

6th ESTP International Expert Workshop
"Adversity of thyroid follicular cell hypertrophy/hyperplasia (TFCH/H), differentiation between direct and indirect mechanisms and their implication for risk assessment"

WEDNESDAY 16th May 2018

13.00 - 13.30

Sandwich lunch and coffee

13.30 - 13.45

Welcome, introduction, organizational information

1st session: Principles of pathophysiology of the thyroid gland

13.50 - 14.00

Xavier Palazzi

10'

Adversity in toxicologic pathology - rules of the game

14.00 - 14.20

Tom Rosol

20'

Basic mechanisms of thyroid toxicity in laboratory animals

14.20 - 14.50

Josef Köhrle

30'

Basic mechanisms of thyroid toxicity in humans

14.50 - 15.10

all

20'

Questions regarding the principles of pathophysiology across species

15.10 - 15.30

Coffee break

2nd session: Modes of action of thyroid toxicants and their implication for adversity assessment

15.30 - 15.40

Stephanie Melching-Kollmuss

10'

Basics of rat-specific indirect thyroid toxicity effects

15.40 - 15.50

Taki Harada

10'

Mechanistic studies on thyroid tumor induction by agrochemicals in rats

15.50 - 16.00

Isabelle Damiani

10'

Mechanistic investigation of liver-mediated thyroid toxicity: Phenobarbital-like MoA

16.00 - 16.10

Josef Köhrle

10'

Role of TSH in thyroid neoplasia

16.10 - 16.20

Sue Marty

10'

Thyroid Evaluations in the Extended One-Generation Study: Lessons from Two Case Studies

16.20 - 16.40

all

20'

Questions regarding the examples presented today

16.40 - 18.00

80'

Expert discussion: Basic requirements for an adversity call of thyroid gland lesions in lab animals

THURSDAY 17th May 2018

3rd session: Case examples of TFCH/H and adversity decision

9.00 - 9.10

Hetty van den Brink

10'

Adversity call in OECD 421/422 Studies with Changes in Thyroid Gland Parameters – Case Examples

9.10 - 9.20

Barbara Lenz

10'

A case of thyroid follicular cell hypertrophy in the dog

9.20 - 9.30

Lise Bertrand

10'

Toxicity of an iodinated compound in rodents and dogs

9.30 - 9.40

Ronnie Chamanza

10'

Thyroid and pituitary hypertrophy secondary to thyroid hormone metabolism and TSH increase in the dog. Is the dog more similar to the rat?

9.40-10.30

all

50'

Questions regarding the examples presented today

10.30 - 10.45

Coffee break

3rd session (continued)

10.45 - 10.55

Maïke Huisinga

10'

Thyroid gland pathology, the relation of histopathological findings to weight changes and hormonal changes in BASF rat studies

10.55 - 11.05

Volker Strauss

10'

Thyroid hormone measurement in pups and adult rats of regulatory OECD TG studies

11.05 - 11.15

Hans Harleman

10'

Interpretation of thyroid changes and assumptions made on developability

11.15 - 12.30

75'

Expert discussion: what are the challenges understanding modes of action in the thyroid gland? How do we factor that in the adversity call?

12.30 - 13.45

Sandwich lunch and coffee

4th session: Regulatory considerations and risk assessment of TFCH/H

13.45 - 13.55

Charles Wood

10'

Regulatory issues for TFCH/H at the U.S. EPA

13.55 - 14.05

Sabine Francke (webinar)

10'

Regulatory considerations at US FDA for TFCH/H

14.05 - 14.15

Midori Yoshida

10'

Regulatory considerations and toxicological evaluation of TFCH/H. Specifications of the Japanese approach through secondary effects of 4HPPD inhibitors on thyroid

14.15 - 14.25

Agnes Schulte

10'

Regulatory specificities in Europe regarding assessment/classification of TFCH/H

14.25 - 14.45

all

20'

Questions regarding the regulatory perspective

14.45 - 15.30

45'

Expert discussion: key regulatory issues and differences across different sectors

15.30 - 15.45

Coffee break

5th session: wrap-up

15.45 - 15.55

Barbara Lenz

10'

Summary of workshop results: Adversity of TFCH/H, viewpoint of toxicological pathologists

15.55 - 16.05

Xavier Palazzi

10'

Summary of workshop results: TFCH/H in laboratory animals - meaning for risk assessment in humans

16.05 - 16.20

all

15'

Questions from the audience

16.20 - 17.45

85'

Expert discussion: conditions and step-wise approach of adversity decisions related to TFCH/H

17.45 - 18.00

Gabriele Pohlmeier-Esch

15'

Closing remarks