

The logo for the Health and Safety Authority (HSA) features the letters 'HSA' in a serif font. The 'H' and 'S' are dark blue, while the 'A' is orange. A thin orange horizontal line is positioned below the letters.

HSA

An tÚdarás Sláinte agus Sábháilteachta  
Health and Safety Authority

# EU Chemicals Strategy for Sustainability Conference

The logo for the Environmental Protection Agency (EPA) features a stylized green leaf icon above the lowercase letters 'epa' in a blue sans-serif font. Below the letters, the full name of the agency is written in a smaller font.

epa  
Environmental Protection Agency  
An Ghníomhaireacht um Chaomhnú Comhshaoil

October 18<sup>th</sup> 2023



chemsec

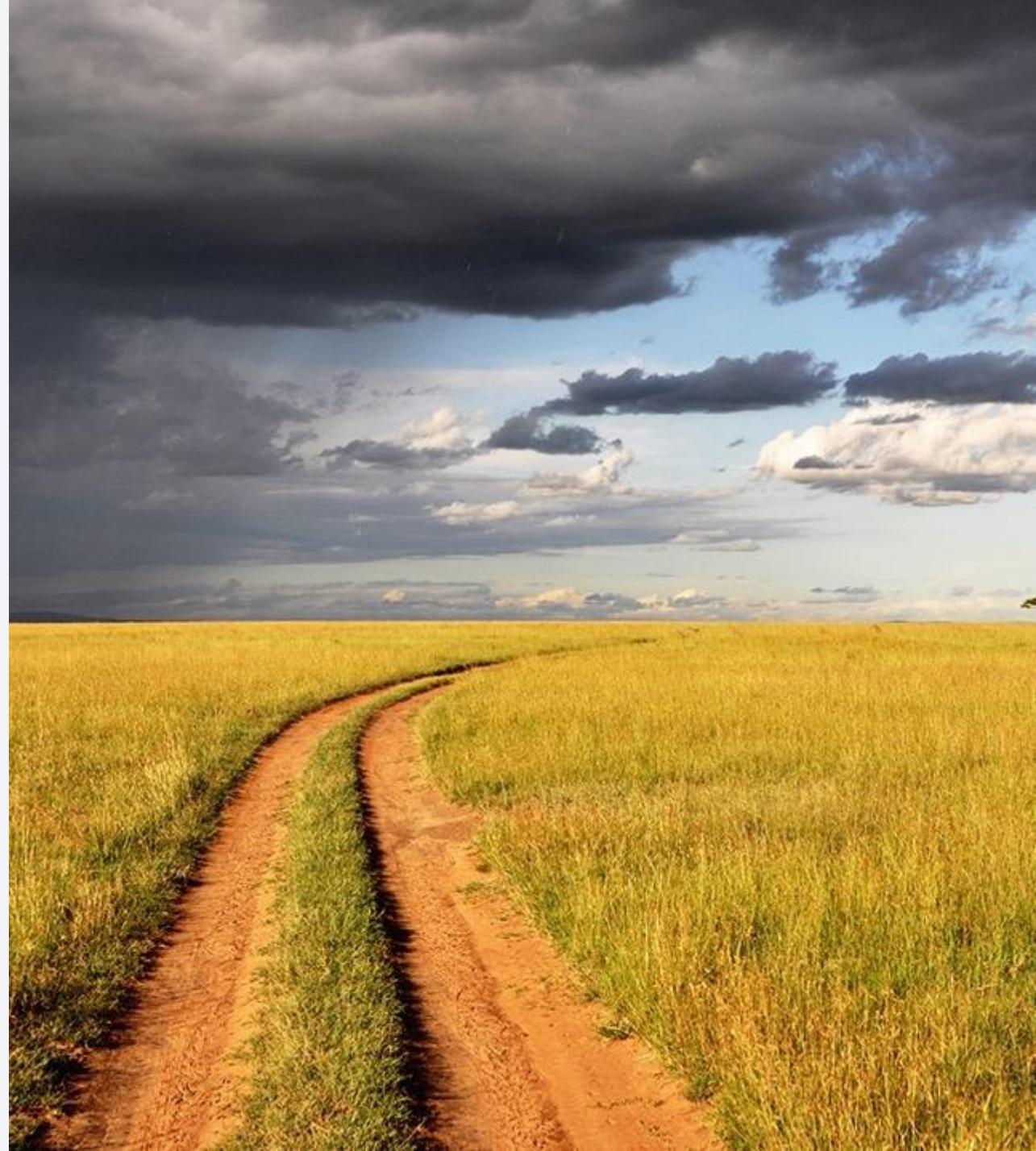
INTERNATIONAL CHEMICAL SECRETARIAT



# HOW TO REACH A TOXIC FREE ENVIRONMENT

# OUTLINE

- ChemSec intro
- The urgency
- Implications of the Chemical Strategy for Sustainability
- How to transition the market
- Trends and opportunities for the industry
- ChemSec tools





- Environmental NGO aiming to reduce the use of hazardous substances
- Cooperates with different stakeholders to drive the change to safer chemicals
- Receives funding from the Swedish Government and various charity funds

# WHAT WE DO AT CHEMSEC

- Drive the political discussion on hazardous chemicals
- Challenge companies to improve their chemicals management
- Develop online tools to help companies switch to safer chemicals
- Inform investors about risks and opportunities in the chemical industry



# CHEMSEC BUSINESS GROUP



EurEau

Polestar



adidas



ShawContract®



H&M Group



SONY®

SKANSKA

COOP

Kingfisher

# CHEMSEC TOOLS

 chemsec  
**SIN LIST**

 chemsec  
**CHEMSCORE**

 chemsec  
**PFAS GUIDE**

 chemsec  
**MARKETPLACE**

 chemsec  
**SIN PRODUCERS**

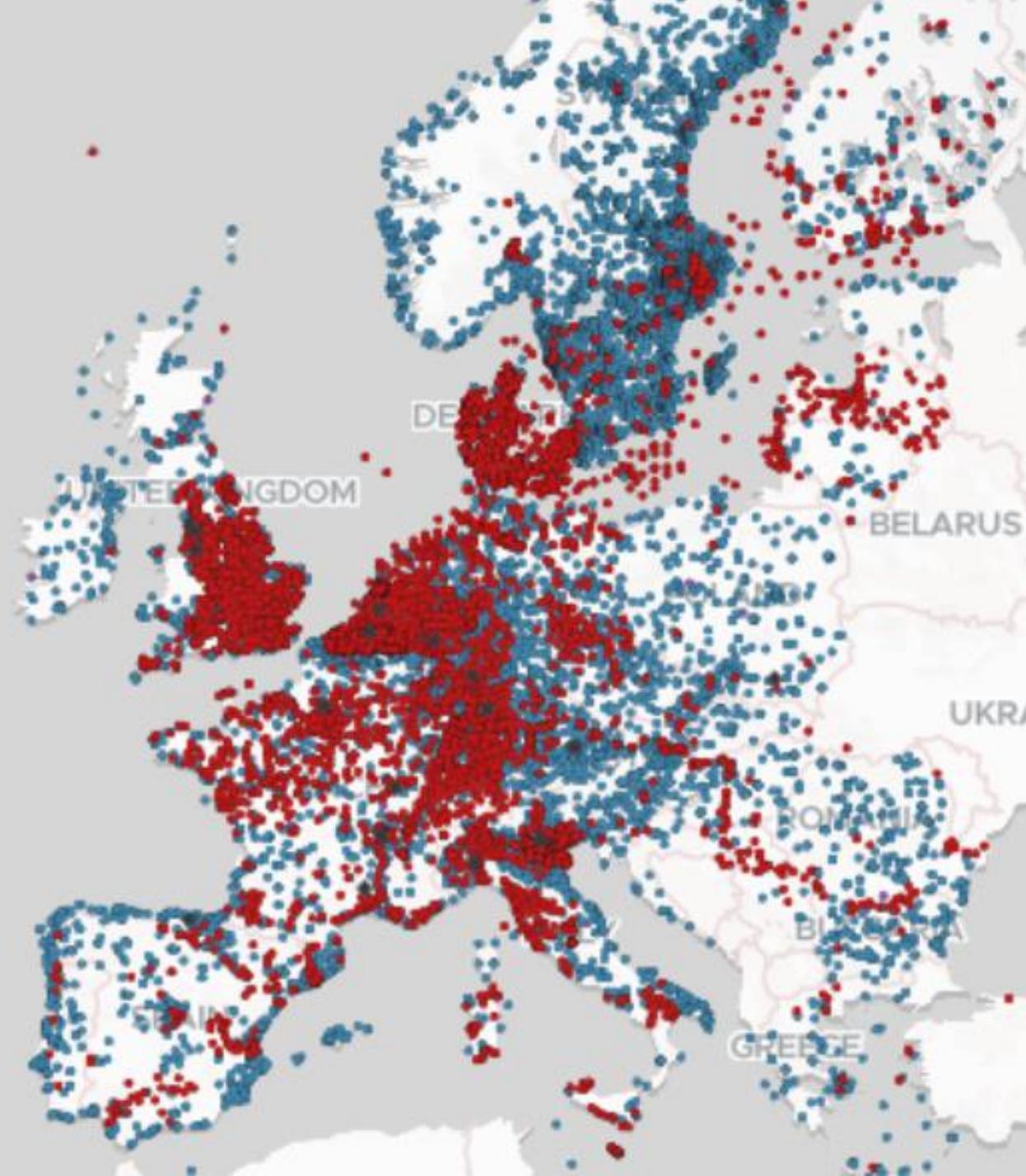
# THE URGENCY

- More and more scientific reports show the urgent need for change
  - exposure to toxic chemicals to a loss of four to five IQ points in children
  - men in the western world produce half as much sperm as they did 40 years ago
- We are overstepping the planetary boundaries
- The most harmful chemicals need to be phased out
- Business as usual is not an option



# PFAS AS AN EXAMPLE

- PFAS is a global problem- found everywhere
- PFAS is found in the most remote areas and species in the world
- Almost every person tested has PFAS in the blood
- Drinking water in many places have higher levels of PFAS than what is safe to drink



**SOCIETAL COSTS OF  
PFAS: €16 TRILLION**

PFAS revenue per year:  
€26 billion 

PFAS market price: €19 per kg

**True cost\*: €18,374 per kg**

\*Including societal costs



## WHAT WE HAVE

The most ambitious chemical regulation in the world

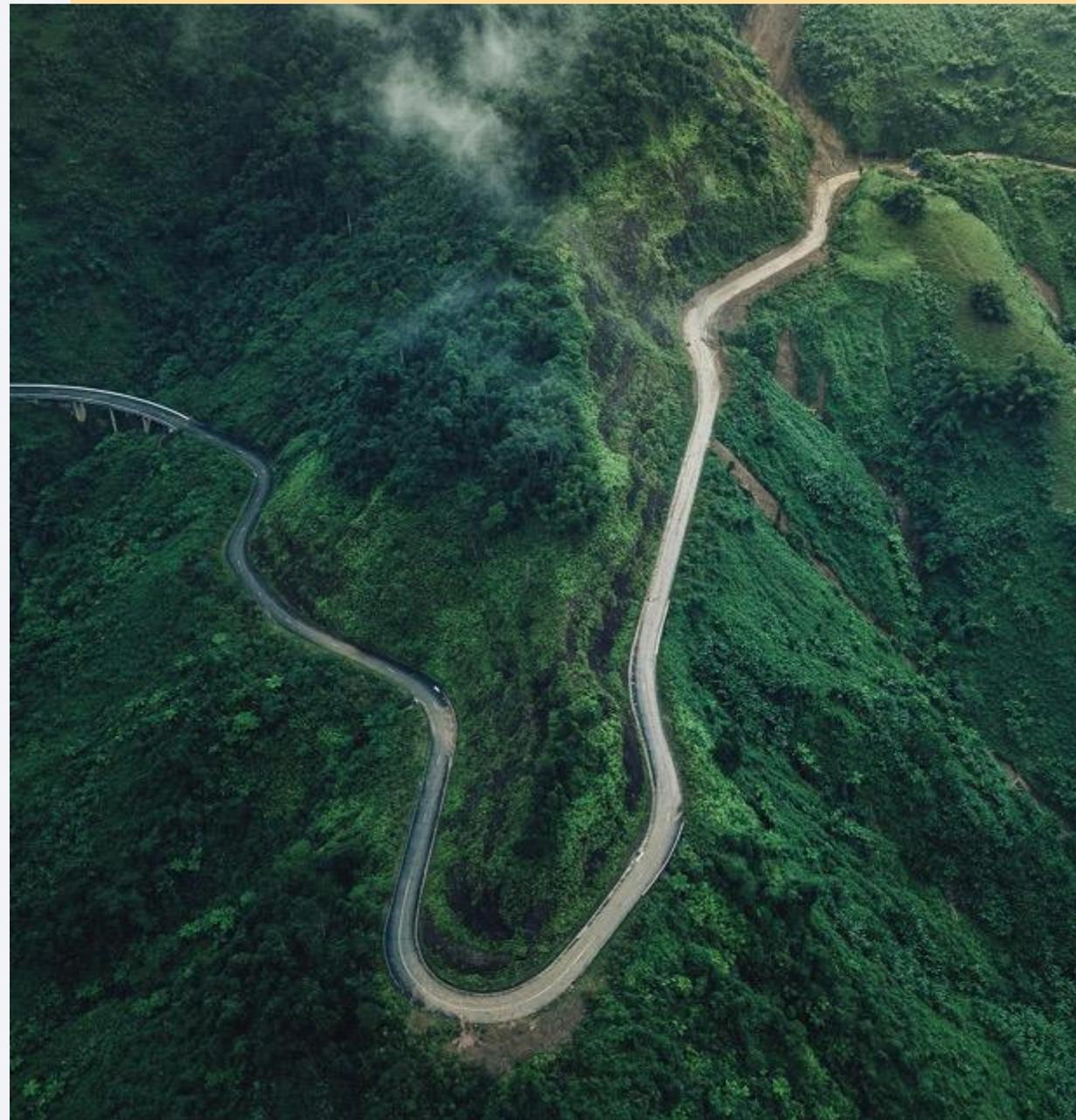
- Burden of proof is on industry
- Registration of all chemicals on the market

Many good elements but not efficient enough

- Protection of humans and the environment
- Non-toxic circular economy
- Substitution has not occurred at the expected pace

# ARE WE HEADING TOWARDS TOXIC FREE?

- Green Deal
- Chemical Strategy for Sustainability
  - Aims to make EU regulation more efficient
  - Top priority - phasing out the most harmful chemicals instead of trying to control the exposure of them.
  - Not a question about *if* but *how*
- Universal restriction of the whole group of PFAS





# WILL INDUSTRY MANAGE THE CHANGE?

- Part of the chemical industry has voiced concerns and some have even used all their powers to fight new regulation
- Business as usual is not an option
- Most companies are adapting to the Chemical Strategy and working hard to be Sustainable
  - being more transparent
  - developing alternatives
  - using alternatives
  - phasing out the most harmful chemicals

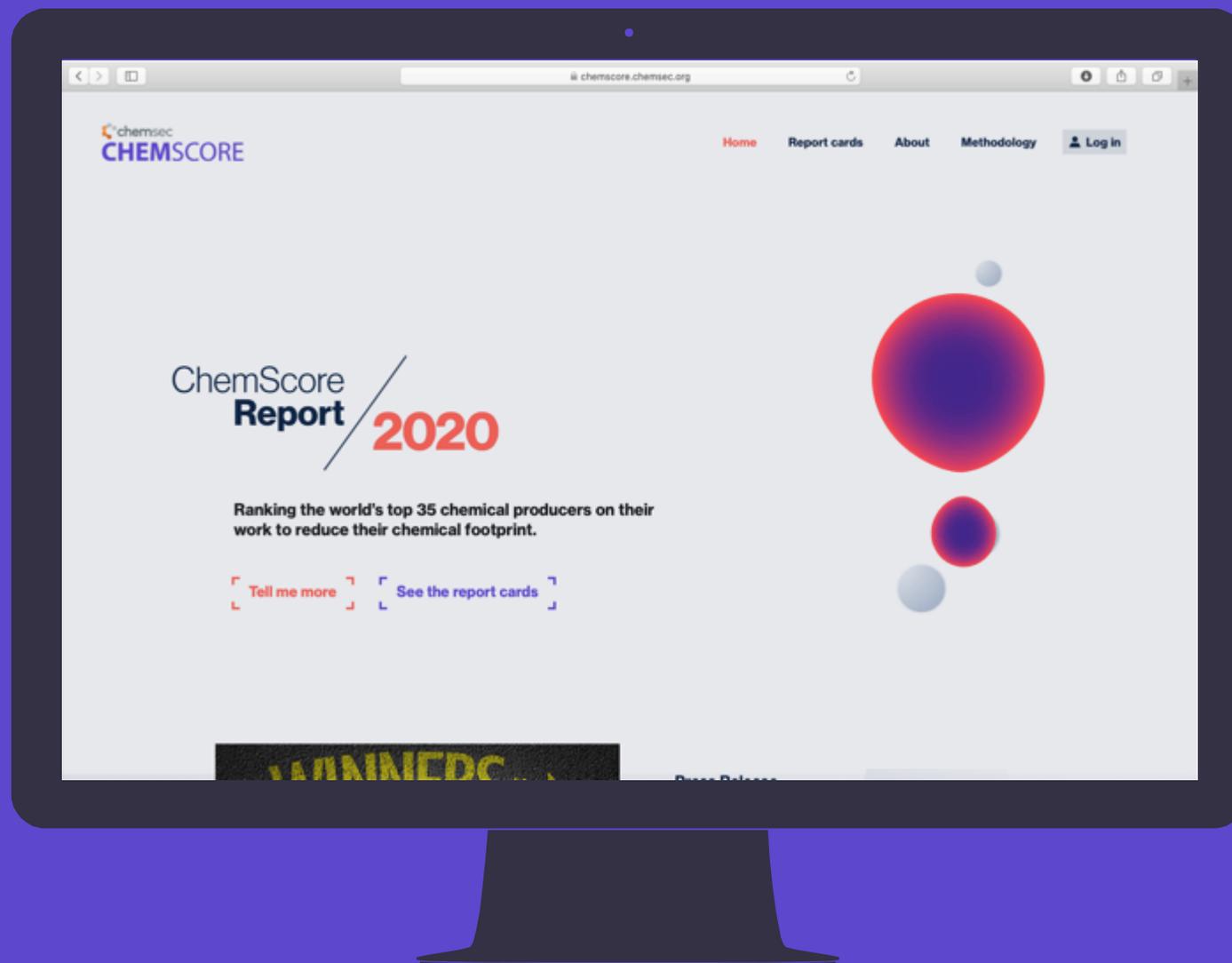


# TRANSITIONING THE MARKET IS KEY

- EU has a strong and competent industry- we need to support the ones developing and using safer alternatives
- EU Citizens expect all companies to work hard on being more sustainable and not sell products with the most harmful chemicals
- Expect the chemical industry to develop better chemicals
- Incentives needed
- Predictability and Regulation is key



ChemScore ranks the world's largest chemical producers on their efforts to reduce their chemical footprints.





