

# Navigating Sustainability: *Safe by Design* Strategies across Industries



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10 Giugno 2024









Leading **science solutions**  
for **toxicological consultancy**

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Toxicological  
services

Biotechnological  
consultancy



## Toxicological services



PHARMA



COSMETICS



BIOMEDICAL DEVICES



FOOD CONTACT MATERIAL



CHEMICAL SECTOR



POLYMER SECTOR



OCCUPATIONAL TOXICOLOGY



PDE and CLEANING VALIDATION



TRAINING COURSES





# S&C Best - Eurotox Corporate Program



S&C BEST Srl is one of the 12 Companies  
worldwide  
joining the EUROTOX Corporate Program  
<https://www.eurotox.com/corporate-program/>







**“We cannot be successful nor can we call ourselves successful in a society that fails”**

Feike Sijbesma,  
CEO/Chairman of the  
Managing Board



# Sustainability: core value

**People:** improving people's lives through DSM's activities, products and innovations (People+). Respect for people and recognition of their fundamental rights.



**Planet:** improving the environmental footprint through DSM's activities, products and innovations (ECO+) (*more value with less environmental impact*)



**Profit:** creating profitable business and value for DSM's shareholders while meeting DSM's objectives to provide solutions to global societal needs.



# In the meantime....

SoYou BV

BioEvol Srl

Wakonda SpA



Sustainability refers to the ability to meet the current needs of society without compromising the future





What is Sustainability FOR YOU?



Safe-by-Design  
is about including safety  
at the earliest possible stage  
of product and process development



WHAT is SAFE BY DESIGN for YOU?











How far  
**YOU**  
WANT to go in your decisions  
towards  
«safe by design»?





Ikea ritira 4 milioni di lampade per bambini: a  
«rischio strangolamento» - Il Secolo XIX

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**YOU**  
can make the differences, with your choice  
as person, and even more, as PROFESSIONAL



# Sustainability - 2030 agenda

## SUSTAINABLE DEVELOPMENT GOALS



## *Historical background*

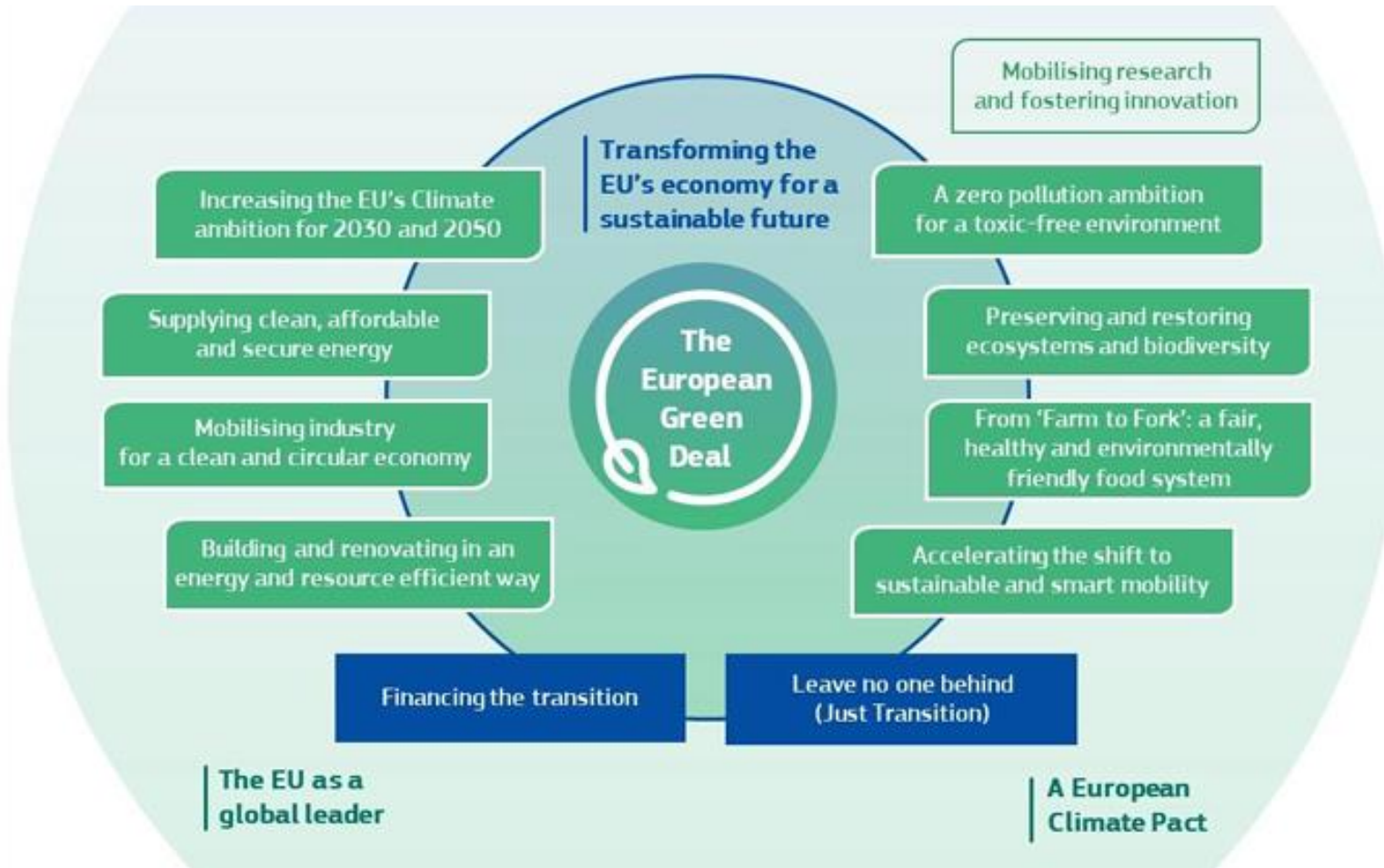
- ❑ «Earth Summit» in Rio de Janeiro (1992)
  - Adopted *United Nations Framework Convention on Climate Change (UNFCCC)* to cooperate as member states to combat "dangerous human interference with the climate system" and to stabilize greenhouse gas concentrations in the atmosphere
- ❑ «Kyoto Protocol» in Kyoto (1997)
  - implemented the objective of the UNFCCC to reduce the onset of global warming by reducing greenhouse gas concentrations in the atmosphere to "a level that would prevent dangerous anthropogenic interference with the climate system"
- ❑ «Paris Agreement» in Paris (2015)
  - New actions and requirements to limit the increase to 1.5 °C, recognizing that this would substantially reduce the effects of climate change.

