Applying predictive risk management tools for targeted surveillance

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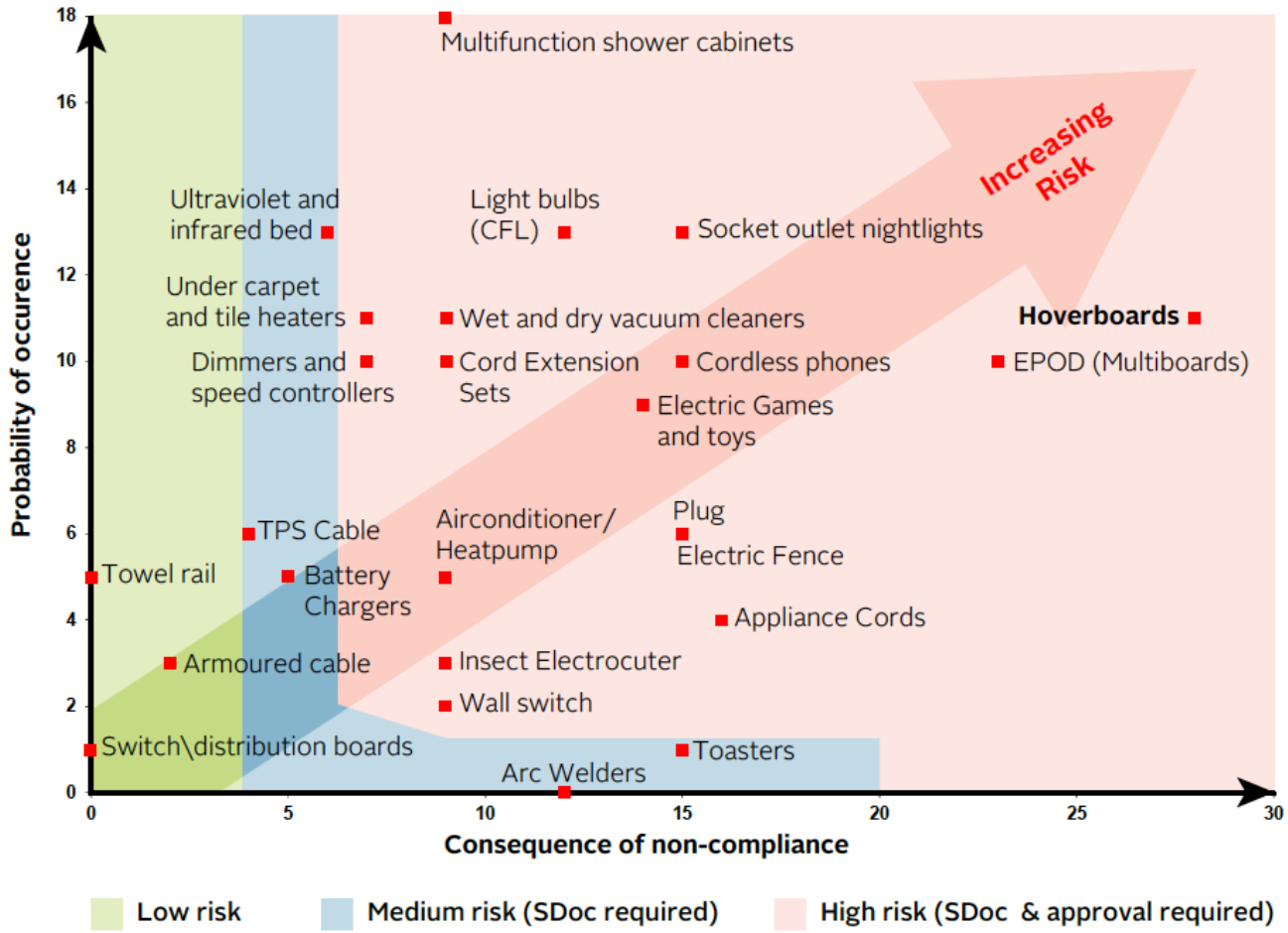
GRM and the risk management trends

Proactive MS and prioritization problem

- New products
- Unknown products
- Unknown supply chains
- Untested products
- ”No complaints” products