# Investor Initiative on Hazardous Chemicals

Supported by ChemSec



50+ INVESTORS  
\$11 TRILLION





## KEY ASKS:

1. Increase transparency
2. Phase out persistent chemicals
3. Improve the company's ChemScore

# TRENDS AND OPPORTUNITIES

- Biodiversity high on the agenda- closely linked to chemicals
- PFAS is a clear case- showing the need for phase-out
- Growing interest from Investors
- Groups of chemicals instead of one by one
- Phase out
- Transparency
- Market opportunities -moving ahead



# CHEMSEC TOOLS

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**SIN LIST**

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**CHEMSCORE**

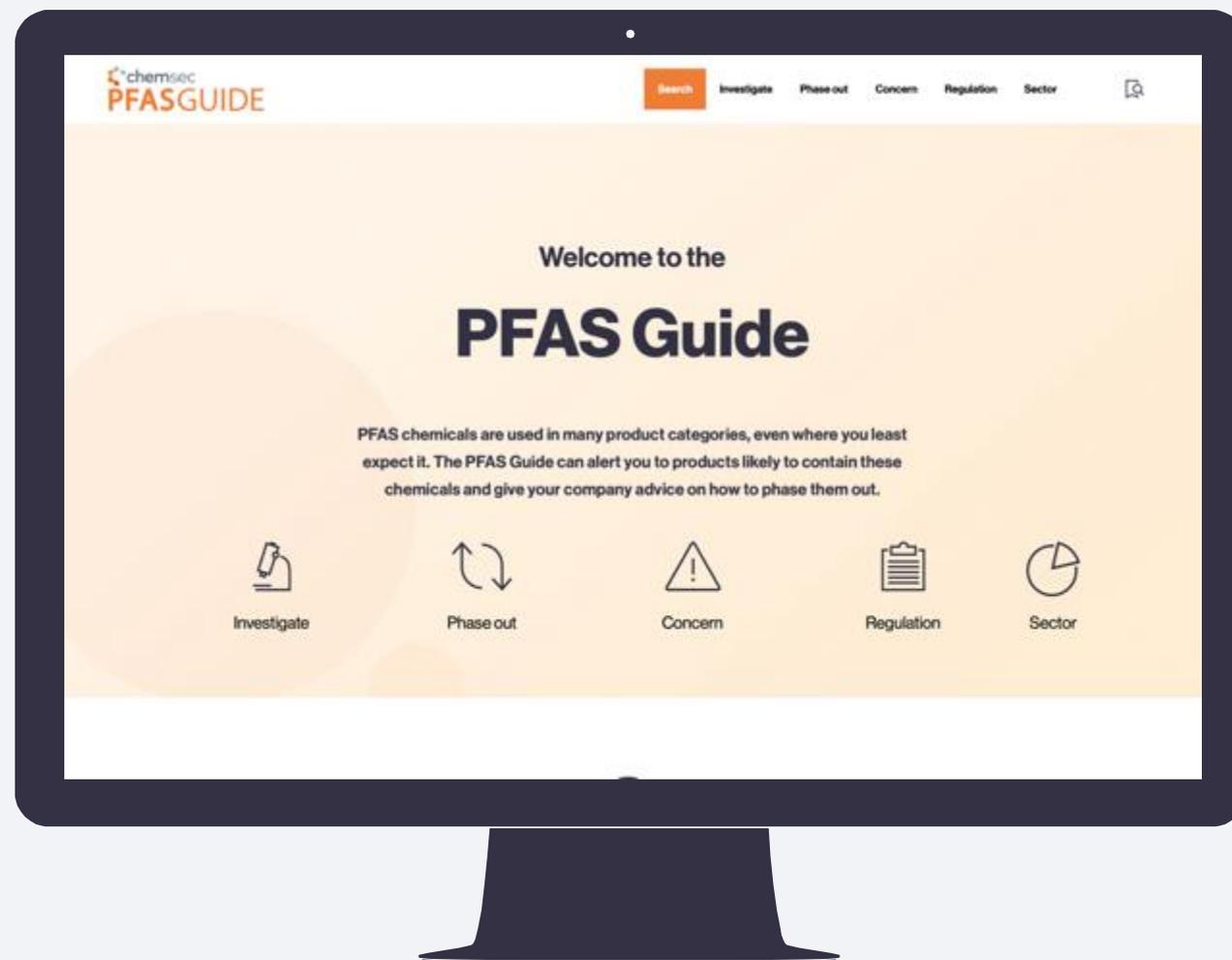
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# PFAS GUIDE

A tool for mapping if, where and why there is PFAS in your products or processes



# INFORMATION PART

- Typical PFAS uses, supply chain communication and chemical analysis
- Substitution as a phase-out method. Find, evaluate and compare alternatives
- What are the problems with PFAS? PFAS and human health
- Regulation in the EU and the US
- Links to sector-specific reports



## Investigate

This chapter will teach you about typical “red flags” indicating that PFAS could be in a product. You will also find suggestions on how to communicate about PFAS in the supply chain and what to do if you do not get the answers you need from your suppliers, or want to verify them.



## Phase out

To phase out PFAS you need to find a way to achieve the same functionality without them. The most straightforward approach is to simply replace one chemical with a safer one. But this can be tricky. Other ways include changing materials, technologies or production processes.



## Concern

PFAS continue to be used on a broad scale despite their adverse health effects, linking them to issues such as cancers and infertility. Since these “forever chemicals” do not degrade, they are now found all over the planet in our environment and in the blood of every single human being.



## Regulation

It has taken some time, but regulation is now finally stepping up to address this vast and problematic family of chemicals. A comprehensive PFAS ban is expected in the European Union within the coming years and a range of regulatory actions are in the pipeline in other regions as well.



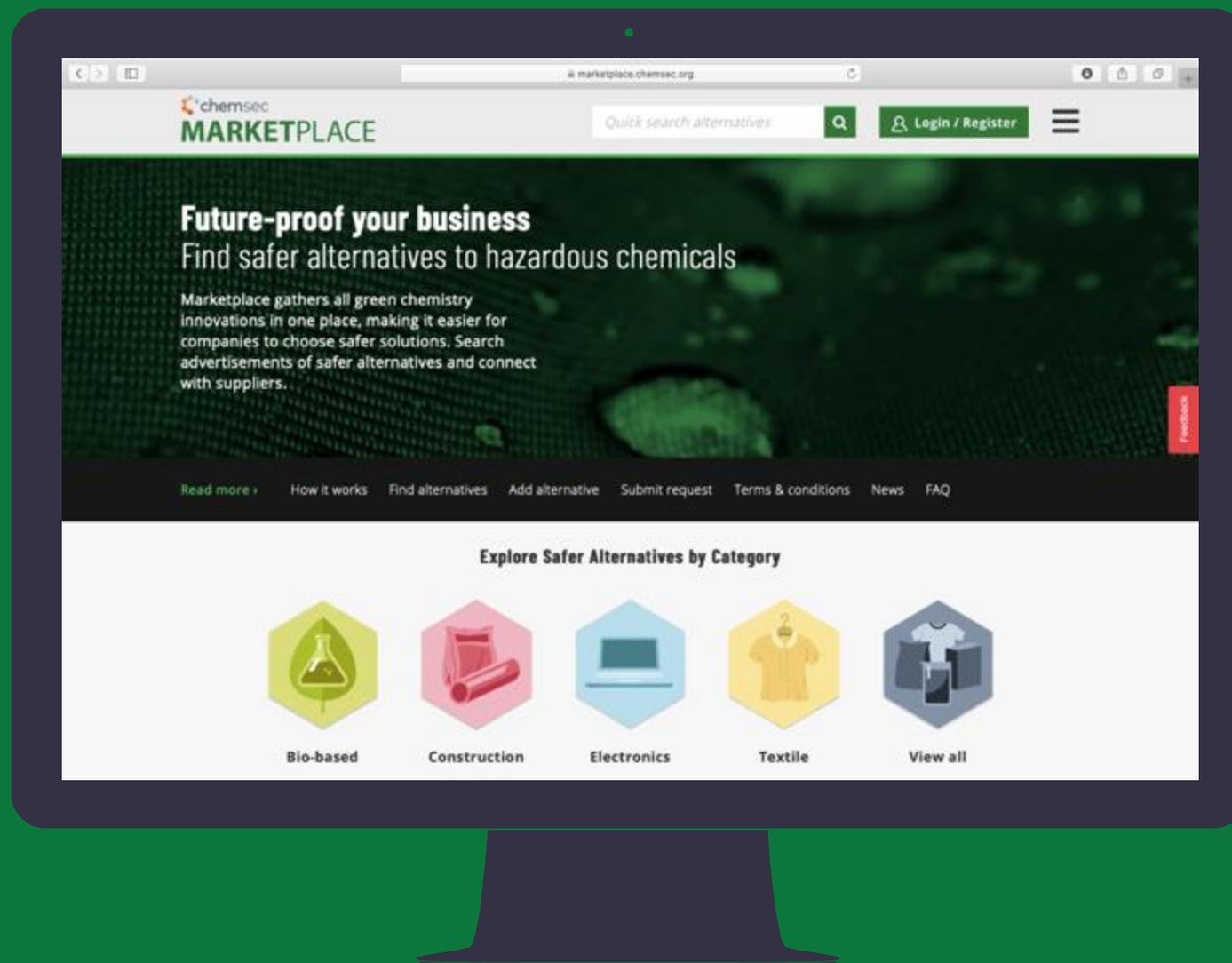
## Sector

Many industries use PFAS in some way or another for a variety of functions and purposes. These uses can be hard to find at a first glance. In this part of the guide, we publish reports with information on PFAS use and substitution with relevance for specific industry sectors.



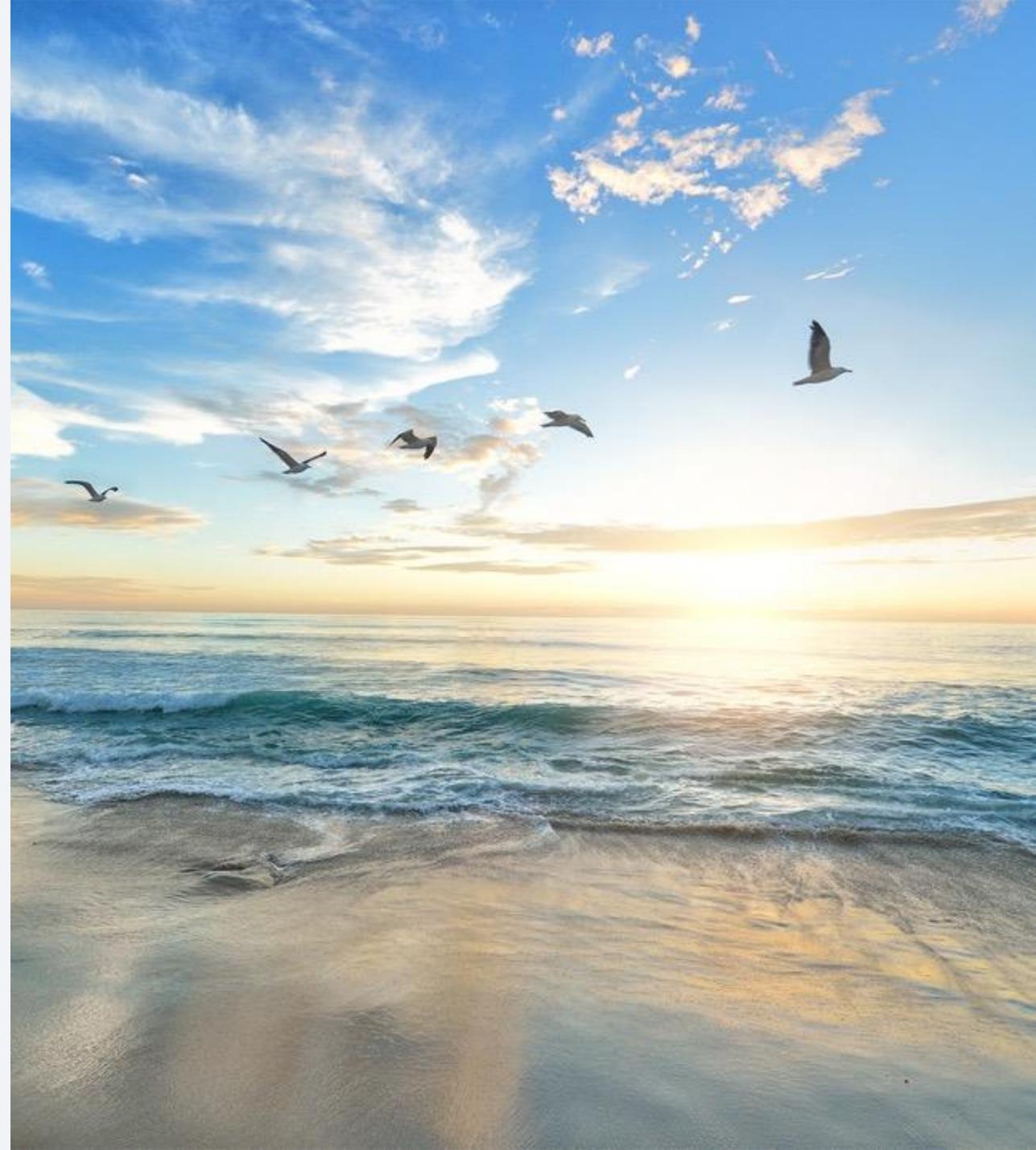
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**MARKETPLACE**

Marketplace is a global B2B platform where you can find safer alternatives to hazardous chemicals.



# SUMMARY

- Science is clear
- Business as usual is not an option
- The required changes are challenging
- Transparency
- Knowledge
- Innovation and moving to safer alternatives
- Focus on the opportunities!





# THANKS FOR LISTENING!

Frida Hök, Deputy Director at ChemSec

[frida@chemsec.org](mailto:frida@chemsec.org)

# STAY IN TOUCH WITH CHEMSEC

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# Application of an Essential Use Concept to the Manufacturing of Medicinal Products



Louise Loughran  
EFPIA Chemicals Expert



# About us

“

*Wherever the art of Medicine is loved, there is also a love for of humanity.*

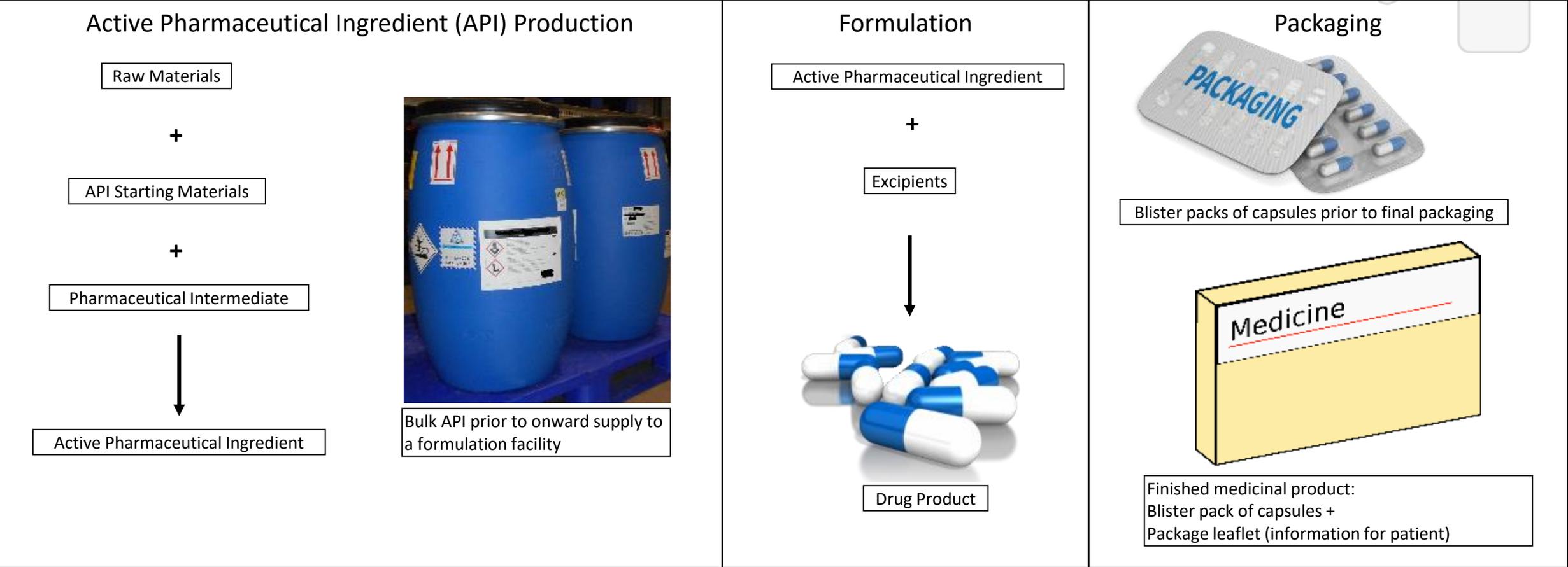
*– Hippocrates*

”

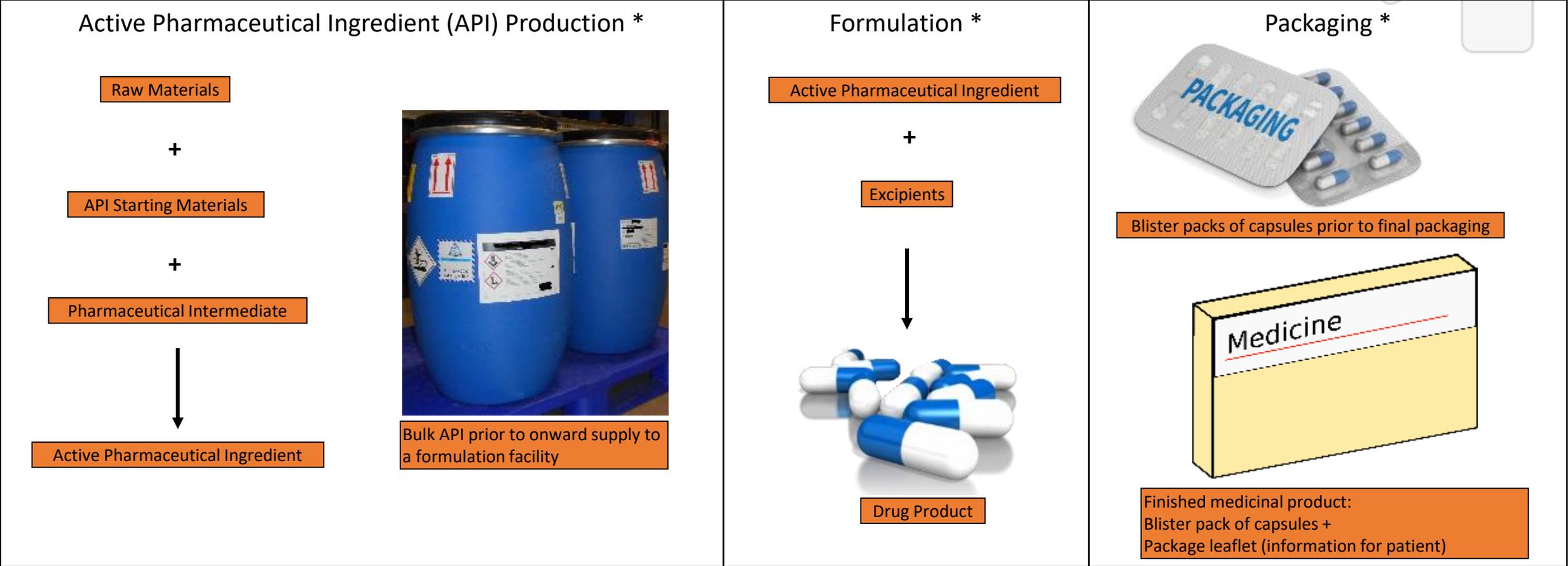
## **The European Federation of Pharmaceutical Industries and Associations (EFPIA)**

represents the pharmaceutical industry operating in Europe. Through its direct membership of 37 national associations and 38 leading pharmaceutical companies, with a growing number of small and medium-sized enterprises (SMEs). EFPIA is the voice on the EU scene of 1,900 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world.

# Specified Substance in Marketing Authorisation of a Medicinal Product – Overlaps with REACH



# What is Essential in the Manufacturing of a Medicinal Product?



Key:  
  Points in supply chain which are also subject to REACH Restriction – no sectoral specific medicinal products exemptions apply, unless derogations are granted  
 \* Activities occur within industrial settings, which are governed by REACH, CLP, OSH, IED and medicinal products regulation

# Introduction of an Essential Use Concept in REACH

## *A novel approach to the regulation of SVHCs (substances of very high concern)*



### Chemical Strategy for Sustainability<sup>1</sup>:

*“Define criteria for essential uses to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health”*

### Essential Use Concept to inform:

- General exemptions and information requirements for authorisation applications
- Derogations included in Restriction proposals

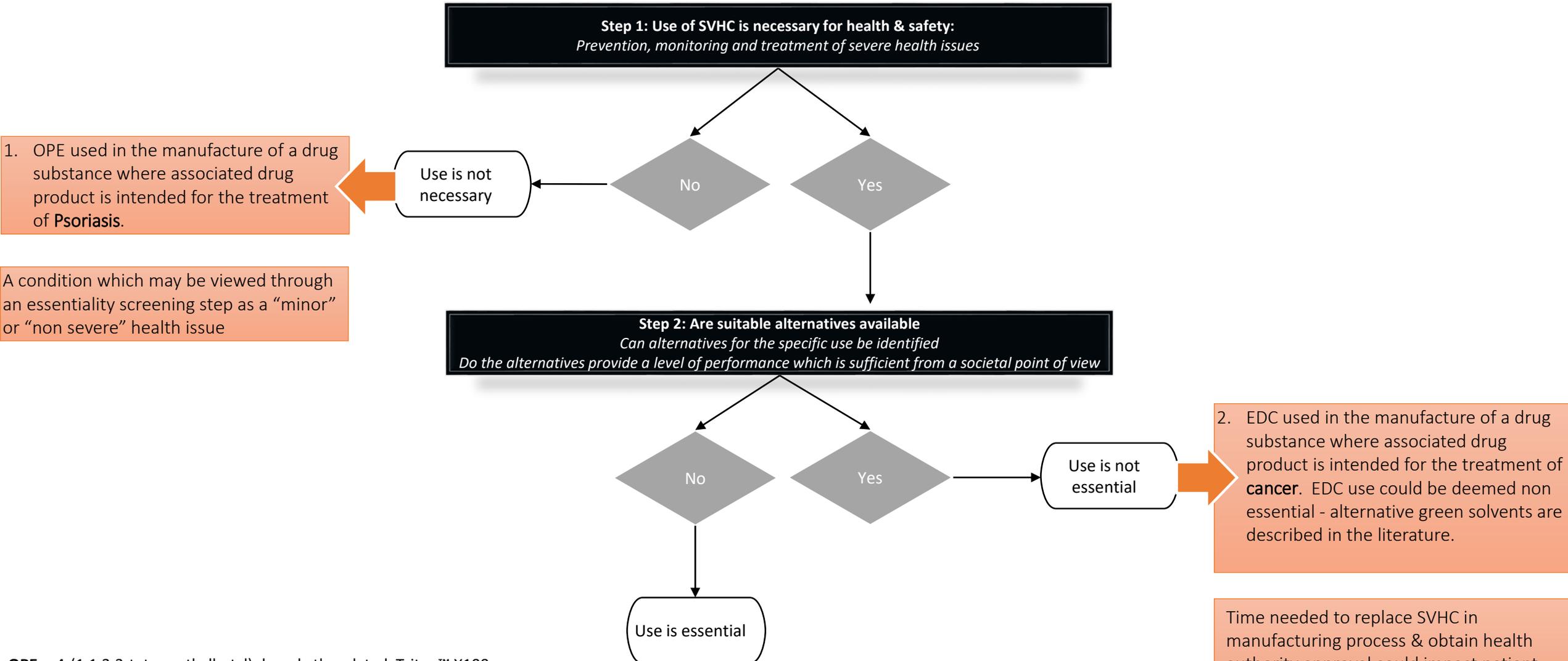
### Proposed criteria to determine necessity for health, and/or safety<sup>2</sup>:

*The use if one of the most harmful chemicals is necessary for preventing, monitoring or treating **severe health issues**. Uses may include those in medical devices, pharmaceuticals, healthcare, or other health-related uses, directly linked to the prevention, monitoring, or treatment of **severe health issues**.*

1. Commission Document [COM\(2020\) 667 final](#) – Chemical Strategy for Sustainability Towards a Toxic Free Environment  
2. [WSP Report](#) – Study to Support the Commission in Developing an Essential Use Concept (Bougas *et al*) March 2023

# Proposed Essentiality Screening Process in REACH

WSP Report - Study to Support the Commission in Developing an Essential Use Concept (Bougas et al) March 2023

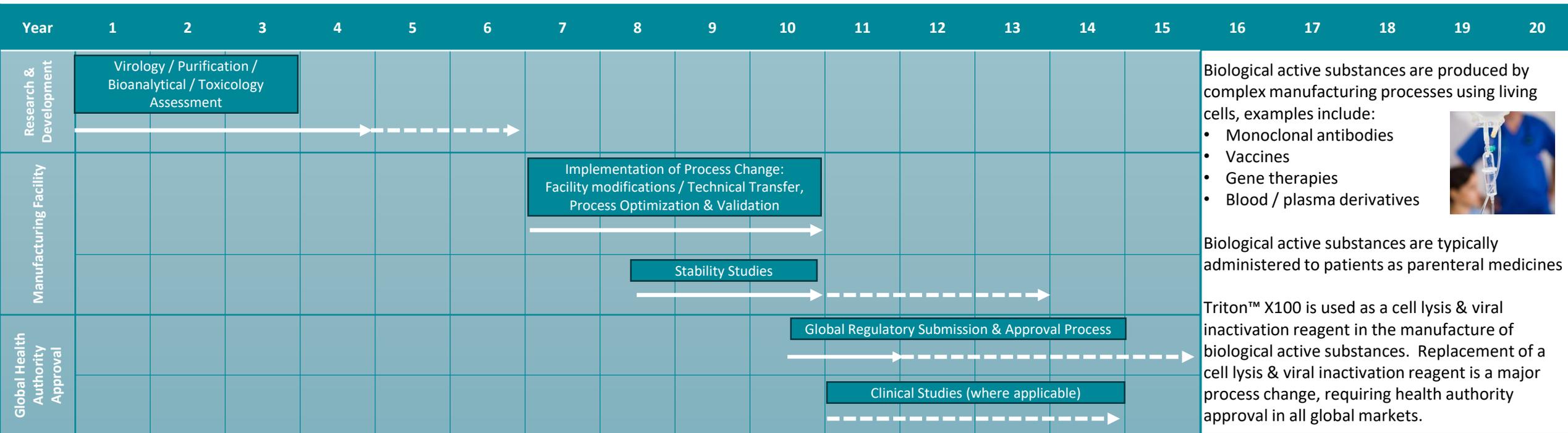


**OPE** 4-(1,1,3,3-tetramethylbutyl)phenol ethoxylated; Triton™ X100

**EDC** Ethylene Dichloride; 1,2 dichloroethane

# Potential Disruption in Supply of a Medicinal Product - Influences Ability to Substitute SVHC in Commercial Manufacturing Process

## Replacement of Triton™ X100 with a Suitable Viral Inactivation Method - Substitution Timeline & Estimated Market Short Fall in the Supply of a Monoclonal Antibody



**8½\* - 13 Years - Medicines Not Available to Patients**

\* There is no stability data on the active ingredient beyond 2½ years. If active substance is held in inventory beyond 2½ years, there is a risk of producing a medicine which fails product safety criteria. Medicine shortages could occur earlier - the amount of active substance in strategic reserves (safety stock) may be depleted before 2½ years

# Key Takeaways

Reform of Authorisation and Restriction is necessary but Essential Use Concept could make decision making process more complex

## Our obligation as a sector -

- Ensure safe and sustainable process design programs are embedded in research and development pipelines → to avoid use of SVHC or suspect SVHCs
- Implement and sustain the strategies necessary to minimise the environmental footprint of pharmaceutical manufacturing processes

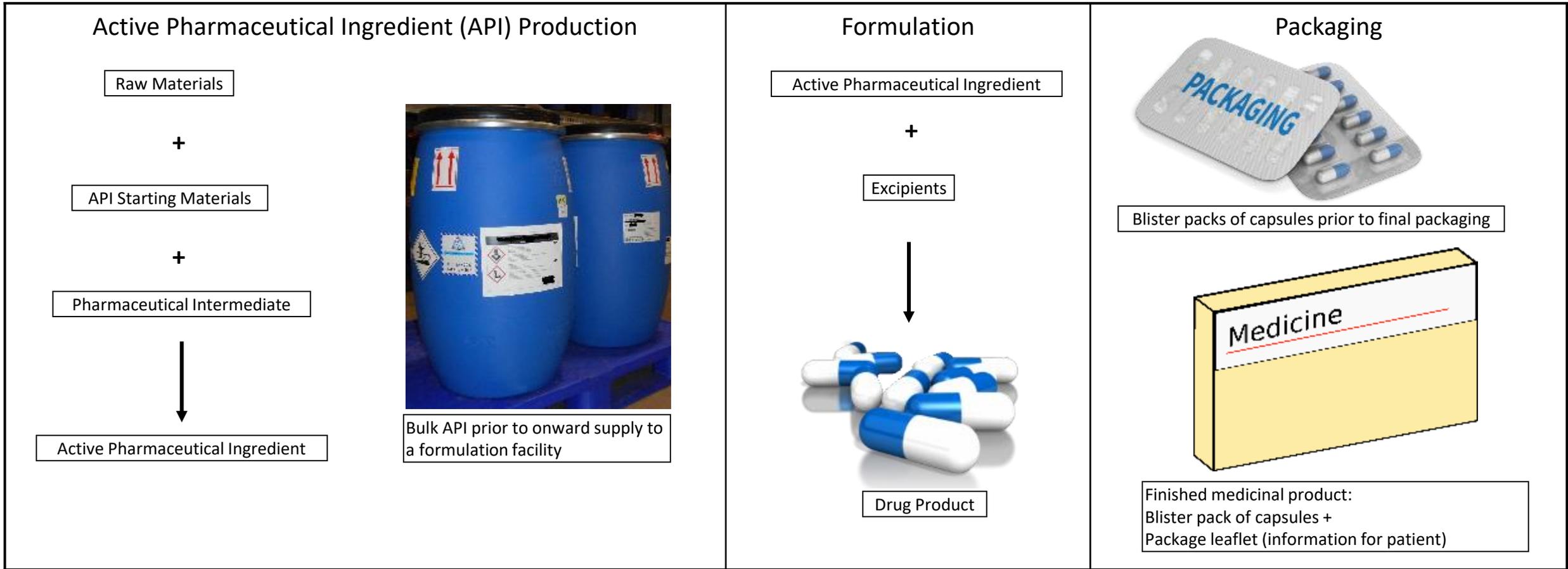
## Our ask of the REACH reform –

- Commission directorates and all agencies work collaboratively to produce a future-proof chemicals regulatory framework that does not have any adverse impact on the development, manufacture and supply of medicinal products



# Additional Background Information

# Specified Substance in Marketing Authorisation of a Medicinal Product – Overlaps with CLP / REACH



CLP & REACH	Medicinal Products Marketing Authorisation – Specified Substance Type						
	Raw Material	Starting Material	Pharmaceutical Intermediate	Active Pharmaceutical Ingredient (API)	Excipient	Drug Product	Finished Medicinal Product
Classification, Labelling & Packaging	In scope	In scope	In scope	In scope	In scope	Exempt if in “finished state intended for final user”	Exempt
Title II of REACH – Registration	In scope	In scope	In scope	Exempt	Exempt	Exempt	Exempt
Title VII of REACH - Authorisation	In scope – authorisation application required	Transported & on-site intermediates exempt	Transported & on-site intermediates exempt	Formulation of drug product exempt	Formulation of drug product exempt	Exempt	Exempt
Title VIII of REACH - Restriction	In scope unless COM grants derogation	Only on-site intermediate exempt	Only on-site intermediate exempt	In scope unless COM grants derogation	In scope unless COM grants derogation	In scope unless COM grants derogation	In scope unless COM grants derogation

## Glossary of Terms

Raw Material	A raw material is a substance or mixture of substances that is used in the production process of a drug substance, but which is not incorporated as a significant structural fragment into the structure of the drug substance (e.g. process solvent, catalyst, reagent)". => Pharmaceutical manufacturers are typically the downstream user of raw materials
API Starting Material	Starting materials determine where the API (Active pharmaceutical ingredient) manufacturing process begins. A starting material should be a substance of defined chemical properties and structure. Non-isolated intermediates are usually not considered to be starting materials. A starting material is incorporated as a significant structural fragment into the structure of the API [ICH Guideline Q11] => Meets the definition of Intermediate as defined in REACH Article 3(15)
Pharmaceutical Intermediate	A material produced during steps of the processing of an API that undergoes further molecular change or purification before it becomes an API. Intermediates may or may not be isolated. [ICH Guideline Q7] => Meets the definition of Intermediate as defined in REACH Article 3(15)
Active pharmaceutical ingredient	An active substance or API (Active pharmaceutical ingredient), is intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body. [ICH Guideline Q7] => As per Article 2(5)(a) of REACH – Active substances used in the manufacture medicinal products are exempt from Authorisation and Registration
Medicinal Product	Medicinal product as defined in Directive 2001/83/EC - Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.
Excipient	A constituent of a medicine other than the active substance ( <a href="https://www.ema.europa.eu/en/glossary/excipient">https://www.ema.europa.eu/en/glossary/excipient</a> ) => As per Article 2(5)(a) of REACH – excipients used in the manufacture medicinal products are exempt from Authorisation and Registration
Bulk product	Any product which has completed all processing stages up to, but not including, final packaging [EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines]
Finished medicinal product	A medicinal product which has undergone all stages of production, including packaging in its final container [EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines]
On-site or transported intermediate	As per Article 3(15), an intermediate is a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as "synthesis"). If the manufacture and subsequent synthesis of an intermediate into another substance takes place on the same site, this is an on-site intermediate. If an intermediate is transported between or supplied to other sites, for synthesis into another substance, this is a transported intermediate. => Article 2(8)(b) of REACH - intermediates, as defined in Article 3(15), are exempt from Authorisation. Article 68(1) of REACH - restrictions in general do not apply to on-site intermediates

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October 18<sup>th</sup> 2023

# Chemicals - monitoring, emerging issues and research on assessing risks to inform strategies

Prof. Fiona Regan, Director, DCU Water Institute

EU Chemicals Strategy for  
Sustainability Conference

Towards a toxic-free environment -  
the future for EU chemicals legislation

**DCU** Ollscoil Chathair  
Bhaile Átha Cliath  
Dublin City University

# Outline

- The emerging challenges and policy landscape
- Chemical cocktails –
- Monitoring –
- Data from studies –
- Effects and risk assessment

# Challenges From Emerging Contaminants

- Emerging contaminants (EC's) are pollutants of growing concern.
- They are mainly organic compounds such as: pesticides, pharmaceuticals and personal care products, hormones, plasticizers, food additives, wood preservatives, laundry detergents, surfactants, disinfectants, flame retardants, and
- other organic compounds that were found recently in natural wastewater stream generated by human and industrial activities.

Wired data  
Wireless data  
Instrument

contaminants

contaminants  
by physical f  
sorbent.

# Towards an improved risk assessment framework

...design of better chemicals,

Chemical pollution can have long-term and large-scale environmental impacts

The new term “toxic-free environment” is considered, by some, to be political, while for others, the phrase might appear non scientific as, in the end, everything can be toxic depending on the dose or concentration.

The zero pollution ambition for a toxic-free environment implies a continuous improvement of the environmental status;  
Currently risk assessments do not predict the impact of a chemical, especially a persistent one, in years from now by continued emission.

Inconsistent risk assessments can create public mistrust, as with glyphosate and bisphenol-A

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## Additional Water treatment requirements

- EU law – Urban Wastewater Treatment Directive → removal of micropollutants
- Adding a 4<sup>th</sup> level of treatment
- Ireland must improve compliance – currently at 51% of current standards whereas EU average is 90%



# Chemical Cocktail

Chemical cocktails harmful to wildlife found in 81% of English rivers and lakes

Campaigners call for rigorous testing of waterways to protect species

after analysis reveals scale of problem

In Europe, the chemicals policy has evolved since the 1960s and has generated over 40 pieces of legislation.

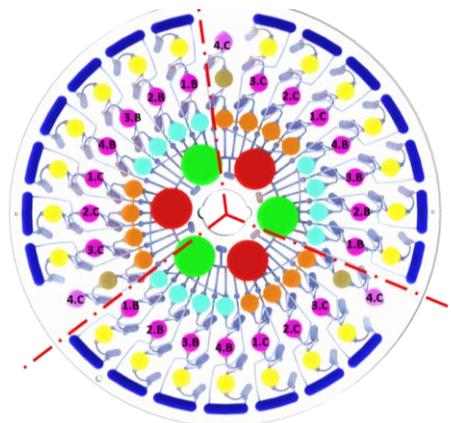
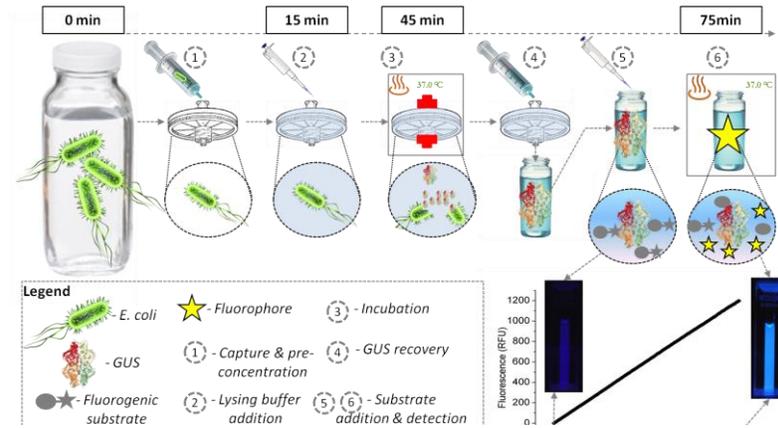
all European policies on the environment should be based on the precautionary principle

the polluter should pay

risk assessment process should be harmonized.

The EU tries to achieve this by enabling a “one substance— one assessment” approach.





- Biological antibody mixing reservoir
  - Chemical sample load reservoir
  - Chemical antibody/peptide mixing reservoir
  - Test reservoir
  - Control reservoir
  - Waste storage
  - Chelex resin loaded reservoir (Control)
  - Test Reservoir for Heavy metals only
- 1.B Saxitoxin detection, and derivatives
  - 2.B Microcystin detection, and derivatives
  - 3.B Azaspiracid detection, and derivatives
  - 4.B Domoic acid detection, and derivatives
  - 1.C Naphthalene
  - 2.C PFOS

# DCU Water PolluTech Lab

# Monitoring

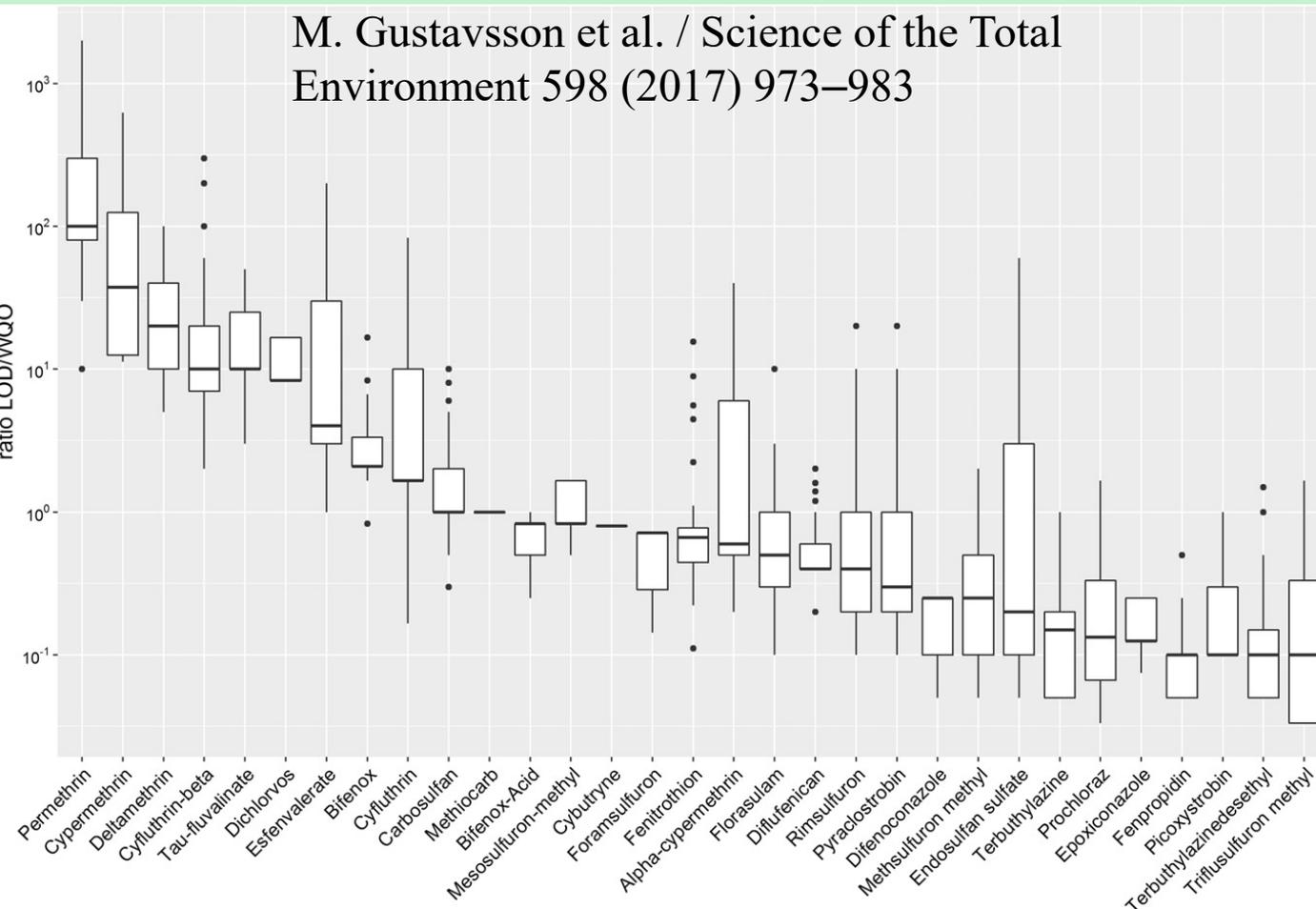
- Matrix challenges

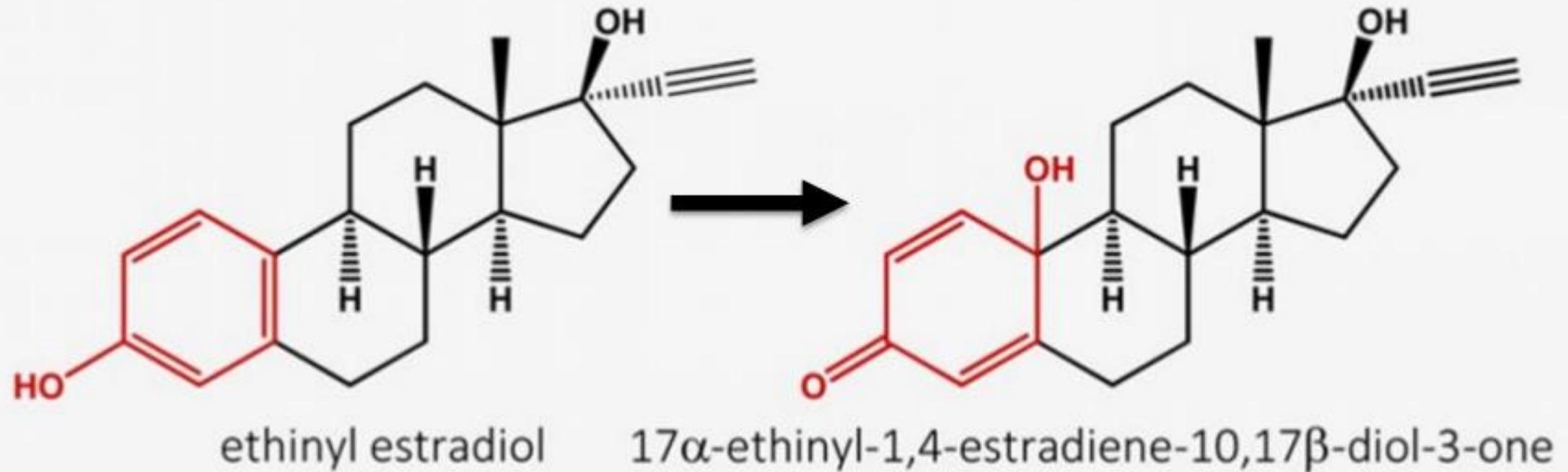
- Analytical methods

Few studies have incorporated the analysis of the **metabolites of sulfonamide** in wastewater such as N<sub>4</sub>-acetyl sulfamethoxazole and N<sub>4</sub>-acetyl sulfamethazine.

metabolites - during wastewater treatment should be routinely considered → known to be transformed back to the parent compounds in wastewater environments.

