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EFSA meeting summary report

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EFSA AND GMO RISK ASSESSMENT FOR HUMAN AND ANIMAL HEALTH AND THE ENVIRONMENT

14-15 September 2009, Brussels, Belgium

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The views or positions expressed in this booklet reflect the views and positions expressed in the context of the GMO Conference [14-15 September 2009, Brussels] and do not necessarily represent in legal terms the official position of the European Food Safety Authority. The European Food Safety Authority assumes no responsibility or liability for any errors or inaccuracies that may appear. As announced during the conference, a booklet describing the proceedings during the conference is hereby published. The views and positions expressed in this booklet were summarized according to the minutes recorded.

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About EFSA

The European Food Safety Authority (EFSA) was established and funded by the European Community as an independent agency in 2002 following a series of food crises that caused the European public to voice concerns about food safety and the ability of regulatory authorities to fully protect consumers.

In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides objective scientific advice on all matters with a direct or indirect impact on food and feed safety, including animal health and welfare and plant protection. EFSA is also consulted on nutrition in relation to Community legislation.

EFSA's work falls into two areas: risk assessment and risk communication. In particular, EFSA's risk assessments provide risk managers (EU institutions with political accountability, i.e. the European Commission, European Parliament and Council) with a sound scientific basis for defining policy-driven legislative or regulatory measures required to ensure a high level of consumer protection with regard to food and feed safety.

EFSA communicates to the public in an open and transparent way on all matters within its remit.

Collection and analysis of scientific data, identification of emerging risks and scientific support to the Commission, particularly in case of a food crisis, are also part of EFSA's mandate, as laid down in the founding Regulation (EC) No 178/2002 of 28 January 2002.

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PREFACE

The European Food Safety Authority is tasked with providing a robust scientific basis for decision makers to help protect consumers from risks in the food chain in Europe. Our most critical commitment is to provide independent, evidence-based advice and clear communications, grounded in the most up-to-date scientific information and guided by the principles of scientific excellence, transparency, openness and responsiveness.

In the field of GMOs, EFSA serves the European Union mainly by providing independent scientific risk assessments on new GMO applications and renewals of existing authorisations for the use of GMOs in the internal market. The Authority has developed a range of Guidance Documents to describe its approach to risk assessments, define data requirements for applicants and generally provide guidance on the application process. These documents, which are subject to public consultation, are regularly updated to reflect the current state of scientific knowledge.

In delivering its scientific advice, EFSA pursues an active policy of consultation with stakeholders and interested parties. Through the regulatory framework, the competent authorities in Member States are engaged in the evaluation process. Consultation is particularly important in fields such as GMOs where there are differing views and where the scope of EFSA's mandates extends beyond the traditional remit of food safety to include, for example, environmental risk assessment. It is crucially important that EFSA clearly describes its role in the assessment of new technologies, strengthens its understanding of consumer perception of risk and builds its dialogue with stakeholders.

This EFSA conference therefore had a dual purpose: (i) to describe and discuss the roles and responsibilities of EFSA, Member States and the European Commission in the GMO risk assessment process; and (ii) to hear the views and experiences of key stakeholders in the GMO field.

Over 150 participants attended the event. This included national experts, representatives from stakeholder and NGO organisations, from public authorities, and from international and non-EU organisations.

The engaging discussions and constructive comments from all participants helped create a truly successful conference. I would like to warmly thank all speakers, the Chairs, the audience for supporting the event, and of course, the staff at EFSA that organised this event both on the day and those behind the scenes in Parma. The discussions during these two days will feed any future initiatives of the Authority.

Catherine Geslain-Lanéelle
Executive Director

I INTRODUCTION

GMO Risk Assessment - working in cooperation

The Panel on Genetically Modified Organisms (GMOs) was established in 2003 to provide independent scientific advice on the safety of GMOs (such as plants, animals and micro-organisms) and GM food and feed for humans, animals and the environment. The EFSA GMO Panel, composed of 21 internationally recognised scientists with a broad range of expertise, carries out its work either in response to requests for scientific advice from risk managers or on its own initiative. Several Working Groups involving some 50 external scientists with relevant expertise support the EFSA GMO Panel in the production of scientific opinions. The EFSA GMO Panel meets regularly in plenary sessions to discuss work in progress and to adopt finalised scientific opinions. The EFSA GMO Unit, composed of 25 staff members (scientists, administrators and assistants), provides scientific, administrative and managerial support to the activities of the EFSA GMO Panel. The GMO Unit also contributes to the efficient and transparent communication of scientific aspects related to the risk assessment of GMOs and GM food and feed to risk managers, stakeholders and the general public.

The main fields of activity are:

- **Risk assessment of GM food and feed applications**. The EFSA GMO Panel assesses the safety of GM food and feed and their derived products submitted for authorisation in the EU under Regulation (EC) No 1829/2003 and Directive 2001/18/EC. The outputs of the EFSA GMO Panel are scientific opinions which support the European Commission and Member States when taking decisions on the authorisation of GMOs in the EU.
- **Development of guidance documents.** A crucial part of the EFSA GMO Panel's remit is the development of guidance documents to present its approach to risk assessment and to provide notifiers with clear guidelines for the preparation and presentation of applications. The EFSA GMO Panel can work on its own initiative, when it identifies scientific issues that require further investigation ("self-tasks") and it can produce opinions on these. Often, the subjects of self-tasks are related to the development of guidance documents (e.g. GM plants used for non-food, non-feed purposes, statistical considerations, allergenicity of GM plants).

- **Scientific advice in response to ad-hoc requests from risk managers.** The EFSA GMO Panel also provides scientific advice on requests from the European Commission; for example, in cases of presence of an unauthorised GMO in the EU and in relation to national Safeguard Clauses submitted by Member States as grounds for banning certain GM products on their territory.

- **Dialogue and interaction with Member States.** EFSA works with Member States on safety issues related to GMOs and GM food and feed. During the GMO risk assessment process, Member States experts can comment and give input on all application dossiers via GMO EXTRAnet, a secure IT platform, and each comment is regarded and answered in Annex G of the opinions. Moreover, EFSA's GMO Panel and Member State experts discuss and exchange views both on general principles of risk assessment and on specific topics related to the safety of individual GMOs. They do so in dedicated meetings through EFSA's Advisory Forum, for example in the context of Safeguard Clauses, or – starting from 2010 – in the frame of the new EFSA Scientific Network for Risk Assessment of GMOs.

- **Dialogue and interaction with stakeholders.** EFSA organises meetings to bring together risk assessors from Member States, risk managers, and representatives from stakeholders, including industry, consumer and environmental groups from the EU and beyond. In addition, dedicated meetings with NGOs active in the field of GMOs or with applicants are organised on a regular basis.

- **Communication to the general public.** EFSA aims to provide appropriate, consistent, accurate and timely communications on its scientific work, including that on GMOs, to all stakeholders and the general public. All EFSA scientific outputs are published on the EFSA website. In addition, EFSA seeks to raise awareness and further explain the implications of its work through press releases, press briefings, web communications, newsletters and other tools.
  During the elaboration of its guidance documents, EFSA makes these available in draft for public consultation, through which anyone can provide scientific input and comments. All comments received are considered by the EFSA GMO Panel when preparing the final guidance documents.

- **International activities**. EFSA's risk assessment guidelines are in line with internationally agreed principles and standards such as those indicated by OECD, *Codex Alimentarius* and FAO/WHO. Therefore, building bridges between international institutions with interest in the risk assessment of GMOs is part of EFSA's international strategy. This approach is also reflected in the fact that experts from other organisations (EMEA, ECDC) participate in EFSA's GMO Panel Working groups, and by cooperation at institutional level (JRC, ICGEB, FDA) in areas of common interest.

OECD Organisation for Economic Co-operation and Development

FAO/WHO Food and Agriculture Organization of the United Nations/World Health Organization

EMEA European Medicines Agency

ECDC European Centre for Disease Prevention and Control

JRC Joint Research Centre

ICGEB International Centre for Genetic Engineering and Biotechnology

FDA US Food and Drug Administration

II WELCOME BY CATHERINE GESLAIN-LANÉELLE, Executive Director of the European Food Safety Authority

Distinguished guests, colleagues, ladies and gentlemen

Introduction

I would like to welcome you to Brussels for this European conference on the risk assessment of GMOs. Today's event provides a valuable opportunity to bring together a broad range of expertise and a wide representation of interests in GMOs and I must say it is very encouraging to see that so many of you have accepted our invitation to what I hope will be a stimulating and informative event. We are very honoured and privileged to have such a strong panel of speakers for the next two days. They bring a wide range of perspectives and experiences from across the sector which will no doubt enrich our understanding of the issues we face.

Similarly, it is very pleasing to that we have such a full and representative audience here today. I thank you very much for taking the time to participate, particularly our non-European guests who have travelled a long way to be here. A special word of thanks also to the two Directors-General of the European Commission: Robert Madelin, Director-General Health and Consumers, for his opening address, and Karl Falkenberg, Director-General Environment, who will address us tomorrow.

Background

EFSA was established as the EU's independent risk assessor in 2002. In relation to GMOs, our role is laid down by the EU regulatory framework and in particular in our Founding Regulation. EFSA's core task is to independently assess any possible risks of GMOs to human and animal health and the environment. Like all fields in which we operate, we are guided by the principles of independence, transparency and scientific excellence and we are committed to operating in the most open and inclusive manner that we can practically achieve. In relation to EFSA's role in this field, we should bear in mind that we cannot take decisions on authorisation. That is the remit of the risk manager.

Our experts act in an independent capacity to deliver our core mission of providing scientific advice to the risk managers. EFSA is neither pro- nor anti-GMO; our role is strictly limited to transparently providing scientific opinions on the basis of the scientific evidence.

Why are we here

Let me focus for a moment on our purpose here today and tomorrow. The field of GMOs is characterised by significant divergence in opinion among the various actors, low social acceptability and differing views on the potential benefits and beneficiaries of the technology. Like in other fields of EFSA's work there are remaining areas of scientific uncertainty which risk managers must take into account when taking their decisions. Our role is to clearly identify where the uncertainties lie, explain their significance and together with all interested parties, including the broader scientific community, work towards reducing these over time.

Frequently, we also find there is confusion on the role of EFSA in the authorisation process.

So first and foremost, this conference was conceived to clarify EFSA's role in the risk assessment of GMOs and I am joined today by a number of colleagues who will describe our processes and approaches in detail. We are also very pleased to have several members of our GMO Panel who will give their perspectives on risk assessment methodologies.

But we are here not only to inform but also to listen and learn. We want to get as wide a range of views and experiences as possible. We are aware that our published opinions in this field are not as accepted as in others and we are sensitive to the differing views in this complex field. That is why we continue to strengthen our engagement with all stakeholders. The process of authorisation of GMOs highlights the need for openness and inclusiveness both for risk assessors and risk managers and in EFSA we have taken several initiatives to address this.

Member States are intimately involved in the risk assessment process and their comments are addressed in a special annex to EFSA's scientific opinions. When a safeguard clause is invoked by a Member State, we meet with the Member State and their experts to discuss the scientific issues.

In May this year we convened a technical meeting with national experts to discuss scientific aspects of the risk assessment of maize MON810 and their input was very informative in the risk assessment of that particular GMO.

In recent years we have scheduled meetings with non-governmental organisations in Parma and these have proved to be a very useful platform to exchange views on scientific and procedural issues and the next one is scheduled for October 2. We also meet with applicants – industry – on an annual basis to ensure that they understand the guidance for preparing dossiers for GMO applications and to exchange views on procedural issues. We continually review and update our guidance for applicants to ensure that it reflects the latest scientific developments.

Another important tool that we use to engage stakeholders is public consultation. We have consulted with you on several GMO-related issues, for example recently in the context of the updates of our guidance document for the risk assessment of genetically modified plants and derived food and feed and also on guidance for statistical models for the analysis of the data from field trials, to mention but two examples.

The outcomes of those consultations have been taken into account during the finalisation of the scientific opinions.

Programme

The conference programme has been drawn up in the spirit of cooperation and dialogue. The first session has been designed to ensure that EFSA staff members involved in GMO risk assessment have an opportunity to provide a detailed description of their work. In addition, three members of the GMO Panel will give us their first-hand experience in GMO risk assessment. The first session provides two other crucial perspectives – that of a Member State – Austria, presenting its views on how to perform environmental risk assessment, and that of a risk manager, DG Environment, which will address the post-market environmental monitoring of GMOs.

The second session is devoted to environmental impact and we have striven to ensure broad representation from those with an interest in this field.

We are delighted to have speakers from the Organisation for Economic Cooperation and Development, the Joint Research Centre of the European Commission, Friends of the Earth, the European farmers association, Copa-Cogeca, the biotech industry and finally we will hear the views of a Member State – Spain – in relation to GM crop cultivation. At the end of each session, we have devoted time for discussion and I am confident that the debate will be lively and stimulating.

Conclusion

In conclusion, I would like to thank you once again for participating in this conference and I trust that we will all benefit from it. We in EFSA will certainly be mindful that we use the outcomes to guide our future initiatives.

I would now like to hand over to Robert Madelin for the opening address.

Thank you.

III OPENING ADDRESS BY ROBERT MADELIN, Director-General, DG Health and Consumers, European Commission

Ladies and Gentlemen

I'm very pleased to have this opportunity to address you, not as a scientist because I'm not, but as a risk manager and as a historian.

As a risk manager I can tell you as I wrote last week in "European Voice" that Europe badly needs a more stable consensus on the risks Europe accepts. It's clear that the absence of a risk consensus in Europe on any issue is an embarrassment for decision-making. And as a historian I can tell you, on the basis of my 5 years experience in the present job, that sound science structured as a primary feature of risk management as it is today in Europe has not proved, alone, able to deliver that consensus. It is therefore extraordinarily important that this audience, as scientists, advises those of us who are not how to do better. I think that this sort of work is central to the role of the Food Safety Authority and I very much welcome EFSA's initiative in calling this conference.

I wanted to say five or six things about, not GM risk assessment, but the broader context within which this conference's outcome can help to push Europe in the direction that we need.

Firstly, I think that scientific risk assessment as it is conducted today in Europe needs to be explained better, more patiently, and in more detail, to those who are outside the process. In the last couple of years the part of the Commission cooperating with the risk assessment agencies, has done two things to try to build towards that explanation. To enable the chairs of the risk assessment processes both within EFSA and within other similar European organisations to come together so that we can demonstrate that risk is not vertically segmented, that there is a coherent joined-up process of risk assessment across the policy areas in Europe. And to reach out from that risk assessment community to people like the new members of the new European Parliament. In December we will be having another of our so-called "risk assessment weeks" for people who are holding key positions in the Parliament can sit with risk assessors and risk managers again to try to establish a more coherent, more broadly shaped view of what risk is and what we're doing about it. So, that is really the first thing we need to do.

The second need, and this conference is a step in that direction, is to open up the conversation on risk assessment so that different voices come into the scientific process. Here we have as a proxy scientists working in different cities and fields talking to scientists working within the EFSA field. If you look at the debate about science and society, the most ambitious research papers would suggest that ultimately we'll need to go a step further and actually include the things that worry ordinary citizens in the mandates we give to risk assessment scientists. So, the mindset of risk assessment can be challenged and opened up by interaction with other voices without undermining the scientific nature of the process.

Thirdly, I think we need to bear in mind that these sorts of changes, this opening up and this explanatory process are global. So, the third point I will make is we have to take this sort of debate which, as the title says, is a European conference and embed it in global concerns about risk assessment and risk management and risk because the products and substances on which EFSA is delivering an opinion and advising are also in global trade. This Commission has begun that debate, in November 2008 in this room there was the first conference involving Transatlantic but also Asian and Latin American and African players on risk assessment because it is important as well that Europe not hold a parochial conversation on this, that we get input from others. Without in any way saying that Europe will be buying the lowest common denominator of views, we need to recognise that this is a global issue and that we need to work with our partners around the world to manage risk property.

Those are the first three points. The other three points are more aspirational.

First maybe we need to change the structure of risk management in Europe. You see this question even in the guidelines that President Barroso has presented in preparation for the mandate of the next Commission. I don't want to discuss that, but simply to note that the principles we have concerning subsidiarity in the treaty have to be aligned with political realities. For GM cultivation, this means that maybe the allocation of responsibilities needs to be revisited. My personal vision is that the question affects more risk management than risk assessment.

Secondly, I think it is intimately linked with that first issue; we clearly need political will such that whatever the decision is, it is taken quickly. We manage risks for our societies. We manage our societies so that they offer sustainable growth, jobs, environmental sustainability and function as a vehicle also for education and health, for European values. We cannot claim as Europe to have innovation first and foremost on our strategic agenda if item-by-item we fail to bring quickly to market, or decide to exclude from the market, the products of innovation. This is clearly not a theoretical argument about who does what, but a linked political question about whether we have a new structure, we can decide more quickly. For the risk manager, speed and decisiveness is the crucial challenge. I would say that is a reality check for the discussions we're going to be having over the next two days. What I would aspire to is not just an outcome that would make scientists feel more comfortable but one where scientists would feel more comfortable and we expect, as a result, decision taking could be more expedited.

Finally, incremental improvements. Many of the things I've said sound as if they are a long way from where you are today, from where EFSA is today. But actually I think that we have shown in the past between EFSA and SANCO and the companies of EuropaBio that we can change our processes within the current rules. Simply, for example, that we sit together more frequently, including with our colleagues from DG Environment; that we are working together to understand each other more. I would say incremental improvements made by the operators within the risk process are also crucial.

To conclude, this is the right sort of conversation to have in a period of transition, it's the most influential moment to have it, so I hope that the conclusions from this conference will be extremely clear. The spirit in which today's agenda opens up EFSA to other players in science across society is showing the right way to go.

Personally I expect much of this conference as of other conversations in the course of the autumn. I'm sure we can do better in future than in the past and I'm sure that the future Commission will echo the current Commission in saying we want to nurture modern biotechnology as a tool for European well-being and competitiveness. The only tricky bit is for you to tell us how to do it.

Thank you very much.

IV SCIENTIFIC SESSIONS

▶ Session 1:
GMOs: assessing the risks for human and animal health and the environment

Chair: Riitta Maijala, Director of Risk Assessment, EFSA

The first day opened with experts from EFSA's GMO Panel and the GMO Unit presenting the EU legal framework for GMOs and EFSA's updated guidelines on the risk assessment of GM plants. These updated guidelines are being developed at the request of the European Commission and are based on the latest scientific developments. Such specific, detailed guidelines ensure greater clarity for applicants regarding data requirements and a more harmonized and transparent risk assessment approach. In addition, an expert from Member State Austria presented its view on environmental risk assessment of GM plants. The topic of environmental monitoring of GM plants, even though a risk management issue, is linked to environmental risk assessment and was presented by a speaker from the European Commission Directorate General Environment. The European Commission (EC) and Member States are currently considering adoption of the updated food and feed section of the guidance as a new Regulation supporting the implementation of Regulation (EC) No 1829/2003.

EU Risk Assessment of GMOs – Roles of EFSA, Member States and European Commission

PER BERGMAN
GMO Unit, EFSA

Introduction:

Per Bergman, Head of the GMO Unit at EFSA, has previously performed research in genetics and plant breeding at the Swedish University of Agricultural Sciences and acted as advisor on GMO issues at Sweden's Ministry of Agriculture. As an introduction to the topic of the conference he presented the complex interplay between EFSA, Member States and European Commission in the risk assessment of GM plants.

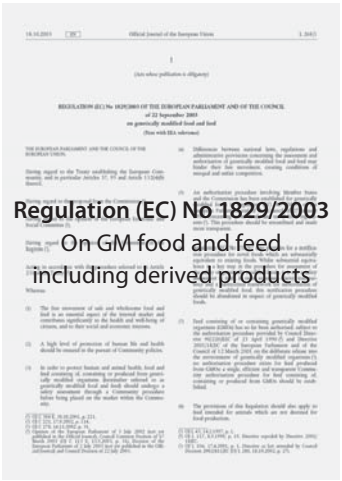
Presentation:

GMO regulation in EU

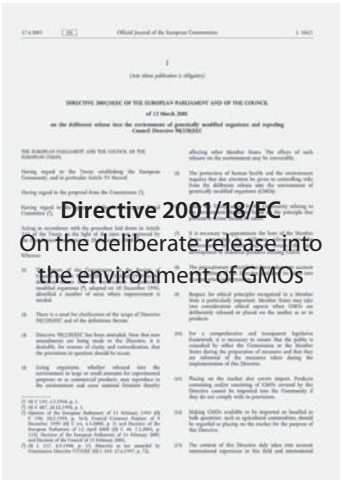
In the EU, products that are, contain, or are produced from GMOs must have an authorisation prior to entering the market

Legal framework for GMO risk assessment

- EFSA's role is to carry out scientific Risk Assessment on GMOs under two regulatory frameworks:



Regulation (EC) No 1829/2003
On GM food and feed including derived products



Directive 2001/18/EC
On the deliberate release into the environment of GMOs

- EFSA also provides independent scientific advice to risk managers

Mandate of EFSA GMO Panel

- **GMO Panel** delivers opinions through guidance documents, applications and scientific questions regarding genetically modified organisms
- **Plenary meetings** every 1,5 months for adoption of opinions
- European Commission are observers
- GMO Unit to give scientific and administrative support to the GMO Panel

The GMO Panel

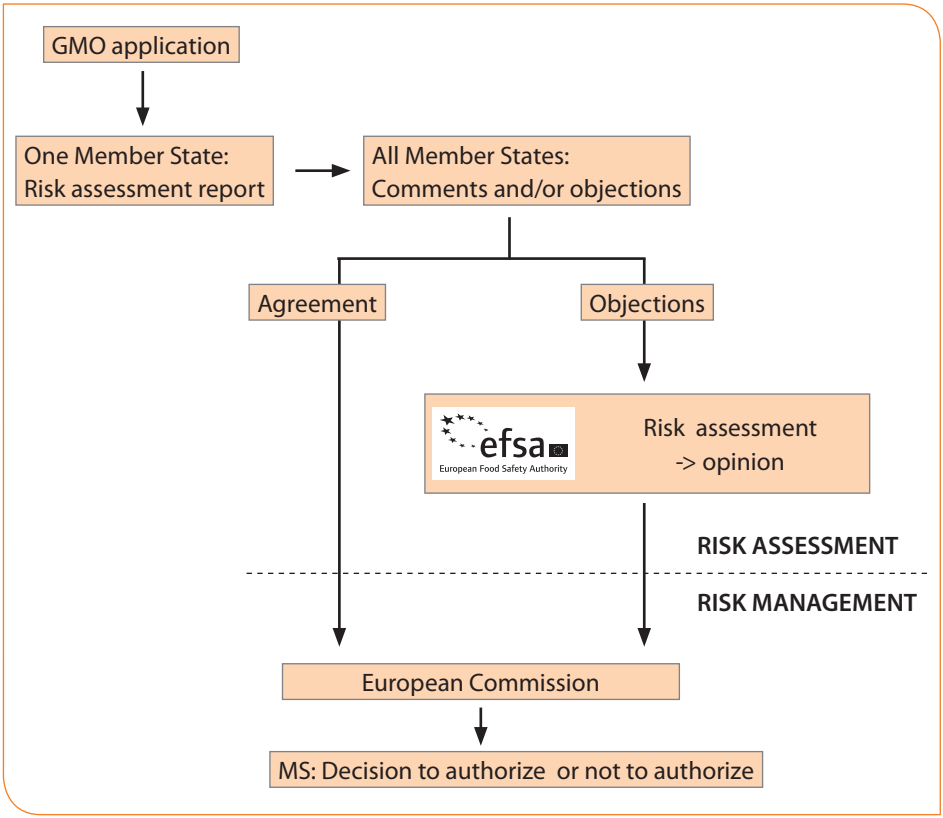
- Covering the necessary expertises
  - **For molecular characterisation**: biochemistry, food and environmental microbiology, soil microbiology, molecular biology, genetics, plant breeding
  - **For food feed safety**: toxicology, immunology, biotechnology, food chemistry, nutrition, animal feed
  - **For the environment**: ecology, plant biology, agronomy, entomology, biometrics and statistics
- Assisted by 40 *ad hoc* experts in working groups, representing expertise in e.g. for pesticides, natural toxins, environmental monitoring, food sciences, animal pathology

Role of EFSA in GMO authorisation process

- EFSA's scientific Opinions on GMOs are published on EFSA's website and forwarded to the European Commission and Member States
- It is the Risk managers who then take the decision to authorise a GMO or not

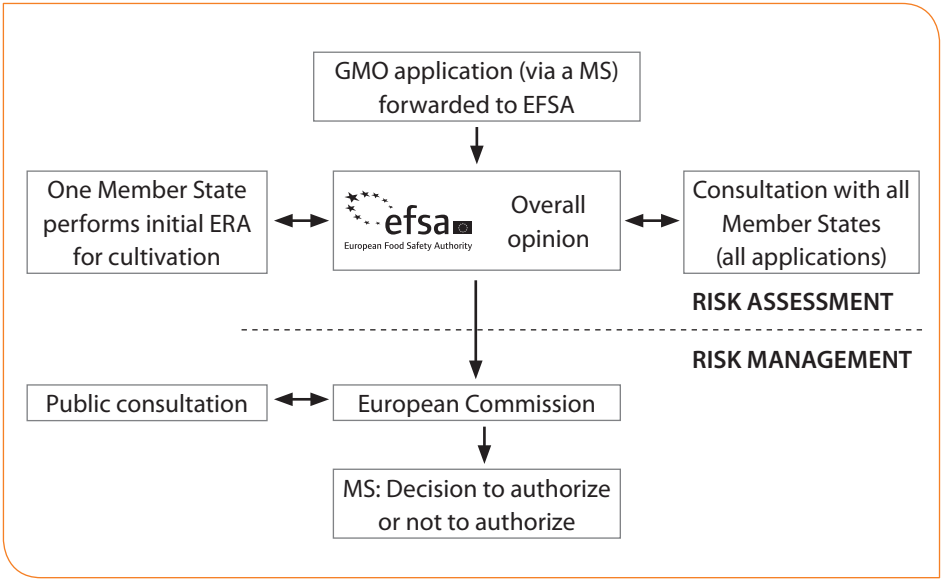
Roles under Directive 2001/18/EC

Member States perform risk assessment.
EFSA is consulted in case of divergence of opinion



Roles under Regulation (EC) No 1829/2003

Member States have access to all GMO applications and provide input through "EFSAnet". One member State performs the environmental risk assessment (ERA).



