



# Should I drink out of this?



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SR+ Seminar  
5 December 2013



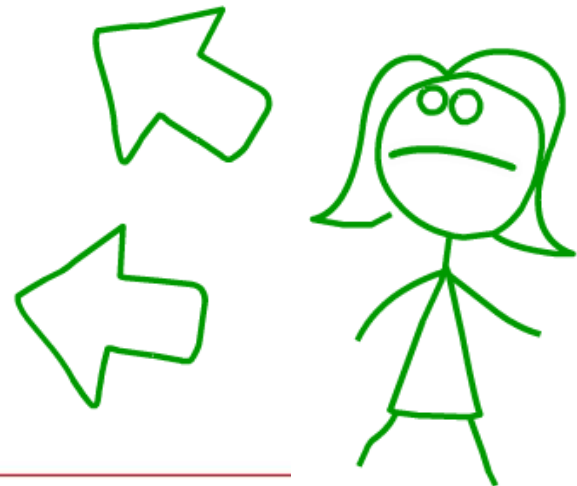
We are, through the media, as ordinary citizens, confronted daily with controversy and debate across a whole spectrum of public policy issues. But typically, we have no access to any form of systematic 'evidence base' — and therefore no means of participating in the debate in a mature and informed manner.

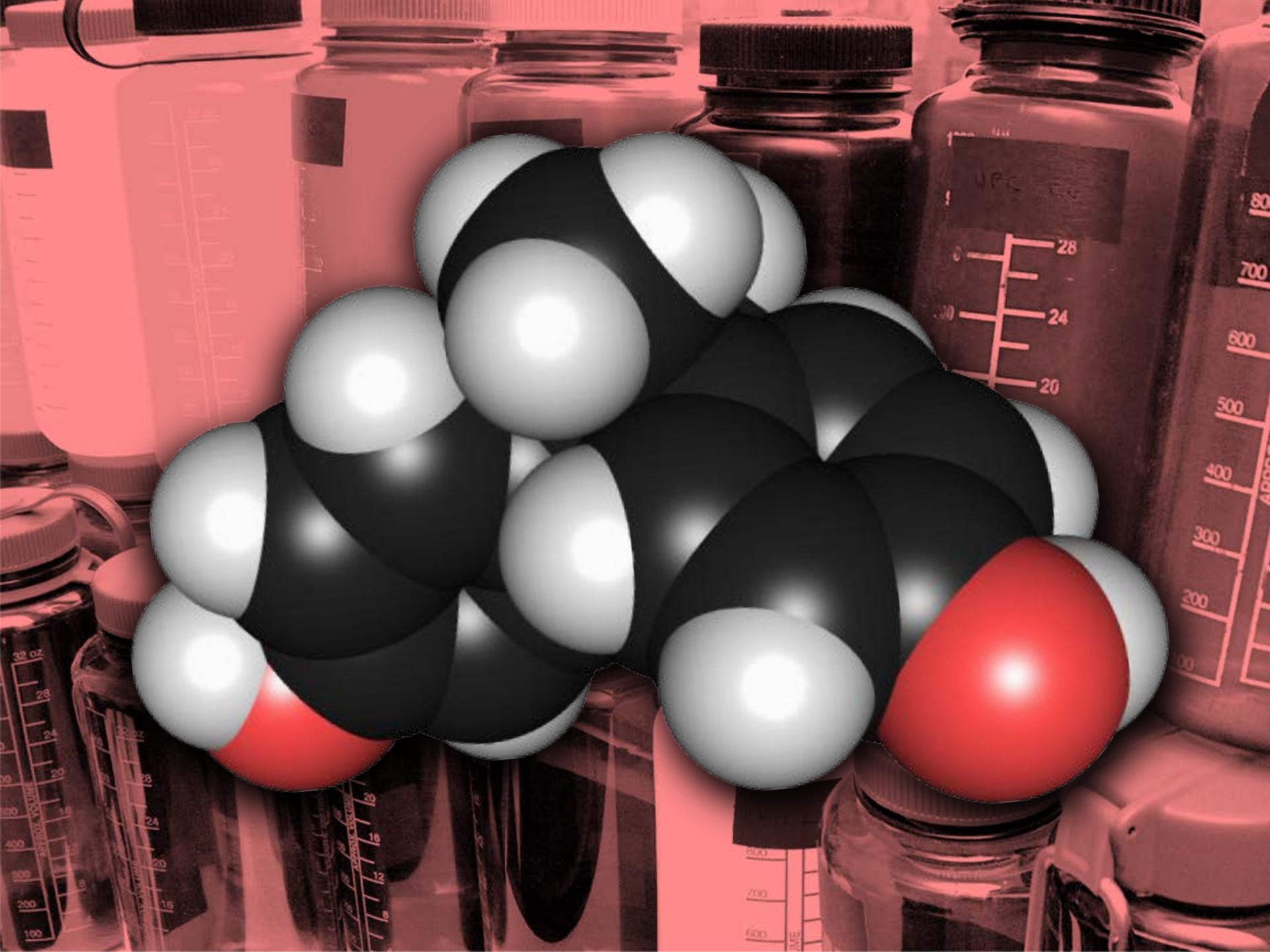
*Prof. Sir Adrian Smith*



# Ever think about any of these?

- **Directive 2011/65/EU:** The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS)
- **Regulation EC 1907/2006:** Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- **Regulation EC 1107/2009:** Marketing of Plant Protection Products
- **Regulation EC 1223/2009:** Cosmetics Regulation
- **Regulation EC 1935/2004:** Food Contact Materials