Significant complications in the quantification of antibiotics by liquid chromatography–mass spectrometry (LC–MS) → matrix-specific factors, vary depending on the origin and

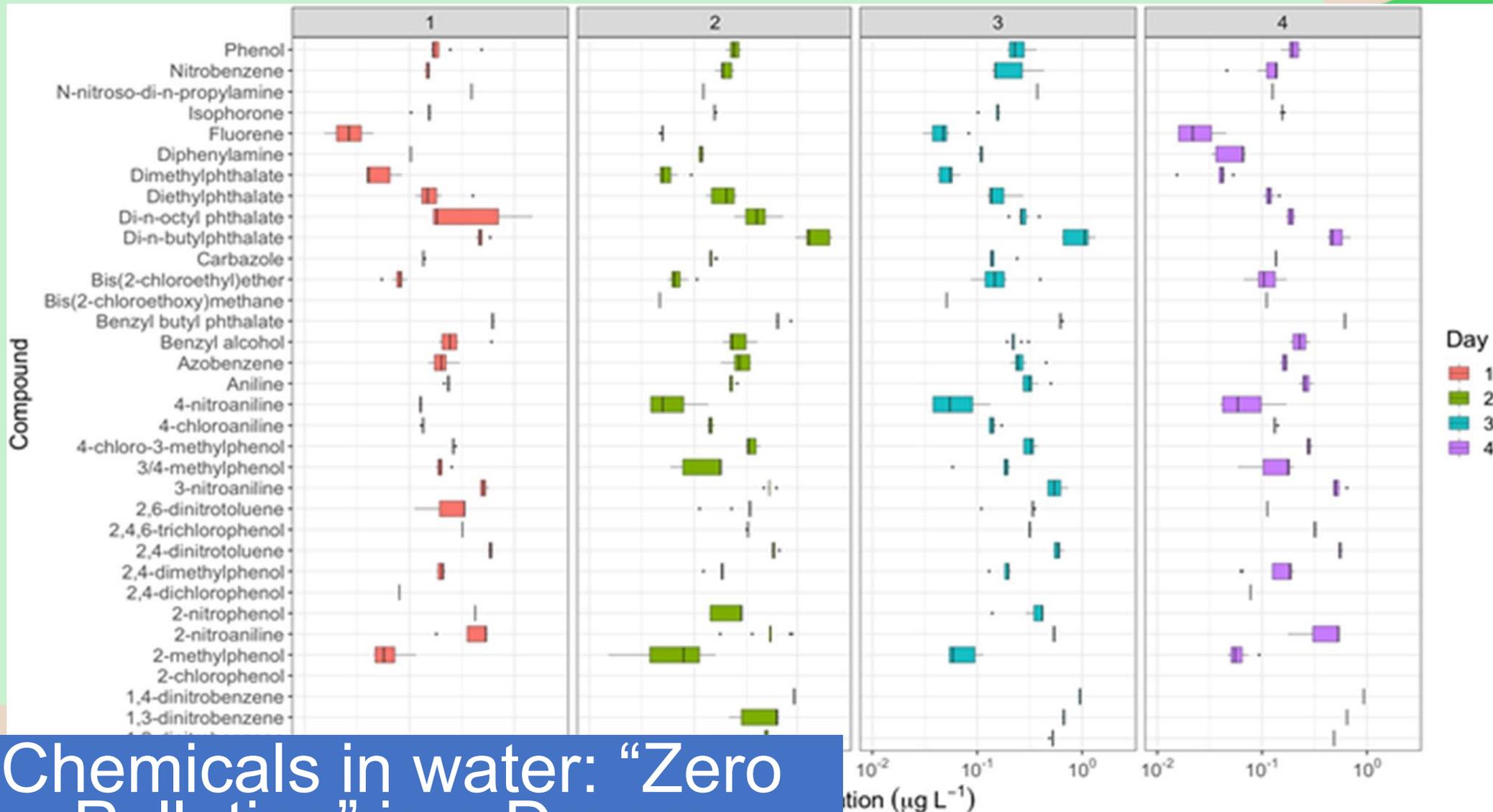




## Oxidation of Ethinylestradiol

Transformation product has a higher estrogenicity than the parent compound

# Surface water as an indicator



Chemicals in water: “Zero Pollution” is a Dream

# Studies

Phthalate – occurrence and human exposures

PFAS – occurrence and potential sources

Pharmaceuticals – during and after COVID-19

Pesticides – in wastewater and surface water

# Cycle of Phthalates and their Metabolites in the WWTP

Phthalates are ubiquitous synthetic organic compounds

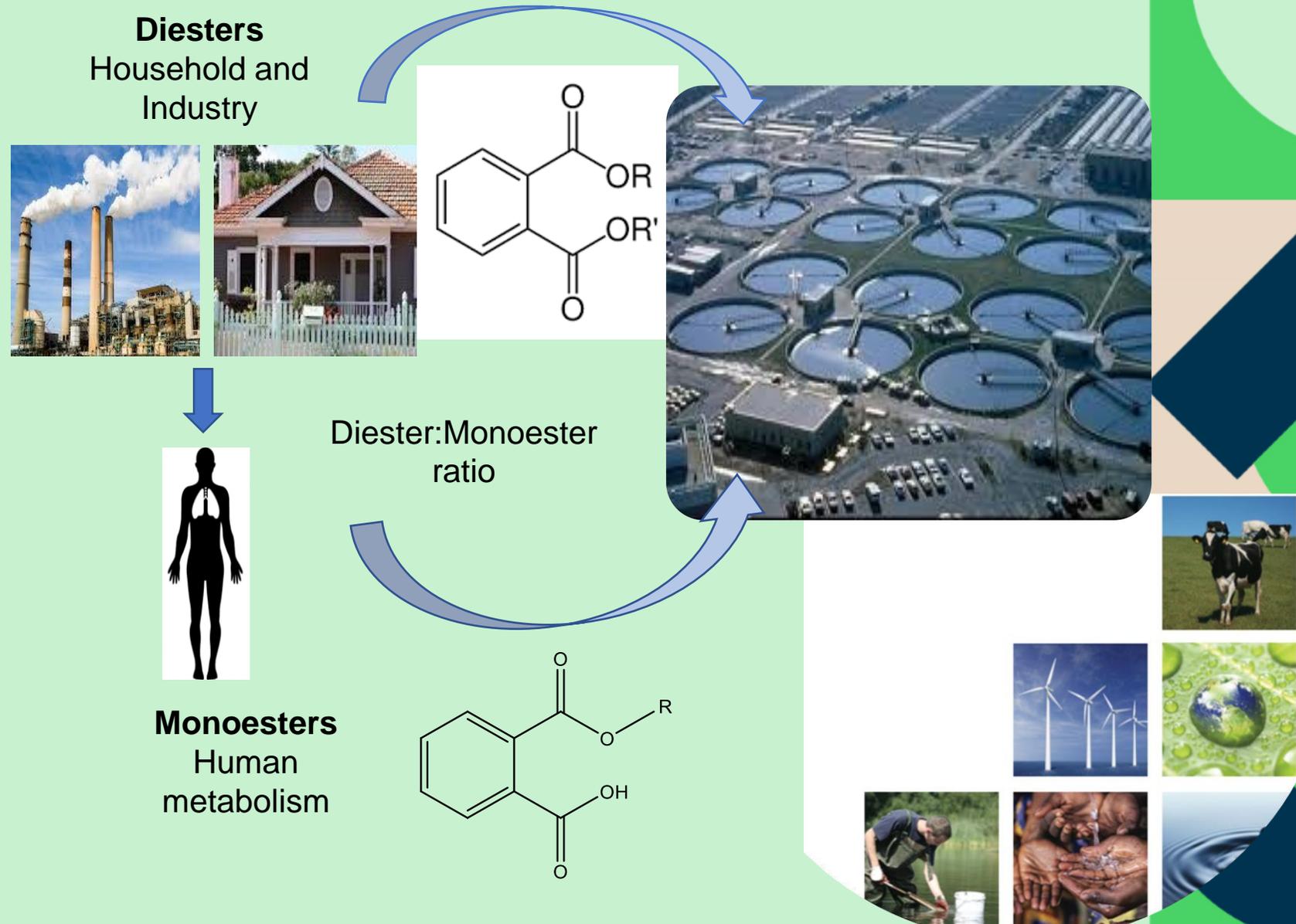
- Plasticisers
- Endocrine disruptors
- Banned/limited in manufacturing

Exposure routes:

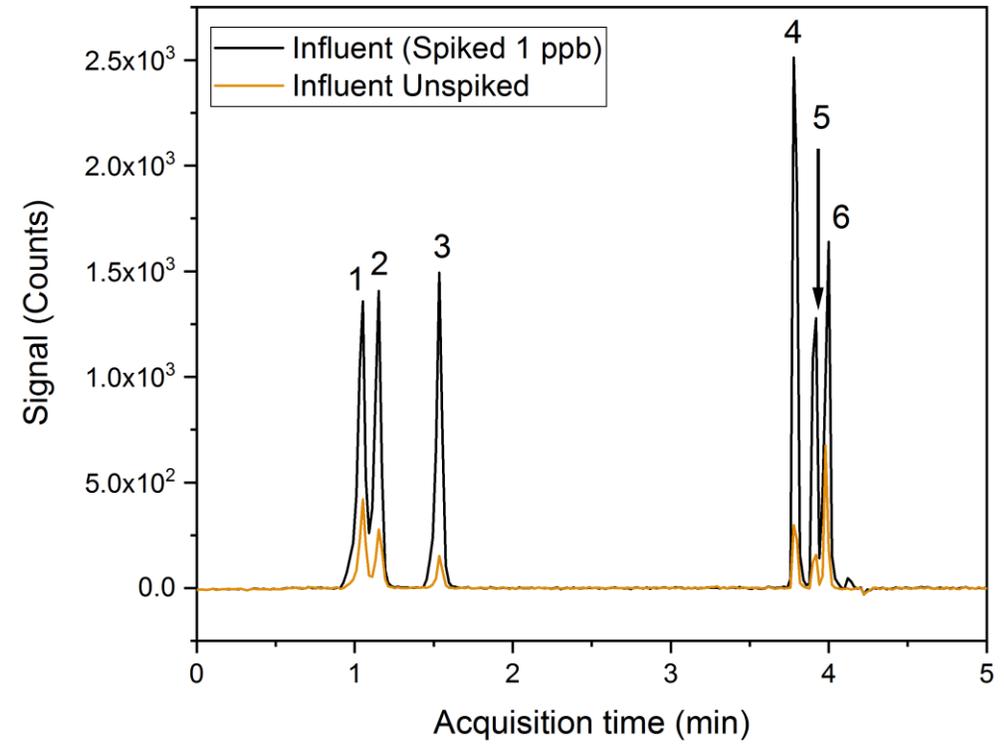
- Ingestion
- Inhalation
- Absorption

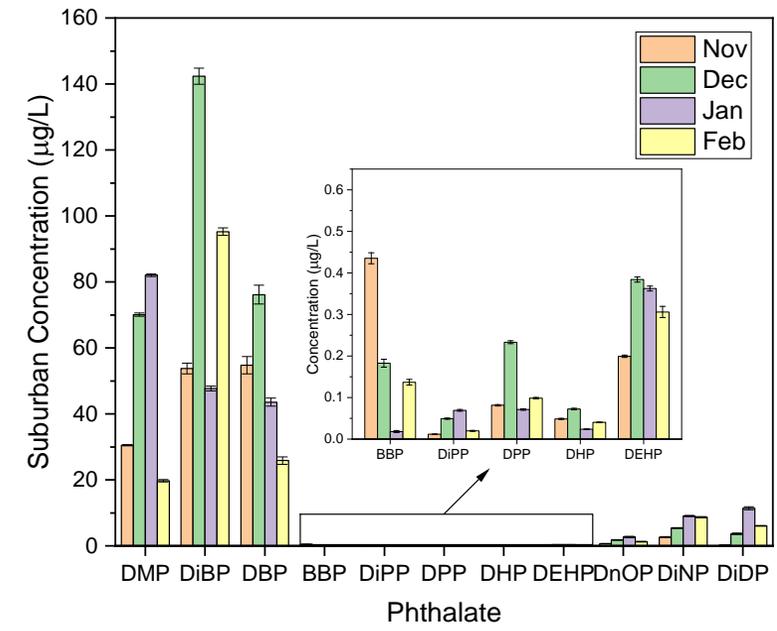
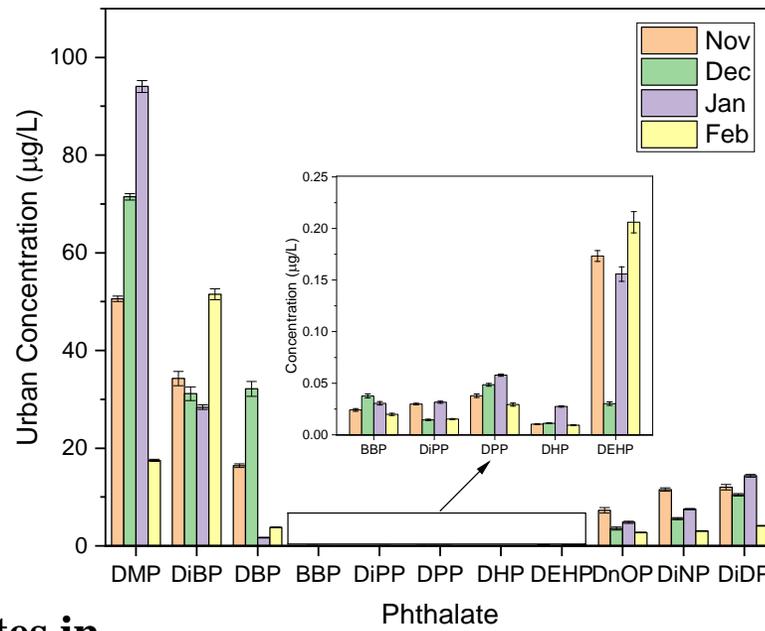
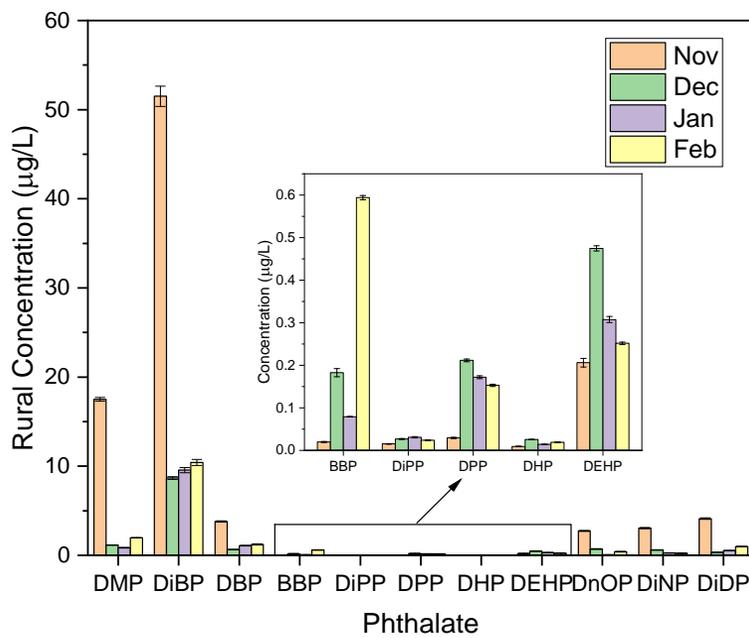
Health Impacts:

- Male Birth Defects
- Impaired neurological development in children
- Obesity



Monoester analytical method application to wastewater influent samples.



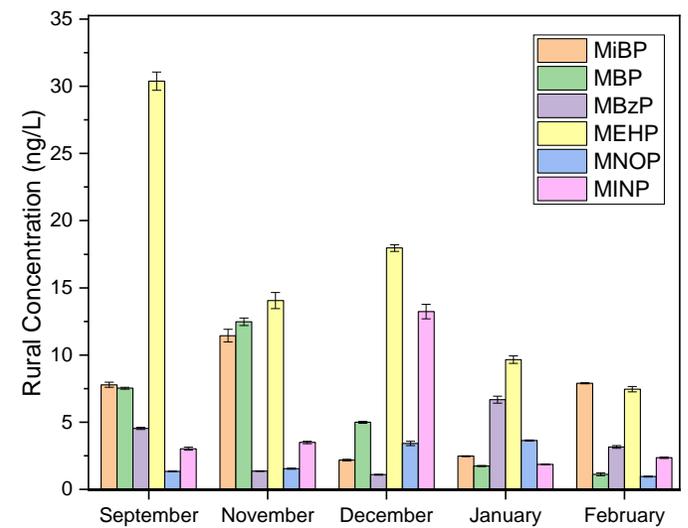
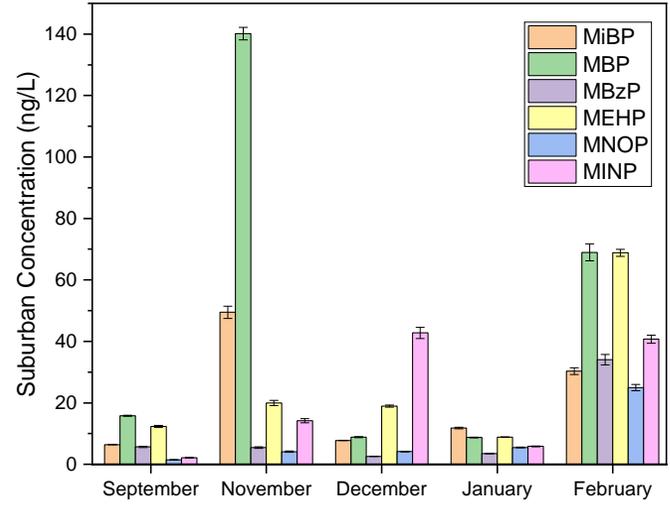
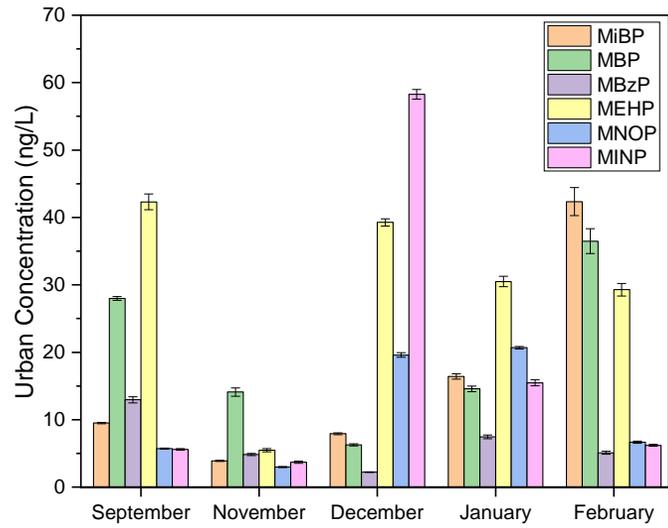


## International Comparison of Phthalates in Wastewater Influent (µg/L)

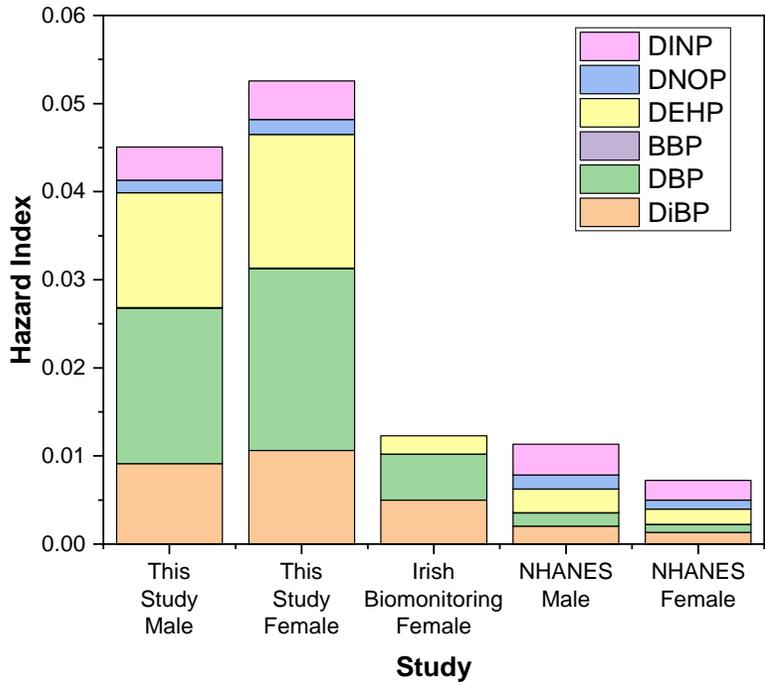
Location	DMP	DBP	BBP	DEHP	DOP	Reference
U.K*	0.26	2.54	1.46	23.6	0.11	(Oliver et al., 2005)
France*	1.5	4.1	4.0	33.3	0.7	(Tran et al., 2015)
Austria	N.D.– 2.4	N.D.– 8.7	0.31– 3.2	3.4– 34.0	N.D.– 1.1	(Clara et al., 2010)
China	4.05– 6.49	8.73– 24.46	N.D.– 5.67	2.42– 30.99	4.63– 12.84	(Gao et al., 2014)
South Africa*	–	0.92– 18.26	N.D.– 6.54	N.D.– 53.21	–	(Gani and Kazmi, 2019)
Ireland	0.80- 95.76	0.58- 78.60	0.01- 0.60	0.03- 0.48	0.08- 7.85	**This Study
India	–	0.928– 18.06	0.90– 19.63	9.17– 218.4	–	(Gani et al., 2016)
South Africa	0.89– 24.51	3.12– 2497	N.D.– 52.25	6.16– 96.18	3.08– 67.37	(Salaudeen et al., 2018)
Puerto Rico*	520	13020	16920	7490	–	(Soler-Llavina et al., 2017)

