

**Intertek**



# Intertek Risk

Comprehensive risk assessment screening

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February 26, 2007

Orlando, FL

You've already been asking yourself the tough questions.

Are there any safety risks with my product line ?

When it comes to my overall portfolio, how do I find the riskiest products among the thousands that are safe ?

Where should my company focus our resources to best deal with this issue?

How will I demonstrate that I've done my due diligence to ensure the safety of my product down the road ?

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Due Diligence  
Brand Value

Recalls  
Negative Publicity

The Media  
Public Opinion

Risk Management

European  
General Product  
Safety Directive

U.S.  
Consumer Product  
Safety Act

Technical  
Files

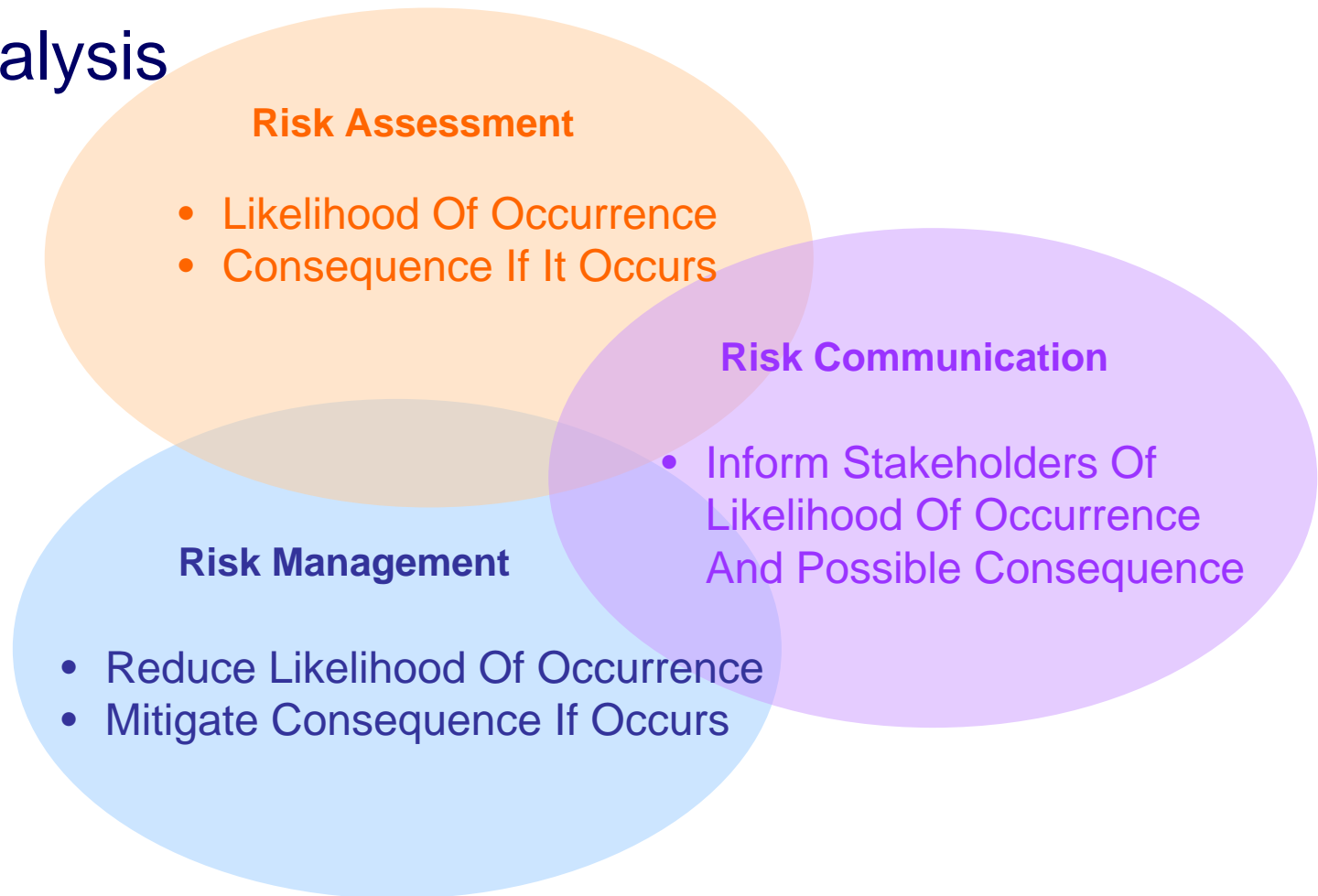


What factors will determine whether my company is subjected to a civil penalty?

