

Naar een correct, kosteneffectief en communicatief alternatief voor de EN689 (5.5.2) preliminary test

NVvA Symposium

05-04-2023, 11.30 – 12.00 uur

Theo Scheffers, Peter van Balen &
Robert Emonds

Conclusie 2022 Sessie T

- $C_{95,70\%}$ beoordeelt het blootstellings risco beter dan de preliminary test
- Voor blootgestelden en opdrachtgever
 - voor N= 3, 4, 5
- De uitleg van de statistische test in EN689 Annexen E-H is beroerd
- Communicatief inferieur t.o.v. Preliminary test

Three consecutive inhalable dust measurement OELV 5 mg/m³/8 hours

result (mg/m ³ /8hr)	% OELV	Preliminary test	GM	GSD	C _{95,70%}	Statistical test 5.5.3 Confidence C _{95%} ≤OELV
0.76	15.2%					
1.52	30.4%					
0.81	16.2%	no decision	0.98	1.47	2.87	85.0% Compliance

5.5.2 Preliminary test a) 1)

Compliance if all results are below 0,1 OELV for a set of three exposure measurements

5.5.3 Statistical test

at least 70 % confidence that 95 % of the SEG distribution is at or below the OELV

NB: Meetonzekerheid is hier niet in meegenomen

4th consecutive inhalable dust measurement OELV 5 mg/m³/8 hours

result (mg/m ³ /8hr)	% OELV	Preliminary test	GM	GSD	C _{95,70%}	Statistical test 5.5.3 Compliance if C _{X≥95,70%} =OELV X=
0.76	15.2%					
1.52	30.4%					
0.81	16.2%					
0.6	12%	no decision	0.87	1.49	2.29	92.5% compliance

5.5.2 Preliminary test a) 2)

Compliance if all results are below 0,15 OELV for a set of three exposure measurements

5.5.3 Statistical test

Less than 5 % of exposures in the SEG exceed the OELV with at least 70 % confidence

Example

5th consecutive inhalable dust measurements
OELV 5 mg/m³/8 hours

result (mg/m ³ /8hr)	% OELV	Preliminary test	(log)normal	GM	GSD	C _{95,70%}	Statistical test 5.5.3 Compliance if C _{x≥95,70%} =OELV X=
0.76	15.2%						
1.52	30.4%						
0.81	16.2%						
0.6	12%						
0.28	5.6%	no decision	logNormal	0.69	1.84	2.79	88.4% compliance

5.5.2 Preliminary test a) 3)

Compliance if all results are below 0,2 OELV for a set of three exposure measurements

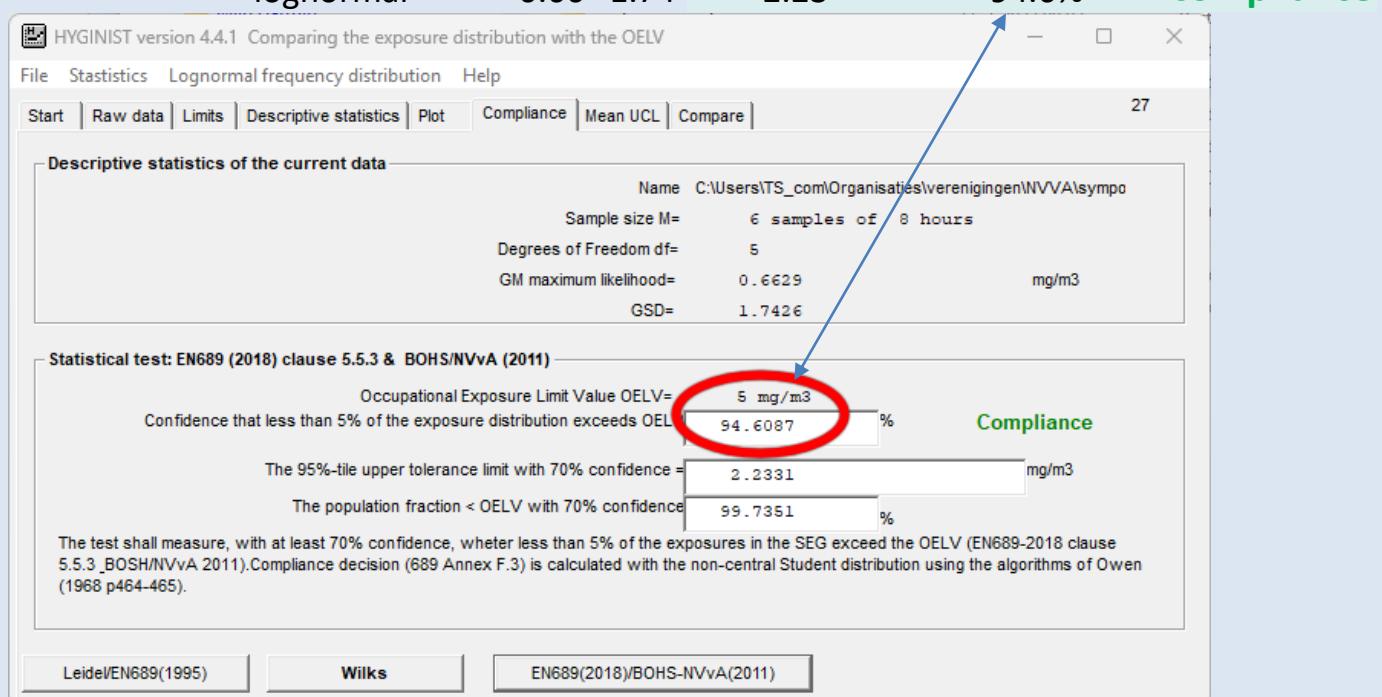
5.5.3 Statistical test

Less than 5 % of exposures in the SEG exceed the OELV with at least 70 % confidence

6th consecutive inhalable dust measurements

OELV 5 mg/m³/8 hours

result (mg/m ³ /8hr)	% OELV	Preliminary test	(log)normal	GM	GSD	C _{95,70%}	Statistical test 5.5.3 Compliance if C _{X≥95,70%} =OELV X=
0.76	15.2%						
1.52	30.4%						
0.81	16.2%						
0.6	12%						
0.28	5.6%						
0.54	10.8%		lognormal	0.66	1.74	2.23	94.6% compliance



IH-Aligner

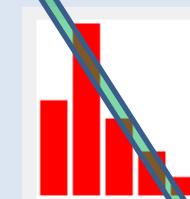
Raw data | Compliance testing EN689 | IHSTATS_EN689 | BWStat V3 | IHSTATS_Bayes | Hyginist | IHDA | Expostats Tool1 | Expostats Tool2

Versie: 9.3.2

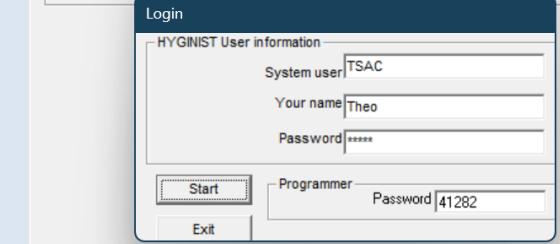
PBC1



BWStat version 3.0.2.



