Theo Scheffers

OELV compliance decisions & the EN689 preliminary test

NYF Vårkonferanse Oslo 21 April 2022

The CEN TC 137 / WG1 (2014-2018)

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 689:2018+AC

April 2019

ICS 13.040.30

Supersedes EN 689:2018

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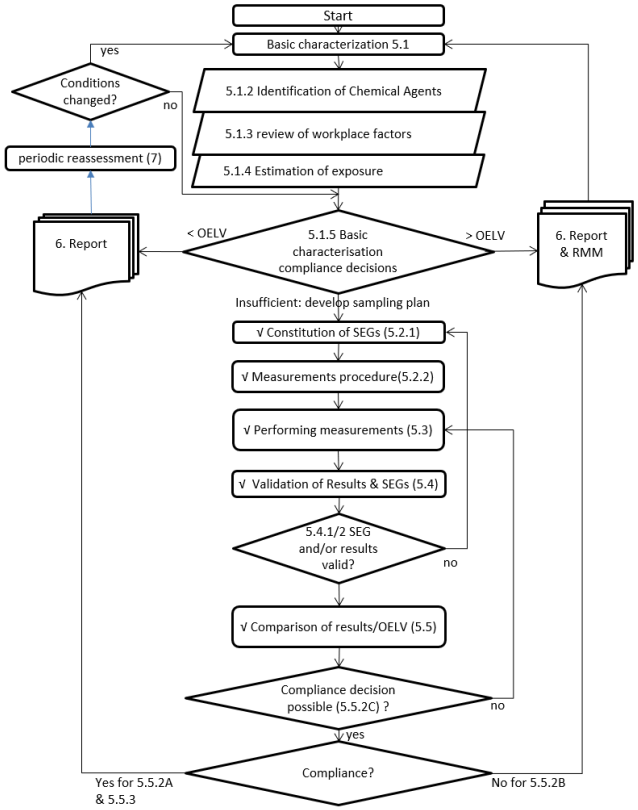
CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN 689:2018+AC:2019 E



Aims

EN689 Introduction

- High degree of confidence C≤OELV
- Dealing with exposure variability
- use a small number of measurements
- Cost effective

Compliance testing EN689

1. Basic characterisation §5.1.4
2. Preliminary test § 5.5.2 / Statistische test §5.5.3

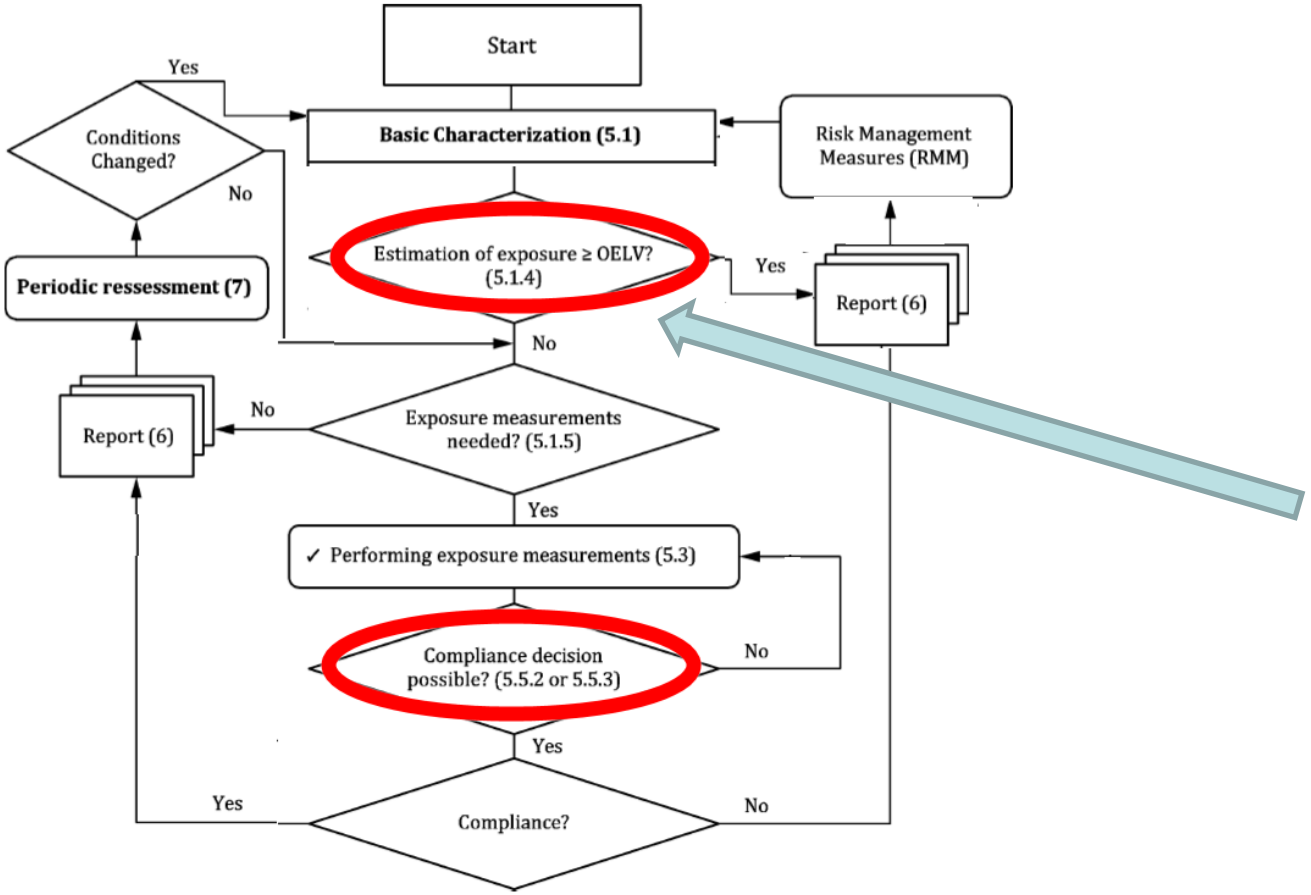
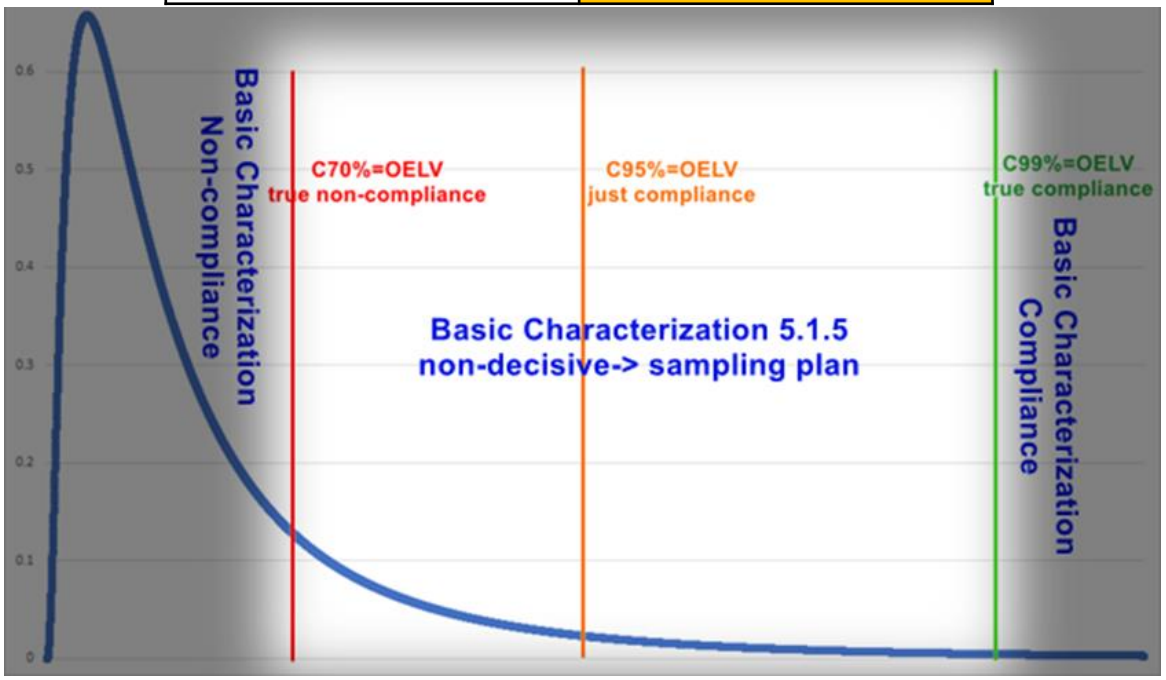


