Proceeding of

International Workshop on Environmental Risk Assessment /

Biodiversity Assessment of Genetically Modified Organisms

遺伝子組換え植物の生物多様性影響評価に関する国際ワークショップ報告書

主催 ： 特定非営利活動法人国際生命科学研究機構
Organized by ：ILSI Japan

協賛 ：バイテク情報普及会
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遺伝子組換え植物の生物多様性影響評価に関する国際ワークショップ

International Workshop on Environmental Risk Assessment / Biodiversity Assessment of Genetically Modified Organisms

July 27 (Thursday), 2006 **10:00－15:00** 講演会
15:30 – 17:30 座談会

東京芸術劇場５F 中会議室 **Tokyo Metropolitan Art Space**

Lecture (More than 80 perticipants) **Round Table (by 9 panelists)**

President Dr. Kimura

Dr. T. Nickson

Dr. M. Oka

Dr. J. Walt

Dr. K. Kawaguchi

Dr. J. Sweet

ILSI International Life Sciences INSTITUTE

主催 ： 特定非営利活動法人日本国際生命科学協会
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目次

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主催：International Life Science Institute Japan
協賛：バイテク情報普及会

1. 目的：　遺伝子組換え作物が最初に商品化されてからすでに 10 年以上が経過し、この間、環境に対する影響に関しては、米国をはじめとして世界各地で多くのデータが採取され、それに基づきリスク評価が行われてきました。我が国においても国や企業の研究機関において、10 年以上に渡って安全性に係わる研究が進められ、多くの知見やノウハウが蓄積されると共に、リスク評価が進められて参りました。カルタヘナ法が施行されてから 2 年がたち、改めて、リスクマネジメントのハーモナイゼーションという観点から、リスク評価を捕らえ直してみることは、意義あることと考えます。評価をする立場から、あるいは、評価を受ける立場から、リスク評価のあり方を捕らえ直し、合理的で信頼性のあるシステムを構築していくことは、我が国の国益にとっても重要です。本ワークショップでは、国内外よりリスク評価研究の専門家を講師としてお招きして講演会および座談会を行うことにより、日本の専門家と海外専門家の交流の場を設定するとともに、関係各方面の皆様に対して情報発信をしていきたいと考えています。

2. プログラム

10:00 – 10:10　はじめに
木村 修一（**ILSI Japan** 理事長）

10:10 – 11:10　Evaluating the consequences of environmental release of genetically engineered crops using principles of ecological risk assessment
Jeff Wolt (Professor, Iowa State University, USA)

11:10 – 12:10　Environmental risk assessment and post market monitoring: the European approach
Jeremy Sweet (Vice chair, Europe Food Safety Authority (EFSA), UK)

12:10 – 13:20　休憩

13:20 – 14:20　Ecological Risk Assessment for Crops Derived through Modern Biotechnology
Thomas Nickson (Chairman, Risk Assessment of Global Industry Coalition, USA)

14:20 – 14:40　カルタヘナ法に基づく遺伝子組換え作物の使用規制と生物多様性影響評価
川口健太郎　（農林水産省　農林水産技術会議事務局技術安全課国際基準専門官）

14:40 – 15:00　遺伝子組換え作物の環境影響評価
岡　三徳　（独立行政法人農業環境技術研究所研究 コーディネーター）

15:00 – 15:30　休憩

15:30 – 17:30　招待演者５名に日本の規制に関する専門家を交えた座談会

出席予定者：Jeff Wolt 氏（座長）、Jeremy Sweet 氏、Thomas Nickson 氏、川口健太郎氏、岡三徳氏、新本英二氏（農林水産省・消費安全局　調査官）、林健一氏（農林水産先端技術産業振興センター(STAFF)　常任顧問）、與語靖洋氏（農業環境技術研究所　有機化学物質研究領域長）、若狭暁氏（東京農業大学　教授）

＊　海外演者の講演は、逐語訳を行います。また、日本の演者は、日本語で講演いたします。座談会は、同時通訳で行います。

5. 講演者略歴

＜Dr. Jeff Wolt＞

- 植物バイオテクノロジーに主眼点をおいた農業における新技術のリスク評価の研究者。
- 環境及び環境毒物のリスクアセスメントの研究や土壌化学と環境化学を応用した環境モニタリング・環境毒物・環境消長の研究を行っている。

＜Dr. Jeremy Sweet＞

- 組換え農作物のリスクアセスメント、特に環境及び農業への影響とジーンフローの研究者。
- ナタネのジーンフローに関する BBSRC/NERC 及び EU COEXTRA に参加。
- European Commission, Danish parliament, UK government, FAO 等のアドバイザー。
- 過去には、除草剤耐性ナタネ及びテンサイの輪作におけるマネージメント及び影響に関する UK BRIGHT プロジェクトのコーディネーターや組換え農作物の影響評価に関する ESF プログラムのコーディネーターも務めた。

＜Dr. Thomas Nickson＞

- 米国モンサント社、Ecological Technology Center のディレクター。
- 14 年間、組換え農作物の研究に携わる。
- 組換え農作物の生態リスクアセスメントモデルを改善し、リスクアセスメントの原則及びプロセスのハーモナイゼーションを図る活動を行っている。

＜Dr. Kentaro Kawaguchi＞

- 1988 年農林水産省入省。農業生物資源研究所、北海道農業試験場畑作物生産部栽培生理研究室、北海道農業試験場畑作研究センター品質制御研究チーム、独立行政法人北海道農業研究センター地域基盤研究部冷害生理研究室を経て、2005 年 2 月農林水産省農林水産技術会議事務局技術安全課国際基準専門官に着任、現在に至る。
- 職務内容：バイオセーフティに関するカルタヘナ法の下での第一種使用規程承認申請に係る生物多様性影響評価検討会及び第二種使用規程承認申請に係る拡散防止措置確認会議の事務局

＜Dr. MItsunori Oka＞

- 1981 年農水省入省。水稲、キャッサバ、サトウキビ等の熱帯作物の栽培生理・育種、植物遺伝資源研究に従事。
- 2001 年以降、農業環境技術研究所で植生研究グループ長、生物環境安全部長として、農業生態系における生物多様性、外来生物、組換え生物、生物機能の 4 課題に関わる生物環境研究の推進と調整を担当。特に、組換え生物の環境安全性評価の課題では、カルタヘナ法の円滑な実施に向けた環境影響評価手法の開発や標準化に尽力。
- 2006 年 4 月からは、国際研究協力担当の研究コーディネーターとなり、併せて組換え生物、外来生物に関わる研究の推進と調整を担当。
- 環境省特定外来生物等専門家会合　委員、農水省遺伝子組換え作物栽培実験指針検討会　委員、東京農業大学　客員教授

日本国際生命科学協会（ILSI Japan）: http://www.ilsijapan.org/newWeb/index.html
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はじめに

木村　修一（ILSI Japan 理事長）


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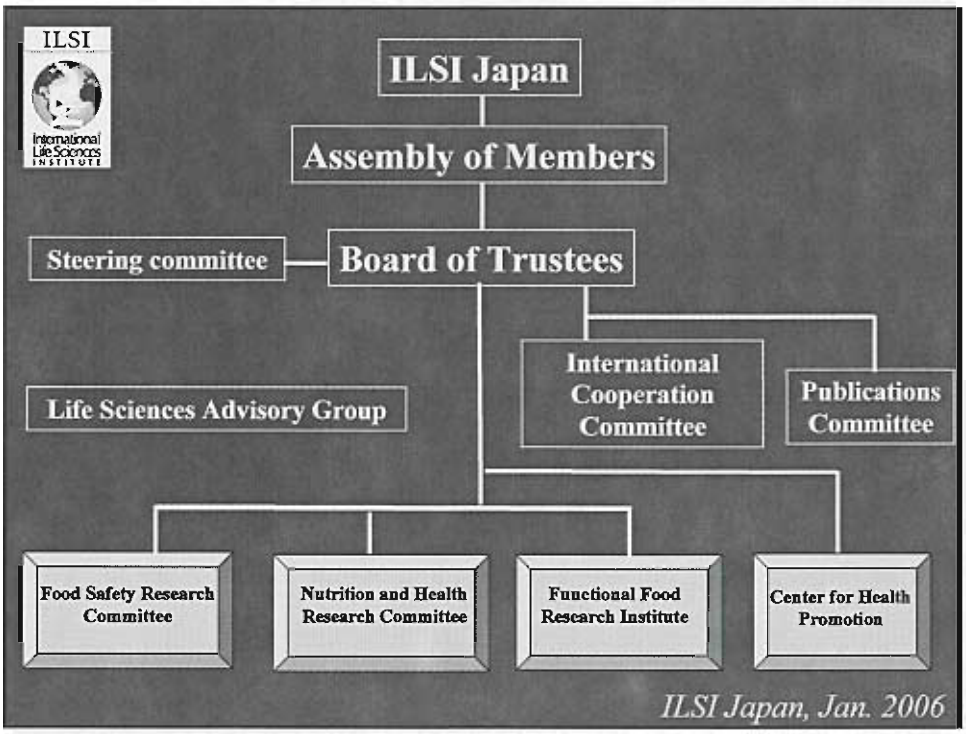
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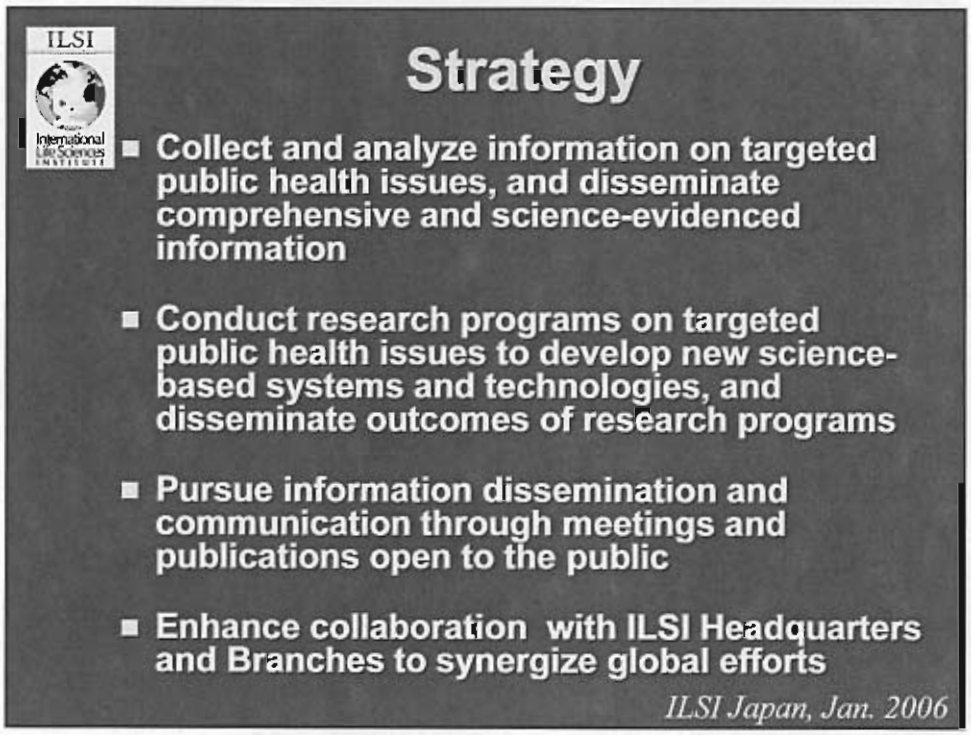
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Risk Assessment and Biotechnology

- ILSI Japan was the pioneer in introducing the concept of risk assessment in Japan. In 1983 the ILSI International symposium on Safety Assessment was held to introduce the concept to the public including MHW.
- ILSI Japan held International symposium on Foods Produced by New Biotechnology at the request of MHW in 1993. The report became the base for guidelines for Safety Assessment for GMO Foods published by MHW.
- ILSI Japan hosted FAO/WHO Symposium on Biotechnology and Food Safety in 2000.
- ILSI Japan held International Symposium on Biotechnology in collaboration with IFBiC in 2005

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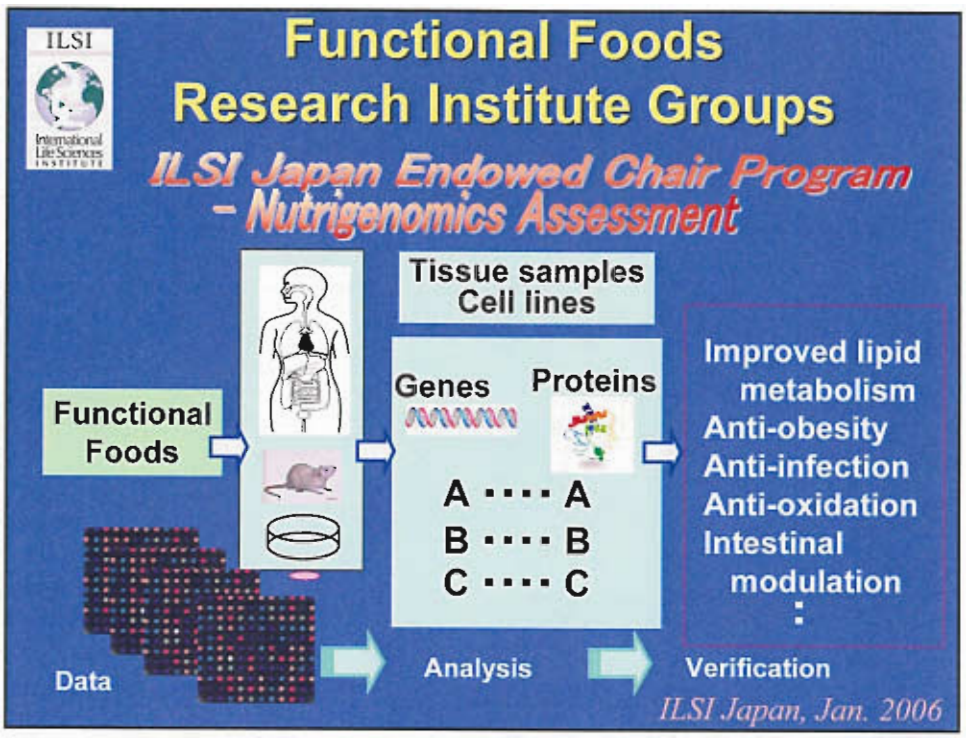
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Evaluating the Consequences of Environmental Release of GE Crops: Using Principles of Ecological Risk Assessment

Jeff Wolt
Biosafety Institute for Genetically Modified Agricultural Products (BIGMAP)
Iowa State University
Ames, IA

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Biosafety Institute for Genetically Modified Agricultural Products (BIGMAP)
Iowa State University
Ames, IA
July 2006

Summary

Regulatory experience with genetically engineered organisms (GEOs) in the United States provides a positive record of successful evaluations and subsequent safe use of the commercial products. This argues for a further streamlining of the process for regulatory approvals with a focus on the ecological risk assessment (ERA) framework as an objective science-based process for identification of risks that may adversely impact human health and the environment. To date, the ERA framework as applied to GEOs has been sufficiently flexible to deal with concerns surrounding biotechnology. The case-specific problem formulation using common data elements serves as important precursor information that directs the ERA toward risk assessment for consequential concerns.

US Regulatory Experience with GEOs

Regulatory authorities within the United States have more than 25 years experience with environmental evaluations of genetically engineered organisms (GEOs) and more than 10 years experience with commercial deployment of GE crops. The original field releases of GEOs (ice nucleating bacteria in 1983) predated the formalized recognition of a regulatory structure and were conducted consistent with National Institutes of Health (NIH) "Guidelines for Research with Genetically Engineered Organisms." The Coordinated Framework (OSTP, 1986) subsequently described the shared mandate among federal agencies for considerations of GEO safety utilizing existing regulation.

Under the Coordinated Framework, the United States Department of Agriculture (USDA) has broad authority to permit and deregulate GEOs, which are evaluated from the standpoint of environmental risk under statues pertaining to introduction of plant pests into US agriculture. USDA Animal Plant and Health Inspection Service (APHIS), Biotechnology Regulatory Services (BRS) has current responsibility in this regard.

The United States Environmental (EPA) has authority to regulate GEOs that express pesticidal traits (insect or disease resistance proteins) as plant incorporated protectants (PIPs) under the Federal Fungicide, Insecticide, and Rodenticide Act (FIFRA). EPA conducts comprehensive human and ecological safety assessments and grants time-limited registrations for these traits. The EPA Office of Pesticide Programs (OPP), Biopesticides and Pollution Prevention Division (BPPD) is responsible for registration of PIPs.

Food safety issues for GEOs are addressed by the US Food and Drug Administration (FDA) Office of Food Additive Safety, Division of Biotechnology & GRAS Notice Review. Food safety evaluations currently involve a consultative process between FDA and product developers.

All federal agencies within the US must consider environmental values in regulatory decision-making under the National Environmental Protection Act (NEPA). NEPA requires consideration of environmental impacts of proposed regulatory actions and reasonable alternatives to those actions. Therefore, if any agency undertaking regulatory actions relative to GEOs determines that risk findings are incomplete they will prepare an Environmental Impact Statement (EIS) to establish no significant impact to the environment. For instance, BRS has undertaken an EIS to determine what further regulatory responsibilities USDA may have as it writes regulation to streamline the risk assessment process for GEOs. Similarly, all federal agencies are required to specifically address endangered species concerns relevant to the decisions under the Endangered Species Act (ESA).

The Coordinated Framework has allowed for commercial deployment of GE crops into the US market in a timely and effective manner, while adhering to high standards of human and ecological safety. As a consequence there has been rapid adoption of GE crops. In 2004, the proportion of US crops planted to GE varieties represented 45% of corn, 85% of soybean, and 76% of cotton; representing herbicide resistance traits, insect resistance traits, stacks and pyramids. Keys to regulatory success in dealing with GEOs in the US can in part be attributed to use of an ERA framework, flexibility in addressing novel products on a case-by-case basis, focused evaluations where initial problem formulation serves to prioritize concerns that are addressed by regulators, and emphasis by regulators on consequential concerns (established hazards and real risks).

The ERA Process and Framework

Ecological risk assessment (ERA) is a process for describing technology risk as a likelihood of harm to occur under realistic conditions of exposure. Within the United States, this process has been successfully applied to regulatory policy and science-based decision-making for 25 years. Similar approaches to ecological risk are well-recognized and used in other regions of the world. The ERA process has a strong focus on toxicological testing and exposure assessment; therefore, some have questioned the applicability of this technique toward assessment of potential risks associated with the wide scale release and cultivation of genetically engineered (GE) crops. Recent publications have described conceptually how ERA can be applied to GE crops (Dutton et al., 2003; Wilkinson et al., 2003; Hill, 2005; Romeis et al., 2006a). Published examples of the application of GE crop ERA are now common (Wolt et al., 2003, 2005; Peterson et al., 2006; Romeis et al., 2006b). In this presentation, the process of ERA is briefly described with respect to the environmental and ecological risks posed by deployment of GE crops. The focus of this presentation is on ERA as it relates to non-target arthropods (NTA), but the broad methodology is applied to non-target organisms in general and is adaptable to questions of gene flow and weediness (Raybould and Cooper, 2005).

Regardless of the particular environmental or ecological concern that may be addressed, the ERA is focused on a science-based process that evaluates exposure and effect (the consequence of the exposure in terms of likelihood of harm). Focusing on the consequences of environmental release of GE crops rather than concerns regarding GE crop deployment provides an objective means to use science-based information for regulatory and public policy decisions.

The ERA utilizes a 'framework approach' providing a hypothetical description of a complex process through application of a logical scheme for organizing complex information. The goals of an ERA framework are to

- develop a unified conceptual approach to environmental assessment;
- facilitate cooperation/collaboration between assessment-related disciplines;
- increase transparency of risk assessments to users (risk managers);
- provide standardized tools and techniques; and
- dispel the perception that ecological risk assessment is impossible (Barnthouse, 2006).

Specifically within the US, ERA has been defined as "the process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors [or actions]" (USEPA, 1992; 1998). The key to success in applying ERA to a wide variety of technologies is recognition that the ERA is a process – that is, a particular course of action intended to achieve a result (a procedure). And not a technique – a specific approach to performing the assessment.

Application of ERA to GE Crops

In applying ERA to GE crops, it is necessary to understand that the overall process of risk assessment does not start with the ERA. Rather the ERA relies on a body of precursor information that establishes with reasonable certainty that, other than for the expression of the trait of interest, the GE crop is equivalent to non-transformed comparators (see for example EuropaBio, 2003, 2004). Once equivalence has been established on the basis of the GE crop characterization, the ERA can proceed with emphasis on stressor-mediated effects, where the potential stressor (that is the agent capable of causing harm) is the expressed trait, for instance a Bt protein conferring insect resistance to a crop. Thus, the general philosophy toward the ERA for GE crops:

- entails weight-of-evidence based on comprehensive evaluation of data;
- proceeds from general understanding to specific entities of concern;
- supports findings with quantitative data and analyses to the fullest extent possible;
- provides risk-based findings that focus on harm that may be manifested at environmentally relevant exposures; and
- seeks a determination of reasonable certainty of no harm to the environment or ecological entities in that environment.

The ERA process as it is applied to GE crops is consistent with the overall ERA framework; however, complexities exist due to the relatively recent nature of biotechnology and the fact that biological information is not fully quantifiable. Furthermore, the fact that we simultaneously consider within GE crop risk assessments the effect of stressor on individuals and populations as well as the effect of deployment on populations and communities, leads to confusion by some with respect to how evaluation of stressor-mediated effects (the core consideration of ERA) can address uncertainties regarding effects at an ecological scale. In applying the ERA framework to GE crops, the stressor is recognized as the expressed product that elicits harm (for example, an insecticidally active Bt toxin). A relevant action is deployment of an event expressing the Bt toxin within a given region. Emphasis in the GE crop ERA should be given to the stressor-mediated effects, as demonstration of reasonable certainty of no harm from direct exposure to the stressor provides reasonable certainty that indirect effects arising from the action of deployment will not be ecologically relevant.

The ERA for GE crops relies on a tiered process of both testing and subsequent assessment. This process proceeds from well-controlled, focused, laboratory studies conducted under very conservative assumptions regarding exposure potential, to less certain field studies and monitoring that seek the manifestation of hazard under real world conditions. Because controlled laboratory studies are conservative indications of likelihood for risk to be manifested under real world conditions (that is, of risk), the majority of GE crop ERAs conducted to date have relied on laboratory studies. In cases where confirmatory field studies and monitoring were conducted, laboratory study findings have proven adequate to determine that there is reasonable certainty of no harm associated with environmental release.

Confirmation of the Adequacy of the ERA Process for GE Crops

For GE crops evaluated to date laboratory studies have been adequate to determine that there is reasonable certainty of no harm associated with environmental release. This is confirmed by case-by-case instances of field surveys and census, field surveillance monitoring, and experience with large scale deployment of GE crops. This has also been confirmed with respect to risk findings associated with Bt corn and monarch butterfly.

In the instance of risks of Bt corn to nontarget Lepidoptera, EPA's original ERA found negligible risks from incidental exposure to potentially sensitive insects such as monarch butterfly, but failed to adequately manage and communicate that finding in subsequent decision-making. Thus, the subsequent reporting of hazard to monarch from Bt corn pollen elicited considerable public concern and uncertainty within the scientific community. Substantial subsequent public sector research and ERA as well as EPA's reanalysis supported the original finding of negligible risk to nontarget butterflies. The monarch controversy was not due to failure in the ERA process (the original ERA was conservative and has been supported by subsequent research), however, risk management and risk communication failures led to a lack of understanding.

In terms of field studies and monitoring, there has been concern addressed by some (NRC, 2002) as to the adequacy of the ERA process for understanding of ecological effects from large scale commercial release. Through application of the case-by-case paradigm risk assessment, both EPA and USDA have required substantial nontarget field studies for GE crops as a means for verification of the adequacy of risk findings based on laboratory studies and exposure assessments conducted within an ERA framework. Published field studies involving Bt corn and nontarget organisms show that to date there have not been significant unanticipated effects from field release of GE crops. US regulators continue to consider monitoring a case-by-case consideration and requests for monitoring will be hypothesis-driven on the basis of uncertainties arising form the ERA process.

Problem Formulation and Common Data Elements of the GE crop ERA

Success of the ERA is very much tied to the initial step of problem formulation which sets the stage for the risk assessment. The problem formulation identifies and interprets existing information to focus on consequential concerns. It also outlines the analysis plan for the risk assessment and specifies what studies are needed to address issues of consequence and the ecological entities of concern that should be the focus of assessment. Problem formulation additionally identifies the relevant starting point (tier) and the appropriate endpoints of concern for the ERA.

Precursor information on the GE crop is evaluated in the problem formulation stage of the ERA to establish key product attributes. First, it is necessary to establish protein equivalency for the crop-expressed and experimental test substance; since, bacterially-produced protein is commonly used in toxicity testing. Product characterization needs to show that the plant-produced and bacterially-produced proteins are biologically, biochemically, and immunologically equivalent.

Additionally, the precursor information – or the subsequent ERA analytical plan – must provide relevant information on expression and hazard. Levels of stressor expression of the stressor allow prediction of exposure concentrations and need to be measured or conservatively estimated with consideration of variation within the plant, over relevant stages of growth, and across environments. Hazard potential must be established. This is generally done through Tier 1 (maximum hazard dose) laboratory ecotoxicity testing using a series of representative species in order to confirm the anticipated spectrum of activity and hazard to non-target organisms. Selection of appropriate surrogate species for testing should consider activity profile, host crop, and environment where deployed. Exposure estimates are developed on the basis of expression data to determine High End Exposure Estimates (HEEE) in plant tissues, and Estimated Environmental Concentrations (EEC) in soil and water.

The exposure estimates are compared against hazard testing results to predict risk as a joint function of hazard and exposure. For GE crops this is typically done by considering the relationship of the limit dose used in ecotoxicity studies to the appropriate HEEE or EEC. The risk characterization should demonstrate the ability of the testing scheme that has been employed to characterize hazard at or above environmentally relevant exposure

concentrations. The subsequent risk conclusions should confirm the adequacy of risk characterization through correspondence of the product specific findings with general understanding for the donor, host, and product class being considered. In addition there should be internal consistency in study results and risk findings that indicates directional correctness of overall product and risk characterization. For GE crops that have been evaluated to date within the general framework of ERA, field studies, monitoring, and history of safe deployment have confirmed that the conservatism of the conclusion arising from the ERA process is in keeping with the degree of uncertainty considered within regulatory decisions.

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Evaluating the Consequences of Environmental Release of GE Crops:

Using Principles of Ecological Risk Assessment

Jeff Wolt
Biosafety Institute for Genetically Modified Agricultural Products (BIGMAP)
Iowa State University
Ames, IA
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- US regulatory experience with GEOs
- The ERA framework
- ERA framework as applied to GEOs
- Problem formulation & common data elements for the ERA

Biotechnology Regulatory History in the US –

25+ years experience with environmental evaluations
10+ years experience with commercial deployment of GE crops

Biotechnology Regulatory Milestones in the US (with respect to ERA)

1978	NIH implements Guidelines for Research with Genetically Engineered Organisms
1983	Field tests of the genetically engineered "ice-minus" strains of Pseudomonas syringae and Erwinia herbicola
1986	Office of Science and Technology Policy (OSTP) publishes the "Coordinated Framework for Regulation of Biotechnology"
1987	USDA publishes a rule for permitting field tests "Introduction of Genetically Engineered Organisms"
1988	First field test of a potential commercial product - Calgene plants Tobacco Mosaic Virus-resistant tomatoes USDA Biotechnology, Biologics and Environmental Protection (BBEP) established to regulate biotechnology and other environmental programs
1992	USDA APHIS deregulates a product for the first time, Calgene's FLAVR SAVR tomato
1993	USDA publishes alternative requirements for field testing–Notification Procedures for the Introduction of Certain Regulated Articles and rules to allow determinations that certain plants are no longer Regulated Articles– Petition for Nonregulated Status
1995	EPA registers first pest protected plant—Monsanto's New Leaf potato
2002	USDA creates Biotechnology Regulatory Services (BRS) to focus on regulating and facilitating biotechnology.
2004	USDA initiates an Environmental Impact Statement (EIS) in preparation for revised GEO regulation

Coordinated Framework

A shared mandate for considerations of safety

- USDA – plant pests
- EPA – pesticidal traits
- FDA – food safety
- NEPA – National Environmental Protection Act mandates environmental impact considerations for all regulatory decisions

Deployment of GE Crops in the US Market

Proportion of crop planted to GE varieties

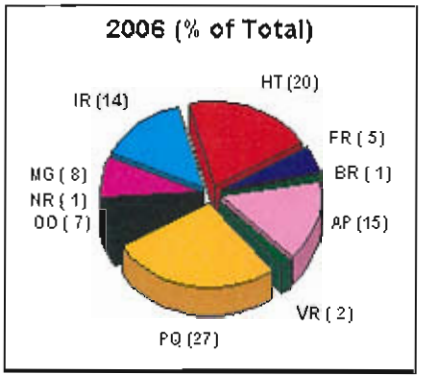
- 45% Corn
- 85% Soybean
- 76% Cotton

Representing ..

