Challenges pertaining to the comparative assessment of potential adverse effects of GM plants on non-target organisms
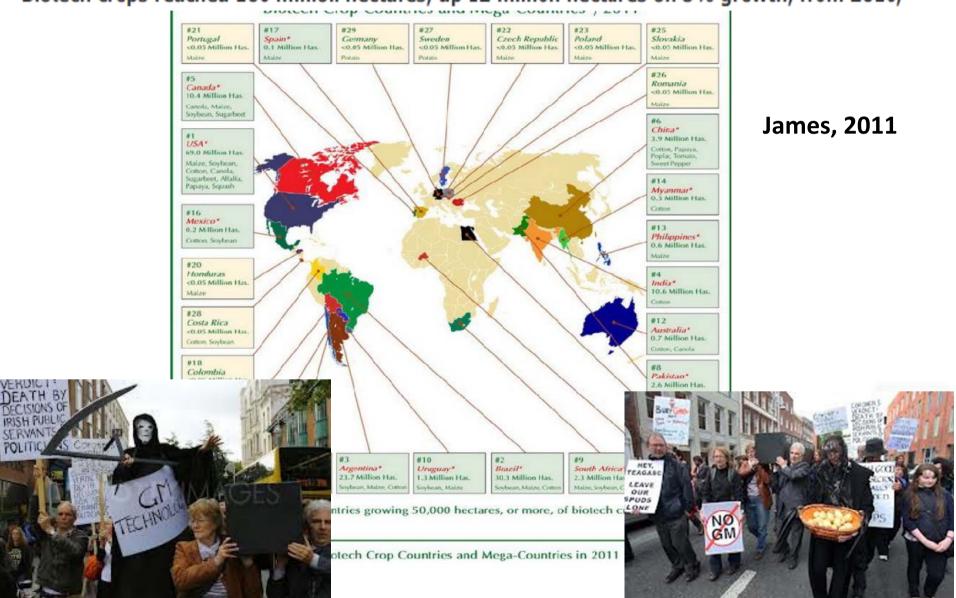
ENEA
ITALIAN NATIONAL AGENCY
FOR NEW TECHNOLOGIES, ENERGY AND
SUSTAINABLE ECONOMIC DEVELOPMENT

Salvatore ARPAIA - ENEA

EFSA@10

Challenging boundaries in risk assessment – sharing experiences
Parma, 7-8 November 2012

Who wants GMOs?

Biotech crops reached 160 million hectares, up 12 million hectares on 8% growth, from 2010,

James, 2011

Non-target Organisms

It is a practical concept which has no relationships with ecological roles

"all living organisms, that are not meant to be affected by newly expressed compounds in GMPs, and that can be potentially exposed, directly or indirectly, to the GM plant and/or its products in the agro-ecosystem where GMPs will be released or in adjacent habitats".

Arpaia, 2010 *(Coll. Biosaf. Rev.)*

Possible exposure mechanisms for NTOs and consequences

Channel	Mechanism	Non-target group	Ecosystem Functions
AIR	Pollen flow, seed dispersal	-Sexually compatible plants; -Herbivores ingesting pollen; -Spermophagous species	Pollination Food turnover (impacts on biodiversity)
PLANT	Trophic chain effects	-Primary consumers (herbivores); - Higher order consumers *(carnivores) including mammals, birds, etc.*	Pollination Food turnover (impacts on biodiversity)
SOIL	Horizontal Gene Transfer, Release of plant products	Microorganisms, meso- and macro-fauna	Food turnover (impacts on biodiversity)

Arpaia, 2010 *(Coll. Biosaf. Rev.)*

Agricultural Effects of GM Plants

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

Directly, or through changes in agricultural practices

Ecosystem Services

Ecosystems provide "services" that:

- moderate weather extremes and their impacts

- disperse seeds

- mitigate drought and floods

- protect people from the sun's harmful ultraviolet rays

- protect stream and river channels and coastal shores from erosion

- detoxify and decompose wastes

- contribute to climate stability

- purify the air and water

- regulate disease carrying organisms

- **control agricultural pests**

- **preserve soils and renew their fertility**

- **maintain biodiversity**

- **cycle and move nutrients**

- **pollinate crops and natural vegetation**

Ecosystem Services

... and these services are commonly associated to particular guilds of organisms

Over 100,000 different animal species - including bats, bees, flies, moths, beetles, birds, and butterflies - provide free pollination services.

