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The Bisphenol A (BPA) Controversy

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THE INDEPENDENT

POP OUT OF THE CLOSET

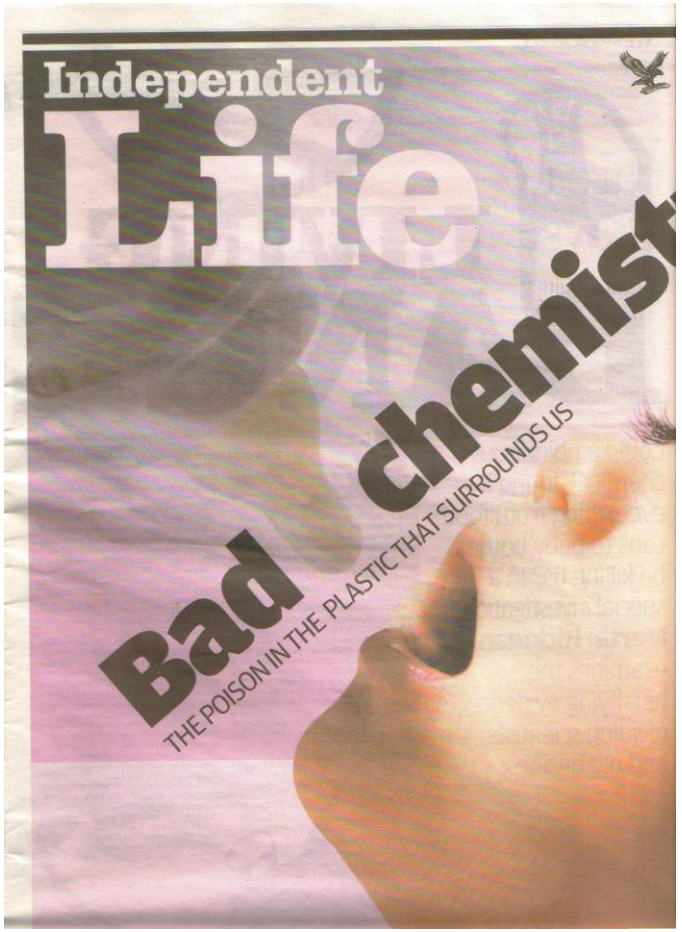
Ricky M

Scandal of danger chemical in baby bottles

Leading British retailers selling products banned in Canada and US

Martin Hickman

Investigation



Independent

Life

Bad chemist

THE POISON IN THE PLASTIC THAT SURROUNDS US

12 NEWS INVESTIGATION

Revealed: the nasty secret in your kitchen cupboar

18 of 20 most popular tins made with controversial bisphenol A in lini

By Martin Hickman

CONSUMER AFFAIRS CORRESPONDE

SOME OF Britain's best-know

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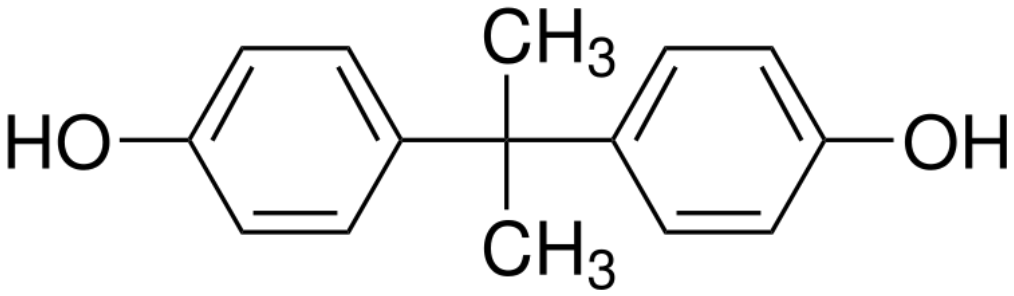
Bisphenol A



Used in manufacture of polycarbonate and epoxy resins for over 50 years

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Bisphenol A in food contact materials

- Polycarbonate
  - infant feeding bottles, tableware (plates, mugs, jugs, beakers), microwave ovenware, storage containers, returnable water and milk bottles, refillable water containers and water pipes.
- Epoxy resins
  - internal protective lining for food and beverage cans, coating on metal lids for glass jars and bottles.
  - Also as a surface-coating on residential drinking water storage tanks and wine vats.

