

Aquatic

UPDATE OF THE TEST GUIDELINES

- OECD 209: Activated Sludge, Respiration Inhibition Test (Carbon and Ammonium Oxidation)
- OECD 210: Fish, Early-life Stage Toxicity Test
- OECD 211: Daphnia magna Reproduction Test

The following guidelines, directly relevant for REACH registration dossiers, have been updated improving different elements. The new updated guidelines represent a scientific enhancement and are directly relevant for addressing the REACH information requirements within the scope mentioned in the ECHA guidance documents for the previous versions:

NEWLY ADOPTED TEST GUIDELINES

OECD 236: Fish Embryo Acute Toxicity test (FET)

Title of the test guideline and the year of approval: OECD 236: Fish Embryo Acute Toxicity (FET) test, 2013

Keywords: acute fish toxicity, fish embryo toxicity, animal alternatives

Link to the OECD site: http://www.oecd-ilibrary.org/environment/test-no-236-fish-embryo-acute-toxicity-fet-test_9789264203709-en

How to use this method under REACH:

The short-term toxicity test on fish is a standard information requirement under Annex VIII, 9.1.3. In ECHA's opinion, the results of the TG 236 would usually not be sufficient alone to meet the information requirement of Annex VIII, 9.1.3.

In the light of the analysis made by ECHA, there are certain limitations in the use of this test guideline and the registrant, who wants to adapt/waive the standard test needs to take these limitations into account.

Based on current knowledge, ECHA considers that OECD TG 236 might be used within a weight of evidence approach together with other independent, adequate, relevant and reliable sources of information leading to the conclusion that the substance has or does not have a particular dangerous property (for further information see Annex XI, 1.2 to the REACH Regulation and the considerations below).

As there is an OECD *ad hoc* group working to address the use of TG 236 within the aquatic testing strategy, registrants are encouraged to follow that activity as well as the updates to this ECHA web page in regard to the potential for adaptation.

The specific scope and limitations of the test

The OECD test guideline 236 describes a Fish Embryo Acute Toxicity (FET) test with the zebrafish (*Danio rerio*).

In the OECD 236, the newly fertilised zebrafish eggs are exposed to the test chemical for a period of 96 hours. Every 24 hours, up to four apical observations are recorded as indicators of lethality:

1. coagulation of fertilised eggs,
2. lack of somite formation,
3. lack of detachment of the tail-bud from the yolk sac, and
4. lack of heartbeat.

At the end of the exposure period, acute toxicity is determined based on a positive outcome in any of the four apical observations recorded, and the LC50 is calculated.

In 2015, ECHA commissioned a study entitled: “Analysis of the relevance and adequateness of using Fish Embryo Acute Toxicity test (FET) Test Guideline (OECD 236) to fulfil the information requirements and addressing concerns under REACH”.

The project aimed to gather and analyse publicly available data on fish embryo toxicity (FET), comparing it with available data on standard acute fish toxicity (AFT), and setting up the parameters defining the applicability domain and limitations of a FET test in comparison to AFT. The analysis focused mainly on chemical structure, mode of action and several key physico-chemical characteristics of tested compounds (e.g. solubility, lipophilicity).

The conclusions of the scientific analysis performed within ECHA's project are available in the report prepared by the consultant at: <http://echa.europa.eu/publications/technical-scientific-reports>

The results of ECHA's project will also contribute to other, currently ongoing international projects at the OECD level related to the regulatory application of this new OECD TG 236.