

# Test ecotossicologici per la classificazione HP14:

*Approccio CLP*

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# Council Regulation (EU) 2017/997 - HP 14 «Ecotoxic»

COUNCIL REGULATION (EU) 2017/997

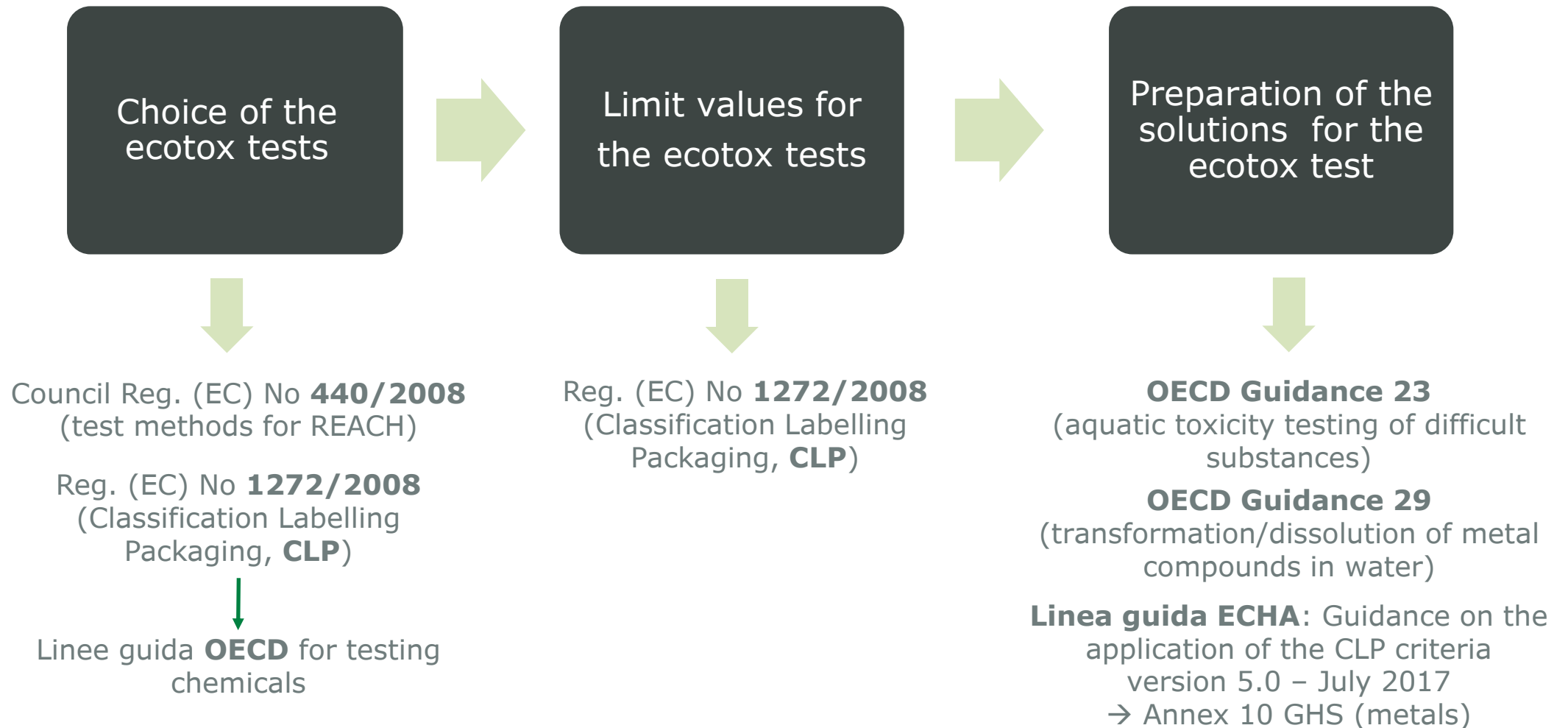
of 8 June 2017

amending Annex III to Directive 2008/98/EC of the European Parliament and of the Council as regards the hazardous property HP 14 'Ecotoxic'

