

Biotechnology Regulation

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Biotechnology Regulation

- Safety: environmental safety (biosafety), food safety, worker protection
- Product Regulation: seed registration, pharmaceuticals, pesticides, etc.
- Generic issues: IPR, ethics, liability, etc.

Biosafety Regulation

Topics:

- Historical and international context
- Biosafety Protocol
- National Biosafety Frameworks

Historical and international context

1972: First rDNA organism: great expectations and deep concerns.

1974/5: Asilomar conferences

1986: OECD rDNA safety recommendations

1992:
- (Rio de Janeiro) UNCED – Agenda 21
- Convention on Biological Diversity.

Historical and international context

The Convention on Biological Diversity:

- ❖ Art. 8.g: “*In situ conservation of biodiversity*”
Obligation to develop national biosafety systems
- ❖ Art. 19.3: “*Handling biotechnology and distribution of its benefits*”
Consider a protocol on biosafety

The Cartagena Protocol on Biosafety

1995: COP Decision to develop a biosafety protocol

1996 – 2000: Negotiations

2000, January: Adoption of the Biosafety Protocol

2000, November: GEF strategy for capacity building

2002, September: WSSD, Johannesburg plan

2003, May: Report of the UN Secretary-General on biotech

2003, September: Biosafety Protocol comes into force

2004, February: First Meeting of the Parties to the BSP

Article 8g of the CBD and
Article 2 of the Biosafety Protocol:

“...Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations ...”

>>> National Biosafety Frameworks

National Biosafety Frameworks (NBFs)

NBFs vary from country to country, but usually have a number of common components:

1. Policy on biotechnology and biosafety
2. Regulatory regime for biosafety
3. System to handle notifications/requests for permits
4. Enforcement and monitoring
5. Public information and public participation

National Biosafety Frameworks (NBFs)

1. Policy on biosafety
2. Regulatory regime for biosafety
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Biosafety policies

Commonalities in existing biosafety policies:

- Biosafety policy is almost always part of broader policies (biotechnology, agriculture, science, etc.)
- The process builds consensus and integrates different goals into single national vision.
- The written policy serves as guidance for future choices

National Biosafety Frameworks (NBFs)

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Regulatory regimes for biosafety

Key considerations:

- Objective(s)
- Scope
- Structure

Regulatory regimes for biosafety

Objective(s):

Take into account:

- The national policy on biosafety and biotechnology
- International obligations (E.G: CBD, BSP, WTO, CODEX ALIMENTARIUS, ETC.)

Regulatory regimes for biosafety

Scope

2 Elements:

- *Which activities?, e.g.:*
 - Contained use,
 - Introduction into the environment,
 - Placing on the market,
 - transboundary movement.
- *With what? e.g.:*
 - LMOs/GMOs
 - Organisms with novel traits

Regulatory regimes for biosafety

Structure - different regulatory levels:

- Enabling legislation
(Act, Bill, Law)
Parliamentary involvement
- Implementing regulations
(Regulation, Order, Ordinance, Decree, Rule)
Issued by the Government
- Guidelines
“non binding”

Regulatory regimes for biosafety

Structure

Key questions:

- Use existing regulatory (sectoral) regime or develop a new, comprehensive regime?
- One national competent authority, local competent authorities?
- What is addressed on which level?
 - Act – Implementing regulations – Guidelines

The Regulatory regime for biosafety of Croatia

Topics:

- The overall framework
- The Nature Protection Act
- The draft GMO Act

The Regulatory regime for biosafety of Croatia

The overall framework: Two Acts specifically addressing GMOs (The Nature Protection Act and the Food Act), and a variety of laws that can also apply to GMOs (e.g. Water Protection Act).

