



# Towards a scientifically and legally rational regulatory approach to natural health products in Europe

Robert Verkerk PhD  
[www.anh-europe.org](http://www.anh-europe.org)

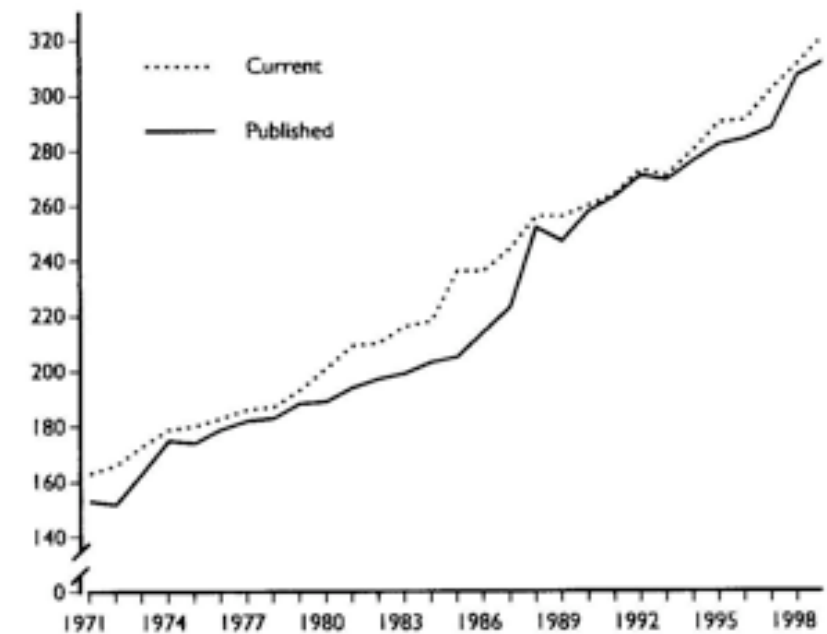
# EU legislation impacting natural health

- **Why** are we concerned?
- **What** are we concerned about?
- **How** are the laws being implemented?
- **What if** they are fully implemented?

# Why?

- We are all concerned about the same thing!
- Chronic diseases rampant — preventative health care is now a necessity
- The need to communicate credible information about the health benefits of foods, nutrients and other natural ingredients
- Concern over unwarranted infringement of freedom of speech and unjustifiable restriction of consumer access to safe products

