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The application of Risk Management principles to achieve Good Regulatory Practice and MRA design

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Content

In this presentation we will explore:

- The WTO objectives relating to risk Management
- The fundamentals of Risk Management
- New Zealand's EEE Regulatory system
- The NZ Risk approach to determining Regulatory intervention
- Regulatory Co-operation (including Hazard alerts)
- Mutual Recognition agreements
- NZ's EEE co-operation agreement (MRA) with China

Introduction

When Good Regulatory Practice is being applied to regulatory systems, the WTO expects risk management techniques to be applied

Likewise, the WTO expects that International Standards are used as the basis for assessing compliance with Regulatory objectives, and,

That MRAs are employed to reduce the impact of Regulatory Intervention on traded goods

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Risk Management Principles

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Concept of Risk

Risk can be expressed as the combination of hazard and the probability of that hazard occurring;

$$R=H * P$$

Where H represents the level of technical risk (Hazard) and P represents the probability of that hazard occurring

There are many examples of this technique being applied to industry, particularly the aircraft industry, but it's analytical application to achieve Good Regulatory Practice is not common

Common Regulatory approaches

It is most common for Regulatory systems to be based on statistical historic data derived from incidents and accidents or by a simple analysis of the potential hazards that particular types of electrical equipment might possess

NZ, Australia, ASEAN and Chinese Taipei however have begun to depart from these approaches and explore a more analytical methodology

Reactive to predictive

- The systems commonly applied to date can be described as being lagging, or reactive, systems relying on historic information
- The systems being promoted by NZ, Australia ASEAN and Chinese Taipei can be described as leading or predictive
- In today's rapidly changing marketplace and increasing technical evolution, the application of reactive (lagging) systems is becoming increasingly ineffective
- This is particularly applicable to technical changes driven by other Regulatory objectives

Pre and Post market controls

The compliance of products in a particular marketplace is a combination of the level and effectiveness of both the pre-market and post-market controls

Both controls have particular advantages and disadvantages, which need to be considered when designing a regulatory system, particularly one that operates over a number of different jurisdictions such as the NZ / Australia single economic market

Outcome of Regulatory intervention

While the risk to society posed by a particular type of equipment is created by a number of factors, including the adequacy of the Standard applied, and the behaviour of the user, the principle outcome that is achieved by a regulatory intervention, such as pre-market certification, is the certainty of compliance of the product with it's relevant safety Standard

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New Zealand's Regulatory System

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NZ's EEE Regime

New Zealand currently operates an EEE Safety regime that has three levels of intervention

The products included in each level are set by a risk management system closely aligned with the system operating in Australia

Low Risk products

Low risk products are only required to meet fundamental safety requirements

This is regulated by mandating compliance with AS/NZS 3820, a joint Standard derived from the EU LVD

Most common products have Standards that form a recognised means of compliance

Medium Risk

All medium risk products are required to be covered by a supplier declaration of conformity with the fundamental safety requirements, SDoC

Test Reports are not required, and compliance with the recognised Standards is not mandatory

Compliance with recognised Standards is however formally recognised as meeting the fundamental safety requirements

High Risk products

All high risk products are required to be approved by either the NZ regulatory office or an Australian Regulator or alternatively certified by a certification body recognised under an MRA or recognised by the NZ regulatory office or an Australian Regulator

Certification may only be issued for products that comply with the recognised Standards

SDoC

High risk products are also subject to SDoC requirements

Thus both the medium and high risk products have SDoC requirements

In both cases the SDoC must include a reference to the means of compliance being applied

Marking

The NZ has no mandatory marking requirements

A voluntary marking system (the RCM) is however available if suppliers wish to use it

High risk products are required to be marked to show compliance with a recognised certification scheme

Proposed NZ system

New Zealand proposes to retain the three level system but to increase the level of intervention in the medium risk category and introduce SDoC in the low risk category

Type 5 certification is also being considered for products in the high risk category that are not compliant with the relevant product Standard

Medium Risk products

Medium risk products will be required to be the subject of an SDoC that includes compliant test reports to a relevant Standard

The testing laboratory will not be required to have been formally accredited

Performance based provisions

Products that are not compliant with the applicable product Standards will be entitled to be sold in NZ on the basis of compliance with fundamental safety requirements, but will be subject to higher levels of intervention

Compliance Table

	Low Risk	Medium Risk	High Risk
Recognised Standard applied	SDoC to ISO/IEC 17050.1 Compliant Test Report not mandatory (Module 1)	Compliant Test Report required to support SDoC to ISO/IEC 17050.2 Test Lab accreditation not mandatory (Module 2)	Type 1 certification (approval) required to support SDoC to ISO/IEC 17050.2 (Module 3)
Essential Safety applied	Compliant Test Report required to support SDoC to ISO/IEC 17050.2 Test Lab accreditation not mandatory (Module 2)	Type 1 certification (approval) required to support SDoC to ISO/IEC 17050.2 (Module 3)	Type 3,4 or 5 certification (incl. compliance monitoring) required to support SDoC to ISO/IEC 17050.2 (Module 4)

