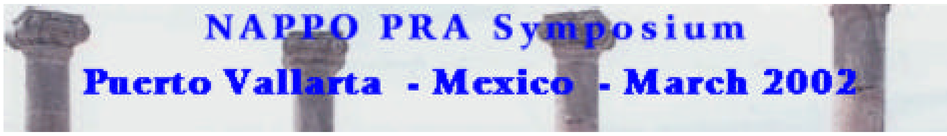

Probabilistic Scenario Analysis (PSA) – A Methodology for Quantitative Risk Assessment

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Risk assessment is a technique for identifying, characterizing, quantifying and evaluating hazards. Risk assessment seeks to answer the following questions: a) what can go wrong that could lead to an outcome of hazard exposure? b) how likely is this to happen? and c) if it happens, what consequences are expected?

Probabilistic Scenario Analysis (PSA) is a methodology for quantitative risk assessment that has been used for about sixty years. It was first used in the 1940's to assess the risks associated with the development and use of the atomic bomb. In the 1950's it was used to assess the-what if scenarios of nuclear proliferation. By 1960 it was being used in financial analysis, engineering applications and general economic evaluations. It is the method most frequently used in conducting quantitative risk assessments in plant and animal health. It has been well tried, and has proved useful in many fields.

This paper presents the probabilistic scenario analysis methodology, in the context of the three questions that risk assessment seeks to answer. This paper strives to present PSA as a structured and practical approach to the conduct of a quantitative risk assessment. A PSA methodology implementation example is presented.

It is important that risk assessments be credible, scientifically valid, transparent, well documented, and provide useful results. Probabilistic Scenario Analysis is a method for quantitative risk assessment that is well structured, and if applied correctly will yield a risk assessment that can be used for decision-making.

The Attributes of a Good Quantitative Risk Assessment

The purpose of phytosanitary risk assessment is to help decision-makers make informed decisions about SPS regulations. Article 5 of the SPS agreement mandates that members shall ensure that their sanitary or phytosanitary measures are based on a risk assessment. Science based decision making depends on several analyses (risk, economic, environmental). The validity, quality & objectivity of these analyses is essential. Decision Makers need to understand & have confidence in these analyses. These analyses should be able to stand up to scrutiny (Scientific and non-scientific).

The risk assessment is a key assessment from which the economic and environmental analyses get their initiating conditions. It is very important that the risk assessment be credible, scientifically valid, transparent, well documented, and provide useful results. If not, any SPS decision/rule (made based on the risk assessment) to prevent or allow the import of plants or animals will be vulnerable to repeal in local and international courts, if the decision/rule is challenged.

This paper presents some suggestions of things to strive towards in developing a robust risk assessment. These attributes are presented in the context of standards. If met, these standards would ensure the quality of risk assessments, and ensure that quality information is provided to, and used by, SPS decision

Probabilistic Scenario Analysis

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- Terminology
- Background – Decision-making under Uncertainty
- Risk Assessment
- Probabilistic Scenario Analysis Methodology (PSA)
- PSA Example - Importing Fruit from Utopia
- Attributes of a good Risk Assessment

Terminology: What is Risk & Hazard?

- The concise Oxford Dictionary
  - defines risk (noun) in terms of a hazard, chance, bad consequences, loss, etc., exposure to mischance.
  - It defines risk (verb) in terms of: to expose to chance of injury or loss, venture on, accept the chance of.
- However in general, they can be defined as follows:
  - Hazard is the potential to cause disease/injury/harm/damage/loss;
  - Risk is the likelihood of disease/injury/harm/damage/loss and the magnitude/severity of that disease/injury/harm/damage/loss.

Terminology - Hazards

Potential to cause disease/injury/harm/damage/loss

TYPE of Hazard	**Examples**
Food Safety	E. coli in meat, Salmonella in eggs, mercury in fish
Human Health	Poor eating habits, Stress, exposure to disease
Animal Health	FMD introduction, BSE introduction via imports
Plant Health	Import of fruit with SOS, CBS. ALB Intro via SWPM
Chemical	Toxic chemicals released from chemical process
Thermal	high energy explosion from a chemical reactor
Mechanical	kinetic or potential energy from a moving object.
Electrical	potential difference, electrical and magnetic fields, electrical shock
Ionizing Radiation	Radiation released from a nuclear plant

Terminology
APHIS - RISK ASSESSMENT

- The evaluation of the likelihood of entry, establishment, or spread of a pest or disease within the United States according to the sanitary or phytosanitary measures which might be applied, and of the associated biological and economic consequences.
- Evaluation of the biological effectiveness of contemplated risk mitigation strategies is an essential part of the assessment of sanitary and phytosanitary risk for Proposed and Final Rules.

Terminology: Uncertainty and Variability

- **Uncertainty** - refers to lack of knowledge about specific factors, parameters, or models. Includes:
  - Parameter uncertainty (measurement, sampling, and systematic errors)
  - Model uncertainty (due to necessary simplification of real world processes, mis-specification of model structure, model misuse, use of inappropriate surrogate variables)
  - Scenario uncertainty (descriptive errors, aggregation errors, errors in professional judgment, incomplete analysis)
- **Variability** - refers to differences attributable to true heterogeneity, or diversity in population or parameter. Sources are a result of natural random processes and stem from environmental/lifestyle/genetic differences among humans, animals, plants, cells, or microbes. Examples of variability include:
  - Plant, Animal or human: physiological variation (Age, bodyweight, height, blood pressure, heart rate, drinking water intake rates)
  - Climatic variability, variation in soil types, differences in contaminant concentrations
- **Further measurement or study**:
  - Reduces Uncertainty
  - Better Characterizes Variablity

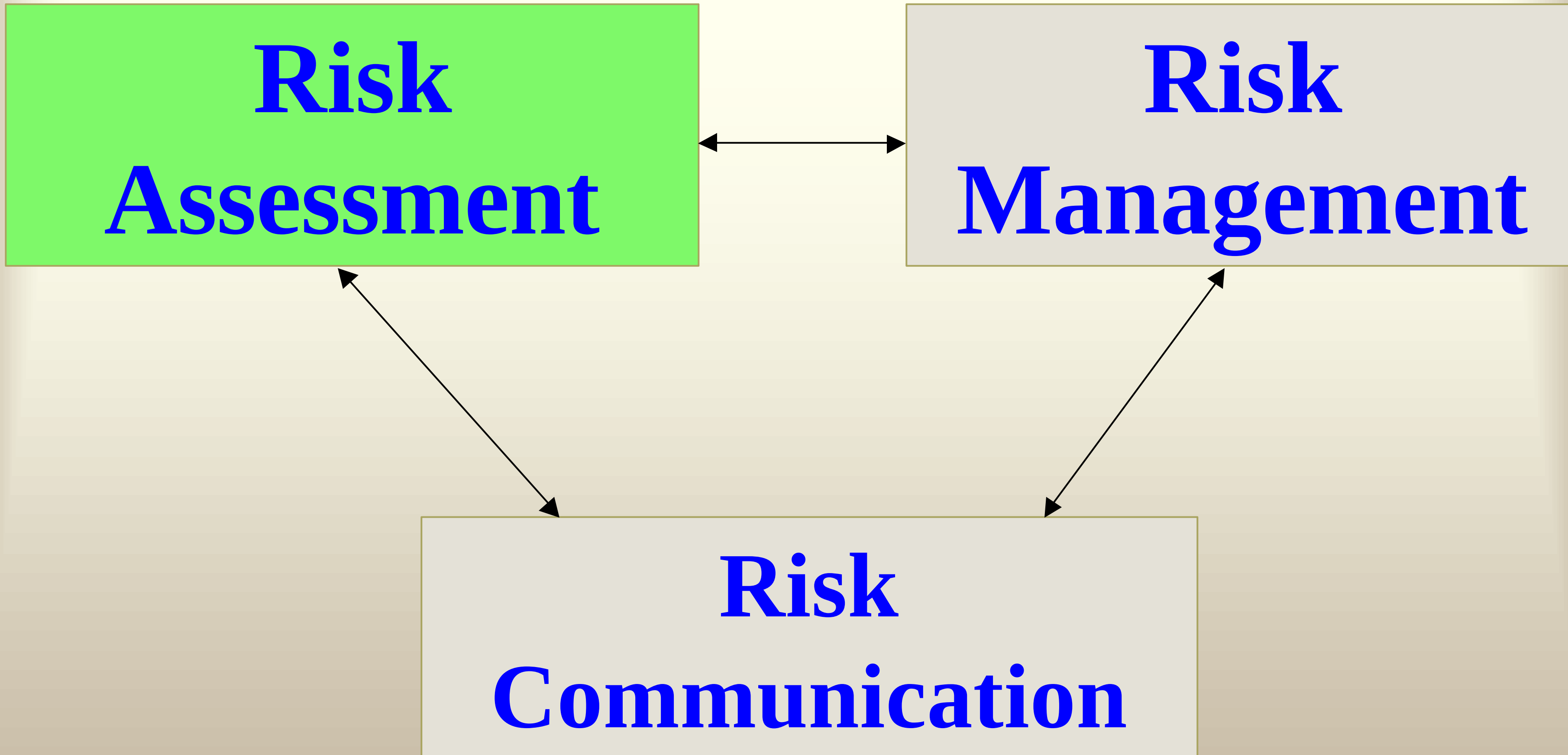
Decision-making under Uncertainty

- The purpose of SPS risk assessment is to help decision-makers make informed decisions about SPS regulations.
- Risk assessments should inform decision-makers about the level of biological risk associated with contemplated or proposed regulatory options.
- Risk assessments should also inform decision-makers about the level/degree of uncertainty surrounding the risk values presented.

