A future task in good hands

Federal Agency for Nature Conservation

GMO Risk Assessment - EU experiences and recent developments

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Prologue

The German Federal Agency for Nature Conservation (BfN)

Central scientific authority of the German federal government for national and international nature conservation and landscape management.

Regulatory tasks

- Evaluation and performance of environmental risk assessment
- Evaluation and development of monitoring plans
- Evaluation of monitoring data

one of the Competent authorities (CAs) under the German Genetic Engineering Act concerned with the regulation of genetically modified organisms on national and EU level – lead authority Federal Office for consumer protection an food safety

Prologue

The German Federal Agency for Nature Conservation (BfN)

GMO-related scientific and collaborative tasks:

- Advancement of scientific tools for the environmental risk assessment
- Development of scientific concepts and advancement of methods for the monitoring of GMOs
- Deliver scientific expertise and advise to the Ministry and the Federal States
- Cooperation with national and international research institutions

Topics of this presentation

- Cultivation in Europe – applications and pipeline
- The current practice of environmental risk assessment
- Two current examples - MON 89034 x 88017 and MON 87460
- The LLP project
- Conclusions

Planned Maize Cultivation in Europe

Maize events applied for cultivation in Europe

Monsanto	YieldGard	MON810	Insect resistance (corn borer, lepidopterans)
Monsanto	Roundup Ready	NK603	Herbicide tolerance (to glyphosate)
Stack		NK603xMON810	
Stack		NK 603xMON 89034	
Monsanto	YieldGard VT	MON88017 *	Insect resistance (to coleopterans)
Stack		MON88017xMON 89034	
Dow AgroSciences Pioneer Hi-Bred,	Herculex I	1507	Insect resistance (to lepidopterans)
Dow AgroSciences Pioneer Hi-Bred	Herculex	RW 59122	Insect resistence (to coleopterans)
Stack		59122x1507	
Stack		59177x1507xNK603	
Syngenta	Agrisure GT	GA21	Herbicide tolerance (to glyphosate)
Bayer CropScience		T25	Herbicide tolerance (to glufosinate)

Stein & Rodriguez-Cerezo, JRC, 2009

GM maize pipeline

Maize events authorised in at least one country but not yet commercialised in Europe

Monsanto	YieldGard VT PRO	MON89034 *	Insect resistance (to lepidopterans)
Monsanto	High lysine	LY038 *	Crop composition (high lysine content)
Syngenta	n/a	3272 *	Crop composition (amylase content)
Syngenta	Agrisure	MIR604 *	Insect resistance (to coleopterans)

Stein & Rodriguez-Cerezo, JRC, 2009

GM maize pipeline

GM maize in the advanced R&D pipeline worldwide

Monsanto 2010	n/a	MON87754	Crop composition (high oleic content)
Pioneer Hi-Bred 2010	Optimum AcreMax 1	n/a	Insect resistance (to coleopterans)
Monsanto and BASF 2012	n/a	MON87460	Abiotic stress tolerance (to drought)
Dow AgroSciences 2012	DHT	n/a	Herbicide tolerance
n/a (India) 2014	n/a	cry1Ac + cp4epsp4	Insect resistance herbicide tolerance
Syngenta 2015	n/a	n/a	Abiotic stress tolerance (to drought)
BASF Plant Science 2015	NutriDense	n/a	Crop composition (protein, amino acid and phytase content)

Stein & Rodriguez-Cerezo, JRC, 2009

Soybean commercialisation

Commercialised soybean events in at least one country

Monsanto	RoundupReady	MON 40-3-2	Herbicide tolerance (to glyphosate)
Monsanto	RoundupReady 2	MON89788	Herbicide tolerance (to glyphosate)
Bayer CropScience	LibertyLink	A2704-12	Herbicide tolerance (to glufosinate)
Bayer CropScience	LibertyLink	A5547-127 *	Herbicide tolerance (to glufosinate)
Pioneer Hi-Bred	Optimum GAT	356043 *	Herbicide tolerance (to ALS inhibitors and glyphosate)