-Comments from reviewers:

- 1) very good to present an overview of the overall framework on the Croatian biosafety web site
- 2) Overview shows need for coordination

The Regulatory regime for biosafety of Croatia

The current Nature Protection Act: a framework Act of which details will be worked out in by laws

Comments from reviewers:

NPA is in general similar to systems in many countries and is good basis for a workable, transparent system that is in line with Croatia's obligations, provided attention is given to:

- coordination
- by laws
- 'Ban'

The Regulatory regime for biosafety of Croatia

- Coordination: need to avoid duplication with Food Act and other legislation
- Implementing by-laws: balance placing technical details in by-laws and other guidelines
- 'Ban': article 114 effectively contains a unqualified 'ban'. Such as 'ban' is not in place in any other country inside or outside the EU, goes against the 'case by case' approach of the rest of the NPA and goes against the EU Directives

Regulatory regimes for biosafety

Main types of provisions

- General provisions
- Operational provisions
- Other and final provisions

Regulatory regimes for biosafety

General provisions

1. Objective
2. Definitions
3. Scope
4. Institutional arrangements
(e.g. designation of authority)
5. General obligations
(e.g. internal biosafety systems).

Regulatory regimes for biosafety

Operational provisions

Examples:

1. Contained use
2. Introduction into the environment
3. Placing on the market
4. Import/export

Regulatory regimes for biosafety

Operational provisions

Obligation to:

1. Carry out a risk assessment prior to the activity
2. Apply adequate safety measures
3. Request permit for or notify certain activities
4. Procedures for decision making
5. Follow up (monitoring, enforcement)

Regulatory regimes for biosafety

Operational provisions - Contained use

Two complementary components:

- Containment measures (e.g. building, equipment)
- Work procedures (e.g. “Good Laboratory Practice)

Regulatory regimes for biosafety

Operational provisions - Contained use

Containment levels depend on:

1. The organisms involved (micro-organisms, plants, animals)
2. The involved genes and modifications
3. The type of facility (Laboratory, green house, Animal facility, Large scale facility)

| | Micro – Organisms | Plants | Animals |
|-------------------------|----------------------|--------|---------|
| Laboratory | Levels 1 – 4 | | |
| Green house | | | |
| Animal facility | | | |
| Large scale facility | | | |

Regulatory regimes for biosafety

Operational provisions - Contained use

Containment levels can be found in:

- Regulations
- decision documents (permits, authorisations)
- Guidelines

Regulatory regimes for biosafety

Operational provisions - Contained use

Internal biosafety system:

1. Internal instructions how to apply safety measures
2. Internal organisation, e.g. biosafety committees
3. Internal audits (“inspections”)
4. Administration

Regulatory regimes for biosafety

Operational provisions

Examples:

1. Contained use
2. Introduction into the environment
3. Placing on the market
4. Import/export

Regulatory regimes for biosafety

Operational provisions

Examples:

1. Contained use
2. Introduction into the environment
3. Placing on the market
4. Import/export

Regulatory regimes for biosafety

Final and other clauses

Examples:

1. Procedural provisions:
 - Information requirements
 - Public information
 - Confidentiality
 - Appeal
2. Enforcement, Compliance, Liability
3. Review mechanism
4. Entry into force, transition period

Regulatory regimes for biosafety

Important aspects:

- ❖ Clarity (objective, scope, structure)
- ❖ Transparency (procedures)
- ❖ Consistency
- ❖ Workability
- ❖ Enforceability
- ❖ Adaptability

National Biosafety Frameworks (NBFs)

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Handling notifications and requests for permits

Steps:

1. Administrative processing

2. Risk assessment

3. Decision making

Handling notifications and requests for permits

1. Administrative processing

- registering
- checking
- storing
- forwarding

Handling notifications and requests for permits

2. Risk Assessment:

>> Understand the science and practice of the genetic modification

PLANT VARIETY DEVELOPMENT

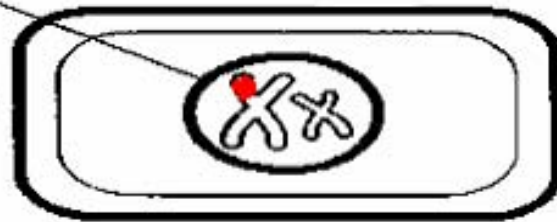
- **GREENHOUSE**
- **FIELD TESTING**
- **VARIETY DEVELOPMENT**
- **COMMERCIALIZATION**