Biodiversity

- **Ecosystem diversity**
- **Species diversity**
- **Genetic diversity**
- **Functional diversity**

We assume that a change in biodiversity may trigger a change in the functioning of the agro-ecosystem
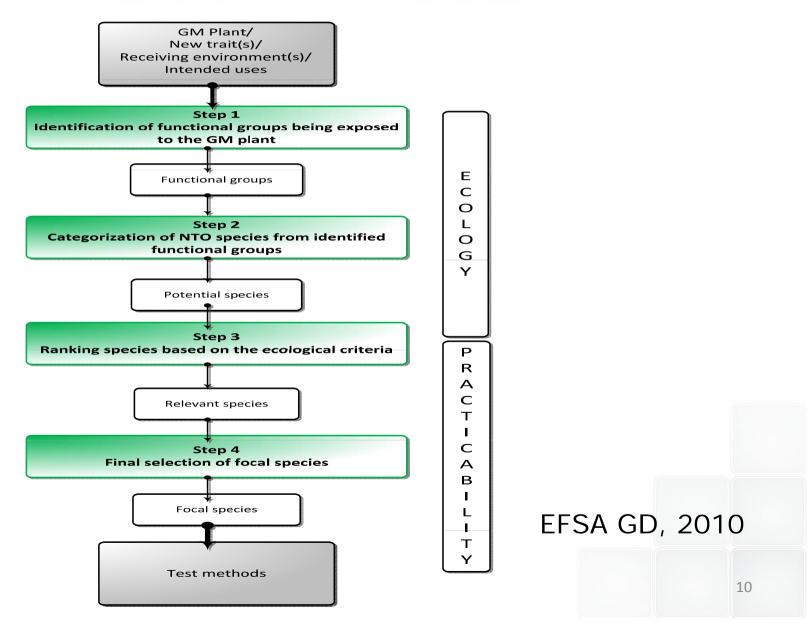
Functional groups

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

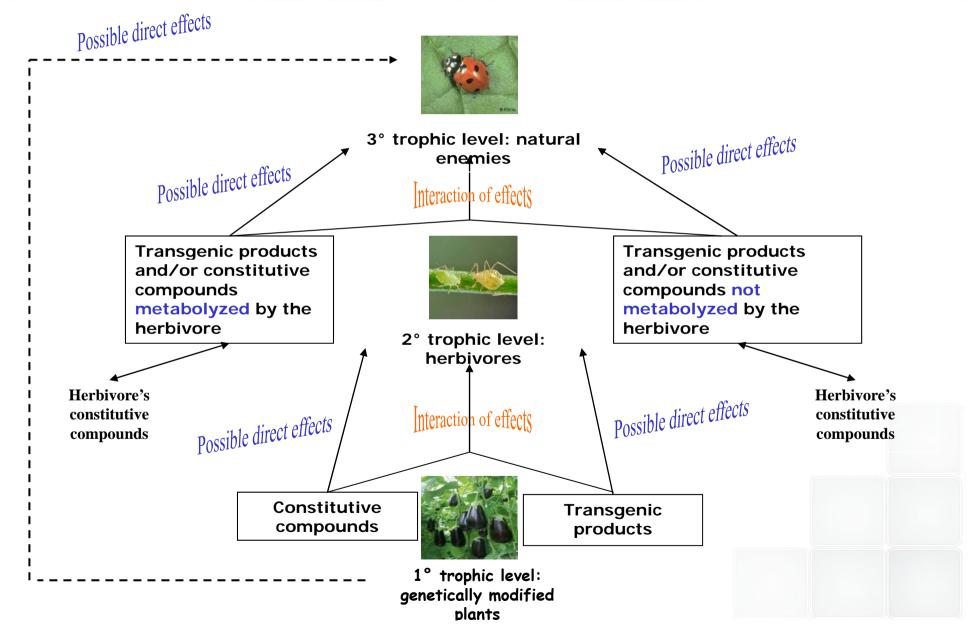# Selection of "focal species"