Predictive risk management tools: before an accident/test



Example received from Mr. Peter Morfee, New Zealand

Risk-based surveillance: non-compliance risk

Not dangerous when non-compliant/high probability

Dangerous when non-compliant/high probability

Not dangerous when non-compliant/low probability

Dangerous when non-compliant/low probability

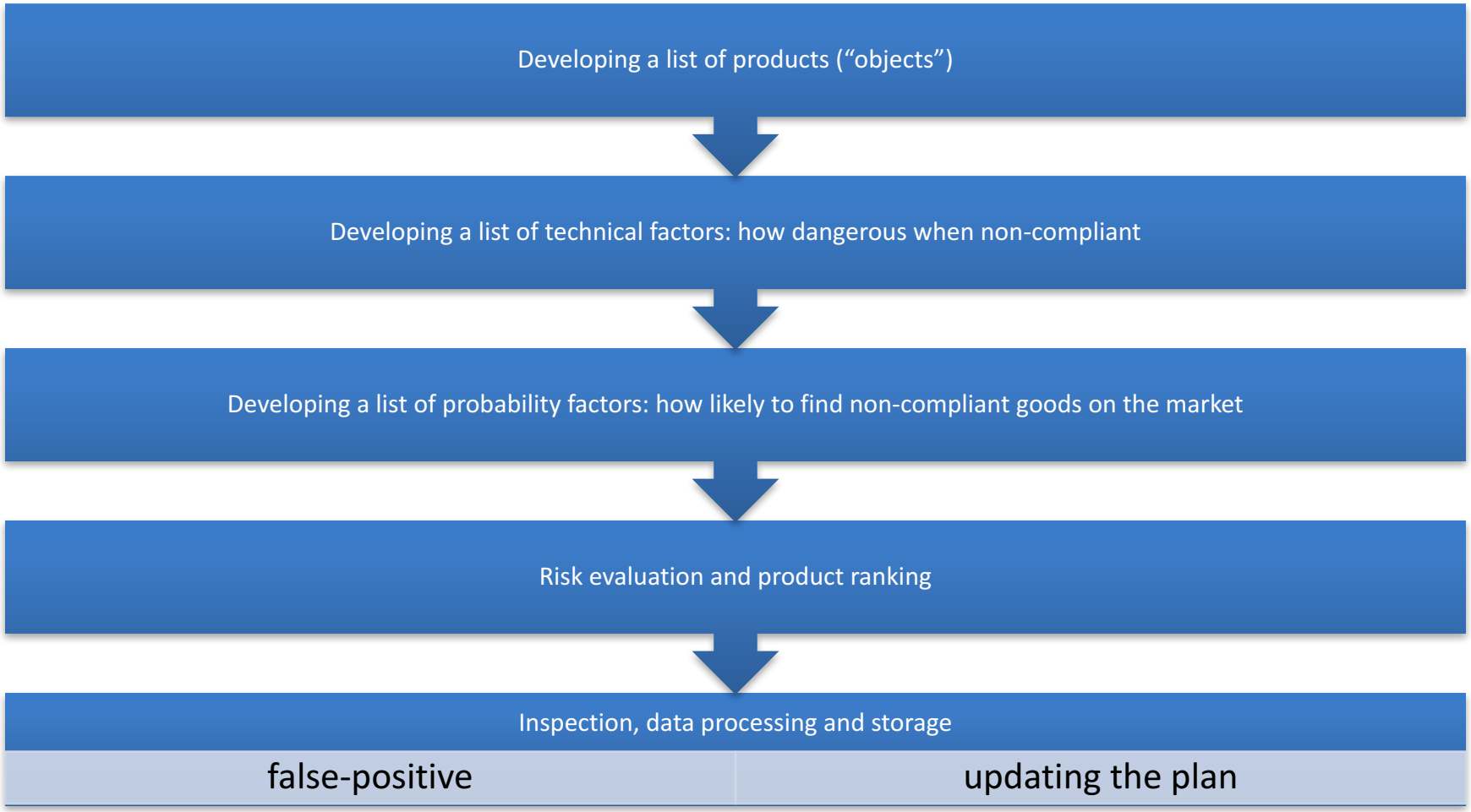
Risk management and regulatory errors (and immunity)

