EU Risk assessment of genetically engineered crops

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Testbiotech e. V.
Institute for Independent Impact Assessment in Biotechnology

17 September 2010

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Testbiotech

- promotes independent research,
- examine ethical, social and economic issues and
- assess risks to health and the environment.

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Risk Reloaded

Risk analysis of genetically engineered plants within the European Union

**A report by Testbiotech e.V.
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Agro-Biotechnology:
New plant pest caused by genetically engineered corn

The spread of the western bean cutworm causes massive damage in the US

Testbiotech Report March 2010, prepared for Greenpeace Germany

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Agro-Biotechnology:
Testbiotech opinion concerning the application for market approval of genetically modified maize 1507 (DAS-Ø15Ø7-1)

DOSSIER

International Federation of Organic Agriculture Movements EU Group

Economic impacts of labelling thresholds for the adventitious presence of genetically engineered organisms in conventional and organic seeds

SEED PURITY: COSTS, ADVANTAGES AND RISK MANAGEMENT FOR MARKETS AVOIDING GENETICALLY ENGINEERED PLANTS

Christoph Then / Matthias Stolze

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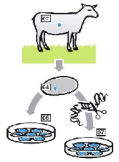

Agro-Biotechnology:
Cloned farm animals - a 'killing application'?

Risks and consequences of the introduction of cloned animals for food production

Authors: Christoph Then, Ruth Tippe
A Testbiotech Report prepared for Martin Häusling, MEP

May 2010

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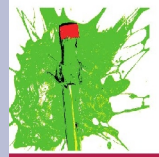

Synthetische Biologie
**Teil 1:
Synthetische Biologie und künstliches Leben – Eine kritische Analyse**

Juni 2010
Autoren: Christoph Then, Sylvia Hamberger

grassroots foundation

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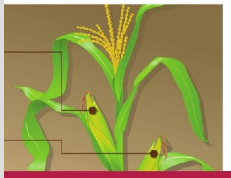

Agro-Biotechnology:
Testbiotech opinion on EFSA's draft guidance on the environmental risk assessment of genetically modified plants

A Testbiotech report for

The Greens EFA in the European Parliament

THINK Bio DIVERSITY

**July 2010
Author: Christoph Then**

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Synthetische Biologie und künstliches Leben – eine kritische Analyse