IHDataAnalyst - AIHA 2022
Version 2022.01



Three consecutive inhalable dust measurement OELV 5 mg/m³/8 hours

result (mg/m ³ /8hr)	% OELV	Preliminary test	GM	GSD	C _{95,70%}	Statistical test 5.5.3 Confidence C _{95%} ≤OELV
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IH-Aligner Versie: 9.3
PBC1

HYGINIST version 4.4.1 Comparing the exposure distribution with the OELV

File Statistics Lognormal frequency distribution Help

Start Raw data Limits Descriptive statistics Plot Compliance Mean UCL Compare 27

Descriptive statistics of the current data

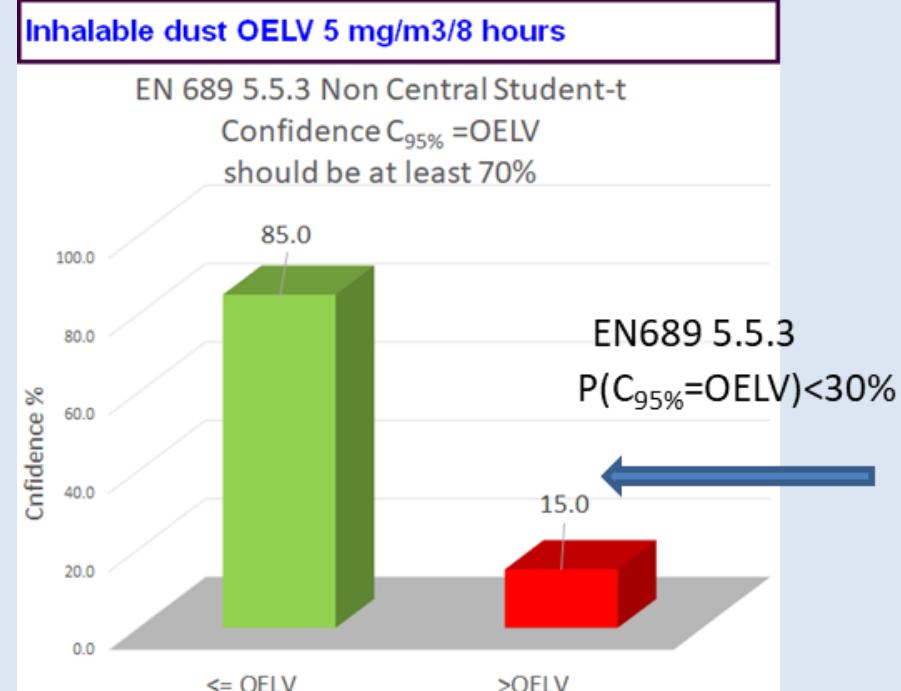
Name: C:\Users\Theo
Sample size M= 3
Degrees of Freedom df= 2
GM maximum likelihood= 0.9781 mg/m ³
GSD= 1.4669

Statistical test: EN689 (2018) clause 5.5.3 & BOHS/NVVa (2011)

Occupational Exposure Limit Value OELV= 5 mg/m ³
Confidence that less than 5% of the exposure distribution exceeds OELV = 85.0459 % Compliance
The 95%-tile upper tolerance limit with 70% confidence = 2.0694 mg/m ³
The population fraction < OELV with 70% confidence = 99.4186 %

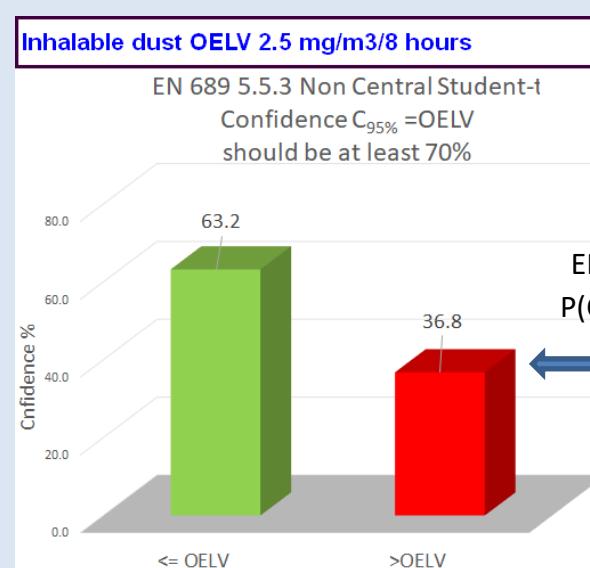
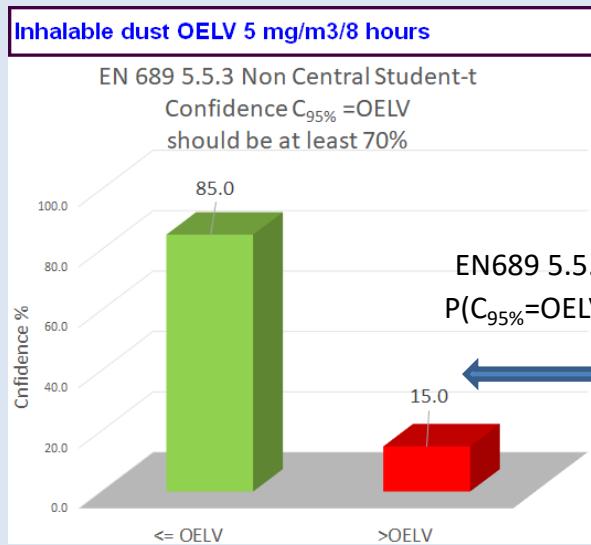
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EN689(2018)/BOHS-NVVa(2011)



$C_{95\%}$ confidence for inhalable dust

OELV = 1.25, 2.5, 5 & 20 mg/m³/8 hours



AIHA Exposure categories

A Strategy for Assessing and Managing Occupational Exposures

Fourth Edition

IH professionals will find this newly updated resource beneficial in allocating resources for assessing and managing occupational exposures to chemical, physical, and biological agents.

