

**The long and winding road to  
breakthrough health food innovations  
An industry perspective**



***New Governance for Innovation  
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# Agenda

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- Introduction: the future of health foods
- Innovations in health foods: the **pro.activ** case
- Learnings from introduction of **GMO-foods** in Europe
- Changing requirements for successful innovation
- Conclusions

# Introduction

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- Trends in health foods (main drivers)
  - Beginning of information age
  - Globalisation
  - Ageing of society
  - Rise of sophisticated consumers
  - Science and technology -particularly molecular biology and IT
  - Ethical issues to the fore
  - Changing boundaries between health and health care
- Nutrigenomics: leading to breakthrough innovations ?

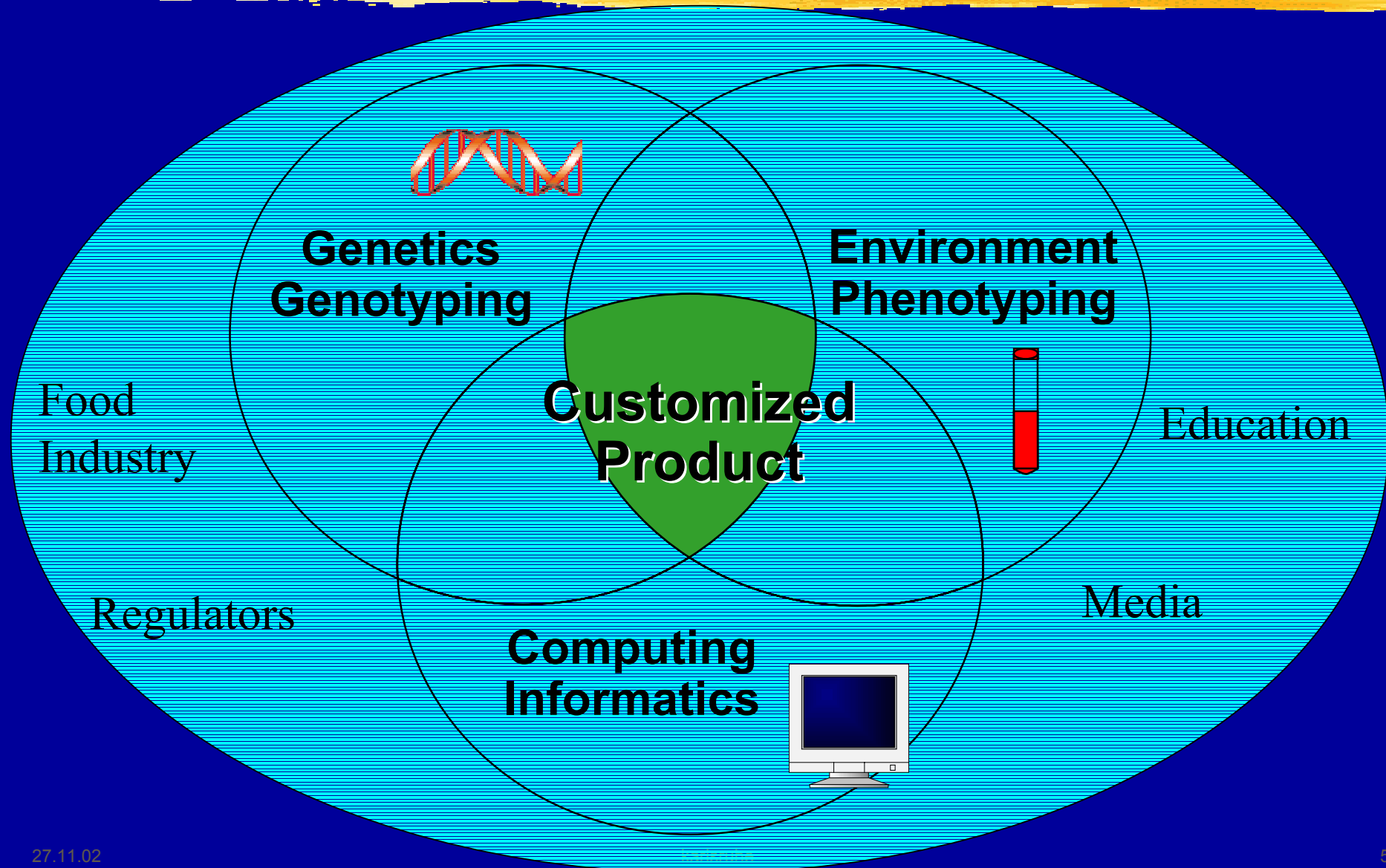
# Introduction

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- Trends in health foods (main drivers)
- **Nutrigenomics: leading to breakthrough innovations ?**
  - Study of the relationship between what we eat and how our genes function
  - Issues that we may face
    - scientific: will we find real benefits for consumer ?
    - economic: can we communicate the benefits and ask a premium ?
    - social: how to manage impact on health care ?
    - ethical: what is our position on the ownership and use of individuals genetic make up ?

