
Alternatives to Risk-Based Decisionmaking

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**The Precautionary Principle and
Canada's Approach to Risk**

**Canadian Health Coalition
Ottawa
9 May 2005**

Challenge to Health Canada's “Smart Regulation” Proposals: Bisphenol-A (BPA)

vom Saal, Frederick, and Claude Hughes.
2005. An extensive new literature concerning
low-dose effects of bisphenol A shows the
need for a new risk assessment.
Environmental Health Perspectives (in
press).

Bisphenol-A

(cont.)

- **Monomer for polycarbonate plastic**
 - **Liner in most food and beverage cans**
 - **Baby bottles, additive in many consumer products**
 - **One of the largest-volume chemicals: 6.4 billion pounds (2003)**
 - **Estrogenic (i.e., a hormone-disrupting chemical)**
 - **Leaches when heated, or washed repeatedly; and when exposed to acidic or basic foods**
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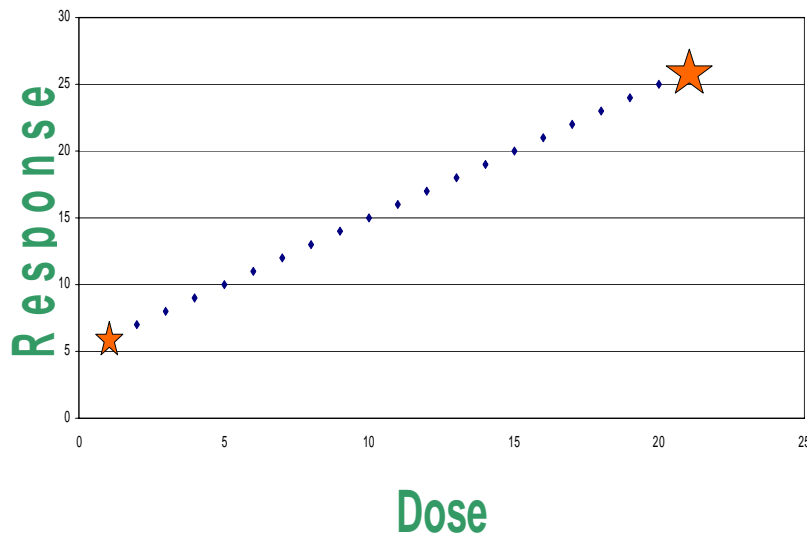
“The Dose Makes the Poison”

- In U.S (2003)
 - 95% of people have BPA in their urine (0.4 - 8 ppb)
 - Median of 1.3 parts per billion
- Most recent U.S. EPA risk assessment: 1980s
 - Lowest dose tested: 50 parts per thousand
 - Lowest observed adverse effect (LOAEL): 50 parts per thousand
 - U.S. “safe” dose: 50 parts per billion per day
- Nagel et al. 1997: BPA caused enlarged prostate in male offspring mice when females were fed 2 parts per billion

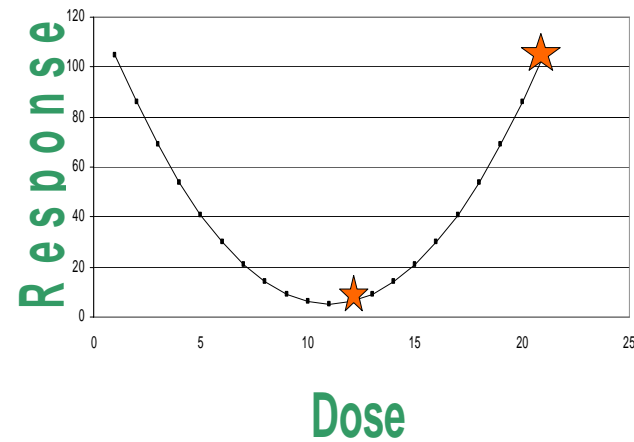
"The Dose Makes the Poison"

(cont.)

"Classic"



Bisphenol A and How Many Others?



“The Dose Makes the Poison”
(cont.)

“Low dose effects”

Effects reported for chemicals at doses lower than those used in traditional toxicological studies

“The Dose Makes the Poison”

(cont.)