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Other uses of BPA

- Medical and dental devises
- Household electronic equipment
- CDs, DVDs
- Sports equipment
- Printing inks, thermal paper
- Paints, wood filler, adhesives
- Laboratory equipment

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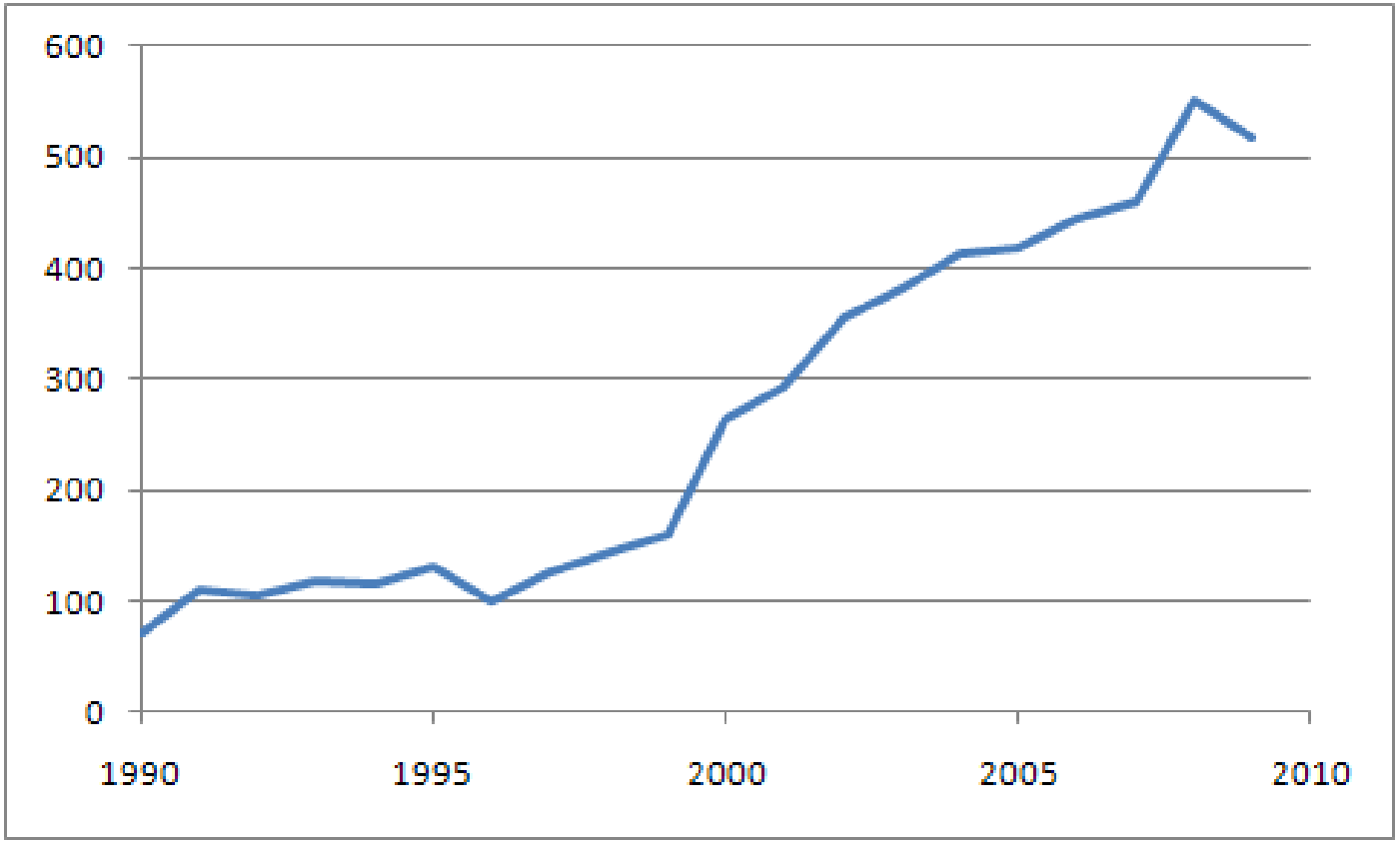
Publications per year (PubMed)



