

Food microbiology proficiency testing and performance testing of culture media in accordance with ISO 11133:2014: a case study

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The Istituto Zooprofilattico Sperimentale delle Venezie (IZSve) Production Service Center (CSP), ISO 9001 certificate, is responsible for ensuring high quality culture media for the IZSve laboratories. The CSP activity allows microbiology laboratories to perform reliable analyses and the proficiency testing provider (PTP) to correctly verify the microbiological homogeneity and stability for a high quality test sampling.

ISO 11133:2014 requires rigorous performance testing of culture media, too expensive (figure 1), not efficient (figure 2) and not suitable for the CSP organization.

FIGURE 3: FMEA METHOD - CRITICALITY MATRIX

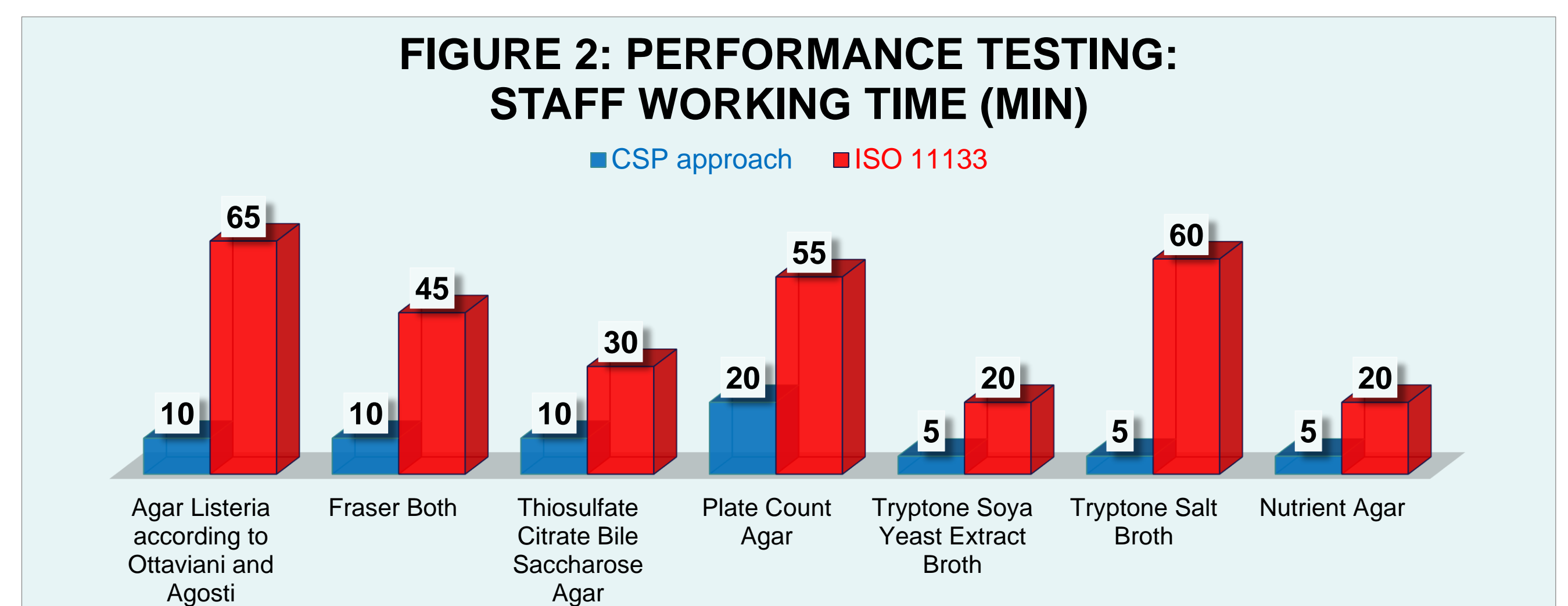
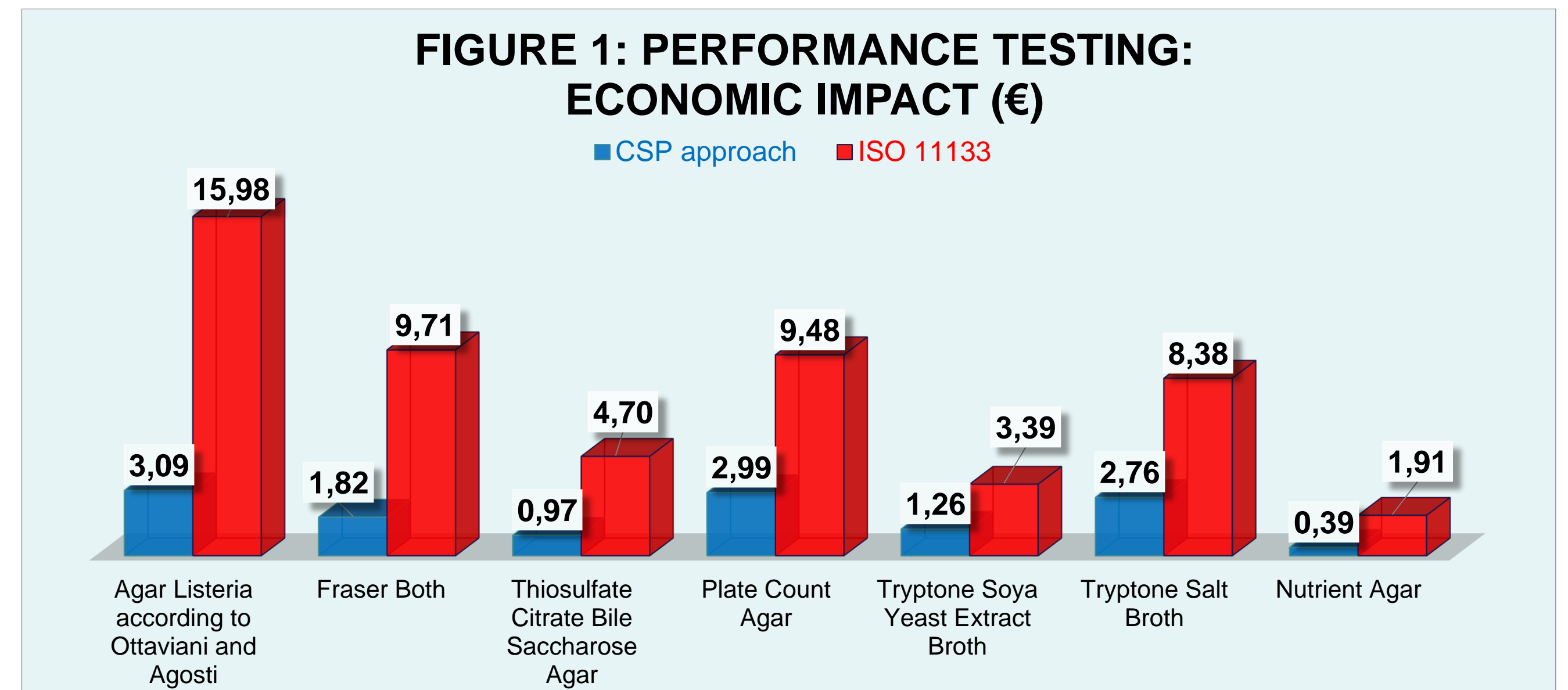
		Severity				
		very low	low	moderate	high	very high
Occurrence	very high	5	10	15	20	25
	high	4	8	12	16 (R7)	20
	moderate	3	6 (R5)	9	12	15 (R6)
	low	2	4	6	8	10 (R2 - R3)
	very low	1	2	3	4 (R1)	5 (R4)

