Kiel, 9. März 2015, AK RegTox

Advanced Course / Workshop

Anforderungen an die Toxikologie unter REACH – Theorie und Praxis

des Arbeitskreises „Regulatorische Toxikologie“
in der Gesellschaft für Toxikologie

Klaus Schneider

FoBiG, Forschungs- und Beratungsinstitut Gefahrstoffe GmbH

Freiburg, www.fobig.de

FoBiG
Forschungs- und Beratungsinstitut
Gefahrstoffe GmbH

Agenda

Thema	Referent
Begrüßung, Einführung	W. Aulmann/AK Regulatorische Toxikologie, Düsseldorf und K. Schneider, FoBiG, Freiburg
REACH-Anforderungen, ECHA-Prüfungspraxis, Beispiele	U. Reuter/ECHA, Helsinki
Mittagspause 12:45 – 13:45 Uhr	
Zwei Beispiele zur Bewertung von «Read-across» durch ECHA: Ablehnung und indirekte Akzeptanz	W. Teubner/BASF Schweiz AG, Basel
Erfahrungen bei alternativen DNEL-Ableitungen und Read-Across/Kategorie-Approach	D. Beyer/Bayer Health Care, Wuppertal
Kaffeepause 15:00 – 15:15	
Waiving von Datenanforderungen und Optionen zum Daten-Waiving bei Bioziden – Gegenbeispiele zu REACh aus der Praxis	M. Werner/SCC GmbH
Abschlussdiskussion und Round-table discussion von Fallbeispielen aus dem Auditorium	alle

Anhängige Appeal cases

Endpunkte / Art des Disputs	Ausgangspunkt
Developmental neurotoxicity study / scientifical justification	Substance eval.
Prenatal developm study (first species) / read-across	Dossier eval.
Scope of exposure assessment – environmental assessment	Dossier eval.
Prenatal developm study (first species) / weight-of-evidence	Dossier eval.
Prenatal developm study (second species) / read-across	Dossier eval.
Dermal absorption study / 28 day inhalation study / exposure assessment / scientific justification	Substance eval.
Extended one generation reprotox study / proportionality	Substance eval.
Extended one generation reprotox study / consideration of results from studies provided by other registrants	Testing proposal

Schwerpunkte in Dossierbewertungen (eigene Projekte)

- OECD 414, zweite Spezies
- Ames-Test, 5. Stamm (E.coli oder TA 102)
- (Arbeitsplatzgrenzwerte kein DNEL-Ersatz)
- (Adsorptions-/Desorptionsstudie: leichter Bioabbau kein Waiving-Grund)
- (Genauere Begründung von Expositionsparametern)

Annex IX

COLUMN 1 STANDARD INFORMATION REQUIRED		COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1	
8.7.2.	Pre-natal developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure (B.31 of the Commission Regulation on test methods as specified in Article 13(3) or OECD 414).	8.7.2.	The study shall be initially performed on one species. A decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant available data.

Annex X

8.7.2.	Developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure (OECD 414).

ECHA Guidance on IR and CSAR, R.7a

Table R.7.6-1. Summary of standard information requirements for reproductive toxicity in REACH.

Study	Annex VII	Annex VIII	Annex IX	Annex X
Screening test for reproductive /developmental toxicity (OECD TG 421 or 422)		Required	Strongly recommended if no higher tier fertility study (such as OECD 443) is/will be available	
Prenatal developmental toxicity study (EU B.31, OECD TG 414)		May be proposed in case of (serious) concern[1] for prenatal developmental toxicity. However, it is strongly recommended to consider conducting a screening study in addition to the prenatal developmental toxicity[2] study	Required in one species; second species may be triggered[2]	Required in two species
Extended one-generation reproductive toxicity study (EU B.56, OECD TG 443)[3]		Recommended instead of the screening study in case of serious concern[1] for fertility	Required if triggered[4]	Required

Thank you for your attention!

FoBiG
Forschungs- und Beratungsinstitut
Gefahrstoffe GmbH