



World Federation for
Hospital Sterilization Sciences

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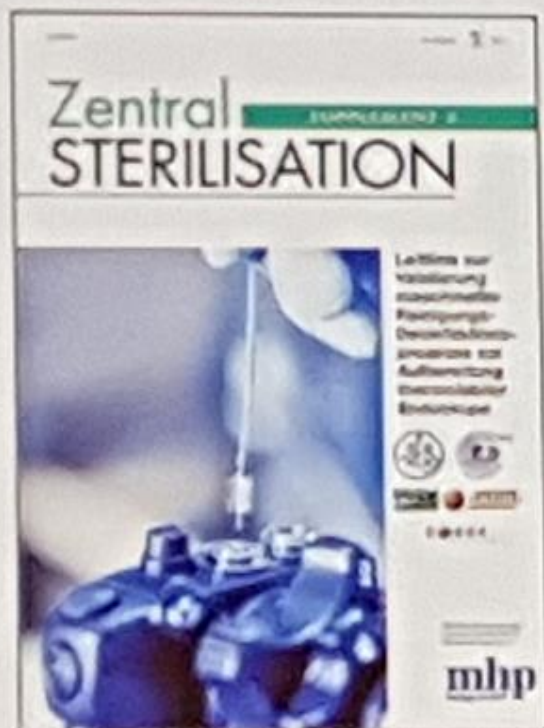
Deutsche Gesellschaft für
Sterilgutversorgung e.V.

WORLD CONFERENCE
CENTER BONN

Dr. Markus Wehrl

Control of cleaning efficacy
of EWD processes: Annex 8-PCD

Validation of EWD Processes in DE

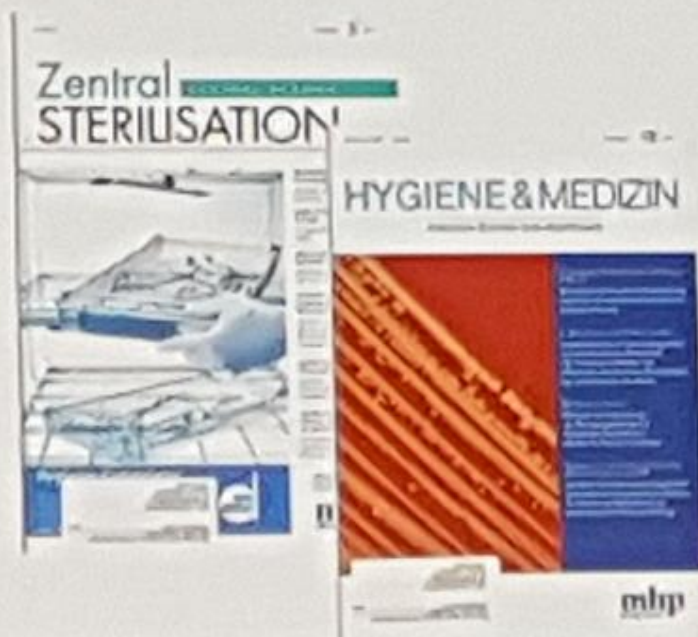


Guideline, 1. edition 2011

- 15 Annexes
- 6 Check matrices
- 9 Check lists

Background to the guideline:

- EN ISO 15883-1, -4, -5
- European Guideline of ESGE / ESGENA



Annex 8 – Process Challenge Devices (PCD) for cleaning

CentralService 2011(5): 357-361 (EN)
HygMed 2011 36(10): 402-406 (DE)



Control of Process Efficacy



Controls for Performance Qualification (PQ)

- | | |
|-----------------|--|
| Cleaning | <ul style="list-style-type: none">• Process Challenge Devices (PCD) for cleaning efficacy (Annex 8) |
| Disinfection | <ul style="list-style-type: none">• No control |
| Overall process | <ul style="list-style-type: none">• PCD for overall process efficacy (Annex 9)• „Real-life instruments“ after reprocessing (Annex 10) |

PCD for Cleaning: Annex 8

- PTFE-tube, length: 200 cm
- Inner diameter: 2 mm



- Quantified amount of reactivated sheep blood



Quantification of protein residues
(protein is main parameter)

Acceptance criteria in 2011*:

- Visual cleanliness
- Guide value: $\leq 800 \mu\text{g PCD}^{-1}$ **
- Warning level: $800 < x \leq 1600 \mu\text{g PCD}^{-1}$
- Limit value: $> 1600 \mu\text{g PCD}^{-1}$



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* DGKH, DGSV, DGSV, DEGEA und AIG: Leitlinie zur Validierung maschineller Reinigungs-Desinfektionsprozesse zur Aufbereitung thermolabiler Endoskope. ZentralSteril 2011, Supplement 3

** The Guide value was chosen with reference to the value of $< 6.3 \mu\text{g cm}^{-2}$ published by: Alfa M.L., Degagne P., Ghon N., 1999: Worst-case soiling levels for patient-used thermolabile endoscopes before and after cleaning. Am J Infect Control 1999; 27: 168-177

Reference for Acceptance Criteria of 2011



		Endoscope $\mu\text{g} / \text{cm}^2$		PTFE-tube L: 2m / ID: 2mm
		Before cleaning	After cleaning	After cleaning
Bronchoscope Channel: 2,2mm	Mean	28,3 μg	6,12 μg	804 μg
	Min/Max	1,8 - 95,8 μg	3,5 - 8,6 μg	
Duodenoskop Channel: 2,8-3,2 mm	Mean	11,32 μg	1,17 μg	147 μg
	Min/Max	1,8 - 29,4 μg	0,2 - 2,26 μg	
Coloscope Channel: 3,2 mm	Mean	37,0 μg	0,87 μg	109 μg
	Min/Max	1,8 - 116 μg	0,5 - 1,2 μg	

Alfa M.J., Degagne P., Olson N., 1999:
Worst-case soiling levels for patient-
used thermolabile endoscopes before
and after cleaning. *Am J Infect Control*
1999; 27: 392-401

The deduced "acceptable" reference
value of $6.4 \mu\text{g cm}^{-2}$ was also referred
to by AAMI TIR30:2003

Applicability for Annex 8-PCD ?
Relevant for the recent "State-of-the-Art" ?