ERA under Regulation (EC) No 1829/2003

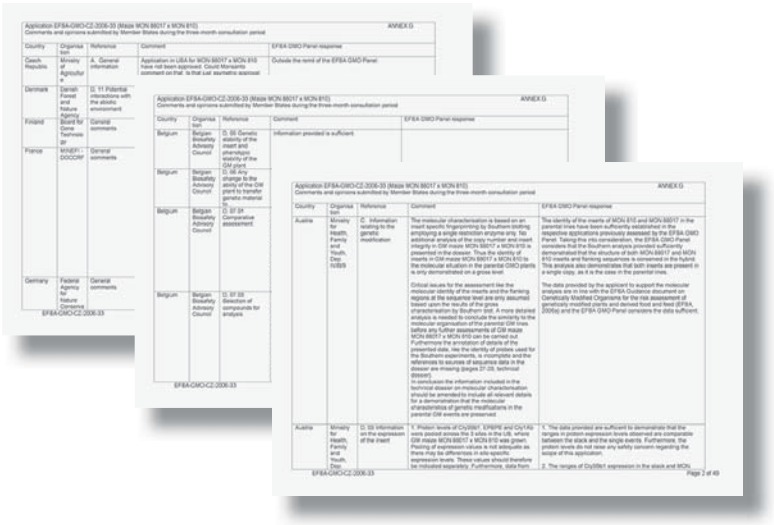
One MS performs initial ERA (cultivation dossier only)

If cultivation of GMO is applied for through Regulation 1829/2003 then Member States are asked to volunteer to carry out ERA

UK-2005-17	1507 x NK603 maize	Spain
NL-2005-22	NK603 maize	**Spain**
NL-2005-23	59122 maize	**The Netherlands**
NL-2005-24	40-3-2 soybean	**Germany**
NL-2005-26	MON810 x NK603 maize	Spain
NL-2005-28	1507 x 59122 maize	**The Netherlands**
UK-2006-30	59122 x1507 x NK603 maize	Belgium
NL-2007-46	T25 maize	UK
CZ-2008-54	MON88017 maize	Belgium
UK-2008-60	GA21 maize	Czech Republic
DE-2008-63	H7-1 sugarbeet	Germany
NL-2009-69	AV43-6-GT potato	Sweden
BE-2009-71	MON89034xMON8017 maize	Belgium
NL-2009-72	MON89034xNK603 maize	The Netherlands
RX-MON810 (20.a)	MON810 maize	**Spain**
RX-T25	T25 maize	UK

Member State input

Consultation with all Member States (all applications)



EFSA considers each and publishes all as part of each Opinion

Structure of the overall opinion

- EFSA shall publish an overall opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003
- List of annexes
  - Annex A: Scientific opinion of the GMO Panel (EFSA)
  - Annex B: Cartagena Protocol
  - Annex C: Labelling
  - Annex D1: Validation report (CRL)
  - Annex D2: Validated detection method (CRL)
  - Annex E: Certified reference materials
  - Annex F: Monitoring plan
  - Annex G: Member States comments

Published Guidance Documents for Risk Assessment

1. GM plants and derived food and feed (2006)
2. GM microorganisms and their derived products intended for food and feed use (2006)
3. Renewal of authorisations of existing GMO products (2006)
4. Post Market Environmental Monitoring – PMEM (2006)
5. GM plants containing stacked transformation events (2007)
6. Use of animal feeding trials for safety assessment of whole GM food/feed (2008)
7. Guidance for non-food/non-feed use of GM plants (2009)
8. Statistical considerations for the safety evaluation of GMOs (2009)

Submissions and opinions under Regulation (EC) No 1829/2003

	1829/2003 Application Submitted	1829/2003 Opinion Adopted
2003	-	-
2004	8	-
2005	20	6
2006	8	3
2007	38	5
2008	13	5
2009	12	15

Ongoing work on Guidance for Risk Assessment

- Further elaboration upon already published guidance
  1. Update on molecular characterisation and food and feed sections of guidance for GM plants and derived food and feed (EFSA update 2008, in support of new EC regulation)
  2. Update on ERA section of guidance for GM plants and derived food and feed (2010)
  3. Self task on allergenicity assessment of GM plants (2010)
- De novo guidance development
  1. Guidance on GM animals (2011)
     a. For import and processing - food and feed safety RA
     b. For Environmental release in Europe – ERA

Key messages

- EFSA performs public consultation on all guidance ensuring that views and experience are taken into account
- We aim to develop a shared understanding of the updated guidance that will support risk assessment
- GMO risk assessment work is done in close cooperation with Member States
- EFSA listens and learns, but cannot get drawn into wider debates

Development of EFSA's Food and Feed Guidance Document on GM plants

HOWARD DAVIES
EFSA GMO Panel

Introduction:

Howard Davies, a biochemist by background, is Director of Science Coordination at the Scottish Crop Research Institute (Dundee) and coordinates the Scottish Government's research programme on profitable and sustainable agriculture-plants. He is now in his third term as a member of EFSA's GMO Panel. His talk focused on the update of the Food and Feed section of the Guidance Document[1] on GM plants elaborated by the EFSA GMO Panel.

1. Scientific report of EFSA prepared by the GMO Unit on Public Consultation on the Updated Guidance Document of the Scientific Panel on Genetically Modified Organisms (GMO) for the risk assessment of genetically modified plants and derived food and feed.
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902590526.htm

Presentation:

EFSA Guidance GM Plants and derived Food and Feed

- Adopted on 24 September 2004
- Updated in December 2005 (PMEM)
- Published in May 2006
- Complemented in
  - December 2006 (Renewals)
  - March 2007 (Stacked events)

Updated Guidance 2009

Rationale

1. Science and technology evolves together with experience thus updates can always be expected. Role of Self Tasks.
2. Significant driver: The Commission wishes to build greater consensus (improve legal and scientific certainty) for applicants and to increase the overall transparency of the evaluation process. The guidance by EFSA was updated and adopted in 2008 to be used as a basis to draft legal texts in respect of the evaluation of GMOs.

   Document launched for consultation in July until September 2008.

   The document is now under final discussions at EC level with MS before it is presented for voting.

Relevant Guidance and Self Tasks

Guidance Documents

- Stacked events (conventional crosses)
- Renewal dossiers
- Post Market Environmental Monitoring

Self Tasks

- Animal feeding trials (published)
- Antibiotic resistance marker genes in GM plants (published)
- Field trial design and statistical analysis (published)
- Allergenicity
- Interplay GMO and pesticide legislation
- Selection of comparators

Major Updates of Guidance Document

- Elaboration on principles and strategies for risk assessment of GMOs
- More details on required information in the various chapters
- Required information on stacked events incorporated into various chapters where appropriate
- Extended chapters on experimental design field trials and statistical analysis of results
- Reference to standardised protocols for toxicity testing of single compounds
- Details on performance of animal feeding trials with whole GM food/feed and conditions when needed
- Further details on nutritional assessment of GM food/feed
- Further precision of the final integrative risk characterisation of GM plants
- Introductory paragraphs in the various chapters to explain why information is required
- Per chapter summary of conclusions

Overview of the updates

- Risk Characterisation
  - Chapter updated to improve the performance of the final risk characterisation
  - How should the evidence collected from the molecular analysis, the comparative compositional analysis, the food and feed safety assessment and the e.r.a. be interpreted and considered in risk characterisation
  - Issues to be considered:
    - Evaluation of the quality of results, lack of data
    - Application of extrapolation factors
    - Can threshold levels/safety limits be established
    - Identification of uncertainties
    - Long term impact on humans, animals and the environment

Molecular Characterisation

- A clear description of the insert, including all information necessary to interpret molecular data: primer binding sites, restriction sites, probe locations
- Information on the safety of the source of the sequences intended to be inserted
- The requirement for the description of the helper plasmid (if used) has been reintroduced
- Southern analyses should cover the insert flanking regions
- The sequence similarity search for detection of interrupted host genes should also use databases containing sequences from other species than the transformed plant
- All sequences between stop codons, not limiting the length of the sequence should be considered when searching for new ORFs spanning the novel junctions
- Bioinformatics searches should be conducted on the possible new ORFs not just at the insert-genomic DNA junctions, but also at the junction sites arising due to internal rearrangements of the insert(s)

- Expression analysis of potential new ORFs identified at the junction sites created as a result of the genetic modification shall be provided only in cases when complementary information (e.g. potential for transcription/translation and similarity to known allergens/toxins) indicates a potential safety issue.
- Protein expression data from field trials (not glasshouse trials). The same material should be used as for compositional analysis.
- Developmental protein expression levels are not required in all cases (e.g. food-feed import and processing)
- On case-by-case basis data may be required on potential reduction of protein levels other than those intended (RNA techniques)
- RNA levels might be required on a case-by-case basis
- Multiple generation is now defined as five to demonstrate trait stability .

Food and Feed Analysis

- Field Trials and Statistical Analysis
- Comparators and Comparative Analysis
- Toxicology and Nutrition
- Allergenicity

Comparators

- Vegetatively propagated crops: conventional counterpart shall, in principle, be the non-GM isogenic variety used to generate the transgenic lines and with a history of safe use. In the case of crops that reproduce sexually, the conventional counterpart shall have a genetic background that is as close as possible to the GM plant and with a history of safe use.
- Null segregants when used with other non GM comparators are useful but cannot be considered as a non GM comparator with history of safe use.
- This is line with *Codex Alimentarius* Guidelines, 2003 where it is explained that for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts.
- Comparator Self Task due to report ca. March 2010.

EFSA Report Animal Feeding Trials

"Safety and Nutritional Assessment of Genetically Modified Plants and Derived Food and Feed: The role of animal feeding trials"

Report of the EFSA GMO Panel Working Group on Animal Feeding Trials
Adopted by the EFSA GMO Panel on 12 September 2007

Food and Chemical Toxicology
volume 46, supplement 1,
March 2008, pages S1-S70

http://www.efsa.europa.eu

Animal Feeding Trials with Whole GM Foods/Feed

- Case by case approach, hypothesis driven, not routinely required
- If molecular, compositional, phenotypic, agronomic and other analyses have demonstrated equivalence of the GM food/feed, animal feeding trials do not add to the safety assessment
- Minimising the use of experimental animals

Toxicology

- Performance of a 90-day rodent feeding study with whole GM food/feed can be used for reassurance of the performed risk assessment.
- This should be performed in case of extensive alterations in the composition of the GM food/feed or in case of indications for the occurrence of unintended effects based on evaluation of molecular, biochemical, compositional, and phenotypic and agronomic aspects.
- The limited sensitivity and specificity of the study prevents it from being used as the main test in the safety assessment. Thus, a case-by-case approach is recommended.
- Importance of at least two dose levels in the 90-day rodent feeding study to allow for assessment of a dose-response relationship and the toxicological relevance of any observed difference(s) between groups.
- Laboratory animal feeding studies with defined single substances should be conducted according to the OECD Guidelines for the Testing of Chemicals (OECD Test Guidelines) and in compliance with the principles of Good Laboratory Practice (GLP).
- Regarding the testing of GM foods and feeds, an adaptation of the existing OECD protocol for subchronic oral toxicity testing in rodents is recommended.
- Newly expressed protein: source and history of previous consumption molecular and biochemical characterisation search for homology with known toxic proteins resistance to proteolytic enzymes (e.g. pepsin) stability under expected treatment of the food/feed.
- Unless reliable information is provided which demonstrates the safety of the newly expressed protein, the safety assessment of proteins with no history of safe use (for consumption as food) should normally include a repeated-dose toxicity test (normally 28 days) and not rely on acute toxicity testing.
- **Stacks:** The risk assessment of stacked events requires a case-by-case approach focused on the identification of potential interactions between the events. For example, The assessment of potential interactions between newly expressed proteins is foreseen at several places.
- If the potential for interactions is identified, which may impact on food/feed safety specific studies including animal feeding trials with the whole GM food/feed may be required.

Nutrition

- For the risk assessment of GM plants with an altered level of specific nutrients and GM plants intended to provide health benefits, existing reference values for acceptable or tolerable levels of intake of the specific substance(s), e.g. the Acceptable Daily Intake (ADI) or Tolerable Upper Intake Level (UL), should be taken into account.
- If no such value has been derived, information for the toxicological and nutritional assessment has to be provided This may include comprehensive toxicological testing of the single substances, including studies in humans as well as bioavailability studies.
- Health, nutritional status and dietary practices of specific population(s) anticipated to consume the food should be considered in the assessment.
- The Panel will consider the need for new guidance on this subject based on the experience from the evaluation of new products.

Allergenicity

- The allergenicity section remains essentially unchanged.
- Comments on allergenicity are not addressed in this report. The EFSA GMO Panel is currently working on a self task activity entitled "the assessment of allergenicity of GM foods/feed" where valid comments that are not addressed in Annex B, will be considered. The document produced by the self tasking Group will be available for public consultation during the course of 2009.

Environmental Risk Assessment

- Additional consultation on the environmental components of the risk assessment is foreseen (mandate from the Commission and GMO Panel Self Task).
- Will provide update on issues such as assessing potential long-term environmental effects of cultivation and potential risks to non-target organisms by traits such as insect-resistance in GM plants.

Conclusions

- EFSA Guidance document continues to present a robust strategy for the risk assessment of GM plants and derived foods and feed
- Elaboration on the structure of the risk analysis process
- Description of the purposes of the different steps of risk assessment
- Further precision of requirements
- Specific guidance for field trial designs and statistical analysis of results
- Reference to existing test toxicological protocols
- Conditions and protocol for animal testing of whole GM Food/Feed
- International setting is important

Discussion:

Participants addressed several questions related to EFSA's updated Guidance on GM plants and derived food and feed.

A question was posed by a representative of the Austrian Agency for Health and Food Safety with regard to the uncertainties linked with the extrapolation of medium-term toxicological studies to a long-term exposure. A member of EFSA's GMO Panel responded that this issue has been addressed in depth by the peer-reviewed animal feeding trials report[1] of the EFSA GMO Panel. From literature data it is clear that most effects observed in a long-term chronic study will also be found in a medium-term subchronic study and vice versa. Furthermore, most applicants conduct subchronic studies even when not required by EFSA's guidance to do so.

A delegate from the German Federal Agency for Nature Conservation posed the question whether plans exist to develop a test in the context of whole-plant testing, which is considered from the delegate's perspective as crucial as carrying out tests on individual substances. With regard to whole-food testing, Howard Davies referred to inherent difficulties of designing such food and feed studies. It is not always possible to feed test animals with the whole food to be tested as this might not be sufficient from a nutritional perspective. Another member of EFSA's GMO Panel added that the issue has been addressed in the EFSA GMO Panel's animal feeding trial report. Differences between a GM plant and its non-GM comparator during comparative assessments are used to focus the safety assessment and in such cases single-compound studies are often preferred. These might include digestibility studies, and, on a case-by-case basis, oral toxicity studies in addition to bioinformatics analysis to assess potential toxicity or allergenicity of newly expressed proteins. Whole food tests might be performed in case where the food has undergone complex modifications and where no appropriate comparator or closely genetically related line are available. Such GM crops have not been encountered to date.

The German delegate also requested further clarification on the evaluation of possible interactions between stacked genes in GM crops where an interaction may be expected. Howard Davies replied that, with regard to the next generation of GMOs where the metabolism of the plant might be altered by modifying the expression of two or more genes using stacking approaches, it might be possible to predict the effects based on the knowledge of biochemical pathways. However, the testing of expected interactions requires a case by case approach and may require more extensive compositional, phenotypic and agronomic analyses. For example, the EFSA GMO Panel is already considering possible interactions between stacked Cry proteins on a case-by-case basis.

1. *EFSA GMO Panel (2008) Safety and nutritional assessment of GM plants and derived food and feed: The role of animal feeding trials. Food and Chemical Toxicology 46 (2008) S2–S70 http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902590265.htm*

Statistical evaluation of field trials for food and feed safety

CLAUDIA PAOLETTI
EFSA GMO unit

Introduction:

The update of the food and feed section of the Guidance Document on GM plants includes more detailed data requirements concerning design and statistical considerations for the evaluation of field trials. Claudia Paoletti, who studied plant genetics and biometry, is a senior scientist in the GMO Unit of EFSA, and coordinates the EFSA GMO Panel Working Group on Statistics. In her talk she described a new assessment approach of combining two statistical tests (test of difference and test of equivalence). This is the first time that these two tests are used in combination in the agronomic area, and this approach provides a richer and more objective framework for the risk assessment of GM crops. The detailed definition of the statistical requirements will lead to further harmonisation between dossiers and contribute to the overall transparency of the risk assessment approach.

Presentation:

Objective of New Approach

- Current 2006 Guidance:
  - Description of general principle
  - No strict rules for design of experiment + statistical analysis
- New approach delivers:
  - Minimum requirements for experimental design of field trials (replications, inclusion of commercial varieties)
  - Criteria for appropriate evaluation of 'background variation'
  - New statistical methodology for data evaluation: maximum efficiency and statistical power
- New approach allows:
  - Harmonization of approach across dossiers
  - Allow better interpretation of differences (or lack of equivalence) within a risk assessment framework

Exp. design for field trials within site: one GM event

GM	C	CV1	CV2	CV3	CV4
CV3	CV2	CV1	GM	C	CV4
CV4	CV3	C	CV2	CV1	GM
C	CV2	GM	CV3	CV4	CV1

C = *Non-GM comparator*

CVs are different commercial varieties

GM, ***non-GM comparator*** *& commercial varieties are all randomised and replicated*

replication must be at least *4 if there are only three commercial varieties then the replication must be* at least *5*

must be at least *three commercial varieties at each site*

Exp. design for field trials within site: multiple events, same crop

Example for 1 site:

GM1, GM2 and GM3 = 3 different GM maize events
NIC1, NIC2 and NIC3 = 3 respective conventional counterparts
CV1, CV2, CV3 and CV4 = 4 commercial varieties

Block	Plot								
	1	2	3	4	5	6	7	8	9
1	GM2	CV2	CV1	GM3	NIC3	NIC1	CV3	GM1	NIC2
2	CV2	GM2	CV3	NIC3	NIC2	GM1	NIC1	CV4	CV1
3	NIC1	NIC3	GM1	CV1	GM3	NIC2	CV2	CV4	CV3
4	GM3	GM2	CV1	NIC1	CV2	NIC2	NIC3	CV3	CV4

- Each counterpart occurs together with its GMO in the same block
- All GMOs, their counterparts, comm. varieties: randomized in each block
- GMOs are assessed separately
  (e.g. for GM1: only plots 2,3,6,7,8,10 in block 1 enter the analysis)

Exp. design for field trials between sites

must be at least 8 sites, over one or more years

must be the same **GM**, ***non-GM comparator*** *at each site*

may be different commercial varieties at each site

must be at least 6 commercial varieties over all the sites

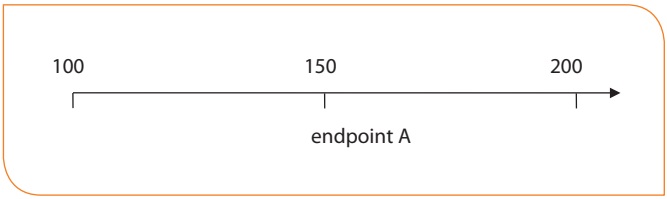
Two tests: Difference & Equivalence

- **Test of Difference**:
  To verify whether the GMO is different from the non-GM comparator (identification of possible hazard)
- **Test of Equivalence**:
  To verify whether the GMO is equivalent to appropriate reference variety/varieties (need to define equivalence limits)

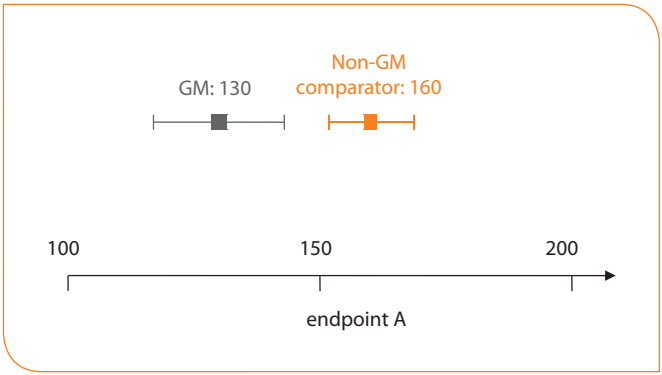
Results of both tests are displayed on a single graph simultaneously for comprehensive evaluation

simple, informative, transparent evaluation…

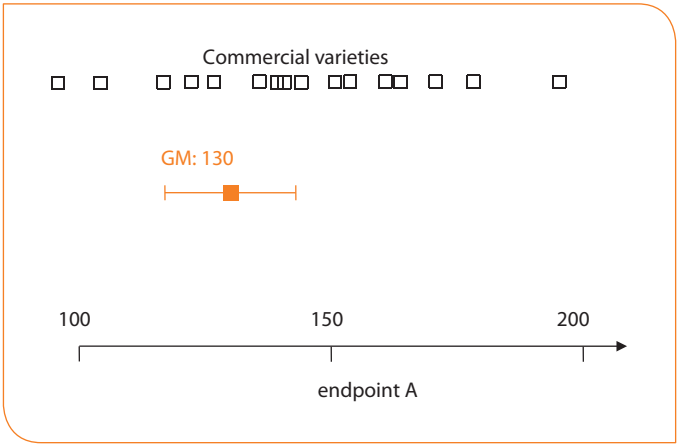
Example: single endpoint



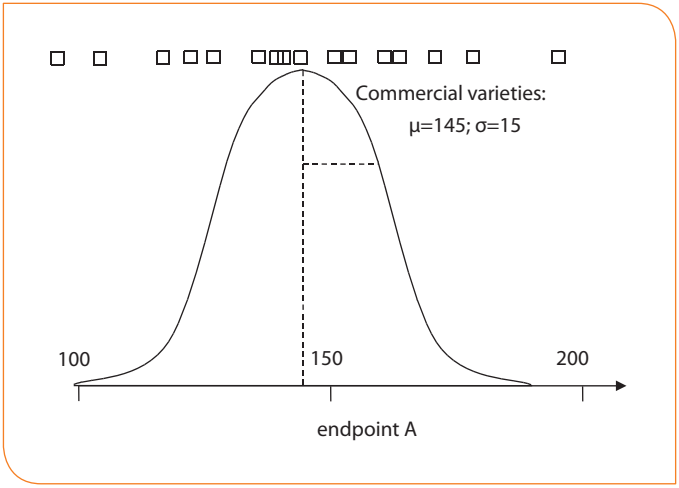
A test of difference: GMO vs comparator



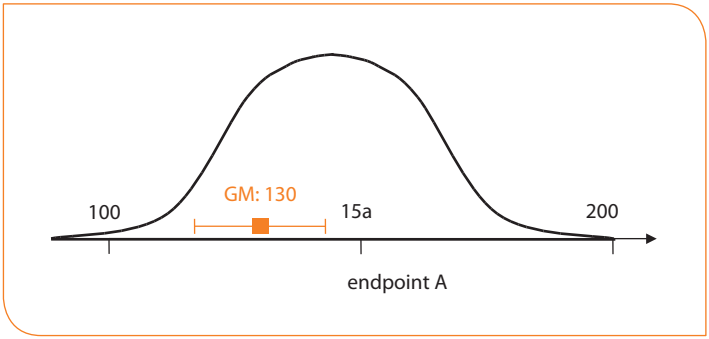
The principle of substantial equivalence



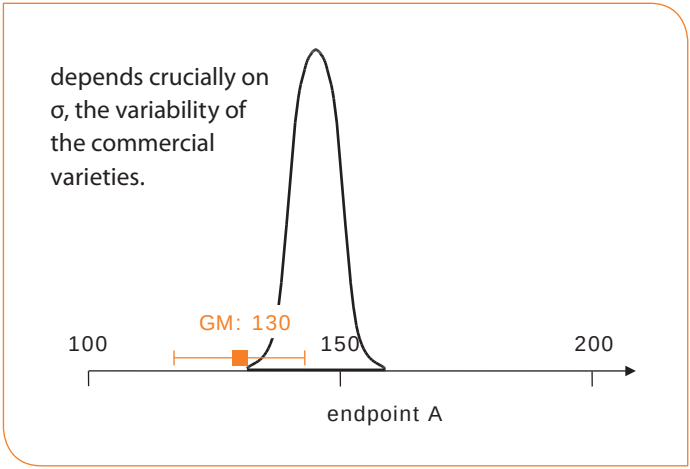
Commercial varieties form a distribution



Assessing whether the GMO is equivalent



or not equivalent…

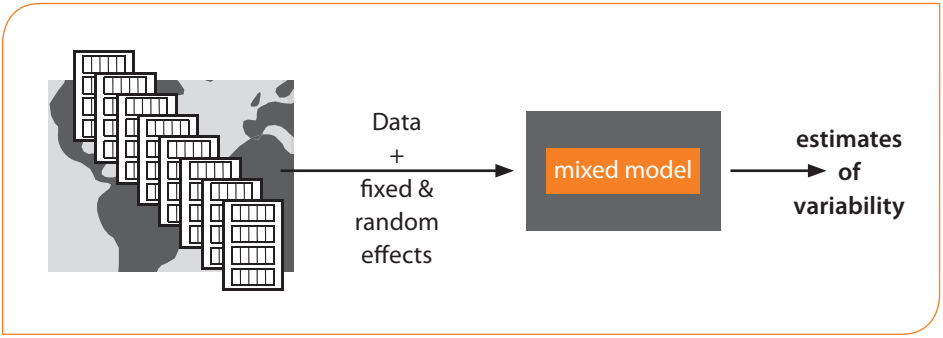


A statistical mixed model

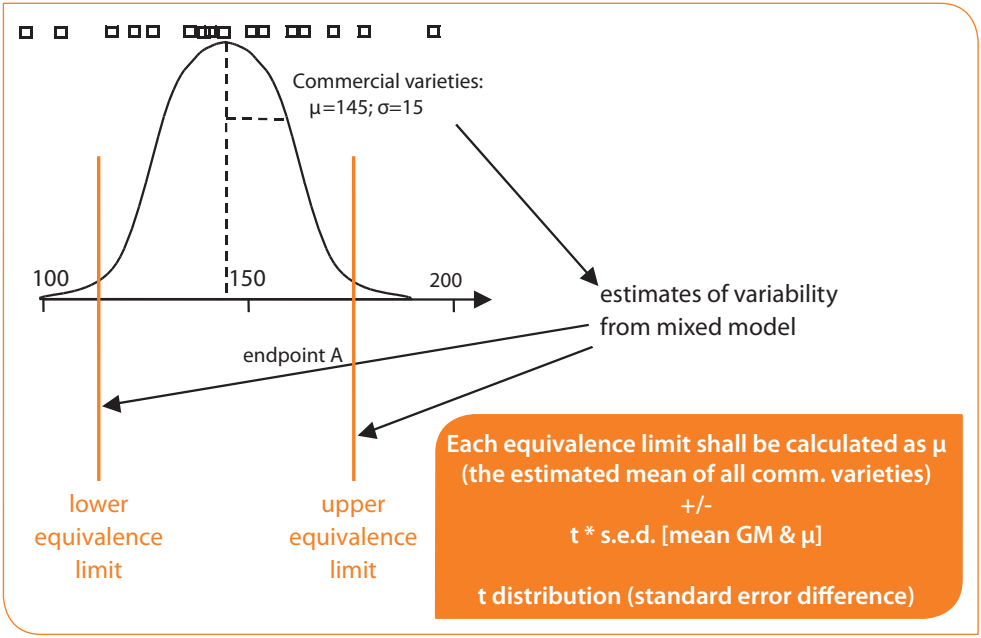
All of the parameters that represent the variability in the field trials are estimated simultaneously from the **full set of field trial data**, including:

- sites
- years (if applicable)
- the GM
- the non-GM comparator
- the commercial varieties
- randomized blocks within sites, etc

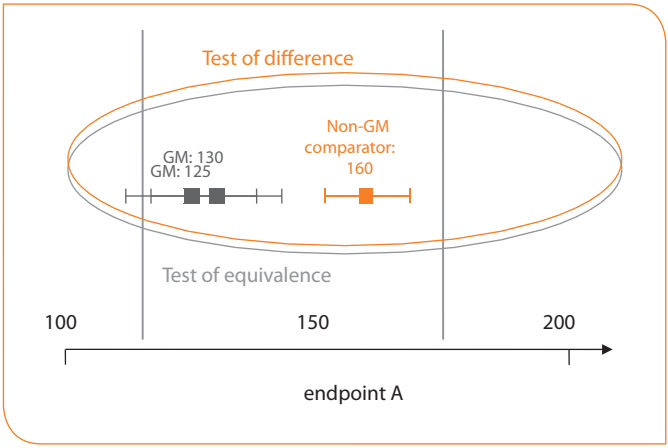
using what is technically termed a '**statistical mixed model**'