Benefits of Intervention

An analysis of each intervention has identified that each systems benefits differ principally with regards to; enforcement simplicity (speed) and certainty of compliance with safety outcomes and applicable Standards

Compliance Costs

Each intervention also has different compliance costs with the greater costs applying to the heavier interventions

It is important therefore that the intervention level is kept at the minimum needed for regulatory purposes

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NZ's Risk based approach to Determining Regulatory Intervention

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New Zealand Approach

New Zealand has proposed, and implemented, a risk analysis system that applies the formula

$$R = P * T * C * N$$

Where P relates to the probability of non-compliance, T to technical safety factors, C to the consequences of the hazard and N reflects the number of products in the marketplace.

Technical Compliance

A number of technical factors have been identified that contribute to the determination of the importance of compliance

The factors identified relate to products that have particular features

Technical Factors #1

Product providing an electrical safety function

Product relies on isolation between LV and exposed ELV parts.

Product likely to be moved during or between uses.

Product used in circumstances where the user is not able to readily disconnect with normal physical reaction to electric shock or burns

Product relying on guards and barriers to prevent mechanical injury

Technical Factors #2

Product is likely to be used by unsupervised children

Product commonly used in damp locations or where the skins resistance is bypassed.

Product's Standard is recognized as being barely adequate

Products subject to likely significant misuse.

Product is high powered (heat or mechanical energy)

Technical Factors #3

Product has assessable live parts – relies on safety impedances, or current controls or cadence.

Electrical installation related product, likely to be installed by unskilled persons.

Product relies on safety cut-off for primary safety.

Product is commonly used locally in an unattended mode but classified internationally as attended.

Probability of Compliance

A number of technical factors have been identified that contribute to the probability of compliance

Factors that improve or reduce compliance have been identified

The factors identified are listed below

Probability Factors #1

Testing is: expensive / difficult / not readily available in dominant supplier's markets / is not readily available internationally. (Type 1 & 5)

Standards – No adequate standard exists in: local market / dominant supplier's markets / internationally. (Type 1)

Regulatory Control – Product is not controlled in: regional market / dominant supplier's markets / global markets. (Type 1)

Probability Factors #2

Deviations – Relevant Standard deviates from: regional Standard / dominant supplier's market Standard / international Standard or another significant market's Standard. (Type 1)

Compliance disincentive from: cost / complexity / inappropriate conversion. (Type 5)

Changes to product designs have resulted from: amendments to applicable Standards / other regulatory requirements / new technology applications. (Type 1 & 5)

Probability Factors Improving Compliance

Product recognized as safe in local market if compliant with relevant international Standard.

Product is controlled *internationally* using Standards considered adequate for local application.

Dominant suppliers market Standard considered suitable for local market.

Consequence

The value for C is set as:

C=1 for probable death or significant fire caused by non-compliance,

C=0.5 for serious injury, fire or burns

C=0 otherwise.

Quantity

The value for N is set as:

N=1 for item commonly used in most households

N=0.5 for item found in many households

N=0 otherwise.

Outcome of Regulatory intervention

While the risk to society created by a particular type of equipment is created by a number of factors, including the adequacy of the Standard applied and the behaviour of the user, the principle outcome that is achieved by a regulatory intervention, such as pre-market certification, is the compliance of the product with it's relevant safety Standard

Pre-market controls

New Zealand has now concluded that the best method of determining what equipment in the NZ market should be subject to pre-market controls is to simplify the formula to

$$R = T * P$$

Where:

T is a number derived from the technical hazards a product possesses and

P is derived from the compliance / non-compliance drivers in the marketplace

This may not be the best method in other markets however

Use of weighting

Our analysis has convinced us that, while weighting factors might be derived and applied to the system, and the probability factors might be subdivided to relate to groups of technical factors (such as electric shock), the end result of such an analysis does not appear to improve the analysis, probably because the quality of such information is not sufficient

Expert Knowledge

We also note that, while expert input is a vital to improve the surety of the calculation system, generally expert input is too closely coupled to the historic processes and most related a T based system