Field Investigation

Aim

Collection of updated data on the residual protein content of Annex 8-PCD used for Performance Qualification (PQ) in hospitals and doctor's practices.

Initial meeting of the guideline group and validation laboratories and manufacturers of PCD on Januar 28th 2015 at wfk, Krefeld

4 validation laboratories agreed on participation (alphabetically):

- Belimed Deutschland GmbH
- Cleanical GmbH
- Olympus Deutschland GmbH
- Valitech GmbH & Co KG

Data collection:

April to September 2015

followed by anonymized analysis and presentation



6 Month of Data Collection

Number of Annex 8-PCD: **2298**

Number of checked EWD-processes: **888**

EWD - with type testing 97.2 %
 - without type testing 2.8 %

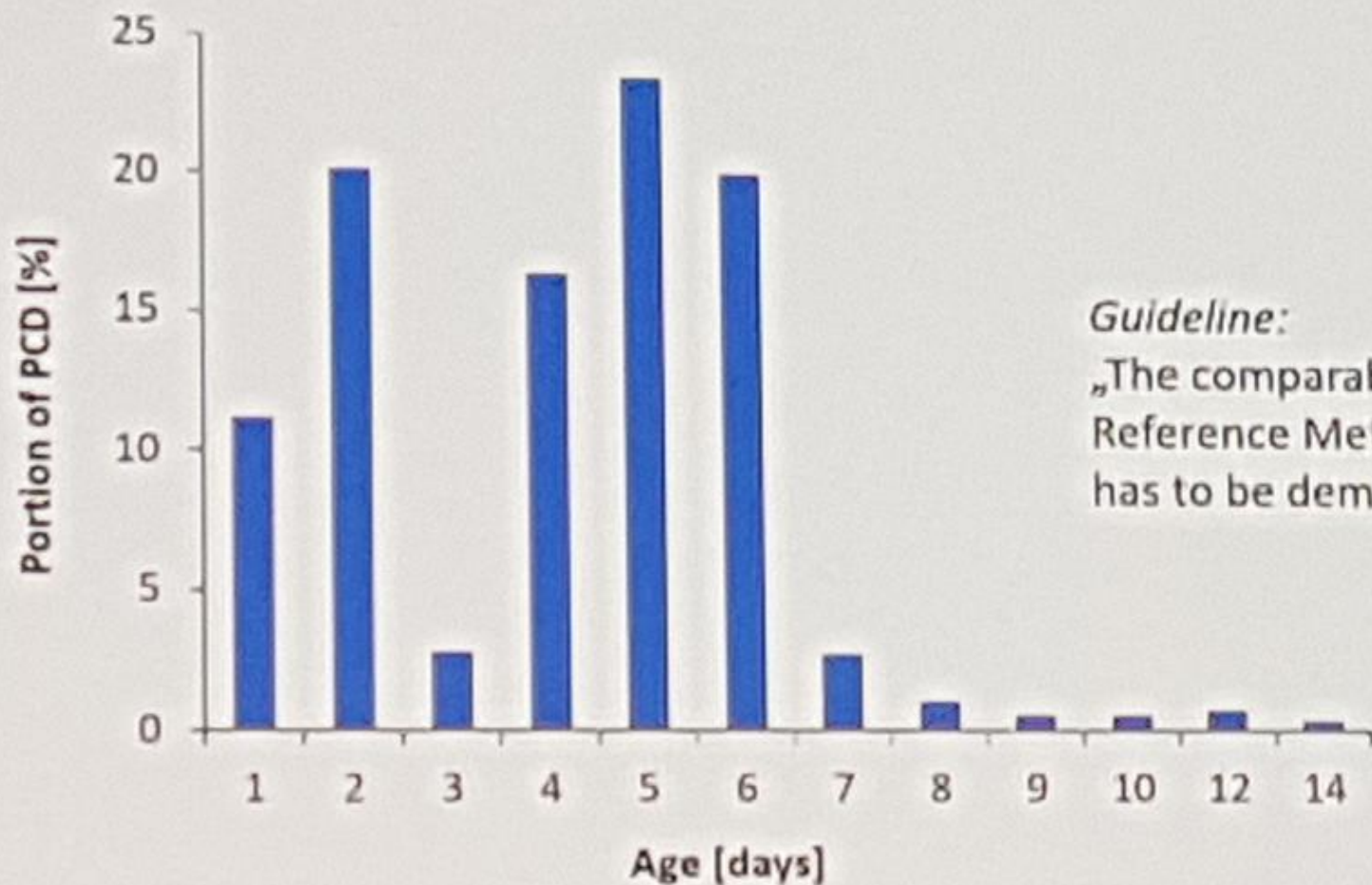
Processes at - 1. PQ 19.0 %
 - repeated PQ-testing 81.0 %

