



# Endocrine disruptors: be prepared!

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Paris Packaging Week 2025



# What is an Endocrine Disruptor (ED)?

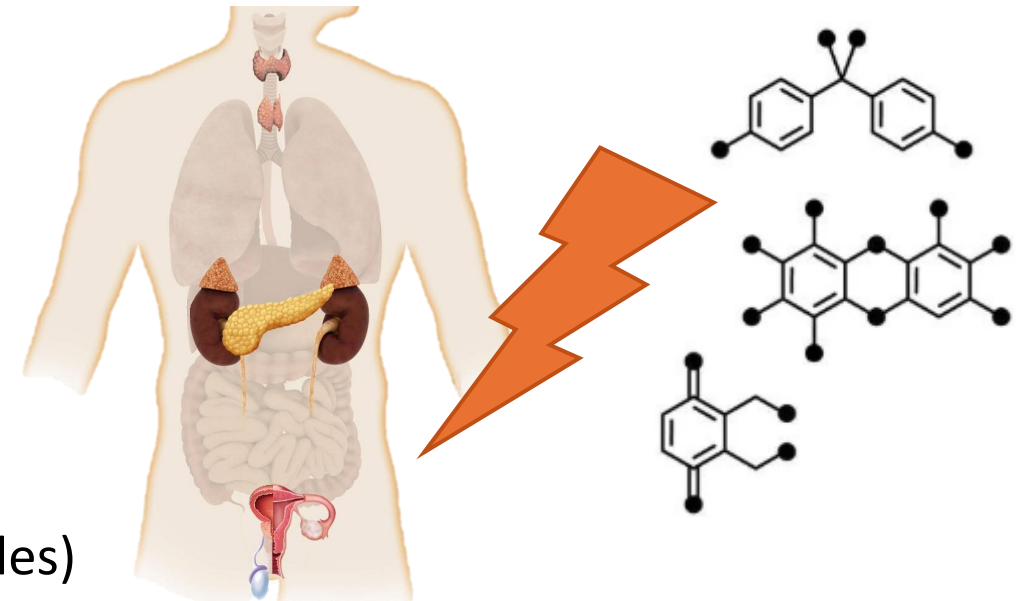


An endocrine disruptor is a chemical substance, natural or man-made, that **interferes with** the normal functioning of **hormonal systems**

These substances can **mimic, block hormones** or **alter their synthesis or transport**, leading to adverse health effects such as:

- Increased risk of infertility
- Impaired brain development of fetuses or children
- Obesity
- Type 2 diabetes
- Hormone-dependent cancers
- Feminisation of male animals (fish, amphibians or reptiles)

...





# How endocrine disruptors are regulated?

## DEFINITION



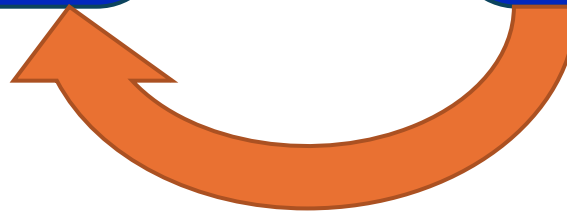
A substance has endocrine disrupting properties if it meets all the following 3 criteria:

### 1- ADVERSITY

It shows an adverse effect  
in an intact organism  
or its progeny (offspring)

### 2- ENDOCRINE ACTIVITY

It has an endocrine mode of action  
i.e. it alters the function(s) of the  
endocrine system



