

Substitution of hazardous chemicals:

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Fundamental concepts, examples and challenges for FCMs

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The Substitution Principle

"If risks to the environment and human health and safety can be reduced by replacing a chemical substance or product either by another substance or by some non-chemical technology, then this replacement should take place."

(Swedish Chemicals Agency, 2007).



The Substitution Principle

- ☐ Includes the protection of human health and the environment.
- ☐ Goes beyond *chemical* substitution.
- ☐ Incentives phasing out compounds and products with particularly problematic characteristics.
- ☐ However, even problematic compounds remain on the market (or are even gaining market approval), if no alternatives are available.

The Substitution Principle in European Chemical Regulation

- ☐ Industrial chemicals in REACH (EC/1907/2006)
- ☐ Biocides in the Biocide Product Regulation (EU/528/2012)
- ☐ Pesticides, in the Regulation on Plant Protection Products (EC/1107/2009)
- ☐ NOT considered for human and veterinary pharmaceuticals.
- ☐ Only considered for a SMALL SUBSET of REACH chemicals.



The Substitution Principle under REACH

- ❑ “Substances of very high concern” (SVHC) are compounds that are carcinogenic, mutagenic, reprotoxic, endocrine disrupters, and/or are persistent, bioaccumulative, toxic.
- ❑ Memberstates propose compounds as SVHC.
- ❑ ECHA compiles identified SVHCs into a candidate list.
- ❑ Prioritized into authorization list (REACH Annex XIV).



The Substitution Principle under REACH

- ☐ Substances on this list require authorization for specific uses after a given sunset date.
- ☐ Application for authorization submitted to ECHA.
- ☐ Committees for Socio-Economic Analysis (SEA) and Risk Assessment (RAC) provide opinions.
- ☐ Public consultation.
- ☐ European Commission takes final decision.



The Substitution Principle under REACH

- ❑ **14 733** unique compounds collected in ECHA's database.
- ❑ Candidate list comprises **169** compounds.
- ❑ Annex XIV comprises **31** compounds.
- ❑ **91** Applications for authorization from **172** applicants for **155** uses.
- ❑ **59** Commission decisions.



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The general approach

Identification of a candidate for substitution (CFS)



The general approach

Identification of a candidate for substitution (CFS)



Functionality needed?



MADE
RIGHT
HERE

FRESH
PRODUCE

CONVENTIONAL

MADE
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HERE

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MADE
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FRESH
PRODUCE

CONVENTIONAL

MADE RIGHT HERE!



Coop Denmark and the popcorn ban...

Case: Fluorinated Substances



Coop: Farvel til popcorn skal lægge pres på producenten

af Keld Vrå Andersen · 15. maj 2015, 19:40

Coop-koncernen, der blandt andet omfatter butikker som Superbrugsen, Fakta og Kvickly har fjernet mikroovnspopcorn fra hylderne. Popcornene vil ikke blive solgt i butikkerne, for der er fundet en løsning på emballagens problemer med fluorerede stoffer, oplyser Coop.



FORBRUG & LIV

Bolig Sundhed Digitalt Forbrug Biler Livsstil

FOREVARER 15. maj 2015 kl. 19:03

Dansk Supermarked fortsætter salg af popcorn med hormonforstyrrende stoffer

Coop vil skåne kunderne for sundhedsskadelige stoffer i emballagen.





The general approach

Identification of a candidate for substitution (CFS)



