

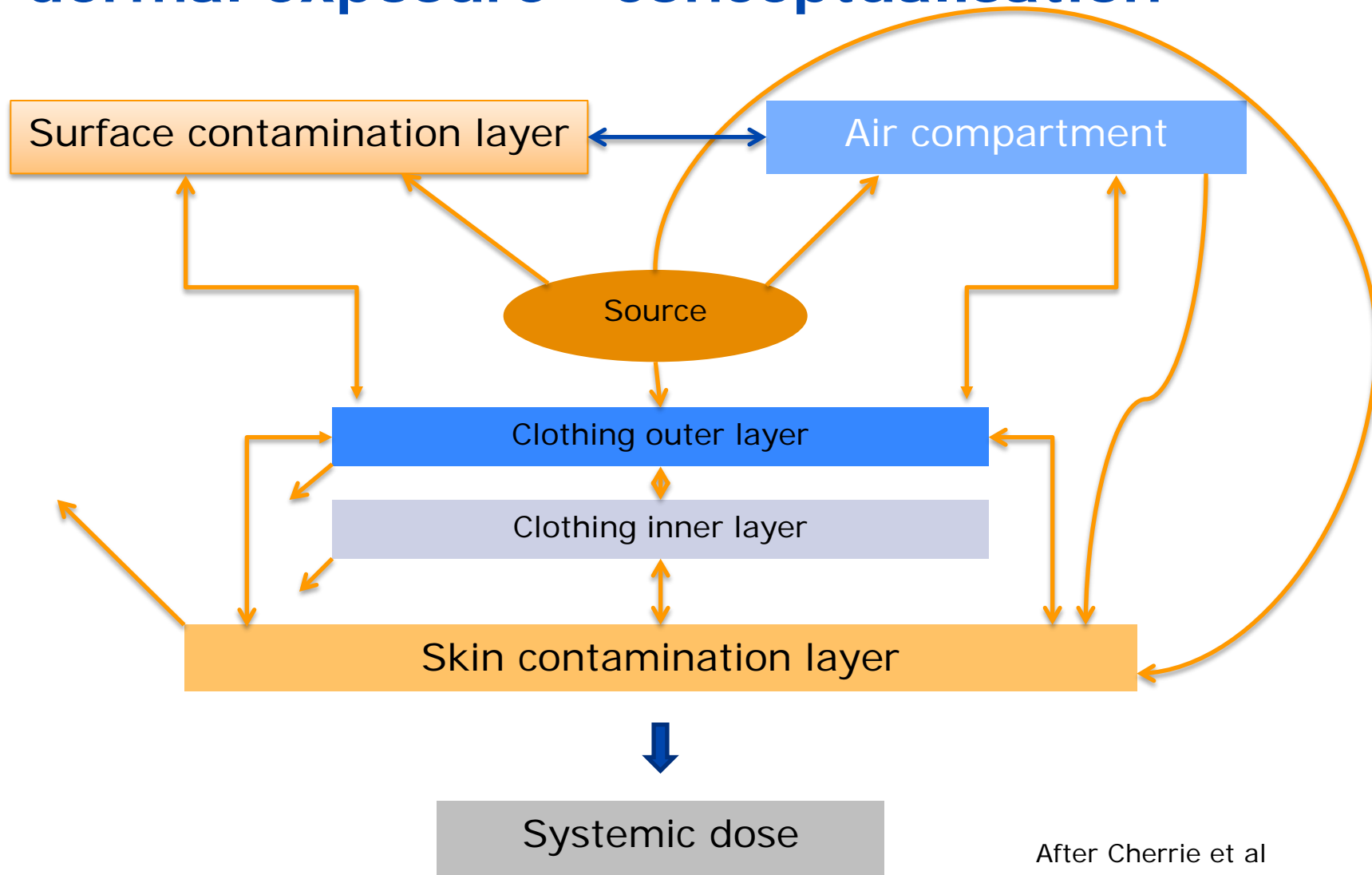
Proposal for a Tier-1 dermal exposure assessment approach

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Andrew Phillips
European Chemicals Agency