## International Comparison of Phthalates in Sludge Reported in mg/kgdw

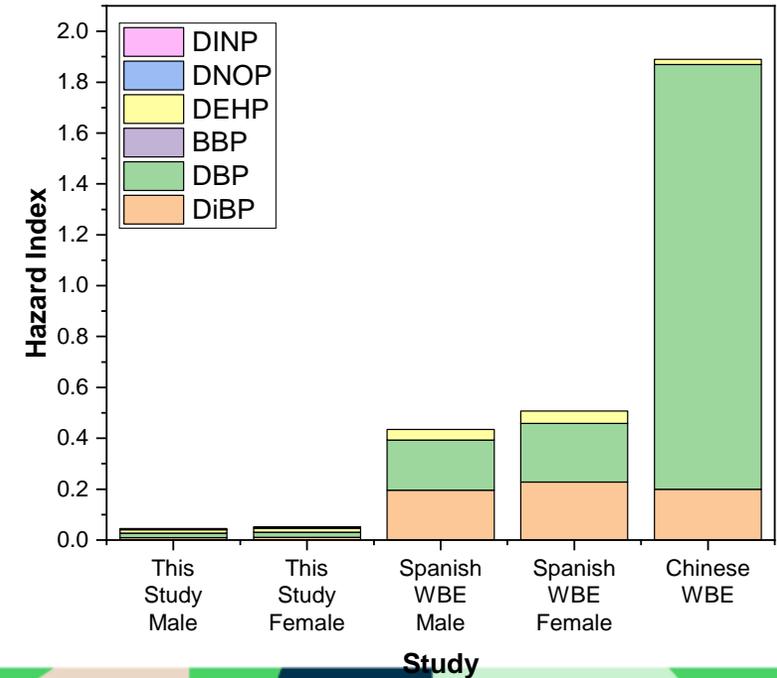
Samples	DMP	DBP	BBP	DEHP	DOP	Reference
China	0.19– 0.91	0.54– 1.94	N.D.– 6.89	1.85– 9.41	1.11– 8.09	(Gao et al., 2014)
U.K.*	0.04	0.97	1.45	30.2	0.14	(Oliver et al., 2005)
France*	2.7	0.09	0.37	72.1	1.9	(Dargnat et al., 2009)
South Africa	–	0.13– 3.16	N.D.– 10.21	N.D.– 76.47	–	(Gani and Kazmi, 2019)
Ireland	6.76- 90.84	24.65- 314.23	1.43- 41.53	6.75- 74.55	0.19- 7.46	**This Study
Turkey	1.4-2.7	0.6-4.6	2.8-6.2	18-490	–	(Çifci et al., 2013)
South Africa	6.00-6.10	939- 1248.6	277- 621.8	271- 352.7	71.9- 94.9	(Salaudeen et al., 2018)
Korea	0.0024–	0.58-	N.D.-	1.40-	–	(Lee et al., 2019)



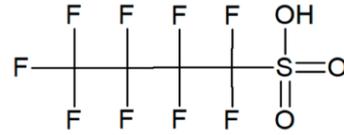
**Hazard Index of Exposure to Phthalates from this study Compared to a Small-Scale Irish Biomonitoring Study (Cullen et. Al 2017) and a Large-scale International Biomonitoring Study (NHANES, 2013-2014)**



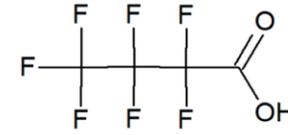
**Hazard Index of Exposure to Phthalates from this study Compared to a WBE studies from Spain (Gonzalez-Marino et al., 2017) and China (Du et al., 2018)**



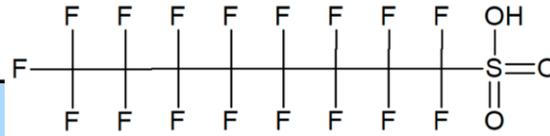
# Poly- and perfluoroalkyl substances (PFASs)



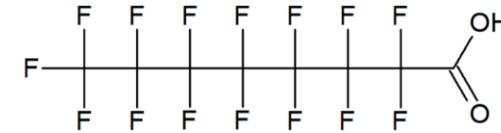
PFBS



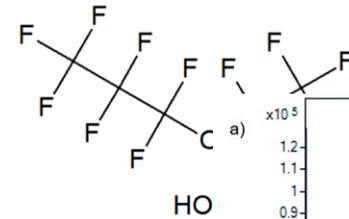
PFBA



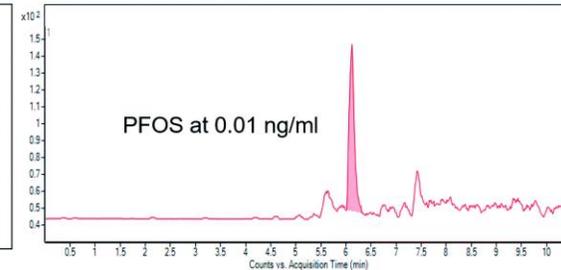
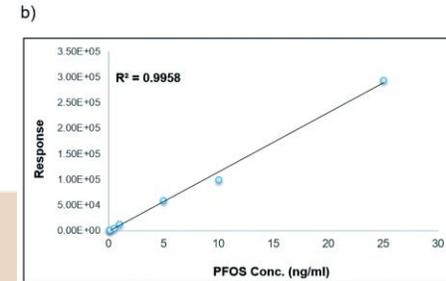
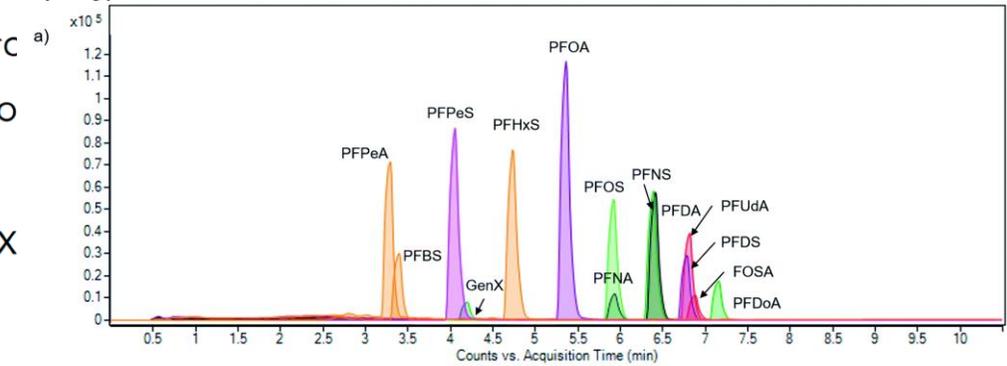
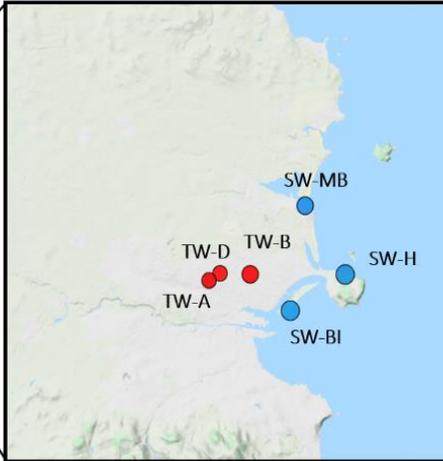
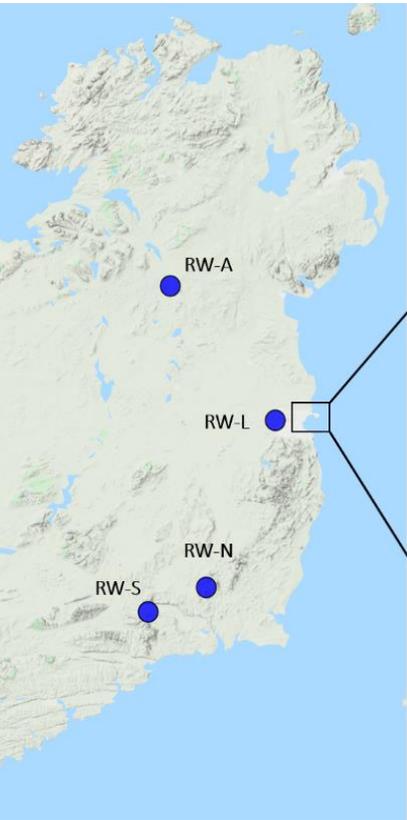
PFOS



PFOA



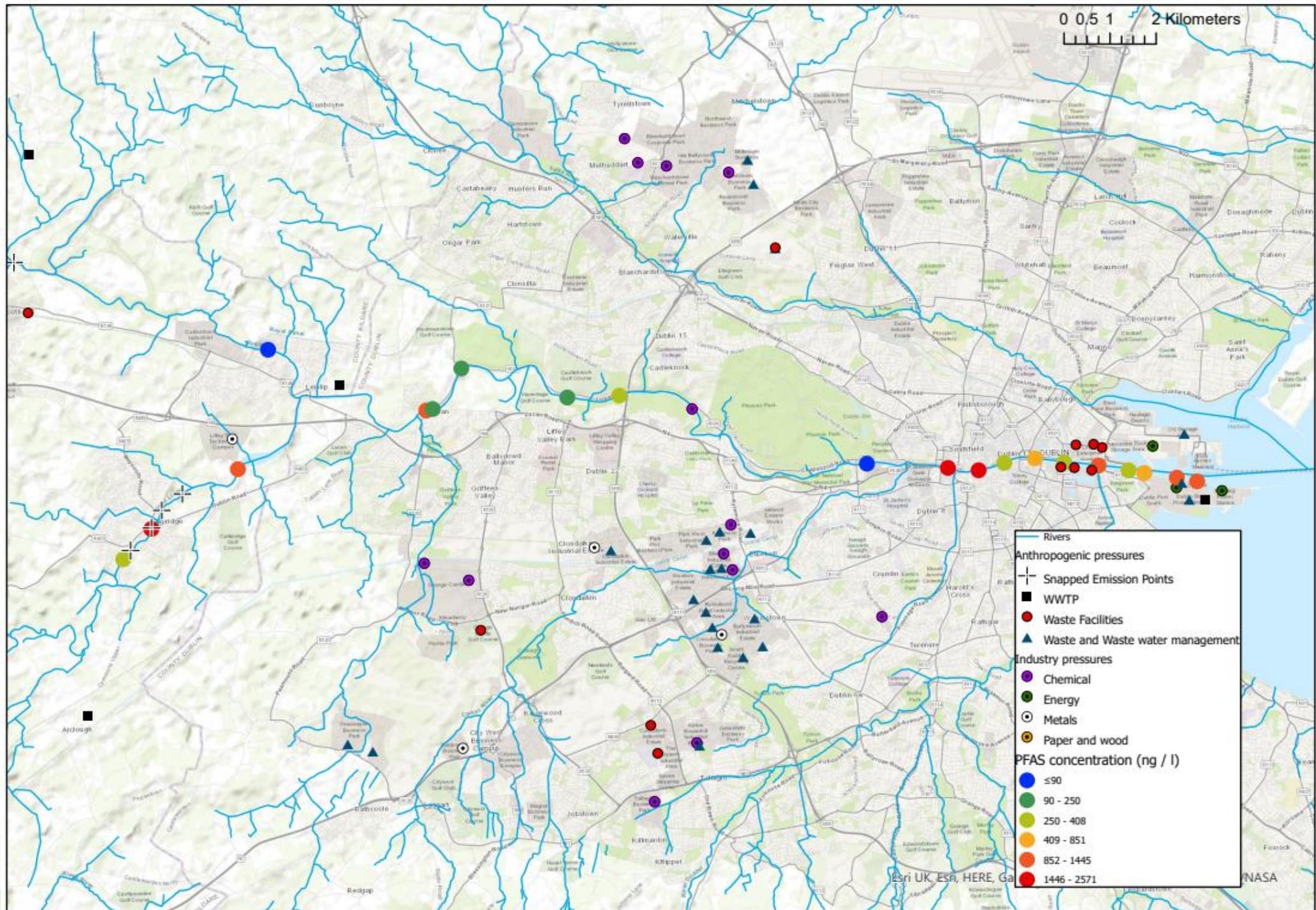
GenX



Forever chemicals



0 0.5 1 2 Kilometers



**Rivers**

**Anthropogenic pressures**

- ⊕ Snapped Emission Points
- WWTP
- Waste Facilities
- ▲ Waste and Waste water management

**Industry pressures**

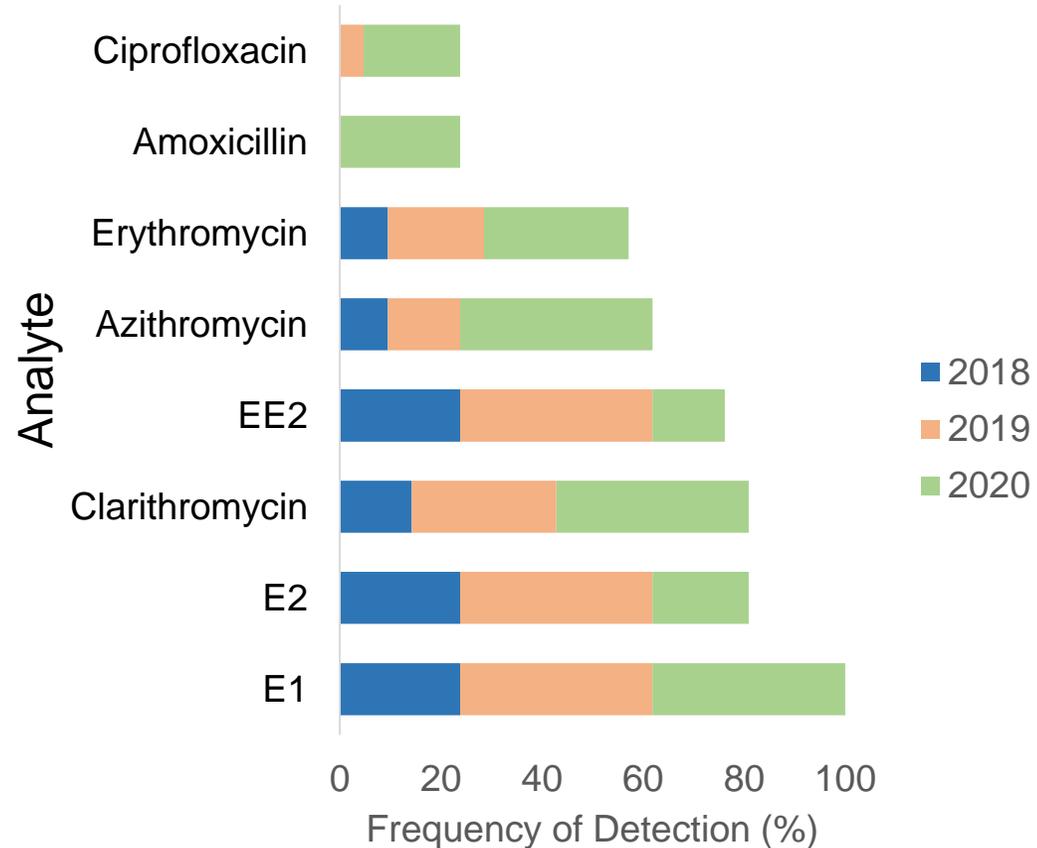
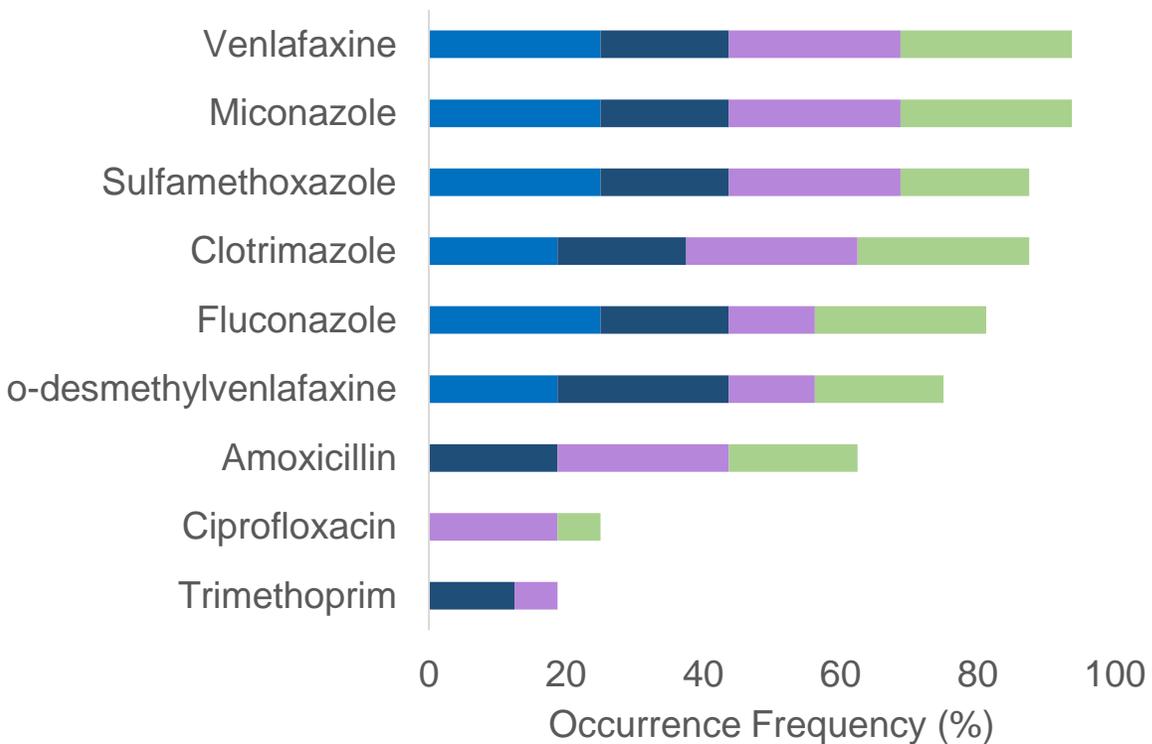
- Chemical
- Energy
- ⊙ Metals
- Paper and wood