A formal test of equivalence requires equivalence limits



The two tests displayed on one graph

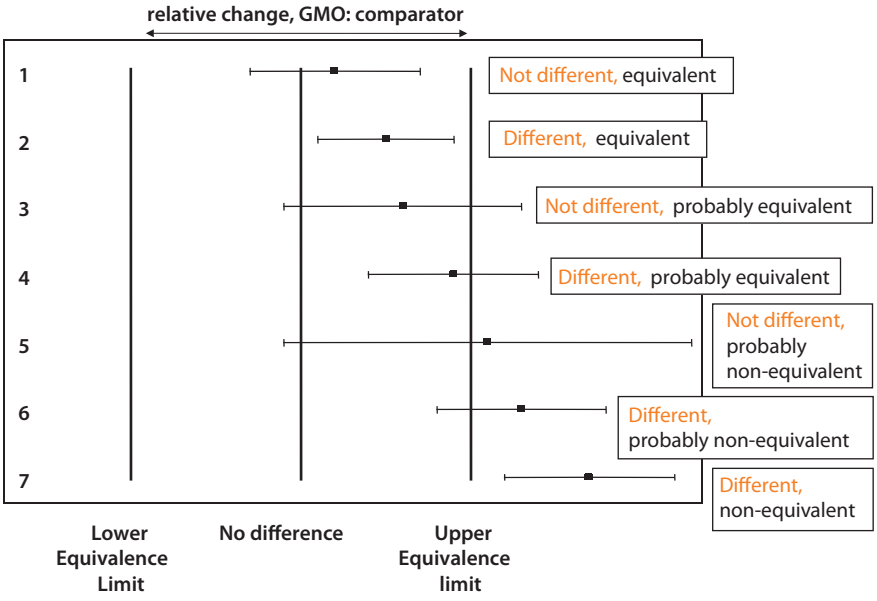


The two tests: null hypotheses

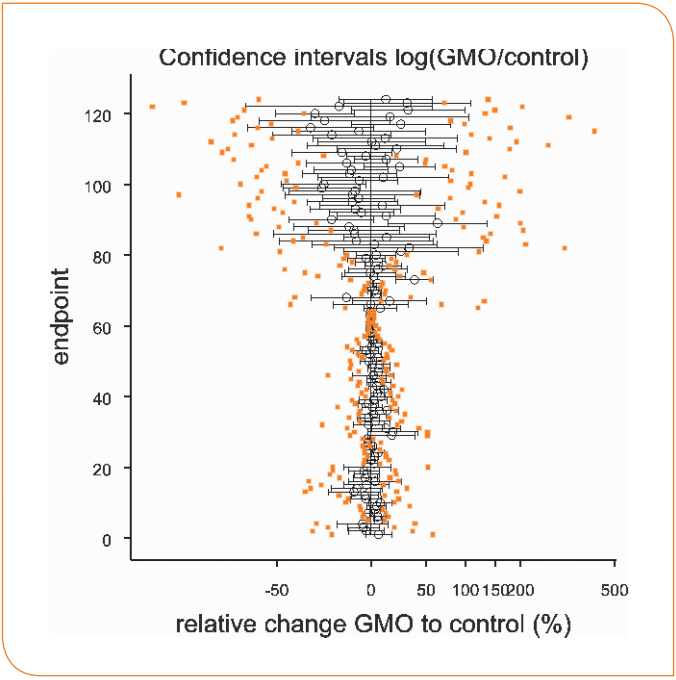
Test of Difference		Verdict	
		Not different	Different
Truth	H_0: Mean of GM and comparator the same	OK	**Type I error 'false positive' Risk to Producer**
	H1: Mean of GM and comparator NOT the same	**Type II error 'false negative' Risk to Consumer**	OK

Test of Equivalence		Verdict	
		Not Equivalent	Equivalent
Truth	H0: non-equivalent (GM mean outside lower or upper equiv. limit)	OK	**Type I error 'false positive' Risk to Consumer**
	H1: equivalent (GM mean strictly within equiv. limits)	**Type II error 'false negative' Risk to Producer**	OK

Seven possible outcomes



Example for many endpoints



Take home message

The two tests are complementary:

Difference → changes → biologically relevant
Difference → changes → biologically NOT relevant

Equivalence → changes → within natural range of variation
Equivalence → changes → outside natural range of variation

A procedure combining both approaches (test of difference and test of equivalence) provides a richer and more objective framework for GMO risk assessment

Where to find more details

This presentation relates to the **experimental design** and **statistical analysis** of field trials to collect data for **compositional assessment**. Methods may also prove useful for the analysis of appropriate data, but do not relate to the design of animal feeding trials.

- **July 2008**: Report of the EFSA Statistics Working Group
- **July – September 2008**: Public consultation
- **April 2009**: Adoption of GMO Panel Opinion (including: experimental design in case of multiple events of the same crop; a worked example; software code SAS + Genstat)
- **August 2009**: publication of Opinion + summarised answers to public comments

Future - Annex II Scientific Requirements for Risk Assessment concerning Food and Feed Safety Aspects

EFSA GMO Statistics Working Group

- Panel members:
  - Hans Christer Andersen
  - Salvatore Arpaia
  - Gijs Kleter
  - Harry Kuiper (formal chair)
  - Joe Perry
  - Willem Seinen
- *Ad hoc* experts:
  - Marco Acutis
  - Ludwig Hothorn
  - Jim McNicol
  - Hilko van der Voet (acting chair)
- EFSA scientists:
  - Claudia Paoletti
  - Billy Amzal

Discussion:

The discussion highlighted technical issues but also general concerns related to statistical requirements for field trials.

A representative of EuropaBio raised the issue that non-equivalence of a GM plant with its non-GM comparators does not necessarily imply a safety concern. Claudia Paoletti responded by stating that in the updated Guidance the term "equivalence limits" and not "safety limits" is clearly used to avoid misperception. In case of non-equivalence, experts will decide whether the absence of equivalence has a significance either from a biological, toxicological or nutritional point of view.

According to the view of a participant from the Austrian Environment Agency, the outcome of the equivalence test is closely linked to the variability of the comparators used. An increase in the number of comparators leads to an increase in variability, particularly in the case of inclusion of data from commercial varieties and scientific literature. Therefore, he asked whether it may be feasible to set not only the minimum but also the maximum number of comparators in order to be more restrictive. In response, Claudia Paoletti explained that due to regional variation in agronomic conditions, the selection of commercial varieties is crucial and should be done taking into account the varieties normally used in a particular region. Appropriate choice of commercial varieties reflects the local agronomic practice and may actually improve the estimate of variation for those environmental conditions. According to EFSA's Guidance Document, the applicant must justify his choice of varieties used as comparators and this choice subsequently is evaluated by the EFSA GMO Panel.

An attendee from the Hungarian Gene Technological Authority criticised that the approach proposed for testing equivalence uses data from different locations, which does not necessarily mean equivalence at a regional level. Such a broad view could lead to results indicating equivalence that may not be valid for a given location. Claudia Paoletti acknowledged the concern about a possible 'global dilution effect'. She stressed that the Guidance Document specifies that a GMO must be tested in a location that reflects the environmental and ecological system where the GMO is meant to be cultivated. The attendee further asked that if considering that non-equivalence does not mean risk, then does equivalence necessarily mean safety? Claudia Paoletti stressed that the methodology presented provides an objective and sound statistical approach towards natural variation. The biological implications of the results of the analysis are then assessed by the experts.

Perspective of a Member State: Austria's scientific view on how to perform environmental risk assessment of GM plants

ANDREAS HEISSENBERGER
Federal Environmental Agency of Austria

Introduction:

Andreas Heissenberger from Austria's Environment Agency has been involved in several studies on risk assessment and monitoring of GMOs. He studied biology and microbial ecology and presented an overview of the scientific issues underlying Austrian's critical position towards GMOs resulting in the government's invoking of several safeguard clauses. His talk focused on Austria's perception of present shortcomings and proposals for improvements in the environmental risk assessment.

Presentation:

Introduction

- General criticism
- ERA model and problem formulation
- Field trials
- Regional aspects
- Non-target organisms
- Monitoring
- Conclusions

General Criticism

- Data provided by the applicant not sufficient to perform a comprehensive ERA
- Basic requirements sometimes not met (low number of replicates, data incomplete, pooling of data, …)
- Extrapolation not sufficiently justified (different regions, different GMOs)

The ERA model and problem formulation – current problems

- GMO = plant + new compound
- Substantial equivalence
- Testing of the new compound only, e.g. Bt-toxin
- Secondary stressors (e.g. herbicides) excluded
- No investigation of possible unintended effects
- Secondary effects neglected
- Risk research hypothesis is missing
- Choice of comparators often not scientifically sound (influence on outcome)
- Effects are declared as „biologically irrelevant“

The ERA model and problem formulation – proposals

- Definition of hazard and scope
  - Focus on possible adverse effects that pose high risk
  - Define case (plant, novel trait + phenotypic characteristics, receiving environment)
- Exposure assessment
  - Research hypothesis and selection of test organisms based on relevant exposure pathways
- Determination of possible effects
  - Practical testing (testing vs. extrapolation)
- Risk characterisation
  - Data evaluation (outcome linked to hypothesis)

Field Trials – current problems

- varying and inconsistent design and methods
- data presentation often unclear
- insufficient characterisation of locations
  - representative?
  - comparable to the environment where the GMO will be used?
- duration (in many cases only one season)
- comparators (not always specified clearly)
- replication (no power analysis, lack of information, varying numbers, …)
- pooling of data across locations, from different field trials,…

Field Trials – proposals

- Clear guidance necessary
  - Definition of the aim of the field trial(s) or trial series
  - Experimental units (plot sizes, number of plants, sampling plan,…)
  - Number of locations and replicates necessary
  - Criteria for the selection of locations
  - Comparators
  - Statistical evaluation and interpretation of results

Regional Aspects – current problems

- Receiving environments (according to Directive 2001/18/EC) not considered sufficiently
- EU field trials very limited
- Different climatic conditions lead to different ecological situations
  - Physiology of the plant
  - Non target organisms
- Extrapolation of data not or not sufficiently justified

Regional Aspects - Proposals

- Choice of areas for field trials should cover different ecological situations
  - EEA model of bio-geographic areas
- Special consideration of ecological sensitive areas and/or protected areas
  - Council Conclusions December 2008

Non Target Organisms – current problems

- Lack of problem formulation, research hypothesis
- Insufficient description of test design and methodology
- Selection of test organism
  - Ecologically not always relevant
  - Not from receiving environment
  - Developmental stages not tested adequately
- Tiered approach
  - No criteria to evaluate if data are sufficient (stop testing or move to next tier)

Non Target Organisms – proposals

- Clear research hypothesis for laboratory tests and field trials (also for tiered approach)
- Selection of target organisms – stepwise approach
  - Functional groups (e.g. herbivores, pollinators, soil organisms) for relevant environment
  - Select most important species from each functional group (focus will reduce species to test)
- Test protocols need to be improved (whole plant studies vs. isolated protein)

Monitoring – current problems

- Lack of case specific monitoring
  - E.g. effects on non target organisms
- General surveillance
  - No or only few scientific studies
  - Mainly based on farmers questionnaires
  - Lack of scientifically sound long term data for renewal of applications

Monitoring – proposals

- Uncertainties and shortcomings in the ERA need to be considered for case specific monitoring
- General surveillance
  - Definition of parameters and aspects to be monitored
  - Use of existing networks and programs, check if routine data are adequate for GM monitoring
  - Scientific studies

Conclusions

Case-by-case principle is necessary and should be followed

but

for certain aspects (e.g. statistical approach, design of field trials, etc.)
better standardisation is absolutely necessary to guarantee quality of data
and a scientific sound approach to environmental risk assessment.

Discussion:

The audience raised questions related to the methodological criticisms put forward by Heissenberger concerning the methodology laid out in the updated EFSA Guidance Document for the risk assessment of GM plants.

At the request of Claudia Paoletti, Andreas Heissenberger clarified that, although steps in the right direction have been taken by the EFSA GMO Panel, the use of data from scientific literature should not be taken into account in the estimation of the background variation in the context of comparative analysis as this will cause a dilution effect. In response, Claudia Paoletti indicated that the updated Guidance Document does not foresee the use of literature data but recommends the inclusion of commercial varieties in the field trials.

A representative of EuropaBio stated that it is important to differentiate between risk assessment and risk research. The conclusion of a risk assessment is either a 'yes' or 'no' with regard to the fulfilment of the requirements. In comparison, the outcome of risk research generates many further technical questions. However, risk research is in his view not in the area of responsibility of applicants and not part of an application dossier. Andreas Heissenberger responded that risk research is the basis of risk assessment and the source of data needed for the safety assessment.

A former EFSA GMO Panel member from the Julius Kühn Institut criticised Andreas Heissenberger's statement that investigation of possible unintended effects of GMOs is not being carried out. EFSA assesses unintended effects by using molecular characterisation of the plant flanking sequences and of possible open reading frames created by the insertion of the novel DNA, as well as through compositional and phenotypic analyses. Andreas Heissenberger acknowledged that such techniques are used to detect unintended effects. He stated that almost no environmental data, however, are provided which can identify unintended effects, perhaps due to difficulties in their definition. To detect unintended effects in environmental risks assessment, he suggested one might use tests related to food webs, secondary effects and outcrossing.

Assessment of effects on non-target organisms in EFSA's guidance

SALVATORE ARPAIA
EFSA GMO Panel

Introduction:

Salvatore Arpaia, an entomologist, is now in his second term as member of the EFSA GMO Panel and has a long track record of research in the biosafety of GM plants. The environmental risk assessment (ERA) of GM plants is a complex area in which science is continuously evolving. EFSA's guidelines are currently being updated on ERA to take into account latest scientific developments. In his presentation, he introduced the approaches followed by the EFSA GMO Panel in assessing the effects of GM plants on non-target organisms.

Presentation:

"Non target" organisms

Non target organisms are defined as *all those species directly and/or indirectly exposed to the GM plant, and which are not the targets of the newly expressed metabolite(s) in these plants*

Environmental Exposure to GM Plants

- **AIR**: Transgene escape (via pollen) and its consequences on biodiversity
- **PLANTS**: Effects on non target organisms
  - Arthropods (herbivores, natural enemies, pollinators)
  - The wider environment: Mollusca, rodents, birds, mammals
- **SOIL**: Toxin production and transgene escape
  - Horizontal gene transfer
  - Effects on soil organisms

Agricultural Effects of GM Plants

- Gene escape/invasiveness
- Indesirable effects on non-target organisms: damage to the "ecosystem services" (Daily,1997):
  - Natural biological control
  - Pollination
  - Decomposition
- Soil functioning

Directly or through changes in agricultural practices

Guidance Document, EFSA 2006

- Comparative assessment approach
- Intended and unintended effects, immediate and delayed effects
- Hazard identification (including trophic layer effects), Exposure Studies, monitoring
- Case by case approach

Case study MON810

- **26 pages of references, 322 documents were reviewed**

- **6.1.4.** Interactions between the GM plant and non-target organism
  - **6.1.4.1.** Natural enemies: predators and parasitoids
  - **6.1.4.2.** Non-target Lepidoptera
  - **6.1.4.3.** Pollinating insects: honeybees
  - **6.1.4.4.** Water-dwelling organisms
  - **6.1.4.5.** Soil organisms: earthworms
  - **6.1.4.6.** Soil organisms: enchytraeid worms
  - **6.1.4.7.** Soil organisms: nematodes
  - **6.1.4.8.** Soil organisms: isopods
  - **6.1.4.9.** Soil organisms: collembolans
  - **6.1.4.10.** Soil organisms: diplopods

- **125 pages of comments by Member States**
- **Safeguard Clauses from Austria, France, Germany, Greece, Hungary, Luxembourg**

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ERA of the GM maize MON810

- Questions of the EFSA GMO Panel

  24/04/2008: 1st round questions from EFSA GMO Panel

  - Molecular characterisation aspects

  12/11/2008: 2nd round questions from EFSA GMO Panel

  - Food-feed aspects (lack literature review)
  - Considering European non-target Lepidoptera species likely to be found in and around maize crops, request to provide a comprehensive risk assessment including the levels of exposure to Cry1Ab toxin and potential impacts on populations.

  11/02/2009: 3rd round questions from EFSA GMO Panel

  - Food-feed aspects (updates bioinformatics-supported studies)

- Delegation to the Spanish Competent Authority

  09/05/2008: 1st round questions from Spanish CA

  - IRM
  - Lack recent publications about i) the likelihoods of the occurrence of the potential adverse effects, ii) laboratories and field studies in European countries or with European organisms
  - Lack of references to PMEM in different European countries

18/07/2008: 2nd round questions from Spanish CA

- Further information on the assessment of risks to NT Lepidoptera in representative EU maize growing regions
- Further analysis of studies on potential effects on NTOs + organised by exposure/effect assessment on NTOs/ecological process (predators, decomposers, pollinators)
- Revision of the PMEM plan proposed

Hazard characterization

- NATURAL ENEMIES: In general, invertebrate parasitoids appear to be more sensitive than predators. Mechanisms direct/indirect effects
- NON TARGET HERBIVORES: Larvae of a range of lepidopteran species are susceptible to the Cry1Ab toxin
- WATER-DWELLING ORGANISMS: Trichoptera might be susceptible to the Cry1Ab toxin
- POLLINATORS: no toxic effects of Cry toxins on the health of honeybees and bumblebees

Exposure

- NATURAL ENEMIES
  - Expected abundance of non-target invertebrates: **Near-isogenic control fields>Bt>Insecticides**
- POLLINATORS: In most cases, the proportion of maize pollen as a total of all pollen collected during a summer will be low. Moreover, due to the low concentration of Cry1Ab in MON810 pollen, honeybees will only be exposed to very low concentrations of the toxin.
- WATER-DWELLING ORGANISMS: due to the low level of Cry proteins in aquatic systems, exposure of Trichopterans in aquatic ecosystems is likely to be very low.
- SOIL ORGANISMS GM Plants may induce changes in species assemblages, but these usually follow within ranges of natural variability (due to e.g. plant variety, soil type, chemical composition, etc.).

Exposure: Non target herbivores

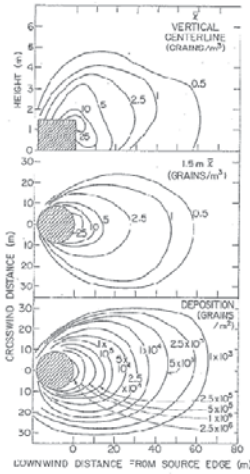


Fig. 1. Typical concentration ($\bar{\chi}$) and deposition patterns from a corn pollen area source represented by the shaded figures. Concentrations are shown in the horizontal at a height of 1.5 m and in the vertical along the plume centerline.

Losey et al., 1999 Nature Corn pollen lethal to monarch larvae

P.N.A.S., October 2001

Hellmich et al. *Monarch larvae sensitivity* to Bacillus thuringiensis- purified proteins and pollen PNAS 98: 11925-11930

Oberhauser et al. *Temporal and spatial overlap* between monarch larvae and corn pollen PNAS 98: 11913-11918

Pleasants et al. *Corn pollen deposition on milkweeds* in and near cornfields PNAS 98: 11919-11924

Model of exposure for three European species of Lepidoptera (Perry et al., submitted)

Full model predicts proportion suffering mortality is:

$$M = yzvxa\,(25e\sqrt{Ch} + mfg)/(25e\sqrt{C} + fD)$$

The model was run with parameter estimates submitted by the EFSA GMO Panel Environment Working Group.

100% exposure is reduced successively by multiplying by proportions representing various effects

7 parameters largely specific to the particular area/host-plant combination being modelled

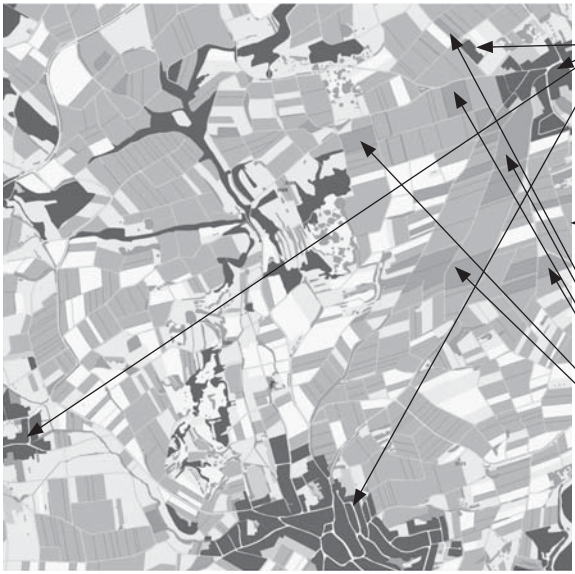
4 parameters specific to the species modelled.

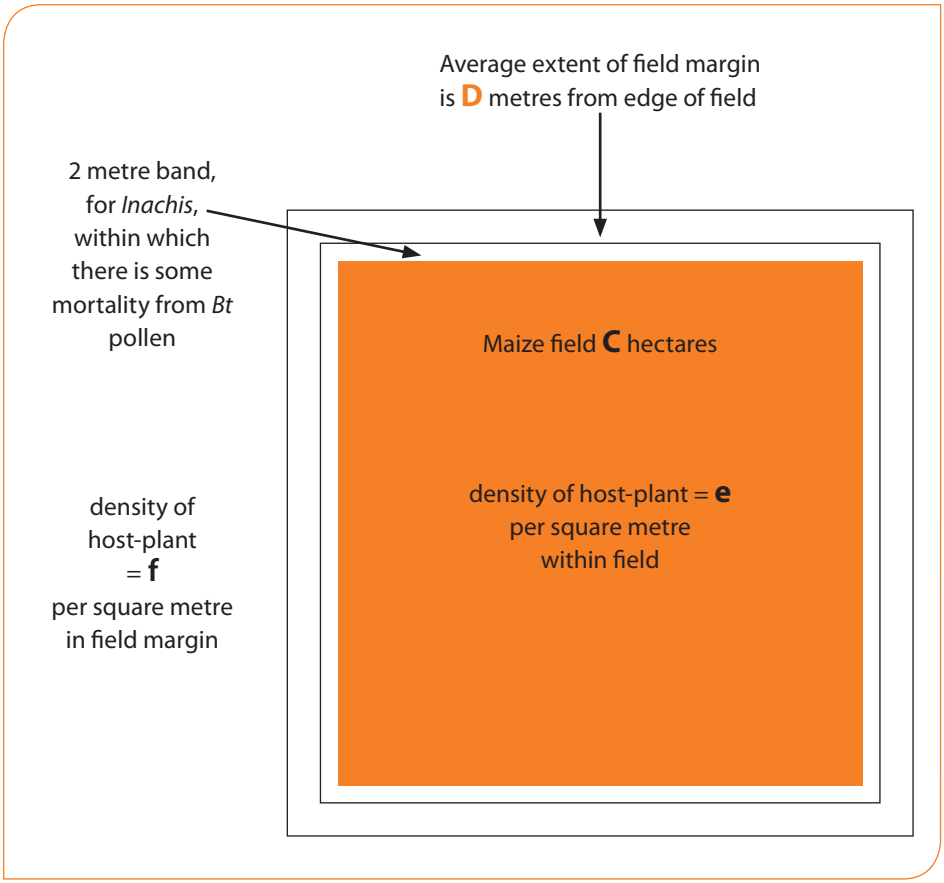
Regions and species considered in the model

Inachis io *Vanessa atalanta* *Plutella xylostella*

Germany	Oderbruch, Achen, Grebbin, Berkatal, Upper Rhine Valley
Italy	Po Valley
Hungary	Tolna County
Spain	Madrid, Catalunya

Area-specific parameters



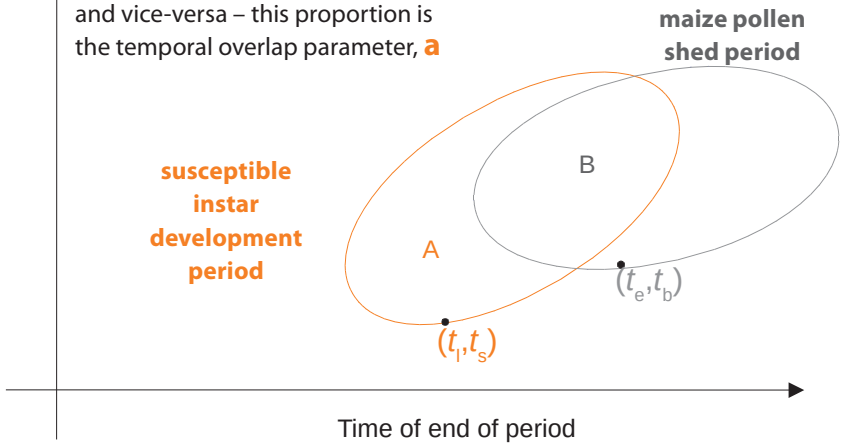

Average extent of field margin is D metres from edge of field
2 metre band, for *Inachis*, within which there is some mortality from *Bt* pollen
Maize field C hectares
density of host-plant = e per square metre within field
density of host-plant = f per square metre in field margin

Species-specific parameters

Time of start of period

Any point in area A is entirely within the ellipsoid for instar development, but outside that of maize pollen shed. Any point in area B is within both ellipsoids.

The larger the proportion B/(A+B) the larger is the overlap, and vice-versa – this proportion is the temporal overlap parameter, **a**



physical effects parameter,
x,
proportion of larvae remaining exposed after allowance for:

larvae feeding on underside of leaves,
'shading' of lower leaves by upper,
rain washing pollen off leaves,

etc.

Death in the field and margins

proportion of larvae suffering mortality in the field – worst-case scenario, **h**	proportion of larvae suffering mortality in the 2 m marginal band – worst-case scenario, **g**

Conclusions

- Variability in estimated mortality and sublethality results from (i) natural variation between areas; (ii) differences between experts' estimates; (iii) uncertainties arising from variation between (the limited number of) datasets.
- For the majority of areas for *I. io* and *V. atalanta*, the best estimate for mortality was less than one individual in every 1800, and of sub-lethality was less than one individual in 550.
- For the majority of areas for *P. xylostella*, the best estimate for mortality was less than one individual in every 300, and of sub-lethality was less than one individual in 100.
- Under worst-case scenario of maximum uptake of MON810 maize by growers (80%).
- The amounts of MON810 pollen grains found in and around maize fields are unlikely to adversely affect a significant proportion of non-target lepidopteran larvae. (0,5% additional mortality for *P. xylostella*)
- The GMO Panel is aware that all modelling exercises are subject to uncertainties and further data are required to reduce the variability of the estimates reported here.

General Conclusions on NTOs

1. The EFSA GMO Panel is of the opinion that maize MON810 will not cause reductions to natural enemies that are **significantly greater than those caused by pesticides used to control corn borers**.
2. The amounts of MON810 pollen grains found in and around maize fields are unlikely to adversely affect a significant proportion of non-target lepidopteran larvae.
3. The likelihood of adverse effects on bees is expected to be negligible.
4. There is no evidence to indicate that the placing of maize MON810 and derived products on the market is likely to cause adverse effects on soil organisms.

Recommendations

- The EFSA GMO Panel considers it advisable that, especially in areas of abundance of non-target Lepidoptera populations, **the adoption of the cultivation of maize MON810 be accompanied by management measures in order to mitigate the possible exposure** of these species to MON810 pollen.
- As an example, the planting of border rows of non-Bt-maize adjacent to uncultivated field margins of maize MON810 fields, could limit the exposure to those individuals feeding on weeds present within maize field borders and also could contribute to the required percentage of non-Bt-maize necessary to constitute refuge areas for lepidopteran target pests in the framework of resistance management plans.