**Teil 2:
Die Erzeugung und Nutzung von Biokraftstoffen der zweiten Generation („Synthi-Fuels")**

September 2010
Autoren: Christoph Then, Christof Potthof und Sylvia Hamberger

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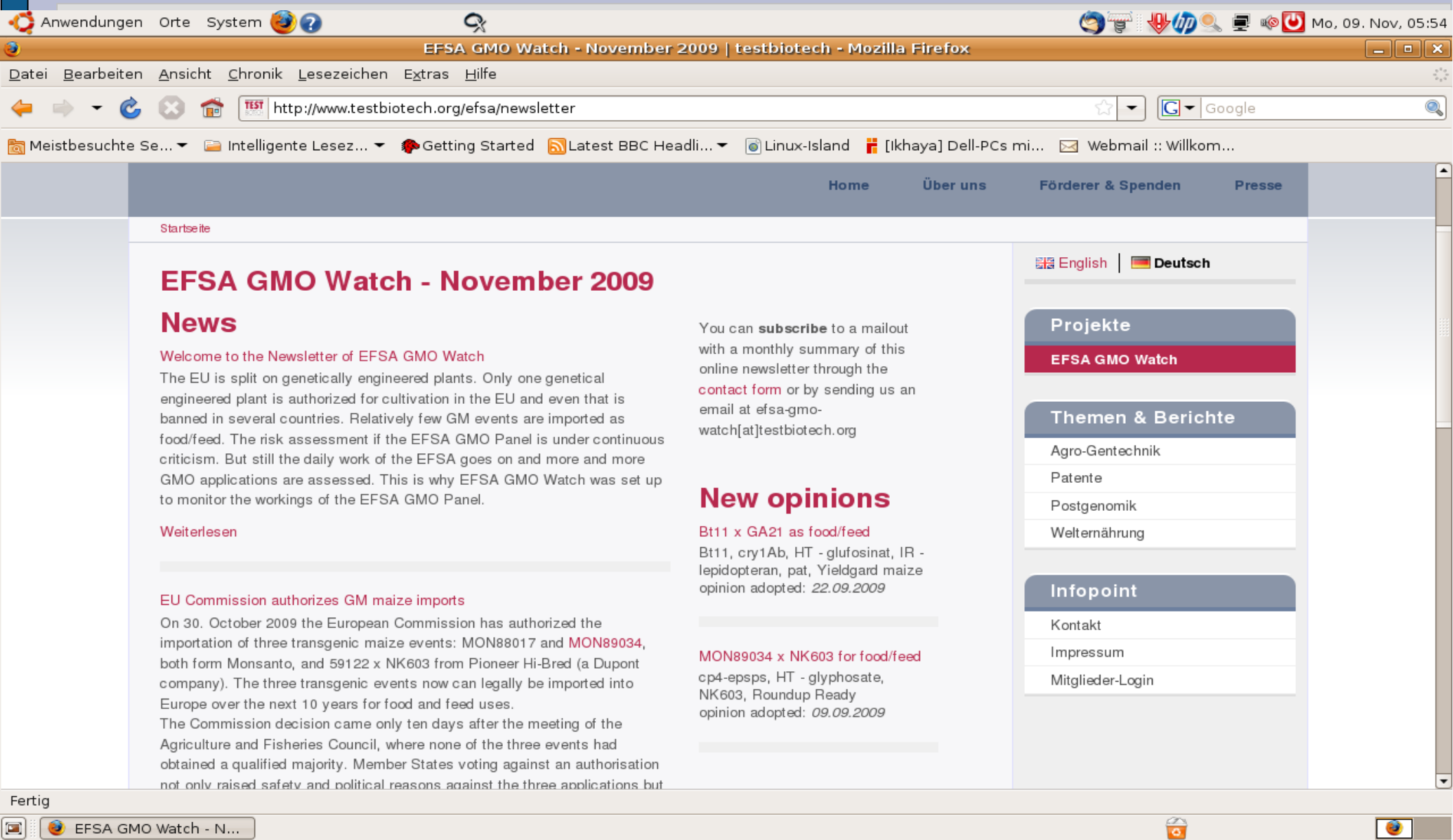
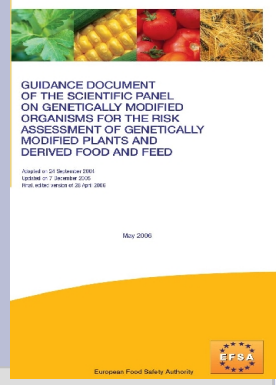


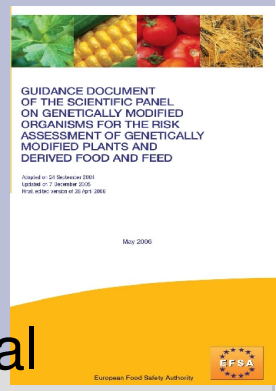
Work of EFSA based on substantial equivalence



"The concept of substantial equivalence is based on the idea that an existing organism used as food/feed with a history of safe use, can serve as a comparator when assessing the safety of the genetically modified food/feed [...]." (EFSA, 2006)

(EFSA Guidelines, 2006/2008)

Work of EFSA: Based on presumptions



"The current generation of GM plants cultivated for commercial purposes has been modified through the introduction of one or a few genes coding for herbicide tolerance, insect resistance or a combination of these traits. In these plants the genetic insert leads to the production of a gene product, which does not interfere with the overall metabolism of the plant cell, and does not alter the composition of the GM plant except for the introduced trait."

EFSA (2007) Assessment of Genetically Modified Plants and Derived Food and Feed: The Role of Animal Feeding Trials (...) Food and Chemical Toxicology, Volume 46, Supplement 1, March 2008, http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902590265.htm

EFSA in accordance with standards such as ...