→ **The Green Deal** (11 December 2019)



# The European Green Deal

«a new growth strategy that aims to transform the EU into a fair and prosperous society, with a modern, resource-efficient and competitive economy where there are no net emissions of greenhouse gases in 2050 and where economic growth is decoupled from resource use»





# Key points of EU Green Deal



Be the first climate-neutral continent



Aim to at least 55% less net greenhouse gas emissions by 2030, compared to 1990 levels



Plant 3 billion additional trees by 2030

**HOW** →

*actions on:*

TRANSPORT

ENERGY

RESEARCH

INDUSTRY



# Economia circolare



# Esempio di safe by design nell'economia circolare



A photograph of laboratory glassware, including a large Erlenmeyer flask and a smaller beaker, both containing a bright green liquid. The glassware is set on a dark surface, and the background is blurred.

# CHEMICAL INDUSTRY

## one of the main targets

There are already many regulatory instruments in place that affect the chemical industry

### WHY?

1. EU is the 2<sup>nd</sup> global producer of CHEMICALS
2. Chemical industry has a major impact on
  - HUMAN HEALTH
  - ENVIRONMENT
3. High number of chemicals



# Inside toxicity of chemicals

CHEMICALS: Chemicals are the building blocks of the goods we use, and for high-tech materials needed for a circular and climate neutral economy

- Substances (raw materials)
- Final products (citizens are the users)

In the production of chemicals:

↑↑ ENERGY  
↑↑ CO<sub>2</sub>



NEED FOR THE RIGHT CHEMISTRY TO  
LIMIT THE EMISSIONS



# EU Chemicals Strategy for Sustainability (CSS)

- It is an integral part of EU Green Deal
- It aligns with EU's commitment to a TOXIC-FREE environment

## KEY POINTS



**Banning Harmful Chemicals**



**Cocktail Effect Consideration**



**Phasing Out PFAS**



**Investment in Safe and Sustainable Chemicals**



**Simpler Risk Assessment Process**



**Global leadership**





# *Insight into toxicity of chemicals*

Actions to implement the sustainability about chemicals go via chemical regulation updates, targetting very hazardous chemicals, also called «Substances of Very High Concern» (SVHC)

## HUMAN HEALTH

- ▶ Carcinogenic, Mutagenic, Reproduction Toxicant
- ▶ Endocrine disruptors

## ENVIRONMENT

- ▶ PBT
- ▶ PMT

(in general «forever chemicals»)



**Persistent chemicals** have high intrinsic molecular stability and do not easily degrade in the environment or in living organisms or during technical processing. Persistent organic pollutants (POPs) is a specific subcategory, with polychlorinated biphenyls (PCBs), per- and polyfluorinated alkyl substances (PFAS) and organomercury being examples.

**Mobile chemicals** are either very water soluble or very volatile making them difficult to remove with abatement and remediation technologies.

**Accumulation** occurs in the environment or in humans if the rate of input exceeds the rate of removal.

**Bioaccumulation** occurs when chemicals accumulate in living organisms, typically due to a long-term intake of food or water contaminated with chemicals that are not efficiently removed from the organism. Accumulation of fat-soluble

chemicals occurs in fatty tissues (e.g. PCBs and dioxins), but chemicals may also accumulate in the blood and organs (e.g. PFAS).

**Endocrine-disrupting chemicals (EDCs)** interfere with the development or the functioning of the hormonal system such as the female sex hormones (oestrogens), male sex hormones (testosterone) or thyroid hormones. Examples include bisphenol A (BPA) and phthalates (e.g. di-(2-ethylhexyl) phthalate, DEHP).

**Developmentally toxic chemicals** damage the development and future functioning of the endocrine (hormonal) system, the immune system or the neurological system (affecting brain development). Critical windows of exposure are associated with different stages of the development of an organism. Organotins (e.g. tributyltin, TBT) and perfluorooctane sulfonate (PFOS) are examples of

immunotoxic substances, whereas lead, organomercury and organophosphate pesticides are examples of neurotoxic chemicals.

**Substances of very high concern (SVHC)** is a term used in the EU chemicals regulation REACH (registration, evaluation, authorisation and restriction of chemicals), for single or groups of chemicals that are subject to authorisation. EU legislation requires that SVHCs should be substituted with less harmful alternatives and the REACH Regulation provides for risk management processes to achieve this aim. The SVHC criteria target substances that have one or more of the following properties: carcinogenic; mutagenic; toxic for reproduction; persistent, bioaccumulative and toxic (PBT); very persistent and very bioaccumulative (vPvB) or giving rise to equivalent levels of concern. Examples of the substances causing equivalent concern include neurotoxic and endocrine-disrupting chemicals. ■

