

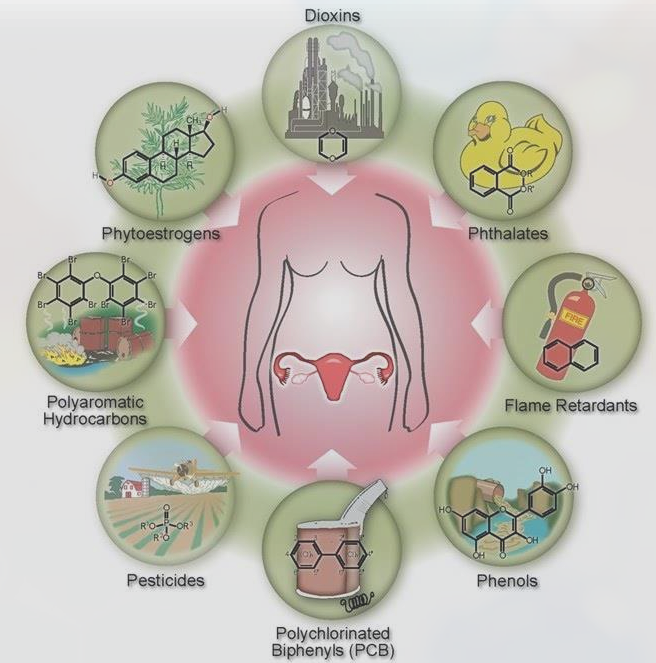
ENDOKRINNÍ DISRUPCE A REGULATORNÍ BUDOUCNOST

Mgr. Martin Weiszenstein, PhD

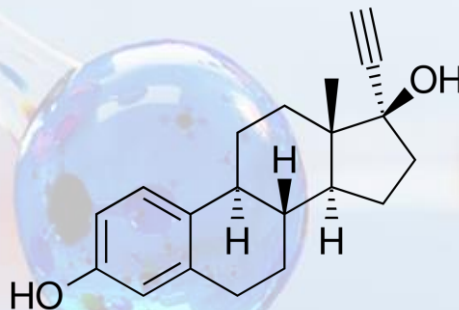
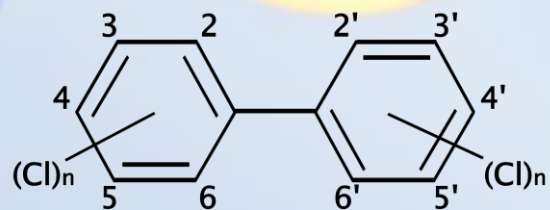
OSNOVA

- Úvod
- Definice
- Historie pojmu
- Mechanismus
- Minulost, současnost a budoucnost z regulační perspektivy