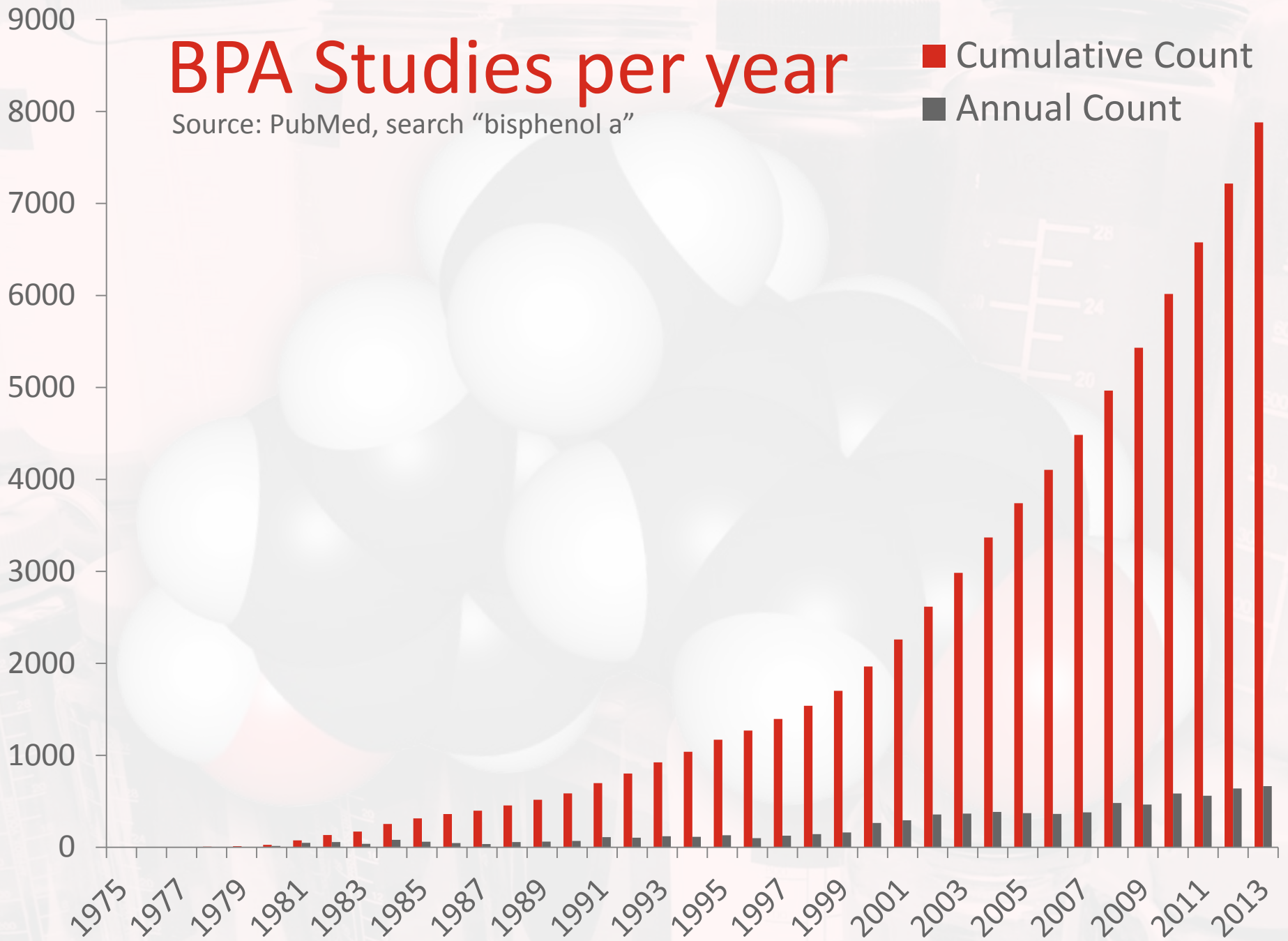


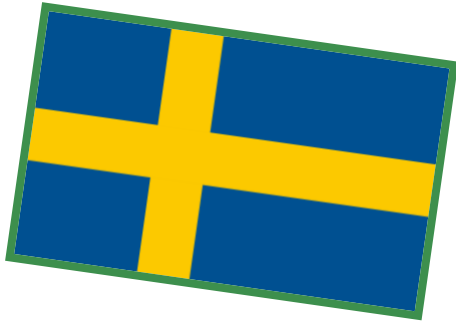


# BPA Studies per year

Source: PubMed, search "bisphenol a"

- Cumulative Count
- Annual Count





# Legal Battle Erupts Over Whose Plastic Consumers Should Trust

by JOH HAMILTON

July 30, 2012 4:01 PM

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NATURE NEWS BLOG

### Europe's food agency maintains BPA stance

02 Dec 2011 | 11:50 GMT | Posted by Daniel Cressey | Category: Chemistry, Health and the Environment

Europe's food-standards agency has rejected calls for a tougher stance on bisphenol A on ongoing research.

Bisphenol A (commonly known as BPA) is widely used in the manufacturing of plastic products, and concerns have been raised over its possible toxicity, with its presence in baby bottles being particularly contentious. Some countries have banned it outright in certain products.