Figure 1 —Schematic overview of the occupational exposure assessment procedures

When to develop a EN 689 5.2 sampling strategy?

5.1.5 basic characterization

Exposure is well below the OELV	Compliance
Exposure is higher than the OELV	Non-compliance
fr(OELV)<C_{max} ≤OELV	No decision⇒more measurements



Compliance testing with measurements

5.5.2 preliminary test
N=3, 4 & 5

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

5.5.3 statistical test
N≥2

$C_{95,70\%} \leq$OELV	Compliance
~~? (Annex F)~~	~~Non-compliance~~

«It is therefore outside the scope ... to use [5.5.3] to measure non-compliance»

Live voting

1. Who performs 3 to 5 measurements within a SEG or exposure profile ?
    1. If YES , next question #2
    2. If NO wait for question #3
2. If YES , which compliance test do you use?
    1. preliminary test (EN689:2018 § 5.5.2)?
    2. statistical test $C_{95,70\%}$(EN689:2018 § 5.5.3)?
    3. both
    4. otherwise ……..
3. If NO, why not ?
    1. I'm using only the basic characterisation (models, databases, 1 or 2 measurements etc.) § 5.1.5
    2. I always take at least 6 measurements
    3. Otherwise ……..

Live voting (2)

Is preliminary test more reliable than the statistical test for 3 to 5 measurements?

1. Yes, as it is the general line in Europe
2. No, the variability of exposure is not sufficiently taken into account
3. otherwise ……..
4. No idea!

Example

1st Inhalable dust measurement

OELV 5 mg/m³/8 hours

result (mg/m³/8hr)	% OELV	Preliminary test	(log)normal	GM	GSD	$C_{95,70\%}$	Statistical test 5.5.3 Compliance if $C_{X\geq 95,70\%}$=OELV X=
0.76	15.2%						

Example

2nd consecutive Inhalable dust measurement

OELV 5 mg/m^3/8 hours

result (mg/m^3/8hr)	% OELV	Preliminary test	(log)normal	GM	GSD	$C_{95,70\%}$	Statistical test 5.5.3 Compliance if $C_{X\geq 95,70\%}$=OELV X=	
0.76	15.2%							
1.52	30.4%		unknown	1.07	1.63	8.49	88.99%	**$C_{95,70\%}$>OELV**

Example

3th consecutive Inhalable dust measurement

OELV 5 mg/m3/8 hours

result (mg/m3/8hr)	% OELV	Preliminary test	(log)normal	GM	GSD	$C_{95,70\%}$	Statistical test 5.5.3 Compliance if $C_{X\geq95,70\%}$=OELV X=	
0.76	15.2%							
1.52	30.4%							
0.81	16.2%	no decission	Normal	0.98	1.47	2.87	99.42%	compliance

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

Example

4th consecutive Inhalable dust measurement

OELV 5 mg/m³/8 hours

result (mg/m³/8hr)	% OELV	Preliminary test	(log)normal	GM	GSD	$C_{95,70\%}$	Statistical test 5.5.3 Compliance if $C_{X\geq 95,70\%}$=OELV X=	
0.76	15.2%							
1.52	30.4%							
0.81	16.2%							
0.6	12%	no decission	logNormal	0.87	1.49	2.29	99.87%	compliance

5.5.2 Preliminary test a) 2)
Compliance if all results are below 0,15 OELV for a set of three exposure measurements

Example

5th consecutive Inhalable dust measurements

OELV 5 mg/m³/8 hours

result (mg/m³/8hr)	% OELV	Preliminary test	(log)normal	GM	GSD	$C_{95,70\%}$	Statistical test 5.5.3 Compliance if $C_{X\geq 95,70\%}$=OELV X=	
0.76	15.2%							
1.52	30.4%							
0.81	16.2%							
0.6	12%							
0.28	5.6%	no decission	logNormal	0.69	1.84	2.70	99.10%	compliance