# Nutrigenomics

## What is it ?

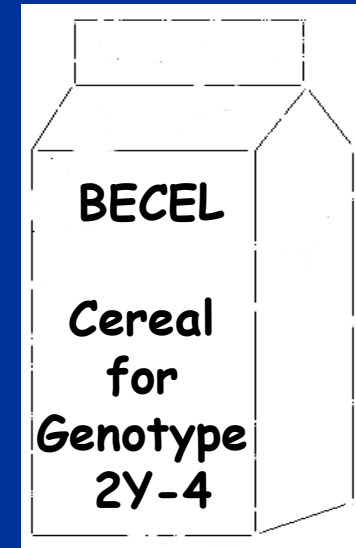
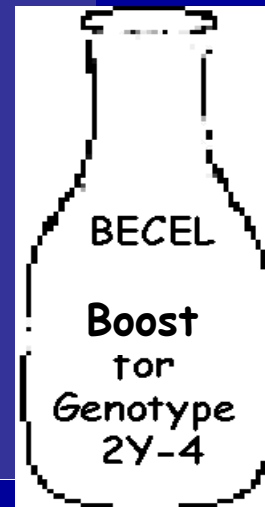
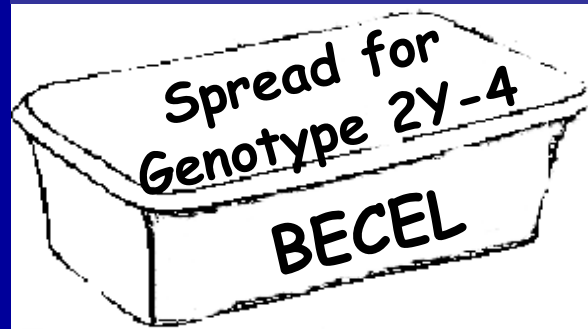


# Example of nutrigenomic innovation

Consumer has his/her genetic profile analysed and gets advice on foods and activities (SCIONA)