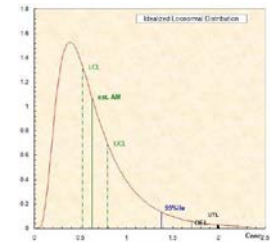


dermal exposure - conceptualisation



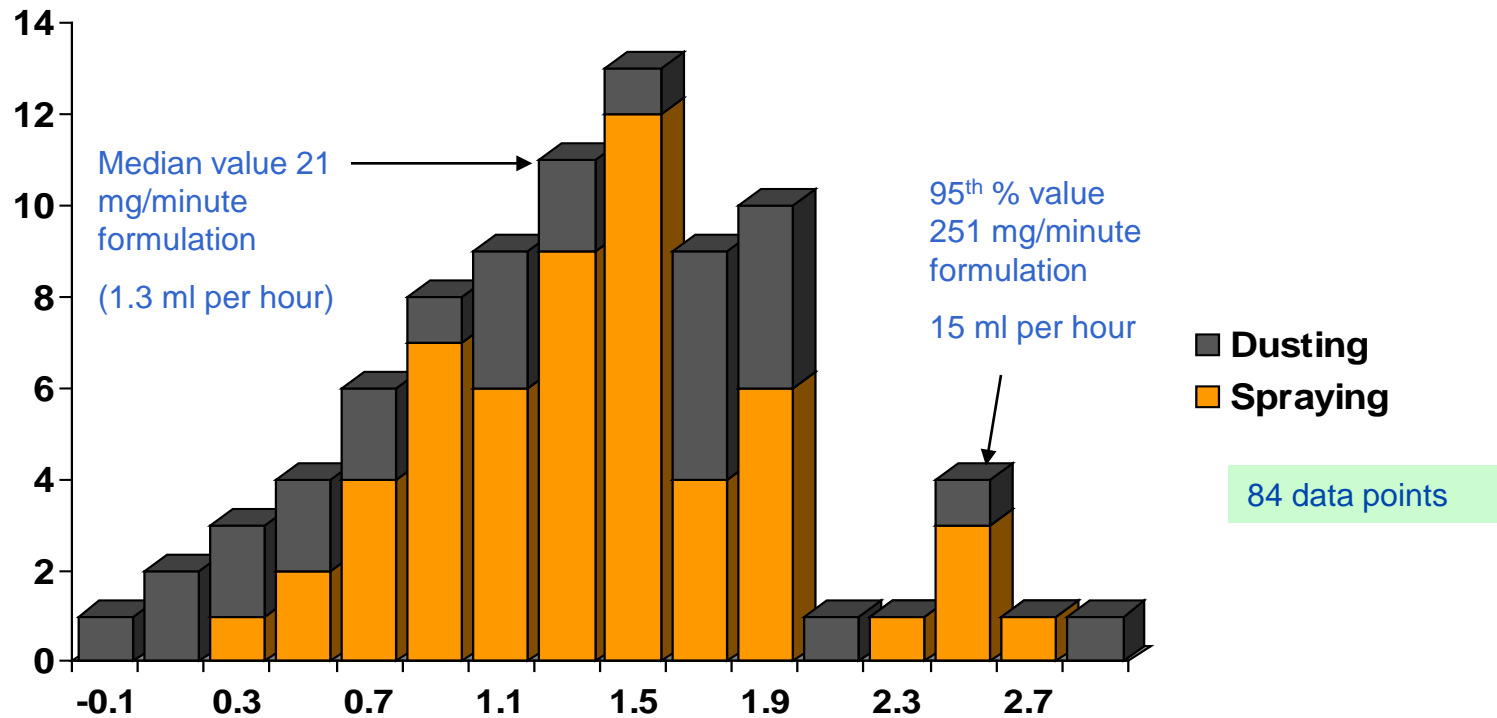
Dermal exposure is a distribution

- Log normal distribution (but often very wide)
 - a central tendency value (geometric mean)
 - a spread (geometric standard deviation)
- Time dependency (exposure opportunity and duration)
- Best expressed as a rate of deposition (e.g. mg/min)
- Tasks generate interpretable deterministic models



