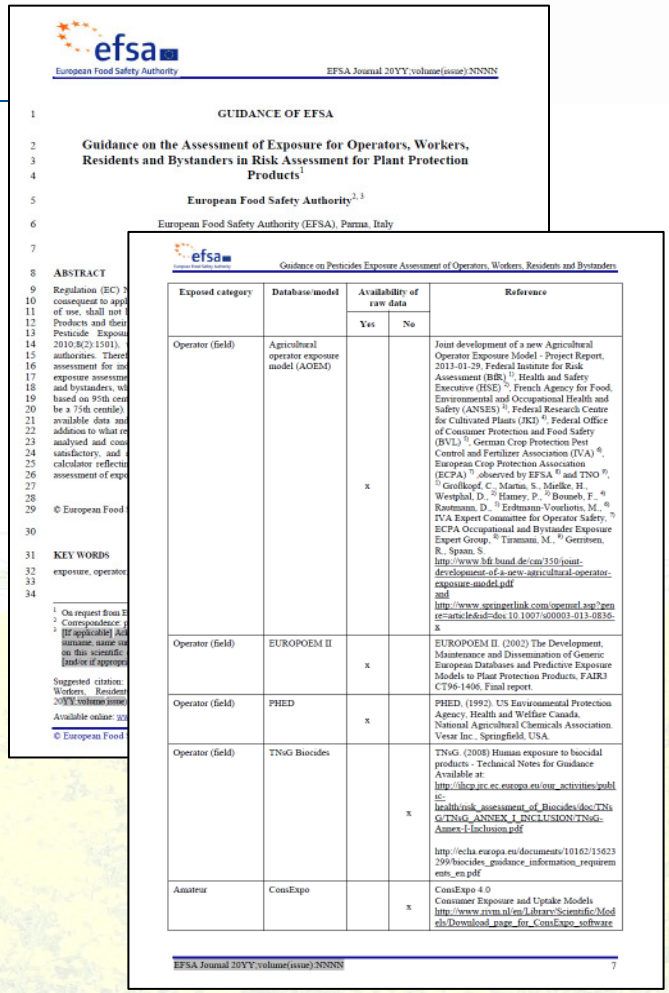
[1] Claudia Großkopf, Sabine Martin, Hans Mielke, Dieter Westphal [2] Paul Hamey [3] Francoise Bouneb [4] Dirk Rautmann [5] Martina Erdtmann-Vourliotis [6] IVA Expert Committee for Operator Safety [7] ECPA Occupational and Bystander Exposure Expert Group [8] Manuela Tiramani [9] Rianda Gerritsen, Suzanne Spaan

http://www.bfr.bund.de/cm/350/joint-development-of-a-new-agricultural-operator-exposure-model.pdf

http://www.springerlink.com/openurl.asp?genre=article&id=doi:10.1007/s00003-013-0836-x

# Implementation

- May 2014 - Draft EFSA Guidance for consultation,
- Discriminates between acute and chronic assessments,
- Consideration of potential exposure and actual exposure using different kind of PPE,
- The deterministic methods is still suggested in routine risk assessment for individual PPPs, because of the limitations of the currently available data,
- June 2014 “European Conference on Safe Use of Plant Protection Products”


efsa
European Food Safety Authority
EFSA Journal 20YY;volume(issue):NNNN

GUIDANCE OF EFSA

Guidance on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

KEY WORDS

Guidance on Pesticides Exposure Assessment of Operators, Workers, Residents and Bystanders

| Exposed category | Database/model | Availability of raw data | | Reference |
|---|---|---|---|---|
| | | Yes | No | |
| Operator (field) | Agricultural operator exposure model (AOEM) | x | | Joint development of a new Agricultural Operator Exposure Model - Project Report, 2013-01-29, Federal Institute for Risk Assessment (BfR) [1], Health and Safety Executive (HSE) [2], French Agency for Food, Environmental and Occupational Health and Safety (ANSES) [3], Federal Research Centre for Cultivated Plants (JKI) [4], Federal Office of Consumer Protection and Food Safety (BVL) [5], German Crop Protection Pest Control and Fertilizer Association (IVA) [6], European Crop Protection Association (ECPA) [7], observed by EFSA [8] and TNO [9], [1] Großkopf, C., Martin, S., Mielke, H., Westphal, D., [2] Hamey, P., [3] Bonneté, F., [4] Rautmann, D., [5] Erdtmann-Vourliotis, M., [6] IVA Expert Committee for Operator Safety, [7] ECPA Occupational and Bystander Exposure Expert Group, [8] Tiramani, M., [9] Gerritsen, R., Spaan, S. http://www.bfr.bund.de/cm/350/joint-development-of-a-new-agricultural-operator-exposure-model.pdf and http://www.springerlink.com/openurl.asp?genre=article&id=doi:10.1007/s00003-013-0836-x |
| Operator (field) | EUROPOEM II | x | | EUROPOEM II. (2002) The Development, Maintenance and Dissemination of Generic European Databases and Predictive Exposure Models to Plant Protection Products, FAIR3 CT96-1406, Final report. |
| Operator (field) | PHED | x | | PHED, (1992). US Environmental Protection Agency, Health and Welfare Canada, National Agricultural Chemicals Association. Vesar Inc., Springfield, USA. |
| Operator (field) | TNsG Biocides | | x | TNsG. (2008) Human exposure to biocidal products - Technical Notes for Guidance Available at: http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/doc/TNsG/TNsG_ANNEX_I_INCLUSION/TNsG-Annex-I-Inclusion.pdf http://echa.europa.eu/documents/10162/15623299/biocides_guidance_information_requirements_en.pdf |
| Amateur | ConsExpo | | x | ConsExpo 4.0 Consumer Exposure and Uptake Models http://www.rivm.nl/en/Library/Scientific/Models/Download_page_for_ConsExpo_software |

EFSA Journal 20YY;volume(issue):NNNN 7

From then on, COM will decide how to deal with the available Guidance (e.g. need of additional meetings with managers, transitional periods, etc…)

In the meantime - Re-assessment of the data of the Southern Europe Greenhouse model
- Finalisation of BROWSE

Bundesinstitut für Risikobewertung

# Thank you for your attention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