EFSA GD, 2010

Cry1f-expressing maize

- *Danaus plexippus* originally chosen as a surrogate species, its LC50 >24750

- Using the Perry et al. model for European species, local and global estimated mortality increase monotonically with the five levels of species sensitivity studied

- The EFSA GMO Panel concludes that there is a risk to certain highly sensitive non-target lepidopteran species where high proportions of their populations are exposed over successive years to high levels of maize 1507 pollen deposited on their host-plants and recommends that mitigation measures are adopted to reduce exposure in such situations

Possible Exposure of Natural Enemies to Transgenic Proteins

Possible direct effects

3° trophic level: natural enemies

Interaction of effects

Possible direct effects

Possible direct effects

Transgenic products and/or constitutive compounds metabolyzed by the herbivore

Transgenic products and/or constitutive compounds not metabolyzed by the herbivore

2° trophic level: herbivores

Herbivore's constitutive compounds

Herbivore's constitutive compounds

Possible direct effects

Interaction of effects

Possible direct effects

Constitutive compounds

Transgenic products

1° trophic level: genetically modified plants

What are the stressorS?

- The newly expressed protein(s) and their metabolite(s)

- The GM plant

Strategies for ERA of GM plants
The 6 steps of the ERA

Legal basis:
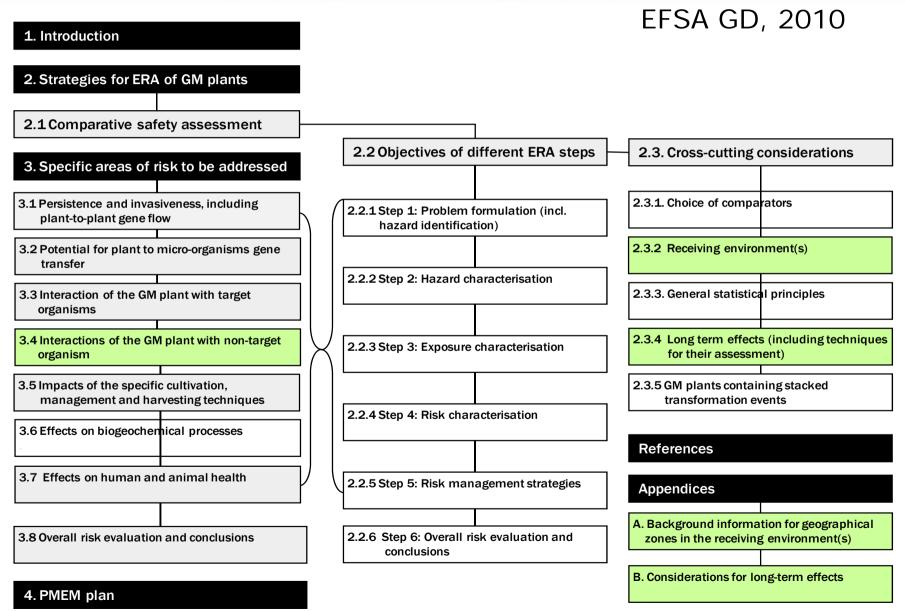✓ the 6 steps are described in Directive 2001/18/EC

Principles:
✓ Systematic review following the 6 steps but

✓ the assessment of the GM plant is done on a case-by-case basis

EFSA GD, 2010

Environmental Risk Assessment (ERA)

(1) Problem formulation (including hazard identification)

