Organized by

FIPRA

Green Transition, Energy & Industrials

PFAS: The challenge for highly regulated and essential sectors

6 December 2022

[redacted]russels (& Online)

[redacted]

ChemSec

[redacted]

Merck Healthcare KGaA Germany

[redacted]

European Semiconductor Industry Association (ESIA)

[redacted]

Siemens Healthineers

[redacted]

FIPRA

Programme

9h00 **Opening remarks,** [redacted] FIPRA

9h15 **Panel discussion** (10min/speaker):

- [redacted], ChemSec
- [redacted] Merck KGaA, EFPIA
- [redacted] European Semiconductor Industry Association (ESIA)
- [redacted], Siemens Healthineers, COCIR

9h55 **Panel debate & Q&A session**

10h40 **Concluding remarks,** [redacted], FIPRA

10h45 **Coffee & Networking session**

PFAS- A CHALLENGE

chemsec
INTERNATIONAL CHEMICAL SECRETARIAT

[redacted], ChemSec, PFAS , December 2022

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
INTERNATIONAL CHEMICAL SECRETARIAT

THE URGENCY

- Scientific reports show the urgent need for change
- Overstepping the planetary boundaries
- Business as usual is not an option
- EU regulations good start but not enough
- Substitution has not occurred at the expected pace
- The most harmful chemicals needs to be phased out in all but “essential uses”

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OPPORTUNITIES WITH ESSENTIAL USE

- Better protection of human health and the environment
- Making the regulation more efficient
- Using public resources for the most important cases
- Focus on substation for the most harmful chemicals
- Incentive for innovation and substitution

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IT'S NOT ABOUT THE IMPORTANCE OF SPECIFIC PRODUCTS

– BUT ABOUT WHEN WE CAN ACCEPT VERY HAZARDOUS SUBSTANCES

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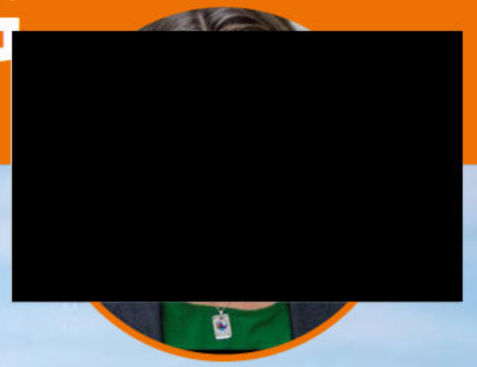
HOW TO DECIDE WHAT IS ESSENTIAL USE AND WHAT IS NOT

- Necessary for health and safety" and "critical for society. Clarified by: “Severe health issues” and “basic conditions for human life and health”.
- Is the chemical (for example PFAS) essential for the function of the product?
- Are alterantives available?


WE SUPPORT STRICT LEGISLATION TO PFAS
No to
PFAS
in produ
CHEMSEC'S CORPORATE PFAS MOVEMENT

THANK YOU FOR LISTENING



European Federation of Pharmaceutical Industries and Associations

PFAS in the Pharmaceutical Industry

[redacted]





FIPRA Discussion
6 Dec 2022

Use of PFAS in (Bio)-Pharmaceutical Production

PFAS in Industrial Use, not part of the product

PFAS Parts or
Raw Materials

PFAS Process Chemical or **Material**
Catalyst, Filter

Intermediate
Partial API
Molecule

Production

PFAS Containing or Coated
Production or Manufacturing
Equipment

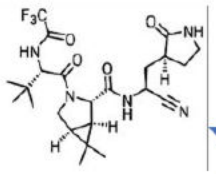
Substitution is Challenging because of unique substance properties and manufacturing process validation

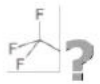
PFAS R&D or
Analytical Chemicals

Production or
Lab Waste

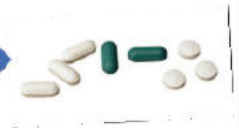
Exempt, handling or disposal requirements may apply

PFAS API Drug Substance or Product



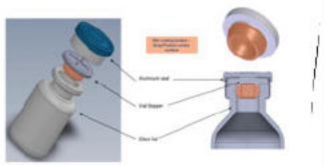


R&D



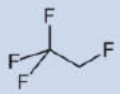
Substitution Impossible (API = molecule *)