The EFSA Journal (2009) 1149, 1-85

Conclusions

efsa
European Food Safety Authority

- The development of resistance of the corn borers *O. nubilalis* and *Sesamia* spp. has been identified as a risk
  - IRM under case-specific monitoring is recommended
- Mitigation measures for non-target Lepidoptera
- No specific measures for other taxa

MINISTERIO DE MEDIO AMBIENTE, Y MEDIO RURAL Y MARINO

- The development of resistance of the corn borers *O. nubilalis* and *Sesamia* spp. has been identified as a risk
  - IRM under case-specific monitoring is recommended
- For non-target Lepidoptera, effects have to be considered more deeply in Monitoring plans.
- No specific measures for other taxa

Transgene Product	Number of cases (% in parentheses)				
	Negative significant	Negative n.s.	Neutral	Positive n.s.	Positive significant
Predators					
Cry1Ab/c/2A	69 (21)	67 (21)	166 (51)	12 (4)	10 (3)
C. carnea only	55 (30)	35 (19)	89 (49)	4 (2)	0 (0)
Without C. carnea	14 (10)	32 (23)	77 (55)	8 (6)	10 (7)
Cry 3A/Bb	3 (4)	13 (18)	45 (62)	11 (15)	1 (1)
GNA/CpTI, OCI *	19 (26)	10 (14)	28 (38)	9 (12)	7 (10)
Parasitoids					
Cry1Ab/c	61 (37)	17 (10)	78 (47)	7 (4)	2 (1)
Cry1Ab/c+CpTI *	22 (44)	12 (24)	15 (30)	1 (2)	0 (0)
Other Cry toxins	8 (47)	3 (18)	5 (29)	0 (0)	1 (6)
GNA/CpTI, OCI *	66 (23)	57 (20)	134 (46)	22 (8)	12 (4)

Lovei, Andow & Arpaia, 2009. Environ. Entomol: 38(2): 293-306

How many species have been tested?
Arpaia, in press.

Functional group	Order	Family	No. of species
Predators	Heteroptera	Anthocoridae	4
Predators	Heteroptera	Nabidae	1
Predators	Heteroptera	Geocoridae	2
Predators	Heteroptera	Miridae	2
Predators	Heteroptera	Reduvidae	1
Predators	Heteroptera	Pentatomidae	1
Predators	Coleoptera	Coccinellidae	9
Predators	Coleoptera	Carabidae	17
Predators	Neuroptera	Chrysopidae	1
Predators	Araneae	Araneidae	2
Predators	Acarina	Phytoseidae	1
Parasitoids	Hymenoptera	Braconidae	8
Parasitoids	Hymenoptera	Ichneumonidae	3
Parasitoids	Hymenoptera	Eulophydae	1
Parasitoids	Hymenoptera	Aphelynidae	1
Parasitoids	Hymenoptera	Encyrtidae	1
Parasitoids	Hymenoptera	Trichogrammatidae	1
Pollinators	Hymenoptera	Apidae	5

Need to update (Tabiano Colloquium, 2007)

EFSA established a self-tasking working group on NTO with the aim of:

1. producing a scientific review of the current guidance document of the EFSA GMO Panel for Environmental Risk Assessment, focusing on the potential impacts of GM plants on NTOs;
2. proposing criteria for NTO selection; and
3. advising on standardised testing methodologies.

- General update of the GMO Panel ERA Guidance Document
- **Non-target organisms**
- Long-term effects
- Receiving environments
- Farming practices
- Field trials
- General discussion

Self-tasking Working Group on environmental impacts of GM plants on Non-Target Organisms (NTOs)

- At the end of its 2-year mandate, the self-tasking working group will prepare a scientific opinion as well as specific NTO guidelines to update the overall ERA guidance document
- Focus on arthropods and some invertebrates

Deadline	Deliverable
March 2009	Intermediate report
May 2009	Review by referees
October 2009	Adoption by GMO Panel
December-January	Public Consultation
March 2010	Final document

Species selection

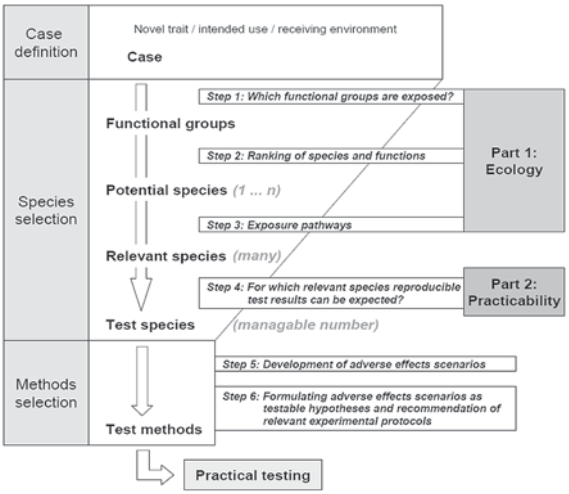
- Not everything can be tested
- Not every species/process is equally important
- Finite resources are available for biosafety testing
- Current practice for selecting test organisms (surrogate species):
  - What is available (parasitoids: *Cotesia flavipes*), already used in ecotoxicological tests (*Daphnia magna*, springtail *Folsomia candida*), team has experience with organism (green lacewing, *Chrysoperla* spp.). Abundance/widespread distribution (Cowgill et al. 2003)

Selection of "focal species"

Preserving the functional biodiversity

- Herbivores
- Predators
- Parasitoids
- Pollinators, pollen feeders
- Decomposers
- **Species of conservation/cultural concern**

Self-tasking Working Group on environmental impacts of GM plants on Non-Target Organisms

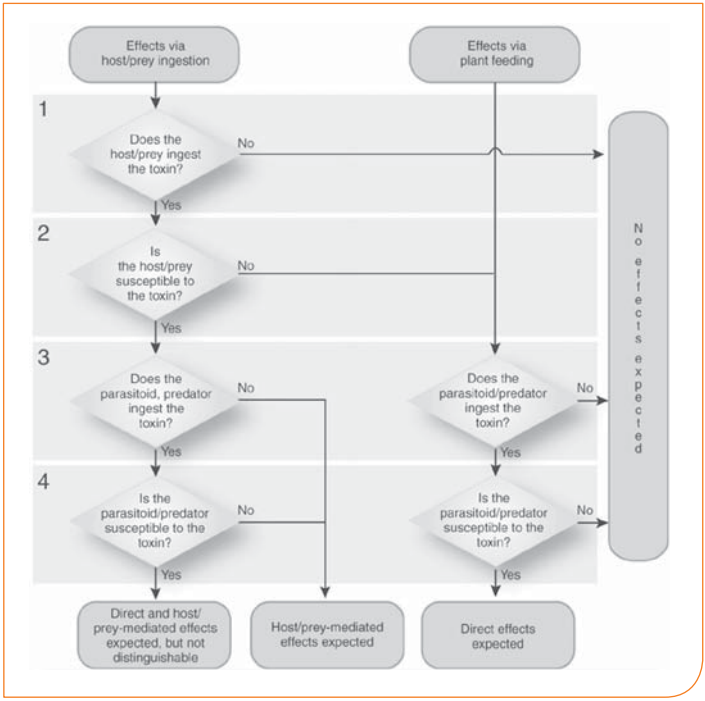


after Hilbeck et al., 2008

Prioritization Criteria

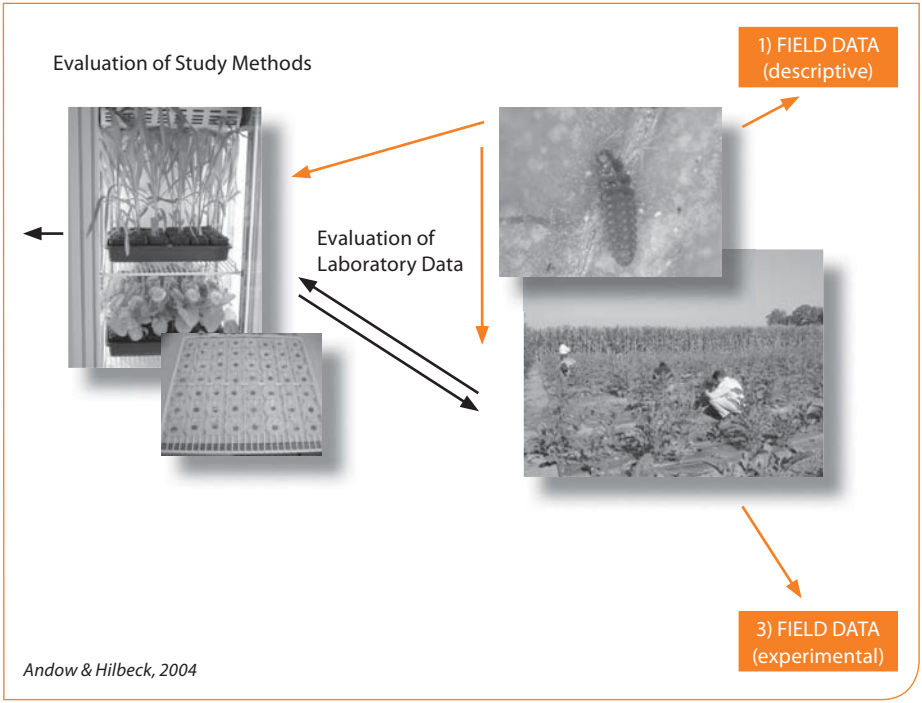
- **Diet regimes** (e.g. larvae vs. adults, mixed feeding by certain carabids, coccinellids, *Orius* spp, etc.).
- The **occurrence/presence** of NTOs/arthropods (considering specifically exposed life stages) during the most likely period of exposure;
- **Ecological significance** of the species;
- **Abundance** of the species;
- **Susceptibility** of NTOs (i.e. are certain populations already threatened and thus more sensitive to additional pressures?);

Tiered Approach



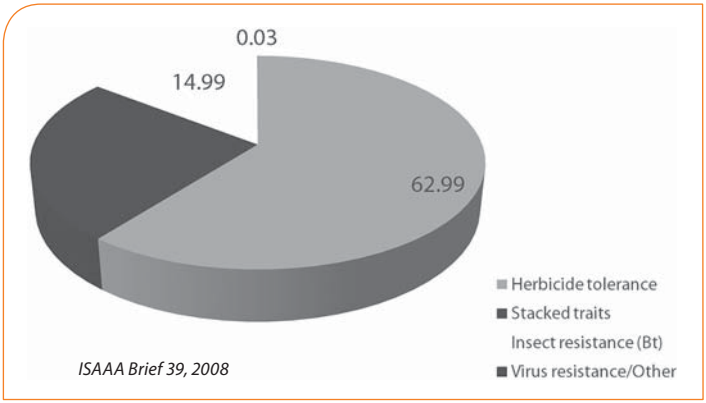
(Romeis et al., 2006)

Ecological approach



Andow & Hilbeck, 2004

Adoption of GM Crops by trait (%) - 2008



ISAAA Brief 39, 2008

Hypothesis driven

- Specific hypothesis-driven investigation
  - Tiered approach including "in-planta" tests, tritrophic exposure and measurement endpoints for sub-lethal effects
- General hypothesis-driven investigation (possible impacts on ecosystem functions)
  - The optimal standard would be field trials under the design requirements defined in the updated GD. Semi-field trials, extended compositional analysis, modelling, and any additional information might be considered case by case (Case studies are currently being examined).

Discussion:

The discussion focused on the methodology related to testing of risks for non-target organisms.

A representative of the French Institute for Agricultural Research asked about the quality of studies on effects on non-target organisms regarding MON810 maize, and how this could influence the updating of the Guidance Document with respect to non-target organisms. According to Salvatore Arpaia, the quality of these studies is quite diverse in terms of number of replicates, accuracy, selection of the non-target organisms and the developmental stage of target species. The revised Guidance Document will contain recommendations for applications including, for example, laboratory tests to study sublethal toxicity effects that improve the overall quality of the application.

A participant from the Dutch National Institute for Public Health and the Environment asked whether testing related to effects on non-target organisms would also be required in the case of a GMO that expresses no new metabolites, such as an amylose-free potato. Salvatore Arpaia responded that in one of the three case studies which the EFSA GMO Panel is working on at the moment, the GM plant exhibits modified composition. An assessment in such a case would begin as with any other case, i.e. with the usual problem formulation to address the possible over-expression of compounds and interference with other organisms, such as pests. However, it may be the case that the problem formulation concludes that no new questions arise.

Assessment of long-term environmental impacts in EFSA's guidance: herbicide tolerance as a case study

JEREMY SWEET
EFSA GMO Panel

Introduction:

Jeremy Sweet, a plant pathologist by background, has a long track record in the field of environmental and agronomic impacts of GMOs, in particular gene flow to crops and wild relatives. He has coordinated numerous European projects and acts as advisor at national and international level. He is now in his third term as a member of EFSA's GMO Panel. His talk highlighted strategies on the assessment of long-term environmental impacts of herbicide tolerant (HT) GM plants in the context of the currently ongoing update of the environmental risk assessment section of the Guidance Document on GM plants.

Presentation:

- General update of the GMO Panel ERA Guidance Document
- Non-target organisms
- **Long-term effects**
- Receiving environments
- Farming practices
- Field trials

Long-term effects (LTE)

- LTE categories:
  - GM plant or practice cause change in organisms and/or ecosystems over a period of time (ie several generations) in an environment
    - effect may sometimes start immediately but is not detected until effect size is increased (eg: cumulative effect)
  - occurrence of new issues at later stage due to ecological complexity or effects that occur in different contexts from those initially tested (eg: ecological shifts not related to GMO – subsequently interacting with GMO – climate change)
  - Occurrence of system changes and new contexts (eg changing farming practices).
    - often only experienced after full commercial release for several years
  - All ecosystems in flux at local level as well as through climatic shifts
  - Farming systems undergo substantial changes due to varietal improvement, agronomic innovation, economic and market forces, weather/climate etc…

- Detection of long-term effects - Requirements:
  - Rigorous environmental base lines and data from comparators over several years
  - Selection criteria for most appropriate biophysical indicators and comparators
  - Measurements of significant environmental changes occurring on time scale that GMO effect is being considered
  - Effects of management of GMO, as well as GMO impacts (eg HT crop impacts)

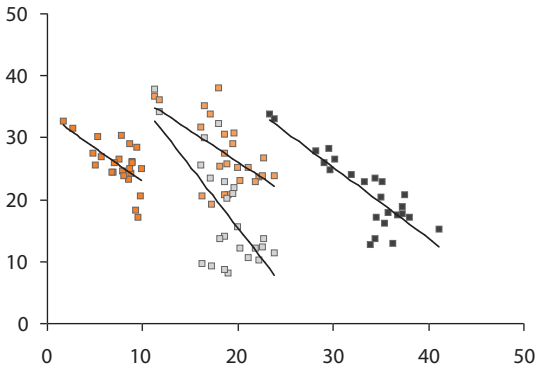
Techniques to assess long-term effects

Objectives:

- To determine if GM cropping is likely to affect any of the main variables in the system, above the existing 'noise' and trends
- Is the impact environmentally damaging (cf existing system)

Major tools:

- Reference to long term or large scale datasets
- Parallel or similar developments with conventional crops
- Experiments, monitoring, modelling



% of spring barley (vertical) and winter wheat (horizontal) in different regions over 25 years

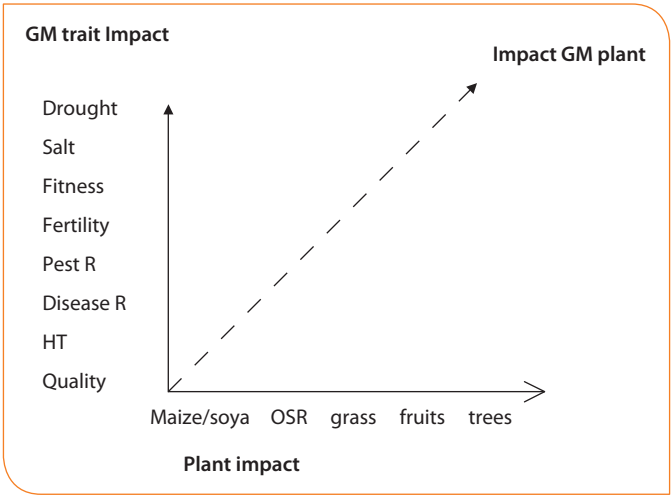
Historical Info:

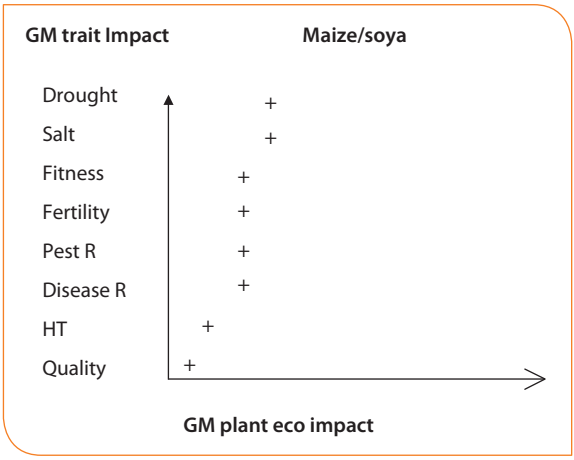
1. Knowledge of Plant :
   - ▷ Annual – perennial
   - ▷ Pioneer, specialist, niche, invasive, competitive, > climax vegetation
   - ▷ Native --- introduced -- alien
   - ▷ Characteristics of compatible relatives

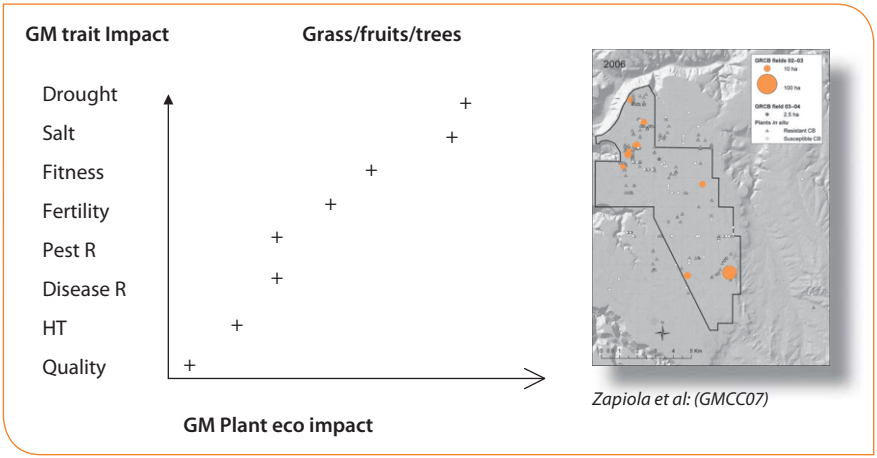
Invasive plants characterised by c 40 characters

2. Characteristics of Trait
   - ▷ Pest and disease resistance effects on fitness of plants and other species… + NTO effects
   - ▷ Drought and salt tolerant species invasiveness

Ecological Impacts







Zapiola et al: (GMCC07)

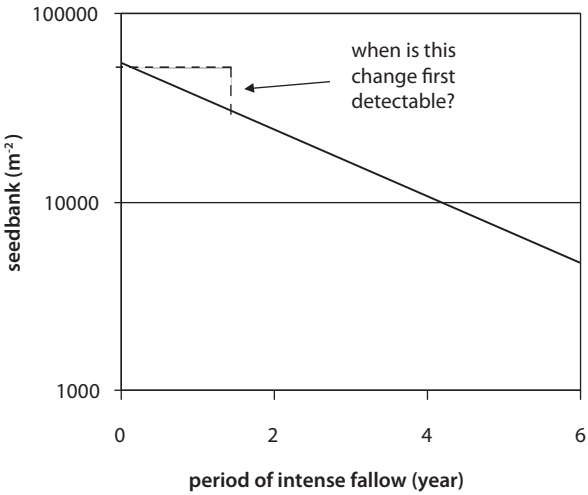
Long-term effects of HT crops

Historical Info: HERBICIDES

- Arable seedbank decline :
  - stressor - continuous high level of weed control
  - Weed function – plant biodiversity and support of food webs
  - Effect – extinction from field of most plants
  - Consequence : loss of primary element of food chain > loss of whole chains > loss of biodiversity
- Primary effect on weeds and seedbank is 'simple' to determine in field plots and observations of fields:
- Secondary effects on distributed food web organisms complex - can't be determined on small plots
- Though decline is steep in absolute numbers, the problem in risk assessment comes in quantifying whether the effect has begun or not following a normal response to changes in practice

Assessment of when change is detectable

- This actual example is for the arable soil seedbank (biodiversity)
- Abundance falls logarithmically when all plants are prevented from re-seeding
- Change was originally detected after 2 years in earlier field experiments (1920s to 1950s)



Brenchley & Warington 1933
Roberts 1958, 1962

HT Crops

- 2001/18/EC: ERA include environmental impacts of the specific cultivation and management of GM crops.
- ERA GM herbicide tolerant (HT) crops : evaluate the environmental impact of herbicide programmes associated with GMHT crops, (+ environmental impacts of GM plant itself).

Herbicide Effects

- Herbicides exclude most weed plants from crop and immediately surrounding area
- Crop contains little botanical diversity (species x number of plants)
- H's remove base of food chain – affect food chain
  → reduction in diversity (sp x n) of phytophagus spp (incl. fungi, bacteria, arthropods, inverts etc..)
  → reduction in diversity of other species: predators, parasites etc…

* Main cause of reductions in farmland biodiversity in Europe (inc. farmland birds)

Resistant Weeds

- Extensive and/or repeated use of same H →
  - Development of resistant weeds
  - Shifts in weed populations to those that avoid the Herbicide.
- Management consequences:
  - Increased use of Herbicide
  - Use of Herbicide mixtures
- Environmental Effects:
  - Reduction in weed diversity (biomass x Spp.)
  - Reduction in Biodiversity

Environmental Effects of Herbicides

Env effects of herbicide depend on :

- Active ingredient (contact, systemic, residual, broad spectrum, selective, etc.)
- Formulation and additives (surfactants, wetters, etc)
- Tank mix (other pesticides etc..)
- Amount applied (dose), droplet size…
- Number of applications
- Timing (in relation to plant development)
- Targeting and precision
- Other agronomic practices
- Crop rotations

Management more important than a.i.

- Careful management of glyphosate > less Env harm than excessive use of more selective H.
- More targeted application… better precision.
- Management measures* being applied to H in many MS to reduce environmental impact.
    - Unsprayed margins of fields (eg 6-12 m)
    - Max dose & no of applications
    - Timing
    - Limit on frequency of use in crop or rotation
    - Drift control measures (droplet size, wind conditions) …

** Legal Requirements with penalties*

Effects of GMHT Maize Management

Considerable research data has shown potential forGMHT crops to change botanical and bio-diversity.

EFSA Opinion NK603 maize

- GMO Panel concluded :
  - Herbicide Management could result in loss of biodiversity and cause environmental harm.
- GMO Panel recommended :
  - Herbicides are managed so as to maintain or improve current levels of biodiversity in crops and fields.
  - Risk managers (eg CAs and EC), together with Applicants, put in place appropriate management systems for use of the herbicides on GMHT crops.
  - This should be done under existing pesticide regulations and regimes operating in MS…

Monitoring of herbicides & NK603

- Stewardship of the herbicide by the agrochemical companies/applicants, under the auspices of the pesticide regulatory systems operating in MSs,
- Record compliance with the approved uses of the herbicides on GMHT, levels of weed control and development of resistant weeds.
  - Case Specific Monitoring Plan:
    – not considered necessary for NK603 as risks due to herbicide management only
  - General Surveillance Plan:
    - monitor NK603 crop environments for unanticipated adverse environmental effects,
    - describe how information will be collected which could be used to assess whether the management is having adverse unanticipated environmental effects.

HT crops (GM)

GMO Panel Proposed procedure for ERA Guidance :
ERA Guidance Proposals

1. The environmental risk assessment should consider the stewardship recommendations in the range of management systems of the GMHT crop likely to be found in Europe. The potential environmental impacts of these recommended herbicide management systems should be compared with those currently observed in equivalent non-HT crops and non-GMHT crops.
2. The risk assessment should consider whether the use of the herbicide could result in reductions in biodiversity leading to environmental damage greater than non-HT crops and non-GMHT crops, taking into account both the different production systems and different levels of biodiversity found in different European farming regions.
3. The applicant should describe plans to consult the appropriate CA's dealing with environmental protection, farmland biodiversity and pesticide registration in each MS where cultivation is intended. These plans should include measures to establish GMHT herbicide programmes that optimize weed management while maintaining adverse environmental impacts at or below current levels, and which are in line with environmental protection goals and biodiversity action plans of that MS. The applicant should consider developing herbicide management strategies to prevent potential adverse effects to both crop and adjacent non-crop environments.

Looking Ahead : GMHT Soya, Beet, OSR…

What happens when these are grown in rotation with GMHT maize ?
Already problems of controlling RR maize volunteers in RR soya in USA…

Discussion:

The overview by Jeremy Sweet on the update of the GM plant environmental risk assessment related to long-term effects triggered a discussion on the need for management strategies.

A question was raised by a delegate from the Dutch National Institute for Public Health and the Environment about the sufficiency of general surveillance in the assessment and management of long-term effects of GM crops that are not herbicide tolerant, e.g. amylose-free potatoes. Jeremy Sweet explained that a case-by-case approach is maintained and that if elements of uncertainty are identified, the EFSA GMO Panel may recommend case-specific monitoring or further studies. Regarding amylose-free potatoes, no long-term effects are anticipated given that conventional potatoes with low amylose content have been cultivated with no indication of negative long-term effects.

A question from a representative of the German Federal Agency for Nature Conservation addressed stacked herbicide tolerance as a possible challenge to some recommendations in the context of risk management. Jeremy Sweet cited the long history of herbicide use, the extensive tracking of herbicide tolerance in weeds and the fact that one can learn from the American experience with the introduction of glufosinate- and glyphosate-tolerant crops. EFSA GMO Panel advises to put into place weed resistance management strategies when a new HT crop is introduced. Resistance management strategies for HT crops should also take into account resistance management strategies for herbicides put forward by companies in the context of the pesticide regulation in Europe. Stacked herbicide tolerance adds another dimension to the issue, also the possibility of gene flow to wild relatives should be taken into account. Examples of the latter already exist, such as in the case of oilseed rape in Canada. However, the issue must be perceived primarily in the frame of pesticide management and not only as GM plant management. Jeremy Sweet also indicated that interaction with HT crops obtained by conventional breeding should be considered.

Post Market Environmental Monitoring: how it works for risk managers

CHANTAL BRUETSCHY
European Commission
DG Environment

Introduction:

EFSA's risk assessment is part of the EU regulatory framework on GMOs. The European Commission, in its role as risk manager, has responsibility for decisions on another aspect, namely the post-market environmental monitoring of GM plants. Chantal Bruetschy, who studied law, has been Head of the "Biotechnology, Pesticides & Health" Unit at the European Commission's Directorate-General for the Environment since 2006. She explained the legal provisions on post market environmental monitoring, the importance of clear reporting and the relationship between monitoring, EFSA's risk assessment and the initial environmental risk assessment carried out by the lead Member State.