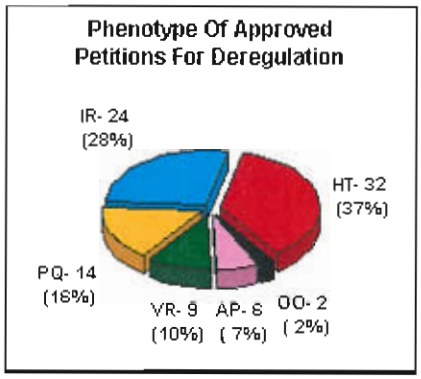
- Herbicide Resistance traits
- Insect Resistance traits
- Stacks and Pyramids

(2004) http://pewagbiotech.org/resources/factsheets/

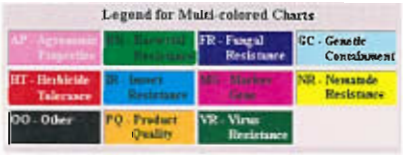
Number of Approved Releases by Phenotype Category, 2006



Number of Deregulated Articles (Total) by Phenotype Category



(Some Petitions have multiple Phenotype Categories)
–APHIS-BRS, 2006



Keys to Regulatory Success

- Use an ERA framework
- Flexibility – the case-by-case paradigm
- Focus – use of problem formulation to prioritize concerns
- Emphasis – consequential concerns

Principles of ERA

have been developed and in use in the USA for about 25 years

Framework approach

- a hypothetical description of a complex process
- a logical process for organizing complex information
- a road map

Goals of ERA Framework

(Bartenhouse, 2006)

- develop a unified conceptual approach to environmental assessment
- facilitate cooperation/collaboration between assessment-related disciplines
- increase transparency of risk assessments to users (risk managers)
- provide standardized tools & techniques
- dispel perception that ecological risk assessment is impossible

ERA

- "the process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors [or actions]"
  - *Framework for Ecological Risk Assessment* Risk Assessment Forum, USEPA (1992) EPA/630/R-92/001
  - *Guidelines for Ecological Risk Assessment* Risk Assessment Forum, USEPA (1998) EPA/630/R-95/002F

The Key to Success

Focus on process not technique

process: a particular course of action intended to achieve a result (procedure)

technique: a specific approach to performing a task

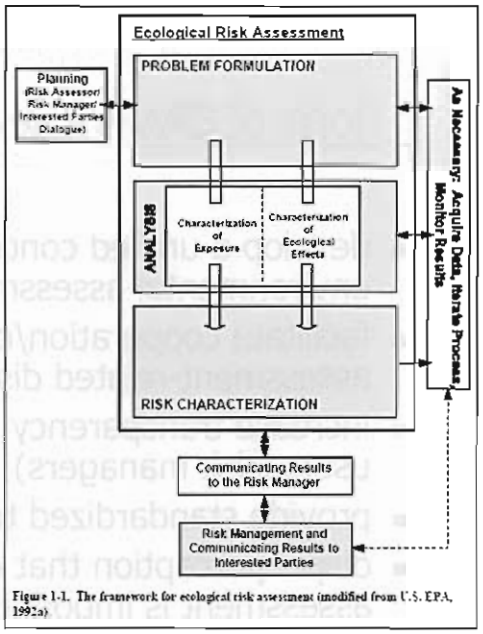
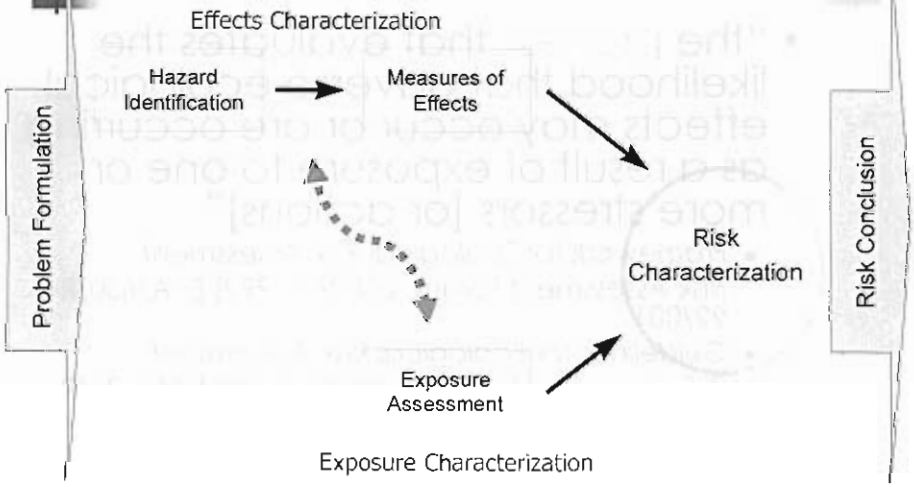
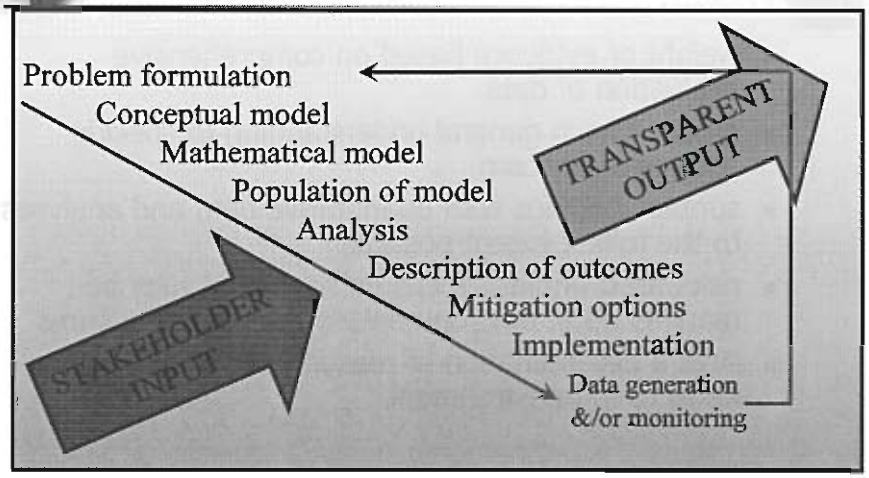


Figure 1-1. The framework for ecological risk assessment (modified from U.S. EPA, 1992a).

the risk assessment process



ERA is a recursive process



flow path for an ERA

ERA for GE crops ...

- is consistent with the framework for RA
  - however, complexities exist due to
    - relatively recent technology
    - biological information is not fully quantifiable
    - two perspectives as to concerns
      - effect of stressor on individuals and populations
      - effect of deployment on populations and communities

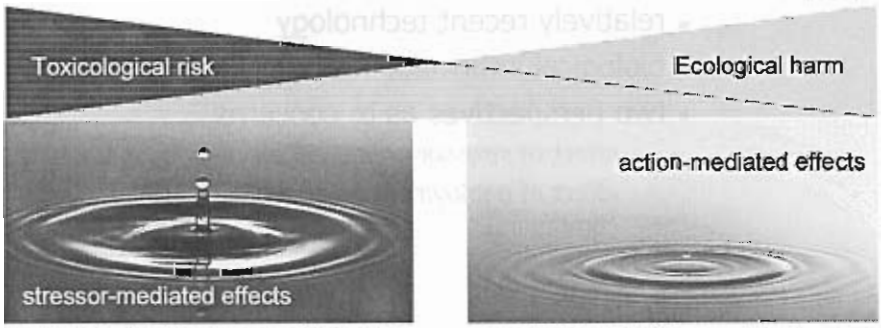
General philosophy toward ERA for GE crops

- weight of evidence based on comprehensive evaluation of data
- proceed from general understanding to specific entities of concern
- support findings with quantitative data and analyses to the fullest extent possible
- risk based findings focus on harm that may be manifested at environmentally relevant exposures
- seek a determination of reasonable certainty of no harm to the environment

GE ERA follows a tiered scheme

lab → extended lab → semi field → field → landscape

"direct" "indirect"



protein toxin effect on a putative sensitive NTO

crop deployment effect on ecological services within a landscape or region

for GE crops evaluated to date ...

Laboratory studies ...

Have been adequate to determine that there is reasonable certainty of no harm associated with environmental release

Confirmed by case-by-case instances of

- field surveys and census
- field surveillance monitoring
- experience with large scale deployment

Confirming the adequacy of the ERA process: Risks of Bt Corn to Nontarget Lepidoptera

1995	EPA finds negligible consequence for adverse effects to nontarget butterflies in first registration of Bt maize *Subsequent risk management decisions and communication fail to document this finding*
1999	Concerns raised over nontarget risk of Bt corn pollen to Monarch [Losey et al., *Nature* 399: 214]
2000	Concerns override consequences. EPA requests further data and analysis as part of the reassessment of the time-limited registrations for Bt crops. Finds negligible consequence for endangered Karner blue butterfly but expresses continuing concerns regarding long-term exposures to Monarch
2001	Publications address concerns [series of 4 publications. 2001. *PNAS* 98:1913-11936]
2001	ERA finds negligible consequence for monarch (short-term exposure) [Sears et al. 2001. *PNAS*, 98:11947-11942]
2003	Screening level ERA establishes adequacy of EPA's original finding of negligible consequence using screening level data and assessment [Wolt et al. 2003. *Environ Entomol*, 32:237-246]
2004	Published ERA finds negligible consequence for Monarch (long-term exposure) [Dively et al. 2006. *Environ Entomol* 33:1116-1125]
2006	Published ERA shows negligible consequence for Karner blue [Peterson et al. 2006. *Risk Anal* 26:845-858]

Learning from the experience with Bt corn and nontarget Lepidoptera

- balance concern and consequence
  - many concerns, but thorough problem formulation and analysis shows most concerns to have limited consequence
  - adhere to ERA framework principles
  - transparency in communication of the results of ERA

Confirming the adequacy of the ERA process: Nontarget field studies with Bt Corn

Protein	Monitoring focus	Reference
Cry1Ab	ECB oviposition & natural enemy abundance	Orr & Landis J. Econ. Entomol. 90 1997
	secondary lep pests	Pilcher et al. J. Econ. Entomol 90 1997
	kernel damaging insects	Dowd J. Econ. Entomol. 93 2000
	black swallowtail	Wraight et al. PNAS 97 2000
	Orius insidiosus	Al-Deeb et al. Environmental Entomology 30, 2001
	monarch	Stanley Horn et al PNAS 2001
	NTO abundance	Wold et al. J. Entomol. Sci. 36 2001
	black swallowtail	Zangerl et al., PNAS 2001
	ECB parasitism rates and NTO abundance	Bourguet et al. Environ. Biosafety Res. 1 2002
	NTO abundance	Hassell & Shepperd J. Entomol. Sci. 37 2002
	NTO abundance	Jasinski Env. Entomol. 32 2003
	pests & predators	Musser & Shelton J. Econ. Entomol. 96 2003
	aphid-brachonid	Pons et al. J. Pest Sci. 76 2003
	NTO abundance	Candolfi et al. Biocontr. Sci. Technol. 14 2004
	monarch	Dively et al. Environ. Entomol. 33 2004

Protein	Monitoring focus	Reference
	predators	Toth Environ. Biosafety Res. 3 2004
	rhizosphere bacteria	Baumgarte & Tebbe Molecular Ecolo. 14 2005
	NTO abundance	Daly & Buntin Environ. Entomol. 34 2005
	predators	de la Poza et al. Crop Prot. 24 2005
	rhizosphere bacteria	Feng et al. Appl. Environ. Microbiolo. 71 2005
	ground beetles	Lopez et al. Env. Entomol. 34 2005
	spiders	Meissle & Lang Agric. Ecosyst. Environ. 107 2005
	five non-target arthropods	Pilcher et al. Environ. Entomol. 34 2005
Cry1Ab+Vip3A	NTO abundance	Dively Environ. Entomol. 34 2005
Cry3Bb	aboveground NTO abundance	Al-Deeb & Wilde Environ. Entomol 32 2003
	NTO abundance	Ahmad et al. Environ. Entomol 34 2005
	ground dwelling invertebrates	Bhatti et al Environ. Entomol. 34 2005
	foliage dwelling arthropods	Bhatti et al Environ. Entomol. 34 2005
	springtails	Bitzer et al Environ. Entomol. 34 2005

Source: L. Higgins, see also Romeis et al. 2006. *Nature Biotechnol* 24:63-71.

Learning from the experience with Bt corn and nontarget monitoring

- integrity of the tiered process
  - risk findings based on laboratory tests and exposure assessments are confirmed in the field
  - maintain a case-by-case paradigm for field studies that is driven by the risk assessment process
  - field tests and monitoring should be hypothesis driven

Problem formulation

& Common data elements of the GE crop ERA

Problem formulation

- Sets the stage for the ERA
- Identifies and interprets existing information to focus on consequential concerns
- Outlines the analysis plan for the RA
  - What studies are needed to address issues of consequence & ecological entities of concern
- Identifies the relevant starting point (tier) and the appropriate endpoints of concern

Ecological Risk Considerations

- Product characterization
  - Host & donor familiarity
  - Activity & specificity
  - Protein equivalency
  - Composition equivalence
  - Expression
- Risk characterization
  - Product characterization plus
  - Hazard
  - Exposure
  - Risk
- Risk conclusion
  - Adequacy of the risk characterization
  - Conservatism in balance with uncertainties

Host & donor familiarity

- History of safe use and environmental exposure
- Regulatory experience
- Broad-based scientific understanding

Activity & specificity

- Confirm or establish nature of activity
- Spectrum of activity against targets
  - *insecticidal activity spectrum study*

Protein equivalency

- Bacterially-produced protein are commonly used in toxicity testing
- Product characterization needs to show that the plant-produced and bacterially-produced proteins are biologically, biochemically, and immunologically equivalent

Compositional equivalency

- Similarity (other than for the protein of interest) of the transformed and non-transformed cultivar must be established by the precursor data in terms of
  - Content of nutrients, antinutrients, toxicants
  - Agronomic performance and plant phenotype

Expression

- Key to prediction of exposure concentrations
- Should describe distribution
  - over time
  - among plant parts
- Supplemented with data describing variance across generations and environments

Hazard

- Multi species laboratory ecotoxicity testing is used to confirm the anticipated spectrum of activity and hazard to non-target organisms
- Selection of appropriate surrogate species for testing should consider activity profile, host crop, and environment where deployed

Exposure

- On the basis of expression data determine
  - High End Exposure Estimates (HEEE) in plant tissues, and
  - Estimated Environmental Concentrations (EEC) in soil and water
- Use for comparison against hazard testing results (multi species ecotoxicity tests)
- Exposure estimates are meant to represent the upper bound (90^{th} percentile) of reasonably anticipated environmental concentrations

Risk = f(hazard, exposure)

- Quantitatively describe risk as a function of exposure and hazard
- For GE crops this is typically done by considering the relationship of the limit dose used in ecotoxicity studies to the appropriate HEEE or EEC

example of risk characterization for Bt cotton

Non-target organism	Dose*	Effect endpoint	Result
Honeybee	1.98 ug Cry1F + 11.94 ug Cry1Ac per mL sugar water	mean survival to emergence	no effect of limit dose LC_{50} > 4x pollen expression
Collembola	709 ug Cry1F + 22.6 ug Cry1Ac per g diet	adult survival and reproduction	no effect at 10x field level
Green lacewing	5.2 ug Cry1F + 46.8 ug Cry1Ac per g moth eggs	mean survival to pupation	effect of dose in 1 of 2 studies LC_{50} > 14x pollen expression
Parasitic wasp	5.2 ug Cry1F + 46.8 ug Cry1Ac per mL sugar water	mortality at 10 d	no effect of limit dose LC_{50} > 13x pollen expression
Ladybird beetle	300 ug Cry1F + 22.5 ug Cry1Ac per mL sugar water	mortality at 15 d	no effect of limit dose LC_{50} > 780X Cry1F pollen expression and > 8x Cry1Ac pollen expression
Monarch butterfly	dose-response for indivdual proteins in artifical diet	growth reduction after 7 d	EC_{50} > 10^5 the dietary pollen exposure for Cry1F and > 10X the dietary pollen exposure for Cry1Ac

confirmation of the adequacy of risk characterization

- correspondence of product specific results
  - with general understanding for the donor, host, and product class being considered
- internal consistency/directional correctness
  - of overall product and risk characterization
- ability to characterize hazard at or above *environmentally relevant exposure concentrations*
- confirmatory data (if available) from field studies
- conservatism of the risk conclusion is in keeping with the degree of uncertainty

Conclusions

- US regulatory experience with GEOs
  - positive record of successful evaluations and subsequent safe use of the commercial products
  - argues for further focus and streamlining of the process
- The ERA framework
  - enables a focused, objective science-based process
- ERA framework as applied to GEOs
  - has been sufficiently flexible to deal with concerns surrounding biotechnology
- Problem formulation & common data elements for the ERA
  - Constrain and focus the risk assessment to consequential concerns ('real risks')

European Approach to Environmental Risk Assessment of genetically modified plants

Dr. Jeremy Sweet
Vice-chair EFSA GMO Panel

ENVIRONMENTAL RISK ASSESSMENT OF GM PLANTS IN THE EU

Jeremy Sweet, Environmental Consultant, Cambridge, UK

jeremysweet303@aol.com

Introduction to Environmental Risk Assessment of GMPs

A conceptual framework is critical in risk assessment and risk management. It can provide a common language for regulators, registrants and scientists. It can also provide a predictable pathway for requesting, acquiring, organizing and evaluating data. Such a framework consists of four steps: (1) evaluation of need, (2) problem formulation, (3) information gathering, and (4) overall assessment. The initial evaluation of need determines whether a risk assessment is required for a specific case. Clearly defining the need as it meets the expectations of the final audience will help in the design of the risk assessment and determine how the information is to be communicated. Common reasons for conducting an Environmental Risk Assessment (ERA) include regulatory requirements, scientific inquiry, and response to public perception of risk. The main focus of this talk is risk assessment that is triggered by the regulatory requirements of the EU. Once the need for the ERA has been clearly defined, the risk assessment moves forward to the problem formulation phase.

Problem formulation

The ERA is initiated through the process of problem formulation (USEPA 1998; EFSA 2004). Problem formulation is used to define the scope of the risk assessment through generation of relevant risk hypotheses. For the ERA to go forward, a body of precursor information must determine that, other than for the expression of the trait of interest, the transgenic plant is equivalent to non-transformed comparators (see for example EuropaBio 2003). Once equivalence has been established on the basis of the transgenic plant characterization, the ERA can proceed with emphasis on expressed trait effects (stressor effects). The problem formulation considers the specifics of the trait mode of action, the spectrum of activity and susceptibility, mode of expression, and relevant exposure profiles. Additionally, it must also take into account ecological considerations that might affect the nature and extent of possible environmental impacts. One of the most significant factors in this regard is the intended scale of cultivation since ecological consequences of non-target impacts are likely to be positively correlated with scale. On this basis, the problem formulation then identifies assessment endpoints reflecting management goals and the scale and nature of the receiving ecosystem that is being considered. It should culminate in a conceptual model and analysis plan that is consistent with the risk hypotheses and establishes the relationship of the expressed trait to ecological impacts of concern. It also outlines an exposure analysis that accounts for the intended use and nature of the deployment of the transgenic plant.

Regardless of where in the world the ERA is conducted, the problem formulation approach should be very similar, using similar information that is modified by local

cropping system information. The process underlies the locally relevant testing schemes, which should also reflect the basic design principles outlined below. The overall process may reflect additional national and regional regulatory needs and it must be within the specific capacities and capabilities of the agency conducting the ERA.

The framework and progressing through it

With pesticidal GM plants a tiered risk assessment is recognized as being the most rigorous approach to assess non-target effects both from a scientific as well as from a regulatory standpoint. Both hazard and exposure can be evaluated within different methodological levels or "tiers" that progress from worst case hazard and exposure to more realistic scenarios. Lower tier tests serve to identify potential hazards, and tests are conducted in the laboratory to provide good replication and study control and maximum power to test hypotheses. Where potential hazards are detected in these early tier tests, additional information is required. In these cases, higher tier tests can serve to confirm whether an effect might still be found at more realistic rates and routes of exposure. Higher tier studies including semi-field or field-based tests offer greater environmental realism, but they may have low statistical power. These tests are only triggered when early tier studies in the laboratory indicate potential hazards at environmentally relevant levels of exposure. In exceptional cases, higher tier studies may be conducted at the initial stage when early tier tests are not possible, for example because purified toxin is not available. Higher levels of replication or repetition may be needed to enhance statistical power in these circumstances.

In cases where a potential hazard is detected in a lower tier test, regulators have the flexibility to undertake further lower tier tests in the laboratory to increase the taxonomic breadth or local relevance of test species, thus avoiding the costs and uncertainties of high tier testing. They may also progress to higher tier testing, particularly in cases where there is no previous experience with the crop or toxin under investigation. The various tiered approaches that have been described for non-target risk assessment (e.g. Dutton et al. 2003; EuropaBio, 2004 and submitted manuscript; Rose 2006) differ in the specific definitions of individual tiers, but they all follow the same underlying principles.

Movement between tiers during information gathering is based on the sufficiency of information that is available. If sufficient data and experience from toxicological testing and exposure analyses are available to characterize the potential risk as being acceptable, then there is no need to do additional testing. The process is designed to optimize the use of resources and to identify and define sources of potential risk. Where no hazard is evident, effective tiered processes prevent costly and unnecessary testing from taking place.

The following paragraphs 8-11 summarise the similarly numbered paragraphs of the Environmental Risk Assessment (ERA) in the EFSA Guidance Document on the Risk Assessment of GMPs.

8. Mechanism of interaction between the GM plant and target organisms (if applicable)

The assessment should describe the expression and mode of action of any new traits (for example insect tolerance, herbicide resistance) present in the modified plant. The likely effects on the target organism and its population dynamics should be described. If more than one novel trait is present then interactions between the traits and their effects on target organisms should also be described. The potential environmental implications of, for example, the development of resistance/tolerance by the target organisms are included in Section 9.4 below.

9. Potential changes in the interactions of the GM plant with the biotic environment resulting from the genetic modification

It is important to determine whether the GM plant or hybrids formed with related plant species have changes in their environmental fitness. The assessments of potential changes in the interactions between the GM plant and the biotic environment (*e.g.* non-target organisms) are carried out on a case-by-case basis taking into account the biology of the transformed plant and, where gene transfer might occur, of any other recipient organisms, the characteristics and expression of the introduced genetic material, the properties and consequences of the genetic modification, the scale of release and gene transfer and the assessment of any risk to the receiving environment that might arise from the release of the GM plant.

Genes inserted in a GM plant should be evaluated for their potential impact on the environment. Where the GM plant contains more than one transgene assessment should include consideration of the impact of interactions between transgenes. The assessment should also consider the consequences of low frequencies of gene transfer to related and unrelated organisms, and take into account any potential for enhanced gene transfer reported.

Possible interactions between the GM plant and its biotic environment include:

(a) effects on the population dynamics and genetic diversity of populations of species in the receiving environment (plant, animal, microbe);

(b) altered susceptibility to pests and pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors;

(c) compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments;

(d) effects on beneficial plant-microbial associations and biogeochemistry (biogeochemical cycles), particularly on microbial-mediated carbon and nitrogen recycling through changes in soil decomposition of organic material.

Data should be provided from field experiments in areas representative of those geographical regions where the GM plant will be grown commercially in order to reflect relevant meteorological, soil and agronomic conditions. Where data from field studies on other continents are supplied, the applicant should submit a reasoned argument that the data is applicable to European conditions.

Risk assessments should be carried out for each of the different environmental compartments that are exposed to the GM plant. Whether or not any parts of it will remain in the environment after harvest will depend on the specific plant, its management regime and agronomic practices. Where changes to environments are predicted, the nature and the extent of the changes should be described and related to those caused by equivalent non-GM plants. Where the changes differ from those of non-GM plants then an assessment of the relative harm to the receiving environment should be made.

If appropriate, an assessment of the potential impact of growing GM crops on wider biodiversity in the crop ecosystem would require the combination of several different approaches (ACRE, 2001b). However, since crop ecosystems are highly disturbed and dynamic areas, predicted changes in biodiversity may not necessarily be associated with environmental harm as defined in Directive 2004/35/CE (EC, 2004c). Comparisons should be made with existing crops systems and assessments of impact related to impacts of current non-GM crops.

9.1 Persistence and invasiveness

If a GM plant or hybrids formed with related plant species become more persistent or invasive then they are more likely to have an environmental impact. An assessment is required of the likelihood of the GM plant becoming more persistent than the recipient or parental plants in agricultural habitats or more invasive in natural habitats. The likely consequences of this increased persistence should be assessed.

Hybrids formed with related plant species are referred to Section 9.5.

The assessment should consider GM plant specific traits which may have an impact on increased persistence and spread both in natural and cultivated areas.

9.2 Selective advantage or disadvantage

An assessment is required of any selective advantage or disadvantage conferred to the GM plant. If appropriate, comparisons should be made with the non-GM parent/relative grown in similar circumstances and with similar phenotypes that are available from conventional breeding.

Hybrids formed with related plant species are referred to Section 9.5.

The assessment should, if appropriate, refer to data collected from representative field trials they are relevant to environmental interactions concerning GM plant fitness. If no specific field data are provided, the applicant must discuss any consequences of selective advantage or disadvantage of the new trait(s) both in natural and cultivated areas.

9.3 Potential for gene transfer

An assessment is required of the potential for gene transfer to the same or other sexually compatible plant species under conditions of planting the GM plant and any selective advantage or disadvantage conferred to those plant species. Consideration should also be given to the fact that the gene flow characteristics of related species may differ from those of the transformed plant so that the potential for gene transfer might change.

The potential consequence arising from out-crossing to other plant cultivars should be considered and assessed for environmental risk. This will vary with species and traits. For example, the release of GM oilseed rape raises the issue of gene transfer, since this crop will readily cross-pollinate with nearby oilseed rape crops and may spontaneously hybridise also with some wild relatives. In cases where gene transfer cannot be limited between certain adjacent plants, the risk assessment should focus on the consequences of cross-pollination. The potential consequence arising from out-crossing to compatible wild species should be considered and assessed for environmental risk (Saeglitz and Bartsch, 2002). This will depend on non-GM sexually compatible plants being present in regions where the GM crops are being grown and which are available to receive pollen and produce fertile hybrids. The selective advantage of any transferred trait should be evaluated in different habitats where the selection pressures are likely to be different. For example, drought may be the main cause for the limited geographic distribution of a given plant species but where drought stress can be alleviated using a GM approach the ecological behaviour of the corresponding wild population may change after transgene introgression.

9.4 Interactions between the GM plant and target organisms

An assessment is required of the potential immediate and/or delayed environmental impact resulting from direct and indirect interactions between the GM plant and target organisms, such as predators, parasitoids and pathogens (if applicable). An example of this is provided by the EU Working Group on Bt who have developed risk assessments and protocols for evaluating the development of resistance in target insects to Bt toxins (SCP, 1999).

Data on the comparative susceptibility of the GM plant to pests and diseases compared with that of the non-modified plants are useful indicators of effects, together with observations on agronomic performance during greenhouse and experimental field trials.

9.5 Interactions of the GM plant with non-target organisms

An assessment is required of the possible immediate and/or delayed environmental impact resulting from direct and indirect interactions of the GM plant with non-target organisms (also taking into account organisms which interact with target organisms), including impact on population levels of competitors, herbivores, symbionts (where applicable), predators, parasites and pathogens. An example of direct interaction approaches is provided by the Working Group on Bt (SCP, 1999).

Assessors should use a tiered approach to this risk assessment, first identifying potential hazards in controlled tests and then evaluating exposure in the field in order to estimate potential risks. If first tier tests do not identify sensitivity in exposed species then second and third tier test may not be required.

Impact should be assessed on non-target species in the crop ecosystem (which may include pollinators, beneficial, predatory and phytophagous species), and, if appropriate, the aquatic environment. Studies should be designed in order that sufficient statistical power is obtained to detect possible effects on non-target organisms. Adequate statistical power can be achieved from the proper control of variation and replication, since power depends on sample size, the degree of random variation between experimental units and the chosen significance of the tests. An appropriate approach might be to select a desired level of statistical power and the size of effect to be detected, collect preliminary data to estimate within-treatment variability and then to calculate the required sample size for the proposed study. The duration of experiments to assess the risks to non-target organisms should be sufficient to reflect the pattern and duration of exposure that these organisms are likely to experience under field conditions (Perry *et al.*, 2003; Marvier, 2002). However, it is important that food chain effects due to reductions in target prey species, (e.g. declines in parasitoids populations) are differentiated from, for example, population declines due to the effects of GM toxin accumulation in food chains.

9.6 Effects on human health

An assessment is required of the possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the GM plant and persons working with, coming into contact with, or in the vicinity of the GM plant release(s). This assessment is particularly required for GM crops which are not destined for human or animal consumption and where impacts on human health may not have been so meticulously studied.

9.7 Effects on animal health

An assessment is required of the possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from exposure to or consumption of the GM plant and any products derived from it, if it is intended to be used as animal feed.

9.8 Effects on biogeochemical processes

An assessment is required of the possible immediate and/or delayed effects on biogeochemical processes resulting from potential direct and indirect interactions of the GM plant and target and non-target organisms in the vicinity of the GM plant release(s).

The applicant should address, where appropriate, the potential impact on biogeochemical processes as these influence ecosystem function, *e.g.* in relation to soil microbial communities. Examples are CO_2-evolution, organic matter turnover, nitrogen fixation (Nannipieri *et al.*, 2003). Soil fertility strongly influences the growth and productivity of plants. As plant-associated (rhizosphere) and soil microbial communities perform the vital biotransformation that underpins soil fertility any negative impact(s) on microbial

participants in this key compartment would have to be carefully evaluated. This should be assessed on a case-by-case basis with particular reference to the nature of the introduced trait and the consequences of the genetic modification/alteration in the GM plant.

The risk assessment should aim to establish if direct or indirect effect(s) of the genetic modification in the GM plant have any long-term or sustainable deleterious effect on the recognised soil microbial communities and the associated functional activities that are responsible for maintaining soil fertility and plant productivity. The assessment should also address the fate of any (newly) expressed gene products and derivatives in those environmental compartments where they are introduced and which result in exposure of non-target organisms (*e.g.* in soil after the incorporation of plant material). Exposure should also be estimated to relevant soil biota (*e.g.* earthworms, micro-organisms, organic matter breakdown) in relation to the impact on decomposition processes. Risk assessment should also include an analysis to determine if a shift occurs in populations of deleterious organisms in the presence of the modified plant.

