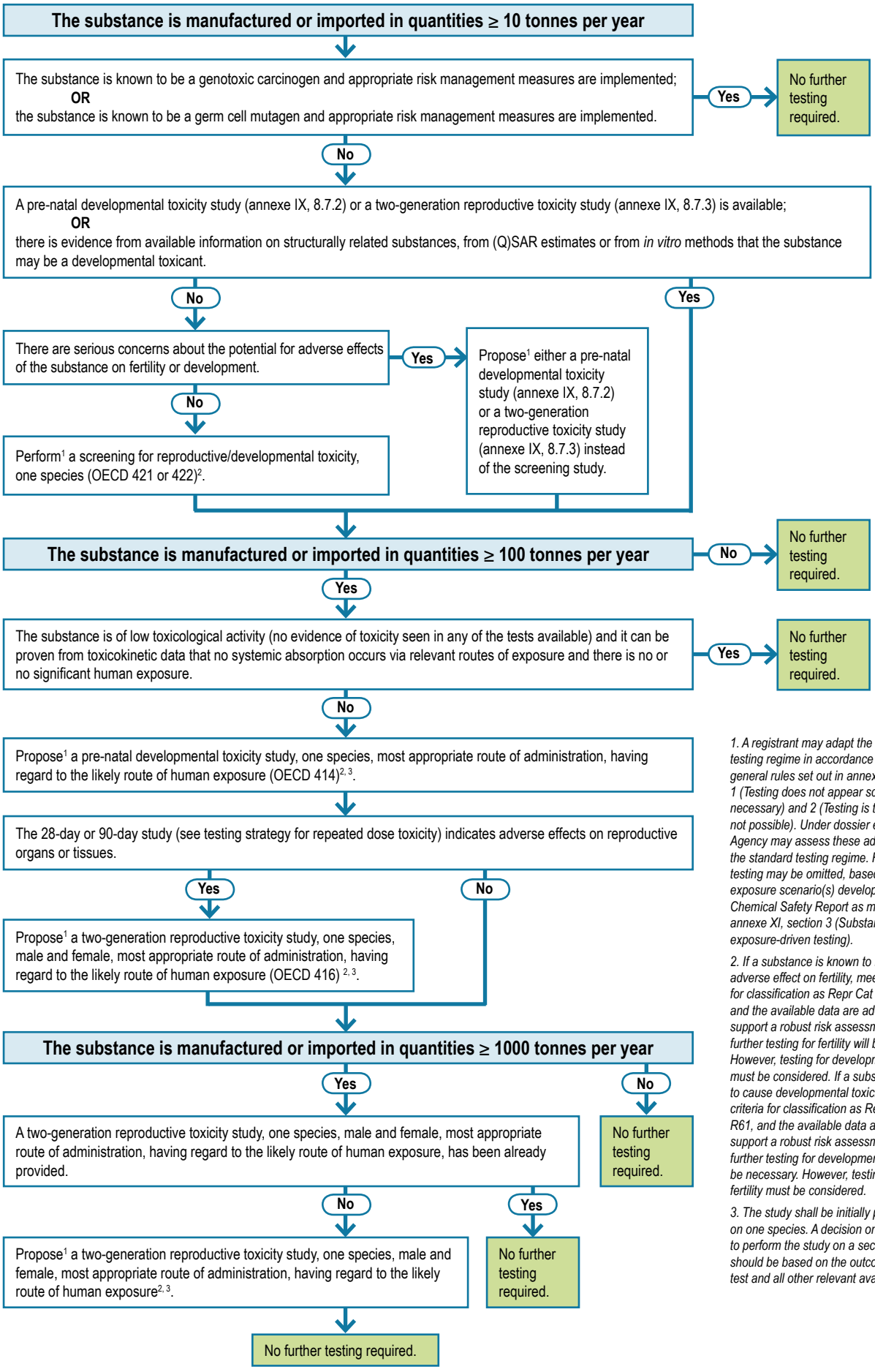
Integrated testing strategy for reproductive toxicity under REACH



1. A registrant may adapt the standard testing regime in accordance with the general rules set out in annexe XI section 1 (Testing does not appear scientifically necessary) and 2 (Testing is technically not possible). Under dossier evaluation the Agency may assess these adaptations to the standard testing regime. Furthermore, testing may be omitted, based on the exposure scenario(s) developed in the Chemical Safety Report as mentioned in annexe XI, section 3 (Substance-tailored exposure-driven testing).

2. If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1 or 2: R60, and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for development toxicity must be considered. If a substance is known to cause developmental toxicity, meeting the criteria for classification as Repr Cat 1 or 2: R61, and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.

3. The study shall be initially performed on one species. A decision on the need to perform the study on a second species should be based on the outcome of the first test and all other relevant available data.

Prévention du risque chimique, France, 2007

REACH Registration, Evaluation, Authorisation of Chemicals