MONSANTO

"An important point for our work on stacked events is that conventional breeding is not necessarily safe, but it has a history of safety developed over time. In addition, we can use our knowledge of breeding to produce stacked events that meet criteria of acceptable safety (as safe as)."

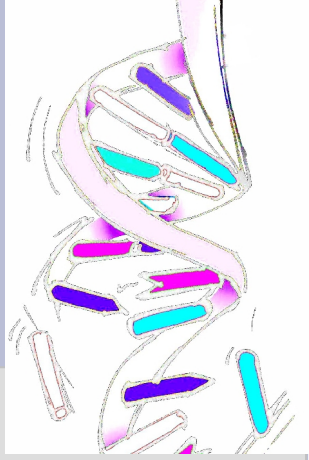
Thomas Nickson, Monsanto Company, USA, 2009-07-10, http://bch.cbd.int/onlineconferences/stacked2_ra.shtml?threadid=1214

EFSA in accordance with standards such as ... the Golden Rice Consortium

"The experiments were no more dangerous than feeding the children a small carrot since the levels of beta-carotene and related compounds in Golden Rice are similar."

From the website of the Golden Rice Consortium

The industrial gene paradigma



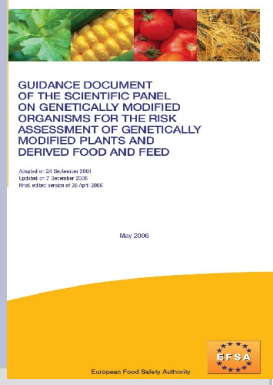
"The industrial gene is one that can be defined, owned, tracked, proven acceptably safe, proven to have uniform effect, sold and recalled," said Jack Heinemann ..."

(Jack Heinemann, New York Times, 2007)

Don't look – don't find

But how to perform a better risk assessment?

Work of EFSA: without alternative?



"Where no appropriate comparator can be identified, a comparative safety assessment cannot be made and a comprehensive safety and nutritional assessment of the GM crop derived food/feed per se should be carried out."

(EFSA 2006/2008)

Monsanto about unintended effects:

MONSANTO

"Nonetheless, the frequency of success of enhancing the transgenic plant is low due to a number of factors including the low predictability of the effects of a specific gene on the plant's growth, development and environmental response, the low frequency of maize transformation, the lack of highly predictable control of the gene once introduced into the genome, and other undesirable effects of the transformation event and tissue culture process."

Source: WO2004053055

Some basic requirements

drop the concept of substantial equivalence

drop the concept of substantial equivalence

Genetically engineered plants are technically derived products without true comparator. By the invasive method of genetic engineering, DNA is introduced beyond the borders of species by using methods that are not based on the mechanisms of common gene regulation and heredity.

The newly introduced gene constructs have a specific potential to escape and /or disturb the process of normal gene regulation that is unique for this certain technology.

Some basic requirements

generate a broad range of non biased data before field trials

reaction to environmental conditions (climate change), changes in genome and metabolome, genetic stability, introduce stress tests

Generate non biased technical data before field trials

Author	Factor: Impact
Abel & Adamczyk (2004)	- photosynthesis: Bt content and photosynthesis are positively correlated
Bruns & Abel (2007)	- nitrogen fertiliser: Bt content and nitrogen fertiliser are positively correlated
Griffiths et al. (2006)	- soil quality: can increase or decrease Bt content
	- pesticide use: spraying of insecticide increases Bt content in leaves and roots (pyretroid, Decis)
	- growing process: Bt content increases towards flowering
Nguyen & Jehle (2007)	- significant difference between two field sites in different climatic regions
	- growing process: Bt content in leaves increases during growing season

Example: Bt content in MON810, source Then&Lorch, 2008

Some basic requirements

develop a coherent step by step procedure that includes a set of mandatory investigations before and during experimental field trials

