EU Regulatory Framework and Status of Genetically Modified Crops

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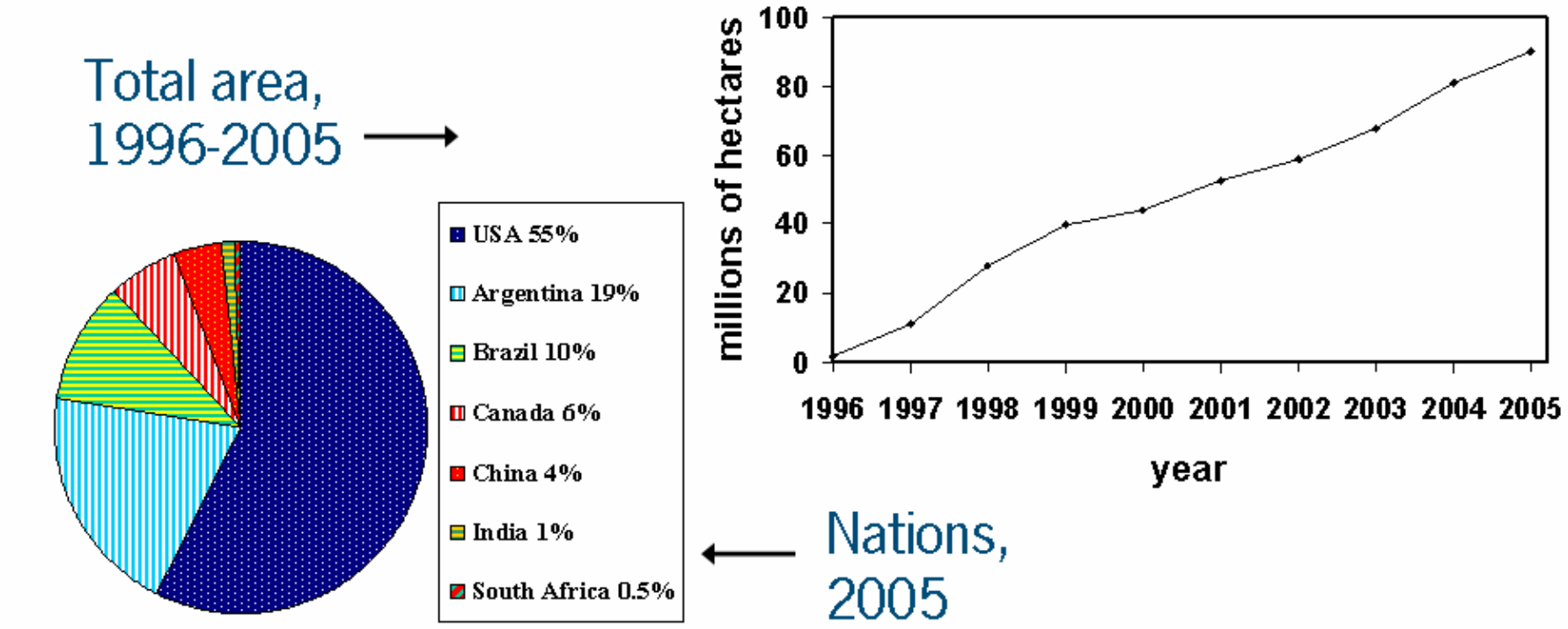
Program

- Introduction, GM crops
- GM crops in the EU
- Safety assessment of GMOs
- Research on GM food safety
- Conclusions

Introduction

The worldwide area of genetically modified crops has rapidly increased



Data source: C. James, ISAAA , 2005

Introduction

Examples of herbicide-resistant genetically modified crops are soybean and canola

Soybean

before herbicide-application after

Canola

Illustrations: Internet

Introduction

Insect-resistant maize and cotton are grown commercially on a large scale

Maize

Cotton

Illustrations: Internet

Introduction

"Golden rice" with additional β-carotene is an example of a future biotech crop

Illustration: Internet

GM crops in the EU

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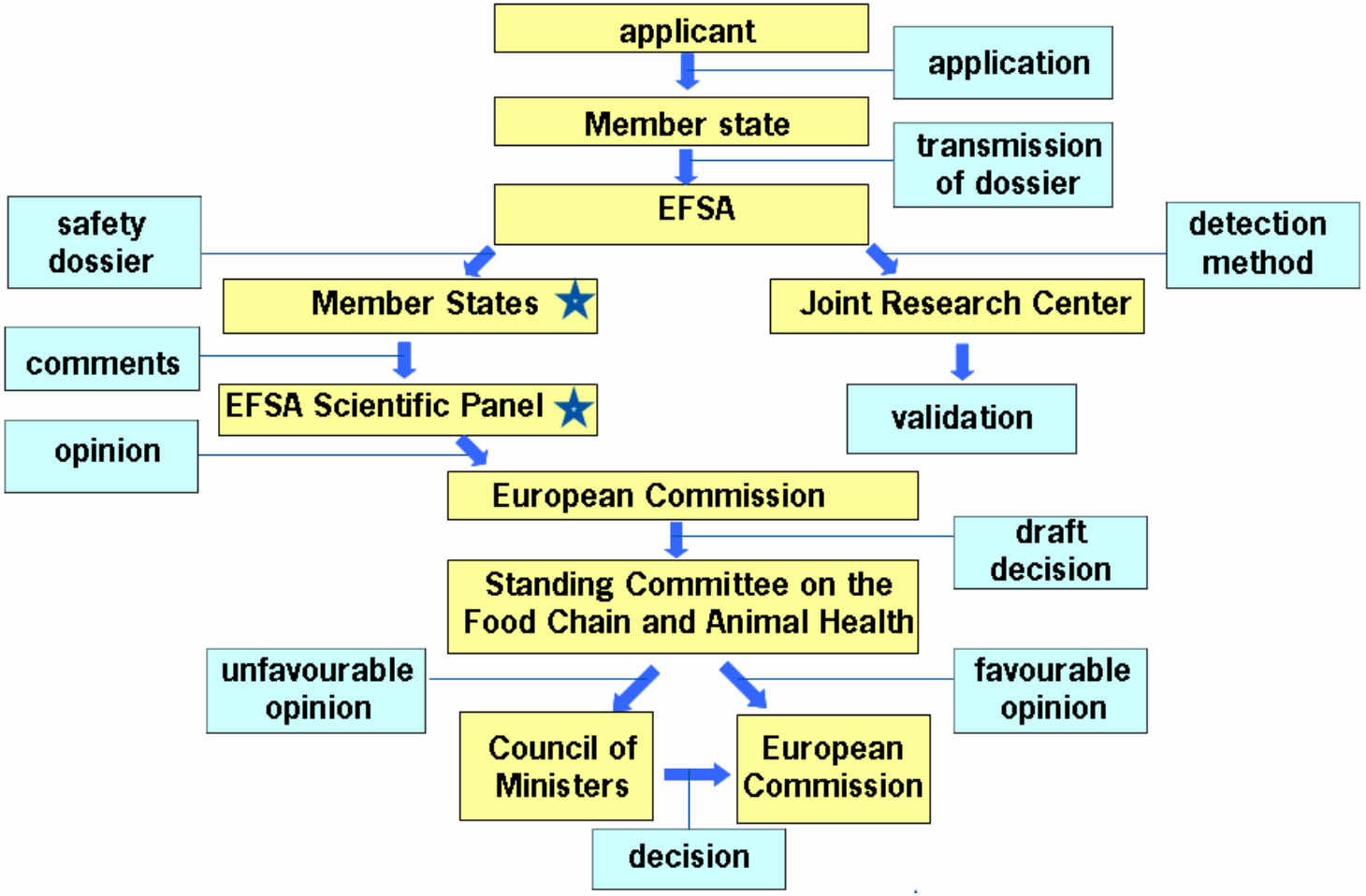
GM crops in the EU

Regulations on GMOs in the EU

- Environmental release (cultivation, import)
  - Directive 2001/18
- Food and Animal Feed
  - Regulation 1829/2003
- Labelling and Traceability of Food and Feed
  - Regulation 1830/2003
- Seeds and propagating material
  - Thresholds for adventitious presence of GM seeds in seedlots for conventional seeds (in preparation)
- Also co-existence, trans-boundary, contained use

GM crops in the EU

EU approval procedure for GM food and feed



★ = scientific issues

GM crops in the EU

GM crops approved for environmental release

Crop	*Trait*	*Applications*	
Soya	Herbicide resistant	Import	
Radicchio	Herbicide resistant	Breeding	
Maize	Herbicide resistant Insect resistant	Cultivation, import	
Canola	Herbicide resistant Hybrid system	Breeding, cultivation, import	

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Illustrations: FAO, Bogaers Gebr., BNF, Agwest

GM crops in the EU

GM crop products approved as novel foods

Crop	*Trait*	
Canola oil	Herbicide resistant Insect resistant	
Cotton seed oil	Herbicide resistant Hybrid system	
Maize	Herbicide resistant Insect resistant	
Soya	Herbicide resistant	