Presentation:

1. Legal provisions in GMO legislation on ERA

1. Very specific requirements as regards Environmental risk assessment (ERA) in legislation
2. EFSA mandated by Commission to update their ERA guidelines by March 2010
3. ERA Guidelines clarify further the requirements of the legislation, which remain applicable ; contribute to clarity and transparency for all players (companies, public authorities, risk assessors, etc.)
4. These updated ERA Guidelines will be submitted by COM to Member States for vote in course of 2010

2. Who are the risk assessors in the case of cultivation files ?

- The company notifiying the request for authorisation (notification)
- The Member State who is designated the "lead competent" authority
- EFSA

3. ERA informs monitoring

1. The environmental risk assessment delivered by the three "*main players*" (company; lead CA ; EFSA) has to cover inter alia risk assessment and a "**management strategy**"
2. Legislation specifies for example:

   Step 5 of ERA states "*The risk assessment may identify risks that require management and how best to manage them and a risk **management strategy** should be defined*"

   Step 6 of ERA states "*An evaluation of the overall risk of the GMOs should be made taking into account any **risk management strategies** which are proposed*".

   Annex II C.2 of Directive 2001/18/EC and Regulation (EC) No. 829/2003 describes the steps in the ERA

3. **Risk Management** includes :
   - ▷ management measures as such (refuge zones, borders rows, studies, etc)
   - ▷ monitoring measures.

4. Legal provisions for monitoring

Objective and principles of monitoring plan

- confirm adverse effects identified in the ERA: Case specific monitoring (CSM)
- anticipate adverse effects not identified in the ERA: General Surveillance (GS)
- Case-by-case basis

Annex VII of Directive 2001/18/EC,COM Decision 2002/811/EC – guidance notes supplementing Annex VII, Commission Decision (Article 4)

Notification: Inclusion of monitoring plan is mandatory

Article 13, Annex VII – Directive 2001/18/EC
Article 5, 17 - Regulation (EC) No 1829/2003

Authorisation: must specify monitoring requirements

Article 19 – Directive 2001/18/EC
Article 16, 19 – Regulation (EC) No 1829/2003

5. Purpose of monitoring

Must be useful

- to protect the environment effectively
- to confirm the ERA
- to reassure public at large on safety of product

May be adapted depending on results: is therefore instrumental

Must be made available to the public: specific provisions in the legislation requiring public access

6. Who is responsible for monitoring

- The company (consent holder): to carry out the monitoring, comply with the monitoring requirements and reporting back
- Commission and MS: to define as risk managers the most appropriate risk management
- Member States: may also carry out monitoring in context of their responsibility of ensuring implementation at national level, what happens in a number of Member States (FR, SP, DE, etc.)

7. Reporting/transparency

Post-market monitoring and reporting

Post-market monitoring and reporting are obligatory
Monitoring plan may be adapted

Article 20 – Directive 2001/18/EC
Articles 9, 21 - Regulation (EC) No 1829/2003

Public Access to monitoring reports

Article 19, 20 – Directive 2001/18/EC
Article 9, 21 - Regulation (EC) No 1829/2003

8. Follow up to monitoring

- Monitoring reports have to be useful
- Discussion initiated by DG ENV with MS in 2009 to analyse the reports
- DG ENV will make monitoring reports available on internet (public availability also at national level)
- Role of lead CA

9. Standard reporting format

- Content and presentation of monitoring reports instrumental
- Standard format also useful to have transparency, clarity and comparability over time and between various GMOs

  "*facilitate the implementation and explanation of this Annex*"
  (Dir 2008/27) Annex VII of Dir 2001/18.

- Standard format voted by large majority of Member States in 2009 and will come into force before end of 2009
- Under new format consent holder will for example be specifically invited to:
  - interpret and analyse data (for example literature review);
  - explain how the monitoring results and their interpretation support the conclusions.

10. Monitoring key to ERA

Article 10
"After completion of a release and thereafter at any intervals laid down in the consent on the basis of the results of the ERA the notifier shall send to the CA the result of the release in respect of any risk to human health or the environment…"
("Reporting by notifiers on releases")

Monitoring must therefore be :

- clearly designed
- useful to protect the environment
- transparent and inform the public at large

Particularly important in the case of cultivation files where is no consensus as regards risk and also to build gradually confidence

Biotechnology website

http://ec.europa.eu/environment/biotechnology/index_en.htm

Discussion:

The discussion focused on different types of monitoring and the obligation of carrying out post market monitoring and reporting. The discussion also referred to the need for coordination of management aspects covered by the GMO and plant protection product legislation in the case of herbicide tolerant crops. While respecting the separation between risk assessment and risk management, it is important to be as complete and clear as possible regarding data and scientific information. Member States, EFSA and the GMO Panel must work closely together in an informed and transparent manner.

A question was raised by a participant from the Austrian Agency for Health and Food Safety about the coordination of post-market monitoring of herbicide-tolerant plants if the applicants for the GM herbicide tolerant plant and for the herbicide are different. Chantal Bruetschy answered that coordination of management with regard to plant protection products and GM plants needs to be promoted between the respective competent authorities in Member States. The GM legislation is clear on the need to risk assess changes in management practices due to the GM trait, and on the need for coordination between the different legislative authorities. A series of productive discussions have been conducted with Member States on environmental safety related to the release of a herbicide tolerant crop.

A representative of the World Health Organization requested an explanation of the difference between the environmental post-market monitoring system of GMOs and the food and feed related monitoring system. A representative of Directorate General for Health and Consumers explained that environmental monitoring is compulsory in all cases and that food and feed monitoring is only conducted when the safety assessment has concluded that there is a need to do so. No EFSA opinion has yet mentioned in its conclusion the need for food and feed monitoring of a GMO. Experience exists with post-market monitoring in novel foods. The methodology of this monitoring is challenging, and mainly depends on the nature of the outcome of the safety assessment.

Session 1: Summary of the chair and general discussion

Riitta Maijala, chair of the session, thanked all the speakers for their contributions and summarized some of the points raised during the session.

She underlined that EFSA's main role is to provide independent scientific risk assessment of GMO applications and its commitment to continuous development of guidelines that reflect state of the art science and methodology. EFSA's efforts in updating the guidelines on GM plants were comprehensively presented by EFSA GMO Panel experts Howard Davies, Salvatore Arpaia, Jeremy Sweet and EFSA GMO staff scientist Claudia Paoletti who explained the science and new approaches in these guidelines. The updated guidelines should be clear, consistent and transparent by providing more detail on data requirements which should lead to more complete dossiers being submitted to EFSA for risk assessment.

Riitta Maijala pointed out that the updated GM plant guidelines related to food/feed safety have been further elaborated in close consultation with Member States and stakeholders. They are in the process of final discussion together with the European Commission and Member States; it is anticipated that a greater common understanding of the best approaches in the risk assessment of the GMO food and feed safety will be reached thereafter.

Riitta Maijala reflected on the presentations on environmental risk assessment which is a particularly complex area. The GM plant guidelines on environmental risk assessment are currently being updated. Critical aspects are effects on non-target organisms as explained by EFSA GMO Panel member Salvatore Arpaia, and long-term effects as presented by EFSA GMO Panel member Jeremy Sweet, as well as the integration of regional aspects. Andreas Heissenberger from Austria pointed out very clearly issues needing more attention especially with regard to field trials and testing of non-target organisms. The EFSA GMO Panel will consider these questions and comments when further updating guidelines on environmental risk assessment. This will be tabled for public consultation and are scheduled to be finalized in March 2010.

Finally, she referred to the presentation of Chantal Bruetschy from Directorate General Environment on risk management aspects. In particular, plans to further develop the reporting on post-market environmental monitoring are very interesting for future risk assessment.

Thereafter, Riitta Maijala invited all attendees to participate in a general discussion. The following points were raised:

An attendee from EuropaBio asked if EFSA is planning communications to clarify that an 'update' of EFSA's Guidance Documents does not necessarily mean that previous opinions were based on insufficient information. In answering, Chantal Bruetschy explained that the mandate sent to EFSA aims at explaining further the detailed regulatory framework for GM risk assessment, which is applicable anyway irrespective of EFSA's guidelines. The update of the latter will increase transparency in what is already needed for all players (applicants, risk assessors at EU and national level, risk managers at EU and national level). By providing greater clarity on what is provided for in the legislation, it will contribute to more predictability for all players and lead to less need for questions of clarification between EFSA and applicants. Therefore, a main objective of the updated guidelines is to expand from a scientific point of view the regulatory framework for GM risk assessment. Integration of the guidance on GM risk assessment in a future Commission decision will also help to build confidence and support from the Competent Authorities, which will vote on it before it is adopted by the Commission. Per Bergman also pointed out that an update is a normal occurrence in the life cycle of a guidance document taking into account both scientific developments and practical experience of the Panel in the risk assessment process.

EFSA was asked by a representative of the UK Food Standards Agency if it needs additional resources in order to handle the workload and high number of applications dossiers, notably in light of the need to constantly update guidelines which also draws resources from the EFSA GMO Panel. Riitta Maijala, EFSA's Director of Risk Assessment, responded that EFSA has doubled the number of staff in the GMO unit and the scientific output has tripled in comparison with last year. A basic issue is also the appropriate deployment of experts in Member States and the establishment of EU-wide networks for collaboration and for discussion of methodological issues. The goal remains to improve transparency and common understanding of how risk assessment in Europe is conducted together with the efficient handling of applications.

A representative from the Instituto de Tecnologia Química e Biológica (Portugal) raised the general question of why safety assessment and concerns are only directed to GM plants, and not to non-GM plants. Safety should be assessed for the product, but not for the process. EFSA GMO Panel member Howard Davies responded that GM plants certainly represent a particular case in that no other breeding approach requires such sophisticated testing to prove safety. However, examples exist of plants produced by conventional breeding methods that had to be withdrawn from the market for reasons of safety. Mutational breeding also remains unregulated. The legal requirements for the risk assessment are much more stringent for GM plants compared with any other form of breeding. Also, there is a lack of definition of the term 'history of safe use' itself.

Chantal Bruetschy referred to the necessity of acknowledging the history behind the legislation and in particular the lack of consensus on the risks linked to GMOs existing still today. Against this background, clear communication by EFSA on possible risks and the cooperation with Member State scientific experts is most welcome, and an important step towards an inclusive discussion based on facts and transparency and confidence building.

It was also pointed out by Jeremy Sweet that adequate measures for the assessment of non-GM crops already are in place with practicable methodologies. All Member States conduct variety testing programmes which address issues including quality, safety and agronomic impacts. Some agronomic impact issues relate to the environment. Chantal Bruetschy added and confirmed that conventional seeds are also subject to EU legislation for marketing with specific criteria (purity, stability, etc).

A delegate from the University of Latvia pointed out the lack of baseline data for the state of the environment as a useful tool for monitoring the impact of GMOs over the years. The delegate stressed the need for a concerted effort by Member States to create such data and asked if EFSA is in a position to encourage other bodies in the European Union to provide environmental baseline information on a European scale.

Jeremy Sweet added that a number of Member States perform environmental studies based on their different environments in order to describe the environmental status quo. Databases are being established and even though they serve primarily to address national management issues, such databases may also establish a baseline and be a useful tool for monitoring the impact of GMOs over the years, as well as that of other techniques and practices.

A member of the audience suggested better harmonisation between GMO registration and pesticide registration in the EU, for example in cases of insect-resistant plants. EFSA GMO Panel member Jeremy Sweet responded by suggesting a change in perspective. The environment itself, instead of the impact of a particular pesticide or GMO, should form the basis of consideration. The establishment of particular goals in environmental protection would allow the assessment and regulation of any new technology in this overall context. Conceptual distinctions between GMO, pesticide and nanotechnology, for example, would no longer occur. Clear goals are lacking in the current approach which considers each product or process separately. A move towards such a change in perspective appears to be underway, albeit slowly. Per Bergman mentioned that EFSA is promoting an integrative approach in risk assessment that involves for instance both the GMO and the Plant Protection Products and their Residues (PPR) Panels in addressing the question of herbicide tolerant plants.

IV SCIENTIFIC SESSIONS

▶ Session 2:
The impact of GM crop cultivation on the environment

Chair: Hubert Deluyker, Director of Scientific Cooperation and Assistance, EFSA

This session aimed at broadening the debate on risk assessment of GM plants to include international perspectives, the views of various stakeholders and the view of a Member State, Spain.

OECD Working Group on Biosafety: environmental considerations for risk/safety assessment

PETER KEARNS
OECD's Biosafety Team

Introduction:

Peter Kearns is a geneticist and head of OECD's (Organisation for Economic Co-operation and Development) biosafety programme. During his time at the OECD, he has mainly focused on promoting international harmonisation in the regulation of biotechnology, and other emerging technologies. His talk illustrated risk assessment from a global perspective and gave an insight into the OECD's working group on biosafety and in particular the environmental considerations for risk/safety assessment. EFSA's guidelines on GM plants are in line with internationally agreed standards such as those specified by OECD.

Presentation:

Organised in two programmes:

1. OECD's Working Group for the Harmonisation of Regulatory Oversight in Biotechnology (Environmental safety of transgenic organisms)
2. OECD's Task Force for the Safety of Novel Foods and Feeds (foods/feeds derived from transgenic organisms)

Participation of the OECD countries and of some Non-member economies:

- Argentina
- Brazil
- Cameroon
- China
- Chile
- India
- Latvia
- Philippines
- Russian Federation
- Slovenia
- South Africa
- Thailand

Who participates?

- **Working Group**: delegates from ministries/agencies responsible for environmental risk assessment of transgenic organisms (competent authorities);
  - Observers and invited experts: UNEP, CBD Secretariat, UNIDO, other stakeholders.
- **Task Force**: delegates from ministries/agencies responsible for risk assessment of novel foods and feeds (competent authorities);
  - Observers and invited experts: FAO, WHO, Codex secretariat, other stakeholders.

The purpose of these programmes is threefold:

- To assist OECD countries evaluate the potential risks of transgenic products to ensure high standards of safety;
- To foster communication and mutual understanding of the regulatory processes in different countries; and
- To reduce the potential for non-tariff barriers to trade.

The work undertaken by the two programmes focuses on the four main areas:

- Creating a common base of scientific information by identifying the potential risks that the products of modern biotechnology may pose to human and animal health as well as the environment.
- Dissemination of information relevant to the risk/safety assessment of products of modern biotechnology, mainly through a website: BioTrack Online.
- Involves organising workshops and meetings where experts from OECD member countries as well as non-member countries.
- Similarities and differences in regulatory frameworks among countries.

Food/Feed Safety Consensus Documents

- Food/feed risk/safety assessment of transgenic varieties follows a comparative approach;
- In other words, is a new food as safe as a traditional counterpart?
- Include information (for use in food/feed safety risk assessment of new varieties) on key:
  - Nutrients
  - Anti-Nutrients
  - Toxicants
  - Allergens
  - Secondary metabolites

Some Published Food/Feed Safety Consensus Documents

- Soybean *(under review)*
- Canola/Oilseed Rape *(under review)*
- Potato
- Sugar Beet
- Maize
- Sunflower
- Alfalfa and Other Temperate Forage Legumes
- Bread Wheat
- Considerations for safety of animal feeds
- Rice
- Cotton
- Barley
- Cultivated mushroom *Agaricus bisporus*
- Tomato

Food/Feed Safety Consensus Documents in preparation

- Cassava
- Sweet Potato
- Papaya
- Sugarcane
- Sorghum

Working Group Biosafety Consensus Documents

- Include a wealth of information (for use in risk assessment) on the ***biology*** of crops and traits:
  - The use of the crop/trait in agriculture practice
  - Taxonomy
  - Reproduction
  - Wild relatives – hybridisation
  - Centre of origin and diversity
  - Weediness

Some Published Biosafety Consensus Documents

- **Crops**: maize, oilseed rape, potato, bread wheat, rice, soybean, sugar beet, cotton, sunflower, peppers, papaya, etc.
- **Traits**: tolerance to glyphosate herbicide, tolerance to phosphinothricin herbicides, virus resistant through coat protein gene-mediated protection, Bt resistance, etc.
- **Trees**: Norway spruce, white spruce, poplars, Douglas fir, Sitka spruce, lodgepole pine, Eastern white pine, European white birch, larches, etc.
- **Micro-organisms**: *Acinobacter*, *Pseudomonas*, baculoviruses, Taxonomy in Risk Assessment, Detection methods, etc.
- **Unique identifier for transgenic plants**: Guidance used by many organisations and databases (OECD, CBD, industry…)

Other Biosafety activities, and main Consensus Documents in preparation

- Cucurbita spp.
- Black spruce
- Brassica spp.
- Tomato
- Atlantic salmon
- *Fusarium*, etc.

- **Environmental Considerations** for Risk/Safety assessment for the release of transgenic plants
- **Molecular Characterisation** of transgenic plants…
- **Low level presence** of transgenic material in seeds and commodities

Three recent innovations related to preparation of Consensus Documents

1. An Introduction to the Biosafety Consensus documents
    - ▷ Describes Regulatory Harmonisation
    - ▷ A common approach to risk/safety assessment
    - ▷ Why consensus documents
    - ▷ Their purpose
    - ▷ How they are used (intended users)
    - ▷ How they are drafted and brought to publication
2. Guide for Preparation of Consensus Documents (process)
    - ▷ The role of the secretariat
    - ▷ The role of the lead country
    - ▷ The role of other stakeholders
    - ▷ Sources of information
    - ▷ Style, Layout, Nomenclature
3. Points to consider for consensus documents
    - ▷ Species of taxonomic group
    - ▷ Reproductive Biology
    - ▷ Genetics
    - ▷ Hybridisation and Introgression
    - ▷ Interactions with other organisms
    - ▷ Human health and biosafety
    - ▷ Additional information

Examples of points to consider

- Reproductive Biology

Generation time and duration under natural circumstances, and where grown or managed

Rationale: *The generation time and duration are indications of the terms in which environmental effects may occur. Precocious generation times and shorter durations in agriculture affect the likelihood of outcrossing with free-living (wild) relatives, and give a general indication of when outcrossing may first occur.*

Reproduction (production of flowers or cones, fruits, seeds, and vegetative propagules)

Rationale: *The reproductive capabilities of a plant determine the means by which the plant can produce progeny and spread or disperse. Both the plant and its progeny may affect the environment, including other organisms, and thus the time frame and geographic area over which effects might occur;*

Pollination (wind, insects, both, etc.), pollen dispersal, pollen viability

Rationale: *Pollen biology is an important component in the assessment of potential for gene flow, and in the evaluation of a need for and the type(s) of pollen confinement strategies such as buffer rows or isolation distances.*

Environmental Considerations

- Weediness and Invasiveness
- Gene Flow and its consequences
- Effects on Organisms and Food Webs
- Effects on Soil Function
- Changes in Management Practices
- Effects on Plant Health, and Incidental Exposure to Animals and Humans
- Effects on Biodiversity

Weediness and Invasiveness: Information Elements

- Weediness or invasiveness of the unmodified plant species
- Potential for cultivation/growth of the transgenic plant beyond the cultivation/growth area for the unmodified species
- Changes in the modified species' reproductive characteristics
- Changes in the modified species' vegetative characteristics
- Changes in the modified species' susceptibility to biotic or abiotic stresses
- Changes in interactions with other plant species (e.g. allelopathy)
- Current cultivation practices used for the unmodified species in cropping systems in the receiving environment
- Anticipated changes in cultivation practices after introduction of the transgenic plant in cropping systems

Effects on Organisms and Food Webs: Information Elements

- Mode of action of the novel protein/metabolite
- Spectrum of activity of the novel protein/metabolite
- Expression pattern of the novel protein/metabolite in the transgenic plant (i.e. concentration in various tissues over time)
- Change in composition of the transgenic plant, compared to unmodified species
- Change in phenotypic characteristics of the transgenic plant, compared to unmodified species
- Potential for cultivation of the transgenic plant beyond the current cultivation area of the unmodified species
- Presence of species of conservation concern in the receiving environment
- Organisms interacting with the unmodified species
- Organisms (individual species or groups) likely to be exposed to the novel protein/metabolite
- Routes and level of exposure of organisms to the novel protein/metabolite
- Toxicity and sub-lethal effects of the novel protein/metabolite on organisms (or surrogate species)
- For transgenic plants with pesticidal properties: level of efficacy on target organisms
- Anticipated cultivation practices (e.g. insecticide use) for the transgenic plant, compared to unmodified species
- Potential impact of changes in cultivation practices (if any) on organisms and food webs

OECD's Biosafety Team

- Peter Kearns
- Yukihiko Fukase
- Bertrand Dagallier
- icgb@oecd.org
- http://www.oecd.org/biotrack/

Discussion:

The discussion focused on the dissemination of information relevant to the risk/safety assessment of products of modern biotechnology and the production of food/feed safety consensus documents on, for example, crop species.

Per Bergman, Head of EFSA's GMO Unit, asked if OECD follows the use of their consensus documents on a global basis. Peter Kearns responded that at each OECD meeting each delegation starts by highlighting relevant events that have occurred in their country or organisation since the previous meeting. This leads frequently to reference to the use of OECD documents, as well as to whether the need exists for their update or extension, or perhaps even for the creation of a new one.

A representative of the Irish Environmental Protection Agency wanted to know how differences between the regulatory processes used in the more than 30 participating countries, e.g. product- versus process-based regulatory regimes, are reconciled. According to Peter Kearns, this presents a minor problem in the case of risk assessment issues. Representatives of different countries can work effectively together, provided that the focus remains on information used in the different regulatory risk assessment situations. This can become more difficult if risk management issues are discussed.

EC/JRC research on global aspects of GM adoption and agricultural benefits of GM in Europe

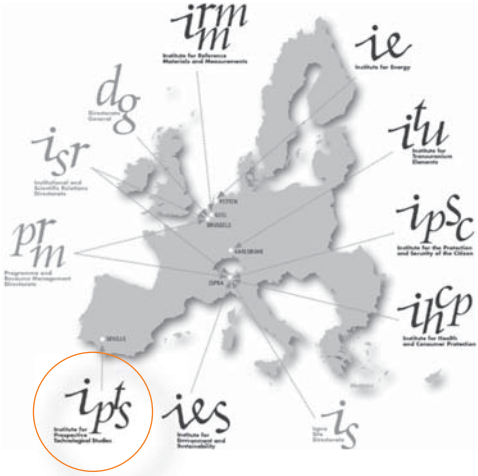
EMILIO RODRÍGUEZ CEREZO
JRC, European Commission

Introduction:

Emilio Rodríguez Cerezo, from the Commission's Joint Research Center (JRC) at the Institute for Prospective Technological Studies (IPTS) in Seville, Spain, is a trained agronomist and plant pathologist. He has been active in research and policy support in the fields of coexistence and economic impacts of GM crops. He presented the impact of GM crops in Spain over the past 10 years by an analysis of the experiences of famers cultivating Bt maize and the reduced use of insecticides and yield increase in various Spanish regions.

Presentation:

- IRMM – Geel, Belgium
  - Institute for Reference Materials and Measurements
- IE – Petten, The Netherlands
  - Institute for Energy
- ITU – Karlsruhe, Germany
  - Institute for Transuranium elements
- IPSC - IHCP - IES – Ispra, Italy
  - Institute for the Protection and the Security of the Citizen
  - Institute for Health and Consumer Protection
  - Institute for Environment and Sustainability
- IPTS – Seville, Spain
  - Institute for Prospective Technological Studies
- Total staff > 2600 people, IPTS 180 people



Outline of the presentation

1. The EU-FP6 SIGMEA project
2. *Ex post* analysis: adoption and impacts of Bt maize in Spain
3. *Ex ante* analysis: adoption and possible impacts of HT maize and HT oilseed rape in Europe
4. Concluding remarks

1. The SIGMEA project

- « *Sustainable introduction of GM crops into European Agriculture* » EU FP6 STREP project (2004-2008)
- WP5: adoption by EU farmers, agronomic and socio-economic impacts

http://www.inra.fr/sigmea

Global adoption-share of GM varieties in main crops (2008)

Soybean	HT	70 %	66 M ha
Cotton	Bt/HT	46 %	15 M ha
Maize	HT/Bt	24 %	37 M ha
Oilseed rape	HT	20 %	6 M ha
Sugarbeet	HT		

2. Ex post *analysis: adoption and impacts of Bt maize in Spain*

Bt maize: the technology

- Resistant to maize borers (ECB/MCB)
- Maize borers are not efficiently controlled by conventional insecticides
- Some farmers assume yield losses (no treatments)
- Hypothesis: Bt maize increases yields in areas affected by maize borers, and may reduce insecticide use
- Increase of farm earnings? Will depend mainly on additional GM seed costs

Evolution Bt maize in Spain

- 1998: two hybrids containing Bt 176, 20000 ha, 5% adoption rate
- 2008: over 50 hybrids containing MON810
- 79000 ha (2008) 20% adoption rate
- 100% of GM maize grain sold to animal feeding industry
- 10 years experience, empirical evidence

Field work (2005): surveying commercial farmers for 2002-2004 data

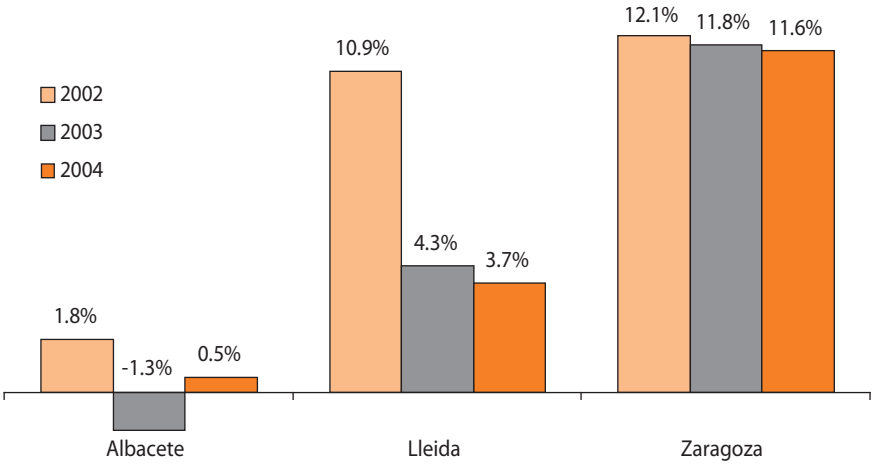
- Regions with high presence of Bt maize
- 2005 adoption rates
  - Aragon (31%)
  - Cataluña (43%)
  - Castilla- la Mancha (16%)
- ZARAGOZA, LLEIDA y ALBACETE

Types of farmers identified

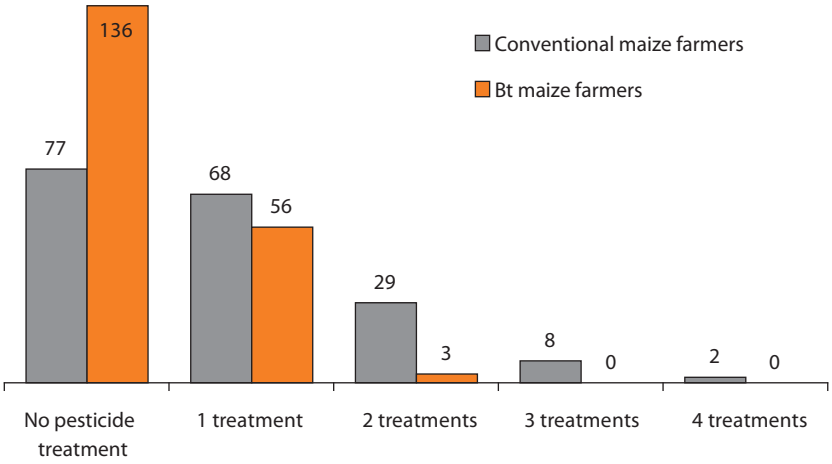
Types of maize grower	Regions			
	Castilla-La Mancha	Catalonia	Aragon	Total
Non-adopters	61	52	71	184
Full adopters	42	66	87	195
Partial adopters	2	16	5	23
Total region	105	134	163	402

Field work May-June 2005

Bt maize yields vs. conventional maize (price paid for harvest identical)



Number of insecticide treatments to control corn borers



Impact on insecticide use

Reduced insecticide use in corn borer control

58 % of conventional maize growers apply insecticide (average 0.86 treatments per year)

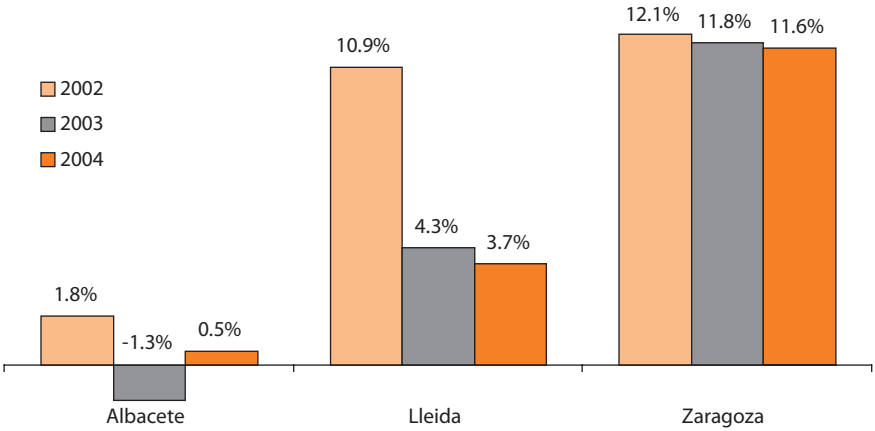
vs.