Medical Device



Packaging

Challenges: registration/market authorisation



PFAS that are F-Gas
Refrigerants, Propellants, Inhalative Substances

Both §§ apply and need to be conflict free

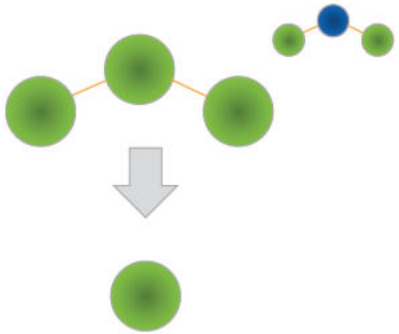
Industrial use with control of materials over the full Life Cycle

Active Ingredients (API) and Medical Devices are regulated separately

Primary packaging is part of the marketing authorization

Regulations must be conflict free in overlapping areas

The OECD PFAS Definition



- **OECD 2018: $-C_nF_{2n}-$, n ≥ 3 or $-C_nF_{2n}OC_mF_{2m}-$, n and m ≥ 1**
- **OECD 2021: $-CF_3$ or $-CF_2-$**

- **OECD 2018 ⇨ OECD 2021: Why was the scope expanded?**
- The intention of the revision of the PFAS definition is **not to expand the PFAS universe, but to** comprehensively **reflect it** … to have a general PFAS definition that is coherent and consistent across compounds from the chemical structure point of view and is easily implementable for **distinguish**ing **between PFASs and non-PFASs, also by non-experts.**
- The term "**PFASs**" is a **broad, general, non-specific term**, which does not inform whether a compound is **harmful or not**, but only communicates that the compounds under this term share the same trait for having a fully fluorinated methyl or methylene carbon moiety."
- The decision to broaden the definition … is **not connected** to decisions on **how PFASs should be grouped in regulatory** and voluntary actions.
- [OECD Report] Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance - PFAS Central

PFAS Risk vs Benefit

- **Risk through PFAS Use**
  - Substances with intrinsic **harmful properties** (e.g. persistent and also mobile/toxic, endocrine disrupting or CMR). In API, being a PFAS or not does **not** determine persistence or bioaccumulative properties
  - **Emissions** of PFAS in Production, during Use or End of Product Life

- **PFAS Use where Risks are Controlled**
  - Products subject to **regulations other than REACH** such as pharmaceuticals or animal health products, where data is available and safety / **environmental risk assessments** were conducted
  - Production and manufacturing materials that do not become product components, such as fluoropolymers in **industrial use**
  - Materials where **emissions are** properly **controlled** over the full life cycle, which may include production materials, but also other machinery or aviation equipment

Substitution

- **Replacing a chemical with a safer alternative is just one way of looking at substitution**
  - More often, basic **innovation** phases out harmful chemicals or other hazards
  - Restricting substances based on structure, regardless of properties and/or risk, severely **impacts R&D** in all technology sectors