EWD - with separate channel connection
 - with pressure chamber

Testing was performed throughout the country



Age of Applied PCD



Guideline:

„The comparability to the Reference Method given in Annex 8 has to be demonstrated“

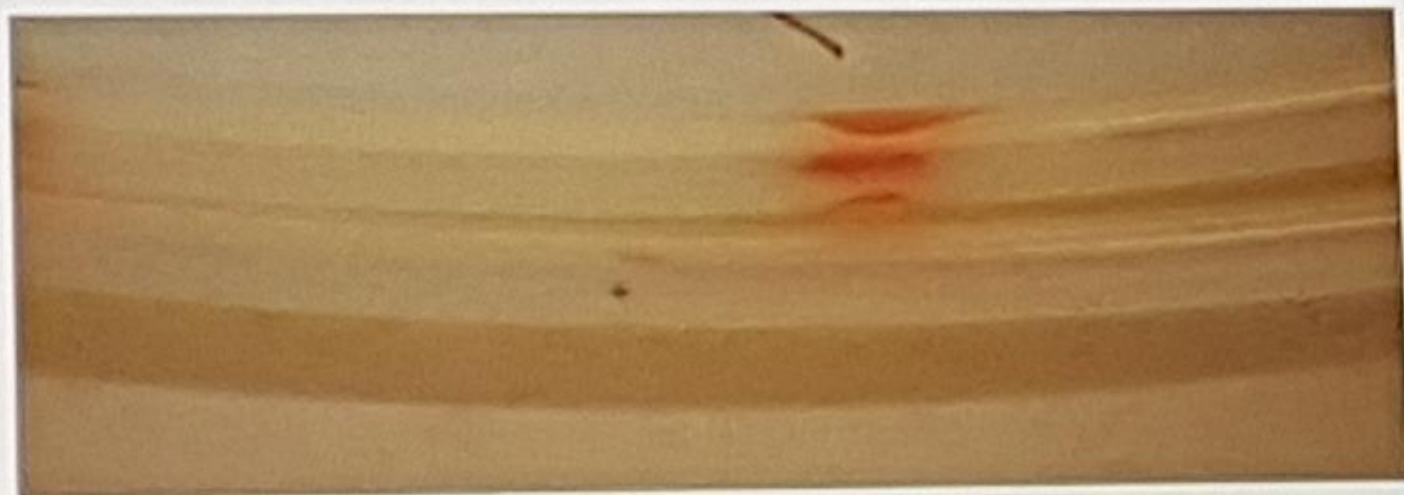


1. Acceptance Criterion: Visual Cleanliness

Number of Annex 8-PCD: 2298

Number of PCD with visible residues 127 ($\approx 5,5\%$)