DNA with
desired traits

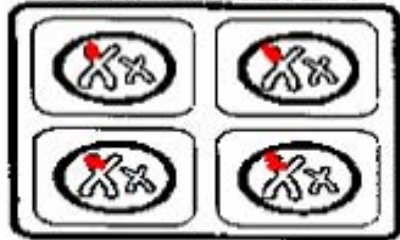


nucleus

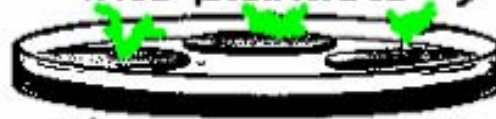
plant cell



Cell division



Cells regenerate
into plantlets

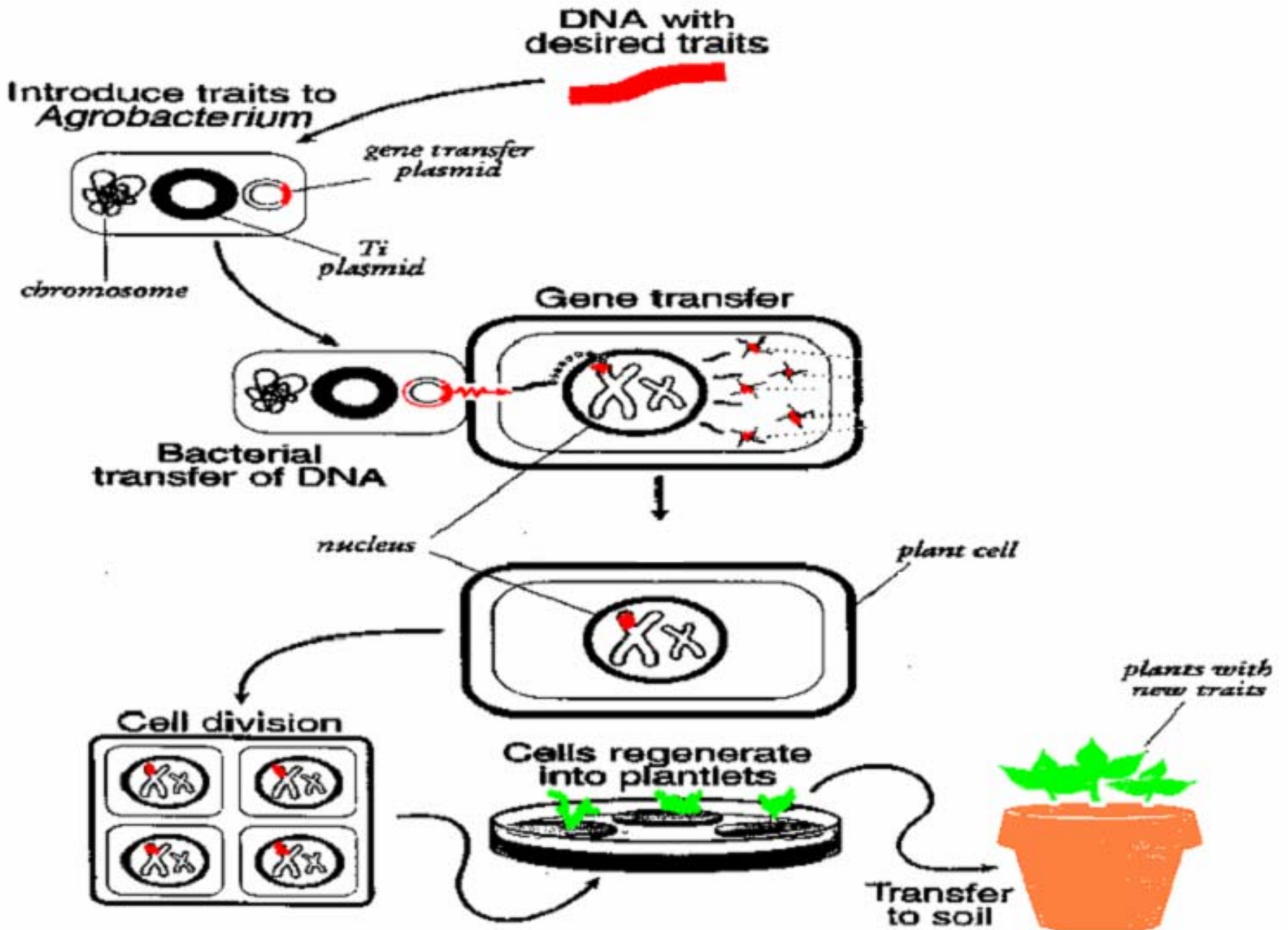


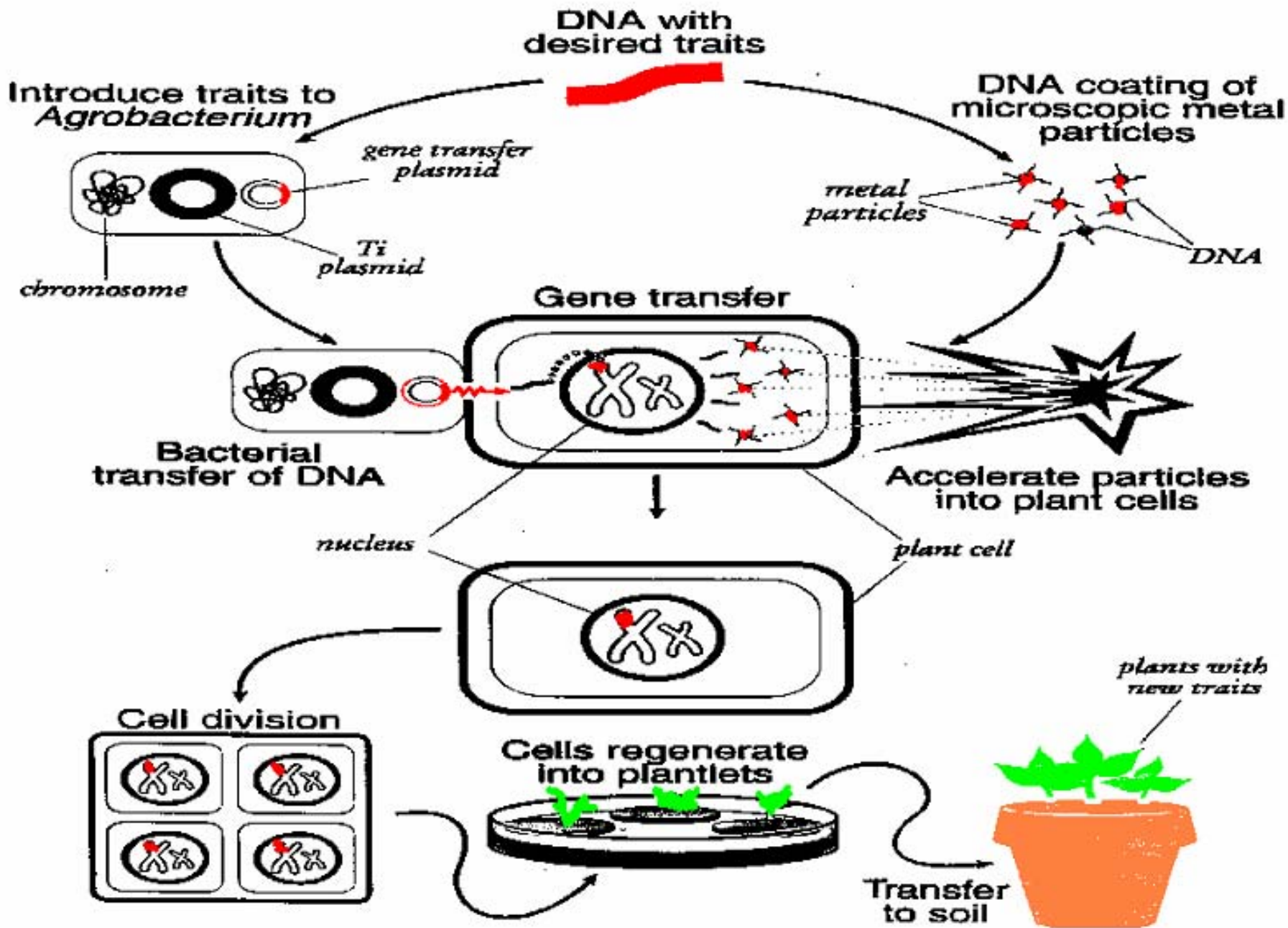
plants with
new traits



Transfer
to soil







GMO PLANT VARIETY DEVELOPMENT

- **LABORATORY**
- **GREENHOUSE**
- **FIELD TESTING**
- **VARIETY DEVELOPMENT**
- **COMMERCIALIZATION**

Handling notifications and requests for permits

Risk Assessment – 5 steps:

1. Identify potential adverse effects
2. Estimate likelihood
3. Evaluate identified risks
4. Consider management strategies
5. Assess overall impact

Handling notifications and requests for permits

Risk Assessment – takes into account:

- * Host organism
- * Inserted genes / sequences
- * Characteristics of the GMO
- * Intended use
- * Receiving environment
- * Existing situation

Handling notifications and requests for permits

Risk Assessment – takes into account:

* 5 Steps

* Taking into account host, inserted genes, type of activity, etc.