5.5.2 Preliminary test a) 3)

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

Example

6th consecutive Inhalable dust measurement

OELV 5 mg/m³/8 hours

result (mg/m³/8hr)	% OELV	Preliminary test	(log)normal	GM	GSD	$C_{95,70\%}$	Statistical test 5.5.3 Compliance if $C_{X\geq95,70\%}$=OELV X=	
0.76	15.2%							
1.52	30.4%		unknown	1.07	1.63	8.49	88.99%	$C_{95,70\%}$>OELV
0.81	16.2%	no decission	Normal	0.98	1.47	2.87	99.42%	**compliance**
0.6	12%	no decission	logNormal	0.87	1.49	2.29	99.87%	**compliance**
0.28	5.6%	no decission	logNormal	0.69	1.84	2.79	99.10%	**compliance**
0.54	10.8%	-	logNormal	0.66	1.74	2.23	99.70%	**compliance**

5.5.3 Statistical test ... shall measure, with at least 70 % confidence, whether less than 5 % of exposures in the SEG exceed the OELV *(or at least 95% equal to the OELV)*

Result Preliminary test

6 consecutive Inhalable dust measurements

OELV 5 mg/m^3/8 hours

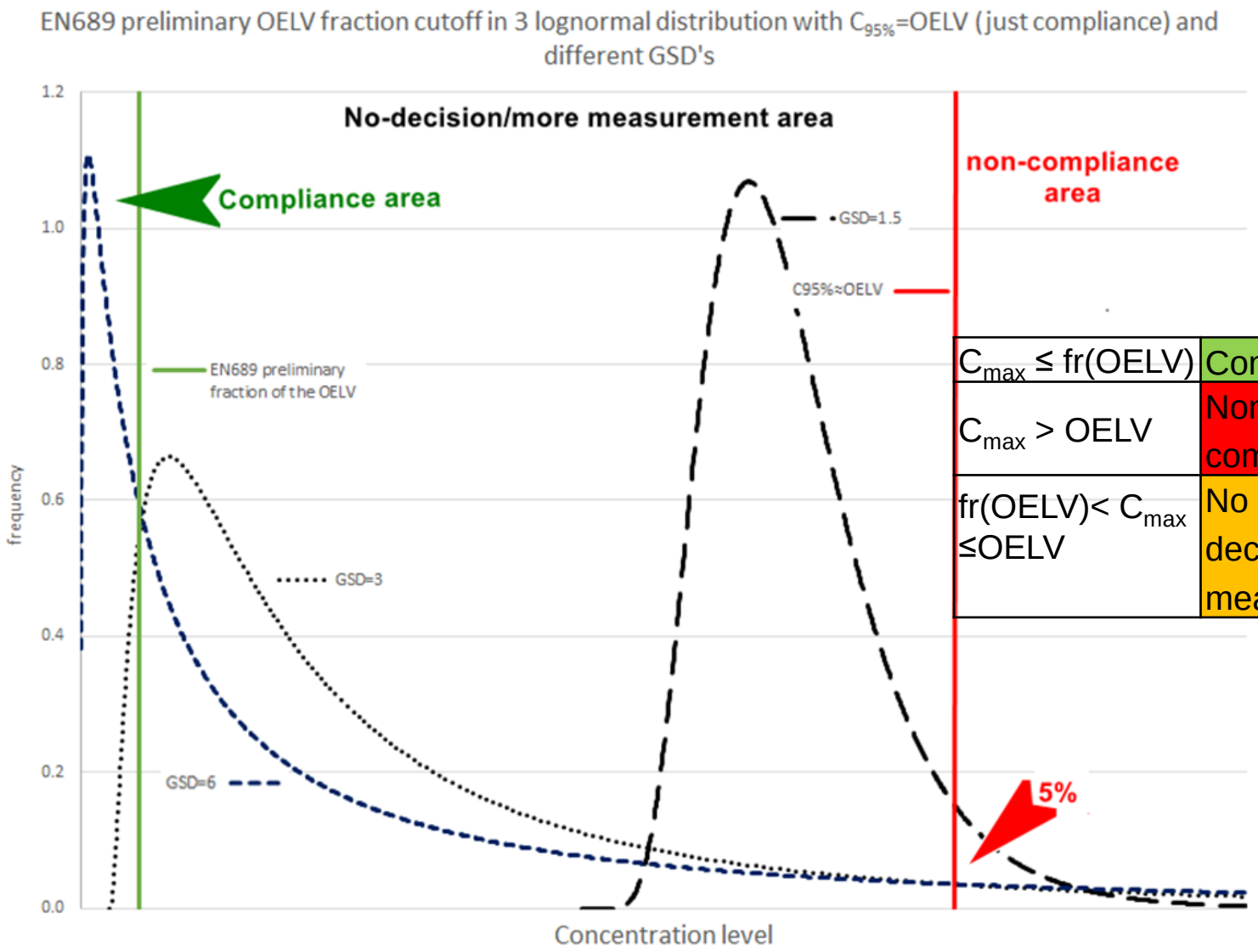
- no-decision for 3, 4 and 5 results
- After the 2nd result, 6 measurements were unavoidable

- After the 3nd result, the statistical test (5.5.3) indicated compliance

5.5.2 preliminary test N=3, 4 & 5=>6	
fr(OELV)<C_{max} ≤OELV	No decision⇒more measurements

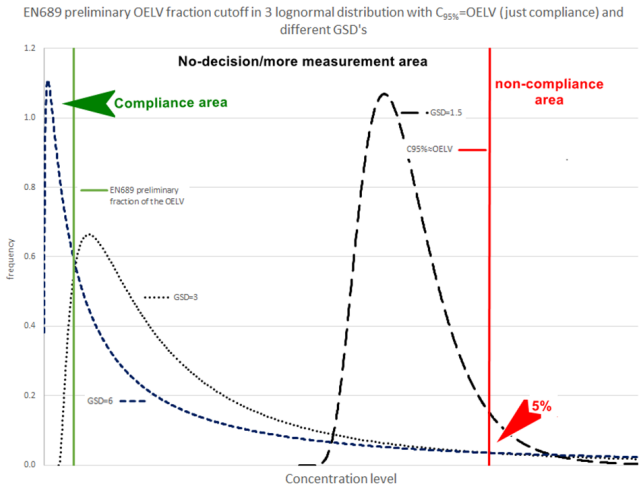
5.5.3 statistical test N=3	
$C_{95,70\%}$ ≤OELV	Compliance

Does the preliminary test performs less?



