The substance is manufactured or imported in quantities \( \geq 1000 \) tonnes per year

The substance is classified as mutagen category 1 or 2.

No

The substance is classified as mutagen category 3 or there is evidence from the repeated dose study(ies) that the substance is able to induce hyperplasia and/or pre-neoplastic lesions;

AND

the substance has a widespread dispersive use or there is evidence of frequent or long-term human exposure.

No

No further testing required.

Yes

Propose a carcinogenicity study.

A carcinogenicity test will normally not be required.

The default presumption would be that a genotoxic mechanism for carcinogenicity is likely.

Yes

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No further testing required.

Yes

Propose a carcinogenicity study.

A carcinogenicity test will normally not be required.

The default presumption would be that a genotoxic mechanism for carcinogenicity is likely.

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. These studies may also be required by the Agency.