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REPUBLIC OF SOUTH AFRICA

Environmental Risk Assessment: A Practical Approach

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South Africa is the 3rd most biodiverse country in the world



2% of the world's land area

7% of the world's reptiles, birds and mammals



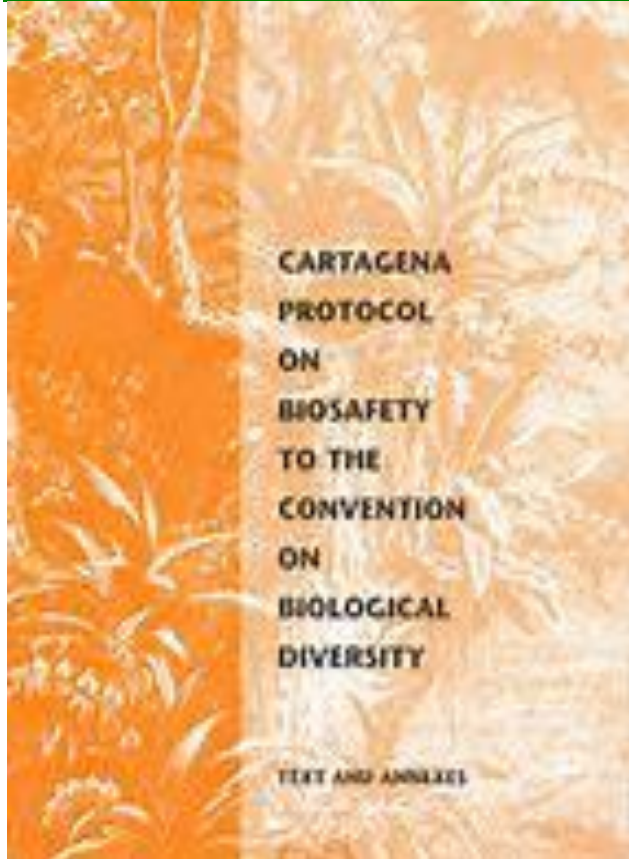
10% of the world's plants



15% of the world's coastal marine species



Background



- Annex III of the Protocol covers tradition 5 step process:
 - Identification of any novel genotypic and phenotypic characteristics
 - Evaluation of the likelihood of adverse effects being realized
 - Evaluation of the consequences
 - Estimation of the overall risk
 - Recommendation
 - Guidance introduces new concepts
- Elements of PFOA