High risk/checked	High risk/not checked
Low risk/checked	Low risk/not checked

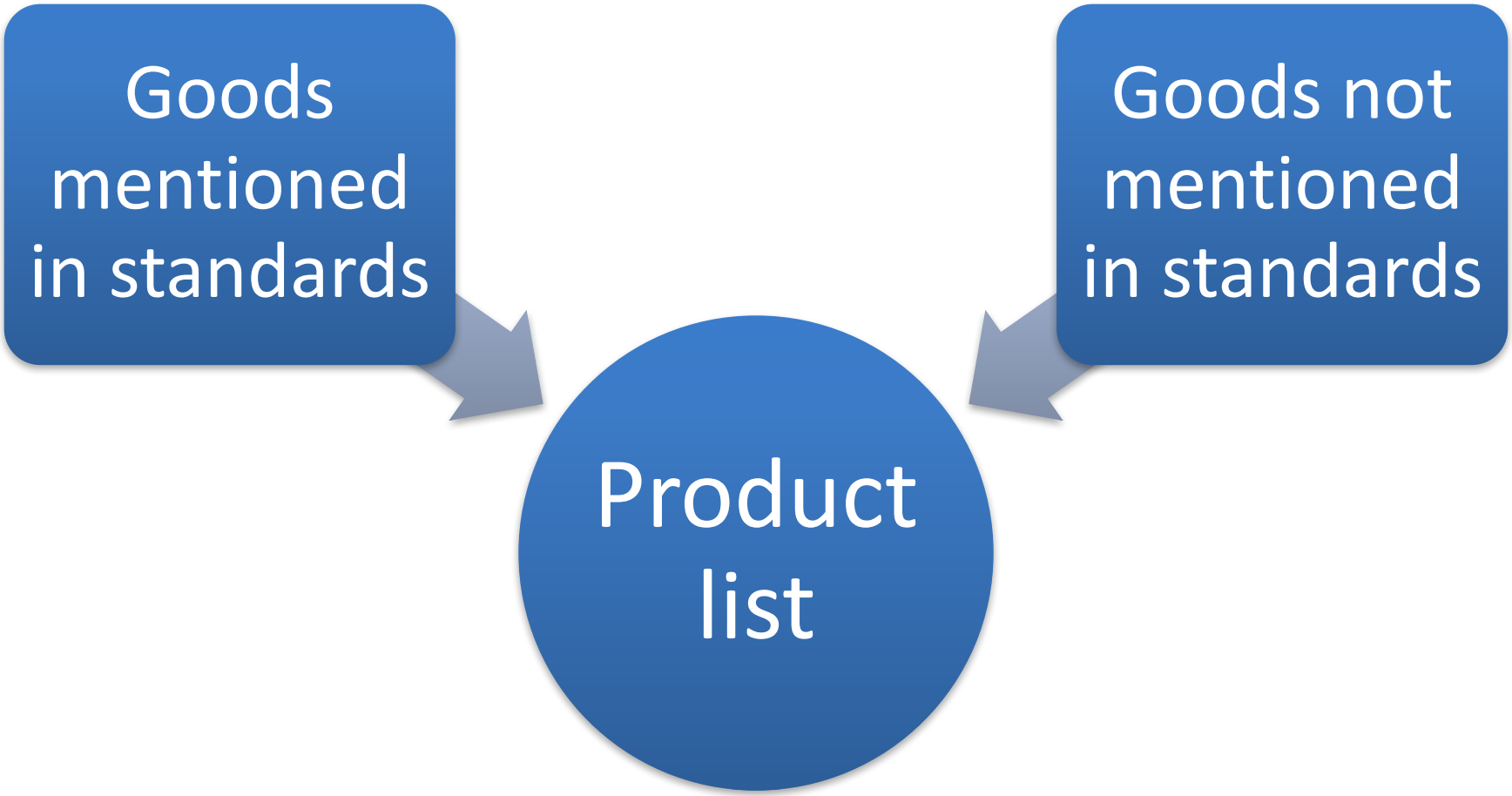
Recommendation for a framework

- A system that is based on the risk of non-compliance of the product:
  - How dangerous when non-compliant
  - Probability of non-compliance
- A system that is predictive
- A system that is learning
  - System that is predicting better as it gets more data

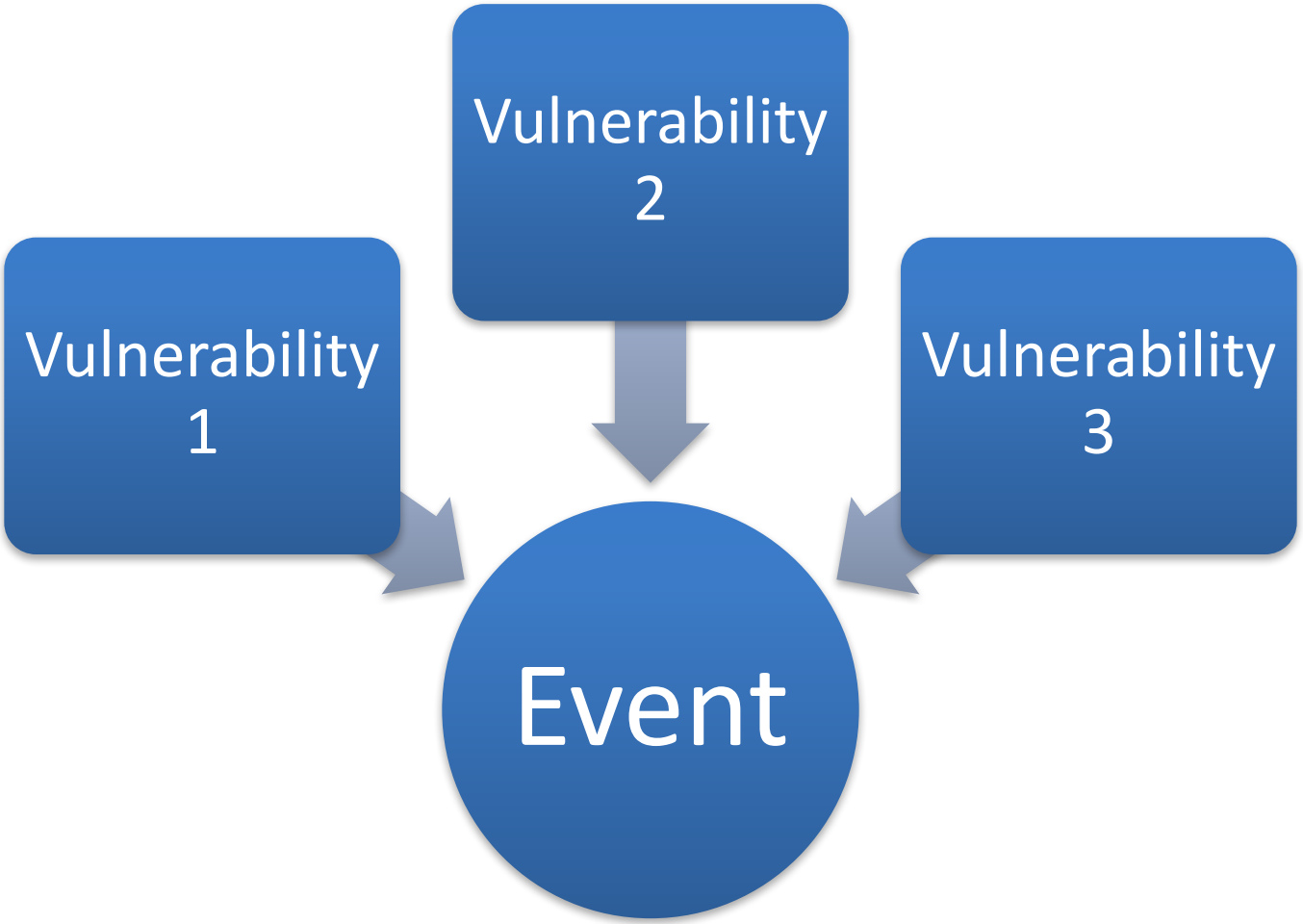
Risk to be a real priority in surveillance