Illustrations: BNF, Agwest, Florida St. Univ., FAO

GM crops in the EU

Labelling and traceability of GM foods

- All GM foods and food ingredients
  - Also without detectable transgenic material
- Documentary system for traceability
- Thresholds for adventitious presence:
  - 0.5% (evaluated)
  - 0.9% (approved)
- Organic products GMO-free
- "GMO-free" label in some member states

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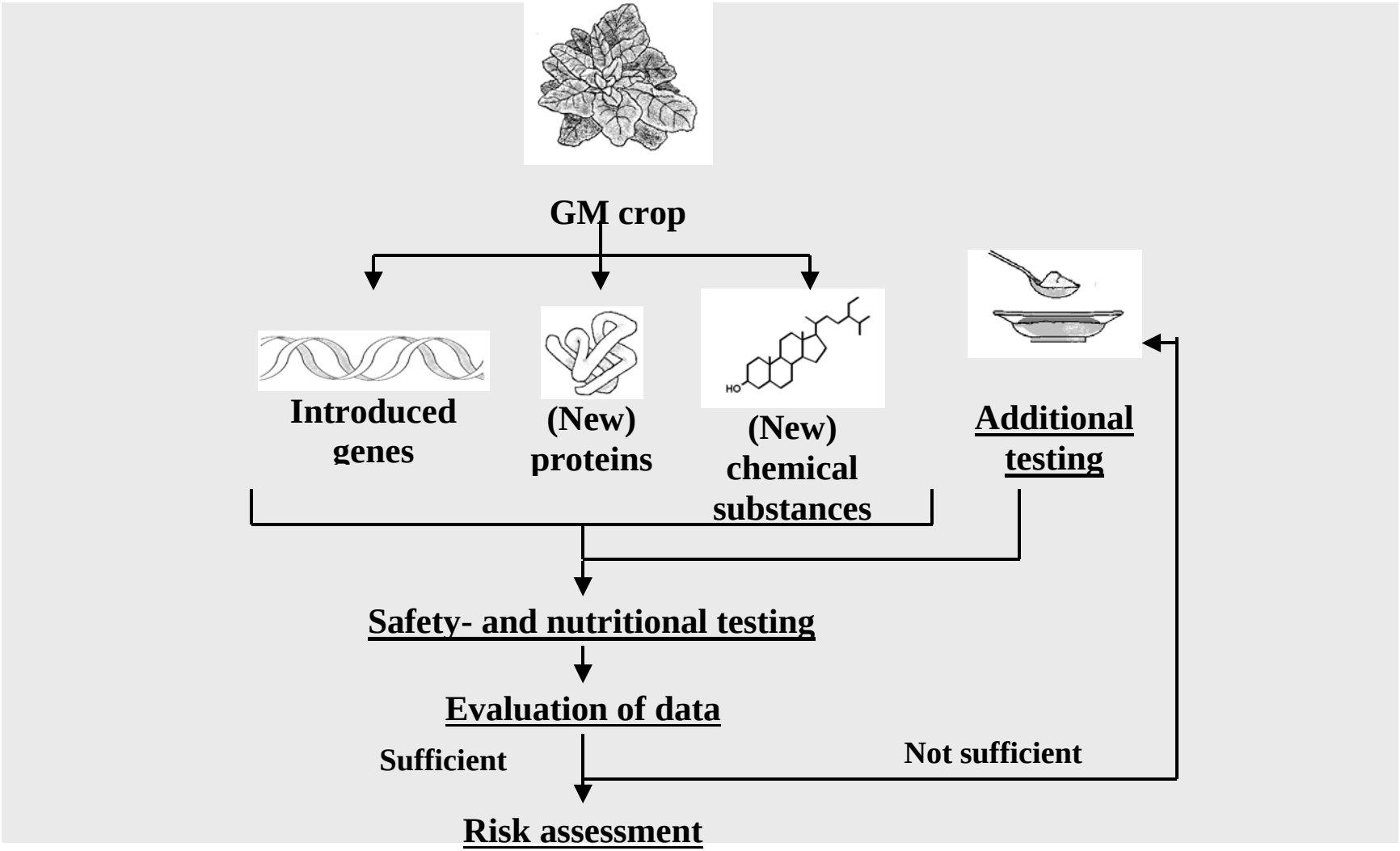
Illustration:
Viktoria Institute
(Andy Warhol)

Safety assessment



Safety assessment

The safety assessment of GM products follows an international consensus approach

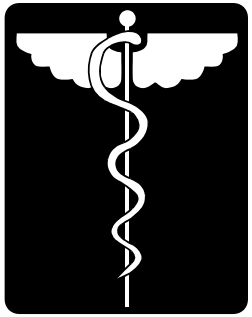
Comparative safety assessment

- Substantial equivalence
- Starting point
- Comparison of phenotype, composition
- Comparator with history of safe use

FAO/WHO, OECD, ILSI

Safety assessment

A number of specific safety issues are commonly addressed (I)



Toxicity

Bioinformatics, degradability, animals

Allergenicity

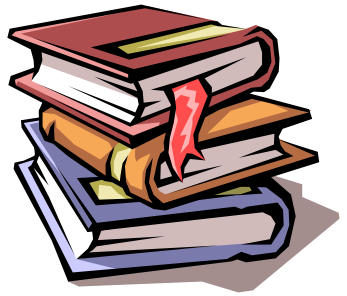
Bioinformatics, degradability, animals, clinical

Gene transfer

Antibiotic resistance, clinical relevance, likelihood of transfer

Safety assessment

A number of specific safety issues are commonly addressed (II)



Unintended effects

- Composition, profiling (future)

