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*A Funny Thing Happened  
on the Way to Regulatory Rationality:  
Perchlorate After the NRC Review*

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# Perchlorate 101

## ■ Uses

- Oxidizer for solid rocket motors and munitions
- Fireworks, flares, air bags, pharmaceuticals

## ■ Other environmental sources

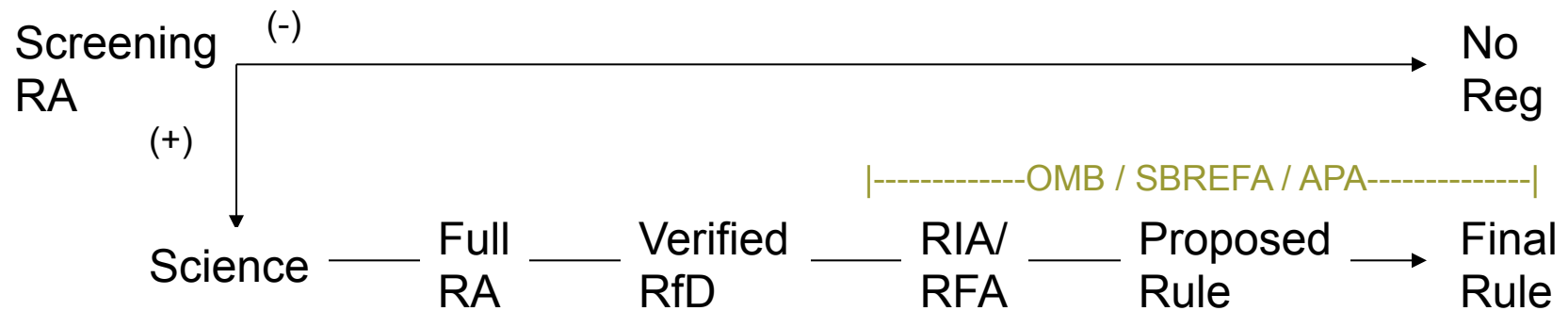
- Organic fertilizer
- Kelp, seaweed, ESTs, atmospheric processes

## ■ Paracelsus

- 1.0: ‘Dose makes the poison’
- 2.0: ‘Concentration defines the deep pocket’

# Risk Regulation:

## Textbook Procedures for Rationality



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# Issues

- Science
  - Information quality; human v. animal data; ‘human testing’
  - Definition of adverse effect
- Science policy
  - Embedded precaution combined with zero risk objective
  - Default inferences to uncertainty; hurdles to overcome
- Regulatory policy
  - De facto regulations are exempt from review and oversight
  - Competing policy goals are ignored when setting standards

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# Definition of the RfD

- An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments.

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(major policy components underlined)

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# Material ‘Science Policy’ Decisions Embedded in the RfD Derivation

- Critical effect
  - First adverse effect or [immediate] precursor
  - What’s ‘adverse’ ?
- Point of departure
  - NOAEL/LOAEL from ‘best’ study
  - What is the ‘best’ study? Who chooses?
- ‘Uncertainty’ factors (5 possible)
  - 1, 3 or 10x (composite range: 1 to 10,000)
  - Stated purpose: scientific uncertainty
  - Practical purpose: public health precaution

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# Critical ‘Science Policy’ Decisions

(applied to perchlorate)

- **Critical effect**
  - If iodide uptake inhibition is adverse, RfD is in ppb
  - If not, RfD is in ppm
- **Point of departure**
  - Use NOAEL/LOAEL from ‘best’ study
  - Use human or animal data
- **‘Uncertainty’ factors**
  - If animal data, composite UF is 100-300
  - If human data, composite UF is 10-30



# The Dispute

## EPA

- Critical effect
  - Iodide uptake inhibition
- Point of departure
  - IUI threshold as NOAEL
- ‘Uncertainty’ factors
  - 100
- RfD = 1 ppb DWEL

## Others

- Critical effect
  - Sustained and significant  
↓ T3, T4
- Point of departure
  - IUI threshold as NOEL
- ‘Uncertainty’ factors
  - $\leq 1$
- RfD  $\geq 200$  ppb DWEL

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# NRC Charge

## EPA Preference

- Adequacy of EPA's risk assessment
- Reasonableness of EPA's proposed RfD

## Others' Preference

- Validity and reliability of the science underlying EPA's risk assessment
- Stop here; the RfD is policy

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## NRC Report

- Validity and reliability of the science underlying EPA's risk assessment
- Adequacy of EPA's risk assessment
- Reasonableness of EPA's proposed RfD
- Recommended RfD

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# NRC's Recommended RfD

- Critical effect
  - 'Iodide uptake inhibition is not adverse'
  - 'RfD should be derived as if it is adverse'
- Point of departure
  - Used NOEL rather than NOAEL/LOAEL
  - NOAEL is 57x greater than NOEL
- 'Uncertainty' factors
  - 10x to ensure safety to sensitive subpopulations
  - No adjustment for using NOEL instead of NOAEL
- NRC RfD = 0.0007 mg/kg-day → 25 ppb DWEL

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# Arrogation or Abdication?