Developing a product inventory



Developing a list of technical factors



NZ Technical (Consequence) Factors

Product providing a safety functions
Product relies on isolation between Low Voltage (LV) and exposed Extra Low Voltage (ELV) parts.
Product likely to move during or between uses
Product used in circumstances where he user is not able to readily disconnect with normal physical reaction to electric shock.
Product relying on guards and barriers to prevent mechanical injury.
Product likely to be used by unsupervised or lightly supervised children
Product commonly used in damp locations or where the skin's resistance is by passed.
Product's Standard is recognised as being barely adequate.
Product subject to likely significant misuse.
Product is high powered (heat or mechanical energy).
Product has assessable live parts – relies on safety impedance, or current controls or cadence to achieve isolation of live parts
Product likely to be installed by unskilled persons or relies on adjustments by unskilled persons.
Product relies on safety cut-out for primary safety.
Product is commonly used locally in an unattended mode but classified internationally (in the relevant international Standard) as attended.
Product has high-energy Storage
Product has hot nonworking surfaces
Product has Radiation risks
Product uses toxic substances
Failure or the product is not readily determined.
Product is generally electrically interconnected with other equipment.

Example received from Mr. Peter Morfee, New Zealand

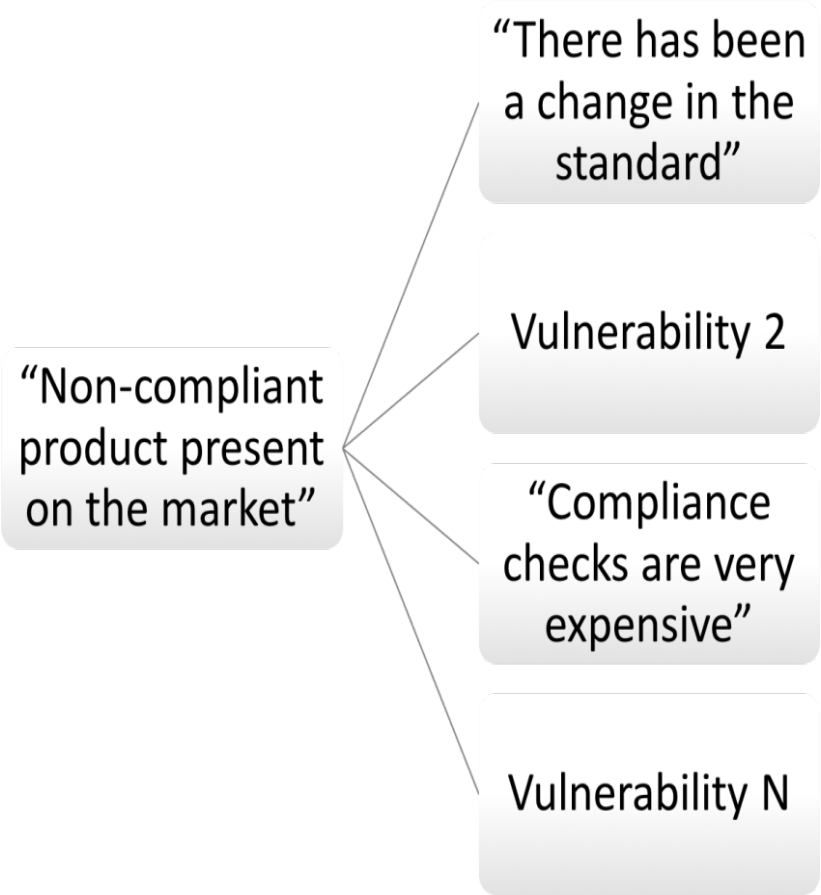
Building a “product – risk matrix”

- Evaluating each product against each technical factor

	Product 1	Product 2	…	Product n
Product relies on safety guards	1	0	…	1
Product moved during use	0	1	…	1
…	…	…	…	…
Technical factor N	0	0	…	0