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### Canadian Government Backs BPA in Food Containers



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The Lancet, Volume 379, Issue 9822, Page 1186, 31 March 2012

doi:10.1016/S0140-6736(12)60496-6 [Cite or Link Using DOI](#)

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### Controversy continues over safety of bisphenol A



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### Britain to fight landmark ban on chemical linked to cancer

French plan to outlaw from baby bottles

MARTIN HICKMAN | TUE

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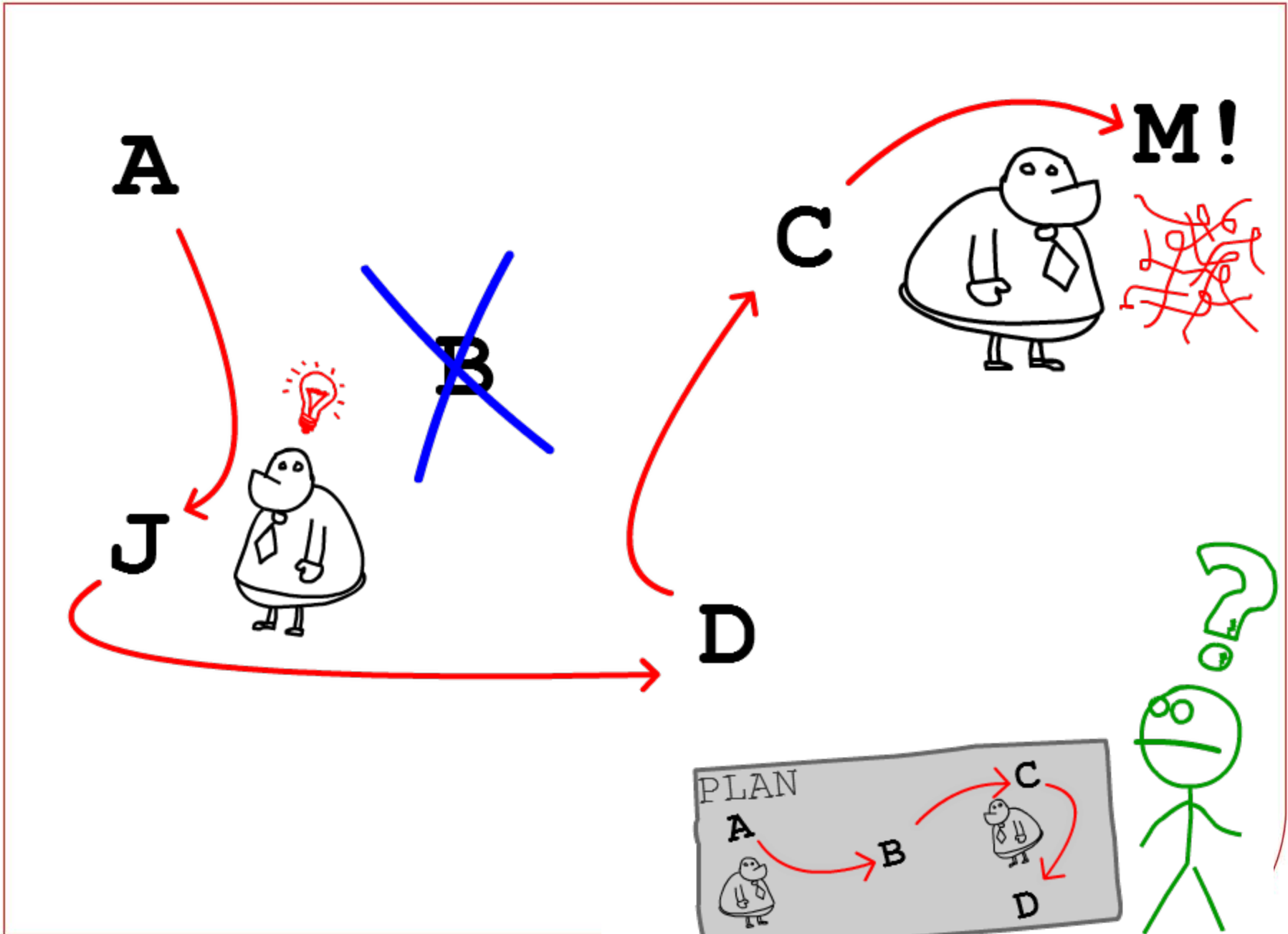
### Endocrine Society criticises US FDA for rejecting BPA

