

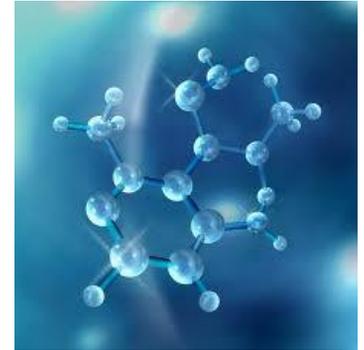
Chemical Application

Background

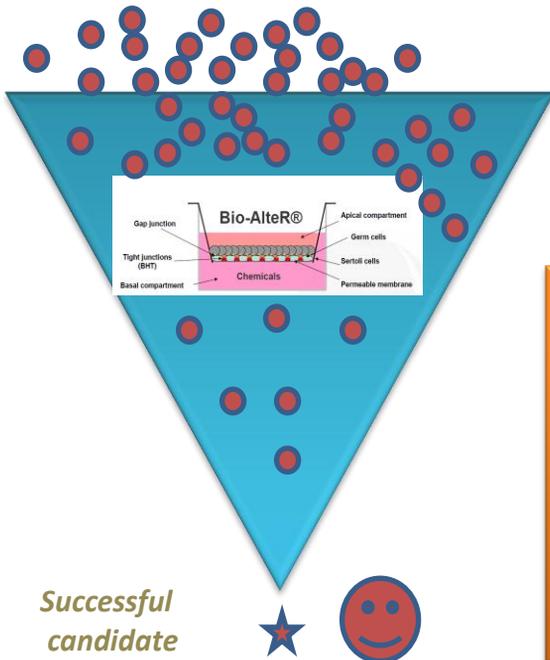
The identification of male fertility toxicants and their mechanisms of action is a major scientific challenge during safety assessment of chemicals. This has been magnified since the establishment of REACH*.

Thorough data profiles for chemicals products are required to support the risk assessment. Regulatory authorities rely on *in vivo* studies to evaluate the impact of these substances on testicular function. These studies are costly, time-consuming, and require a high number of animals to be sacrificed, and do not yield relevant data on the substance's mechanisms of action. *In vitro* alternatives are a cost effective solution, recommended by some authorities to avoid animal testing.

*REACH: Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals. It entered into force on 1st June 2007. It streamlines and improves the former legislative framework on chemicals of the European Union (EU).



FROM A SCREENING PLATFORM....



Successful candidate

Bio-AlteR[®] adult or juvenile model

Blood testis barrier (BTB) integrity
Trans-epithelial resistance (TEER) measurement

✓ Modification of cell number populations
Cell viability and FACS analysis
Specific cell gene expression analysis
(6 different testicular cellular population and BTB components)

✓ Endocrine Disruptor effects
Specific cell gene expression analysis
(hormones & signalling pathway)
✓ Bio-AlteR[®] Sertoli Focus
✓ Sertoli cell culture / Leydig cell culture
(primary cells or cell line)

.....TO A MODE OF ACTION DETERMINATION

Chemical Application

Why is Bio-AlteR® the solution to your testicular toxicity issues ?

- Bio-AlteR® is a **3D cell based assay unique on the market.**
- Bio-AlteR® allows you to **assess, anticipate and address potential testicular toxicity issues due to xenobiotics.**
- Bio-AlteR® provides **reliable safety data on male fertility, relevant to effects on humans.**
- Bio-AlteR® allows substance testing at **«physio-toxicological» concentrations.**
- Bio-AlteR® is a **medium throughput assay** allowing the testicular toxicity screening of a large number of compounds, (8 weeks in average between the compound reception and the data report sending).
- Bio-AlteR® provides a deep understanding of the **mechanisms of toxicity in male fertility.**
- Bio-AlteR® **dramatically reduces the use of animals** (from 20 to 30 times).
- Bio-AlteR® is a **cost effective** solution for reprotox studies during the REACH Process.