

Delivery address:

Biosafe – Biological Safety Solutions Ltd.

Microkatu 1 M, 70210 Kuopio, Finland

Sample requirements for each test

[See the video clip on our website.](#)

EFSA requirements for sampling vary depending on the test. These instructions are valid primarily for fermentation products, whether solid or liquid (e.g. enzymes, amino acids, vitamins).

<p>Identification (isolation of DNA for whole genome sequencing)</p> <ul style="list-style-type: none"> Viable test strain: two ampoules of freeze-dried cells, agar slant culture OR DMSO/glycerol stock
<p>Antimicrobial susceptibility of the test strain</p> <ul style="list-style-type: none"> Viable test strain: two ampoules of freeze-dried cells, agar slant culture OR DMSO/glycerol stock
<p>Antimicrobial production by the test strain</p> <p>Feed/Novel food:</p> <ul style="list-style-type: none"> Cell-free culture supernatant from three independent batches (20 mL each) Growth medium, as control in the test (20 mL) <p>Food enzyme:</p> <ul style="list-style-type: none"> Enzymes samples from three independent batches (20 ml/g each) Growth medium, as control in the test (20 mL)
<p>Cytotoxicity of the Bacillus test strain (Vero cell assay)</p> <ul style="list-style-type: none"> Viable test strain: two ampoules of freeze-dried cells, agar slant culture OR DMSO/glycerol stock OR cell-free culture supernatant sample from three independent cultures (20 mL each) Growth medium, as control in the test (in both cases) (20 mL)
<p>Absence of the production strain from the product</p> <ul style="list-style-type: none"> Viable production strain, as control: two ampoules of freeze-dried cells, agar slant culture OR DMSO/glycerol stock Samples: At least three samples, taken from a minimum of three independent industrial production batches (altogether at least 9 samples, approximately 100 g or 100 mL each). If these are not available, samples from pilot scale process can be used if the process represents (is similar) to the industrial process. Samples should be taken from the most concentrated intermediate in downstream processing and should not contain carriers or preservatives. <p>NOTE: The same samples can be used to analyse the presence of DNA from the production strain in the product.</p>
<p>Presence of DNA from the production strain in the product</p> <ul style="list-style-type: none"> Viable production strain, as control: two ampoules of freeze-dried cells, agar slant culture <u>OR</u> DMSO/glycerol stock Samples: At least three samples, taken from a minimum of three independent industrial production batches (altogether at least 9 samples, approximately 100 g or 100 mL each). If these are not available, samples from pilot scale process can be used if the process represents (is similar) to the industrial process. Samples should be taken from the most concentrated intermediate in downstream processing and should not contain carriers or preservatives. <p>NOTE: The same samples can be used to analyse the absence of production strain from the product.</p>
<p>Compatibility of the test strain with other authorized additives</p> <ul style="list-style-type: none"> Viable production strain, as control: two ampoules of freeze-dried cells, agar slant culture OR DMSO/glycerol stock
<p>Any other test samples agreed with Biosafe (Test, samples)</p>

NOTE: Viable strains are handled in a strictly confidential manner and will be destroyed after the completion of the analyses (We will store the samples for 3 months after completion of studies).