Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

Using problem formulation to identify relevant and reliable information for environmental risk assessment to support decision-making

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Outline

- The environmental risk assessment
- Some Definitions
- Using problem formulation
- The policy context
- Profiling in Risk Assessment
- Conclusions

Risk is a Function of Hazard and Exposure

Hazard

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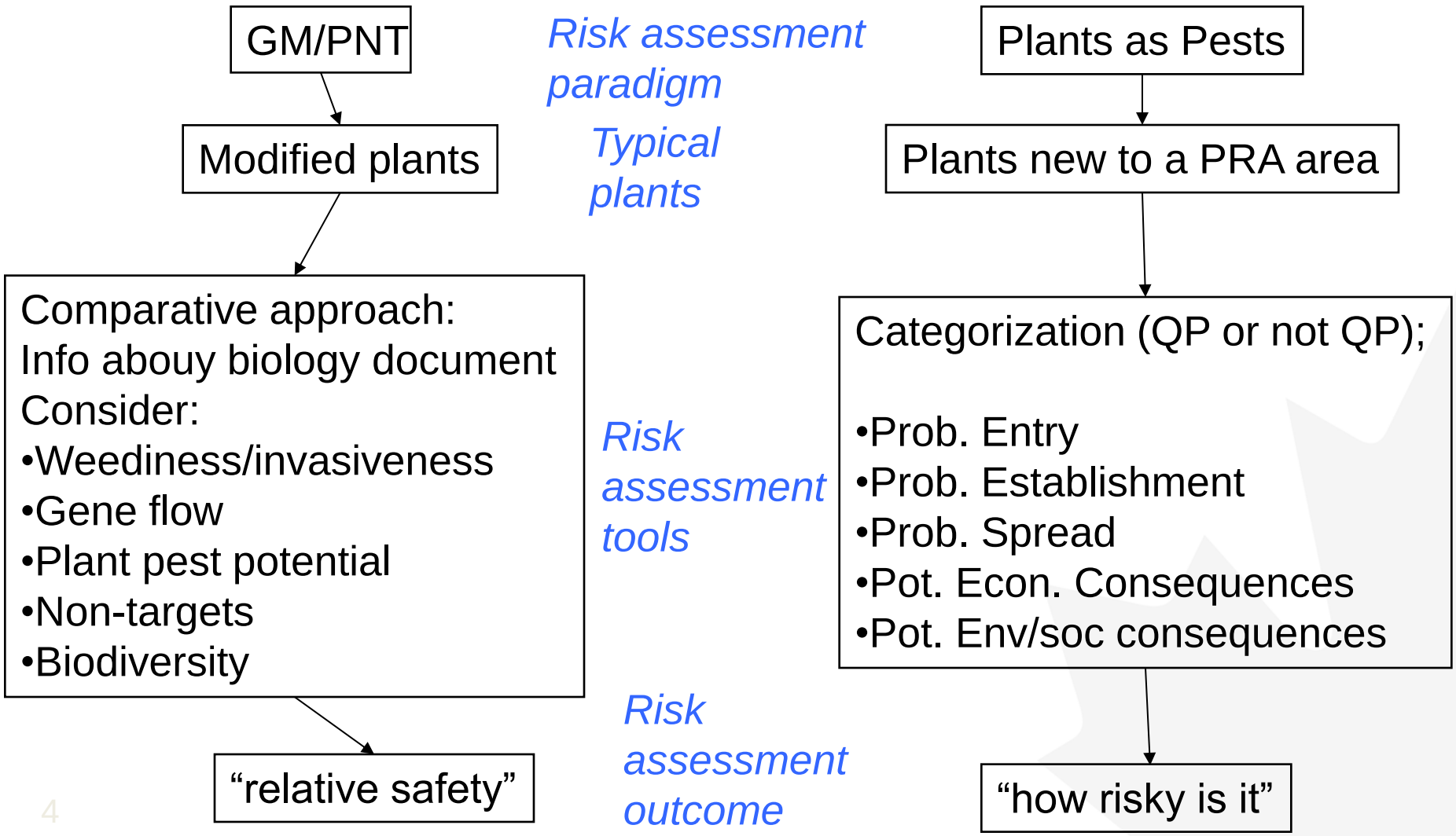
No exposure

= No risk

Hazard + exposure =

Risk

GM Plant and Weed Risk Assessment Approaches



Policy or Science Driven Problem Formulation?