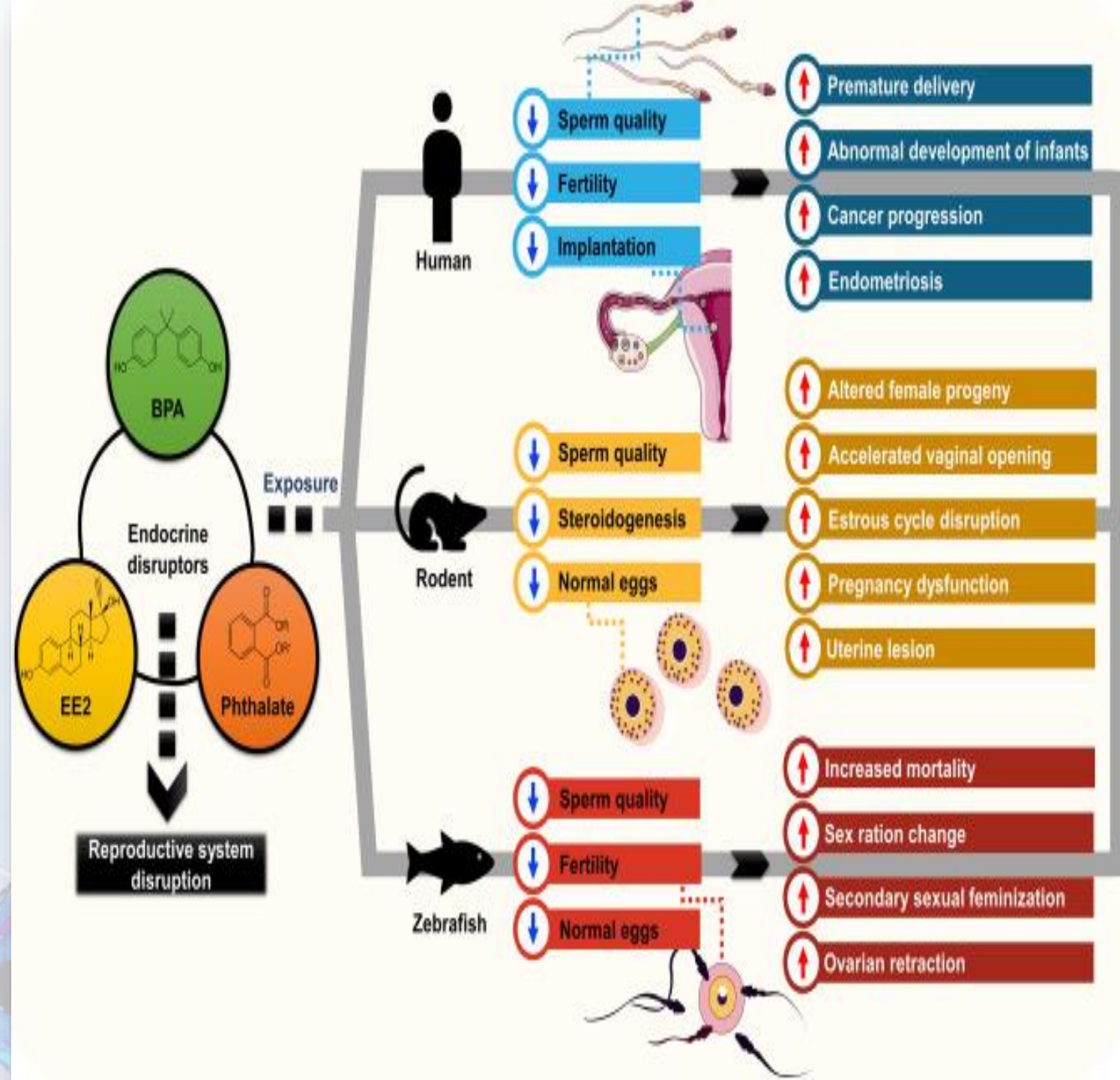
Endocrine Disrupting Chemicals



ÚVOD



ÚVOD



DEFINICE

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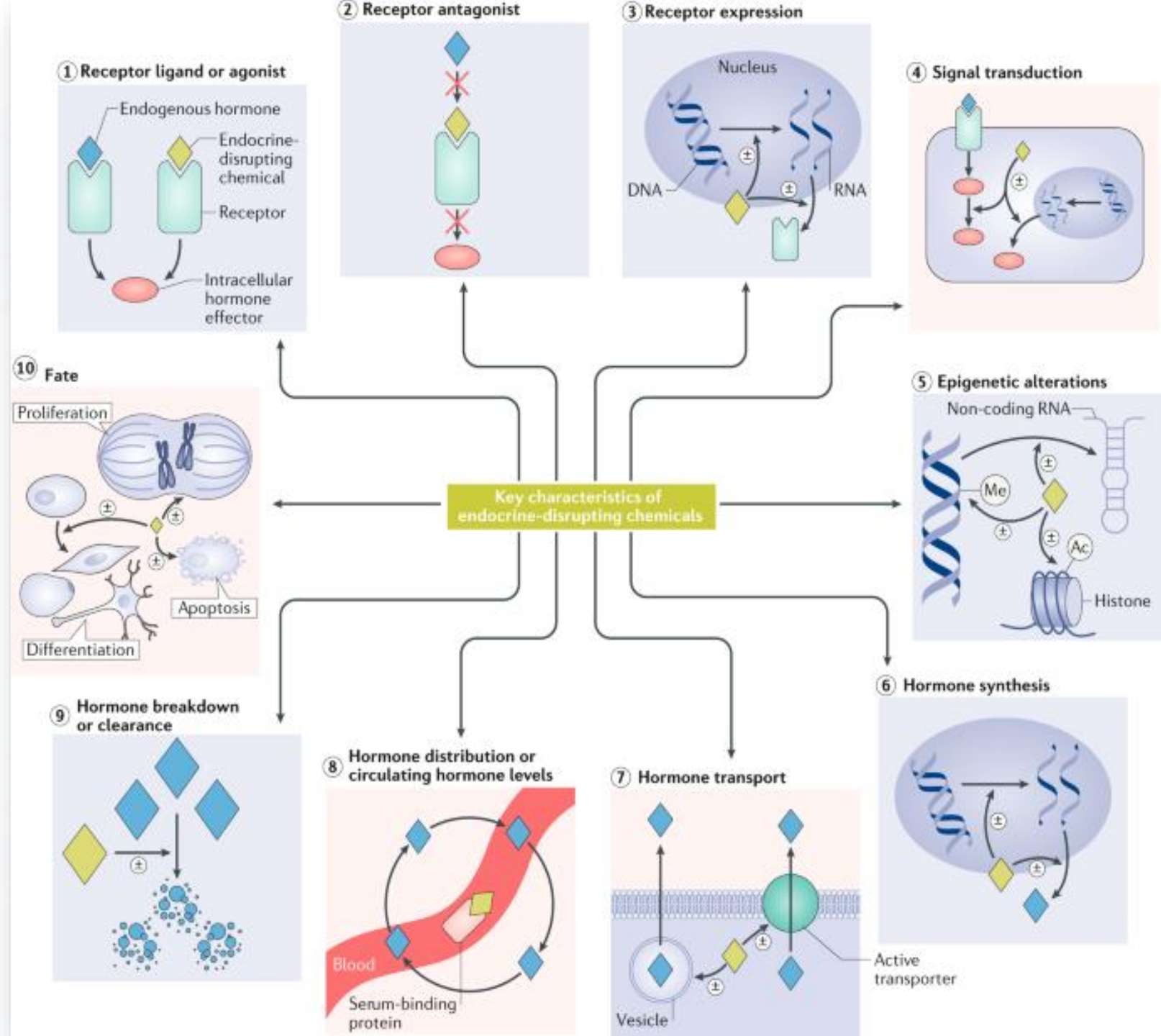
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HISTORIE POJMU

Large numbers and large quantities of endocrine-disrupting chemicals have been released into the environment since World War II. Many of these chemicals can disturb development of the endocrine system and of the organs that respond to endocrine signals in organisms indirectly exposed during pre-natal and/or early postnatal life; effects of exposure during development are permanent and irreversible. The risk to the developing organism can also stem from direct exposure of the offspring after birth or hatching. In

MECHANISMUS



REGULATORNÍ MINULOST

OECD Conceptual Framework for the Testing and Assessment of Endocrine Disrupting Chemicals

Note: Document prepared by the Secretariat of the Test Guidelines Programme based on the agreement reached at the 6th Meeting of the EDTA Task Force