>> Systematic approach:

- cover note
- Start “gene by gene”
- Worksheets

Handling notifications and requests for permits

1. Administrative processing

2. Risk assessment

3. Decision making

Handling notifications and requests for permits

Decision making – important aspects

- * **Accountability: the Law**
- * **Transparency: Decision documents**

Handling notifications and requests for permits

Decision documents

- * Summary of the request
- * Summary of the risk assessment
- * Summary of other considerations relevant to decision making, e.g. public consultation.
- * Draft or final decision

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Enforcement and monitoring:

1. Enforcement

- Looks at compliance with the rules
- done by the Government / Inspectors

2. Monitoring environmental effects

- Observing possible effects on the environment
- done by applicant or Government

Enforcement: Inspections

- What needs to be done?
- How do you prepare?
- Who will do it?
- What tools do inspectors need?
- Why increase transparency?

Inspections: What needs to be done?

- Clear legal basis for inspection
- Train inspectors
- Prioritize inspections
- Record keeping
- Evaluate performance of system
- Maintain transparency

Some powers of inspectors

- Enter premises
- Take written statements
- Issue notices (correction, abatement)
- Give testimony for prosecutions

Training of inspectors

- Technical knowledge
- Legal training
- Interpersonal skills

Prioritize inspections

- Level of risk:
 - ✓ Assessment made at application
 - ✓ Assessment made at previous inspection
- Time since last inspection
- Past performance of applicant
- Other factors: Public opinion, politics

Enforcement: Record keeping

- Systematic
- Records accessible
 - ✓ Inspectors
 - ✓ Reviewers
- Secure confidential information

Preparing for an inspections

- Previous inspections
- Correspondence – compliance with earlier recommendations
- Usually request 2-3 weeks before visit, but sometimes unannounced visits

Inspections - recommendations

- qualified, well trained personnel
- close links between inspectors and reviewers
- clear assessments and permit conditions
- communication