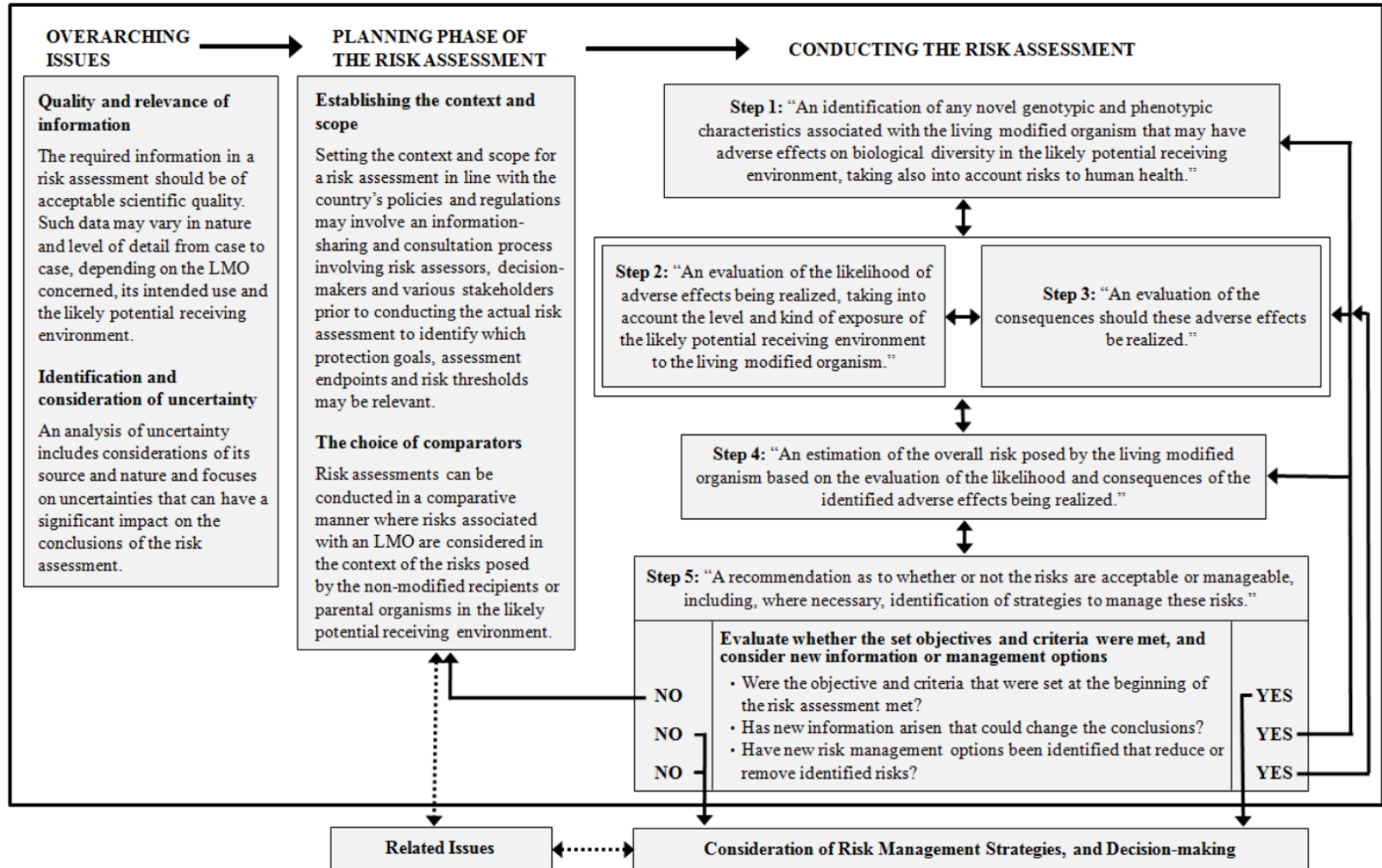


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Flowchart in the Roadmap:



Environmental Legislation, policy and tools identify protection goals

- National Environmental Management Act (1998)
 - Basic principles and EIA provisions
- National Environmental Management Protected Areas Act(1998)
 - Restrictions on land use
- National Environmental Management Biodiversity Act (2004)
 - Monitoring of commercial releases
 - EIA for specific GMOs considered a threat
- National Biodiversity Strategy and Action Plan
- National Biodiversity Framework
- Guidance documents:
 - Environmental risk assessment frameworks for plants, pharmaplants, aquatic organisms