Decision-making under Uncertainty

- Science based decision making depends on several analyses (risk, economic, environmental)
- The validity, quality & objectivity of these analyses is essential.
- The data and assumptions in all analytical documents used to support decision-making must be consistent.
- Decision Makers need to understand & have confidence in these analyses.
- The analyses should stand up to scrutiny
- RA, EA, and EIS need to be Credible, Scientifically valid, Transparent, and should provide useful assistance to the decision-makers.

Risk Analysis



Risk Assessment

- **Risk Assessment is a technique for identifying, characterizing, quantifying, and evaluating hazards.**
- Risk Assessment is the process of identifying a hazard and evaluating the risk of that hazard, whether in absolute or relative terms.
- It includes estimates of uncertainty and is based on the best reasonably obtainable and sound scientific knowledge available

How is Risk Assessment done?

Risk Assessment consists of answering these questions:

1. What can go wrong that could lead to an outcome of hazard exposure?
2. How likely is this to happen?
3. If it happens, what consequences are expected?

The Probabilistic Scenario Analysis Methodology of Risk Assessment

The PSA methodology has the following steps:

- Identify the hazard of interest.
- State the question to be investigated.
- Develop a success or as planned scenario.
- Develop an "event tree" or "scenario tree"
- Collect evidence to evaluate the nodes of the event tree
- Quantify the nodes of the event tree
- Link the information generated by the scenario analysis with the empirical evidence

Probabilistic Scenario Analysis (PSA) History

- 1st use (1940's) - work on the atomic bomb.
- In the 1950's, Hermann Kahn of RAND Corporation used the concepts of PSA to evaluate the "what if" scenarios of nuclear proliferation (Cooke, 1991).
- By 1960 - financial analysis, engineering applications, and general economic evaluations.
- The method has been well tried and proved useful in many fields, including plant and animal health (Kaplan, 1993; Miller et al., 1993; McElvaine et al., 1993).
- It is an excellent tool for estimating the probability or frequency of unwanted event's occurring.

Relating Probabilistic Scenario Analysis (PSA) to the 3 questions that Risk Assessment answers

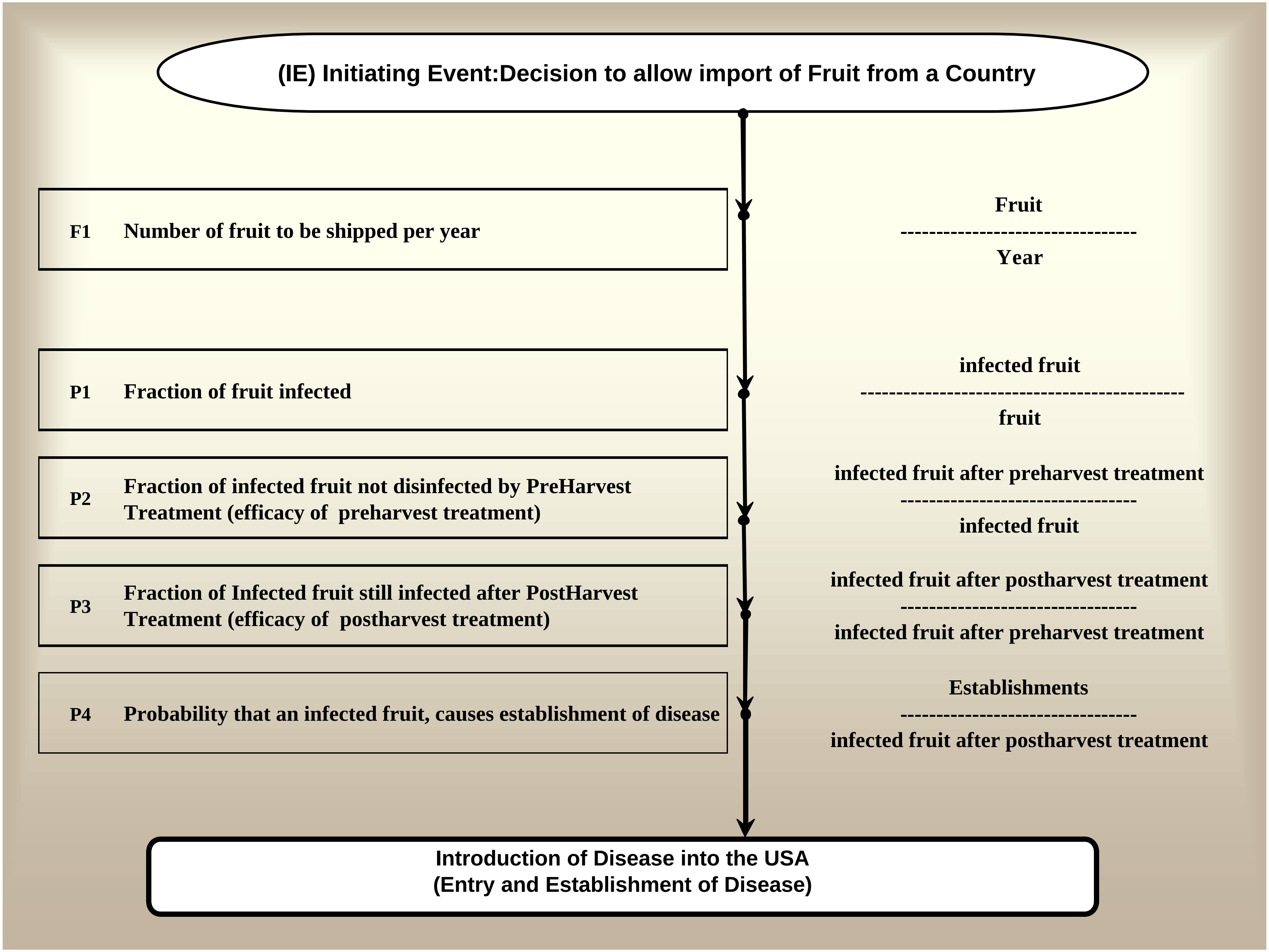
	Risk Assessment	Probabilistic Scenario Analysis
1	What can go wrong that could lead to an outcome of hazard exposure? (Identification & Characterization of risk)	1. Identify the hazard of interest. 2. State the question to be investigated. 3. Develop a success or as planned scenario. 4. Develop an "event tree" or "scenario tree"
2	How likely is this to happen? (Quantification of Risk) Likelihood and Magnitude	5. Collect evidence to evaluate the nodes of the event tree 6. Quantify the nodes of the event tree 7. Link the information generated by the scenario analysis with the empirical evidence
3	If it happens, what consequences are expected?	

Relating Probabilistic Scenario Analysis to the 3 questions that Risk Assessment answers

	Risk Assessment	Modified PSA
1	What can go wrong that could lead to an outcome of hazard exposure? (Identification & Characterization of risk)	1. Identify the hazard of interest. 2. State the question to be investigated. 3. Identify the critical control points (mitigations). 4. Perform a scenario/pathway analysis and Develop an "event tree" or “scenario tree” or “risk pathway”
2	How likely is this to happen? (Quantification of Risk) Likelihood and Magnitude or Frequency	5. Collect evidence to evaluate the nodes of the event tree 6. Quantify the nodes of the event tree 7. Link the information generated by the scenario analysis with the empirical evidence
3	If it happens, what consequences are expected?	

