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Trade-off effects of current regulatory practice

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Balanced Regulation for Biological
Plant Protection Products
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- **Aim:** to examine the drawbacks and benefits of current regulation of biological control agents (BCA) in the EU in terms of its consequences for plant protection, farmers, consumers and food safety
- REBECA WP6 organized a **workshop** on the topic and conducted a **survey** among biocontrol industry concerning their experiences with regulation of BCA and future plans concerning product development

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- **Costly and lengthy registration of BCA restricts severely their market entry in the EU**
- **Leads to trade-off effects in areas such as**
 - **farming activities**
 - **human health**
 - **environment**
 - **commercial biocontrol activities**



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Availability of microbial pesticides:

- some **60 products** available in the USA
- EU-wide registration for only **6 products**



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REBECA survey results on registration cost (k€)

	Overall total	External
• EU Annex I inclusion:	1890	970
• US-EPA	na	na

Proportion of total costs due to

• efficacy tests	21 %
• toxicological tests	43 %
• ecotoxicological studies	23 %
• other required studies	13 %



Survey results on registration time

- EU Annex I inclusion: mean 75 months
- US-EPA 28 months

Country registrations, **examples** (in months)

AT	19	FR	29	NO	15
BR	72	GR	7	PT	27
CA	17	HU	48	SE	12
CH	24	IT	14	UK	22
CN	18	JP	12		
ES	>34	MX	24		
FI	12	NL	22		



Limited BCA availability affects farming:

- continued/increased reliance on chemical pesticides

pesticide sales (in tn) in EU15
increased by 12% from 1992 to 2001

- increased difficulties to control pests due to pesticide resistance
e.g. pollen beetle resistance to pyrethroids on oilseed rape,
pests of protected crops e.g. in Almeria, Spain
- lack of effective controls esp. in vegetables and fruits
- overuse of existing products > rapid loss of compounds
- higher costs for farmers, less efficient production, if effective plant
protection products are not available
- organic farming has less options for plant protection
- sustainability of farming systems suffers



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Limited BCA availability affects human health:
Applicators – bystanders – consumers

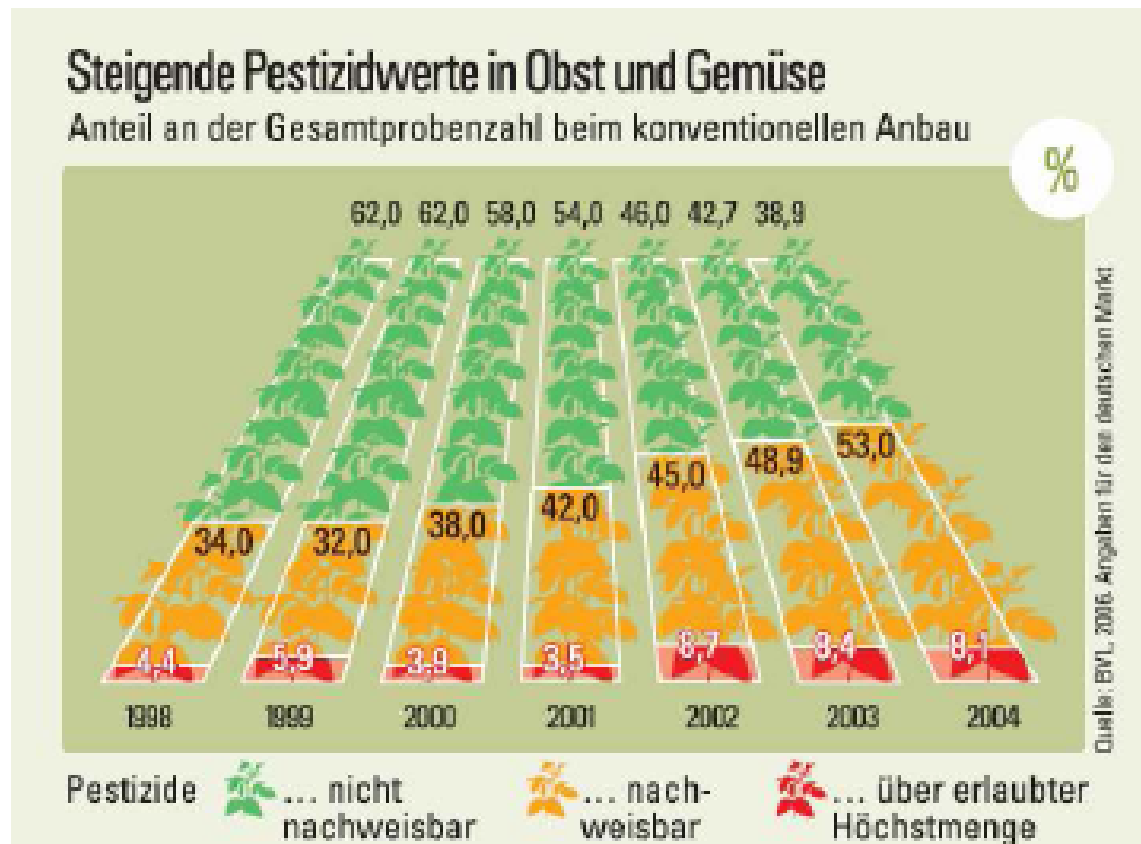


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Limited BCA availability affects human health: Applicators – bystanders – consumers