Edited by Steven D. Jahn, William H. Bullock, and Joselito S. Ignacio



A Publication by
American Industrial
Hygiene Association

AIHA Exposure categories

A Strategy for Assessing and Managing Occupational Exposures

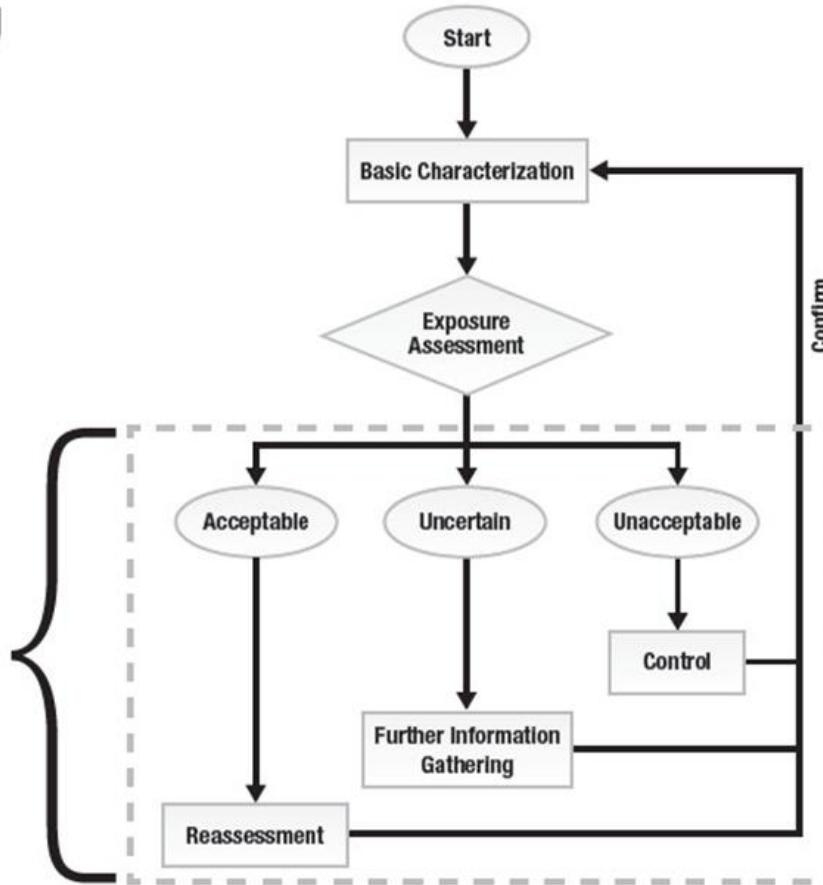


4th Edition

Steven D. Jahn, CIH, MBA
William H. Bullock, DHSc, CIH, CSP
Joselito S. Ignacio, CIH, CSP, MPH, REHS/RS

Management and Exposure Control Categories	
SEG Exposure Control Category**	Applicable Management/Controls
0 (<1% of OEL)	no action
1 (<10% of OEL)	procedures and training, general hazard communication
2 (10-50% of OEL)	+ chemical specific hazard communication, periodic exposure monitoring
3 (50-100% of OEL)	+ required exposure monitoring, workplace inspections to verify work practice controls, medical surveillance, biological monitoring
4+ (>100% of OEL, Multiples of OEL; e.g., based on respirator APFs)	+ implement hierarchy of controls, monitoring to validate respirator protection factor selection

**Upper Tail Statistic decision = 90th, 95th, 99th percentile



Chapter 1: Introduction2

By John Mulhausen and Joseph Damiano

AIHA (NIOSH 1977 p118) objective: “Employer should try to attain 95% confidence that no more than 5% of employee days are over the standard”

AIHA Exposure categories

result (mg/m ³ /8hr)	% OELV	Preliminary test	GM	GSD	C _{95,70%}	Statistical test 5.5.3 Confidence C _{95%} ≤OELV
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0.81	16.2%	no decision	0.98	1.47	2.87	85.0% Compliance

Probability distribution of C95% over the 5 AIHA exposure Categories

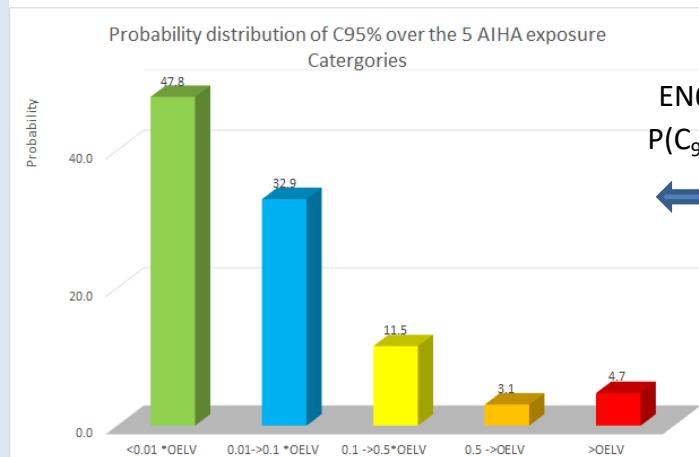
SEG Exposure Control Category**	Applicable Management/Controls
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4+ (>100% of OEL, Multiples of OEL; e.g., based on respirator APFs)	+ implement hierarchy of controls, monitoring to validate respirator protection factor selection

IH-Aligner Version: 9.3
<https://real-statistics.com/students-t-distribution/noncentral-t-distribution/>

REAL STATISTICS
USING EXCEL

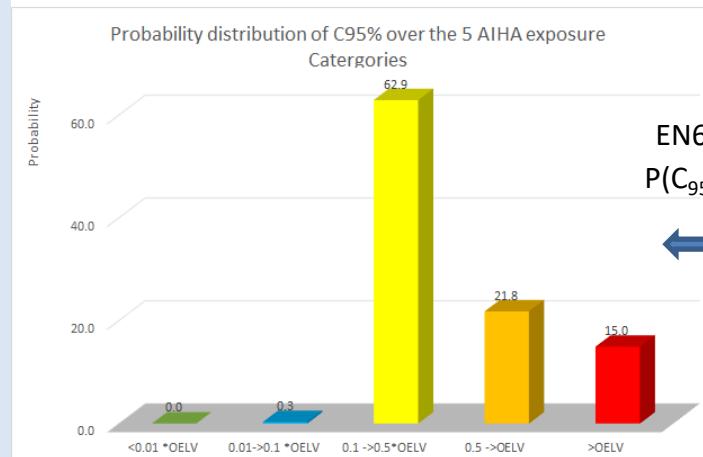
AIHA Exposure categories inhalable dust for OELV 1, 2, 5 & 20 mg/m³/8 hours

