Integrated testing strategy for reproductive toxicity under REACH

1. The substance is manufactured or imported in quantities ≥ 10 tonnes per year
   - The substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented; OR the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented.
   - No further testing required.
   - A pre-natal developmental toxicity study (annexe IX, 8.7.2) or a two-generation reproductive toxicity study (annexe IX, 8.7.3) is available; there is evidence from available information on structurally related substances, from (Q)SAR estimates or from in vitro methods that the substance may be a developmental toxicant.
     - No
     - Yes
   - There are serious concerns about the potential for adverse effects of the substance on fertility or development.
     - No
     - Yes
   - Perform a screening for reproductive/developmental toxicity, one species (OECD 421 or 422).
     - No
     - Yes

2. The substance is manufactured or imported in quantities ≥ 100 tonnes per year
   - Yes
   - No further testing required.
   - No
   - No further testing required.

3. The substance is manufactured or imported in quantities ≥ 1000 tonnes per year
   - Yes
   - No further testing required.
   - No
   - No further testing required.

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 developmental 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.