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

Visual assessment preliminary test

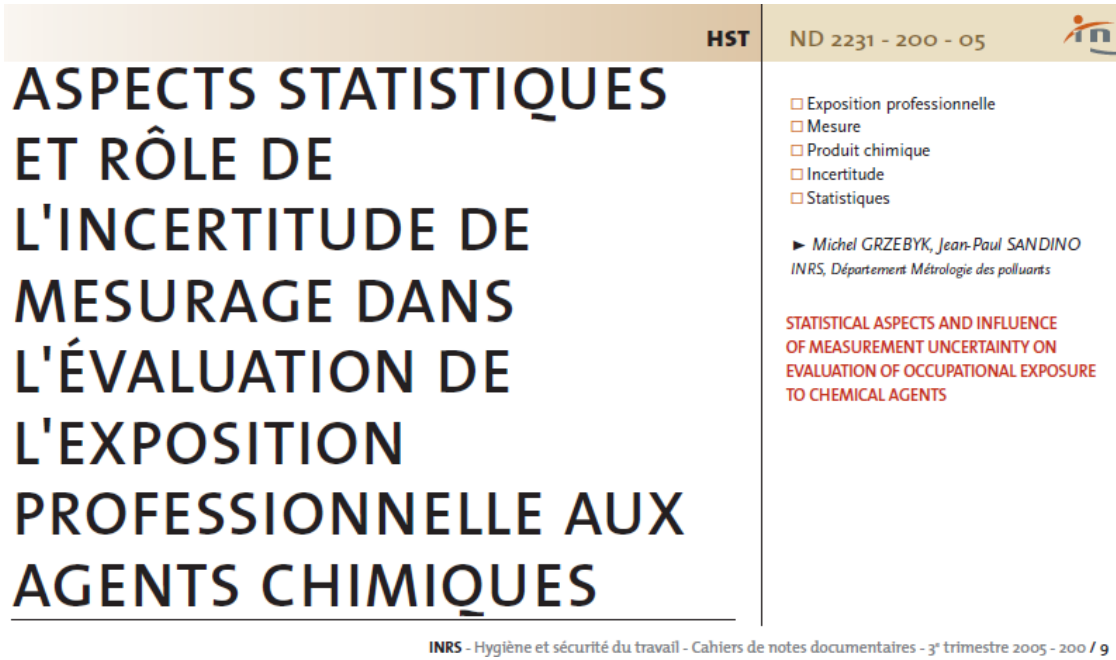


If a appraiser decide to perform a sampling plan based on a high qualty basic characterisation, then the preliminary test will almost always conclude to ‘No decision/more measurements’ if GSD is ‘small’

What is small?

Is the PM test validated?

- No peer review publication
- INRS publication (2005) ND2231, not specific for the fr(OELV) and $C_{95,70\%}$ used in EN689



HST ND 2231 - 200 - 05

ASPECTS STATISTIQUES ET RÔLE DE L'INCERTITUDE DE MESURAGE DANS L'ÉVALUATION DE L'EXPOSITION PROFESSIONNELLE AUX AGENTS CHIMIQUES

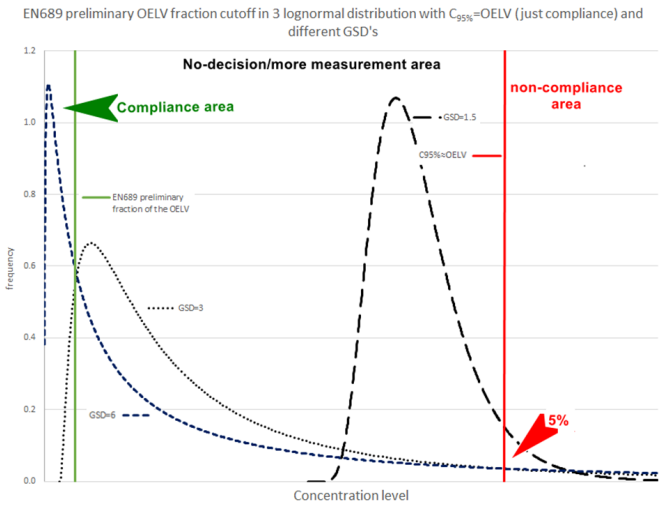
- ☐ Exposition professionnelle
- ☐ Mesure
- ☐ Produit chimique
- ☐ Incertitude
- ☐ Statistiques

► *Michel GRZEBYK, Jean-Paul SANDINO*
INRS, Département Métrologie des polluants

STATISTICAL ASPECTS AND INFLUENCE OF MEASUREMENT UNCERTAINTY ON EVALUATION OF OCCUPATIONAL EXPOSURE TO CHEMICAL AGENTS

INRS - Hygiène et sécurité du travail - Cahiers de notes documentaires - 3e trimestre 2005 - 200 / 9