Consumer shops for customised food product



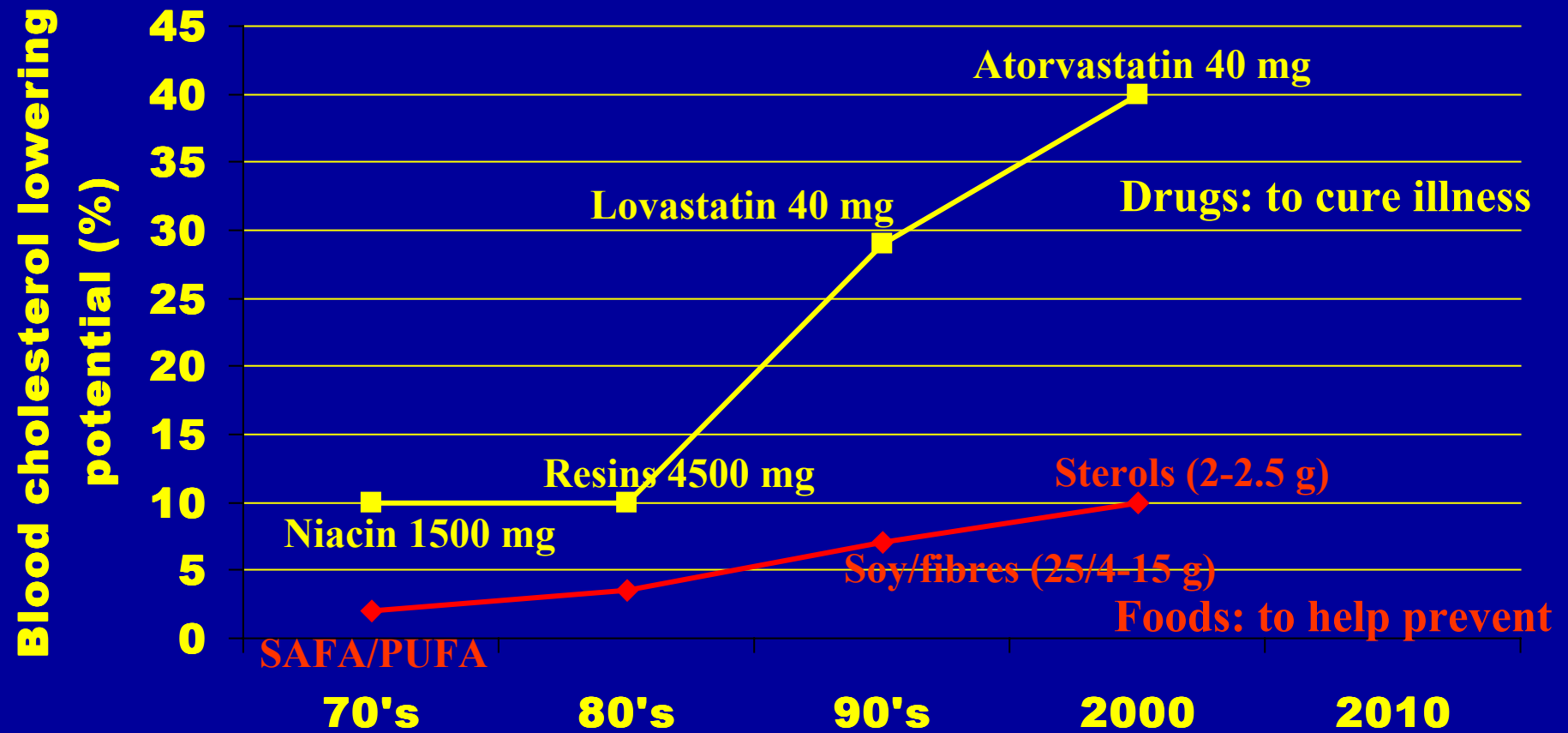
# Introduction

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- Trends in health foods (main drivers)
- Nutrigenomics: leading to breakthrough innovations ?
  - Issues that we may face
    - scientific: will we find real benefits for consumer ?