9.9 Impacts of the specific cultivation, management and harvesting techniques

An assessment is required of the possible immediate and/or delayed, direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques used for the GM plant where these are different from those used for non-GM plants.

The ERA should describe the appropriate commercial management regimes for the GM crop including changes in applications of plant protection products (pesticides and/or biocontrol agents), rotations and other plant management measures for the GM plant where these are different from the equivalent non-GM plant under representative conditions. The applicant should aim to assess the direct and indirect, immediate and delayed effects, of the management of the GM plant. This should include the biodiversity within the GM crop and adjacent non-crop habitats likely to be affected by the GM crop and its cultivation.

The extent of such studies will depend on the level of effect associated with a particular GM plant and on the quality and availability of the literature that is relevant to the particular risk assessment. For example, the published results of the UK's Farm Scale Assessments of genetically modified herbicide-tolerant crops (Squire *et al.*, 2003) may give information relevant to other herbicide-tolerant crops. However, it will be necessary to compare the relative efficacy of different herbicides and their management programmes on weed species in order to assess the impact of herbicide regimes on biodiversity.

The management and utilisation of a GM crop may vary from region to region and farm to farm. It may be difficult to predict the range of farming practices that will be deployed with the GM crop. The risk assessment should assess the consequences of this unpredictability of farm management and relate this to monitoring (see Section 11.).

10. Potential interactions with the abiotic environment

The assessments on potential changes in the interactions of the GM plant with the abiotic environment should be carried out on a case-by-case basis taking into account the

biology of the recipient plant, the characteristics of the introduced genetic material, the properties and consequences of the genetic modification, the scale of release and the assessment of any risk to the receiving abiotic environment that might arise from the release of the GM plant.

Examples of possible interactions between the GM plant and its abiotic environment are:

(a) alteration of climatic conditions (*e.g.* altered production of greenhouse gases),

(b) altered sensitivity to, or tolerance of, climatic conditions (*e.g.* cold, heat, humidity),

(c) altered sensitivity to, or tolerance of, abiotic fractions of soil (*e.g.* salinity, mineral nutrients, mineral toxins),

(d) altered sensitivity to, or tolerance of, gases (*e.g.* CO_2, oxygen, NH_4),

(e) alteration of mineralisation (*e.g.* root exudates changing the soil pH).

Changes in the abiotic environment caused by any GMO may have impacts on the biotic environment so these consequences should be evaluated.

11. Environmental Monitoring Plan

An environmental monitoring plan is required for applications where the natural or cultivated environment will be exposed to GM plant propagules or GM plant products. Applications concerning only food/feed or ingredients (for example, imported into but not cultivated within the EU) will thus not normally be required to describe a detailed environmental monitoring plan if the applicant has clearly shown that environmental exposure is absent or will be at levels or in a form that does not present a risk to other living organisms or the abiotic environment.

Monitoring can be defined as the systematic measurement of variables and processes over time and assumes that there are specific reasons to collect such data, for example, to ensure that certain standards or conditions are being met or to examine potential changes with respect to certain baselines. Against this background, it is essential to identify the type of effects or variables to be monitored, an appropriate time-period for measurements and, importantly, the tools and systems to measure them. Monitoring results, however, may lead to adjustments of certain parts of the original monitoring plan, or may be important in the development of further research. The Council Decision 2002/811/EC (EC, 2002b) provides no clear differentiation between the monitoring principles of either case-specific monitoring or general surveillance (Den Nijs and Bartsch, 2004). This Guidance document provides further assistance in the following sections.

11.2 Interplay between environmental risk assessment and monitoring

Monitoring of effects: Foreseen and unforeseen

The environmental monitoring of the GM plant will have two focuses: (1) the possible effects of the GM plant, identified in the formal risk assessment procedure, and (2) unforeseen effects. Where there is scientific evidence of a potential adverse effect linked to the genetic modification, then case-specific monitoring should be carried out after placing on the market, in order to confirm the assumptions of the environmental risk assessment. Consequently, case-specific monitoring is not obligatory and is only required to verify the risk assessment, whereas a general surveillance plan must be part of the application. Applicants who are proposing to have no case-specific monitoring are encouraged to provide arguments in support of this position. These arguments should relate to the assumptions applicants have made in the environmental risk assessment, as well as to the lack of any identified adverse effects in tier 1, 2, or 3 tests.

Monitoring framework

Council Decision (2002/811/EC) (EC, 2002b) explicitly suggests that general surveillance should include long term monitoring, to allow for unexpected effects that may occur after longer periods of environmental exposure.

Changes in the management and cultivation techniques of new GM crops may affect the environment *e.g.* through changes in agrochemical usage. Directive 2001/18/EC requires that the impacts of any such indirect effects, *e.g.* changes of cultivation methods, should be addressed by the monitoring plan based on the outcome of the environmental risk assessment.

The environmental monitoring plan should describe in detail the monitoring strategy, methodology, analysis, reporting and review as laid down in Council Decision 2002/811/EC. In this respect,

(a) **background and baseline environmental data** *e.g.* soil parameters, climatic conditions, general crop management data *e.g.* fertilisers, crop protection, crop rotations and previous crop history should be collected to permit the assessment of the relevant parameters listed under b):

(b) **GM plant-based parameters** will depend on the particular GM plant, trait and environment combination. Key parameters to be observed may include species/ecosystem biodiversity, soil functionality, sustainable agriculture, or plant health. Indicators should be measurable, appropriate, adequate in terms of statistical power, and comparable with existing baseline data.

Monitoring goal

The ultimate goal of the environmental monitoring plan should be to determine whether the data collected during case-specific monitoring and general surveillance identify specific unintended or unforeseen effects due to commercialisation of the GM plant, in both managed and natural environments, compared with current farming practices or other alternatives, which may result in environmental harm/damage.

11.3 Case-specific GM plant monitoring

The main objective of case-specific monitoring is to determine the significance of any adverse effects identified in the risk assessment. The assessment of risk should be based on Annex II of the Directive (2001/18/EC).

Case-specific monitoring should be targeted at those environmental factors most likely to be adversely affected by the GM plant which were identified in the environmental risk assessment. The specific and intensive, scientific measurement and data collection should have an experimental approach based on defined experimental approaches to test a specific hypothesis of expected adverse effects derived from the environmental risk assessment. The monitoring programme design should also reflect levels of exposure in different geographical regions and other specific management influences. Such monitoring may be carried out at a limited number of sites ('local monitoring'), where exposure is greatest and intensive recording and data collection can take place. This would be particularly appropriate when it is envisaged that there will be a phased or gradual introduction of the GM crop into a limited number of regions in various EU Member States. The scale of the monitoring should be increased as the area and range of the GM crop expands, and the crop is grown in more regions. The monitoring should consist of the systematic recording of relevant parameters at representative locations where there is significant and repeated growing of the GM crop. This might also be defined according to the extent of the cultivation of the GM crop, the occurrence of targeted pest species or particular climatic/eco-regions. Comparisons should be made with equivalent non-GM crops growing in the same or similar localities. However, the lack of availability of non-transgenic, isogenic varieties and the lack of statistical power due to the small number of comparable locations may reduce the sensitivity of these experiments. The methods selected, the duration of the monitoring and the extent or number of areas, will be determined by the specific case and the parameters to be monitored. Whilst the planning and execution of case specific monitoring is under the applicant's responsibility, it may be appropriate for the applicant to involve public institutions in carrying out some or all of the agreed work.

11.4 General surveillance of the impact of the GM plant

General surveillance should be adequate for monitoring any GM crop grown in any environment since it is not based on the risk assessment, but from a desire to observe unanticipated effects in the environments in which it is grown. Thus there should be no principle differences between general surveillance of similar crops grown in rotations with each other *e.g.* arable crops such as maize (corn), wheat, or oilseed rape.

The objective of general surveillance is to identify unforeseen adverse effects of the GM plant or its use, on human health and the environment, which were not predicted in the risk assessment. General surveillance should not be experimental, should be largely based on routine observations and should be conducted over a wider range of sites and environments with a range of parameters observed at a low intensity (ACRE, 2004). If unusual observations are reported, more focussed in-depth studies can be carried out in improved case-specific monitoring plans. Existing surveillance systems should be used where practical *e.g.* routine farm recording systems, and any "abnormal" effects not usually

occurring in similar situations with conventional cropping should be recorded. However, direct comparison with non-GM crop reference areas is not always necessary. Reference can be made to the historical knowledge and experiences of the "observer" (*e.g.* farmers, inspectors, botanical surveyors) in relation to the situation prior to the introduction of the GM plant.
The new EU Directive EU 2004b, on environmental liability and damage defines in particular conservation goals in relation to (1) protected species and natural habitas, (2) water, and (3) land. It has been suggested that general surveillance should focus on these conservation goals (Sanvido et al. 2004). In addition the GMO Panel considers that sustainable agriculture is an additional subject for environmental protection, and where damage should be avoided.

These four fields would be a pragmatic starting point for focusing the general surveillance. A number of intensively managed agro-ecosystems are neither 'natural habitats' nor do they harbour 'protected' species as defined in the Directive. However they merit environmental protection to conserve biota present and to sustain agriculture in these regions. These remaining agro-ecosystems in the EU with protected species and natural habitats are already part of national environmental monitoring programs so that baseline data and surveillance systems are already established in EU member states, and could be exploited. However the regulatory framework lays the responsibility for data reporting within GMO General Surveillance to the applicant so that the applicant will need to access and co-ordinate these other sources of information

General surveillance should complement this general environmental monitoring conducted by Member States. The higher the ecological integration and scale (from the individual to a population, from single farms to regions) the more difficult it is to distinguish potential effects of the GM plants from other factors. Initially, general surveillance should focus on each transgenic plant and type individually. Ultimately, when several GM plants have been commercialised, the interactions between these GM plants and their management regimes should be examined where appropriate.

The examination of ecological interactions between different GMO at a regional or national level may be considered primarily to be a governmental task and additional to the monitoring requirements for a single applicant following placing on the market. In the Directive 2001/18/EC, the possibility of additional surveillance by government authorities is described in Item 44 of the Conciliation Committee. The applicant should be aware of all relevant surveys and monitoring in areas where the GM plants will be grown and should refer to the results of this monitoring in reports to the Competent Authority and the Commission, since the approach as stated in paragraph 1.3 of Council Decision 2002/811/EC (EC, 2002b) foresees monitoring in many cases as a iterative process.

Existing surveillance systems

In conjunction with the exploitation plan for the GM plant, the applicant should define the infrastructures that will be established and exploited in order to conduct general surveillance of regions where the GM plant is grown. The applicant should describe how he will evaluate and select existing surveillance systems which are already monitoring one or

more of the relevant parameters/elements. He/she should describe how arrangements for collecting, collating and analysing data will be made.

The applicant should also identify which additional surveys will be asked to contribute to the general surveillance (for example, public institutions, farmer associations) in selected Member States. Although detailed arrangements may not have been agreed at the time of the application, the applicant should describe how formal agreements and procedures will be established with the Commission and Member States before commercial market introduction. For example, when the GM cultivar is registered in the EU variety catalogue.

New surveillance systems: Involving Farmers/Growers of GM crops and suppliers of GM crop seeds

Applicants can obtain useful information directly from growers and seed suppliers of GM crops and should involve them in supplying data on seed sales, areas sown, crop management etc (Schmidt et al 2004, Wilhelm et al 2004). Applicants should also be pro-active in developing reporting systems so that farmers (or their agents and advisors) intending to purchase genetically modified seeds will be involved in reporting adverse occurrences during and after the cultivation of the GM crop. The applicant should describe the number of farmers/growers involved, the reporting methods and the suitability of the data collected for statistical analysis. Applicants may periodically use farmer questionnaires with a list of environmental parameters. These questionnaires will also allow the applicant to check if farmers comply with the recommendations made (*e.g.* obligations related to an insect resistance management plan or recommendations related to stewardship plans).

11.5 Reporting the results of monitoring

Following the placing on the market of a GMO, the applicant under Article 20(1) of the Directive 2001/18/EC, has a legal obligation to ensure that monitoring and reporting are carried out according to the conditions specified in the consent. The applicant is responsible for submitting the monitoring reports to the Commission, the competent authorities of the Member States, and where appropriate to EFSA. Information should also be made publicly available in line with the requirements of Article 20(4) of the Directive. Applicants should describe the methods, frequency and timing of reporting in their monitoring plan.

Although no time frame for reporting is specified in Council Decision 2002/811/EC (EC, 2002b), reports should be submitted

- annually confirming that monitoring has been carried out according to the given consent together with a summary of major preliminary results that are important for a short-term feed-back on the environmental risk assessment ('annual reports'), and
- periodically (*e.g.* every third year) covering longer periods in which observations and data collected are analysed in detail and which therefore provide more comprehensive reports that are important for a longer term feed-back on the environmental risk assessment ('comprehensive report').

The comprehensive monitoring report should include in more detail the results of any relevant monitoring by third parties, including the farmers/growers, seed companies, independent surveyors, local, regional and national environmental surveyors. In addition, the applicant should evaluate these results and incorporate full analysis and conclusions in the submitted monitoring report. If appropriate, the applicant should provide access to raw data for stimulating scientific exchange and co-operation.

Flow of information on the cultivation of GM plants:

Where GM plants are grown the following procedures should be complied with:

(a) All GM seeds must be labelled with the variety, and should also contain information on the construct, the supplier's name and address, full instructions on any specific cultivation requirements, and reporting procedures for any incidents, including the address of the Consent Holder for the marketing of the seeds.

(b) The farmer/grower is required to declare the variety, sowing date, amount of cultivated crops and exact geographic location to the national cultivation register according to Directive 2001/18/EC - Art 31 (3b).

(c) The farmer should record all relevant cropping and management data for that GM crop and these data should be available for inspection.

Flow of information in instances where GM plants are thought to have caused unusual or adverse effects:

If effects have been detected in areas where GM plants are grown or where there is a suspicion that the GM plants may be associated with an incident, the following procedures should be complied with:

(a) Farmers should follow the procedure agreed at the time of purchase of the GM seeds and provide information to the seed supplier/consent holder of any unusual observations without delay.

(b) The applicant should notify any relevant information immediately to the Member State Competent Authority and to both the Commission and EFSA.

(c) If unusual effects are detected by external organisations (*e.g.* public institutions), these must be immediately communicated to the Seed supplier/Consent Holder, to the Member State Competent Authority, to the Commission and to EFSA.

(d) The Seed supplier/Consent Holder must carry out a preliminary examination of the report in order to verify whether a GM plant-related effect has really occurred and within a defined period (*e.g.* one month or dependent on the event) and should provide the Competent Authority with a report on the result of its preliminary investigations, including an assessment of potential harm.

(e) Either directly upon receipt of the information or at the latest upon receipt of the Consent Holder's report, the Competent Authority should decide whether further authority action is required. If further action is required the Competent Authority should inform the Commission of the reported observation and, together with the applicant and professionally competent institutions or experts, should investigate the causes and consequences of the reported incident. The Competent Authority should submit a full report to the Commission and EFSA to include the extent of any environmental damage, remedial measures taken, liability and recommendations for the future use/management of the GM plant.

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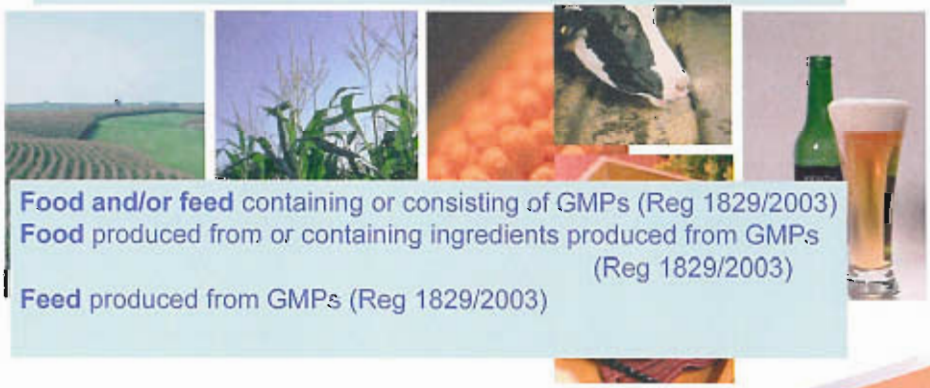
European Approach to Environmental Risk Assessment of genetically modified plants

Dr. Jeremy Sweet
Vice-chair EFSA GMO Panel

European Food Safety Authority

EFSA Guidance document: Scope

Genetically modified higher plants (GMPs) (Dir 2001/18/EC) for food and/or feed use ~ *Cultivation, import and processing*



Food and/or feed containing or consisting of GMPs (Reg 1829/2003)
Food produced from or containing ingredients produced from GMPs (Reg 1829/2003)
Feed produced from GMPs (Reg 1829/2003)

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Objectives

- To provide a **general concept of risk assessment** of GMOs
  - Requirements for **food/feed safety assessment**
  - Requirements for **environmental risk assessment**
  - Outline an **Environmental Monitoring Plan**
- Update of the 2003 EU Guidance Document prepared by the Joint Working Group on Novel Foods and GMOs
- Guidance document is **not a protocol** for carrying out specific analytical, toxicological and nutritional testing or feed trials

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Guidance Document : Risk assessment of genetically modified plants and derived food and feed

- **Publication of draft document on EFSA website** on 7 April 2004
- **Public Consultation**
- **Stakeholder meeting**
- **Final adoption – September 2004**
- **Publication 30 November 2004**
- **General Surveillance Monitoring added in 2005.**

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Comprehensive Approach

- **Case-by- case assessment**

- **The available evidence determines the extent of specific testing (tiered approach, feeding trials…)**
- **All the available information should be taken into account**

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Safety Assessment Strategy for GM Crops: Two-step Procedure

1. **Identification of differences** between the GM and non-GM crop: intended and unintended changes
2. Assessment of the safety and the environmental impact of **identified differences**

   - ***Concept of Familiarity***
   - ***Concept of Substantial Equivalence or Comparative Safety Assessment***

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Identification of Unintended Effects

- Molecular, agronomic, morphological, compositional analysis
  - **Single parameter analysis (targeted approach)**
  - **Profiling analysis (non-targeted approach) potentially powerful, but need further development**
- Environmental risk assessment
- Post-market food/feed monitoring
- Environmental monitoring

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Key Elements in the Assessment of GMOs

- **Characterization of donor and host organism**
- **Molecular characterization of the genetic modification event**
- **Analysis of agronomical and compositional properties**
- **Specific toxicity/allergenicity/ nutritional testing**
- **Environmental risk assessment**
- **Post-market Case Specific monitoring (based on ERA)**

- **GENERAL SURVEILLANCE**

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Molecular Characterisation

- **Good indicator but Should not be considered a stand alone risk assessment**
- **Case by Case**
- **Quality in presentation and approaches expected**
- **Not prescriptive in terms of methodologies**
- **ACRE:** "Guidance on best practice for presentation of molecular data"
http://www.defra.gov.uk/environment/acre/molecdata/index.htm

INFORMATION RELATING TO THE GM PLANT

- **Trait(s), characteristics introduced/ modified**
- **Information on the sequences actually inserted or deleted**

- Does inserted sequence differ from original plasmid?
- DNA sequence changes modifying amino acid sequences
- Copy number of detectable inserts,
- Complete and partial , TDNA and backbone
- Southern blots....
- Numbers of flanking regions to be dealt with?

Size, function of deleted region(s)

Trait stacking

Interbreeding of independent approved GM lines; re-transformation existing approved GM line

- Need for further molecular analysis will be case-by-case Based on the nature of the genetic modifications involved.
- Stability of copy number and insert size should be demonstrated where relevant.
- Further insert sequencing may be required on a case by case basis

Food /Feed Safety

- **Materials : seed, leaf etc...**
- **New Products and changes of old products caused by the transformation:**
  - **Allergenicity**
  - **Toxicity**
  - **Nutrition etc...**

Environmental Risk Assessment:

Guidance - update of previous Annexes & Guidance Notes:

- **More Emphasis on :**
  - **Direct Impacts - consequences of gene flow/introgression**
  - **Indirect impacts**
    - ***non-target effects at different trophic levels***
    - ***impacts of changes in management & cultivation***
    - ***impacts from scale - - Monitoring***
    - ***delayed impacts - - Monitoring***

Environmental Risk Assessment:

- Understand the organism that is being transformed
- Generic risk assessment for each crop plant
- Understand the novel trait(s)
- How will the transgene effect plant behaviour, ecology, interaction with other species.
- Will GM plant have direct or indirect effect on other species, ecosystems etc
- Will GM crop management change impacts on other species or environment

ERA

8.Mechanism of interaction between the GM plant and target organisms (if applicable)

Understanding these mechanisms is Key part of ERA for pesticidal plants

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ERA

- **9. Potential changes in the interactions of the GM plant with the biotic environment resulting from the genetic modification**

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Possible Effects include:

- effects on population dynamics and genetic diversity of populations of species in the receiving environment (plant, animal, microbe);
- altered susceptibility to pests and pathogens facilitating the dissemination of infectious diseases and/or creating new reservoirs or vectors;
- compromising prophylactic or therapeutic medical, veterinary, or plant protection treatments;
- effects on beneficial plant-microbial associations and biogeochemical cycles , particularly on microbial-mediated carbon and nitrogen recycling through changes in soil decomposition of organic material.

in comparison with non-GM parent/relative:

9.1 Persistence and invasiveness

- traits which may have an impact on increased persistence and spread both in natural and cultivated areas and their impacts.

9.2 Selective advantage or disadvantage

- any selective advantage or disadvantage conferred to the GM plant.
- data collected from representative field trials >> GM plant fitness.

ERA :

9.3 Potential for gene transfer

..gene transfer to the same or other sexually compatible plant species ..and any selective advantage or disadvantage conferred to those plant species.

Potential consequences arising from out-crossing to other plant cultivars should be ..assessed for environmental risk.

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ERA

9.4 Interactions between the GM plant and target organisms :

- eg effects on ECB populations and development of resistance to Bt

9.5 Interactions of the GM plant with non-target organisms
eg: impacts on beneficials etc..
Toxicity >> populations effects

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Tiered Approach to ERA

- **Tier 1. Laboratory Experiments** > **Hazard**, Impacts at first trophic level, direct non targets.
- **Tier 2. Growth Room/Glasshouse** > Interactions, 2nd trophic level, indirect non targets.
- **Tier 3. Field Experiments** > **Exposure** at range of trophic levels, indirect/agronomic effects
- **H X E >> RISK > > > ASSESSMENT**
- **Tier 4. Monitoring** > long term/large scale impacts
  - **Confirm ERA**

ERA:

- 9.6 Effects on human health
  - Esp: non-food exposure (pollen, dust, touch etc.)
- 9.7 Effects on animal health

9.8 Effects on bio-geochemical processes

effects on beneficial plant-microbial associations and biogeochemical cycles, particularly on microbial-mediated carbon and nitrogen recycling through changes in soil decomposition of organic material.

= *Functional systems*

9.9 Impacts of the specific cultivation, management and harvesting techniques

eg HT effects on Biodiversity

ERA:

- **10. Potential interactions with the abiotic environment**
  - **Soil (mineralisation), water, air .....**

Post Market Environmental Monitoring

- Plan required from all applicants
- Parameters to be used in a monitoring plan
- Case Specific Monitoring - based on factors or uncertainties identified in risk assessment, often impacts of scale/time of exposure
- General Surveillance : Monitoring for harmful unanticipated effects

Case Specific Monitoring (CSM) and General Surveillance (GS)

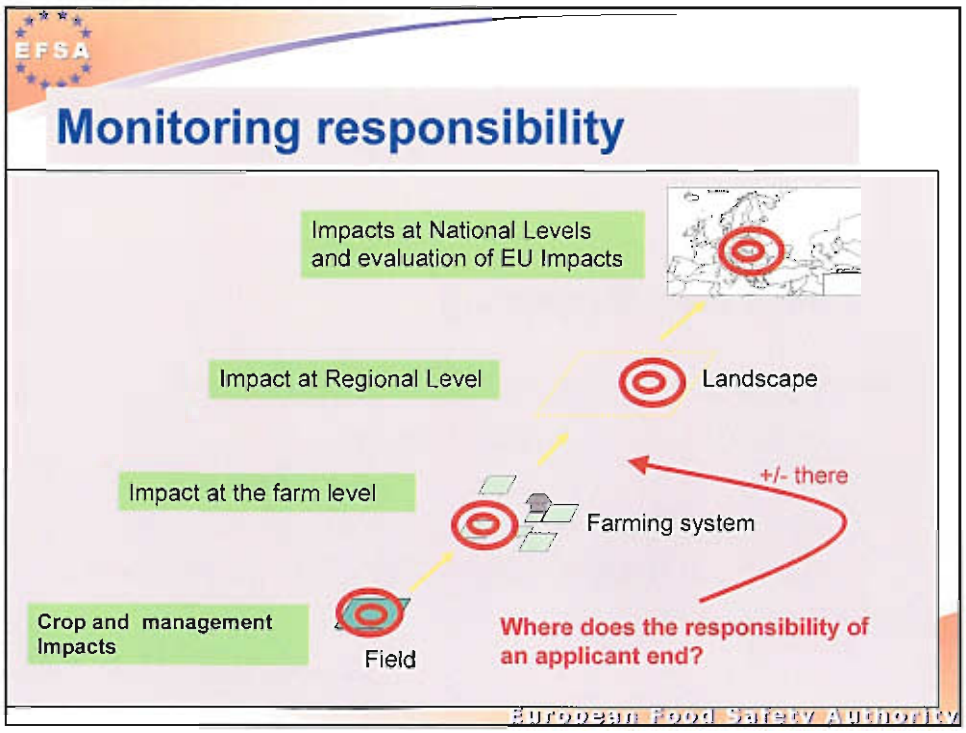
1. CSM is hypothesis driven,(GS not).
2. CSM depends directly on ERA results , (eg on uncertainty or potential long term consequences). - GS not
3. CSM may use experimental approaches, GS not.
4. CSM is focused and limited in time and space .
5. GS is unfocussed and in principle unlimited (thus dependant on routine surveillance systems).

The principles of General Surveillance

- **Unanticipated Adverse Effects**
- **Largely based on routine observation (e.g. by public or private institutions)**
- **Proportionate scale, costs, and burden**
- **Environmental exposure as starting point**
  - **risk equation: hazard not known**
- **Protection goals as focus point**

Protection goals as focus point

- **Environmental goals (as indicated in 2001/18/EC)**
  - Biodiversity
  - Ecological functions
  - Sustainable agriculture
  - Include effects on human/animal health
- **Reference to 2004/35/EC**
  - e.g. to address natural variability


EFSA
Monitoring responsibility
Impacts at National Levels and evaluation of EU Impacts
Impact at Regional Level
Landscape
Impact at the farm level
+/- there
Farming system
Crop and management Impacts
Field
Where does the responsibility of an applicant end?
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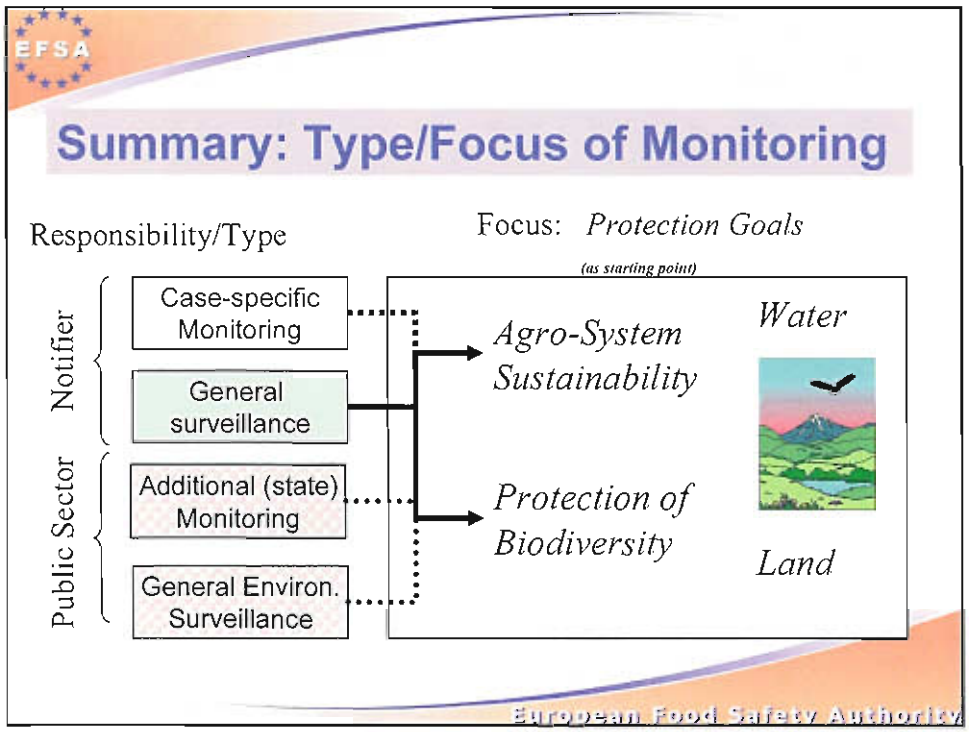
EFSA
Summary: Type/Focus of Monitoring
Responsibility/Type
Focus: Protection Goals
(as starting point)
Notifier
Public Sector
Case-specific Monitoring
General surveillance
Additional (state) Monitoring
General Environ. Surveillance
Agro-System Sustainability
Protection of Biodiversity
Water
Land
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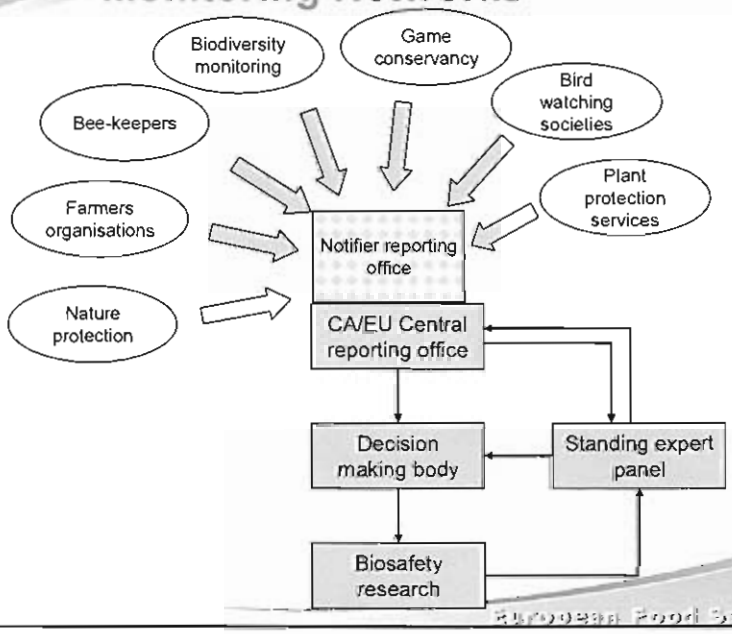
Reporting

- **Routine annual reporting**
- The applicant is responsible for reporting any unusual effect immediately.
- If significant adverse effects are indicated: Conduct investigations to determine cause and effect.