→ **Cleaning efficacy insufficient**



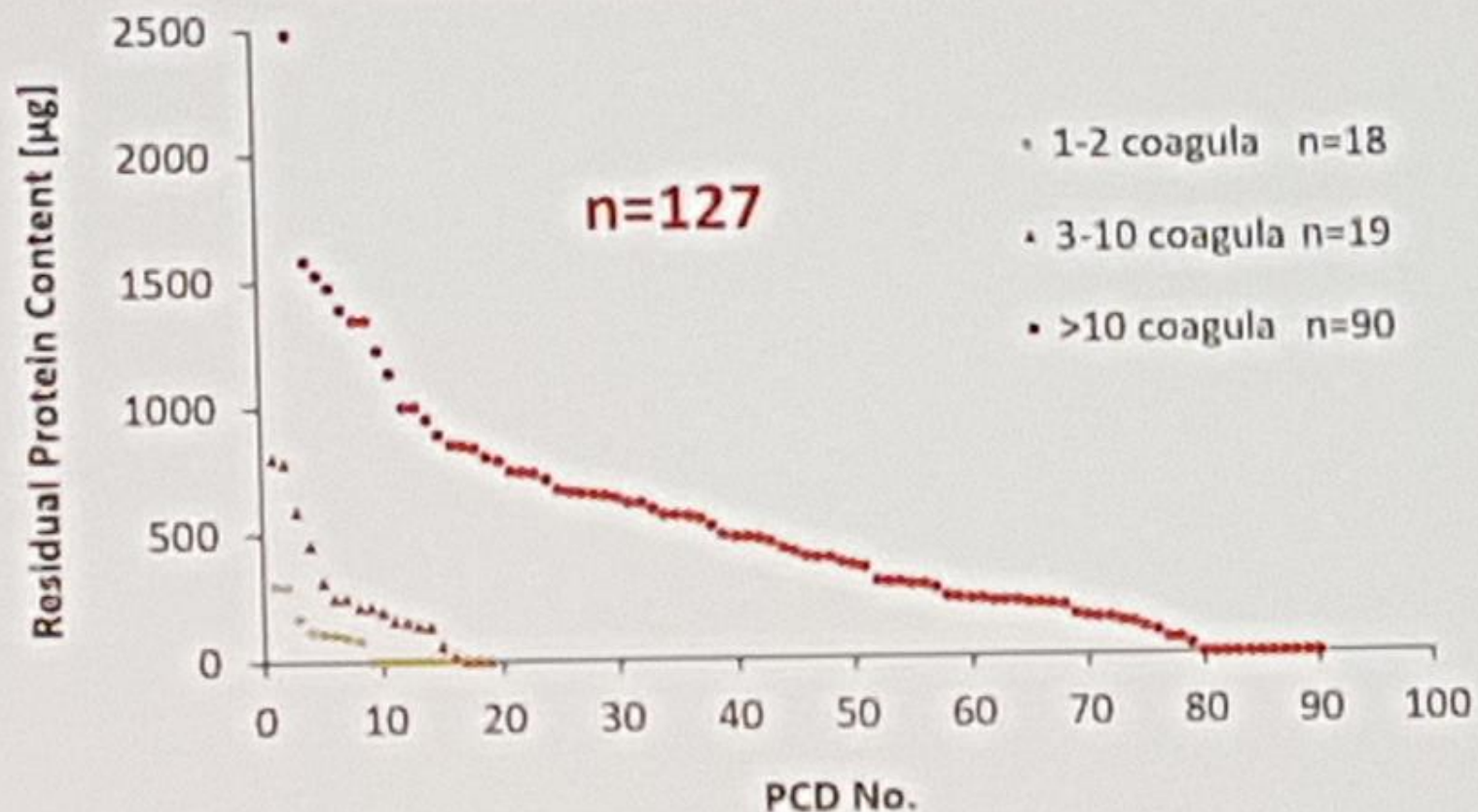
PCD with Visible Residues



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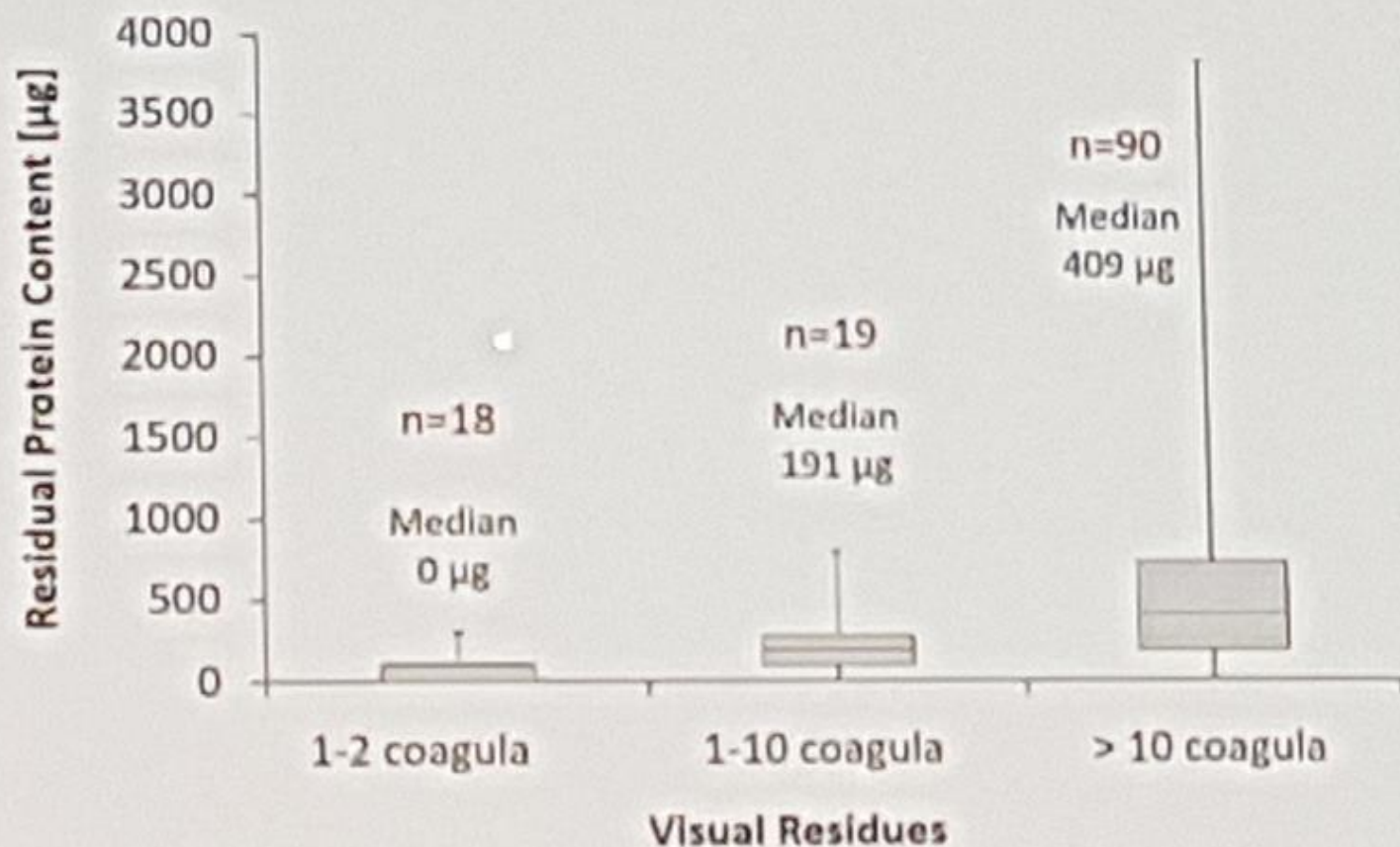
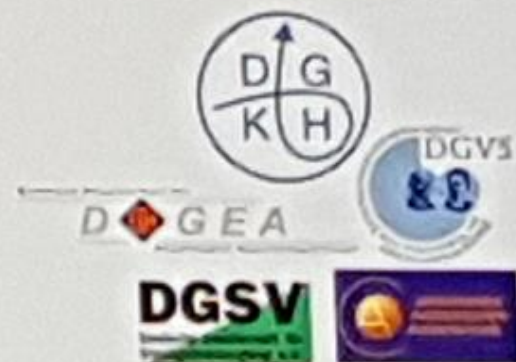