### 3- CAUSAL LINK

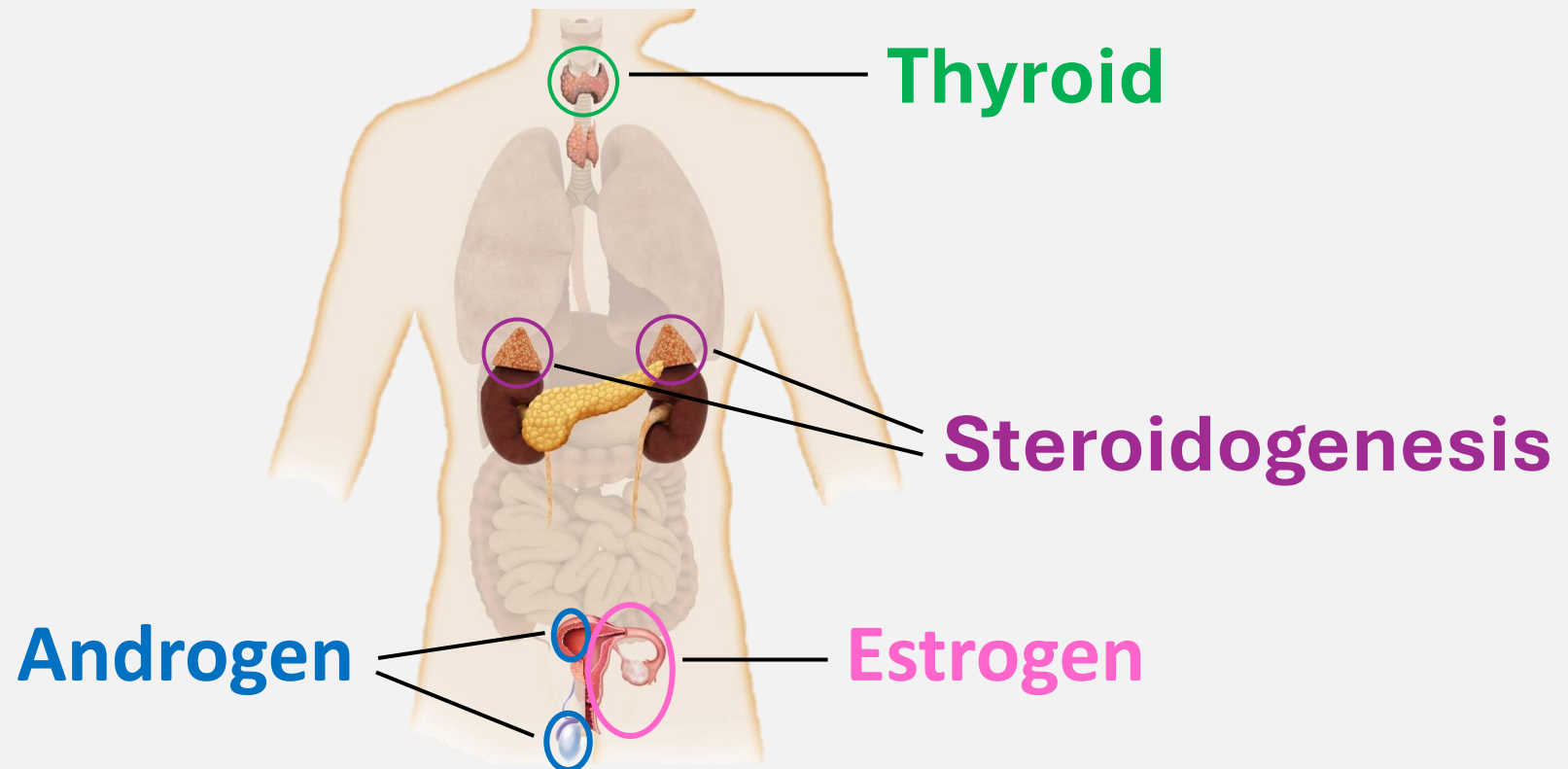
The adverse effect is a consequence  
of the endocrine mode of action

# How endocrine disruptors are regulated?

## IDENTIFICATION



Many physiological functions are regulated by hormones but **four endocrine systems** are mainly considered in regulatory dossiers:



# How endocrine disruptors are regulated?

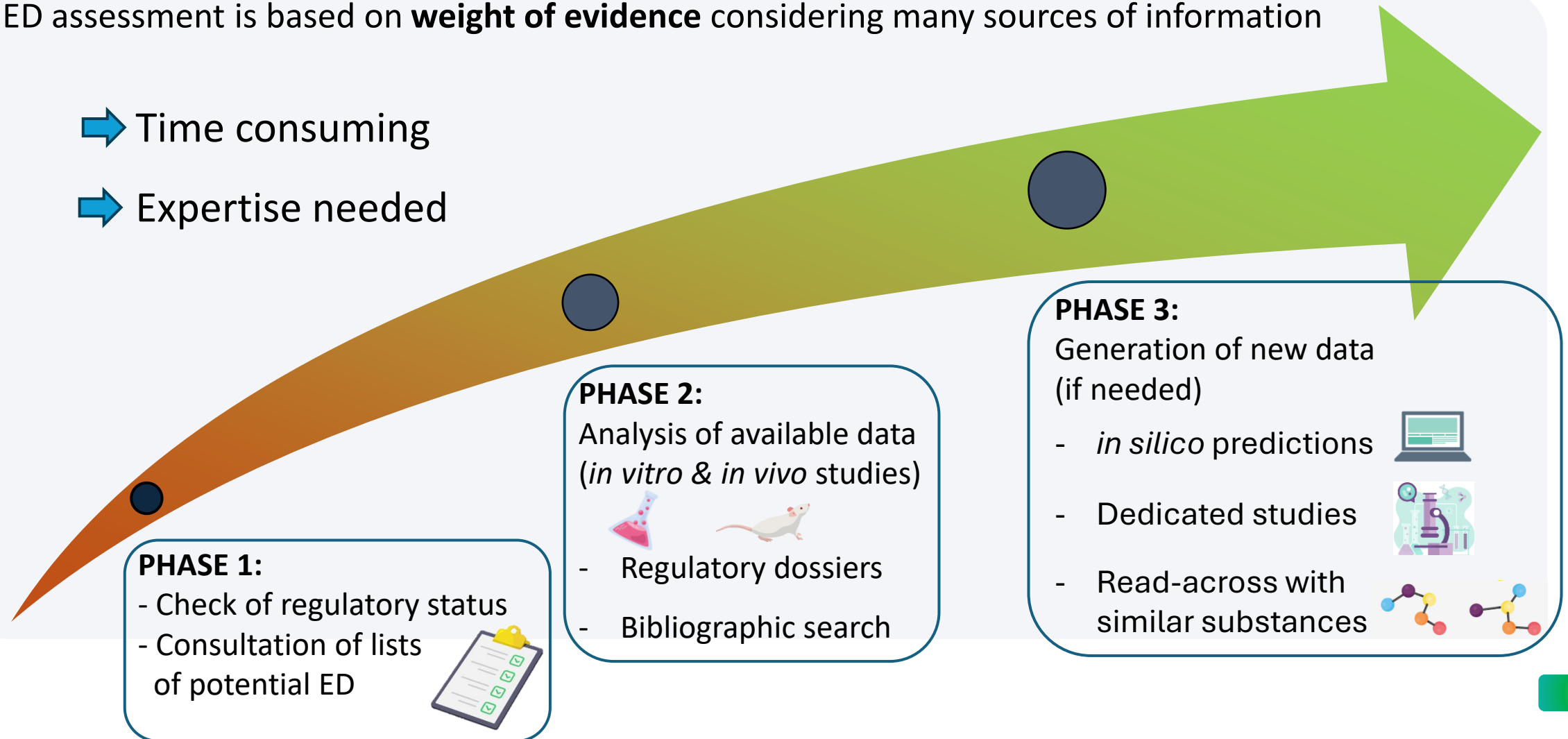
## ANALYSIS



ED assessment is based on **weight of evidence** considering many sources of information

➡ Time consuming

➡ Expertise needed





# Classification & labelling



## New hazard classes in Classification, Labelling & Packaging (CLP) regulation since 20 April 2023



- Endocrine Disruption for Human Health (HH):

**Category 1 - EUH 380 May cause** endocrine disruption in humans

**Category 2 - EUH 381 Suspected of causing** endocrine disruption in humans



- Endocrine Disruption for Environment (ENV):

**Category 1 - EUH 430 May cause** endocrine disruption in the environment

**Category 2 - EUH 431 Suspected of causing** endocrine disruption in the environment

No pictogram, no hazard phrase or precautionary statements (H & P phrases)