1. What can go wrong that could lead to an outcome of hazard exposure?

- Given a system/process with defined goals/methodologies:
  - failures of components/procedures/safeguards/mitigations can occur - leading to hazards being manifested
- To determine what can go wrong:
  - Identify the hazard of interest.
  - State the question to be investigated.
  - Identify the CCP's - Develop a success or as planned scenario.
  - Develop an "event tree" or "scenario tree"
- The process of defining the possible scenarios that lead to the outcomes or events of interest, is called **Scenario Analysis**
- The graphic depiction of all the events (successes and failures of safeguards/procedures/components) that lead to the outcomes of hazard exposure/prevention, is called an **Event Tree**, **Scenario Tree**, or **Risk Pathway Tree**.


(IE) Initiating Event:Decision to allow import of Fruit from a Country
F1 Number of fruit to be shipped per year
Fruit / Year
P1 Fraction of fruit infected
infected fruit / fruit
P2 Fraction of infected fruit not disinfected by PreHarvest Treatment (efficacy of preharvest treatment)
infected fruit after preharvest treatment / infected fruit
P3 Fraction of Infected fruit still infected after PostHarvest Treatment (efficacy of postharvest treatment)
infected fruit after postharvest treatment / infected fruit after preharvest treatment
P4 Probability that an infected fruit, causes establishment of disease
Establishments / infected fruit after postharvest treatment
Introduction of Disease into the USA
(Entry and Establishment of Disease)

2. How likely is this to happen?

- Once a scenario tree has been developed to depict what can go wrong/right, and how it can happen.
- The next step is to quantify how likely it is for the hazard depicted in the scenario/event tree to occur.
  - What is the probability that the hazard will occur?
  - How frequently will it occur each year?
  - How many years until the next occurrence?

- In order to answer these questions, one needs to assign probabilities to the branches of each node in the tree.
  - Collect evidence to evaluate the nodes of the event tree
  - Quantify the nodes of the event tree
  - Link the information generated by the scenario analysis with the empirical evidence

How likely is this to happen? – Parameter Estimation

Evaluate Origin, Commodity, and Destination factors

- **Origin Risk Factors:** Does region contain Pest/Disease ?
  - Prevalence of pest or disease, Geographic & Environmental characteristics, SPS status of neighbors & trade partners, Regulatory & SPS infrastructure, Surveillance systems, Previous RA's
- **Commodity Risk Factors:** Does the commodity contain Pests/Diseases, and can it transmit them?
  - Type or class of commodity, Nature of raw material, Intended use, Handling, Pest or disease agent survivability, Interception data.
- **Destination Risk Factors:**
  - Does the pest/disease survive, multiply, establish and spread?
  - What are the consequences/response (SPS, economic, environment)?

Parameter:	**P1**
Description:	**Proportion of diseased fruit in a region this year**
Units	**Disease Fruit in the Region --- Fruit in the region**
Evidence	
1	**Gill et al.[1] in their survey found 1 in 1000 fruit infected.**
2	**Gill et al.[2] in further studies in abandoned groves……..**
3	
References	
1	**Gill, T., Potter H., Horticultural Science, 3:7, 1965. [page 23, par 4]**
2	**Gill, T., Potter H., Horticultural Science, 3:7, 1965. [page 42, table 8]**
3	
Evaluation of evidence	
1	**Based on Evidence 1 & 2, the most likely value for F1 is .001**
2	**Based on evidence 2, 4, 7, 23 and 24, the maximum value was obtained by averaging the experts maximum values.**
3	

3. What consequences are expected?

- A scenario tree has been developed to depict what can go wrong/right.
- The likelihood of the hazard occurring has been quantified.
- The next step is to determine what the consequences are, given that the hazard occurs:
  - Given various management options, the specific question asked are:
    - What are the SPS consequences?
    - What are the economic consequences?
    - What are the environmental consequences?
- These questions need to be asked for all plausible combinations of mitigations & management options

The Likelihood, Frequency & Consequences of a hazard Under Varying Management Options (MO)

	BL 0	MO 1	MO 2	MO 3	MO 4
Likelihood					
Frequency					
Years till next occurence					
SPS Consequence					
Economic Consequence					
Environmental Consequence					

Import of Fruit Example

Import of Fruit Example

Risk Assessment consists of answering these questions:

1. What can go wrong that could lead to an outcome of hazard exposure?
2. How likely is this to happen?
3. If it happens, what consequences are expected?

Import of Fruit - What can go wrong?

FACTS:

Utopia, has asked to be allowed to export fruit to your country.

Utopia has disease/pest X.

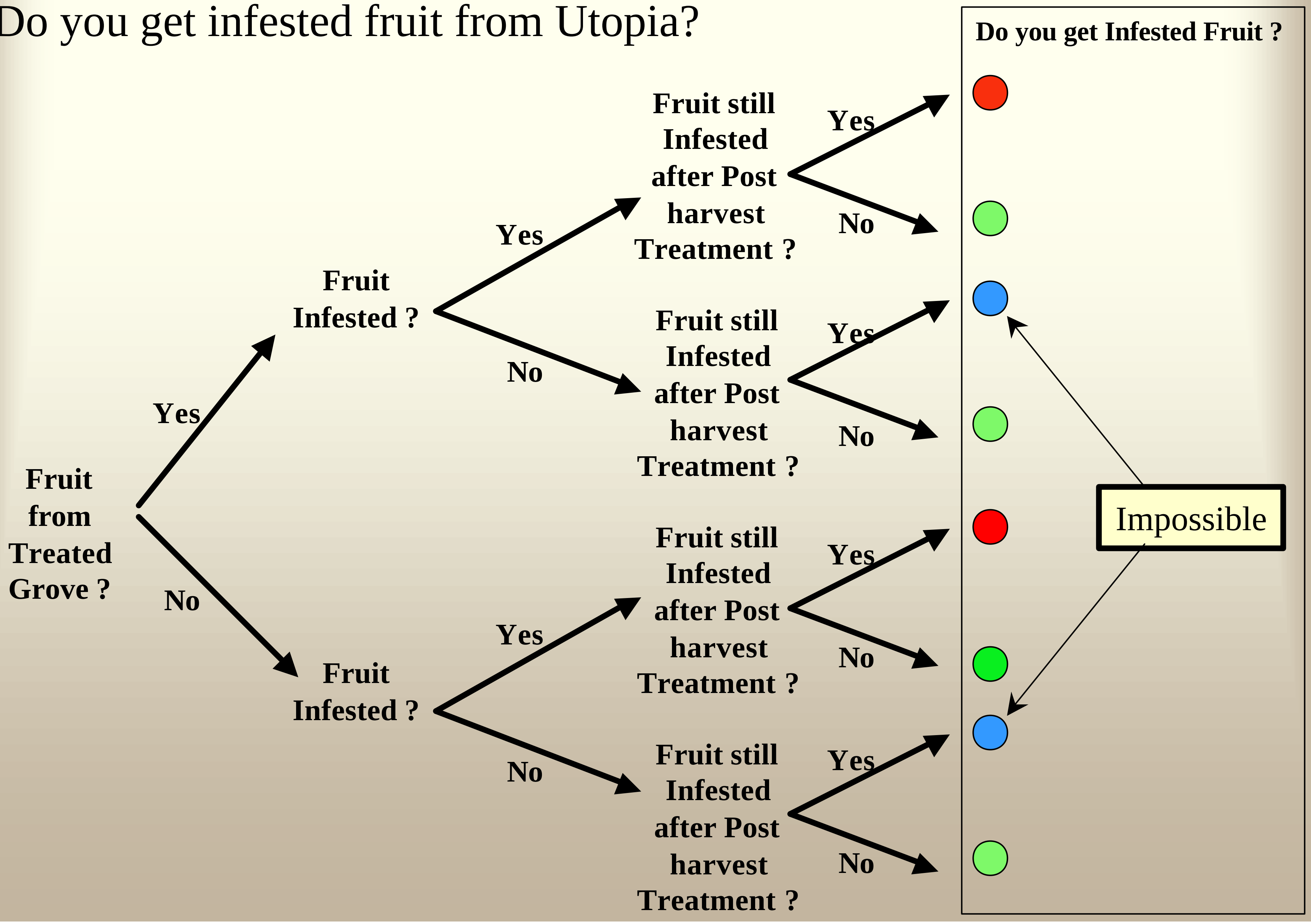
You do not have disease/pest X - quarantinable.

Fruit movement can be a a possible pathway for disease/pest X spread and establishment in non-infected areas.

