DANISH SAFETY TECHNOLOGY AUTHORITY

Risk assessment: What tools can market surveillance authorities' use?

UN-ECE Conference on Risk Assessment and Management

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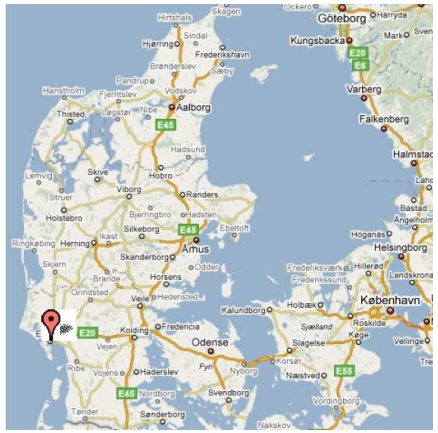
Danish Safety Technology Authority - in a nutshell



DANAK

The Danish Accreditation and Metrology Fund

European Cooperation in Legal Metrology
WELMEC

OIML

DIRECTIVES:

LVD - ATEX
GAD - MID
PYRO
GPSD - TOYS

95 Empl.

Ministry of Ecomimic And Business affairs

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PROSAFE
PRODUCT SAFETY ENFORCEMENT FORUM OF EUROPE

EMARS II
Enhancing Market Surveillance through Best Practice

Supported by the
Consumer Affairs Directorate
DG Health & Consumers

EMARS II Activities

A. Best Practice
B. Management and Planning of Future Joint Actions and Coordinated Market Surveillance Activities
C. Risk Assessment
D. Market Surveillance Guidance Material for External Stakeholders
E. Training
F. Continuous Improvement of National Market Surveillance Programmes
G. Standards Related Activities
H. Liaison with Notified Bodies

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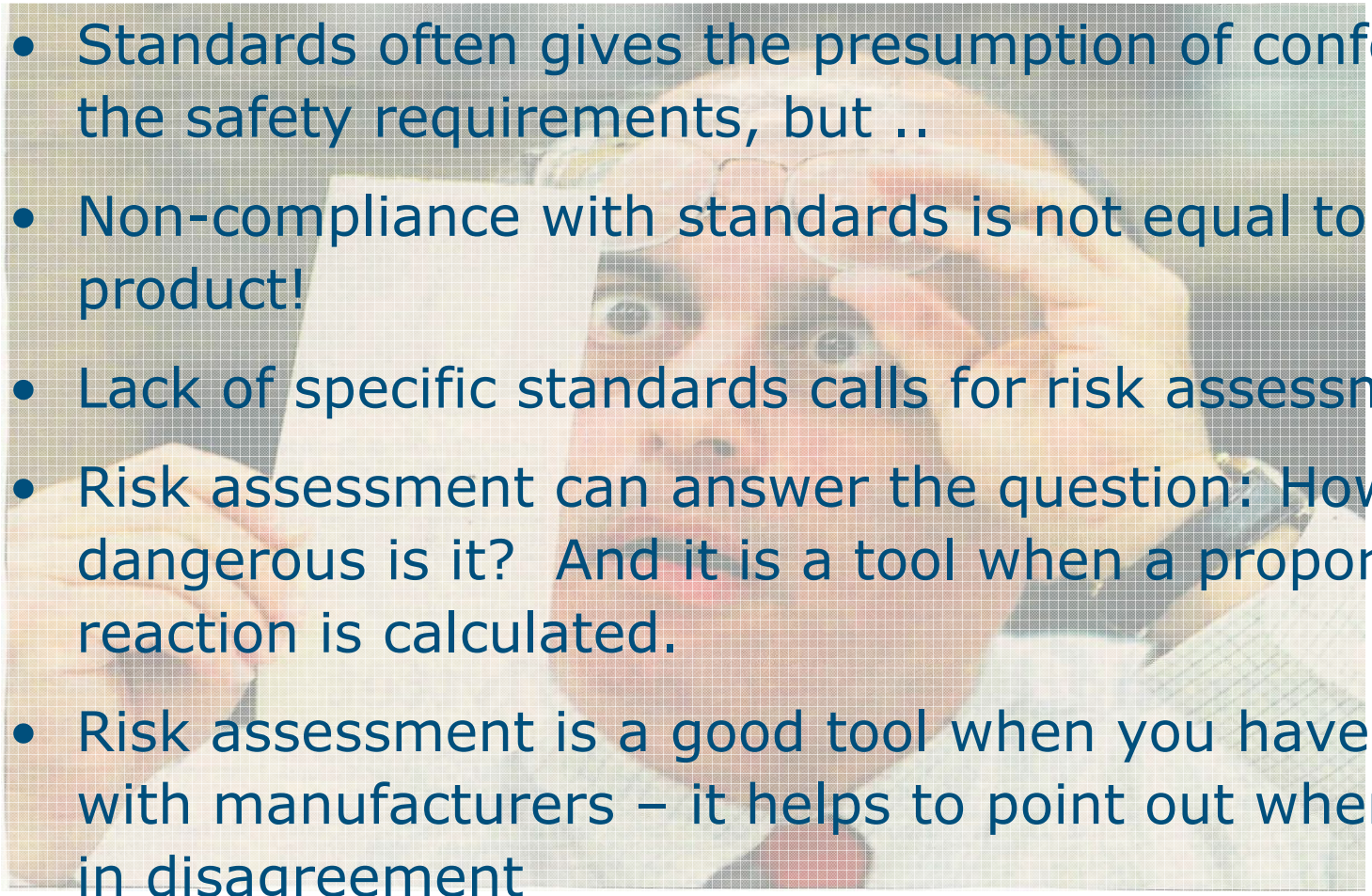
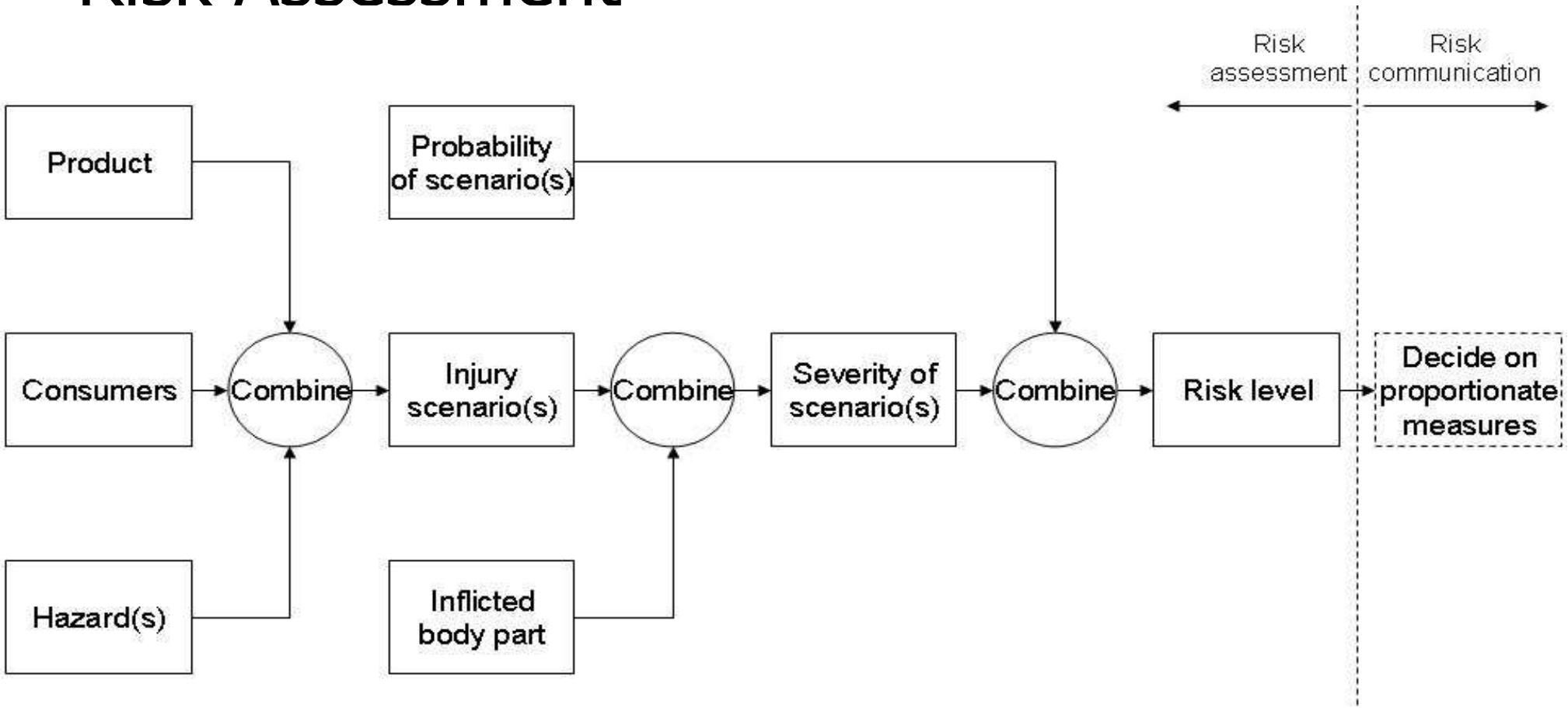
Why use risk assessment?