By December 2004

- **115 studies using doses below LOAEL of 50 parts per thousand**
 - **94 report significant effects**
 - **34 report effects below the “safe dose” of 50 parts per billion**
-

“Safe Dose”: 50 ppb | U.S. people: 0.4-8 ppb

- **At low doses, BPA alters:**
 - **Rate of growth and sexual maturation (2.4 ppb, maternal)**
 - **Hormone levels in blood (2 ppb, maternal)**
 - **Reproductive organ function(2 ppb, maternal)**
 - **Fertility (decreased sperm) (0.2 ppb)**
 - **Stimulation mammary gland development (0.025 ppb, maternal)**
 - **Immune function (2.5 ppb)**
 - **Enzyme activity (0.2 ppb)**
 - **Brain chemistry (25 ppb)**
 - **Behavior (e.g., aggression, 2 ppb)**
 - **Many effects due to exposure during gestation and/or lactation**
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Reviews of BPA studies

- **European Union (1998)**
 - Only five low-dose BPA studies available
 - **Harvard Center for Risk Analysis (Gray, et al. 2004)**
 - The review was funded by American Plastics Council
 - Reviewed 19 of 47 studies available by April 2002; published 2.5 years later.
 - “The weight of the evidence for low-dose effects [of BPA] is very weak”
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Reviews of BPA studies (cont.)

- **vom Saal and Hughes (2005)**
 - **Reviewed all 115 low-dose studies available by Dec. 2004**
 - **94 of 115 studies report low-dose effects of BPA**

“There is now overwhelming evidence for adverse effects of one of the highest-volume chemicals in commerce below the previously-predicted ‘safe’ daily dose for humans.”

Low-dose Bisphenol A Studies by 2004: Government and Chemical Corporations

		REPORTED STUDY OUTCOME	
		Positive	Negative
SOURCE OF FUNDING	Government	94 (90.4%)	10 (9.6%)
	Chemical Corp.	0 (0%)	11 (100%)

What does the story of BPA tell us about ...

- Where the best available knowledge is?
 - The value of “science-based risk management”?
 - Whose science?
 - Whose risk assessments?
 - Whether the public interest is being protected?
 - Whether processes for regulating harmful substances are being efficient?
 - Whether the public is being told about hazards?
 - Whether “harmonizing” with trading partners is wise?
 - The need for alternative regulatory processes than those being proposed?
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Alternatives

“[A]lternatives to BPA already exist for many products.”

RISK-DRIVEN “PRECAUTION”

PROPOSED OR ONGOING ACTIVITY/MATERIAL
(e.g., food additive or pharmaceutical drug)



**SOME EVIDENCE OF POTENTIAL HARM,
WITH UNCERTAINTY**



PRECAUTIONARY PRINCIPLE

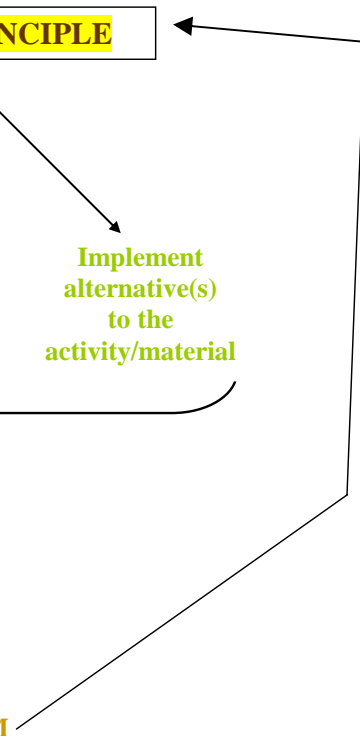
- No change**
- Ban/phaseout**
- Modify the activity/
material**
- Implement alternative(s)
to the activity/material**



