

**Recommended information to be gathered by food supplement producers for each microorganism used in their products.** This is based on the FSAI Scientific Committee [report](#) on the assessment of the safety of “probiotics” in food supplements.

1. Food supplement product details			
<b>Food supplement product name:</b>			
<b>Date:</b>			
<b>Manufacturer/Distributor:</b>			
2. Identification of the microbial strains			
Identification details for each microbial strain, including genus, species and subspecies, if appropriate.	Microorganism*	Phenotypic identification method	Genotypic identification method
	1		
	2		
	3		
	4		
	5		
	6		
	7		
	8		
	9		
	10		

*\*Add additional rows as appropriate if food supplement contains more than 10 microorganisms*

3. Characterisation of the microbial strains		
<b>(Genus, species and strain designation)</b>		
<b>Strain 1*.</b> _____		
Origin of the strain		
Strain number as given by the internationally recognised culture collection where it is deposited		
	<b>Yes/No</b>	<b>Details</b>
Adverse events associated with consumption of this microbial species or strain		
History of safe use of the microbial strain in food and/or food supplements		
Inclusion of the microbial species on EFSA’s QPS list		
If the strain was not used in food in the EU prior to 15 May 1997, its use has been authorised under the novel food Regulation (EU) 2015/2283		
If the strain was genetically modified, it has been authorised under Regulation (EC) No 1829/2003		

on genetically modified food and feed, and under Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms		
Presence of plasmids, bacteriophage or mobile genetic elements such as insertion sequences, integrons or integrative and conjugative elements		
Antimicrobial susceptibility test results are available for the strain		
Resistance to antimicrobials (see Section 2.1.3) <ul style="list-style-type: none"> <li>Is there a known association between the resistance profile and the presence of resistance genes?</li> <li>List identified acquired (transferable) antimicrobial resistance genes</li> <li>List identified intrinsic antimicrobial resistance genes</li> </ul>		
Encoded virulence factors (see Section 2.1.4)		
Phenotypic evidence of virulence (as relevant) <ul style="list-style-type: none"> <li>Haemolytic activity</li> <li>Toxin production</li> <li>Other virulence factors</li> </ul>		
Biogenic amine production		
Relevant scientific publications related to the microbial strain		

\* For additional strains, please copy "Characterisation of the microbial strains" table

4. Strain manufacturing safety		
Manufacturer(s) of the microbial strains:		
	Yes/No	Details
Microbial cultures are pure		
Microbial cultures are maintained to minimise genetic drift		
Microbial cultures are fully re-characterised at a minimum frequency of annual intervals to monitor for genetic drift		