- In Utopia:
  - Groves are pre-harvest treated for disease/pest X
  - Groves are selected and Fruit is harvested from them
  - The fruit are post harvest treated for disease/pest X
  - They are packed and then exported to you
- **Hazard:** infested/infected fruit exported from Utopia to you.
- **Questions:**
  - What is the likelihood that fruit exported to you from Utopia is diseased?
  - What is the likelihood that disease/pest X is established in your country as a result of imports of fruit from Utopia?

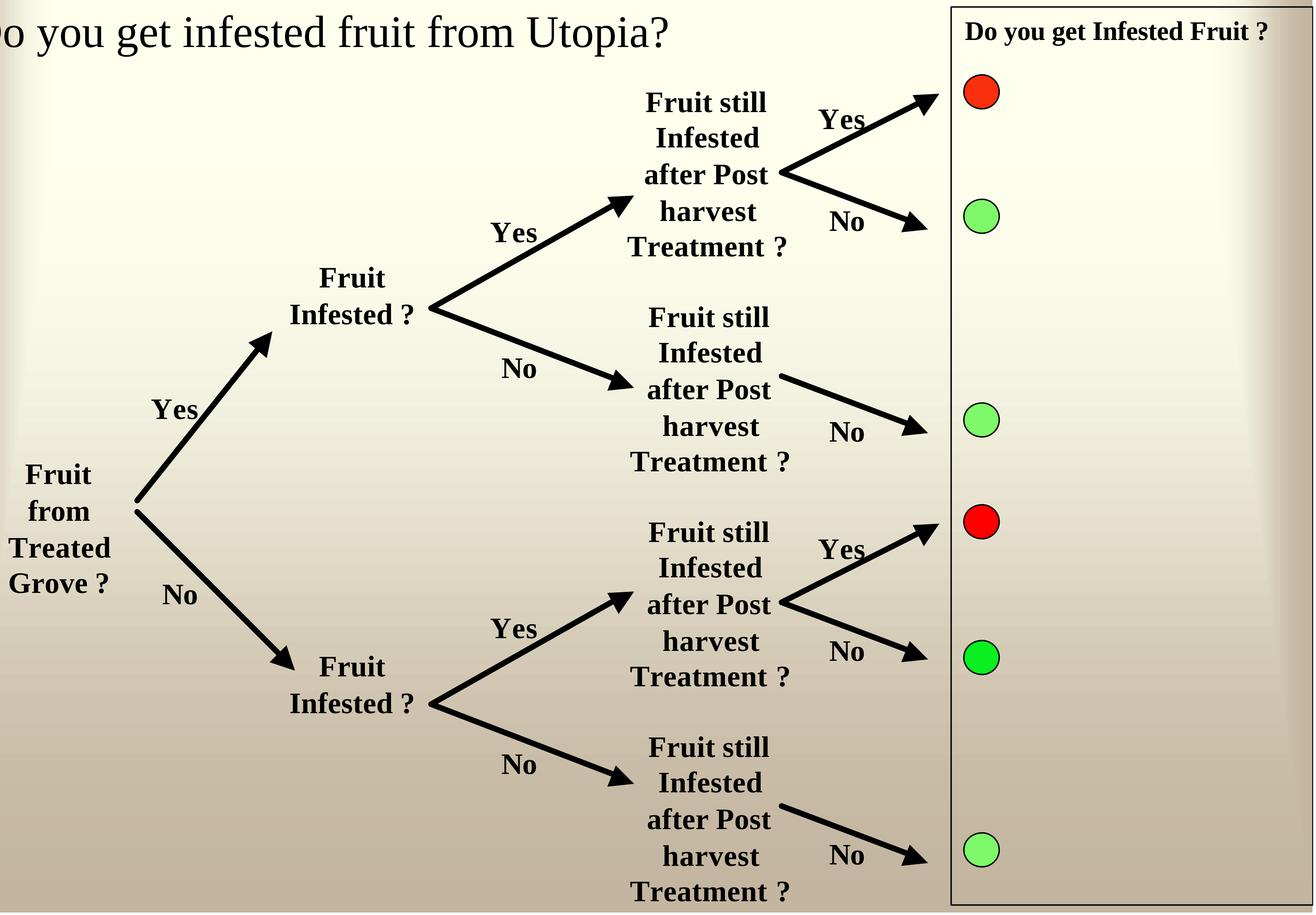
Develop an Event Tree, Scenario Tree of What can go wrong?

Do you get infested fruit from Utopia?



Event Tree or Scenario Tree of What can go Wrong ?

Do you get infested fruit from Utopia?



NEXT STEP

Risk Assessment consists of answering these questions:

1. What can go wrong that could lead to an outcome of hazard exposure?
2. How likely is this to happen?
3. If it happens, what consequences are expected?

2. How likely is this to happen?

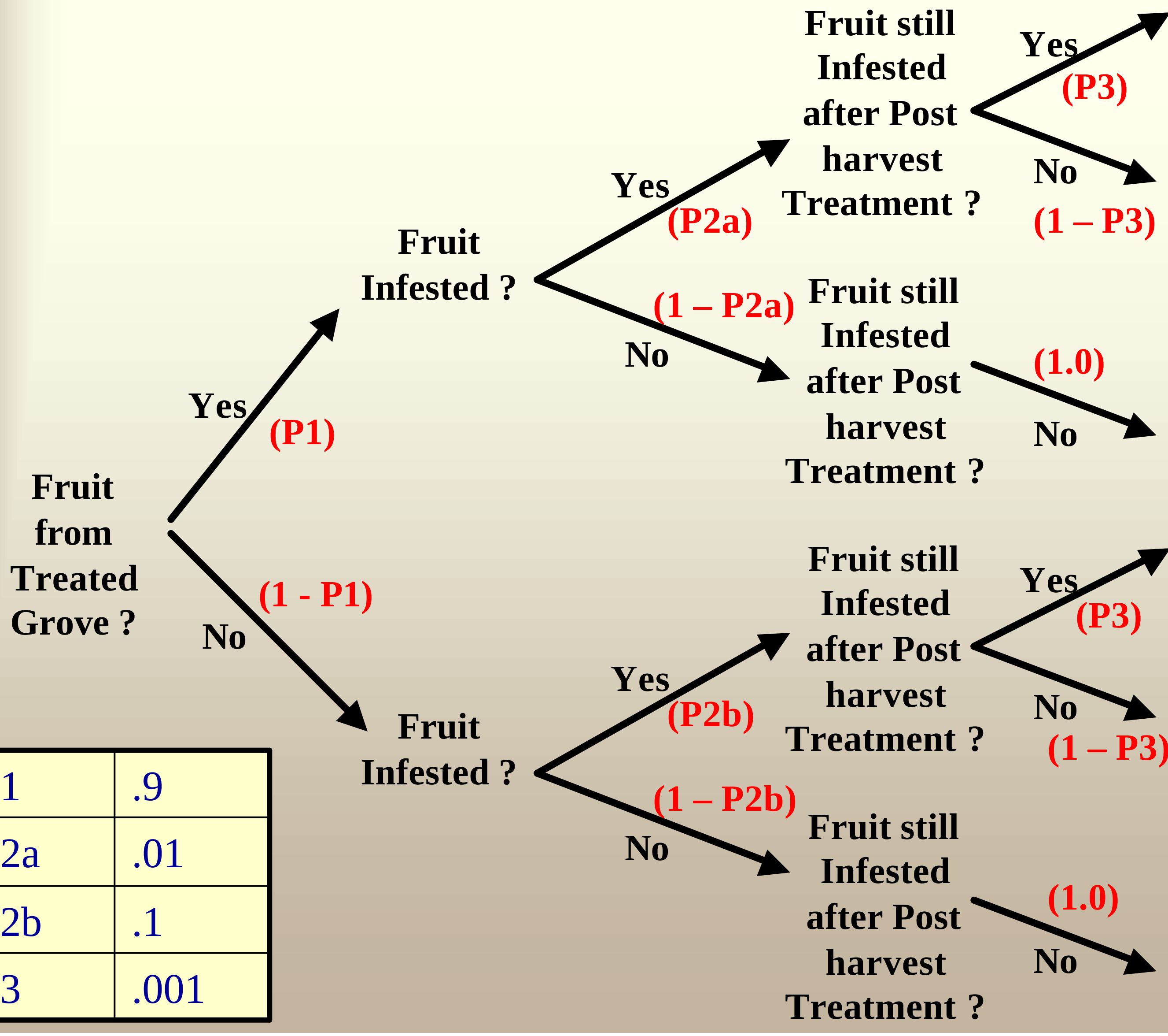
- A scenario tree has been developed to depict what can go wrong/right, and how it can happen.
- The next step is to quantify how likely it is for the hazard depicted in the scenario/event tree to occur.
  - What is the probability that infected fruit from Utopia will enter the USA?
  - How many infected fruit will enter the USA each year?
  - How many years until the next occurrence?

