# Risk Assessment for Regulatory system design

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# APEC Regional Regulation

- Typically, the Regulation of Electrical and Electronic Equipment (EEE) in the Asia Pacific Region is achieved through premarket intervention systems applying either ISO Guide 67 Type 1 or Type 5 principles
- In many APEC Economies only those products considered to justify intervention are controlled, although in some jurisdictions there are general safety requirements applying to all products

# NZ's Risk Engine

To assist economies in the APEC region, and members of the ASEAN community to meet the WTO expectation of applying Risk Management principles to achieve GRP, NZ undertook to develop a method of ranking the risk associated with EEE for the purposes of determining appropriate levels of regulatory intervention based on the concepts embodied in: **AS/NZS 4360 / ISO 31000**

# Engine design

The basic Risk Engine design was then refined to identify product for inclusion in NZ's two pre-market regulated medium and high risk categories

*NZ operates a three level regime which requires fundamental safety for all low risk products, Type 1 certification for high risk, and an SDoC supported by testing results for medium risk products*

# Conceptual Overview

While most existing risk assessment tools, derive risk classifications using qualitative assessments that rely on 'expert' opinion, New Zealand's Risk Engine applies a quantitative assessment system based on product-specific features and identified market factors that influence the likelihood of non-compliance with the safety regime, thus making the system more **systematic, objective and consistent.**

# The Model

Qualitative risk analysis methods express risk by an equation such as R=P*C where:

- P is related to the likelihood of the circumstances giving rise to the risk, and
- C is related to the consequence.

The NZ Risk Engine quantifies risk by the formula: R=*f*(P, T).

*The 'Consequence' factors are referred to as "T" (technical safety) factors in the engine*

# P and T factors

Both the P and the T factors used in the Engine have been validated by referral to a panel of experts. They are then applied in a quantitative manner.

Examples of the probability factors include:

- Regional Regulatory coverage
- Simplicity of testing
- Deviations from International Standards

# T factors

Examples of the Technical factors include:

- Product likely to be used by unsupervised children
- Product relying on safety cut-off or interlock for primary safety.
- Product that is generally electrically interconnected with other products.
- Product that provides an electrical safety function.