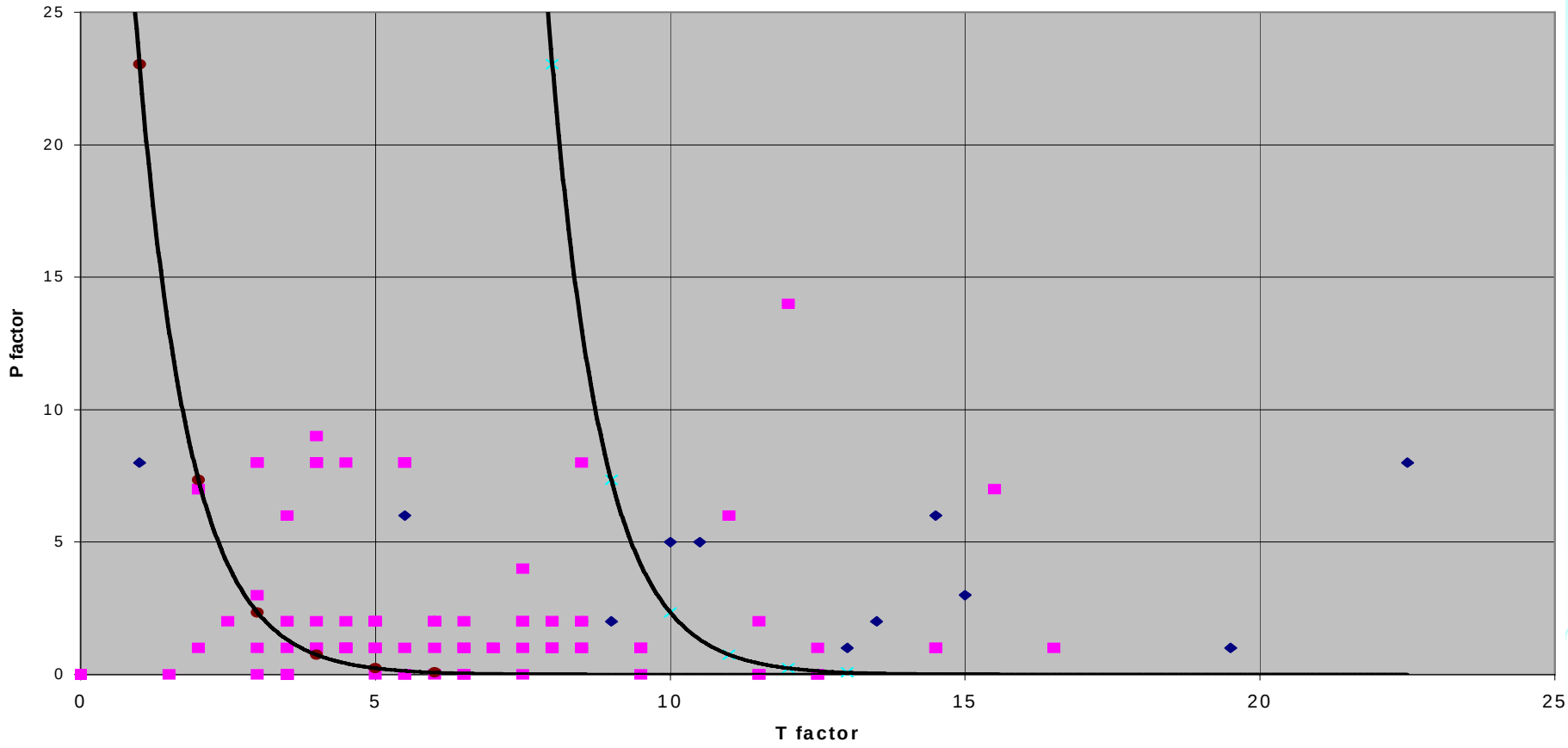
Without suitable coaching or analysis, the collection of expert input can be misleading