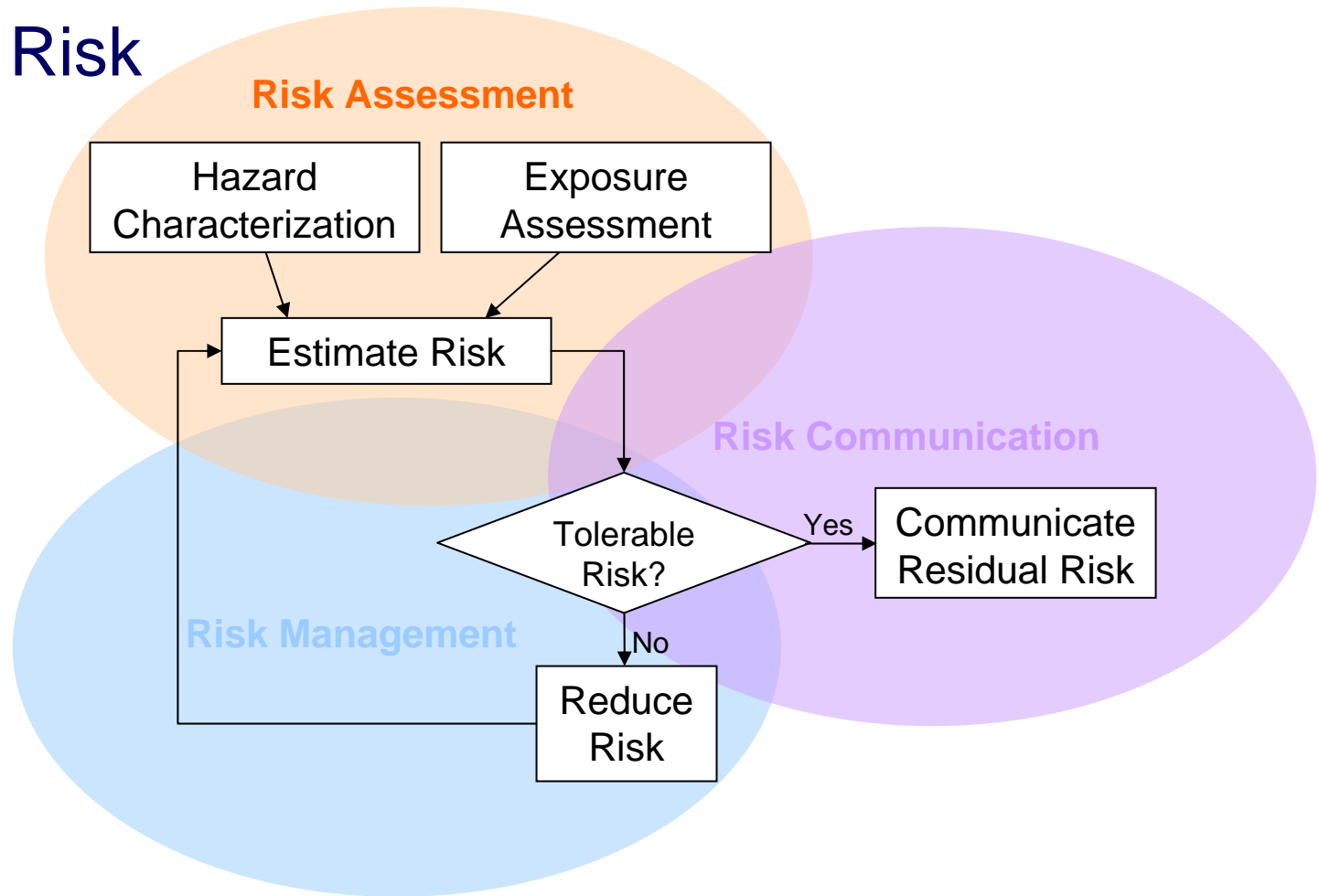
According to Section 15(b), Consumer Product Safety Act:

- The nature of the product defect.
- The severity of the risk of injury.
- The number of defective products distributed.
- The occurrence or absence of injury.
- Penalty in relation to the size of the business.