Stein & Rodriguez-Cerezo, JRC, 2009

Soybean pipeline

GM soybeans in the advanced R&D pipeline worldwide

Syngenta 2011	n/a	n/a	Nematode resistance
Monsanto 2012	Omega-3	MON87769	Crop composition (stearidonic acid content)
Monsanto 2012	n/a	n/a	Herbicide tolerance (to dicamba)
Monsanto 2013	n/a	n/a	Insect resistance and herbicide tolerance (to glyphosate)
Dow AgroSciences 2013	DHT	n/a	Herbicide tolerance
Monsanto 2014	Vistive III	MON87754	Crop composition (high oleic content)
Syngenta 2014	n/a	n/a	Herbicide tolerance (to HPPD inhibitors)
Bayer CropScience 2015	n/a	n/a	Herbicide tolerance (to HPPD and glyphosate)
Bayer CropScience 2015	n/a	n/a	Herbicide tolerance (to HPPD and glufosinate)

Stein & Rodriguez-Cerezo, JRC, 2009

Pipeline characteristics

New herbicide resistence, further stacking, some crop composition traits

New Herbicide Traits:

Dicamba – mimics naturally occuring plant hormones (auxins), destroys tissue through uncontrolled cell division and growth

DHT – Dow AgroSciences Herbicide Traits, confer resistence to 2,4 D and „fop“herbicides

fop herbicides are aryloxyphenoxypropionate ‘fop’ grass herbicides

HPPD inhibitors – Hydroxyphenylpyruvate deoxygenase inhibitor, HPPD is important for tyrosine catabolism, tyrosine is important for protein building and plays an important role in photosynthesis

ALS inhibitors – Acetolactate synthase inhibitors

Current Practice of Environmental Risk Assessment

http://www.bfn.de/0502_gentechnik.html?&no_cache=1

STANDARDISING THE ENVIRONMENTAL RISK ASSESSMENT OF GENETICALLY MODIFIED PLANTS IN THE EU

Marion Dolezel
Marianne Miklau
Michael Eckerstorfer
Angelika Hilbeck
Andreas Heissenberger
Helmut Gaugitsch

Federal Agency for Nature Conservation

BfN – Skripten 259

2009

Federal Agency for Nature Conservation

The Current Practice of Environmental Risk Assessment

Main Shortcomings

- Focusing on the transgene and not on the GMO as a whole
- Transgene product testing mainly when pesticidal properties – derived from a bacterial production source
- No tests on equivalence for the bacterial derived product and the GMO produced transgene product
- No description and integration of relevant aspects of representative receiving environments
- No adequate exposure analysis
- No or unsufficient integration of NTOs from

The Current Practice of Environmental Risk Assessment

Main Shortcomings

- Pooling of data from field trials over several locations
- Data from one or maximal 2 vegetation periods only
- Plot size often not adequate
- No meaningful statistical evaluation
- No integration of species of conservation concern
- Toxicological assessment unsufficient

A current example
MON 89034 x MON 88017

Traits and Scope of the Application

Traits:

Cry 1A.105 + Cry 2Ab2 = 89034

Cry 3Bb1 + epsps (glyphosate-resistence) = 88017

Scope

Cultivation of MON 89034 x MON 88017

Seed production of MON 89034

A current example
MON 87460

Drought tolerance

Expresses prokaryotic CspB - cold shock protein

Contains npt II

Action very unspecific – mode of action how drought tolerance is achieved not understood

Binds to single stranded RNA – influences expression of proteins by stabilizing the mRNA for translation

several provided studies used test, control or reference material contaminated with MON 87460 or maize NK 603

Low Level Presence – the Dimension

"But as soon as a GMO is cultivated in a country that is exporting to the EU, even on a small scale, the repercussions can be big: for instance in the case of Herculex, the corresponding GM maize was grown on only one percent of the total maize acreage in the USA, but in approximately two thirds of all samples tested subsequently,traces of Herculex maize were found (Toepfer 2008)."

Stein & Rodriguez-Cerezo, JRC, 2009

Conclusions

- There is need of improvement of the RA on the conceptual and methodological side
- Receiving environments and especially protected areas and species of conservation concern need more attention
- Comparators and comparisons are of growing importance and difficulties
- Stacked genes and traits need new consideration - concerning i.a. different numbers of stacks and segregation patterns
- There is growing evidence of contaminated controls and test substances – what is the impact on the validity of data in the RA?

A future task in good hands

Thank you very much for your kind attention!

Dr. Beatrix Tappeser

Federal Agency for Nature Conservation, Germany

Division II 3.3

GMO-Regulation, Biosafety

http://www.bfn.de/0301_gentechnik.html