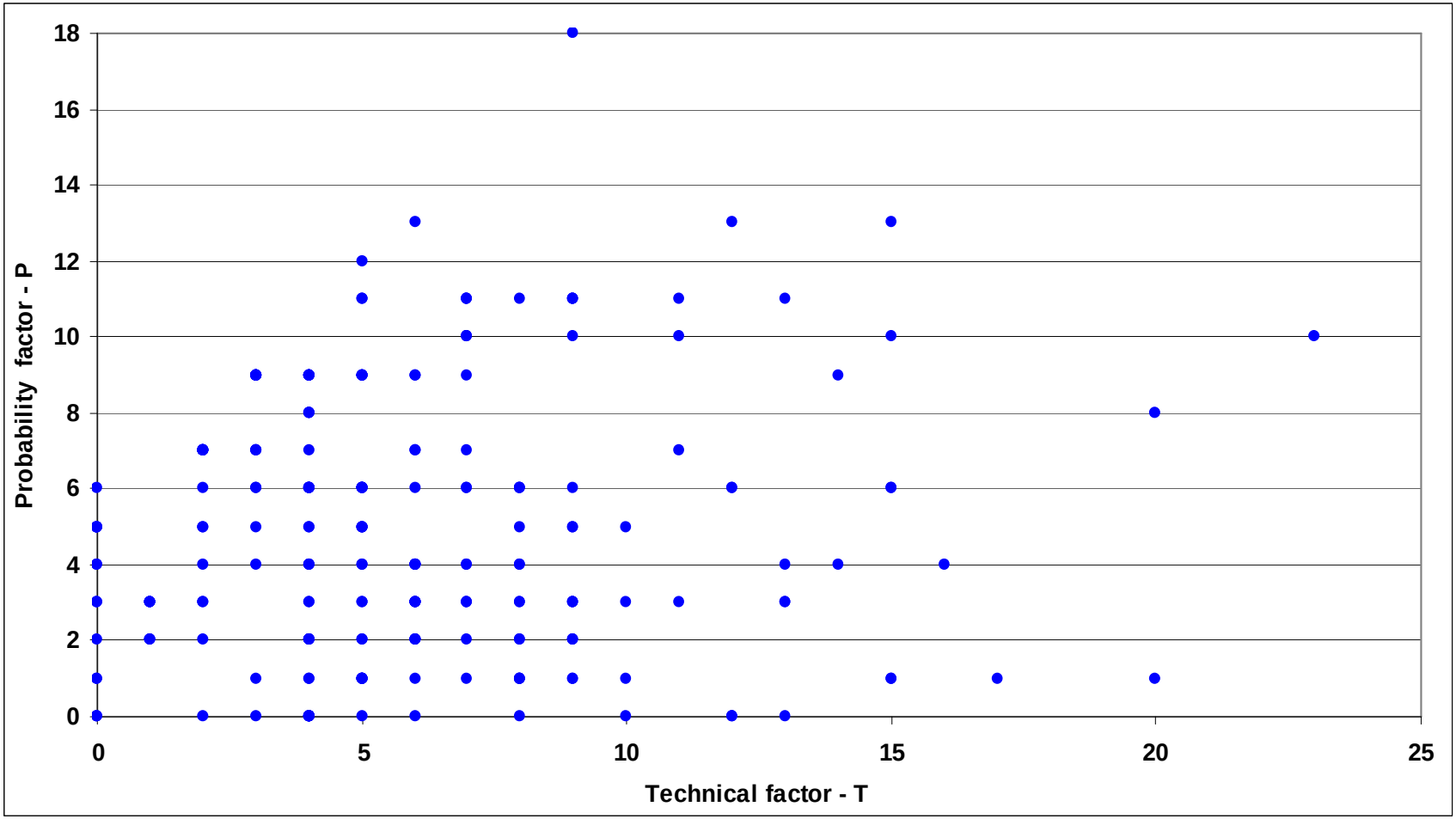
The quantitative approach of the Engine reduces the technical judgement inconsistencies that occur in a qualitative system

# Graphical Presentation

Because the relative importance of P and T is not recognisably identical, nor linear, a graphical method has been employed where P and T are plotted on the two axes of a graph

This allows the contributions of both factors to be seen and considered in the assessment