- Standards often gives the presumption of conformity with the safety requirements, but ..
- Non-compliance with standards is not equal to dangerous product!
- Lack of specific standards calls for risk assessment
- Risk assessment can answer the question: How dangerous is it? And it is a tool when a proportional reaction is calculated.
- Risk assessment is a good tool when you have to discuss with manufacturers – it helps to point out where you are in disagreement

Risk Assessment



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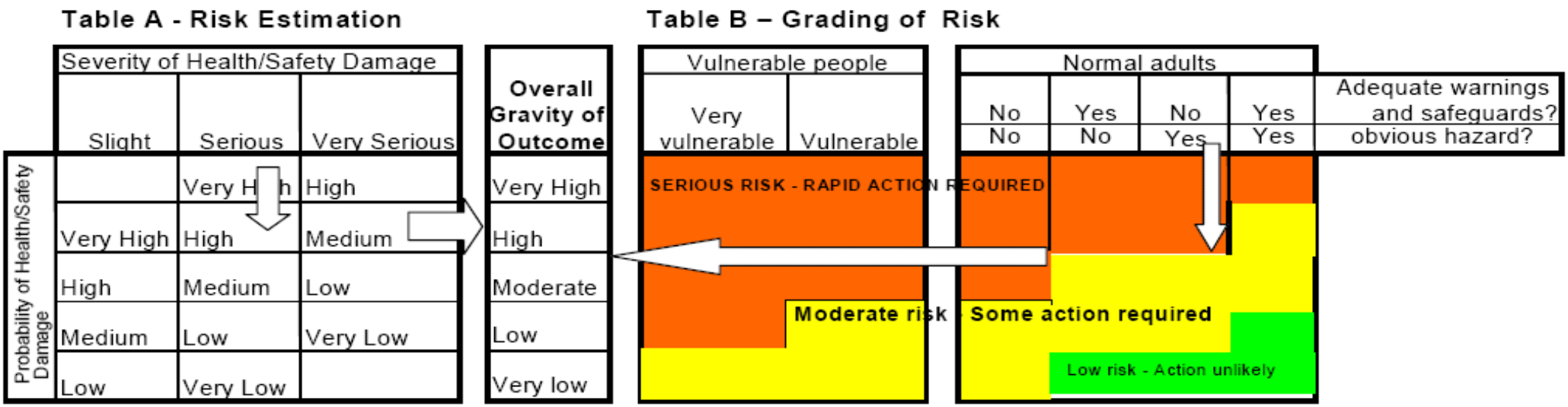
The tools... Old/Existing GPSD



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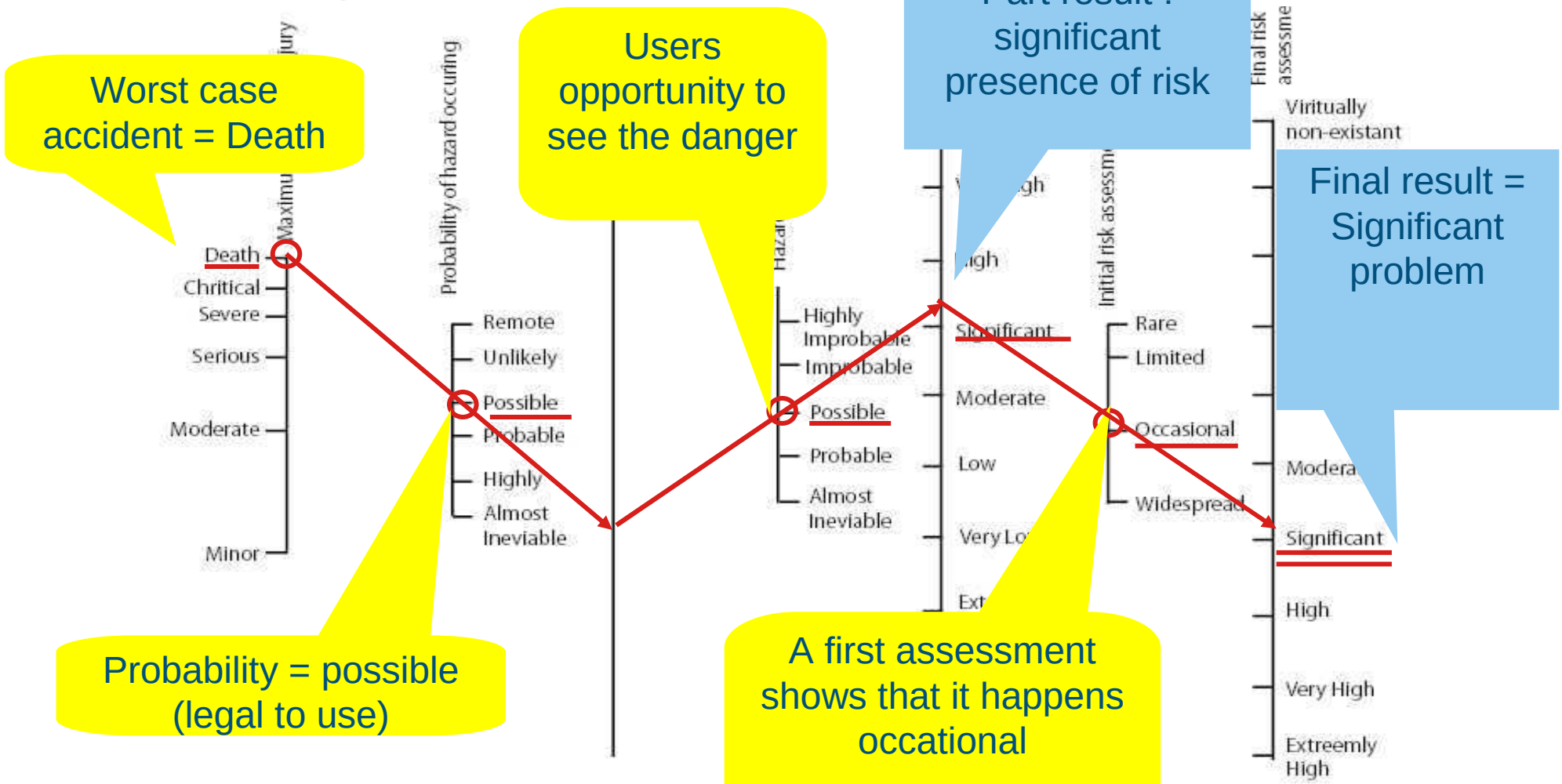
Nomogram – Lack of connection of safety earthing when a CEE-7 is used in Denmark