Inhalable dust OELV 20 mg/m³/8 hours



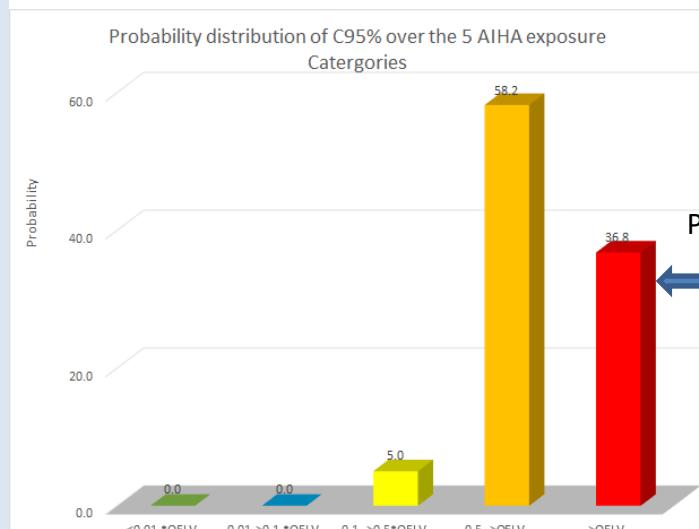
EN689 5.5.3
 $P(C_{95\%} = \text{OELV}) < 30\%$

Inhalable dust OELV 5 mg/m³/8 hours



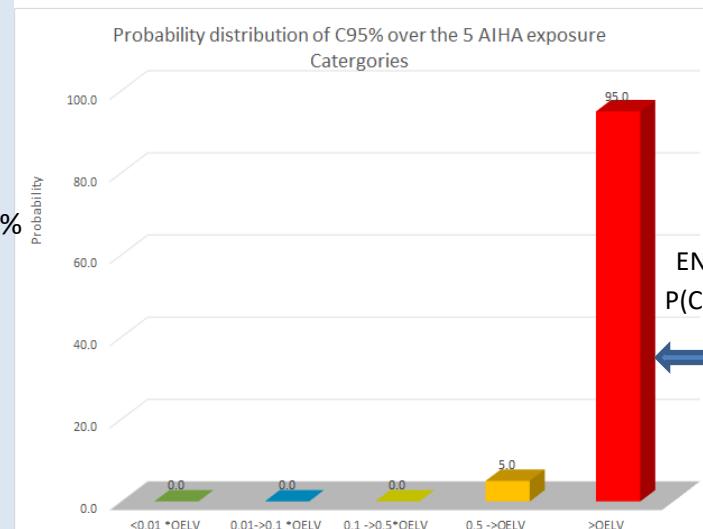
EN689 5.5.3
 $P(C_{95\%} = \text{OELV}) < 30\%$

Inhalable dust OELV 2.5 mg/m³/8 hours



EN689 5.5.3
 $P(C_{95\%} = \text{OELV}) < 30\%$

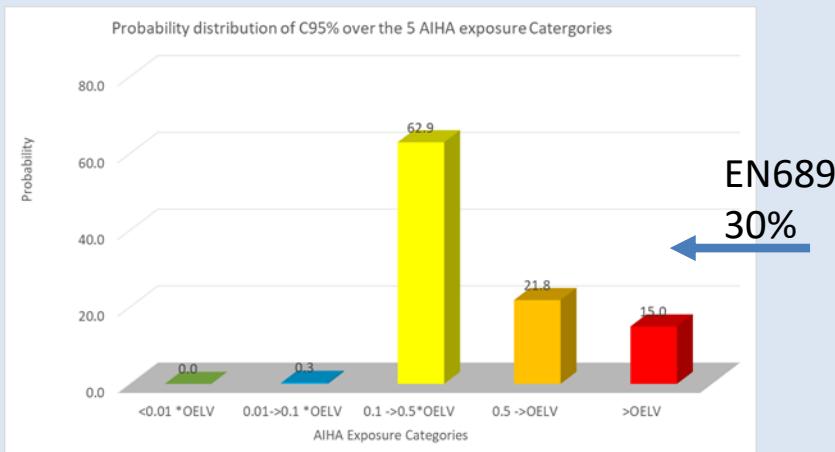
Inhalable dust OELV 1.25 mg/m³/8 hours



EN689 5.5.3
 $P(C_{95\%} = \text{OELV}) < 30\%$

Numerical method & applications (1)

- IH-Aligner using
 - HYGINIST or
 - ‘RealStatistics’ Excel addin



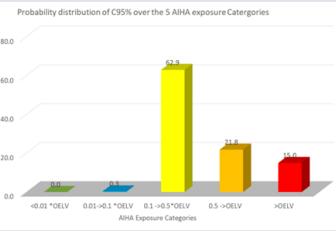
The screenshot shows the HYGINIST version 4.4.1 interface. The main title is "IH-Aligner" with "Versie: 9.3 PBC1" below it. The window title is "HYGINIST version 4.4.1 Comparing the exposure distribution with the OELV". The menu bar includes File, Statistics, Lognormal frequency distribution, Help, Start, Raw data, Limits, Descriptive statistics, Plot, Compliance, Mean UCL, and Compare. The "Descriptive statistics of the current data" section shows sample size (N=3), degrees of freedom (df=2), GM maximum likelihood (0.9781), and GSD (1.4669). The "Statistical test: EN689 (2018) clause 5.5.3 & BOHS/NVvA (2011)" section displays the Occupational Exposure Limit Value (OELV) as 5 mg/m³. It also shows the confidence that less than 5% of the exposure distribution exceeds the OELV at 85.0459%, which is highlighted with a green circle. The 95%-tile upper tolerance limit with 70% confidence is 2.8694 mg/m³, and the population fraction < OELV with 70% confidence is 59.4126%. A note at the bottom states: "The test shall measure, with at least 70% confidence, whether less than 5% of the exposures in the SEG exceed the OELV (EN689-2018 clause 5.5.3, BOHS/NVvA 2011). Compliance decision (689 Annex F.3) is calculated with the non-central Student distribution using the algorithms of Owen (1968 p464-465)." A link at the bottom left is "EN689(2018)/BOHS-NVvA(2011)".