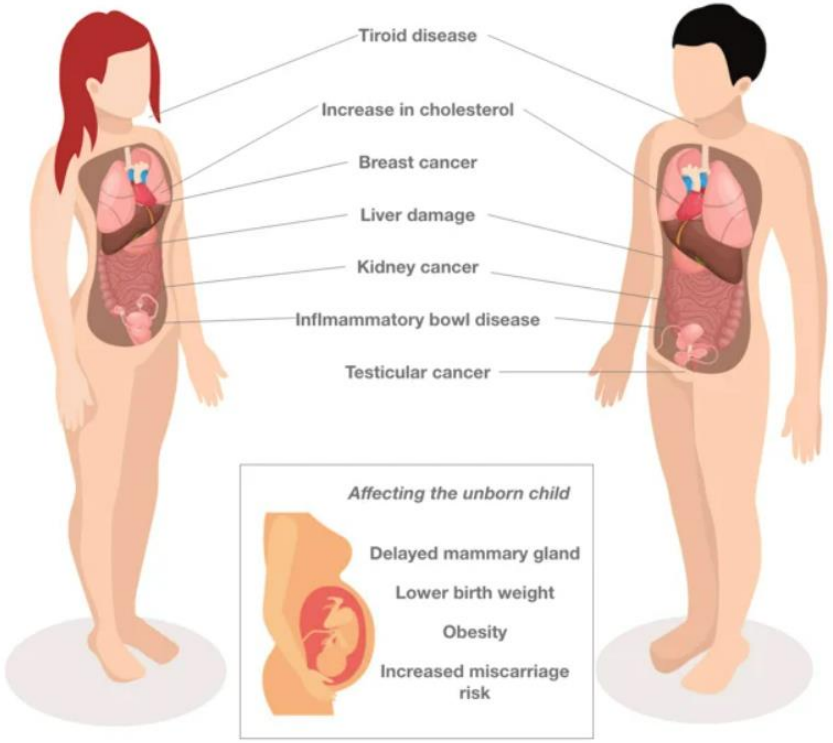


# *Insight into toxicity of chemicals*

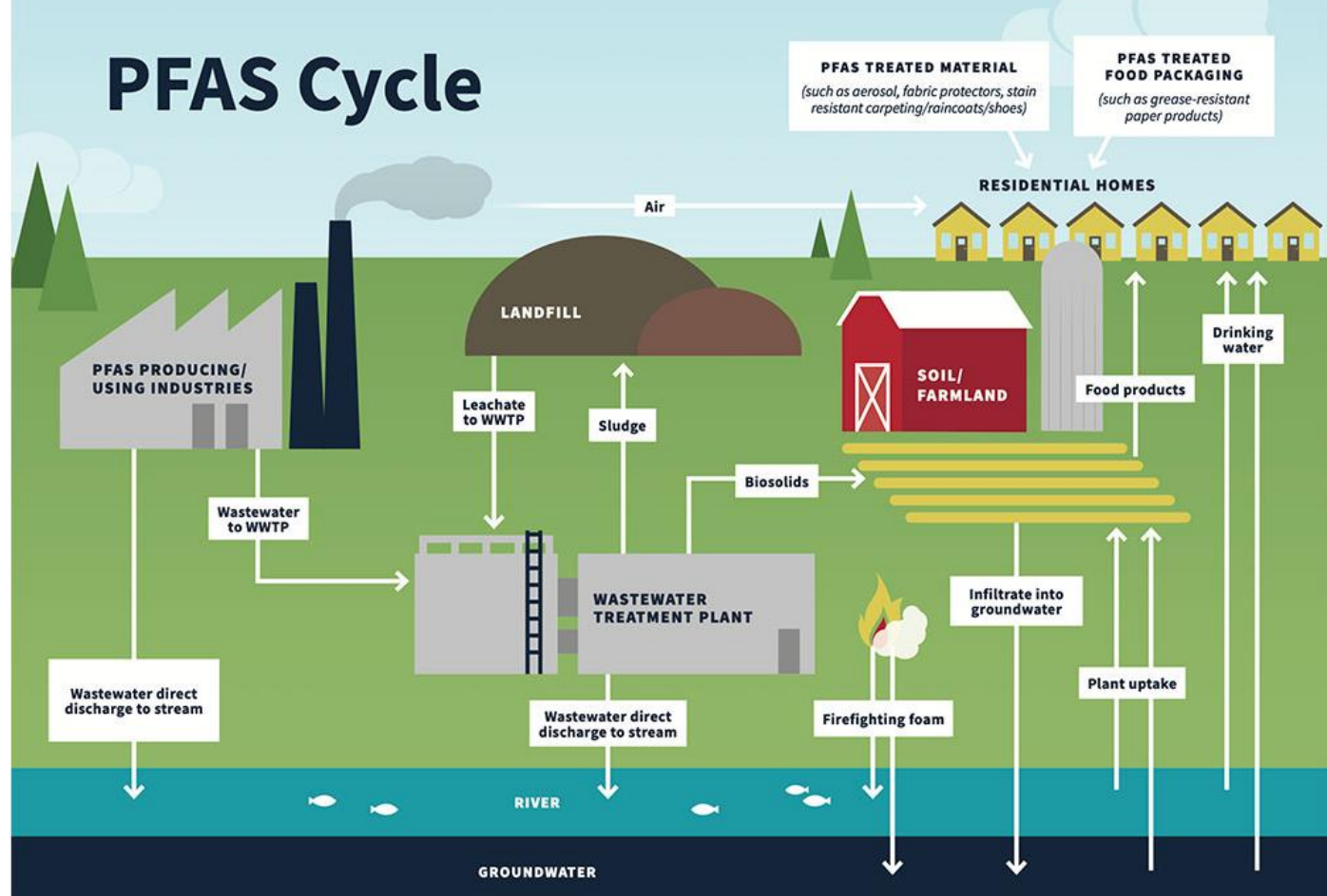
- Carcinogenic → cause cancer
- Mutagenic → interact with DNA, causing different adverse effects, also cancer
- Reproduction toxicant → cause problems in reproduction (i.e. fertility decrease) or to the development
  
- Endocrine disruptors → Definition (WHO, 2002): *“An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations.”*



## EFFECTS OF PFAS ON HUMAN HEALTH



## PFAS Cycle

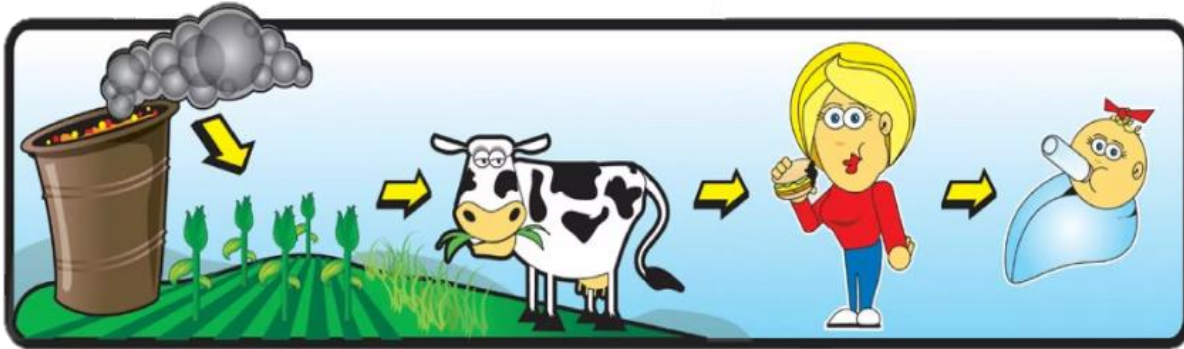


# PFAS = forever chemicals



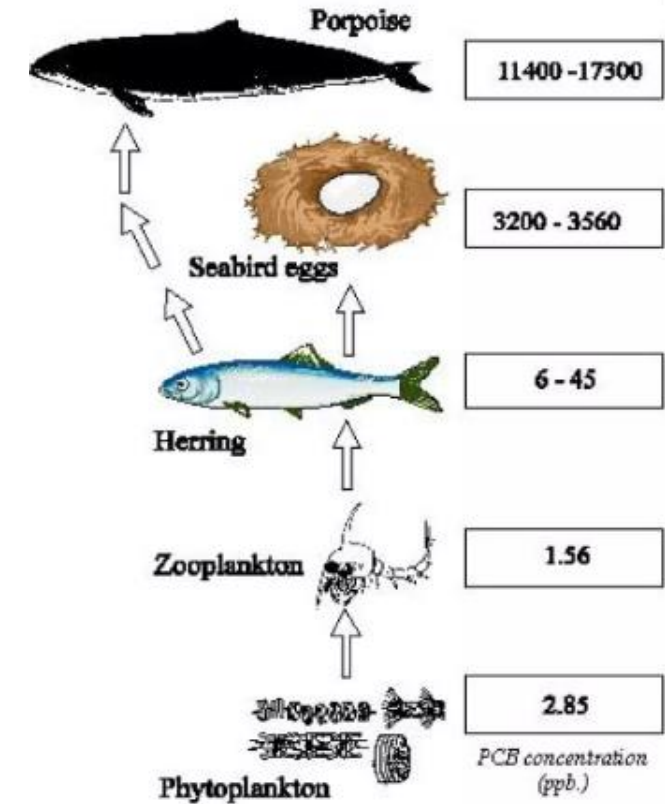
# ISSUE with FOREVER CHEMICALS

## BIOACCUMULATION



Il safe level è dell'ordine di picogrammi/kg food (EFSA, 2018)

## BIOMAGNIFICATION





# How CSS will happen

## ▶ REACH revision

- ▶ More information on substances
- ▶ Registration of polymers

## ▶ CLP revision

- ▶ New hazard criteria
  - ❖ Immunotoxicity
  - ❖ Neurotoxicity
  - ❖ Endocrine disrupters
  - ❖ PBT, vPvB, PMT, vPvM (those are persistent chemicals)

**REACH (Registration, Evaluation, Authorisation, and Restriction of Chemicals)** (REACH Regulation (EC) No 1907/2006) is a crucial **EU regulation** designed to safeguard human health and the environment from the risks posed by chemical substances. Here are the key aspects of REACH:

**1.Registration:** Companies are required to **register** chemical substances they manufacture or import in quantities exceeding one ton per year. This process ensures that essential safety information about these substances is available.

