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# A test method to assess operator safety using Close Transfer Systems

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# Initial Situation

- Draft Paper of EU Commission demands the assessment of negligible exposure to an active substance in a plant protection product (PPP) under realistic conditions of use.

  EU (2015): Commission Notice - Technical guidance on the interpretation of points 3.6.3. to 3.6.5, and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, in particular regarding the assessment of negligible exposure to an active substance in a plant protection product under realistic conditions of use. DRAFT - May 2015, 17 pages.

- This applies for the exposure of humans in particular during the filling process of pesticide application equipment (PAE) when the operator is exposed to contamination by undiluted PPP.
- These new requirements concerning negligible exposure can have an impact on the future capability for the approval of PPP.
- Close Transfer Systems (CTS) can contribute to operator safety and could be a technical solution to fulfill the requirements of negligible exposure.

# What is CTS

- Devices for contactless transfer of PPP into PAE
- Based on a connection port mounted on the sprayer and an adaptor on the sealed PPP canister
- Unsealing of the canister happends within the closed systems
- CTS can be mounted on a wide range of different types of PAE
- CTS allows partial draining with precise dosing
- Containers of different sizes can be used
- Containers can be rinsed within the closed system before the connection is unlocked
- Contact surfaces of port and adaptor can be rinsed before unlocking

# Aim of the project

If CTS can significantly reduce the risk of operator exposure it can be taken into account for risk assessment within the PPP authorization process .

Against this background a method to assess operator exposure based on conventional fillings against those using CTS und realistic conditions of use has to be established.

# Materials and Methods

Different varieties of fillings on a conventional field crop sprayer (RAU D2) were simulated by seven different persons wearing protective clothes.

Criteria for test persons:

- Different body heights (1.70-1.98m)
- Having a certificate of competence for plant protection
- Not experienced with CTS
- 4 out of 7 test persons were experienced with conventional filling

Varieties of fillings

(1) induction hopper

(2) dome shaft

(3) induction hopper with CTS

(4) dome shaft with CTS

# Materials and Methods

Two step assessment:

In pretests with seven different persons the canister size (1, 5, 10 liters) leading to highest operator exposure during conventional filling (varieties 1 and 2) was figured out.

In a second step three different persons performed all varieties of fillings (1-4) with the predefined canister size (worst-case-scenario).

Test fluid:

Instead of PPP, water and Pyranin were filled into canisters of different sizes and sealed.

Dosimeters used:

Overall, nitrile protective gloves, protective visor

Additional worn beneath: one way laboratory gloves, long underwear (leackage)

# Analysis

- Overall and long underwear were washed three times directly after each other with 17 liters of demineralized water at 30°.
- The water from first and second washing was used for determination of tracer content, the water from third washing for the definition of the blank value.
- Gloves and protective visor were rinsed off by hand with destilled water (200ml/400ml)
- The collected rinsing/washing water was analyzed using fluorescence spectroscopy.
- Detection limit (LOD) and determination limit (LOQ) were calculated
  - All values beneath LOD were considered to be zero
  - All values between LOD and LOQ were considered to be at the avarage value between both limits
- The retrival rate was determined for all dosimeters with 50µl tracer dripped onto the dosimeters (mean retrieval rate 83.22% for overall and 99.9% for gloves)

# Calculations

- Absolute tracer mass:

$$m = \frac{(x - B)}{a} \cdot V_{wf} = c_p \cdot V$$

- Tracer amount on dosimeter:

$$V_d = \frac{m}{c_0}$$

- Retrival rate:

$$R = \frac{V_d}{V_0} \cdot 100\%$$

with:

m = mass of tracer

x = measured value (including limit definitions)