- In order to answer these questions, one needs to assign probabilities to the branches of each node in the tree.
  - Collect evidence to evaluate the nodes of the event tree
  - Quantify the nodes of the event tree
  - Link the information generated by the scenario analysis with the empirical evidence

Scenario Tree – How likely is this to happen

R = Q1+Q4 = .000019

Compute the likelihoods



Do you get Infested Fruit ?

Q1=P1*P2a*P3

Q1=.9*.01*.001= .000009

Q2=P1*P2a*(1-P3)

Q2=.9*.01*.999= .008991

Q3=P1*(1-P2a)*1.0

Q3=.9*.99= .891

Q4=(1-P1)*P2b*P3

Q4=.1*.1*.001= .00001

Q5=(1-P1)*P2b*(1-P3)

Q5=.1*.1*.999= .00999

Q6=(1-P1)*(1-P2b)*1.0

Q6=.1*.9 = .09

P1	.9
P2a	.01
P2b	.1
P3	.001

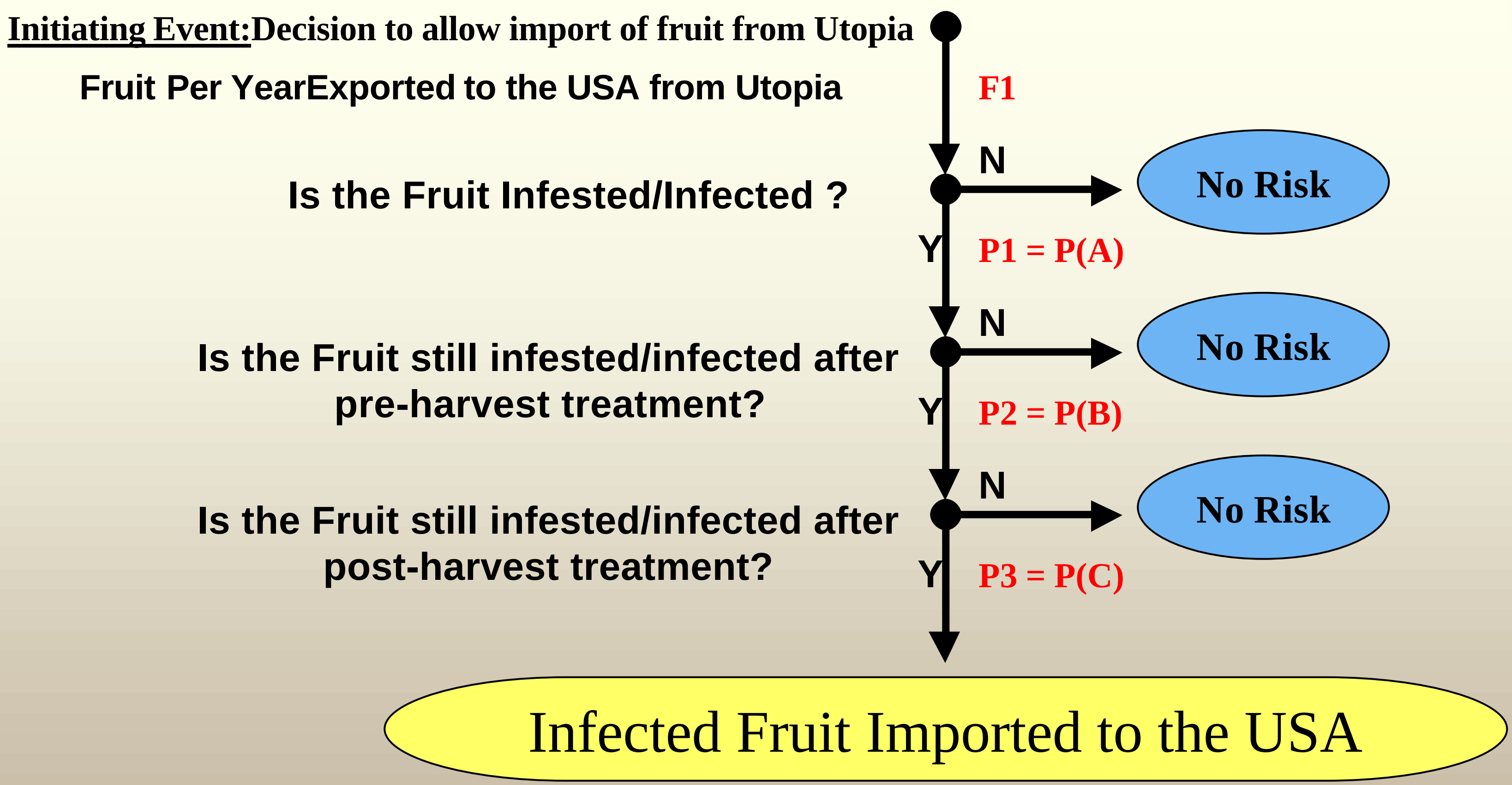
Pictorial representation of probability: Risk Pathway Tree

Denote events as follows:

A = fruit is infected/infested

B = fruit still infested after preharvest treatment

C = fruit still infested after postharvest treatment

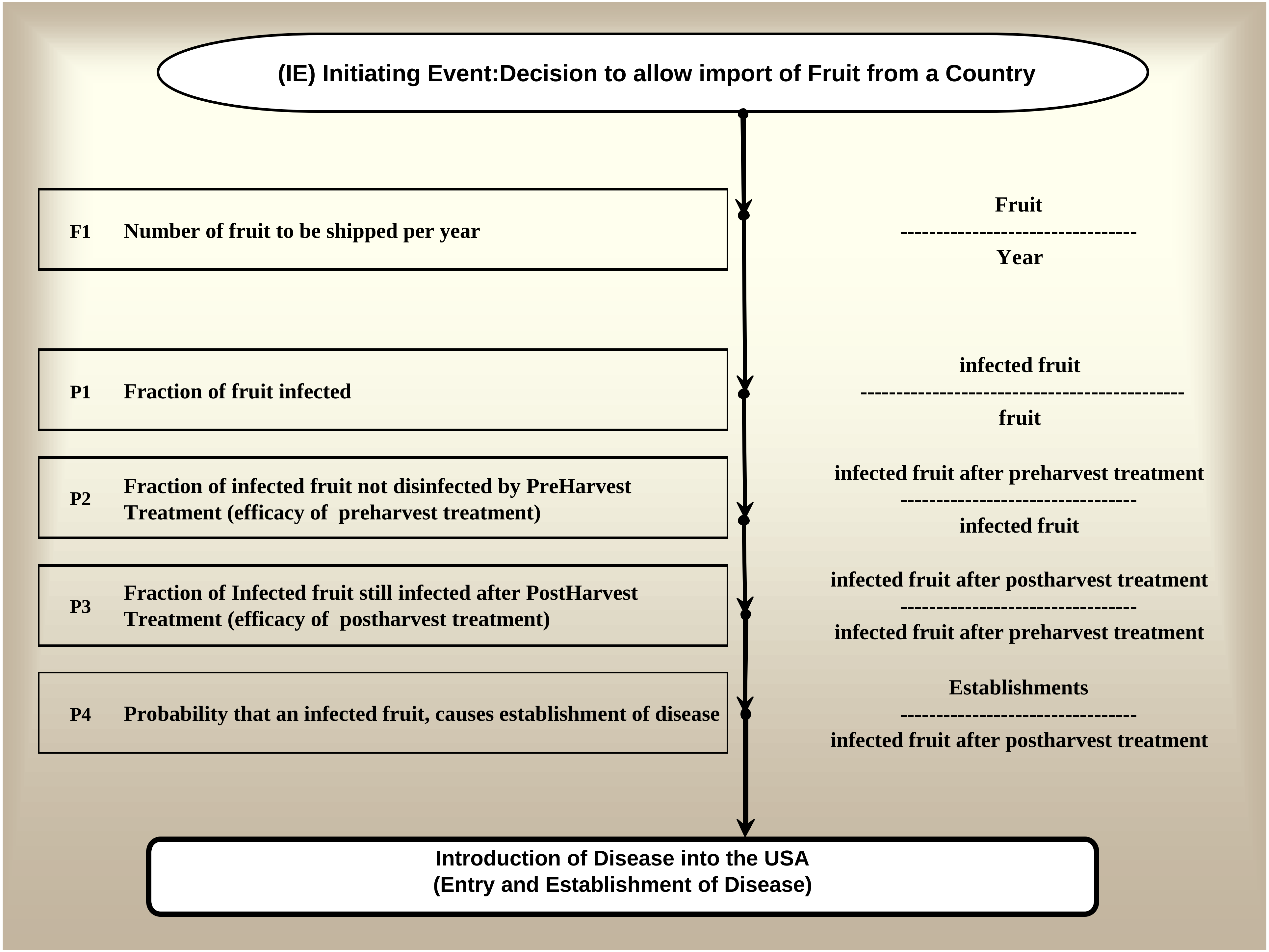


Prob. Imported fruit is infected:	$Q = P(A)*P(B)*P(C)$
Prob. at least 1 Imported fruit is infected:	$R = 1 - [1 - Q]^F$
Frequency of importing infected fruit:	$S = F*P(A)*P(B)*P(C)$