(2) Hazard characterisation

(3) Exposure characterisation

(4) Risk characterisation

(5) Risk management strategies

(6) Overall risk evaluation and conclusions

Feedback

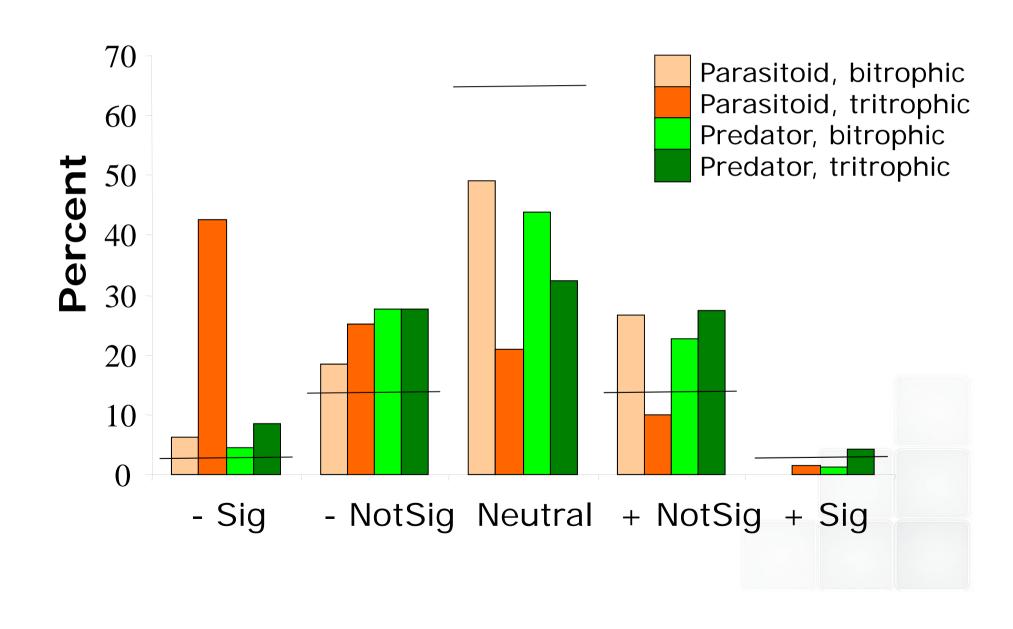**Overall Risk Management, including Post Market Environmental Monitoring (PMEM)**

The EFSA Approach to ERA

EFSA GD, 2010

1. Introduction

2. Strategies for ERA of GM plants

2.1 Comparative safety assessment

3. Specific areas of risk to be addressed

3.1 Persistence and invasiveness, including plant-to-plant gene flow

3.2 Potential for plant to micro-organisms gene transfer

3.3 Interaction of the GM plant with target organisms

3.4 Interactions of the GM plant with non-target organism

3.5 Impacts of the specific cultivation, management and harvesting techniques

3.6 Effects on biogeochemical processes

3.7 Effects on human and animal health

3.8 Overall risk evaluation and conclusions

4. PMEM plan

2.2 Objectives of different ERA steps

2.2.1 Step 1: Problem formulation (incl. hazard identification)

2.2.2 Step 2: Hazard characterisation

2.2.3 Step 3: Exposure characterisation

2.2.4 Step 4: Risk characterisation

2.2.5 Step 5: Risk management strategies

2.2.6 Step 6: Overall risk evaluation and conclusions

2.3. Cross-cutting considerations

2.3.1. Choice of comparators

2.3.2 Receiving environment(s)

2.3.3. General statistical principles

2.3.4 Long term effects (including techniques for their assessment)

2.3.5 GM plants containing stacked transformation events

References

Appendices

A. Background information for geographical zones in the receiving environment(s)

B. Considerations for long-term effects

Cry Toxins & non-random effects

Lack of knowledge and further progress

➢ Limited number of species studied (while it has improved in the last few years) and their geographic distributions;

➢ Limited choice of assessment endpoints (mostly detection of acute toxic effects, development, growth, fecundity, fertility should be addressed);

➢ Need for properly designed experiment with the sufficient power to detect adverse effects

➢ Addressing long term effects (Monitoring, Modelling)

Underlying principles

- Selection of **specific receiving environment** trying to encompass the largest possible variability of environmental conditions;

- Selection of **"focal" species and/or ecological functions** as potential bioindicators of environmental effects according to crop-trait-environment and agricultural practices in the selected areas;

- Planning experimental designs according to a **prospective power analysis and to the experimental designs** advised in the EFSA Guidelines.

