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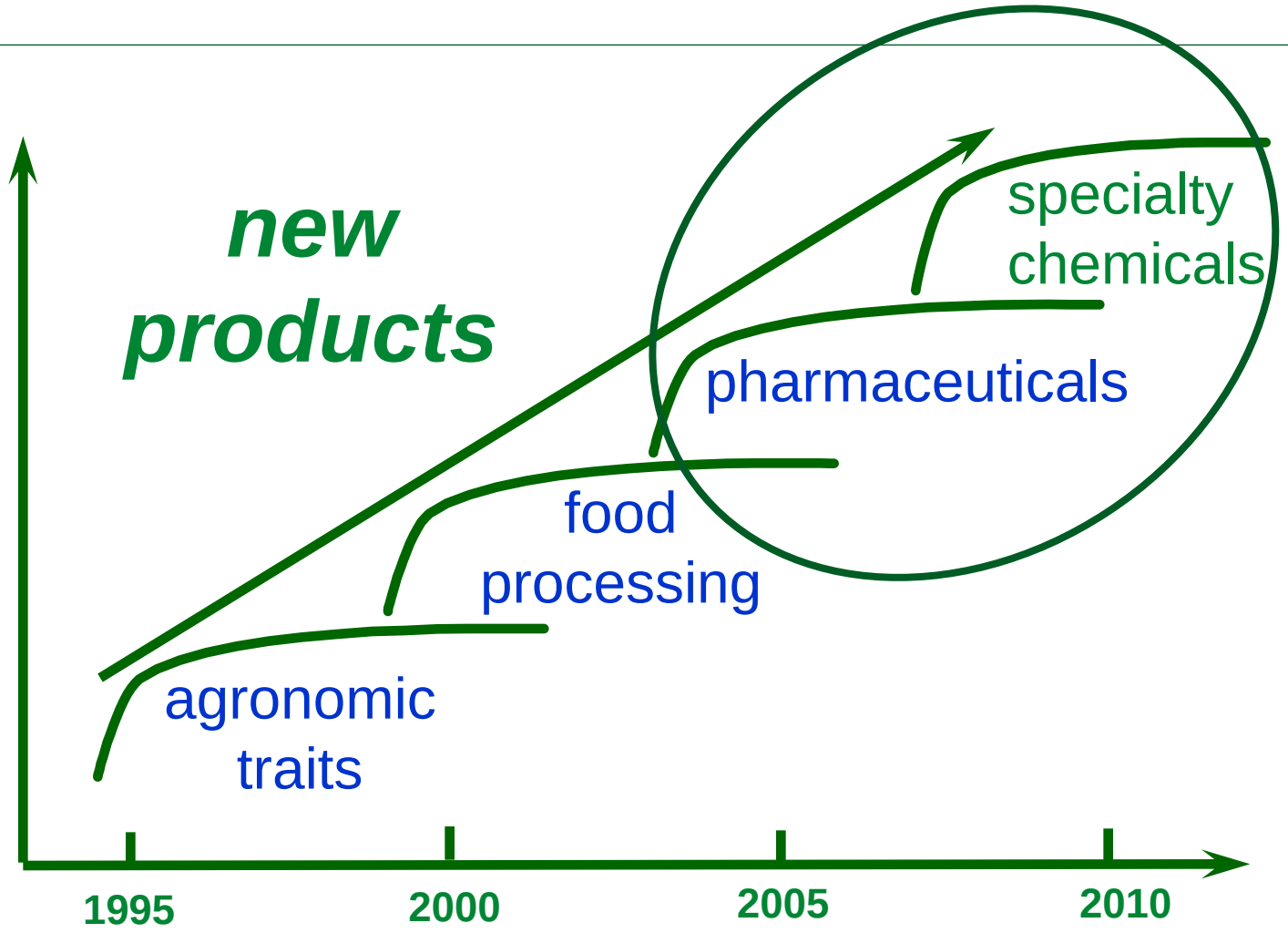
CONTRACT BIOOK RESEARCH

Quo Vadis Biosafety

Heike Mikschofsky and Inge Broer, University of Rostock



Source: R. Fraley (1994)

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Biosafety research today

Since1987 the German Ministry of Science promotes Risk assessment studies but:

- Tasks and weight are not defined
- Results are rarely recognized
- They are only accidentally the basis of political decisions
- But if, they quite often rely on publication with low scientific standard
- Rules for a good experimental praxis are missing

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Demands

- We need a better definition of the tasks and the importance of biosafety research
- We need clear rules for a good scientific practice
- We need better public relations and a stronger impact of biosafety issues on education
- We need to go beyond Bt maize

Biosafety and environment

Topics adressed :

GMP specific interaction with the environment (e.g. NTO, soil)

