

Challenges and limitations for the collection of field data on the biosafety of Genetically Modified Plants (GMP)

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- Scope: research – risk assessment – monitoring
- Requirements on field trials
- Example: Non-target organisms in Bt maize

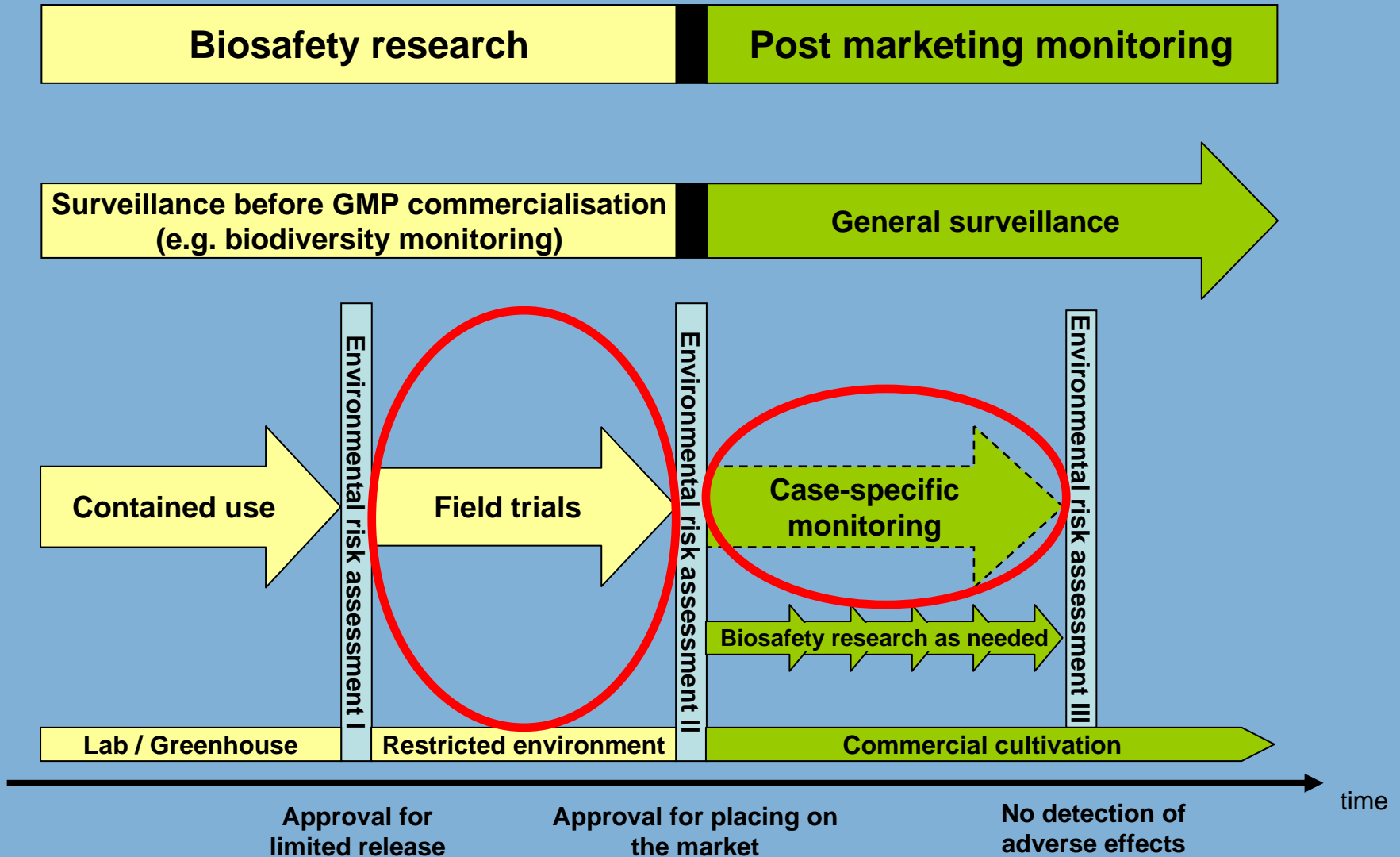


Elements of GMP regulation

- Environmental risk assessment (ERA)
- Monitoring
 - Case specific monitoring
 - to confirm that assumption regarding the occurrence and impact of potential **adverse** effects of the GMO or its use are correct
 - General surveillance
 - identify the occurrence of **adverse** effects of the GMO or its use on human health or the environment which were not anticipated in the ERA



Interplay between biosafety research and monitoring



- Tool for
 - biosafety research – studies for the environmental risk assessment (ERA)
 - case specific monitoring
- Goal
 - proof of safety of GMPs with regard of environment, animal and human health
 - to confirm that assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use are correct (2001/18/EC)
- Additionally field trials shall be
 - scientifically sound
 - cost effective

Bt-maize and non-target organisms

- Looking for effects of growing Bt-maize on non-target organisms
- Identification of indicator species or groups

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What do ecologists want?