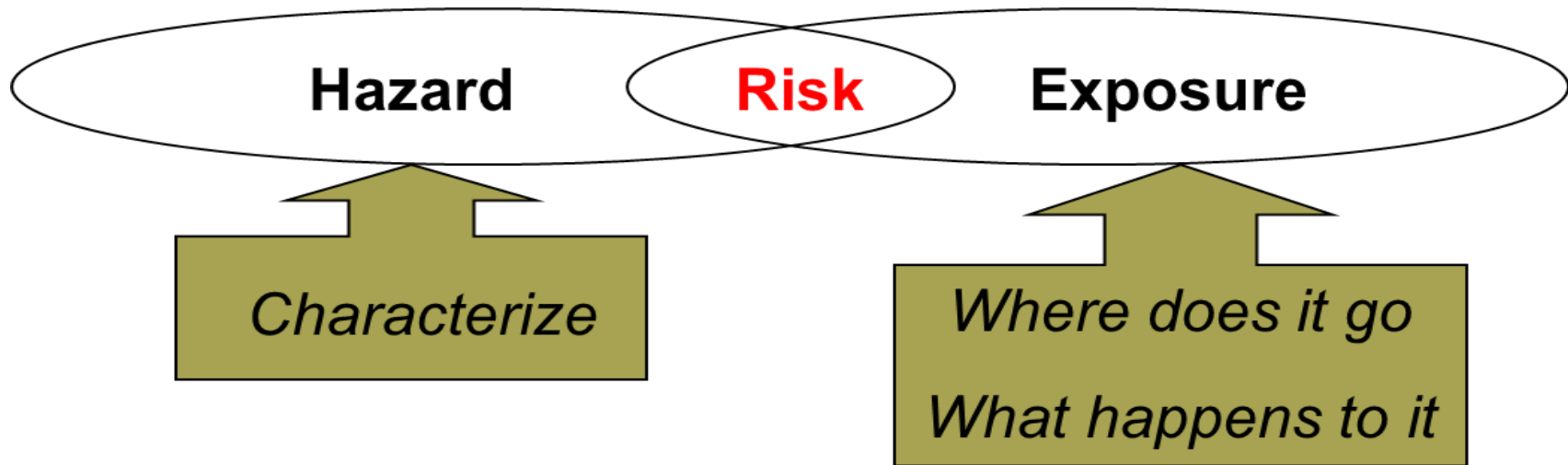


Defining Environmental Assessment end points

- Assessment endpoints - *environmental values that are to be protected (operational)* e.g biodiversity impacts - non-target organisms
- Measurement endpoints - *quantifiable indicator of change in the assessment endpoint, constitutes measures of hazard and exposure* e.g fitness levels
- Determination of Protection goals and endpoints key to problem formulation



Regulatory Approach to Environmental Risk Assessment



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Tiered Approach

- Tier 1 – lab studies where non-target organisms are exposed to purified protein (10X the expected environmental concentration) to determine potential adverse effects
- Tier 2 – lab studies using actual plant material (leaves, roots, pollen assays) to determine potential effects on NTOs using environmentally relevant exposure concentrations; could involve multiple trophic levels if applicable
- Tier 3 – long-term lab tests, greenhouse or semi-field studies
- Tier 4 – field monitoring studies
 - Tests proceed to Tier 2 only if results from Tier 1 studies show adverse effect AND if exposure to NTO is probable
 - The tiered approach system is cost effective, minimizes environmental risk



Environmental Risk Assessment is central.....

- Environmental safety assessment takes into account (checklist)
 - the plant's potential to become a weed or to invade natural habitats
 - the potential consequences of gene flow to related species
 - the potential for the plant to become a plant pest
 - the potential impact on non-target organisms, including humans
 - the potential impact on biodiversity
 - Changes in agricultural practices



Environmental Risk Assessment is central.....

- Other environmental considerations:
 - Wetland delineation
 - Species identified for which this a breeding ground
 - TOPS and protected species, IUCN red data list
 - Map of sensitive areas
 - Map of CBAs from Bioregional Plan and Provincial Biodiversity Conservation Plan
 - Listed Ecosystem map
 - NPAES
 - Vegetation map



Practical considerations

- Non-target organisms species selection criteria for Arthropod biodiversity study
 - Indicator species
 - Representatives of functional group
- Weediness potential
 - AIS Regulations and risk assessment framework
- Gene Flow
 - BGIS maps
 - Natural distribution maps
 - TOPS lists



ENVIRONMENTAL PROTECTION GOALS

- Environmental Protection Goals - broadly defined and valued environmental outcomes
- Choice of protection goals informed by national policies and legislation as well as globally and agreed upon standards
- Expression of the environmental value to be protected
- Well defined in SA context



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Conclusions

- GM crops play significant role in SA agricultural productivity
- Key drivers of biodiversity loss:
 - Land use change
 - Alien and invasive species
 - Climate change
 - Species loss/unsustainable use
- Uncertainty still remains
 - Tolerable levels of impact
 - Species and ecosystem types conservation status
 - Ecosystem goods and services
- ERA is an iterative, case by case process underpinned by

science

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THANK YOU

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