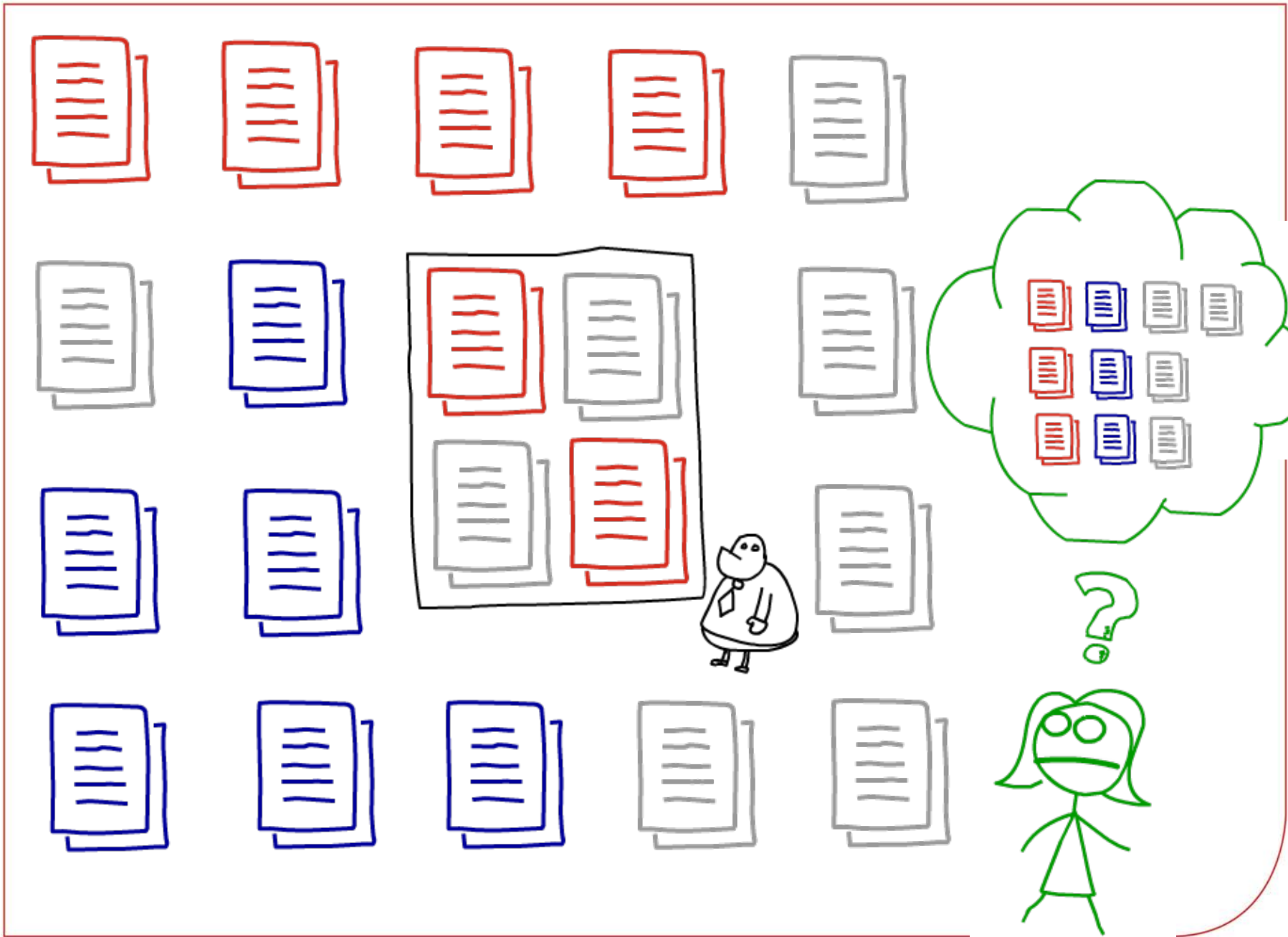
6 April 2012 / United States

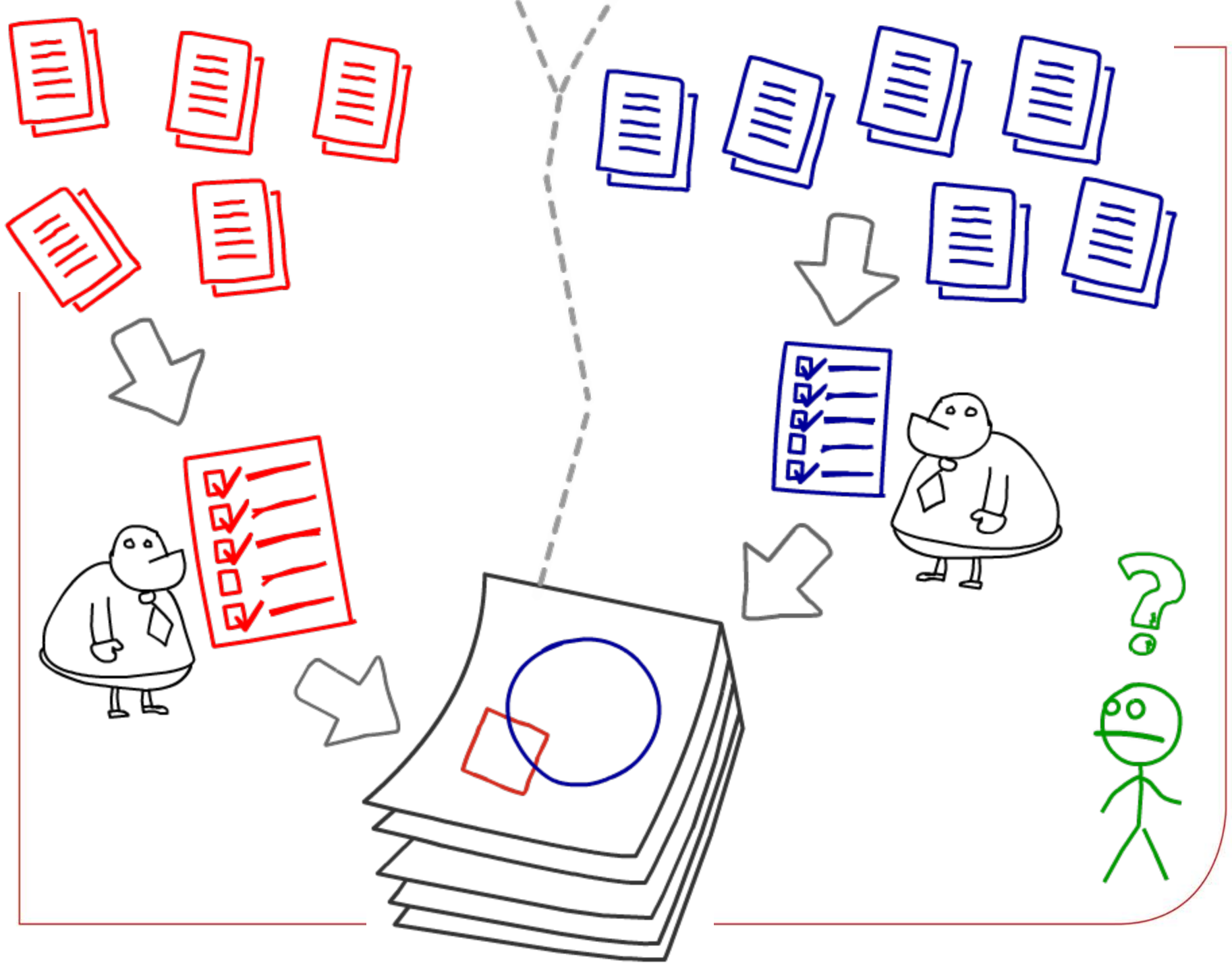














# What really happens?

- EFSA 2010 Opinion on BPA
- EFSA 2013 Draft Opinion on BPA (exposure part)



EFSA Journal 2010; 8(9):1829

## SCIENTIFIC OPINION

**Scientific Opinion on Bisphenol A: evaluation of a study on neurodevelopmental toxicity, review of recent scientific data on neurodevelopmental toxicity and advice on the Danish risk assessment**

EFSA Panel on food contact materials, enzymes and processing aids (CEF)<sup>2,3</sup>

European Food Safety Authority (EFSA), Parma, Italy

### ABSTRACT

Bisphenol A (BPA) is used in the manufacture of plastics, to produce bottles and other food storage containers. EFSA was asked to evaluate the safety of BPA in food contact materials based on the current Tolerable Daily Intake (TDI) of 0.04 mg/kg body weight (b.w.)/day as set by EFSA in 2006 and recent scientific literature (2007-2009) and the Danish ban of BPA in food contact materials for infants aged 0-3 years. The impact of these studies on the current Tolerable Daily Intake (TDI) of BPA in food contact materials for infants aged 0-3 years was assessed. Advice on the Danish ban of BPA in food contact materials for infants aged 0-3 years was based on the No-Observed-Adverse-Effect Level (NOAEL) derived from a comprehensive evaluation of recent toxicity data, the