    - economic: can we communicate the benefits and ask a premium ?
    - social: can we manage the consequences for our health care systems ?
    - ethical: can we develop a broadly accepted position on the ownership and use of individuals genetic make up ?

# The **pro.activ** case

## Strive for higher efficacy





# The **pro.activ** case

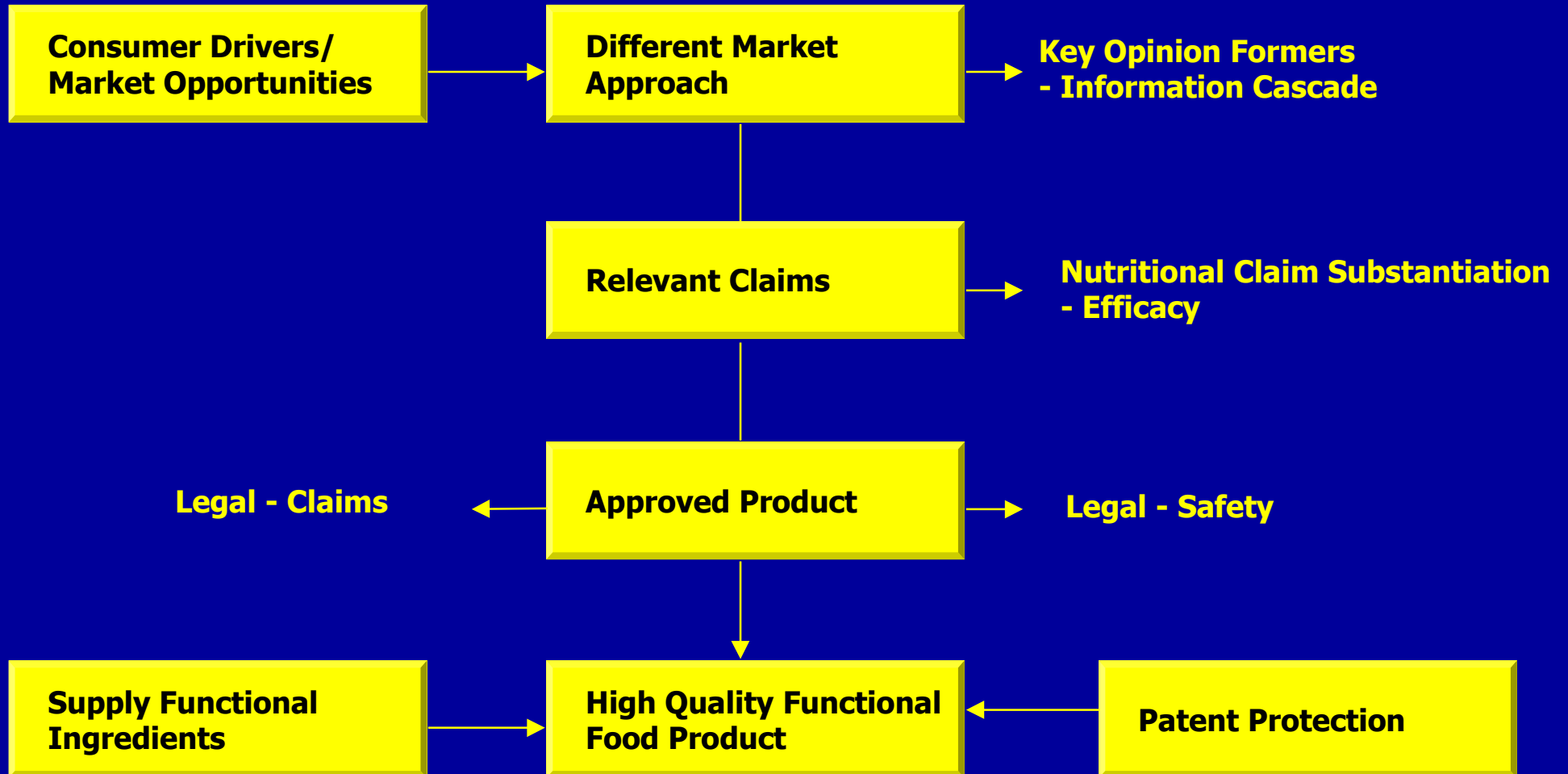
## What is it ?