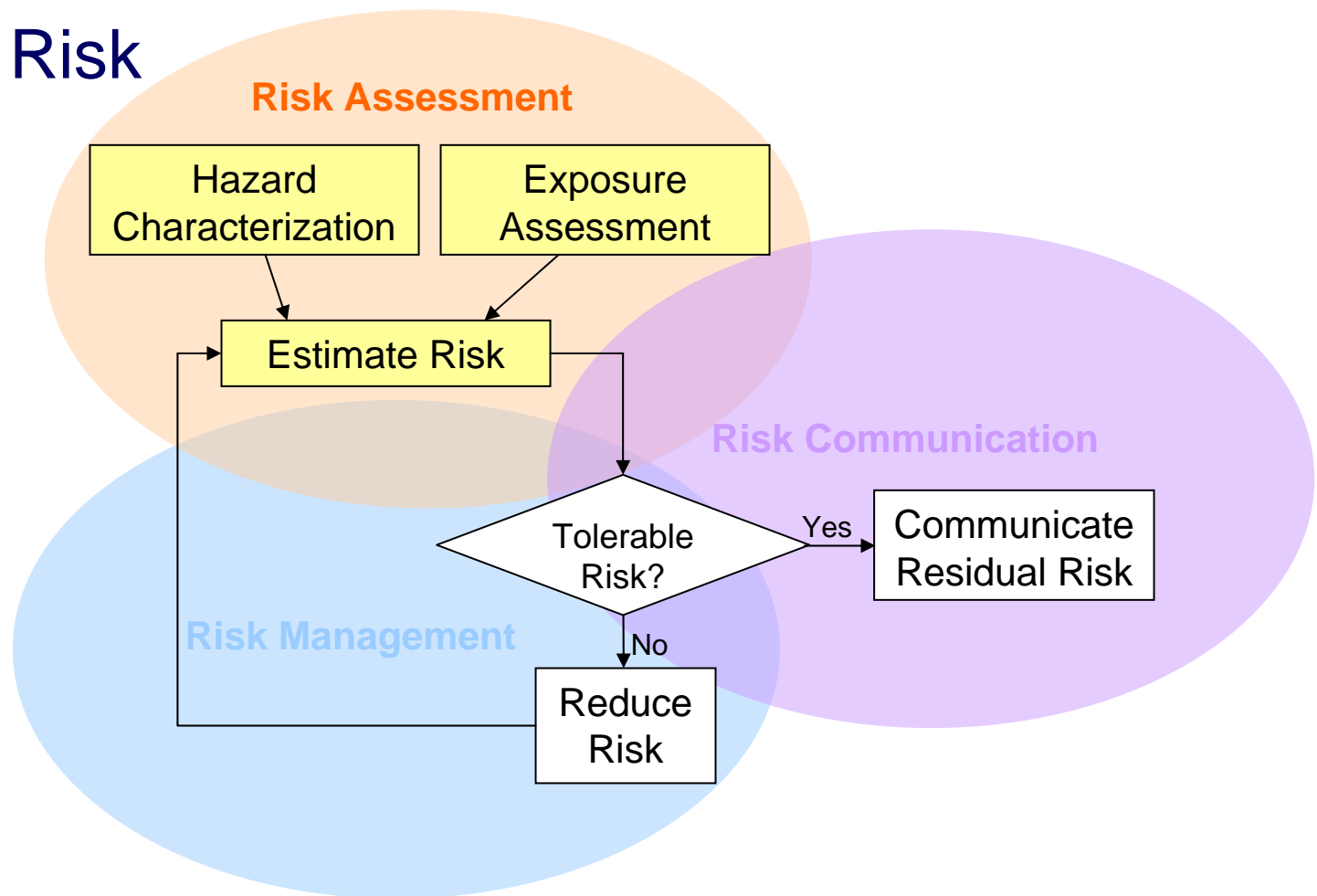
# Risk Analysis



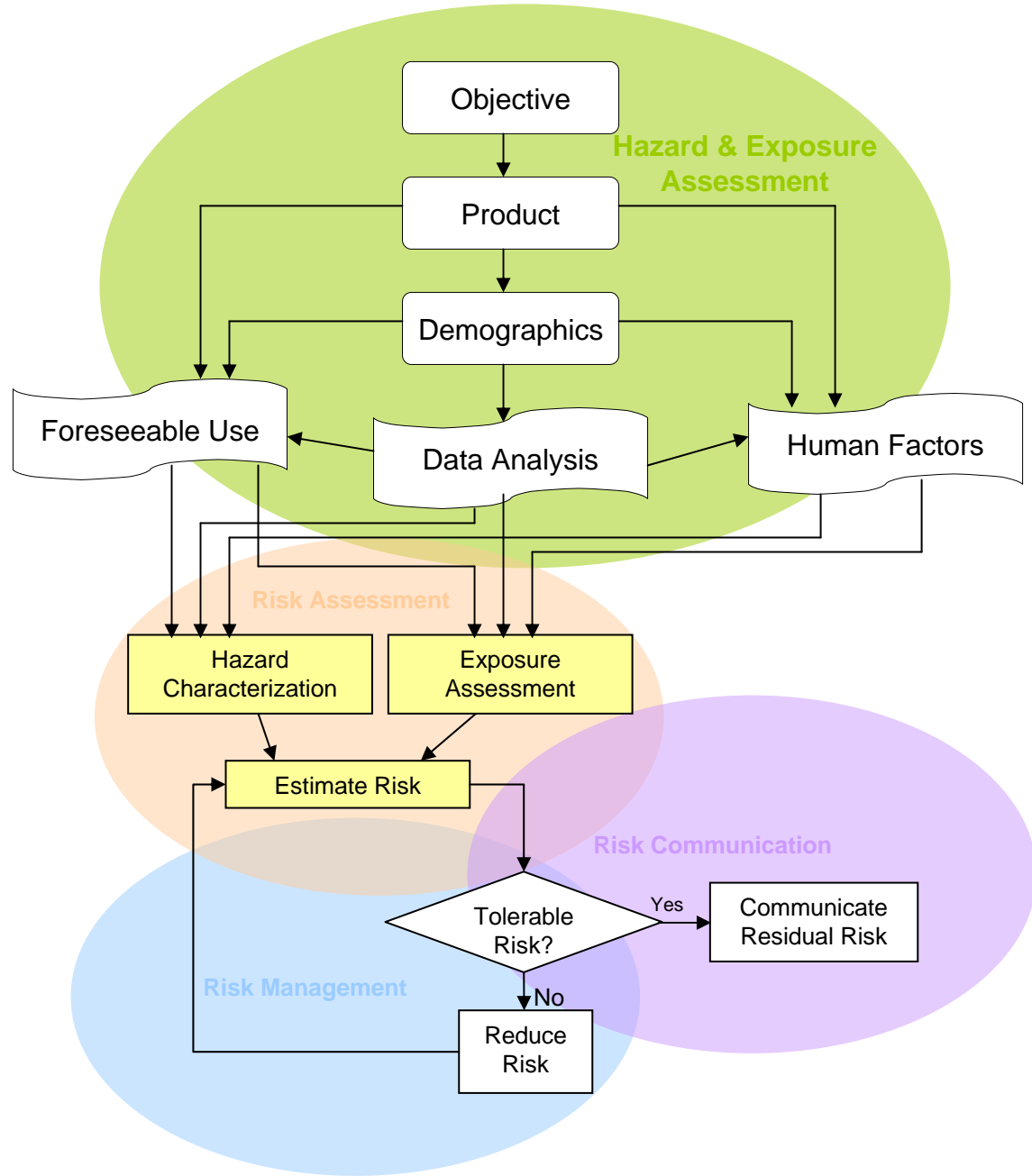
# Intertek Risk



# Intertek Risk

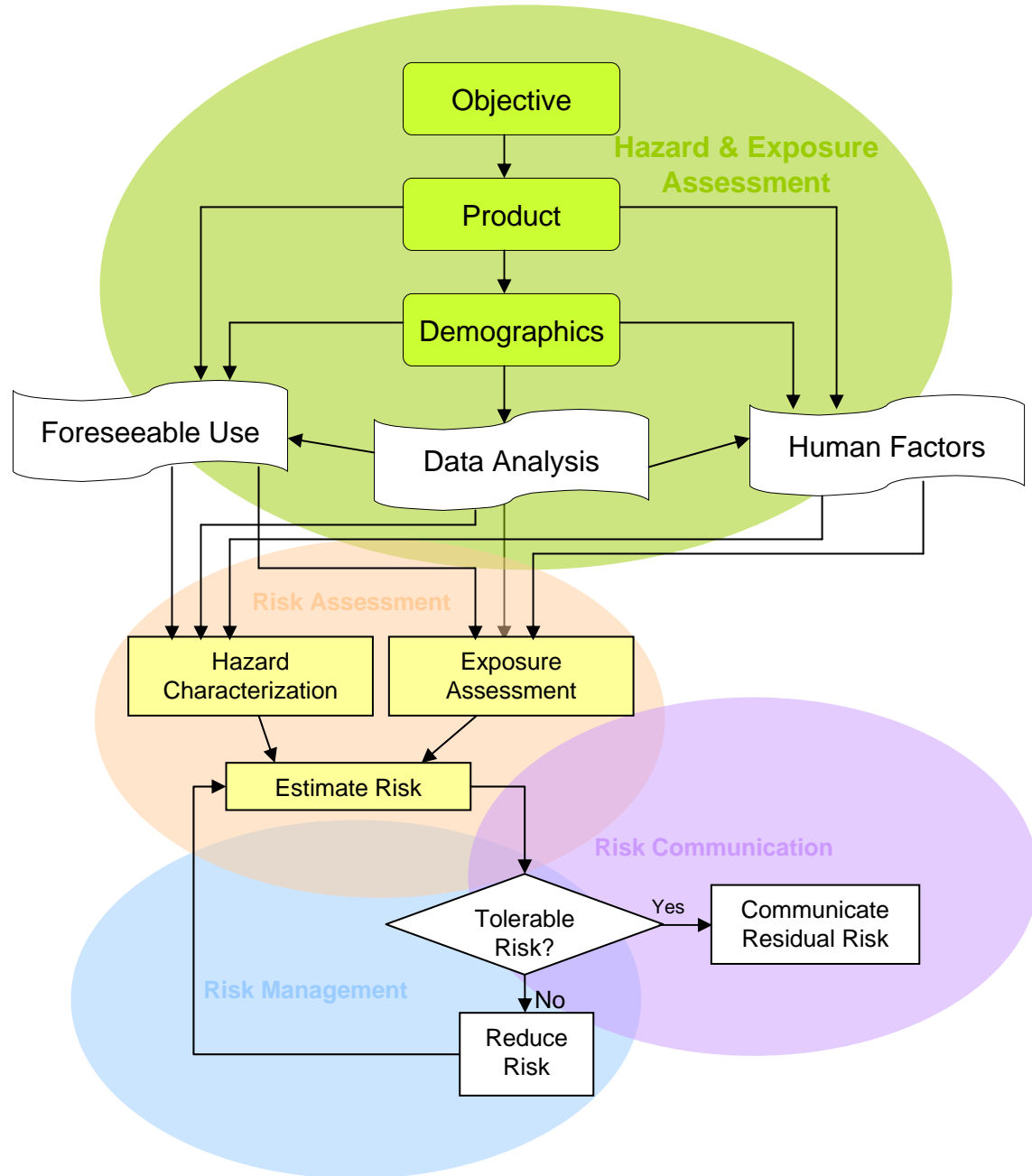


# Intertek Risk



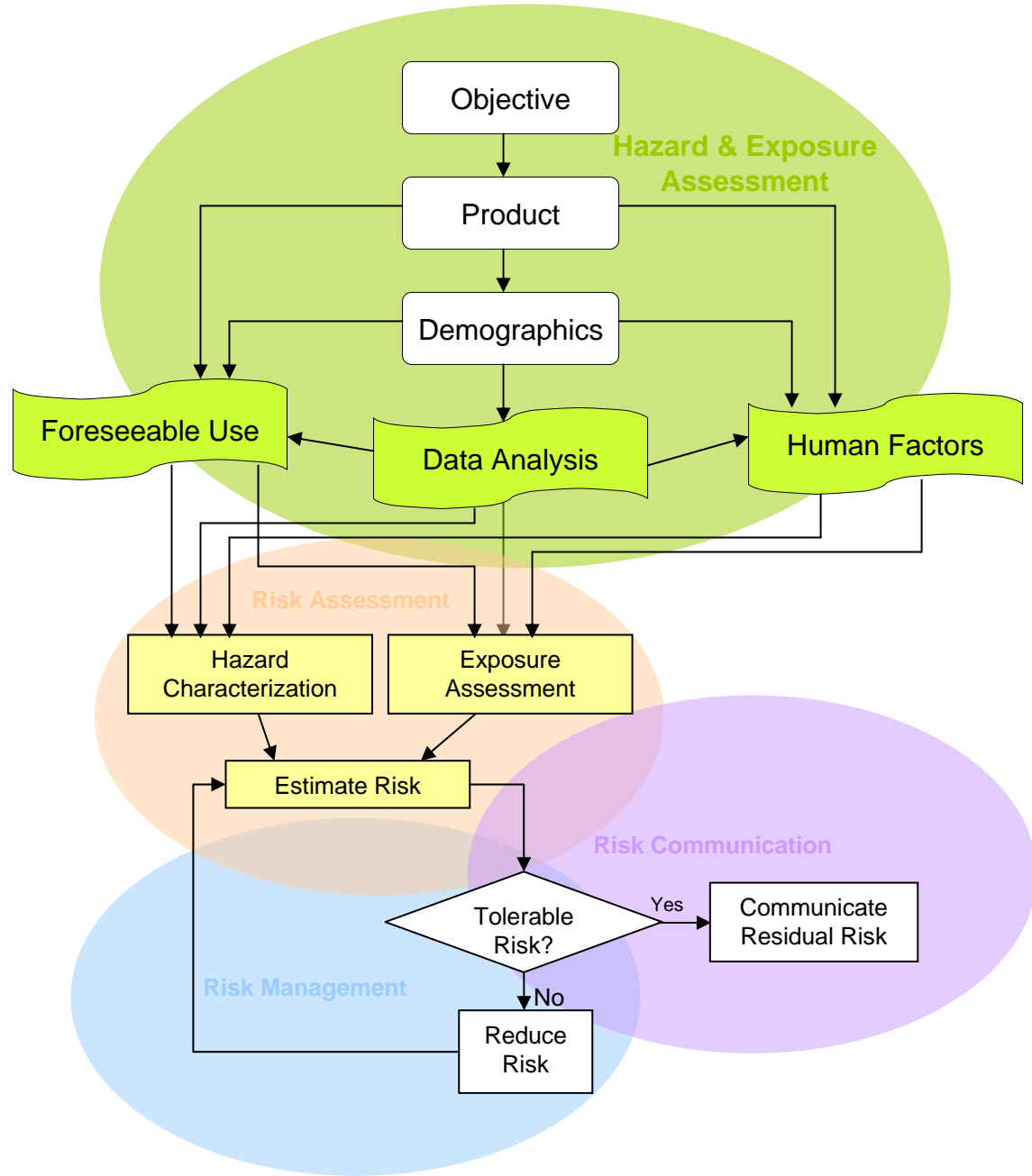
# Intertek Risk

- Objective
  - Background
  - Scope of Work
  
- Product
  - Distribution Quantity
  - Distribution Method
  - Lifespan / Duration
  - Characteristics
  - Function
  
- Demographics
  - Population
  - Subpopulation
  - Susceptibility
  - Variability

