



# Registrants Considerations in Proposing Global Joint Review/Work Share

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# Presentation Overview

- Background – current Environment
- Attraction of Work Share
- Implications for Registrant
  - New products development
  - Minor Crops



# Crop Protection Business Environment

- Consolidation in the industry
- Highly competitive business environment
- High competition for resources within companies
- Increasing costs for product development and defense
- Relatively long timelines

Project Management and Financial Analysis are used to define and manage business decision making



# Key Considerations for New Projects

- Strategic business fit
- Market dynamics  
Size, growth rate, profitability, degree of competition
- Timelines (time value of money and market risk)
- Costs (regulatory and others)
- Availability of resources
- Uncertainties/risks
- Project value (net present value)

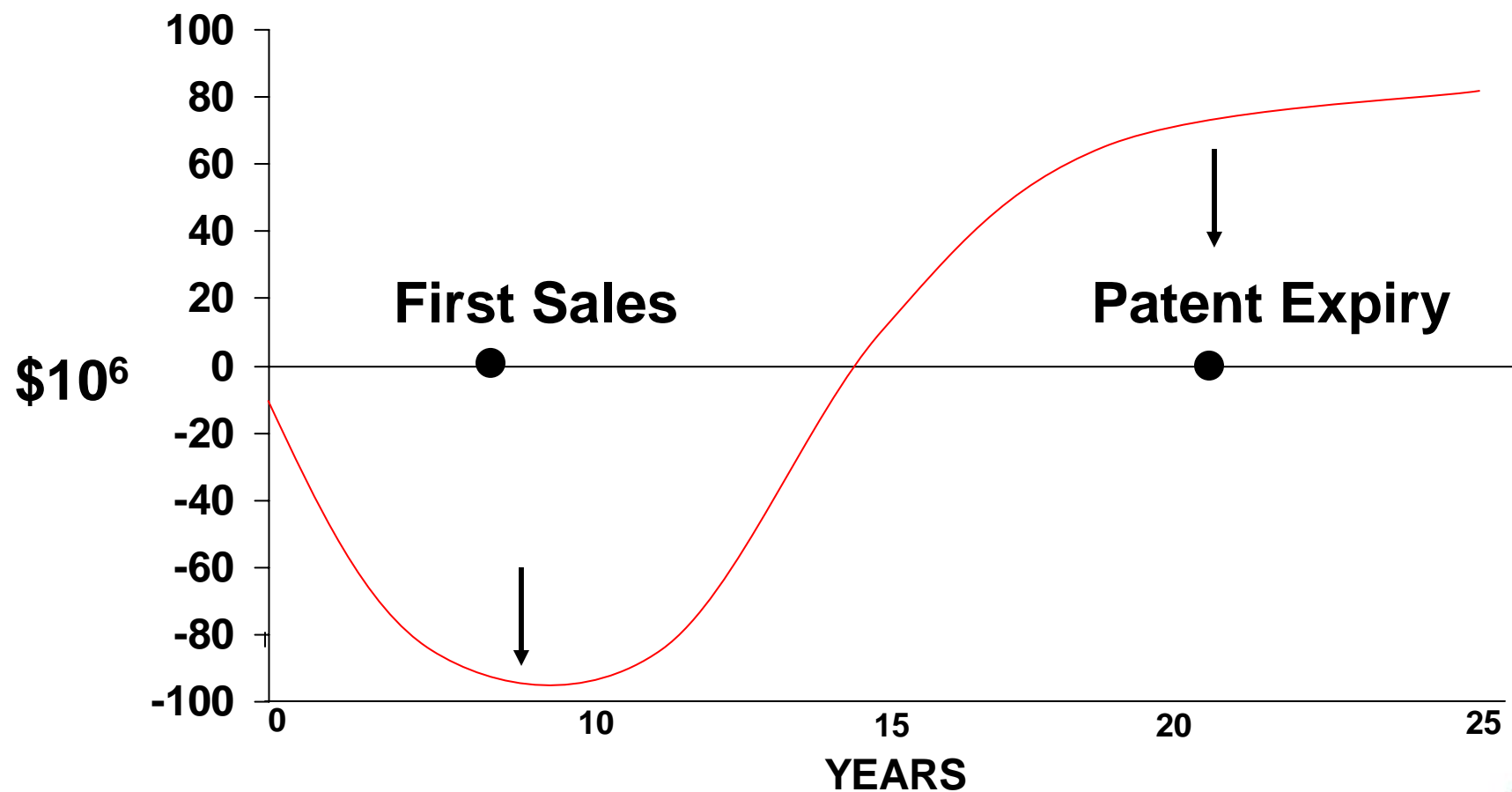


# Potential Benefits of Joint Review/Work Share

- Shorter timelines – better return on investment
- Reduced uncertainty for business planning – reduced project risk
- Broader labels – including minor crops
- Availability of new crop protection technologies to growers expedited
- Overall reduction of business risk