- NRC proposed a compromise perchlorate policy minimally grounded in science
  - Scientific review rejected all EPA positions
  - Intense political pressure from environmentalists
  - Knowingly (and without apology or credible defense) violated 25+ years of conventional practice
- Bush administration accepted the deal
  - EPA incorporated the NRC's RfD in IRIS

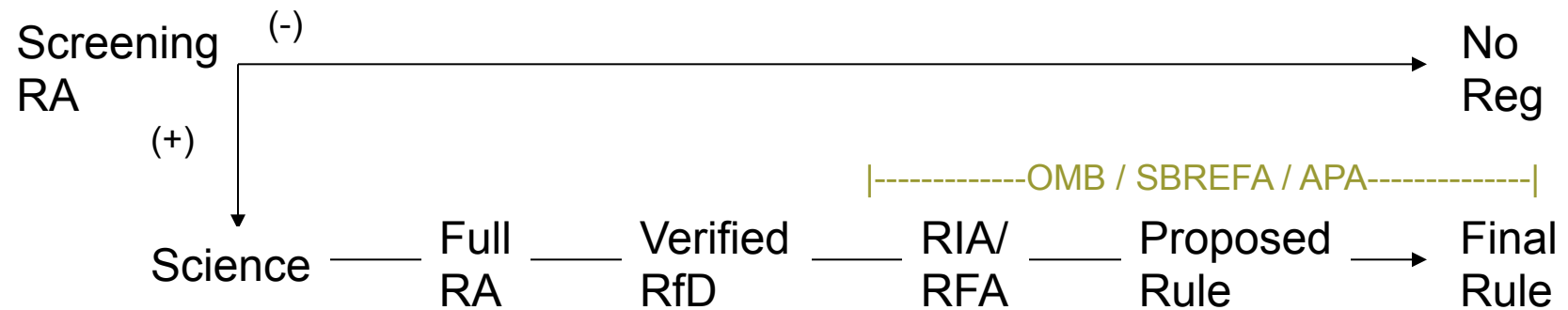
# Placing the NRC Report in Perspective

**Margins of Safety for Sensitive or Susceptible Subpopulations  
at Various Suggested Doses and/or Drinking Water Levels**  
*(Conventional USEPA Practice Highlighted in Gray)*

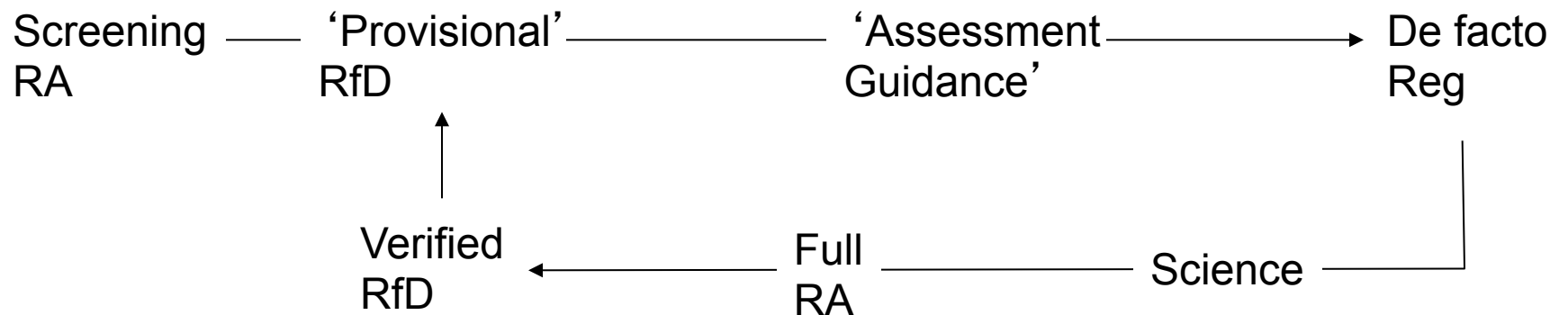
Source of Risk Value	Reference Dose (RfD) (mg/kg-d)	ppb-Equivalent (70 kg, 2 L/day)	Margin of Safety
<b>NRC 2005 science + EPA practice UB</b>	<b>0.4</b>	<b>14,000.</b>	<b>1.</b>
<b>NRC 2005 science + EPA practice LB</b>	<b>0.04</b>	<b>1,400.</b>	<b>10.</b>
NRC NOEL 2005	0.007	245.	57.
NEL in Greer et al. 2002	0.0052	182.	77.
Strawson et al. 2004	0.002	70.	200.
EPA 1998 dRfD1	0.001	32	438
<b>NRC recommended RfD 2005</b>	<b>0.0007</b>	<b>25.</b>	<b>571.</b>
California EPA 2004, 2005 (PHG)	--	6.	2,333.
EWG 2001	--	4.2	3,333.
EPA 1995 pRfD; EPA 1999 'Assessment' Guidance	0.00005 to 0.00001	4.0 to 18.	3,500 to 777.
EWG 2005	--	2.5	5,600.
EPA 2002 dRfD2	0.00003	1.0	14,000.
Massachusetts DEP 2004 RfD	0.00003	1.0	14,000.
Environment California 2005	--	0.4 to 2.5	35,000 to 5,600.
EWG 2003	--	0.1	140,000.