Index

Developing a list of probability factors



P Factors

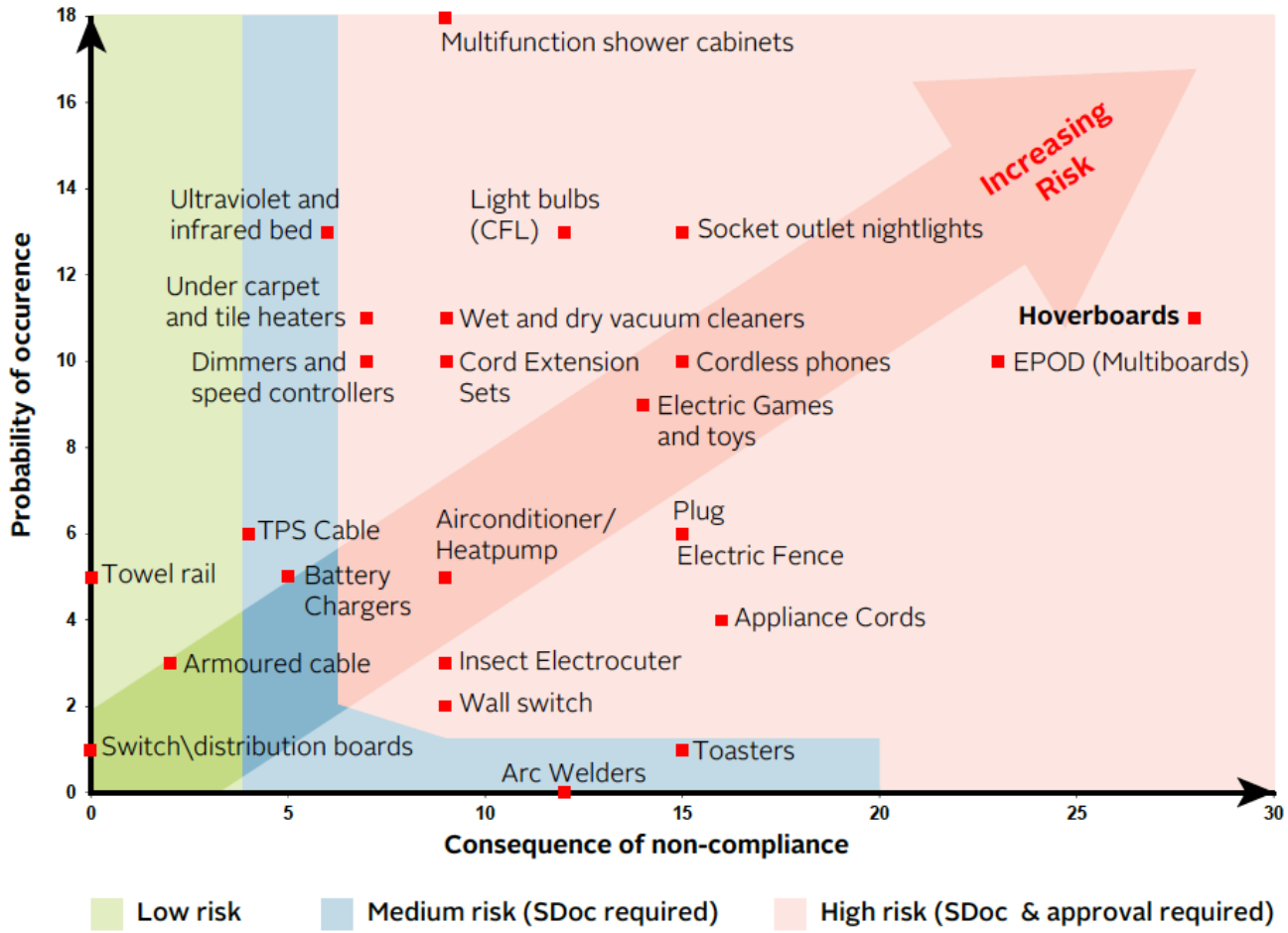
Product uses new technology or lacks a relevant International Standard.
EEE that is not controlled in Australia
EEE that is not controlled in Asia
Product consider safe in local use only with the significant deviation to applicable international Standard.
Product is not suitable for safe local use but can be converted to local supply conditions without significant alterations.
Product is controlled internationally using Standards considered inadequate for local application.
Dominant supplier's market does not use international standards or local standard.
There are cost disincentive for compliance
Standards recently updated
Compliance with the applicable Standard is complex or technically difficult.

Example received from Mr. Peter Morfee, New Zealand

Developing a list of probability factors

- Dependent on the local market
- Analyzing the supply chain
- Compliance disincentives

Predictive risk management tools: basis for a plan of work



Example received from Mr. Peter Morfee, New Zealand

“Prediction-reality” mapping

Prediction:

How dangerous when non-compliant

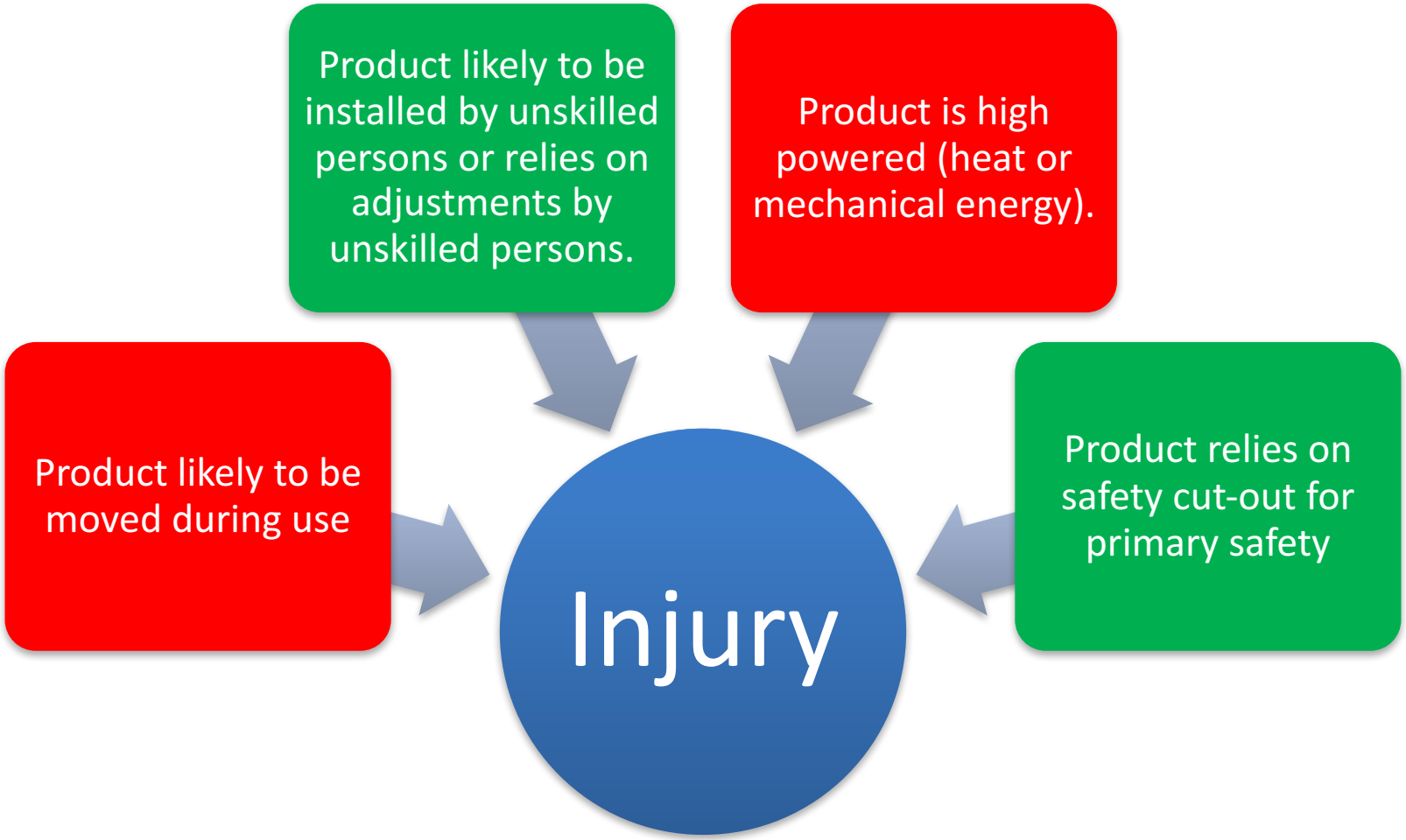
Probability of non-compliance

Reality:

Injuries caused by non-compliant products

Non-compliant (compliant) product at the market

Data processing and storage



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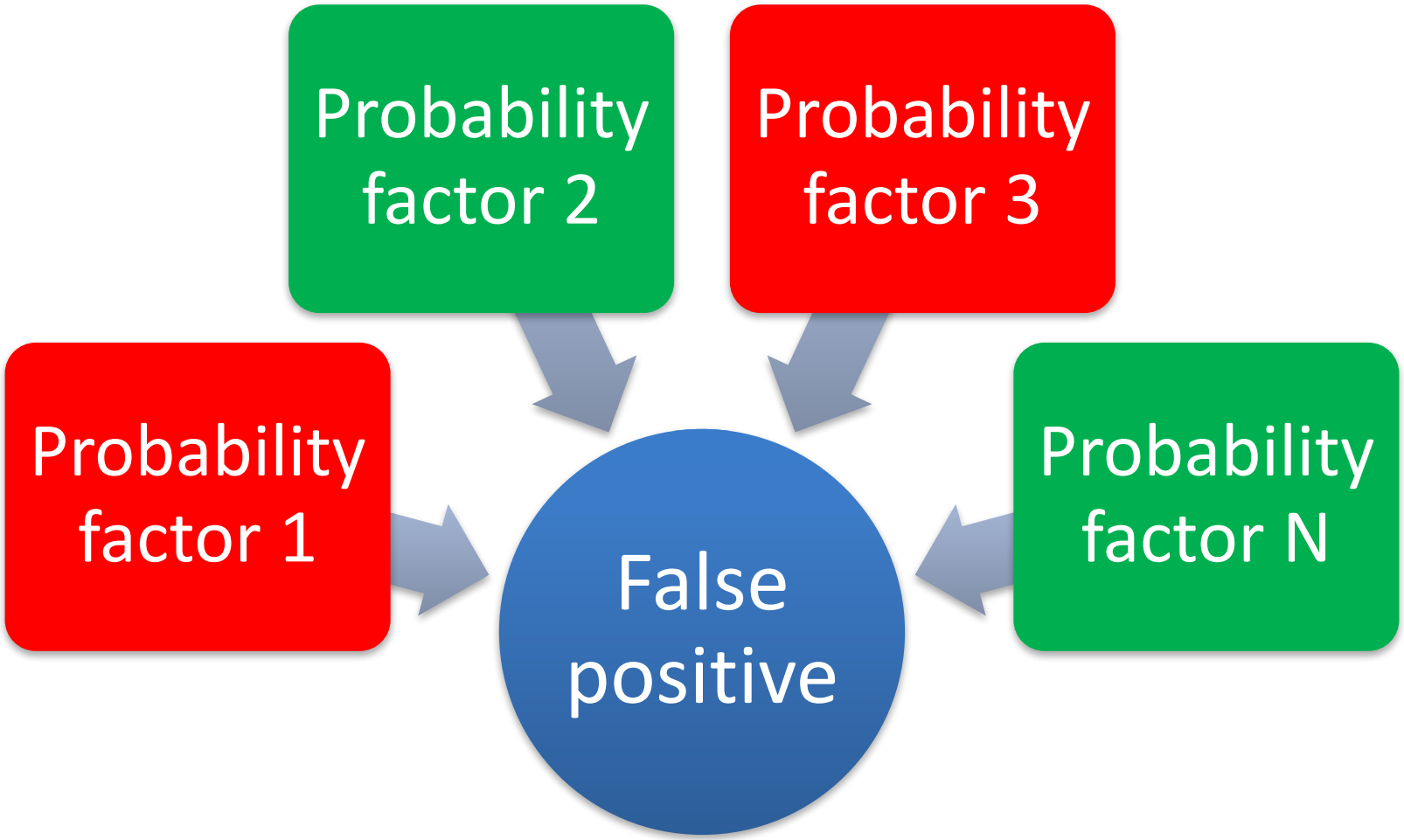