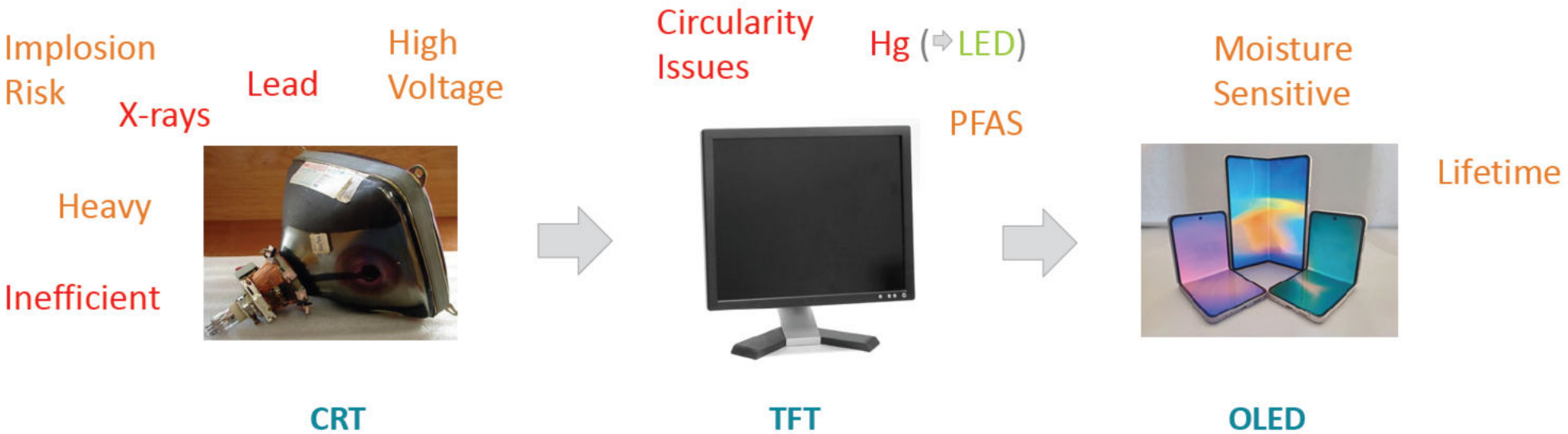


Image Source: Wikipedia

Conclusion: What To Look For in a Simple, Applicable and Efficient Restriction

- **Include**
  - **Proportional** measures addressing the problem „emission of harmful substances to the environment“
  - **Criteria** to identify „**Harmful** PFAS“
  - Derogations for demonstrated **low/controlled emissions** of PFAS over the full Life Cycle
  - **Essential Use** derogations on a case-by-case basis **as a last resort**

- **Exclude**
  - **Undefined terminology** and **avoidable complexity**, leading to uncertainty in implementation. Unclear requirements create effort in the industry and the authorities without benefit, slowing down substitution and other beneficial developments.
  - **REACH** aspects overlapping with **pharmaceutical regulations**, or those of medical devices or veterinary products
  - Impact on **EU manufacture** of pharmaceutical materials
  - Negative impact on innovation or research

European Semiconductor Industry Association

PFAS in the semiconductor industry

[redacted], ESIA

ESIA Members

The voice of the semiconductor industry in Europe

Represent the interests of the European-based semiconductor industry and advocate for its international competitiveness

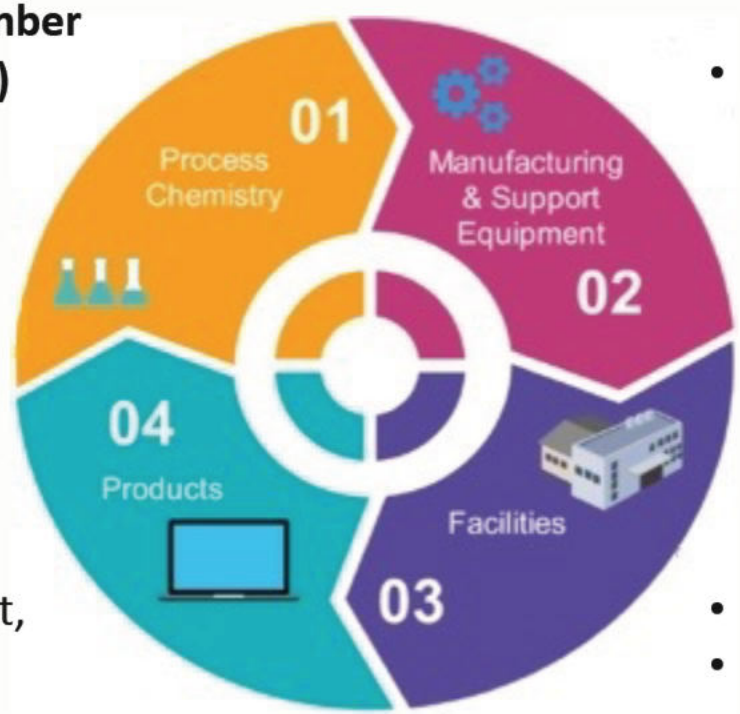
- most R&D-intensive sector
- highly-developed global supply chain
- fierce competition & price fluctuation
- short innovation cycles
- multiplier for growth, electronics boost innovation
- global market estimated at $ 556 billion in 2021 (+26.2% yoy)
- Europe strongest market for automotive (29%)

EU

- ca. 10% of global market
- direct employment 200.000
- indirect up to 1.000.000
- ESIA is member of the World Semiconductor Council (WSC)

PFAS use by the semiconductor industry

- **Constituent of specialty process chemistry formulations (photolithography, chamber cleaning/etching, and other mixtures)**
- **Direct criticality**
- **> 13 types of distinct uses / material functionalities**



- Semiconductor manufacturing equipment (HTFs)
- Fluoropolymer articles in manufacturing equipment and chemical distribution systems (filters, tubing, linings, o-rings, etc.)

- Fluoropolymers in articles (component, wire, cables, printed circuit boards, batteries, insulators, capacitors, etc.)

- Factory infrastructure ‘Fabs’
- Fluoropolymer articles in water purification, chemical delivery and waste management systems (tank and duct linings, pipes, etc.)