Describe and evaluate the evidence for each Node & Parameter

- **Clearly Label & Identify each parameter on the event tree:**
  - **F**, Number of Fruit Exported to the USA Per Year from Utopia
  - **P1**, Probability that a fruit is Infected
  - **P2**, Probability that pre-harvest treatment does not sanitize the fruit
  - **P3**, Probability that post-harvest treatment does not sanitize the fruit
  - **P4**, Probability that an imported infected fruit causes establishment of disease

- For each Node/Parameter:
  - Gather evidence, associate it with the appropriate node/parameter, and reference it in a bibliography.
  - Evaluate the evidence quantitatively or descriptively. Determine the MIN, ML, and MAX values of each Parameter that are consistent with the available evidence


(IE) Initiating Event:Decision to allow import of Fruit from a Country
F1 Number of fruit to be shipped per year
Fruit

Year
P1 Fraction of fruit infected
infected fruit
----
fruit
P2 Fraction of infected fruit not disinfected by PreHarvest Treatment (efficacy of preharvest treatment)
infected fruit after preharvest treatment
----
infected fruit
P3 Fraction of Infected fruit still infected after PostHarvest Treatment (efficacy of postharvest treatment)
infected fruit after postharvest treatment
----
infected fruit after preharvest treatment
P4 Probability that an infected fruit, causes establishment of disease
Establishments
----
infected fruit after postharvest treatment
Introduction of Disease into the USA
(Entry and Establishment of Disease)

Parameter:	**P1 …… (0.0001, 0.001, 0.1)**
Description:	**Proportion of diseased fruit in Utopia this year**
Units	**Diseased Fruit** **---** **Fruit**
Evidence	
1	**Gill et al.[1] in their survey found 1 in 1000 fruit infected…..**
2	**Gill et al.[2] in further studies in abandoned groves……..**
3	
References	
1	**Gill, T., Potter H., Horticultural Science, 3:7, 1965. [page 23, par 4]**
2	**Gill, T., Potter H., Horticultural Science, 3:7, 1965. [page 42, table 8]**
3	
Evaluation of evidence	
1	**Based on Evidence 1 & 2, the most likely value for F1 is .001**
2	**Based on evidence 2, 4, 7, 23 and 24, the maximum value, 0.1, was obtained by averaging the experts max. values.**
3	**Green et al., according to evid. 3, state…min value is 0.0001**

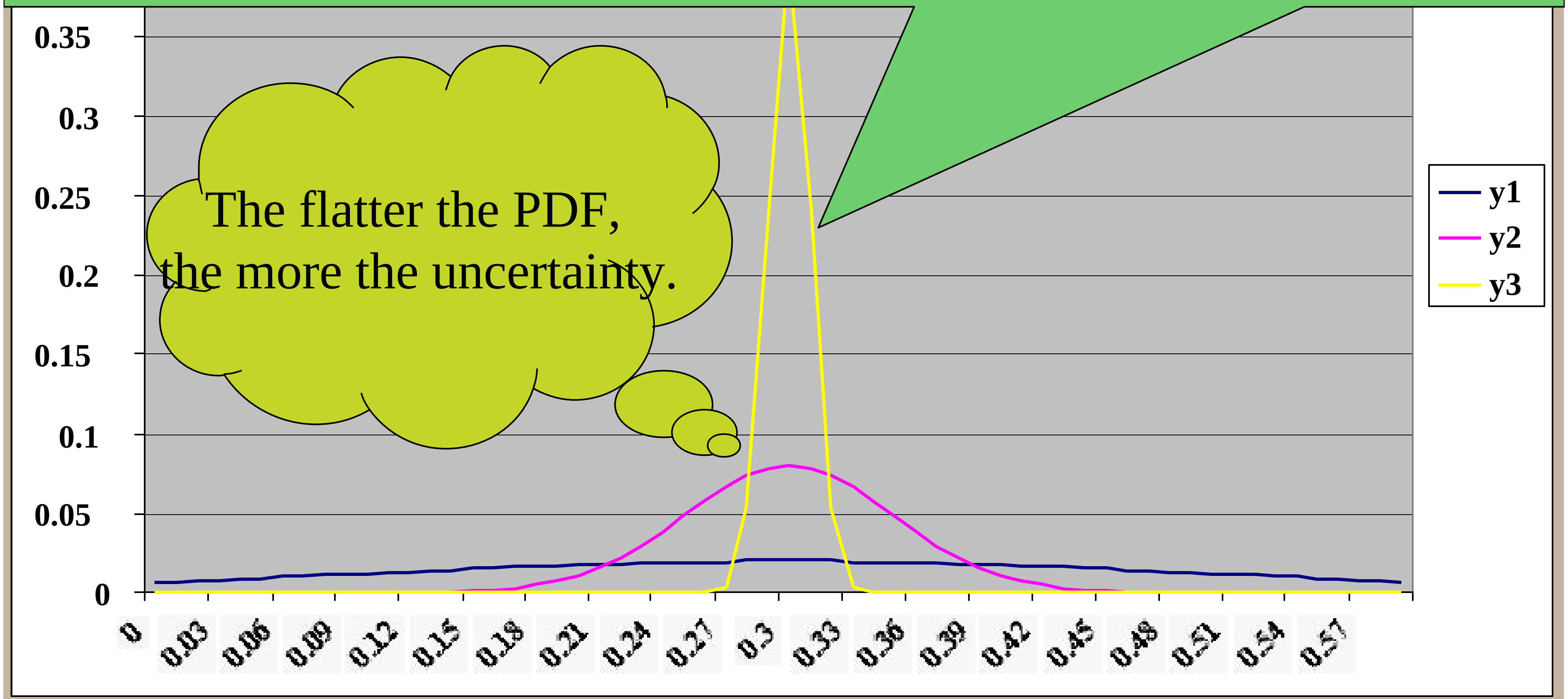
Uncertainty in P1, Prop. Infected Fruit (Prevalence)

Probability density function (PDF) [also known as probability function/frequency function]

•PDF - Expresses the probability that a continuous random variable falls within some very small interval.

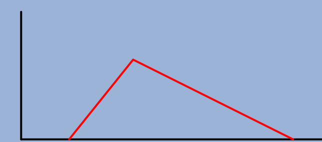
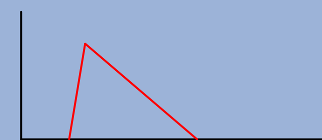
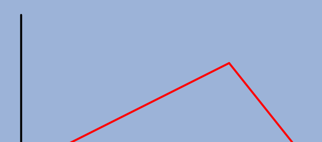
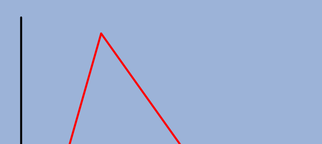
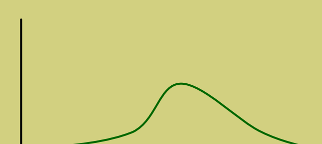
•PMF - Expresses the probability that a discrete random variable takes on a specific value.