# Spread of products that have been assessed



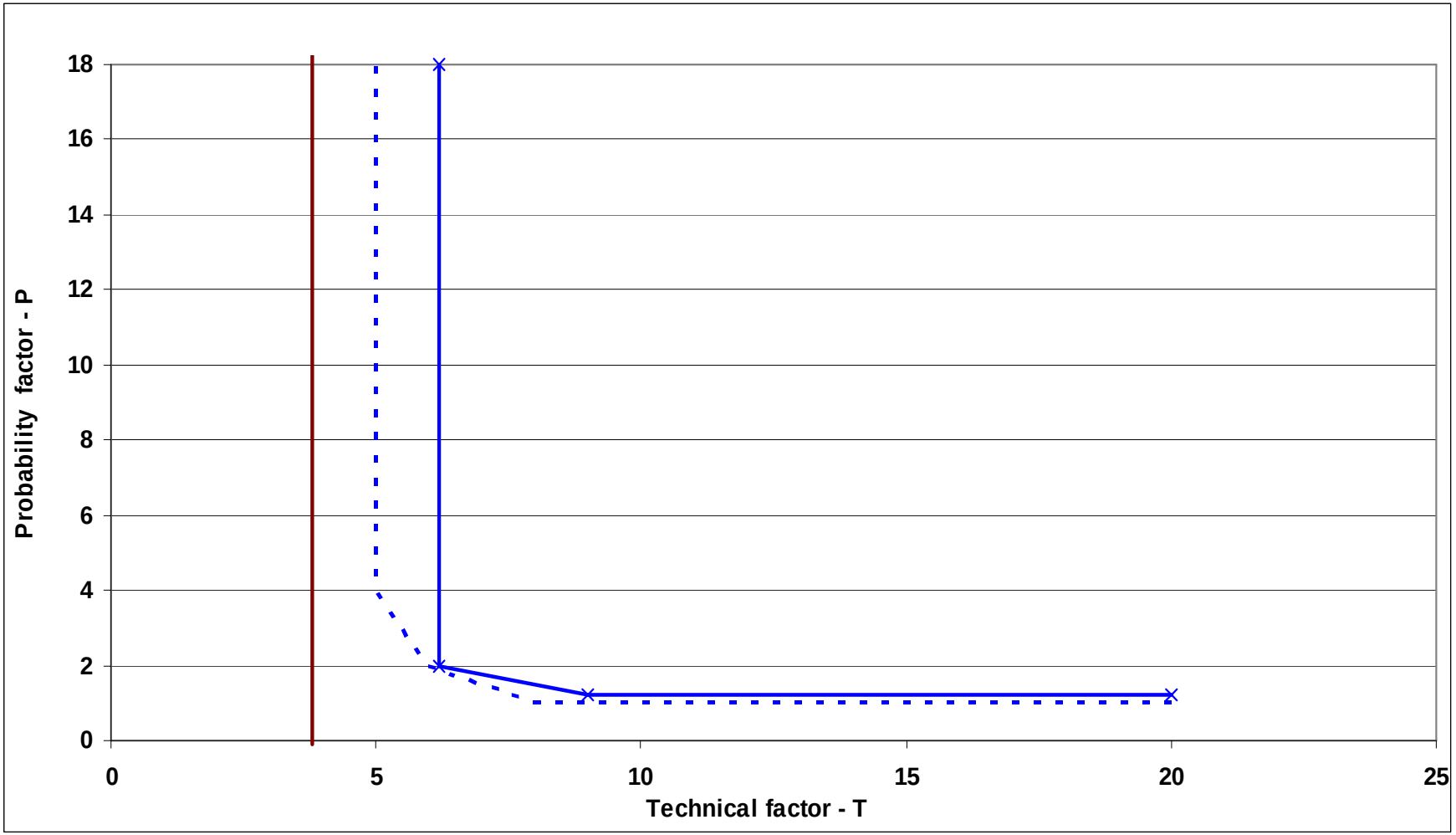
# Delineation lines

Delineation lines statistically derived, and validated, by expert input, are then added to the graph to identify products for inclusion in each category on intervention