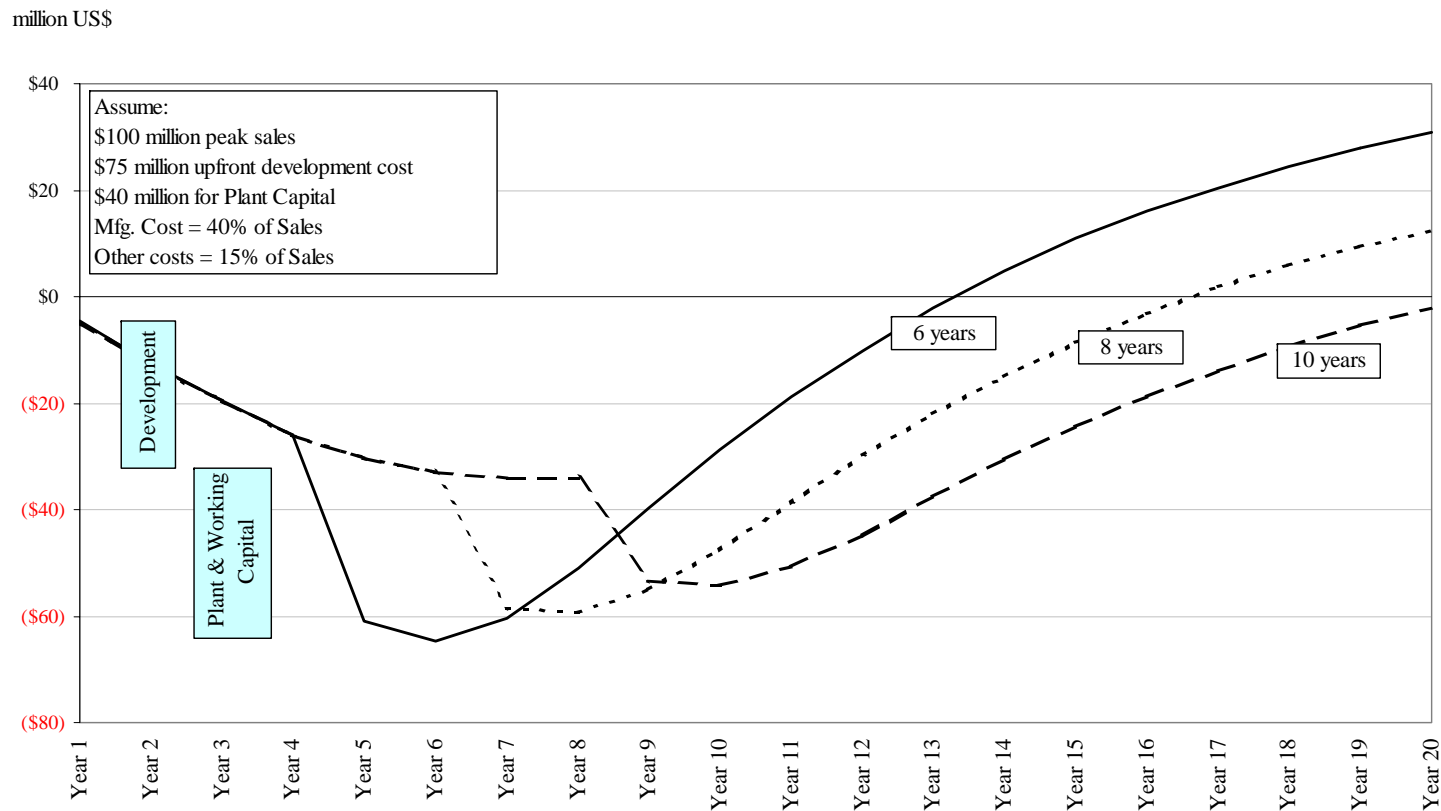


# Typical Cumulative Discounted Cash Flow for a Successful New Product



# Importance of Shorter Review Cycle

CUMULATIVE DISCOUNTED CASH FLOW vs. TIME TO REGISTRATION



# Predictability of Regulatory Approval Process

- Joint Review requires strict timetable
  - ✓ Better launch planning
  - ✓ Reduced inventory cost
- Well defined rules and procedures for conduct of project stages
- Clearly defined expectations of participants and milestones
- Regular meetings to keep the project on track



# Maximised Label and Market Access

- Positive influence on overall financials
- Leveraging of one dossier globally
- Opportunity for harmonisation of MRLs
- Minimise non-tariff trade barriers



# Implications for New Product Development (1)

- Upfront planning and coordination of registration and development, globally (incl. minor crops)
- Careful planning of efficacy and residue trials
- Early definition of GAP
- Resource requirement for early preparation of complete dossier
- Realistic possibility for expedited review and approval (specifically for minor uses?)



