

A view from the industry

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A Question

- What do you all wish to achieve with regulation?

My guesses?

- You want a balanced system which encourages use of biological control whilst reassuring consumers and minimising environmental impact
- You want "sustainable agriculture"

An IBMA view

- IBMA members welcome regulation of our products as a means of ensuring public confidence in our activities
- We do not oppose regulation for the sake of opposition
- We do oppose over-regulation

What might you get?

- A system which blocks new product development
- Destroys small companies
- Restricts access to niche products
- Removes access to biological control in some countries

What do we mean by risk ?

- Regulators
 - Risk to the environment?
 - Risk to the grower and consumer?
- Industry
 - Risk that our investment is wasted?
 - Risk of negative publicity?
 - Risk of product or company failure - is the business economically viable?

Commercial decision making

- What is the estimated value of the market?
- What is the predicted market share?
- What is the predicted cost of development?
- What is the predicted cost of regulation?
 - Fixed or variable?
 - Will extra studies be demanded?

Is it worth continuing?

- If a product has low potential
 - Minor crop, specific pest, low value crop
- If a product has high potential costs
 - Dossier submission fees
 - Costs of data generation
 - An open budget
- Cease development

An insecticide example

- Abamectin in the UK
- Label recommendation for *Liriomyza* on lettuce and tomato
- Regulator demanding efficacy data against *Liriomyza huidobrensis* and *L. trifolii* on lettuce and other crops

Liriomyza spp.

- Quarantine pests in UK - except *L. bryoniae*
- No in-house studies possible
- UK market for abamectin on lettuce is small
- External trials expensive - who can do EPPO standard trials in quarantine
- Read across from *L. bryoniae* on tomatoes not accepted

- Plant Health Department state that abamectin is a critical part of their quarantine strategy
 - Efficacy of abamectin is implicit in this statement
- Regulators do not accept this argument
 - Still want more data
- Available European data not accepted

What are our options?

- Spend a lot of money on trials?
 - Potential income cannot justify this expenditure
- Re-write the label?
 - Remove the use on lettuce
 - Remove claims against *L. huidobrensis* and *L. trifolii*
 - Minimal loss of income and minimal cost
 - Preferred option

Result?

- Inappropriate regulation has cost the growers and Plant Health Department a useful tool.
- Nobody has gained anything

Forecasted market size versus value for Sweden 2006

Total biopesticides Scandinavia	100%	\$7,100,000
Percentage as Invertebrates	46.9%	\$3,330,000
Estimated proportion Sweden	25%	\$832,500
Wholesale value	50%	\$416,250
Market share	30%	\$124,900
Gross margin	40%	\$49,960
Fee Kr 2000/yr x 10 products	- \$3,000	\$46,960
Sales, admin, advice?	?	?

Market value from Frost and Sullivan 2001



UK: invertebrates market value

- Total estimated annual value of the UK market is \$7.5 million (Frost and Sullivan 2001)
- Three main companies
 - Average 25 products, mainly commodity products common to all producers
 - Average retail value \$100,000/product/company = \$12,000 earned
 - Many niche products with lower value

Cost

- Individual studies
 - Contracted out? - Minimum \$10,000/study
 - In House? Facility and labour costs
 - Space, heat, light etc
- How many studies required?
 - The cost of studies quickly approaches or exceeds the potential income from any given product

Consequences

- High risk groups will be avoided
 - Potential for phytophagy - e.g. Miridae
 - Potential for establishment
- Low risk groups will be selected
 - Even if they are poorer candidates
- Business risk
 - What are the chances of losing your investment?

Consequences

- Regulation *per se* could restrict availability of products
 - Over cautious approach to risk
 - By excluding small companies - too expensive for them
 - By excluding niche products - no value

Consequences

- Business reaction to regulation could restrict availability of products
 - To countries with small market potential
 - Of new products requiring investment
 - Of products we perceive to have a small chance of passing the regulatory hurdles

Experiences with existing regulation

- UK system has existed since 1981
- Difficulty has increased - more questions asked
 - Same agency deals with GM crops
- DEFRA policy is to move staff every 2 years
 - Good - poor - excellent - indifferent
- Continuity is lost

Specific examples

- *Eretmocerus eremicus* - first application rejected
- Re-worked and re-submitted
- Second application gets an experimental licence
 - Competitors get licences at the same time on the basis of my work
- Why did I bother?

Typhlodromips montdorensis

- Thrips predator from Australia
- Not tolerant of low temperatures
 - Data on mortality at low temperature were included in the original dossier
- UK dossier rejected
 - "No published information except taxonomic works"
 - Might survive the winter

Typhlodromips montdorensis

- Re-application disappeared without trace
- ACRE Annual Report 2004 states that we were issued a licence (WCA/04/08)
- No licence was ever received
- DEFRA state that no licence was issued

What should regulation not be?

- An obstacle to entry for small companies
- A barrier to competition
- A disincentive to product development
- A source of income for researchers

Regulation should be...

- Open and transparent
- Proportionate to the environmental risk posed by the product
- Proportionate to the value of the products regulated
- It must recognise the potential benefit of the products

Test methods

- Simple and suitable for any company to perform
- Not requiring expensive equipment
- Not exclusive to particular laboratories
- Developed with the active participation of industry

Thank you!