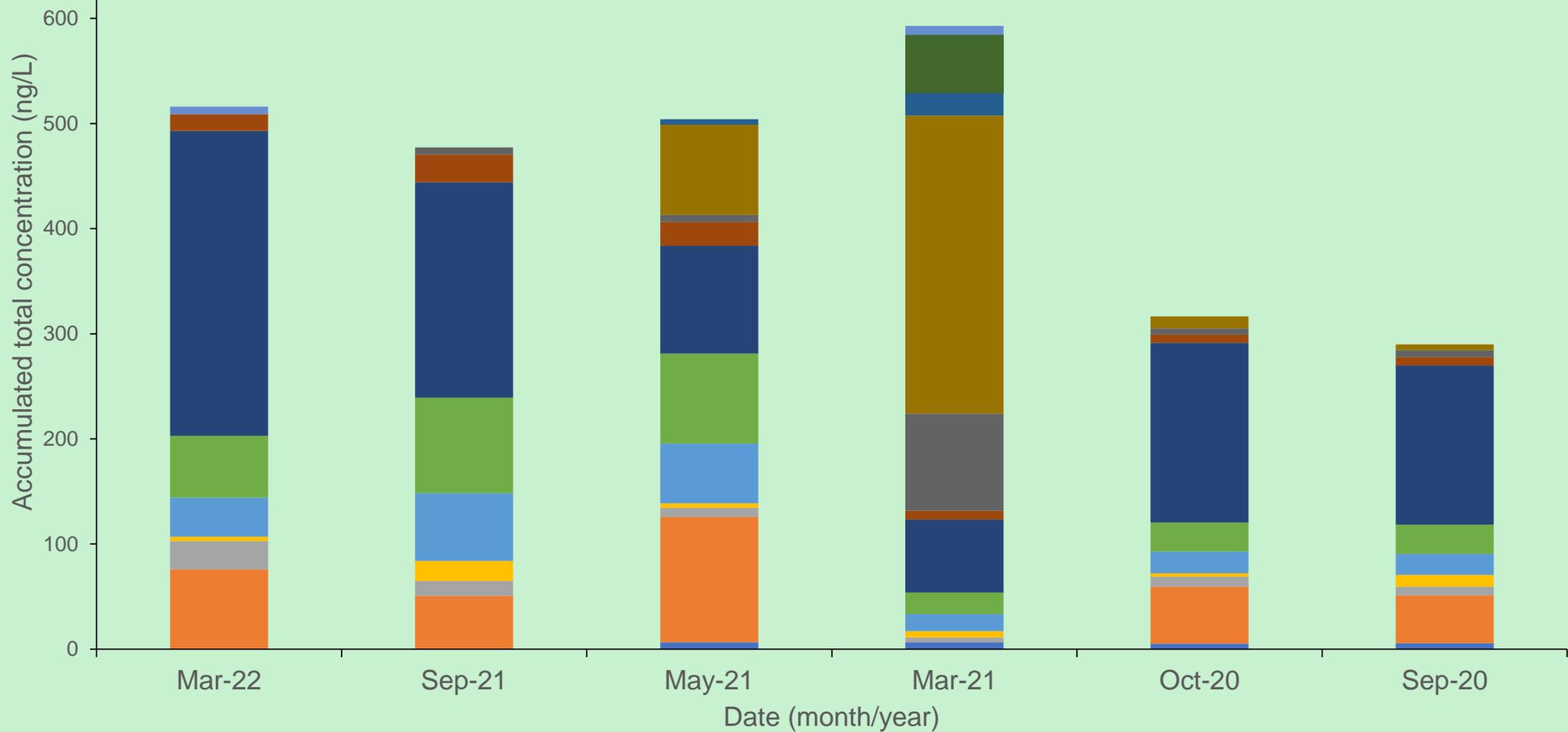
**PFAS concentration (ng / l)**

- ≤90
- 90 - 250
- 250 - 408
- 409 - 851
- 852 - 1445
- 1446 - 2571

# Pharmaceutical occurrence

- Watch List Monitoring



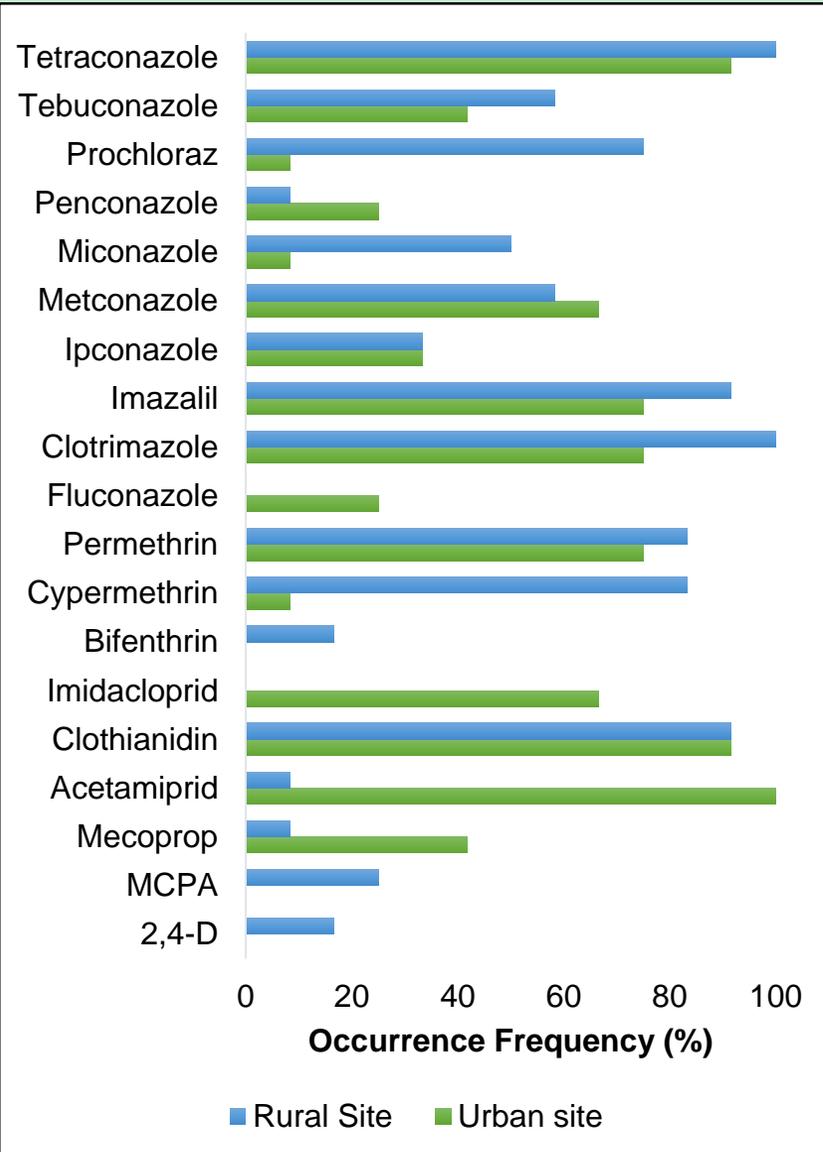


- Metformin
- Gabapentin
- Trimethoprim
- Ciprofloxacin
- Venlafaxine
- O-desvenlafaxine
- Sulfamethoxazole
- Carbamazepine
- Diclofenac
- Gemfibrozil
- E1
- Erythromycin
- E2

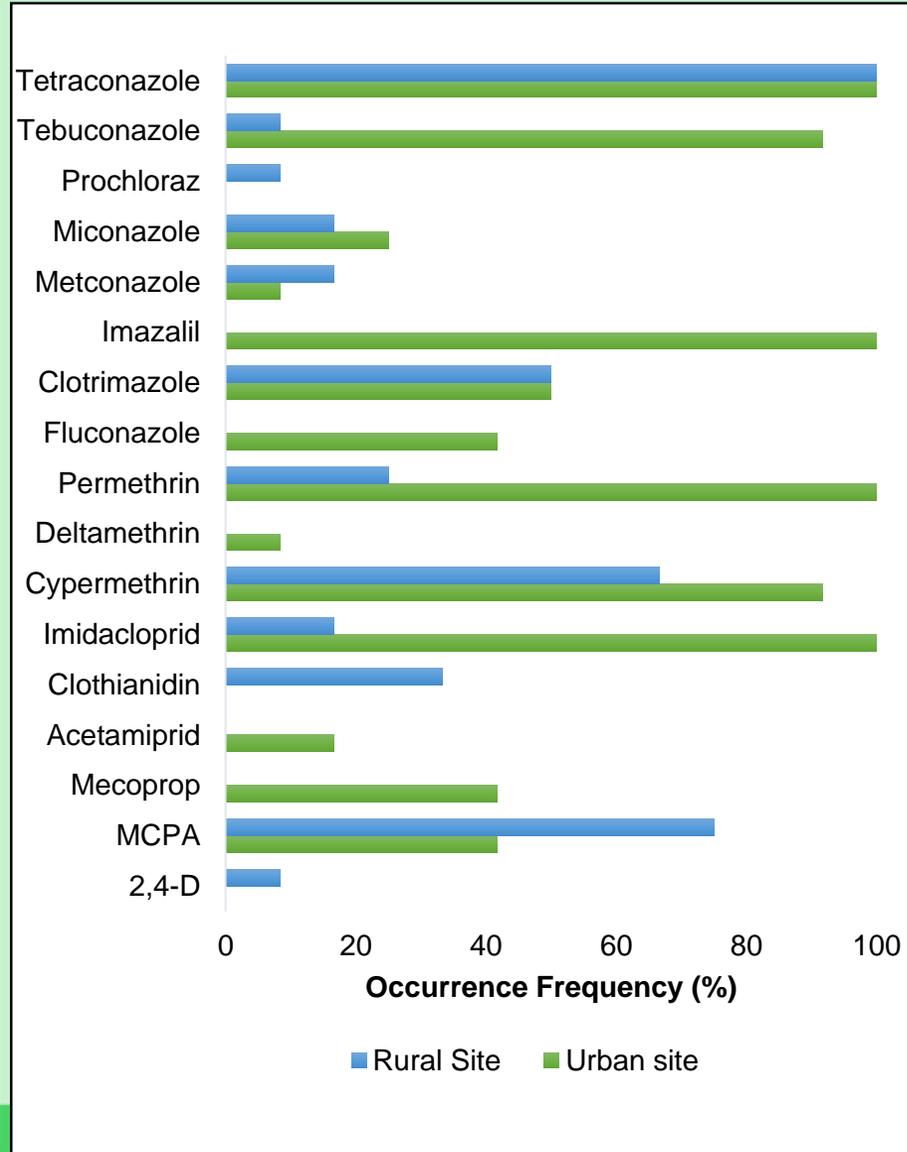


# Pesticide Occurrences

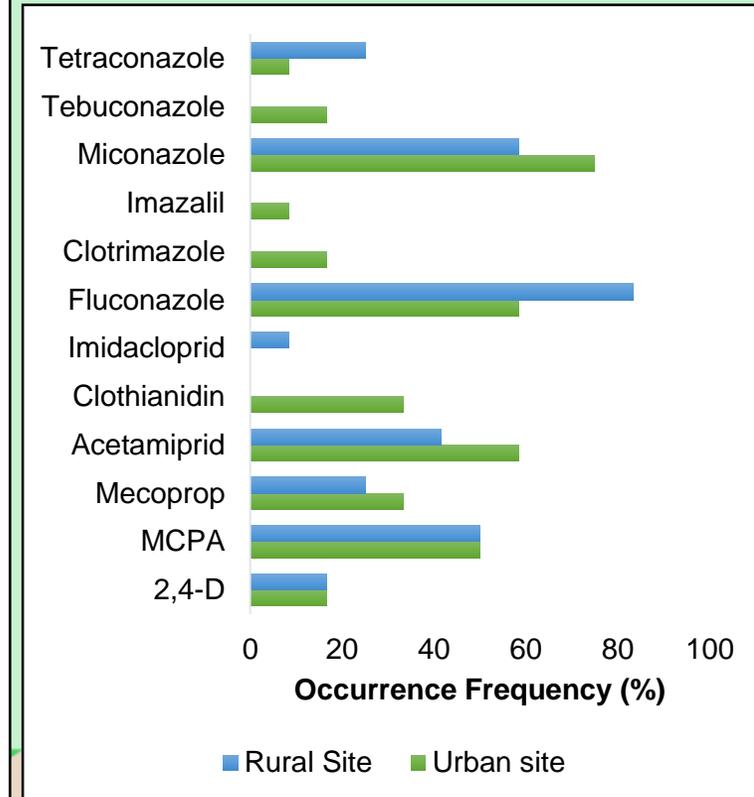
## Wastewater Influent

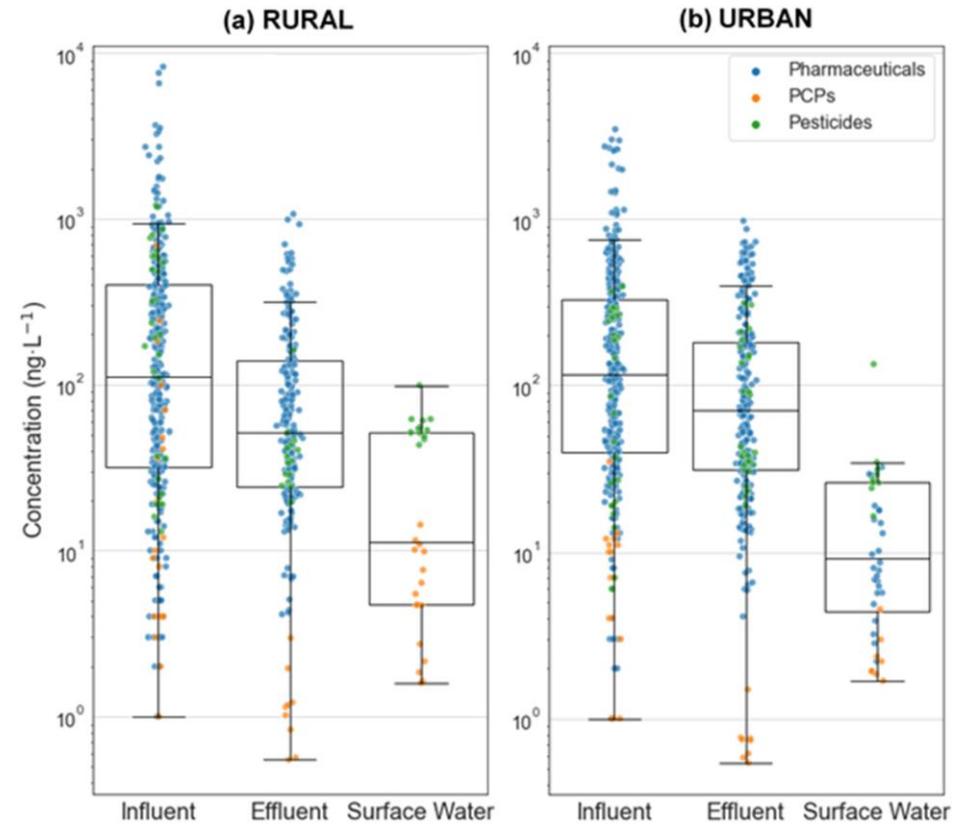
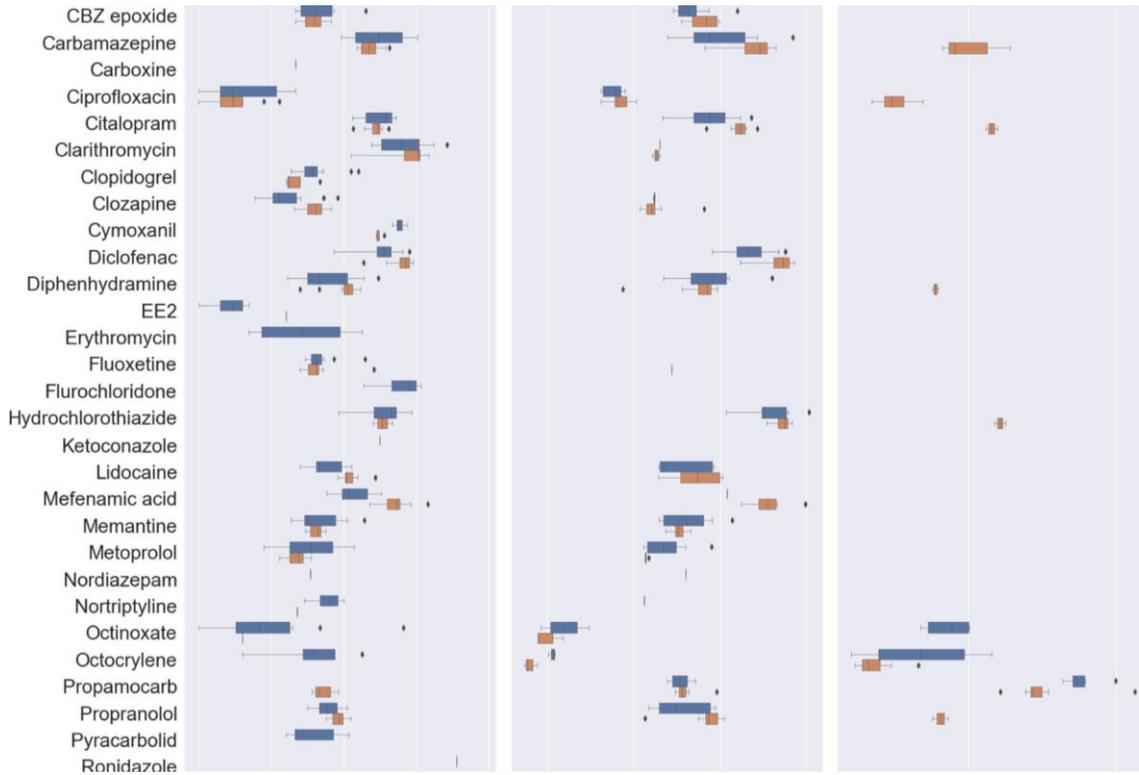


## Effluent



## Receiving Waters



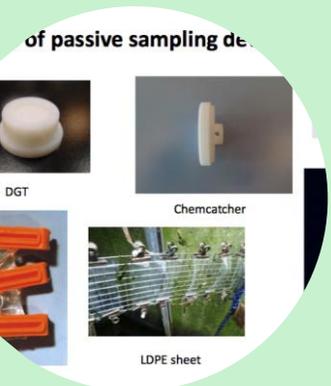
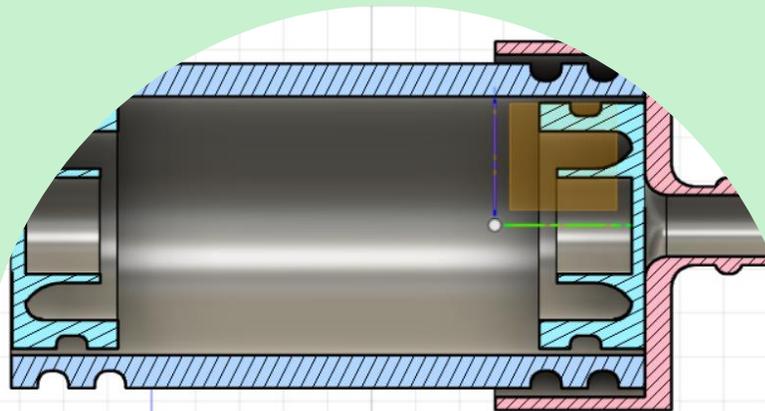
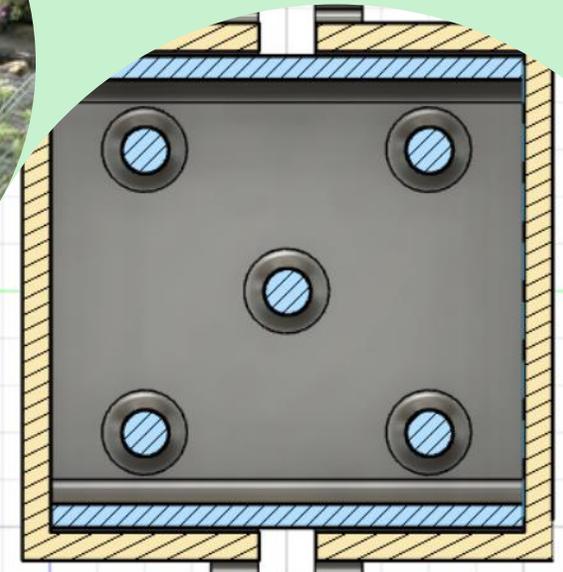


# 12-month study

Combined concentrations of all CECs (colour-coded by class) measured in the rural (a) and urban areas (b) across the year-long campaign.

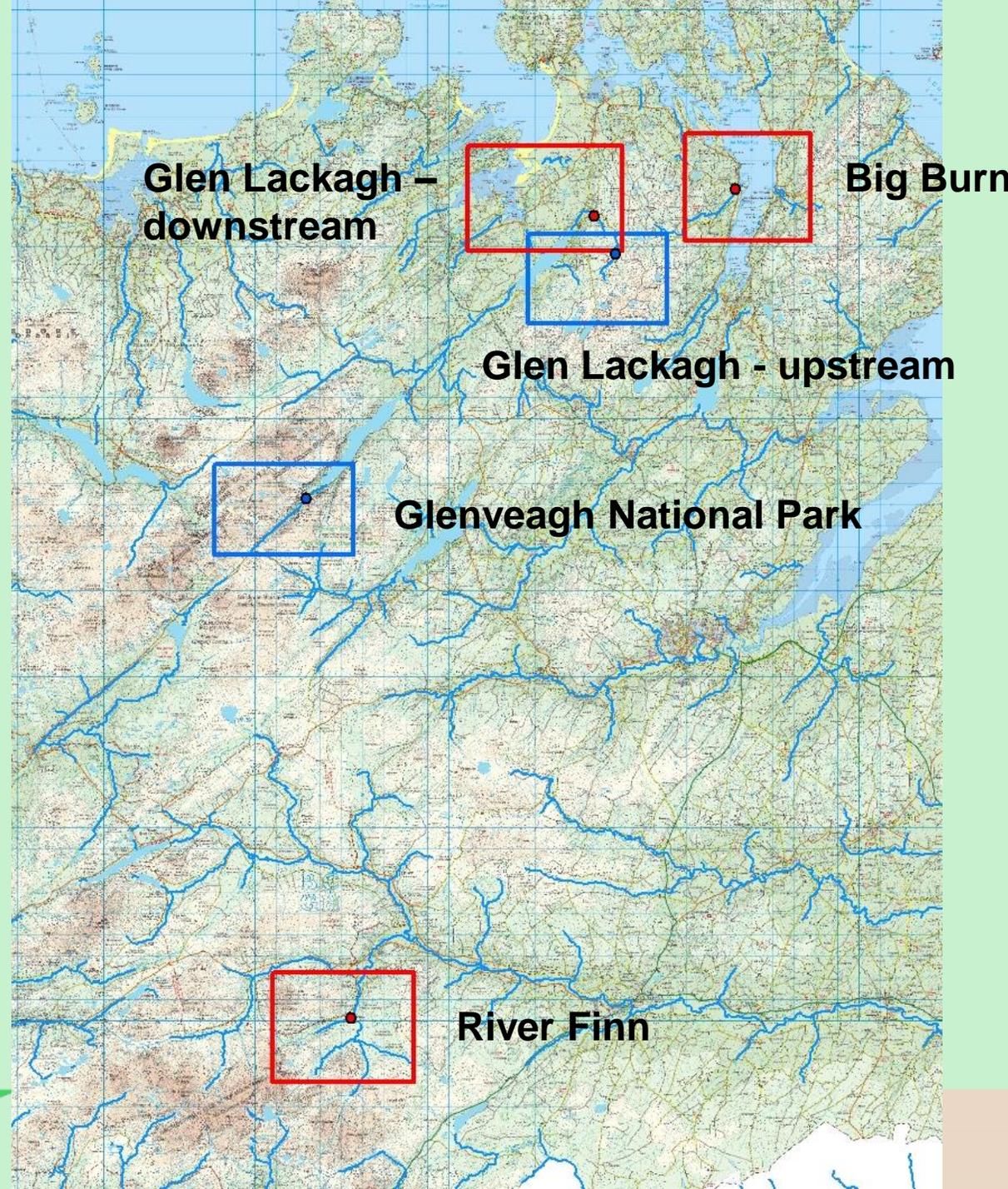
# Passive Sampling

- Time weighted average concentration measurements;
- Screening for chemicals;
- Trend monitoring;
- A valuable tool in environmental assessment
- New 3D printed dynamic passive samplers



3 Sensitive  
potentially  
impacted sites

2 Control sites



# Investigative cypermethrin results

Location	April Water ng/L	May Water ng/L	PDMS** deployed	PDMS field blank	SPMD ng/L	Comment
Glen Lackagh Upstream*	1.17	1.47	++	+/-	<70	Exceeded EQS in water and at low conc in PDMS
Glen Lackagh midstream A*	n/a	1.67	-	-	-	Exceeds EQS
Glen Lackagh midstream B	n/a	1.38	-	-	-	Exceeds EQS
Glen Lackagh midstream C	n/a	1.73	-	-	-	Exceeds EQS
Glen Lackagh Bridge*	1.08	1.78	+++	+/-	<70	Exceeded EQS in water and at higher conc in PDMS

Red = exceeds UK Total Cypermethrin EQS. 0.08ng/L \* Average of n = 2.