'Step by step' is legally required

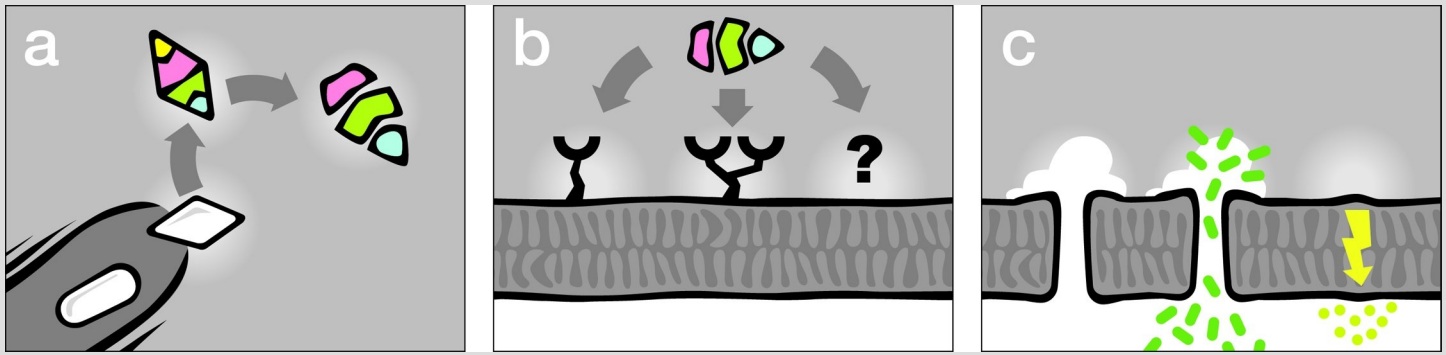
"The introduction of GMOs into the environment should be carried out according to the step by step principle. This means that the containment of GMOs is reduced and the scale of release increased gradually, step by step, but only if evaluation of the earlier steps in terms of protection of human health and the environment indicates that the next step can be taken."