**2.Evaluation:** Authorities assess the safety data submitted during registration. They evaluate the potential risks associated with the substances and take necessary actions to mitigate any identified hazards.

**3.Authorisation:** Certain hazardous substances, known as **Substances of Very High Concern (SVHCs)**, require specific authorization for their use. Companies must apply for authorization if they wish to continue using these substances.

**4.Restriction:** REACH empowers authorities to impose restrictions on the use of hazardous chemicals when necessary to protect human health or the environment. These restrictions apply across the EU.

**5.Safety Information:** REACH ensures that safety information about chemicals is available to consumers, enabling informed choices. It also promotes innovation and competitiveness within the EU chemicals industry.

CLP Regulation (EC) No 1272/2008 aligns EU legislation with the GHS (Globally Harmonized System of Classification and Labelling of Chemicals). It governs the classification, labelling, and packaging of hazardous chemical substances, providing essential information to users about workplace consequences<sup>123</sup>. In summary:

**1. Classification:** CLP defines criteria for categorizing chemicals based on health and environmental risks.

**2. Labelling:** Standardized labels communicate clear information about health effects and necessary precautions.

**3. Packaging:** CLP sets requirements for safe chemical packaging, including container specifications, hazard symbols, and safety instructions



# REACH

Regulation (EC) 1907/2006 concerning the

Registration, Evaluation, Authorization and Restriction of Chemicals as establishment of the European Chemicals Agency (ECHA)

## GOALS of REACH

- ▶ Ensure a high level of protection for human health and the environment
- ▶ Ensure the efficient functioning of the internal market
- ▶ Stimulate innovation and competitiveness in the chemical industry

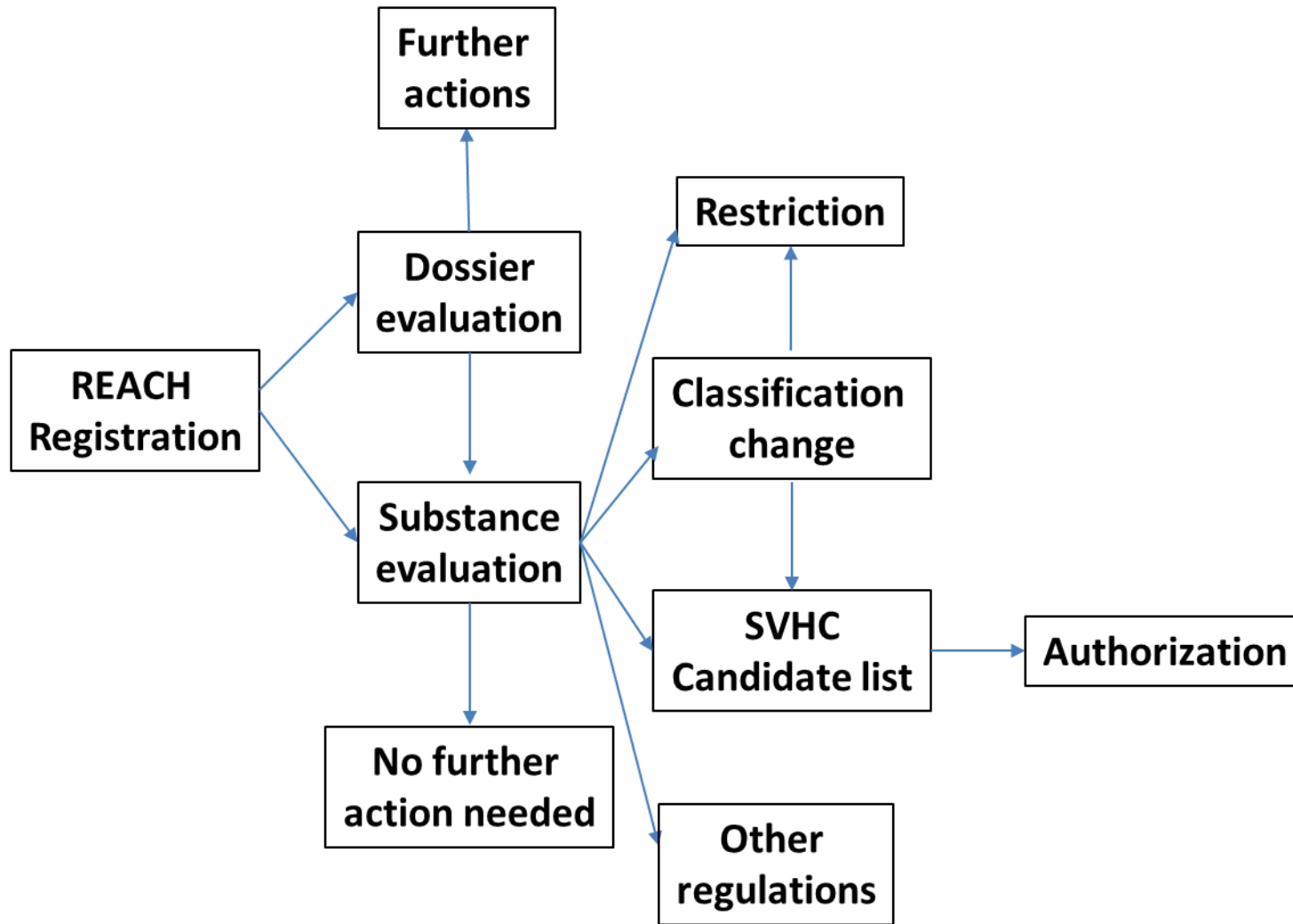
## MAIN PRINCIPLE OF REACH

*No data, No market*





# How REACH works



# CLP

- ▶ Regulation (EC) No 1272/2008
- ▶ The CLP Regulation (for "Classification, Labelling and Packaging") is a European Union regulation from 2008, which aligns the European Union system of classification, labelling and packaging of chemical substances and mixtures to the Globally Harmonised System (GHS).