Panel on food contact materials, enzymes and processing aids (CEF) concluded that no new study could be identified. The Panel on food contact materials, enzymes and processing aids (CEF) is based on the No-Observed-Adverse-Effect Level (NOAEL) derived from a study in rats, and the application of the Margin of Exposure (MOE) approach.



EFSA Journal 20YY:volume(issue):NNNN

## ENDORSED FOR PUBLIC CONSULTATION DRAFT SCIENTIFIC OPINION

**DRAFT Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs – Part: exposure assessment<sup>1</sup>**

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)<sup>2,3</sup>

European Food Safety Authority (EFSA), Parma, Italy

### ABSTRACT

# Literature Review Toolkit



- Clarity of objective
- Use of a pre-published protocol
- Declaration of interests
- Search method: reproducible and comprehensive
- Selection process: all relevant evidence
- Appraisal of **external validity** of included studies
- Appraisal of **internal validity** of included studies
- Consistency of answer with review findings

# Summary of findings

Component	2010 Opinion	2013 Draft Opinion
Objective	✗	✓
Protocol	✗	✗
Interests	✗	✗
Search Method	✓	✗
Study Selection	✗	✗
External validity	?	?
Internal validity	✗	✗
Clarity of answer	✓	✗

# Woops!

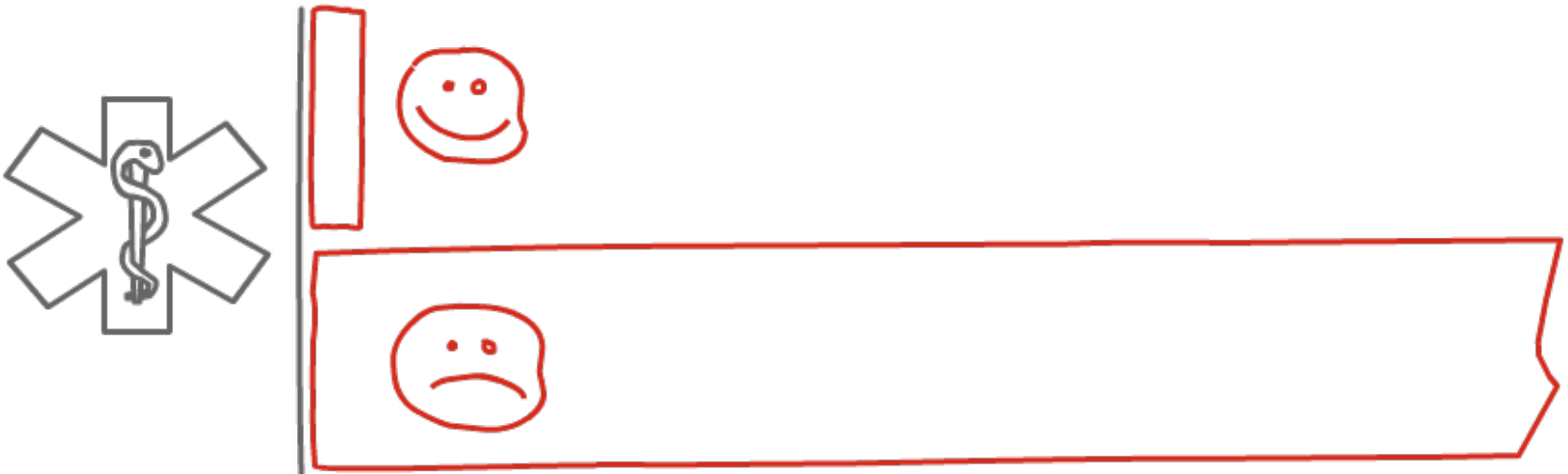
- Scientifically embarrassing
  - one standard for studies
  - another for reviews
- But not surprising