Level 1 Sorting & prioritization based upon existing information	<ul style="list-style-type: none">•Physical & chemical properties, e.g., MW, reactivity, volatility, biodegradability•Human & environmental exposure, e.g., production volume, release, use patterns•Hazard, e.g., available toxicological data
Level 2 <i>In vitro</i> assays providing mechanistic data	<ul style="list-style-type: none">•ER, AR, TR receptor binding affinity•Transcriptional activation•Aromatase & Steroidogenesis <i>in vitro</i>•Aryl hydrocarbon receptor recognition/binding•High Through Put Prescreens•Thyroid function•Fish hepatocyte VTG assay•QSARs; Others (as appropriate)
Level 3 <i>In vivo</i> assays providing data about single endocrine Mechanisms and effects	<ul style="list-style-type: none">•Uterotrophic Assay (estrogenic related)•Hershberger Assay (androgenic related)•Non-receptor mediated hormone function•Fish VTG assay (estrogenic related)•Others (e.g. thyroid)
Level 4 <i>In vivo</i> assays providing data about multiple endocrine mechanisms and effects	<ul style="list-style-type: none">•Enhanced OECD 407 (endpoints based on endocrine mechanisms)•Male and female pubertal assays•Adult intact male assay•Fish gonadal histopathology assay•Frog metamorphosis assay
Level 5 <i>In vivo</i> assays providing data on effects from endocrine & other mechanisms	<ul style="list-style-type: none">•1-generation assay (TG415 enhanced)•2-generation assay (TG416 enhanced)•Reproductive screening (TG421 enhanced)•Combined 28 day/reproduction screening test (TG 422 enhanced)•Partial and full life cycle assays in fish, birds, amphibians & invertebrates (development & reproduction)