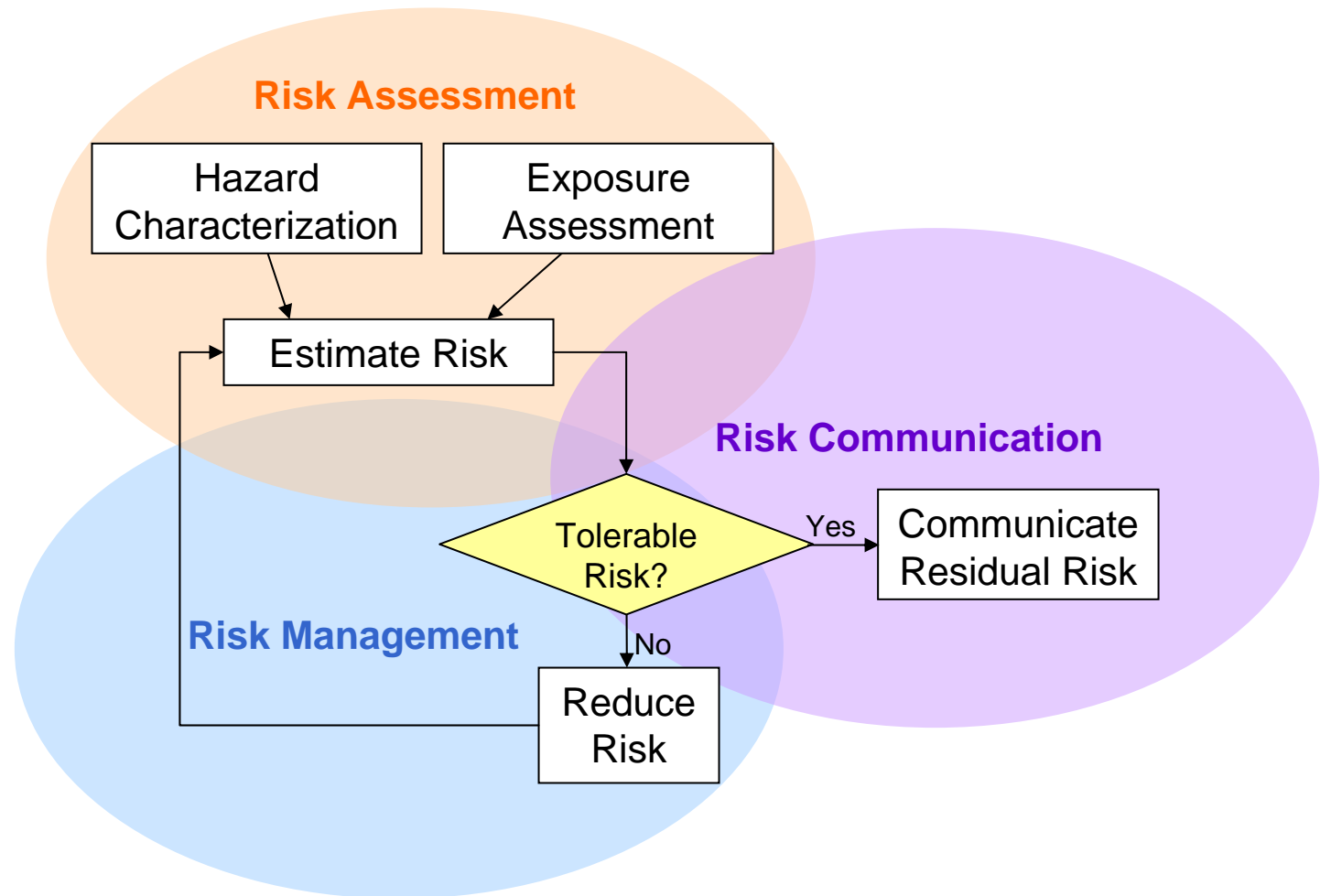


# Intertek Risk

- Foreseeable Use
  - Attractiveness
  - User Perception
  - Accessibility
  - Frequency of Use
  
- Human Factors
  - Mechanism of Injury
  - Severity of Injury
  
- Data Analysis
  - Incident Type
  - Mechanism
  - Cause
  - Severity



# Assessing and Reducing Risk



# Data Reporting

Probability \ Severity	Very Low	Low	Medium	High	Very High
Non-Hospitalization Injury	Green	Green with circle	Yellow	Yellow	Yellow
Hospitalization Injury	Yellow	Yellow	Yellow with circle	Red	Red
Grievous/Fatal Injury	Yellow	Yellow	Red	Red with circle	Red

Green	Low Risk	No Action
Yellow	Medium Risk	Monitor, Action May be Recommended
Red	High Risk	Action Recommended

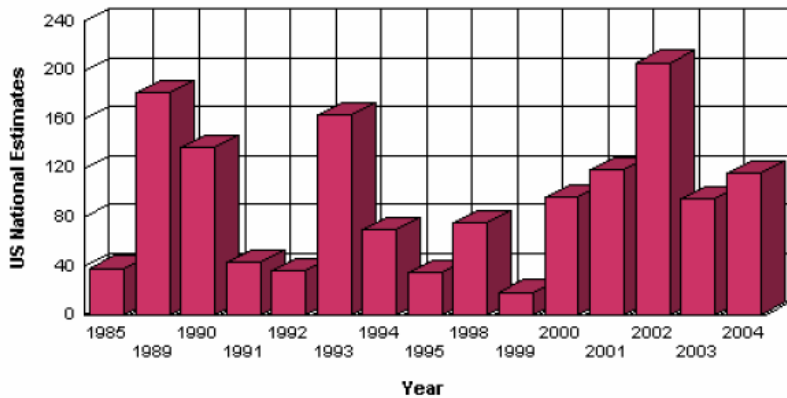
- Proceed With Product Introduction.
- Follow-up With Any Incidents And/Or Complaints.
- Repeat Risk Assessment If Product Changes Or If Repositioned Within Market.

- Product Revision May Be Considered.
- Design Hazard Analysis (DHA) Is Optional.
- Monitor Product Introduction – Fully Investigate All Incidents And/Or Complaints.

- Design Hazard Analysis (DHA) Is Recommended.
- Product Revision May Be Necessary, Dependent On DHA Results.
- May Need To Consider Discontinuation Of Product Introduction.

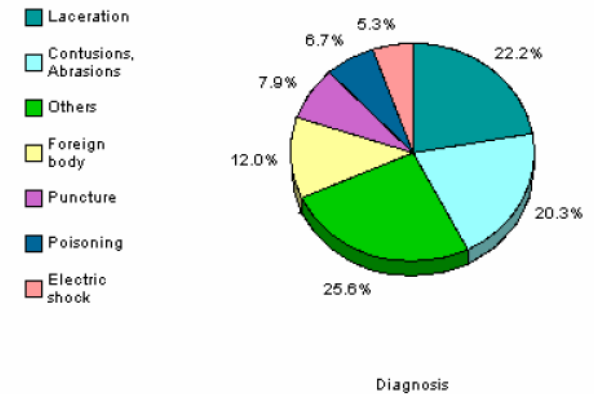
## Injury/Fatality Data Analysis

Figure 2.2 US National Estimates by Year, Injury



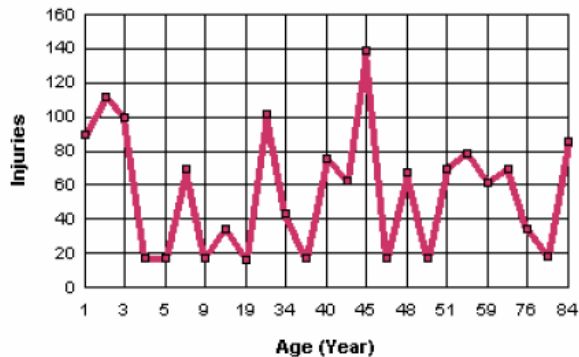
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Figure 2.5 Diagnosis, Injury