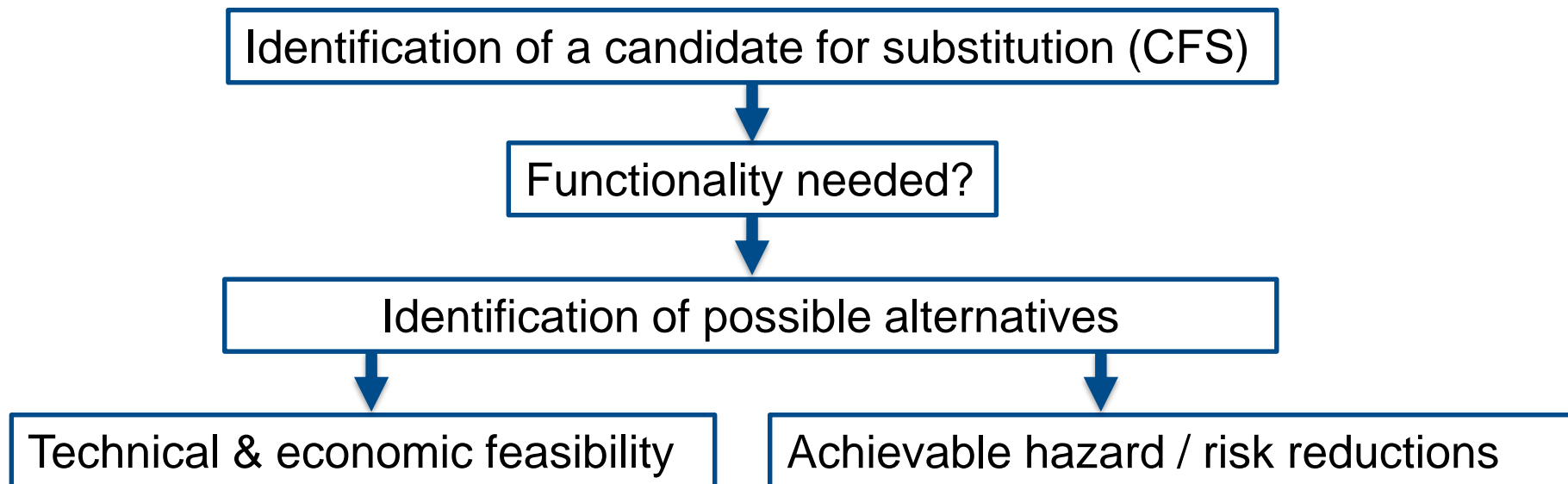
Functionality needed?