•CDF - Cumulative distribution function F(x) = Prob (P1 " x)



Monte Carlo Analysis/Simulation

- A computer based method of analysis developed in the 40's that uses statistical sampling techniques in obtaining a probabilistic approximation to the solution of a mathematical equation or model

Symbol	MIN	ML	MAX	PDF
F1				
P1				
P2				
P3				
Result	**$q=P1*P2*P3$ or $r = 1 - (1-q)^{F1}$**			

NEXT STEP

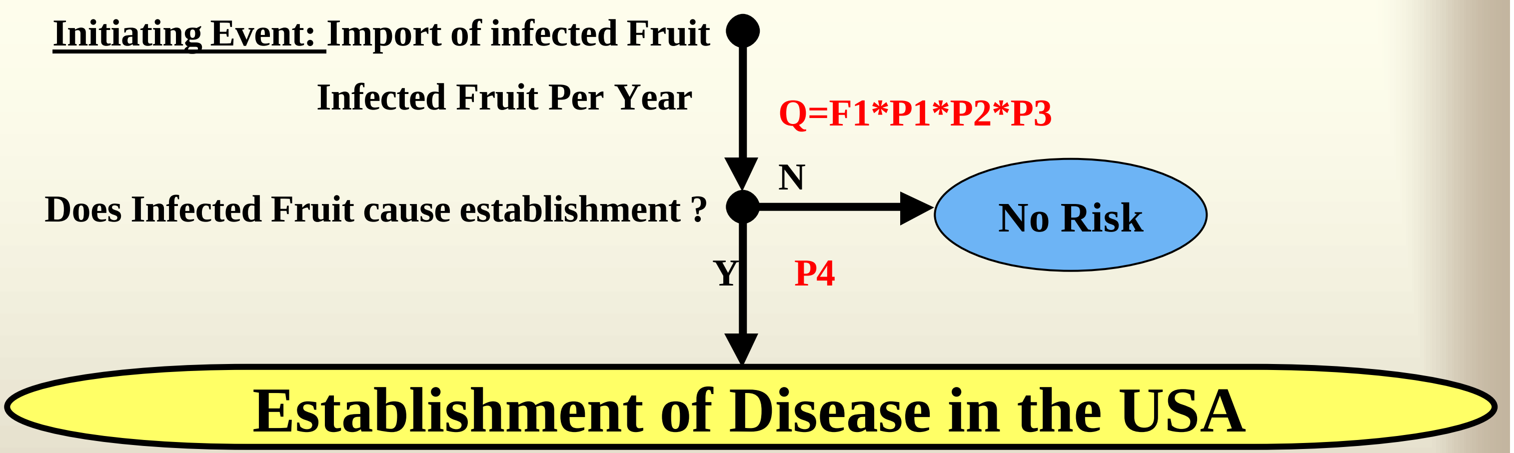
Risk Assessment consists of answering these questions:

1. What can go wrong that could lead to an outcome of hazard exposure?
2. How likely is this to happen?
3. If it happens, what consequences are expected?

3. What consequences are expected?

- A scenario tree has been developed to depict what can go wrong/right.
- The likelihood of the hazard occurring has been quantified.
- The next step is to determine what the consequences are, given that the hazard occurs:
  - Given various management options, the specific question asked are:
    - What are the SPS consequences?
    - What are the economic consequences?
    - What are the environmental consequences?
- These questions need to be asked for all plausible combinations of mitigations & management options

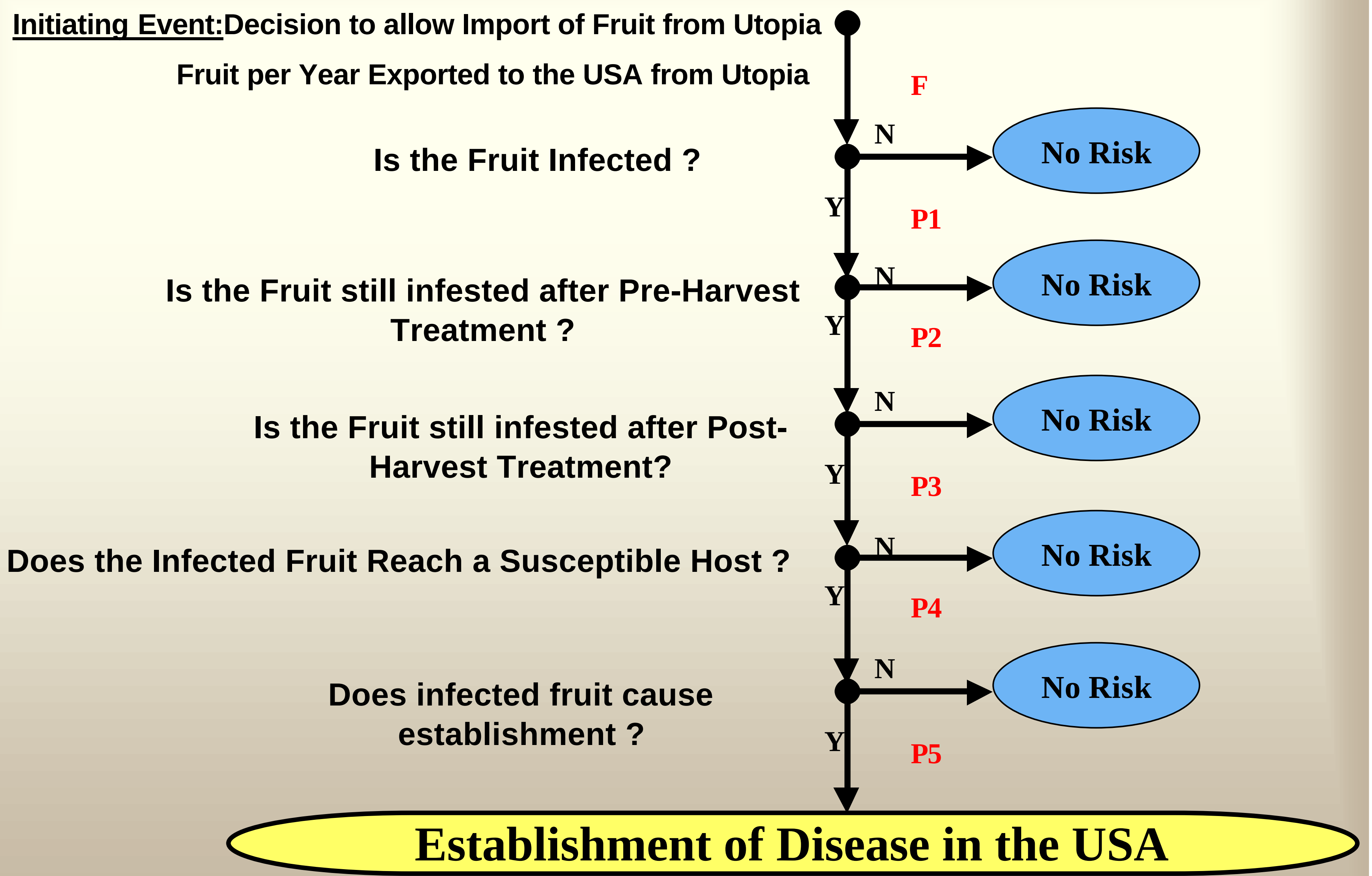
Consequences: Risk Pathway Tree



Frequency of Entry of Infected Fruit into the USA: q = F1*P1*P2*P3

Frequency of Establishments caused in USA: k = q*P4

Pictorial representation of probability: Risk Pathway Tree - Consequences



Prob. Imported Fruit causes Establishment: $p = P1*P2*P3*P4*P5$

Prob. Of at least 1 establishment: $q = 1 - [1 - p]^F$

Frequency of Establishments: $k = F*p$

The Likelihood, Frequency & Consequences of infected fruit from Utopia causing Establishment in the USA
Under Varying Management Options (MO)

	BL 0	MO 1	MO 2	MO 3	MO 4
Likelihood					
Frequency					
Years till next occurence					
SPS Consequence					
Economic Consequence					
Environmental Consequence					

Conclusion - The PSA Methodology

The PSA methodology has the following steps:

- Identify the hazard of interest.
- State the question to be investigated.
- Identify the mitigations (baseline and program).
- Develop an "event tree" or "scenario tree"
- Collect evidence to evaluate the nodes of the event tree
- Quantify the nodes of the event tree
- Link the information generated by the scenario analysis with the empirical evidence. Compute the likelihoods.
- Report the results.

Questions that Risk Assessment strives to answer vs Probabilistic Scenario Analysis to the

	Risk Assessment	Probabilistic Scenario Analysis
1	What can go wrong that could lead to an outcome of hazard exposure? (Identification & Characterization of risk)	1. Identify the hazard of interest. 2. State the question to be investigated. 3. Identify the mitigations (CCP's). 4. Develop an "event tree" or "scenario tree"
2	How likely is this to happen? (Quantification of Risk) Likelihood and Magnitude	5. Collect evidence to evaluate the nodes of the event tree 6. Quantify the nodes of the event tree 7. Link the information generated by the scenario analysis with the empirical evidence
3	If it happens, what consequences are expected?	