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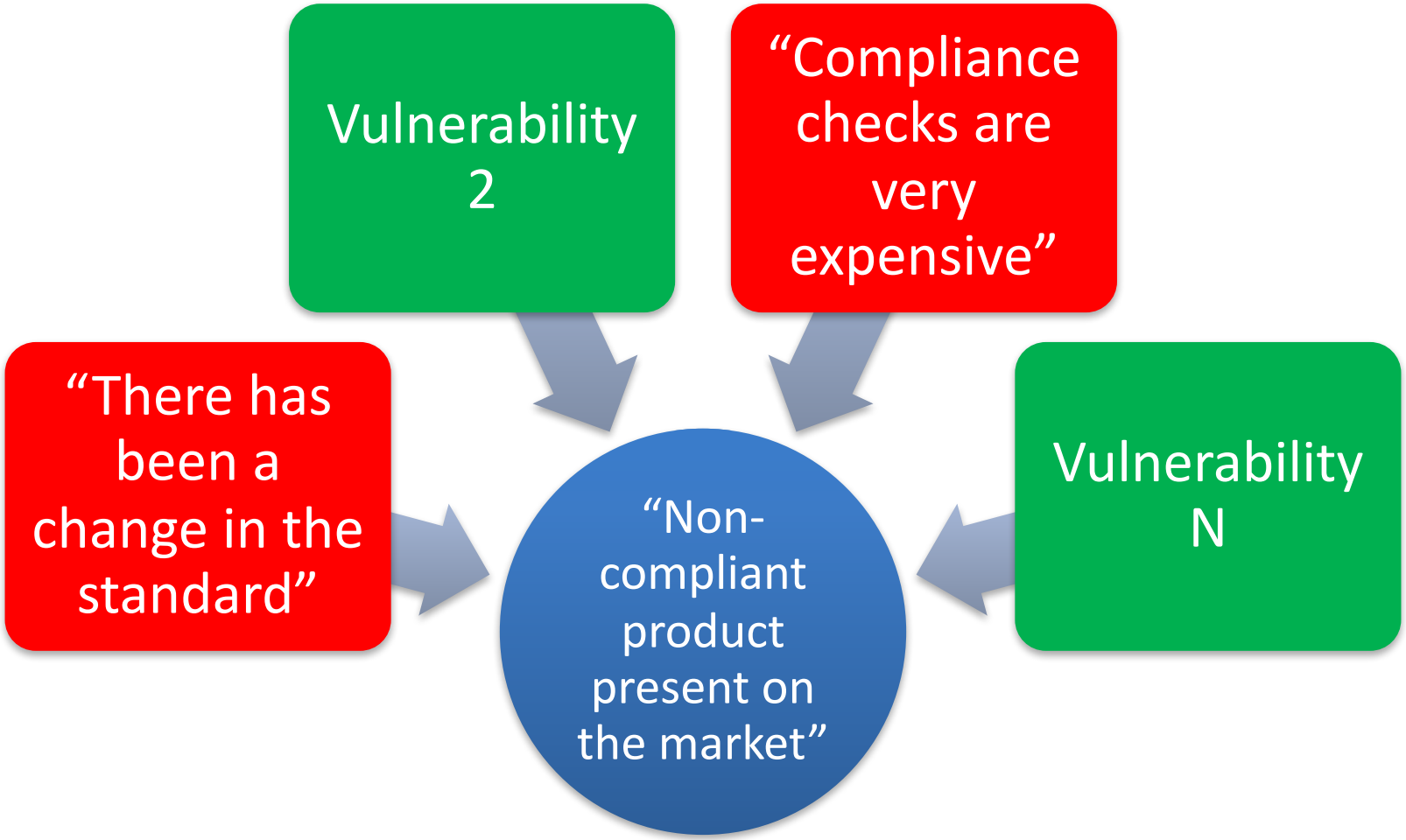


Recommendation: setting the scene

The Working Party on Regulatory Cooperation and Standardization Policies,

- **Emphasizing** that achieving absolute safety cannot be the goal of a regulatory system,
- **Noting** that excessively stringent controls can create unnecessary barriers to trade,
- **Recognizing** the importance of ensuring that products on the market (including imported goods), physical infrastructure, commercial and industrial facilities are compliant and safe so as to protect consumers, citizens and the environment
- **Emphasizing** the importance of applying predictive risk assessment tools for planning the activities of market surveillance/compliance authorities at the “before an accident”/”before the non-compliance reported” stage,

Recommendation: setting the scene

- **Stressing** that risk-based surveillance frameworks should help avoiding:
  - Excessive controls on low risk products and
  - Omitted or insufficient controls on high risk products,
- **Recognizing** that authorities need to efficiently allocate limited resources and that risk-based targeted surveillance on products on the market (as well as on installations and facilities) provide an important means to that end,
- **Aiming to** provide guidance in the use of predictive risk management techniques so as to increase the efficiency of the existing risk assessment tools and data sharing platforms,
- **Aiming** to complement the existing risk assessment tools applied by market surveillance authorities,

Recommendation: the main part

- **Recommends that**: Authorities plan surveillance activities on the basis of the evaluation of the non-compliance risk of products/businesses within their jurisdiction. The evaluation of the non-compliance risk should reflect:
  - How dangerous a certain product is when it is non-compliant to standards,
  - How much risk is added by the business entity in its management of the product,
  - What is the probability that a non-compliant product of this type is present on the market
  - What is the probability of the business entity being non-compliant in its operations.

Recommendation: the main part

- The Working Party recommends that
  - national authorities, with due consideration for their individual resources, needs and priorities,
  - develop and implement methodologies and processes that allow for an evaluation of the risk of non-compliance of products/businesses
  - within their jurisdiction to relevant standards and regulations.