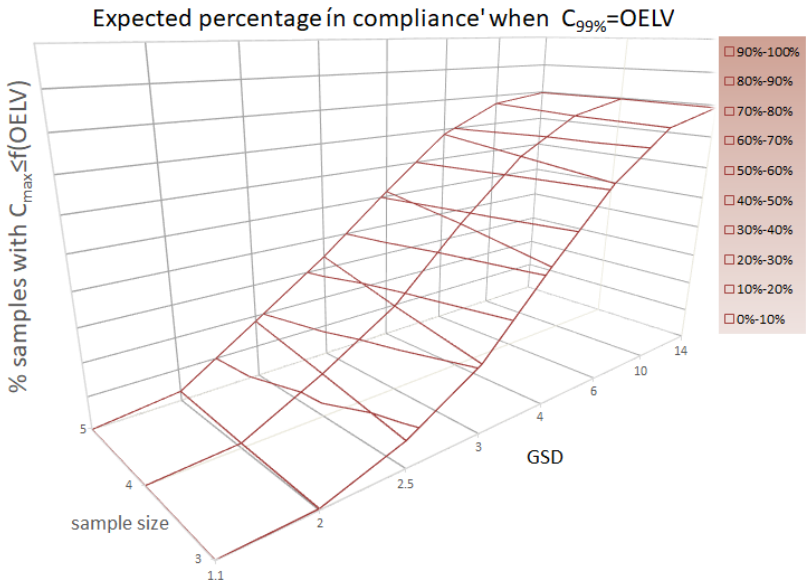
Validation



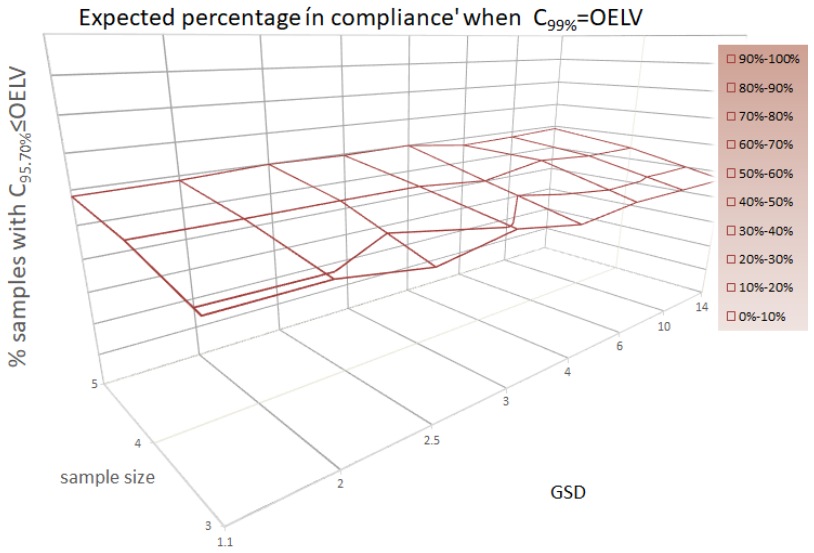
1. Statistical:
   - P(C≤fr(OELV))^N=3,4,& 5
2. Monte-Carlo:
   10000 samples
   from a lognormal population distribution
   - N=3, 4 & 5
   - GSD=1.1, 1.5, 2, 2.5, 4, 5, 6, 10 & 14
   - $C_{99\%}$, $C_{95\%}$ & $C_{70\%}$
3. Cumulative Binomial for OELV exceedance