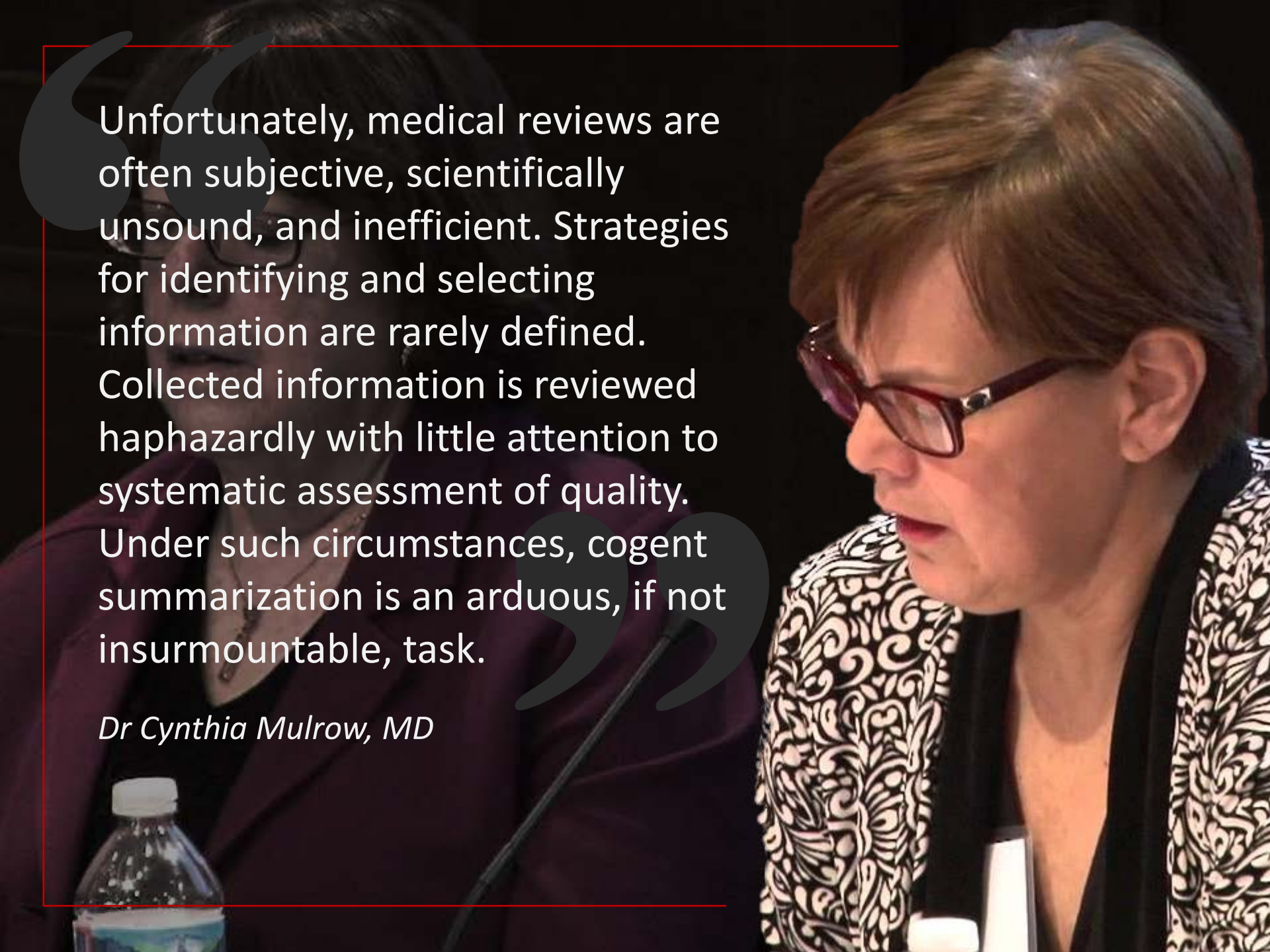




# Same problem in medicine

- In 1987, Cynthia Mulrow showed that of 50 reviews published in the top 4 medical journals, only one had been conducted according to scientific standards





Unfortunately, medical reviews are often subjective, scientifically unsound, and inefficient. Strategies for identifying and selecting information are rarely defined. Collected information is reviewed haphazardly with little attention to systematic assessment of quality. Under such circumstances, cogent summarization is an arduous, if not insurmountable, task.