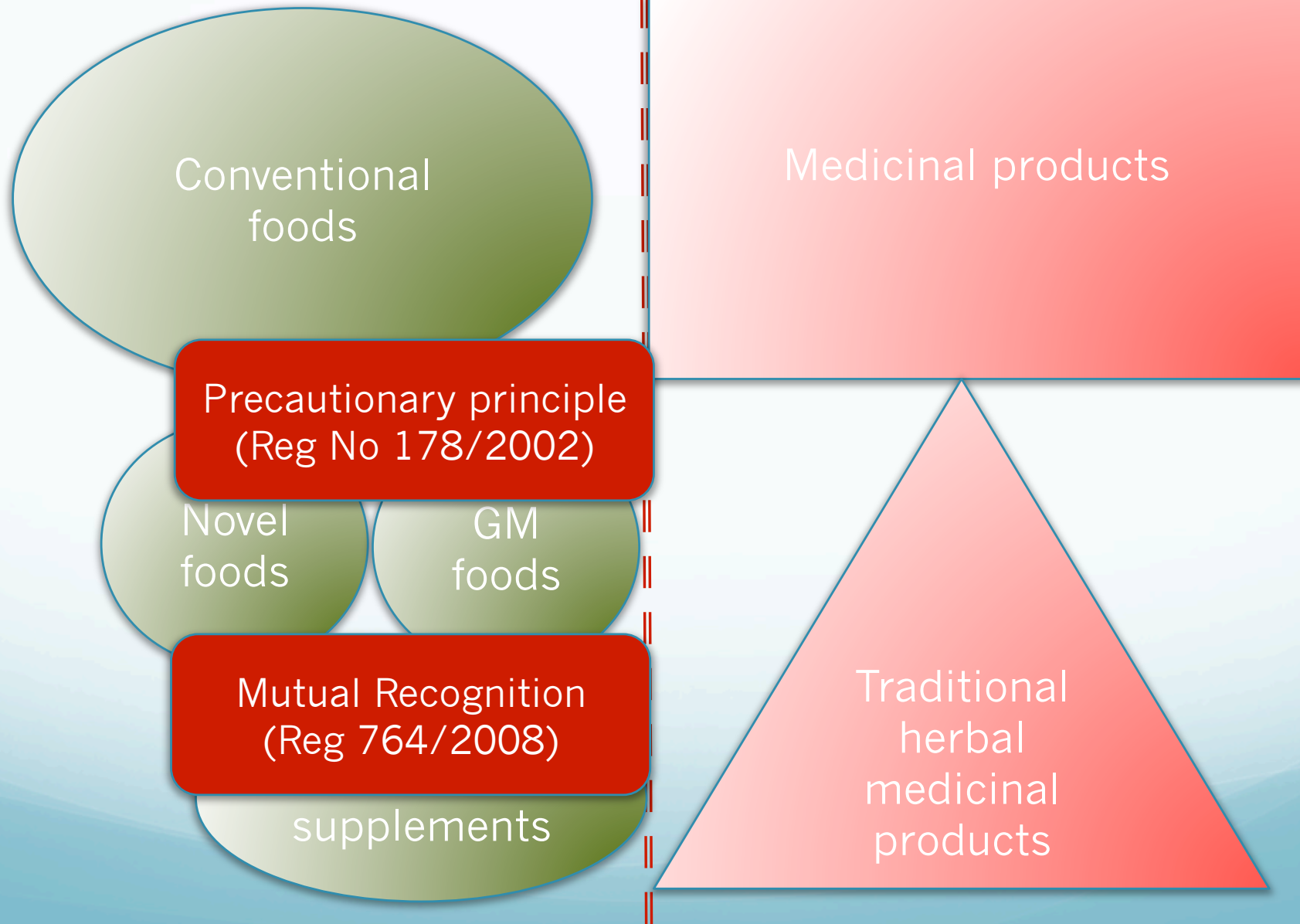
**Figure 1B** Number of registrations (thousands) published in ARVs and currently (October 2003) on the NCIC database, England



# What?

- A new regulatory framework that has yet to be fully implemented
- Problems caused by the totality of directives, regulations and guidance
- Key elements:
  - Food Supplements Directive (2002/46/EC)
  - Novel Food Regulation (258/97)
  - Nutrition & Health Claims Regulation (1924/2006)
  - Traditional Herbal Medicinal Products Directive (2004/24/EC)
  - Human Medicinal Products Directive (am. 2004/27/EC)