<https://real-statistics.com/students-t-distribution/noncentral-t-distribution/>

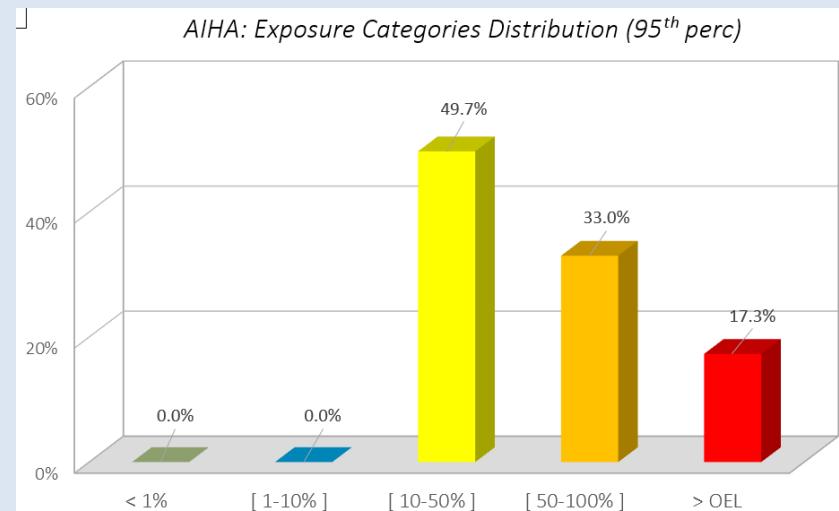
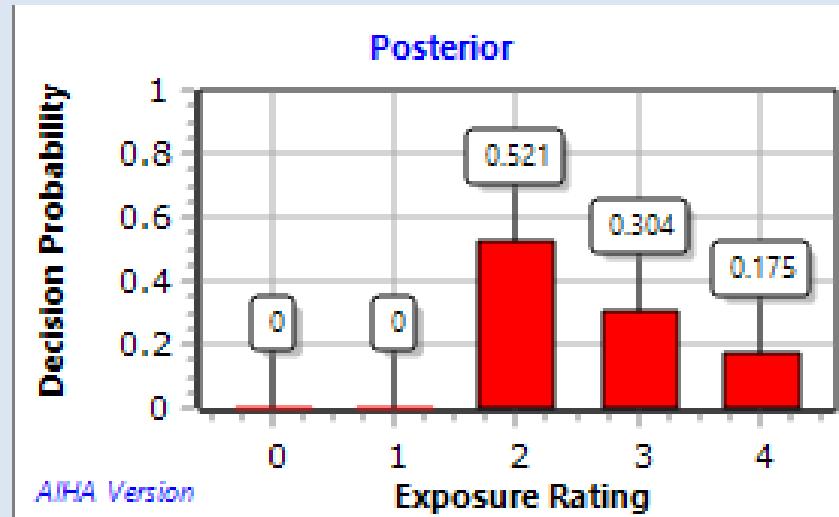
REAL STATISTICS
USING EXCEL

$$\text{Confidence} = \text{NT_DIST}((\ln(F.OELV) - \ln(GM)) / \ln(GSD)) * \sqrt{N}; N-1; \sqrt{N} * \text{NORM.S.INV}(0.95))$$

Bayesian/Monte-Carlo applications (2)



- IHDA-AIHA
- Outcome depend on prior settings
- IHStat_Bayes NL version!
- Varying Outcome (MonteCarlo)



AIHA exposure categories

Advantages

- Professional looks/
impressive

Disadvantages

- 5 cat# is not EN689 and
overdone
- No formal compliance level
- Complex within Excel
- Complex installation IHStat

Does this improve risk communication with stakeholders?

EN689: two & three categories

5.1.5 basic characterization

$C_{95\%} << OELV$	No sampling
$C_{95\%} >> OELV$	No sampling
$C_{95\%} \approx OELV$ No decision=>	Sampling plan

5.5.2 preliminary test $N=3, 4 \& 5$ samples

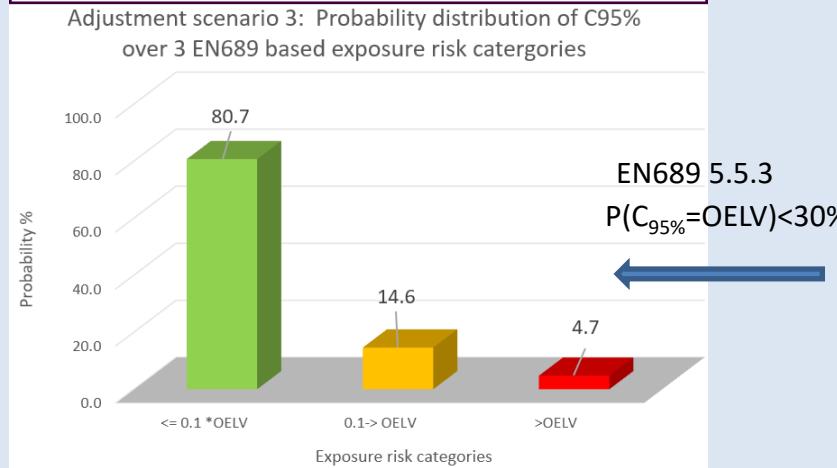
$C_{max} \leq fr(OELV)$	Compliance
$C_{max} > OELV$	Non-compliance
$fr(OELV) < C_{max} \leq OELV$	No decision=>more measurements

