Il percorso verso la costruzione di Norme armonizzate: organizzazione e gestione di studi interlaboratorio

Sandro Spezia - UNICHIM

TECHNICAL SPECIFICATION (TS)

- A Technical Specification is a normative document made available by CEN in the three official languages.
- A Technical Specification is established and approved by a CEN Technical Committee by a weighted vote of CEN National Members.
- This implies that an existing Technical Specification shall be withdrawn if the publication of a subsequent EN brings the Technical Specification into conflict with that EN.

- CEN introduced the Technical Specification to provide an 'appropriate' consensus/transparency solution to a market need where there is no immediate need for national implementation and withdrawal of conflicting national standards.
- A Technical Specification can be transformed into a European Standard (EN) and thus may serve as a CEN 'pre-standard'. The Technical Specification can act as a pre-standard, but it can also be accepted that the 'appropriate consensus' represented by the Technical Specification could continue to meet a market need without eventual conversion into an EN.

A Technical Specification may be established with a view to serving for instance the purpose of:

- publishing aspects of a subject which may support the development and progress of the European market but where a European Standard is not feasible or not yet feasible;
- giving guidance to the market on or by specifications and related test methods;

EUROPEAN STANDARD (EN)

- The European Standard is a normative document made available by CEN in the three official languages, English, French and German.
- The rigour in the development of the EN makes it the ideal deliverable to support European legislative needs, or where the standardization need is focused on protecting health and safety or as support to certification.
  The values that the EN derives from the characteristics of its development process, are:
  - Consensus;
  - Openness;
  - Transparancy;
  - National commitment;
  - Technical coherence.
- **Consensus**: General agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments
- **Openness** (open to all stakeholders): All interested parties have the right to participate in (via national delegations) and contribute to the elaboration of an EN.
  Transparency: At the initiation phase, the project is made public (via announcement in standards bulletins, etc.). Procedures for the preparation of an EN are transparent, unbiased and non-discriminatory.
  The CEN programme of work is available as public information and everybody may react during the obligatory public commenting phase (the CEN enquiry).
  National commitment: Formal adoption of an EN is decided by a weighted majority vote of all CEN National Members and is binding on all of them;
- **Technical coherence**: the European Standards form a collection which ensures continuity and consistency of technical content for the benefit of users, both at European and national levels.

WG3 – ILS programmati

- 1) Plant Biostimulants - Detection of Shigella spp
- 2) Plant Biostimulants - Detection of Staphylococcus aureus

- 3) Plant Biostimulants - Determination of Azospirillum spp.
- 4) Plant Biostimulants - Detection of Listeria monocytogenes
- 5) Plant Biostimulants - Detection of Salmonella spp
- 6) Plant Biostimulants - Determination of Rhizobium spp.
- 7) Plant Biostimulants - Anaerobic plate count

- 8) Plant Biostimulants - Determination of mycorrhizal fungi
- 9) Plant Biostimulants - Determination of the pH
- 10) Plant Biostimulants - Determination of Enterococcaceae
- 11) Plant Biostimulants - Detection of Vibrio spp.
- 12) Plant Biostimulants - Determination of Escherichia coli
- 13) Plant Biostimulants - Determination of Azotobacter spp. fungi
- 14) Plant Biostimulants - Determination of the yeast and mould content

WG4 – ILS programmati

Call no.	Validation of the methods in the standardization project
1	Plant biostimulants – Determination of specifics elements - Part 2: Determination of total content of Cd, Pb, Ni, As, Cr, Cu and Zn) [(a)]
2	Plant biostimulants – Determination of specifics elements - Part 3: Determination of mercury [(a)]
3	Plant biostimulants – Determination of chromium (VI)
4	Plant biostimulants – Determination of dry matter
5	Plant biostimulants – Determination of phosphonates
6	Plant biostimulants – Determination of inorganic arsenic
[(a)] This project includes the digestion according to part 1 Digestion by aqua regia for subsequent determination of elements	

