



One-stop service - world-class, worldwide

Endocrine Disruptor Assessments

Helping you fulfil the global regulatory requirements for assessment of potential endocrine disrupting substances.

An emerging area of concern, with impact on human and environmental health, is endocrine disruption, the potential for chemical substances and mixtures to affect the endocrine systems of mammalian, vertebrate and invertebrate species.

The effects of certain substances and compounds which disrupt the actions of naturally occurring hormones have become a central point of focus for the scientific community and an area of concern for the wider public. Globally, endocrine disruptors are being tackled by authorities all over the world - discussions are taking place to establish the policies that will regulate the future of ED testing.

In recent years the potential impact of endocrine disruptors has been increasingly regulated on a global scale with a variety of legislative implementations such as one of the first extensive endocrine screening programs, namely the US Endocrine Disruptor Screening Program (EDSP), with specific regulatory triggers highlighted in the Food Quality Protection Act (FQPA) in 1996.

More recently European legislation has come into force which specifically mandates that potential disruption of mammalian and non-mammalian endocrine systems need to be considered.

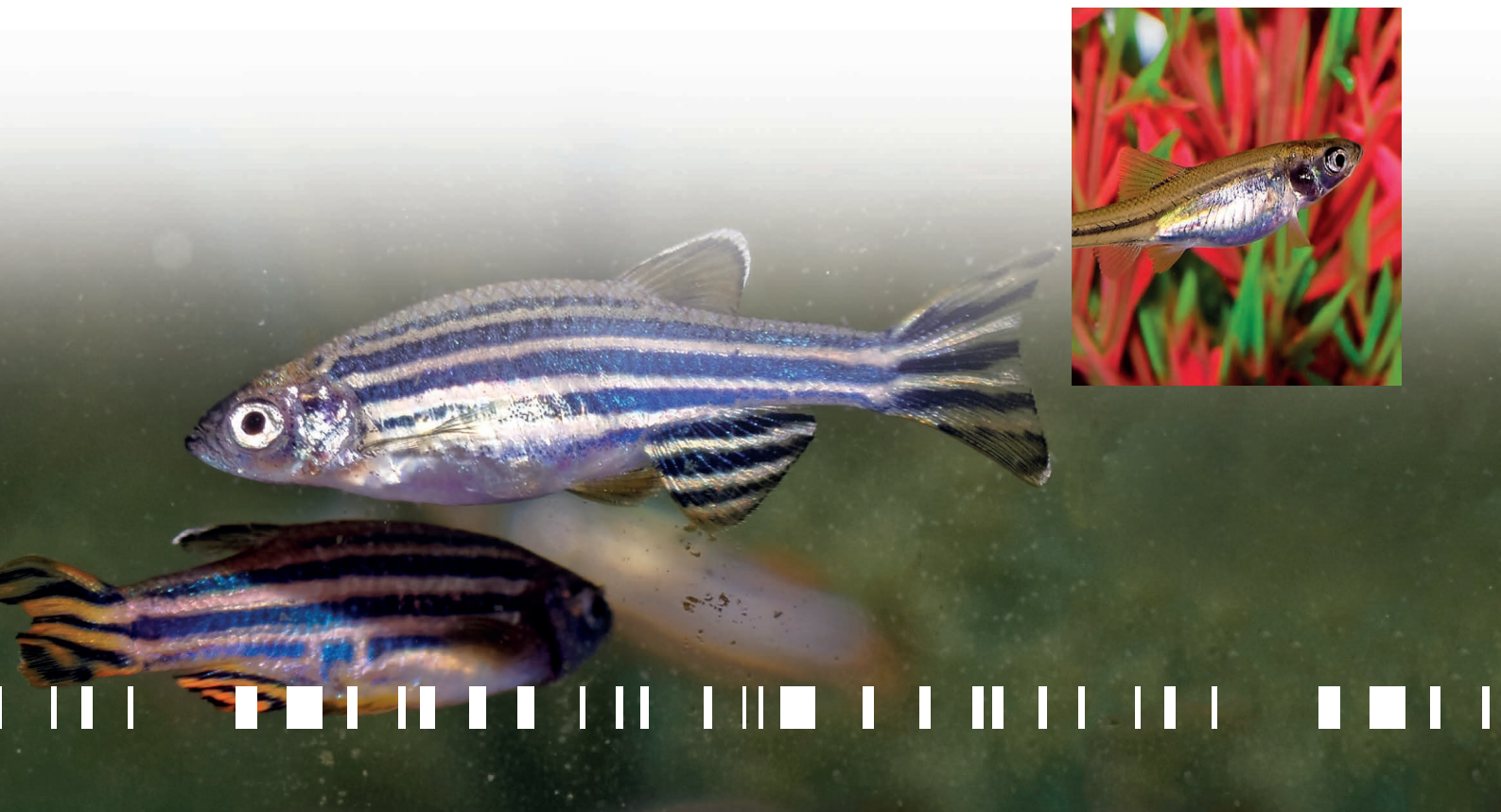
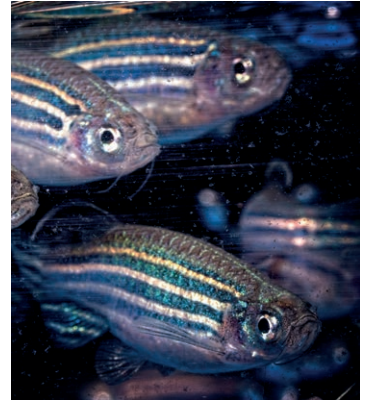
In response to these concerns, we have been at the forefront of developing specific tests to address the questions that concern the chemical industry, government and non-government organisations and the wider public; we are the go-to Contract Research Organisation for complex multigenerational and long term studies with vertebrates and invertebrates.