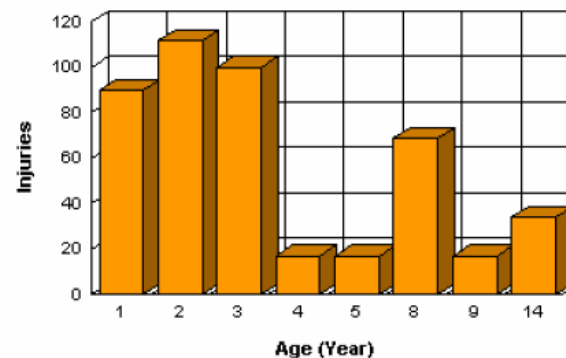
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Figure 2.3.1 Age Distribution, Injury (All Ages)



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Figure 2.3.2 Age Distribution, Injury (Under 15)



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# Application: Foreseeable Use

**Attractiveness Scoring**

	Intended to be Used By	Likely to be Used By	Purpose or Intended Use of Product	Size / Weight	Quality / Durability	Images	Whole Product	Color	Textures	Movement	Light	Sounds/Noises	Smell/Taste	Physical	Challenge	Influential People/Things	Total
Birth to 3 months	H	H	N/L	M/L	N/L	H	M	N/L	H	N/L	N/L	N/L	N/L	N/L	N/L	N/L	M/H
4 to 7 months	H	H	N/L	M	N/L	H	M/H	M/H	H	N/L	N/L	N/L	N/L	N/L	N/L	N/L	H
8-11 months	H	H	N/L	M/H	N/L	H	M/H	H	H	N/L	N/L	N/L	N/L	N/L	N/L	N/L	H
12-18 months	H	H	N/L	M/H	N/L	H	H	H	H	N/L	N/L	N/L	N/L	N/L	N/L	N/L	H
19-23 months	M/H	H	N/L	H	N/L	H	H	H	H	N/L	N/L	N/L	N/L	N/L	N/L	N/L	H
2 years	M/H	H	M/L	H	N/L	H	H	H	H	N/L	N/L	N/L	N/L	N/L	N/L	N/L	H
3 years	M	H	M/L	H	N/L	H	H	M/H	M/H	N/L	N/L	N/L	N/L	N/L	N/L	N/L	M/H
4-5 years	M	H	M/L	H	N/L	H	H	M	M	N/L	N/L	N/L	N/L	N/L	N/L	N/L	M/H
6-8 years	M/L	H	M	M/H	M/L	M	M/H	M/L	M	N/L	N/L	N/L	N/L	N/L	N/L	N/L	M
9-12 years	M/L	H	M/H	M	M	M/L	M	M/L	M	N/L	N/L	N/L	N/L	N/L	N/L	N/L	M/L
13-17 years	N/L	M	H	M	M/H	N/L	M/L	M/L	M	N/L	N/L	N/L	N/L	N/L	N/L	N/L	M/L
18-25 years	N/L	M/L	H	M	M/H	N/L	M/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L	M/L
Young Adult	N/L	M/L	H	M/H	H	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L	M
Mature Adult	N/L	N/L	M	M	H	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L	M/L
Junior Elderly	N/L	N/L	M/L	M/L	H	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L	M/L
Senior Elderly	N/L	N/L	N/L	M/L	M/H	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

**Mitigation Scoring**

	Caregiver Perception	User Perception	Value	Labeling Effectiveness	TOTAL
Birth to 3 months	H	N/L	M/H	M/H	H
4 to 7 months	H	N/L	M/H	M/H	H
8-11 months	M/H	N/L	M/H	M/H	H
12-18 months	M/H	N/L	M/H	M/H	H
19-23 months	M/H	N/L	M/H	M/H	H
2 years	M/H	N/L	M/H	M	H
3 years	M	N/L	M/H	M	H
4-5 years	M	M/L	M/H	M/L	H
6-8 years	M/L	M	M	M/L	M/H
9-12 years	N/L	M	M	M/L	M/H
13-17 years	N/L	M/L	M/L	N/L	M/L
18-25 years	N/L	M/L	N/L	N/L	M/L
Young Adult	N/L	M/L	N/L	N/L	M/L
Mature Adult	N/L	M/L	N/L	N/L	M/L
Junior Elderly	M/L	M/L	M/L	N/L	M
Senior Elderly	M	M	M	M/L	M/H

**Exploration Strategy Scoring**

	Mouthing Objects	Alternating Mouththing & Looking	Rotating Objects	Insertion (Body into Object)	Insertion (Object into Body)	Transferring Hand to Hand	Banging Objects	Dropping Objects	Throwing Objects	Combining Objects	Matching Objects	Using Appropriately	Representational Play	Using Imaginatively	Testing the Limits
Birth to 3 months	H														
4 to 7 months	H	M/H		M/H					H						
8-11 months	H	M/H		H		H	H	M/H	M/H						
12-18 months	M/H		H	M/H		H	H	M	H	M	M/L	M/L	M/L	M/L	
19-23 months	M/H		H	M		H	H	H	H	H	M/L	M	M/L	M/L	
2 years	M/H		H	H		H	H	H	H	M	M/L	M/H	M	M/L	
3 years	M		H	H		H	M	H	H	M	M	M/H	M	M/L	
4-5 years	M/L		H	H		H	M/L	M/L	H	M/L	M	M/H	M	M	
6-8 years	M		H	M		M/L	M/L	M/L	M	M/L	M/H	M/L	M/L	H	
9-12 years	M/L		M/L	M/L							M/H		L	H	
13-14 years	L		L	L							M/H			H	

# Human Factors

## 4.0 Hazards Identification

Potential hazard(s) associated with the product are identified below. Further assessment needs to be carried out in order to confirm the validity of the concern(s).