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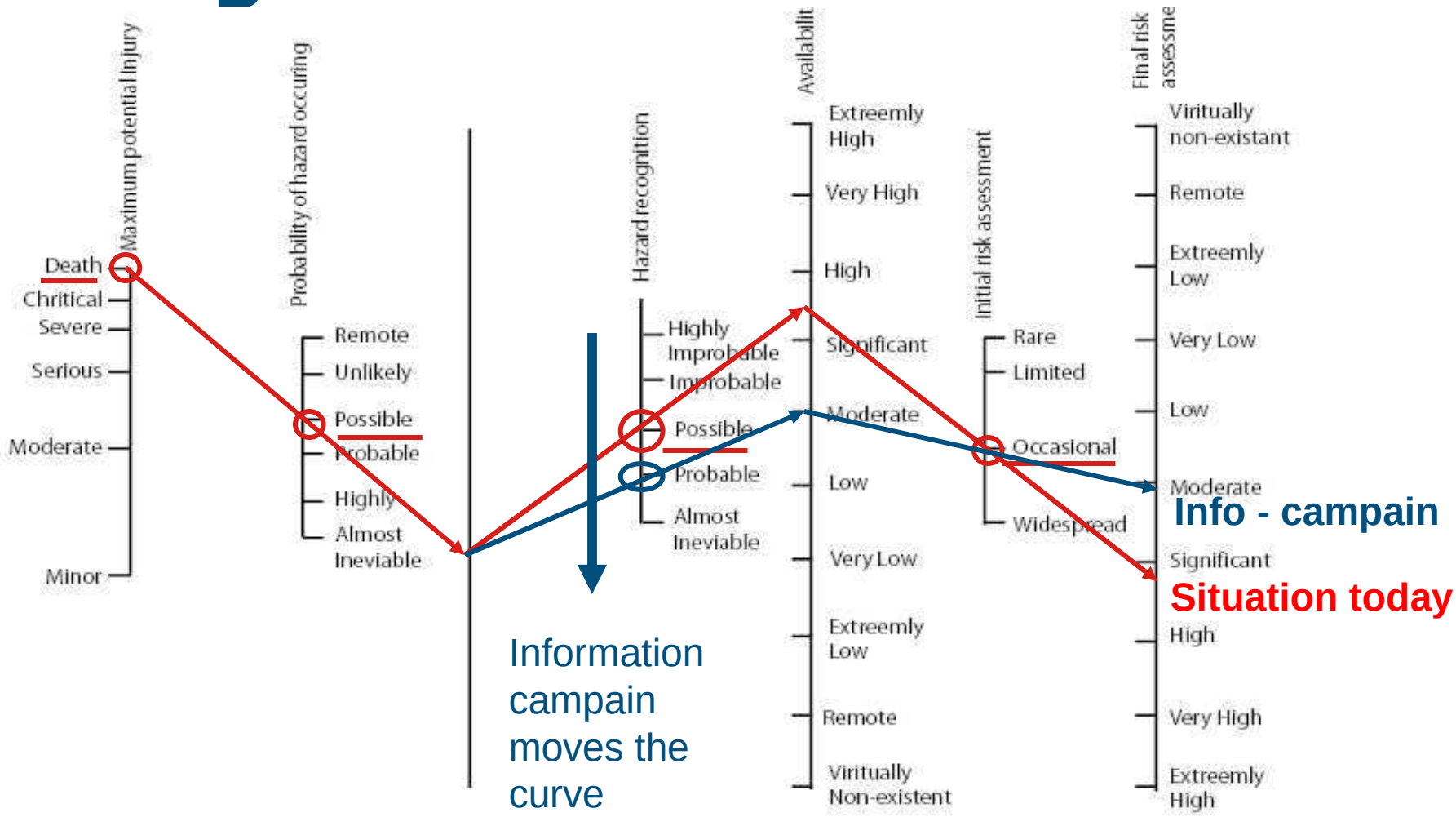
Nomogram - Information



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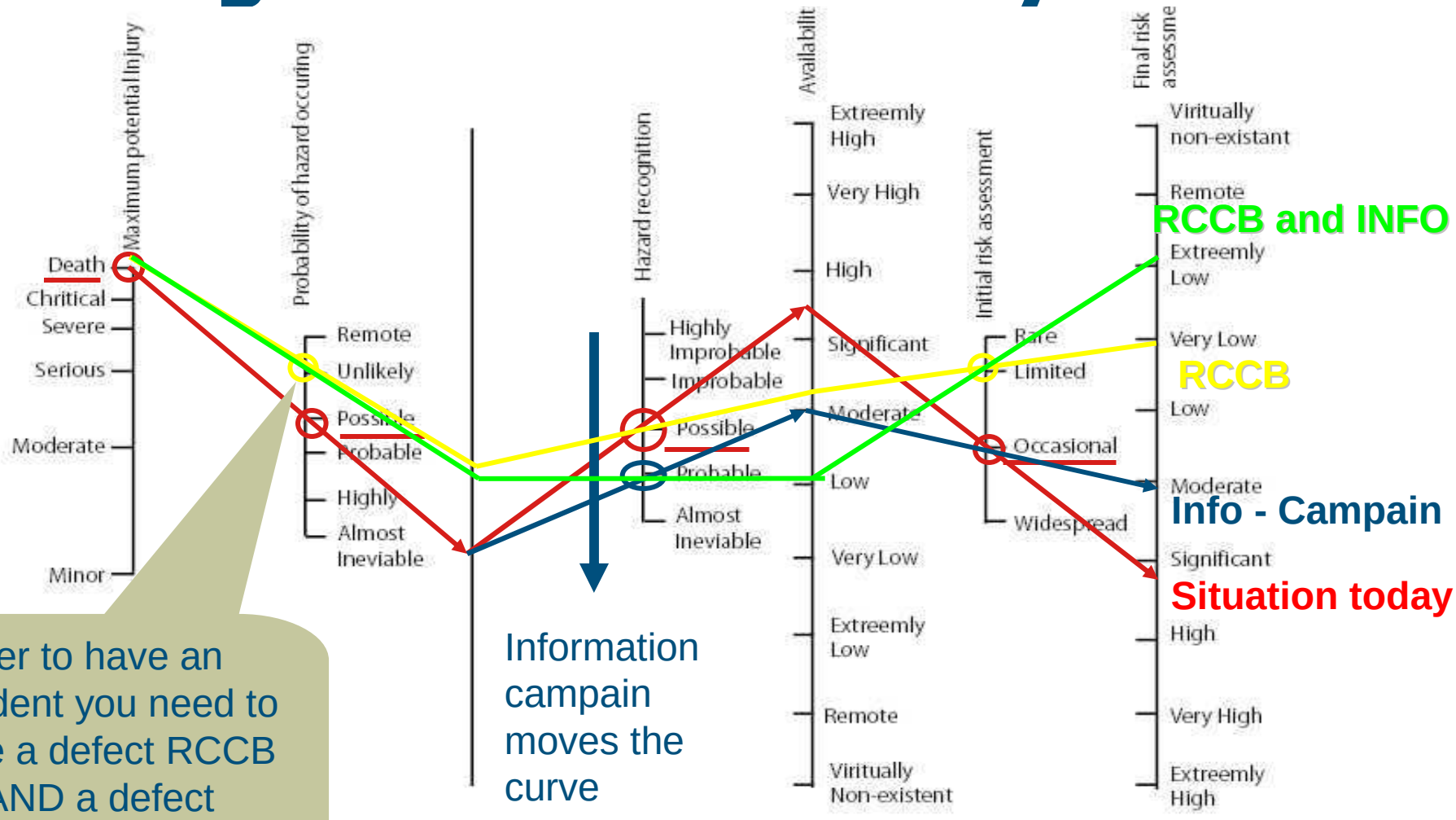
Nomogram – Mandatory RCCB