There are new hazard classes for

- ▶ Endocrine disrupting chemicals (ED HH, ED ENV)
- ▶ Persistent, Bioaccumulative and Toxic (PBT) or very persistent and very bioaccumulative (vPvB) chemicals
- ▶ Persistent, Mobile and Toxic (PMT) or very persistent and very mobile (vPvM) chemicals



# Endocrine Disruptors = Interferenti endocrini



Ad Aprile 2023, EC ha introdotto nuove frasi di pericolo per gli ED oppure per miscele contenenti ED



Nei prossimi anni, le etichette di queste sostanze cambieranno di conseguenza (e anche sezione 2 degli SDS)

Codice di classe e di categoria di pericolo	Codice di indicazione di pericolo	Indicazione di pericolo
ED HH 1	EUH380	Può interferire con il sistema endocrino negli esseri umani
ED HH 2	EUH381	Sospettato di interferire con il sistema endocrino negli esseri umani
ED ENV 1	EUH430	Può interferire con il sistema endocrino nell'ambiente
ED ENV 2	EUH431	Sospettato di interferire con il sistema endocrino nell'ambiente



# Food Contact Material (in plastic)

- ▶ EU Reg 10/2011 on plastic materials and articles intended to come into contact with food

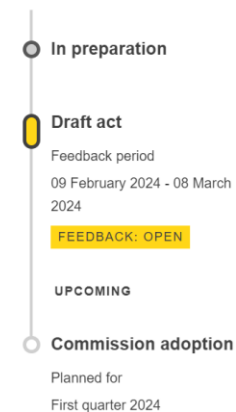
4. The substances not listed in the Union list or provisional list referred to in paragraph 2(b) shall not belong to either of the following categories:

- (a) substances classified as 'mutagenic', 'carcinogenic' or 'toxic to reproduction' in accordance with the criteria set out in sections 3.5, 3.6. and 3.7 of Annex I to Regulation (EC) No 1272/2008 of the European Parliament and the Council <sup>(3)</sup>;



# Food Contact Material (in plastic) and Cosmetic Reg : BPA

- ▶ As from 2009 is listed in the EU Reg 1223/2009 as forbidden in cosmetic products
- ▶ Food has been identified as the main source of human exposure to BPA, followed by dermal absorption, air and dust inhalation, revealing ubiquitous and continuous contact with BPA.
- ▶ Bisphenol A (BPA) is authorised for use as a chemical compound for the production of plastic food contact materials (FCMs) under Regulation (EU) No 10/2011.
- ▶ As from 2011, it is forbidden in the biberon production EU Reg 321/2011
- ▶ According to requirements of the Regulation (EU) No 2018/213, BPA has been banned in the manufacture of polycarbonate drinking cups or feeding bottles intended for infants and young children.
- ▶ As from 2018, stricter limit on BPA in food contact material
- ▶ We are preparing for full ban



## About this initiative

**Summary** This initiative will impose a ban on the use of BPA in food contact materials (FCMs), including plastic and coated packaging. This follows the publication of the European Food Safety Authority's opinion, which indicates a concern for human health.

The measure will also:

- address the use of other bisphenols in FCMs to avoid replacing BPA with other harmful substances
- set out derogations and transitional periods that may apply to businesses.

**Topic** Food safety

**Type of act** Regulation

**Committee** [C20408](#)

## Draft act

**FEEDBACK: OPEN**



# Medical Devices Regulation

- ▶ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance. )

Devices,

shall only contain the following substances in a concentration above 0,1 % weight by weight (w/w) where justified pursuant to Section 10.4.2:

- (a) substances which are carcinogenic, mutagenic or toxic to reproduction ('CMR'), of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council <sup>(1)</sup>, or
- (b) substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council <sup>(2)</sup> or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council <sup>(3)</sup>, in accordance with the criteria that are relevant to human health amongst the criteria established therein.

10.4.2. Justification regarding the presence of CMR and/or endocrine-disrupting substances

The justification for the presence of such substances shall be based upon:



**IT CAN ALSO AFFECT MY WORK**





**Do you want to make the difference?**  
**Make the right choice at work**



# Detox campaign



Promoted by Greenpeace, due to high pollution caused by TEXTILE INDUSTRIES

ZERO DISCHARGE HAZARDOUS CHEMICALS

- ▶ Main goal: eliminate all the hazardous chemicals (i.e. SVHC) from supply chain
- ▶ Black-list prepared
- ▶ Companies take responsibility over the production chain
- ▶ 79 Detox committed companies including 19 global fashion leaders joined the campaign

## *WHY THE TEXTILE INDUSTRY?*

- textile industry is the second largest polluter of fresh water worldwide
- 3.500 chemical substances are used to turn raw materials into textiles
- the compliance with law does not prevent the pollution of water and the presence of hazardous chemicals in final products



# ZDHC international program

Acronym of «Zero Discharge of Hazardous Chemicals»

Target companies: the entire supply chain shall comply to the program

- ▶ from raw materials producers to brands in the textile and footwear sectors



## HOW TO COMPLY

introduce certain types of substances into the production cycle, which are expressly classified in a special list “MRLS” (*Manufacturing Restricted Substance List*), which lists the substances that are subject to restriction in production processes.

manage wastewater, respecting the concentration limits imposed by the Wastewater Guideline (also issued by ZDHC)

demonstrate that a system of research and development of alternative substances is being implemented



ASOS	adidas	ANTA	UNITED COLORS OF BENETTON
BURBERRY	C&A	DECATHLON	Desigual.
Ermengildo Zegna Group	F&F	FAST RETAILING	G-STAR RAW
H&M Group	HUGO BOSS	INDITEX	JCPenney
KERING	Australia and New Zealand	LVMH	LEVI STRAUSS & CO.
LI-NING	LOJAS RENNER S.A. RIO DE JANEIRO SÃO PAULO BRASÍLIA RECIFE	lululemon	MARKS & SPENCER LONDON
MANGO	Nike	NEW BALANCE	NEXT
NORDSTROM MADE	OTB	PRIMARK	PUMA
RIVER ISLAND	STONE ISLAND	TENDAM GLOBAL FASHION RETAIL	TARGET
Tchibo	TEDDY GROUP MISTRUCOLE PERSONE COSTRUIAMO UN MONDO	THE CHILDREN'S PLACE	TOM TAILOR