Identification of possible alternatives

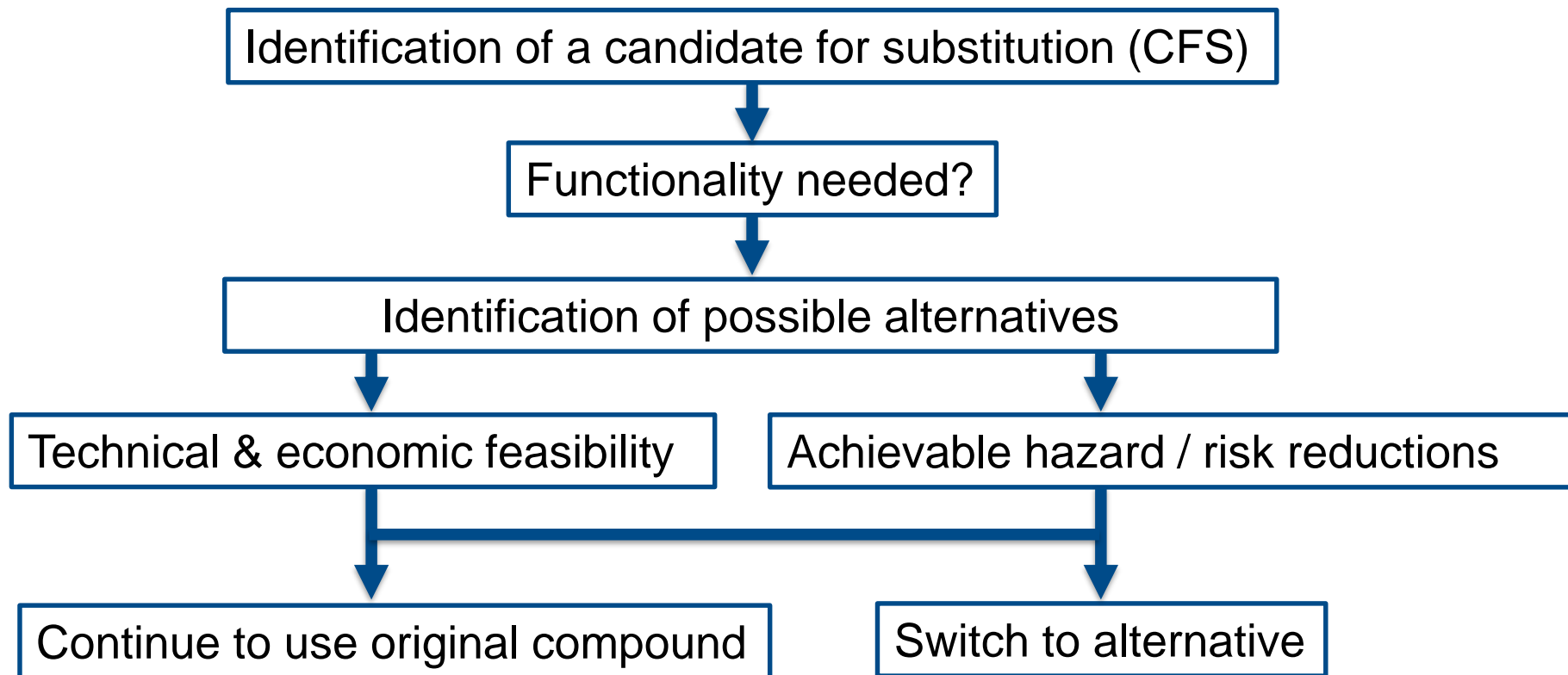


The general approach



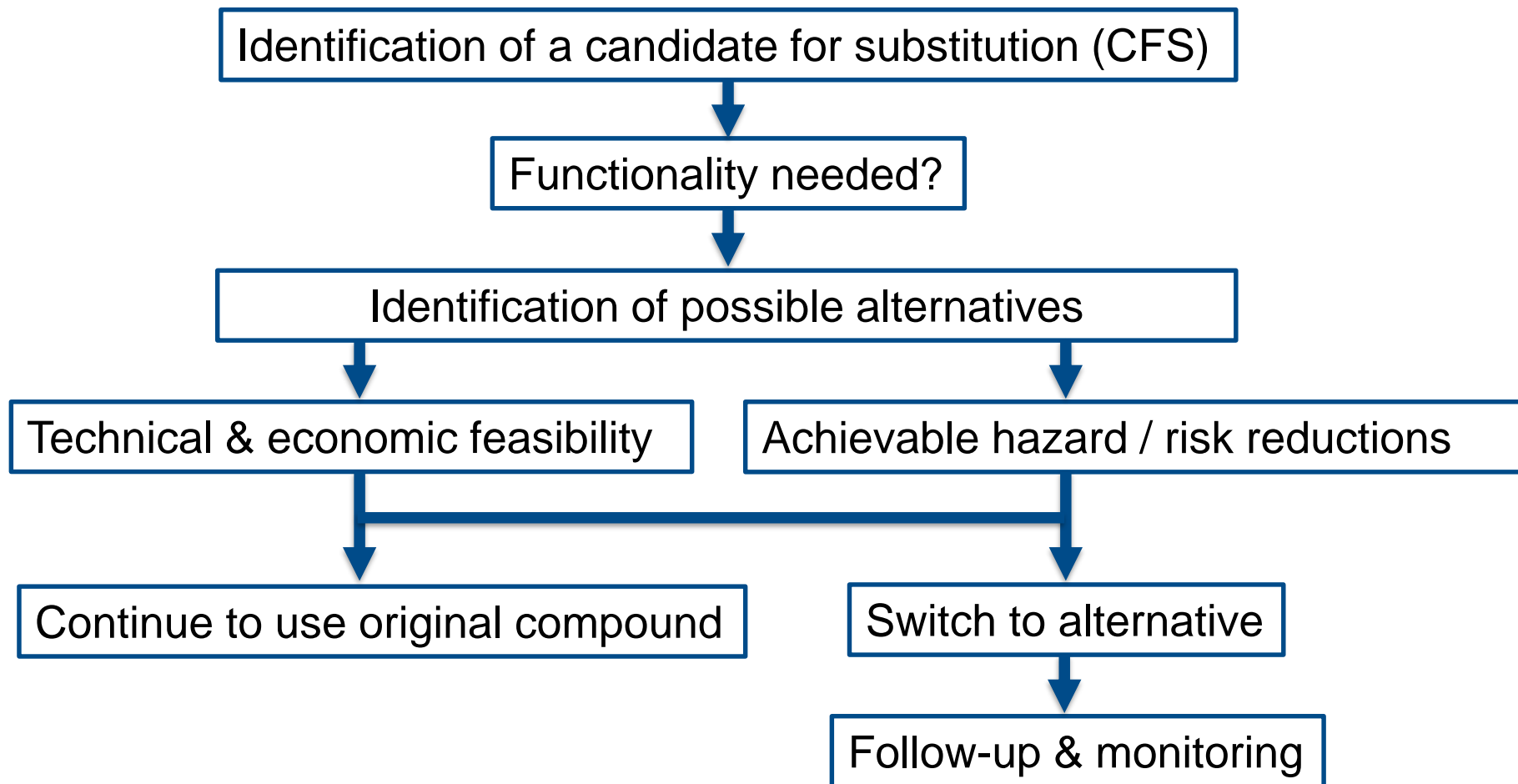


The general approach



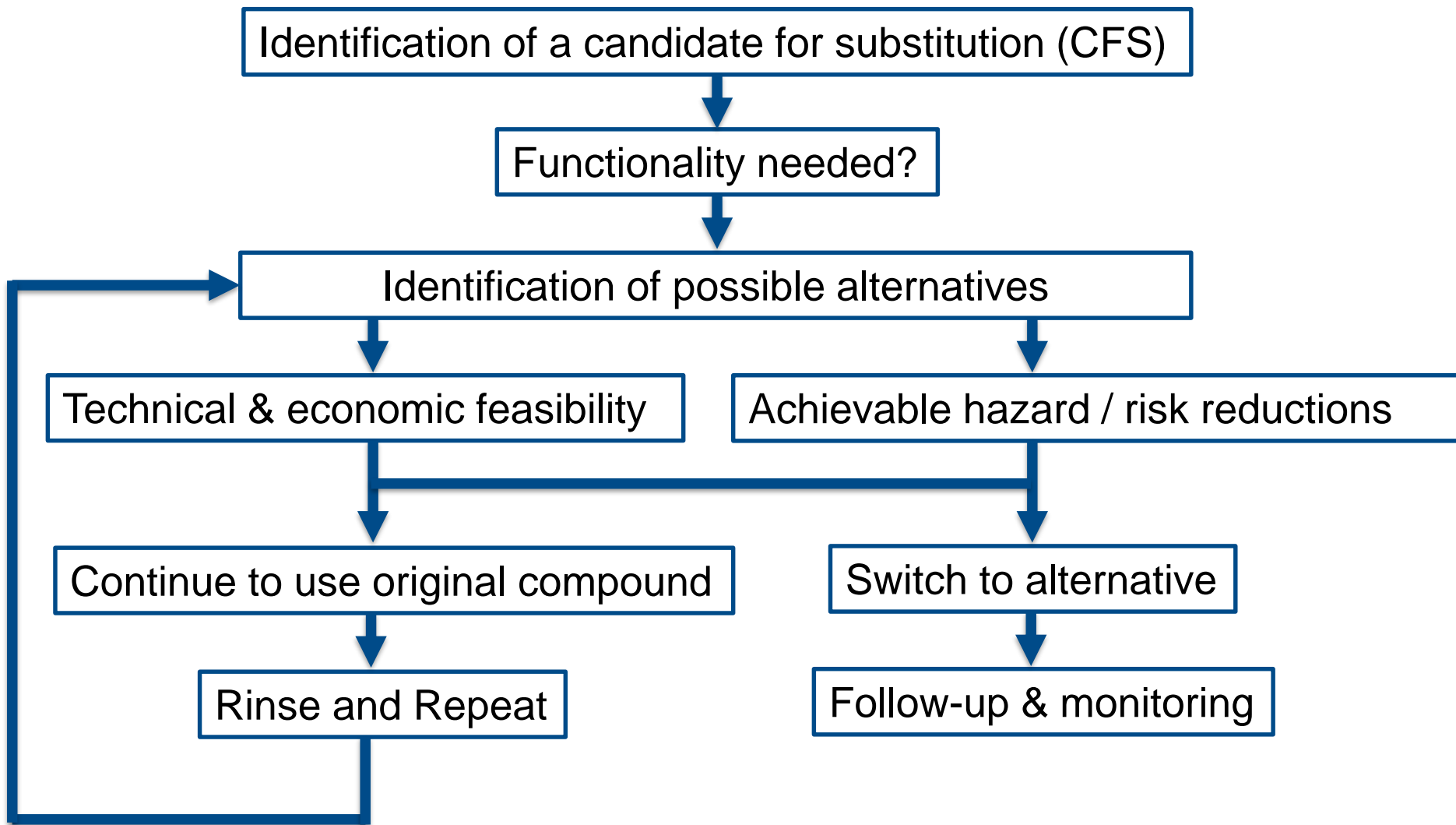


The general approach





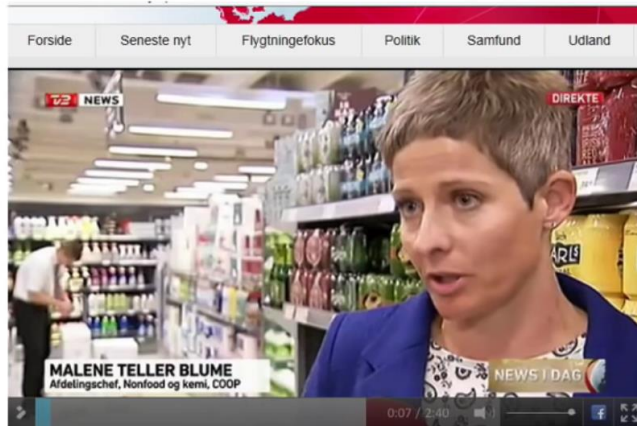
The general approach





Coop Denmark and the reverted popcorn ban...

Case: Fluorinated Substances



Coop: Farvel til popcorn skal lægge pres på producenten

Af Keld Vih Åndersen · 18. maj 2015, 19:46

Coop-koncernen, der blandt andet omfatter butikker som Superbrugsen, Fakta og Kvickly har fjernet mikroovnspopcorn fra hylderne. Popcornene vil ikke blive solgt i butikkerne, før der er fundet en løsning på emballagens problemer med flourerende stoffer, oplyser Coop.