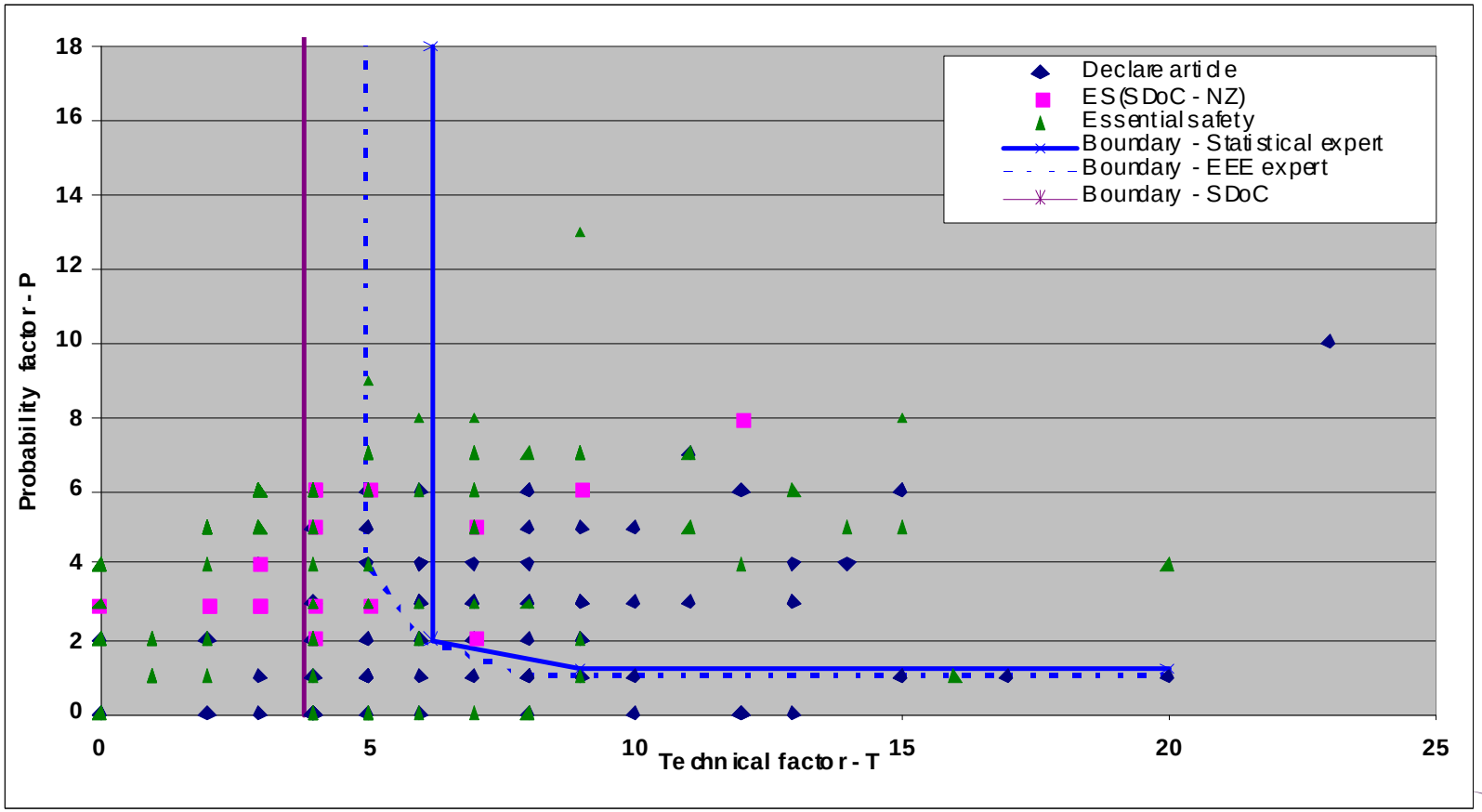
In NZ’s case, two lines were established

The dotted line is the statistically derived separation line derived from expert input

# Delineation lines chosen for the NZ three level Regulatory Regime



# Graph showing the assessed products and their present regulated risk category




Note: It is proposed to adjust NZ's controlled products to reflect their assessed risk levels