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GUIDANCE



ADOPTED (ECHA): 5 June 2018

ADOPTED (EFSA): 5 June 2018

doi: 10.2903/j.efsa.2018.5311

Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009

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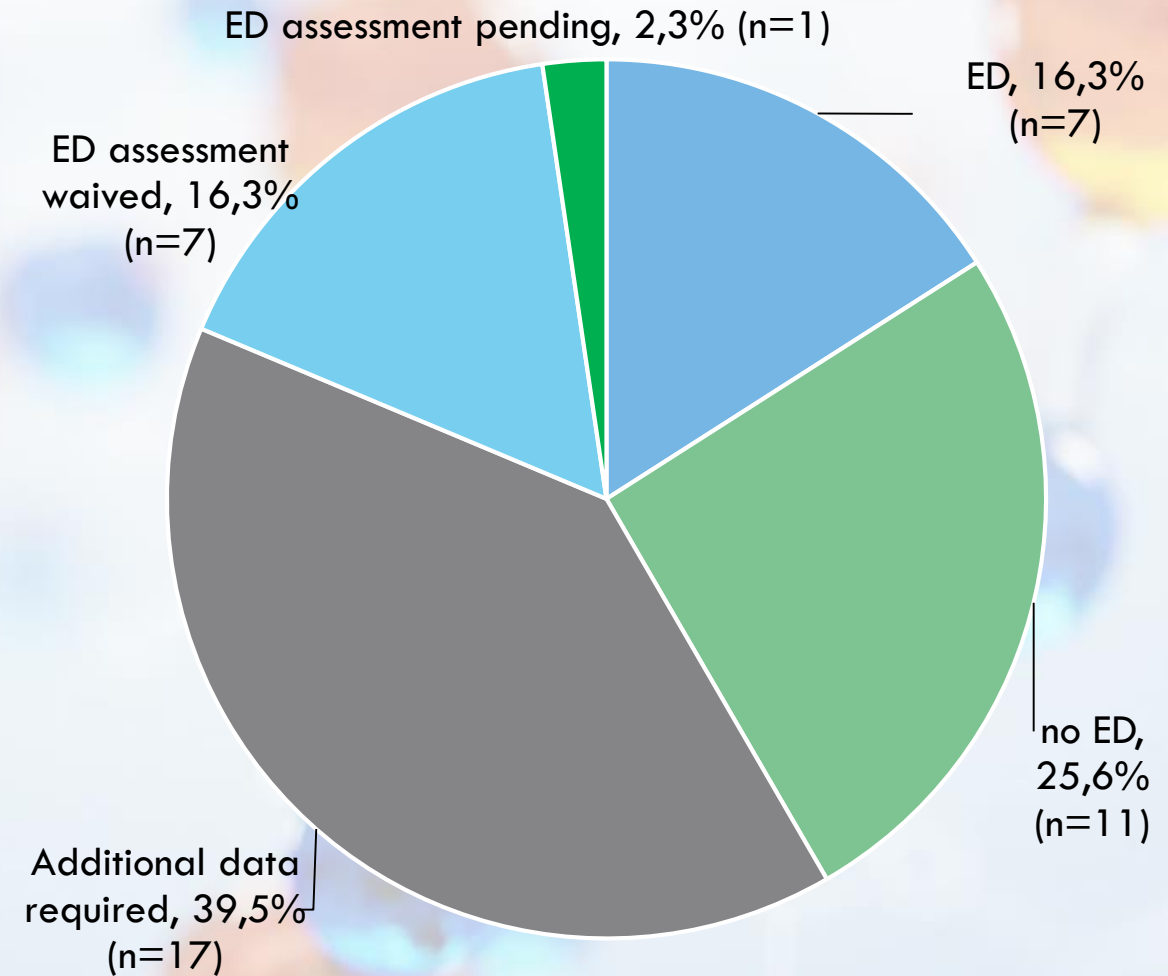
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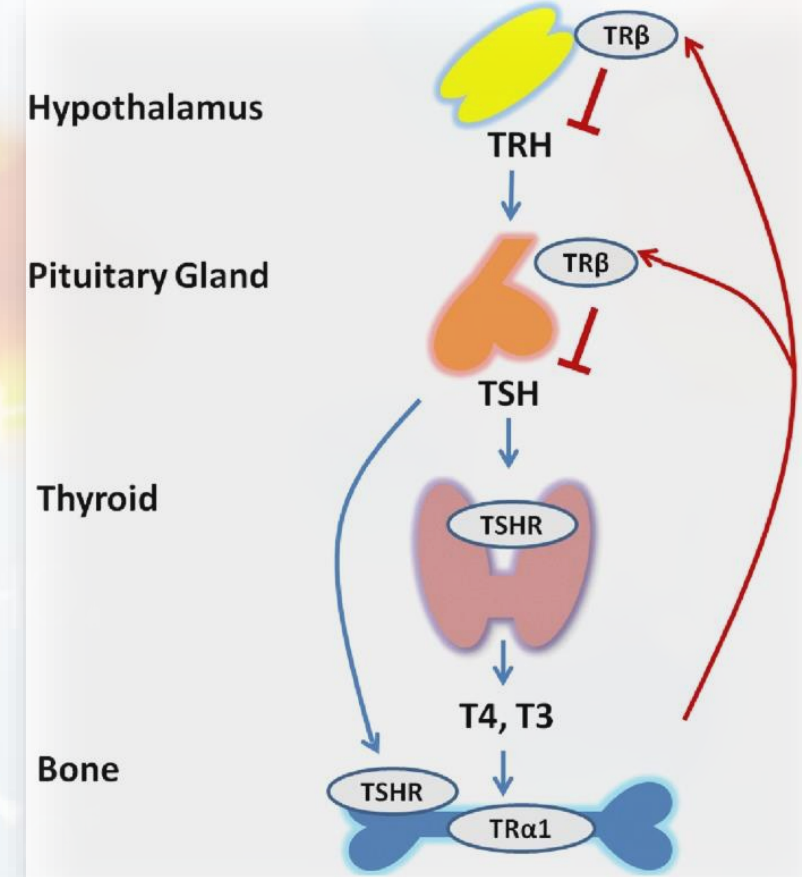
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REGULATORNÍ BUDOUCNOST



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Component classified as:	Generic concentration limits triggering classification of a mixture as:	
	Category 1 endocrine disruptor for human health	Category 2 endocrine disruptor for human health
Category 1 endocrine disruptor for human health	$\geq 0,1 \%$	
Category 2 endocrine disruptor for human health		$\geq 1 \%$

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Label elements of endocrine disrupting properties for human health

Classification	Category 1	Category 2
Symbol/pictogram		
Signal Word	Danger	Warning
Hazard Statement	EUH380: May cause endocrine disruption in humans	EUH381: Suspected of causing endocrine disruption in humans
Precautionary Statement Prevention	P201 P202 P263 P280	P201 P202 P263 P280
Precautionary Statement Response	P308 + P313	P308 + P313
Precautionary Statement Storage	P405	P405
Precautionary Statement Disposal	P501	P501

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ODKAZY K PROBLEMATICE

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KONTAKT

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