Reporting System from Existing Monitoring Networks



Comments and questions welcome..
Thank you

jeremysweet303@aol.com

http://www.efsa.eu.int

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Ecological Risk Assessment for Biotechnology-derived Crops: principles, process and harmonization

Thomas E. Nickson, Ph.D.
Global Industry Coalition
Risk Assessment Workgroup

Ecological Risk Assessment for Biotechnology-derived Crops:
principles, process and harmonization

Thomas E. Nickson, Ph.D.
Global Industry Coalition
Risk Assessment Workgroup

Biotechnology-derived (GM) crops have been used commercially for 10 years. In 2005, GM crops were planted in 21 countries by more than 8 million farmers. Prior to commercial use, each product underwent an assessment and independent regulatory review that examined the potential risks to food, feed and the environment. The ecological risk assessment information used in the regulatory review has been grounded in five consensus principles that are: science-based, comparative, case-by-case, iterative or recursive, and inclusion of all available information. While the specifics of the assessment process for commercial release vary from country to country, the scientific approach includes an assessment of the potential hazards and exposure, which are integrated subsequently in a qualitative, and where possible, quantitative characterization of the risk. Based on the risk characterization, possible post-marketing activities such as monitoring may be recommended or required. Importantly data requirements for the specific risk assessment should be a function of a number of factors including the proposed use (e.g., commercial release vs. importation for food or for feed or processing vs. field trials) as well as the nature of the crop, the trait, the receiving environment and the interactions among these. The Global Industry Coalition (GIC) Risk Assessment Workgroup promotes rational, science-based and harmonized risk assessment approaches to the evaluation of GM crops. This presentation describes the principles used in ecological risk assessment, a science-based process to evaluate GM crops and some important considerations based on the experience of the GIC.

Ecological Risk Assessment for Biotechnology-derived Crops: principles, process and harmonization

Thomas E. Nickson, Ph.D.
Global Industry Coalition
Risk Assessment Workgroup

Agenda

- Ecological Risk Assessment Principles
  - Science-base
  - Data requirements
  - Decision-making
- Ecological Risk Assessment Process

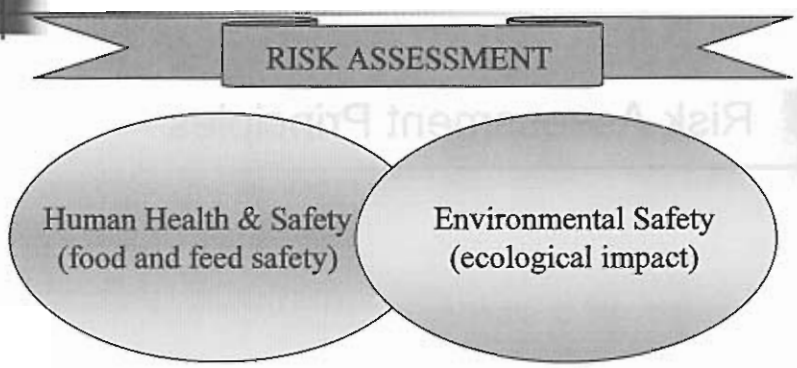
Risk Assessment Principles

Key Terms

- Risk is "a possibility of loss or injury"
  (Webster's New Collegiate Dictionary)
- Modern Biotechnology
  - Distinguished from traditional breeding techniques by the Cartagena Protocol on Biosafety (CPB) and other instruments:

    "the application of: (a) *In-vitro* nucleic acid techniques, including recombinant ... DNA and direct injection of nucleic acid into cells and organelles, or (b) Fusion of cells beyond taxonomic family, ... not techniques used in traditional breeding and selection;" (CPB, 2000)

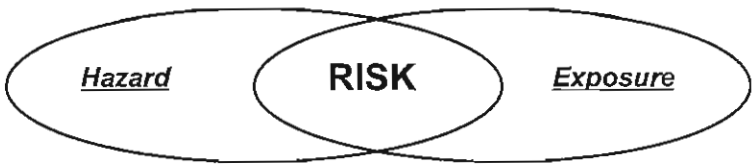
Risk Assessment of GM Crops



Integrating science into decision-making...
directed by public and regulatory policy

Risk = Hazard x Exposure

- Risk is the potential for harm to occur
- Two distinct components
  - The Harm (Hazard)
  - The Potential to Occur (Exposure)



Core Risk Assessment Principles for GM Crops

Risk assessments should be:

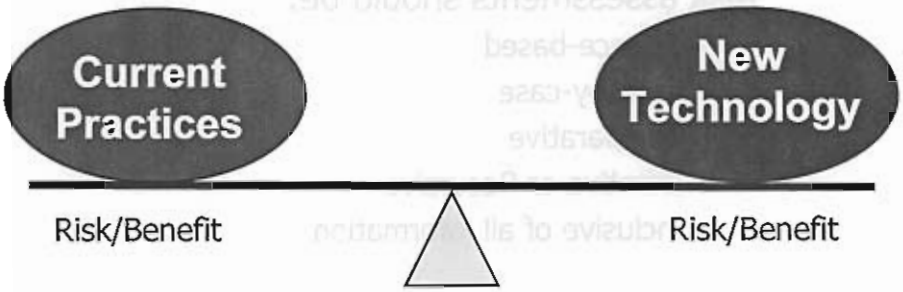
- Science-based
- Case-by-case
- Comparative
- Iterative or Recursive
- Inclusive of all information

Planning a risk assessment for the GM crop must consider the nature of the trait, the nature of the crop, the likely receiving environment and the interaction among these.

Core Data Principles

- Appropriateness and Proportionality
  - Appropriate to the crop, trait and use
  - Proportional to the estimated risk
    - Commercial release (large scale)
    - Import for processing (living modified organism for direct use in food or feed or for processing- LMO-FFP)
    - Confined field trials (small scale)
- Transportability
  - Lab testing results (toxicity tests, germination tests, etc) are independent of environment.

Core Decision-making Principle: weigh the risks and the benefits



Balance "reasonable" certainty with scientific (absolute) certainty, and risks associated with a "no" or delayed decision.
e.g., loss of benefits and/or trade barrier due to delays

Risk Assessment Process

Risk Assessment Process is Guided: what are the key questions?

- What is the proposed use?
  - Commercial, LMO-FFP, field trial
- What is the experience with the traditional crop?
  - Assess familiarity (OECD, 1993)
- What are reasonable potential hazards?
  - Compared to the non-GM crop and based on the trait
- What are reasonable potential exposures?
  - Compared to the non-GM crop and based on the trait
- What, if any, is the estimated magnitude of comparative risk?
  - Compared to the non-GM crop
- What actions could be reasonably taken to reduce the risk or ensure that the decision was appropriate?
  - Monitoring?

Overall Risk Assessment Process

- Plan
  - Collect information based on the nature of the trait, the nature of the crop, the likely receiving environment and the interactions among these.
- Assess
  - Conduct controlled experiments
- Characterize
  - Describe the risk, and
- Refine as needed

Plan

- Ecological Assessment Planning also must consider...
  - exposure scenarios and pathways;
  - direct and indirect as well as immediate and delayed effects;
  - potential impacts related to changing the agricultural practices;
  - country specific requirements.

Consensus Potential Environmental Hazards

- Increased weediness of the crop or sexually compatible wild relative
- Adverse effects on non-target organisms
- Adverse effect on biogeochemical processes
- Induced or increased pathogenicity
- Adverse impact on the conservation and sustainable use of biodiversity

Assess: Types of Studies

- Hazard Identification
  - Product Characterization Testing
    - Molecular analysis
    - Comparative phenotypic evaluation
- Hazard Identification
  - Effects Testing
    - Non-target organism toxicity and dose response tests
    - Evaluation of soil microbial processes
- Exposure Assessment
  - Expression analysis
  - Gene flow studies
  - Environmental fate studies

Hazard Identification: Characterization of the Trait

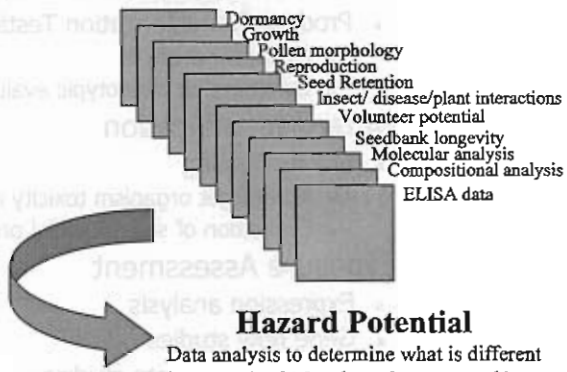
- Toxic and allergenic potential
  - Bioinformatics
  - Potential impact to non-target organisms
- History of safe use (familiarity)
  - Similarity to known proteins or genes
    - Sequence homology
  - History in food chain
- Mode of action information

Do we need further testing/refinement of hazard potential?

Hazard Identification: Crop/Plant Characterization

Assessment Planning → Data collection

Dormancy	≡
Vegetative growth	≡
Reproductive growth	≡
Pollen Morphology	≡
Pre-harvest seed loss	≡
Insect observ.	≡
Pathogen observ.	≡
Seedbank longevity	≡
Competition	≡
Replacement	≡
Pathways/Gene flow	≡
Hybridization	≡
Volunteer potential	≡
Allelopathy	≡
Plant biogeography	≡
Molecular analysis	≡
Compositional data	≡
Expression analysis	≡



Hazard Potential

Data analysis to determine what is different between the GM and nonGM crop and how it could relate to an adverse effect?

Hazard Identification: Core Comparative Data on a GM crop

- Comparative Data ("Familiarity"), Core Studies
  - Dormancy and germination
  - Phenotypic
    - Crop specific guidance
    - Plant-insect, plant-disease, plant microbe interaction
  - Volunteer potential
  - Compositional data

Do we need further testing/refinement of hazard potential? Conduct refined hazard assessment tests on meaningful differences such as dose response testing.

Effects Testing: Non-target Arthropods

- Based on surrogate test species concept
  - Selection based on:
    - Taxonomy, *e.g.*, insect order
    - Function, *e.g.*, pollinators
    - Nature of the trait
  - Historical precedent in the chemical industry
  - Lab system allows for data transportability
  - Acute (short-term) tests with high dose to address uncertainty
  - Adapted for Biotech crops: species, test length, flexibility on the test article (protein or tissue)
- Based on a Tiered Testing system
  - Progression through tiers based on lower tier results

Effects Testing: Plant-Soil Microorganisms

- Emerging regulatory concern/guidelines
- Current data gaps/allegations in soil ecology
- Lack of information on baseline variability of soil microbial populations- critical to assess potential impacts of GM crops on soil organisms and processes
- Initial focus should be on evaluating soil microbial processes (e.g., C/N mineralization)

Hazard Assessment Summary

- First: The assessment plan is developed based on the nature of the trait, the nature of the crop, the likely receiving environment and the interaction among these.
  - Hazard identification using both deductive and inductive approaches (possibilities)
  - Dose response or consequences assessment (calibrating the magnitude of the harm)
- Second: Product characterization identifies those aspects/elements of the GM crop/plant and trait that are meaningfully different compared to a conventional (safe) counterpart AND pose a potential hazard (i.e., weediness, adverse effect on NTOs, etc)
  - A well-constructed product characterization addresses potential secondary effects
- Third: Effects testing estimates that potential magnitude of the harm.

Exposure Assessment: defining the likelihood of the harm being realized

- Expression analysis
  - Tissues and temporal patterns
- Pathways analysis
  - Gene flow assessment
  - Trophic transfer
  - Exudation
- Mitigating Factors
  - Environmental fate/degradation
  - Dilution

Gene Flow Assessment Overview

- Gene flow is NOT a risk...
  - Risk Assessment occurs in steps (above)
    - 1st characterize the risk(s) associated with the trait and the GM crop
    - 2nd assess the likelihood that gene flow will occur based on the nature of the crop and trait
    - 3rd if there is evidence of risk or unacceptable uncertainty, assess whether the risk is manageable
  - Based on the nature of the risk identified, appropriate risk management could be developed.
    - It may be possible to manage or mitigate the potential harm and/or reduce the likelihood that gene flow will occur to acceptable levels

Environmental Fate Studies

- Laboratory soil degradation to estimate environmental exposure
  - Protein degradation or loss of functional bioactivity, dissipation profile, and degradation rate estimates
- Field accumulation and persistence
  - Is there accumulation or persistence during the growing season and over multiple years of consecutive use ??
  - Exposure value for risk assessment: Environmental Concentration (μg protein/g soil)

Exposure Assessment Summary

- Exposure assessment estimates likelihood by considering:
  - The nature of the crop/plant,
    - Gene flow, pollen and seed dispersal, ecological interactions with other organisms
  - The likely receiving environment,
    - Presence of sexually compatible relatives
  - Levels of the potential hazard agent(s) or trait,
    - Tissues, surrounding soils and phytophagous pests
  - Fate of the potential hazard agent(s).

Assessment Summary: Hazard and Exposure

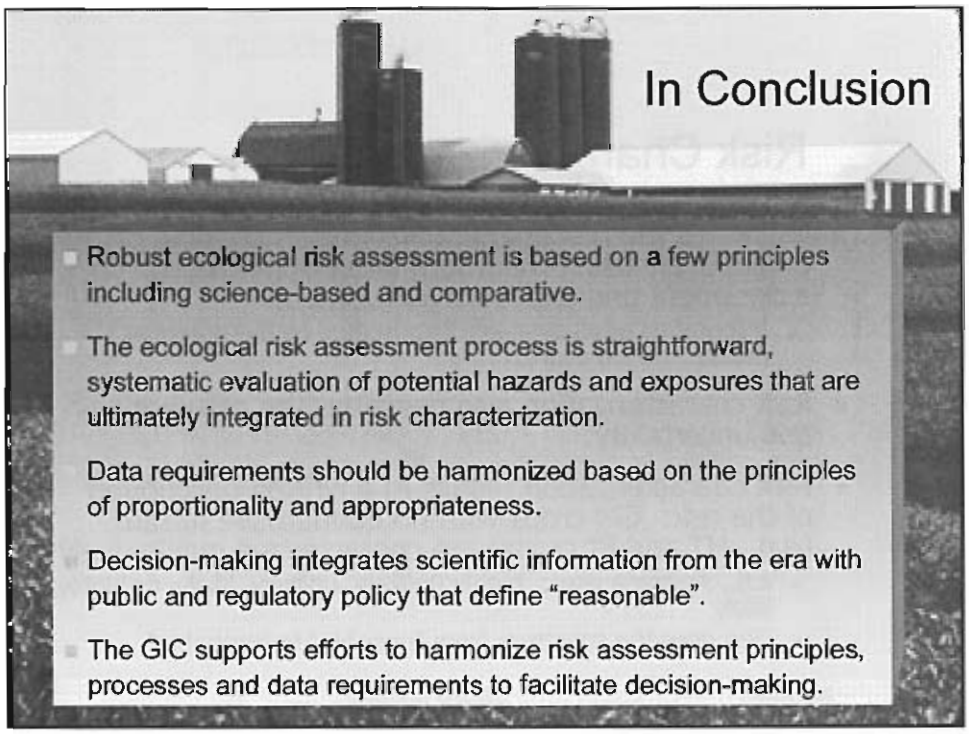
- Identification of hazard potential: Trait
  - Mode of action of gene product
  - Bioinformatics
  - Toxicity data
  - Feeding studies
    - mouse gavage
    - rat/bird/fish feeding
- Identification of hazard potential: Plant
  - Phenotypic and environmental interaction information from plant characterization studies
- Exposure assessment
  - Expression levels of the gene product
    - Season-long
    - Key plant parts
  - Gene Flow
    - Pollen and/or seed
    - Biogeographic data
  - Environmental Fate
    - Levels in soil
    - Levels in plant litter
    - Levels in phytophagous insects

Risk Characterization

- Estimates the risk quantitatively when possible or qualitatively using the information from hazard assessment and exposure assessment.
  - Integration of all available information on the potential hazard and exposure.
- Risk characterization also describes the assumptions and uncertainty.
- Risk characterization results in a written description of the risk: GM crops with no quantitative hazard (e.g., HT and Bt crops) are characterized qualitatively
  - e.g., Australia uses: highly unlikely, unlikely, likely, or highly likely
  - Describes the spectrum from "possible" to "probable".

Environmental Risk Assessment Science-based Challenges

- Reasonable certainty
  - Zero risk does not exist, we must explicitly or implicitly accept some level of uncertainty.
    - GM crops can not be made safer than biology itself. Rather, are the risks acceptable?
- Defining "safe"
  - Not absolute but relative safety: "as safe as"
- Appropriate comparators
  - Conventional agriculture and traditionally bred crops are the baseline from which to evaluate effects.
- How much data are sufficient for decision making: need to know vs. nice to know



Additional Slides

Global Industry Coalition (GIC) Risk Assessment Workgroup

GIC Risk Assessment Workgroup

- Promotes harmonization of environmental risk assessment for GM crops.
- Provides technical support on risk assessment issues across industry
- Addresses risk assessment related issues of general concern to industry
  - CPB negotiations on risk assessment
  - OECD harmonization efforts
  - IPPC and NAPPO efforts related to biotechnology

The GIC Case for Harmonization

It is in the best interest of stakeholders to support harmonization activities that will make the regulatory process for GM organisms more consistent, efficient, predictable and commensurate with the potential risks.

- Harmonization creates a more predictable regulatory environment.
  - Consistency in data requirements, experimental methods, regulatory review processes and timing, and terminology facilitates the overall process of gaining regulatory approvals.
- In the process of harmonization, the sharing of information and ideas generates greater understanding among the negotiating parties.
  - Supports future negotiations and allows the parties involved to be better prepared for such discussions.
- The sharing of information and expertise facilitates capacity building and forming supportive alliances among countries that are interested in creating efficient and effective regulatory systems.

GIC LMO-FFP Concerns

- International trade of commodity LMO-derived grain is currently vulnerable to disruption
  - Both CPB and International Plant Protection Convention have considered the issue of LMO FFPs
  - Guidance provided by Annex III (BSP) and ISPM 11 needs a harmonized framework
- Import decisions must be based on the principles of data proportionality and appropriateness
  - Decisions often can be made based on existing information, experience with the conventional FFP, expert opinion, and scientific principles
  - A tiered approach provides flexibility to manage to an appropriate standard of safety

Core Data: Dormancy Assessment

- Purpose:
  - Generate data to assess a key aspect of weediness, and to evaluate if the genetic modification caused unintended changes in the dormancy or germination characteristics of the crop.
- Methods:
  - Seed from multiple locations with different environmental conditions
  - Conducted in growth chamber under various temperature regimes
    - Optimum (AOSA standards)
    - Sub-optimum (range of temperatures from ~10 to 40C)
  - Assess dormant (hard), germinated, firm swollen and dead seed

Core Data: Phenotypic Characteristics Assessed

- Maize
  - Seedling vigor
  - Early stand count
  - Date of 50% pollen shed
  - Date of 50% silk
  - Pollen size & viability (single site)
  - Stay green
  - Ear height
  - Plant height
  - Dropped ears*
  - Stalk lodging*
  - Root lodging*
  - Final stand count
  - Yield
  - Plant-insect interactions
  - Plant-disease interactions
  - Plant-abiotic stress interactions
- Soybean
  - Early season vigor
  - Early stand count
  - Date of 50% flowering
  - Flower color
  - Pollen size and viability (single site data)
  - Plant height
  - Pubescence
  - Lodging*
  - Shattering*
  - Yield
  - Nodule characteristics
  - Plant-insect interactions
  - Plant-disease interactions
  - Plant-abiotic stress interactions

*Characteristic directly related to potential changes in crop weediness

Core Data: Volunteer Potential Assessment

- Purpose:
  - Generate data to evaluate if the genetic modification caused unintended changes in the ability of the crop to volunteer from seed in a subsequent growing season.
- Methods:
  - 4 location evaluation representing range of areas of expected cultivation
  - Assess ability of seed to over-winter and emerge as a seedling in a subsequent growing season.

Additional Refining Experiments (If necessary)

- Replacement Capacity
  - Comparative assessment of the survival of a population of the crop in unmanaged vegetation
- Residual Effects
  - Comparative assessment of allelopathic effects of the crop
- Seedbank Longevity
  - Comparative assessment of survival of the seed in soil over longer time periods (than in volunteer potential assessment)
- Competition
  - Comparative assessment of the competitive ability of the crop with another species

Representative Organisms

Common Name	Species	Tissue	Function
Collembola	*Folsomia candida*	Leaf Tissue	Detrivore
Catfish	*Ictalurus spp.*	Grain	Grain
Daphnia	*Daphnia magna*	Pollen	Aquatic primary consumer
Earthworm	*Eisenia fetida*	Protein	Detrivore
Ground Beetles	*Poecilus chalcites*	Protein	Pollen-Seed Feeder/Predator
Honeybee Adult	*Apis mellifera*	Protein	Nectar Feeder
Honeybee Larvae	*Apis mellifera*	Protein	Pollen Feeder
Lacewing	*Chrysoperla sp.*	Protein	Pollen Feeder/Predator
Ladybird Beetle	*Coleomegilla maculata*	Protein	Pollen Feeder/Predator
Parasitic Wasp	*Ichneumon promissorius*	Protein	Parasitoid
Pirate/Flower Bug	*Orius insidiosus*	Protein	Pollen Feeder/Predator
Quail	*Colinus virginianus*	Grain	Bird/Grain Feeder

Post-Marketing Monitoring (PMM)

There are 3 reasons to conduct Post-market monitoring:

1. Stewardship
   - provide information for farmers and other stakeholders
2. Expand basic knowledge
   - supports basic research
3. Regulatory Requirement
   - an outcome of a science-based risk assessment
   - supports decision-making or prescriptive conditions of approval

And, there are reasons to not conduct Post-market monitoring:

1. Cost
   - the value of the information is not justified
2. Uncertainty
   - the reason for PMM is unclear
   - PMM can lead to a perception that something is "wrong"

Assessing Familiarity: The role of Plant Characterization

Thomas E. Nickson* and Michael J. Horak;
Ecological Technology Center, Monsanto Company,
800 N. Lindbergh Blvd, St. Louis, MO 63167, USA

Abstract

This paper presents an overview of the concept of Familiarity and plant characterization. Familiarity is a concept useful to decision-makers because it comes from preexisting knowledge, experimental results as well as expert opinion, and experience gained over time. Familiarity encompasses familiarity with the crop, the trait, the environment and interactions. Plant characterization focuses on the collection and evaluation of biological and ecological data on the GM crop. It is based on a comparative assessment approach that considers the GM crop in the context of an appropriate non-GM control and the known variation for the crop. This discussion will include overviews of the scientific elements of the studies involved as well as an interpretation approach for evaluating statistically significant differences. Plant characterization data will be discussed in the context of the concept of Familiarity.

Key words: Plant characterization, risk assessment, Familiarity, genetically modified crops, phenotypic analysis, comparative assessment

Introduction

Biotechnology-derived (GM) crops have been used commercially for 10 years, and in 2005, GM crops were planted in 21 countries by more than 8 million farmers (James, 2006). Prior to commercial use, each product underwent a scientific assessment and independent regulatory review to examine potential risks to food, feed and the environment. Data that characterize the biology and ecology of the GM plant relative to the traditional crop are needed for the environmental risk assessment. When planning a characterization a scientist considers the nature of the trait, the crop being modified, the desired product concept, the likely receiving environment and the potential interactions among these as they relate to environmental risk and ultimately decision-making. In the course of this characterization, experience with the crop, the trait and the receiving environment will be gained that will provide the basis on which data will be evaluated and meaningful differences interpreted. This experience also provides a comparative context that will be used to establish "Familiarity" and ultimately characterize the risks posed by a particular GM plant.

This paper presents an overview of the concept of Familiarity and plant characterization. Familiarity is a concept useful to decision-makers because it comes from preexisting knowledge, experimental results as well as expert opinion, and experience gained over time. Familiarity encompasses familiarity with the crop, the trait, the environment and

interactions. By definition, familiarity increases with time and experience, and thus it helps address uncertainty in the risk assessment and direct future information collection (e.g., monitoring). Importantly, Familiarity is not a safety conclusion, but rather it encompasses the information available at a given point in time; and serves as a basis from which the risk assessment should proceed. Plant characterization focuses on the collection and evaluation of biological and ecological data on the GM crop. It is based on a comparative assessment approach that considers the GM crop in the context of an appropriate non-GM control and the known variation for the crop. This discussion will include overviews of the principles of ecological risk assessment and the scientific elements of the studies involved. In addition, plant characterization data will be discussed in the context of the concept of Familiarity.

General Principles of Ecological Risk Assessment for GM Crops

Ecological risk assessment for LMOs should be based on the general principles of ecological risk assessment (*era*). These principles have been described in several sources (Suter, 1993; US EPA, 1998). According to the literature, a valid *era* should be science-based, utilize a systematic approach that is inclusive of all available information and iterative based on new information. In addition, the fundamental elements of risk (hazard + exposure/frequency) should be explicitly described in order to accurately characterize and analyze the overall risk. *Era* approaches to genetically modified plants have been described (Tiedje *et al.,* 1989; OECD, 1993; Rissler and Mellon, 1996; Kjellson, 1997; Nickson and McKee, 2002), which recommend further that assessments of LMOs be case-by-case, giving detailed consideration to the biology of the crop, the nature of the trait and the environment into which the LMO will be released.

The Concept of Familiarity

The concept of Familiarity was jointly developed by different groups (NRC 1989, Tiedje *et al.* 1989; OECD, 1993) and is a key approach used in identifying and evaluating environmental risks and in informing practices that may be needed to manage recognized risks. Underlying this concept are two important assumptions: (1) the process of genetic engineering is not inherently more risky than conventional plant breeding and introduced transgenes behave in essentially the same manner as any other gene within the plant genome; and (2) there is a significant history of introducing new traits into crop plants and in evaluating these new varieties in agriculture.

Initially, a risk assessor uses familiarity with the crop in the context of the regulatory concerns to collect the information that is relevant for the risk assessment. Risk assessment of a GM plant begins by assembling knowledge of the properties of the conventional crop under environmental conditions that are representative of the proposed use of the GM crop. Our understanding of familiarity is modified as new data become available from comparative field tests using the GM crop and an appropriate control and references. Information gathered enables the risk assessor to determine with greater certainty and precision those characteristics of the GM plant that are different from the conventional crop and may be of regulatory concern. According to Hokanson *et al.* (1999), "familiarity allows decision-makers to draw upon the vast experience with

introduction of plants into the environment, and to compare genetically engineered plants to their non-engineered counterparts." Methods including comparative compositional analysis and agronomic/phenotypic evaluations constitute an integral component by which modified crops are characterized. As such, Familiarity embraces the concepts that evaluations should be comparative (modified vs. non-modified), and that cumulative experience allows risk assessors to refine their understanding of the potential risks associated with the GM crop. For most of the major crop species, there is ample literature and data available to provide the risk assessor a context for assessing familiarity. For example, consensus documents developed by the OECD, CFIA and USDA are readily available on many crop species.

As more experience is gained with biotech traits in multiple crops and geographies, familiarity increases and can further serve as a baseline for the food, feed, and environmental risk assessments of other GM crop concepts. For example, an ERA for the herbicide-tolerant trait in a new Roundup Ready crop or new geography for an existing Roundup Ready crop may draw on the previous knowledge and experience gained for CP4 EPSPS, the expressed protein conferring tolerance to glyphosate. CP4 EPSPS is a member of a family of enzymes common to plants and microorganisms. There is no toxicity associated with this family of proteins, and since they are ubiquitous in plants and microorganisms, they have a history of safety in the environment. As traits such as glyphosate tolerance and Bt-based insect protection continue to expand in acreage and in diverse environments, valuable experience and information is gained in the safe deployment of these trait and crop combinations.

Plant Characterization

The current approach to assessing GM plants includes a scientifically rigorous comparative assessment of the plant's phenotypic characteristics (germination, emergence, growth and reproduction), and the plant's interactions with the environment.

In a comparative assessment various phenotypic characteristics of a GM plant are compared to those of a control that is generally accepted as environmentally "safe" under known conditions of use. Thus, it is important to select an appropriate control and appropriate phenotypic characteristics for comparison. In addition, commercial references are included in the experimental design to provide information on characteristic values common for the crop.

In a phenotypic characterization, the control must be as genetically similar to the GM plant as possible. However, pure isogenic conventional comparator plants are not available due to the nature of plant systems (e.g., genetic recombination during selfing or backcrossing, self-incompatibility, alloploidy, hybridization) and current transformation technology. Since the GM trait is often backcrossed to the conventional parent to fix the gene in the parental genetic background, a near isogenic, null-segregant, or parental line is often the best available control.