- pro.activ - a new variant to Unilever's Heart Health spreads (Becel & Flora)
  - No other spread is as effective in lowering blood cholesterol
- Addition of natural plant sterols (8-10%)
  - Novel ingredient in Europe
- 10% lowering of blood Cholesterol levels
  - 20g spread/day (=1.6g plant sterols)



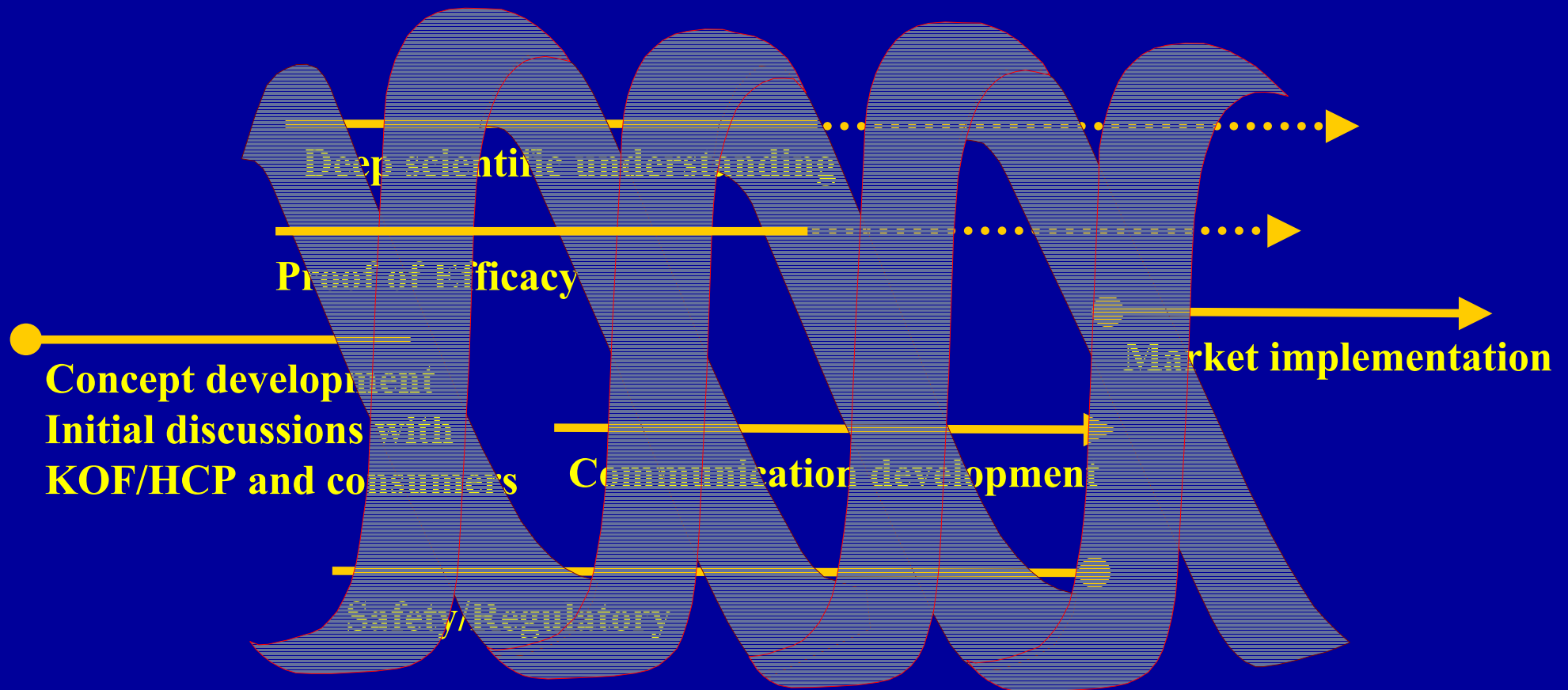
# The **pro.activ** case

## A new product with a strong claim



# The **pro.activ** case

## Innovation process for **pro.activ**



**A highly parallel and interconnected innovation process**

**Total process ~ 6 y.**

# The **pro.activ** case

## Establishing safety

Internal safety clearance  
based on extensive safety testing  
according to OECD guidelines  
(7 publications)

Regulatory approval via extensive  
dossiers and consultation:

- FDA - GRAS
- Novel Foods -EU
- ANZFA
- Brazil, Czech Republic,  
Switzerland, South Africa, Japan



# The **pro.activ** case

## Regulatory approval



- EU: Novel Foods Regulation
  - 90 day assessment in country of submission
  - 60 day reaction other member states
  - objections and questions: dossier handed over to SCF for evaluation
  - decision by Standing Committee on July 24th, 2000



- USA: GRAS affirmation and 90 day FDA Notification



# The **pro.activ** case

## Issues with regulatory process

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- Not a shared view in EU states on functional foods
- Mechanism to handle process not transparent nor predictable
- Open dialog with regulators sometimes very hard
  - > SANCO discussion paper on improvements
  - > Incentive of industry to invest via (limited) exclusivity

# The **pro.activ** case

## Issues with claim approval process

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- Still a local process: no EU mandate  
(total ban, pre-market approval, voluntary schemes)
- Communication via pack, print, TV and other means often regulated and monitored by different authorities
- No clarity on criteria for scientific substantiation  
(PASSCLAIM?)

# The Round-Up Ready Soy case

- April 1996: EU-Commission approves introduction of GE soy in EU
- Oct. 1996: big food companies in Germany announce to abstain from GE soy
- Sept. 1998: Labelling regulations of GE foods into force in EU
- Feb. 1999: major supermarket chains in France, UK go GMO-free
- June 1999: EU announces factual ban on new GE product approvals
- August 1999: Deutsche Bank declares GE market for dead
- End 1999: all major food companies announced to be GMO-free.





# The Round-Up Ready Soy case

## Learnings from introduction in Europe

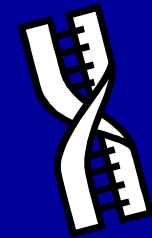
- End-benefit for consumer not clear
- Conflicting messages on the safety and environmental impact
- No firm position of authorities (based on emotions, not facts)
- Media created hype: "Frankenstein foods"
  - > Became part of political agenda



# Nutrigenomics issues

## Ethical and regulatory challenges on the horizon

- Storage of DNA samples
- Data storage and privacy
- Genetic discrimination (“genetic underclass”)
  - Employment and Insurance
- Validity of scientific basis of products and services
- Diversion of investment from developing nations and urgent health needs
- No regulations by
  - Food Standards Agency, Medical Devices Agency, Medical Control Agency (UK)
- Uncertainty in position with Human Genetics Commission
  - Quasi regulator
  - Leading the way in public consultation and policy formation