....many organisms



etc..

What do ecologists want?

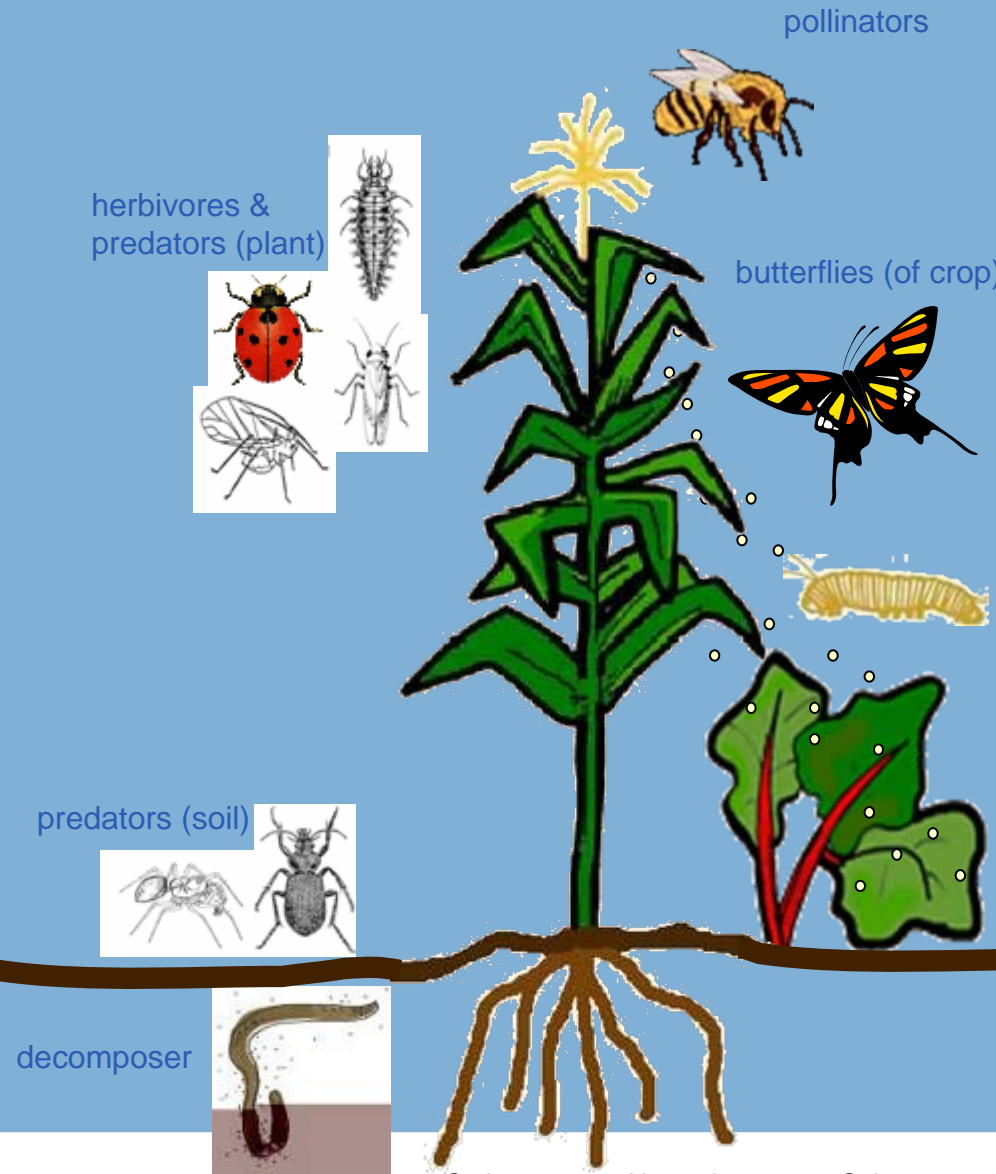
- Many organisms
- Representative for rare (endangered) organisms

- Trophic/functional groups

- decomposer
- herbivores
- predators
- parasitoids
- pollinators

- Compartments

- soil
- plant
- in crop
- off crop

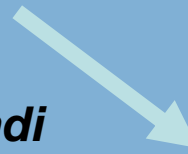




Aphids
Rhopalosiphum padi



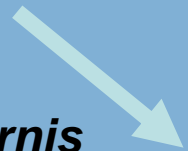
aphidphagous
predators



parasitic
Hymenoptera



Thrips
Frankliniella tenuicornis
Limothrips cerealium



Bugs
Orius spp.



saprophytic
insects
Lathridiidae
Collembola



What do ecologists want?