- Policy objectives are necessary to structure the risk assessment
- Without policy guidance, risk assessors are left to make a series of small policy decisions throughout the risk assessment
- With the push towards big data and the capacity to generate prodigious amounts of data it is easy for scientific curiosity to lead risk assessors down unproductive roads

Some Definitions

- Hazard- any source of potential damage or harm
- Risk – the probability that harm will result
- Harm- the negative outcome from the hazard
- Pathway to harm- a series of events that need to occur for a harm to be realized

Some Definitions

- Protection goal- broadly stated environmental objectives often articulated in policy or regulations such as protection of biodiversity
- Assessment endpoint- an environmental value to be protected where effects from a risk can be measured for example beneficial insect abundance
- Risk hypothesis- a statement about possible outcomes such as releasing a GM crop or using a pesticide will not pose an unacceptable risk

Problem Formulation

- The first step in risk assessment is problem formulation also called hazard identification
- A series of risk hypotheses that describe potential pathways to harm are constructed
- Requires a clear understanding of the assessment endpoints
- Endpoints reflect what we are trying to protect e.g. endangered species in the environment, and reflect societal consensus
- Problem formulation establishes the parameters of risk assessment (problem context)

Problem Formulation

- The problem formulation step is where you will identify your assumptions
- Failure to engage in proper problem formulation can compromise the entire risk assessment and lead to inadequate or unnecessary risk management decisions
- Endpoints are value driven, the process to assess harm to an endpoint should be firmly based in science and hypothesis driven
- Comparative risk assessments should be based on reasonable risk hypotheses that focus on realistic potential differences

Environmental Assessment for GM Crops

- Environmental assessment considers relative safety of the product in both the short and longer term

- Comparative
  - Information about the novel plant is compared to information known about the biology of the counterpart
  - May includes a molecular characterization

- Considers the expected trait in the context of the unmodified plant and considers how it can effect things we value by using indicators we can measure


Species of “special concern” in Canada

Tiered Approaches

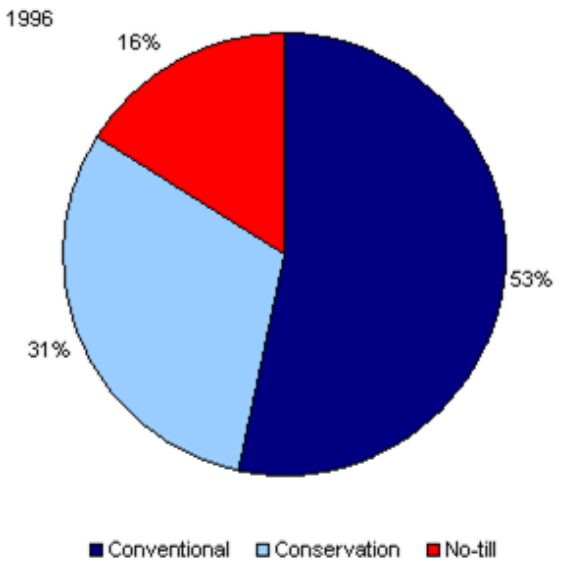
- The risk assessment proceeds in a structured manner based on the risk hypothesis
- Laboratory tests will often identify the worst case scenario
- If the first tier of testing does not identify a risk, then the assessment should stop
- Tiered testing is prevalent in pesticide testing
- This can be an avenue to reduce data requirements

Risk Hypotheses

- a hypothesis that growing a certain GM crop will cause no harm, is really a hypothesis that growing the GM crop will cause no greater harm than that cultivation of the non-GM crop it may replace.
- a hypothesis that growing a certain GM crop will poses no unacceptable risk, is really a hypothesis that any increase in risk caused by growing the GM crop will be acceptable
  - Valuable context for risk managers

Substantial Equivalence

Adoption of Minimum Disturbance Tillage in Canada



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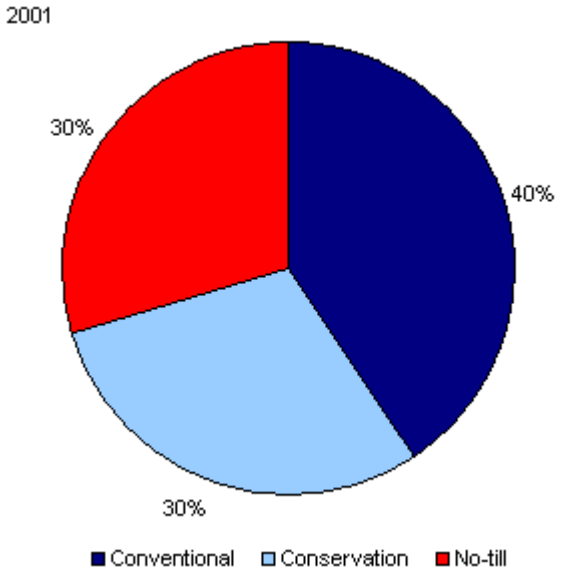