Output

- **A network of laboratories able to perform small and medium scale studies of environmental impacts of GMPs** based on <u>commonly established and verified ERA protocols</u>

Non-target herbivores outside agricultural areas
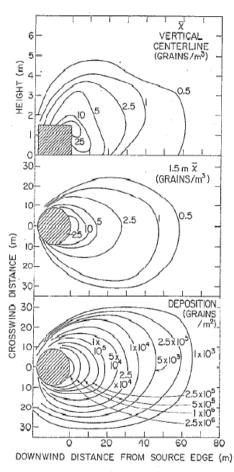
Fig. 1. Typical concentration $(\overline{\chi})$ and deposition patterns a corn pollen area source represented by the shaded f Concentrations are shown in the horizontal at a heig 1.5 m and in the vertical along the plume centerline.

IT9220090 - SCI Costa Ionica and Foce Bradano

Masseria Marinella

Agricultural Area

Humid area

Pine orchard

Mediterranean Woodbrush

Sand Dune

Life+ 2008 Project MAN-GMP-ITA

Image © 2010 DigitalGlobe
© 2010 Tele Atlas

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L'ENERGIA E LO SVILUPPO ECONOMICO SOSTENIBILE
CENTRO RICERCHE TRISAIA

SCI IT4050024

Casone del Partigiano

Life+ 2008 – Project MAN-GMP-ITA

Diurnal butterflies in SCI IT9220090

Papilionidae
Papilio machaon Linnaeus

Geometridae
Ascotis selenaria ([Denis & Schiffermüller

Noctuidae
Grammodes stolida (Fabricius)
Eutelia adulatrix (Hübner)
Ophiusa tirhaca (Cramer)

Arctiidae
Coscinia striata (Linneus)

Lycaenidae
Lycaena phlaeas (Linnaeus)
Polyommatus thersites (Cantener)
Polyommatus icarus (Rottemburg

Nymphalidae
Coenonympha pamphilus (Linnaeus)
Lasiommata megera (Linneus)
Maniola jurtina (Linneus)
Pararge aegeria (Linneus)
Vanessa atalanta (Linneus)
Vanessa cardui (Linneus)

Anthocharis cardamines (Linnaeus)
Colias croceus (Geoffroy)
Gonepteryx cleopatra (Linnaeus)
Gonepteryx rhamni (Linnaeus)
Pieris brassicae (Linneus)
Pieris napi (Linnaeus)
Pieris rapae (Linnaeus)
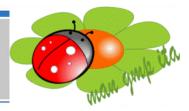*Pontia daplidice* (Linnaeus)
Pontia edusa (Fabricius)

Lasiocampidae
Lasiocampa (Lasiocampa) quercus (Linnaeus)

Database of Lepidoptera

Anthocharis cardamines

2010	mar	mar	mar	apr	apr	mag	mag	giu	giu	lug	lug	ago	ago	ago	set	set
	01	15	29	12	26	10	24	07	21	05	19	02	16	30	13	27

2011	mar	mar	mar	apr	apr	mag	mag	giu	giu	lug	lug	ago	ago	ago	set	set
	01	15	29	12	26	10	24	07	21	05	19	02	16	30	13	27

AREA AGRICOLA
PINETA
ZONA UMIDA
MACCHIA MEDITERRANEA
DUNA

Lasiommata megera

2010	mar	mar	mar	apr	apr	mag	mag	giu	giu	lug	lug	ago	ago	ago	set	set
	01	15	29	12	26	10	24	07	21	05	19	02	16	30	13	27

2011	mar	mar	mar	apr	apr	mag	mag	giu	giu	lug	lug	ago	ago	ago	set	set
	01	15	29	12	26	10	24	07	21	05	19	02	16	30	13	27

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Gonepteryx rhamni

2010	mar	mar	mar	apr	apr	mag	mag	giu	giu	lug	lug	ago	ago	ago	set	set
	01	15	29	12	26	10	24	07	21	05	19	02	16	30	13	27