- Many organisms
- Representative for rare (endangered) organisms
- Different trophic groups
- Cover as much as possible compartments
- Trophic interactions and/or small communities
- Data over several vegetation periods (multi year studies)
- Multiple comparisons (control, different varieties, conventional management)

What do statisticians want?

- Proper experimental design
 - + clearly defined endpoints
 - + low variability
 - + sufficient number of individuals
 - + no replications with low number of individuals or no individuals
- = many replications in biological system

What do ecologists (and statisticians) often miss?

- Sufficient money
 - condition set by funding institutions
 - limitation of (financial) resources
- Time
 - thinking about statistical analysis in advance
 - consulting statisticians
- Understanding for demands of other stakeholders
(for each other, regulators, public etc.)

Problem 1: Experimental design in a landscape with constraints

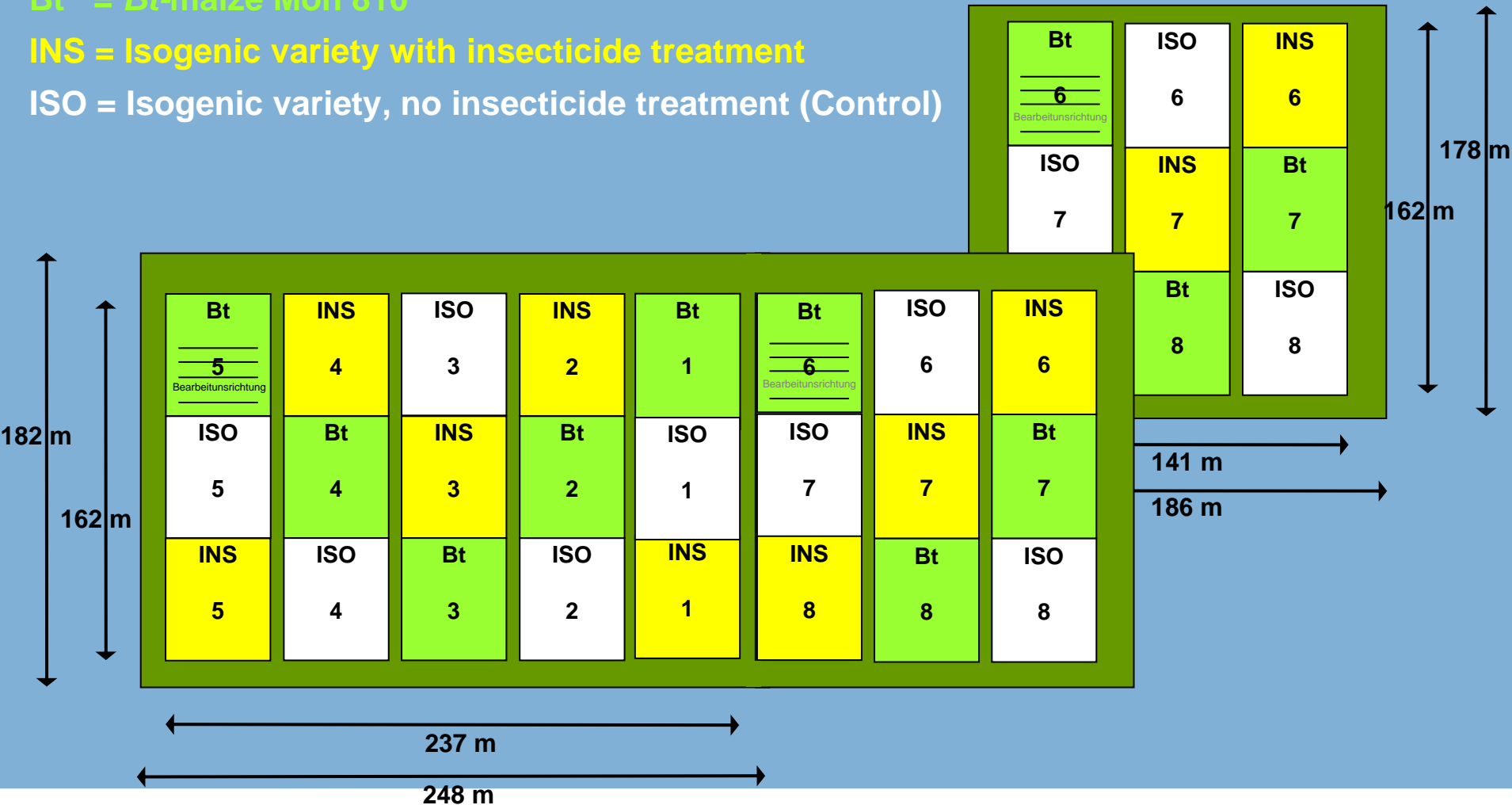
- Original design
 - three treatments
 - randomized block design
 - plot size of 0.25 ha to exclude edge effects
 - 5 replications
- Improvement after statistical consultation
 - 8 replications
- General problems then
 - availability of a sufficient overall field matching the size
 - finding a farmer who is willing to grow GMP

