



## Methods

### Methodological guide to the assessment of biological safety and security risks

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Laboratory activities using pathogenic micro-organisms or toxins pose potentially significant risks of harm to humans and the environment. ANSES's Committee for the Control of Biological Risks in Laboratories (CMRBL) offers a **general method for identifying hazards and analysing and assessing risks related to the use of micro-organisms and toxins (MOTs)**, as defined by the Decree of 30 June 2010<sup>1</sup>, and in the rules for good practice drawn up by the French National Agency for Medicines and Health Products Safety (ANSM)<sup>2</sup>. This method is derived from the Failure Mode and Effects Analysis (FMEA) method. It is based on a model proposed by the ANSM. However, the method presented in this guide takes into account the particularities of ANSES's reference and research laboratories. The hazard identification questionnaires have been adapted accordingly, as well as the scales for ranking biological safety and security risks. These calculation methods were tested with various pathogens used in ANSES's laboratories and then adjusted before being definitively adopted by the CMRBL.

This guide includes four separate sections:

- Presentation of the risk assessment model
- Presentation of the micro-organism or toxin
- Booklet 1: Analysis of biological safety risks
- Booklet 2: Analysis of biological security risks

**The complete version of the methodological guide is available at the following address:**  
<http://www.ansespro.fr/euroreference/Documents/ER11-MethodologicalGuideEN.pdf>

1. Decree no. 2010-736 of 30 June 2010 on micro-organisms and toxins.

2. Ministerial Order on rules of good practice tending to guarantee biological safety and security mentioned in Art. R.5139-18 of the French Public Health Code.