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Bolig Sundhed Digitalt Forbrug Biler Livsstil

FODEVARER 19. MAJ 2015 KL. 15:03

Dansk Supermarked fortsætter salg af popcorn med hormonforstyrrende stoffer

Coop vil skåne kunderne for sundhedsskadelige stoffer i emballagen.





Risk- versus Hazard-based Substitution

Substitution can be triggered by

- the intrinsic properties of an identified chemical, or
- on the risk resulting from a chemical in a given product

Hazard

- Carcinogen?
- Endocrine disrupter?
- Reprotoxic?
- Take action if compound fulfills any of the criteria

Risk

$\text{Risk} = \text{Hazard} / \text{Exposure}$

- Take action if use of a product leads to unacceptable risks



Risk- versus Hazard-based Substitution

Substitution can be triggered by

- the intrinsic properties of an identified chemical, or
- on the risk resulting from a chemical in a given product

	Hazard-based
Pro	<ul style="list-style-type: none">- Easy to communicate and regulate on- Does not rely on technical measures



Anticontraceptive patch

- ☐ Ethinylestradiol as active ingredient
- ☐ Major environmental contamination caused by improper disposal of unused patches
- ☐ 80% of initial dose lost
- ☐ Oral contraceptives significantly less environmental risky





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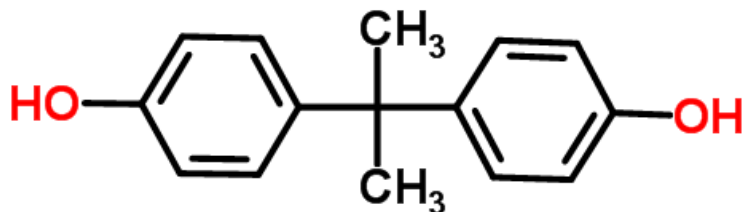
Regrettable substitution



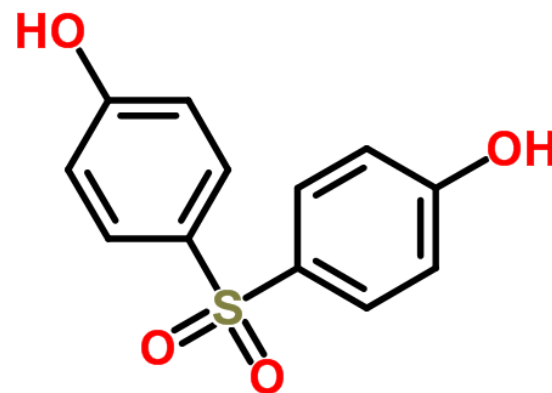


Regrettable substitution

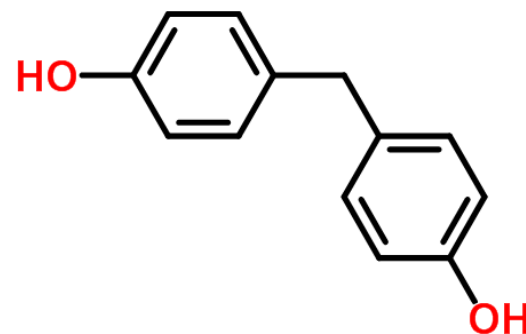
Bisphenol A



Bisphenol S



Bisphenol F





How to avoid regrettable substitution?