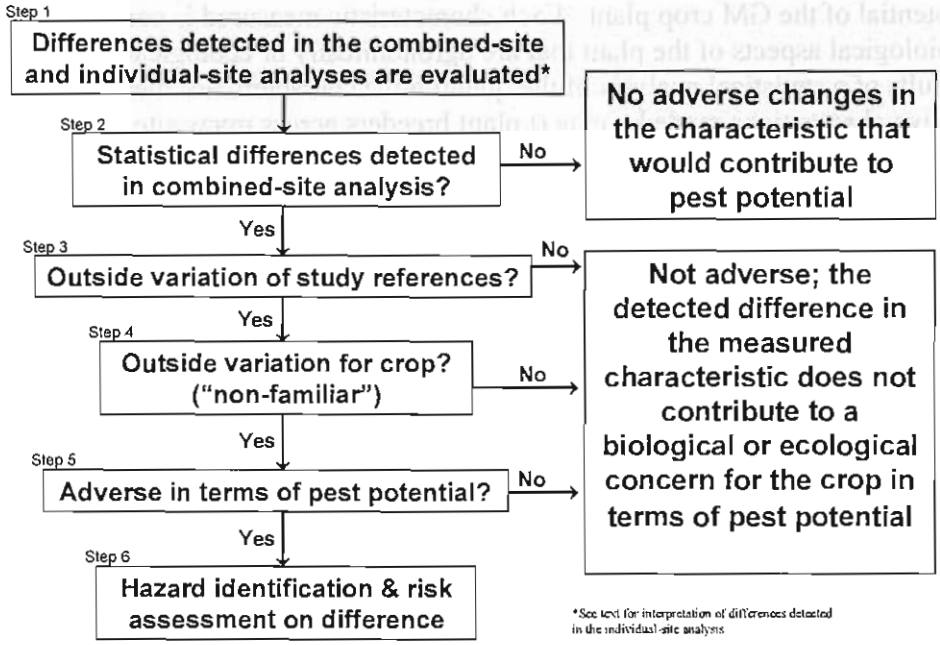
The phenotypic characteristics evaluated in a characterization are selected based on the biology of the crop and experience from conventional breeding (familiarity). All data from the phenotypic observations are used to characterize the plant, while a certain subset (e.g., dormancy, lodging, seed retention on the plant) are used to directly assess altered pest potential of the GM crop plant. Each characteristic measured is correlated to one or more biological aspects of the plant that are agronomically or ecologically important. The results of a statistical analysis of the quantitative characteristics measured and qualitative observations made by expert plant breeders across many sites and environments provide data and information for a robust assessment of potential phenotypic differences between a GM plant and an appropriate conventional comparator.

Data from reference lines incorporated into the experimental design or from published literature can provide valuable information in a plant characterization. Understanding the inherent variability for a characteristic within a crop provides important background data derived from familiarity with commercially accepted values for the characteristic and is important to the interpretation of the implications of any detected changes.

Typically, several experiments are conducted to collect comparative plant characterization data. The data from these experiments may be qualitative or quantitative. The qualitative data are summarized to describe field scientist observations. The quantitative data are analyzed to determine if there are statistically significant differences between the GM plant and its conventional control for a specific characteristic.

Assessing Experimental Results.
Comparative plant characterization data between a biotechnology-derived crop and the control are considered in the context of contributions to pest/weed potential. Plant phenotypic characteristics are inherently variable and thus statistically significant differences are sometimes detected in phenotypic analyses necessitating further assessment. Characteristics for which no differences are detected support a conclusion of no increased pest potential of the biotechnology-derived crop compared to the conventional crop. Characteristics for which differences are detected are considered in the step-wise method described below. Any detected difference for a characteristic is considered in the context of whether or not the difference increased pest/weed potential of the biotechnology-derived crop. Ultimately, a weight of evidence approach considering all characteristics and studies is used for the final risk assessment of differences and their significance in terms of increased pest potential.

Methods for interpretation of detected differences



During steps 1 & 2, combined-site and individual-site statistical analyses are conducted and evaluated on each measured characteristic/parameter. When statistical analysis indicates that the GM plant is not different from the conventional counterpart for a specific characteristic, that characteristic would be considered within an acceptable range. The data for that characteristic would support a conclusion of no changes in pest potential for the GM plant relative to its conventional counterpart. Differences detected in the individual-site analysis must be observed in the combined-site analysis to be considered further for potential adverse effects in terms of pest/weed potential. A difference in the combined-site analysis is further assessed regardless of whether or not the difference is detected in the individual-site analysis.

When a combined-site analysis indicates that the GM plant is not different from the conventional counterpart for a specific characteristic, that characteristic would be considered within an acceptable range. The data for that characteristic would support a conclusion of no changes in pest potential for the GM plant relative to its conventional counterpart (Figure 1, step 2, answer "no"). Differences detected in the combined-site analysis may indicate a biological change in the GM plant (Figure 1, step 2, answer "yes").

If a detected difference were observed in the combined site analysis, the variability for that characteristic present in the references grown as part of the same experiment and under the same conditions is considered (Figure 1, step 3). Further assessment is warranted if the mean value for the characteristic were outside the accepted range of a) values for the crop (i.e., the inherent genetic variability present in the species), as

indicated from the references in the experiment; or b) those presented in published literature. The characteristic with such an outlying value would be non-familiar for that crop or background genetics (Figure 1, steps 3 and 4).

Any non-familiar characteristic is then considered in the context of the direction of the change in terms of pest potential (Figure 1, step 5). If an adverse effect (hazard) is identified, risk assessment on the difference is conducted (Figure 1, step 6). The risk assessment considers contributions to enhanced pest potential of the crop itself, the impact of differences detected in other measured characteristics/parameters, and potential for, and effects of trait transfer to feral populations of the crop or a sexually compatible species. It is important to note that an adverse effect is not just a function of the plant; the nature of the GM trait is also a factor in determining if a plant has increased environmental risk.

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Impact assessment of genetically modified crops upon biological diversity under regulatory framework in Japan

Secretariat of Agriculture, Forestry and Fisheries Research Council (AFFRC)
Ministry of Agriculture, Forestry and Fisheries (MAFF)

Kentaro KAWAGUCHI

演題：カルタヘナ法に基づく遺伝子組換え作物の使用規制と生物多様性影響評価
Impact assessment of genetically modified crops upon biological diversity under regulatory framework in Japan

川口健太郎
農林水産省 農林水産技術会議事務局 技術安全課

遺伝子組換え技術は、生活の質を高めたり様々な分野における諸問題を解決したりすることができると期待されている技術のうちの１つです。しかし、新しい技術であるために、その扱いに十分な経験がないため、環境に対して望ましくない影響を及ぼす可能性もあるのではないかと考えられ、その安全性の確認が求められています。

日本は２００３年９月１１日に国際発効した「生物の多様性に関する条約のバイオセーフティに関するカルタヘナ議定書」を同年１１月２１日に批准したことを受けて、国が遺伝子組換え生物の環境安全性を確保するために、２００４年２月１９日に「遺伝子組換え生物等の使用等の規制による生物の多様性の確保に関する法律（カルタヘナ法）」を施行し、生物多様性への影響という観点で、法律に基づく規制の枠組みを整備しています。

これにより、わが国で遺伝子組換え生物を使用する場合には、その使用方法を明記した「第一種使用規程」とその規程に従って使用した場合に生物多様性に及ぼす影響を科学的に評価した「生物多様性影響評価書」を提出し、大臣による承認を受けなければならないこととされています。従って、わが国では、科学的に安全性を確認された遺伝子組換え生物だけが栽培や流通ができる仕組みとなっています。ここでは遺伝子組換え植物を環境中で使用する際に行われる生物多様性影響評価について、その考え方と実際の進め方についてを中心に紹介します。

Impact Assessment of Genetically Modified Crops upon Biological Diversity under Regulatory Framework in Japan

「カルタヘナ法に基づく遺伝子組換え作物の使用規制と生物多様性影響評価」

Secretariat of Agriculture, Forestry and Fisheries Research Council (AFFRC)
Ministry of Agriculture, Forestry and Fisheries (MAFF)
Kentaro KAWAGUCHI

農林水産省農林水産技術会議事務局技術安全課　川口健太郎
2006年7月27日(木)　ILSI

Title

MAFF's Policy for Recombinant DNA Techniques

遺伝子組換え技術に対する基本的な考え方

- Recombinant DNA techniques have great potential for welfare of humankind.
- It is crucial to sufficiently assess risks of GMOs on human health and environment.
- It is important to appropriately address concerns of public and to provide relevant information.

Introduction 1/3

Number of Approved Type 1 Use Regulation

第一種使用規程の作物別承認件数及び経過措置件数

Crops	Isolated Field Trials	Cultivation and/or FFPs	Interim Measure
Corn	6	21	4
Rice	18		
Cotton	1	12	
Oilseed rape		2	8
Soybean	2	1	3
Carnation		5	
Alfalfa		3	
Rose	2		
Sugarbeet	1		
Bentgrass	1		
Papaya			1
Total	31	44	16

Introduction 2/3

GM Crops in Japan

日本における遺伝子組換え作物の状況

- There is no commercial cultivation.
- A large amount GM products are imported as FFPs (Direct use as food, feed, or for processing).
- Some local governments have set up guidelines on cultivation of GM crops.
- Public concerns unintended presence of GM crops in non-GM crops.

Introduction 3/3

Today's Topics

1. Biosafety framework: The Cartagena Law
2. Approval Procedure of GM Crops
3. Impact Assessment on Biological Diversity

（1）カルタヘナ法に基づく規制の枠組み
（2）申請から承認までの手順
（3）科学的方法によるリスク評価の手順

Body1/14

The Cartagena Law (2004)

"Law concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms"

遺伝子組換え生物等の使用等の規制による生物の多様性の確保に関する法律

Contents

1. General Provisions
2. Measures to Prevent Adverse Effects on Biological Diversity Caused by the Use of Living Modified Organisms in Japan
   1. Type 1 Use of Living Modified Organisms
   2. Type 2 use of Living Modified Organisms
   3. Testing of Organisms
   4. Provision of Information
3. Measures Concerning Export
4. Miscellaneous Provisions
5. Penal Provisions

Body2/14

Measures Corresponding to the Mode of Use of LMOs

遺伝子組換え作物の使用形態に応じた措置

[Releasing to Environment]

Type 1 Use: Uses without containment measures

第一種使用:拡散防止措置をとらない使用

Including "Isolated Field Trial" and "FFP"

Applicants must submit ***Biological Diversity Risk Assessment Report*** to obtain approval for ***Type 1 Use Regulation*** from competent ministers.

[Preventing from Dispersal]

Type 2 Use: Uses with containment measures

第二種使用: 環境中への拡散を防止して行う使用

Applicants must take containment measures confirmed by competent ministers to be effective.

("The Cartagena Law", Article 2 paragraph5 & 6)

Body3/14

Competent Ministries

主務大臣

Agriculture

MAFF
(Ministry of Agriculture, Forestry and Fisheries)

\+ MOE
(Ministry of the Environment)

MEXT
(Ministry of Education, Culture, Sports, Science and Technology) — Research & Development

MOF
(Ministry of Finance) — Liquor Production

MHLW
(Ministry of Health, Labour and Welfare) — Pharmaceuticals

METI
(Ministry of Economy, Trade and Industry) — Mining & Manufacturing

\+ MOE

Body4/14

Dossiers for Application

申請の際の提出書類

Users must submit dossiers and obtain approval for Type 1 Use Regulation from competent ministers.

- Type 1 Use Regulation
  第一種使用規程
  Example:
  - Provision as food, provision as feed, cultivation, processing, storage, transportation, disposal and acts incidental to them.
  - 食用又は飼料用に供するための使用、栽培、加工、保管、運搬、及び廃棄並びにこれらに付随する行為
- Biological Diversity Risk Assessment Report
  生物多様性影響評価書
- Accompanying documents

Body5/14

Biological Diversity Risk Assessment Report

生物多様性影響評価書の構成

Structure

Part 1. Information collected prior to assessing　情報収集

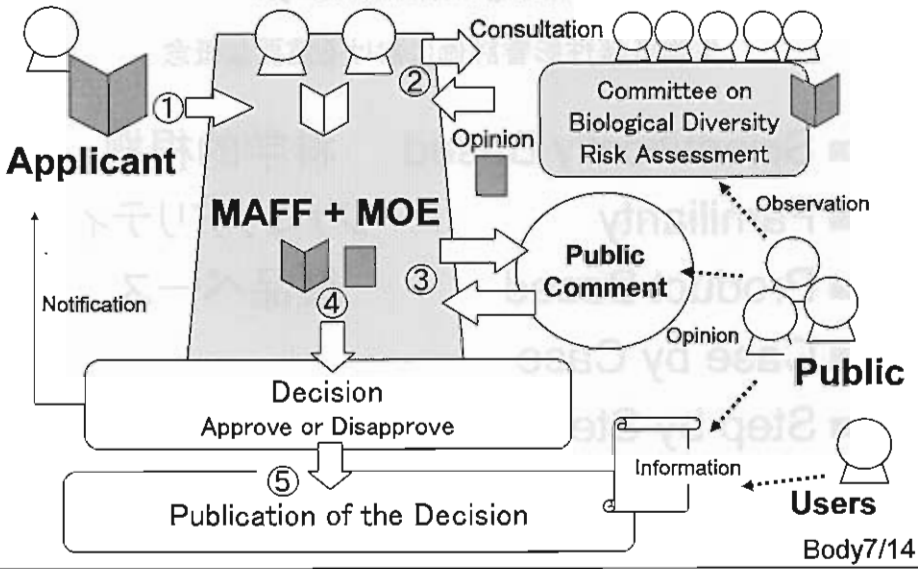
Part 2. Item-by-item assessment of adverse effect against each property of the GMO　項目ごとの評価

Part 3. Comprehensive evaluation　総合的評価

"The guidance of Implementation of Assessment of Adverse Effect on Biological Diversity of Type 1 use of Living Modified Organisms. " (Table 4)

Body6/14

Application - Approval Type 1 use regulation of GM Crops
第一種使用規程の承認手続き



Body7/14

Committee on Biological Diversity Risk Assessment
生物多様性影響評価検討会

- Sub-Committee for Crops 農作物分科会
  - Experts: Persons with specialized knowledge and experience concerning Adverse Effect on Biological Diversity
  - Applicant
  - Secretariat (MAFF and MOE)
- Integrated Committee 総合検討会
  - Open to Public
    - Experts
    - Secretariat (MAFF and MOE)
    - Observers

Body8/14

Basic Concepts in Impact Assessment upon Biological Diversity

生物多様性影響評価における重要な概念

- Scientifically Based　科学的根拠
- Familiarity　ファミリアリティ
- Product Based　製品ベース
- Case by Case
- Step by Step

Body9/14

Assessment Items

Property of living modified organisms which might cause Adverse Effect on Biological Diversity

生物多様性影響を生じさせる可能性のある遺伝子組換え植物の性質

- **Competitiveness**　競合における優位性

  Wildlife may be crowded out from territory.

  Property of competing against wild plants for resources such as nutrients, sunshine, habitat, etc. and interfering with their growth. (Higher growth and reproduction rate, Seed production capacity, Higher tolerance to environmental stress etc.)

- **Productivity of harmful substances**

  有害物質の産生性　Wildlife may be wiped out by the substance

  Property of producing substances interfering with the living and growth of wild li

  - Allelopathic agents, etc

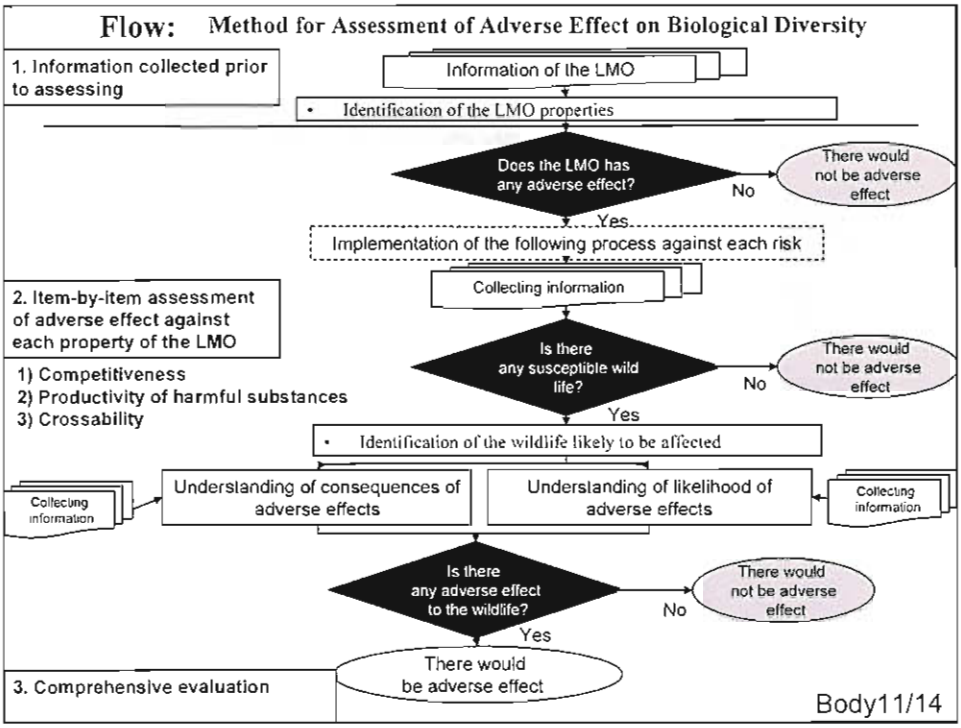
- **Crossability** 交雑性　Wildlife may be replace by the hybrids.

  Property of hybridizing with related wild plants and transmitting nucleic acid transferred by the technologies regulated by the Law to them.

  - Pollen production capacity, Compatibility between pollen and stigma, Rate of fertilization, Germination rate of the hybrid seeds, Fertility of the posterity, etc.

"The guidance of Implementation of Assessment of Adverse Effect on Biological Diversity of Type 1 use of Living Modified Organisms. " (Table 2)

Body10/14



Procedure for Assessment of Adverse Effect on Biological Diversity

生物多様性影響評価の手順

- 1. Identification of wild life likely to be affected
  - 影響を受ける可能性のある野生動植物等の特定
- 2. Evaluation of concrete details of adverse effect
  - 影響の具体的内容の評価
- 3. Evaluation of likelihood of adverse effect
  - 影響の生じやすさの評価
- 4. Judgment of existence of Adverse Effect on Biological Diversity
  - 生物多様性影響が生じるおそれの有無等の判断

"The guidance of Implementation of Assessment of Adverse Effect on Biological Diversity of Type 1 use of Living Modified Organisms. " (Table 3)

Body12/14

Criteria of approval for Type 1 Use Regulations in environment

第一種使用規程の承認とその基準

- The competent minister must, when recognizing that no adverse effect that could pose an unacceptable risk that impairs the preservation of species or populations of wild fauna or flora or no other Adverse Effect on Biological Diversity, give approval for said Type 1 Use Regulations.
  - 主務大臣は、生物多様性影響が生ずるおそれがないと認めるときは、第一種使用規程の承認をしなければならない。
    - ("The Cartagena Law", Article 4, Paragraph 5)
- No impair for the preservation of the species or population of the wildlife
- If Japan has experience in the long-term use of the recipient organism of living modified organism or the species to which the recipient organism belongs, judgment may be based on whether the degree of adverse effect is not higher compared to that of the recipient organism or the species to which the recipient organism belongs.
  - 特定された野生動植物の種または個体群の維持に支障を及ぼすおそれがないと認められる。
  - 長期間の使用経験のある宿主であり、それと比較して生物多様性に及ぼす影響の程度が高まっていないと認められる。
    - ("The basic matters under the Provisions of Article 3 of the Cartagena Law")

Body13/14

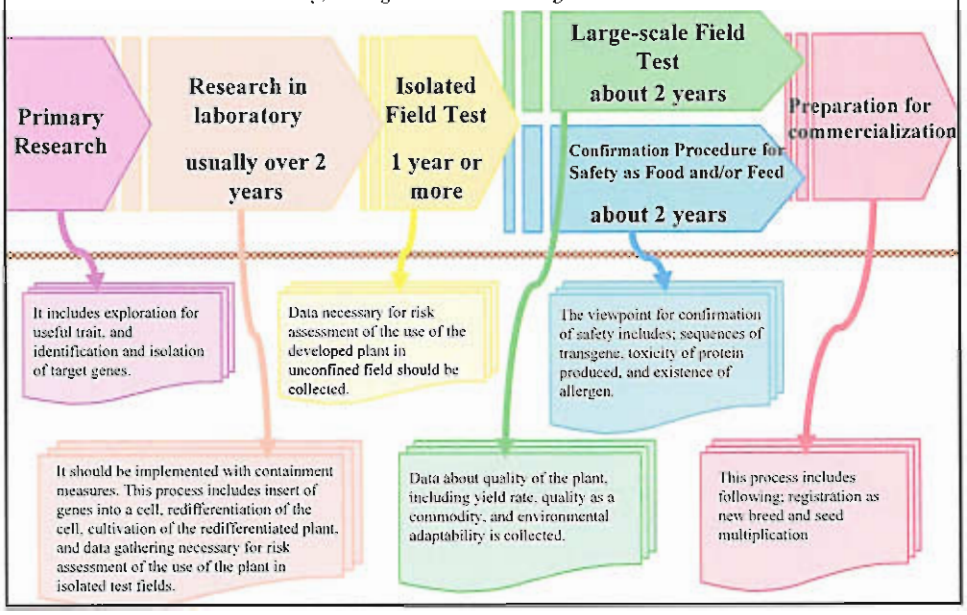
Web Sites

- Biotechnology Safety Division in MAFF
  - http://www.s.affrc.go.jp/docs/anzenka/index.htm
- Japan Biosafety Clearing House (J-BCH)
  - http://www.bch.biodic.go.jp/

Body14/14

The pipeline for commercialization of GM crops

Commercialization of GM crops has to go through pipeline described as follows. That is, the crops are developed and their risks are assessed in a stepwise fashion, moving from the laboratory to the isolated field test and finally, to large-scale field testing.



Environmental risk assessment of genetically modified crops

Mitsunori OKA
Research coordinator, National Institute for Agro-Environmental Sciences

演　題：遺伝子組換え作物の環境影響評価
Environmental risk assessment of genetically modified crops

岡　三徳
独立行政法人農業環境技術研究所　研究コーディネーター

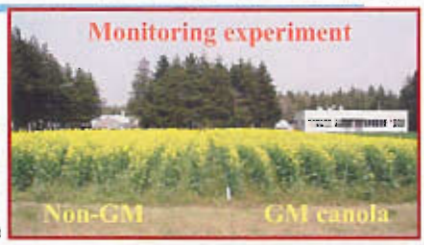
要　旨：
この数年の間に、遺伝子組換え作物を巡る環境影響評価と栽培利用の２つの点で世界の状況が大きく変化した。2003 年に発効したカルタヘナ議定書によって、人体への安全性評価に加えて組換え作物の生物多様性影響評価が義務づけられ、他方では組換え作物と非組換え作物との共存による栽培利用への関心が国際的に高まっている。本講演では、国内における組換え作物の生物多様性影響評価に向けた最近の研究成果から、とくにこの５年間に取り組んだ組換え作物のモニタリング試験結果、及び組換えダイズと東アジアに固有なツルマメとの交雑に関する調査研究の現状を紹介する。

International Workshop of ILSI, 27 July 2006

Environmental risk assessment of GM crops

By M. Oka, Research Coordinator
National Institute for Agro-Environmental Sciences

Soybean & wild relative

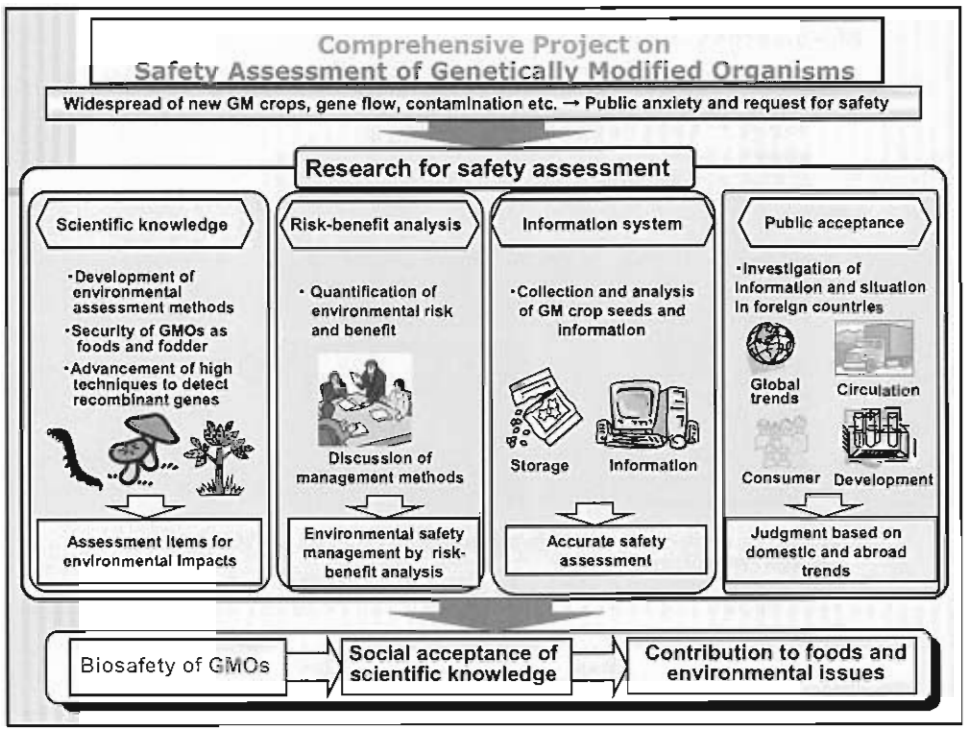


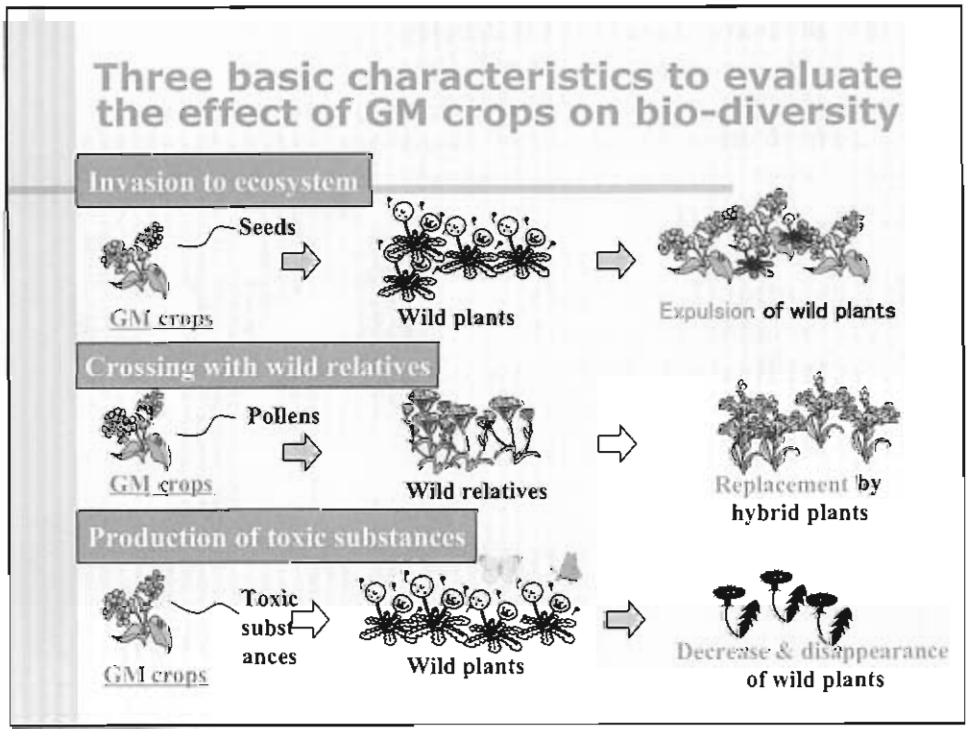
NIAES

Distinction of outcrossing by "xenia"

The Cartagena Protocol on bio-safety, & domestic law & regulations in Japan

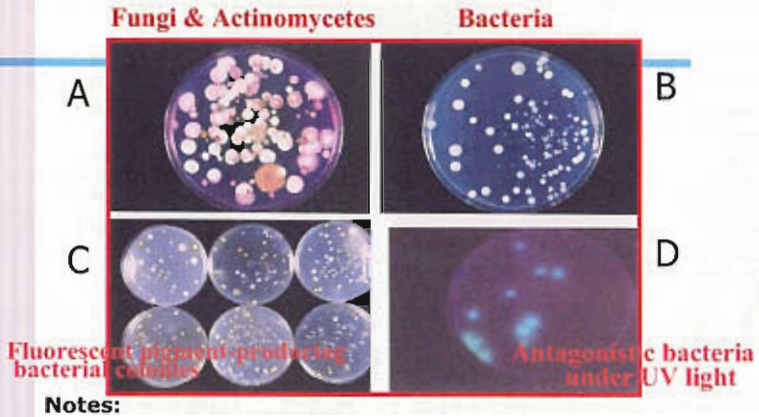
- The Protocol was enforced on September 11, 2003.
- Japanese Government ratified the Protocol on November 21, 2003.
- The domestic law, ministerial ordinances & regulations related to the Protocol was enforced on February 19, 2004 in Japan.
- The guideline for the open-air field experiments of GM crops was announced on February 24, 2004 in Japan.


