

Revisión de la Norma EN 689:1995 y la aplicación informática BWStat

La Asociación Española de Higiene Industrial 16 de octubre, 2015 Horario: 09.30 – 13.00 y 14.00-17.00

AEHI Barcelona, viernes, 16 de octubre 2015, Centre Civic Vil·la Florida, Muntaner 544

Agenda				
When	What	Who		
09:30 - 10:00	Welcome and introduction	Rudolf		
10:15 – 11:00	Industrial Hygiene and EN 689 Basic characterization 5.1 Similar Exposure group (SEG) 5.2.1	Theo		
11:00 - 11:15	Break			
11:15 – 12:00	Validity measurement 5.4.1 (outliers, LoQ) and the SEG 5.4.2 + Annex E & XX	Theo		
12:00 – 13:00	Testing compliance 5.5 & Undetectables Differences with the current 689	Theo		
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14:00 - 15:00	Introduction to BW Stat v2	Tom		
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15:15 – 16:30	BW Stat v2 exercise	Tom		
16:30 - 17:00	Feedback and evaluation	Rudolf		
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Aim of Industrial Hygiene: Keep exposure in control!

- Workers health & workplace hygiene
- Law (penalty)
- Installation integrity
- Insurance rates
- Liability claim
- Reputation management

EU Directive (98/24): Employer, keep the occupational exposure to chemicals in control, every day and on every workplace







Today

Not in the workshop:

- Biological Monitoring
- Skin permeation
- Mixtures
- Deriving OELVs

Mathematical Models

to Chemicals

Occupational Exposure

for Estimating

Models

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IIn



The Chartered Society for

Worker Health Protection

Vereniging



Ideally: control in space, time & population

- Possible for ionising radiation, noise, ozon
- Difficult for most other occupational loads including chemical exposure
 - sampling limitations
 - analytical limitations
 - costs

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A rather empty space-time universe

Occupational contact with chemicals:

- X billion workers exposed
- >40 year working life
- Up to 250 shifts a year
- Up to 8-12 hours a day
- 110.000 Notified substances in Europe
 Exposure databases: >1.000.000 results

We know just a little bit about exposure! But we need to say something with confidence







Even more complex: Exposure variability

- Today : TWA_{8 hours}=1 ppm
- What will it be tomorrow? 1, 0.1 or 10?
- A group of workers doing the same: Are their TWA_{8 hours} equal? little different? much different?
- And on the average throughout say one year?











The EU solution: EN 689 & BW_Stat!



A sampling strategy using:

- a limited number of measurements
- · carried out in conditions representative of normal activities

British Occupational Hygiene Society

Pride Park Derby

DE24 BLZ, UK

2011

 of a similarly exposed group (SEG) of workers and a statistical test to decide whether exposures in the SEG comply with the limit value.





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EN 689 working document N029 (June 2015)



λ	be working document Noze (June z	U
ſ	CEN/TC 137	
	Date: 2015-06	
	prEN 689:2015	
	CEN/TC 137	
	Secretariat: DIN	
	Workplace exposure — Measurement of exposure by inhalation to chemical agents — Strategy for testing compliance with occupational exposure limit values	
-	5 Occupational exposure assessment	
	5.1 Basic Characterization	
	5.1.1 Identification of chemical agents	
	5.1.2 Identification of determinants of exposure	
	5.1.3 Estimation of exposure	
	5.2 Sampling strategy	
	5.2.1 Constitution of Similar Exposure Groups (SEGs) 9	
	5.2.2 Definition of a measurement procedure	
	5.3 Performing exposure measurements	
	5.4 Validity of SEGs and results	
	5.5 Comparison of results with OELVs	
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EN 689 (2015) first steps







Initial Survey: Stakeholder question



- Stakeholders like employer, employee, government, insurance or any others may demand a skilled appraiser to perform an chemical exposure assessment or to advice if such an exposure assessment is needed.
- The appraiser performs an initial survey based on his/her professional judgement and if possible on a visit of the workplace.
- The appraise shall motivate, report and communicate his decision to the stakeholders.