The system in operation

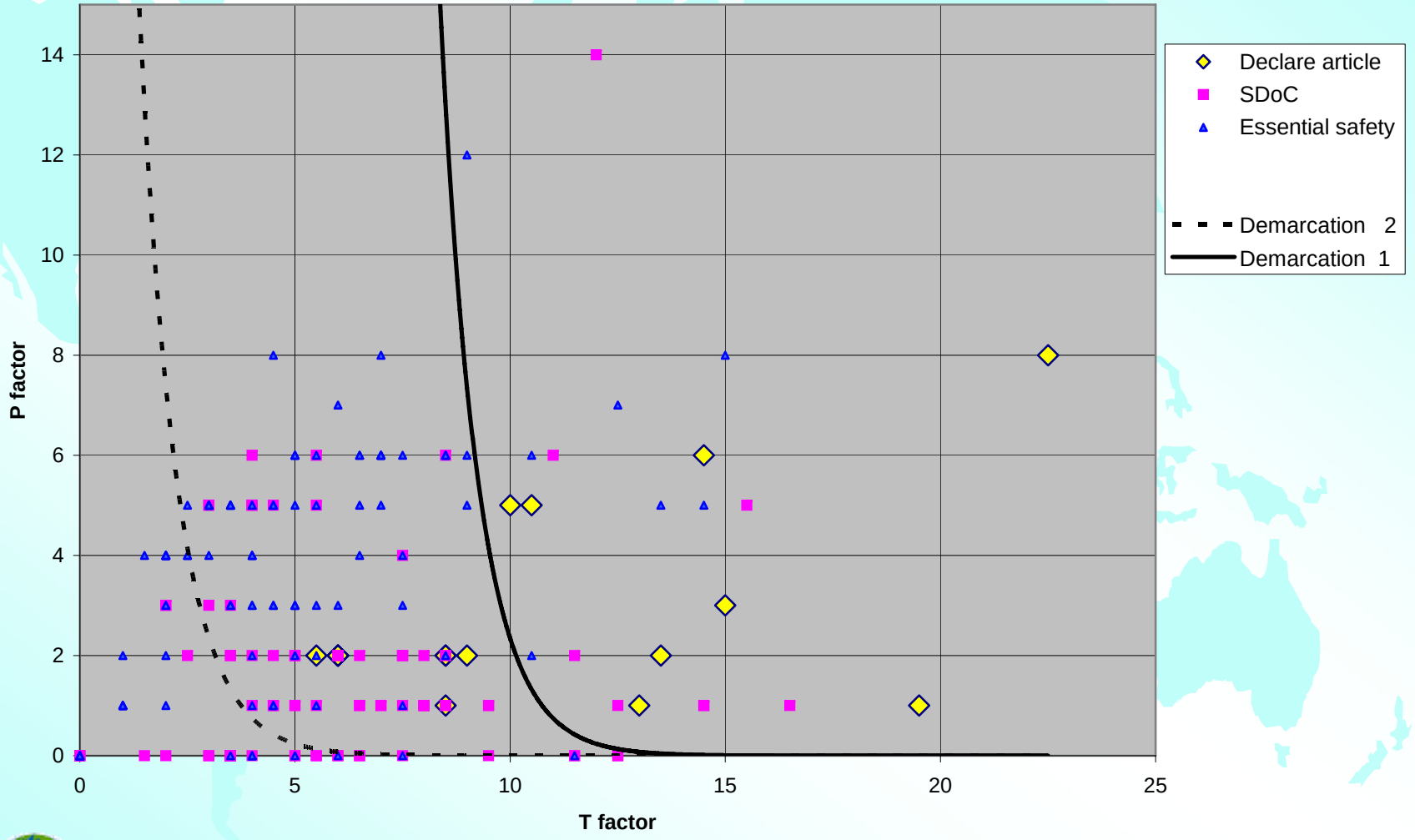
New Zealand has now adopted a graphical presentation method to display the calculation system, plotting P and T on two axis of a spatial graph

This has two advantages; in that it allows the influence of P and T to be individually seen and considered, and it also allows products with very high technical hazard levels or compliance probability factors to be considered on that factor alone

Graphical Risk Engine Output



Technical & Probability Factors
(235 electrical equipments)



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P * T

The mathematical multiplicative effect is achieved by plotting on the graph delineation curves of constant P * T

Likewise, when determining what products should be subject to control, there is a flexibility to use curves that accentuate either of the P of T factors or set base P and T levels

The factors

- Both the P and T factors are derived by considering what particular features differentiate a particular type of equipment from a typical general electrical product
- Obviously there are hazards common to all appliances, and compliance failures that occur in all manufacturing processes
- The analysis only considers those factors that are significantly different across the spectrum of equipment types, to contribute to a differentiation of one product from another

Probability

The probability that must be used in the calculation is the probability that the product will not comply with the Standard and not the probability that the product does of itself, create a hazard

In a risk management system that relies on accident and incident information, or a simple technical analysis of the product, this clarity of relationship is not adequate.

Accidents and incidents

Unless accident data is carefully analysed, products prone to misuse are likely to feature prominently

Also, when using accidents and incidents the regime tends to have a significant time lag while data builds up

Pre-market systems should be predicatively focussed – *post market systems are the only systems that can operate effectively with a time lag*

Technical Hazard analysis

When the technical hazards possessed by particular products are used alone to determine products subject to pre-market controls, products having high levels of technical hazard will dominate the system despite the pre-market system's inability to effect a change to the level of hazard

A similar situation exists for products where the applicable Standard is inadequate.