Nutritional value

- Composition, target animals

Pesticide residues

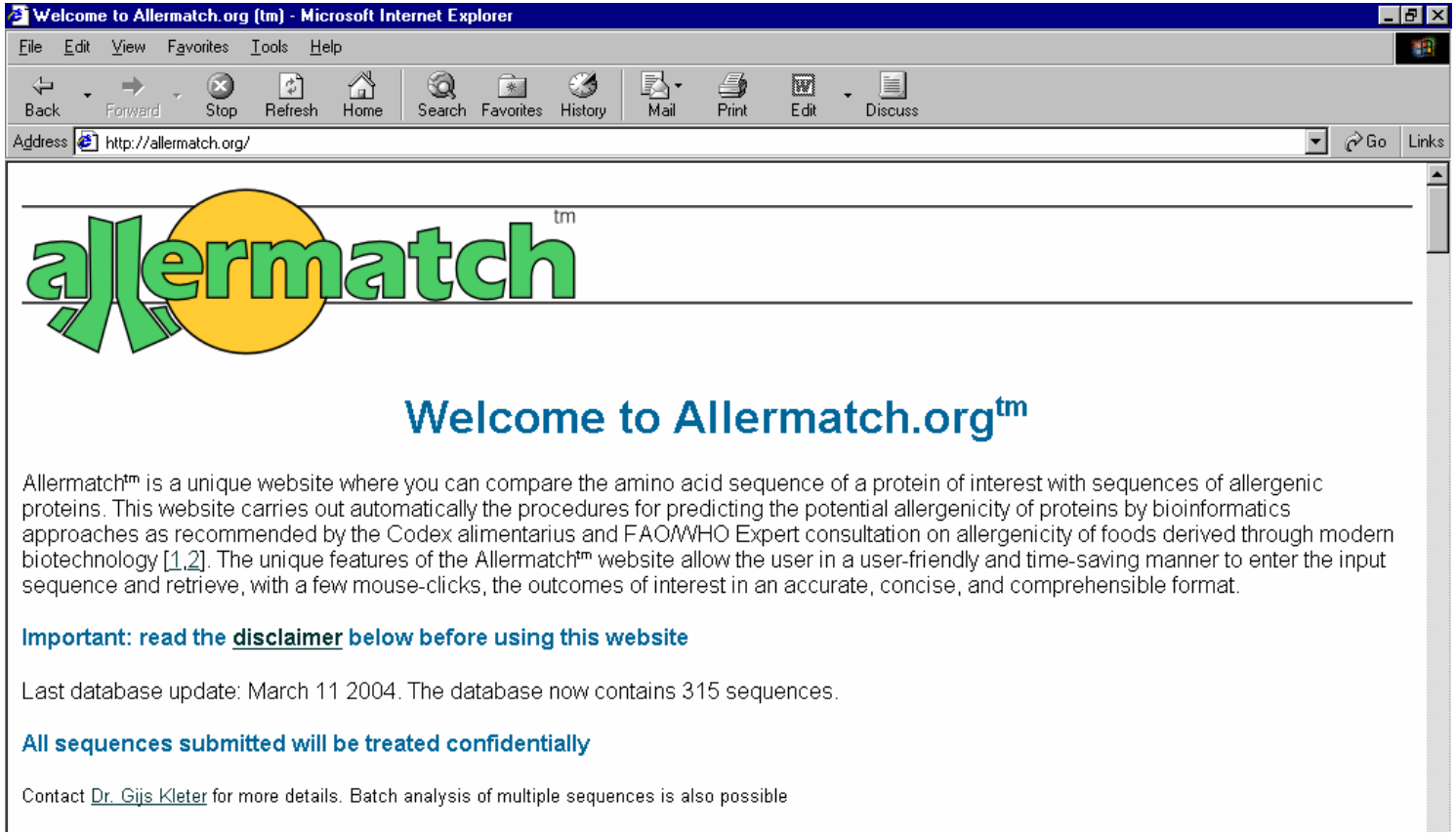
- Residue data, metabolism

Safety assessment

http://www.efsa.eu.int/science/gmo/gmo_guidance/660_en.html

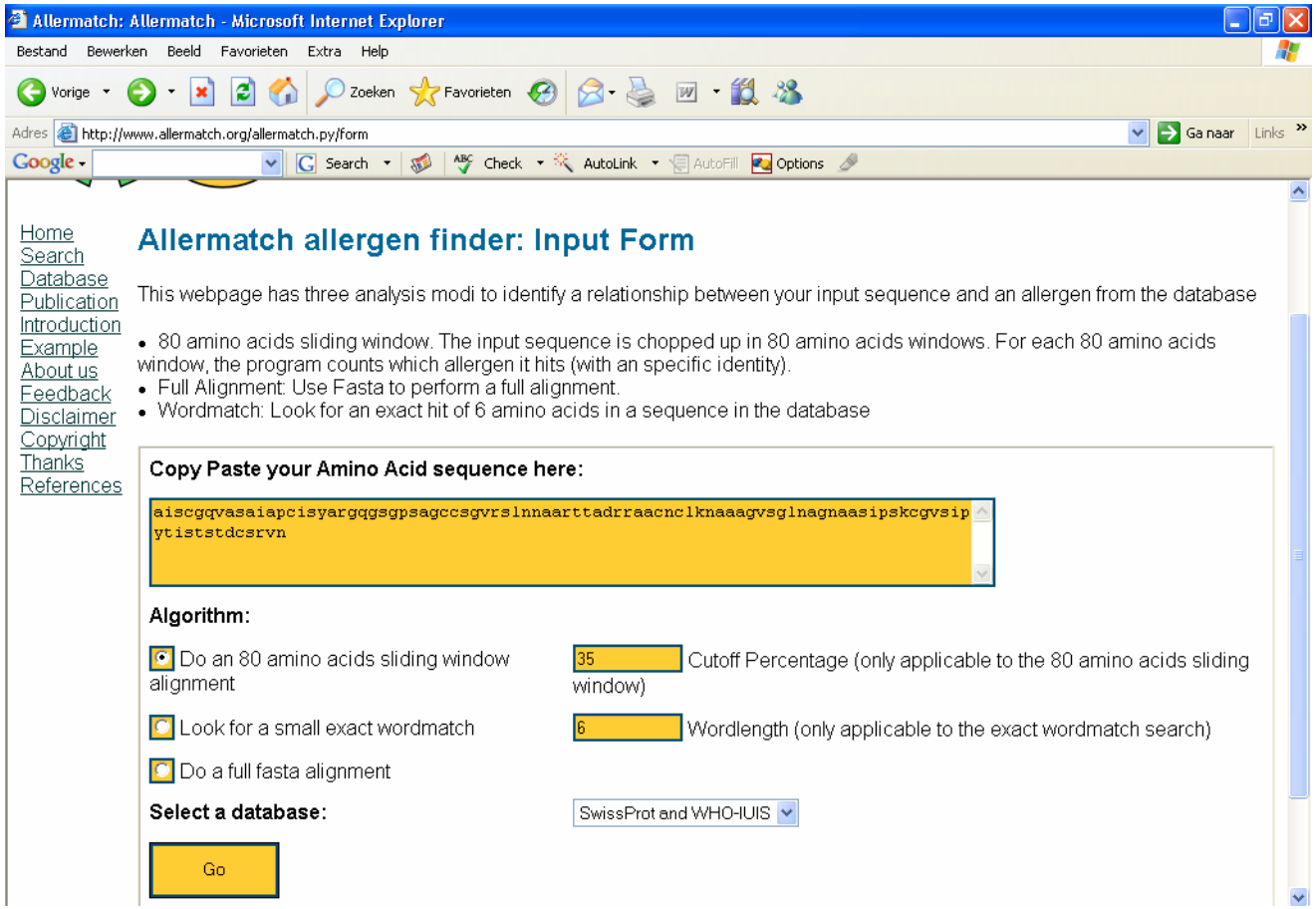
Safety assessment

Allermatch tm (www.allermatch.org) for bioinformatic prediction of similarity of proteins with allergens