30 % of Bt maize growers (average 0.32 treatments per year)

Bt maize economic benefits (2002-2004) for Spanish farmers

- Yield increase : variable from neutral to 12% variable
- Harvest price Bt-conventional: identical
- Reduced insecticide costs
- Increased seed costs
- Gross margin effects for Bt maize adopters in Spain: from neutral to 120 €/ha/year (2004)

Recent evolution of Bt maize adoption in Spain is consistent with the pattern of observed benefits



7957 ha (2005)
3659 ha (2007)
-54%

16830 ha (2005)
23013 ha (2007)
+37 %

21259 ha (2005)
35860 ha (2007)
+68%

Conclusions Bt maize agronomic and economic impacts (2002-2004)

- Yield increase from neutral to 12%
- Identical market price for harvests
- Reduced use and cost of insecticides against borers
- Bt seeds price differential
- Impact on farmer's gross margin from neutral up to 120 €/ha/year
- Geographic variability of benefits is reflected in the recent evolution of adoption (an indirect evidence of success)

Spanish farmers adopting Bt maize are not different than conventional maize farmers

- No statistical differences in farm size, age, education, experience as maize growers, socio-economic level (50 variables)
- Yield differences mostly due to the use of Bt maize
- Differences in perception of risk of corn borer
- A "divisible" technology (comes in seeds)

3. Ex ante *analysis: adoption by EU farmers and possible impacts of HT maize, HT oilseed rape*

Herbicide-Tolerant (HT) Maize

- Allows using non-selective herbicides
- Simple weed management
- 63% maize area in USA (23% HT, 40% BtxHT)
- Yield and Economic impacts

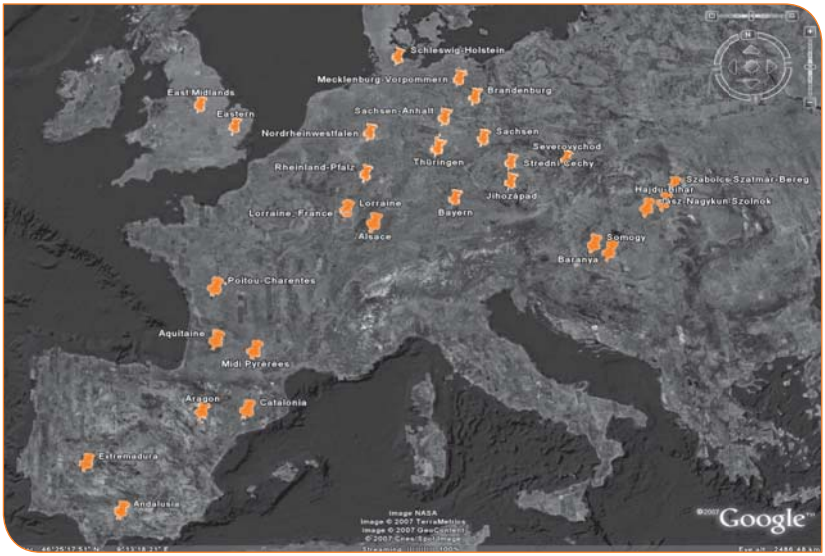
HT Oilseed rape

- Allows using non-selective herbicides, simpler weed management
- Canada: 98% canola is HT (over 80% transgenic)
- 80% under minimum tillage
- France: €24 M/year in savings in weed control (*Desquilbet et al*. 2001)

Ex ante analysis of adoption and effects of HT maize and HT oilseed rape in Europe

- Field survey in 2007 (over 1200 farms)
- Potential adoption by farmers
- Factors determining decision to adopt or not
- Model the impact of adoption on herbicide use and no tillage practices
- Model the impact on farmer's economies
- Influence of coexistence measures in adoption

Field work: surveyed farms (2007)



Field work-surveyed farms (2007)

Trait/ Crop	Country	Number of farmers	Regions (Nuts1 or Nuts2)
HT rapeseed	Germany	208	Mecklenburg-Vorpommern, Brandenburg, Sachsen-Anhalt, Thüringen, Sachsen, Schleswig-Holstein, Nordrheinwestfalen, Rheinland-Pfalz Bayern
	United Kingdom	200	East Midlands, East of England
	Czech Republic	200	Strední Cechy, Jihozápad, Severovýchod, Jihovýchod
HT maize	Spain	104	Andalusia, Extremadura
	France	101	Aquitaine, Midi Pyrénées, Poitou-Charentes, Alsace, Lorraine
	Hungary	100	Del-Dunantul, Eszak-Alfold
Bt/HT maize	Spain	100	Aragon, Catalonia
	France	101	Aquitaine, Midi Pyrénées, Poitou-Charentes, Alsace, Lorraine
	Hungary	100	Del-Dunantul, Eszak-Alfold
	Total	**1214**	

Preliminary results: potential adoption of HT maize and HT rapeseed by EU farmers

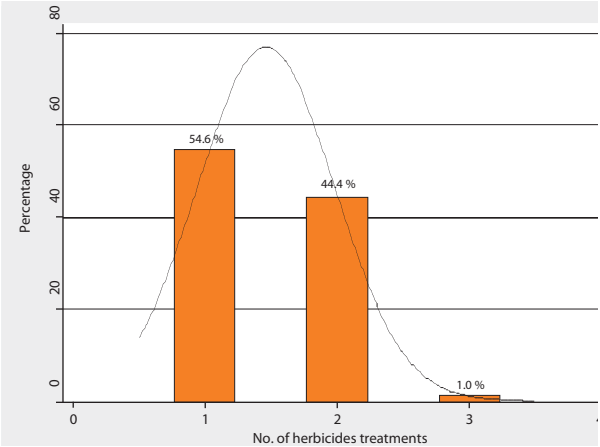
Trait/Crop	Country	(1) Likely+very-likely %	(2) Unlikely + Very-unlikely %	Ratio (1)/(2)
HT rapeseed	Germany	53,4	31,7	1,68
	United Kingdom	44,0	25,5	1,73
	Czech Republic	43,9	28,1	1,56
HT maize	Spain	36,5	38,5	0,95
	France	37,6	33,7	1,12
	Hungary	38,0	38,0	1,00
Bt/HT maize	Spain	48,3	35,0	1,38
	France	46,5	28,7	1,62
	Hungary	25,3	57,6	0,44
	Total average	**41,5**	**35,2**	**1,18**

Herbicide use in conventional maize EU

Number of herbicide treatments

EU

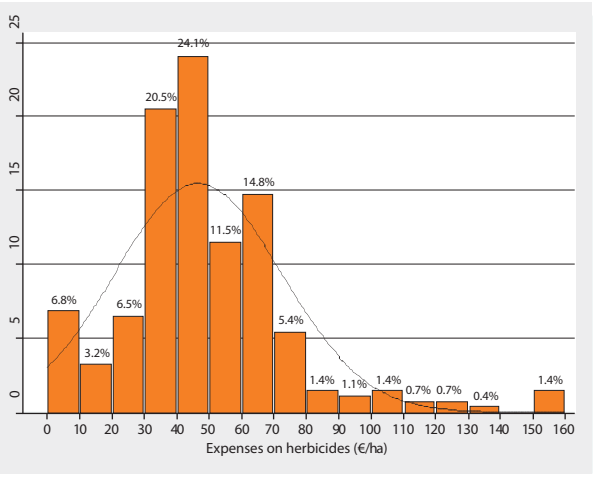
Obs= 304; Mean= 1.46; Median= 1; Std. dev.= 0.52



Expenses on herbicides (€/ha)

EU

Obs= 279; Mean= 47.77; Median= 45; Std. dev.= 31.98



Preliminary conclusions ex-ante analysis of adoption HT crops in EU

- High potential adoption by farmers
- Experience on the crop associated to likelihood of adoption
- Baseline of current herbicide use and herbicide costs completed
- Modelling effects of HT crop adoption on herbicide use changes and farmers revenues: ongoing work
- Coexistence measures may have an impact on the decision to adopt

4. Concluding remarks

- Agricultural economics research is essential
  - to understand potential benefits of GM crops and its social distribution
  - to quantify indirect effects on the environment (i.e. changes in pesticide use)
- Experience and academic excellence exists in Europe, but few projects on-going
- Networking, integration and funding needed

http://www.jrc.ec.europa.eu
http://ipts.jrc.ec.europa.eu

Discussion:

The discussion focused on clarification related to the reported benefits for farmers in the context of the cultivation of MON810 in Europe.

A delegate from the French National Institute for Agriculture (INRA) questioned why, according to data presented by Emilio Rodriguez Cerezo, farmers adopting MON810 are still using insecticides significantly to control the European corn borer and the Mediterranean corn borer. This GM crop is regarded to be very active against the pests and effective in controlling up to 99 percent of the larvae. His explanation was that the practices of some farmers do not follow technical reasoning: they will use all the weapons they have at hand against the corn borer.

A representative of the UK National Farmers Union asked if factors other than reduction in pesticide use are contributing to the increase in the gross margins of 120 Euros per hectare in the case of Bt maize in Spain. Emilio Rodriguez Cerezo pointed out that this increase is almost solely caused by savings in insecticide use. He expects the situation to be different with herbicide tolerant crops where there is more impact on labour and energy use, and different practices of soil conservation.

An EFSA GMO Panel member asked about differences in market price between Bt and non-Bt maize in the food area. Emilio Rodriguez Cerezo explained that production of maize for human consumption is totally segregated from the feed production chain in Europe and farmers in the food sector are only growing conventional maize.

Potential outstanding concerns for the environment

HELEN HOLDER
Friends of the Earth Europe

Introduction:

Helen Holder has a degree in biochemistry and in business. She has worked on biotech and farming issues since 1998 and joined the European secretariat of Friends of the Earth as campaign coordinator in 2005. She was invited to give the perspective of an environmental NGO on environmental risk assessment of GM plants.

Presentation:

Friends of the Earth Europe

- Federation of 70 national autonomous organisations, including FoE US
- Campaigning for social and environmental justice
- Over 5000 grassroots groups worldwide
- 31 organisations in the European network
- European secretariat in Brussels with @ 30 staff
- campaign on GMOs for 10+ years
- member of EFSA stakeholder platform
- speaking today as a non-scientist
- NGO meeting at EFSA to discuss GMO issues in October 2009

Introduction

- **EFSA GMO panel has been source of controversy with criticism from various sources (NGOs, scientists, member states)**
- **December 2008 Environment Council Conclusions (16882/08 ENV 961):**
  - "necessary to look for improvement of the implementation of [GMO] legal framework"
  - signal to EFSA and to the Commission for the risk assessment review

Issues since EFSA established

- **EFSA GMO Panel since it was established**
  - Does not ask biotech companies to submit evidence of long term impact assessments
  - Has shown little or no evidence of taking Member States' divergent opinions into account
  - Has shown no evidence of taking areas of scientific uncertainty into account
  - No acknowledgement of scientific controversy either in terms of risk assessment protocols or of impacts
  - Poor in expertise on ecology
  - Evidence of poor quality work
- **FoE Europe research into EFSA GMO panel (2004):**
  - One member direct financial links with the biotech industry and others had indirect links
  - Two members appeared in promotional videos produced by the biotech industry.
  - Several members of the Panel, including the chair were involved with an EU-funded project which aimed to agree safety assessment, risk management and risk communication procedures to "*facilitate market introduction of GMO's in Europe, and therefore bring the European industry in a competitive position.*"
  - The EFSA chair sat on a working group that also included staff from Monsanto, Bayer Cropscience and Syngenta.
  - One of the first experts used by the GMO Panel was a well known advocate of GM technology who had previously undertaken research for both Monsanto and Bayer CropScience.

NB panel has since been renewed twice in accordance with EFSA rules

- **There have been some improvements at EFSA**
- **Review process is welcome, but real change needed**
- **Two examples:**
  - A recent EFSA opinion
  - Approach taken to herbicide resistant (HT) crops

GM Maize MON810

EFSA Opinion issued end June 2009

Analysis commissioned by Friends of the Earth Europe and Greenpeace, published July 2009

- **Environmental Safety**
  - Non-target organisms: lack of key laboratory studies on European species
  - This critical issue has been raised by Member States
  - Rather than admitting this area of uncertainty, EFSA established a non peer-reviewed model
  - Recommends "management measures in order to mitigate the possible exposure of these species to MON810 pollen"
  - Reminder: environmental risk assessment of "potential effects of genetically modified plants on non-target organisms "specifically mentioned in Council Conclusions
- **Human Safety**
  - EFSA acknowledges that there are new unknown fragments of genetic material in plant cells derived partly from the inserted MON810 genes and the maize genome Have potential to produce new unknown proteins
  - BUT instead of requesting that the applicant (Monsanto) assess toxicology properties, EFSA assumes they are safe without any further scientific studies or reference to peer-reviewed literature
  - Issue of unknown fragments of genetic material was looked at in NK603 but not in MON810
  - Silence "not justified and of poor scientific standard"
  - EFSA accepts that applicant (Monsanto) did not update its information on details of genetic sequence inserted into MON810
  - Because of RNA and DNA fragments around inserted genetic material, this is a cause for concern (fragments have been detected in blood of animals)

- EFSA sees shortcomings in scientific articles raising potential risks but accepts all articles to the contrary including ones where MS have raised shortcomings
- Omission of studies (easily identified in scientific databases) that point to a risk or that demand further evaluation

- **Overall conclusion is that the EFSA opinion is not to good scientific standard**
- **On key issue (Non Target Organisms) there is simply a "management measures" proposal**
- **In addition, Opinion was given to Monsanto before publicly made available**
  - Monsanto put out a press release
  - EFSA policy
  - Inappropriate for a supposedly independent agency

EFSA on Herbicide Tolerant (HT) Crops

- **2008 EFSA working document**
- **USA: "continuous and repeated application of glyphosate is causing changes in weed flora and development of more resistant weeds"**
  "This is resulting in changes to herbicide programmes and hence additional adverse environmental consequences"

Herbicide Tolerant Crops and pesticide use in the US

- **1994-2005**: **15-fold increase** in the use of glyphosate on soybeans, maize and cotton. In 2006, glyphosate use on soybeans jumped by **28%**.
- An epidemic of glyphosate-resistant weeds, and rising use of other herbicides to control them: the amount of **2,4-D** (a component of Agent Orange) applied to U.S. soybeans **more than doubled** from 2002 to 2006.
- The use of **atrazine** (banned in the EU due to links to health problems) on corn/maize increased by **12%** between 2002 and 2005.

Herbicide Tolerant crops in Brazil

- Brazilian government authorities have documented an **76.9%** increase in glyphosate use from **2000 to 2005**, together with the rapid emergence of weeds that are resistant to the chemical.

Weed resistance and Herbicide Tolerant crops in Argentina: Johnsongrass

- Considered to be one of the worst weeds in the world
- In 2007, reported in 6 provinces in Argentina
- Recommendation to control resistant weeds is to use a cocktail of herbicides including some of the most toxic.
- Estimations are that additional 25 million litres of such herbicides will be needed each year
- **Estimation that herbicide costs will double in affected areas**
- **Increase in production costs expected**
- **Bill drafted by Argentinean Congressman in 2007**
  - Acknowledges that "***market forces cannot control this pest***" and that a special fund is needed to fund eradication measures. Fund would include taxpayers money, and contributions for International organisations

Herbicide Tolerant crops

- Promise of GMHT crops reducing pesticide use has not delivered

Syngenta Crop Science CEO:

"*[Weed] Resistance is actually quite healthy for our markets, because we have to innovate*" (source: ETC)

- 62% of field trials in the US are for Roundup Ready crops
- Roundup Ready Flex cotton (to withstand higher applications of Roundup)
- Monsanto developing "Dicamba" resistant crops (same class as 2,4 D), partnership with BASF
- Other HT GM crops for ex by DuPont Pioneer

EFSA and GMHT crops

- "***The EFSA GMO panel recommends that monitoring of the herbicides is conducted as part of the stewardship of the herbicides by the agrochemical companies involved, under the auspices of the pesticide regulatory systems operating in MS…***"
- Point of comparison is intensive conventional farming, not modern ecological farming (in context of climate change, IAASTD)
- Fails to admit the scale of the problem and avoids the issue and ignores future problems
- Again, this issue was specifically raised by Environmental Ministers in December 2008

Conclusions

- **Review of risk assessment is much needed and welcome initiative**
- **Improvements can be seen over past few years**
- **BUT, need for real change not window dressing: this is the only way to start getting public credibility**
- **Recent work still inadequate which is cause for concern**
- **Pushing the problem onto management and monitoring is not enough**
- **Independent research and input from wide range of scientists**
- **End privileged access for biotech companies**
- **Open up input from stakeholders prior to publication**
- **Sound risk management from the European Commission is urgently needed**
- **Wider context: sustainable and competitive farming in Europe**

GMOs and pesticide use
http://www.foeeurope.org/GMOs/Who_Benefits/FULL_REPORT_FINAL_FEB08.pdf
http://www.foeeurope.org/GMOs/Who_Benefits/QA_FINAL_FEB08.pdf

Who Benefits from GM crops in a food price crisis?
http://www.foeeurope.org/GMOs/Who_Benefits/full_report_2009.pdf

GMO crops in the EU, factsheet 2008
http://www.foeeurope.org/GMOs/Who_Benefits/EU_briefing_2009.pdf

Animal feed price increase and GMOs (« zero tolerance »)
http://www.foeeurope.org/GMOs/animal_feed/Briefing_animal_feed_GMOs_May_2008.pdf
http://www.foeeurope.org/GMOs/ZERO_TOLERANCE_Campaigner_briefing_FINAL.pdf

Jobs and competiveness
http://www.foeeurope.org/publications/2007/FoEE_biotech_MTR_midlifecrisis_March07.pdf

Discussion:

Helen Holder from Friends of the Earth acknowledged improvements in EFSA's risk assessment work, but reported some concerns of her organization with regard to environmental risk assessment and criticised some of EFSA's scientific opinions on GMOs. In this context she cited the Environment Council Conclusions of December 2008 as a clear signal to EFSA and to the Commission to improve the implementation of the GMO legal framework and to review risk assessment.

Catherine Geslain-Lanéelle, Executive Director of EFSA, stated that in the recommendations made by the EU Council of Environment Ministers at the end of 2008, the Council stressed the importance of improving transparency and the cooperation with Member States in the context of the risk assessment process but not the review of the risk assessment process as such. EFSA has worked very seriously on the basis of the recommendations and continues to foster transparency and cooperation with Member States in the context of the risk assessment process. EFSA has published a short document on its website in which for each recommendation action points by EFSA are listed. EFSA 's Executive Director suggested that the follow up on the Council recommendations would be in the agenda of the annual meeting with environmental NGOs that was scheduled on 2nd October in Parma.

An EFSA GMO Panel member asked what Helen Holder deemed as specifically missing in the EFSA opinion on MON810 with respect to the key non-target organism species considered in the opinion. He pointed out that much European independent research had been conducted, such as the ECOGEN project and a German three-year study on MON810 and non-target organisms that included butterflies. Helen Holder answered that some studies have not been referred to in the opinion which should be discussed.

EFSA GMO Panel member Howard Davies countered the criticism of Helen Holder with regard to a missing assessment of unknown gene fragments in MON810 maize. He stated that EFSA addresses potential new fusion proteins through comprehensive bioinformatic searches, following internationally agreed protocols, e.g. CODEX, also used by other institutions.

With regard to the model used in the MON810 opinion Helen Holder expressed regret that the possibility of peer review or consultation has not been used. EFSA GMO Panel member Salvatore Arpaia replied that EFSA opinions cannot, in themselves, be subjected to peer review, but that the model used to assess the exposure of European species of Lepidoptera was currently under review by a very prestigious journal in Europe. In the modelling exercise, an effort was made to quantify possible uncertainty, the result of which indicated the need for appropriate management measures.

Per Bergman, Head of EFSA's GMO Unit, clarified what was referred to in the presentation as privileged access for Monsanto regarding EFSA's opinion on MON810. Due to an error, the EFSA opinion was briefly made available on its website a day prior to the final publication. Thinking that EFSA had published its opinion, Monsanto prepared and published its press release which was issued a day before actual publication of the EFSA opinion. It was emphasised that notifiers are usually informed on the day of publication.

Helen Holder agreed with a participant from the floor that weed resistance is not unique to use of GM crops. However, an increase in the use and toxicity of herbicides has occurred. Such issues must be carefully examined and alternatives may be considered, such as non-GM seeds or different farming models.

Helen Holder stressed that the Council conclusions underline the particular need to study potential consequences to the environment of changes in the use of herbicides triggered by herbicide-tolerant GM crops. They also note the mandate to develop and update the guidelines of EFSA regarding environmental risk assessment and, in particular, detailed assessment of long-term environmental effects.

Experiences and views from farmers

ARNAUD PETIT
COPA-COGECA

Introduction:

Arnaud Petit, who studied agronomy and economy, is responsible for the Commodities and Trade Department of the COPA-COGECA (Committee of Professional Agricultural Organisations - General Confederation of Agricultural Cooperatives in the European Union), which represents EU-wide farmers and agricultural cooperatives. He talked about the expectations and concerns expressed by European farmers on cultivation of GM crops, and their wish to retain the choice between GM, conventional or organic farming.

Presentation:

What are Copa and Cogeca ?

- **Copa – European farmers**

  Reprenseting 60 farmers' organisations from EU27

- **Cogeca – European Agri Cooperatives**

  Representing 35 national organisations of agri-coops from EU27

Two organisations…

- Representing 30 million farmers and their families;
- As well as around 40,000 cooperatives;
- We take care about the concerns as well as of conventional, organic and biotech agriculture.

COPA-COGECA and GM

- **Few experiences** in EU (except Spain and Roumania)
- European Farmer's point of view is based on **2 guidelines**:
  - **freedom of choice** for the farmers and consumers;
  - **Liability** of the scheme;
- **The coexistence** of the various types of Agriculture is our priority;
- **The mainstream for farmers** in relation with GM in the future:
  - Competitiveness;
  - Choice of consumers;
  - Environmental regulation.

Impact of GM crops on environment

- **Decrease of pesticide used** and impact on environment:
  In Spain cut by 26 to 36% for insecticide;
  Concerning herbicide (not used in UE) but possibility of cut by 10%.
- The GM could also open an opportunity to shift from conventional tillage to a **more simplified tillage**
- More knowledge is necessary concerning **saving carbon emission** ?
  - less input needed;
  - less fuel due to the simplified till;
  - the sequestration capacity of the soil ?

Questions for the future ?

- A European risk assessment, also for environmental aspect, should be managed only at European level;
- The impact of climate change on the various strategies to fight again new pests or virus should be assessed;
- The coexistence measures are in the field of risk management but farmers need more science evidence also to implement properly G.M. (work of JRC).

www.copa-cogeca.eu

Discussion:

The discussion highlighted practical problems related to coexistence.

There was a question from the floor about whether the use of GM crops is compatible with organic farming with respect to coexistence. Arnaud Petit noted that it is important to define coexistence measures on the field, in order to maintain high seed purity, which is crucial for organic farmers that do not allow GMOs. Although 100% seed purity is practically unfeasible even for conventional seeds, due to cross pollination, the only way to face this problem would be to put appropriate coexistence measures into place. An example is the Austrian system, where farmers create cooperatives in order to grow organic crops and to ensure the highest possible level of seed purity. This illustrates that seed purity can be achieved not only by legislative tools but also practically in the field.

Experiences and views from the biotech industry

WILLY DE GREEF
EuropaBio

Introduction:

Willy De Greef is a plant biologist with extensive experience in tropical breeding. He has been head of regulatory affairs for multiple companies. He has been involved in policy and public debate on agricultural biotechnology (OECD, UNIDO, Biodiversity Convention, Cartagena Biosafety Protocol) and in the development of the regulatory framework since 1986. At this moment he is Secretary General of EuropaBio, a European association for bioindustries and he was invited to give the view of the biotech industry.

Presentation:

Back to basics

- There is a lot of **experience** with the environmental, economic and technical performance of GM crops
- Is it informing either policy or product approval?

How did we get there?

Is this a new situation?

- 1983 - 1991: GNE on biosafety in biotechnology
  - The blue book
  - Follow up with detailed technical guidelines for risk assessment
- Still the technical basis for most biosafety governance WW!

Learnings

- In risk assessment, the distinction between **risk assessment** and **risk research** has disappeared
- The RA process does not have a place for **experience** of safe use
- The EU process does not learn from its own EC funded risk research programs

RA vs. RR

- Risk **research** produces **knowledge** which is never complete
  - Conclusion of every paper: "we need more research"
  - It is usually not comparative
  - Biodiversity being essentially infinite, there is infinite research to be done
- Risk **assessment** produces **management decisions**, based on the best available information, which is never complete
  - It can only be **comparative**: needs to be measured against alternative agricultural decisions
  - It needs to extrapolate from thorough, but necessarily limited **experiments**
  - The most effective source of risk assessment is **experience**

The quest for zero risk

- RA in the EU is not comparative nor proportionate
- It is by definition impossible to prove zero risk, yet after the first stage of risk assessment, we behave as if we should
- The zero risk debate is fuelled by a lot of misuse of science
  - Over-extrapolation from special cases
  - Misinterpretation of scientific information
  - Confusion between risk and hazard

Experiments and experience

- Safety management has 2 major sources of information:
  - Experiments
  - Experience
- Some history: OECD GNE (1983-1992): how to regulate pro-actively in the absence of history of use?
- Today, the experience with safe use of GM crops worldwide is not taken into account in EU risk assessment
  - There is no place for this information in the RA process
  - There is no interest in the post-release monitoring already done

EU funded biosafety research

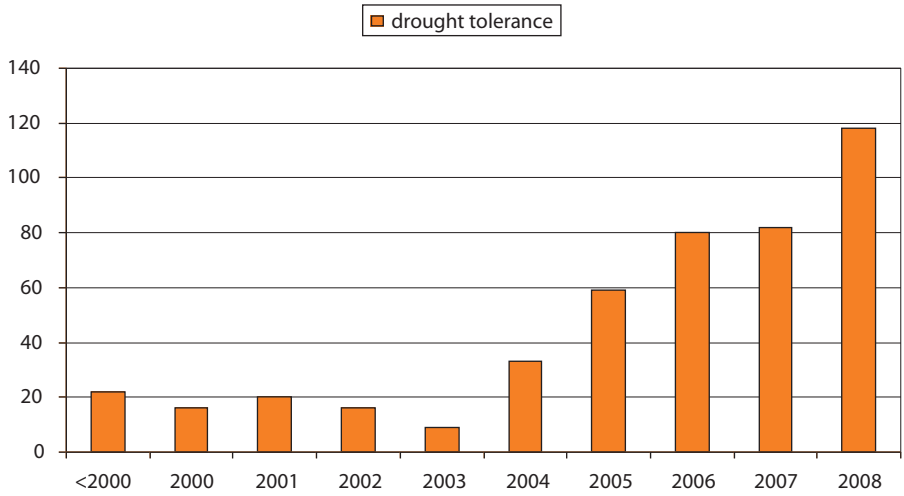
A history of public investment in biosafety research

- 1997: EC conference on safety of GM crops
- 2001: EC publication of the orange book

  - >400 projects in biosafety research
  - >70 M€ invested
  - What have we learned? What have we used in risk management?
- 2010: Publication of the next "orange book"?