Physical Mechanical Hazards		
Hazard	Description	Comment
Abrasion/Contusion	Penetration injury of the skin caused by contact with a rough surface	Falls from the table may result in Abrasions and Contusions. This is also possible should a folding table unexpectedly collapse.
Laceration	Penetration injury of the skin caused by contact with a sharp edge	Falls from the table may result in Lacerations. This is also possible should a folding table unexpectedly collapse.
Puncture	Penetration injury of the skin caused by contact with a sharp point	Any fixtures and fittings have the potential to cause puncture wounds i.e. nails and screws.



# Product/Design Comparison

Severity \ Probability	Probability				
	Very Low	Low	Medium	High	Very High
Non-Hospitalization Injury	Low Risk	Low Risk	Medium Risk (4-14, 65+)	Medium Risk (0-3, 15-64)	Medium Risk
Hospitalization Injury	Medium Risk (All Ages*)	Medium Risk	Medium Risk	High Risk	High Risk
Grievous/Fatal Injury	Medium Risk (0-14, 65+ 15-64)	Medium Risk	High Risk	High Risk	High Risk

Low Risk	No Action
Medium Risk	Monitor, Action May be Recommended
High Risk	Action Recommended

Severity \ Probability	Probability				
	Very Low	Low	Medium	High	Very High
Non-Hospitalization Injury	Low Risk	Low Risk	Medium Risk	Medium Risk	Medium Risk (All Ages)
Hospitalization Injury	Medium Risk	Medium Risk	Medium Risk (65+)	High Risk (0-64)	High Risk
Grievous/Fatal Injury	Medium Risk (65+)	Medium Risk (0-64)	High Risk	High Risk	High Risk

Low Risk	No Action
Medium Risk	Monitor, Action May be Recommended
High Risk	Action Recommended

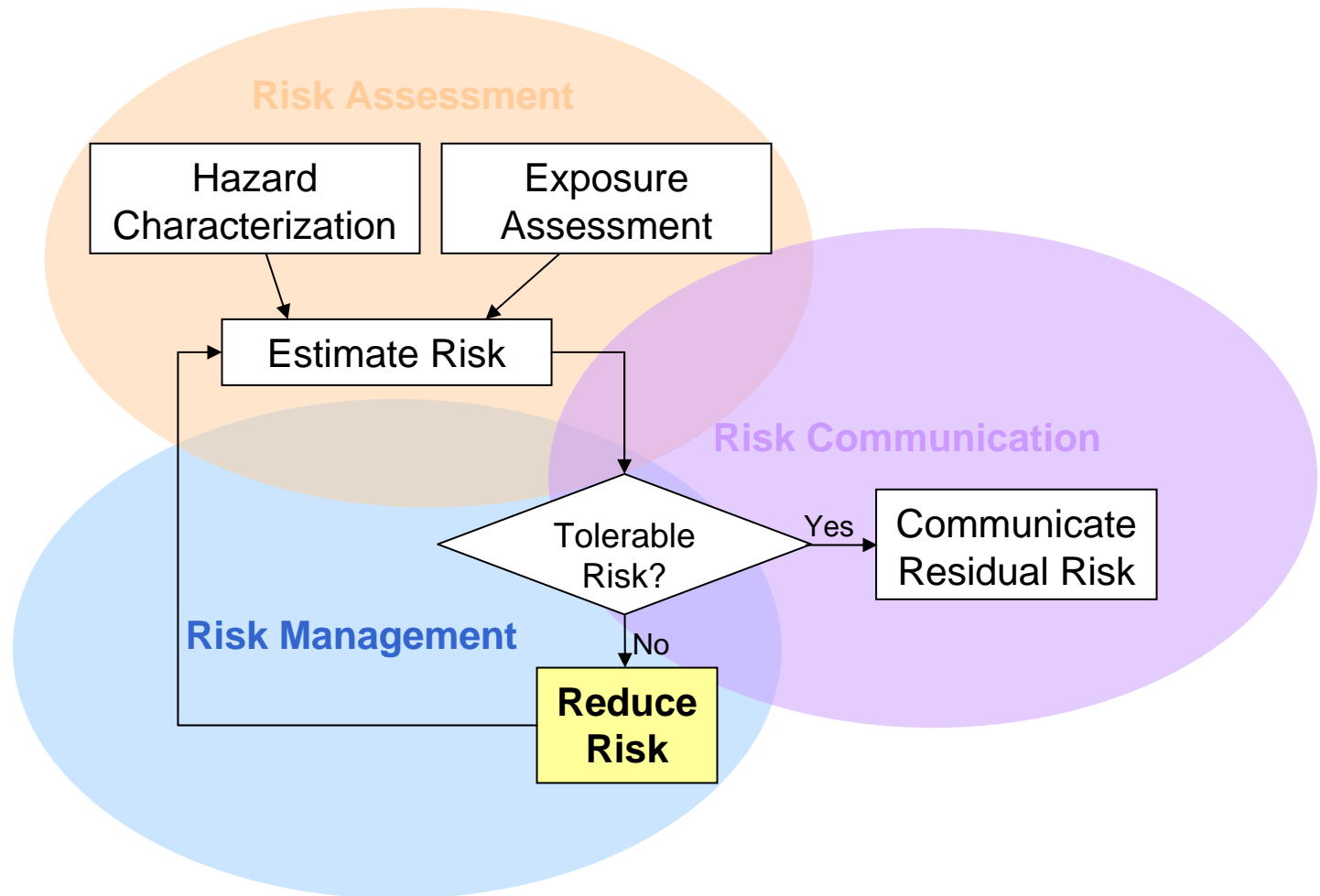
Figure ES-1 Decision Matrix for Product Category