Comprehensive Project on
Safety Assessment of Genetically Modified Organisms
Widespread of new GM crops, gene flow, contamination etc. → Public anxiety and request for safety
Research for safety assessment
Scientific knowledge
•Development of environmental assessment methods
•Security of GMOs as foods and fodder
•Advancement of high techniques to detect recombinant genes
Assessment items for environmental impacts
Risk-benefit analysis
• Quantification of environmental risk and benefit
Discussion of management methods
Environmental safety management by risk-benefit analysis
Information system
•Collection and analysis of GM crop seeds and information
Storage
Information
Accurate safety assessment
Public acceptance
•Investigation of information and situation in foreign countries
Global trends
Circulation
Consumer
Development
Judgment based on domestic and abroad trends
Biosafety of GMOs
Social acceptance of scientific knowledge
Contribution to foods and environmental issues


Three basic characteristics to evaluate the effect of GM crops on bio-diversity
Invasion to ecosystem
Seeds
GM crops
Wild plants
Expulsion of wild plants
Crossing with wild relatives
Pollens
GM crops
Wild relatives
Replacement by hybrid plants
Production of toxic substances
Toxic substances
GM crops
Wild plants
Decrease & disappearance of wild plants

Bio-diversity assessment & development

1. Monitoring of microorganisms in fields



Notes:

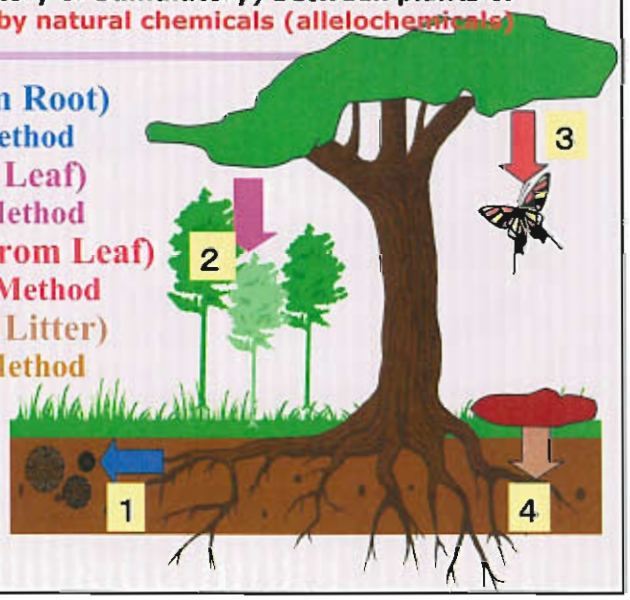
A: Colonies of fungi and actinomycetes detected on the Rose Bengal medium.
B: Bacterial colonies appeared on the PTYG medium.
C: Fluorescent pigment-producing bacterial colonies on the PTYG medium.
D: Detection of fluorescent *pseudomonades* on the King's B medium under UV light.

Bio-diversity assessment & development

2. Allelopathy and Evaluation

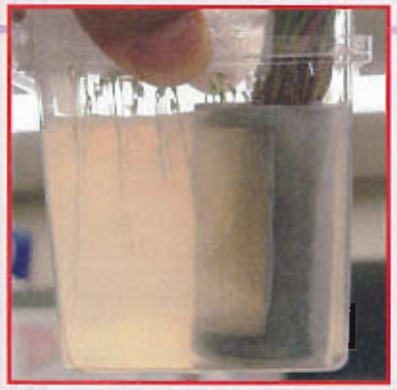
Interaction (inhibitory or stimulatory) between plants or plant to other life by natural chemicals (allelochemicals)

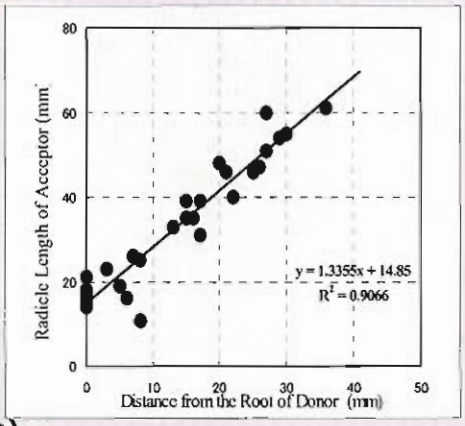
1. Exudation (from Root)
   -----> Plant Box Method
2. Leaching (from Leaf)
   ------> Sandwich Method
3. Volatilization (from Leaf)
   -------> Dish Pack Method
4. Leaching (from Litter)
   ------> Sandwich Method



Bio-diversity assessment & development

2-1. Plant Box Method for root exudates





- Sand culture of GM plants for 1-2 months
- Agar Medium (no nutrients)
- Root zone separation by gauze

Bio-diversity assessment & development

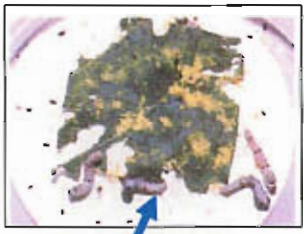
3. Development of evaluation methods in terms of pollen diffusion

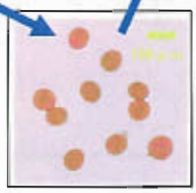
– pollen toxicity and out-crossing -

Setting pollen traps at regular intervals from corn field

Pollen trap

Feeding examination





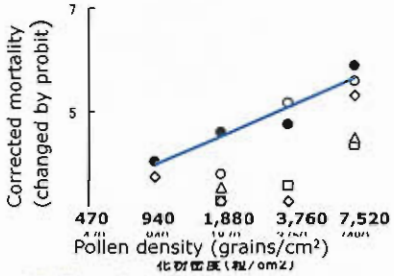
Pollen Number

Impact assessment of bio-diversity

3-1. Bioassay of GM Bt-corn pollen toxicity *Lepidopterous* insects

Monarch Caterpillars on a milk leaf dusted with pollen. Photo by K. Loeffler, 1999

Food plant: *Oxalis corniculata*



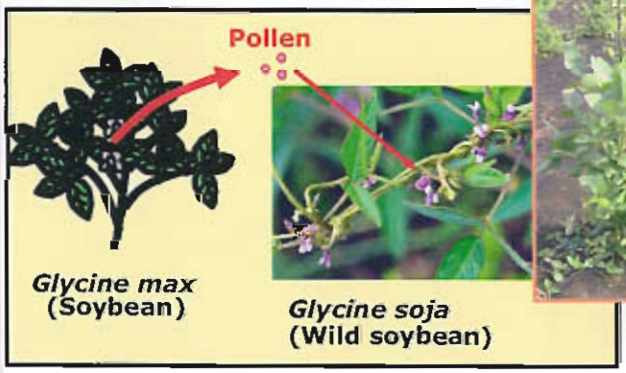
Pollen density and mortality of the 1st instar larvae

Black circles and solid line indicate for Bt-corn variety N4640Bt

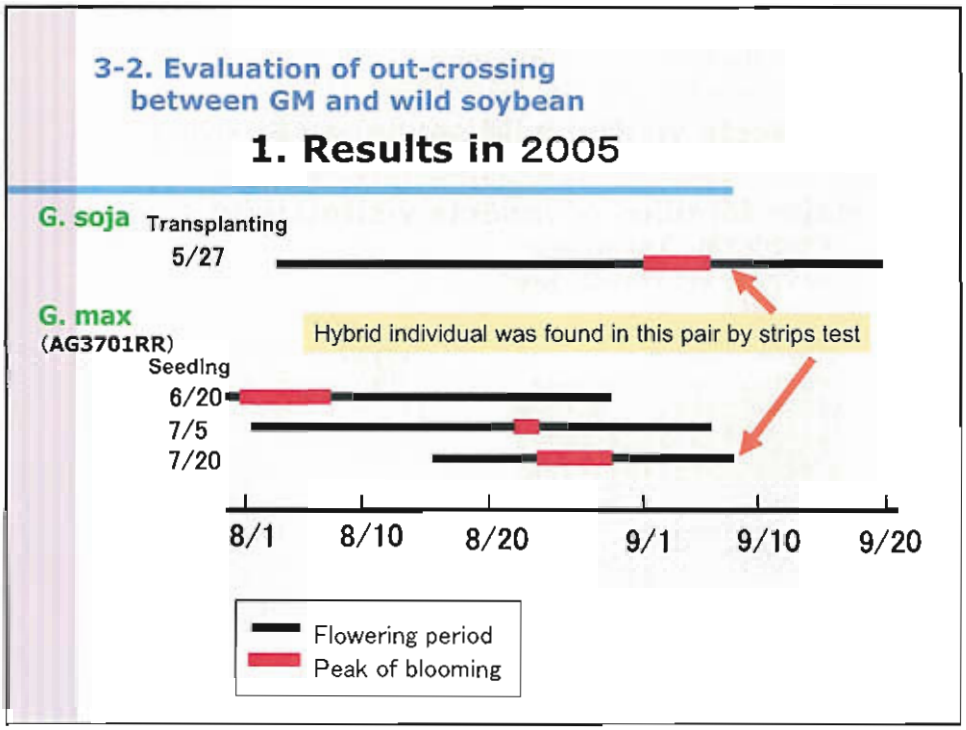
Bio-diversity assessment & development

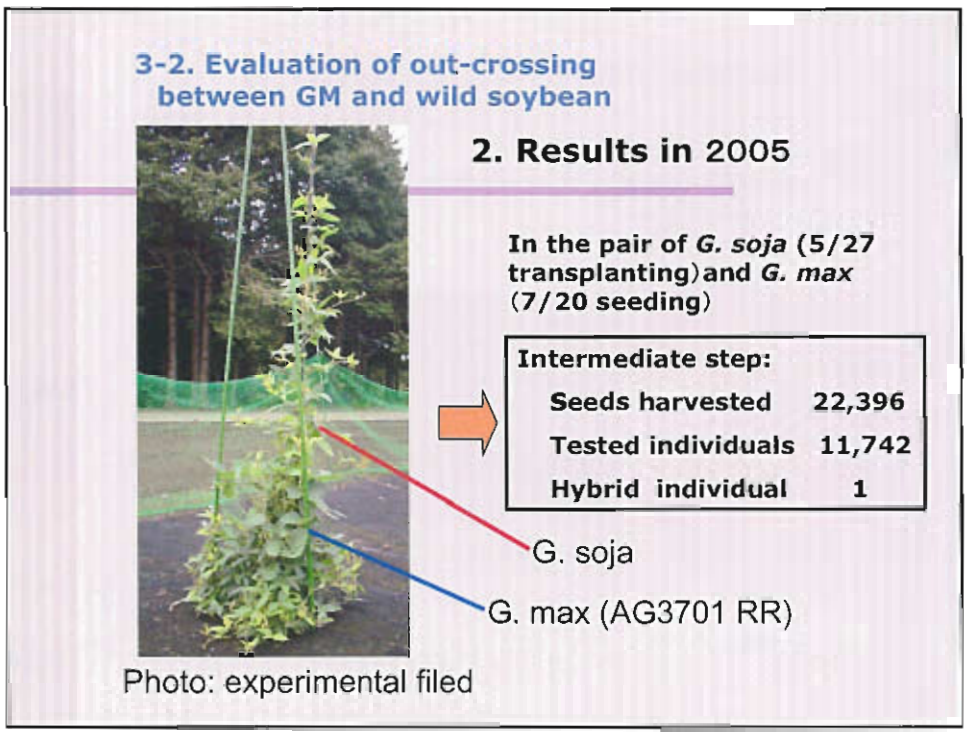
3-2. Evaluation of out-crossing between GM and wild soybean

Natural growing areas of wild soybean: Eastern China & Russia, the Korean Peninsula, Taiwan & Japan



Experimental field of wild soybean 2005, NIAES


3-2. Evaluation of out-crossing between GM and wild soybean
1. Results in 2005
G. soja
Transplanting
5/27
G. max
(AG3701RR)
Seeding
6/20
7/5
7/20
Hybrid individual was found in this pair by strips test
8/1
8/10
8/20
9/1
9/10
9/20
Flowering period
Peak of blooming


3-2. Evaluation of out-crossing between GM and wild soybean
2. Results in 2005
In the pair of G. soja (5/27 transplanting) and G. max (7/20 seeding)
Intermediate step:
Seeds harvested 22,396
Tested individuals 11,742
Hybrid individual 1
G. soja
G. max (AG3701 RR)
Photo: experimental filed

3-2. Evaluation of out-crossing between GM and wild soybean

Insects visited wild soybean (G. soja)

Major families of insects visited wild soybean:

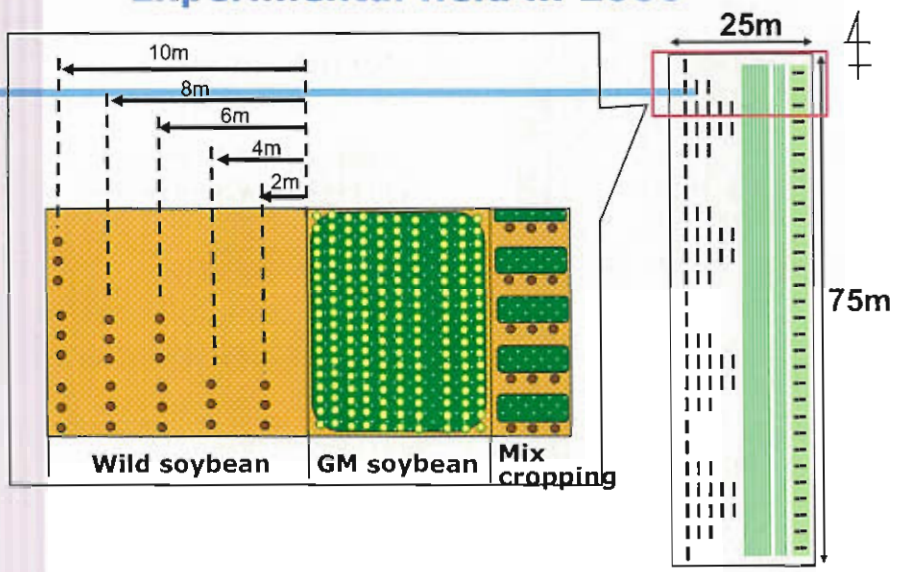
- アザミウマ科: **Thripidae**
- コハナバチ科: **Halictidae**

アカガネコハナバチ:
Halictus(Seladonia) aerarius

ヒラズハナアザミウマ:
Frankliniella intonsa

Two photos were cited from websites.

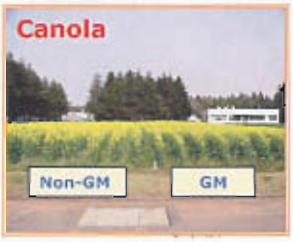
Experimental field in 2006

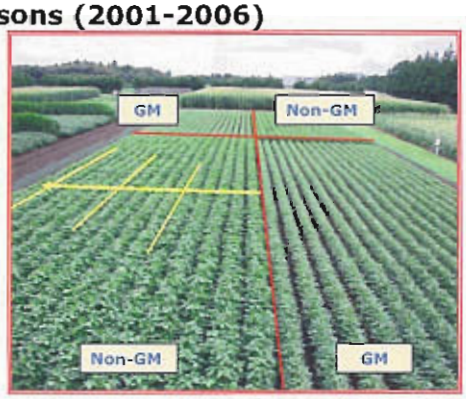


Monitoring experiments of GM crops

Plants, Insects, Microorganisms & Out-crossing

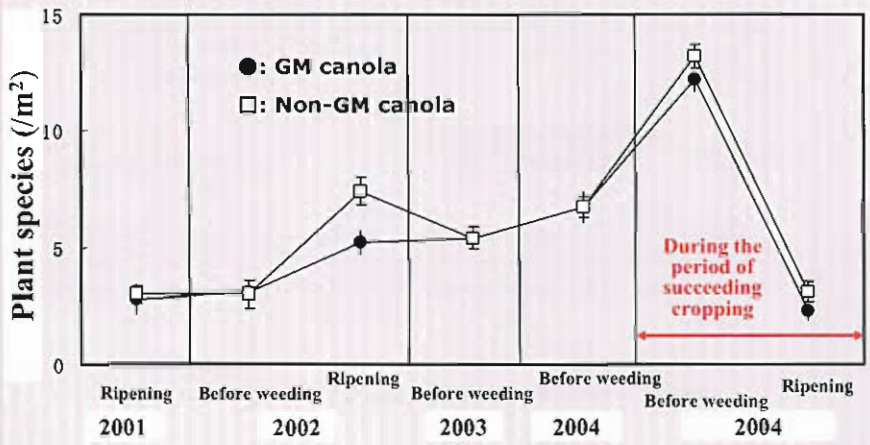
- Crops: Maize, Soybean, Rice, Canola
- Organizations: NARO(3) & NIAES
- Period: 5 cropping seasons (2001-2006)





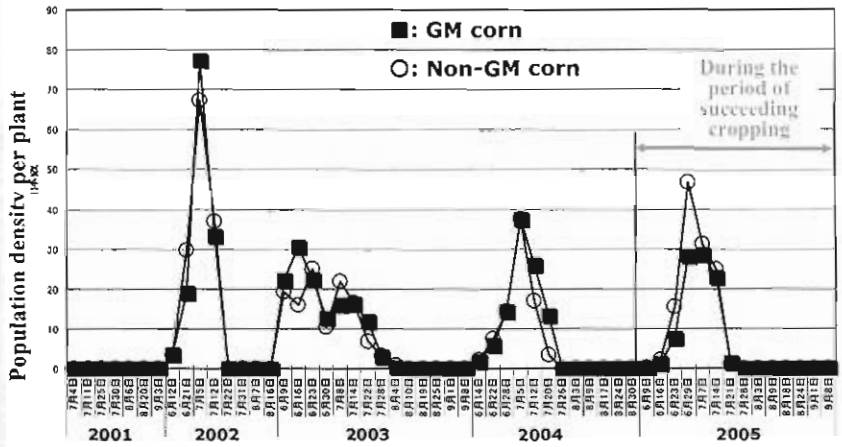
Soybean

Plant species appeared in canola monitoring field



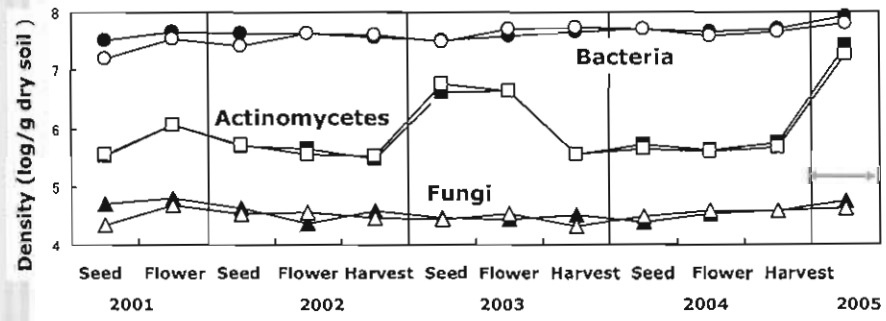
Note: Succeeding crop in 2005 was soybean.

Population density of *Anaphothrips obscurus* (クサキイロアザミウマ) in corn monitoring field



Note: Succeeding crops in 2004 to 2005 was Italian ryegrass and non-Gm corn.

Density of soil microorganisms in soybean monitoring field



Note: succeeding crop in 2005 was wheat.

Pollen diffusion & out-crossing with non-GM crops

Large scale monitoring for risk assessment of GM crops

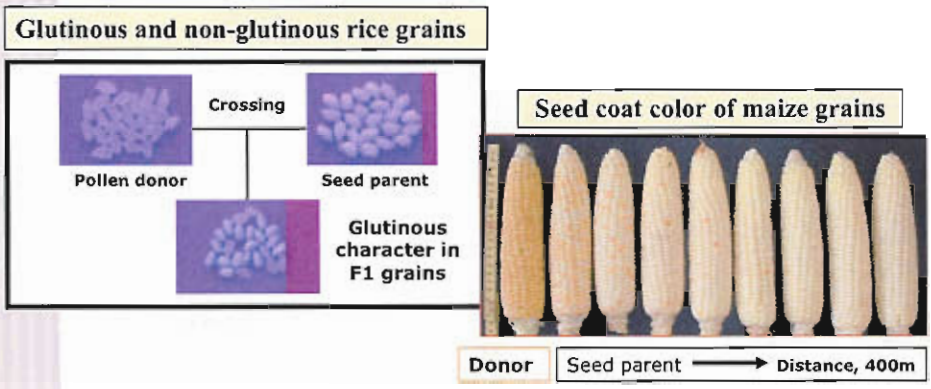
- **Out-crossing**: GM crops hybridize with non-GM crops and wild relatives, and the newly introduced genes introgress into the population.
  "To analyze the phenomena, a long-term and large scale monitoring are required"
  /Simulation
  /Pollen diffusion & out-crossing
  /Population dynamics of hybrid progeny

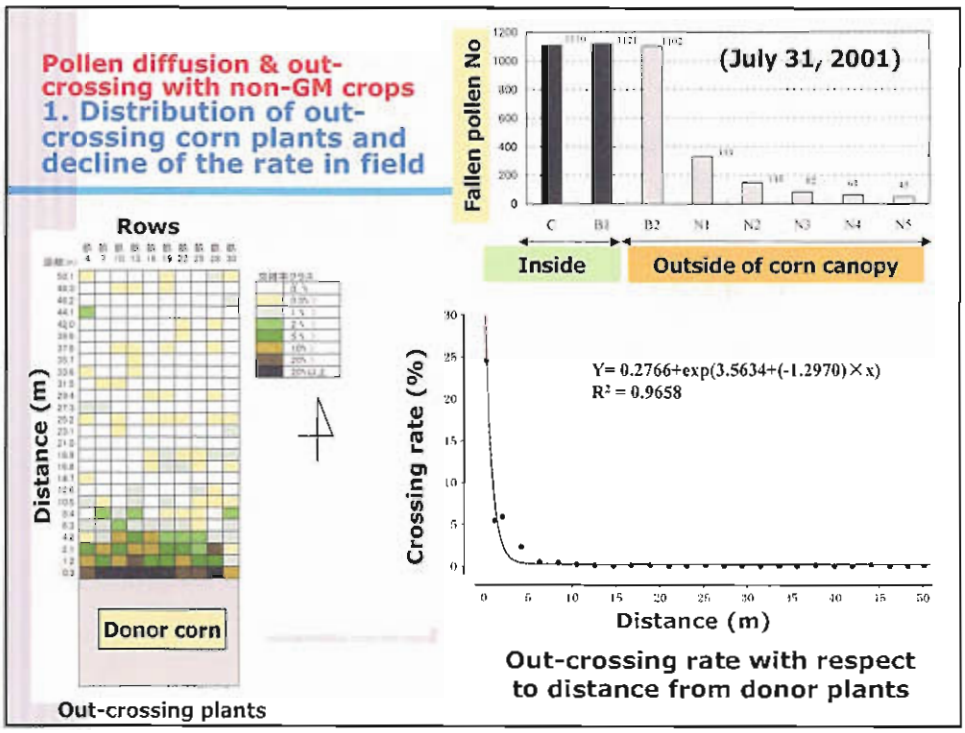
  "Implementation of empirical experiments for the quantitative evaluation of the results obtained"

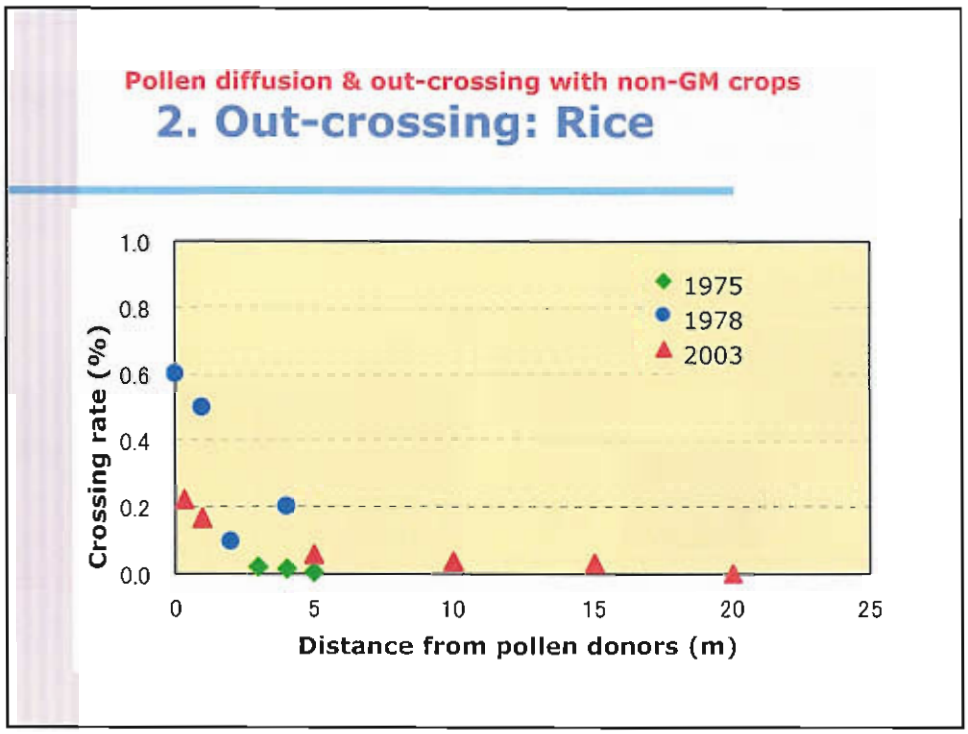
- **The dilemma**: The large scale monitoring experiments using GM crops are indispensable before their commercial use, while the environmental risk assessments of GM crops are also indispensable for the large scale monitoring experiments.

Natural out crossing and Co-existence

Estimation of natural out-crossing using "xenia" expressed in the endosperm characteristics

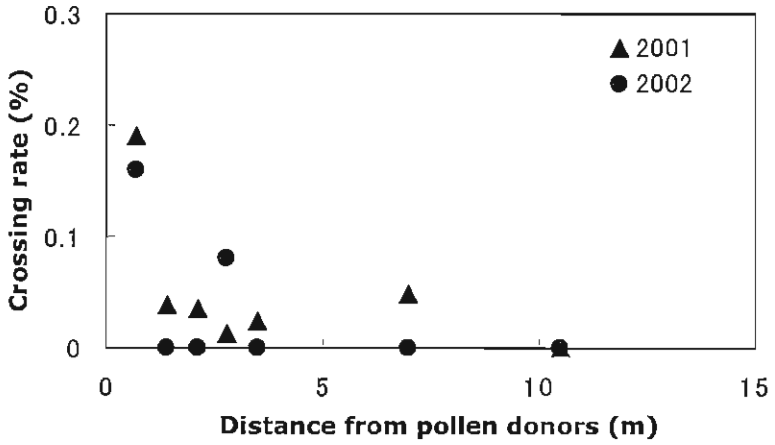



Pollen diffusion & out-crossing with non-GM crops
1. Distribution of out-crossing corn plants and decline of the rate in field
Rows
Distance (m)
Donor corn
Out-crossing plants
Fallen pollen No
(July 31, 2001)
C
B1
B2
N1
N2
N3
N4
N5
Inside
Outside of corn canopy
Crossing rate (%)
Y= 0.2766+exp(3.5634+(-1.2970)×x)
R² = 0.9658
Distance (m)
Out-crossing rate with respect to distance from donor plants


Pollen diffusion & out-crossing with non-GM crops
2. Out-crossing: Rice
Crossing rate (%)
1.0
0.8
0.6
0.4
0.2
0.0
1975
1978
2003
0
5
10
15
20
25
Distance from pollen donors (m)

Pollen diffusion & out-crossing with non-GM crops

3. Out-crossing: Soybean



NIAES, 2001 & 2002

"Risk communication"

Visit of the citizens to GM crop fields & mutual communication

Explanation of experimental design for residents at NIAES, 3 June 2006

Long-term monitoring field of GM soybean in summer season

アンケート

御所属＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿

お名前＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿

1．　本日の講演の内容について　　難しすぎる　＿＿＿
　　　　　　　　　　　　　　　　ちょうど良い　＿＿＿
　　　　　　　　　　　　　　　　簡単　＿＿＿

2.　会場の設営について　　聞きづらかった　＿＿＿
　　　　　　　　　　　　　見づらかった　＿＿＿
　　　　　　　　　　　　　ちょうど良かった　＿＿＿

3.　本日の講演に対してご意見、ご感想をお願いいたします。

4.　本日の座談会についてご意見、ご感想をお願いいたします。

5．その他、お気づきの点がございましたらお書きください。

どうもありがとうございました。ILSI Japan
CBI Japan

アンケートの集計結果（回収率38%）

1. 講演内容	簡単	1	5%
	ちょうど良い	14	70%
	難しすぎる	5	25%
2. 会場の設営	ちょうど良かっ	18	86%
	聞きづらかった	3	14%
	見づらかった	0	0%

3. 講演の意見・感想（概要）
○米国、EU、日本、企業の実状が聞けて有意義だった（意見多数）。
○基本的な考え方についてよく理解できた。
○GMOを実用化を目指すにはどのようなことが求められるか、詳しくわかった。
○通訳のおかげでよく理解できた。
○企業が行っているリスク評価の具体的な話がもう少しあるとよかった。
○概念的な話が多かったので、具体的な話がききたかった。
○和訳された資料が欲しかった。

4. 座談会の意見・感想（概要）
○実際上の問題についての各演者の意見がよくわかり、とても有意義だった（意見多数）。
○こぼれ落ちナタネの話が興味深かった（意見多数）。
○上手に進行、まとめられた。
○良い企画であった。
○同時通訳の方がとても上手で内容がよく理解できありがたかったです。
○生物多様性の評価の仕方が依然として明確にならないのが残念。難しい問題といえる。

5.その他（概要）
○今後もGMOの理解を深めるためにもGMOに関するワークショップを企画して頂きたい。
○大変密度の高い有意義な時間をありがとうございました
○座談会に同時通訳がついたのは大変ありがたかった。
○もう少し広い会場の方がよかった。
○国としての科学的リスク評価を進めて、国民の理解が得られるようにして戴きたい。

遺伝子組換え植物の生物多様性影響評価に関する国際ワークショップ報告

国際ワークショップ・タスクフォース

要　旨

遺伝子組換え作物が初めて商品化されてから既に10年以上が経過した。遺伝子組換え作物の商業利用は、事前にリスク評価を経るシステムのもとで進められてきた。その結果、雑草化や近縁野生種との交雑などによって環境への悪影響が生じたという例は、これまでに確認されていない。また、同時に、この10年間の経験や実績により多くの知見やノウハウが蓄積された。これらを整理し検討することは、科学的で国際的整合性のとれた、より信頼性のあるシステムを構築していくためにも意義のあることと考える。

本ワークショップは、国内外よりリスク評価研究の専門家を招き、交流の場を設定するとともに、リスク評価に関与する各方面への情報発信の場とすることを目的として企画された。当日は、大学や国の研究者、行政、地方自治体、企業など多方面から多くの参加者を得ることができ、講演会および座談会では、今後の遺伝子組換え植物の生物多様性影響評価のあり方を含めた活発な意見交換が行われた。

本稿では、招待演者の講演内容や出席者の感想を取りまとめるとともに、座談会について、(1)これまでの環境リスク評価による経験、(2)米国・EU・日本の環境リスク評価における共通性、(3)今後の商業栽培について、の3つの観点から討議をまとめた。私たちは、今後、本ワークショップを元に、より発展させた企画を提供したいと考えている。

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<Summary>

We have had experienced for more than 10 years to study Genetically Modified Organisms (GMO) from many aspects since commercialization of GMO. These results have demonstrated less concern of GMO based upon science world widely. However, in terms of risk assessment of environment and biodiversity all countries do not necessarily make concert together and do not harmonize well enough. Therefore, we believe that it is very useful to discuss what risk assessment is made and how to manage the risk assessment for environment. Based upon the scientific research so far, now we may tell what we know and what we do not. A sort of harmonization in terms of risk assessment of environment must be critical. Through the discussion among the stakeholder such as researchers, regulators and industry people worldwidely, we would like to find the best way for the assessment based upon science.