Recital 24 of EU Dir 2001/18

Some basic requirements

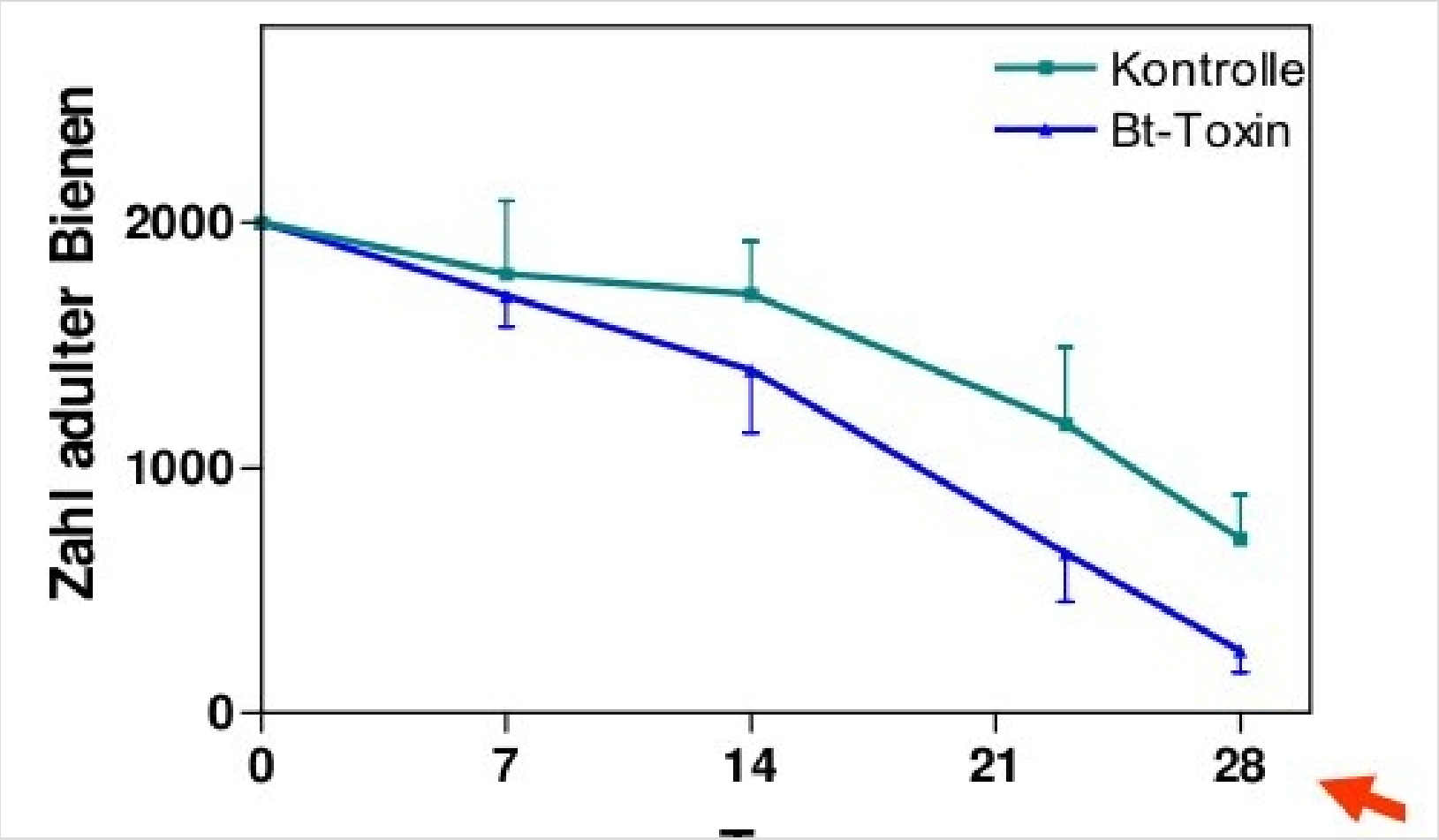
- include all levels of food web, do not only rely on a tiered approach
- take into account accumulated and combinatorial effects
- treat stacked events as new products that have to be assessed by their own

Expect the unexpected: Combinatorial effects



Example: no final theory for mode of action of bt toxins.
Combinatorial effects play a significant role. Source: Then, 2009

Expect the unexpected: Combinatorial effects



Example: combinatorial effects in honey bees
Source: Kaatz, 2005

Some basic requirements

request feeding studies over life time of certain animal species including the following generations.

feeding studies

Table 1: Selected feeding studies as accepted by EFSA

Company/product	Trait	Duration, animal species	Issue in investigation
Bayer/LLRice62	Rice with herbicide tolerance	42 days, poultry 96 days, pigs	Feed conversion
Monsanto/MON863	Maize with Bt toxin	90 days, rats	Health risks
Monsanto/NK603	Maize with herbicide tolerance	90 days, rats	Health risks
Pioneer/1507	Maize with Bt toxin	90 days, rats	Health risks
Syngenta/ Bt11	Maize with Bt toxin	14 days, cows 14 days, poultry	Feed conversion

Source: Then&Potthof, 2009

feeding studies

"As regards food safety, even if some GM products have been found to be safe and approved on a large scale..., the lack of general surveillance and consequently of any exposure data and assessment, means that there is no data whatsoever available on the consumption of these products – who has eaten what and when. (...) in the absence of exposure data in respect of chronic conditions that are common, such as allergy and cancer, there simply is no way of ascertaining whether the introduction of GM products has had any other effect on human health."