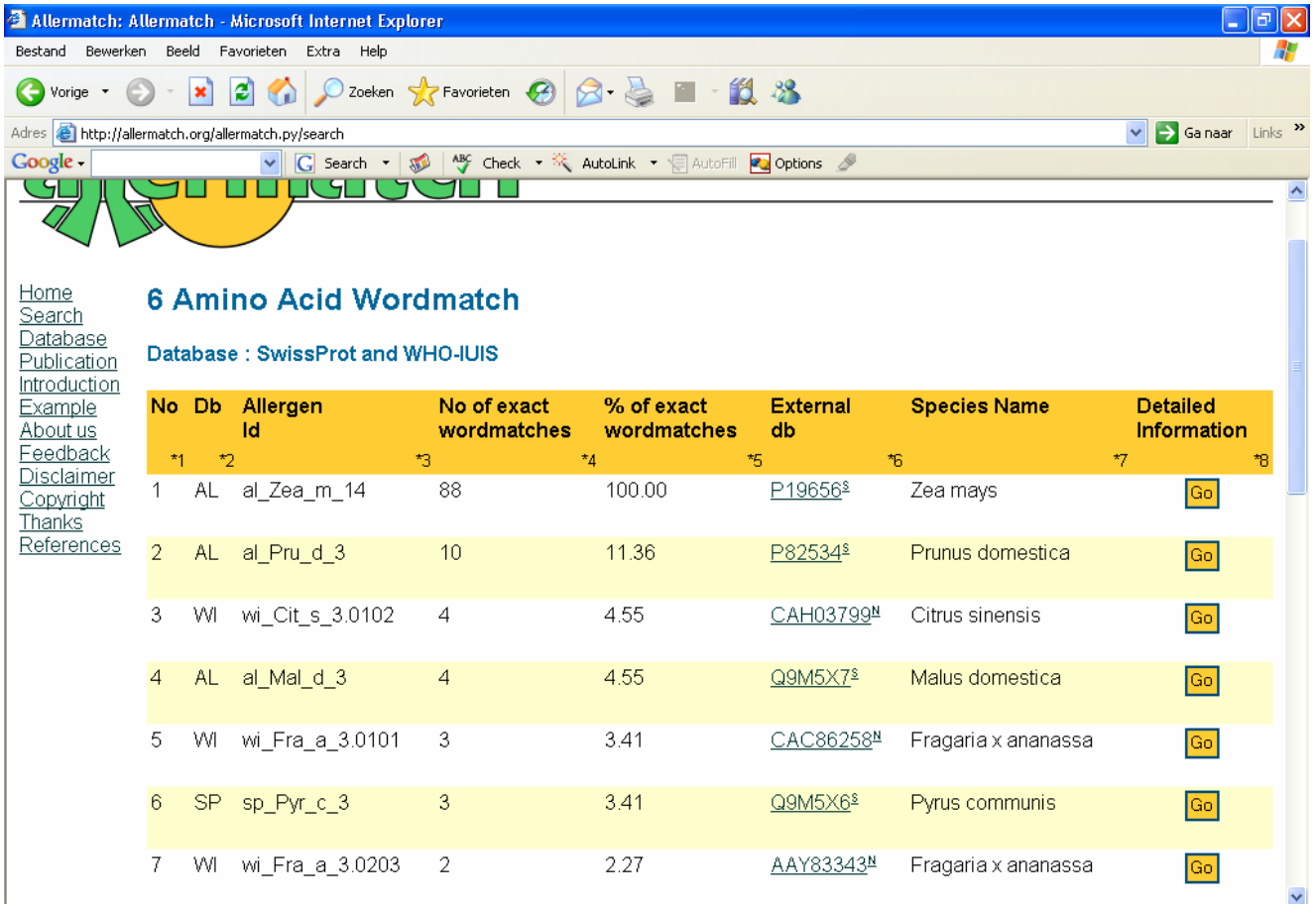
Safety assessment

Example: model sequence Zea m 14, start search



Safety assessment

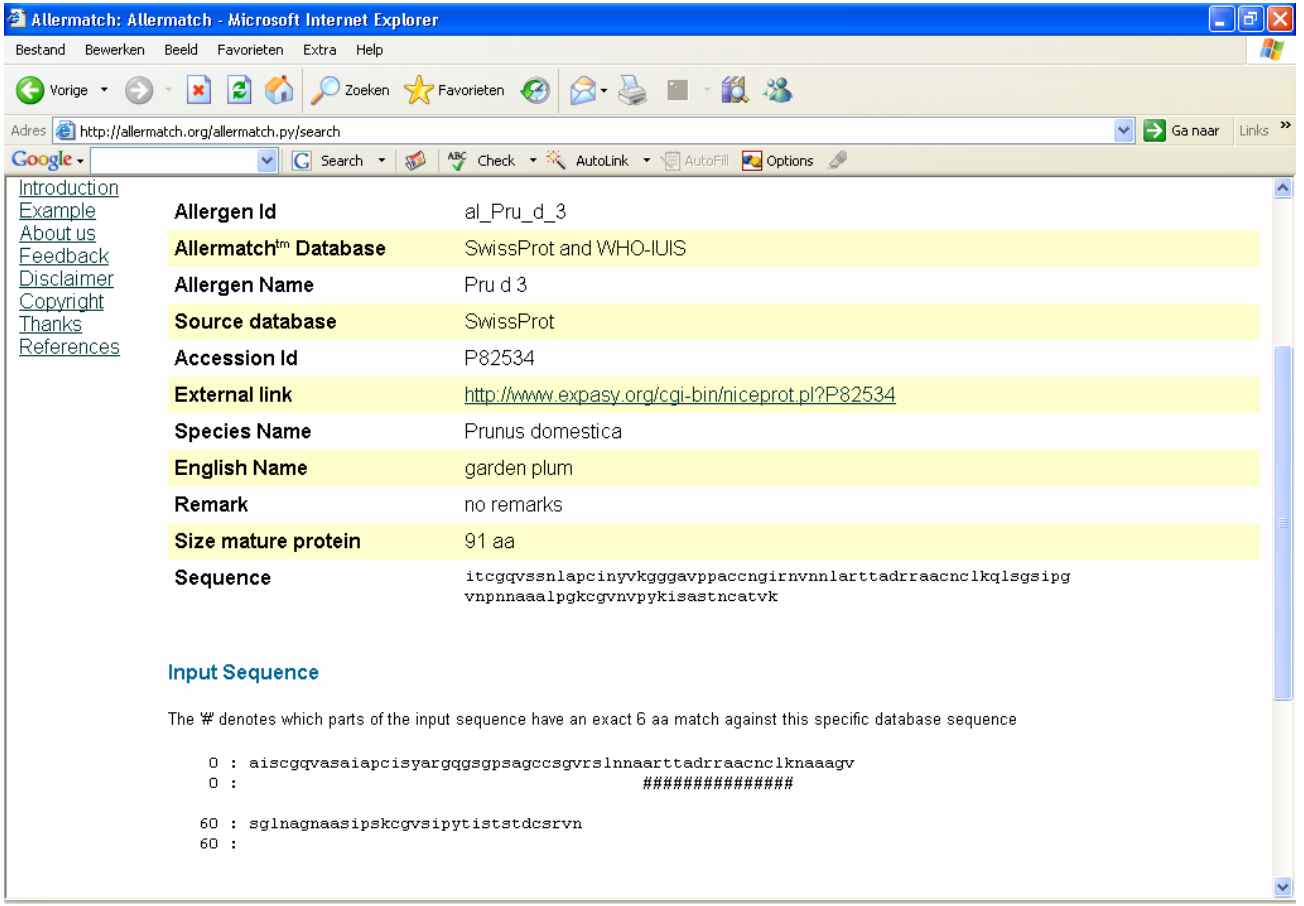
Example: output list, 16 hits besides Zea m 14



No *1	Db *2	Allergen Id *3	No of exact wordmatches *4	% of exact wordmatches *5	External db *6	Species Name *7	Detailed Information *8
1	AL	al_Zea_m_14	88	100.00	P19656[S]	Zea mays	Go
2	AL	al_Pru_d_3	10	11.36	P82534[S]	Prunus domestica	Go
3	WI	wi_Cit_s_3.0102	4	4.55	CAH03799[N]	Citrus sinensis	Go
4	AL	al_Mal_d_3	4	4.55	Q9M5X7[S]	Malus domestica	Go
5	WI	wi_Fra_a_3.0101	3	3.41	CAC86258[N]	Fragaria x ananassa	Go
6	SP	sp_Pyr_c_3	3	3.41	Q9M5X6[S]	Pyrus communis	Go
7	WI	wi_Fra_a_3.0203	2	2.27	AAY83343[N]	Fragaria x ananassa	Go

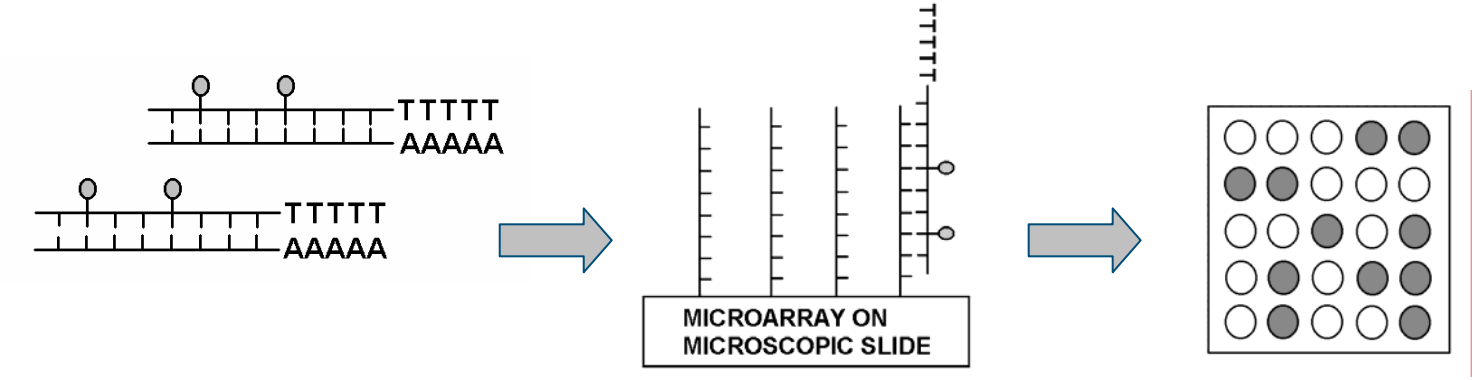
Safety assessment

Example: detailed information for allergen Pru d 3



Research on GM food safety

mRNA profiling with microarrays



Synthesize cDNA from mRNA | **Hybridize to microarray** | **Hybridization pattern**

Tomato gene expression during the subsequent stages

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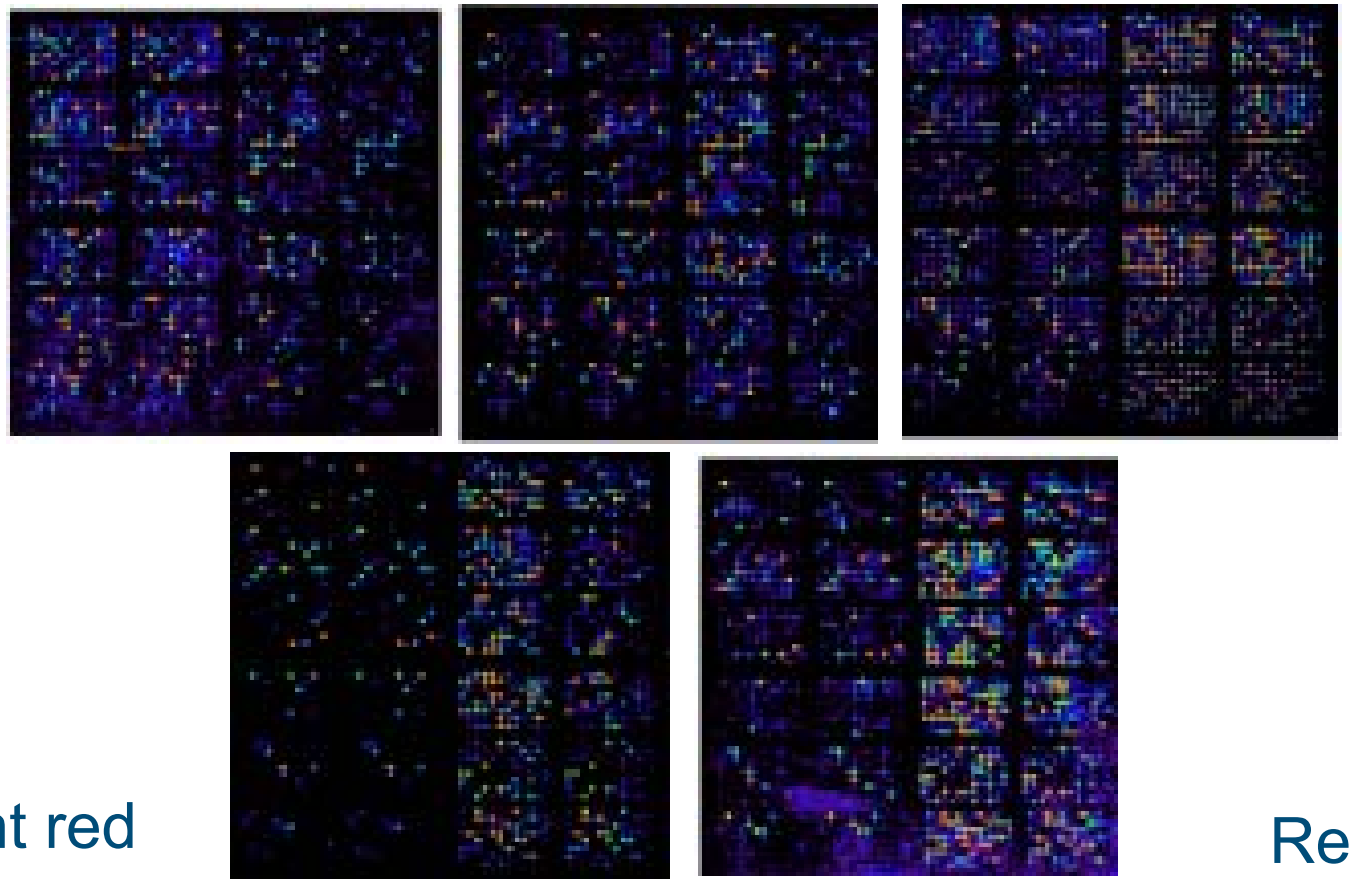
Tomato illustration: E. Kok, MSc