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The Nordic failure code list (LVD)

Technical deficiencies	Codes 1	2	3
Accessible live part in normal use			3
Accessible basic insulated parts on class II products		2	
Luminaries and domestic equipment of class 0	1		
The creepage and clearance distance is less than 10% of the requirement in relevant standard			3
The creepage and clearance distance is more than 10% and less than 50% of the requirement in relevant standard		2	
The creepage and clearance distance is more than 50% of the requirement in relevant standard	1		
Cord extension set with class 0 plug and class 1 outlet	1		
Cord extension set with class 1 plug and class 0 outlet			3
Cord extension set with class 2 plug and class 0 or 1 outlet			3
Class 1 plug on 2-conductor cable to class 0-device.			3
Phase and earth mixed up in earthed coupling			3
The equipment lacks thermal cut-out and/or current cut-out.		2	(3)
The rated current in the equipment is one step too high	1		
The rated current in the equipment is more than one step too high		2	
The rated current in equipment is so high that it is a fire hazard			3
The marking is incomplete or missing		2	(3)

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Final remarks

- New GPSD Guideline to be published in December – mandatory Risk Assessment for RAPEX
- EMARS II/Task C, Risk assessment: Annual risk assessment seminar on December 1. – 2.
- We are still in the learning phase!

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If time allows: An example of the steps in risk assessment

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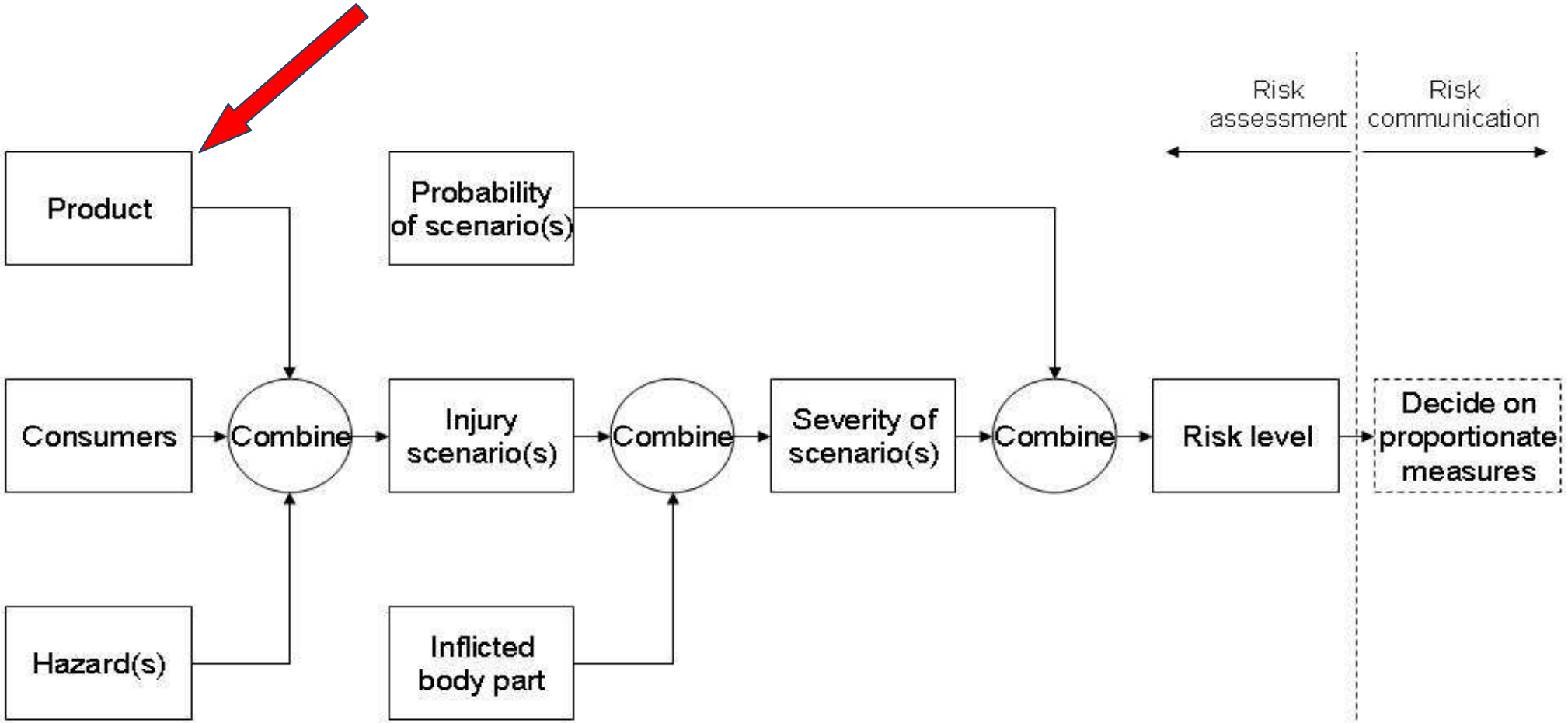
Step 1, define the product