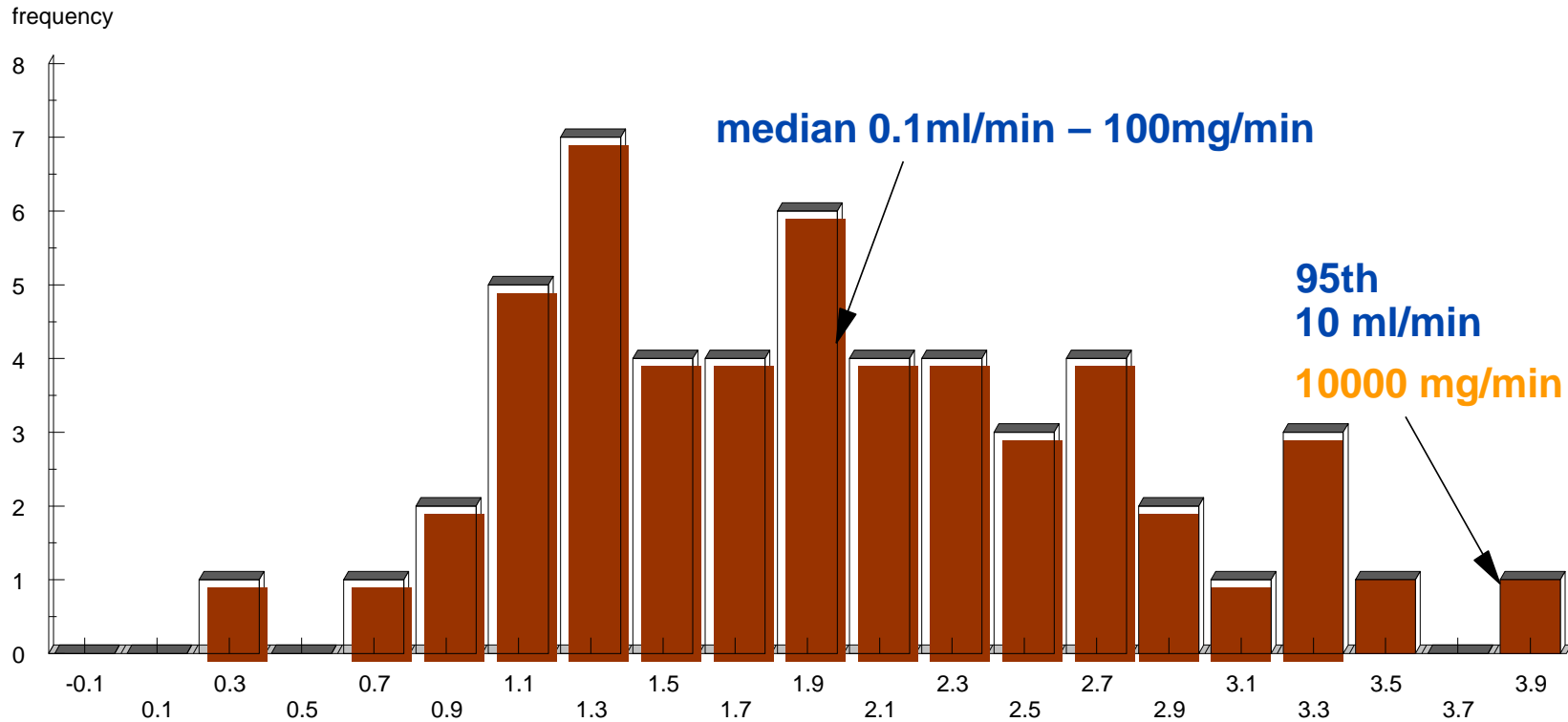
REACH demands quantitative assessment

Example distribution: Gentle spray application of dusts and liquids



Log₁₀ mg formulation/minute (deposition on worker outer clothing)

Example distribution: Pressure washer spraying



Log₁₀ mg formulation/minute (deposition on worker outer clothing)

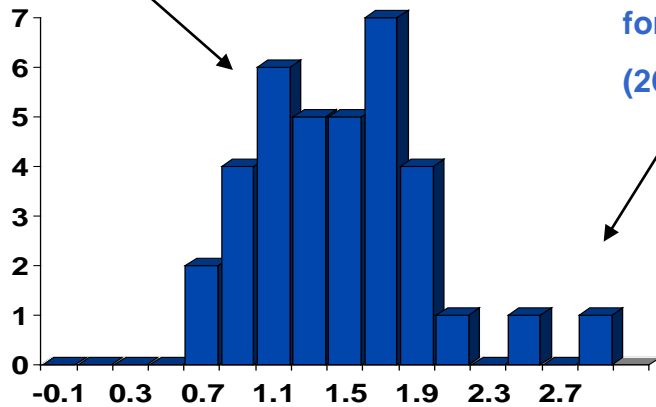


Intermittent handling tasks

Median value

26.5 mg/min
formulation

(1.6 ml per hour)