Research on GM food safety

Microarray analysis of tomato development

Green Breaker Turning



Light red

Red

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Illustration: E. Kok, MSc

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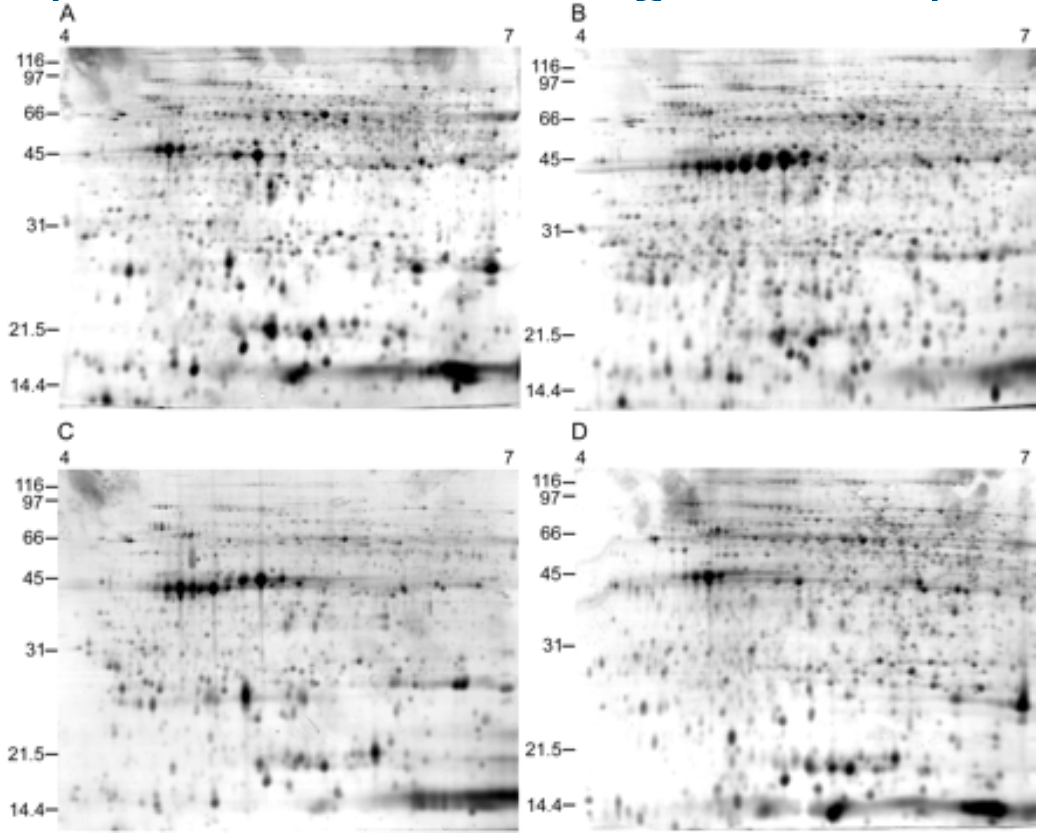
Potato proteomics with 2-D gel electrophoresis

Cv. Désirée



Cv. Maris Piper

Landrace

S. phureja

Lehesranta et al. (2005) Plant Physiology 138:1690-1699

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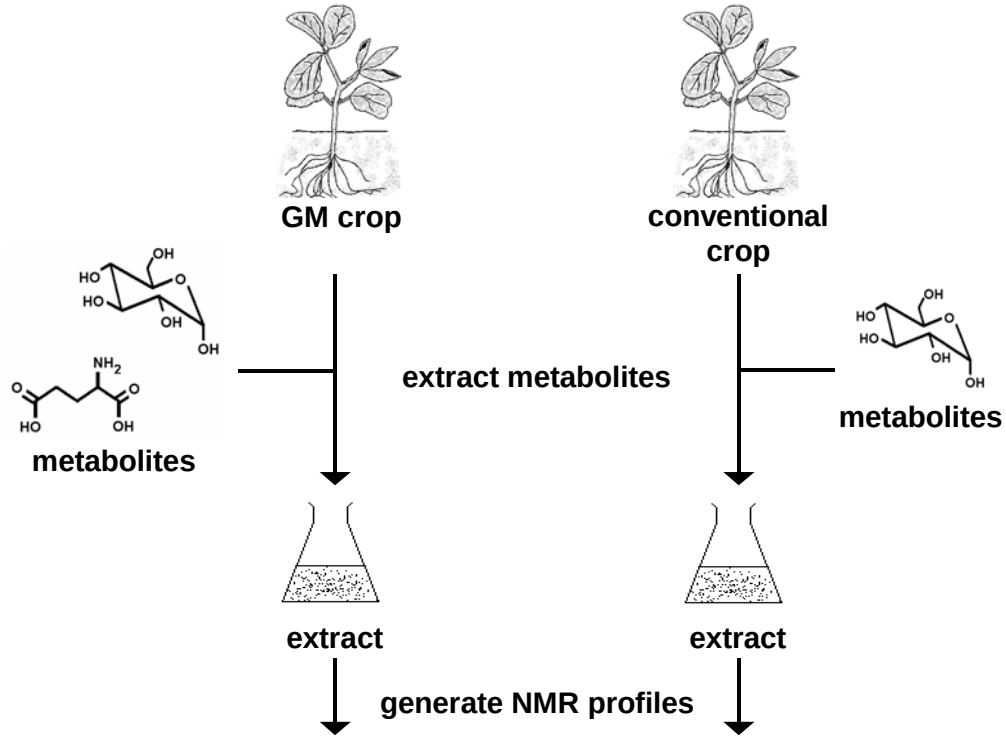
Profiling using liquid-chromatography coupled to nuclear magnetic resonance (LC-NMR)



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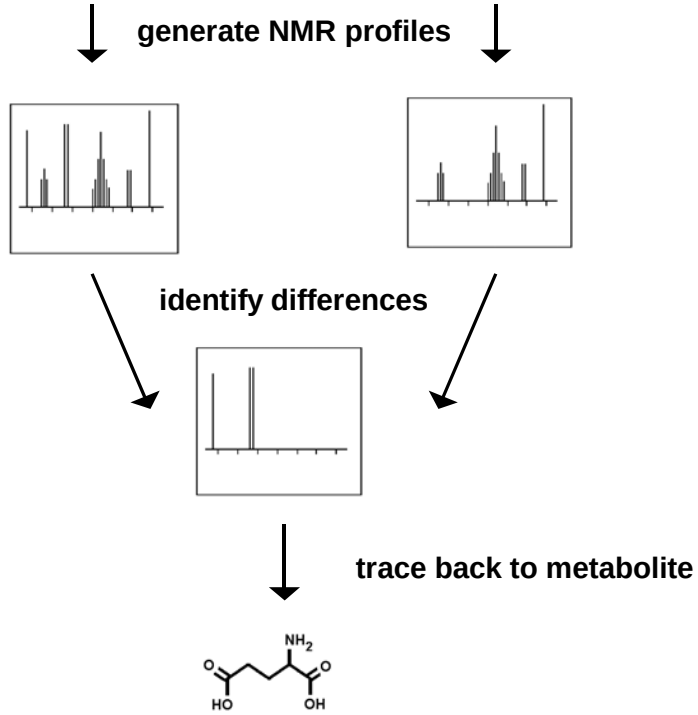
Profiling using LC-NMR (continued)