\*\*Relative cypermethrin concentration scale based on corrected sample injection volume but not for PDMS sampling rate.



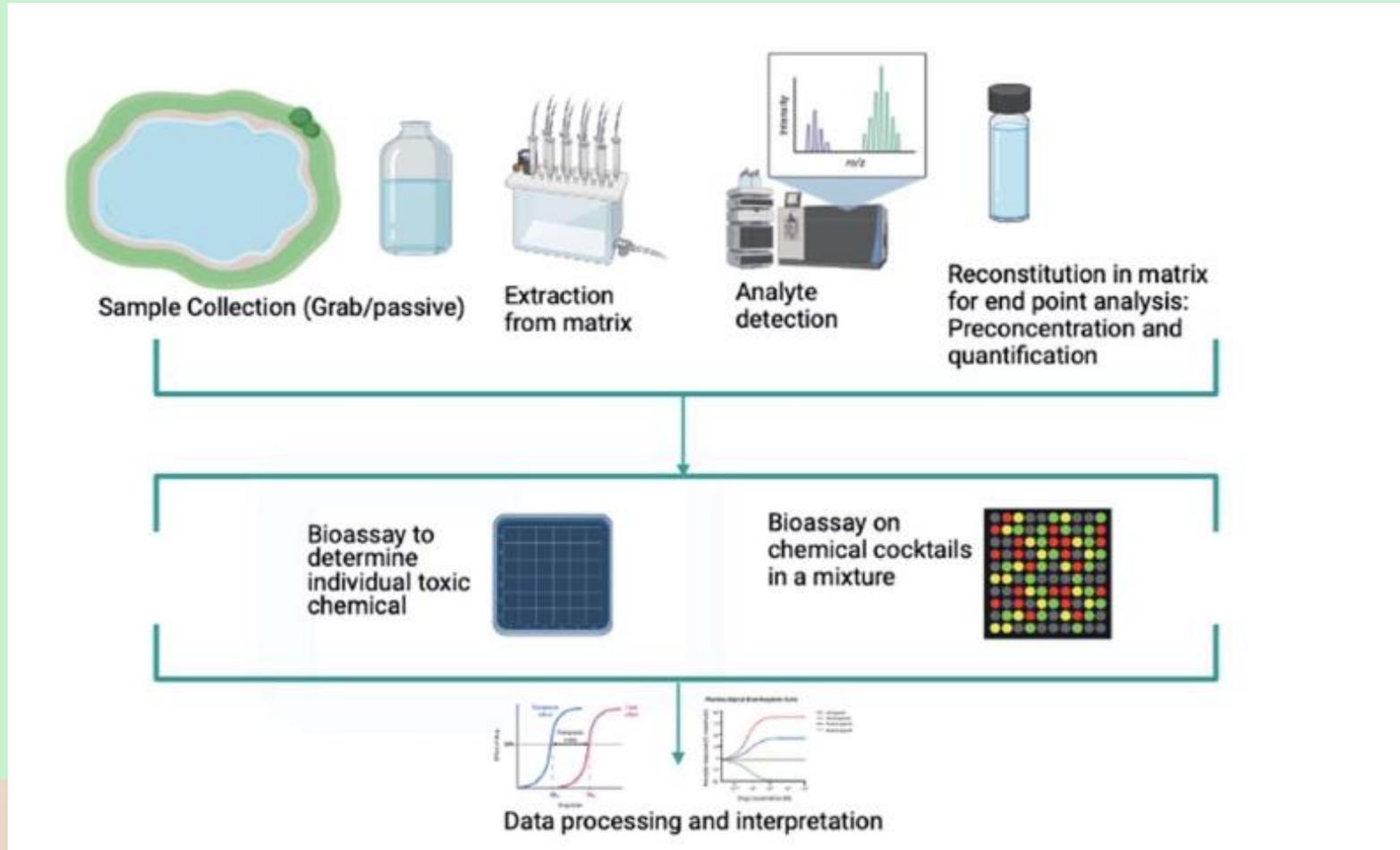
Table 53. Table of TWA concentrations determined from passive samplers deployed during summer 2021, \* denotes semi-quantitative results only.

	TWA concentration per site in ng L <sup>-1</sup>						
	Liffey			Donegal			
	US	WWTP	DS	Glen A	Glen B	Glenadowan (Clogher)	Cranford (Big Burn)
2,4-D	2923.4 ± 501.5	4144.5 ± 559.6	184 2.7	~	~	~	~
MCPA	280.2 ± 33	427.4 ± 129.8	302. 3	~	~	~	~
Mecoprop	15.04 ± 6.4	15.2 ± 7.02	38.9 4	~	~	~	~
Bifenthrin*	~	~	~	3830.7 ± 429	3575.6	~	~
Cypermethrin*	~	~	~	50519.	8	20048.9	~
Deltamethrin*	~	~	~	34947.3 2156.4 ± 493.8	~	~	~
Permethrin*	~	~	~	45259.	5	~	~
Imazalil	~	~	~	25165.5 41.3 ± 23.7	~	26.6 ± 11.4	12.6 ± 7.8
Ipconazole*	~	~	~	6.5 ± 2.2 207.6 ± 155.01	~	~	~
Metconazole*	~	~	~	235.7	~	131.4 ± 85.3	198.5 ± 60
Miconazole*	~	~	~	13.7 ± 1.3 217.1 ± 37.7	~	~	~
Penconazole	~	~	~	37.7	339.5	115.1 ± 87.2	111.6 ± 82.8
Tebuconazole*	~	~	~	59.3 ± 3.9	~	~	68.2 ± 3.2
Tetraconazole*	~	~	~	~	~	~	~

Figure 77. Map of sampling sites selected for study of a combined approach to catchment monitoring. Top right shows site 2 sites selected for study in the Donegal area, site key: (1) Glenadowan (Clogher), (2) National Park, (3) Glen A, (4) Glen B, (5) Cranford (Big Burn). Bottom right shows three sites in Kildare for Liffey study, site key: (1) Liffey Upstream, (2) Liffey Midstream, (3) Liffey Downstream.

# Biological Effects

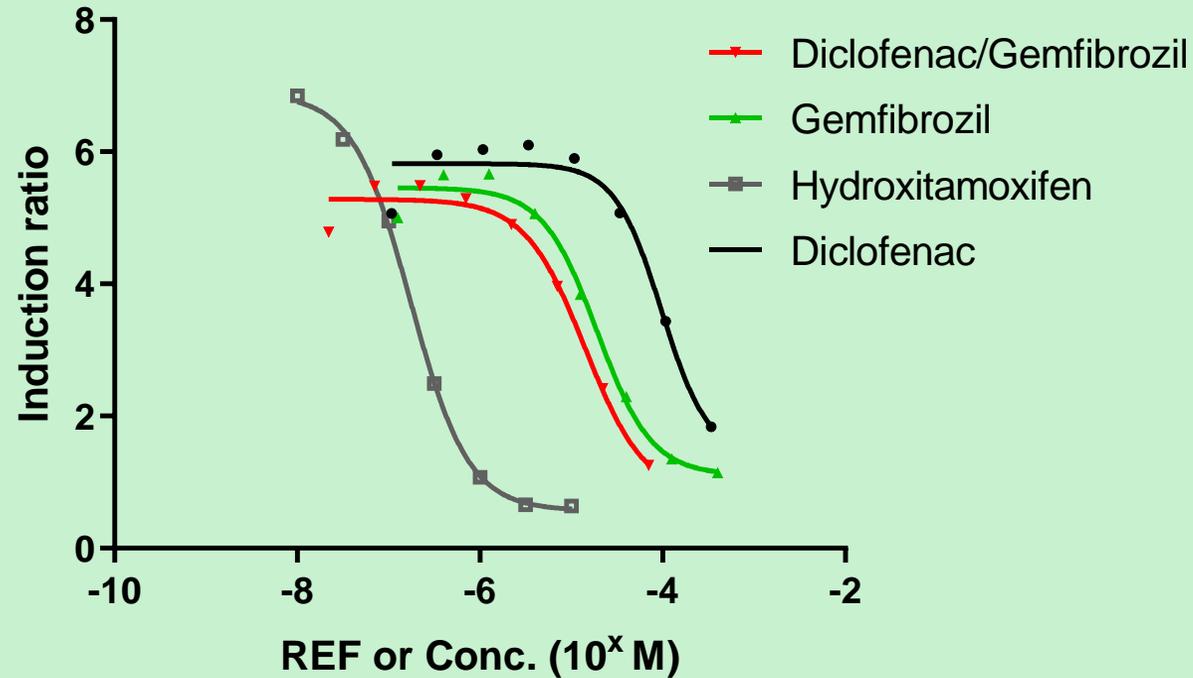
- Anti-estrogenic
- Algal inhibition tests



A typical workflow for assessment of water samples to determine biological effects of chemicals

# Cocktail of diclofenac and gemfibrozil shows anti-estrogenic activity at low concentration compared to individual drugs

- Mixture of gemfibrozil and diclofenac at 20 mg/L each
- Individual drug at 100 mg/L
- Exposure for 24 h



*Cocktail effect of diclofenac and gemfibrozil on antagonising estrogen receptor activities*

# Mixture effect based on modelled CA

- Exposure concentration from CA prediction (120 h)

- $IC_{mix} = \sum_{k=1}^n \left(\frac{P_k}{IC_{yk}}\right)^{-1}$

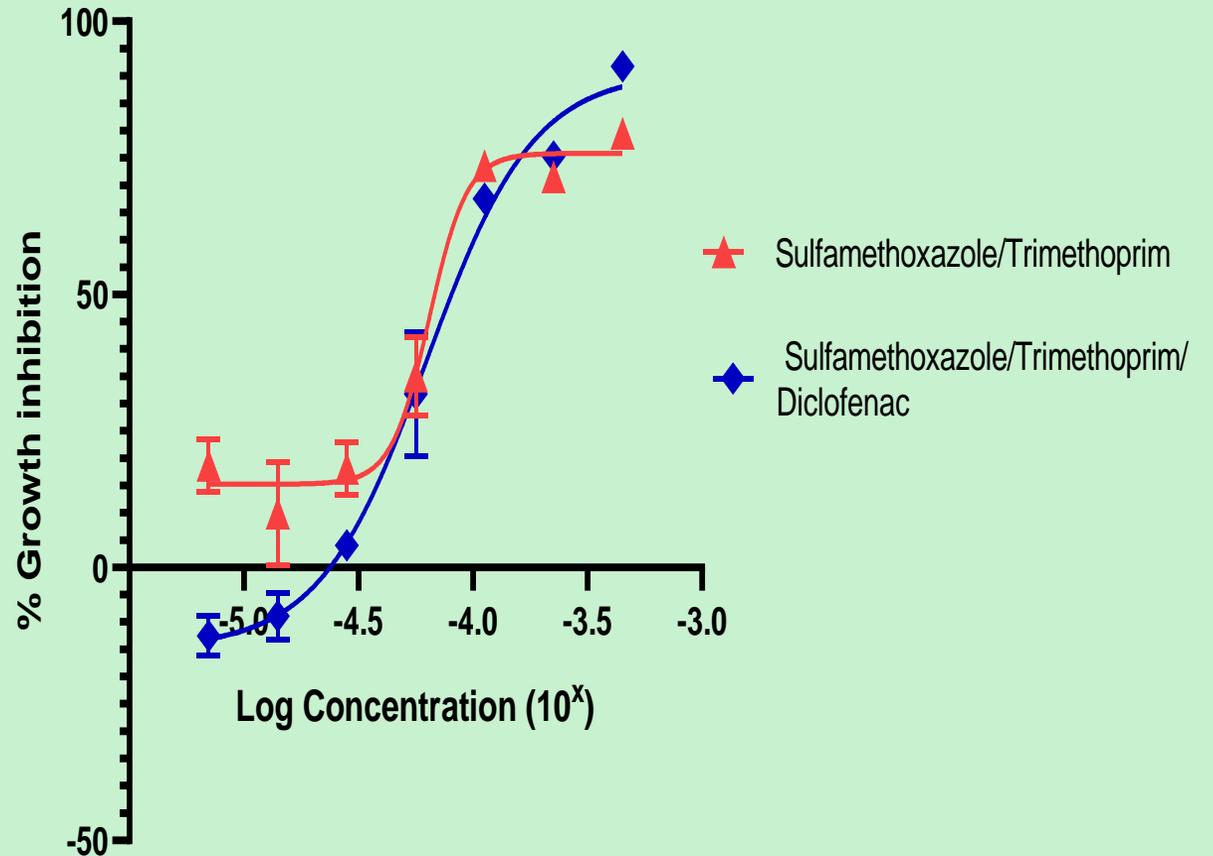
- concn range used predicted to have 5% to 95% growth inhibition

- ST achieved 18.66% to 85% and STD achieved - 12.67% to 96.8% inhibition

- *Dolichospermum flos aquae*. exposure for 96 h

- Concentrations around the IC50 of sulfamethoxazole used for both S and T

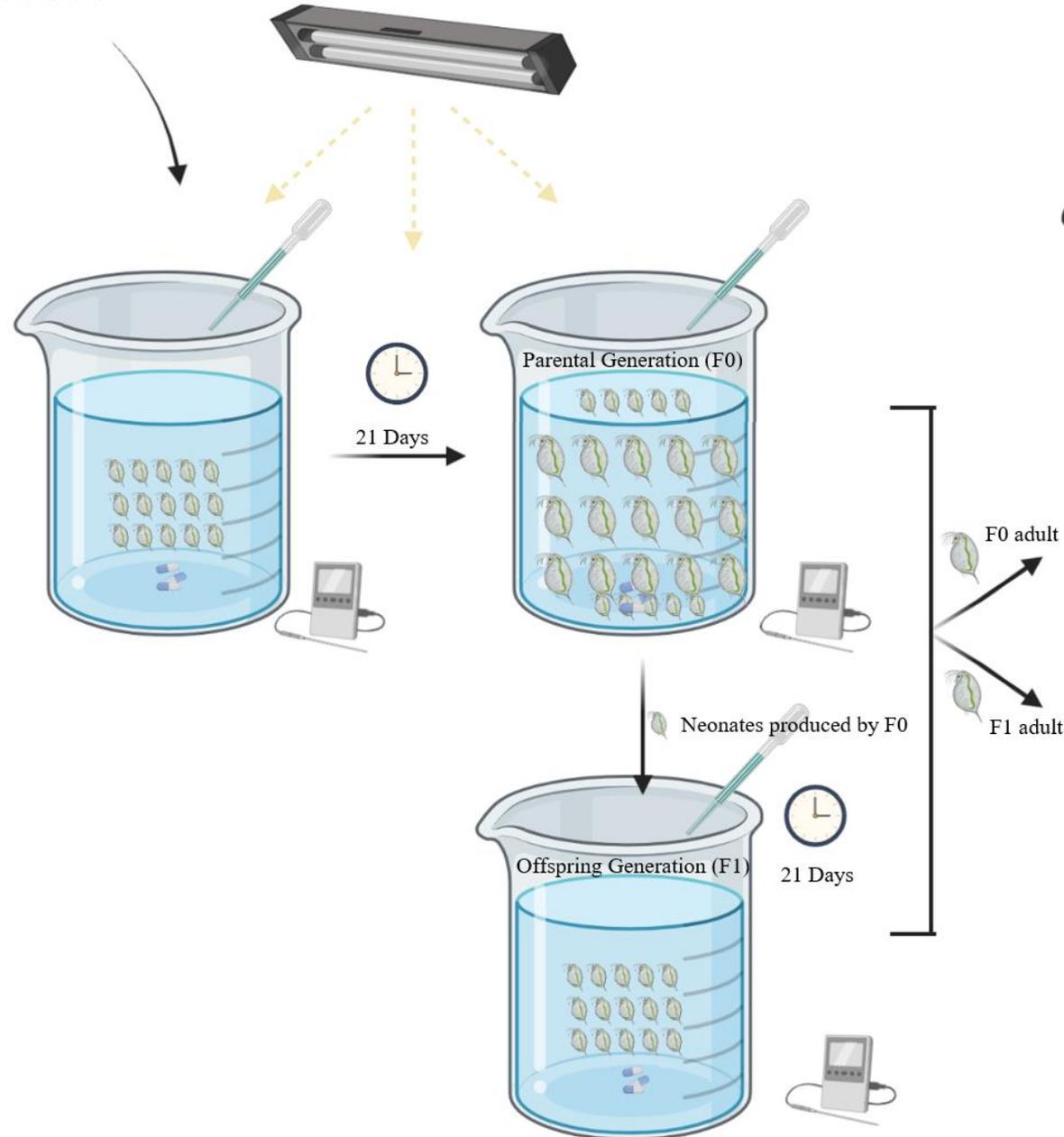
- Diclofenac IC50 selected for S, T and D cocktail



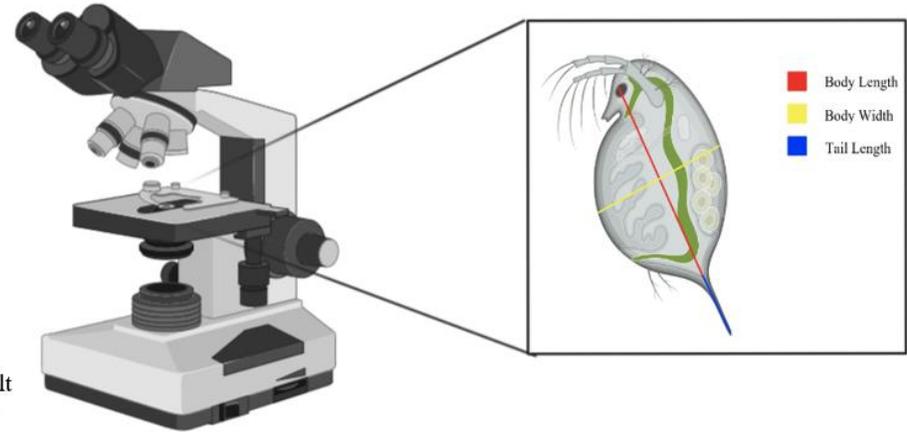
# Invertebrate studies

- Reproduction
- Heart rate

Randomly introduced neonates, < 24 hours old, derived from parthenogenic females showing no signs of stress

