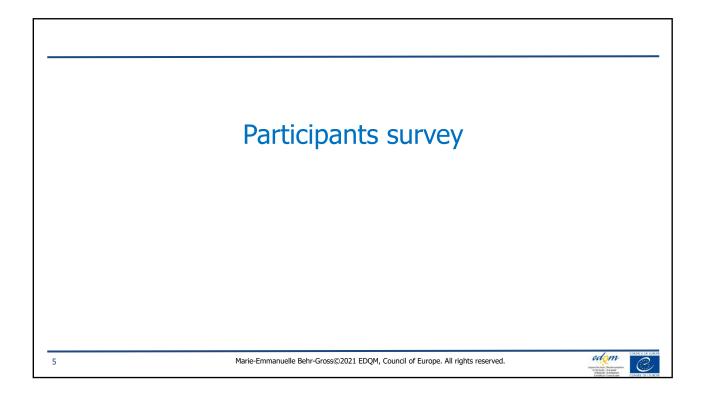
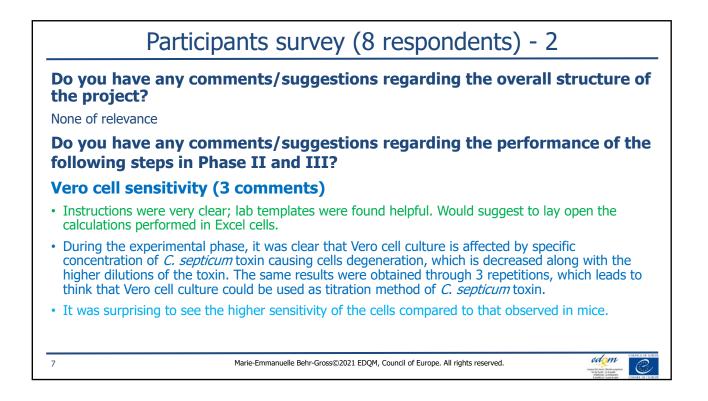
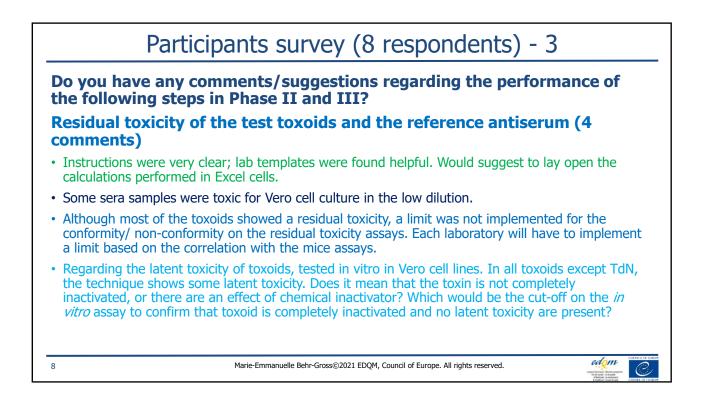


Pr	resentation on field enquiries				
Participants	Study performance and learnings PA/PH/BIO (20) 23 DEF				
	Speaker: ME Behr-Gross (EDQM)				
Manufacturers	Questions to manufacturers regarding implementation of <i>in vitro</i> methods PA/PH/BIO 20 (24) DEF				
	Speaker: Catrina Stirling (EPAA)				
Acknowledgements Natalia Sinitskaya and Sally Woodward (DBO)					
4	Marie-Emmanuelle Behr-Gross©2021 EDQM, Council of Europe. All rights reserved.				