Total of 5689 scientific publications up to 19 June 2010

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Human health problems that have been linked to BPA

- Endocrine disruption
  - Oestrogen mimic
  - Disruption of thyroid hormones
- Heart disease
- Liver damage
- Impaired neurobehavioural development
- Attention deficit hyperactivity disorder
- Diabetes
- Obesity
- Breast cancer
- Male sexual dysfunction
- Miscarriage

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http://www.food.gov.u... | Hidden danger in baby... | http://www.efsa.euro... | Breast Cancer UK - Ca...

http://www.breastcanceruk.org.uk/campaigns/

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Campaigns

No More BPA Campaign

Breast Cancer UK have launched the No More BPA campaign calling for the Government to take action to stop BPA being used in the manufacture of baby bottles.

Scientists have, for the last decade, been highlighting potential links from exposure to BPA with increased risk of breast cancer and other chronic health conditions. Newborn babies are not able to clear the chemical as quickly as adults and due to their bodies being in a rapid stage of growth they may be more susceptible to the harmful effects of BPA.

Breast Cancer UK and over 60% of the public agree that the British Government should not allow BPA baby bottles to be sold in the UK.

Find out more about the No More BPA Campaign.

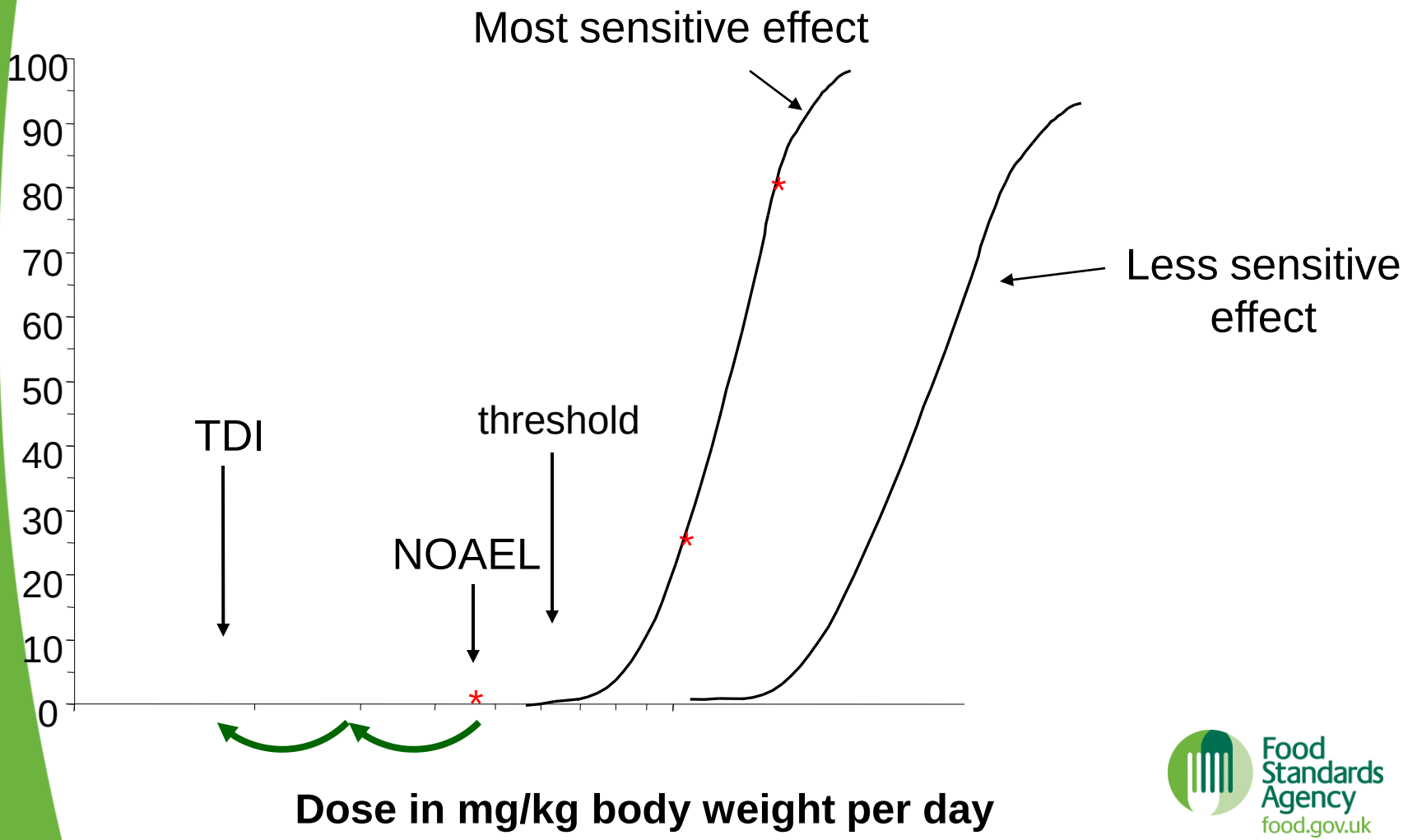
No More Breast Cancer

In 2005 Breast Cancer UK launched the No More Breast Cancer campaign with the publication of *Breast Cancer: an environmental disease*. The intention was to:

- Challenge a number of prevailing views and attitudes about breast cancer.
- Establish a novel view of breast cancer as a preventable rather than inevitable disease.