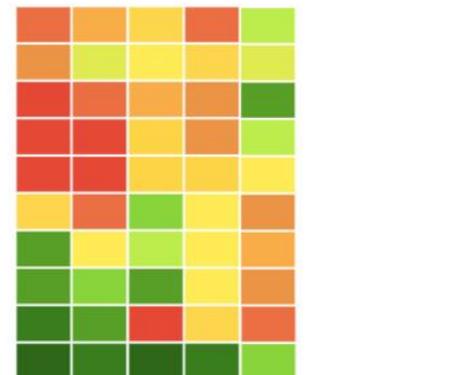


Morphological Analysis

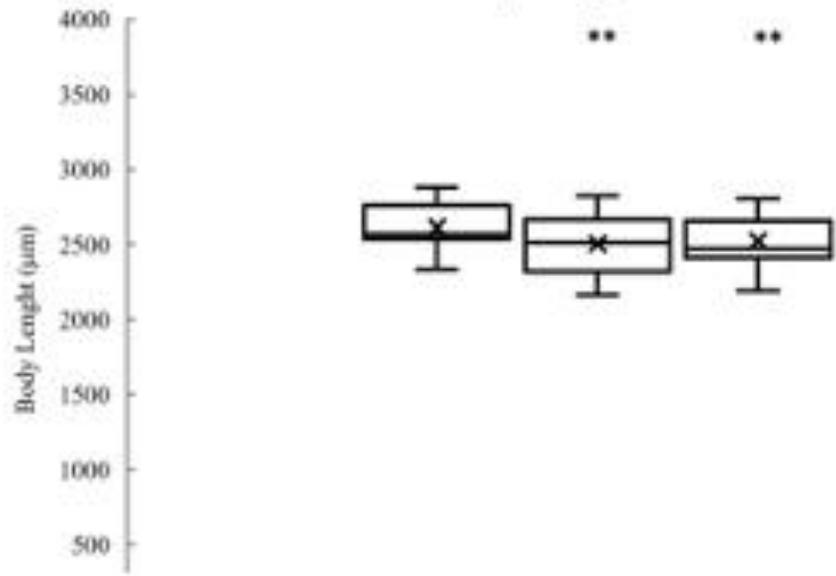


&

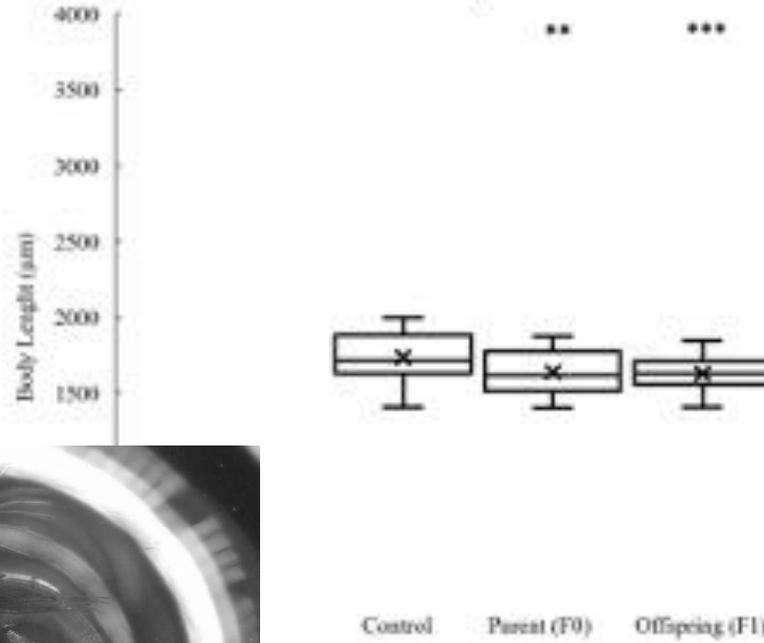
Transcriptome Analysis



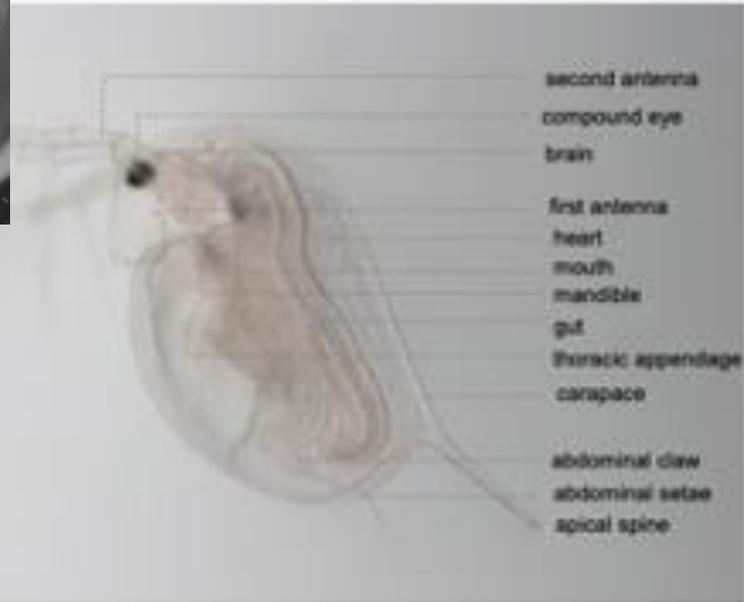
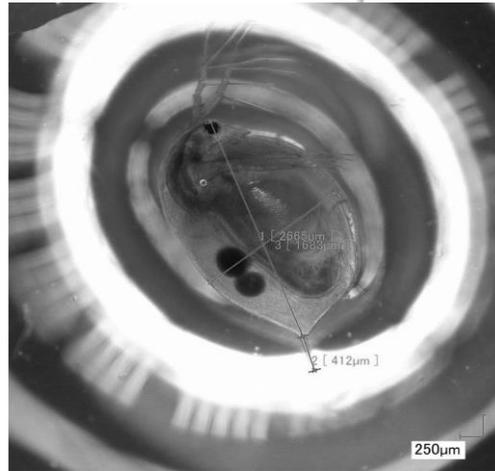
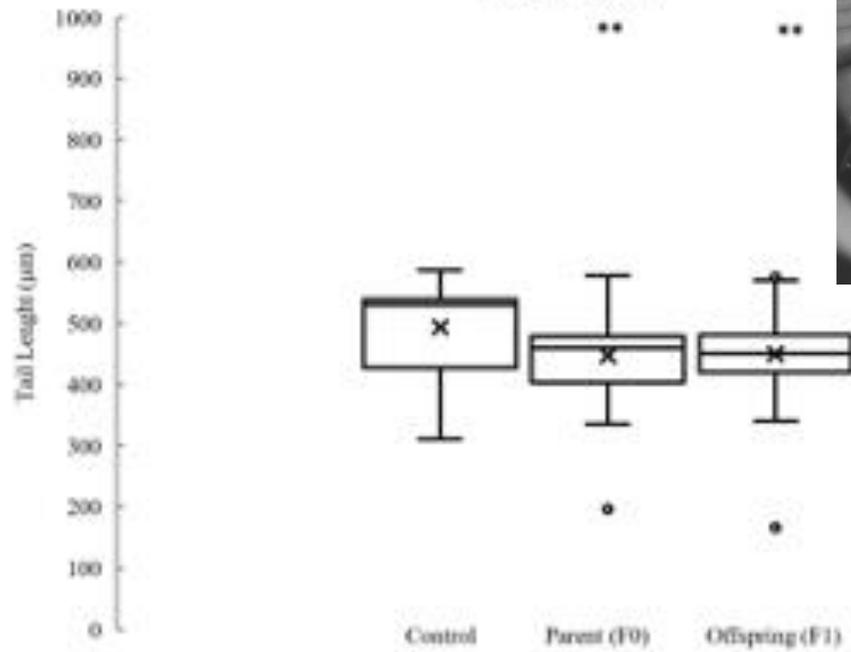
### Body Length



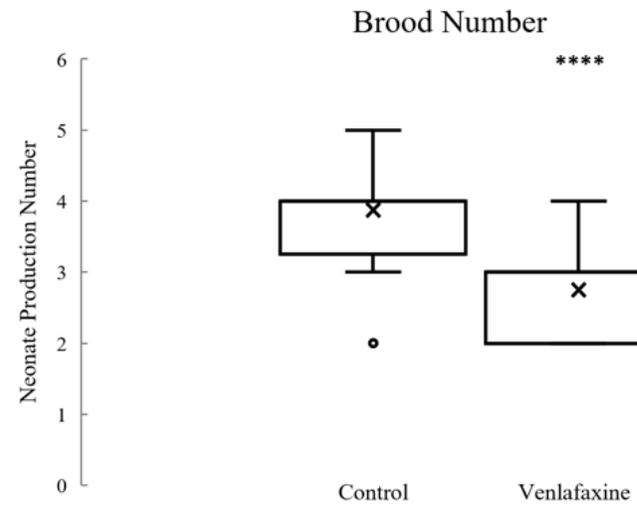
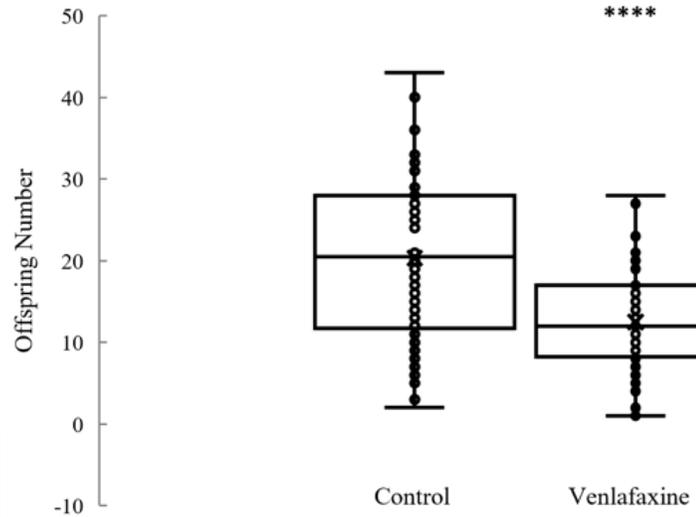
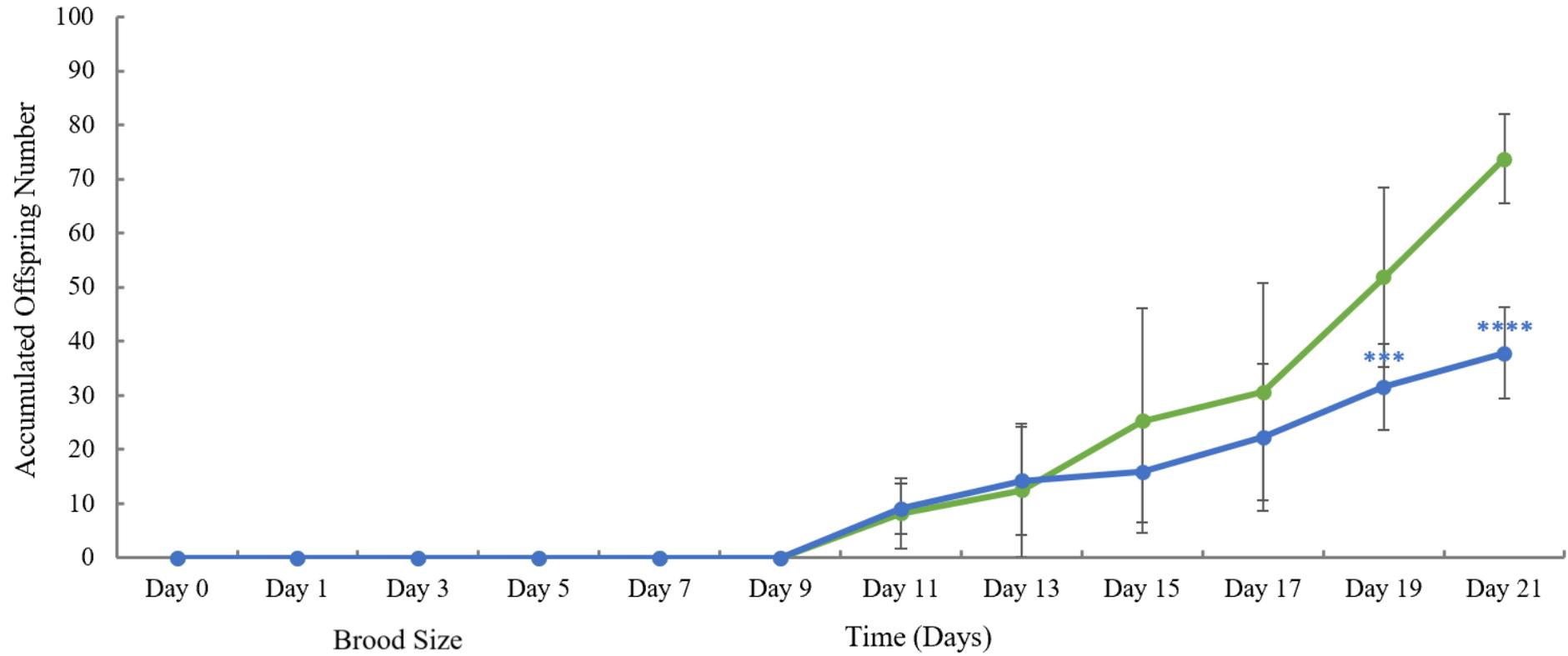
### Body Width

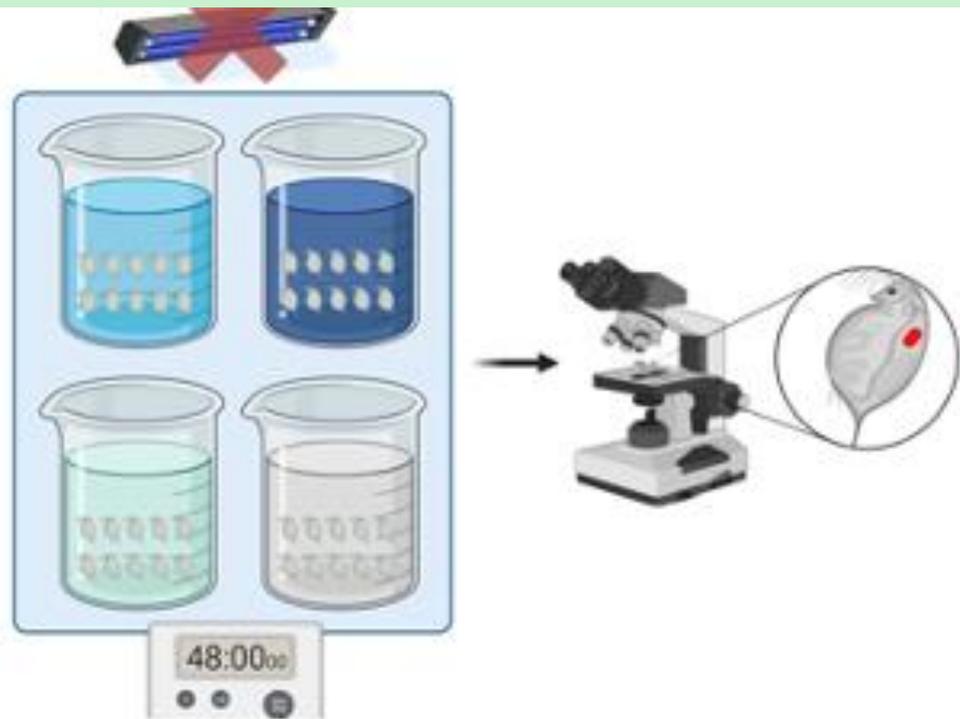


### Tail Length



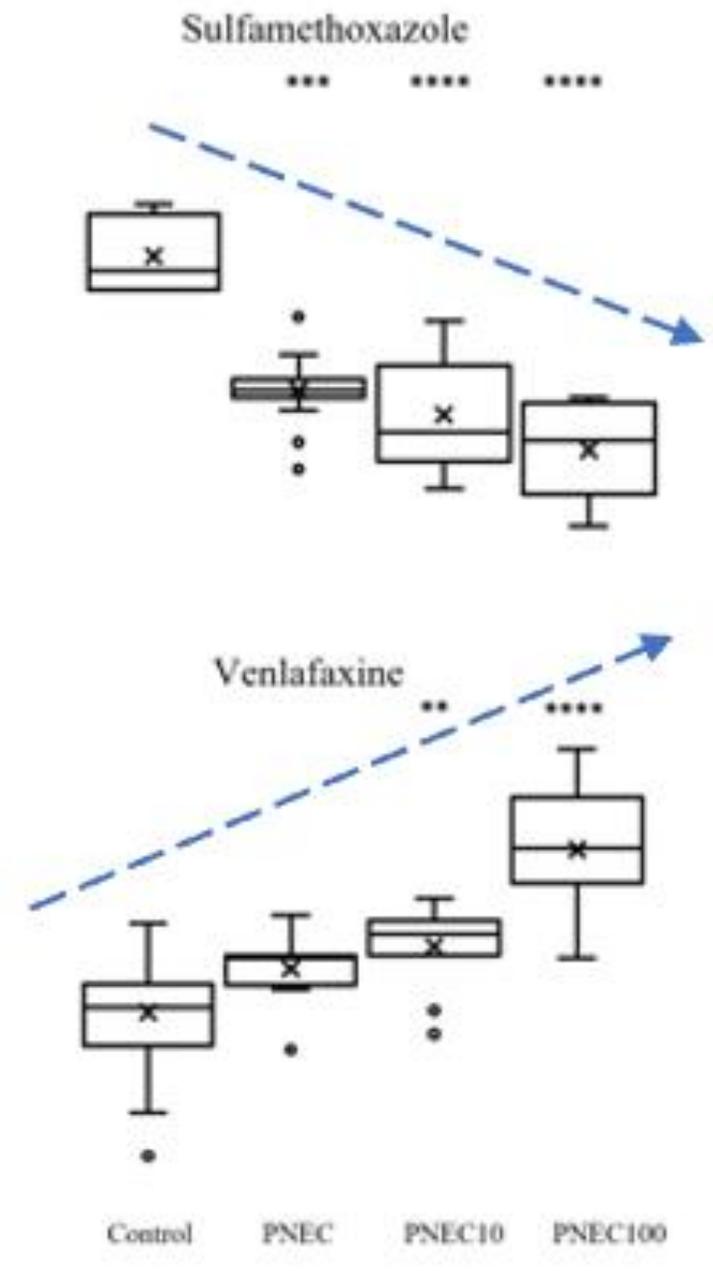
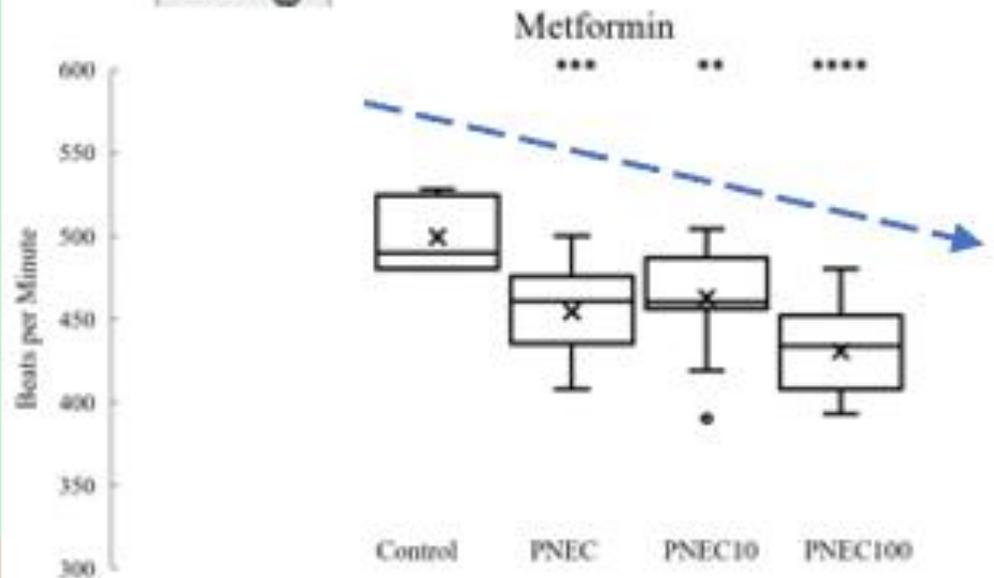
Control Venlafaxine Exposed





Beats per Minute

Beats per Minute



Control PNEC PNEC10 PNEC100

Control PNEC PNEC10 PNEC100

## Chemicals (exposure)

# Risk index

## Bioanalytical and analytical Tools (Effect)

- Zero chemicals  
Meets WFD requirements
- Polar or readily degraded
- Bioaccumulates
- Persistent and mobile
- Mixtures and transformation products

- Target analysis
- Suspect screening
- Passive sampling
- Ecotox tests (algal screening)  
Chronic-acute
- Non target analysis
- Endocrine effects
- Adaptive Stress
- Other MOA

Where we are in current monitoring

Need to develop effect-based tools to assess risk

Zero Pollution Limit (Threshold)

Toxic Lower Limit (threshold)

Water      Algae      Invertebrate      Fish/biota      Sediment

Sample Matrix → Risk evaluation

# Conclusion

- Policy context requires monitoring in different ways for compliance;
- Failure of wastewater treatment → leads to chemical occurrence in surface water;
- Diffuse sources also;
- Methods of sampling and analysis are complex, typically target based – not considering transformation products;
- Challenges of sample matrices and stability for analytical protocols;
- Bioassays demonstrate effects at low concentrations;
- Need assessments that assign risk to waterbodies;



# Acknowledgements

Stefania Scurtu, Thomas McLoughlin, Linda Holland, Kristyna Mrstna, Dylan O'Flynn, Blanaid White, Anne Parle-McDermott, Denise Harold, Jenny Lawler, Imogen Hands, Helena Rapp-Wright, Catherin Allen, Lisa Jones, Azeez Yusuf, Leon Barron.





**@DCUWater**



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**[www.DCUWater.ie](http://www.DCUWater.ie)**

The logo for the Health and Safety Authority (HSA) features the letters 'HSA' in a serif font. The 'H' and 'S' are dark blue, while the 'A' is orange. A thin orange horizontal line is positioned below the letters.

HSA

An tÚdarás Sláinte agus Sábháilteachta  
Health and Safety Authority

# EU Chemicals Strategy for Sustainability Conference

October 18<sup>th</sup> 2023

The logo for the Environmental Protection Agency (EPA) features a stylized green leaf icon above the lowercase letters 'epa' in a blue sans-serif font. Below the letters, the full name of the agency is written in a smaller font.

epa  
Environmental Protection Agency  
An Ghníomhaireacht um Chaomhnú Comhshaoil

## Questions and Answers

# EU Chemicals Strategy for Sustainability Conference

October 18<sup>th</sup> 2023

Panel discussion  
**Challenges and Opportunities facing Irish Companies**

The logo for the Health and Safety Authority (HSA) features the letters 'HSA' in a serif font. The 'H' and 'S' are dark blue, while the 'A' is orange. A thin orange horizontal line is positioned below the letters.

HSA

An tÚdarás Sláinte agus Sábháilteachta  
Health and Safety Authority

The logo for the Environmental Protection Agency (EPA) features a stylized green leaf icon above the lowercase letters 'epa' in a blue sans-serif font. Below the letters, the full name of the agency is written in both Irish and English.

epa  
Environmental Protection Agency  
An Ghníomhaireacht um Chaomhnú Comhshaoil

The logo for the Health and Safety Authority (HSA) features the letters 'HSA' in a serif font. The 'H' and 'S' are dark blue, while the 'A' is orange. A thin orange horizontal line is positioned below the letters.

HSA

An tÚdarás Sláinte agus Sábháilteachta  
Health and Safety Authority

# EU Chemicals Strategy for Sustainability Conference

October 18<sup>th</sup> 2023

Closing Remarks

The logo for the Environmental Protection Agency (EPA) features a stylized green leaf icon above the lowercase letters 'epa' in a blue sans-serif font. Below the letters, the full name of the agency is written in a smaller font.

epa  
Environmental Protection Agency  
An Ghníomhaireacht um Chaomhnú Comhshaoil