Verification

Like any Risk management system, the NZ system relies heavily on a process of verification and expert input

The verification process includes:

A comparison with the currently regulated products,

A comparison with the products identified for future controls under the old system

Expert input

Expert input is being obtained by NZ in respect of the voracity of:

The process as a whole, including a close interaction with the experts in Chinese Taipei,

The technical factors

The probability factors

The assignment of the technical and probability factors

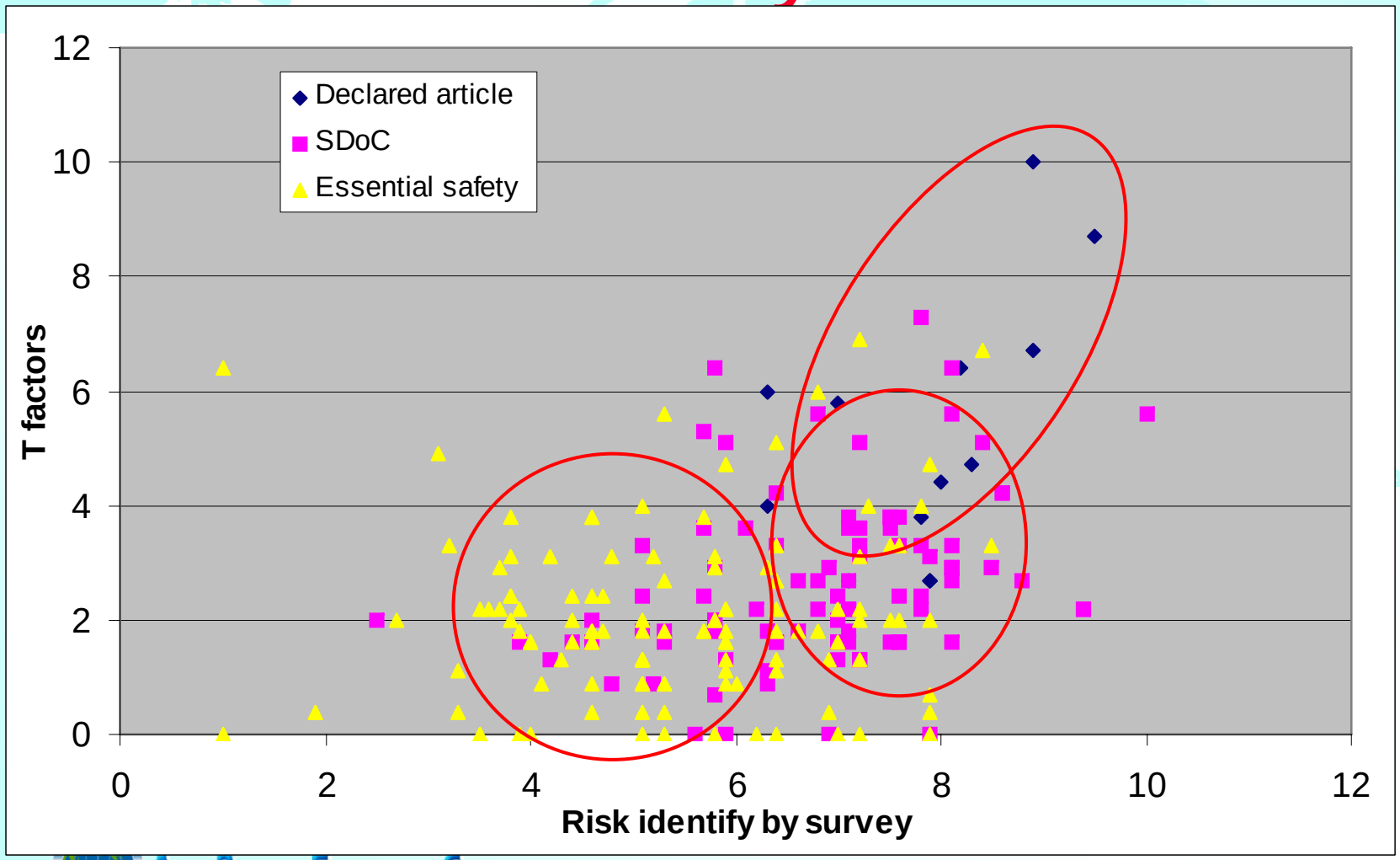
Expert input

We are also obtaining an assessment of product risk ratings (3 categories) by experts independent of the system