EU restriction
Challenges and impacts

- PFAS containing specialty formulations are a prerequisite for semiconductor manufacturing in Europe
- Industry transition from PFOA & PFOS to short-chain PFAS specialty formulations (process chemistries)
- Industry will remove PFHxA according to regulatory timeline
- Broad current draft scope of EU restriction
- Global industry sector with a global supply chain
- Semiconductors are crucial for countless applications (manufacturing, healthcare, transport, etc.)

Context of EU Chips Act

Growth expectation

- Double global market share from 10% today to at least 20% in 2030
- Strengthen EU's research and technology leadership on small and fast chips
- More than €43 billion of policy-driven investment until 2030

Tightening environmental regulations

- PFAS restriction
- F-Gas Regulation

Questions?

Thank you for your attention!

http://www.eusemiconductors.eu/

Twitter : @eSemiconductor
LinkedIn: European Semiconductor Industry Association

Medical devices sector: On the phasing out of SoC and sustaining EU innovation

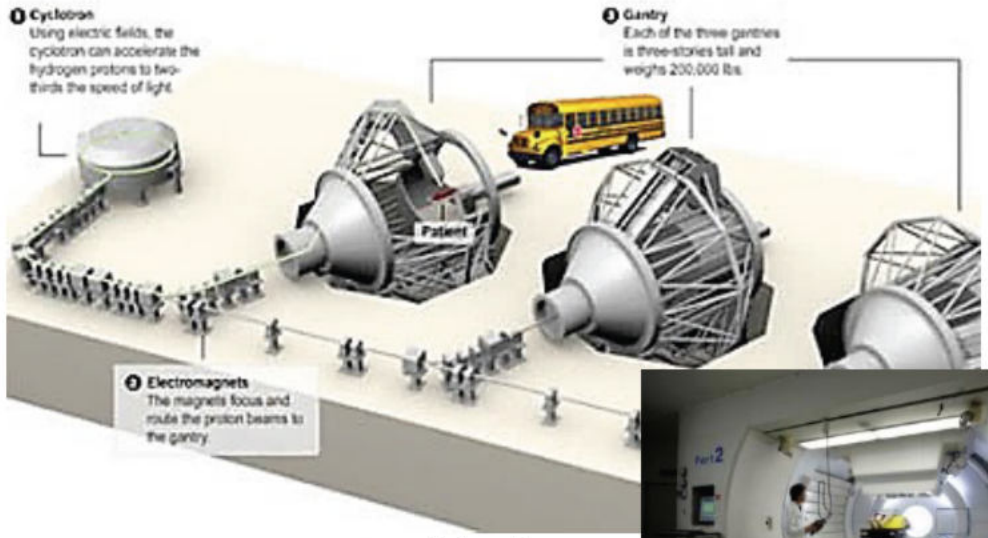
[redacted]

Global Sustainable Chemicals Lead - Siemens Healthineers

MEDICAL IMAGING and THERAPY DEVICES:
an introduction

The Medical Technology sector, plays an **essential role for the running of hospitals, clinics to the benefit of society, improving healthcare** through early detection, screening, prevention, and treatment.

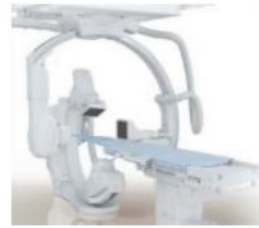
Medical technology is among the most innovative in the world. In the EU, healthcare drives patenting activity, givin g the EU a **decisive competitive position globally.**



Particle therapy installation

Computer tomography

Magnetic resonance



X-RAY

Complex, globally competitive products with long design cycles

COMPLEXITY AT ALL LEVELS

Typical MRI unit weighs approx. 10 tons
- 3,600 assemblies
- 27,000 sub-assemblies
- 120,000 component parts
- More than 1,000,000 "articles"

Typical extended supply chain: 5 - 7 levels
- About 11,000 suppliers distributed in the world
- 10 different languages

High value devices, low unit sales numbers
- Limited purchasing leverage even on 1st level suppliers

Regulatory
- The Medical Device Regulation (MDR) 2017/745 is one of the most complex legislations in Europe

INNOVATION/SUBSTITUTION IS A COMPLEX AND LONG PROCESS

Long design cycles
- 7 years design cycle for imaging
- 20 years for IVDs
- 11 years for radiation therapy
- 10 years of market availability

- Since the '70s, only 5 generations of PET scanners

Very high costs for substitution
- 400 millions per company to re-design MRIs to accommodate new lead-free chips
- 100s millions to remove 5g per year from x-ray tube bearings