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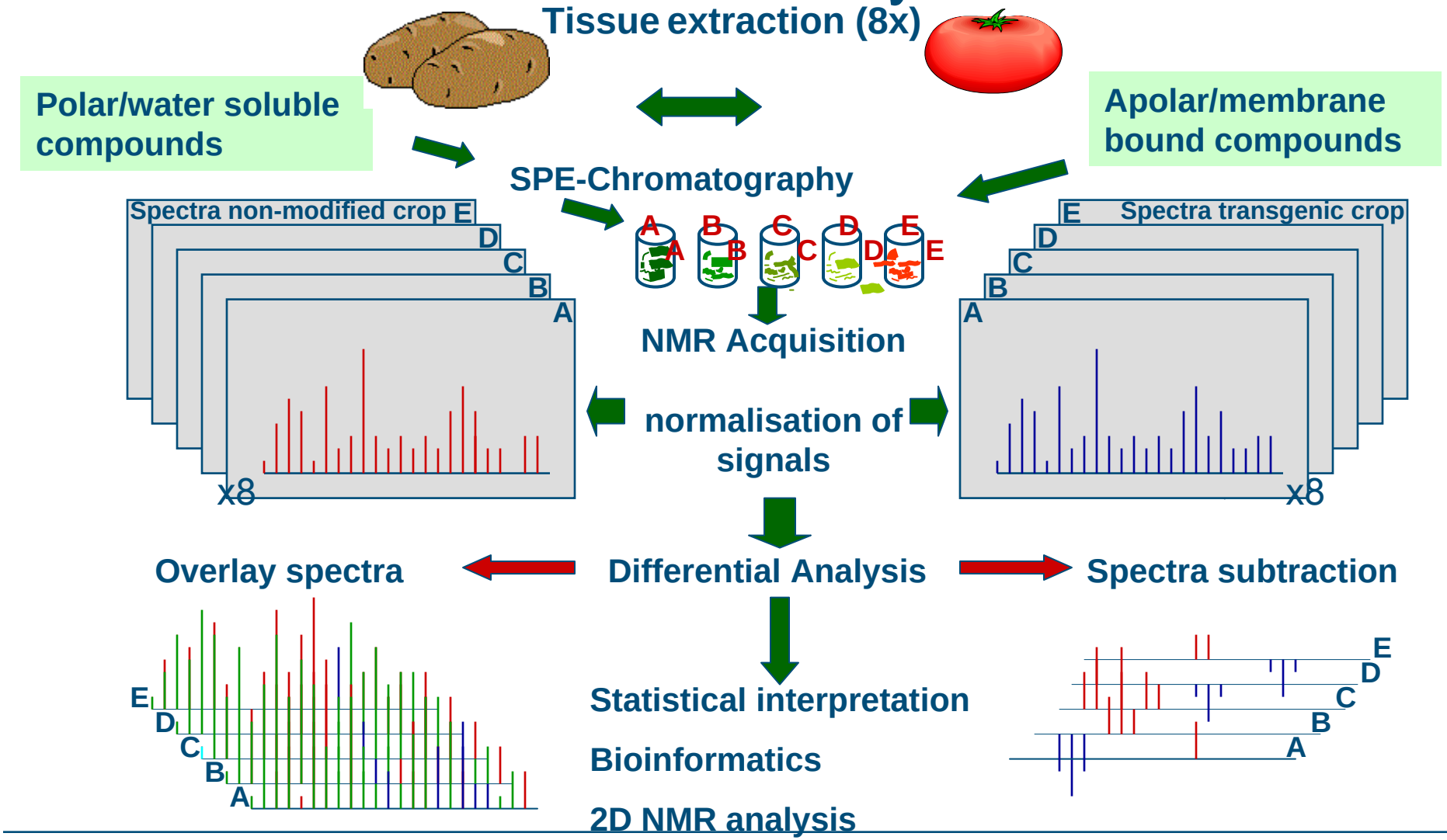

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Illustration: Dr. Noteborn

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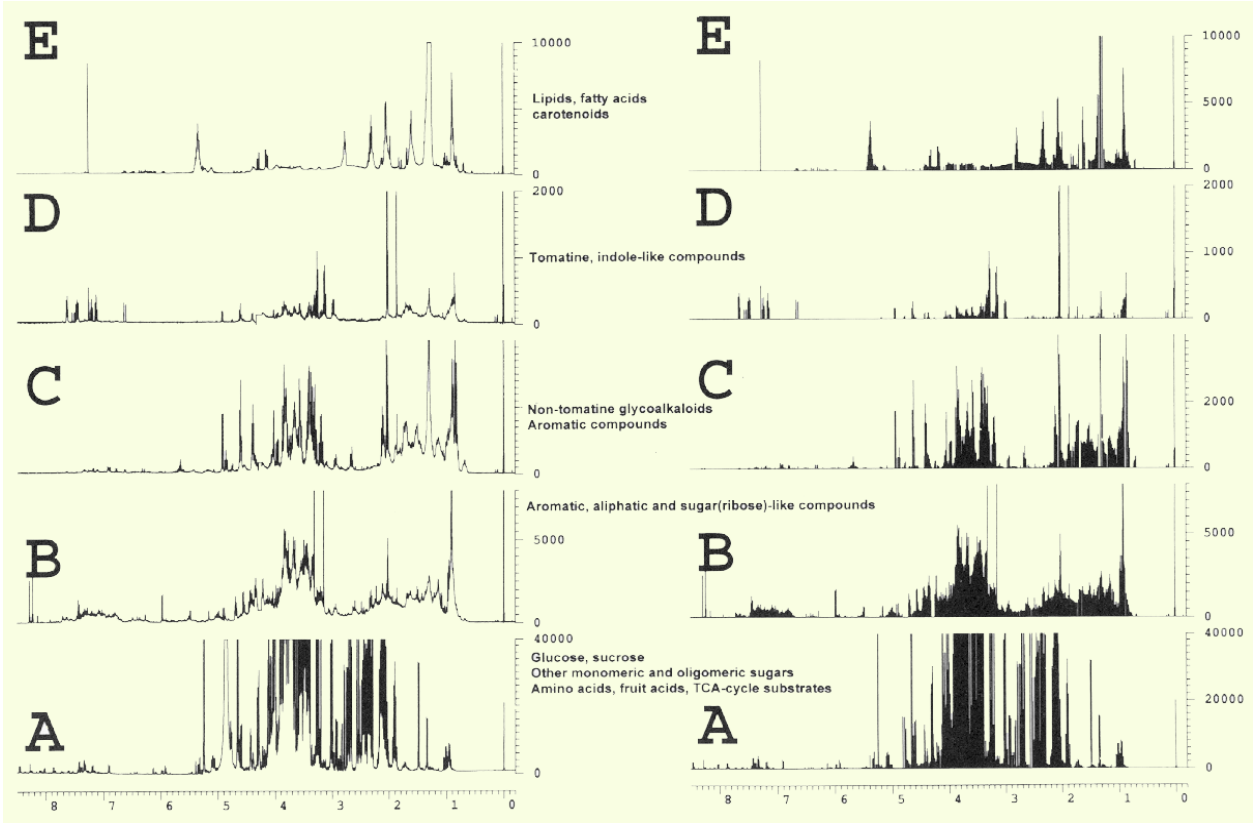
Chemical fingerprinting with NMR



Antisense-exogalactanase RNA tomato (URL);
Noteborn et al. J. Biotechnology 77 (2000): 103-114