For this purpose we had held the "International Workshop on Environmental Risk Assessment / Biodiversity Assessment of GMO" at Tokyo Metropolitan Art Place on July 27th. In addition to Japanese opinion leaders, we invited 3 speakers from overseas for introducing the situation of US and EU. We had 5 speakers' presentations first and then the

International Workshop on Environmental Risk Assessment / Biodiversity Assessment of Genetically Modified Organisms

Members of ILSI International Workshop Task Force

round table discussion together with the other invited Japanese experts on environmental risk assessment.

Invited Speakers and their presentations:

1) Jeff Wolt (Professor, Iowa State University, USA)
   Evaluating the consequences of environmental release of genetically engineered crops using principles of ecological risk assessment
2) Jeremy Sweet (Vice chairman, Europe Food Safety Authority, UK)
   Environmental risk assessment and post market monitoring: the European approach
3) Thomas Nickson (Chairman, Risk Assessment of Global Industry Coalition, USA)
   Ecological risk assessment for crops derived through modern biotechnology
4) Kentaro Kawaguchi (Assistant Director, Agriculture, Forestry and Fisheries, Research Council, MAFF)
   Impact assessment of genetically modified crops upon biological diversity under regulatory framework in Japan
5) Mitsunori Oka (Principal Research Coordinator, National Institute for Agro-Environmental Sciences)
   Environmental risk assessment of genetically modified crops

Round Table Participants:

T. Nickson, J. Wolt, J. Sweet, K. Kawaguchi, M. Oka, E. Shinmoto (Counselor, Plant Products Safety Division, MAFF) , K. Hayashi (Senior Advisor, Society for Techno-innovation of Agriculture, Forestry and Fisheries) , Y. Yogo (Unit leader of Environment Pesticide Assessment, National Institute for Agro-Environmental Sciences), K. Wakasa (Professor of Tokyo Agri. Univ.)

We had more than 80 attendants from variety of fields such as universities, national institutes, administration, local governments, and private companies. We believe that this workshop could give them a good opportunity to notify and to discuss the environmental risk assessment based upon sciences. We hope that this workshop will lead to the further discussion on the environmental risk assessment based upon sciences in Japan.

International Life Sciences Institute of Japan (ILSI Japan):
http://www.ilsijapan.org/
Council for Biotechnology International Japan (CBIJ):
http://www.cbijapan.com/

1. はじめに

遺伝子組換え作物が初めて商品化されてから既に10年以上が経過した。遺伝子組換え作物の商業利用は、食品や飼料としての安全性はもちろん、環境に対する安全性についても事前にリスク評価を経るシステムのもとで進められてきた。その結果、雑草化や近縁野生種との交雑などによって環境への悪影響が生じたという例は、これまでに確認されていない。

同時に、この10年間の経験や実績、世界各地で進められてきた環境影響に関する研究成果により、多くの知見やノウハウが蓄積された。それらを改めて整理し検討することは、この分野の研究のさらなる発展のために重要な取り組みであり、科学的で国際的整合性のとれたより信頼性のあるシステムを構築していくためにも意義のあることと考える。

本ワークショップは、国内外よりリスク評価研究の専門家を招き、交流の場を設定するとともに、リスク評価に関与する各方面への情報発信の場とすることを目的とした。当日は、大学や国の研究者、行政、地方自治体、企業など多方面から多くの参加者を得ることができ、講演会および座談会では、今後の遺伝子組換え植物の生物多様性影響評価のあり方を含めた活発な意見交換が行われた。その概要を紹介する。

＜遺伝子組換え植物の生物多様性影響評価に関する国際ワークショップ＞

主　催：日本国際生命科学協会（International Life Science Institute Japan）
協　賛：バイテク情報普及会（Council for Biotechnology Information Japan）
開催日：平成18年7月27日
会　場：東京芸術劇場5F中会議室
参加者：84人

プログラム

10:00-10:10	はじめに（ILSI Japanの活動について） 木村 修一（ILSI Japan 理事長）
10:10-11:10	Evaluating the consequences of environmental release of genetically engineered crops using principles of ecological risk assessment Jeffrey Wolt (Professor, Iowa State University, USA)
11:10-12:10	Environmental risk assessment and post market monitoring : the European approach Jeremy Sweet (Vice chair, Europe Food Safety Authority (EFSA), UK)
12:10-13:20	休憩
13:20-14:20	Ecological risk assessment for crops derived through modern biotechnology Thomas Nickson (Chairman, Risk Assessment of Global Industry Coalition, USA)
14:20-14:40	カルタヘナ法に基づく遺伝子組換え作物の使用規制と生物多様性影響評価 川口 健太郎（農林水産省 農林水産技術会議事務局 技術安全課 国際基準専門官）
14:40-15:00	遺伝子組換え作物の環境影響評価 岡 三徳（独立行政法人農業環境技術研究所研究 コーディネーター）
15:00-15:30	休憩
15:30-17:30	座談会 出席者（アルファベット順） 林 健一（社団法人農林水産先端技術産業振興センター 常任顧問） 川口 健太郎 Thomas Nickson 岡 三徳 新本 英二（農林水産省 消費安全局 調査官） Jeremy Sweet 若狭 暁（東京農業大学 教授） Jeffrey Wolt（※座長） 與語 靖洋（独立行政法人農業環境技術研究所 有機化学物質研究領域長）

2. 講演の概要

80名以上の出席者があった講演会の様子
A sight of the lecture (More than 80 people attended)

図1　リスク評価プロセスの模式図（Wolt氏のスライドより）
Figure 1　Schematic figure of the risk assessment process

(1) Jeffrey Wolt氏

【略歴】農業における新技術のリスク評価の研究者で、環境および環境毒物のリスク評価の研究や、土壌化学と環境化学を応用した環境モニタリング・環境毒物・環境消長の研究に携わっている。

【講演内容】

米国における環境リスク評価やリスク管理について講演した。

米国では、リスク評価やリスク管理がバイオテクノロジーの進展や遺伝子組換え作物の実用化を妨げることなく機能しており、その成功の理由として、次のような点が挙げられる。第一に、米国には既に、環境リスク評価（ERA）の分野において25年以上にわたる取り組みの実績がある点である。その豊富な経験の蓄積により、環境リスクがハザード（悪影響を与える形質）とエクスポージャー（暴露量）によって定量的に表わされることを規制当局はよく認識している。その原則を遺伝子組換え作物の環境リスク評価にも応用して、どのようなプロセスをとるべきか判断し、作物の特性に応じたケース・バイ・ケース（個別事例ごと）の評価に非常に柔軟に対応できている（図1）。

もう一つ重要な点は、優先課題の順位づけを明確にした上でのリスク管理を行っていることである。リスク評価の結果に基づいた順位づけにより、広範な懸念要因の中から、環境に対して大きな影響を与えかねないようなリスクの高い要因に焦点をあてることができる。個人レベルの懸念は数多くあるが、所管当局は、環境放出による安全性の観点から規制の対象とすべき懸念のみに集中する必要がある。

(2) Jeremy Sweet氏

【略歴】European Commission、Danish parliament、UK government、FAOなどのアドバイザーを務める。組換え作物のリスク評価、特に環境および農業への影響とジーンフローの研究者で、除草剤耐性ナタネおよびテンサイの輪作におけるマネージメントおよび影響に関するUK BRIGHTプロジェクトのコーディネーターや、組換え作物の影響評価に関するEuropean Science Foundation（ESF：欧州科学財団）プログラムのコーディネーターを務めた経験も持つ。

【講演内容】

EUにおける環境リスク評価やリスク管理について講演した。

米国と同様に、EUで採用されている環境リスク評価も、ケース・バイ・ケースによる検討を伴う包括的アプローチにより段階的に実施している（Two-step procedure）。第一段階で、遺伝子組換え作物と非組換え作物とを比較した際の相違点を確定し、第二段階で、その確定された相違点に関して環境に対する影響を評価する。評価で求められるコアデータ（中心となるデータ）には、米国におけるリスク評価との共通性が数多くみられる（図2）。

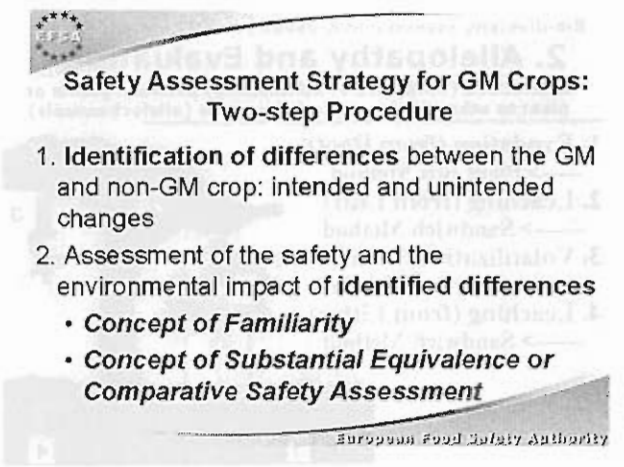


図2　段階的な環境リスク評価法（Sweet氏のスライドより）
Figure 2　Safety assessment strategy for GM crops: two-step procedure

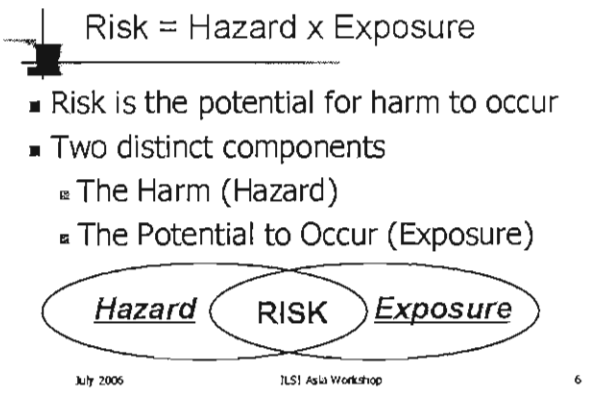


図3　リスクの定義（Nickson氏のスライドより）
Figure 3　Definition of risk

また、EU指令に基づいて実施されている承認取得後の環境モニタリングには二種類あり、一つ目はリスク評価の結果に基づき想定された仮説に対応することを目的とした個別のモニタリング、二つ目は予期せぬ影響の発見を目的とした一般的なモニタリングである。リスク評価には必ず不確実性が伴うものである。不確実性には、承認取得後にモニタリングを実施することで対応し、新たな知見があればリスク評価を見直すという論理的なアプローチをとっている。

その他、スペインにおける遺伝子組換え農作物の商業栽培により得られた知見とともに、その成功事例がEU諸国に波及しつつある現状も紹介した。

(3) Thomas Nickson氏

【略歴】遺伝子組換え作物の環境リスク評価の原則について、14年間遺伝子組換え作物の研究に携わり、環境リスク評価モデルの改善や評価プロセスの国際的調和を図る活動を行っている。米国モンサント・カンパニー、Ecological Technology Center のディレクター。Risk Assessment of Global Industry Coalitionの議長を務める。

【講演内容】

遺伝子組換え作物の環境リスク評価の原則について講演した。(図3)

環境リスクは、ハザードとエクスポージャーによって決まり、環境リスク評価の原則は5項目に要約できる。第一に科学的根拠に基づくこと、第二にケース・バイ・ケースで実施すること、第三に既存物質のリスクの度合いとの比較により評価すること、第四に新たな知見が得られればリスク評価を見直して反映させること、第五として、以上四項目の結果から得られたすべての情報を盛り込むこと、である。

環境リスク評価の際には、ハザードやエクスポージャーに関する情報をはじめとして、文献や分析結果から得られたすべての情報を総合的に検討する必要があるが、同時に、「適切」かつ「比例相対的」であることが重要である。「適切」とは、作物の種類や形質、使用方法に対応することである。「比例相対的」とは、例えばエクスポージャーは、商業栽培（大規模）、輸入や加工、隔離圃場試験栽培（小規模）とでは当然異なるので、コアデータの要件も比例して異なる、というものである。

さらに、毒性試験や発芽テストのような制御された環境下で行われる試験のデータは、他の地域における環境リスク評価の際にも適用可能であり、それによってより合理的な評価ができる。

(4) 川口　健太郎氏

【略歴】農林水産省農林水産技術会議事務局技術安全課の国際基準専門官。バイオセーフティに関するカルタヘナ法の下での第一種使用規程承認申請に係わる生物多様性影響評価検討会および第二種使用規程承認申請に係わる拡散防止措置確認会議の事務局を務める。

【講演内容】

カルタヘナ法に基づく日本の環境リスク評価と規制の現状について紹介した。

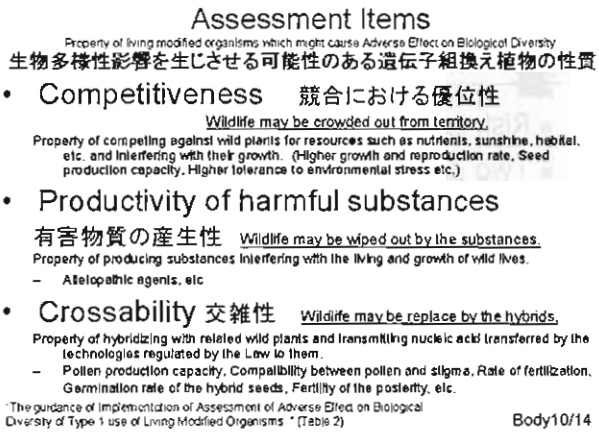


図4　日本における重要な評価項目（川口氏のスライドより）
Figure 4　Key items for assessment in Japan

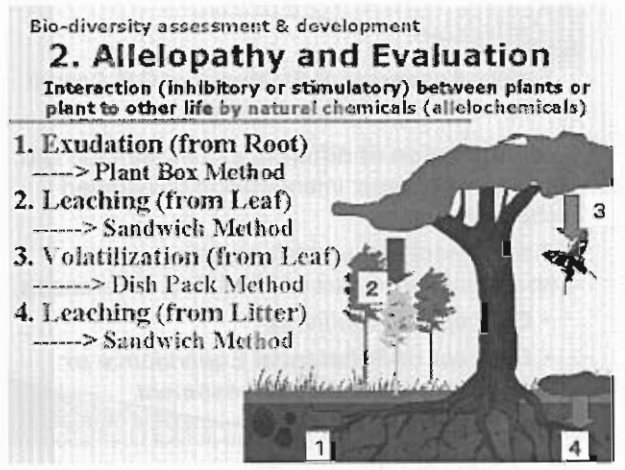


図5　アレロパシーとその評価方法（岡氏のスライドより）
Figure 5　Allelopathy and evaluation

日本は2003年9月11日に国際発効した「生物の多様性に関する条約のバイオセーフティに関するカルタヘナ議定書」の批准国として、生物多様性への影響という観点で規制の枠組みを整備し、2004年2月19日に「遺伝子組換え生物等の使用等の規制による生物の多様性の確保に関する法律（カルタヘナ法）」を施行した。

カルタヘナ法の概念は、米国やEUと同様の原則に立ち、科学的根拠に基づき、ファミリアリティを基盤とした個別製品ベース、ケース・バイ・ケース、スッテプ・バイ・ステップ方式を採用している。はじめに遺伝子組換え作物の使用形態に応じて、環境中への拡散防止措置をとらない第一種使用と、環境中への拡散を防止して使用する第二種使用とに分け、それぞれに対応した環境リスク評価を行っている。生物多様性影響を生じさせる可能性のある遺伝子組換え植物の性質として、「競合における優位性」「有害物質の産生性」「近縁野生種との交雑性」を重要な評価項目としている（図4）。

(5) 岡　三徳氏

【略歴】独立行政法人農業環境技術研究所研究コーディネーター。農業生態系における生物多様性や組換え生物などに関わる生物環境研究の推進と調整を担当し、組換え生物の環境影響評価手法の開発や標準化に携わってきた。

【講演内容】

日本における遺伝子組換え作物の環境リスク評価について紹介した。

日本の承認申請時に必要な評価項目のうち、他国と比較して特徴的なものは微生物の多様性への影響に関する研究である。この試験は、根や葉などから分泌される物質によって、他の動植物のみならず微生物の多様性に影響を与える可能性、特に根の滲出物の影響について評価することを目的に実施される（図5）。

その他、日本でこれまでに行われた生物多様性影響に関する研究成果として、組換え作物の長期モニタリング試験や遺伝子組換えダイズと野生種ツルマメとの交雑性に関する調査研究などを発表した。長期モニタリング試験については、5年間にわたり遺伝子組換えトウモロコシ、ダイズ、イネおよびナタネを用いて調査を行ったところ、栽培圃場およびその周辺の生物相への影響は対照の非組換え体と比較して差は認められなかったという結果が紹介された。

3. 座談会での議論

招待演者5名と日本の遺伝子組換え作物に関する専門家4名を交えて、各国で実施されてきた環境リスク評価や管理手法などの報告や現状における問題点、さらに今後の見通しやEUや日本における商業栽培の可能性など活発な情報交換や検討が行われた。その一部をテーマごとに紹介する。

9名の専門家による座談会
Round table discussion by 9 panelists

(1) これまでの環境リスク評価による経験

◆EUの事例① 英国における大規模圃場試験栽培の結果

EUでは長期間にわたって遺伝子組換え作物の環境リスクについて検討を行っており、英国では農場レベルの大規模な試験圃場を使って除草剤耐性遺伝子組換え作物と在来作物との比較調査も実施した。それらの結果から、EUでは現在どのような考え方を持つようになっているのかについてSweet氏より報告された。

環境リスクを減少させるためには承認取得後の適切な管理こそが重要

英国における大規模調査の結果、遺伝子組換え作物の栽培によって生物多様性が減少したケースもあったが、逆に生物多様性の増大がみられたケースもあり、作物種によって影響は異なっていた。また、EU域内の他国との比較においても結果に違いがみられた。例えば、除草剤耐性テンサイの栽培によって英国の試験では生物多様性が減少したが、ドイツ、デンマークおよびフィンランドにおいては生物多様性の増大が観察された。その理由は、国によって栽培方法などが異なるためである。遺伝子組換え作物の環境リスクについてEU域内すべてに適用できるような一般的な結論を出すことは非常に難しいというのが、長年の議論からEUがたどり着いた見解である。

管理手法の研究によって生物多様性の改善に成功

そこでEUでは現在、承認取得後に各国で適切なリスク管理を行うことで対応しようとする方向に変化している。隔離圃場試験などのリスク評価から知り得ることには限界がある。遺伝子組換え作物が、各国でどのように導入管理されるのかという点に注視し、各国の所管当局に管理を委ねるようになっている。

管理手法に着目した研究も進められており、英国では栽培方法の改善によって除草剤耐性テンサイの雑草防除を非常に高い基準で維持しつつ生物多様性を増大させることに成功している。現在では、EUの産業界や生産者さらに環境保護主義者からも、除草剤耐性作物は生物多様性を少なくとも在来作物と同レベルに維持するか、もしくは生物多様性を改善する可能性さえあると評価されるようになってきている。

◆EUの事例② スペインにおける長期モニタリング試験の結果

スペインで実施された長期モニタリングは、参加者の関心が特に高かったトピックスの一つであった。長期モニタリングの概要や結果についてSweet氏から報告された。

6年間にわたる調査で予期せぬ影響は確認されず

スペイン政府は、研究機関や企業と協同でBtトウモロコシなどの数種類のBt作物を対象とした長期モニタリングに取り組み、このたび6年間の調査結果を取りまとめたレポートを公表した。そのレポートでは、昆虫の生息数など環境に対する悪影響は特になかったこと、予期せぬ特別な影響などは一つも見られなかったことが報告された。また、Bt作物の栽培によって、たとえ個体群に一時的な変化がみられてもその変化は畑全体にわたって一貫して起こっているわけではなく、通常の慣行栽培でも生じる変化と同程度であったと報告されている。なお、米国やカナダその他の地域におけるこれまでの長期栽培でも同様の結果が得られている。

◆日本の事例① 隔離圃場試験の見直しの必要性

日本の研究者から、栽培に関する規制が非常に厳しいために、日本では適正な環境の中でリスク評価を実施すること自体が困難な状況であることが問題点として挙げられた。

研究目的の栽培を制限しない環境を求める

現在、日本では遺伝子組換え作物の栽培は、研究所内において小規模にしか実施できないような状況におかれている。しかし、ある程度の規模で栽培しなければ本当の意味での環境リスク評価はできない。研究上の観点から農場レベルでの試験栽培を実施できるような体制づく

りが必要である。将来的には、EUが実施しているように商業的な栽培が行われる中でリスク評価が進められるのが理想的ではないか。

輸入・加工を目的とした遺伝子組換え作物のリスク評価について

日本の隔離圃場試験における環境リスク評価では、ごく少量のこぼれ落ちた種子から遺伝子流動（Gene Flow）が起こるかもしれないという懸念のために、輸入・加工目的であっても栽培目的の認可とほぼ同等の厳しいデータが要求されている現状である。輸入・加工目的の遺伝子組換え作物のエクスポージャーは、栽培目的と比べて小さく環境リスクも比例して低くなる。よって、こぼれ落ちた種子から想定されるリスクをきちんと把握した上で、輸入・加工を目的とする遺伝子組換え作物の試験項目をサイエンス・ベースで見直す必要はないだろうか。

◆日本の事例②　評価項目が増加してきている

実際に日本の隔離圃場試験に携わった日本の研究者からは、日本の環境リスク評価において必要とされるデータの内容は増加している傾向にあり、非常に広範で細部にわたって求められるようになってきているとの感想が述べられた。これに対して、海外の研究者からは下記のような意見が出された。

米国：環境リスク評価のために必要なデータかどうかを明確にすべき

科学者は、自分が知らないことすべてを対象としてたくさんの情報を集めがちであるが、たとえ科学的には有用なデータでもリスク評価においては対象外のデータも多々ある。監督機関やリスクマネジャーは、環境リスク評価の原則を厳守し本当に必要な情報の範囲を明確にして、「試験できるか」ではなく「試験すべきか」という視点で選ぶべきである。

EU：リスクコミュニケーションで取り上げるべき問題とは区別すべき

EUの環境リスク評価担当者の中には、NGOや一部の専門外の研究者から出される意見をリスク評価の専門家の意見と同等に扱うべきであると当然のように考える人もいる。しかし、彼らの意見には作物や環境に関する認識が甘いことに起因するような疑問もあるため、リスク評価において必要な情報かどうかはあくまで科学的に判断すべきである。リスクコミュニケーションにおいては取り上げるべき問題でも、リスク評価においては何が新奇性なのかを見極め、それに焦点をあてた包括的な検討を実施することが大切である。

(2) 米国・EU・日本の環境リスク評価における共通性

◆遺伝子流動について

遺伝子流動そのものはリスクではなく、それによって引き起こされる結果、すなわちエンドポイントが重要であるという点について、日本の参加者をはじめとして一同から賛同の意が表明された。問題は、どのような指標をもって評価すべきかであるとしてEUにおける考え方が紹介された。

保護すべき動植物の有無を明確にして評価する

まず明確にすべきことは、保護対象とするものは何か、影響を受ける動植物が存在するかである。その上で、遺伝子流動によって生じた交雑種などが保護対象とすべき動植物に与える影響を検討するのである。これは、在来作物と比較することによって評価可能である。遺伝子組換えによって変化するのは植物の適応性であり、それは侵襲性や雑草性などに反映されるため実験レベルでの測定も可能である。非標的生物に対する影響に関しては、地域によって保護すべき野生生物の品種が異なるため地域的な評価となる。

◆種子のこぼれ落ち

加工目的で輸入された遺伝子組換え作物が、加工地まで運搬される途中でその一部が偶然にこぼれ落ちることがある。こぼれ落ちた種子について、EUや日本での考え方や対応が報告された。

EU：自生の有無を監視すれば対応できる

こぼれ落ちること自体は問題ではない。問題になり得るとすれば、ヨーロッパで未登録の種子が畑や自然環境に定着して生息すること（自生）であり、EUではそのような未登録の作物が自生しているかどうかを監視している。EUの輸入者は、毎年、加工業者に対して工場周辺などに遺伝子組換え作物が自生していないかアンケートを実施し、加工業者と共同でモニタリングに取り組むシステムを構築している。

また、EUでは、リスク評価の段階で作物の特徴（例えば、種子の大きさ）や港から加工場所までの輸送経路に関する情報などを収集した上でこぼれ落ちや自生の可能性を勘案し、この問題に対応している。

日本：EUのようなリスク管理による対応も必要ではないか

日本では、こぼれ落ちていること自体が関心事項となっているところに問題がある。こぼれ落ちた結果、本当にそのこぼれ落ちた遺伝子組換え作物が対照となる非組換え体と比べて有意に拡散し環境リスクとなっているのかというエンドポイントをみるべきである。

現実的には、全くこぼさないようにすることは不可能であり、対策としては、EUのように自生の有無を確認するモニタリングやこぼさないようにする管理方法などによる対応を今後は検討すべきであろう。日本でも、加工業者や運送業者などが協力してモニタリングを実施するようになればよいのではないか。

米国：科学的な判断基準を設けて、リスクのレベルに応じて対応する

こぼれ落ちの許容度をゼロとした管理は明らかに非現実的であり、在来作物との同等性や非常に低いエクスポージャーを無視した対応は科学的ではない。

問題とすべきは、こぼれ落ちた少数の個体群の一部が安定的に自生した結果どのようなことが想定されるかであり、科学的な判断基準を設けてそのレベル以上に達したら対策をとるような考え方や政策が欠如している国が多いのではないか。

◆スタックの環境リスク評価について

EUの専門家から、二つの遺伝子組換え品種を掛け合わせて作出した交配種（スタック）の環境リスク評価についてEUにおける考え方が紹介された。

EU：予想外の変化が起こっていないかを確認

スタックは、既に親株系統において個別に安全性が確認されているため、その時点で基本的なリスク評価は終わっていると考える。したがって、複数の形質を組み合わせた際の影響に重点をおいてリスク評価を行えばいいのである。そこで重要となるのが、スタックが親株系統から推測されるような動態を示しているかどうかである。仮に遺伝子の変化や発現の増大がみられても、その原因を調べてリスク評価を実施すればよく、EFSAでは最近、この評価アプローチについてのガイドライン（草稿）を公表したところである。また、遺伝子の発現が増大したとしても、その発現の差が親系統のリスク評価の結論を変えるものでなければ、安全性の評価という観点からは意味を持たないものである。

この考え方は、野生植物との交雑種にも適用でき、個々の遺伝子について評価し予想以上に適応性や競合性が高まっていないかを評価することが基本である。

◆生物多様性に対する考え方

以上のように、日本、米国およびEUにおける環境リスク評価には多くの共通認識がみられることが確認されたが、相違点としては、日本では生物多様性影響という考え方を取り入れ、カルタヘナ法に基づいたリスク評価を行っていることが挙げられる。そこで、EUと米国の専門家に、生物多様性影響に関する見解や日本のプロセスに対する意見を聞いた。

EU：現状では生物多様性影響の計測は困難

生物多様性に関するEU指令はあるものの、EUでは現在、生物多様性影響にそれほど関心を向けていない。生物多様性影響を計測することは非常に困難であること、そもそも野生生物は種を変動する傾向があること、長期的影響を調べようにも、比較対照とする基礎データが非常に少なくかつ正確ではないことなどが問題点としてあげられる。

遺伝子組換え作物を導入して栽培体系が変化すれば、野生生物の均衡バランスに影響が出るのは避けられない現象であるが、それが生物多様性へのリスクとなるのかを把握することはとても難しい。環境リスク評価において実施可能なことは、本日かなり広範囲にわたって議論されたようなより明白な影響を探すことであろう。

米国：生物多様性影響を組み入れたとしても、原則は変わらない

生物多様性については、現状ではまだ計測や評価の方法が確立されておらず、基本的な情報を入手するまでにはもう少し時間がかかるであろう。

日本の評価方法が、段階的なプロセスでまとめようとしているのは、理論的には合理的なアプローチである。生物多様性影響という観点を組み入れた評価においても、ハザードは何であるかを明確にして、エクスポージャーの程度に対応した環境リスク評価を行うことが原点であることを忘れてはならない。