Recommendation: the main part

- The approach laid out in Annexes A and B can be used as a basis for the evaluation of the non-compliance risk of a product. Respectively:
  - Annex A assists in evaluating how dangerous a product is when it is non-compliant with standards and regulations,
    - and
  - Annex B assists in evaluating the probability of non-compliance of a product present on the market.

Recommendation: the main part

- **The Working Party encourages** national authorities - with due consideration for their individual resources, needs and priorities - to use, or as necessary develop, data gathering tools for storing data on:
  - Results of market surveillance activities related to products (matching them to the evaluation of the probability of non-compliance made during the planning phase);
  - Injuries and other accidents related to the use of non-compliant products

  and use this data to continuously improve the evaluation of the non-compliance risk of products.
- **Also encourages** national authorities to share the non-compliance risk and injuries related data with their international counterparts, so as to increase the efficiency of regulatory intervention and surveillance,
- **And** recommends that resources be identified for assisting in the development and implementation of these tools both at the national level and internationally.

Annex A

1.Building a list of products

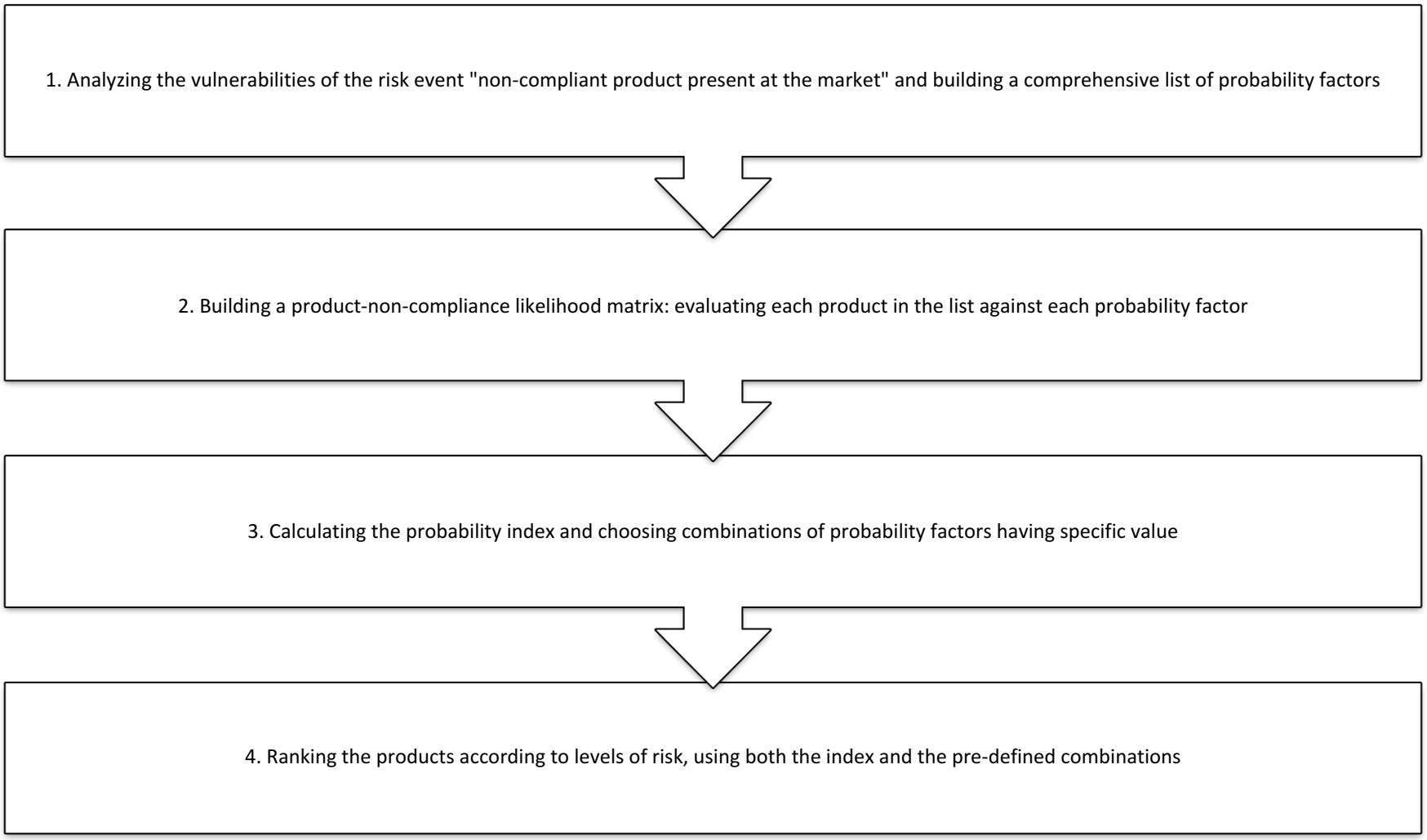
2. Building a comprehensive list of technical factors for a family of products

3. Building a product-risk matrix: evaluating each product in the list against each technical factor

4. Choosing specific combinations of technical factors having specific value; calculating the non-compliance index for each product

5. Ranking products according to levels of risk, using both the non-compliance index and the pre-defined combinations of technical factors

Annex B


1. Analyzing the vulnerabilities of the risk event "non-compliant product present at the market" and building a comprehensive list of probability factors
2. Building a product-non-compliance likelihood matrix: evaluating each product in the list against each probability factor
3. Calculating the probability index and choosing combinations of probability factors having specific value
4. Ranking the products according to levels of risk, using both the index and the pre-defined combinations