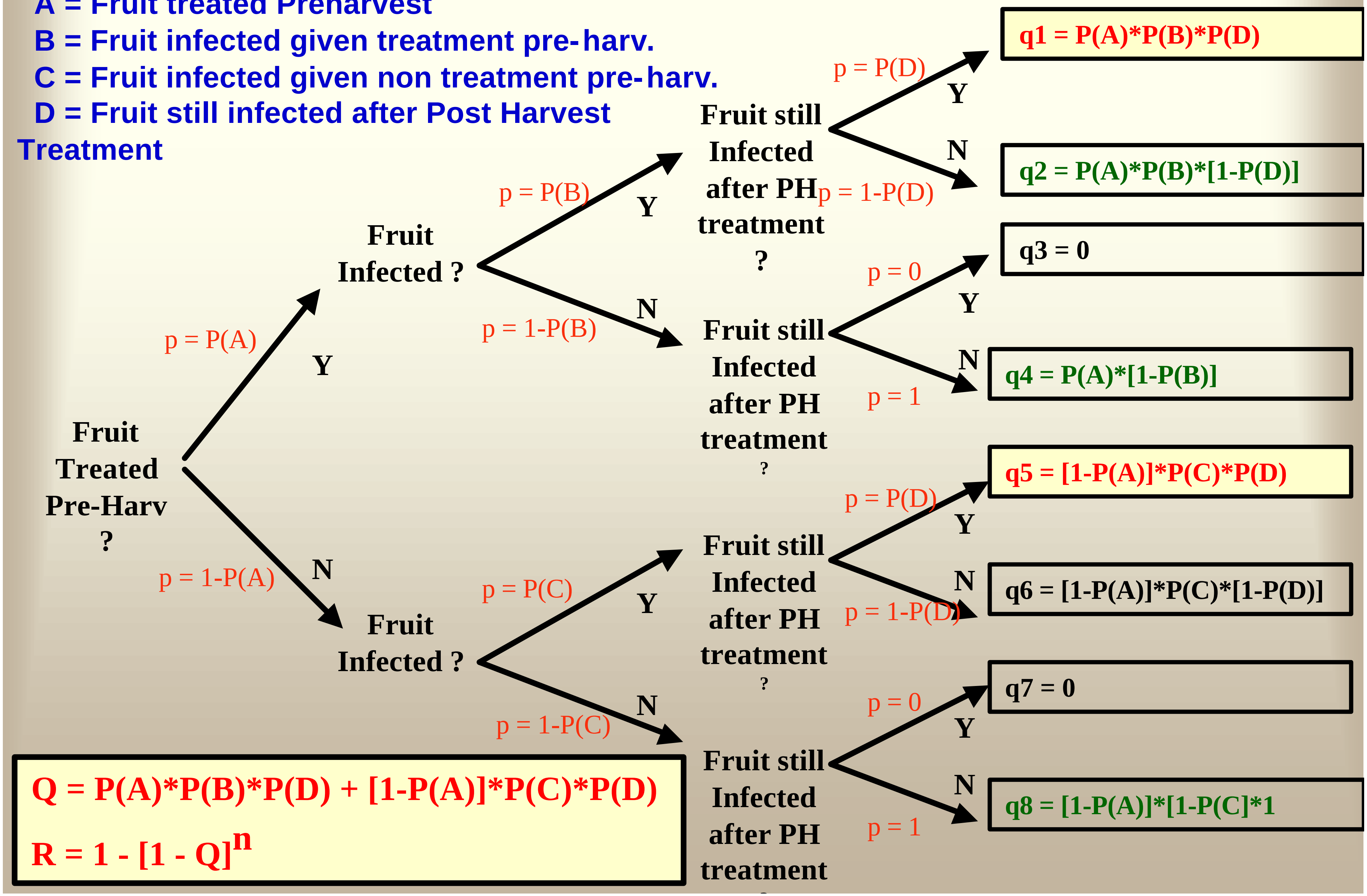
Conclusion

- Risk assessment models:
  - allow the quantification of risk and uncertainty.
  - help to identify gaps in knowledge, thereby defining data needs.
  - help to standardize approaches.
- At a minimum: The Assessment should be transparent, flexible, documented, and consistent.
- The assessment should effectively communicate the insights that it reveals – Be useful for decision making.

Pictorial representation of probability: Event Tree

Denote events as follows:

- A = Fruit treated Preharvest
- B = Fruit infected given treatment pre-harv.
- C = Fruit infected given non treatment pre-harv.
- D = Fruit still infected after Post Harvest Treatment



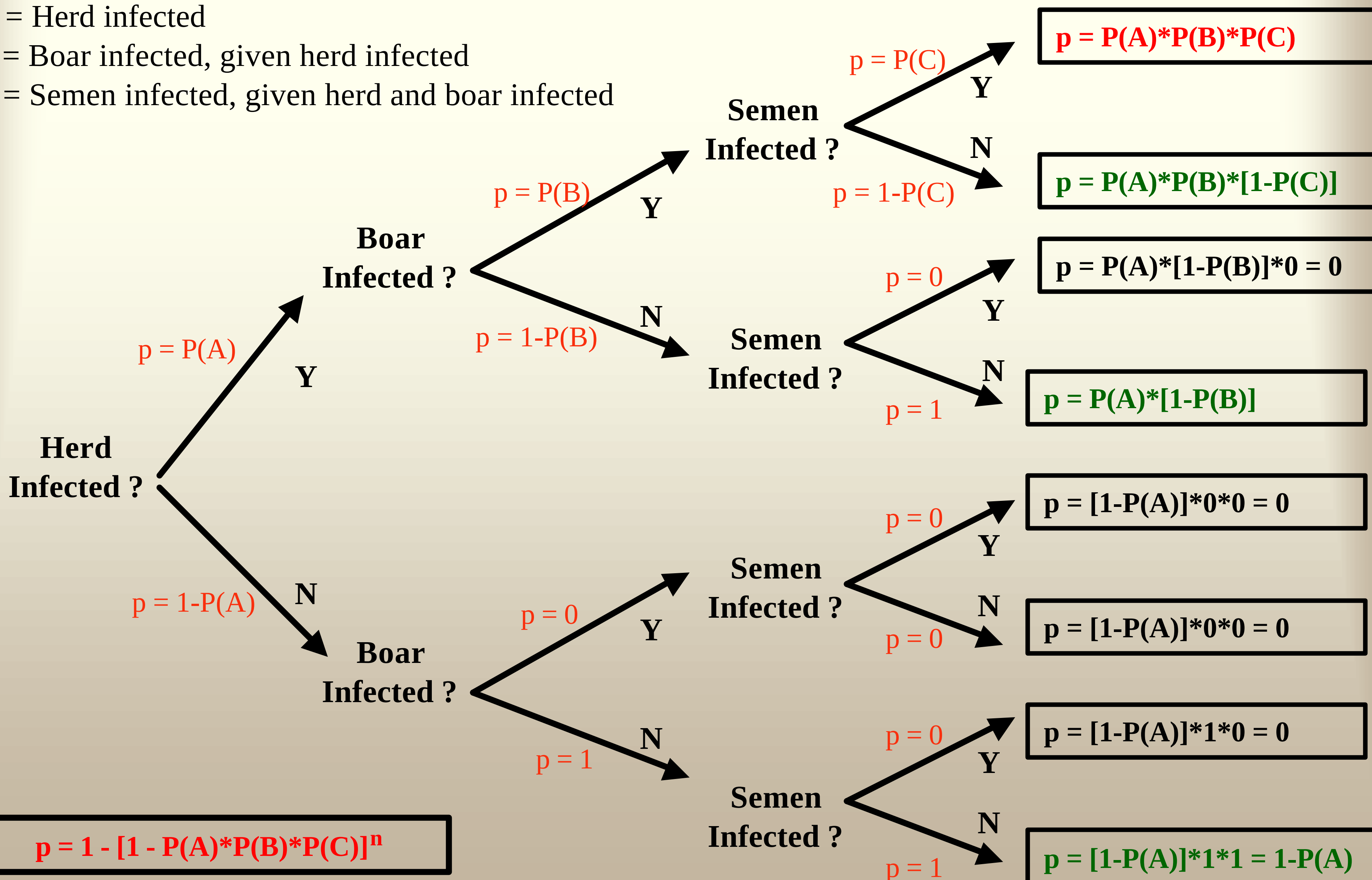
$$Q = P(A)*P(B)*P(D) + [1-P(A)]*P(C)*P(D)$$

$$R = 1 - [1 - Q]^{n}$$

Pictorial representation of probability: Event Tree

Denote events as follows:

- A = Herd infected
- B = Boar infected, given herd infected
- C = Semen infected, given herd and boar infected



$p = 1 - [1 - P(A)*P(B)*P(C)]^n$