**Pesticide residues
in fruits and
vegetables are
increasing: data
from Germany**





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Limited BCA availability affects human health: **Applicators – bystanders – consumers**

In German supermarkets in autumn 2006, two percent (2 %) of vegetable and fruit samples from conventional production had residue levels **exceeding the Acute Reference Dose (ARfD)**

additionally,

11% of samples labelled 'produced in Germany' contained residues of pesticides which are not allowed to be used in Germany (indicating illegal use)



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Limited BCA availability affects the environment

via the negative externalities of continued use of chemical pesticides:

- **contamination of**
 - **biota**
 - **soil**
 - **water**
- **loss of biodiversity**





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Loss of competitiveness of the biocontrol sector in the EU

- No start-ups and spin-offs in biocontrol industry
- High fees of Member States result in companies marketing only major BCA; and biocontrol systems lack measures for less important pests > chemicals
- Regulation keeps smaller and more specific BCA from the market > return to broad spectrum pesticides
- Product innovations are not brought to the market, e.g. progress with new strains or new formulations, because of costs related to registration
- As costs and time related to registration can hardly be predicted, companies cannot produce business plans
> without a business plan no venture capital
> BCA industry remains a small business



REBECA Survey: Do the companies still invest in R&D of BPPP?

- R&D expenditure remained quite constant over years, but in proportion of turnover it declined: means were

1990: >>100% 1995: 83% 2000: 39% 2005: 14%



Impact on new R&D

- **5/8 companies do plan to bring new BPPP into market**
- **new R&D has been started in 2000, 2002, 2005, 2006, 2006**
- **market entry for these expected in 2007, 2009, 2011, 2015**
- **R&D expenditure so far? 15M€ in one case!**
- **3/5 companies do not plan to invest into new R&D for BPPP, because of high registration costs. Products not requiring registration have priority in the R&D of these companies.**



Impact on new R&D (cont'd)

- several companies would bring more BPPP into the market *"if conditions for registration were more favourable"*
- 3 companies indicated that they had shelved BPPP mainly due to registration costs/time (4 products)
- these companies had spent on average 200 k€ in R&D on these products by the time of deciding to discontinue their commercial development
- several companies do not plan to initiate new R&D on BPPP under the current situation, but their **plans depend on "positive results from REBECA"**



Cost-Benefit Analysis of Biopesticides

A workshop at Warwick HRI, UK, found 41 benefit and cost items relating to biopesticides. The **balance of costs and benefits** was found to vary substantially across the six stakeholder groups:

developers	-14
users/growers	-9
retailers	-6
regulators	-1
consumers	+2
opinion formers	+7

Thus, those who bear the private costs of development and application seem to have the most unfavourable balance of costs and benefits, while consumers of the final product and opinion formers have the most favourable balance. This emphasises the importance of considering the balance of private and public goods.

(Wyn Grant, personal communication)



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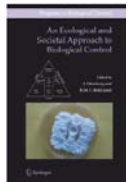
Private vs. public benefits

“The ratio between private and society benefits on UK wheat production is illustrative: for every £1 gained by farmers in private benefits in a move from conventional to integrated farming (with reduction in pesticide usage), there are £6 worth of benefits to the society.”

“The environmental and socio-economic costs of pesticide use in the USA is more than double of that what is paid by farmers, and could be viewed as society subsidies to support this form of pest management.”

“Replacement of chemical pesticide treatments by biological controls would bring immense socio-economic benefits to the society: the benefits from controlling the pests would still accrue, but the negative externalities would disappear.”

Citations from Menzler-Hokkanen 2006: Socioeconomic significance of biological control. pp. 13-25 in Eilenberg & Hokkanen, An Ecological and Societal Approach to Biological Control. Springer.





Conclusions:

The current regulatory system for BPPP in the EU has numerous severe trade-off effects.

These contribute in several key areas to the EU not meeting their stated policy objectives:

- Pesticide reduction programmes
- Increasing proportion of organic production
- Safer food with less pesticide residues
- Safer and more diverse environment
- More jobs
- More SMEs



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**THANK YOU
FOR YOUR
ATTENTION!**