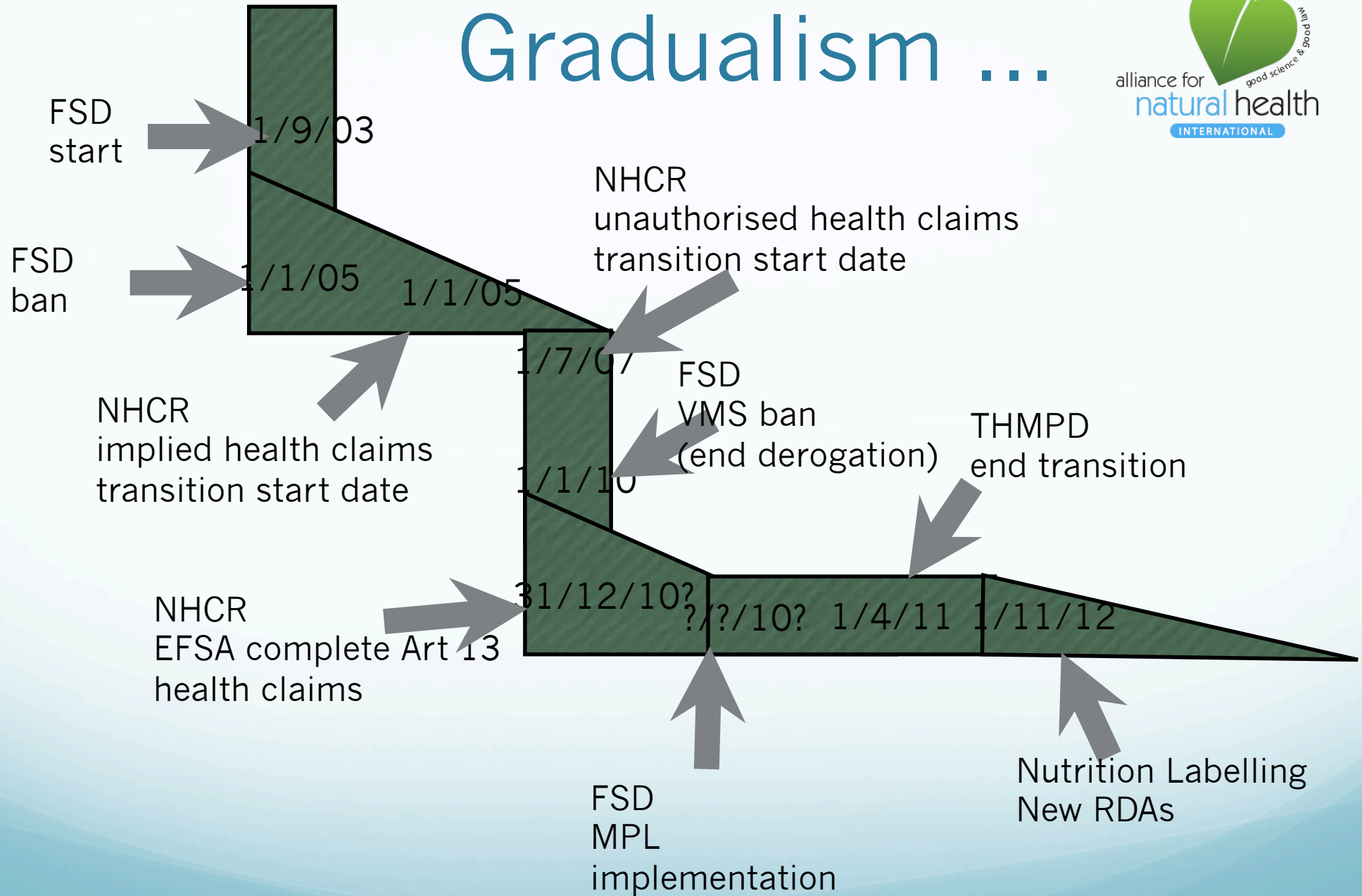
# The food/medicine borderline



# How?

- Full harmonisation, partial harmonisation, EFSA guidelines and MS subsidiarity
- Progressive implementation over time
- Lack of adequate impact assessments overseeing totality of legislation
- EP scrutiny over key issues (e.g. MPLs) insufficiently democratic

