



Background

Food supplements are subject to the requirements of **EU food legislation**. The microbiological harmlessness of such products is crucial for consumer protection and market confidence. In the absence of binding microbiological limits and considering the highly heterogeneous nature of the product spectrum, manufacturers are being urged to adopt a **proactive, risk-based approach** to quality assurance and to define product-specific safety standards.

Regulatory framework

According to EC Regulations **178/2002**, **852/2004** and **2073/2005**, products may only be placed on the market if they comply with **HACCP principles** and ensure that consumer safety is assured. In the absence of specified limit values, it is advisable to draw up a **risk-based specification** that is oriented to the limits for corresponding dosage forms laid down in the **European Pharmacopoeia (Ph. Eur.)**.

New: Risk-based test packages

PhytoLab provides support for your quality management system in the form of four new test packages that take **two key risk factors** into account:

1. **Dosage form** (dry/liquid/semi-solid) – water activity as an indicator of **microbial growth risk**
2. **Plant constituents** (yes/no) – potentially **expanded germ spectrum** (e.g. *Enterobacteriaceae*)

Overview of test packages

Test package	Dosage form	Plant ingredients	Test parameters
NUTRA Basic Dry	solid	No	TAMC, TYMC, <i>E. coli</i> , <i>Salmonella</i> n. d.
NUTRA Plant Dry	solid	Yes	TAMC, TYMC, <i>Enterobacteriaceae</i> , <i>E. coli</i> , <i>Salmonella</i> n. d.
NUTRA Basic Liquid	liquid/semi-solid	No	TAMC, TYMC, <i>E. coli</i> , <i>Salmonella</i> , <i>L. monocytogenes</i> n. d.
NUTRA Plant Liquid	liquid/semi-solid	Yes	TAMC, TYMC, <i>Enterobacteriaceae</i> , <i>E. coli</i> , <i>Salmonella</i> , <i>L. monocytogenes</i> n. d.

Methodology and evaluation

- Determination of the total bacterial count (TAMC/ TYMC) and detection of specified microorganisms in accordance with **Ph. Eur. methods 2.6.12 and 2.6.13**
- Detection of *Listeria monocytogenes* (test packages 3 & 4) in accordance with **ISO 11290-1**
- Examination in accordance with **Ph. Eur. specifications 5.1.4 and 5.1.8** with transparent representation in the test report

Your benefits at a glance

- Analyses in our **DIN EN ISO/IEC 17025**-accredited laboratory
- Exclusive application of **validated and accredited test methods**
- **Highest quality standards** thanks to Ph. Eur.-based methods and specifications
- Clearly defined, verifiable **evaluation criteria**

Expert advice

We would be happy to help you select customised testing strategies for your products and answer any questions you may have regarding analysis results.

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Sources

Regulations (EC) 178/2002, (EC) 852/2004, (EC) 2073/2005
European Pharmacopoeia Ph. Eur. 11.8 (sections 2.6.12, 2.6.13, 5.1.4, 5.1.8)