EN 689 (2015) second step





5.1.1 Identification of chemical agents

- Products, mixtures, by-products -> CAS#/EC#
- Physical Chemical properties
 - Qualitative: molecular dispersion (ppm) or conglomerates (mg/m³)

- Quantitative: Saturation concentration (C_{sat}) or dustiness
- Health hazard properties (GHS/CLP)
- Risk potential assessment tools like Control Bar
- See e.g. http://www.tsac.nl/websites.html











Data rich

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<-Data poor

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Substances with exposure & no OELV

- DOHSBase ES:
 - 170.000 chemicals
 - ~6000 substances with ≥ 1 OELV or DNEL
- REACH DNEL exempted:
 - Registration exempted <1 t/year
 - CSA exempted 1-10 ton/year (> 10000)
 - intermediates, polymers, exemptions (natural, non dangerous) etc.
- CLP ~110.000 substances EU notified as dangerous, no DNEL/OELV
 - Kick-off levels
 - Control banding





https://www.dohsbase.nl/es/content-2-2-2/valores-kick-off-2014

Proposed kick-off values for dust/aerosols

(basis: COSHH Essentials)

Hazard Group	4	3	2 *	1
H-statements	H334, H340, H341, H350, H350i	H300, H310, H330, H351, H360F/D/FD/Fd /Df, H361f/d/fd, H362, H372	H301, H302, H311, H312, H314, H317, H318, H331, H332, H335, H370, H371, H373, EUH071	H303, H304, H305, H313, H315, H316, H319, H320, H333, H336, EUH066, other H- statements n.o.s., REACH Annex IV
Dusts (mg/m³)	0,0001	0,01	0,1	1

*: COSHH Essential Groups B+C combined

Proposed based kick-off values for gases/vapors

(basis: DGUV IFA Spaltenmodell)

azard Group	4	3	2	1
H-statements	H300, H310, H330, H340, H350, H350i, EUH032	H301, H311, H317, H318, H331, H334, H341, H351, H360F/D/FD/Fd/Df, H370, H372, EUH029, EUH031, EUH070	H302, H312, H314, H332, H361f/d/fd, H362, H371, H373, EUH071	H304, H315, H319, H335, H336, EUH066, other H- statements n.o.s., REACH Annex IV
Gases/vapors (ppm)	0,001	0,01	0,1	5

Dust/Aerosol

measurement methods

comprehensive database of OEL's and

The most



Vapor/Gas

5.1.3 Prior Knowledge on Exposure (level and variability)



- Earlier measurements
- Publications
- Exposure databases: MEGA (Ge), COLCHIC & SCOLA (Fr), OSHA (USA), NEDB (UK), EXPO (NO)
- Modelling (deterministic or expert judgment)
- Read across (substance or circumstance)
- e-SDS with exposure scenarios







5.2 Sampling strategy

Since compliance of all workers on all shifts cannot be established, we (= industrial hygienists):

- Group workers by task/job (SEG 5.2.1)
- Use the basic characterisation to focus on substance with high potential risk
- Sample with lowest sound frequency
- Fill data gaps with Lognormal exposure distribution and uncertainty with statistics











What is a similar exposure group?



- A. Workers with the same basic characterisation
- B. An industrial/professional task
- C. Similar job titles
- D. Workers with the same exposure level
- B= Reach exposure scenario,C=Epidemiology (, German IH)D=Occupational health (homogeneous)









- Workers step in and out:
 - When starting and ending their job (long term) and
 - Daily: begin and end of shift
- workers perform tasks within the shift.
- SEG activity may change (slowly) in time

Within REACH SEG's are sometimes defined as exposure scenario's (lower case)









5.2.1 Similar Exposure Group (SEG)



A SEG is group of workers having the same general exposure profile because of

- the similarity and frequency of the tasks they perform,
- the materials and processes with which they work, and
- the similarity of the way they perform the tasks.

(Mulhausen et al, 1998 p 42)









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5.2.2 Sampling strategy

Random stratified sampling

- Within the SEG
- In time/seasons
- Between shifts

to establish the "real" exposure variability!