**A mixture is classified cat. 1** if it contains an **ingredient classified cat. 1  $\geq 0.1\%$  (w/w)**

**A mixture is classified cat. 2** if it contains an **ingredient classified cat. 2  $\geq 1\%$  (w/w)**

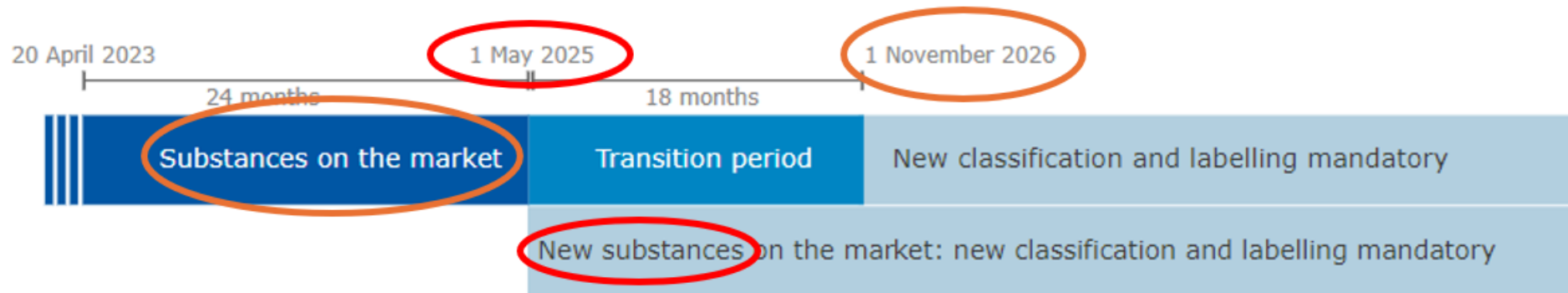


# Regulatory obligations - CLASSIFICATION UPDATE

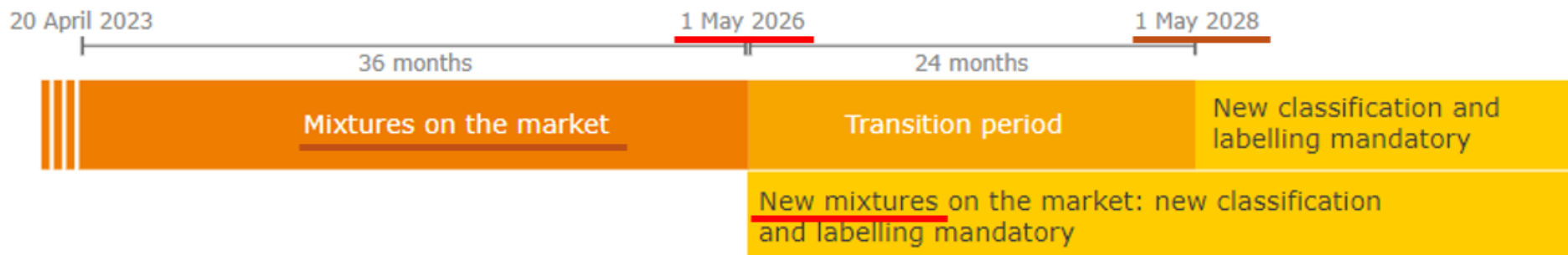


Companies should **review their portfolio** of substances and mixtures and **inform ECHA** about any **new classifications** by updating their REACH registration dossier or CLP notification

**New substances => 1 May 2025 / Substances on the market => 1 November 2026**



**New mixtures => 1 May 2026 / Mixtures on the market => 1 May 2028**





## Regulatory obligations – INFORMATION (AGEC law)



In France, Article 13 of the AGEC law introduces the **obligation to inform the public** of the presence of **endocrine disruptors in products or in packaging** at concentrations  $> 0.1\% \text{ w/w}$

What  
products ?

