

Bird & Bird

# Reproductive Toxicity

Legal framework under Regulation 1272/2008 (CLP)

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# Reproductive Toxicity

***Legal basis: Regulation (EC) No 1272/2008 (CLP), Annex I, Section 3.7.***

Reproductive toxicity covers adverse effects on sexual function and fertility in adult males and females; and developmental toxicity in offspring.

## Category 1

Known or presumed human reproductive toxicants

Subdivided into Cat 1A and Cat 1B

## Category 2

Suspected human reproductive toxicants

The essential distinction between Category 1B and Category 2 is therefore the **strength, quality and convincing nature of the evidence**, assessed using the total weight of available evidence.

# Reproductive Toxicity Classification

*The CLP criteria are set out in Annex I, Section 3.7 and Table 3.7.1(a).*

## Category 1B — Presumed human reproductive toxicant

A substance is classified in Category 1B primarily on the basis of **animal data**.

The evidence must:

provide **clear evidence** of an adverse effect on:

- sexual function and fertility; or
- development;

support a **strong presumption** that the substance has the capacity to interfere with reproduction in humans.

Where other toxic effects are present, the reproductive effect must **not be merely a secondary, non-specific consequence** of those other toxic effects.

## Key qualification:

If **mechanistic** or other information raises doubt about whether the observed animal effect is relevant to humans, **Category 2 may be more appropriate**.

**Legal threshold:** clear and convincing animal evidence supporting a strong presumption of human reproductive toxicity.

# Reproductive Toxicity Classification

*The CLP criteria are set out in Annex I, Section 3.7 and Table 3.7.1(a).*

## Category 2 — *Suspected* human reproductive toxicant

Category 2 applies where there is:

**some evidence** from humans or experimental animals of an adverse effect on:

- sexual function and fertility; or
- development;

but the evidence is **not sufficiently convincing to justify Category 1**.

**Category 2** may therefore be appropriate where:

- the available evidence is less convincing;
- studies have methodological deficiencies affecting the weight of evidence;
- results are inconsistent or uncertain;
- mechanistic information creates doubt about **relevance to humans**.

As with Cat 1B, the reproductive effect should not be classified where it is solely a **secondary, non-specific consequence of other toxic effects**.

### Legal threshold:

positive evidence exists, but it does not reach the level required to establish the *strong presumption* necessary for Category 1B.

# Reroductive toxicity

| Issue                      | Category 1B                                                                           | Category 2                                                          |
|----------------------------|---------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| Regulatory description     | <b>Presumed</b> repro-toxicant                                                        | <b>Suspected</b> repro-toxicant                                     |
| Evidential strength        | Clear evidence in animals                                                             | Some doubts<br>(e.g, mechanistic data → different mode of action)   |
| Human relevance            | Strong presumption of relevance                                                       | Greater uncertainty or doubt                                        |
| Effect with other toxicity | Must not be a secondary non-specific consequence                                      | Must not be a secondary non-specific consequence                    |
| Key question               | Does the evidence support a <b>strong presumption</b> of human reproductive toxicity? | Is there evidence, but <b>insufficient evidence for Category 1?</b> |

# EU Courts case law

## Djchem Chemicals Poland and Goodyear v Commission — Case T-174/24 (General Court, 2026)

This is particularly important because the General Court directly addressed the boundary between **Category 1B** and **Category 2** in relation to DAPD.

The Court confirmed that:

- Category 1B does **not require clear evidence directly demonstrating the relevance of the adverse effect in humans**;
- clear evidence from animal studies can be sufficient;
- where other toxic effects are present, the reproductive effect must be shown not to be a merely secondary, non-specific consequence;
- Category 2 may be more appropriate where information casts doubt on the relevance of the observed effects to humans.

**Importance:** The judgment clarifies that the legal threshold for Category 1B is based on a strong presumption derived principally from animal evidence—not proof of actual human reproductive toxicity.

**Appeal:** the DAPD judgment is under appeal, **Case C-275/26 P**,

# EU Court case law

## General Court case law on weight of evidence — Case T-169/24

The Court has also considered the application of the Category 1B criteria in challenges to harmonised CLP classifications, including issues such as:

- the Commission's scientific discretion;
- read-across;
- maternal toxicity;
- manifest error of assessment.

This confirms that classification is a **scientific and legal weight-of-evidence exercise**, subject to judicial review for errors such as manifest error, failure to consider relevant evidence, or breach of the applicable CLP criteria.

# Conclusion

**Category 1B** = “clear evidence” + “strong presumption” of human repro-toxicity

**Category 2** = evidence of concern, but not sufficiently convincing to reach Cat 1

Key issue → **extrapolation to humans**

Decisive legal exercise → **total weight-of-evidence assessment**

EU General Court case law confirms that Cat 1B can rest principally on robust animal evidence **without** requiring **direct proof** of reproductive harm **in humans**.