# Gradualism ...



# What if?

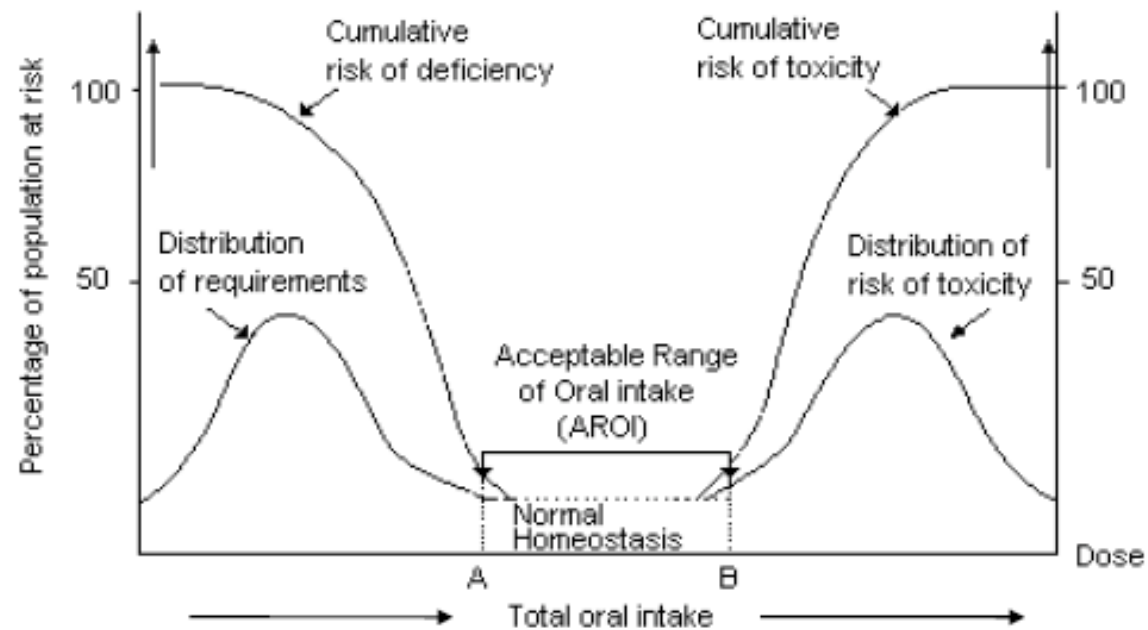
- Profound impacts on:
  - Ingredients
  - Dosages
  - Health claims
- Sectors impacted:
  - Health stores
  - Health foods in multiples
  - Practitioners / heilpraktiker
  - Traditional cultures