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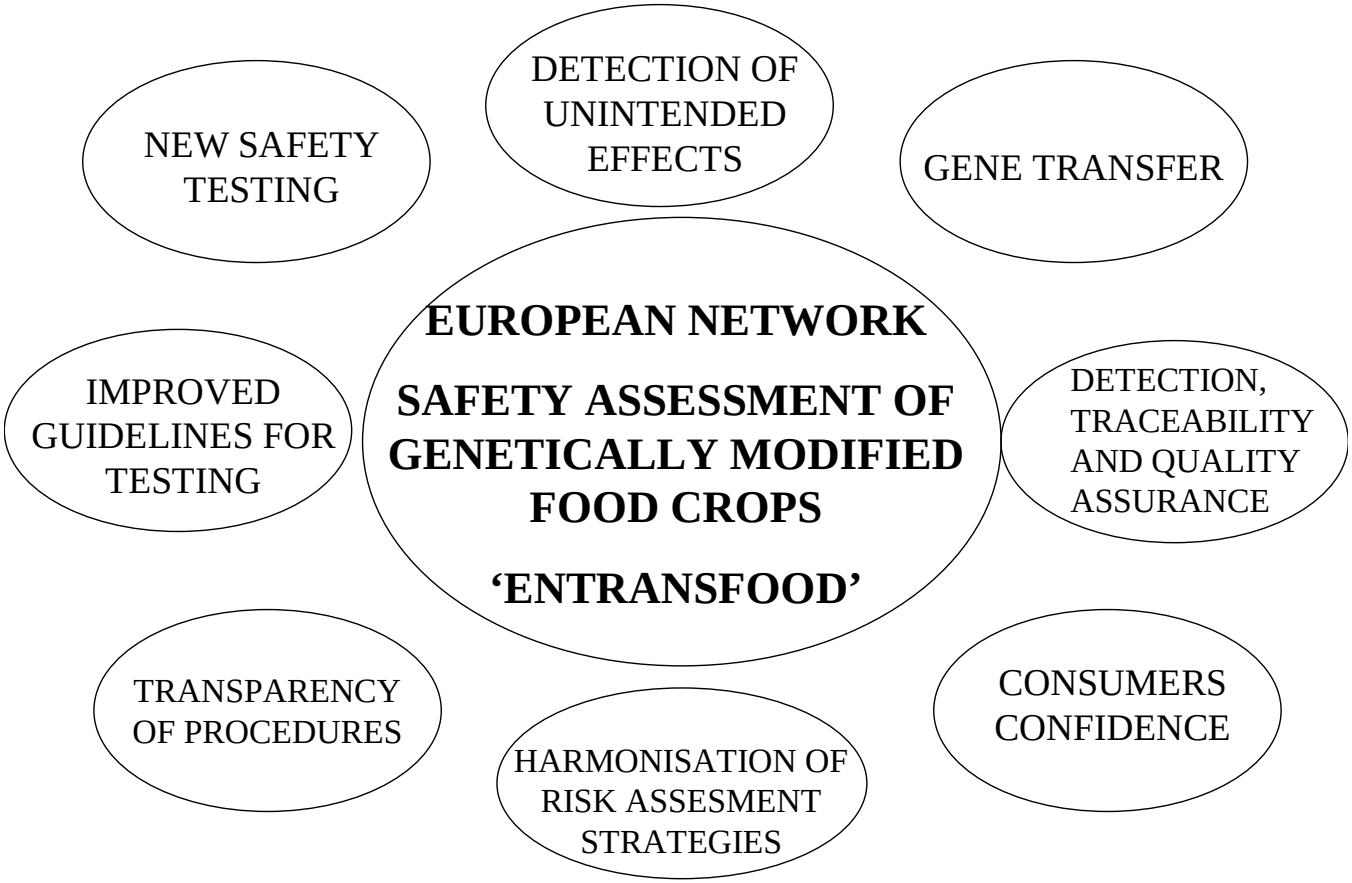
ENTRANSFOOD (www.entransfood.com)



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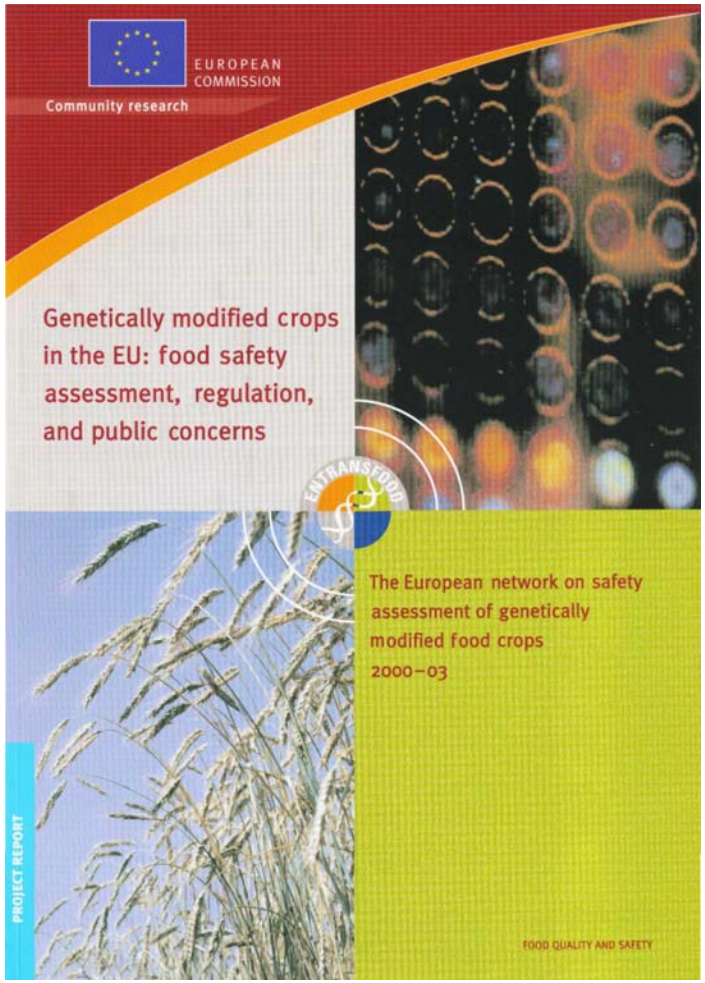
ENTRANSFOOD

Overarching report



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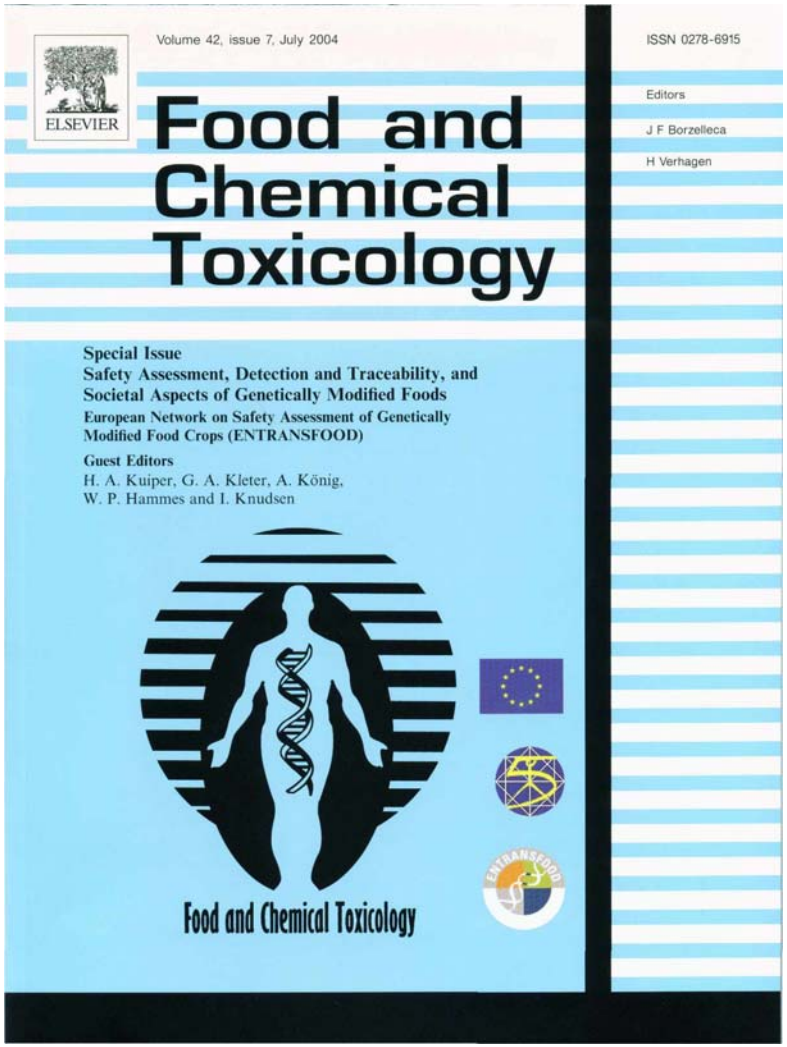
ENTRANSFOOD

Special issue Food and Chemical Toxicology



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SAFE FOODS (www.safefoods.nl)

