# GM risk assessment:
# experiences and views from the biotech industry

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# Back to basics

- There is a lot of **experience** with the environmental, economic and technical performance of GM crops
- Is it informing either policy or product approval?

# How did we get there?

Is this a new situation?

- 1983 - 1991: GNE on biosafety in biotechnology
  - The blue book
  - Follow up with detailed technical guidelines for risk assessment
- Still the technical basis for most biosafety governance WW!

# learnings

- In risk assessment, the distinction between **risk assessment** and **risk research** has disappeared
- The RA process does not have a place for **experience** of safe use
- The EU process does not learn from its own EC funded risk research programs

# RA vs. RR

- Risk **research** produces **knowledge** which is never complete
  - Conclusion of every paper: “we need more research”
  - It is usually not comparative
  - Biodiversity being essentially infinite, there is infinite research to be done

- Risk **assessment** produces **management decisions**, based on the best available information, which is never complete
  - It can only be **comparative**: needs to be measured against alternative agricultural decisions
  - It needs to extrapolate from thorough, but necessarily limited **experiments**
  - The most effective source of risk assessment is **experience**

# The quest for zero risk

- RA in the EU is not comparative nor proportionate
- It is by definition impossible to prove zero risk, yet after the first stage of risk assessment, we behave as if we should
- The zero risk debate is fuelled by a lot of misuse of science
  - Over- extrapolation from special cases
  - Misinterpretation of scientific information
  - Confusion between risk and hazard

# Experiments and experience

- Safety management has 2 major sources of information:
  - Experiments
  - Experience
- Some history: OECD GNE (1983-1992): how to regulate pro-actively in the absence of history of use?
- Today, the experience with safe use of GM crops worldwide is not taken into account in EU risk assessment
  - There is no place for this information in the RA process
  - There is no interest in the post-release monitoring already done

# EU funded biosafety research

A history of public investment in biosafety research

- 1997: EC conference on safety of GM crops
- 2001: EC publication of the orange book


  - >400 projects in biosafety research
  - >70 M€ invested
  - What have we learned? What have we used in risk management?

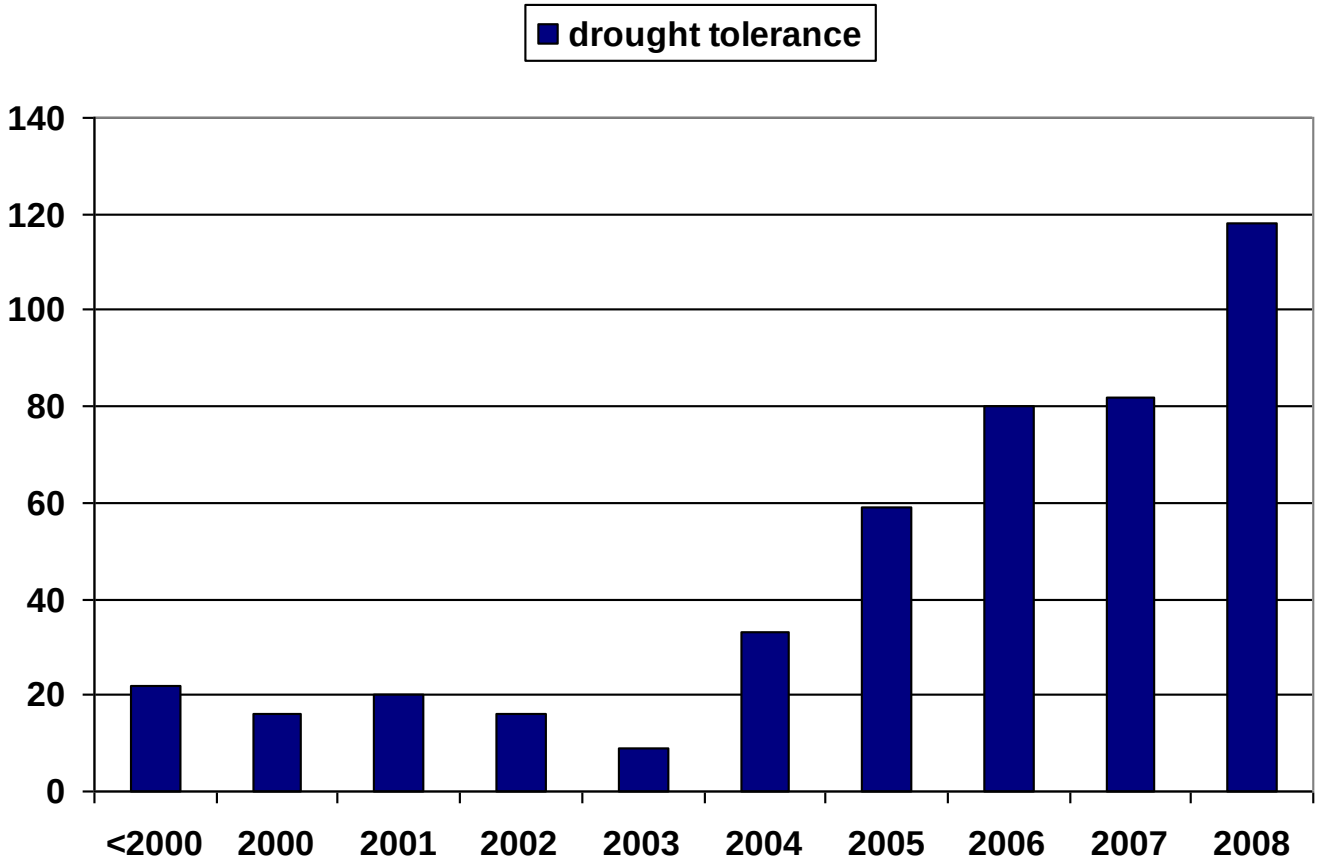
- 2010: Publication of the next “orange book”?

# A history of risk research destruction

- Even experiments are not safe from controversy and sabotage
  - Our experiment targets, and those of activists…
  - Special focus on risk research (SCIMAC trials) and risk assessment trials

- Result:
  - Little really innovative field research on GM crops in the EU
  - Companies focus on registration related trials
  - Public research has severely reduced field work

# AN EXAMPLE




Source: http://www.isb.vt.edu/cfdocs/fieldtests1.cfm

# Risk management & junk science

- Science is based on rigorous quality control
- Most “safety issues” on GMOs have been based on publications of research that were:
  - Preliminary,
  - Special cases,
  - Often with a weak experimental set-up
  - Sometimes fraudulent
- The **communication** of the results of these “safety issues” was highly professional though!
- The rebuttals usually came too late to enter the decision cycle

# Where do we go from here?

- How do we protect risk research and risk assessment trials?
- How do we address the issue of risk communication?
- How do we safeguard quality control in the risk assessment and risk management process?