2011	mar	mar	mar	apr	apr	mag	mag	giu	giu	lug	lug	ago	ago	ago	set	set
	01	15	29	12	26	10	24	07	21	05	19	02	16	30	13	27

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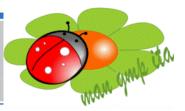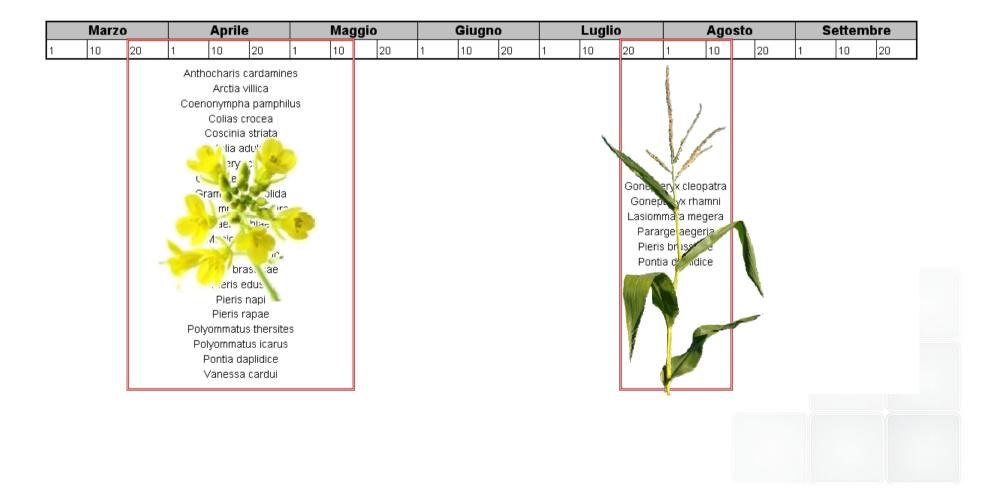
Evaluation of possible exposure

GM Canola

GM Maize

Marzo			Aprile			Maggio			Giugno			Luglio			Agosto			Settembre		
1	10	20	1	10	20	1	10	20	1	10	20	1	10	20	1	10	20	1	10	20

Anthocharis cardamines
Arctia villica
Coenonympha pamphilus
Colias crocea
Coscinia striata
...lia adu...
...ery...
...e
Gram... olida
...m... ...ra
...ae... ...blae
M... ...o
...uc...
...bras...ae
...eris edus...
Pieris napi
Pieris rapae
Polyommatus thersites
Polyommatus icarus
Pontia daplidice
Vanessa cardui

Gone...eryx cleopatra
Gonept...yx rhamni
Lasiomma...a megera
Pararge aegeria
Pieris br...ss...e
Pontia d...lidice

Support to Risk Assessment

Specie saggiata	CL$_{50}$	Stadio larvale	Evento di mais Bt	[Tossina] nel polline	Fonte
Pieris rapae	549	II età	Mais Bt176	3,7 ng/mg di p.s.*	(Felke *et al.*, 2002)
Pieris brassicae	1.962	II età	Mais Bt176	3,7 ng/mg di p.s.*	(Felke *et al.*, 2002)
Vanessa cardui	8.565	I età	Mais 1507	32 ng/mg di p.s.	(EFSA, 2011)

2010	marzo		aprile		maggio		giugno		luglio		agosto		settembre	
	01	15	29	12	26	10	24	07	21	05	19	02	16	30	13	27

2011	marzo		aprile		maggio		giugno		luglio		agosto		settembre	
	01	15	29	12	26	10	24	07	21	05	19	02	16	30	13	27

Data di inzio (gg-mm-aa)	1	01/03/2010
	2	01/03/2011

Scansione temporale (giorni)	14

Georeferenzia

Menù

Analizza Dati

AREA AGRICOLA

PINETA

ZONA UMIDA

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DUNA

Thank you for your attention,

Salvatore