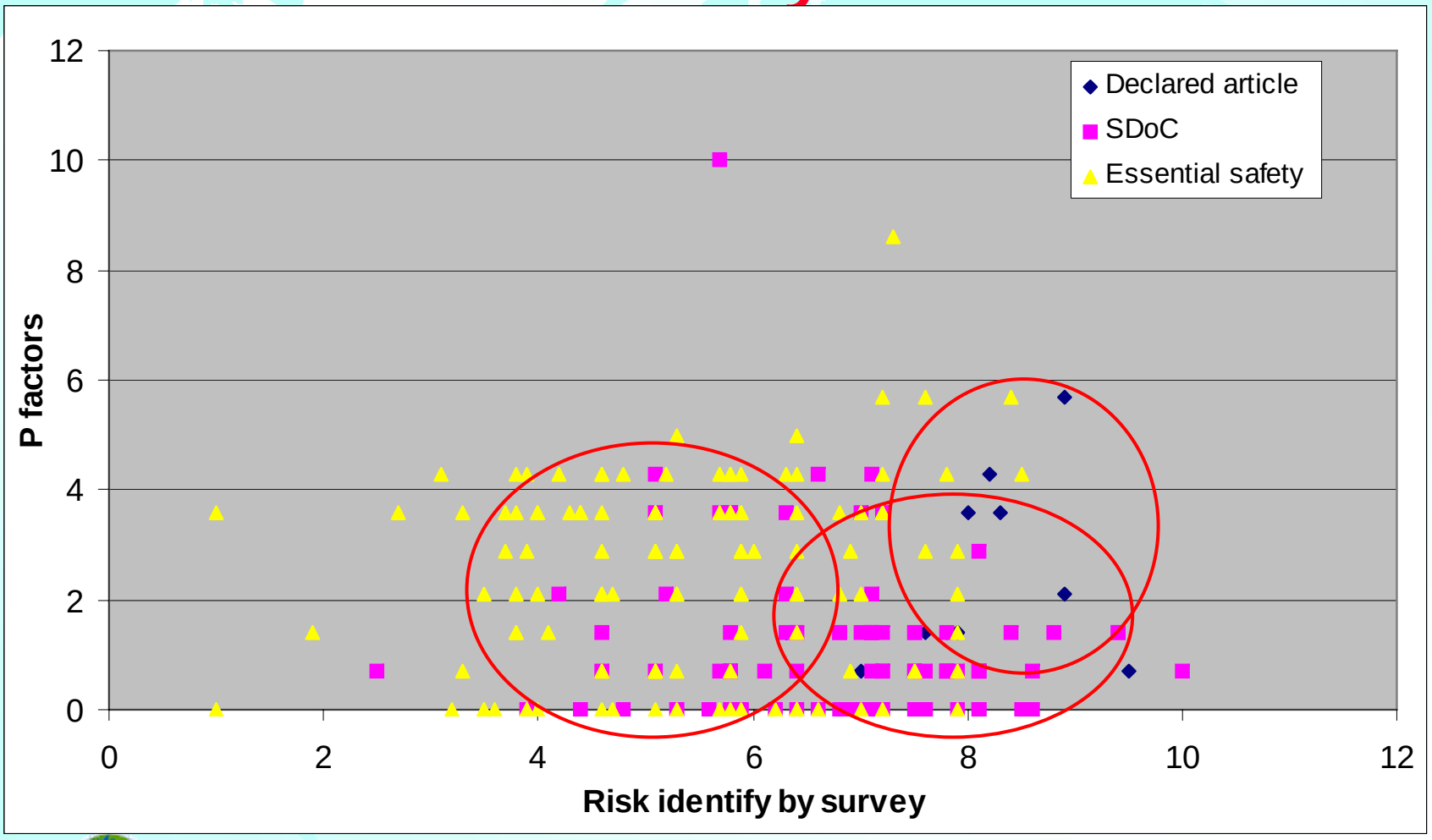
In that rating process we are requesting the factors that the experts are using to set the ratings

This will give us an independent check on the engine and an indication of how much T and incident emphasis the expert input contains