## Implications for New Product Development (2)

- Changes in company internal preparations in key markets for product positioning
- Accelerated market development in some key countries
- Potential for accelerated entry of new products into developing countries
- Front loading synthesis and process development work
- Need for adequate product supply for field development and early launch activities



# Implications concerning Minor Uses/Crops (1)

- Require even more coordinated planning (efficacy; residues)
- Crop grouping differences: need comprehensive structure for grouping (MRLs)
- Where and how can Minor Crops be fitted into Joint Review/Work Share?
- Specialty crops may not be *prima facie* minor crops



## Implications concerning Minor Uses/ Crops (2)

- Will Joint Review/Work Share be able to cope with multitude of minor crops?
- Need for application of principle of extrapolation
- Balance of improved marketing platforms vs cost of development?
- Incentives for industry?
  - ✓ Extension of period of Protection of Regulatory Data
  - ✓ Expedited Review?



# Summary/Conclusions (1)

- Regulators and registrants look to achieve same end
  - ✓ Better quality review
  - ✓ Shorter review times
- Regulatory systems must be consistent in their data interpretation and predictable
- Reduced uncertainty leads to more product development opportunities (incl. Minor Crops)



## Summary/Conclusions (2)

- Increased business risk from extending use recommendation/labels needs to be rewarded with greater returns
- Improved product life-cycle profile required
- Joint Review/Work Share is the way forward, but
  - ✓ Needs to show delivery of its potential and promises with “major” uses/crops
  - ✓ Needs to find solution to integrate minor uses/crops





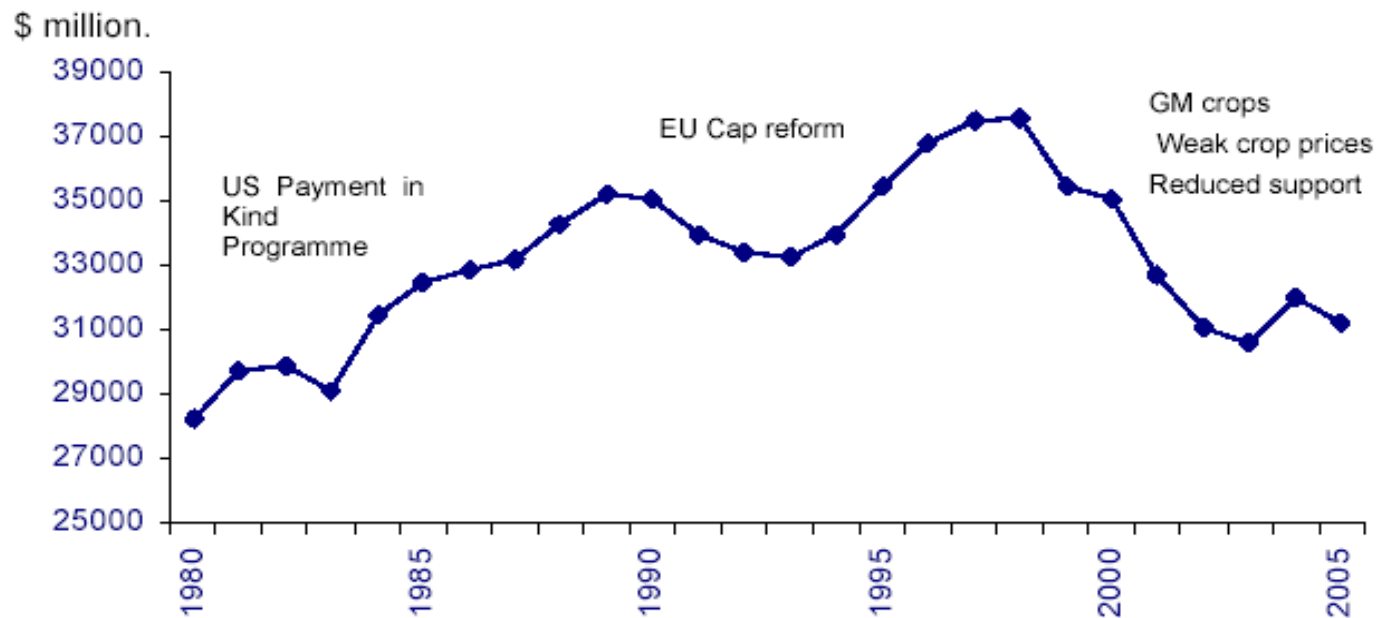
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Thank you very much for your attention