95th % value

431 mg/min
formulation

(26 ml per hour)

■ number of samples

36 data points

water wet objects

Log₁₀ mg formulation/minute (deposition on worker outer clothing)

Median value
2 mg/min
formulation

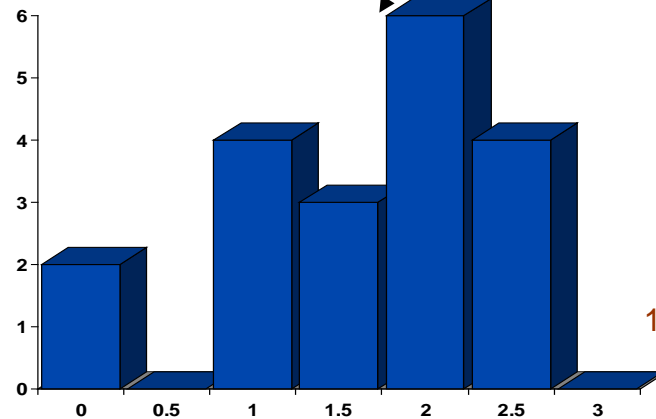
120 mg/hour

Worst case
7.5 mg/min
formulation

450 mg/hour

■ Number of samples

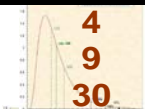

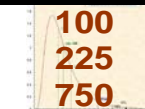
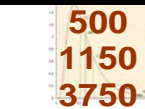
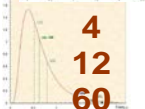


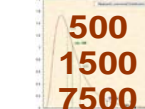
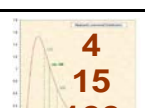
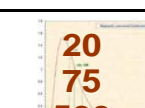

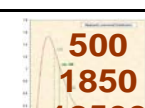
19 data points



solvent damp objects

Indicative distributions - (mg/min)

Putting some numbers on the distributions

| Median deposit, mg.min ⁻¹ | | Percentile | Low 4 mg.min ⁻¹ | Medium 20 mg.min ⁻¹ | High 100 mg.min ⁻¹ | Top 500 mg.min ⁻¹ |
|--------------------------------------|------------------------------------|-------------------|---|--|---|---|
| | Narrow (GSD 3.40) | 50% 75% 95% |  4 9 30 |  20 46 150 |  100 225 750 |  500 1150 3750 |
| | Intermediate (GSD 5.19) | 50% 75% 95% |  4 12 60 |  20 60 300 |  100 300 1500 |  500 1500 7500 |
| | Wide (GSD 7.06) | 50% 75% 95% |  4 15 100 |  20 75 500 |  100 375 2500 |  500 1850 12500 |

Body potential dermal exposure

Indicative distributions (specific to biocides)

| Deposition profile | Deposition rate | | | |
|--------------------|-------------------------------------|--|---|---------------|
| | Low | Medium | High | Top |
| Narrow | Solvent based timber pre-treatment | Amateur antifoulant brushing | | |
| | Cabbed orchard spraying | AF net deployment | | |
| Medium | | Water-based timber pre-treatment Antifoulant mix & load | Antifoulant spraying | Sheep dipping |
| Wide | Public hygiene insecticides (solid) | Public hygiene insecticides (liquid) | Pressure washer spraying Uncabbed orchard spraying | |

See Biocides human exposure guidance 2002 for individual deterministic models

Indicative distributions (Chemicals generic)

| Deposition profile | Deposition rate | | | |
|--------------------|--|--|--------------------------------|----------------------------|
| | Low | Medium | High | Top |
| Narrow | Solvent processes low emission contained process low emission | Amateur painting handling treated objects | | |
| Medium | | Water-based industrial processes Painting mix & load | Professional paint spraying | Turbulent wet processes |
| Wide | Applying solids | Applying liquids by spray | Wide dispersive spraying | |

Launched the development of BEAT
 Bayesian Exposure Assessment Tool

Indicative distributions – not relevant (often) to REACH chemicals

| Deposition profile | Deposition rate | | | |
|--------------------|--|--|--|---|
| | Low | Medium | High | Top |
| Narrow | Solvent processes low emission contained process low emission | Amateur painting handling treated objects | | |
| Medium | | Water-based industrial processes Painting mix & load | Professional paint spraying | Turbulent wet processes – no controls |
| Wide | Applying solids | Applying liquids by spray – no controls | Wide dispersive spraying no controls | |

Probably
not often
REACH
relevant




REACH requirements

- Need to demonstrate 'safe use'
 - Clear link to Exposure Scenarios
 - Under prescribed operational conditions
 - With appropriate risk management measures (RMMs)
- RMMs selection informed by OHS legislation as well – i.e. when handling chemicals under unpredictable conditions need to select appropriate RMMs for unintended events – especially so for dermal exposure
- PPE nearly always necessary so why assess risk without it?
It is a standard requirement.