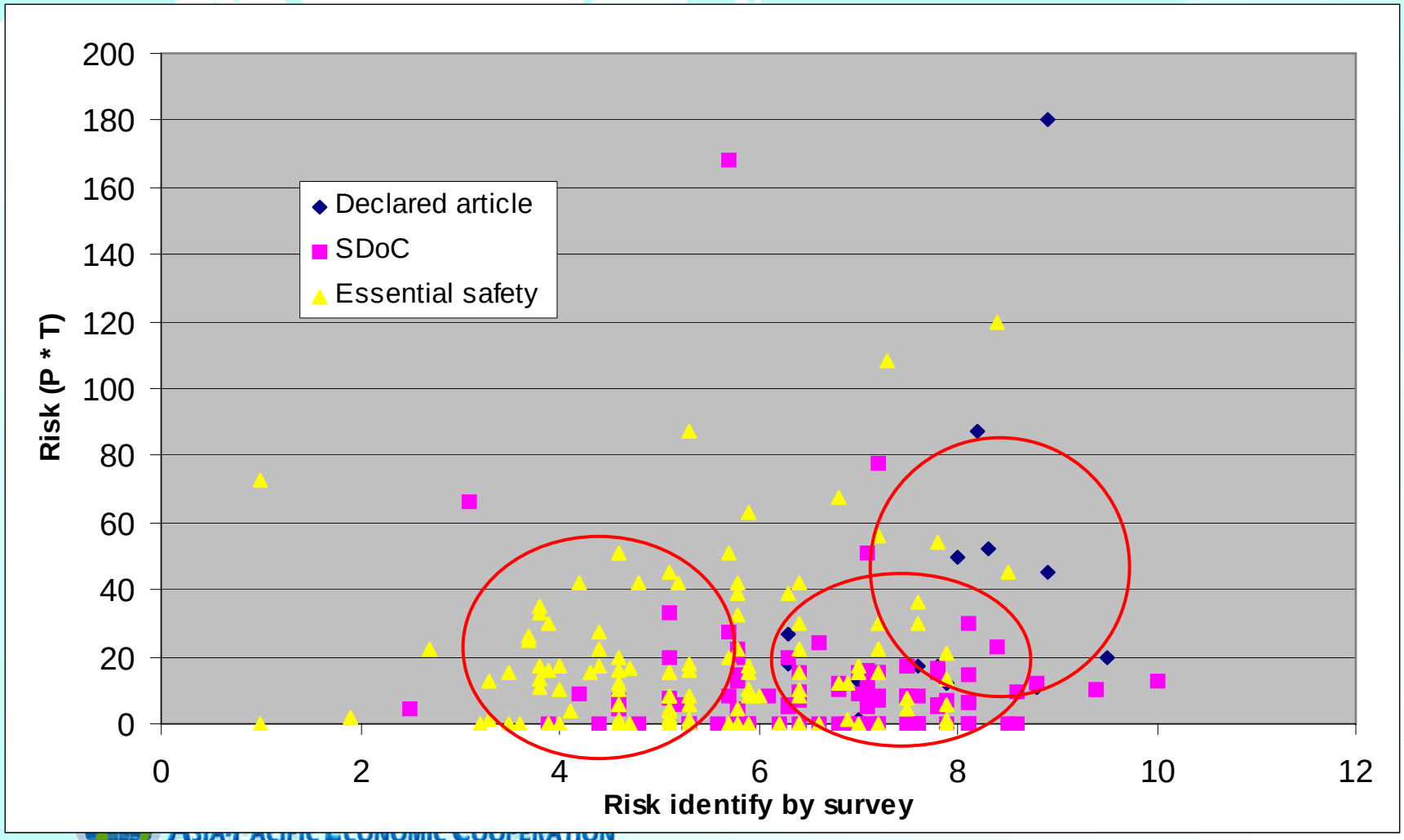
Initial analysis - T



Initial analysis - P



Initial analysis - Risk



Expected product listings

At present it is expected that the NZ declared article list (high risk) will increase from it's present level of approximately 10 to around 20-30 products and that the medium risk list will increase from approximately 40 to around 50-60 products

Recent reviews have seen 2 items added to the NZ High risk list and 5 to the Medium risk list

Another 5-7 items are being proposed to added soon

Post Market surveillance

We will also apply the system to improve the effectiveness of our post market surveillance systems

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Regulatory Co-operation Arrangements

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Co-operation

Recently international interest in MRAs has started to reduce, and some countries have focussed on Regulatory co-operation as a means to facilitate trade

To date however, no specific guidance has been provided on what such co-operation might include

Co-operation agreements

NZ therefore has identified that there is value in documenting the types of co-operative activities that could be implemented.

NZ has now included these in our approach to TBT issues in a formal manner so that we might achieve co-operation through formal agreements for co-operation as part of, or alongside traditional MRAs

Types of co-operation

The types of co-operation identified to date include:

- Exchange on information of regulatory systems
- Exchange of incident data
- Exchange of hazard alerts, product bans, & recalls
- Co-ordination of surveillance activities and exchange of product surveillance information
- Co-ordination of Standards development activities
- Exchange of product certification and approval information
- Development and implementation of enforcement co-ordination protocols
- Co-operation with Regulatory review and implementation

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Hazard Alerts

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Hazard Alerts

One of the simplest components for Regulatory Co-operation is the exchange of information on unsafe or non-complaint products – a Hazard Alert system

Europe's RAPEX system is a very effective example of such as system and is an important contributor to the success of their SDoC system for Electrical end Electronic Equipment

Hazard Alerts

- Hazard Alert systems integrate well into a risk base framework
- Their success is based on increasing the statistical probability of identifying product failures by aggregating product performance across a wider market, making trends more easily identified and by effectively sharing the monitoring burdens between a number of enforcement agencies
- Hazard alert systems also do not require Regulatory harmonisation but work best with higher levels of Standards alignment

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MRAs

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Traditional MRAs

Traditional MRAs have a framework that applies the Standards and Conformity requirements of the country of importation to products being exported to that country from the other partner (s) to the agreement

Traditional MRAs achieve mutual recognition through recognising the accreditation systems of the exporting country, usually through the application of international (ISO) guidelines.