# Recent Trends in the Value of the Crop Protection Market

Conventional Crop Protection Market Value - Constant 2005 Dollars



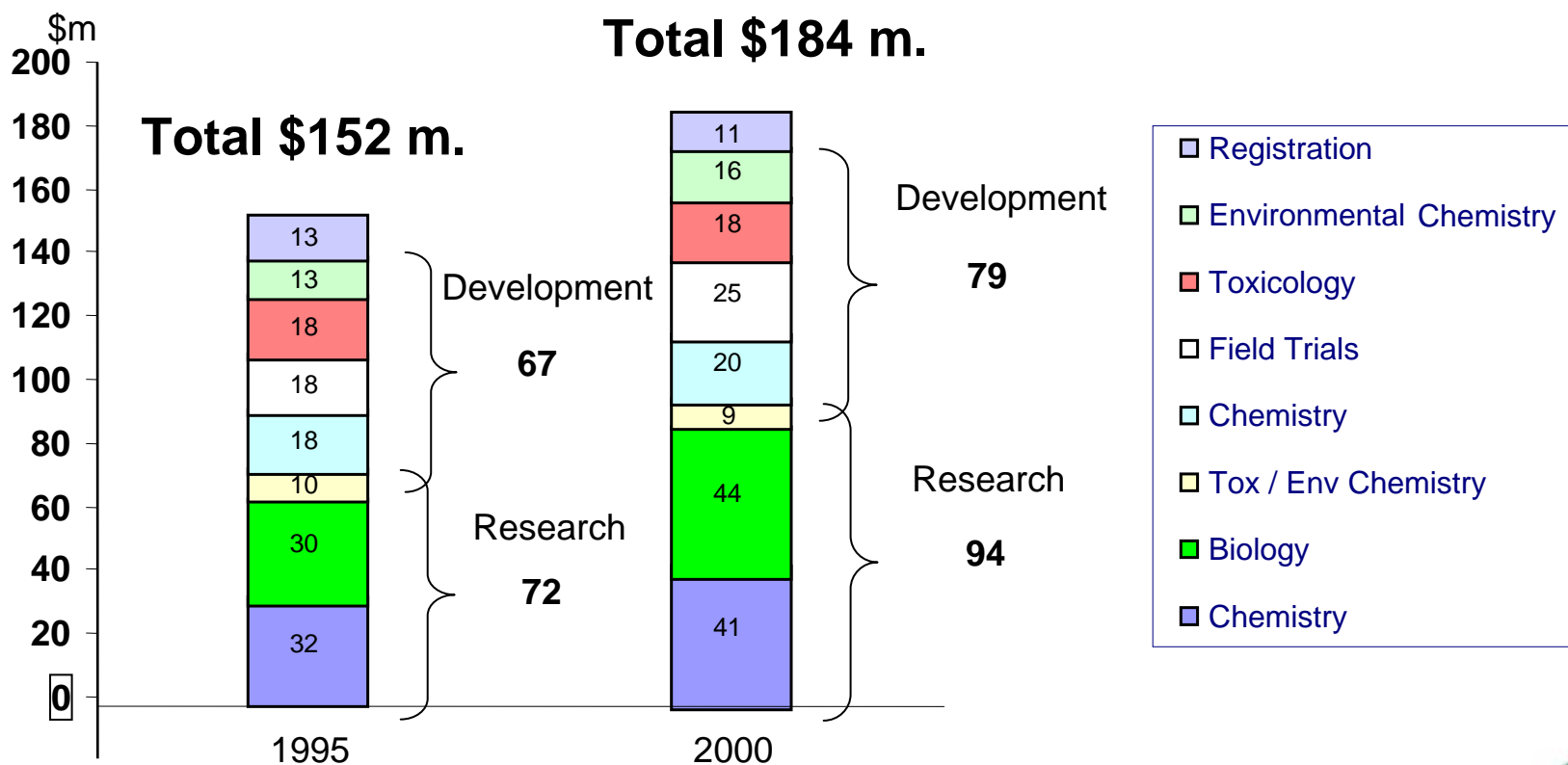
Source : Phillips McDougall study for ECPA and Crop Life America

Global Minor Use Summit, Rome, December 3-7, 2007



# The Challenge for Agrochemical Research

## Cost of New Product R&D In a Regulated Industry



Source : Phillips McDougall study for ECPA and Crop Life America  
Global Minor Use Summit, Rome, December 3-7, 2007