Indicative distributions – new distributions for REACH-relevant processes

| Deposition profile | Deposition rate mg/min median value | | | | | |
|--------------------|-------------------------------------|-----------------------|--|--|--------------------------------|----------------------------|
| | (New) Ultra Low 0.16 | (New) Very Low 0.8 | Low 4 | Medium 20 | High 100 | Top 500 |
| (New) Narrower | | | | | | |
| Narrow | | | Solvent processes low emission contained process low emission | Amateur painting handling treated objects | | |
| Medium | | | | Water-based industrial processes Painting mix & load | Professional paint spraying | Turbulent wet processes |
| Wide | | | Applying solids | Applying liquids by spray | Wide dispersive spraying | |

New distributions for more-controlled REACH processes?



Indicative distributions – some proposals (red text)

| Deposition profile | Deposition rate mg/min median value | | | | | |
|--------------------|--------------------------------------|---|--|---|---------------------------------------|-------------------------|
| | Ultra Low 0.16 | Very Low 0.8 | Low 4 | Medium 20 | High 100 | Top 500 |
| Narrower | Enclosed processes? (PROCs 1,2,3) | Benchmark PROCs | Automated coating processes? (PROC 6) | | | |
| Narrow | Benchmark PROCs | Intermittent contact with volatile solvent based processes? (PROC ?) | Solvent processes low emission contained process low emission | Professional painting (PROC 10) Amateur painting handling treated objects (PROC 13) | | |
| Medium | Benchmark PROCs | Benchmark PROCs | Manual controlled mixing processes | Water-based industrial processes Painting mix & load | Professional paint spraying (PROC 11) | Turbulent wet processes |
| Wide | | | Applying solids | Applying liquids by spray | Wide dispersive spraying | |

Indicative distributions - chemicals (mg/min)

| Median deposit, mg.min ⁻¹ | Percentile | Ultra low 0.16 mg. min ⁻¹ | Very low 0.8 mg. min ⁻¹ | Low 4 mg.min ⁻¹ | Medium 20 mg.min ⁻¹ | High 100 mg.min ⁻¹ | Top 500 mg.min ⁻¹ |
|---|-------------------|--|--|-------------------------------------|--------------------------------------|---|---|
| Narrower | 50% 75% 95% | 0.16 0.24 0.72 | 0.8 1.2 3.6 | 4 6 18 | 20 30 90 | 100 150 450 | 500 750 2250 |
| Narrow (GSD 3.40) | 50% 75% 95% | 0.16 0.36 1.2 | 0.8 1.8 6.0 | 4 9 30 | 20 46 150 | 100 225 750 | 500 1150 3750 |
| Medium (GSD 5.19) | 50% 75% 95% | 0.16 0.48 2.4 | 0.8 2.4 12 | 4 12 60 | 20 60 300 | 100 300 1500 | 500 1500 7500 |
| Wide (GSD 7.06) | 50% 75% 95% | 0.16 0.6 4.0 | 0.8 3.0 20.0 | 4 15 100 | 20 75 500 | 100 375 2500 | 500 1850 12500 |

Body potential dermal exposure

Calculation: paint spraying 95th percentile

| | Metric | Indicative distribution | Deterministic model | ECETOC TRA |
|--------------------------------|------------|-------------------------|---------------------|--------------------|
| Loading | mg/min | 1500 | 750 | |
| Duration 60 mins | mg | 90000 | 45000 | (1-4 hours) |
| Conc 5% | mg | 4500 | 2250 | 2700 |
| Clothing 10% penetration | mg PDE | 450 | 225 | 270 (gloves only) |
| ADE | mg on skin | 450 | 225 | 270 (3.86 x 70) |
| Dermal absorption | 10% | 45 | 22 | |
| Systemic dose - 70Kg worker | mg/kg bw/d | 0.6 | 0.3 | |

Thank You.

Andrew Phillips
andrew.phillips@echa.europa.eu