Compliance performance if $C_{99\%}$=OELV

5.5.2 preliminary test

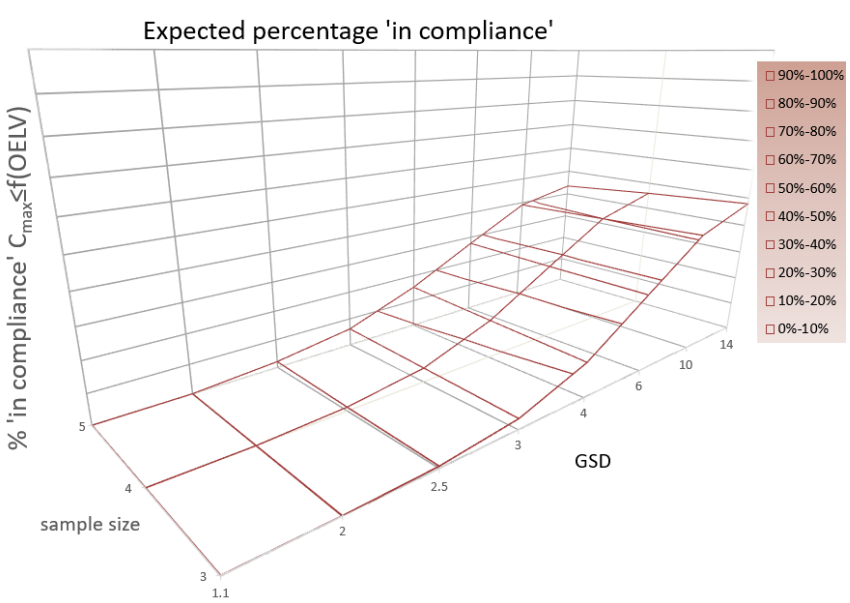


5.5.3 statistical test

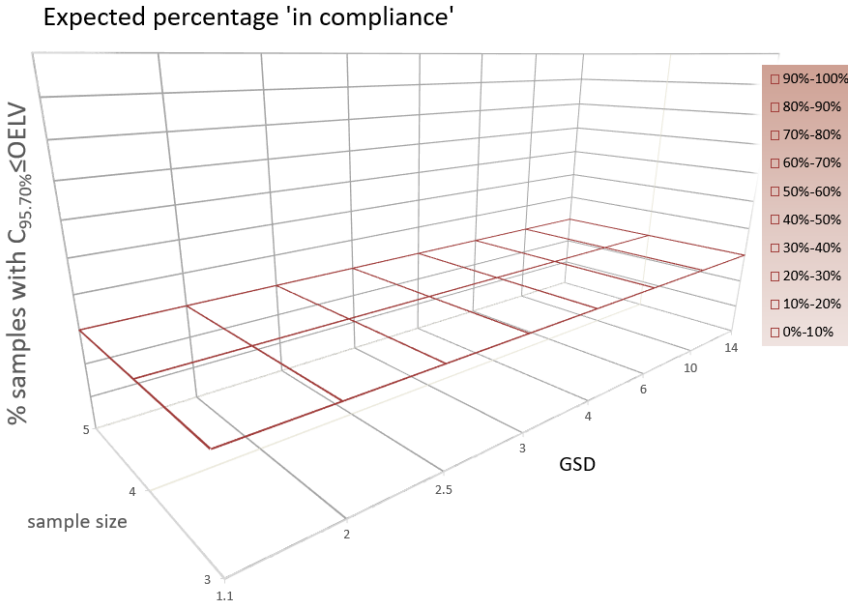


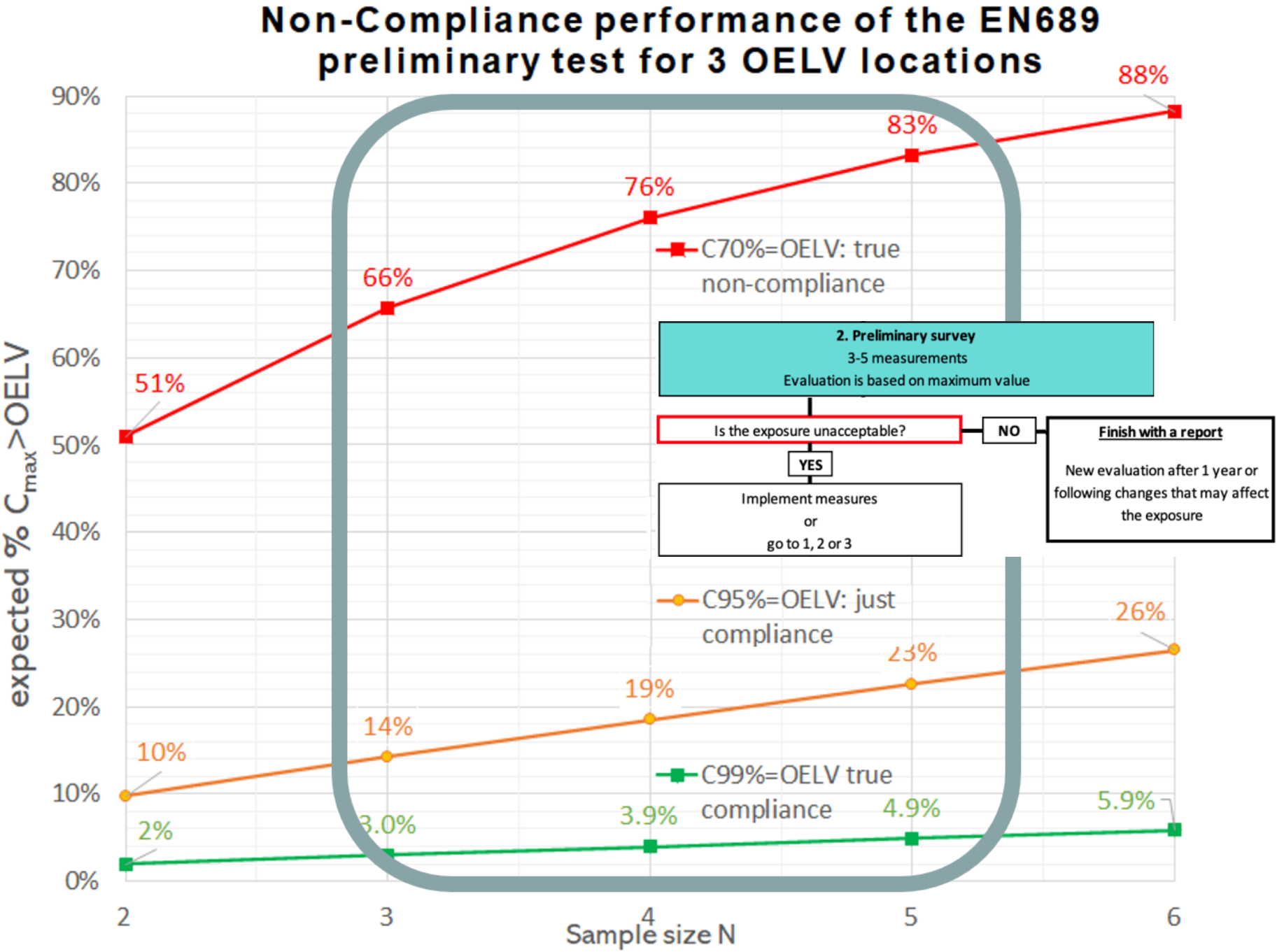
Compliance performance for $C_{95\%}$=OELV

5.5.2 preliminary test

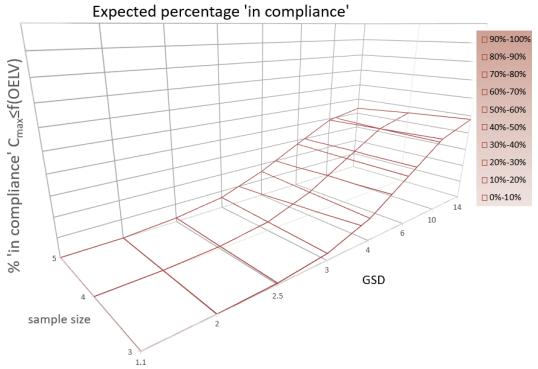


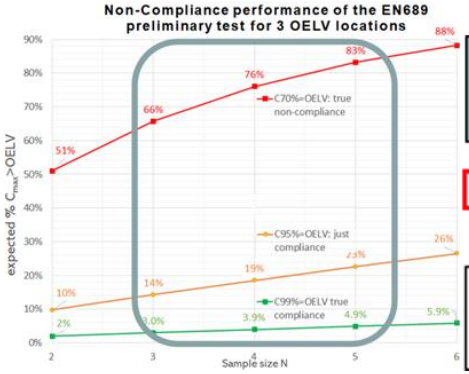
5.5.3 statistical test

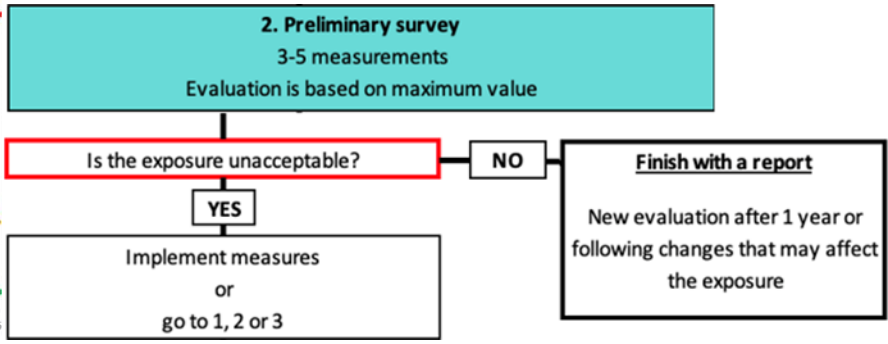



Non-Compliance performance of the EN689 preliminary test for 3 OELV locations
expected % Cmax>OELV
Sample size N
C70%=OELV: true non-compliance
C95%=OELV: just compliance
C99%=OELV true compliance
88%
83%
76%
66%
51%
26%
23%
19%
14%
10%
5.9%
4.9%
3.9%
3.0%
2%
2. Preliminary survey
3-5 measurements
Evaluation is based on maximum value
Is the exposure unacceptable?
NO
YES
Finish with a report
New evaluation after 1 year or following changes that may affect the exposure
Implement measures
or
go to 1, 2 or 3