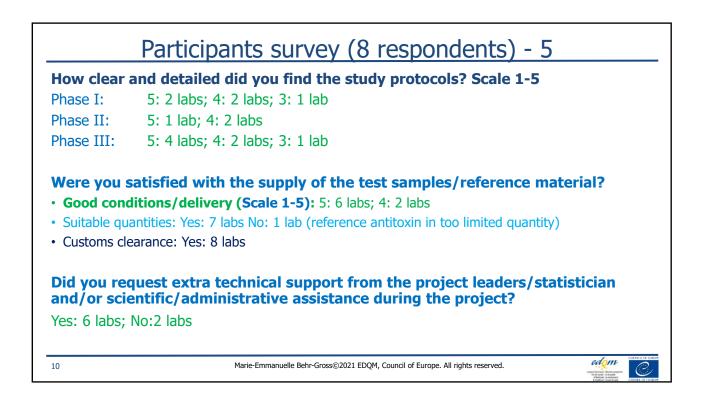


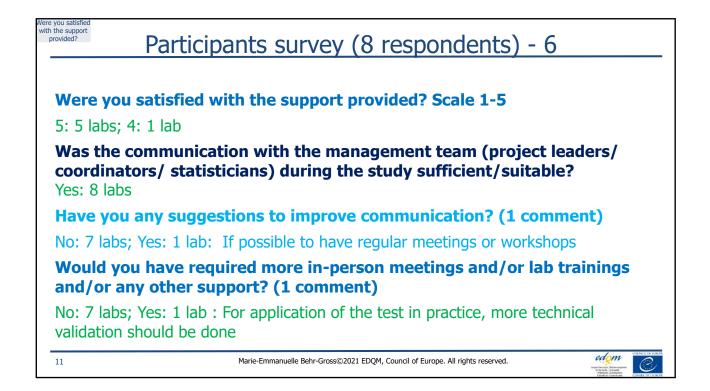
low clear was 5: 7 labs; 4: 1		of the E	SP130 F	Project (	Scale 1-5)		
Which phase(s)	did you par	ticipate i	n?				
Attendance & u	sefulness of	participa	ants' Wor	kshop "V	alidation of	alternative	e/3Rs methods for th
							e, NL) 15-16/09/2015
	Lab	Phase 1	Phase 2	Phase 3	Phase 1 Workshop	Workshop	
	A	+	+	+	+	+	
	В	-	-	+	-		
	С	+	-	-	-		
		+	+	+	+	+	
	D		32	+	+		
	D	+	+	<b>.</b>			
		++++	+	+	-		
				1000	- +	+	
	E	+	-	+	20 C	+ +	-

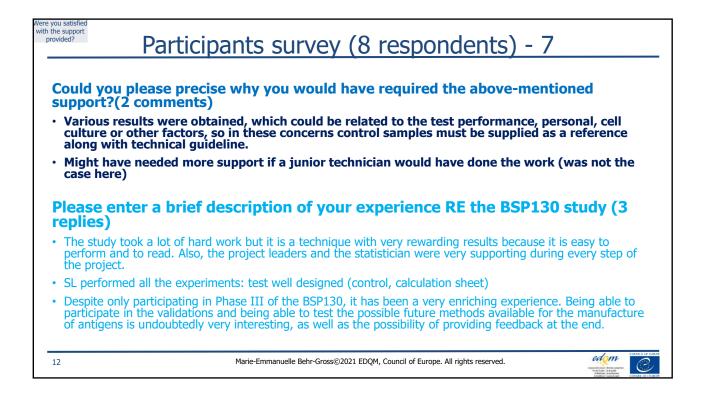




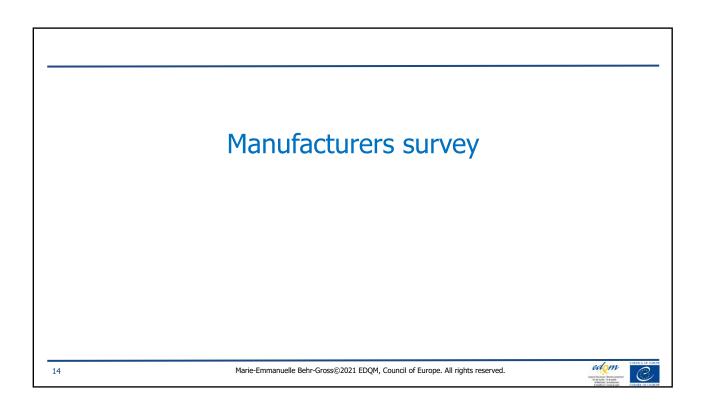
Participants survey (8 respondents) - 4
Do you have any comments/suggestions regarding the performance of the subsequent steps in Phase II and III?
In vitro MLD/TNE+ determination of the reference toxin (2 comments)
<ul> <li>Instructions were very clear; lab templates were found helpful. Would suggest to lay open the calculations performed in Excel cells.</li> </ul>
Different results were obtained
In vitro TCP determination of the test toxoids (3 comments)
<ul> <li>Instructions were very clear; lab templates were found helpful. Would suggest to lay open the calculations performed in Excel cells.</li> </ul>
No technical problem
• Has this <i>in vitro</i> method ( <i>in vitro</i> TCP) been evaluate to study the stability of the antigens/toxoids?
9 Marie-Emmanuelle Behr-Gross©2021 EDQM, Council of Europe. All rights reserved.