# Examples

- Maximum Permitted Levels (MPLS) for vitamins and minerals
- Impact on botanicals used in traditional, non-European healthcare cultures
- Health claim prohibitions

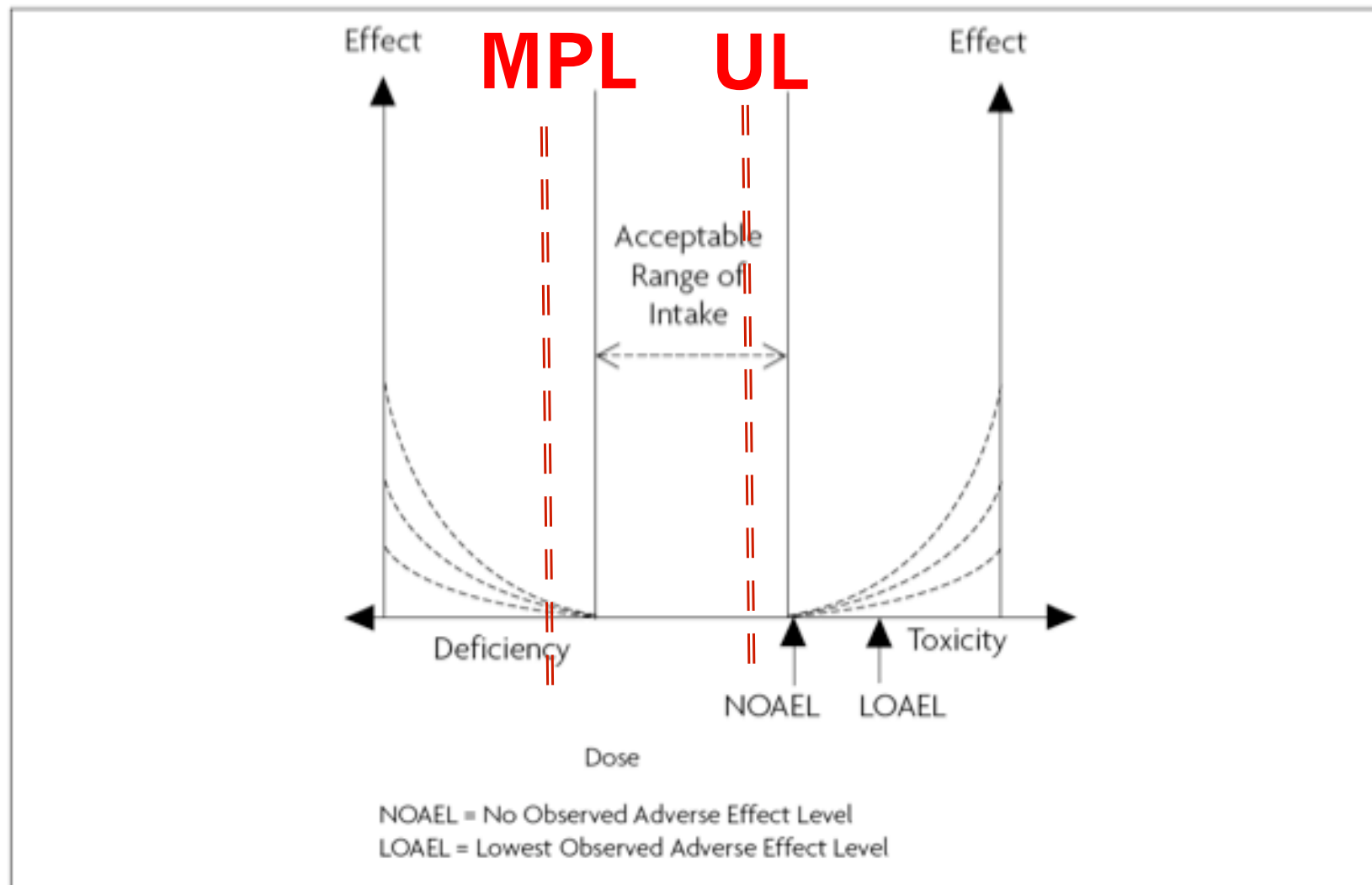
# Maximum Permitted Levels: the old model