# Risk Regulation:

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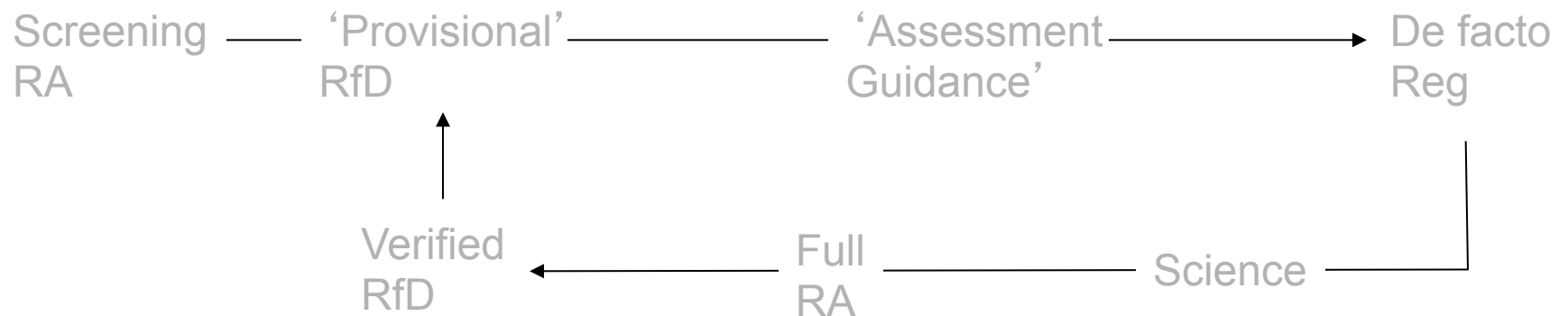
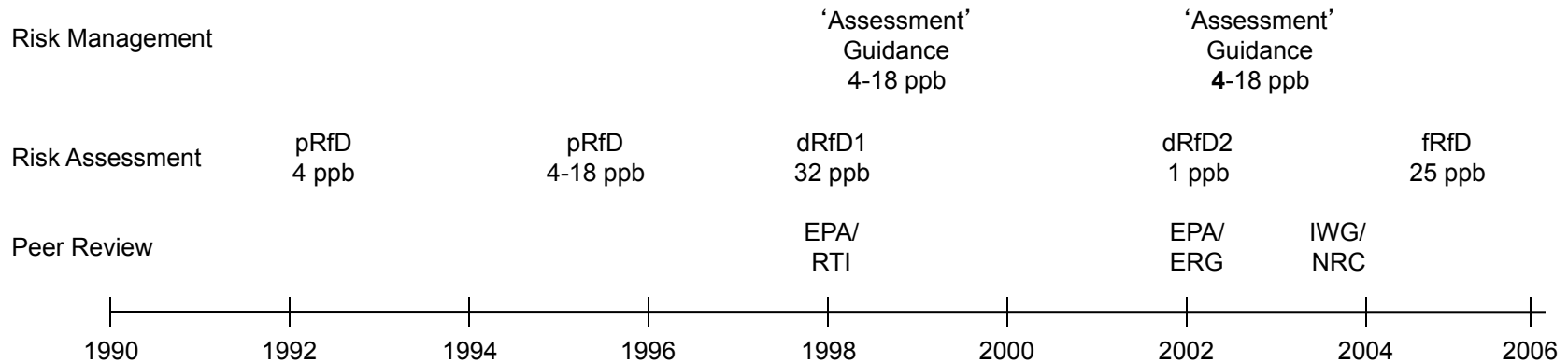


# Risk Regulation: Real World Procedures





# Risk Regulation: Early RA and Guidance Constricts Policy Choice



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# Implications and Consequences

- Scientific integrity of the RfD is seriously damaged
  - Policy and politics were determinative, science incidental
  - Stakeholders should and will contest future RfDs
- NRC may become the new arbiter of risk regulation
  - Studiously opaque procedures
  - Exempt from FACA and oversight
  - Exempt from OMB Peer Review Bulletin
- Problems left unaddressed
  - Science policy: Who decides? What criteria apply? Will decisions be subject to review and accountability?
  - Regulatory policy: Can the regulatory effects of RA be managed? Is there any interest in doing so?