Experimental design

Bt = Bt-maize Mon 810

INS = Isogenic variety with insecticide treatment

ISO = Isogenic variety, no insecticide treatment (Control)

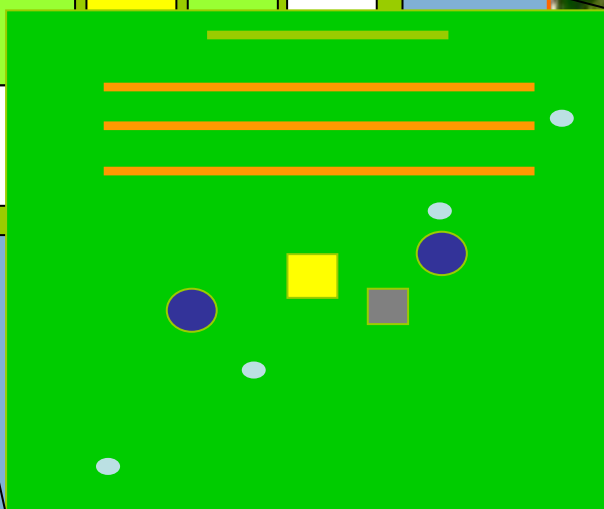


Problem 2: Multiple endpoints

- Different methods result in data sets with
 - repeated measurements
 - low number of individuals
 - no detection of individuals in single plots
 - comparisons between years
 - high variability, typical of biological systems



| | | | | |
|----------|----------|----------|----------|---------|
| Bt 5 | INS 4 | ISO 3 | INS 2 | Bt 1 |
| ISO 5 | Bt | INS | Bt | ISO |
| INS 5 | | | | |



