

## ANNEX II

The studies referred to in Article 3(2) shall include:

- specifications for physico-chemical characteristics of the product, such as pH,  $a_w$ , salt content, concentration of preservatives and the type of packaging system, taking into account the storage and processing conditions, the possibilities for contamination and the foreseen shelf-life, and
- consultation of available scientific literature and research data regarding the growth and survival characteristics of the micro-organisms of concern.

When necessary on the basis of the abovementioned studies, the food business operator shall conduct additional studies, which may include:

- predictive mathematical modelling established for the food in question, using critical growth or survival factors for the micro-organisms of concern in the product,
- tests to investigate the ability of the appropriately inoculated micro-organism of concern to grow or survive in the product under different reasonably foreseeable storage conditions,
- studies to evaluate the growth or survival of the micro-organisms of concern that may be present in the product during the shelf-life under reasonably foreseeable conditions of distribution, storage and use.

The above mentioned studies shall take into account the inherent variability linked to the product, the micro-organisms in question and the processing and storage conditions.

**Changes to legislation:**

There are currently no known outstanding effects for the Commission Regulation (EC) No 2073/2005, ANNEX II.