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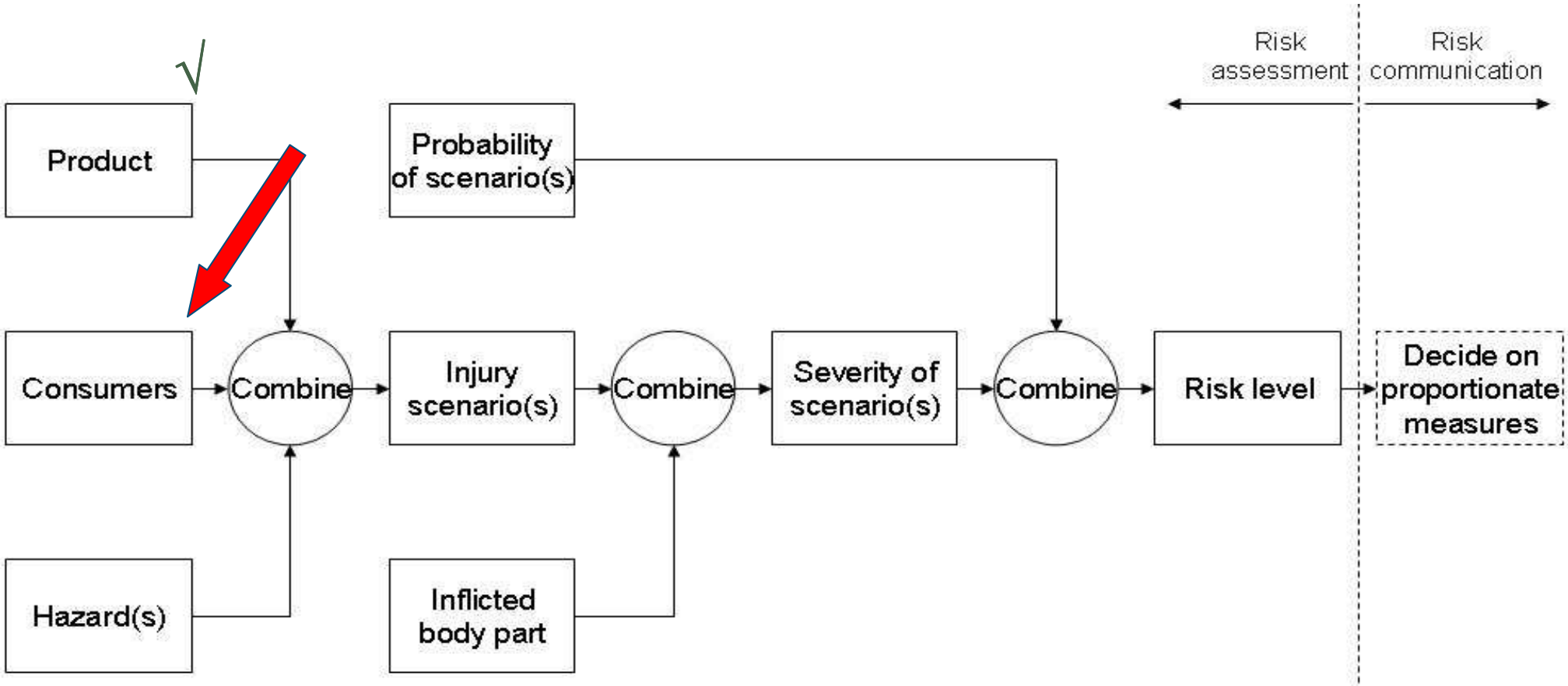
Step 1, define the product

RAPEX notification no. 0125/06

Cross pane hammer with metal handle and black plastic grip.

Step 2, identify the consumer

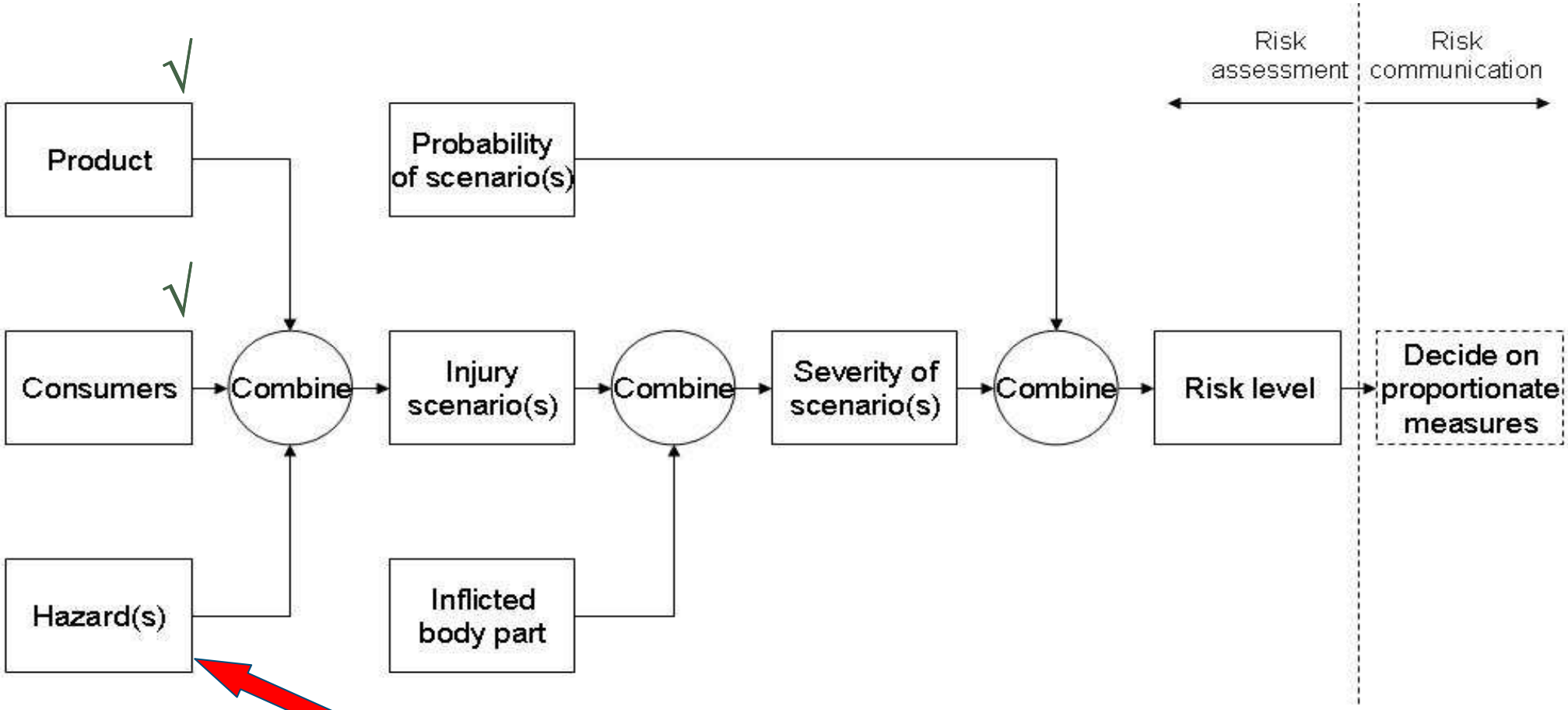


Step 2, identify the consumer

The product is normally used by adults.

Children may want to stand nearby to watch the adult working.

Step 3, identify the hazard(s)



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Step 3, identify the hazard(s)