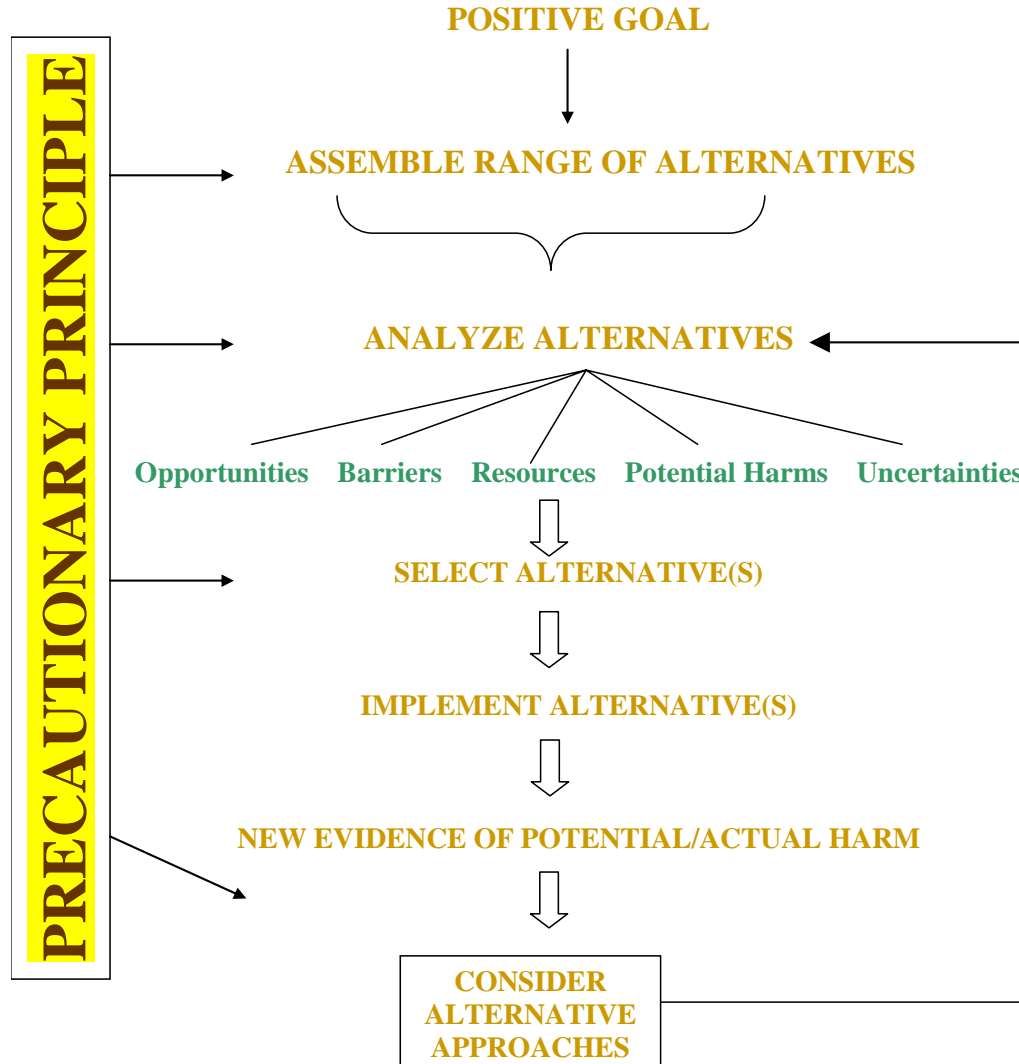
**IMPLEMENT
DECISION**



NEW EVIDENCE OF HARM



PUBLIC HEALTH-DRIVEN PRECAUTION



San Francisco

Precautionary Principle Ordinance

Adopted June 17, 2003

- **Every San Franciscan has an equal right to a healthy and safe environment. This requires that our air, water, earth, and food be of a sufficiently high standard that individuals and communities can live healthy, fulfilling, and dignified lives.**
-

S.F. Precautionary Principle Ordinance

(cont.)

- **Anticipatory Action**
 - **Right to Know**
 - **Alternatives Assessment**
 - **Full Cost Accounting**
 - **Participatory Decision Process**
-

S.F. Precautionary Principle Ordinance

(cont.)

■ Anticipatory Action

The duty to take anticipatory action to prevent harm “..rests on the shoulders of government, residents, citizen groups and businesses alike.”

S.F. Precautionary Principle Ordinance

(cont.)

■ Full Cost Accounting

There is a duty to consider all reasonably foreseeable costs, even if such costs are not reflected in the initial price.

S.F. Precautionary Principle Ordinance (cont.)

■ Right to Know

The community has a right to know complete and accurate information on potential human health and environmental impacts.

“The burden to supply this information lies with the proponent, not with the general public.”

S.F. Precautionary Principle Ordinance

(cont.)

■ Alternatives Assessment

An obligation exists to examine a full range of alternatives and select the least harmful, including the alternative of doing nothing.

“The alternatives assessment is also a public process because, locally or internationally, the public bears the ecological and health consequences of environmental decisions.”

S.F. Precautionary Principle Ordinance

(cont.)

■ Participatory Decision Process

Decisions must be transparent, participatory,
and informed by the best available
information.