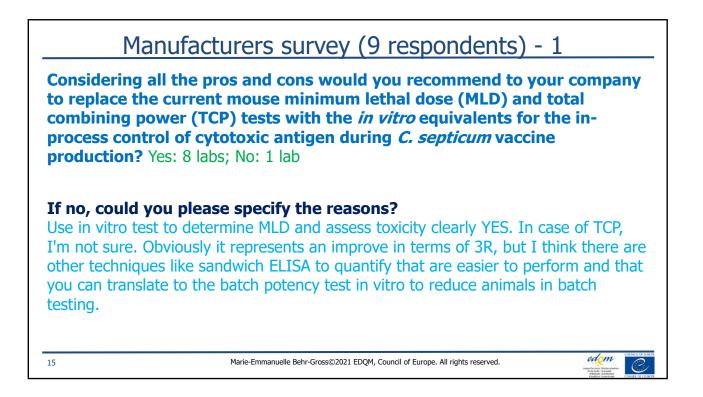


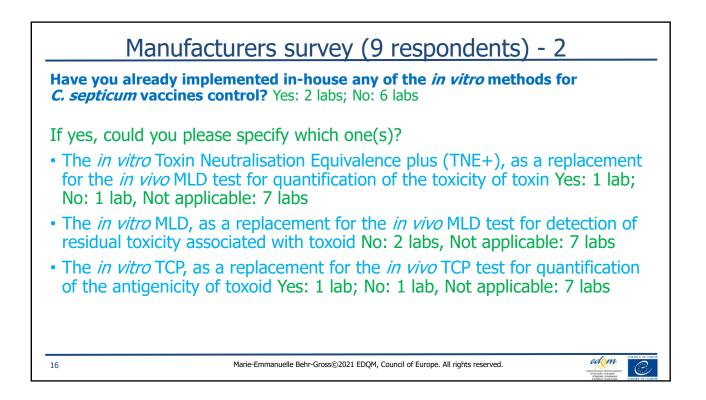




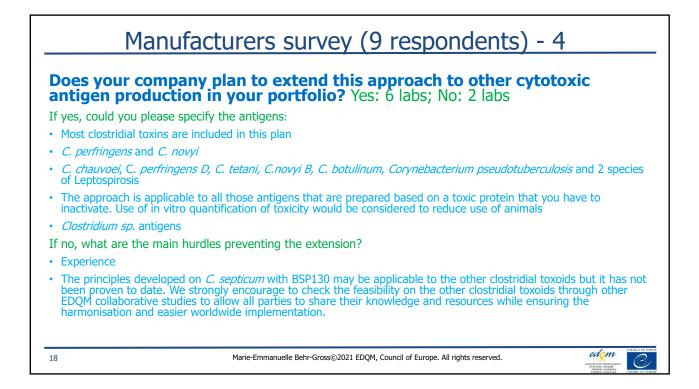
with the support provided?	Participants survey (8 respondents) - 8
Would yo you woul testing?	bu be interested in participating in another BSP project in the future if Id consider it to be relevant in terms of 3Rs/alternatives to animal Yes: 8 labs
Clostridia:	5 labs; other in vitro tests for veterinary vaccines*:4 labs; rabies vaccine: 2 labs; other in vitro tests for veterinary vaccines*:4 labs; rabies vaccine: 2 labs; ontification techniques: 1 lab (*many components cited, multiple answers per lab)
Could you testing?	u please specify your future plans in terms of 3Rs/alternatives to animal
<ul> <li>Mass spe</li> </ul>	ectrum analysis tuberculins/leptospira vaccines (ongoing)
• We are t on this p	trying to find <i>in vitro</i> alternatives for the antigens we use. Any testing to advance point, would be included in our plans
Unfortur     our port	nately our laboratory is not a research lab so we do not have any new method in folio
• Our lab i	is part of Vac2Vac consortium
• We plan	to implement the alternative methods currently available
13	Marie-Emmanuelle Behr-Gross©2021 EDQM, Council of Europe. All rights reserved.







Manufacturers survey (9 respondents) - 3
<b>Do you plan to implement any of the methods in the future?</b> Yes: 6 labs; No: 2 labs
If yes, could you please specify which one(s)?
Residual toxicity and antigen content
<ul> <li>An <i>in vitro</i> assay to replace mice serum neutralisation will be implemented by the end of 2020. Other <i>in vitro</i> assays to replace current <i>in vivo</i> TCP and L+ are planned for the future.</li> </ul>
<ul> <li>In vitro toxicity to replace MLD, and to check residual toxicity of toxoids.</li> </ul>
Potency
<ul> <li>If it is confirmed that this method is applicable to our C. <i>septicum</i> toxoid, and when necessary resources will have been dedicated to ensure the follow up of the project, we are interested by implementing the <i>in vitro</i> MLD, as a replacement for the <i>in vivo</i> test for detection of residual toxicity associated with toxoid.</li> </ul>
<ul> <li>All with the priority being towards the non-toxicity assay.</li> </ul>
17 Marie-Emmanuelle Behr-Gross©2021 EDQM, Council of Europe. All rights reserved.



Manufacturers survey (9 respondents) - 5
Did your company participate in the BSP130 study? Yes: 5 labs; No: 3 labs
How would you rate the general knowledge of the management about the BSP130 project at your company? Scale 1-5
5: 2 labs; 4: 2 labs; 1: 1 lab
Comments: Allowed us to have a good knowledge of the technique, to have access to the necessary reagents and it was an excellent opportunity to participate in an inter-laboratory validation
How would you rate the support and acknowledgement you received for your BSP130 participation from the management at your company? Scale 1-5
5: 3 labs; 4: 1 lab; 3: 1 lab
19 Marie-Emmanuelle Behr-Gross©2021 EDQM, Council of Europe. All rights reserved.