Correlation between visual residues and residual protein content



2 PCD with 3684 and 3878 µg are not displayed

Correlation Residual Protein Content vs. Coagula

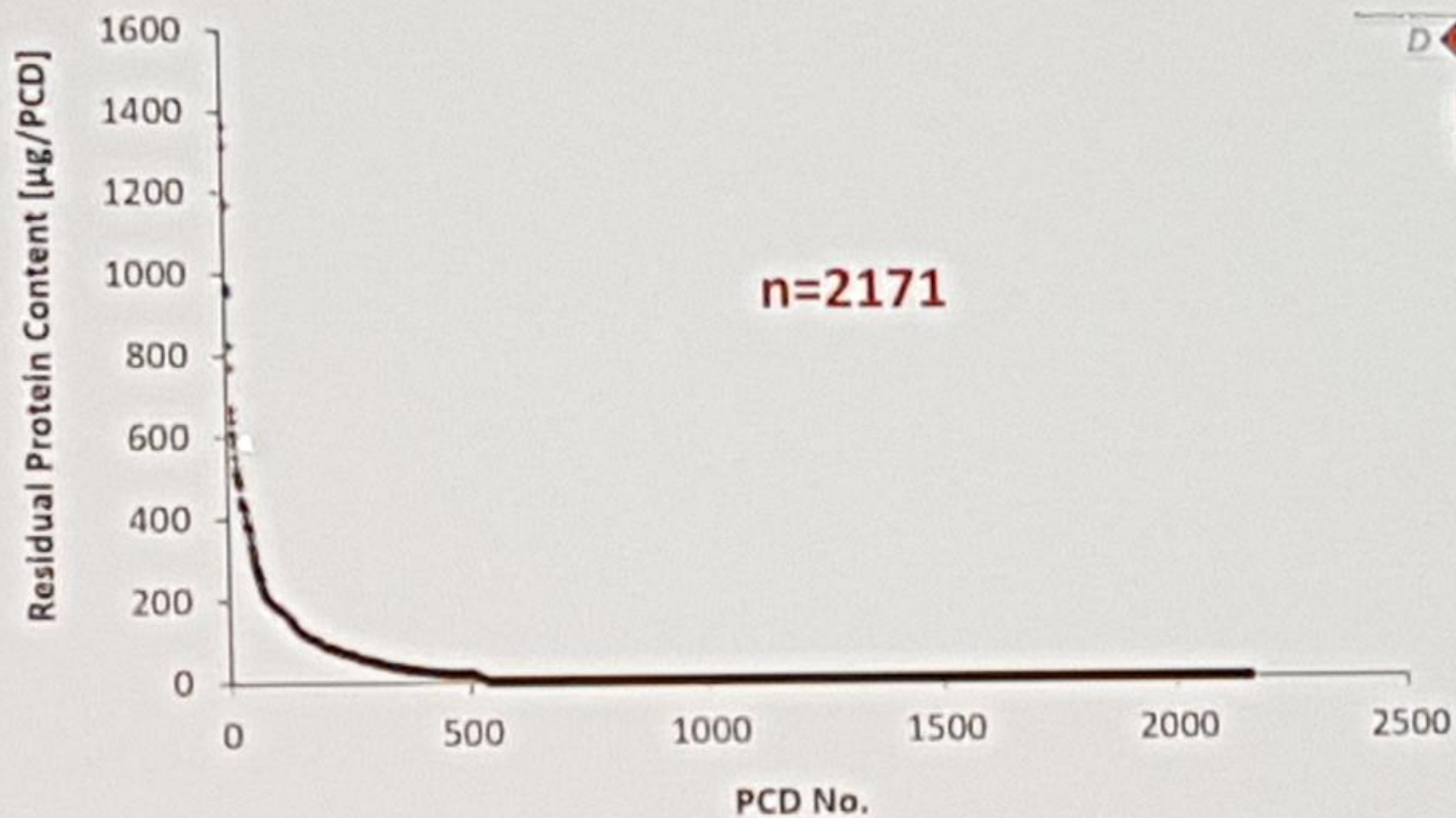


2. Acceptance Criterion: Residual Protein Content



Number of visual clean Annex 8-PCD:	<u>2171</u>
Arith. mean of protein content:	29,9 µg
SD ($\chi\sigma n^{-1}$):	98,4 µg
Median:	0 µg
Lower Quartile:	0 µg
Upper Quartile:	0 µg
Maximum:	1365 µg

Visual Clean PCD



Categories of Residual Protein Content

For analysis categories of protein content were set up:

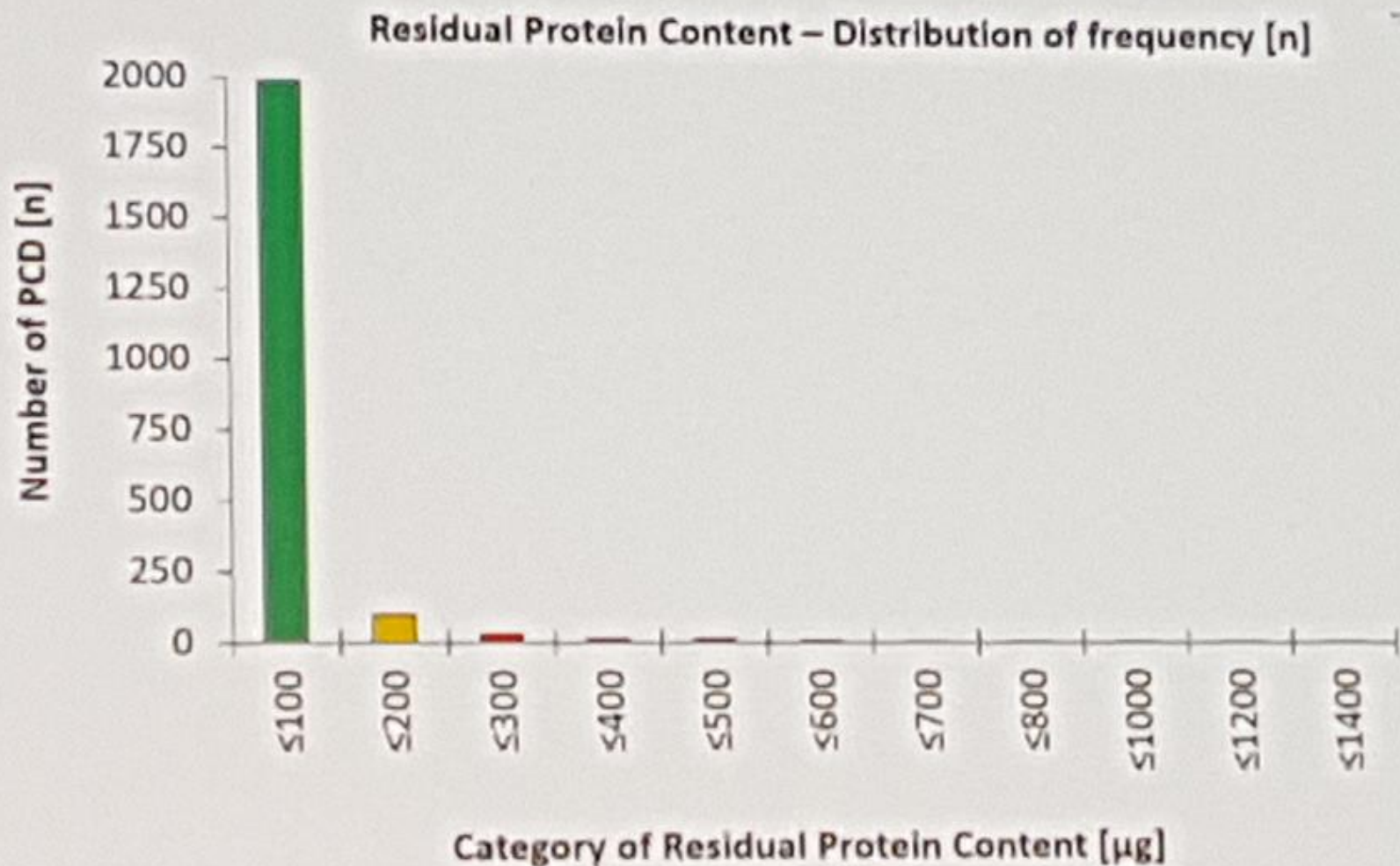
- $\leq 100 \mu\text{g}^*$
- $100 < x \leq 200 \mu\text{g}$
- $200 < x \leq 300 \mu\text{g}$
- etc.

The limit of quantification (LOQ) was not reported by the participants or not known. Therefore results reported as $0 \mu\text{g}$ were summarized with results of $0 \leq 100 \mu\text{g/PCD}$.

Using the modified ortho-phthaldialdehyde (OPA)-method the LOQ is usually in the range of approximately $5 \mu\text{g ml}^{-1}$, or $25 \mu\text{g PCD}^{-1}$