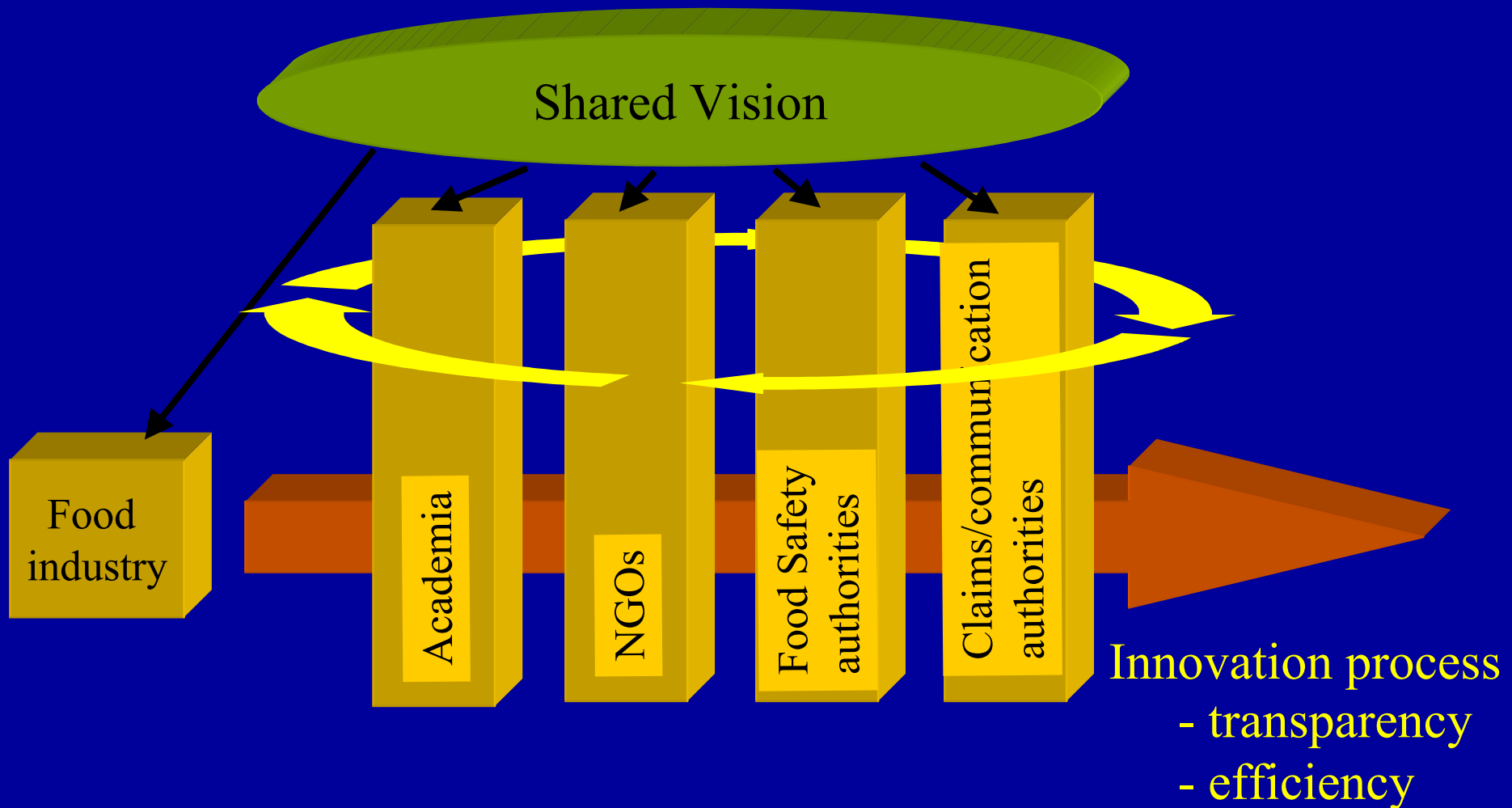


# The path to nutrigenomic innovations

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- Cautious and responsible approach by industry and academia involving consumers and authorities at an early stage
  - Real consumer benefits backed up by good science
  - Honest and open communication
  - Clear and uniform position of all authorities involved
- > political will to successful exploitation of new technology

# Requirements for faster innovation



# Requirements for faster innovation

## Conclusions

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An environment enabling breakthrough health food innovations to the benefit of consumers requires:

- early and constructive dialog with all key stakeholders
- clear and transparent legislation on safety and communication of benefits on regional/global level
- clear political agenda and will to execute at all levels