We are ready to support your risk assessment, performing endocrine testing to characterize the endocrine effects of your product

Our offer

Eurofins Regulatory Science Services is in full compliance with the latest OECD guidelines, and we offer every type of endocrine disruption study from physical chemical data to *in-vitro* testing through to complex multi-generational and long term studies with vertebrates and invertebrates.

With a network of laboratories across the globe, we have a team of experts ready to confirm and characterize the endocrine effects of your product.



Studies Offered

Tests on Endocrine Disruption - in vitro (OECD CF Level 2)

- Androgen receptor binding assay (OPPTS 890.1150)
- Estrogen receptor binding assay (OECD 493 OPPTS 890.1250)
- Estrogen receptor transcriptional activation assay (OPPTS 890.1300, OECD 455)
- Steroidogenesis assay (OPPTS 890.1550, OECD 456)
- Aromatase assay (OPPTS 890.1200)
- Thyroid disruption assays (e.g. thyroperoxidase inhibition, transthyretin binding)
- Retinoid receptor transactivation assays
- Other hormone receptors assays as appropriate
- High-Throughput Screens

Tests on Endocrine Disruption - (OECD CF Level 3)

- Hershberger bioassay, rat (OECD 441, OPPTS 890.1400)
- Uterotrophic bioassay, rat (OECD 440, OPPTS 890.1600)
- Amphibian metamorphosis assay (AMA) (OECD TG 231)
- Fish short-term reproduction assay (FSTRA) (OECD TG 229)(b)
- 21-day fish assay (OECD TG 230)
- Androgenised female stickleback screen (AFSS) (GD 148) Under development
- EASZY assay - Detection of Endocrine Active Substances, acting through estrogen receptors, using transgenic tg (cyp19a1b:GFP) Zebra-fish embryo's (OECD TG 250)
- Xenopus Eleutheroembryonic Thyroid Assay (XETA) OECD TG 248
- Juvenile Medaka Anti-Androgen Screening Assay (JMASA) (draft OECD GD)
- Short-Term Juvenile Hormone Activity Screening Assay Using *Daphnia magna* (draft OECD TG)
- Rapid Androgen Disruption Adverse Outcome Reporter (RADAR) Assay (draft OECD TG)

Tests on Endocrine Disruption - assays providing ED related adverse effects data (OECD CF Level 4)

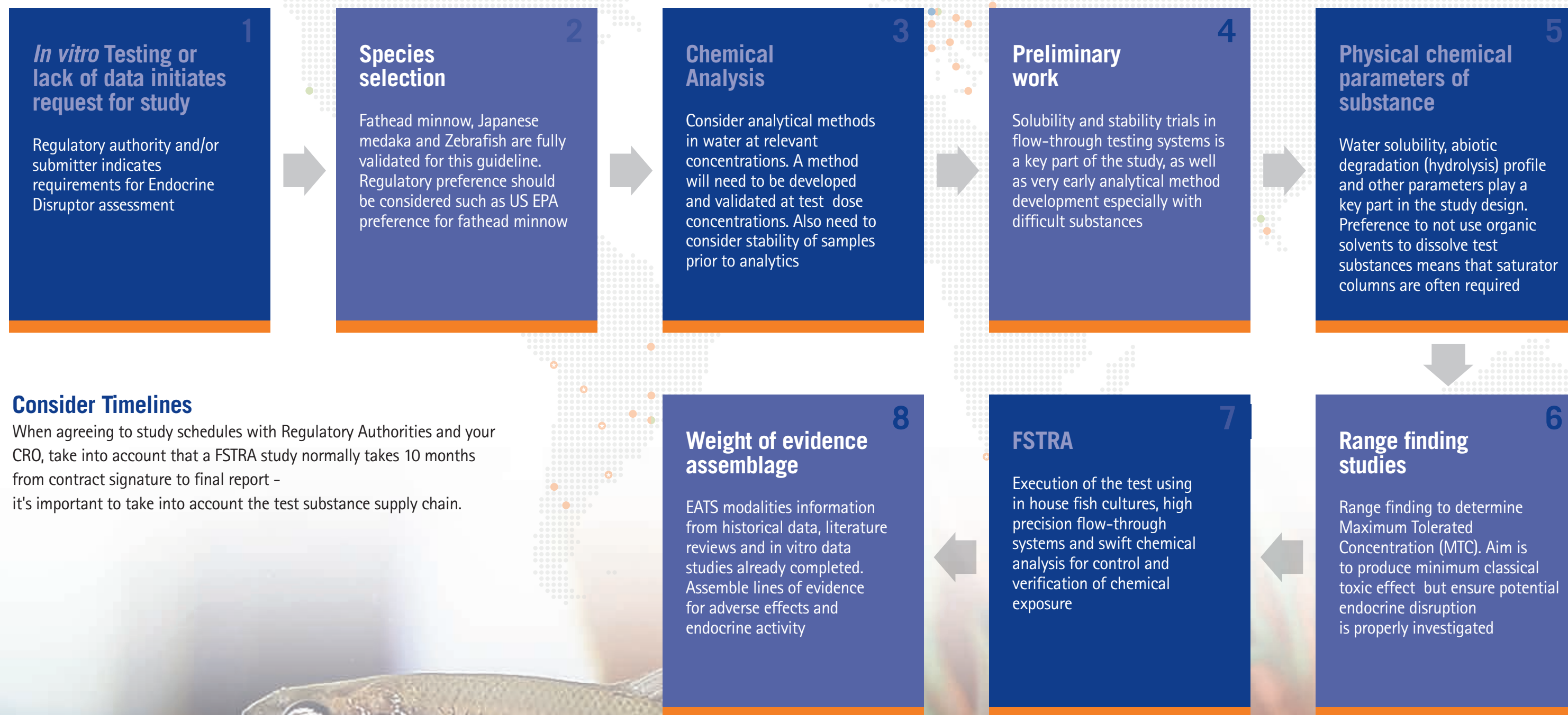
- Pubertal development and thyroid function in female rat (OPPTS 890.1450)
- Pubertal development and thyroid function in male rat (OPPTS 890.1500)
- Repeated dose 28-day (OECD 407) and 90 day studies (OECD 408)
- Prenatal developmental toxicity study (OECD TG 414)