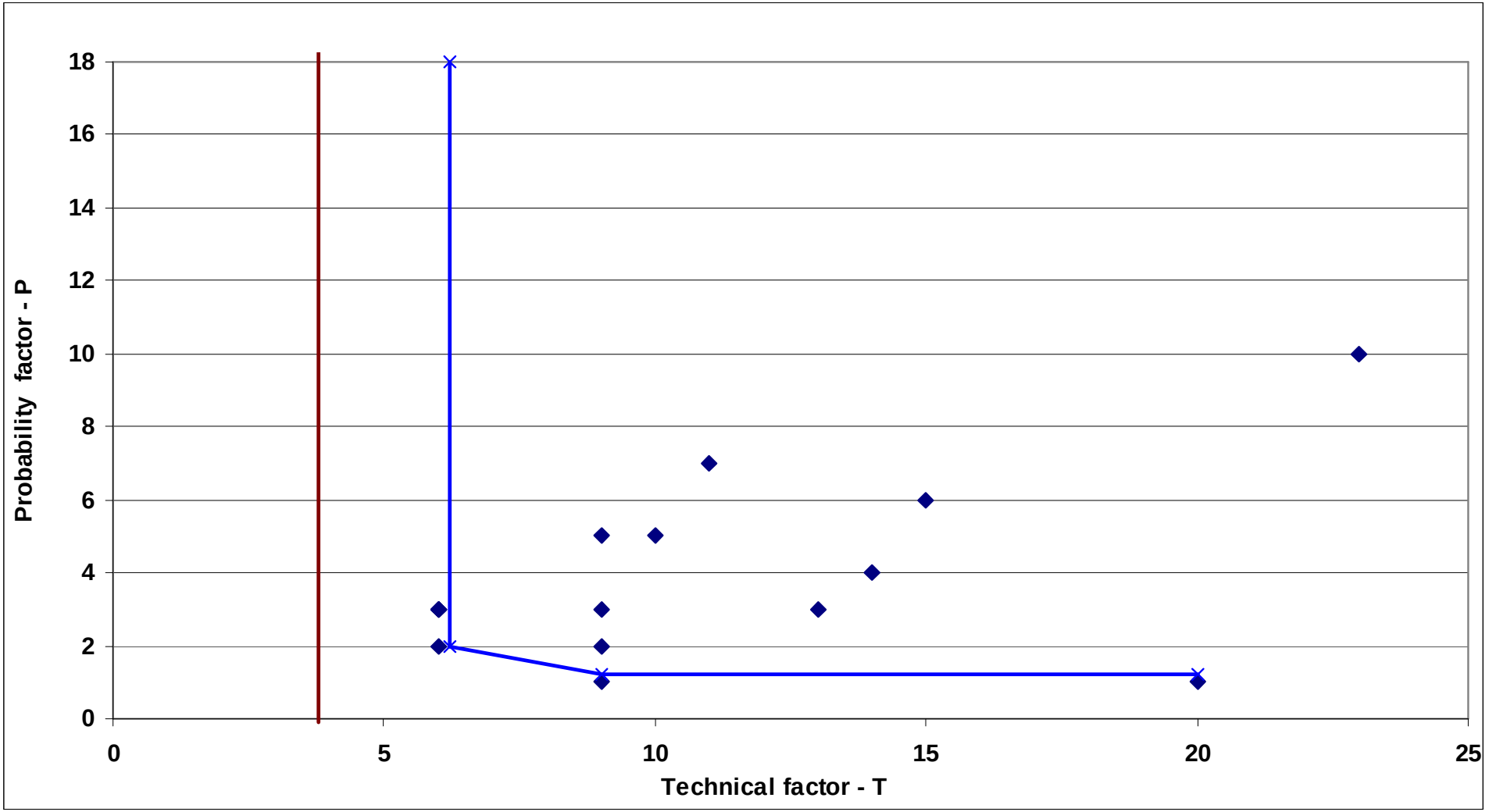
Ministry of Economic Development
Manatū Ōhanga
Energy Safety

# Testing the Engine

The development of the Engine involved an ongoing process of testing and validation. Two processes have been used for the validation engine:

- The use of a panel of “experts” to provide peer advice on the factors and the engine’s assessments
- A comparison of the assessments of the Engine against existing regulatory systems