**Figure 1:** Percentage of the population at risk of deficiency and toxic effects through oral intake of a nutrient (modified from IPCS, 2002)

# MPLs – the problem

Figure 1. Theoretical dose-response relationships in humans




# The problem — defined



Contents lists available at ScienceDirect

Journal homepage: [www.elsevier.com/locate/toxicol](http://www.elsevier.com/locate/toxicol)

## Toxicology



The paradox of overlapping micronutrient risks and benefits obligates

Robert H.J. Verkerk\*

Science Unit, Alliance for Natural Health, The Aflatoxins, Curtis Road, Dorking, Surrey RH4 1XA, United Kingdom

### ARTICLE INFO

Article history:  
Received 19 January 2010  
Received in revised form 15 February 2010  
Accepted 16 February 2010  
Available on line xxx

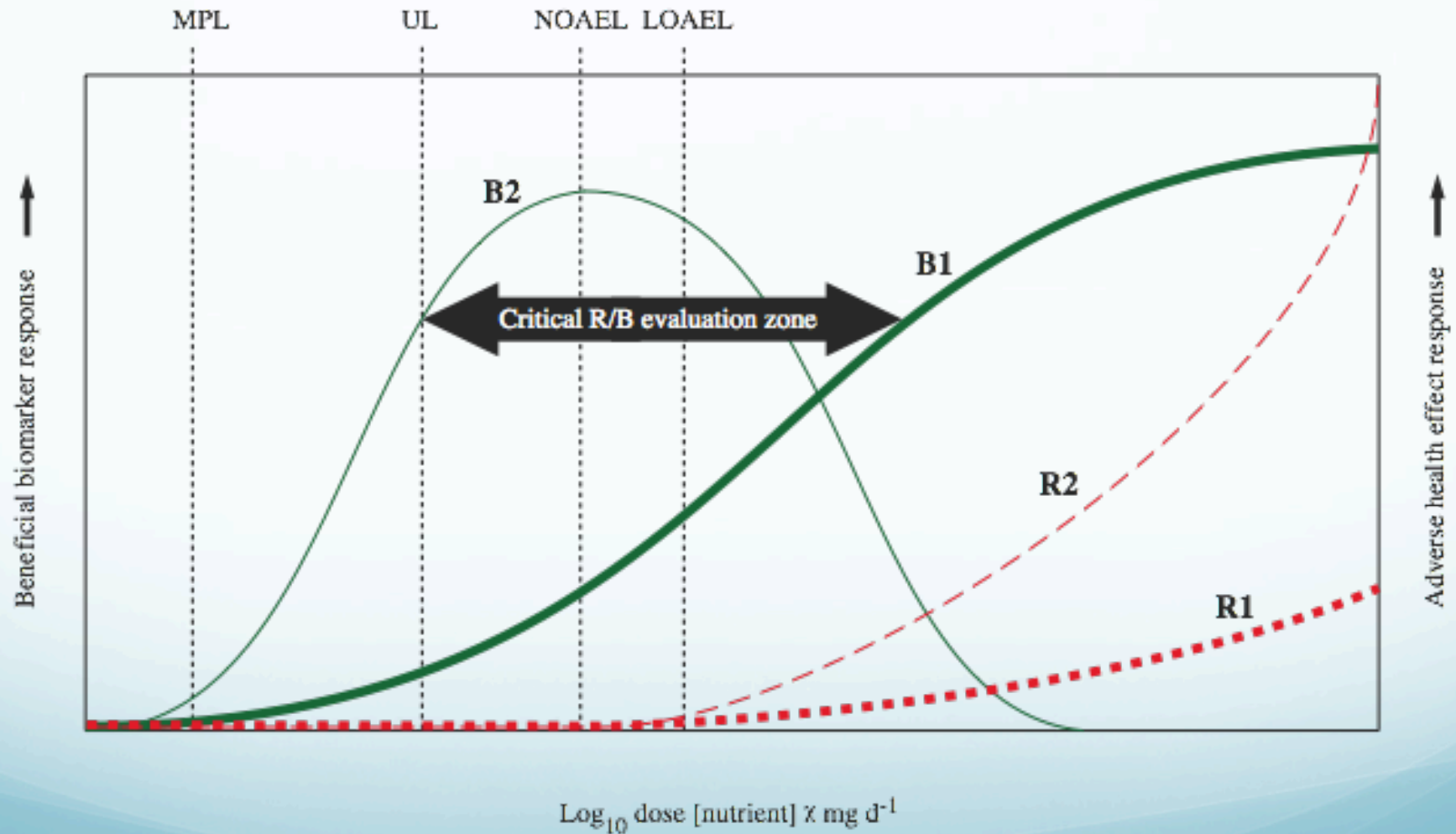
Keywords:  
Food supplement  
Risk-benefit analysis  
Overlap  
Model  
Folate  
Fluoride

### ABSTRACT

With risk analysis methods in the process of being deployed by European authorities for the purpose of limiting maximum dosages of vitamin and mineral supplements across the European Union (EU), scientific validation of recently emerging approaches using existing risk and benefit data is deemed essential. This review explores the function of existing European nutrient risk analysis methodologies applied to two vitamins, niacin and folate, and two minerals, selenium and fluoride. A major weakness of existing models is their exclusive focus on a single, **most sensitive** adverse effect on the most susceptible sub-population. Analysis of the four nutrients revealed, paradoxically, that dosages that induce risks in sensitive populations commonly overlap with those which induce benefits in the majority. This situation appears to be the norm, rather than the exception. Such overlaps are exacerbated when risk evaluations fail to consider differences between molecular forms of the same nutrient. A new conceptual risk model is proposed to replace the over-simplified two-tail risk model that has been used by regulatory authorities in Europe and the USA in recent years. This new model, which takes into account zones of overlap between upper levels would in many cases demonstrate that populations currently experiencing tolerable risks and benefits, demonstrates that a new model of risk analysis is established for dosages that induce both risks and benefits. This new model of risk analysis is established for dosages that induce both risks and benefits. This new model of risk analysis is established for dosages that induce both risks and benefits.

... stimulated by  
... and globally. Vari-  
... y-wide, mandatory  
... and Regulation (EC)  
... provides a scientific cri-  
... with the risk assessment  
... management approaches  
... tied to food supplements.