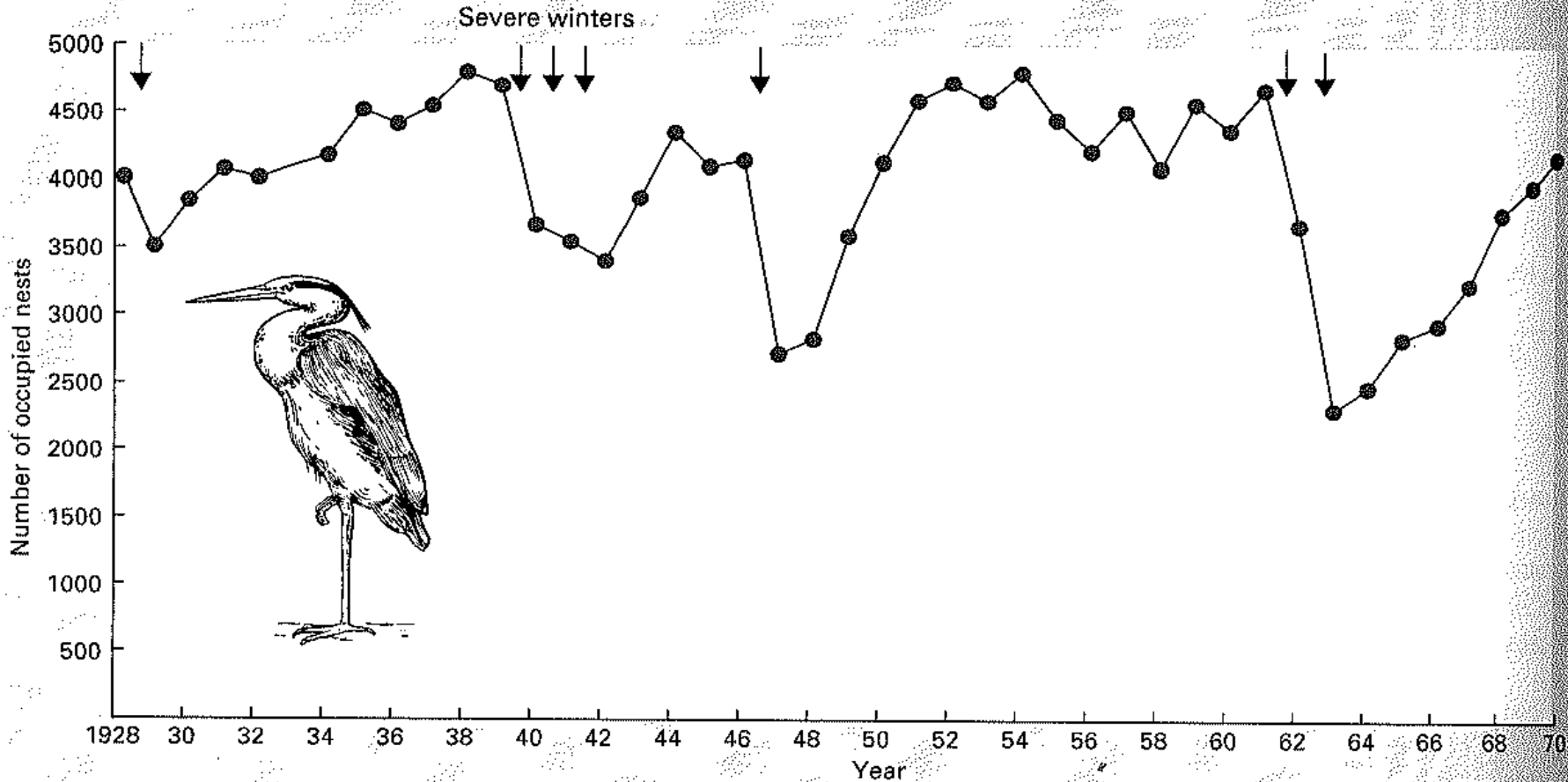
Multiple endpoints

| Method | Years | Sample dates/ year | Sample points/ plot | Number of endpoints (taxa) | Number of collected and specified individuals |
|-------------------------|-------|-----------------------|------------------------|-------------------------------|---|
| Visual assessment | 2 | 8 | 4 | 21 | 125.840 |
| Coloured traps | 3 | 2 | 2 | 19 | 38.069 |
| Sticky traps | 1 | 1 | 1 | 5 | 1.152 |
| Sweep netting | 2 | 1 | 4 | 28 | 2.629 |
| Dislodging form flowers | 3 | 2 | 5 | 10 | 20.932 |
| Sampling of cobs | 3 | 1-2 | 20 | 37 | 48.521 |
| Dislodging weeds | 3 | 2 | 1 | 11 | 1.507 |
| Pit fall traps | 3 | 14 | 1-2 | 107 | 143.720 |
| Total | - | - | - | 247 | 256.530 |

Problem 3: Data interpretation

- About 1000 species in maize known
- Data about population dynamics are not available for many species
- For some species it is known that population dynamics varies in space and time
- Open question which percentage change could be detected with a tenable input
- What is an adverse percentage change (effect) for a species?
- Definition of thresholds decision making is extremely difficult

Population dynamics of heron



Begon Harper Townsend (2001)

- Identification of suitable indicator organisms (6 species)
- Indicator species should be preferably used in further studies
- Close collaboration between statisticians and ecologist to develop an statistical approach regarding the experimental design and measured endpoints
- Use of the ‘proof of safety’ methodology
- However statistical methods can only help ecologists to estimate the data quality and effect size, but they do not help to decide whether results are ecologically relevant

- Analyzing 247 endpoints
- Collecting data over three years
- With 8 different methods

- No adverse effects of Bt maize on non-target organisms could be detected

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Ludgar Wirocks
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Ute Wehres**

**Claudia Zahn
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Jenny Hegewald
Angela Tings
Mario Rendina**

Leibniz
Universität Hannover 

WG Ludwig Hothorn



BMBF for financial support

