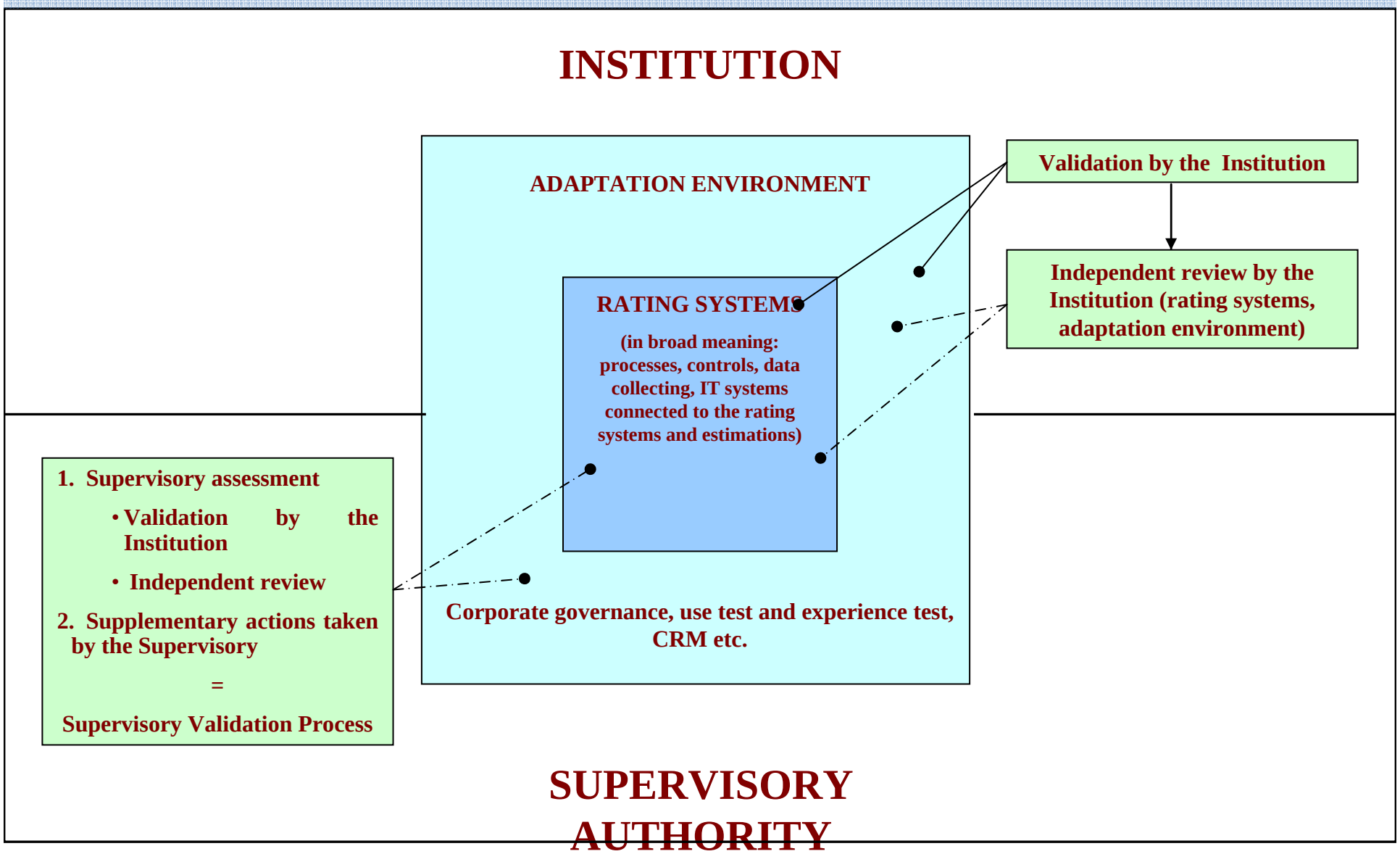Annex 2. The levels of the concept of the validation (IRB)