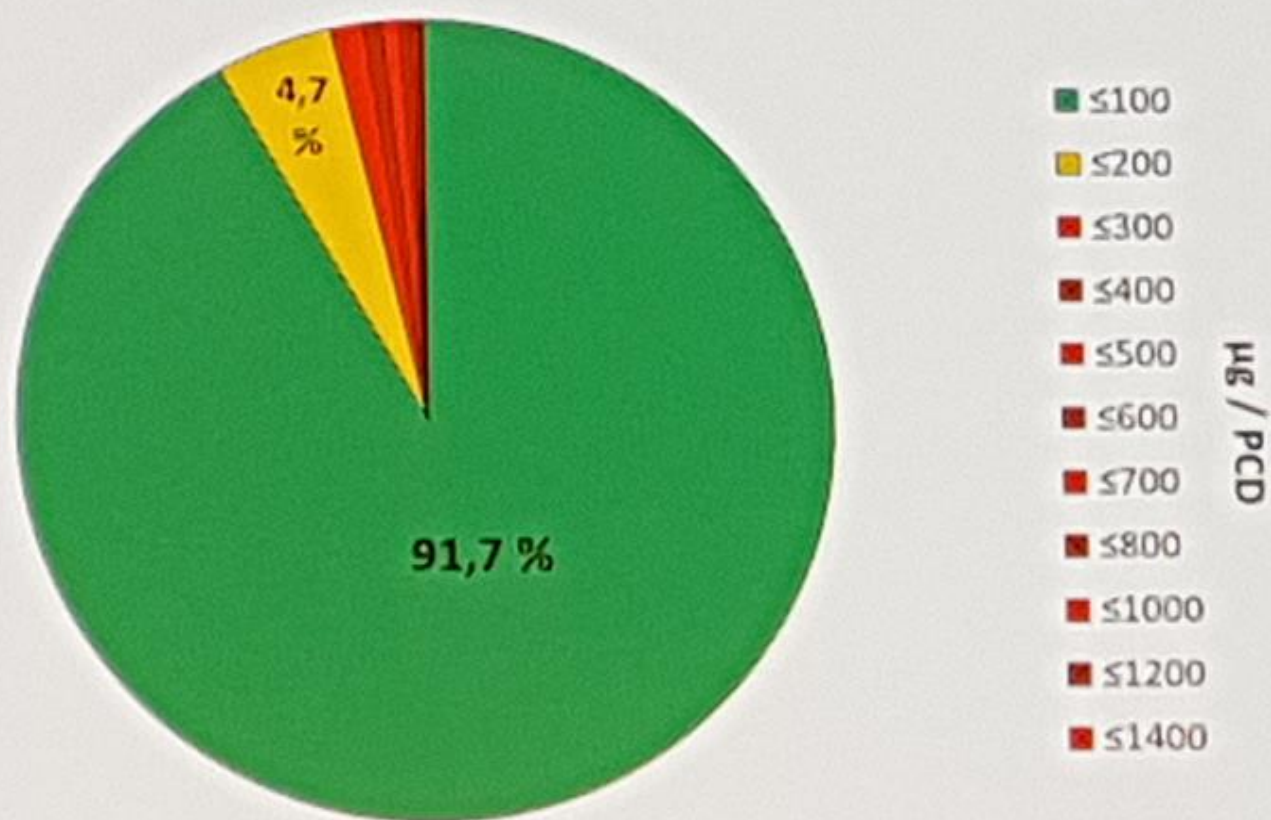


Results: Annex 8-PCD



Results: Annex 8-PCD

Residual Protein Content – Distribution of the relative frequency [%]



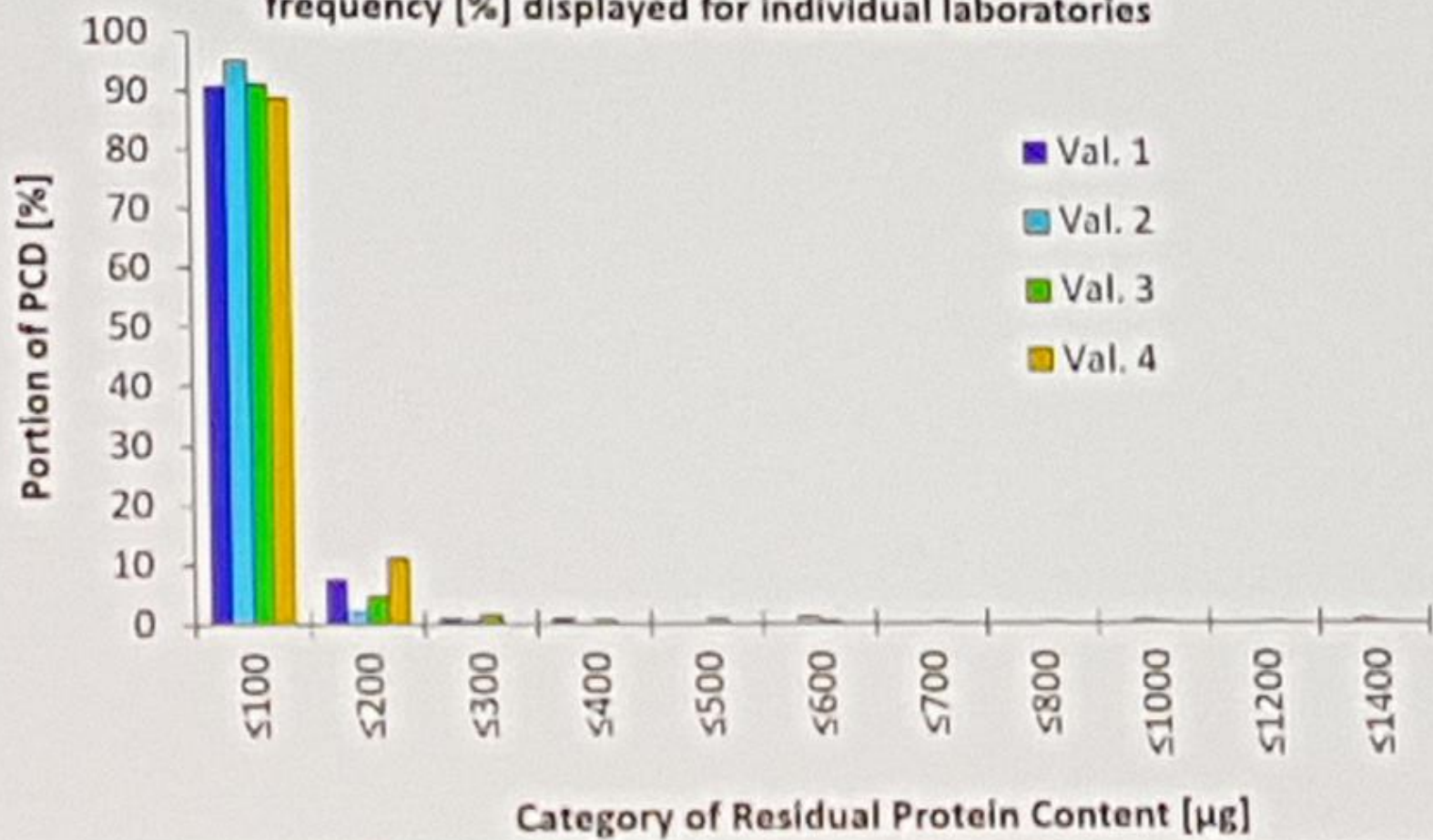
Reproducibility of Results



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Residual Protein Content – Distribution of the relative frequency [%] displayed for individual laboratories