- (8) When a test is performed to assess waste for the hazardous property HP 14 'Ecotoxic', it is appropriate to apply the relevant methods established in Commission Regulation (EC) No 440/2008 <sup>(2)</sup> or other internationally recognised test methods and guidelines. Decision 2000/532/EC provides that, where a hazardous property of waste has been assessed by a test and by using the concentrations of hazardous substances as indicated in Annex III to Directive 2008/98/EC, the results of the test are to prevail. Furthermore, Article 12 of Regulation (EC) No 1272/2008, in particular Article 12(b) and the methodologies for its application, should be taken into account. It is appropriate for the Commission to promote the exchange of best practices with regard to test methods for the assessment of substances as concerns the hazardous property HP 14 'Ecotoxic' with a view to their possible harmonisation.

# Ecotoxicological tests for HP14 classification

*Identification of tests, limits and procedures for test solution preparation*



# Delibera n° 61/2019 del Consiglio SNPA

LINEA GUIDA SULLA CLASSIFICAZIONE DEI RIFIUTI

*Capitolo 4.14 – HP14 «Ecotossico»*

- Calculation method (concentrazione sostanze pericolose)
- Metodi di prova

Ferma restando la necessità di sviluppare metodologie specifiche per la matrice di rifiuto, i test stabiliti dal regolamento 2008/440/CE rappresentano ad oggi il riferimento espressamente richiamato dalla decisione 2000/532/CE e dal regolamento 2017/997/EU e, pertanto, la loro applicazione è senz'altro conforme al dettato normativo.

# Choice of Ecotox tests

Council Reg. (EC) No 440/2008 (REACH)/Reg. (EC) No 1272/2008 (CLP)

## Acute tests

- 1) OECD Test Guideline **201** (Fresh **Alga** and Cyanobacteria, Growth Inhibition Test)
- 2) OECD Test Guideline **202** (**Daphnia** sp. Acute Immobilization Test)
- 3) OECD Test Guideline **203** (**Fish**, Acute Toxicity Test)

## Chronic tests

- 1) OECD Test Guideline **201** (Fresh **Alga** and Cyanobacteria, Growth Inhibition Test)
- 2) OECD Test Guideline **211** (**Daphnia magna** Reproduction Test)
- 3) Chronic tests on fish to be avoided (vertebrates)

These species are considered as surrogate for all aquatic organisms.  
The aquatic plant growth inhibition tests are normally considered as chronic tests but the EC<sub>50</sub>s are treated as acute values for classification purposes.

# OECD Guidance Document N° 23

Aquatic toxicity testing of difficult substances



Organisation for Economic Co-operation and Development

**ENV/JM/MONO(2000)6/REV1**

**Unclassified**

**English - Or. English**

8 February 2019

**ENVIRONMENT DIRECTORATE**

**JOINT MEETING OF THE CHEMICALS COMMITTEE AND THE WORKING PARTY  
ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY**

**GUIDANCE DOCUMENT ON AQUEOUS-PHASE AQUATIC TOXICITY  
TESTING OF DIFFICULT TEST CHEMICALS**

**SERIES ON TESTING AND ASSESSMENT**

**No. 23 (Second Edition)**

# OECD Guidance Document N° 23

- Poorly/sparingly water-soluble test chemicals
- Metal compounds
- Multi-component substances

30. It should be noted that OECD Guidance Document 29 (OECD, 2002) and 98 (OECD, 2008) provide considerations regarding transformation/dissolution of metals and metal compounds in aqueous media and may assist to determine the test solution preparation procedure and hazard assessment of metals and metal compounds. In addition, it may be relevant to consider the same methodology for classification of poorly soluble test chemicals that are known to transform gradually (e.g. via hydrolysis) to substances of higher concern (e.g. as a supplement or alternative to tests based on water-accommodated fractions [WAFs]).