- Foodstuffs & Materials in contact with foodstuffs (including packaging)



- Biocides (Ex: conservatives)



- Plant protection products



- Toys



- Medical devices



- Cosmetics



What  
substances ?

- **Proven, presumed or suspected** Endocrine Disruptors qualified by ANSES
- List of **128 substances** presenting potential endocrine-disrupting properties
- Mostly identified as Substances of Very High Concern (SVHCs) by ECHA



## Revision of the **Packaging and Packaging Waste Regulation**

- Formal adoption by the EU Council in December 2024
  - Will enter into force 20 days after its publication in the EU's Official Journal (January 2025?)
  - Will be applied 18 months after the date of entry into force (July/August 2026?)
- 
- Article 5 of the PPWR: the manufacture of packaging and anything resulting from the processing of packaging waste must **minimize the presence of substances of concern**
  - The **EU Commission and ECHA will identify substances** present in packaging that have an impact on recycling and/or **present risks to human health and the environment**
  - List of substances and restrictions to be applied **by 2027**

- For articles within **REACH (including packaging)**: obligation to provide information in the supply chain (in MSDS) if presence of SVHC substances in concentration > 0.1% by mass

SVHC : substances that have serious and often irreversible effects on human health and the environment such as **Carcinogenic, Mutagenic or toxic to Reproduction (CMR)** substances or **equivalent concern (endocrine disruptors, respiratory sensitizers, ...)**

- EU regulation (1223/2009) of **cosmetic products** does not require ED assessment of cosmetic ingredients, but ...

Lists of **banned substances** (Annex II) and **restricted substances** (Annex III) are **regularly updated**

Some endocrine disruptors already in those lists (because of CMR properties) such as several parabens & UV filters, triclosan...



## Regulatory obligations – BIOCIDES & PPP



- Evaluation of **active substances** for endocrine disruption has been mandatory for **biocides and PPP** since 2018
- The status of the evaluated active substances is updated and available on **ECHA** website (biocides) and **EFSA** website (PPP)
- Identification of Substances of Concern (SoC), including endocrine disruptors, among **ingredients of biocidal products** is required since 2018

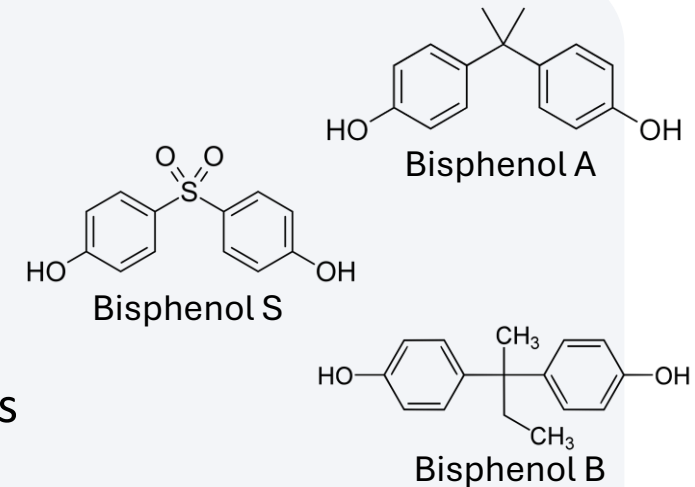
# Endocrine Disruptors listed in AGECE law



ED substances listed in AGECE law, potentially found in packaging:

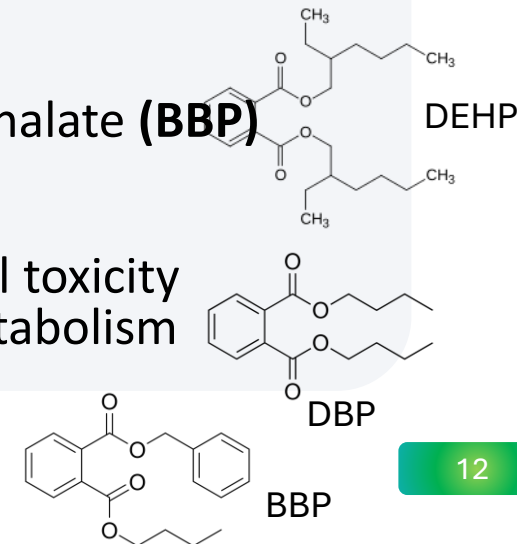
- **Bisphenols:**

- **Bisphenol A** and **some of its alternatives** such as **bisphenol S** and **B**
- Used in the manufacture of **plastics and resins**
- Estrogenic or (anti-)androgenic effects with impacts on fertility  
Effects on neurodevelopment & metabolic and cardiovascular diseases