5.5.3 statistical test $N \geq 2$ samples

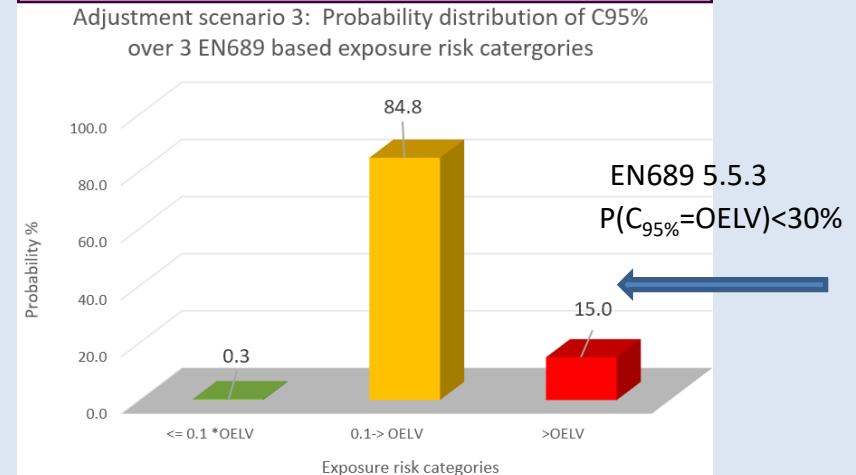
$C_{95,70\%} \leq OELV$	Compliance
$C_{95,70\%} > OELV$	No decision=>more measurements or Exceedance

EN689 exposure categories inhalable dust for OELV 1, 2, 5 & 20 mg/m³/8 hours

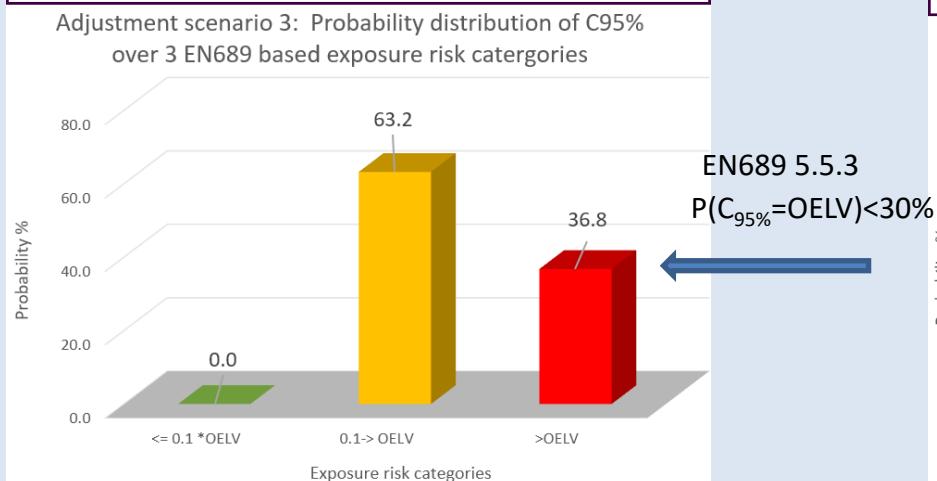
3 metingen inhaleerbaar stof OELV=20 mg/m³



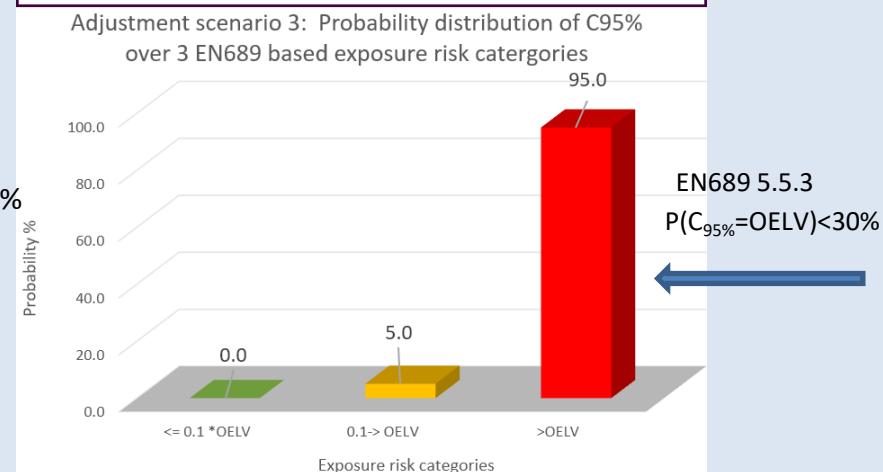
3 metingen inhaleerbaar stof OELV=5 mg/m³



3 metingen inhaleerbaar stof OELV=2.5 mg/m³



3 metingen inhaleerbaar stof OELV=1.25 mg/m³



EN689 & AIHA IHStat combined



IH-Aligner Versie: 9.3
PBC1

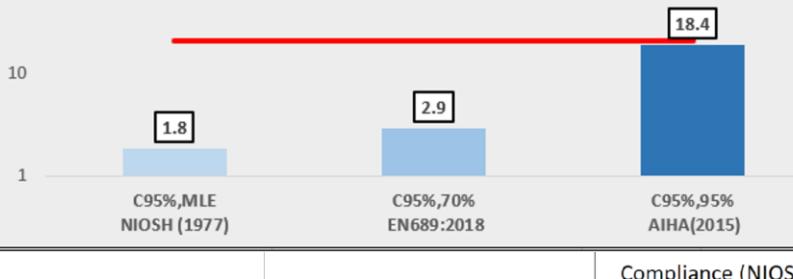
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REAL STATISTICS
USING SPSS AND EXCEL

AIHA (NIOSH 1977 p118) objective:
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Vier uitkomsten

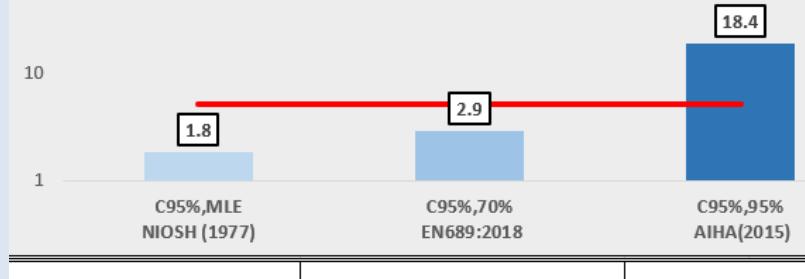
Testing the AIHA, NIOSH & EN689 C_{95%,##} exposures metrics against the the OELV logarithmic scale

— OELV 20 mg/m³



Testing the AIHA, NIOSH & EN689 C_{95%,##} exposures metrics against the the OELV logarithmic scale

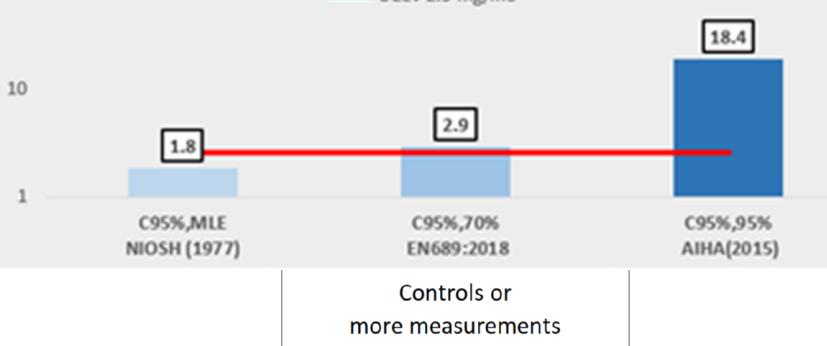
— OELV 5 mg/m³



Compliance according to EN689 and NIOSH employers aim. Reconsider performing measurements in this SEG.