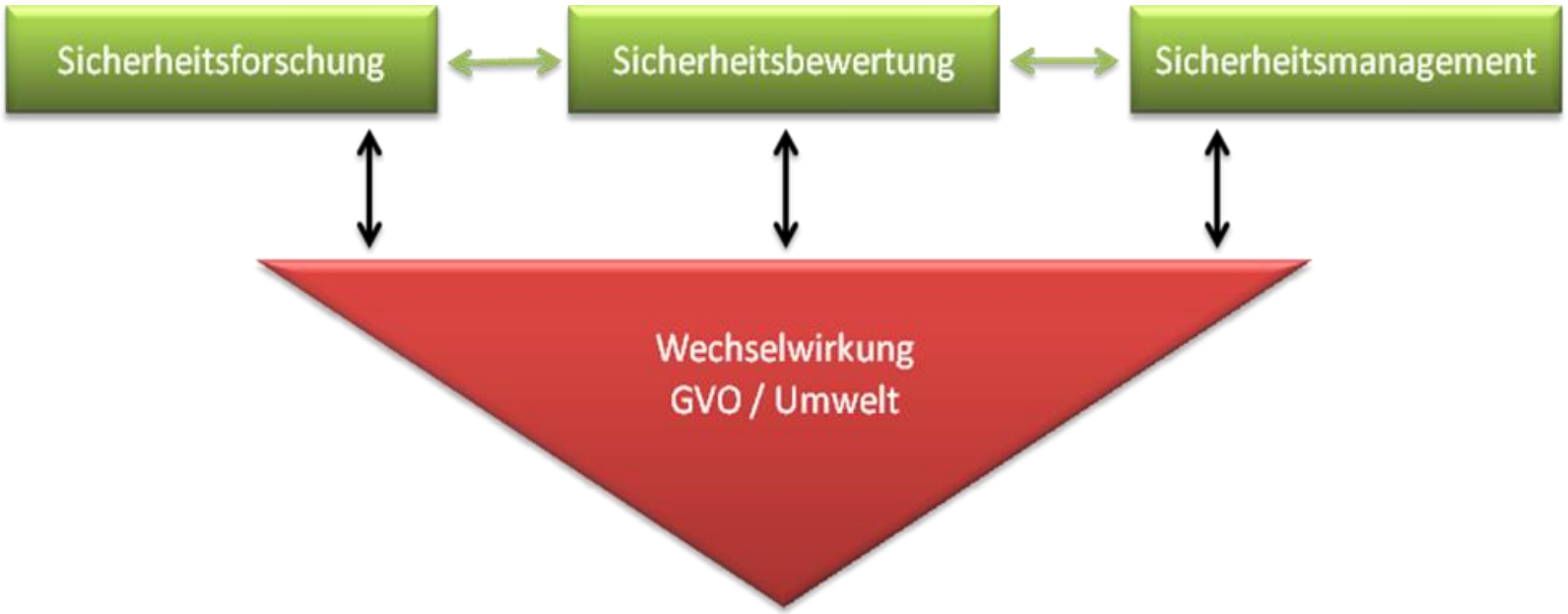
Gene flow

Coexistence

Development of monitoring schemes

Tasks and importance

- creates a knowledge base for biosafety assessment and –management



Tasks and importance

- creates a knowledge base for biosafety assessment and –management
- adapts biosafety assessment and –managment to the scientific state of the art
- recognizes risks and finds solutions to solve the problems
- is not part of the approval of commercial products
- is interdisciplinary and open for all scientific fields as long as the rules for a good scientific praxis are followed

Good experimental practice

- Cause- effect hypothesis,
- Potential harm,
- Confined field releases are important but not indispensable
- Hazard-risk,
- Conclusions have to be restricted to the data,
- Cultivar specific differences have to be taken into account