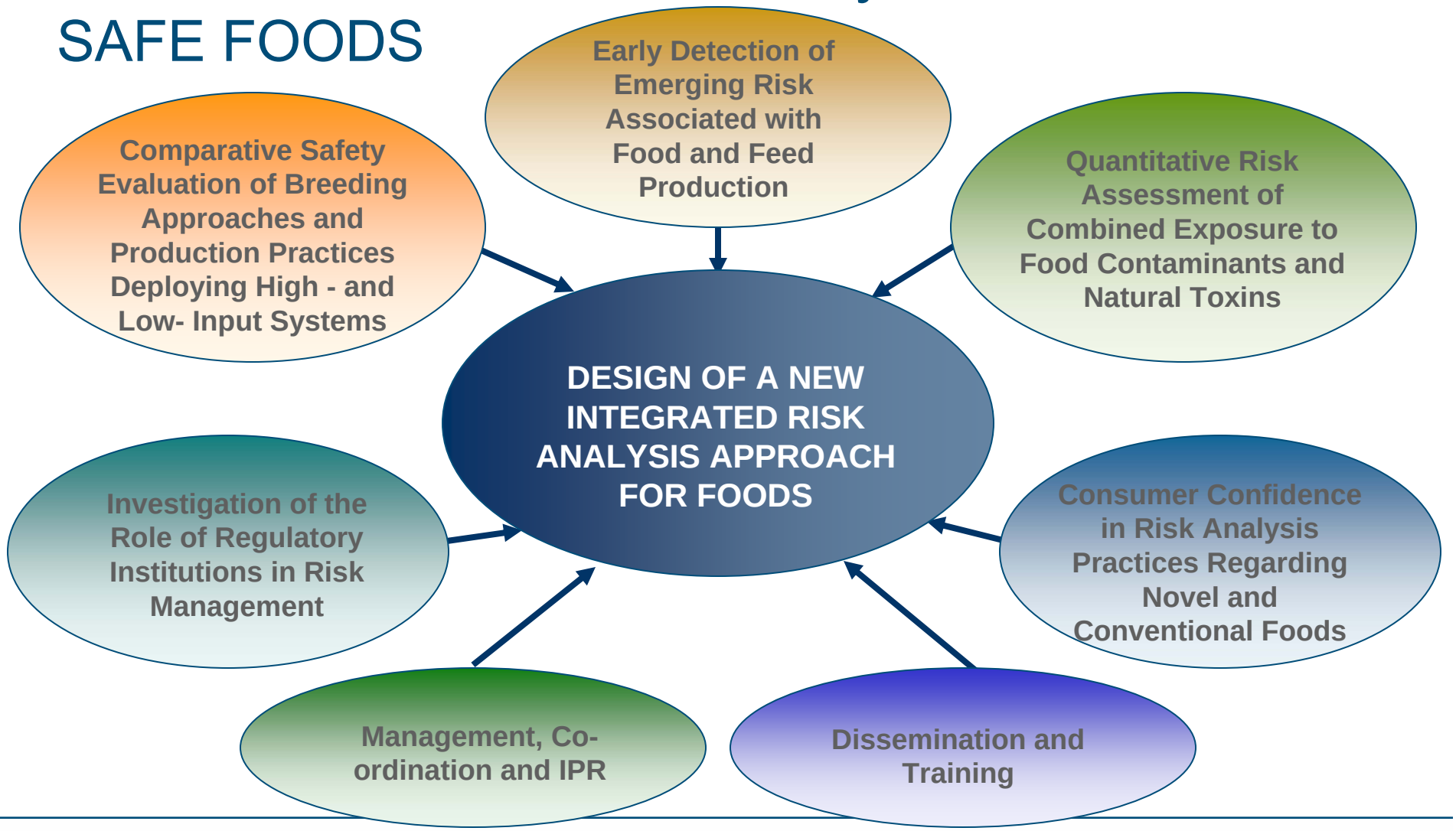
- "This Integrated Project addresses the issue of how consumer confidence in consumer protection and risk analysis can be restored and strengthened.“
- Four-year project
- Kick-off meeting in May 2004

Illustration:

S. Bauer/ARS/K7242-20

Research on GM food safety

SAFE FOODS



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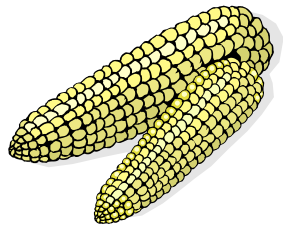
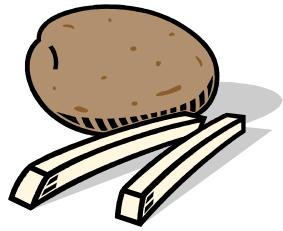
Research on GM food safety

SAFE FOODS Work Package 1

- Comparative evaluation of crops derived through different breeding practices and cultivated according to different agricultural practices
- Potato and maize
- Europe, Africa, and Asia
- Advanced profiling techniques
- Database on natural variation





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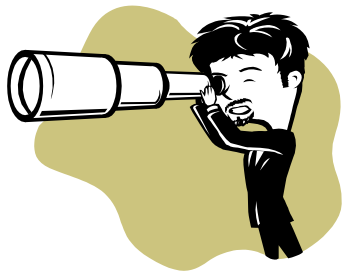
SAFE FOODS Work Package 2

- Emerging risks in the food and feed chain, high- or low-input agriculture
- Microbiological risks, mycotoxins and other chemical risks
- Framework for early risk identification
- Experts database
- Reviews and recommendations
- Training



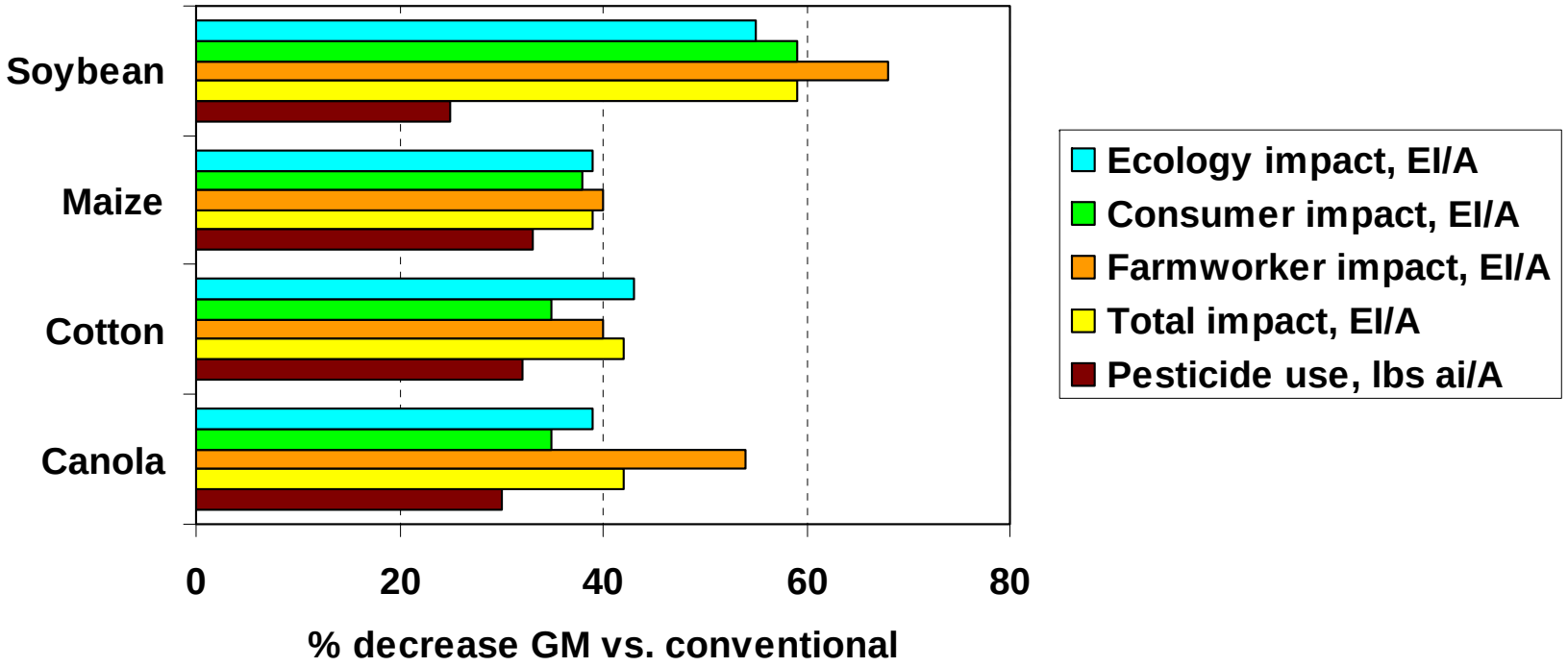
Research on GM food safety

IUPAC Project on impact of pesticides used on GM crops

- Collect data on pesticide use
  - Various surveys, *e.g.* USDA, NCFAP
  - In general, decreased pesticide usage
- Predict environmental impact
  - Indicators such as EIQ
  - Apparent overall decrease in impact
- Consider risks and benefits

Research on GM food safety

IUPAC project: EIQ-methodology applied to HR crops in the US, 2004 (NCFAP data), % change



Conclusions

The new properties of GM crops that are currently on the market are mainly intended for agriculture

The safety assessment of GM foods and feed is based on harmonized international consensus

Research is done on advanced methods for the safety assessment of future crops (GM and conventional)

Acknowledgement

The contributions with materials on profiling of GM crops by the following persons are gratefully acknowledged:

Mrs. E.J. Kok, MSc (tomato microarray)

Dr. H.P.J.M. Noteborn (metabolomics)

Thank you for your attention

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