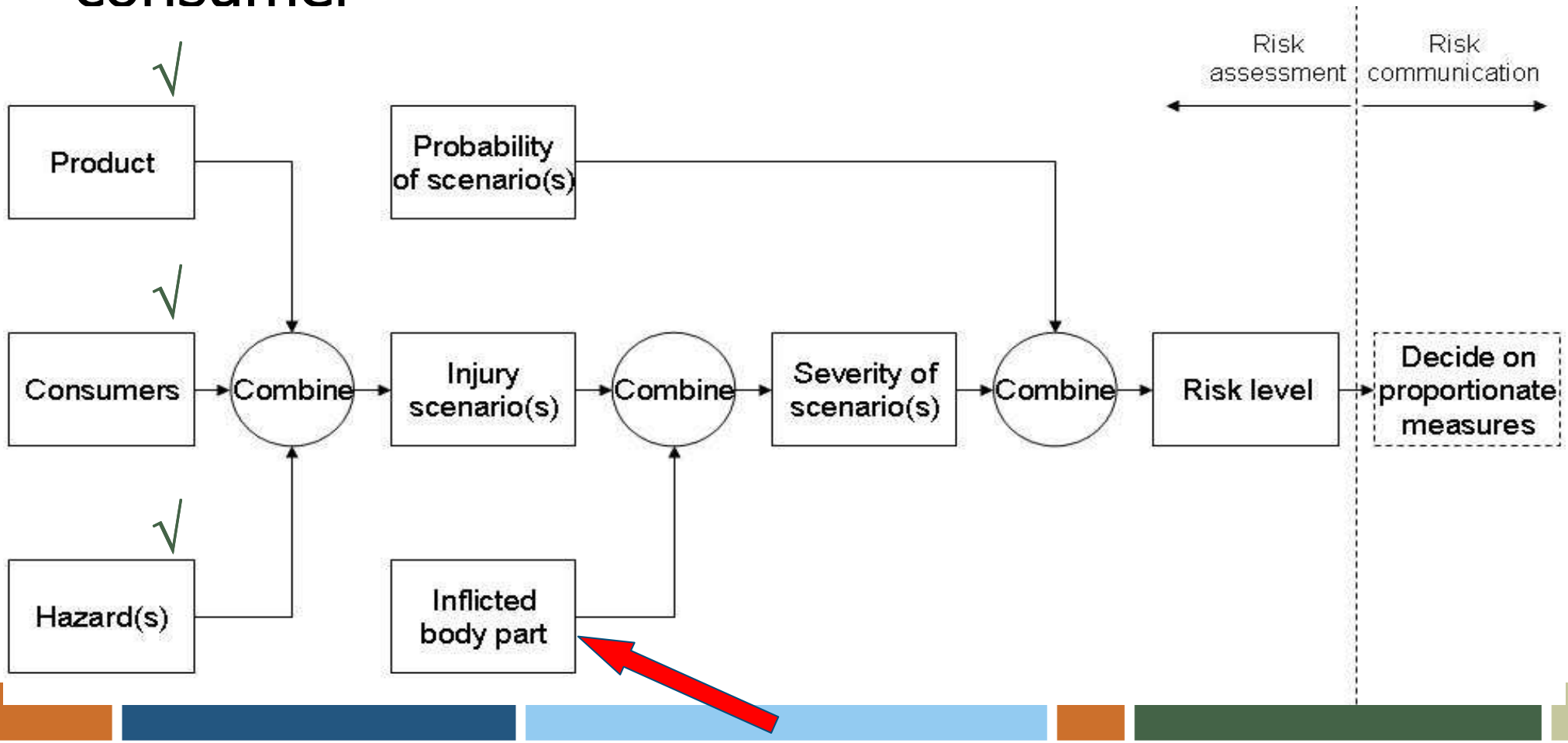
The plastic grip has insufficient mechanical strength and breaks when the user hits a hard surface.

(Only one hazard

is considered

in this example.)

Step 4, how does the hazard inflict on the consumer



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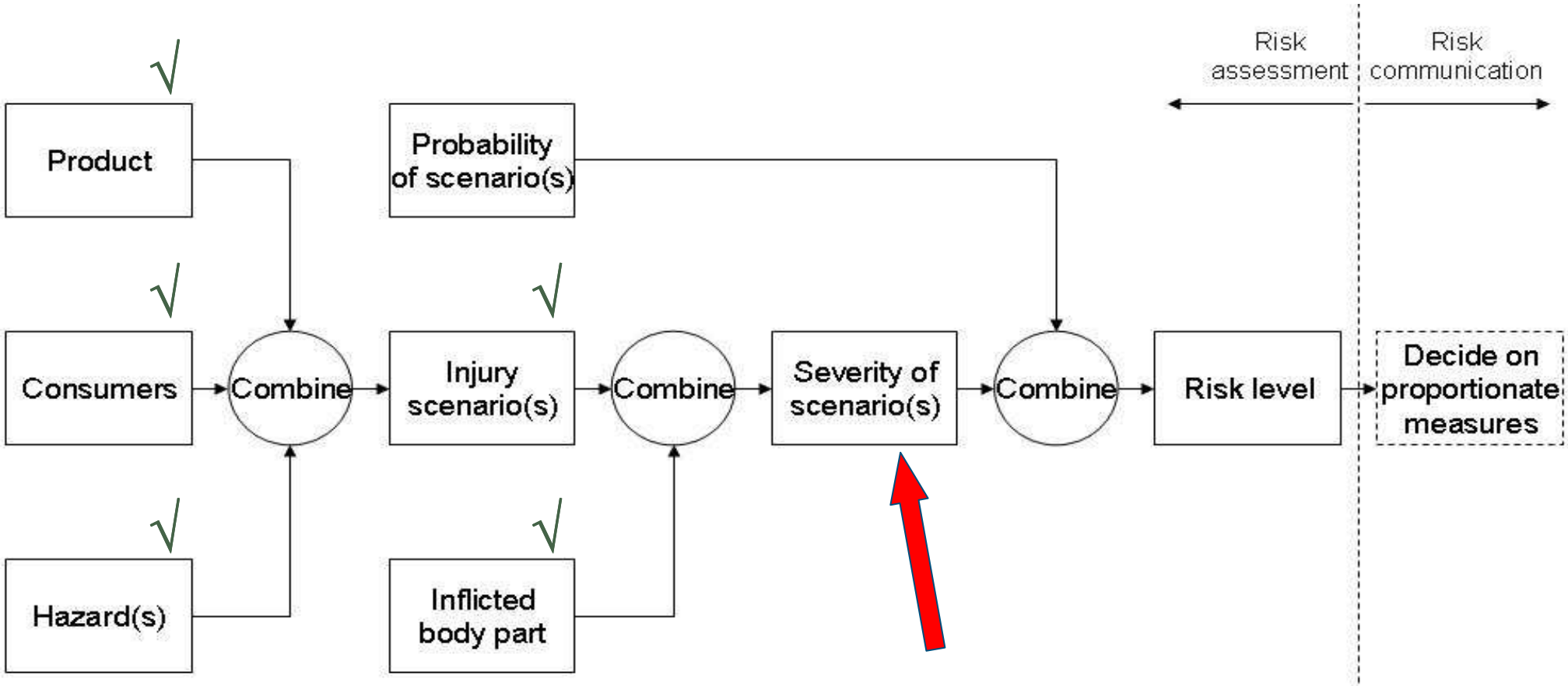
Step 4, how does the hazard inflict on the consumer

The upper part of the hammer bounces back and hits the user's arm. This causes bruising of the arm.