Testing the AIHA, NIOSH & EN689 C_{95%,##} exposures metrics against the the OELV logarithmic scale

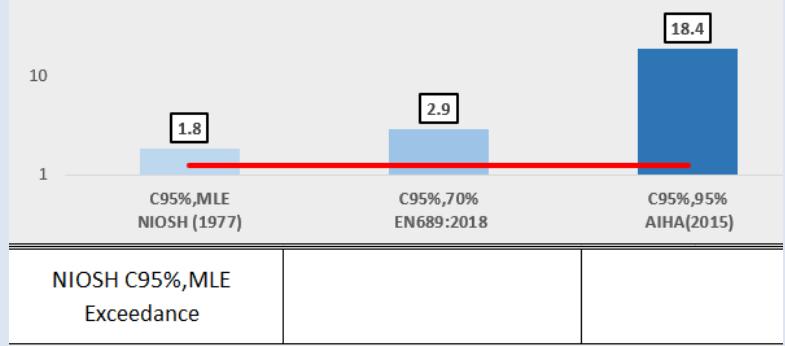
— OELV 2.5 mg/m³



C95,70% exceeds the OELV. Apply control measures or add 16 measurement(s) to proof compliance.

Testing the AIHA, NIOSH & EN689 C_{95%,##} exposures metrics against the the OELV logarithmic scale

— OELV 1.25 mg/m³



C95%,ML exceeds OELV. More measurements will not lead to EN689 or AIHA compliance, Apply control measures.

EN689 & AIHA/IHStat combined

Advantages vs AIHA

- In IH-Aligner
- Makes decision
- Combines EU & US
- Normal/Lognormal
- Periodic monitoring
- No ‘RealStatistics’
- No Monte-Carlo & Bayesian priors
- SER feasibility

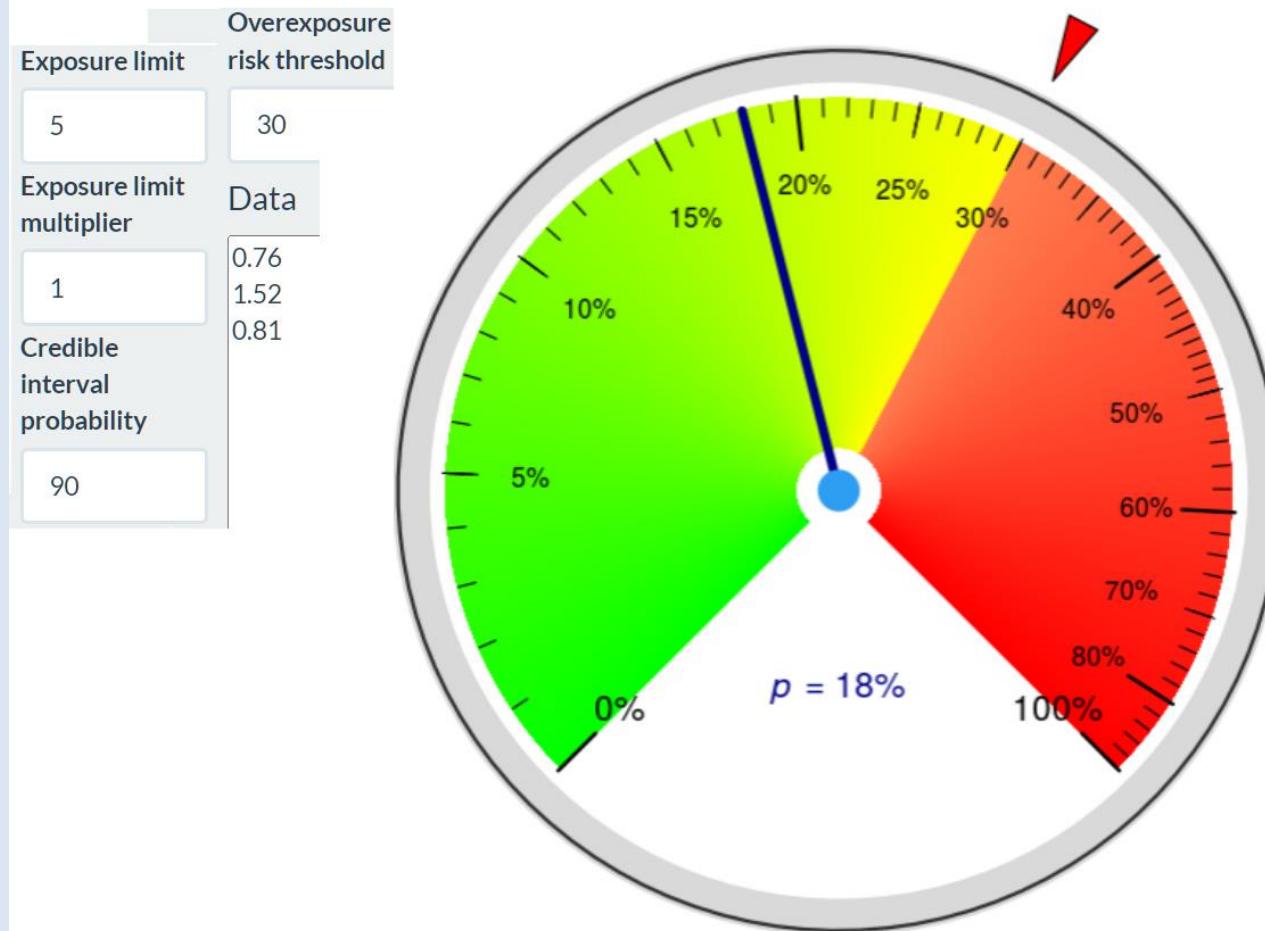
Disadvantages

- Less impressive?