(3) 今後の商業栽培について

◆EUは既に、遺伝子組換え作物の商業栽培に向けて前進している

遺伝子組換え作物に対して慎重な対応を見せていた

EUだが、2005年にフランスやポルトガルで遺伝子組換えトウモロコシの栽培が再開されるなど、新たな動きがみられる。その理由についてSweet氏は、先行して遺伝子組換えトウモロコシを栽培してきたスペインでの成功事例が与えた影響が大きいのではないかとの見解を述べた。

スペインの成功事例からEU諸国は栽培に向けて前進

スペインでは現在、約40,000ヘクタールで害虫抵抗性Btトウモロコシを栽培しているが、これまでの環境モニタリングの結果、有害な影響は観察されず全般的に良好だった。同時に、在来品種との交雑もほとんどみられず、共存に関する問題も特に発生していない。このスペインでの栽培経験を基に、他のEU諸国も自信を持って先へ進むようになってきており、今年はフランスで約6,000ヘクタール、ドイツで約8,000～9,000ヘクタールの商業栽培を実施し、ポルトガルでも試験的な栽培を実施する見込みである。その他にも数か国でBtトウモロコシを栽培するプログラムが開始されている。

現在、試験栽培に取り組んでいるEU諸国においても、特定の範囲の生産者が常時監視しながら段階的に栽培が始まるであろう。特に、遺伝子組換え作物の栽培が利益になり得る地域では、導入に向かって行くと思われる。

◆日本における商業栽培への期待

会場から、日本における今後の遺伝子組換え作物の商業栽培の可能性や、実用化に向けた開発の取り組みについて質問があり、日本の参加者がそれぞれの考えを述べた。

国内商業栽培に向けた政策努力の実施

日本において環境に対する安全性、食品・飼料としての安全性がすべて承認された遺伝子組換え作物は既にあり、法的に日本でも商業栽培ができる状況になっている。日本の生産者の中には、事実として遺伝子組換え作物を栽培したいという意向を持つ農家もいる。農林水産省としても、農業政策の一環として遺伝子組換え技術を用いた品種改良に予算を充て、農家に遺伝子組換え作物の栽培メリットをアピールできるような品種の開発に取り組んでいるところであり、日本においても、遺伝子組換え作物の商業栽培が一つの手法となるように政策努力を行っている。

安全性に関する取り組みはもちろん大切だが、消費者が買いたいと思うような新品種の開発も重要であり、安全性と有用性を消費者自身が判断して選択できるような環境にすることが大切ではないか。

遺伝子組換え作物の共存法の整備

遺伝子組換え作物を商業栽培したいという意向を持っている農家が、周辺の有機栽培や慣行栽培を行う農家と差別されることなく栽培できるような条件を、日本でも早急に整えるべきである。EUをはじめ他の多くの国では、遺伝子組換え作物も他の作物と公平に扱わなければならないという義務を感じ、共存のための制度を整えるようになっている。日本でも政策として共存法の整備を進めてほしい。

最後に座長より、長時間にわたり活発な議論を展開したパネリストと参加者に対する感謝の意が表され、今後もこのような意見交換の場を継続して持つことが確認された。

4. 終わりに

先にも述べたように、当日は予想を上回る80名以上の参加者があり、この中で、意見交換の場を提供するという、本ワークショップの当初の目的を充分果たすことができたのではないかと考えている。今回は、ILSI Japanにとっても、環境というテーマに初めて取り組んだ記念碑的なワークショップとなった。私たちは、今後とも、この灯火を消さぬよう、さらに良い企画を提供していきたいと考えている。

5. 出席者の感想

最後に、座談会の出席者から感想をいただいたので紹介する。

林　健一氏

米国、ECおよび日本から、背景と専門が異なる様々なメンバーによるpresentationおよび討議がなされ、大変有益でした。参加する機会をいただきましたことを御礼申し上げます。

米国とECの両極を含む国際的動向の中で、日本が今後、取るべき方向を裏付ける科学的根拠を構築し、バイテク成果の具体化を進めることが重要と思われます。

川口　健太郎氏

遺伝子組換え生物の環境に与える影響評価は世界各国で行われているが、それぞれの評価の方法およびそれを規定している規制の枠組みは、大まかには類似しているものの国ごとに特色がある。これは、影響を受ける側の環境が地域によってバラエティーに富むことに加え、各国独自の歴史、文化、経済的条件があることも大きな要因であろう。したがって、国境を意識することなく現代のバイオテクノロジーの恩恵に浴するためには、国際的に統一された基準の制定が望まれるものの、上述したような背景があることから、各国の独自性を認めつつその調和を図ることが課題とされている。

農業は、人間による総合活動であり、そこで調和を図るためには人と人とのコミュニケーションが重要な鍵となる。講演では、日本のカルタヘナ法に基づく遺伝子組換え作物の使用規制と生物多様性影響評価について紹介したが、我が国はもとより、他国で安全性評価に取り組んでおられる方々に、日本での規制の枠組みを深く理解していただくきっかけとなったことを願っている。また、パネルではポイントを押さえて各自興味のあるトピックが議論できたことも有意義だった。

最後になりましたが、このような交流を深める場を設定し、運営に当たられた事務局の方々のご努力に感謝いたします。

Thomas Nickson氏

I would summarize my talk by saying:

"Environmental risk assessment for GM crops is well established both scientifically and procedurally. The general principles agreed to around the world are that the risk assessment should be science based, comparative, iterative and inclusive of all information. The challenge for regulators is to determine what information is necessary for decision making and what information would be more academic (nice to know). Efforts to harmonize risk assessments start with the conseusus principles unentioned, but public is essential when deciding between reasonable or acceptable risk and the need for more information"

I would summarize the panel discussion as:

"It was good to hear about the general level of comfort that Japanese scientist have with biotechnology overall. There was no strong feeling that the technology or the current products pose unreasonable risks to the Japanese public or environment. Much work now needs to be done to build acceptance in Japan for the current and future products. This will require scientists being informed with the high quality, credible information that must come from both industry and government scientists."

Jeremy Sweet氏

I thought the whole workshop was planned very well and it was good to have the issues discussed in the round table. I think it was good to ask people to write comments and then collate the questions so that the main issues and concerns could be considered and different views compared. This allowed people from regulatory organizations to freely express their concerns and difficulties and allowed every one an equal opportunity. The list of questions and issues was good and covered a wide perspective. The discussions were good and constructive. The workshop was well coordinated by Jeff Wolt.

若狭　暁氏

遺伝子組換え植物の生物多様性影響評価に関する実際の取り組みは、遺伝子組換え植物の研究者にとっては非常に労力と時間のかかるものとなっている。今回のワークショップは、遺伝子の機能を明らかにすることのみに興味がとらわれがちな研究者にとって、研究のスタートから最終的なマーケットまでを視野に入れて多様性評価の実験を含む多くの評価実験を設定する必要のあることが明確に示された点は印象深い。しかし、研究者個人ですべてを網羅することはできないので、複数の専門家によるチームでの取り組みが、研究の初期から可能であるようなシステムが必要であると認識を新たにした。

Jeffrey Wolt氏

The presentations and discussion of regulatory approaches to ecological risk assessments (ERA) in Japan, the European Union, and the United States showed numerous similarities in terms of the types of data used for determinations of environmental safety. Common principles of ERA, which were elaborated in the

roundtable discussion, are a science-based approach, comparison of the GM plant to its non-GM counterparts, use of case-by-case determinations, comprehensive consideration of all relevant data, and consideration of real world exposure scenarios. Despite these similarities, there remain large differences in the timing of data and assessments. For instance, in Japan, a comprehensive ERA is conducted for importation, whereas in the EU and USA the comprehensive ERA is conducted for commercialization. Additionally, Japanese authorities do require certain studies that are uncommon in other regions of the world. Regulators in Japan have put deep thought into the assessment needs for LMOs under the Convention for Biodiversity, but must yet arrive at a pragmatic approach regarding the amount of detailed studies necessary to meet obligations under the CBD.

與語　靖洋氏

今回のように公開で国際ワークショップを開催したことは、我が国における遺伝子組換え植物の生物多様性への影響を中心としたリスク評価やリスク管理について、今後さらに議論を深め、発展させるために、とてもよい機会であったと考える。しかしながら、座談会も含めて欧米からの情報提供の割合が大きく、議論の時間も限られていたことから、情報交換という観点では、若干物足りないものがあったことは否めない。

遺伝子組換え植物については、モニタリングの位置づけと具体的方法、体内で産生される化学物質の環境中消失や環境毒性、バイオインフォマティクス活用の可能性など、また生物多様性との関連からは、非組換え作物が持つ多様性への影響、農耕地と周辺生態系における多様性保全の違い、長期栽培の影響など、課題が山積している。

我が国における作物の栽培環境や自然環境は欧米とは異なる部分が多く、また遺伝子組換え植物に対する考え方やニーズも異なるであろう。その意味で、これらの課題に対して、リスクーベネフィットの考え方を導入しつつ、幅広い分野や立場の人々を交えて、国内で充分議論する機会を作ることが強く望まれる。

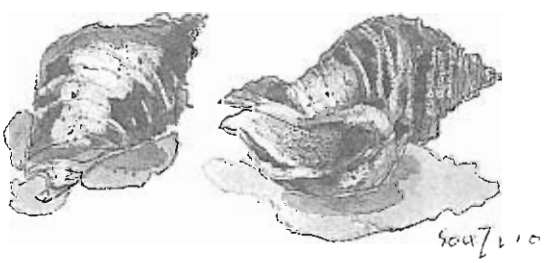
岡　三徳　氏

組換え生物を対象に環境リスク評価の研究をしていると、事象を適切に捉え、評価手法を高度化し、再現性の高いデータを提示することに加えて、社会の理解を得るアウトリーチ活動がいかに重要であるかを痛感する。その研究成果の広範な理解への努力はもちろん、時には圃場試験の実施にさえ多大な事前の努力を払わねばならない。組換え作物のより適正なリスク評価のための圃場試験が、その“事前のリスク評価がない”との矛盾した理由のために、担当者は困難な対話（リスクコミニケーション）を課せられることも多い。私は試験担当者の一人として、社会の理解を得る適正な環境リスク評価のために、カルタヘナ法や組換え作物栽培実験指針を遵守し、周辺住民の理解を得た一般圃場での長期栽培試験（モニタリング）の円滑な実施を望んでいるが、残念ながら現状はまだその段に達していない。多くの市民、行政、そして専門家が参画して、相互の対話や共同作業を通じてアセスメントを行う「参加型試験研究」の実施を想い巡らしているが、これが空想に終わってはならないように思う。

今回、ILSI国際ワークショップに出席して、環境リスク評価に関するTom Nickson氏らの貴重な研究情報に触れただけではなく、ここに参加された組換え作物の可能性や課題を真剣に考える多くの方々との対話や共通理解を深め得たことは、さらに有意義なことであったと考えている。農水省も、全国各地で組換え作物についての双方向型リスクコミニケーションに取り組み始める。今、こうした真剣なアウトリーチ活動を多くの場で積み重ねることが重要である。このためにも、組換え作物の環境リスク評価とそのコミュニケーションには、①組換え技術の大きな可能性が正当に評価されていること、②最新の科学的知見に基づき環境や健康等に与える影響について十分に評価されていること、③消費者の関心や疑問に対して適切に応える必要があること、の３つの基本原則に立ち返った確認と対応が、今後ますます重要となっている。

＊国際ワークショップ・タスクフォース：早川孝彦（デュポン：リーダー）、浅沼陽子（バイエルクロップサイエンス）、笠井美恵子(デュポン)、在田典弘（バイエルクロップサイエンス）、ジョン・ブリーン（ダウ・ケミカル日本)、中井秀一（日本モンサント)、橋本昭栄（社団法人農林水産先端技術産業振興センター(STAFF)）、八田理恵子（シンジェンタ ジャパン)、姫島正樹（ダウ・ケミカル日本)、千川奏（日本モンサント)、山元広海（シンジェンタ ジャパン）

Members of ILSI International Workshop Task Force: Takahiko Hayakawa (DuPont: leader), Yoko Asanuma (Bayer CropScience), Mieko Kasai (DuPont), Norihiro Zaita (Bayer CropScience), John Breen (Dow Chemical Japan), Shuichi Nakai (Monsanto Japan), Shoei Hashimoto (STAFF), Rieko Hatta (Syngenta Jpan), Masaki Himejima (Dow Chemical Japan), Kana Hoshikawa (Monsanto Japan), Hiromi Yamamoto (Syngenta Japan)



＜創立25周年特集＞

ILSI Japan 調査・研究活動の主な成果

バイオテクノロジー研究部会の18年
――情報の収集から普及そして情報の創製へ――

バイオテクノロジー研究部会長
橋本　昭栄

要　旨

ILSI Japanは1988年乳酸菌の遺伝子組換えを検討していた厚生省官民共同プロジェクト「バイオテクノロジー利用乳酸菌の安全性に関する基礎的研究」（粟飯原班）の報告会として「新技術利用発酵食品開発の基礎と社会的評価」国際セミナーを開催した。その成果を生かす形でバイオテクノロジー研究委員会が成立したのは翌年1989年である。爾来、1993年の「バイオ食品―社会的受容に向けて―」国際シンポジウム、1996年のバイオ討論会「歩き始めたバイオ食品」などのシンポジウム開催、「バイオ食品の社会的受容の達成をめざして」、「遺伝子組換え食品を理解する」、「遺伝子組換え食品Q＆A」の発行などの活動を重ねてきた。

第1回コーデックス・バイオテクノロジー応用食品特別部会は千葉市幕張で2000年3月に行われたが、その前日にはFAO/WHOの共催、厚生省ならびにILSI後援による「バイオテクノロジーと食品安全シンポジウム」が行われた。ILSI Japanバイオ部会は事実上の事務局としてこのシンポジウムを運営した。また、その後、ワークショップ「生きた微生物を含む食品への遺伝子組換え技術の応用」の開催、「タンパク質のアレルギー誘発性に関するワークショップ」、「遺伝子組換え作物検知技術国際ワークショップ」、「遺伝子組換えによって栄養改善された食品および飼料の栄養ならびに安全性評価ワークショップ」、「遺伝子組換え植物の生物多様性影響評価に関する国際ワークショップ」の4つの国際ワークショップ開催を通じ、内外の規格基準の策定に貢献してきた。

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<Summary>

ILSI Japan Biotechnology Research Committee was organized in 1989 on the occasion of organizing the International Seminar on Biotechnology.

Since its foundation, the Committee organized many symposia and seminars , and also published several books and reports which advocated domestic modern biotechnology.

In 2000, ILSI Japan contributed to organize successful meeting of the Pre-Codex Symposium on Food Safety and

Major Achievements of ILSI Japan's Study and Research
18 Years of ILSI Japan Biotechnology Research Commitee

SHOEI HASHIMOTO
Chairman
Task Force on Biotechnology
ILSI Japan

Biotechnology in Chiba, Japan.

After then, ILSI Japan Biotechnology Research Committee has continued series of international and domestic symposium in which sciences were discussed to help regulatory framework.

1. 第1期

ILSI Japanバイオテクノロジー研究部会の歴史は、わが国の遺伝子組換え食品の安全性に関する検討の歴史とともにある。1988年、乳酸菌の遺伝子組換えを検討していた厚生省官民共同プロジェクト「バイオテクノロジー利用乳酸菌の安全性に関する基礎的研究」(粟飯原班)の報告会としてセミナーが企画された。しかしながら、セミナー開催母体がなく彷徨えるセミナーとなるところを、ILSI Japanが母体となり開催したというトピックスから歴史は出発する。その成果を生かす形でバイオテクノロジー研究委員会が成立したのは翌年1989年である。将来、実用化が期待されていた遺伝子組換え技術による食料・食品生産の安全性をどのように考えるべきかを調査研究するため、内外の情報を収集するとともに、国際的な視点により評価系の研究を進めてきたが、1990年に開催されたFAO/WHO 合同専門家会議に、高野副部会長らがILSI Japanの専門家として招聘を受け、日本からの出席者としてその調査研究の成果に基づく議論を行った。また、部会はこの機会を生かし、その活動を加速させてきた。

新しい技術の飼料生産への応用が期待されるとして、かつて安全性評価を終えながら、マスメディアと一部消費者による反対キャンペーンによって日本では実用化されなかったシングルセル・プロテイン(いわゆる石油タンパク)というものがあった。安全性評価のあり方を検討する際に、このシングルセル・プロテインについてのケーススタディを行い、このような新技術の発展によってもたらされる消費者製品が、それを最終的に受容する立場の一般消費者にいかに理解され、安心をもって受容され得るかを考えた。

前述の1988年の「**新技術利用発酵食品開発の基礎と社会的評価**」国際セミナーでは、遺伝子組換え技術を利用した食品開発の可能性を学ぶとともに、このような新技術による食品情報を消費者にいかに伝達して理解を得ていくかを議論し、遺伝と遺伝子について触れる、生物学を中心とする啓発および教育が鍵となるとの提言をしている。

1993年バイオ食品国際シンポジウムでのラウンドテーブルディスカッション

1993年の「**バイオ食品―社会的受容に向けて―**」国際シンポジウムでは、既に実用化が始まっていた欧米の事例を学び、安全性評価のあり方、社会的に受け入れられるための望ましい取り組みについて議論した。ここでも、一般消費者が理解を深めるような啓発と教育のためのキャンペーンが必要であり、このような科学についてわかりやすく語るための科学者の役割、理解しやすいように情報を伝達することができるコミュニケーターと広報の必要性が強調された。なお、このシンポジウムでは厚生省「バイオテクノロジー応用食品等の安全性評価に関する研究会」(大谷班)の検討成果も議論され、最終の報告書へと生かされ、わが国の指針策定に貢献した。

一方、ILSI本部は1988年に米国バイオテクノロジー協会(American Biotechnology Association, ABA)と共同で国際食品バイオテクノロジー評議会(International Food Biotechnology Council, IFBC)を設立し、幅広い研究開発の経験と膨大な科学情報をもとに、「導入された遺伝子の特性が充分解明されており、起源となった食品と実質的に同程度に無害であるという科学的な確信が持てる場合には、その組換え体の安全性は起源食品と同等

と考えられる」とする概念をまとめた。この概念をまとめるに際して、IFBCは調査研究の結果を論文として公表、日本を含む13か国以上の関連諸国、150名以上の科学者との検討を行い、国際的なコンセンサスを得た。なお、当時検討し、注釈を加えたコピーは今もILSI Japanの書庫に眠っている。

遺伝子組換え食品の成分とその遺伝子組換え食品に対応する従来食品の成分の間に、等価性があることを前提として安全性評価を進めるとの提案は、その後のFAO/WHO、経済協力開発機構（Organization for Economic Co-operation and Development, OECD）、欧州連合（European Union, EU）、東南アジア諸国連合（Association of Southeast Asian Nations, ASEAN）ならびにわが国はじめ各国での基本方針の構築における手がかりとなった。なお、部会は本論文を日本語に翻訳し、その考え方を日本に紹介した。その結果、この報告書はその後の日本におけるコンセンサス構築のための会議等のテキストとして役立った。またこの考え方は、2000年から始まったコーデックス·バイオテクノロジー応用食品特別部会でも、グリーンピースなどのNGOを含めて合意が得られ、2003年のコーデックス総会で規格として採択された。

ILSIのバイオ関連の初期の出版とその翻訳

2. 第2期

この後のバイオテクノロジー研究部会は主に勉強会を中心とした活動に移る。その間、1995年には報告書「バイオ食品の社会的受容の達成をめざして」を作成した。また、1996年には最初の遺伝子組換え食品の安全性の確認にあわせ、10月には消費者団体の講演会に先駆けてバイオ討論会「歩き始めたバイオ食品」を開催し、モンサント山根部長、ILSI Japan副会長粟飯原先生、厚生省池田課長補佐の講演とパネルディスカッションを行った。また、会員企業の要望にあわせ1997年には「イルシー」誌（No. 57）に特集号として遺伝子組換え食品Q＆Aを掲載した。このQ＆Aはその後多くの組織の出したQ＆Aの母体となった。1999年にはこのQ＆Aを改定し、会員外にも活用していただくように出版した。さらに、同年にはそれまでの調査成果をまとめた「遺伝子組換え食品を理解する」を出版した。また、この活動を踏まえ、倉沢前部会長が農林水産省の設置した検知技術の委員会のメンバーとして参加した。

3. 第3期

1999年、コーデックス委員会は4年間の時限でバイオテクノロジー応用食品特別部会（CTFBT）の設置を決め、議長国に日本が選ばれた。日本としては初めてコーデックスの議長国を務めることとなった。第1回CTFBTは千葉市幕張で2000年3月に行われたが、その前日には食糧農業機構（Food and Agriculture Organization, FAO）／世界保健機構（World Health Organization, WHO）の共催、厚生省ならびに国際生命科学協会（International Life Sciences Institute, ILSI）後援による「バイオテクノロジーと食品安全シンポジウム」が行われ、世界各国から集まった特別部会出席者に、科学的に公正でかつ最新の予備知識を提供することとなった。事務局は多くの場合と同様にILSIであったが、ILSI Japan

コーデックスバイオ食品特別部会への参加

バイオテクノロジー研究部会は事実上の事務局としてこのシンポジウムを運営した（必要経費の3/4はILSI本部、1/5はILSI Japanが支出）。このシンポジウムを通して、CTFBT出席者がバイオテクノロジー応用食品について議論をするために必要な共通の理解を確立することに寄与した。また、2000年3月から2003年3月までの4回のCTFBTと3回のワーキンググループには、ILSI Japanバイオテクノロジー研究部会メンバーも国際NGOとしてのILSIとして、ILSI本部のメンバーと共に参加した。

ILSI Japanのバイオ関連出版物

CTFBTは当初、植物のみを対象としていたが、途中から微生物も対象とすることとなった。その提案が取上げられる3か月前、ILSI Japanバイオテクノロジー研究部会では遺伝子組換え微生物由来の食品の安全性に関する調査活動の成果を生かしたワークショップ「**生きた微生物を含む食品への遺伝子組換え技術の応用**」を開催し、この報告書とILSI Europeの作成した同様の報告書の翻訳を出版した。そして、CTFBTで微生物が取上げられることが報道にリリースされた翌週、関係する官庁などにこれらを届け、そのタイミングの絶妙さが、そしてもちろん内容についても高く評価され、その後のわが国の議論の進展に役立てることができた。


オピニオンリーダー向けシンポジウム会場風景

また、この時期は国内外ともに遺伝子組換え食品への反対運動などが盛り上がり、間違った知識に基づく議論が横行するようになっていた。そのため日本学術振興会160委員会との共催で2000年よりオピニオンリーダー向けの講演会・シンポジウムを開始した。その後2002年までに表示の説明・普及を目的とした、食品産業センターなどとの共催、ILSI Japan単独の開催などの講演会・シンポジウムを10回以上、また、講演会開催の要請に応えた講演会などを数多く行った。しかし、この活動はILSIの活動としてはやや問題もあるとの指摘を本部やEU支部メンバーなどから受けたこと、ILSI Japan以外の組織の講演活動が活発になってきたことなどから、単独の講師としての受託以外は活動を取りやめた。しかし、この活動の理念は2004年から始まったお茶の水女子大学の公開講座「化学・生物総合管理の再教育講座」の中で、「生物総合評価管理学事例研究」として、半年15コマの講義に、主に部会員による講義を行うことで受け継がれている。

一方、2003年からは通産省のプロジェクト「遺伝子組換え体の産業利用におけるリスク管理に関する研究」に参画し収集してきた情報を国のプロジェクトに役立てることができた。

さて、コーデックスに話を戻すと、2003年7月には前述のコーデックスでの検討が終わり、「**モダンバイオテクノロジー応用食品のリスクアナリシスに関する原則**」「**組換えDNA植物由来食品の安全性評価に関するガイドライン**」「**組換えDNA微生物利用食品の安全性評価の実施に関するガイドライン**」のコーデックス規格ができた。しかしながら、さらに検討する必要のある事項が残っていることを考慮し、2003年から毎年、検討を要する事項を課題とする以下のような国際シンポジウム・ワークショップを開催し、内外の有識者や行政を含めた広い議論の場を提供してきた。

- 「タンパク質のアレルギー誘発性に関するワークショップ」
- 「遺伝子組換え作物検知技術国際ワークショップ」
- 「遺伝子組換えによって栄養改善された食品および飼料の栄養ならびに安全性評価ワークショップ」
- 「遺伝子組換え植物の生物多様性影響評価に関する

国際ワークショップ」

(1)「タンパク質のアレルギー誘発性に関するワークショップ」 ILSI-HESIと共催（2003年9月17日 共立薬科大学）

コーデックス特別部会で合意された「組換えDNA植物由来食品の安全性評価の実施に関するガイドライン」および「組換え微生物を利用した食品の安全性評価の実施に関するガイドライン」双方の付属文書として「アレルギー誘発性アセスメント」が策定された。

2003年「タンパク質のアレルギー誘発性に関するワークショップ」

この内容は、ILSI-HESIが1996年に報告した考え方をFAO/WHOの専門家会議で修正した判断樹を基に検討された。評価法は、導入タンパク質の供給源、当該タンパク質と既知のアレルゲンのアミノ酸配列における類似性、構造的特性について確認し、さらに酵素分解性、熱安定性などについて確認するが、さらに、標的血清スクリーニング法等の試験法の開発、国際血清バンクの設置、試験動物モデルの開発、新たな発現タンパク質のT細胞エピトープやアレルゲンに関わる構造的モチーフの研究の推進等の議論があったが、これらの推進のための組織、資金等の目処はたっていない。

HESIではこれらの研究を進めていて、このワークショップでは1996年の報告書の著者を中心に日本における研究も議論された。また、この2003年のワークショップを通じて、HESIを中心とした動物試験のリングドックに国立医薬品食品衛生研究所も参加することがILSI Japanを仲介として決められた。HESIはその後、バイオインフォマティックスに関するシンポジウム、血清バンクに関するシンポジウムなどを世界各地で開催している。

(2)「遺伝子組換え作物検知技術国際ワークショップ」（独）農林水産消費技術センター（独）食品総合研究所と共催（2004年11月25・26日 横浜第2合同庁舎）

遺伝子組換え作物の検知法に関する会合は、最初ILSI EuropeとILSI-IFBiCが中心となってヨーロッパで行われたが（Food Control, 10, DEC 1999特集号）、日本は最大の輸入国であることから、日本で開発された方法がある種のデフォルトとなる面もある。2004年のワークショップは世界との標準化を図りつつ、わが国の開発した方法が国際標準として通用するべく内外の専門家による議論を行った。

なお、日本で開発された方法がISO規格になるべく布藤検出法分科会リーダーが頑張ってきた結果、GMO検知に関するISO規格は、本年初めにサンプリングを除く全規格が発行され、日本の分析法は定量分析法規格（ISO 21570）付属文書に取り入れられた。

(3)「遺伝子組換えによって栄養改善された食品および飼料の栄養ならびに安全性評価ワークショップ」ILSI-IFBiCと共催
（シンポジウム 2005年5月23日 大阪科学技術センター，5月24日 東京芸術劇場
ワークショップ 5月25日 都道府県会館）

コーデックスでは、2003年のコーデックス規格成立の

2005年「遺伝子組換えによって栄養改善された食品および飼料の栄養ならびに安全性評価ワークショップ」

後、必要性が生じたモダンバイオテクノロジーによる食品の安全性評価法等について取りまとめるため、CTFBTを再開し、2005年9月にその第5回会議を開催した。第5回会議では、この先、取り組むべき課題についての検討が行われ、下記の課題が合意された。

1)「組換えDNA動物由来食品の安全性評価の実施に関するガイドライン」の策定
2)「組換えDNA植物由来食品の安全性評価の実施に関するガイドライン」の付属文書としての「栄養もしくは健康上の便益をめざした組換えDNA植物由来食品の安全性評価ガイドライン」の策定

このうち2)については2004年にILSI-IFBiCが報告し、このワークショップをはじめとして世界でその内容について検討してきたものであった。このワークショップでは、2004年の報告書の著者や日本の研究者の報告を基に、内外の有識者や行政による議論で報告書の提言を確認した。

CTFBTでILSIはこの報告書を参考資料として配り、コーデックスでは珍しく専門家会議での検討なしに直接検討資料として取り上げられた。

(4)「遺伝子組換え植物の生物多様性影響評価に関する国際ワークショップ」 協賛 バイテク情報普及会 (2006年7月27日 東京芸術劇場)

生物多様性評価については、ILSI本部は直接の取り組みを行っていない。しかし、生物多様性に関する情報は食品安全性とともに重要な位置づけを持つものであり、ILSI Japanバイオテクノロジー研究部会が他支部に先駆けて取り組む必要がある。

本ワークショップは、国内外よりリスク評価研究の専門家を招き、交流の場を設定するとともに、リスク評価に関与する各方面への情報発信の場とすることを目的として企画された。当日は、大学や国の研究者、行政、地方自治体、企業など多方面から多くの参加者を得ることができ、講演会および座談会では、今後の遺伝子組換え植物の生物多様性影響評価のあり方を含めた活発な意見交換が行われた。今回は、ILSI Japanにとっても、環境というテーマに初めて取り組んだ記念碑的なワークショップとなった。私たちは、今後とも、この灯火を消さぬよう、さらに良い企画を提供していきたいと考えている。<詳細については本誌51頁の詳報を参照いただきたい>

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略歴

橋本　昭栄（はしもと　しょうえい）

1970年　金沢大学理学部化学科 卒業
1972年　金沢大学大学院理学研究科（修士）修了
1972年　サントリー株式会社 入社
　　ビール研究室、研究企画部、先進技術応用研究所
2005年　社団法人 農林水産先端技術産業振興センター 出向
　　企画調査部長
2006年　調査広報部長　　現在に至る

現在　お茶の水女子大学 非常勤講師