A history of risk research destruction

- Even experiments are not safe from controversy and sabotage
  - Our experiment targets, and those of activists…
  - Special focus on risk research (SCIMAC trials) and risk assessment trials
- Result:
  - Little really innovative field research on GM crops in the EU
  - Companies focus on registration related trials
  - Public research has severely reduced field work
- An example



Source: http://www.isb.vt.edu/cfdocs/fieldtests1.cfm

Risk management & junk science

- Science is based on rigorous quality control
- Most "safety issues" on GMOs have been based on publications of research that were:
  - Preliminary,
  - Special cases,
  - Often with a weak experimental set-up
  - Sometimes fraudulent
- The **communication** of the results of these "safety issues" was highly professional though!
- The rebuttals usually came too late to enter the decision cycle

Where do we go from here?

- How do we protect risk research and risk assessment trials?
- How do we address the issue of risk communication?
- How do we safeguard quality control in the risk assessment and risk management process?

Discussion:

The discussion focused on Willy De Greef's views on risk research and his argument that the existing experience of safe use of GM crops should be taken into consideration by EU risk managers.

A recently appointed member of the EFSA GMO Panel pointed to the fact that for independent research institutions it is often difficult to obtain material from commercially approved GMOs due to restricted access. He wondered if efforts are being made, particularly by EuropaBio, to ensure that such plant material can become freely available to the entire scientific community interested in doing independent safety or risk research. Willy De Greef answered that companies that possess approved GMOs are careful with the distribution of such material as there have been some negative experiences concerning their use. However, it is clear to all that the availability of material for public research has become an issue but EuropaBio does not have a policy on this.

Another participant, from the Instituto de Tecnologia Química e Biológica (Portugal), questioned if ulterior economic or political motives may affect information available on safety. The perception may exist that authorisation decisions are delayed by the tactical use of an ever growing number of experiments, questions and requests for proof with regard to the absence of risk. Willy De Greef felt that the history of safe use in North and South America provides information about the behaviour of the respective GM products. Only one such product, MON810 maize, is currently approved and commercialised in Europe and could be used as an example. Willy De Greef stated that experience of farmers in Spain, Portugal and abroad with post-commercial releases should be considered when making decisions concerning renewal of its authorization in the EU. In his view, it is important that positive results are better communicated.

A member of the Belgium Biosafety Council asked if the 'history of safe use argument' can be considered as scientific evidence as there are no relevant epidemiological studies published to support this statement. He noted that for chemicals with a history of safe use science has shown some dangerous effects. Willy De Greef pointed out that the history of safe use has two components: first from experience and absence of reports pointing to negative effects and secondly from the number of studies done on the material being monitored. The experience of European farmers alone could not be compared with a peer-reviewed scientific journal, but could indicate the behaviour of the GMO. Monitoring for negative effects of the GMOs is carried out in North America and while an 'absence of evidence' is not 'evidence of absence', it does provide some information about the potential hazards and whether they may or may not become reality.

Experience of GM crop cultivation in Spain

ESTHER ESTEBAN
Ministry of Environment,
and Rural and Marine Affairs, Spain

Introduction:

Esther Esteban studied agriculture and plant breeding. She joined in 2004 the Spanish Ministry of Agriculture, Fisheries and Food (now the Ministry of Environment, and Rural and Marine Affairs), where she is currently Head of the GMO area in the Sustainable Development for Rural Areas Directorate General. She was invited to give an overview of the economic and environmental impacts of GM maize after several years of cultivation in Spain as this is the member state with the most farmland dedicated to GM crops.

Presentation:

Current situation of maize crop

- 359,600 has. of maize cultivated in Spain in 2009, 90% of this area under irrigation.
- 79,269 has. of Bt maize in 2008 (22% of total).
- Incidence of corn borer attack in most areas is high to medium.
- *Ostrinia nubilalis* is the main borer in Europe but in the Mediterranean Region, *Sesamia nonagrioides* is more preponderant.
- Pesticides against corn borer are seldom used due to their high cost and low efficiency;

WHY Bt-MAIZE? Resistant to corn borers

- *Sesamia nonagrioides* (MCB)
- *Ostrinia nubilalis* (ECB)

Yield losses caused by corn borer

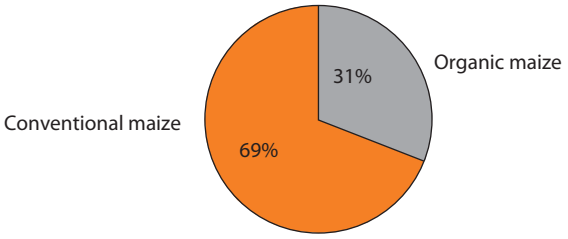
- 15% when the pest attack is high and no treatment is applied.
- 10% when the pest attack is high and treatment is not applied at the right time.
- 5-7% on average at the national level.
- The level of attack is highly variable, depending on changing with the locality, the weather, the sowing date, the use of pesticides and their time of application.

Benefits of using Bt maize

1. Higher yields
   - ▷ When the level of infestation is high the increase of yield ranges from 10 to 20%
   - ▷ When level of infestation is low the increase of yield ranges from 0 to 1%
   - ▷ As an average, the increase of yield is 6.3% (ranging from 2,9 to 12,9%)
2. Lower use of pesticides
3. Higher gross margin for the maize crop
4. Lower incidence of opportunistic fungal infections and thus decrease in contamination of the grain with fumonisines

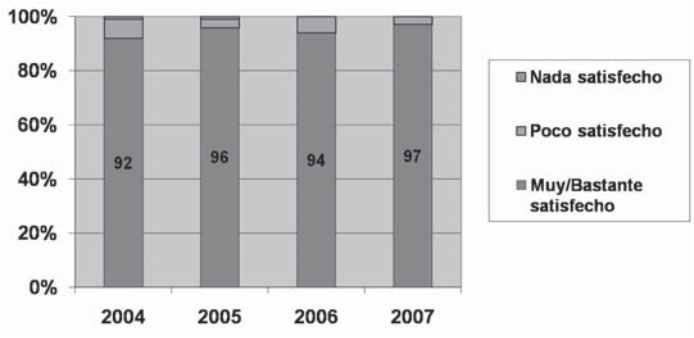
Feed alerts due to contamination of maize with fumonisines

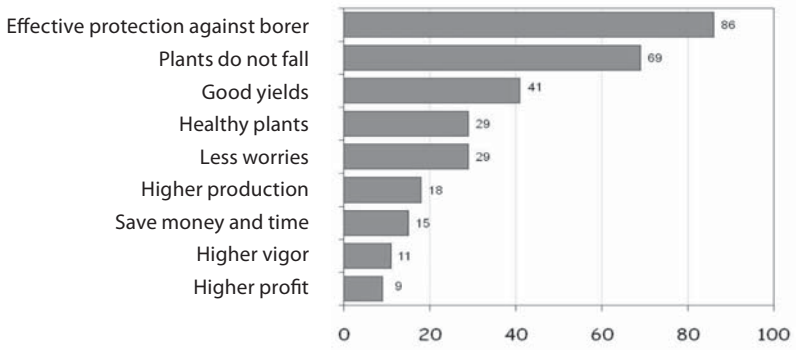
- ▶ No feed alerts from genetically modified corn flour or corn derived products
- ▶ 62 feed alerts from organic and conventional corn derived products



European Commission, DG SANCO

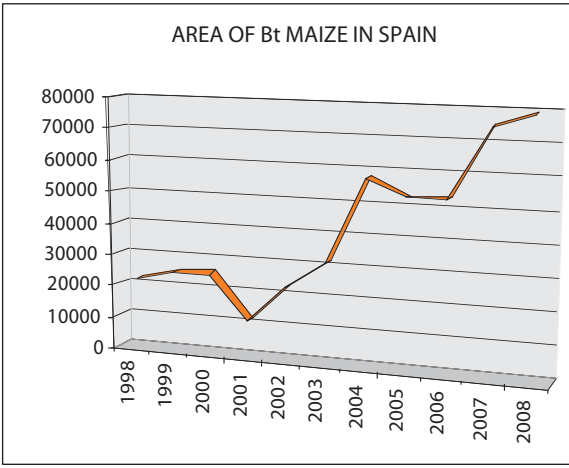
Advantages derived from the use of MON810 varieties as viewed by the grower





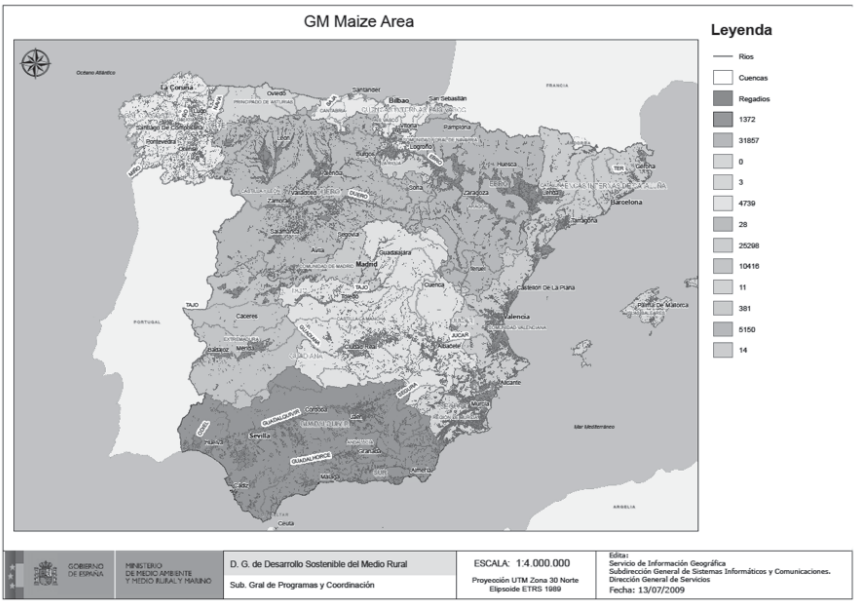
Survey from Markin Institute for MONSANTO (% answers)

Bt maize in Spain



YEAR	AREA
1998	22317
1999	24952
2000	25816
2001	11540
2002	23280
2003	32249
2004	58219
2005	53226
2006	53667
2007	75148
2008	79269

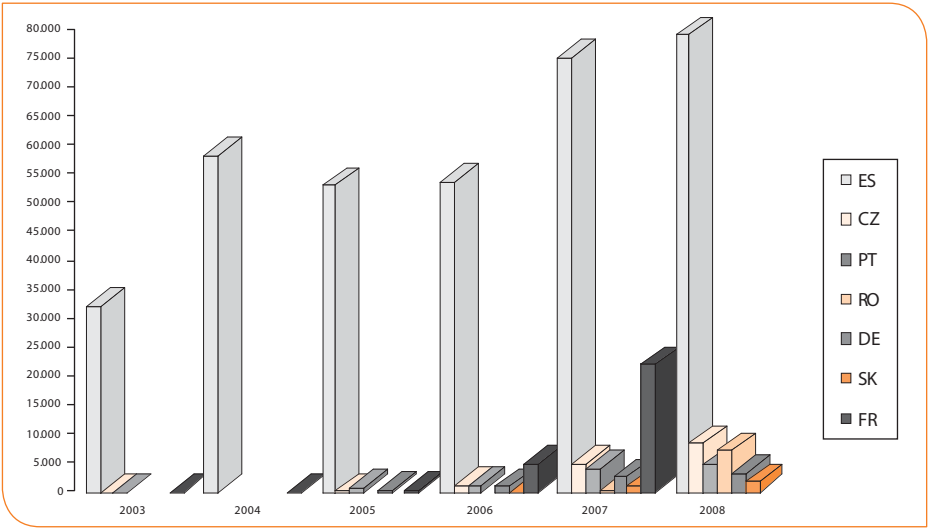
Distribution of Bt corn fields in Spain



124 GM maize varieties derived from MON-ØØ81Ø-6 are authorised for commercialisation in Spain (June 2009)

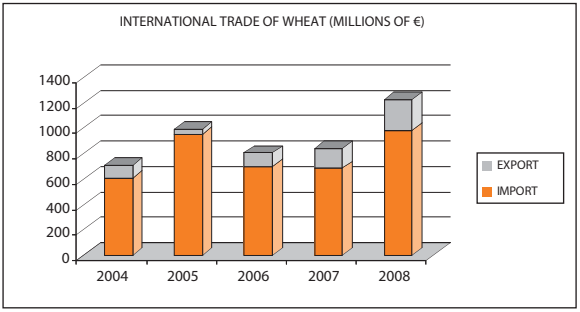
Company	Varieties (authorisation date in the Spanish Official Bulletin or in the European catalog *) * The varieties marked in orange are those registered in the European catalog.
Pioneer Hi-Bred	PR33P67 (11/03/03), PR32P76 (16/02/04), BACILA (11/08/05), PR32R43 (11/08/05), PR32W04 (11/08/05), PR34N44 (11/08/05), PR36R11 (11/08/05), PR31N28 (07/09/06), PR33B51 (07/09/06), PR36B09 (07/09/06), PR31D21 (25/04/08), PR31D61 (25/04/08), PR31P43 (25/04/08), PR32T86 (25/04/08), PR35Y69 (18/04/09), PR32D80 (18/04/09), PR32P27 (18/04/09), PR33D48 (18/04/09). PR33T60 (18/04/09), PR33Y72 (18/04/09), PR34P86 (18/04/09), PR35A56 (18/04/09), PR33W86 (17/06/09), ELGINA (17/09/04), OLIMPICA (17/09/04), BOLSA (17/09/04), LEVINA (17/09/04), PR38F71 (21/04/06), PR39V17 (21/04/06), PR39F56 (22/06/06), PR39D82 (28/08/07), PR38A25 (28/08/07), PR32G49 (16/04/08), PR32K62 (16/04/08), PR39T47 (30/04/08), PR34N23 (24/03/09)
Monsanto Agricultura	DKC 6575 (11/03/03), DKC 6550 (16/02/04), DKC4442YG (11/08/05), DKC5784YG (11/08/05), DKC6041YG (11/08/05), DKC 5018YG (07/09/06), DKC6531YG (06/10/06), DKC6419YG (11/05/07), DKC6451YG (11/05/07), DKC6667YG (11/05/07), DKC6844YG (11/05/07), TABALA YG (25/04/08), CONSUELO YG (12/11/08), EC6303EZA1 (12/11/08), DKC6877YG (18/04/09), ROXXY YG (18/04/09), ES MANADE YG (18/04/09), DKC513 (17/09/04), DKC3421YG (21/04/06), DKC3946YG (28/08/07), DKC2950YG (30/04/08), DKC3350YG (22/08/08), DKC3512YG (22/08/08)
Limagrain Ibérica	ALIACAN BT (11/03/03) , ARISTIS BT (11/03/03), GAMBIER BT (16/02/04), CAMPERO BT (16/02/04), HELEN BT (11/08/05), BELES SUR (07/09/06), LUSON BT (07/09/06), ASTURIAL BT (07/09/06), PONCHO YG (11/05/07), LG3711 YG (25/04/08), ANGOON YG (18/04/09), AVIRRO YG (18/04/09), LG3540YG (18/04/09), NOVELIS (17/09/04), LG3233YG (28/08/07), ANJOU 277YG (15/11/07)
Semillas Fitó	JARAL BT (16/02/04), SF1035T (11/08/05), SF1036T (11/08/05), SF1112T (11/08/05) , SF4701T (07/09/06), AZEMA YG (07/09/06), CARELLA YG (25/04/08)
Arlesa (Euralis)	CUARTAL BT (16/02/04), RIGLOS BT (11/08/05), ES MAYORAL YG (25/04/08), ES ARCHIPEL YG (25/04/08), ES CAJOU YG (25/04/08), ES PAOLIS YG (25/04/08), ES ZODIAC YG (25/04/08), ES LIMES YG (15/11/07), EUROSTAR YG (15/11/07), ES COCARDE YG (21/02/09)
Koipesol	PROTECT (16/02/04), KAPER YG (23/03/07)
Agrar Semillas	FOGGIA (11/08/05), MAS 60YG(11/05/07), MAS 58YG (25/04/08), MAS 71YG (25/04/08), MAS29YG (22/08/08), MAS 52YG (24/03/09)
Corn States Int.	EVOLIA YG (07/09/06), BENJI YG (07/12/06), KOFFI YG (07/12/06), ROCCO YG (07/12/06), PLACIDO YG, (23/03/07), TONIC YG (11/05/07),
KWS	KXA5491 YG (11/05/07), KARTER YG (18/04/09), KURATUS (22/06/06), KARAS YG (22/08/08), KONTRAS YG (22/08/08)
Caussade Semences	VENICI YG (23/03/07), VIVANI YG (18/04/09), MAGGI YG (24/03/09)
RAGT	RUGBYXX YG (25/04/08), BERGXXON YG (18/04/09), GALEXX YG (18/04/09), KOTOXX (18/04/09), KOXXMA (18/04/09), REMIXX (18/04/09), ROXXANE YG (18/04/09),TIXXUS YG (18/04/09), TYREXX YG (18/04/09), LYNXX YG (24/03/09)

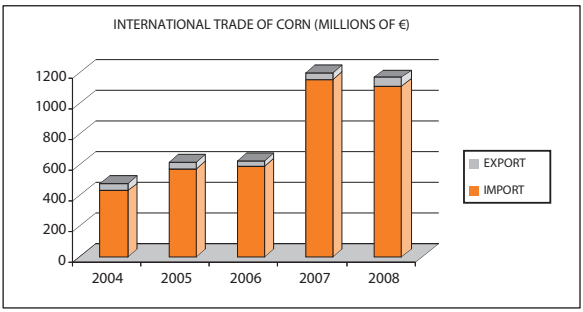
GM (Bt) maize in the EU

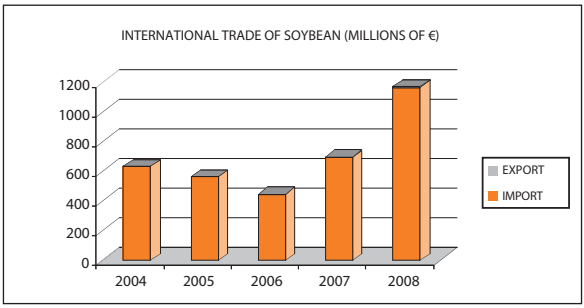


- Spain is the only country in the EU where GM maize is cultivated significantly (more than 50.000 has).
- In 2007 Bt maize was cultivated in seven countries. In 2008 cultivation of Bt maize was banned in France and in 2009 in Germany, so currently five countries cultivate Bt maize in the EU.
- Corn borer attack is a major problem only in southern Europe;

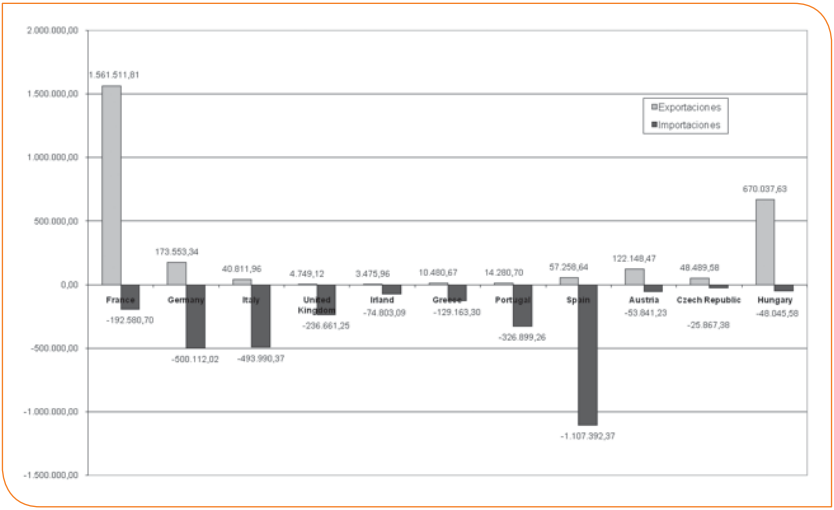
International trade of grain crops in Spain







Maize export-import



Impact on farm income

	Year first planted GM IR maize	Area GM IR maize 2007 (ha)	Average yield impact (%)	Cost of technology 2007 (€/ha)	Net increase in gross margin 2007 (€/ ha)	Impact on farm income at national level 2007 (,000 €)	Cumulative Impact on farm income at a national level year of first use to 2007 (,000 €)
Spain	1998	75,148	+10	35	+201.27	+15,125	+49,339
France	2005	22,135	+10	40	+186.72	+4,133	**+4,806**
Germany	2005	2,685	+4	40	+85.99	+231	**+294**
Portugal	2005	4,263	+12.5	35	+105.51	+450	**+557**
Czech Republic	2005	5,000	+10	35	+107.20	+536	**+614**
Slovakia	2005	948	+12.3	35	+75.03	+71	**+72**
Poland	2005	327	+12.5	35	+90.40	+30	**+31**
Romania	2007	360	+7.1	32	+25.40	+9	**+9**
Total		**110,866**			**+185.67**	**+20,585**	**+55,722**

Source: Graham Brookes, 2009

CO-EXISTENCE

The Spanish experience with co-existence after ten years of cultivation of GM maize

Is co-existence possible?

Field tests and Co-existence studies made in Spain

- The Office of Plant Varieties from Spain that belongs to the Ministry of Environment, and Rural and Marine Affaires, in collaboration with various official institutions, programmed a series of field trials and Co-existence studies during the 2003, 2004 and 2005 campaigns.
- The aim of this study was to analyze the transfer of pollen from a plot sowed with GM maize to a neighbour plot with conventional maize (gene flow).
- In this study it was very important to distinguish cross pollination from direct contamination from seeds remaining in seeders or harvesters.

The co-existence of different varieties of GMO and conventional maize was simulated:

- Under the most extreme conditions,
- On different land surfaces
- With different distances between the crops.

Sources of accidental presence of GMO

The most important sources of accidental presence of GMO in the maize crop are:

- Impurity of the seed
- Contamination from seeders and harvesters
- Remains from the previous crop
- Pollen flow between neighbouring plots
- Storage of the grain.

The accidental presence of GMO cannot exceed the threshold of 0.9 %

Purity of the seed: Results of the analyses carried off on lots of maize seeds in Spain

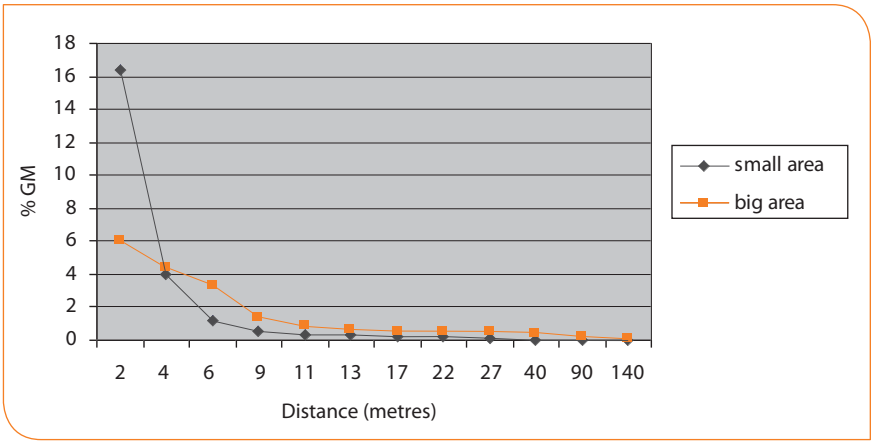
- The main source of accidental presence of GMO in the harvests is the contamination of GMO in seeds
- Every campaign, 800 lots of conventional seeds are analyzed for accidental presence of GMO. The limit is 0.5%

Year	Number of lots analyzed	Number of lots with GMO	% lots with GMO	Number of lots with content of GMO					
				>0.9%	>0.7 % <0.9 %	>0.5 % <0.7 %	>0.3 % <0.5 %	>0.1 % <0.3 %	<0.1 % > 0 %
2005	903 conv	25	2.8	5	0	3	4	12	1 (*)
2006	870 conv	49	5.6	3	0	2	6	15	23
2007	608 conv	79	13.0	2	4	3	11	24	35
	136 MON 810	6 non MON 810	4.4	0	0	0	0	0	6 (**)