*The majority of these studies examined the hormonal activities of Bisphenol S and Bisphenol F and found **their potency to be in the same order of magnitude and of similar action** as Bisphenol A (estrogenic, antiestrogenic, androgenic, and antiandrogenic) in vitro and in vivo.*



Rochester JR, Bolden AL. 2015. Bisphenol S and F: a systematic review and comparison of the hormonal activity of bisphenol A substitutes. *Environ Health Perspect* 123:643–650;



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Conflicting & changing aims





Conflicting & changing aims

- ❑ Coolant in the 1930's: ammonia
- ❑ Replaced because of concerns for human health with chlorofluorocarbons (CFCs)
- ❑ Replaced by hydrochlorofluorocarbons (HCFCs),
- ❑ Replaced by hydrofluorocarbons (HFCs)



Conflicting & changing aims

Chemical	Ozone depleting potential (relative to CFC-11)	Global warming potential (relative to CO ₂)	Other hazardous properties
Ammonia*	0	< 1	Highly toxic (but odor enables evacuation), slightly flammable
Carbon Dioxide*	0	1	Toxic at high doses
CFC-11	1	4,600	
CFC-12	0.820	10,600	
HCFC-22	0.034	1700	
HFC-134a	0	1300	
Hydrocarbons*	0	~20	Flammable

Driving Innovation: How stronger laws help bring safer chemicals to market
Baskut Tuncak, CIEL, 2013



Quantitative consequences

Pesticide Regulation 1107/2009: A compound is classified as a candidate for substitution (CFS), if

- ☐ It meets two of the three PBT criteria
- ☐ Is a carcinogen or toxic to reproduction
- ☐ Is an endocrine disruptor in humans
- ☐ Its ADI is lower than those of the majority of compounds from the same use class
- ☐ Contains a significant proportion of non-active isomers
- ☐ The nature of the critical effect together with the exposure pattern amounts to situations that cause concern even with very restrictive risk management measures



Quantitative consequences

Study for the German market

- ❑ **1378** products on the market in total, of which **351** contain a CFS.
- ❑ Use against **477** pests
- ❑ **3606** different uses for which pesticide products are authorized.
- ❑ **1863 different uses for which pesticide products that contain CFS' are authorized.**

M Faust, et al., Comparative assessment of plant protection products: how many cases will regulatory authorities have to answer?
Environmental Sciences Europe, 2014



The SiN List

- ❑ **Substitute it Now:** compilation of chemicals, their hazardous properties, use patterns and substitution alternatives (Subsport) to facilitate voluntary substitution efforts.
- ❑ As of Oct 2016: includes food contact material as one use category, based on information from EFSA's list of food contact materials.
- ❑ Developed and maintained by ChemSec www.chemsec.org.
Contact Dr. Anna Lennquist (anna@chemsec.org) for details & help.



Summary

- ☐ Substitution is a tool to limit the amounts of hazardous chemicals used in products and processes.
- ☐ Policy instrument to provide incentives for developing better alternatives, which can be combined with e.g. taxes, fees, fast-tracking, etc.
- ☐ Limited scope if necessity of chemical / product is not reflected upon.
- ☐ Identifying a compound as a candidate for substitution does NOT imply the compound cannot be marketed.
- ☐ Depends on the availability of alternatives.
- ☐ Any authorization should be time-limited.



Critical Issues

- ❑ Risk- *versus* Hazard-based approaches.
- ❑ How to handle the problem that toxicological knowledge for potential alternatives is usually lower than for the original compound (comparative assessment)?
- ❑ How to handle conflicting and changing aims?
- ❑ Requires adaptive management in order to minimize the consequences of regrettable substitution and in order to adjust to new findings, technical progress, and changes in priorities.

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