- Address the under-acknowledged and non-lifestyle factors associated with breast cancer.
- Provide a right-to-know document, presenting essential information to the general public.
- Challenge the government to prioritise the primary prevention of breast cancer.

You can visit the No More Breast Cancer website for more information by clicking here.

Tolerable daily intake (TDI)



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Toxicology of BPA

- Established weak oestrogenic effects
- Reproductive and developmental effects
- Effects generally seen at high doses, together with maternal toxicity
- Not carcinogenic in rats and mice
- Effects generally seen at lowest doses are decreased bodyweight gain in reproductive studies and liver toxicity
- NOAEL = 5 mg/kg bw/day

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The “low dose” effects

- Subtle effects in some studies at doses of 0.002-0.05 mg/kg bw/day given to pregnant mice
  - Increased prostate size
  - Sperm changes
  - Early sexual maturation
- Not demonstrated to be robust or reproducible

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Issues in the evaluations

- Laboratory studies
  - Industry vs academic studies
  - Good laboratory practice
  - Shape of dose response relationships
  - Phytoestrogens in the rodent feed
  - Non-oral studies
  - Bioavailability of BPA following ingestion
  - Strain and specifies sensitivity
- Epidemiological studies
  - Measurement of BPA in blood/urine
  - Causality
- Important to have views of independent scientific advisory committee

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EU reviews of BPA in food

- EU Scientific Committee on Food (SCF) 1986
  - Set TDI of 0.05 mg/kg bw/day
  - Specific migration limit of 30 mg/kg food
- SCF 2002
  - Temporary TDI of 0.01 mg/kg bw/day
  - Extra factor of 5 due to uncertainty
  - Migration limits?