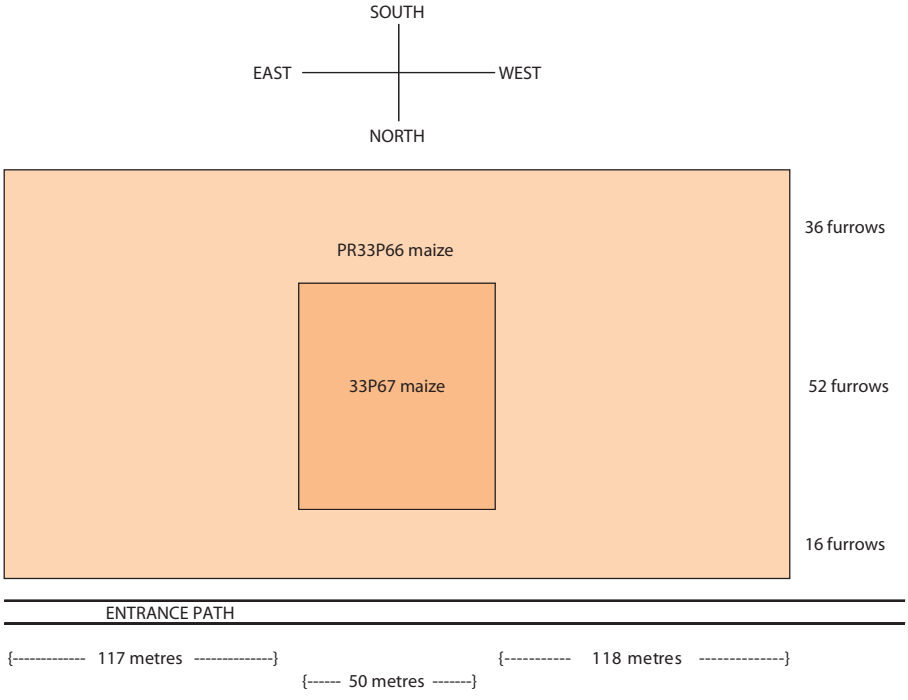
Pollen flow between neighbouring plots

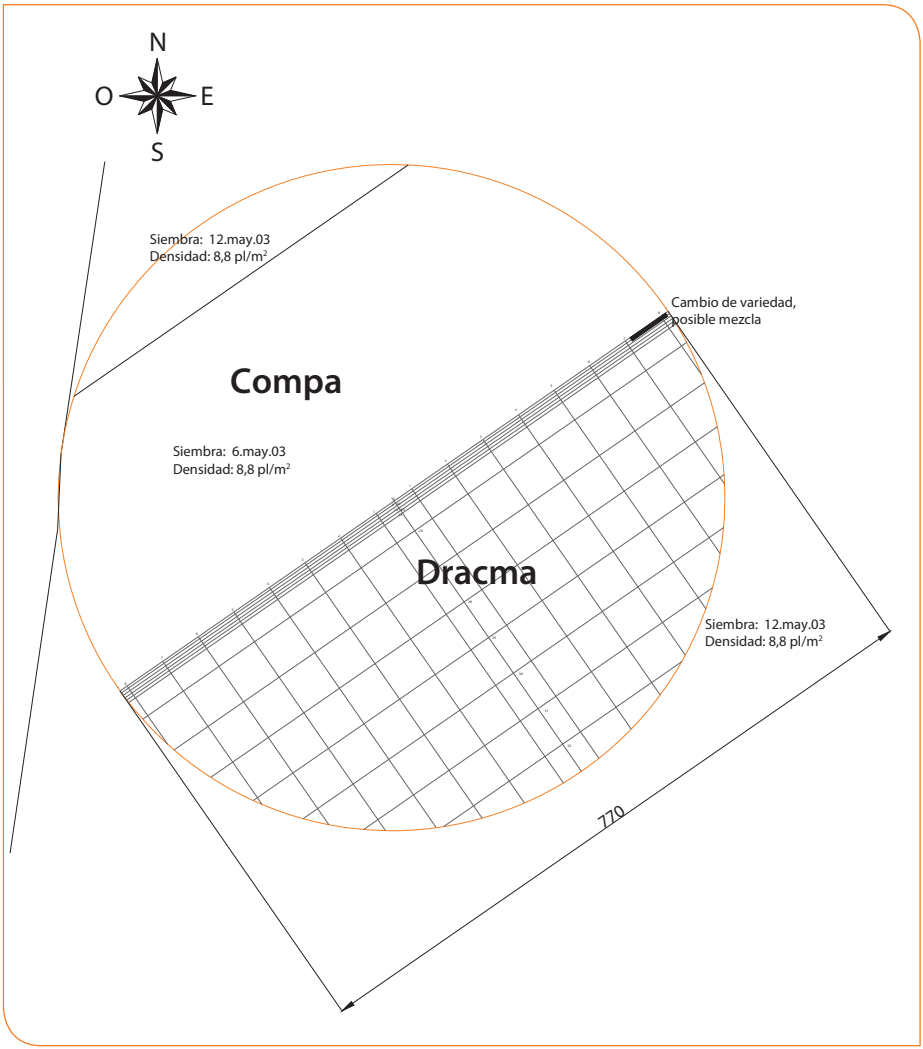
- **Field tests in 2003 with adjacent GM and non GM maize for evaluation of gene flow**
- **For distances greater than 15 meters, the average content of GMO is less than 0.9%.**

Distance Metres	% GMO	
	Small area GM	Big area GM
	Madrid	Albacete
2	16,4	6
4	4,01	4,4
6	1,18	3,3
9	0,58	1,43
11	0,375	0,9
13	0,3	0,67
17	0,24	0,55
22	0,17	0,57
27	0,09	0,5
40	0	0,45
90	0	0,2
140	0	0,07



TEST LAYOUT ON THE "CASA CONCHA" Farm Colmenar de Oreja (Madrid)

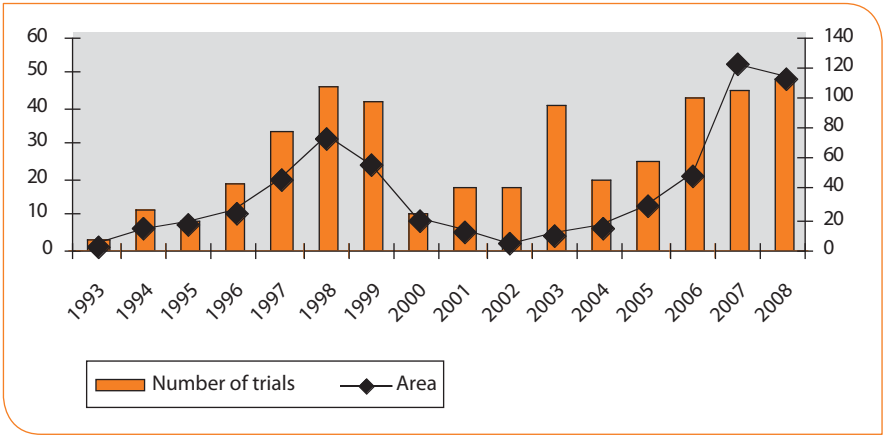



N
O
E
S
Siembra: 12.may.03
Densidad: 8,8 pl/m²
Cambio de variedad, posible mezcla
Compa
Siembra: 6.may.03
Densidad: 8,8 pl/m²
Dracma
Siembra: 12.may.03
Densidad: 8,8 pl/m²
770

Good Agricultural Practices with Bt maize

- Prevention Plan for insect resistance: 20% of conventional maize as a refugee for corn borer.
- Isolation distance: 20 m.
- When the distance is less than 20 m and the neighbour plot is sowed with conventional maize and there is no time delay of 4 weeks in April or 2 weeks in May between them, 12 rows of conventional maize must be sowed that also serve as refuge.
- Comply with the traceability and labelling regulation.

Trials of non authorized GMOs



Monitoring requirements for Bt maize in Spain

Spanish legislation for the registration of commercial varieties since 1998 already implemented the requirements included in Directive 2001/18/EC.

Bt176 varieties (1998-2005)	MON810 varieties (from 2003)

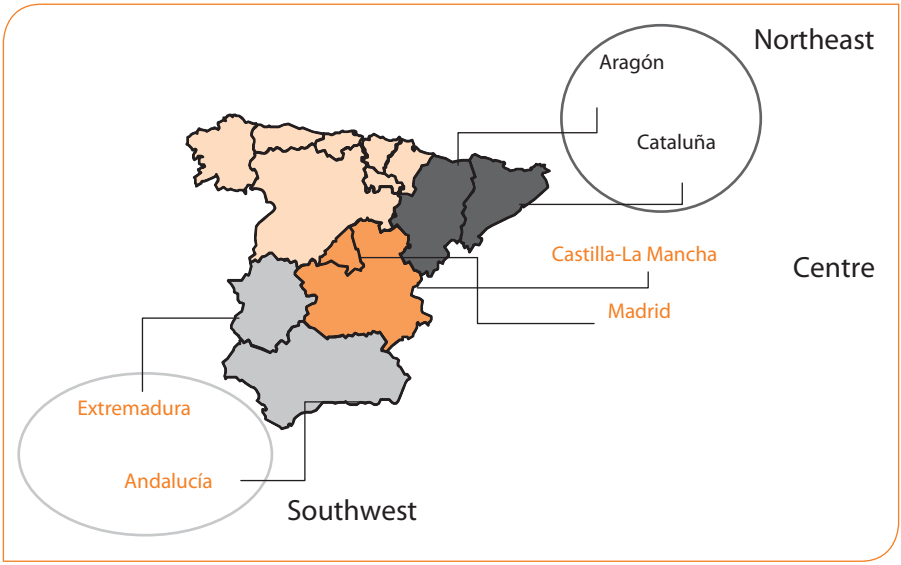
Case Specific
Monitoring of corn borer resistance
Potential effects on non-target arthropods
Potential effects on soil microorganisms
Potential effects on digestive tract bacteria (only for Bt-176)
General Surveillance (only MON810)
Farmer questionnaires
Seed sales by localities. Distribution. Buyers.
Information to farmers on specific measures for GM cultivation

Monitoring of corn borer resistance

Spanish Programme (MARM-CSIC) (1998-2009)	Industry (2004-2009)

a. define the agro-ecological areas of interest.
b. establish the baseline susceptibility to the insecticidal protein.
c. detect changes over time in susceptibility by regular monitoring.

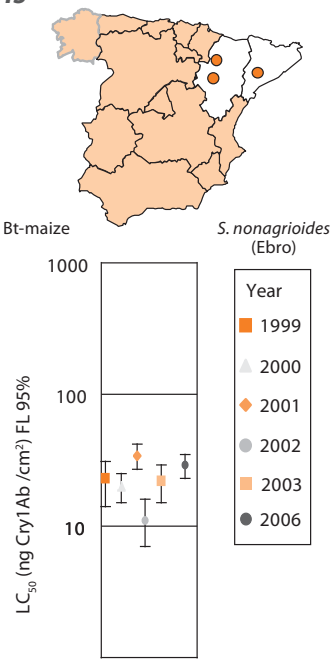
Agro-ecological areas of interest



Susceptibility of field corn borer populations

- First laboratory generation of field collected larvae
- Toxin (Cry1Ab) applied on surface of diet in cells of plastic trays
- 7 concentrations (10- 90% mortality) + Control
- 3 subsamples (16-32 larvae)/dose
- Mortality at 7 days

No increase in the resistance to the toxin.
No changes in the susceptibility



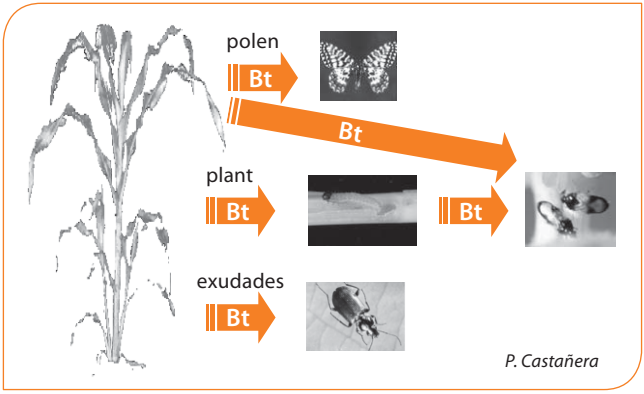
González-Nuñez et al., 2000. J. Econ. Entomol. 93: 459-463

Farinós et al., 2004. Ent. Exp. Appl. 110: 23-30

Summary: Resistance monitoring

The Spanish monitoring programme has found no consistent shifts in susceptibility for field populations of MCB and ECB after ten years of Bt maize cultivation.

Monitoring: potential effects on non-target arthropods



Monitoring strategies for non-target arthropods

Spanish Programme (MARM-CSIC) (2000-2009)	Industry (2004-2009)

- Arthropod fauna in maize fields.
- Exposure of non-target arthropods to Bt maize toxins.
- Field trials to assess abundance and diversity of non-target arthropods.
- Laboratory assays to test worst-case scenarios.

Potential effects on non-target arthropods

Spanish Programme (1998-2006) | **Other scientific information**

- No detrimental effects on composition and abundance of predatory arthropods have been found in commercial Bt-maize fields.
- Bt maize could be compatible with the natural enemies that are common in maize fields in Europe and which contribute to reduce insect pest populations.
- Field trials in the same areas for long periods are necessary to discard potential accumulative effects.
- Additional studies are being conducted for some groups that are poorly studied, such as staphylinids.

Potential effects on soil microorganisms

Ministry of Education-Industry 2000-2002

Analysis of bacteria population levels in soil:

- No effect on total and ampicillin-resistant bacterial population levels
- High percentage of natural ampicillin resistant bacteria (1-20%)
- Lack of detection of gene transfer from Bt-maize to cultivable soil bacteria

Badosa et al. (2004) FEMS Microbiology Ecology 48: 169-178

Discussion:

Practical issues related to the cultivation of maize MON810 in Spain were the focus of the discussion.

A representative of the French Institute of Agricultural Research expressed surprise with regard to the short isolation distance for Bt maize fields which is 20 meters in Spain in comparison to 800 meters in the United States. Esther Esteban called for recommendations from companies, but stated that the 20-meter distance must be adequate as no complaints or reports had been received from conventional maize farmers pertaining to gene flow contamination.

Upon request from a representative of the European Liaison Committee for the Agricultural and Agri-Food Trade (CELCAA), Esther Esteban clarified that the risk alerts mentioned for conventional and biological crops in the presentation were linked to mycotoxins. She clarified that on the slide the absolute numbers are displayed and taking into account the growth area, it could be seen that the number of alerts in organic fields were much higher than in conventional fields.

Session 2: Summary of the chair and general discussion

Hubert Deluyker, chair of the session, summarized the conference from his perspective highlighting that the presentations of session 2 broadened the discussions of the previous day. The talk of Peter Kearns from OECD, highlighted the international dimension of the debate. The perspective presented by Emilio Rodriguez Cerezo from the JRC underlined that the work of EFSA's GMO Panel fits into a broader evaluation by risk managers which includes, for example, economic aspects.

Hubert Deluyker recalled that a lively part of the debate was contributed by the three stakeholders: Arnaud Petit from COPA-COGECA who presented the topic of co-existence as a key concern of farmers. Helen Holder from Friends of the Earth acknowledged some improvement in EFSA's work but also highlighted some general areas of concern. She also detailed specific issues related to MON810 maize which will be further debated in the frame of continuing dialogue at the meeting EFSA is organising with stakeholders on 2 October 2009. Willy De Greef from EuropaBio painted a sombre picture expressing concerns about the disruption of risk research and the utilization and quality of information being used in risk assessment and risk management.

Hubert Deluyker identified the role of risk management and its separation from risk assessment as a recurring theme of the debate. Related to this are issues such as the level of uncertainty that is acceptable to society before making decisions, and the role of post market monitoring, and how it can inform and feed back into both risk assessment and decision making.

Hubert Deluyker then invited all attendees to participate in a general discussion. The following points were discussed:

A representative of the UK National Farmers Union requested information about the northerly movement of the European corn borer. Willy De Greef answered that the pattern of pests, diseases and weeds in crops generally would change as the environment changes, for example moving north as a result of climate change. Emilio Rodriguez Cerezo added that with increasing temperatures there would be an extension of not only the areas where the pest could be found, but also the number of corn borer generations per year (currently three).

An EFSA GMO Panel member commented on the restricted access to GM research material for independent groups. However, independent research is needed. Ways could be found to provide a common sharing of this material, such as conducting field experiments in a corporate system, by combining industry's experience of high-level containment and the broad experience of independent university scientists.

A former EFSA GMO Panel member felt that Willy De Greef had raised the important question of the protection of research and, in particular, that experimental field trials should not be disrupted. It would be in the interest of stakeholders worldwide that such experimental field releases and risk research are performed.

Helen Holder (Friends of the Earth) indicated that there were indeed issues over field trials. Some people involved had taken action because they could not understand how it could be considered a trial if the GMO was already released into the environment. The question now is how to ensure that research does not become a *fait accompli*. Citizens' concerns have to be taken into consideration, especially those of citizens who did not wish to have field trials conducted in their vicinity.

Arnaud Petit from COPA-COGECA pointed out that legislation on risk management of GMOs exists, but better transparency is required. Uncertainty needs to be managed. There is a need to know the perspectives for farming in Europe in the next 15-20 years.

Willy De Greef of EuropaBio emphasised that the European law requires a permit to proceed with biosafety research in field trials, and that it provides for a period of public consultation. He said that if the risk question is not to be resolved, one of the best ways would be to prevent risk research from being undertaken, which hinders the progress of technology and innovation.

An EFSA GMO Panel member pointed out that it is necessary to be prepared for future changes in the status of pests, diseases and weeds and asked about preparatory research being conducted by EuropaBio for the situation in which pests were likely to cause significant damages in larger areas. Willy De Greef explained that agro-business companies often work together with national agriculture research systems. Sophisticated new pest, weed and disease monitoring systems were now in place in Europe and elsewhere and facilitate the issue of early warnings. He pointed out the corn rootworm as a prime example for Europe. For a number of pests and diseases, adequate tools are available in the gene pool of crops to handle new threats with conventional breeding. In Europe, there would be a need for continued funding of early warning and monitoring systems to enhance preparation.

One participant from the French National Institute for Agricultural Research (INRA) questioned how much uncertainty would be acceptable and pointed to the necessity to clarify how much uncertainty exists. He said EFSA's GMO Panel had begun to pay more attention to the limits of statistical power, which was a beginning but could go further in order to have a better idea of the uncertainty in the system. Defining the acceptable level

of uncertainty would not be up to the experts but rather be a political decision reflecting a balance between the level of uncertainty, economics, social issues and more.

An EFSA GMO Panel member approached the subject of confidential business information (CBI). He said that considerable amounts of safety information provided by applicants often came under CBI protection and was of the opinion the practice should be changed as it prevents independent, i.e. non-producer associated, research and peer review. Many studies conducted were not available in the pool of scientific literature; making such information publicly available would help build a knowledge base. He asked if it would be possible for OECD to provide a guidance document on the type of information that could be claimed as CBI and if a standard could be developed. In some countries almost the entire application comes under confidentiality protection whereas the same application in a different country would have almost nothing under CBI protection. Peter Kearns replied that this topic came up repeatedly in various industries including biotech, chemicals or nanotechnology and necessitates international agreement, guidance or standards. National practices were very important. The OECD would not be the proper organisation to address the matter although it promoted the exchange of information, some of a CBI nature, on a bilateral basis between national authorities in some pesticide work previously undertaken.

Hubert Deluyker thanked the speakers and all participants for the informed discussion.

V CLOSING ADDRESS BY KARL FALKENBERG, Director-General, DG Environment, European Commission

Good morning everyone. It is my pleasure being here and I think if I had had a little bit more time, I would have wanted to spend more time in the last day and a half with you here because as a regulator, which I represent speaking on behalf of DG Environment of the European Commission, it is obviously very interesting to learn about GMO acceptability. I think this is what EFSA has allowed you to discuss and therefore I want to thank EFSA for having taken this initiative.

When we look at decision-making, we need to try to base our decisions on best available scientific evidence. We're living in an ever more complicated world. I'm a small humble economist. On many of the questions that are at stake, my own education, by definition, leaves me helpless in coming up with the right decisions. We want decisions that are safe for our citizens, safe for our environment. At the same time we want to allow new products into markets, we want new technology to provide answers to challenges in a world that is growing rapidly. Let's not forget when I was born we were some 2.7 billion people on this planet; in 2050 people are telling us we will be 9 billion.

The challenges that arise out of the dramatic demographic growth of mankind on this planet will not be answered simply by status quo. Hence, the necessity to have research, to have new technology, to develop new answers. GMOs may be an answer. Fundamentally I am, and we in DG Environment will be neutral with regards to this technology. But what is important for us is to know, if we introduce new crops, that there is a reasonable assurance that this is done on the basis of sound research, verification and the best scientific advice available. That is why we very much support the work done by EFSA. EFSA for the European Union is an important partner.

We need EFSA, we need EFSA's advice to be able to base our decisions on state-of-the-art science and that's why we attach so much importance to who is working within EFSA and that the panels that EFSA constitutes on different areas effectively represent comprehensive state-of-the-art knowledge.

We are convinced that the acceptability of EFSA recommendations, EFSA analyses, depends also on the mainstreaming of EFSA's activity and the anchoring of EFSA as a science body within the broader scientific community, the broader European scientific community, and even beyond. We have to understand that science has to be globally valid on this planet. We should avoid the temptation to develop European science or even national sciences within Europe that are fighting with each other and then we jointly fight against United States or Japanese or Chinese science. The environment on this planet is a single environment and the scientific views and research results that we obtain should be globally true and valid. It is also true that science is evolving and therefore verification, continued dialogue, is important. EFSA can certainly be relying on our continued support. As I said, we need EFSA, we need solid scientific recommendations. The clearer they are, the more they facilitate the decisions that the regulators have to make.

But EFSA cannot take the decisions on our behalf. What EFSA produces are scientific recommendations. Regulators have to use these and then take their wider political responsibility and decide what they want to authorise and what not or under what conditions. Within the Commission we are certainly willing and capable of doing this, both on the human health side, and I know that Robert Madelin started your meeting yesterday, as on the environmental side, which I represent now. So, in taking these decisions we want them to be science based and we would, where we want to impose restrictions, need to be able to point out risks. Risks, and I was listening to the concluding discussion here, may be difficult to quantify and to qualify and obviously require political as well as scientific judgement. Science can tell us what is the risk. Whether this risk is acceptable, is tolerable, is a more political question and is a question for the regulator for which the regulator then also has to take public responsibility. In making our decisions with regard to GMOs, we certainly are still struggling as regulators.

We are helped in making our decisions by the scientific views that EFSA is elaborating, but we are, in our broader European Union environment, still facing very substantial questions. I have said on an earlier occasion that the Commission is aware that we have a lot of homework to do in defining how we are going to be dealing with GMOs in order to overcome the very apparent divisions that we see across the European Union.

President Barroso (in his recent address to the European Parliament for a new term of office) has addressed this issue. He has said that he is convinced, that there ought to be a possibility to combine a Community authorisation system based on science, as I have elaborated, with the freedom of Member States to decide whether or not they wish to cultivate GMO crops in their territory. We will have to reflect whether it is possible to find such a solution, a solution by which the European Commission would authorise GM crops within the European Union market, but where Member States may decide on the basis of their regional specificities, on the conditions under which cultivation would take place within their territories, whether this is something that they wish to accept. We need to think about this because this is not at present the legislative reality within the European Union. When my President designate takes the decision that such a solution ought to be found, we will work in that direction, but we will always continue to come up with solutions that we can scientifically explain. We need to make sure that we move away, in these types of decisions, from personally held beliefs and that we try to move to objectively verifiable facts. That means, that we have to focus scientific verification processes on the effects that we fear to see if products are disseminated in the environment, if humans, animals are beginning to consume these products. We need to make sure that this process is fact-based and that we move away from ideologically dominated debates. EFSA should be our science body in this process. That's why EFSA will continue to have our support.

I hope that we can continue to mainstream EFSA's activity also through hearings as the present one hope that EFSA will be even better anchored within the scientific community across Europe, that scientific academies and others are networking together so that when we talk of science we have a shared mainstream body to which we all can refer in confidence. If the last day and a half has produced a little bit of progress in that direction, I think it was more than well worth the effort and I hope that you are all going home in the conviction that both the Commission on the one hand, but also its scientific advisor EFSA are transparent, will continue to be transparent, are looking for dialogue, are prepared to dialogue, but dialogue on the basis of scientifically verifiable facts.

Thank you very much, ladies and gentlemen, and Bon Appetit.

VI CONCLUDING REMARKS

Catherine Geslain-Lanéelle, Executive Director of EFSA, closed the meeting by thanking Director-General Robert Madelin and Director-General Karl Falkenberg for their encouraging words in the opening and closing address, the speakers for the clear presentations, the staff and the participants which made the conference a success. She stated that EFSA is encouraged by the discussions and wants to take advantage of all suggestions, comments and questions. A short summary of the conference and the presentations will be published on EFSA's website within a week. In addition EFSA will elaborate a full report of the conference including the comments and questions raised in November. EFSA will use the outcome of this conference to continue to improve its work and transparency. She stressed the importance to further discuss with all stakeholders on the scientific issues in the future.

ANNEXES

ANNEX 1: PROGRAMME OF THE CONFERENCE

14 September 2009

14.00	Welcome	Catherine Geslain-Lanéelle, Executive Director, EFSA
14.10	Opening address	Robert Madelin, Director-General, DG Health and Consumers, European Commission
Session 1: GMOs: assessing the risks for human and animal health and the environment		Chair: Riitta Maijala, Director of Risk Assessment, EFSA
14.30	EU risk assessment of GMOs – roles of EFSA, Member States and European Commission	Per Bergman, Head of the GMO Unit, EFSA
14.45	Updated EFSA guidance document for the risk assessment of GM plants and derived food and feed	Howard Davies, EFSA GMO panel
15.15	Statistical evaluation of field trials for food and feed safety	Claudia Paoletti, Senior Scientific Officer Risk Assessment GM Plants, EFSA
16.15	Environmental risk assessment: Austrian perspective	Andreas Heissenberger, Federal Environmental Agency of Austria
16.45	Assessment of effects on non-target organisms in EFSA's guidance	Salvatore Arpaia, EFSA GMO panel
17.15	Assessing long term environmental impacts, eg: herbicide tolerance plants	Jeremy Sweet, EFSA GMO panel
17.45	Post Market Environmental Monitoring: how it works for risk managers	Chantal Bruetschy, Head of "Biotechnology, Pesticides and Health" Unit, DG Environment, European Commission
18.15	Summary of the chair and general discussion	

15 September 2009

Session 2: **The impact of GM crop cultivation on the environment**		Chair: Hubert Deluyker, Director of Scientific Cooperation and Assistance, EFSA
09.00	OECD's work on environmental considerations for risk/safety assessment	Peter Kearns, OECD
09.30	EC/JRC research on global aspects of GM adoption and agricultural benefits of GM in Europe	Emilio Rodriguez Cerezo, JRC, European Commission
10.00	EFSA and GMO risk assessment in the EU: an environmental NGO perspective	Helen Holder, the European coordinator: GMOs, food and farming campaign, Friends of the Earth
10.30	Impact of GM crops on environment: farmer's point of view	Arnaud Petit, Director of Commodities and Trade, Copa-Cogeca
11.30	GM risk assessment: experiences and views from the biotech industry	Willy De Greef, Secretary General, EuropaBio
12.00	Experience with GM crop cultivation by a Member State: Spain	Esther Esteban, General Direction of Sustainable Development of the Rural Environment, Ministry of Environment, and Rural and Marine Affairs - Spain
12.30	Summary of the chair and general discussion	
13.00	Closing address	Karl Falkenberg, Director-General, DG Environment, European Commission

ANNEX 2: PARTICIPANTS AT THE CONFERENCE

Name	Affiliation	Country/Unit
Inese Aleksejeva	Ministry of Agriculture	Latvia
Hans Christer Andersson	National Food Administration	Sweden
Chantal Arar	French Food Safety Agency (AFSSA)	France
Salvatore Arpaia	National Agency for New Technologies, Energy and the Environment (ENEA)	Italy
Juliette Auricoste	AgroParisTech ENGREF	France
Ebba Barany	European Commission	DG Research
Detlef Bartsch	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)	Germany
Martin Batič	Ministry of the Environment and Spatial Planning	Slovenia
Petr Beneš	Ministry of Agriculture	Czech Republic
Per Bergman	European Food Safety Authority (EFSA)	
Aurore Bescond	BEAF	Belgium
Barbara Billocci	COPA-COGECA	Belgium
Zuzana Bírošová	Ministry of Agriculture	Slovakia
Anne-Katrin Bock	European Commission	Joint Research Centre (JRC)
Denis Bourguet	French National Institute for Agricultural Research (INRA)	France
Dylan Bradley	Agra CEAS Consulting	UK
Hanneke Bresser	Ministry of Environment	Netherlands
Chantal Bruetschy	European Commission	DG Environment
Filip Cnudde	EuropaBio	
Marco Contiero	Greenpeace	Belgium
Howard Davies	Scottish Crop Research Institute (SCRI)	UK
Willy De Greef	EuropaBio	Belgium

Name	Affiliation	Country/Unit
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Hubert Deluyker	European Food Safety Authority (EFSA)	
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James Ede	NFU	Belgium
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Kirstin Færden	Norwegian Scientific Committee for Food Safety	Norway
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Gerhard Flachowsky	Federal Research Institute for Animal Health, Institute of Animal Nutrtion	Germany
Anne-Laure Gassin	European Food Safety Authority (EFSA)	
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Catherine Geslain-Lanéelle	European Food Safety Authority (EFSA)	
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Name	Affiliation	Country/Unit
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Markus Hardegger	Federal Office for Agriculture	Switzerland
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Margarita Karavangeli	Hellenic Food Authority (EFET)	Greece
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Kasparas Kemeklis	European Parliament	
Jozsef Kiss	Szent Istvan University	Hungary
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