S.F. Precautionary Principle Ordinance

(cont.)

- **“The Precautionary approach to decision-making will help [move] beyond finding cures for environmental ills to preventing the ills before they can do harm.”**
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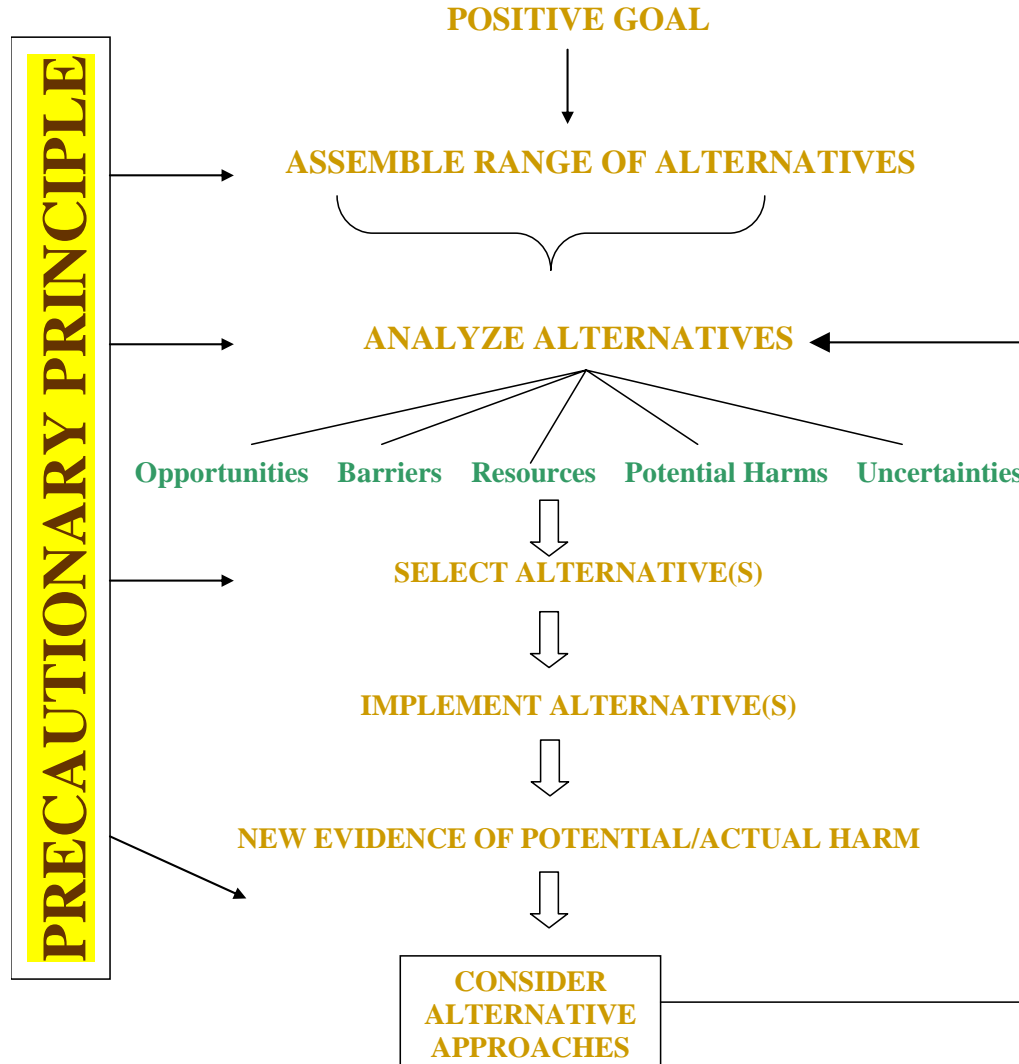
-
- **Every [Canadian] has an equal right to a healthy and safe environment. This requires that our air, water, earth, and food be of a sufficiently high standard that individuals and communities can live healthy, fulfilling, and dignified lives.**
-

What alternative approaches will result in...

- **Anticipatory Action**
- **Right to Know**
- **Alternatives Assessment**
- **Full Cost Accounting**
- **Participatory Decision Process**

....for the health of all?

PUBLIC HEALTH-DRIVEN PRECAUTION



What next steps will you take to establish...

- **Anticipatory Action**
- **Right to Know**
- **Alternatives Assessment**
- **Full Cost Accounting**
- **Participatory Decision Process**

....for the health of all?