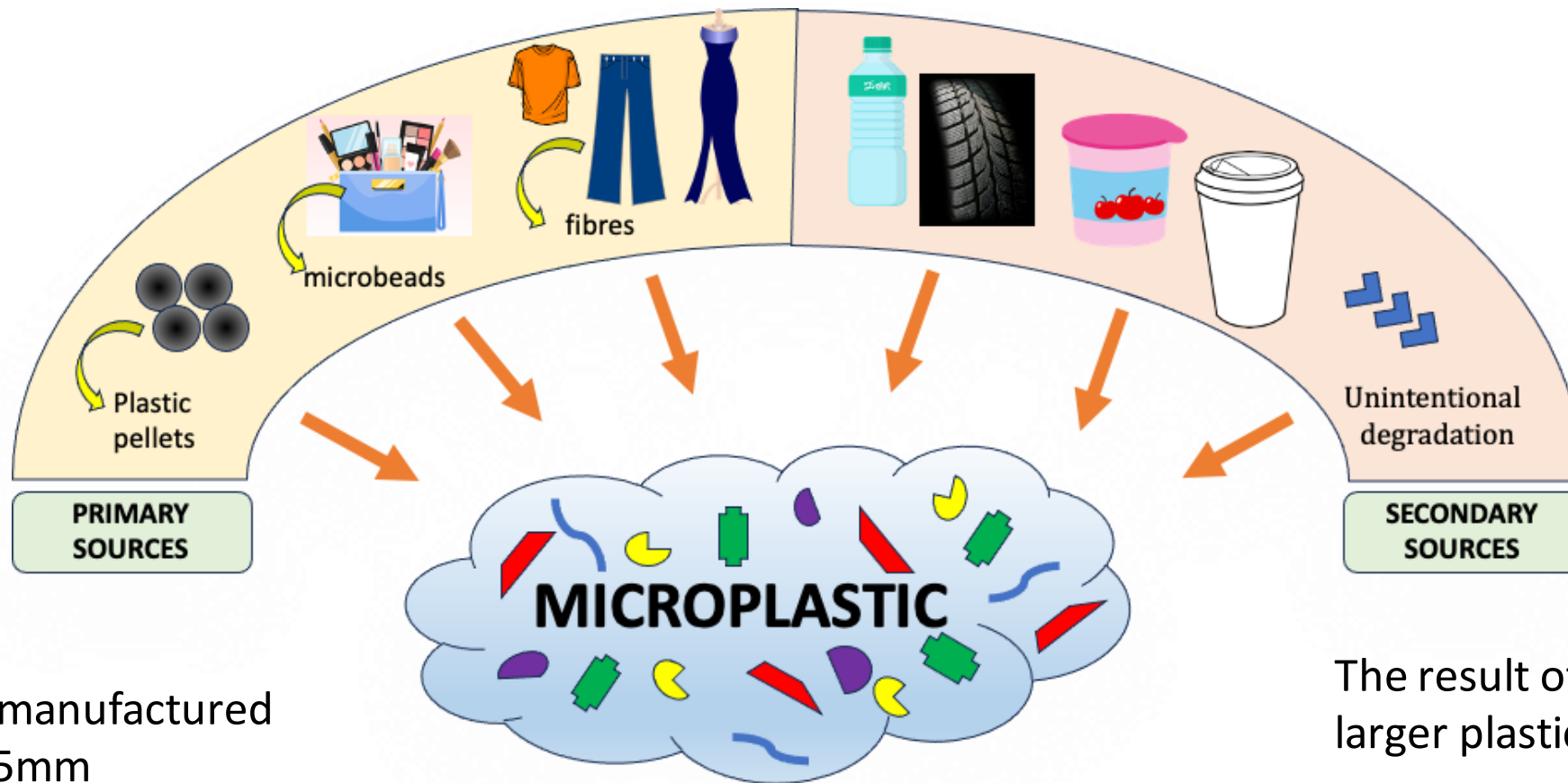
# Microplastics

*”Any Solid or Semi-solid particle consisting of polymers or containing polymers that have a size of 5 mm or less in at least one external dimension”*

[ECHA, 2019]