B = blank value

a = gradient of calibration curve

V =volume of rinsing/washing fluid

$c_p$ = concentration of probe

$V_d$ = volume of tracer on dosimeter

m = mass of tracer

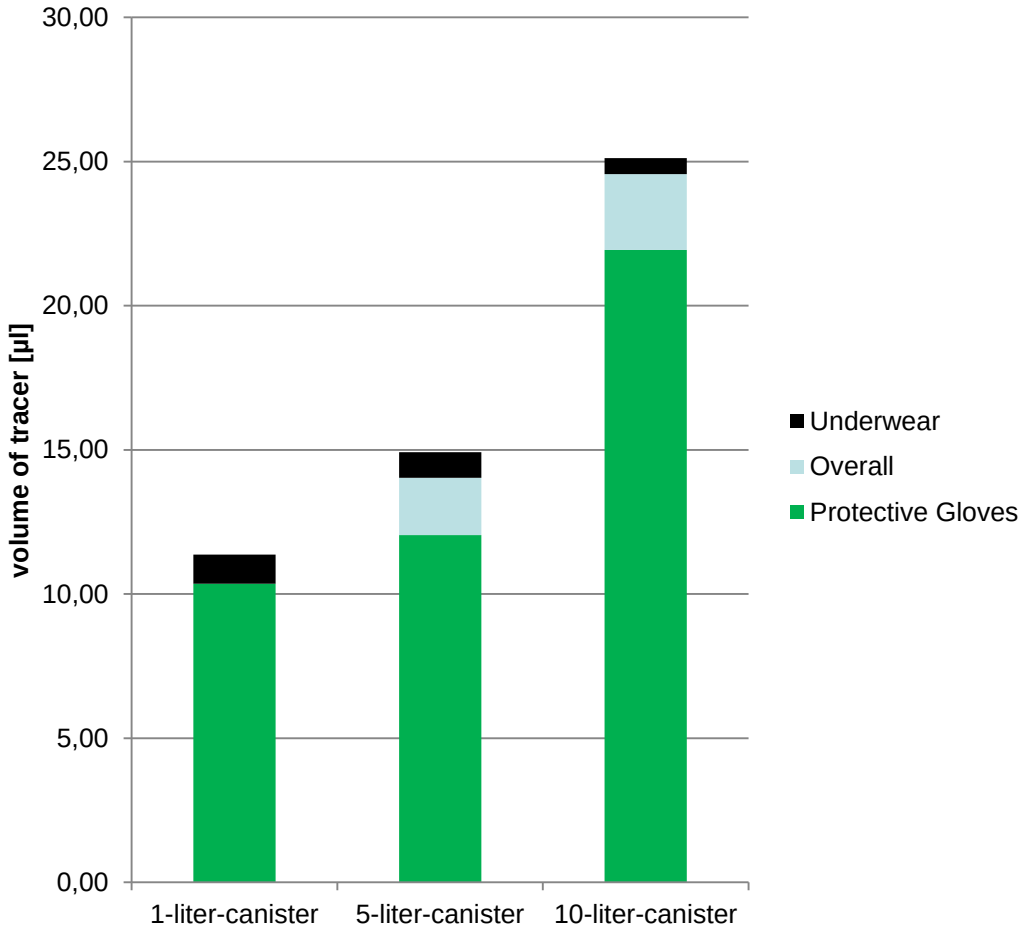
$c_0$ = initial concentration of tracer within canister

R = retrieval rate

$V_d$ = measured volume of tracer

$V_0$ = initial volume of tracer

# Results of first test




Data is based on 75th-percentile.