EN 689: Start with 3 measurements





80

60

40

20

0

5.2.2 Sampling & analytical methods



(Electronic) libraries:

- Método aceptado por el Instituto Nacional de Seguridad e Higiene en el Trabajo (INSHT).
- NIOSH analytical method; (4e edition)
- OHSA Sampling & Analytical Methods
- methods of the 2e list of EU IOLV's;
- GESTIS >100 substances;

Included in DOHSBase ES (>3000)

See

http://www.tsac.nl/websites.html#Workplace_measurement_methods









The test requires 3 to 5 exposure measurements on workers belonging to a SEG.

- 1. If all results are below :
 - 0,1 OELV for a set of 3 exposure measurements or;
 - 0,15 OELV for a set of 4 exposure measurements or;
 - 0,2 OELV for a set of 5 exposure measurements.

Then it is considered that the OELV is respected: **Compliance**.





5.5.2 Screening test (2)



If one of the results is greater than the OELV, it is considered that the OELV is not respected:
 Non-compliance.

In case that the first measurement result is above the OELV, it is not necessary to perform any additional measurements.





5.5.2 Screening test (3)



3. If all the results are below the OELV and a result above 0,1 OELV (set of 3 results) or 0,15 OELV (set of 4 results) or 0,2 OELV (set of 5 results) it is not possible to conclude on compliance with the OELV. No-decision. In this situation it is necessary to carry out additional exposure measurements in order to apply the test based on the calculation of the confidence interval of the probability of exceeding the OELV, as specified in 5.5.2.





5.5.2 Confidence test



The appraiser shall select a statistical test of whether the exposures of the SEG comply with the OELV.

The test shall measure, with at least 70% confidence, whether <5% of exposures in the SEG exceed the OELV.

This afternoon







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5.4 Validity of SEGs and results



- 1. Lognormal goodness-of-fit (5.4.1 & Annex E)
 - Q-Q plot, shape test & best fitting transformation
- 2. Processing undetectables (Annex XX)
 - (fraction LoD), regression, degrees of freedom
- 3. GSD values (E.3.4)
 - Too low or too high: depends on activity
- 4. Individuals in SEG with exceptional exposure
 - Annex E.3.2
 - Location, dispersion, between and within (BWStat)







Rankit or Normal Order Statistics



Outcome, logarithmic scale

Annex E .1.1 through 1.4



Software goodness-of-fit plot and test (Annex E.1 and E.2)





Discrete outcome





Testing log-Normal shape



- The Shapiro & Wilk test
 - Robust
 - sensitive
- What P-value to use in industrial hygiene?
 - Do not fix on say 5 %
 - compare p-values of different transformations

Included in most compliance testing software





Testing goodness-of-fit



Workplace determinants -> Lognormal Analytical random error -> Normal Constant high background-> Normal Complete control -> Normal

- Compare Normal vs log-Normal
- If normal fits better, then use Normal test (not in 5.5)





5.4 Validity of SEGs and results



- 1. Lognormal goodness-of-fit (5.4.1 & Annex E)
 - visual, test & transformations
- 2. Processing undetectables (Annex XX)
 - (fraction LoD), regression, degrees of freedom
- 3. GSD values (E.3.4)
 - Low or high, all is possible
- 4. individuals with exceptional exposure (E.3.2)
 - Location, dispersion, between and within





General principle





Rankit or Normal Order Statistics





Urgent need to treat undetectables more professionally (0,5*LoD)

- Overestimation of GM
- Underestimation of GSD and $C_{95\%}$
- Changing working patterns
- Trends in time
- IH reputation









On the unbiased estimation of GM, GSD and $C_{95\%}$

Estimating GM and GSD from sampling data with undetectables

Regression through the data above LoD and optimizing GM and GSD using Shapiro & Wilks Goodness-of-Fit

HYGINIST 4.2.3



Non-detects in Industrial Hygiene



- Annals Occupational Hygiene (2009-2010, Large sample solutions):
 - Ogden. Editorial: Handling results below the level of detection.
 - <u>Helsel</u>. Incorporating Non-detects in Science.
 - Flynn. Analysis of censored exposure data by the Shapiro-Wilk W statistic.
- BOHS-NVvA guidance: "It is not recommended simply to substitute LoQ/2 or LoQ/ $\sqrt{2}$ for each value<LoQ"
- Free of charge Software solutions(plot & regression): HYGINIST (1990, small samples solution), Altrex, IHDataAnalyst, NDExpo, BW_Stat (2014)