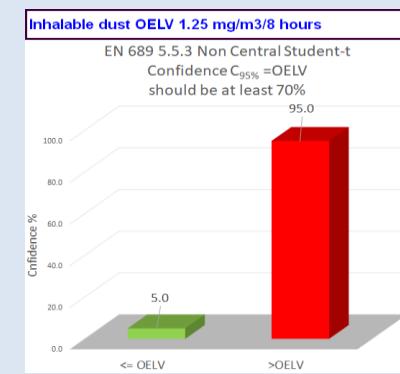
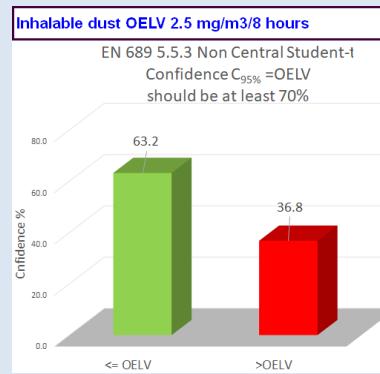
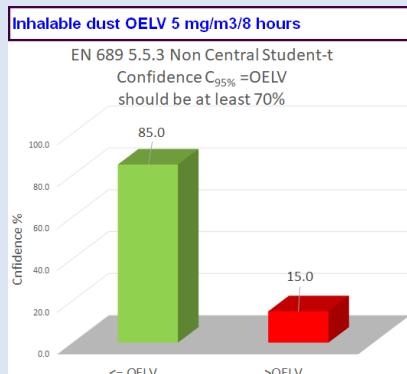
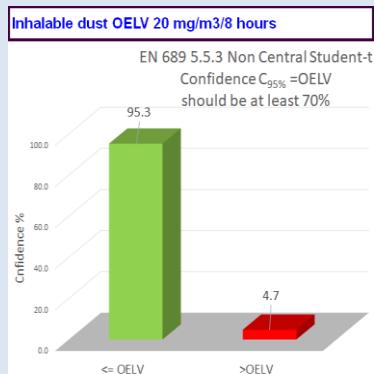
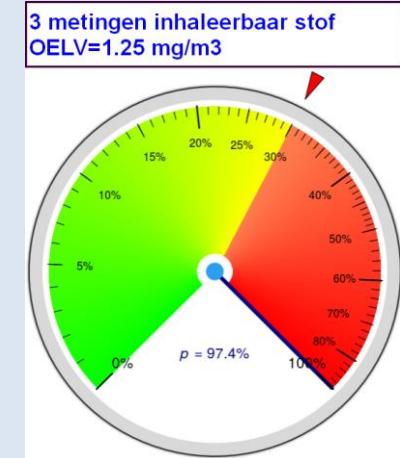
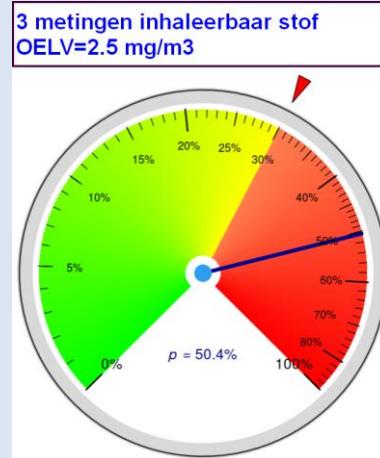
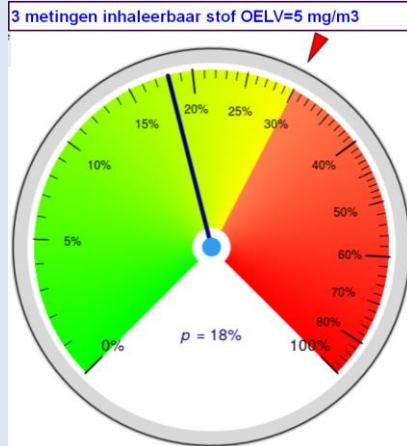
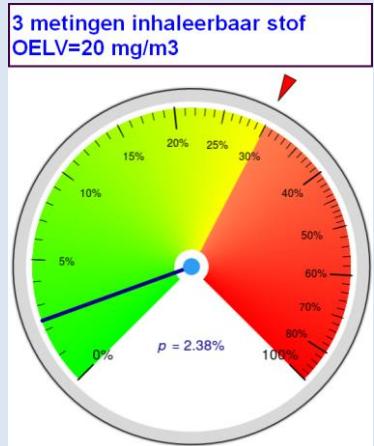
Expostats

<https://lavoue.shinyapps.io/Tool1v3En/>

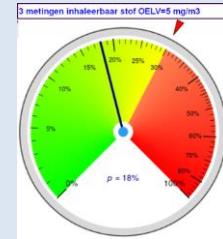
Tool1: Data interpretation for one similarly exposed group



EN689 vs Expostats C_{95%} confidence



Expostats Tool1



Advantages

- Dichotome (like EN689)
- Online
- Easy (if you know what to do)
- Speedometer looks nice

Disadvantage

- Ingrainged Bayes prior may misfit your SEG

May improve risk communication with stakeholders

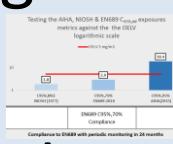
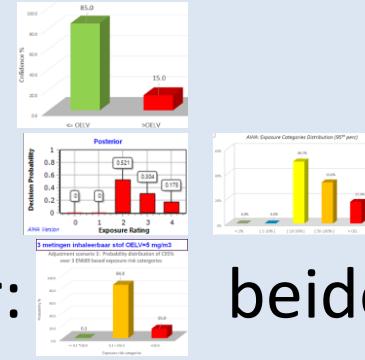
Boodschap 1

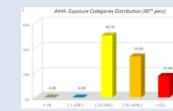
NVvA leden, arbeidshygiënisten en andere blootstellingsbeoordelaars laten bij N=3,4,5 naast elkaar zien wat de uitkomst is van de preliminary test èn de statistische test

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Boodschap

Er zijn voldoende eenvoudige en visuele Apps voor de EN689 statistische test (online, Excel, .exe) vanaf 2 metingen

- Sound science
- Bruikbaar vanaf $N \geq 3$
- AIHA: 5 categorieën = te veel
- 1^e voorkeur:  2^e voorkeur:  beide in IH-Aligner
- Internationaal uitdragen via EPOH



IH-Aligner

Versie: 9.3.2
PBC1