- Combined chronic toxicity and carcinogenicity studies (OECD TG 451-3)
- Reproduction/developmental toxicity screening test (OECD TG 421)
- Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD TG 422)
- Developmental neurotoxicity study (OECD TG 426)
- Subchronic dermal toxicity: 90-day study (OECD TG 411)
- Fish sexual development test (FSDT) (OECD TG 234)
- Larval amphibian growth & development assay (LAGDA) (OECD TG 241)
- Avian reproduction test (OECD TG 206)
- Fish early life stage (ELS) toxicity test (OECD TG 210)
- New guidance document on harpacticoid copepod development and reproduction test with *Amphiascus* (OECD GD 201)
- *Potamopyrgus antipodarum* reproduction test (OECD TG 242) Not currently offered
- *Lymnaea stagnalis* reproduction test (OECD TG 243)
- Chironomid toxicity test (OECD TG 218-219)(d)
- *Daphnia magna* reproduction test (with male induction) (OECD TG 211)
- Earthworm reproduction test (OECD TG 222)
- Enchytraeid reproduction test (OECD TG 220)(d)
- Sediment water *Lumbriculus* toxicity test using spiked sediment (OECD TG 225)
- Predatory mite reproduction test in soil (OECD TG 226)
- Collembolan reproduction test in soil (TG OECD 232)(d)

Tests on Endocrine Disruption – in vivo assays providing comprehensive data on ED endpoints over more extensive life cycle of the organism (OECD CF Level 5)

- Extended one-generation reproductive toxicity study (EOGRTS) (OECD TG 443)
- 2-Generation reproduction toxicity study (OECD TG 416)
- Fish lifecycle toxicity test (FLCTT) (US EPA TG OPPTS 850.1500)
- Medaka extended one-generation reproduction test (MEOGRT) (OECD TG 240)
- Avian Two-generation toxicity test in the Japanese quail (ATGT) (US EPA TG OCSPP 890.2100/740-C-15-003)
- Sediment water chironomid life cycle toxicity test (OECD TG 233)
- *Daphnia* multigeneration test for assessment of endocrine disrupting chemicals (draft OECD TG)
- Zebrafish extended one-generation reproduction test (ZEOGRT) (draft OECD TG)

Example testing strategy and considerations - Fish Short Term Reproduction Assay - OECD 229



Consider Timelines

When agreeing to study schedules with Regulatory Authorities and your CRO, take into account that a FSTRA study normally takes 10 months from contract signature to final report - it's important to take into account the test substance supply chain.



**Proven
track
record**

- Decades of experience in performing simple and complex physical chemistry, biodegradation, toxicology and ecotoxicological testing
- Established relationships with regulatory bodies

**State of
the art
equipment**

- Custom designed state of the art apparatus and equipment
- Unparalleled analytical support
- Modern laboratories equipped to the highest standards

**Study
design**

- Excellent experience in consideration of difficult test substances (UVCBs)
- Customized study designs
- Understand ECHA decisions and will design studies to specifically answer request

**Cost
effective**

- Consideration of reduction of vertebrate testing inherent in our approach