6			
7	**Product hazards**	**Injury scenarios**	**Type of injuries**
8	Identify all hazards that may lead to a consumer injury or health damage. Consider all consumers, including the vulnerable.	If you select a hazard from the Hazard List, a short scenario will be filled in here. **Make this scenario more specific** by describing at least: *the exact hazard or defect in this product and the event that may result; the interaction of a person with the product during the intended and reasonably foreseeable use and the exposure to the hazard; the mechanism of injury.*	For each hazard identified, describe the injury resulting from the injury scenario. If you select a hazard form the Hazard List, a typical injury(ies) will be filled in here. **Make this more specific** by describing both the injury and the body part. Click here to consult the Injury Scale.
12	low mechanical strength	Defect: handle grip breaks because shaft is too short. Top part of hammer bounces back and hits user's arm	Bruising of arm

Step 5, estimate severity of injury



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Step 5, estimate severity of injury

Type of injury	Severity of injury			
	Slight	Moderate	Serious	Very serious
Laceration, Cut	Superficial	External (deep) (>10cm long on body)	Optic nerve	Bronchial tube
		(>5cm long on face)	Thyroid gland	Oesophagus
		Tendon or into joint	Bladder	Aorta
		White of eye	Nerve root cut	Spinal cord (low)
		Tongue (deep)	Brain	Deep lung laceration
		Cornea	Larynx	Deep laceration of intestines, kidney, liver, spleen
		Abdomen (deep but no organ damage)	Neck artery	Severed throat, high spinal cord
			Trachea	Completely severed aorta
			Intestines	
			Kidney	
			Liver	
			Spleen	
			Lungs (superficial)	
			Penis	
Burn/ Scald	1°, up to 100% of body surface 2° or 3°, <6% of body surface	2° or 3°, 6-15% of body surface	2° or 3°, 16-35% of Inhalation burn	
Bruising (abrasion/ contusion)	Superficial	Major	Trachea	
	≤25 cm² on face	>25 cm² on face	Bladder, colon, kidr cord (minor)	
	≤50 cm² on body	>50 cm² on body	Lung (minor)	
		oesophagus	Heart	
		lar[illegible]	Brain	
			Lung, with blood or	
Concussion		Under 1 hour	Over 1 hour	

Product hazards	Injury scenarios	Type of injuries	Severity of injuries	Probablity of factors
Identify all hazards that may lead to a consumer injury or health damage. Consider all consumers, including the vulnerable.	If you select a hazard from the Hazard List, a short scenario will be filled in here. **Make this scenario more specific** by describing at least: *the exact hazard or defect in this product and the event that may result; the interaction of a person with the product during the intended and reasonably foreseeable use and the exposure to the hazard; the mechanism of injury.*	For each hazard identified, describe the injury resulting from the injury scenario. If you select a hazard form the Hazard List, a typical injury(ies) will be filled in here. **Make this more specific** by describing both the injury and the body part. Click here to consult the Injury Scale.	Assign from the Injury Scale: Very serious to Slight. Click into cell below.	For each hazar identified, estim the probability f each step in the scenario (even interaction and injury) e.g.: 1/10; 1/100; 1/8
low mechanical strength	Defect: handle grip breaks because shaft is too short. Top part of hammer bounces back and hits user's arm	[illegible] of arm	Slight	
			Serious	
			Serious	
			Serious	

Select severity
Please select the appropriate severity level from the scale

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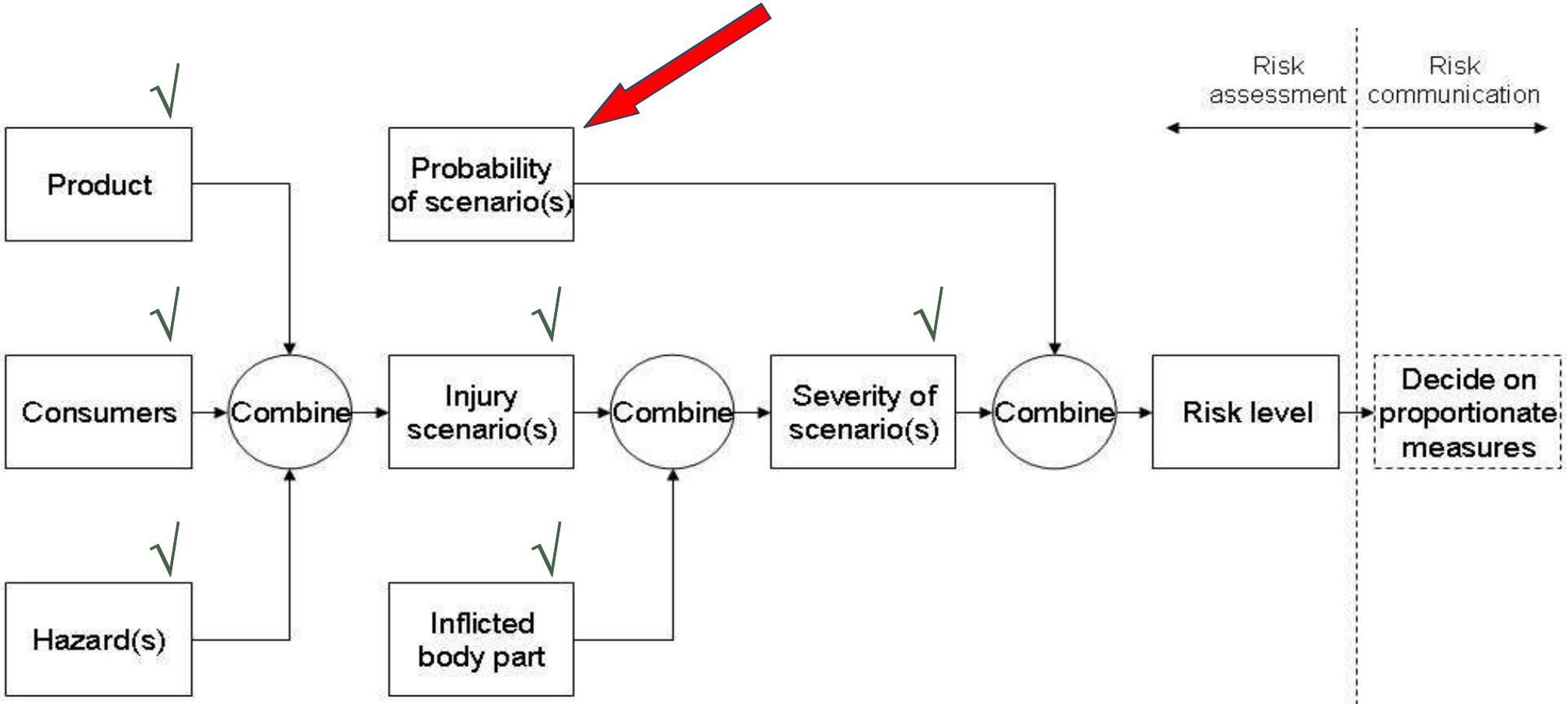
Step 6, the probability of the injury scenario