GM and GSD for different LoD

probability:

Single

Rankit

02 12

censored

estimates

GMg=0,947

GSDg=1,708

not possible

5

71

GSD=1,



Complete sample

One nondetect



Median

0,99

0,32

0,32 4 = 0 0 0/ Asociación Española e ligiene Industrial

Median

0.93



not possible

5

9

GSD=1,



5.4 Validity of SEGs and results



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Operational Conditions (OC) & exposure variability



Low GSD	High GSD
Clean room,	Outdoor,
well controlled industrial OC	Professional OC
Job with single task	Job with multiple tasks
High background level	No background inference





Strategy & exposure variability



Low GSD	High GSD
Short sampling campaign (1	Long-term, mutually
day, one week):	independent sampling
autocorrelation, missing tasks	campaign (months, year)
EM	PAS
Small sample size	Large sample size
Small detection range (Gravimetric, inorganic acids)	Broad detection range (Analytical: AAS, DPP, IC, EC, etc.)
Fixed factor or remove undetectables	Correct handling undetectables





GSD, range, physchem & analytical



- GSD=1,5
- GSD=2
- GSD=3
- GSD=4,1
- GSD=5,4
- GSD=11
- GSD=17

(inorg. acid mist) $0,5 \le C_{95\%} \le 2$ $0,3 \le C_{95\%} \le 3$ (gravimetric) $0,16 \le C_{95\%} \le 6$ (analytical: $0,1 \le C_{95\%} \le 10$ halogens, $0,07 \le C_{95\%} \le 14$ metals, $0.02 \le C_{95\%} \le 50$ P, N, S and $0,01 \le C_{95\%} \le 100$ solvents)





Conclusion (E.3.4)



- Nearly every GSD (1.1 ->17) is possible
- Always compare GSD with what is usual for the specific situation:
 - in time
 - In large databases (Colchis, Mega)
 - Read across
 - Other industries
 - Modelling
 - Physical-Chemical properties
 - Controls





5.4 Validity of SEGs and results



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individuals with exceptional exposure

- This afternoon
- **BW_Stat**



dustr

Occupational

Hygiene Society

Working for a healthier workplace

Lognormal probability plot for group

and selected worker



Compare 689 (1995 & 2015) & NVVA/BOHS



Chapt er	689 (1996)	689 (2015)	NVvA/BOHS
0->4	Intro/Scope/ref/General		1
5	Exposure	assessment	n.a.
5.1	Basic characterisation		n.a.
5.2	strategy		n.a
5.3	Measurements		1.2
5.4	(Mixtures)	Validity of SEG	3.2/5 Validity of SEG
5.5	Compliance: Yes, no and in between -> annexes B, C, D & E	Screening test & Group compliance Annex F	3.3 Screenings test3.4 Group compliance3.6 Individualcompliance
	-	Annex XX 5.5.2 with <loq< td=""><td>3.7 values <loq< td=""></loq<></td></loq<>	3.7 values <loq< td=""></loq<>





Comparison of results with OELVs



test	689 (1996)	689 (2015)	NVvA-BOHS (3)
screening	n.a.	3 samples <0,1 OELV 4 samples <0,15 OELV 5 samples <0,2 OELV	3 samples <0,1 OELV
confidence	n.a.	6+ samples C95%,70% <oelv< td=""><td>6+ samples , several workers C95%,70%<oelv< td=""></oelv<></td></oelv<>	6+ samples , several workers C95%,70% <oelv< td=""></oelv<>
Between Worker differences	n.a.	(5.4. + Annex E)	ANOVA test on individual outside SEG If, so ↓
Within Worker compliance	n.a.	n.a	Individual compliance







Detailed Timeframe European Standard









In summary



Advantages of EN 689:

- Standardized approach
- Broad acceptance
- "No questions asked" execution
- Freedom to do it different, if motivated

Additional advantage of BOHS-NVvA guidance

 Distinguish between improvement of technical and individual control meassures





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