*Dr Cynthia Mulrow, MD*

# This problem kills people

- Steroids and infant mortality
- Heart anti-arrhythmia drugs
- Sleeping position and cot death

# Steroids for mothers

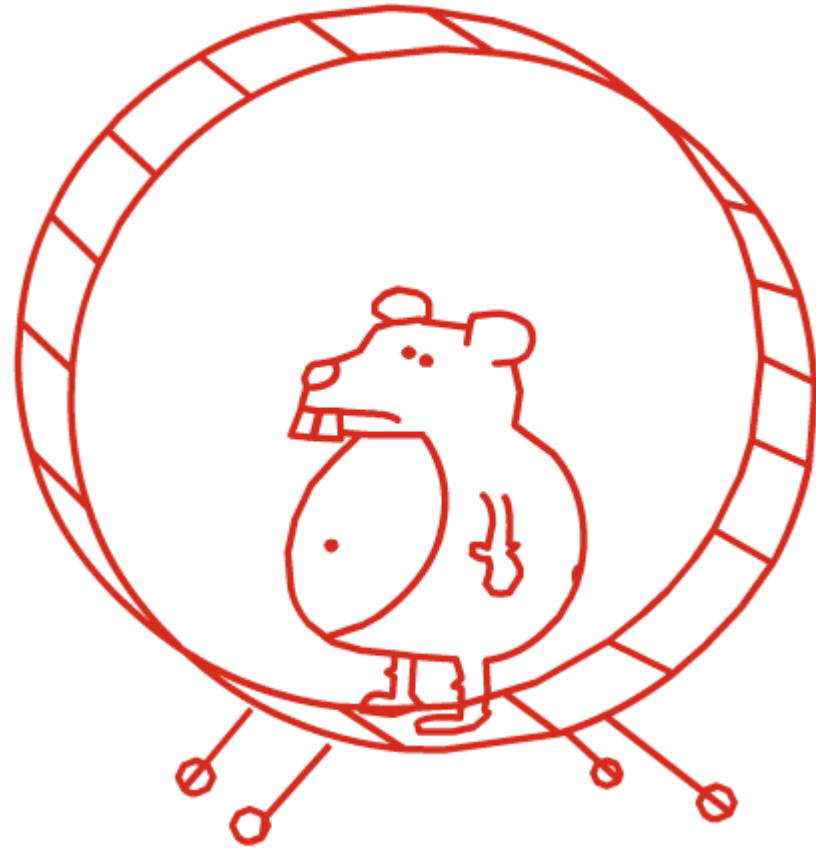
- First fair test: **1972**. Premature babies of mothers who had received a steroid were less likely to die
- Next ten years: more trials but they were small and their individual results confusing
- **1989**: all the data was collected together and assessed. Very strong evidence of the efficacy of steroid treatment was revealed

# Anti-arrhythmia drugs

- After heart attack, men who develop arrhythmia are more likely to die
- Suppressing arrhythmia should therefore prevent a second infarction, right?
- **Wrong.** Peak use in late 1980s, killed more American men per year than Vietnam
- First review of trial data in 1983 had already shown no benefit

# Unnecessary research

- Wastes time
- Wastes money
- Is unethical

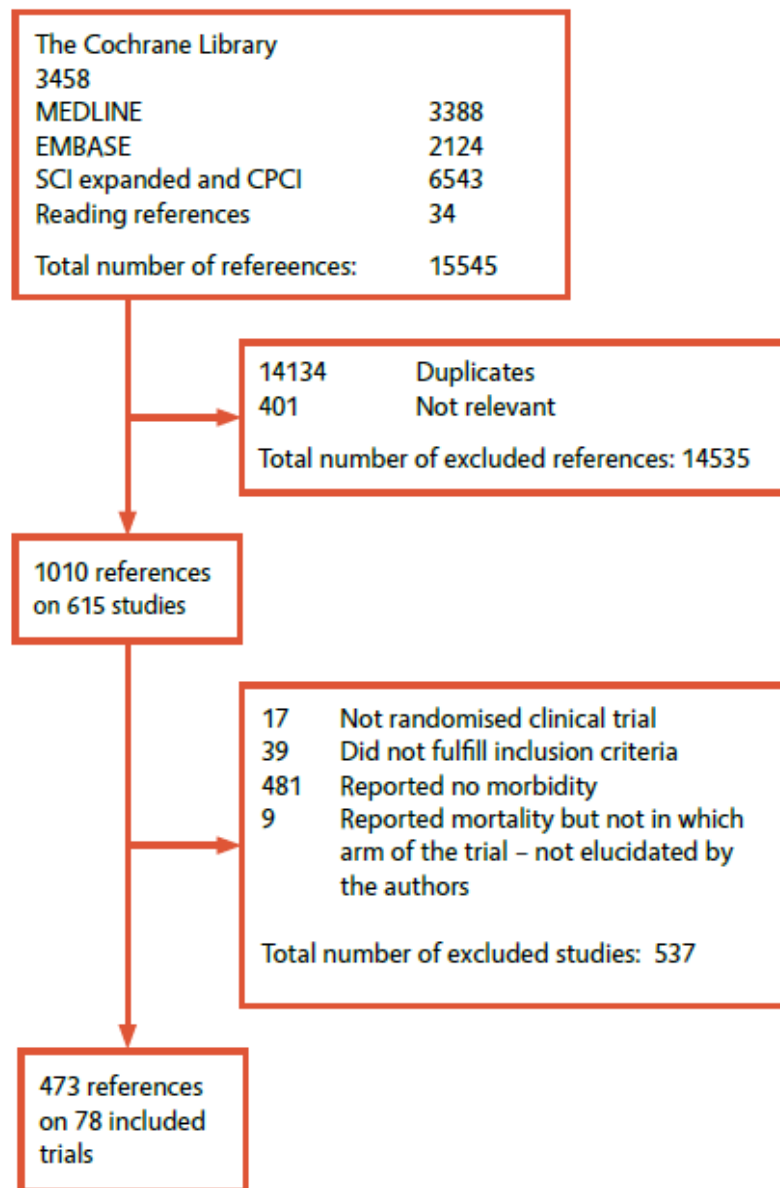


# How did they tackle it?

- By developing Systematic Review techniques

# Some simple

- Fully documenting search strategy
  - Databases
  - Results
  - Exclusions
  - Final set