Source: EU Commission, 2005

Some basic requirements

define some cut off criteria for rejection of market applications such as invasiveness and persistence: Protect evolutionary integrity

Some basic requirements

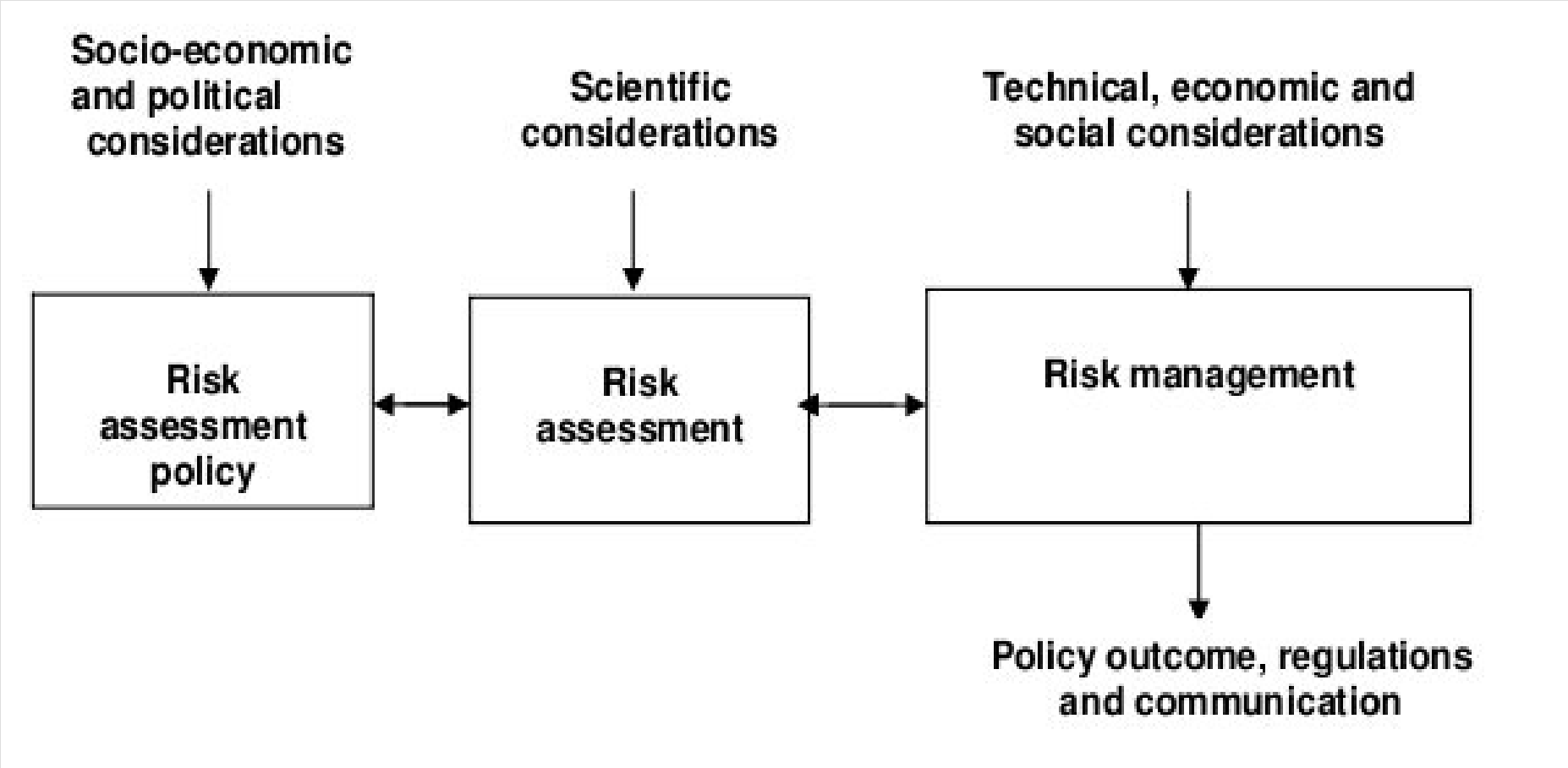
define some general criteria for rejection of market applications
such as compliance with sustainable agriculture

Some basic requirements

develop an integrated approach for risk analysis including criteria for ethical, socio economical issues:

take into account issues like contimantion at early stage, try to reduce not necessary field trials and feeding studies

Risk analysis



Millstone, JRC, 2008

Thank you very much ...

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….and please support us!

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