Figure ES-1 Decision Matrix for Product Category

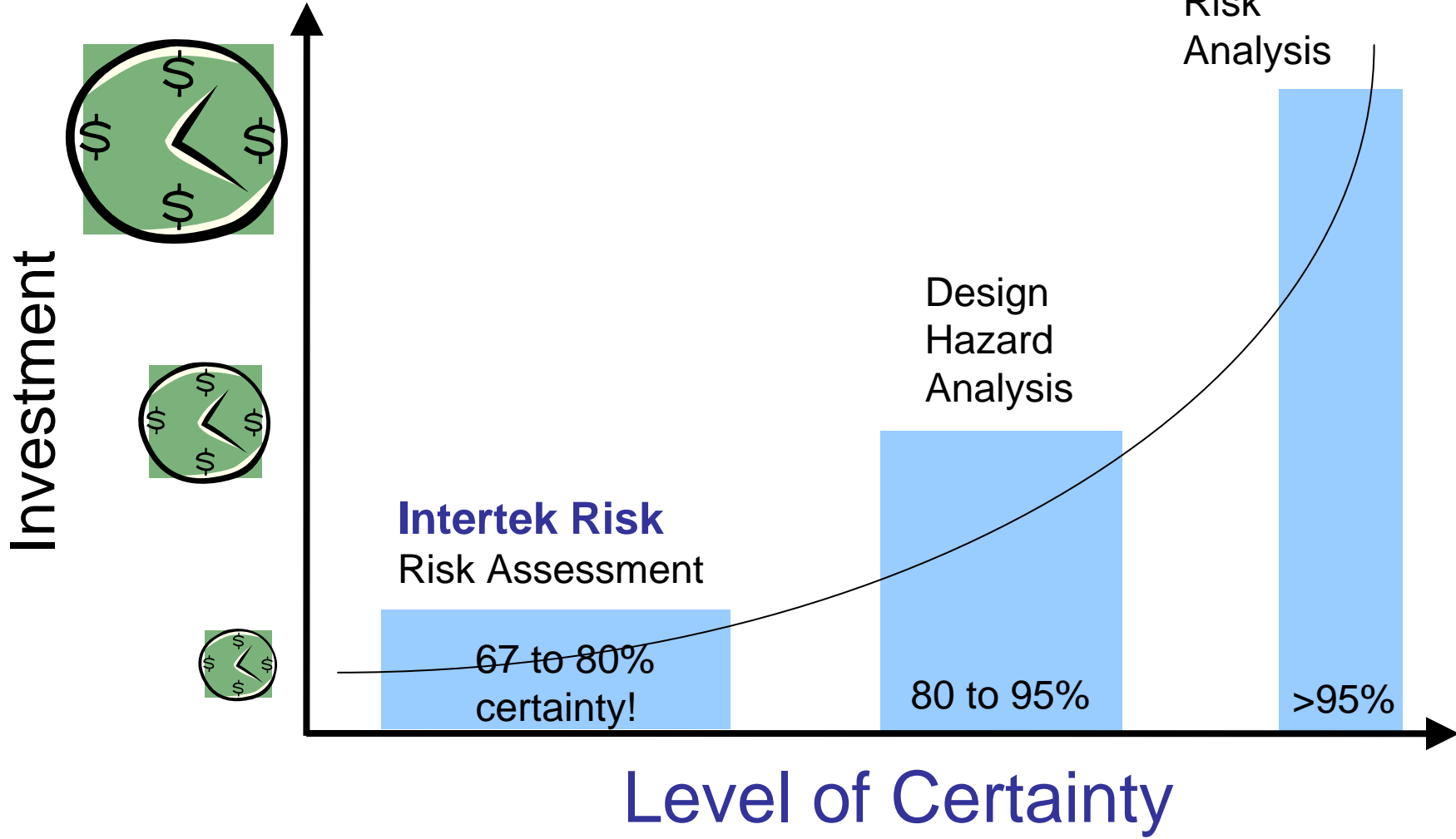
## Electric Toothbrush

## Electric Toothbrush with Accessible Batteries

# Next steps?



# Investment versus Reward



## Managing and/or Reducing Risk

### Intertek Risk

Screening new, improved or alternate designs

### Design Hazard Analysis

Hazard identification and characterization

Recommendations how identified hazards can be reduced

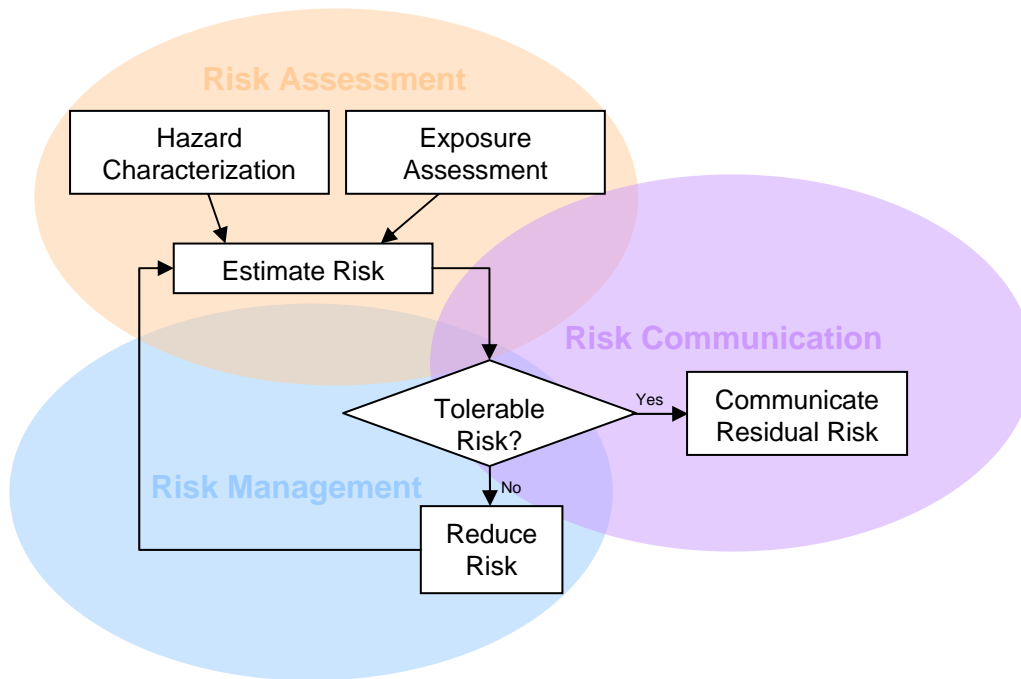
### Quantitative Risk Analysis.

Probability of the adverse event occurring

Potential severity

Highest level of resolution for assessing risk

## Intertek Risk



## SUMMARY

- Quantification of Risk.
- Documented Analysis.
- Quick & Efficient.
  
- Allows Risk Management.
- Product “Screening” Tool.
- “What If” Scenarios.
- Risk Reduction.
  
- Risk Communication.
- Probabilities.
- Influential Parameters.

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## Risk Screening



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*Thank You!*

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