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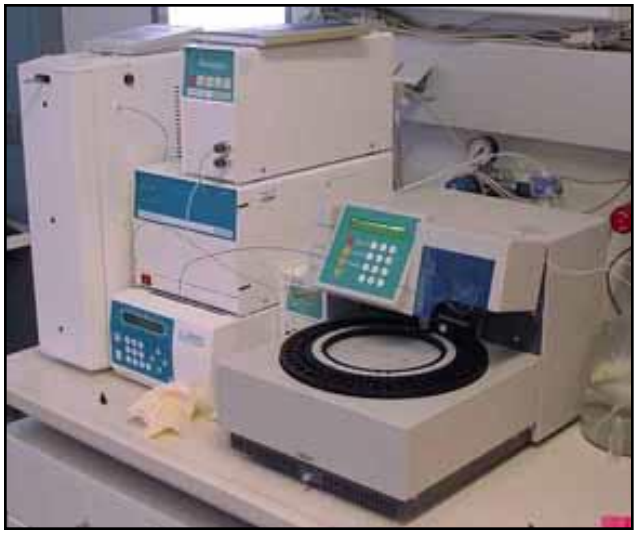
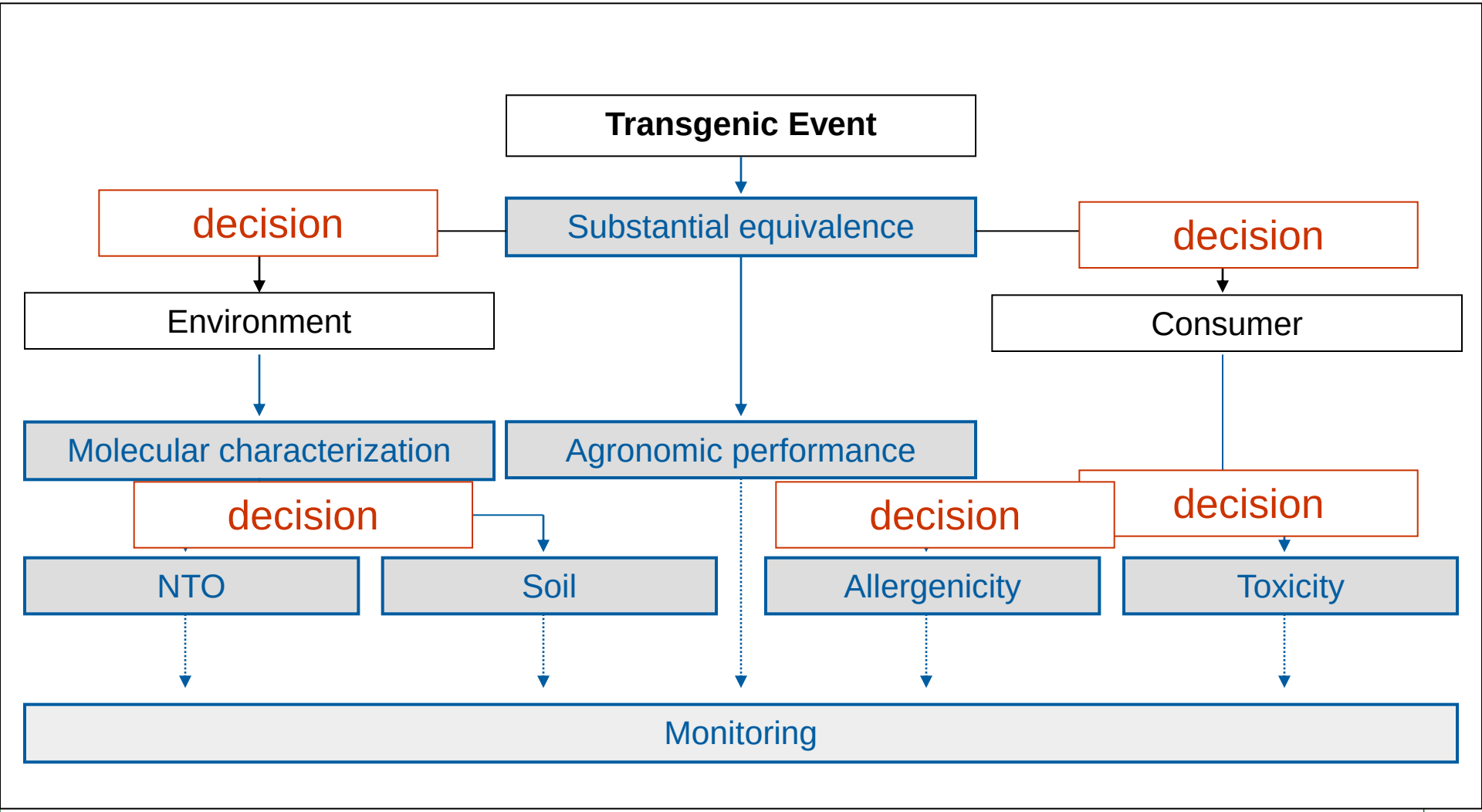
Optimization of methods

- Specific methods for GMP,
- Analyze first the potential cause and then the potential effect,
- identify indicators and thresholds,




Transgenic Event
decision
Substantial equivalence
decision
Environment
Consumer
Molecular characterization
Agronomic performance
decision
decision
decision
NTO
Soil
Allergenicity
Toxicity
Monitoring

Optimization of methods

- Specific methods for GMP,
- Analyze first the potential cause and then the potential effect,
- Identify indicators and thresholds,
- Stick as often as possible to transgene specific and not event specific effects
- Create interdisciplinary consortia using the same plant material

Development of Confinement systems

Confinement systems are necessary if a negative impact on the ecosystem has to be expected via

- inbreeding
- establishment of the GMP in the ecosystem
- or impact on non target organisms

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Development of systems to ease the assessment

- Avoidance of unwanted exposition and establishment of GMP
- Sequence specific integration;
- Expression meeting the demands
- Avoidance of superfluous DNA-sequences;
- Optimized adaptation to plant regulatory mechanisms

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Important research topics

- gene stacking,
- Plant made pharmaceuticals and industrials
- Marginal locations,
- Stress tolerance

are important examples for new fields of research

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Conclusion

Today

1. Parameters assessed depend upon: What is possible and nice to know
2. Event specific
3. Comparison to the near isogenic line (NIL).
4. All changes are regarded as risk relevant
5. No indicators and thresholds
6. Individual , rarely generalizable results

Tomorrow

1. Parameters assessed depend upon a cause- effect hypothesis and a potential hazard
2. If possible transgene and crop specific
3. Comparison to several conventional varieties, changes that do not exceed the natural variability are accepted.
4. The biological relevance of the changes will be assessed
5. Indicators and thresholds
6. Development of analytic systems for transgenes and crops