# Risks and benefits overlap



Source: Verkerk RH (2010) Toxicology [in press]

# Herbal products from TCM and Ayurveda

- None yet registered under THMPD
- Technical and eligibility problems
- Many products likely to ‘fall between two stools’
- Vast majority of products have no safety concerns
- Discriminatory

# Red lights for health claims

- Need to prove causal relationships
- Lack of pre-existing evidence
- Difficulty and cost of demonstrating evidence
- Excessive bias towards clinical trials, rather than observational and plausible evidence
- Particular complications for complex products
- Art 14 prefers big business over small businesses

# Green light for GM

- EFSA approval of GM maize varieties
- EC registration of GM crops
- European Commission vs environment minister concerns
- Abandonment of the precautionary principle



# What to do?

- Dialogue
- Proper and transparent scientific discourse
- Relevant and thorough impact assessments
- Inclusion of small business concerns
- Proper democratic process in law-making
- Awareness of ‘big picture’ with respect to healthcare

# www.anh-europe.org

The screenshot shows the homepage of the Alliance for Natural Health Europe. At the top left is the logo with a green leaf and the text "alliance for natural health EUROPE" and "good science & good life". To the right is a banner with a butterfly and the quote: "I WILL CONTINUE TAKING RESPONSIBILITY FOR MY OWN HEALTH". Below the banner is a navigation bar with a search box, "About us", "Contact us", "LOGIN AREA" (with a note "Not yet registered"), and a "Login" button. The date "Saturday 27th March 2010" is displayed on the right.

**Welcome to the Alliance for Natural Health**

Human health is suffering worldwide. The primary cause? Disconnection from nature and all things natural. The ANH is working to reconnect us. Play your part in the international campaign to regain and maintain our health naturally. Find out more...  
Also see our [Mission Statement](#) and the [Message from the Executive Director](#).

**News & Features**

- ANH Press Release: New ANH study says EU vitamin laws must change track**  
Urgent scientific call for risk/benefit analysis  
Updated: 25 Mar 2010
- ANH Press Release: ANH set to challenge EU herb law**  
Alliance for Natural Health International announces its intention to initiate a legal challenge to the European directive on traditional herbal medicines  
Updated: 22 Mar 2010
- FAO and ANH go head to head on Codex**  
ANH's Robert Verkerk and FAO's Dr Ezzeddine Boutrif debate on Codex Alimentarius at Lancaster University  
Updated: 17 Mar 2010
- ANH taking action today with EU strategy on cancer**  
How much can the democratic process in Europe yield over the

**International Health News**

- Opening statements made in lawsuit against Bayer over experimental rice in commercial market
- How the Health Care Reform Bill affects industry
- Antioxidants show benefits for over-50 sporty-types
- Italy ponders mandatory supplement warning labels – and health claims?
- Cure for cancer in homoeopathy? Oncologists differ
- Seaweed could cut obesity levels
- EU herbal directive faces legal challenge

**More International Health News >**

**twitter**

- anhcampaign: Latest ANH eBlast - ANH moves into top gear <http://url4t.com/04n>
- anhcampaign: ANH eBlast: ANH moves into top gear - <http://eepurl.com/1Jv5>
- anhcampaign: Robert Verkerk due to talk at the Natural and Organic Products show in April 2010 [http://url4t.com/3J\\_](http://url4t.com/3J_)
- anhcampaign: Italy ponders mandatory

**OurFuture**  
Your donations are critical for our future  
[Register & Donate](#) [Quick Donate](#)  
Thanks for your support

**Google Translate**  
Select Language   
Gadgets powered by Google

**Our Campaigns**  
Protecting and promoting natural health worldwide  
  
**Health Choice**  
Stop proposed global restrictions on natural health!

**e-Blast**  
Subscribe to all the latest news from our campaigns  
[Subscribe](#)  
[View archive](#)

**YourViews**  
Vote on some of the latest issues affecting our health  
Do you want to receive the 'swine flu' vaccine?  
 Definitely not - in any event

**Navigation Menu:**  
Home  
Our Campaigns  
News  
Events  
Video/Images/Audio  
Get Involved  
Document Archive  
Practitioners  
Companies  
Support Base  
Forums  
Press Centre

Thank you.