WG5 – ILS necessari

- Plant Biostimulants – Quantity (indicated by mass or volume)

- Plant Biostimulants - Determination of the chloride

Interlaboratory Studies

Specific commercial products

N° ILS – WG and Project name	Type of samples N° of required tests (replicates	N° of required tests (replicates x samples)	Analyses requested to the provider
1-WG3 - Detection of *Shigella* spp	5 SAMPLES (1 blend liquid and 1 blend solid and 3 biostimulant products, 1 liquid (water) e 2 solids (pellet, slow release and substrate)	5 sample (3 rep each)	No presence of the target in the starting material
2-WG3 - Detection of *Staphylococcus aureus*	Same as P #1	5 sample (3 rep each)	No presence of the target in the starting material
3-WG3- Determination of *Azospirillum* spp	5 samples as P#1 (enumeration) + 2 samples (1 pellets and 1 solid blend) (genetic identification)	5 sample (3 rep each) (enum) + 2 (1 rep * 2 samples) (gen id.)	Homogeneity verification (only for enumeration)
4-WG3- Determination of *Listeria*	Same as P #1	5 sample (3 rep each)	No presence of the target in the starting material
5-WG3- Determination of *Salmonella* spp	Same as P #1	5 sample (3 rep each)	No presence of the target in the starting material
6-WG3 - Determination of *Rhizobium* spp	5 samples as P#1 (enumeration) + 2 samples (1 pellets and 1 solid blend) (genetic identification)	5 sample (3 rep each) (enum) + 2 (1 rep * 2 samples) (gen id.)	Homogeneity verification (only for enumeration)
7-WG3 - Determination of the anaerobic plate count	Same as P #1	5 sample (3 rep each)	No presence of the target in the starting material
8-WG3 - Determination of mycorrhizal fungi	5 samples as P#1 (enumeration) + 2 samples (1 pellets and 1 solid blend) (genetic identification)	5 sample (3 rep each) (enum) + 2 (1 rep * 2 samples) (gen id.)	Homogeneity verification (only for enumeration)
9-WG3 - pH in microbial products	Same as P #1	5 sample (3 rep each)	No presence of the target in the starting material
10-WG3 - Determination of Enterococcaceae	Same as P #1	5 sample (3 rep each)	No presence of the target in the starting material
11-WG3 - Detection of *Vibrio* spp	Same as P #1	5 sample (3 rep each)	No presence of the target in the starting material
12-WG3 - Determination of *Escherichia coli*	Same as P #1	5 sample (3 rep each)	No presence of the target in the starting material
13-WG3 - Determination of *Azotobacter* spp	5 samples as P#1 (enumeration) + 2 samples (1 pellets and 1 solid blend) (genetic identification)	5 sample (3 rep each) (enum) + 2 (1 rep * 2 samples) (gen id.)	Homogeneity verification (only for enumeration)
14-WG3 - Determination of the Yeast and Mould content	Same as P #1	5 sample (3 rep each)	No presence of the target in the starting material
Quantity (indicated by mass or volume)	6 packages (weighing) + 3 samples (liquid, thick liquid and very viscous) (density)		Homogeneity verification (only density)
Determination of the chloride	Same as P #1	5 sample (3 rep each)	Homogeneity verification

Interlaboratory Studies

Specific commercial products

CEN/TC 455/WG 5
"Labelling and denominations"

❖ **Quantity (density)**

3 LIQUID PRODUCTS

- Liquid
- Thick liquid
- Very viscous

❖ **Quantity (mass)**

6 SOLID PRODUCTS
(laboratory will have to determine the weight of each one, then will have to send the packages to another laboratory; every 4 laboratories, the packages will be returned to the organizer for an intermediate check).