preliminary test performance







It is conceptually flawed in ignoring exposure variability

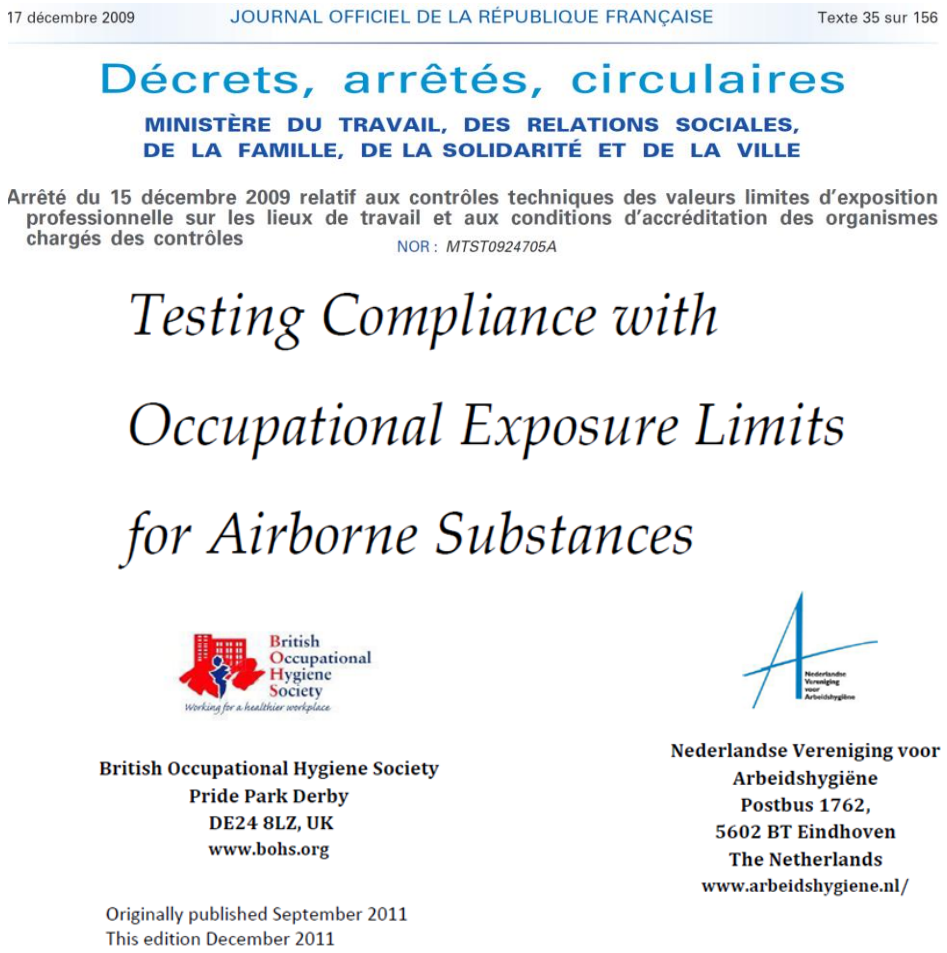
Non-compliance: not or delayed detected
Compliance: almost never found for GSD<3

In daily practice it's a 'No decision/more measurements' test

Origin preliminary test

- Code travail (2009)
- BOHS-NVvA (2011)

Both use 0.1 OELV for 3,4 & 5 measurements



17 décembre 2009 JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE Texte 35 sur 156

Décrets, arrêtés, circulaires

MINISTÈRE DU TRAVAIL, DES RELATIONS SOCIALES, DE LA FAMILLE, DE LA SOLIDARITÉ ET DE LA VILLE

Arrêté du 15 décembre 2009 relatif aux contrôles techniques des valeurs limites d'exposition professionnelle sur les lieux de travail et aux conditions d'accréditation des organismes chargés des contrôles

NOR : *MTST0924705A*

Testing Compliance with Occupational Exposure Limits for Airborne Substances

British Occupational Hygiene Society
Working for a healthier workplace

British Occupational Hygiene Society
Pride Park Derby
DE24 8LZ, UK
www.bohs.org

Originally published September 2011
This edition December 2011

Nederlandse Vereniging voor Arbeidshygiëne
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5602 BT Eindhoven
The Netherlands
www.arbeidshygiene.nl/

Why using a decision scheme?

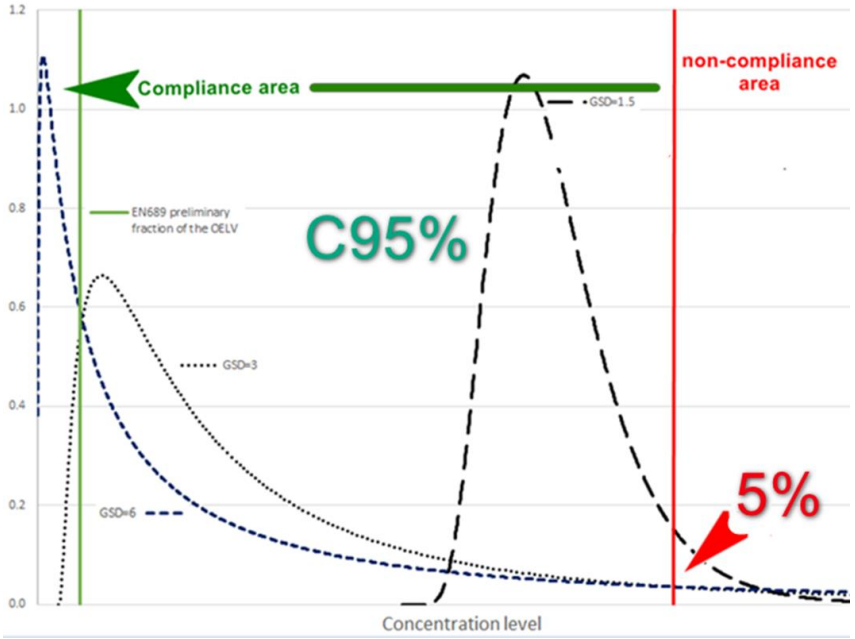
- Obstructions to use statistics in legislation (?)
- Appraisers are insufficient skilled

Inclusion in a EU standard increases its credibility, despite lack of scientific ground

Pseudo science

"The U_T values for sample size 3, 4 or 5 make $C_{95,70\%}$ extreme high"

Only true for GSD>3



Performance Compliance tests EN689

	Preliminary	Statistical $C_{95\%}$<OELV
degree of confidence	Varying (N, GSD)	Always 70%
Dealing with exposure variability	No	Yes
Cost effective	No	Yes
Validated	Limited	Yes
Simple	Yes	for appraisers
Worldwide accepted	No	Yes

Consquences

- Professionals may be held responsible for unnecessary costs and unsafe working conditions when prescribing the test
- Bad reputation EU Industrial Hygiene community

Omisions in EN689:2018

Non compliance :