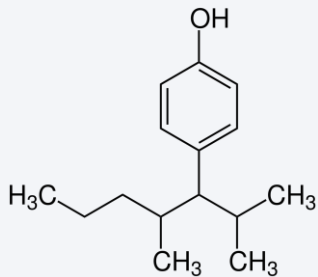
- **Phthalates:**

- Di(2-ethylhexyl) phthalate (**DEHP**), Dibutyl phthalate (**DBP**) and Benzyl butyl phthalate (**BBP**)
- Used as **plasticizers in PVC**
- Estrogenic and/or androgenic effects leading to reproductive and developmental toxicity  
Effects on thyroid hormone levels which may impair neurodevelopment and metabolism

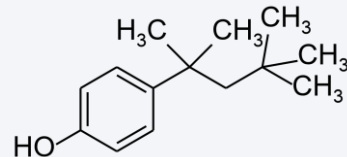


ED substances listed in AGECE law, potentially found in packaging :

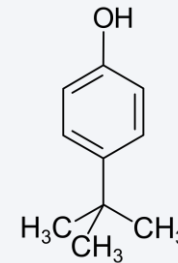
- **Nonylphenols:**
  - **Nonylphenol, 4-tert-octylphenol, 4-tert-butylphenol & tris-nonylphenol phosphite (TNPP)**
  - Used in the manufacture of certain **resins and plastics**
  - Estrogenic activity and anti-androgenic activity leading to impaired fertility  
Effects on thyroid hormone levels which may impair neurodevelopment and metabolism



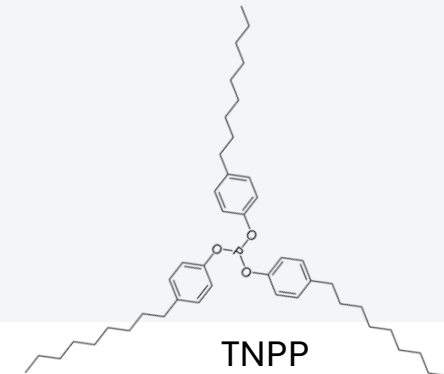
Nonylphenol



4-tert-octylphenol



4-tert-butylphenol



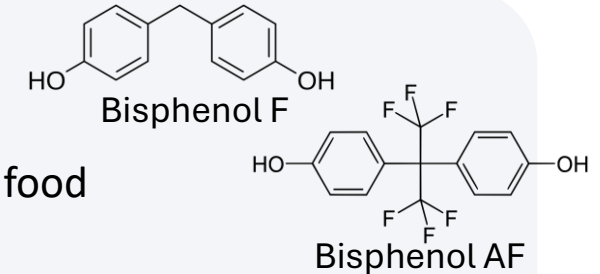
TNPP



ED substances **NOT** listed in AGEC law, potentially found in packaging :

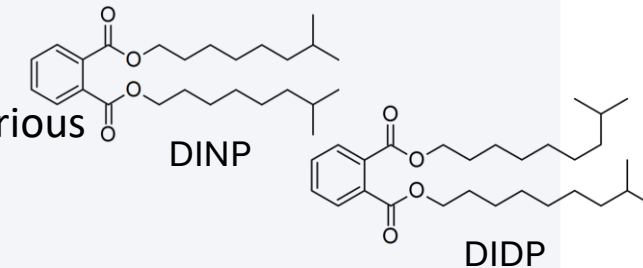
- Bisphenols:

**Bisphenol F and AF:** bisphenol A substitutes, used in **resins and plastics** in contact with food (high thermic resistance)