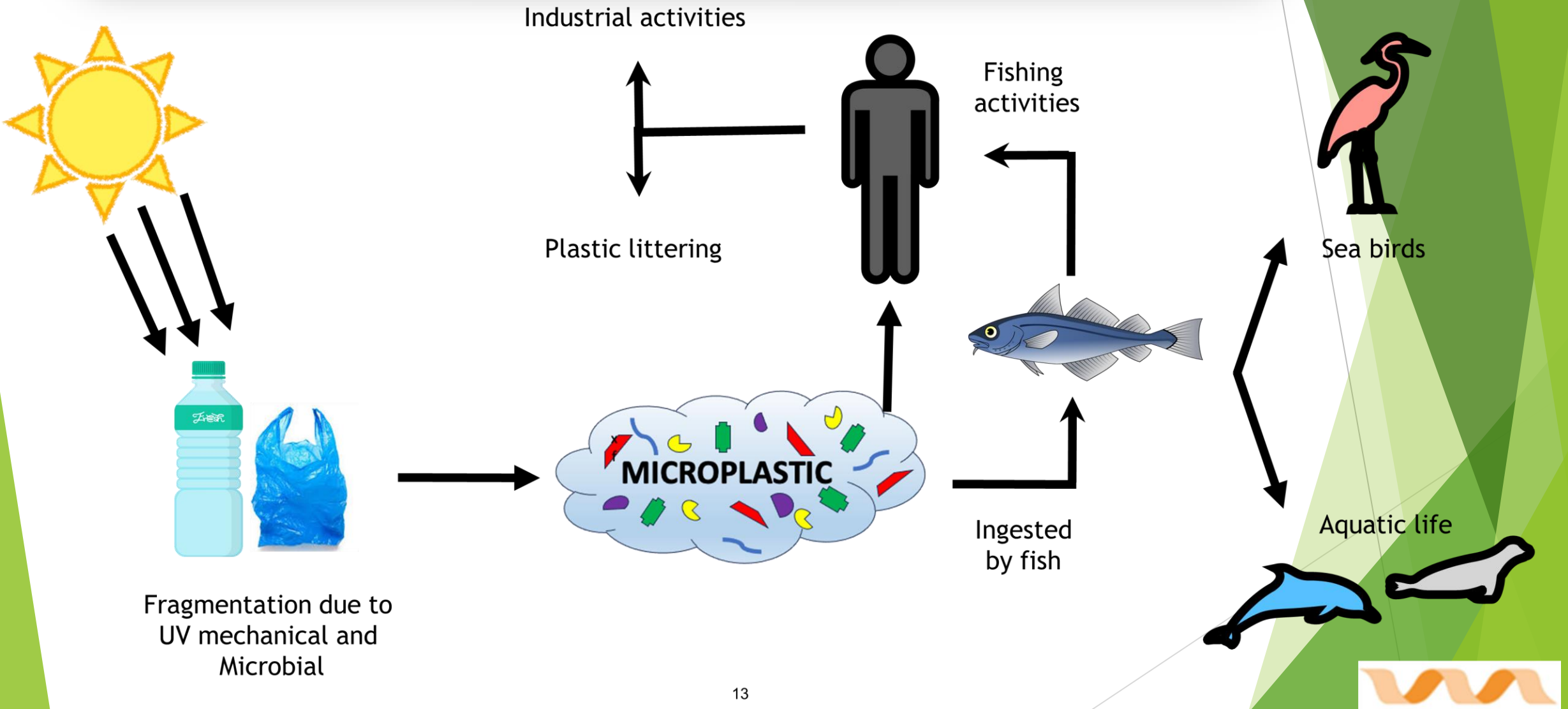


# Microplastics





# Microplastic in food





## But what is the concern about Microplastic?



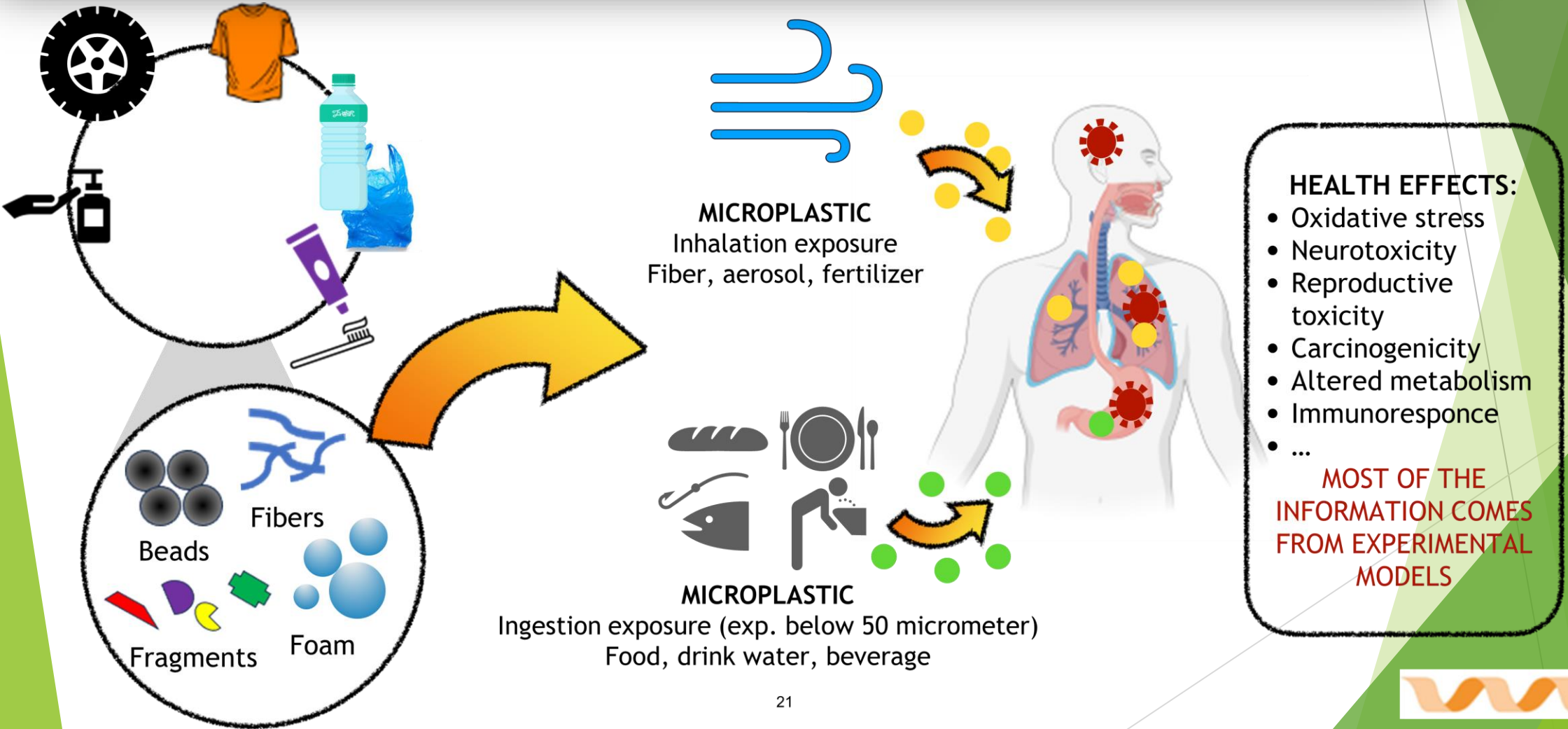
As carrier of toxic substances



Due to their direct interaction with organisms



# Direct health effects of Microplastics



# Guideline and Regulation: what is the EU doing?

25  
September  
2023  
2023/2055/EU

Protecting environment and health: Commission adopts  
measures to restrict intentionally added microplastics

~~Granular infill used on  
artificial sports surface  
Cosmetics (ex. Microbes  
for exfoliation)  
Detergents  
Glitter  
Fertilizers  
Medical device~~

The restriction covers all synthetic polymer  
particles below 5 mm that are organic,  
insoluble and resist to degradation





15 trends spotted at the Spring-Summer 2024  
Fashion Week

[Visita >](#)



**HOW WILL IT AFFECT ME?**





# As citizen

## «BEING PART OF THE SOLUTION»

- More sustainable choices



CASE » **CASE MINIMAL**

**Ad Amsterdam, una casa galleggiante a zero emissioni** Fonti energetiche sostenibili, riciclo dell'acqua e filosofia no waste per un'architettura sull'acqua progettata dallo studio i29 architects nell'area residenziale di Schoonschip