FIGURE 4: FMEA METHOD - PRIORITY MATRIX (RPN)*

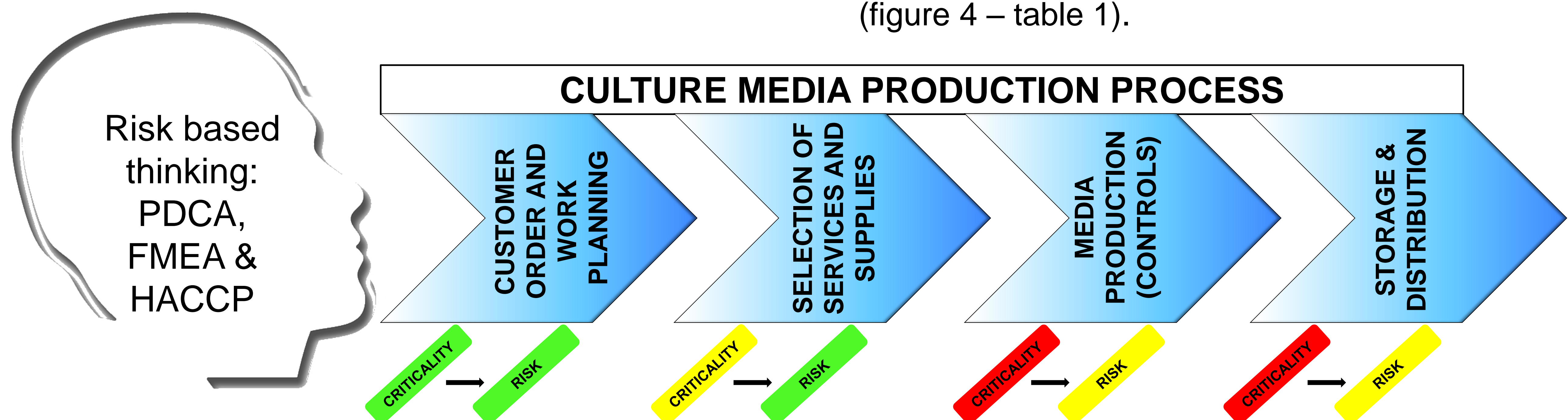
		Detection				
		very low	low	moderate	high	very high
Severity x Occurrence	very high	25	50	75	100	125
	high	20	40 (R7)	60	80	100
	moderate	15	30	45	60 (R6)	75
	low	10	20 (R2)	30 (R3)	40 (R5)	50
	very low	5	10	15	20 (R1)	25 (R4)

*: read table values as "up to"

TABLE 1: FMEA ANALYSIS - EXAMPLES		Criticality	RPN	Priority and Corrective actions
R1	Microbiological contamination of already sterilized media during adding supplements and distribution	4	16	Low - No action (easy to detect)
R2	Poor reagent quality	10	20	Low - No action (not often)
R3	Weighing error	10	30	High - Action: staff recall
R4	Laboratory glassware contaminated with chemical residues	5	25	Moderate - Action: monitoring
R5	Formal labeling errors (eg incorrect batch number)	6	24	Moderate - Action: monitoring
R6	Substantial labeling errors (eg incorrect media identification)	15	60	High - Action: post-production check
R7	Order packaging mistakes	16	32	High - Action: double check



Risk analysis was performed in compliance with ISO 9001:2015 to optimize the application of ISO 11133. The adopted approach was integrated with the HACCP system (Hazard-Analysis and Control of Critical Points). The HACCP allows to transform the quality control approach of the finished product into a quality assurance approach by identifying and controlling the critical points within the process. The FMEA (Failure Mode and Effect Analysis) method was used to identify the specific critical points and risks, and to define the areas which need to be handled with priority. A total of 24 failures were identified and classified in different areas in the criticality matrix (severity x occurrence): 12 green, 10 yellow and 2 red (figure 3). The calculation of RPN (Risk Priority number) (severity x occurrence x detection) allowed the identification of the failures modes involving the highest risk of damage (figure 4 – table 1).



The combined application of PDCA, HACCP and FMEA techniques (the CSP approach) allowed the CSP to define a new management strategy, which provides that, in a process under continuous control, each batch of culture media can be subject to a reduced set of performance testing controls. On the other hand, more stringent controls indicated by the ISO 11133 can be applied to validate the whole production process. The frequency of these controls is constantly re-modulated depending on several parameters, including culture media types, number of non-conformity batches, frequency of media production and the definition of which risks for microbiology laboratory and PTP are related to the non optimal quality of the specific media.

Bibliography

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6. <http://www.creativecommons.it/>