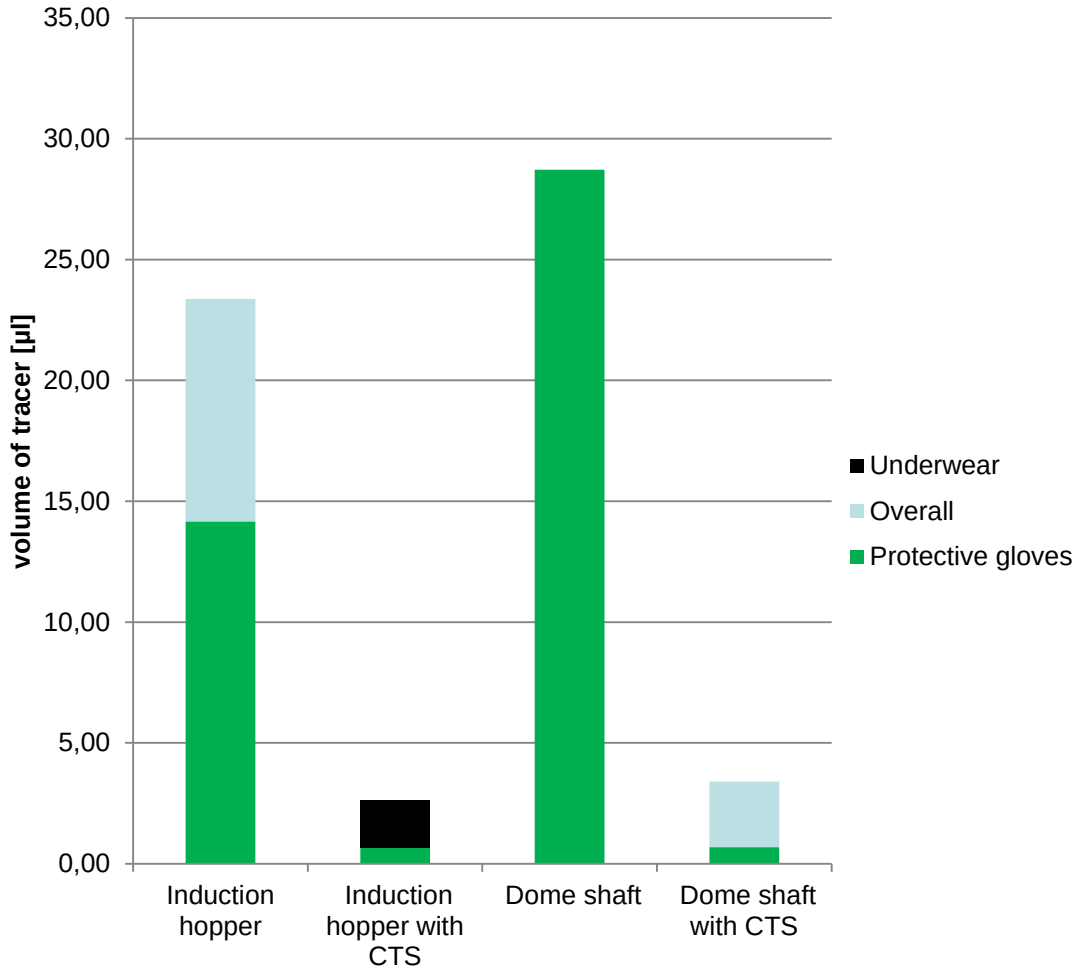
Test performed by seven different persons

**Keyfindings:**

- 10 liter canister leads to highest operator exposure
- Contamination was primarily on protective gloves
- No contamination on protective visor and second pair of gloves worn beneath
- All data found for the underwear was between LOD and LOQ

=> 10 liter canister was chosen for further tests (worst case scenario)

# Results of second test




Data is based on 75th-percentile.

Test performed by three different persons

**Keyfindings:**

- CTS can significantly reduce operator exposure
- Contamination was primarely on protective gloves
- No contamination on protective visor and second pair of gloves worn beneath
- Data found for the underwear in one case was between LOD and LOQ

# Conclusion

- The method presented is able to assess operator exposure when using CTS in comparison to conventional filling of PAE.
- The method is able to quantify operator exposure in an ensured and reproducable way.
- Using 75th-percentile and worst case scenario weakens role and effects of different test persons.
- For future assessment only protective gloves and overall are needed based on the results of these tests.

# Consequences for Inspection

- Actually, there are more than 8.000 CTS in the EU market
- 25% are mobile CTS
- 75% are attached to sprayers

Questions:

- Is there are need for future inspection of CTS?
- What could be the control features for inspection of CTS?
- Which kind of CTS should be inspected (attached, mobile, both)?

# Thank you for your attention!

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