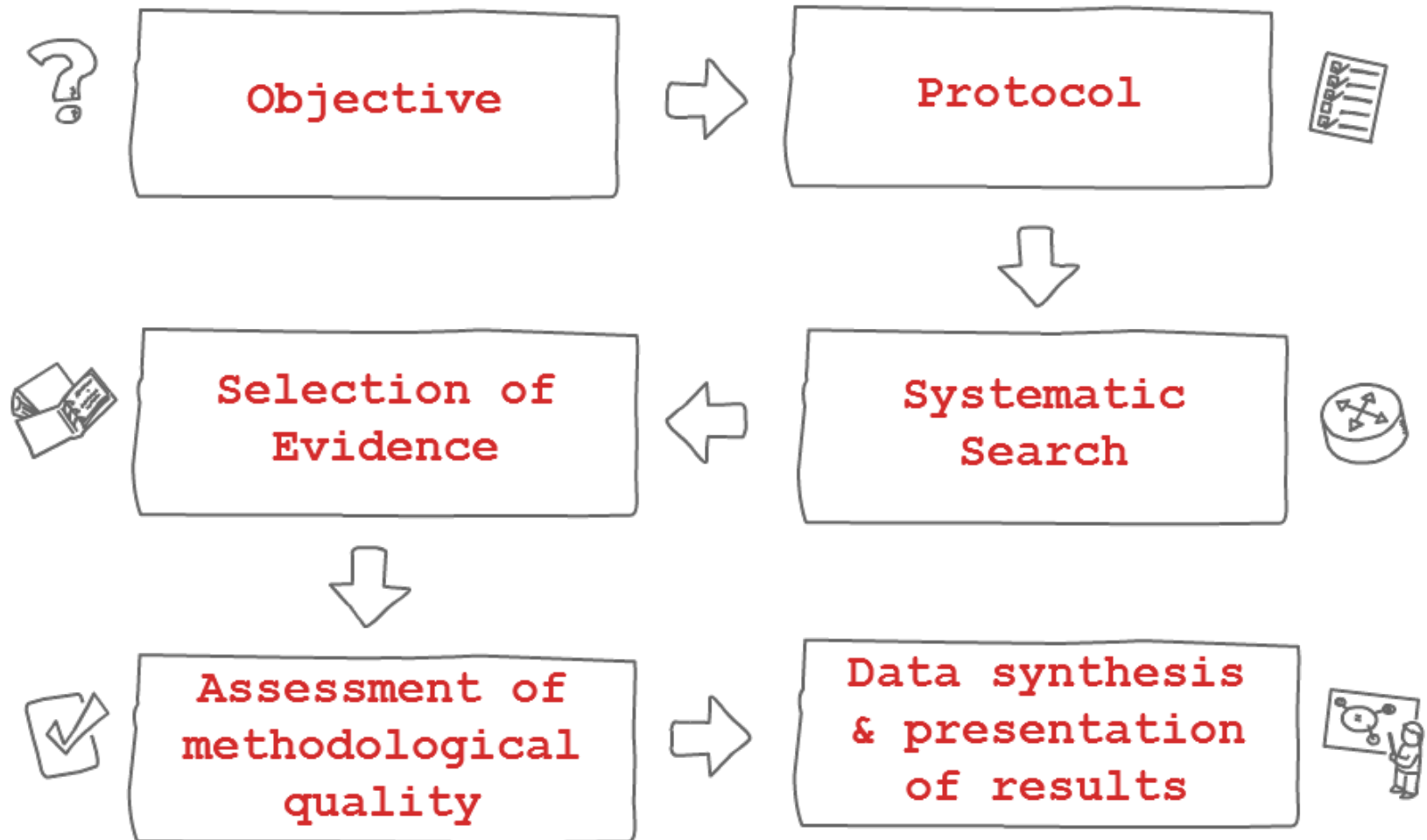


# Some more complicated

Key	
+	Low risk of bias
?	Unclear
-	High risk of bias

	Smith 2008	Barry 2009	Jones 2007	Charles 2011	Hilary 2003	Li 2008	Stein 2011
Adequate sequence generation?	?	+	?	+	+	+	+
Allocation concealment?	-	+	?	+	-	-	+
Blinding?	+	-	+	+	+	?	-
Incomplete outcome data addressed?	+	+	+	-	+	+	+
Free of selective reporting?	+	+	?	?	?	-	-
Free of other bias?	+	+	+	?	?	-	?

# Six elements of systematic review



# It's very simple

- Applying to literature review the same principles we used when doing science at school



# OK, but why?

- How else can we distinguish between the better and worse literature reviews?



**Science is supposed to be cumulative, but scientists only rarely cumulate evidence scientifically.**

*Chalmers, Hedges & Cooper (2002)*