# NZ’s present high risk items

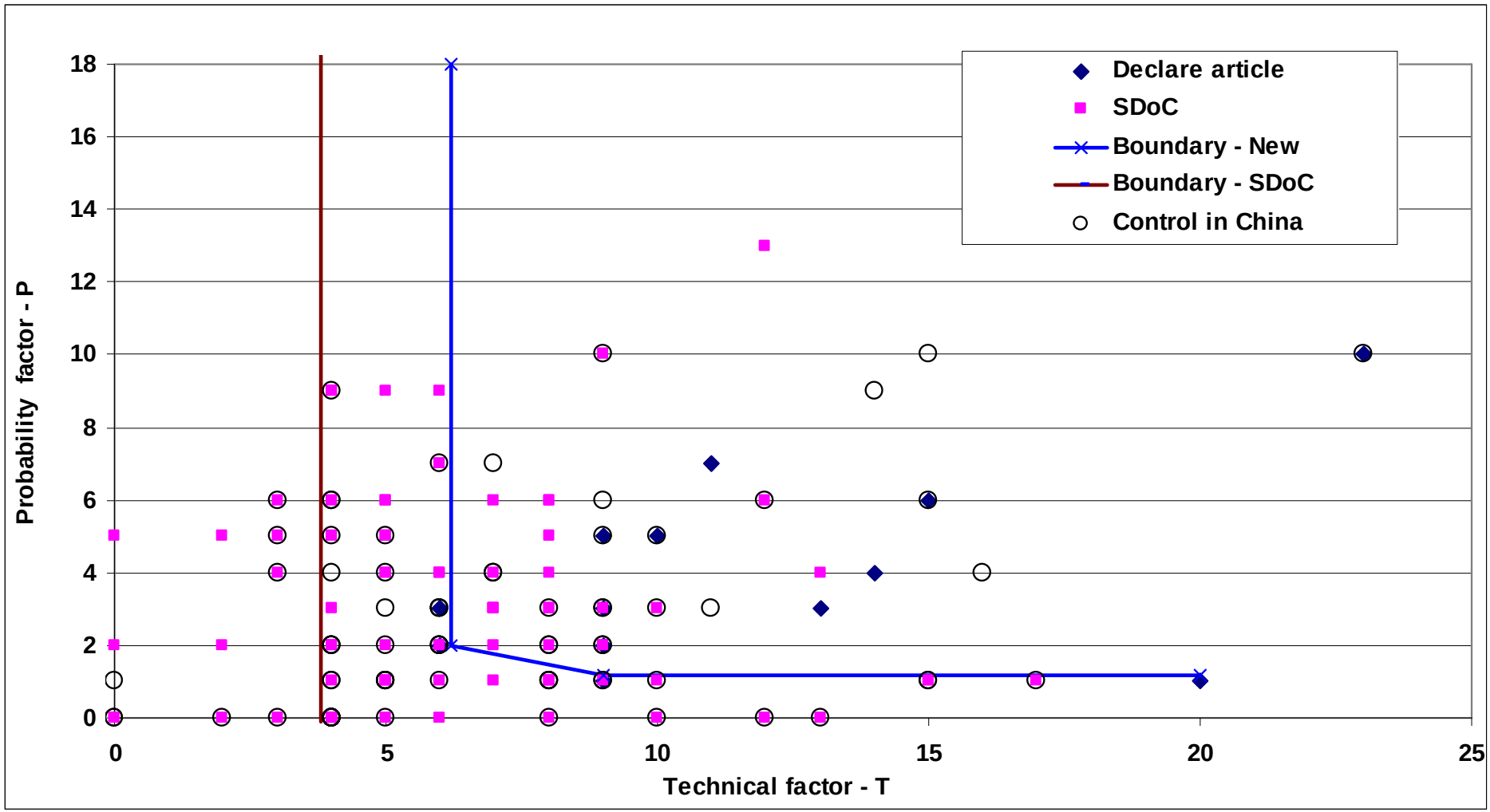


# Other Jurisdictions

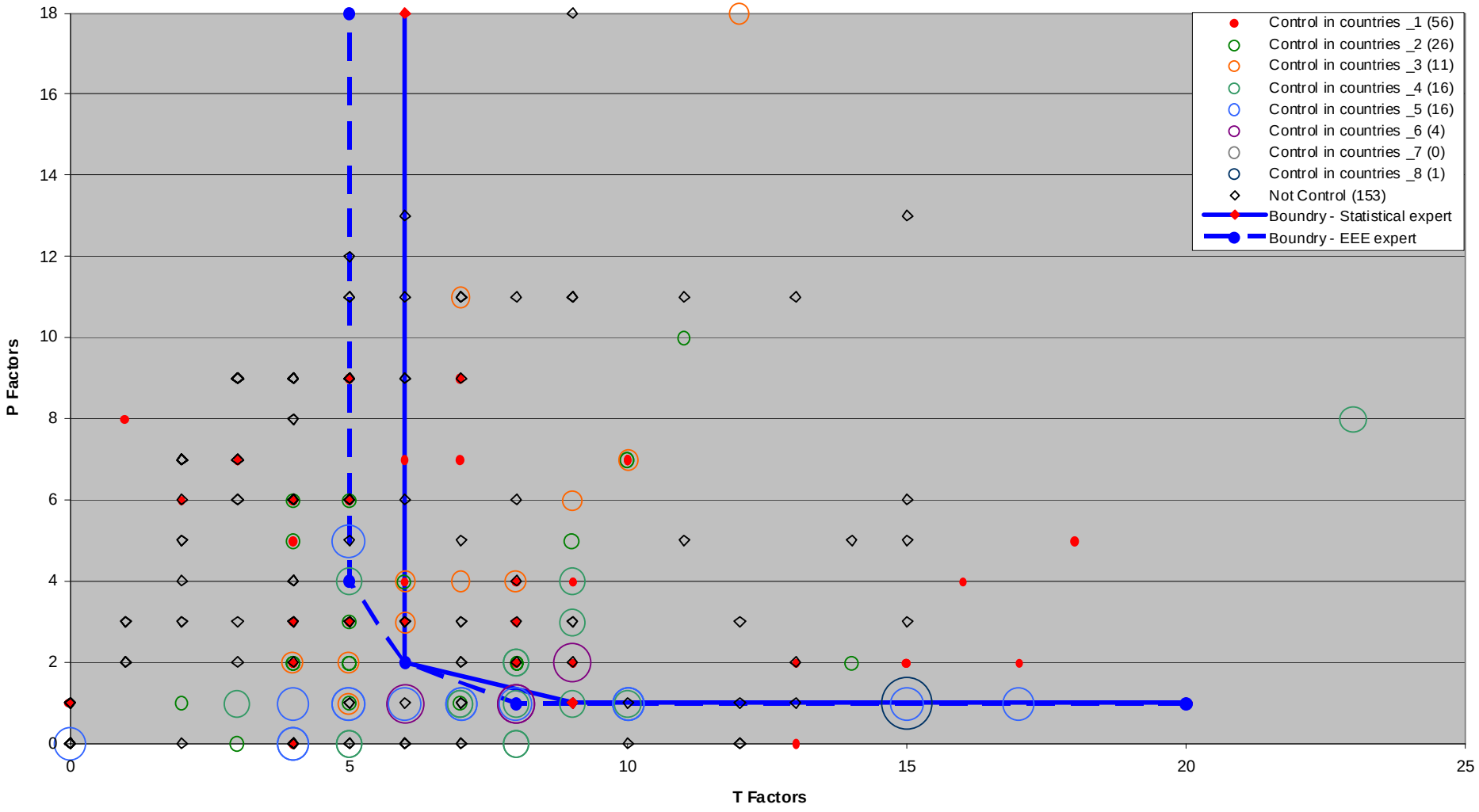
The system has been specifically tuned to reflect NZ's compliance environment, it is possible however to carry out changes to the system that allow it to partially simulate the compliance environment of other jurisdictions

While such simulations have weaknesses in the assessment of the P factors, and the delineation lines, they can give an indication of how a completed assessment might behave

# Comparison of products subject to Medium and High Risk control in NZ and CCC marking in China



# Products controlled in the ASEAN community



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