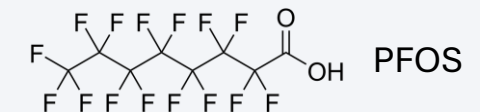


- Phthalates:

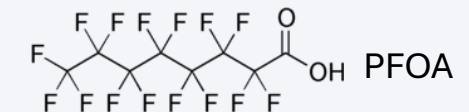
Diisononyl phthalate (**DINP**) and Diisodecyl phthalate (**DIDP**), used as plasticizers in various plastic materials, including some food packaging



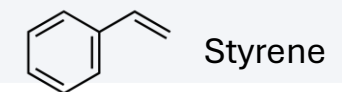
- **Perfluorooctane sulfonate (PFOS)**: from PFAS family, used for its **non-stick and grease-resistant properties in food packaging**, such as food paper and cardboard



- **Perfluorooctanoate (PFOA):** Used in non-stick coatings for food packaging and cookware



- **Styrene:** A constituent of polystyrene, used in food trays, disposable cups and plastic cutlery



- List of AGEC law is **not exhaustive**
- Proven but also **suspected** EDs

Several lists of known or suspected EDs can be consulted with different levels of reliability:

## Identified ED/not ED

- ECHA  
(biocides + chemicals)
- EFSA (PPP)

Full ED assessment  
by competent authorities  
Regularly updated

## Suspected ED

- Regulatory processes
  - CORAP list
- ANSES list (AGEC law)
  - SVHC intentions
  - Authorisation list
- ...

Partial ED assessment  
by competent authorities  
Regularly updated

## Suspected ED

- TEDX list
- SIN list
- ...

Lists from NGOs  
Poorly documented  
Not or not frequently updated

Decreasing reliability of the ED status







# PERSPECTIVES – Expected regulatory changes



- **Revision of Packaging and Packaging Waste Regulation**
  - Entry into force early 2025
  - Application in 18 months
  - List of restricted substances in 2027
- **REACH update** with data requirements for ED properties (first draft by end 2025)
- **Cosmetics regulation update** for inclusion of EDs ? Not before 2026
- Inclusion of hazard classes for ED in **Globally Harmonised System (GHS)** of classification: in several years...



# PERSPECTIVES – Expected advances in France



**Stratégie nationale sur**  
**les perturbateurs endocriniens 2**

- National Strategy on Endocrine Disruptors (SNPE2) 2019-2022
  - Educate and inform (13 actions)
  - Protect the population and the population and the environment (28 actions)
  - Improving knowledge (9 actions)

National authorities recommend the creation of a SNPE3 with the following goals:

- Produce knowledge
  - Educate and inform consumers
  - Reduce emissions of EDs within 10-15 years
- 
- **PEPPER platform: public-private association to help the development and validation of new methods for identification of ED**



# CONCLUSION



- List of ED substances in AGECLow : **not exhaustive** and includes **not proven EDs**



- Many **other lists and sources of information** to be considered:

➔ Requires **time** and **expertise**



- Anticipation is key: **CLP obligations** to be fulfilled in the **coming months/years!**



- Updates of EU regulations** (REACH, packaging, cosmetics) to include ED assessment in the coming months with huge impact on chemical industry



- Ambitious national initiatives** with zero emission goal within the next 10-15 years





## CEHTRA : in a few words



For 20 years, CEHTRA has offered comprehensive **regulatory support** for the marketing of products.

- **70** collaborators  
in toxicology, ecotoxicology and chemistry
- Network in **EU and outside EU**
- Experts on **more than 10 sectors** (REACH, Biocides, Cosmetics, Packaging, Medical devices ...)



**Regulatory affairs**



**QSAR predictions**



**ED assessment**



**Externalisation**



**Trainings**



**Digital tools**



# Our expertise in 10 key sectors



**Biocides**



**Cosmetics**



**Medical devices**



**Packaging**



**Industrial hygiene**



**Food products**



**Pharmaceuticals**



**Plant Protection Products**



**REACH**



**REACH Authorisation**



# Thank you for your attention

## Any question ?

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