

# ISO 16140-6:2019-11 (E)

## Microbiology of the food chain - Method validation - Part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures

---

<b>Contents</b>		<b>Page</b>
Foreword .....		iv
Introduction .....		v
<b>1</b>	<b>Scope .....</b>	<b>1</b>
<b>2</b>	<b>Normative references .....</b>	<b>1</b>
<b>3</b>	<b>Terms and definitions .....</b>	<b>2</b>
<b>4</b>	<b>General principles for the validation of confirmation and typing methods .....</b>	<b>3</b>
<b>5</b>	<b>Strains .....</b>	<b>4</b>
<b>6</b>	<b>Method comparison study .....</b>	<b>4</b>
6.1	General .....	4
6.2	Selection of test strains .....	4
6.3	Inclusivity study .....	4
6.3.1	Testing of target strains .....	4
6.3.2	Family level (non-Salmonella) .....	5
6.3.3	Genus level (non-Salmonella) .....	5
6.3.4	Species level (non-Salmonella) .....	5
6.3.5	Microbial (sub)type level (non-Salmonella) .....	5
6.3.6	Salmonella genus or species level .....	5
6.3.7	Salmonella serovar level .....	6
6.4	Exclusivity study .....	6
6.4.1	Testing of non-target strains .....	6
6.4.2	Family level (non-Salmonella) .....	6
6.4.3	Genus level (non-Salmonella) .....	6
6.4.4	Species level (non-Salmonella) .....	6
6.4.5	Microbial (sub)type level (non-Salmonella) .....	6
6.4.6	Salmonella genus or species level .....	7
6.4.7	Salmonella serovar level .....	7
6.5	Expression and interpretation of results .....	7
6.6	Evaluation .....	9
<b>7</b>	<b>Interlaboratory study .....</b>	<b>10</b>
7.1	General .....	10
7.2	Data sets to be obtained .....	10
7.3	Protocol .....	11
7.4	Expression of results .....	12
7.5	Interpretation and evaluation .....	12
<b>Annex A (normative)</b>	<b>Points to be considered when selecting strains for testing inclusivity and exclusivity .....</b>	<b>14</b>
<b>Annex B (informative)</b>	<b>Example of the validation of an alternative confirmation method to the species level (<i>Listeria monocytogenes</i>) .....</b>	<b>16</b>

<b>Annex C (informative) Example of the validation of an alternative typing method to the Salmonella serovar level (15 different serovars claimed) .....</b>	<b>19</b>
<b>Annex D (normative) Overview of the various options for validation under this document and the acceptability limits .....</b>	<b>23</b>
<b>Bibliography .....</b>	<b>25</b>