CEN/TC 455/WG 3
"Pathogenic and non-pathogenic microorganisms"

2 BLEND PRODUCTS:

- Liquid blend (liquid biostimulant + liquid fertilizer)
- Solid blend (solid biostimulant + solid fertilizer)
- (1 solid blend for genotype identification= solid biostimulant + solid fertilizer)

3 BIOSTIMULANT PRODUCTS:

- Liquid
- Pellet
- Growing substrate
- (1 pellet for genotype identification)

ILS Biostimolanti

- Per enumerazione Biostimolanti o ricerca Patogeni per ciascun ILS sono analizzati 5 campioni
  - 3 biostimolanti (2 solidi e 1 liquido)
  - 2 blend (1 solido e 1 liquido)
  - Previsti inoltre 2 campioni aggiuntivi per l'dentificazione genomica delle specie presenti
- Per analisi densità vengono analizzati 3 campioni liquidi a diversa densità
- Per le analisi di massa sono analizzati 6 campioni di masse crescenti tra i 50 g e i 2 kg.

	Working Group di riferimento	Doggetto ILS	Spedizione campioni prevista	Restituzione analisi prevista
1° Gruppo	WG3	**Determination of mycorrhizal fungi**	10 maggio 2022	30/06/22
	WG5	Quantity (mass and Volume)		
2° Gruppo (Le prove del gruppo tutte su "subsrato" Azotobacter)	WG3	**Determination of Azotobacter spp**.	13 - 17 Giugno 2022	25/07/22
	WG3	Detection of Vibrio spp		
	WG3	Determination of Escherichia coli		
	WG3	Determination of the Yeast and Mould content		
3° Gruppo (Le prove del gruppo tutte su "subsrato" Rhizobium)	WG3	**Determination of Rhizobium spp.**	1 - 5 Agosto 2022	15/09/22
	WG3	Detection of Listeria		
	WG3	Detection of Salmonella spp.		
	WG3	Determination of Enterococcaceae		
	WG3	Determination of pH in microbial products		
4° Gruppo (Le prove del gruppo tutte su "subsrato" Azospirillum)	WG3	**Determination of Azospirillum spp.**	12 - 16 Settembre	15/10/22
	WG3	Detection of Shigella spp .		
	WG3	Detection of Staphylococcus aureus		
	WG3	Determination of the anaerobic plate count		
	WG5	Determination of the chloride		

CONFRONTO INTERLABORATORIO
(Inter Laboratory Comparison – ILC)
Organizzazione, esecuzione e valutazione di misurazioni o prove sugli stessi oggetti o su oggetti simili, da parte di due o più laboratori in conformità a condizioni prestabilite.

PROVA VALUTATIVA INTERLABORATORIO
(Profiency testing – PT):
Valutazione delle prestazioni di un partecipante a fronte di criteri prestabiliti mediante confronti interlaboratorio.

ORGANIZZATORE DI PROVE VALUTATIVE INTERLABORATORIO
(Profiency Testing Provider – PTP)
Organizzazione che si assume la responsabilità di tutti i compiti inerenti lo sviluppo e l'esecuzione di uno schema di prove valutative interlaboratorio

RAPPORTO TECNICO

Accuratezza (esattezza e precisione) dei risultati e dei metodi di misurazione

Guida pratica all'utilizzo della ISO 5725-2:1994 nella progettazione, attuazione e analisi statistica dei risultati di prove interlaboratorio di ripetibilità e di riproducibilità

UNI ISO/TR 22971

LUGLIO 2008

Accuracy (trueness and precision) of measurement methods and results

Practical guidance for the use of ISO 5725-2:1994 in designing, implementing and statistically analysing interlaboratory repeatability and reproducibility results

Il rapporto tecnico fornisce agli utilizzatori una guida pratica per l'utilizzo della ISO 5725-2:1994 e presenta procedure semplificate che, passo-passo, portano alla progettazione, attuazione ed analisi statistica di studi interlaboratorio per la valutazione della variabilità di un metodo di misurazione normalizzato e per la determinazione di ripetibilità e riproducibilità dei dati ottenuti in una prova interlaboratorio.