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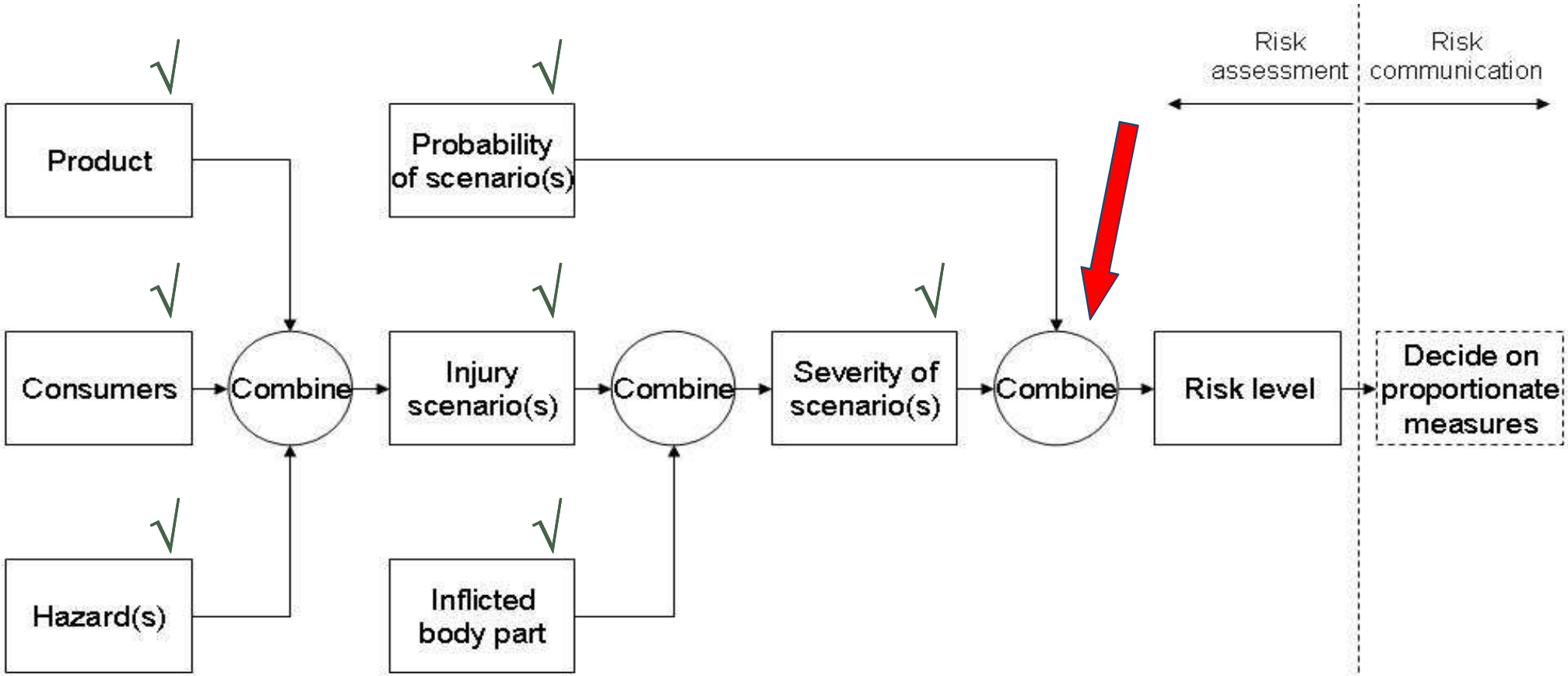
Step 6, the probability of the injury scenario

Injury scenario is broken up in smaller steps.

Find probability of each step

1. Handle breaks (estimated probability 50%)
2. The upper parts hits the arm (estimated probability 20%)

Step 7, combine severity and probability



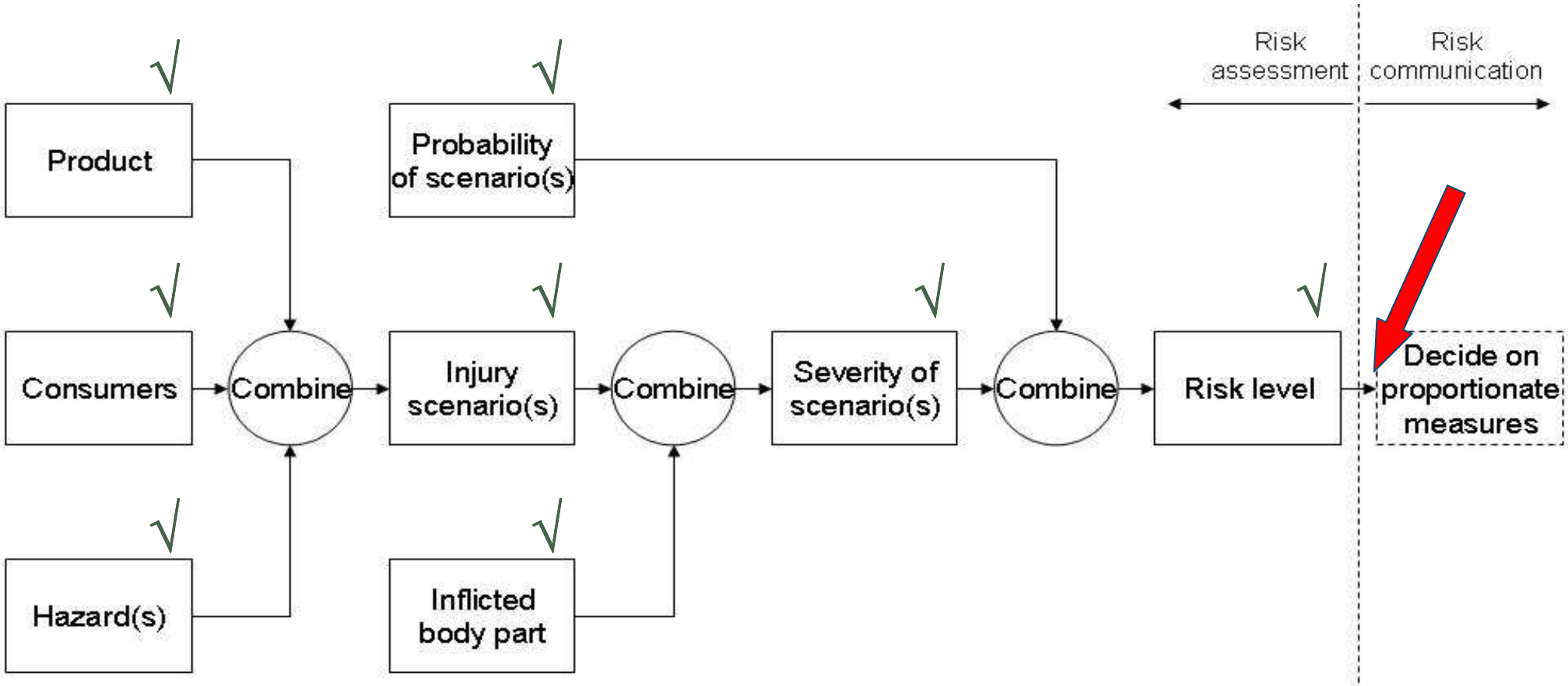
Step 7, combine severity and probability

Severity

Combination of severity and probability to risk level					
		Very Serious	Serious	Moderate	Slight
Almost certain, might well be d	> 50 %	Serious risk - r	Serious risk - r	Serious risk - r	Moderate risk
Quite possible	> 1/10	Serious risk - r	Serious risk - r	Serious risk - r	Low risk
Unusual but possible	> 1/100	Serious risk - r	Serious risk - r	Serious risk - r	Low risk
Only remotely possible	> 1/1.000	Serious risk - r	Serious risk - r	Moderate risk	Acceptable
Conceivable, but highly unlikely	> 1/10.000	Serious risk - r	Moderate risk	Low risk	Acceptable
Practically impossible	> 1/100.000	Moderate risk	Low risk	Acceptable	Acceptable
Impossible unless aided	> 1/1.000.000	Low risk	Acceptable	Acceptable	Acceptable
(Virtually) Impossible	< 1/1.000.000	Acceptable	Acceptable	Acceptable	Acceptable

Probability

Step 8, report result



Step 8, report result

- Identification of product and case, description of the context
- Description of the hazards
- Description of injury scenarios and sensitivity

Injury scenarios	Injury type and location	Severity of injuries	Probability of injuries	Resulting probability	Risk
Defect: handle grip breaks because shaft is too short. Top part of hammer bounces back and hits user's arm	Bruising of arm	Slight	Handle breaking: 1/2 Hitting arm: 1/5	1/10	Low

- Conclusion

  (including reflections on the result.)