Summary

2298 PCD, thereof 127 with visual residues



2171 PCD visual clean

91.7 % of these Annex 8-PCD with a residual protein content of $\leq 100 \mu\text{g}$

96.4 % of these Annex 8-PCD with a residual protein content of $\leq 200 \mu\text{g}$

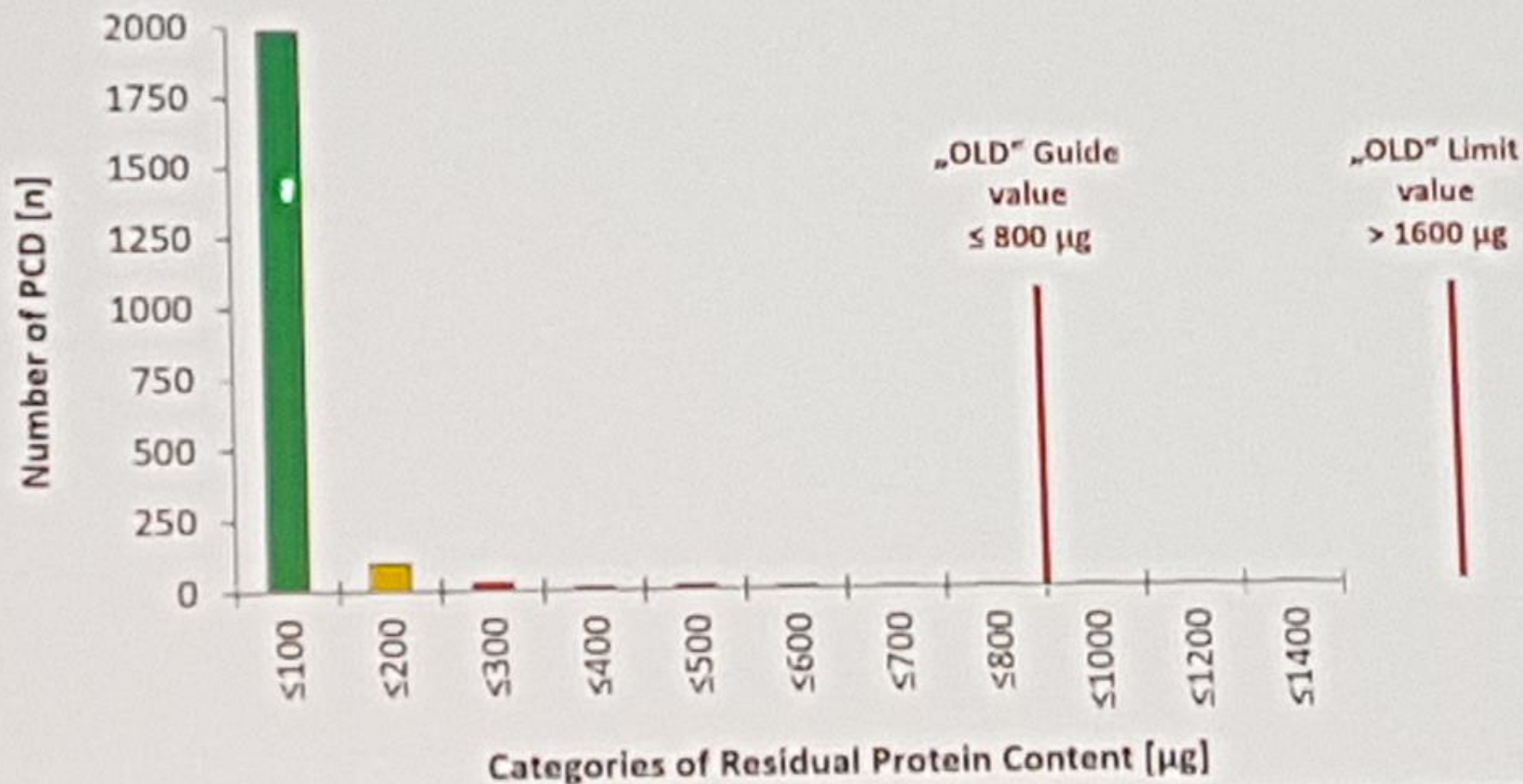
Applying the „OLD“ Acceptance Criteria of 2011:

Guide value of $\leq 800 \mu\text{g}$ → exceeded by 0.32 % of the PCD

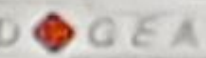
Limit value of $> 1600 \mu\text{g}$ → exceeded by 0.00 % of the PCD



Application of New Acceptance Criteria



Quo vadimus ? Sunt ibi !

The results of the field investigation obliged to a reduction of the Acceptance Criteria. 

The results and the adaption of the guideline were published:

CentralService 2016(4): 220-225 (EN)	Field Investigation
CentralService 2016(4): 204 (DE)	Adaption of guideline
HygMed 2016(7/8): 179 (DE)	Adaption of guideline

Guide value:	$\leq 100 \mu\text{g} / \text{PCD}$
Warning level:	$100 < x \leq 200 \mu\text{g} / \text{PCD}$
Limit value	$> 200 \mu\text{g} / \text{PCD}$ <u>must not be exceeded</u>



Thank you.....



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.....Questions?



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