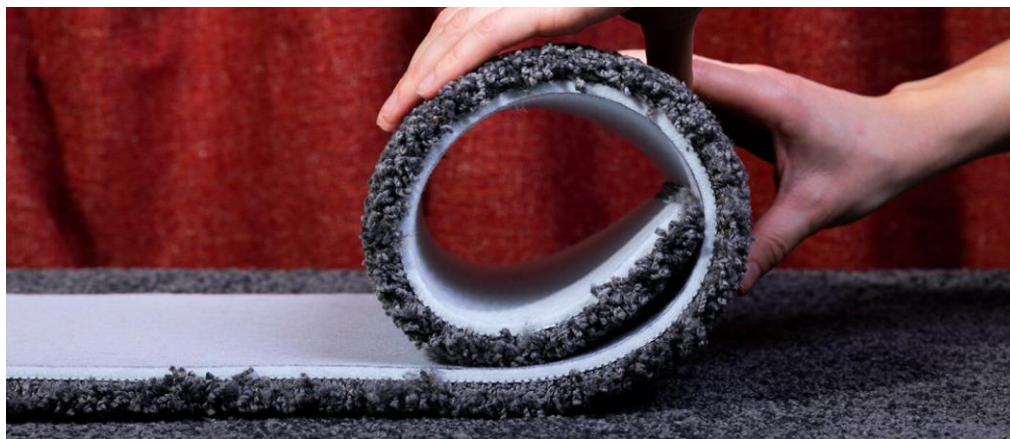


niaga.world

<https://www.niaga.world> · Traduci questa pagina

## Design to use again | Niaga by Covestro AG

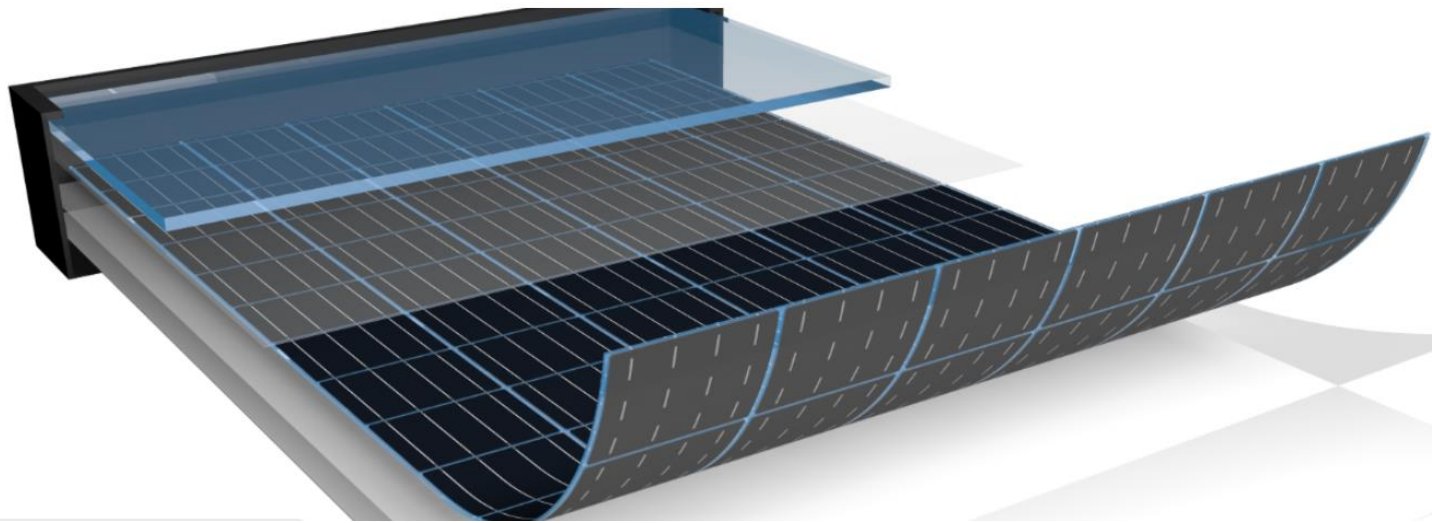
We help our partners redesign products for circularity using fewer, cleaner and infinite materials and reversible connections. Find out how.





## DSM Endurance backsheet

A fully recyclable rear-side film providing long-term protection to solar panels



**YOU**  
can make the differences, with your choice  
as person, and even more, as PROFESSIONAL



**WAKONDA**









Rifertilizzante del suolo



Combatte la desertificazione



Fa bene alla Salute



Ottimo produttore  
di Bioenergia



Zero sprechi e scarti  
in filiera



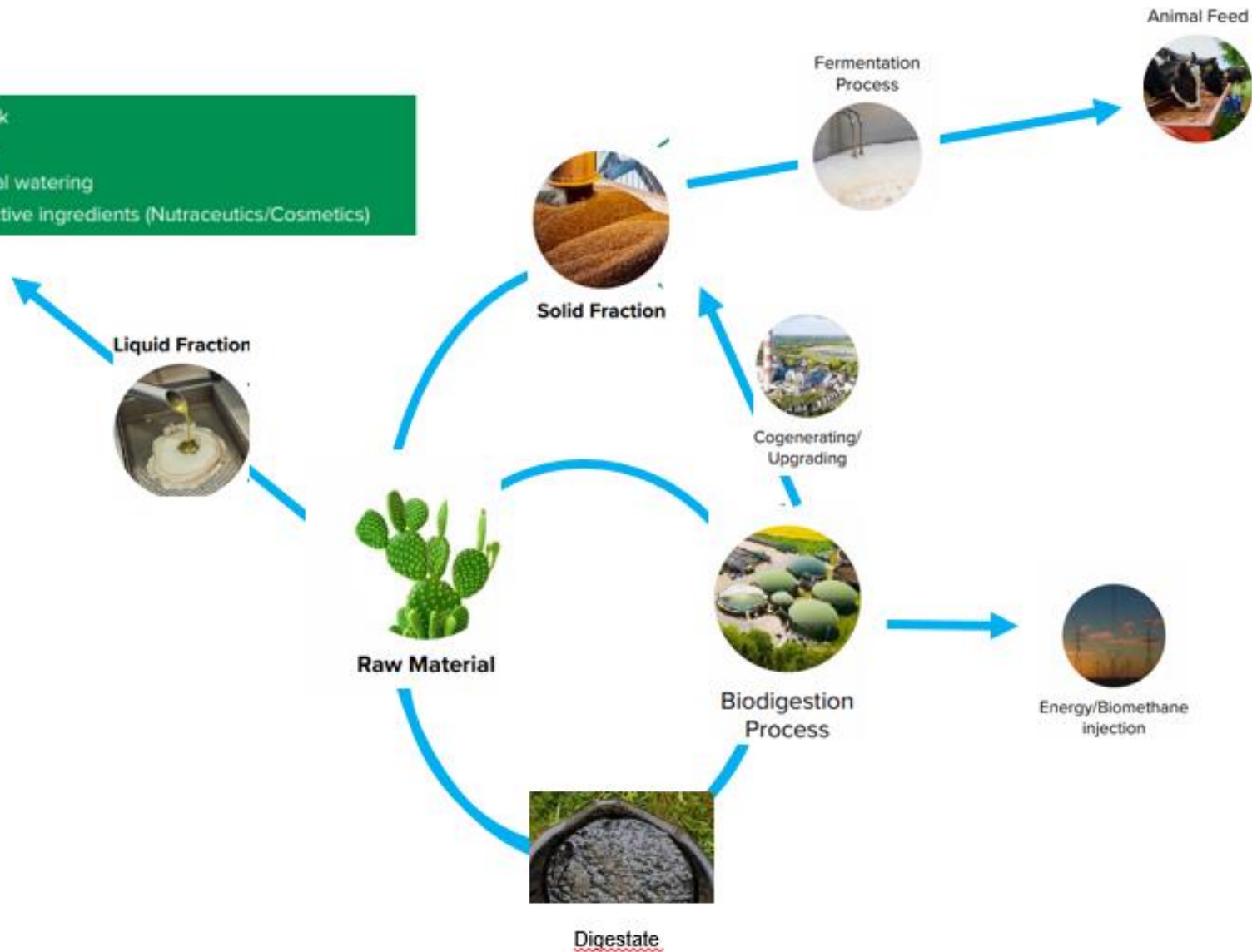
Economica  
e altamente produttiva



Nutrimento di qualità  
per animali



- Functional Drink
- Aromatic water
- Irrigation/Animal watering
- Extraction of active ingredients (Nutraceutics/Cosmetics)



**Walk the Talk**