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FSA survey of canned foods – April 2001

- Estimated high level dietary exposure
  - Adults: 0.00037 mg/kg bw/day
  - Infants: 0.00085 mg/kg bw/day
- Committee on Toxicity concluded:
  - exposure about 2 orders of magnitude below the TDI set by SCF in 1986
  - acknowledged uncertainty regarding endocrine effects of BPA
  - Levels identified unlikely to be a concern for health

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EFSA

- Nov 2006
  - Extensive new data meant extra factor of 5 no longer required
  - TDI of 0.05 mg/kg bw/day
- July 2008
  - Data on age-dependent toxicokinetics
  - No implications for the TDI
- Oct 2008
  - Reviewed study showing links with heart disease, diabetes and liver changes
  - Not sufficient proof of a causal link

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EFSA exposure estimates

- Took into account breast-feeding, infant formula in polycarbonate bottles, consumption of commercial foods and beverages:
  - 3 months infants: 0.0002 mg/kg bw/day
  - 6-12 months infants: 0.013 mg/kg bw/day
  - Young children: 0.0053 mg/kg bw/day
  - Adults: 0.0015 mg/kg bw/day
- All well below the TDI of 0.05 mg/kg bw/day

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Prof Richard Sharpe, MRC Human Reproductive Sciences Unit, University of Edinburgh, answers our questions

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"Q. How much evidence is there to suggest it is dangerous?

A. Very little. Some early animal studies produced results suggesting the possibility of adverse effects relevant to human health, but much larger, carefully designed studies in several laboratories have failed to confirm these initial studies."

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"Q. What happens if we consume too much BPA?

A. Nothing as far as we can tell. There are two very good studies that have shown an association between current bisphenol A levels in adults and certain liver disorders, but it is most likely that this association is diet related, ie those with the disorders have a diet containing more sugary drinks from bottles/cans containing the chemical."

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"Q. Why is BPA banned in some countries but not in Britain?

A. Because some have bowed to extreme pressure from groups advocating that bisphenol A is dangerous - they have given in to pressure and made a decision that has no scientific basis."

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Regulatory action in EU

- Denmark March 2010
  - announced ban on use of BPA in products intended for use by infants and children up to 3 years old
  - Not yet in force
- France 2010
  - Approved ban of BPA in infant feeding bottles
  - Not yet in force

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Possible risks of precautionary action

- Alternatives to BPA in plastic food contact materials
  - Polyesters
  - Water-based acrylics
- Must comply with EU regulations
- Lack of information in the public domain

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EFSA opinion 2010

- September 2010
  - Review of new neurodevelopmental study
  - Literature review of other recently published studies
  - Review of scientific basis for Danish action

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EFSA conclusions I

- Neurodevelopmental study - Stump
  - Influence of BPA on learning and memory behaviour cannot be evaluated
  - Study is inconclusive and cannot be used for the risk assessment of BPA
    - Reassessed by EFSA Analytical Methodology Unit

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EFSA conclusions II

- Low dose effects
  - Most studies several shortcomings
    - Lack of dose response
    - Limitations in experimental design
  - Not aware any clearly reproducible adverse effect expressed at low BPA doses only

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EFSA conclusions III

- Methodolgical shortcomings in studies looking at other neurodevelopmental endpoints
- Considered invalid or inadequate for risk assessment

- Does not consider currently available data sufficiently indicative of neurobehavioural toxicity as an endpoint of concer for BPA

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EFSA conclusions IV

- Overall no new study identified that calls for revision of the current TDI of 0.05 mg/kg bw/day
  - Based on NOAEL from multi-generation study and uncertainty factor of 100
  - UF regarded as conservative based on all information on BPA toxicokinetics

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EFSA conclusions V

- Uncertainties
- Some studies on developing animals suggested other effects of possible toxicological relevance
- Studies had many shortcomings
- Relevance for human health cannot be assessed

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Minority opinion

- One member
  - Because of uncertainties TDI should be considered temporary rather than full
  - No proposal for this or additional uncertainty factor as methodological shortcomings in studies
  - Greatest exposure is for infants and could be reduced by avoiding polycarbonate bottles

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Further evaluations

- World Health Organization
  - Expert consultation Nov 2010
  - To be preceded by stakeholder meeting

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FSA position

- Important to have an agreed position across the EU
- Continue to work closely with EFSA and the Commission
- Continue to review ongoing activity and research
- Will revise out position if it is considered necessary in the interest of consumer safety

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Is the end in sight?

- Scientifically should be a dead issue
- But
- Decisions may not be based on science alone

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The material presented is that of the presenter and should not be assumed to be FSA position or policy

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