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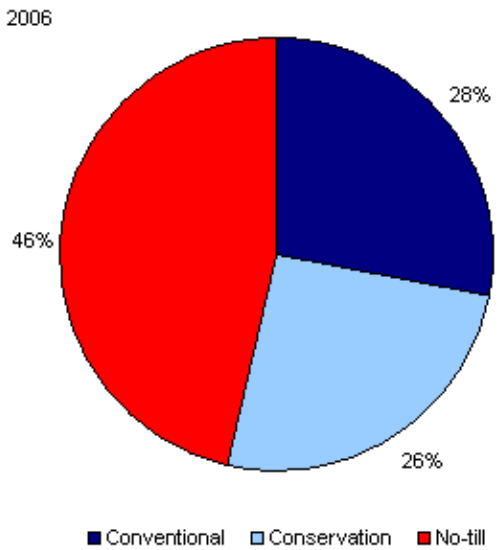

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Applying the Comparative Approach

- Extensive scientific research on variety development in plants using a variety of genetic tools

- In particular, advancements in molecular analysis techniques has given us an unprecedented understanding of plant genomes and genetic changes that occur

Using Profiling in Risk Assessment

- Profiling of GM crops can be carried out at the molecular level, using transcriptomics, proteomics or metabolomics
- This issue was recently discussed in the National Academy of Science report on future products of biotechnology
- Powerful tool for generating a great deal of information to identify statistically significant potential differences

Using Profiling in Risk Assessment

- Without prior policy context, science-led profiling can encourage the idea that producing more data inevitably leads to better risk assessment.

- The introduction of molecular profiling methods into regulatory risk assessments can lead to unfocussed data generation rather than policy-led attitudes to risk assessment.
- Additional data generation will often pose questions for which there are no ready answers leading to a continuing need to produce yet more data

Using Profiling in Risk Assessment

- The purpose of regulatory risk assessment is to evaluate whether the risks posed by a specific use of a specific product are acceptable
- Acceptability of risk is ultimately a policy decision, and response to identified statistically significant differences, rather than careful deliberation about delivering agreed societal objectives is not helpful for risk managers or decision makers

Using Profiling in Risk Assessment

- Profiling can be useful if guided by a hypothesis rather than looking for differences
- Regulators have very specific needs and we should be applying a hypothesis driven analysis guided by policy
- Risk assessors are trained first as scientists and driven by curiosity, it is important to separate “need to know” from “nice to know”
- *how many more rats need to die to demonstrate safety where there is no reasonable expectation of harm?*

Conclusions

- The risk assessment need the policy context- needs to be a clear idea of what the endpoint goals will be for the risk assessm
- Clear policy can help risk assessors who are called upon to make decisions about data throughout the risk assessment
- Science without a policy context can lead risk assessors down unproductive avenues or lead to unfocussed data collection
- The discussion between risk managers and risk assessors is critical to ensure risk assessments provide value to decision makers

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A comparative analysis of insertional effects in genetically engineered plants: considerations for pre-market assessments

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Abstract

During genetic engineering, DNA is inserted into a plant's genome, and such insertions are often accompanied by the insertion of additional DNA, deletions and/or rearrangements. These genetic changes are collectively known as insertional effects, and they have the potential to give rise to unintended traits in plants. In addition, there are many other genetic changes that occur in plants both spontaneously and as a result of conventional breeding practices. Genetic changes similar to insertional effects occur in plants, namely as a result of the movement of transposable elements, the repair of double-strand breaks by non-homologous end-joining, and the intracellular transfer of organelle DNA. Based on this similarity, insertional effects should present a similar level of risk as these other genetic changes in plants, and it is within the context of these genetic changes that insertional effects must be considered. Increased familiarity with genetic engineering techniques and advances in molecular analysis techniques have provided us with a greater understanding of the nature and impact of genetic changes in plants, and this can be used to refine pre-market assessments of genetically engineered plants and food and feeds derived from genetically engineered plants.


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