# OECD Guidance Document N° 29

## Guidance Document on Transformation/Dissolution of Metals and Metal Compounds in Aqueous Media

1. This Test Guidance is designed to determine the rate and extent to which metals and sparingly soluble metal compounds can produce soluble available ionic and other metal-bearing species in aqueous media under a set of standard laboratory conditions representative of those generally occurring in the environment. Once determined, this information can be used to evaluate the short term and long term aquatic toxicity of the metal or sparingly soluble metal compound from which the soluble species came. This Test Guidance is the outcome of an international effort under the OECD to develop an approach for the toxicity testing and data interpretation of metals and sparingly soluble inorganic metal compounds (SSIMs) [ref to Ottawa workshop (1) and to Chapter 7 of the Guidance document]. As a result of recent meetings and discussions [references 1,2,3,4 + Chapter 7] held within the OECD and EU, the experimental work on several metals and metal compounds upon which this Test Guidance is based has been conducted and reported [references 5 to 11].



# Preparation of test solutions (1/2)

Poorly/sparingly water-soluble test chemicals



**Direct addition** (stirring → phase separation)

Multi-component substances



Preparing water-accommodated fractions (**WAF**<sup>1</sup>), no dilution

Containing metals



OECD Guidance Document 29 (2002) and 98 (2008) provide considerations regarding **transformation/dissolution of metals and metal compounds** in aqueous media and may assist to determine the test solution preparation procedure.

Annex 10 of the UN GHS → transformation/dissolution protocol

<sup>1</sup>**WAF** = aqueous test solution containing only the fraction of a multi-component substance that is dissolved and/or present as a stable dispersion. A WAF can contain multiple dissolved components whose proportions depend on individual water solubility and the mass-to-volume ratio of the preparation.

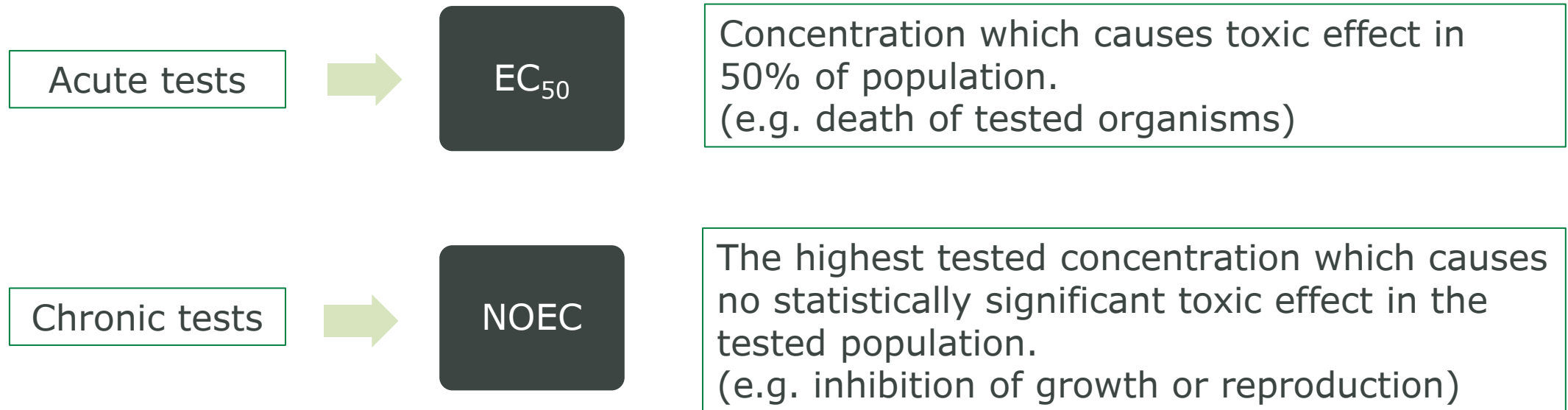
# Preparation of test solutions (2/2)

Characteristics	Method OECD 23 (WAF) and OECD 29
Waste Granulometry	≤1 mm
Medium	As required by each Ecotox test
pH medium	As required by each Ecotox test
Test concentrations	Prepared individually by direct addition (no dilution)
Shaking	Orbital shaker
Shaking Temperature	20 - 23°C
Dissolution time	7 days
Separation Liquid/Solid	1 day of settling, then aqueous phase drawn off
	No filtration
pH Correction	No

Method set up with Arpa Lombardia (Italian Regional Authority)

# Limit values

Reg. (EC) No 1272/2008 (CLP)



**EC<sub>50</sub>** = Effect Concentration 50%  
**NOEC** = No Observed Effect Concentration

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