MONITORING ENVIRONMENTAL EFFECTS

*** GENERAL SURVEILLANCE:**

“KEEPING YOUR EYES OPEN”

E.G. GENERAL CHARACTERISTICS

*** CASE-SPECIFIC MONITORING:**

E.G. DEVELOPMENT OF RESISTANCE

MONITORING ENVIRONMENTAL EFFECTS

DIFFERENT LEVELS / PHASES:

- ❖ **INDIVIDUAL CASES**
 - E.G. CONDITIONS IN PERMITS
- ❖ **GROUP OF CASES**
 - E.G. EFFECT ON PESTICIDE USE
- ❖ **FUNCTIONING OF THE BIOSAFETY FRAMEWORK**

MONITORING ENVIRONMENTAL EFFECTS

GATHER INFORMATION TO TEST:

*** ASSUMPTIONS**

*** CONCLUSIONS**



ASSESSMENT

National Biosafety Frameworks

- 1. Policy on biosafety**
- 2. Regulatory regime**
- 3. System to handle requests and notifications**
- 4. Enforcement and monitoring**
- 5. Public information and participation**

Public Information and Public Participation

1. What is Public Information and Public Participation

2. Legal requirements

3. Practice

Public Information and Public Participation

- **Public information**

- **access to information upon request (passive)**
- **active dissemination of information**

- **Public participation**

- **Input before Government makes decisions**

Public Information and Public Participation

Legal requirements:

1. National legislation, e.g:

- Constitution
- General administrative legislation
- Specific legislation.

2. International and regional agreements, e.g:

- Biosafety Protocol
- Convention on Biological Diversity
- Aarhus convention
- EC Directives

Public Information and Public Participation

Practice

Public information and participation about:

- 1. The National Biosafety Framework**
- 2. Individual cases**
- 3. Special topics**

Implementation

‘ making it work in practice ’

Regulatory regime - implementation

| NBF | | Remarks |
|--|--------------------------------|------------------------|
| <u>Competent authorities</u> <ul style="list-style-type: none">• coordination• handling• enforcement• information | Designate | In the law |
| | Mandate | steps in the procedure |
| | Establish – furnish – train | |

Handling requests - implementation

| NBF | | Remarks |
|----------------------------------|-----------------------------------|----------------------------------|
| Administrative processing | Information formats | - hard copy - electronic form |
| | Data storage | - assign numbers - databases |
| | Screening for completeness | - checklists |
| | Distribution | - manuals |

Handling requests - implementation

| NBF | | Remarks |
|------------------------|--|--|
| Risk Assessment | Furnish / train RA body – secretariat | - in house / external |
| | RA Guidelines | - international harmonisation |
| | Process of RA – Internal Rules | - publish |

Handling requests - implementation

| NBF | | Remarks |
|------------------------|--|---------------------------------------|
| Decision making | Transfer of RA report into a (draft) decision | formats for decision documents |
| | Public participation | |
| | Issuing of final decision | Manual |

Enforcement – implementation

| NBF | | Remarks |
|--------------------|--|----------------|
| Enforcement | Furnish / train inspection bodies | |
| | Inspection manuals | Publish |
| | Inspection plans - surveys | Publish |

Public information – implementation

| NBF | | Remarks |
|---------------------------|--|----------------|
| Public information | Furnish / train involved body | |
| | Public information handbook <ul style="list-style-type: none">• different forms• confidentiality | Publish |

Public participation – implementation

| NBF | | Remarks |
|-----------------------------|--|----------------|
| Public participation | Furnish / train Involved body | |
| | Public Participation handbook <ul style="list-style-type: none">• different forms | Publish |

Information exchange – implementation

| NBF | | Remarks |
|-----------------------------|---|----------------|
| Information exchange | National web site / national BCH | |
| | Provide to BCH | |
| | Reply to Questionnaires | Manual |