figura 2 **Le responsabilità delle funzioni esecutive**

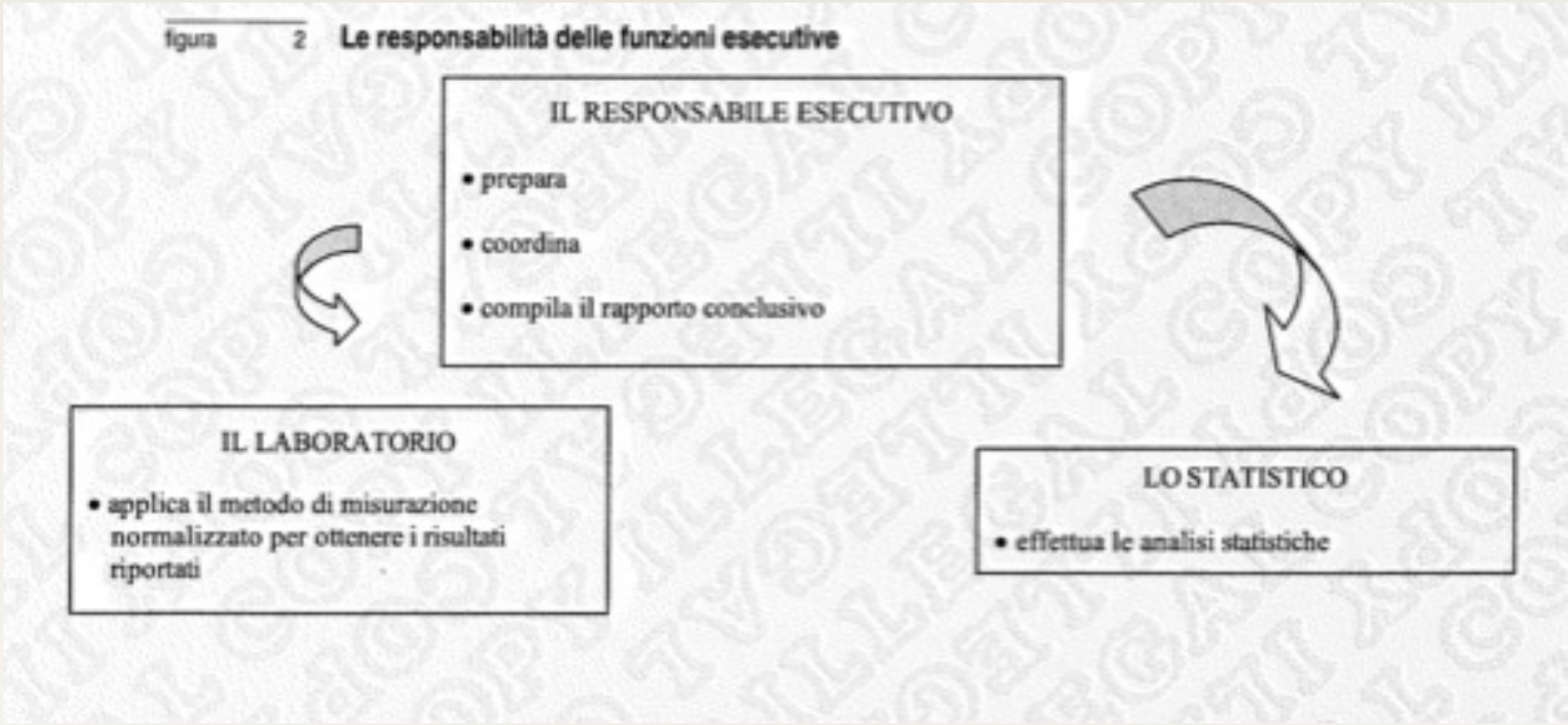

figura 7 **Diagramma di flusso schematico per il trattamento statistico dei dati**