Now only included in the Basic characterisation decision and Preliminary test

1. Exposure index §5.5: not defined
2. Statistical §5.5.3 not defined

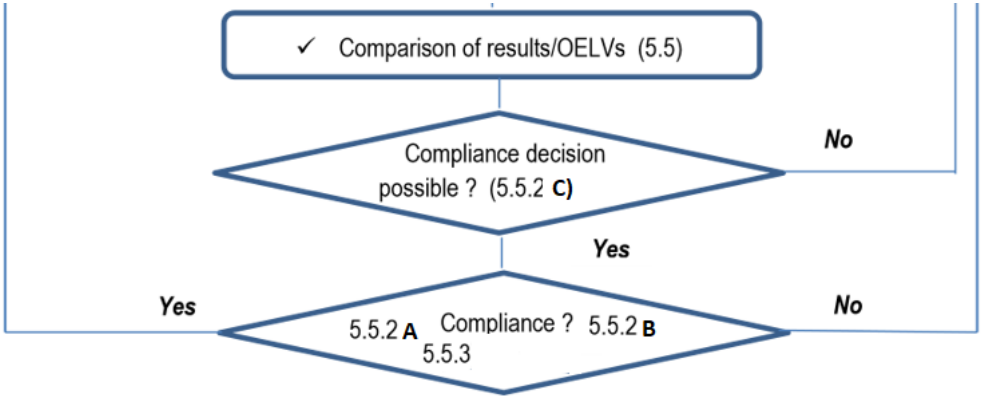


Figure 1 Schematic overview of the occupational exposure assessment procedures[1].

Proposed OELV test improvement

5.1.5 basic characterization

Exposure is well below the OELV	Compliance
Exposure is higher than the OELV	Non-compliance
fr(OELV)<C_{max} ≤OELV	No decision⇒more measurements

5.5 Exposure Index $I = \sum_{i=1}^{n} \frac{Ei}{OELVi}$

Threat I as a concentration and apply 5.5.2 and 5.5.3	Compliance
	Non-compliance
	No decision⇒more measurements

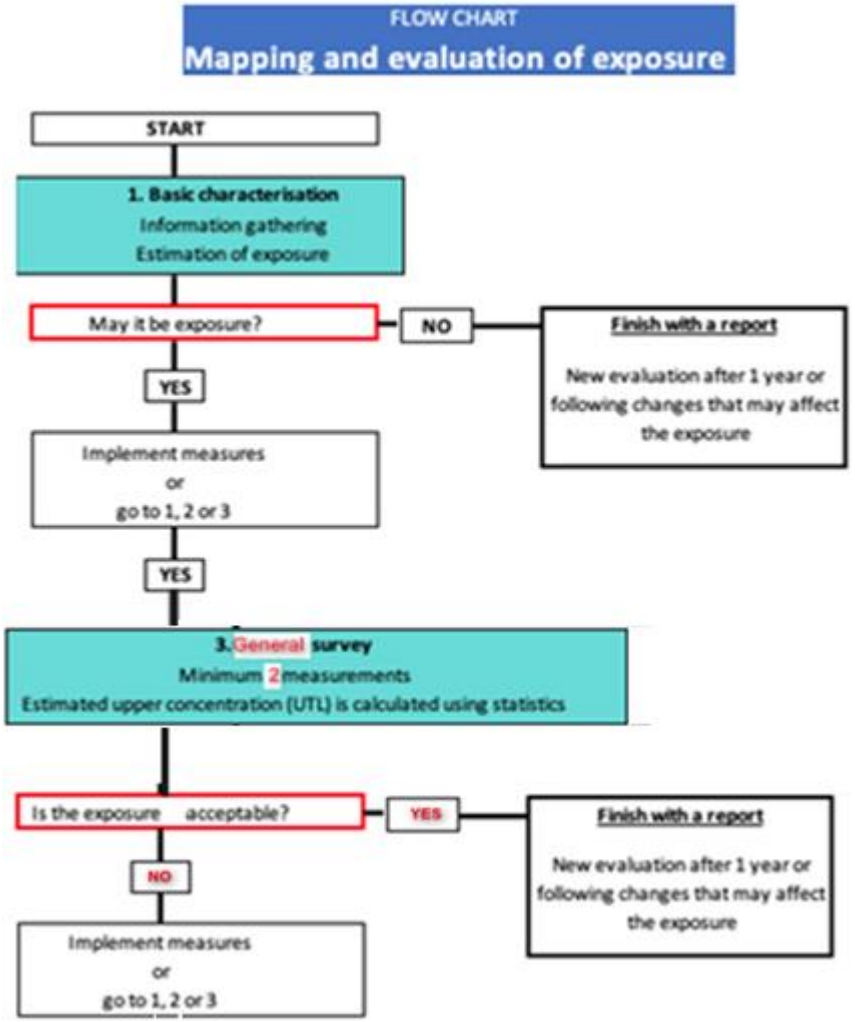
5.5.2 preliminary test N=3, 4 & 5

C_{max} ≤ fr(OELV	ance
C_{max} > OEL	nce
fr(OELV)<C_{max} ≤OELV	No deci ⇒more measurements

5.5.3 statistical test N≥2

$C_{95,70\%}$ ≤OELV	Compliance
$C_{95,\ (ML,\ 30\%\ or\ 5\%)}$ >OELV	Non-compliance
$C_{95,70\%}$>OELV≤$C_{95,\ X}$	No decision⇒more measurements

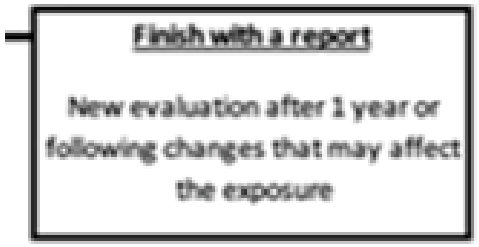
- Simplify the NYF low chart as proposed to the right
- Offer it to the EU IH platform
- Make the preliminary test a self-test for employers (if the variability is not too large)



Other EN689 improvements

"I have tried to find textbooks articles etc. that in a IH relevant manner discuss the use and limitations of the "Noncentral-Student distribution with 70% confidence", but without any success."

- Improve concept and priors for Normal test in Annex F (5.4.3 & EN482 table 1)
- Align U_T test in Annex F with the more universal GM*GSD^UT ≤OELV
- Align the exposure pattern in Annex D with the standard and with Annex G (prolonged exposure) $E_d = C_i \times \frac{t}{8}$
- Expand the subgroup analysis (5.4.3) as described in an BOSH-NVvA 2011/BWStat (ANOVA/homoscedasticity)
- Include i an annual reassessment using $C_{95,70\%}$ ≤OELV to establish the number of measurements



EN689 5.5 Comparing with OELV

5.5.2 preliminary test
N=3, 4 & 5

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

fr=0.1 for N=3
fr=0.15 for N=4
fr=0.2 for N=5
No-decission for N=5

5.5.3 →

5.5.3 statistical test
N≥2

$C_{95,70\%} \leq OELV$

Annex F