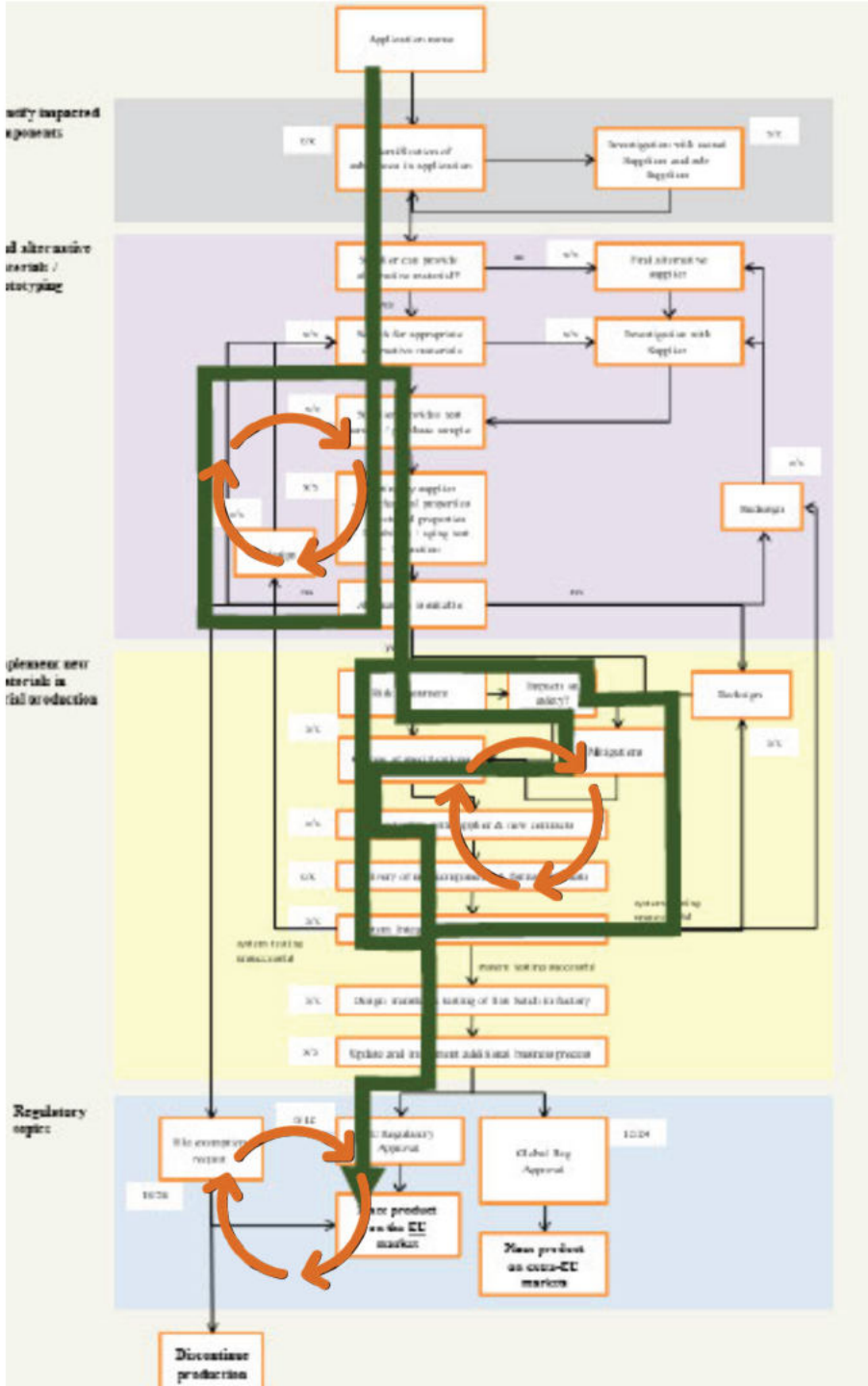
Substituting PFAS in the medical device sector

Analysis of Alternatives

- Identified uses undergo case-by-case analysis of potential alternatives
- Alternative materials lead to potential changes to manufacturing + design
- Rigorous testing, uncertainty as to result
- Elapsed time will depend on technical feasibility > process starts again if tested alternative is not successful

Why we need a solution

- Medical devices being removed from the market as redesign is not possible
- Medical devices being removed from the market due to non compliance of suppliers far-away in the supply chain
- Many PFAS are not on any regulatory list and are non-hazardous, no legal obligation to communicate in the supply chain



A cost/effective solution for PFAS: the "Legacy Device Approach"