Symmetry

Traditional MRAs (like the APEC EE MRA) are also generally symmetrical recognising testing or certification in both directions

Confidence

All MRAs are based on the establishment of one partner in the testing, certification, inspection and accreditation capacity of the other partners infrastructure and is generally strongly underpinned by the Regulatory agency, or general Government oversight of those services

Conformance Strengths

From a risk management perspective however a traditional MRA does not take full advantage of the strengths of each partner's conformance regime

It may be appropriate for an MRA to recognise the Standards, and/or conformance systems, of the exporting country as applicable for exported products

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The New Zealand – China Co-operation agreement

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The Arrangement

The NZ China co-operation agreement is NZ's latest and most advanced "Mutual Recognition Arrangement"

It is the first agreement to combine both trade facilitation and compliance enhancement features under a risk management framework as is reflected in its title.

Overview

- The TBT Chapter of NZ's FTA with China contains an agreement for co-operation on Electrical and Electronic Equipment and Components
- This agreement combines the requirements of a classical MRA with additional provisions designed to enhance the regulatory compliance of goods covered by the agreement
- The design of the agreement is based on Risk Management principles and includes aspects of inter-regulatory co-operation identified to improve compliance

Scope of the Agreement

- The agreement applies to the Safety, EMC and Harmonic emission compliance of a specified list of EEE & C
- The list was derived from the range of EEE & C that are regulated in China under the CCC system and also either a Declared Article in NZ or a product covered by NZ's Supplier Declaration of Conformity scheme (SDoC)
- This list was chosen because it represented those products where the high level of confidence in each country's S & C infrastructure needed to negotiate an agreement could be established

Structure

The MRA differs from most common forms of MRA in that:

It embodies the Equivalence principles of the WTO as far as practical, given the two participant's Regulatory infrastructures

It is not symmetrical (It does not apply the same compliance verification criteria to products traded in either direction); *It takes particular advantage of the strengths of the partners own compliance infrastructures*

It uses international Standards to address the accreditation complexities created by the different languages involved

Structure #2

It is **not** a testing or certification MRA, nor does it apply the importing country's Standards

It contains features specifically designed to support and enhance Regulatory outcomes in both countries

Like other MRAs, not only does it improve speed to market, lower compliance costs, but it also further reduces duplicate testing and accreditation requirements

Framework

The agreement was negotiated to achieve two additional outcomes:

To provide an expandable base framework for electrical and electronic equipment and components

Provide a blueprint for other types of products covered by China's CCC marking scheme

Applicable Standards.

Unlike a classical MRA that simply applies each country's Standards, the Standards have been selected to reinforce compliance

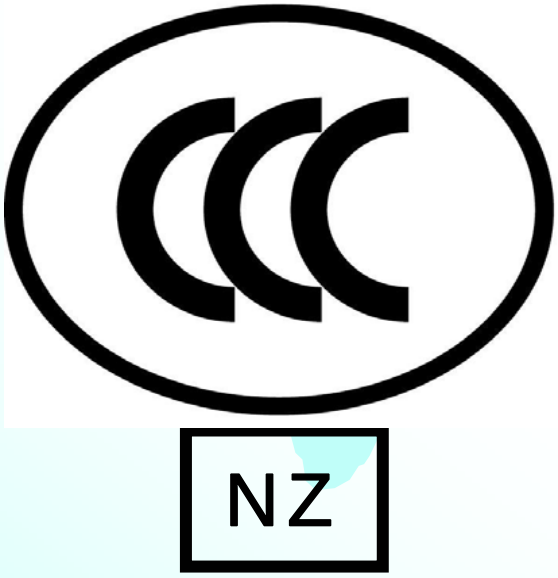
For Products destined for China, IEC Standards are applied to allow NZ's Conformance infrastructure to use existing accreditation processes and avoid language problems

For products destined for NZ, Chinese National Standards (GB Standards based on IEC Standards) are applied to benefit from the strengths of China's own accreditation system

In both cases any necessary deviations are also identified and applied.

“Equivalence”

Under the agreement, NZ recognises CCC marks that include the specified NZ variations



Risk Benefits

The Agreement is based on the principle that the most confidence in testing, certification, and accreditation systems will exist in the Standards and conformance systems that are applied in that country

This is particularly true where the local regulator is applying those Standards and conformance systems

Exchange of information

The use of local Standards also leads to mutual benefits from surveillance and other enforcement activity information interchange and co-operation, by increasing the relevance of one markets information to the other

Enforcement

To protect the agreement from misuse, and to enhance compliance, both countries have committed to carry out compliance enforcement over any of their suppliers and manufacturers who supply non complaint products through the agreement

This provision sits alongside a commitment to exchange information on recalls, prohibitions etc of products within the scope of the agreement, thereby increasing both country's marketplace knowledge

Proposed NZ Regulations

The Secretary may prohibit the manufacture, sale, or export of any fitting or electrical appliance that is marked, labelled or documented as being in compliance with the requirements of any international agreement where that appliance or fitting is not in compliance with that international agreement

A parallel offence provision is also proposed

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