CRITICAL

1. **Exclusion of legacy devices**
   (to include manufacturing process)
   (avoids diverting resources from R&D of innovative medical technologies)

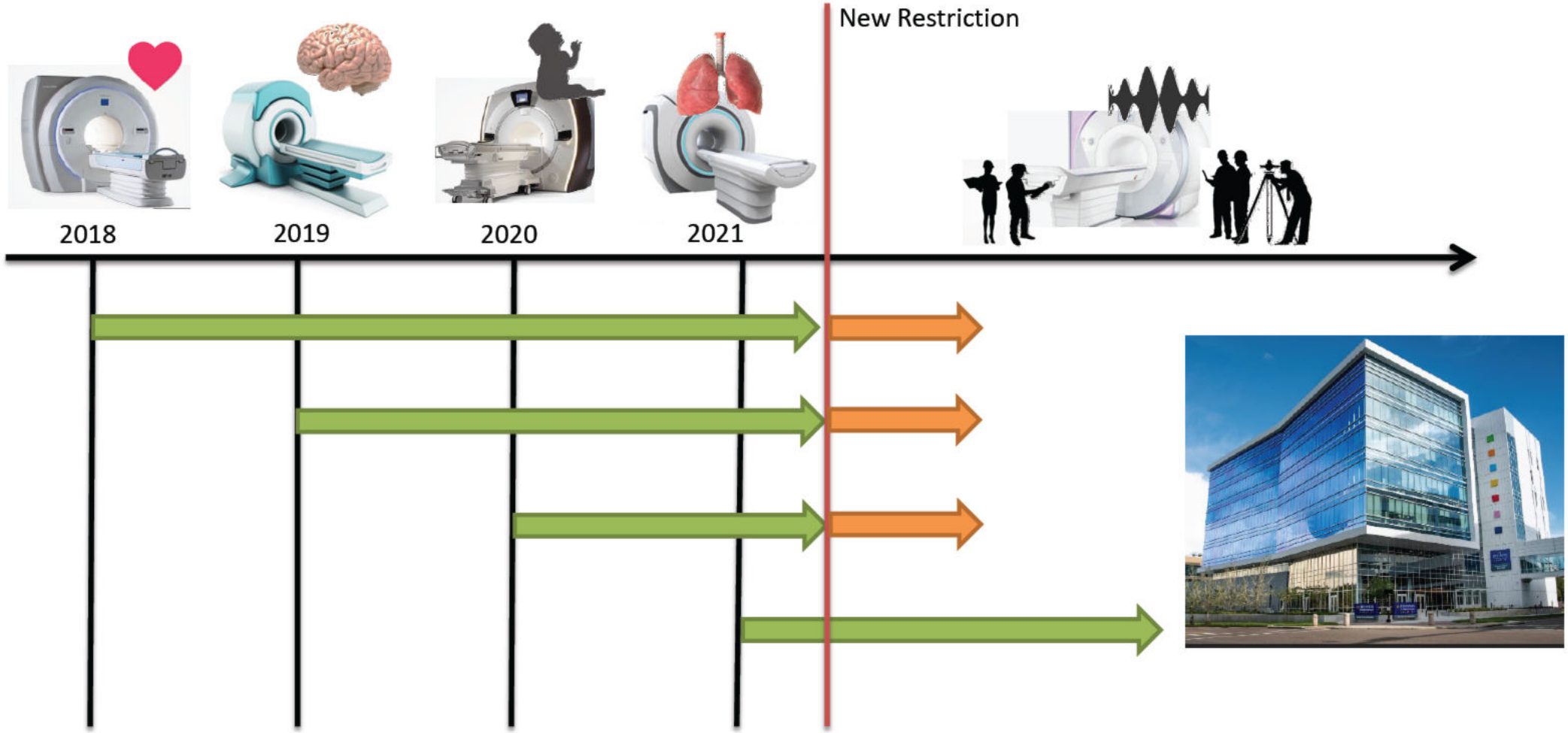
WITH

2. **Long transition times**
   (to substitute, to collect evidence of no alternatives)
3. **Long validity** of derogation (where justified)
   (to look for alternatives and validate them)

WITH

4. **Possibility** to ask for derogations **after** the end of the transition period
   (time is needed to test alternatives and, if conclusion is none is available, submit a derogation request)

A possible cost/effective solution for PFAS : the “Legacy Device Approach”



Already adopted by RoHS successfully across several exemptions

http://www.cocir.org

Questions?

www.linkedin.com/company/cocir/

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