

# Guidance Document for Use of APEC Product Safety Incidents Information Sharing System (APEC PSIISS)

**Sub-Committee on Standards and Conformance** 

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#### **Content**

- 1. <u>Introduction</u>
- 2. Scope
- 3. Terms and definitions
- 4. Framework and Key Considerations of APEC PSIISS
- 5. <u>Consumer Incident Reporting Module</u>
- 6. <u>Business Reporting Module</u>
- 7. Regulators' Module
- 8. Terms of Reference

## **Annexes**

#### List of Figures:

Figure 1: Relationship between Incident Report PSIISS and Product Recall

Figure 2 Incident Information Flow in the APEC PSIISS Part -1

Figure 3 Incident Information Flow in the APEC PSIISS Part – 2

Figure 4: View of Regulators Page

Figure 5 : Data Flow Chart of the APEC PSIISS

Figure 6: Online Consumer Incident Report Form

#### List of Tables:

Table 1: Types of Incidents and Description

<u>Table 2: Risk Type ad Description</u>

#### 1. Introduction

With the onset of globalization and the increasing movement of goods from one economy to another within various regions through complex supply chains, it is difficult to assess how products are used and what risks they pose to consumers in different environments, cultures, weather/climates, languages and regulatory settings. Often safety incidents go unreported until they affect the health and safety of a large population of consumers or vulnerable groups.

Many APEC economies have been affected by safety scandals leading to a loss of trade opportunities; toys, meat, seafood, milk etc. The credibility of the producers and the country of origin is tarnished and consequently, stricter measures of control are imposed by importing economies to protect its consumers, thus adding to the cost of products and affecting the movement of goods across borders.

A viable information sharing system will assist in improving safety of consumer product in the APEC region. The APEC Toy Safety Initiative 2010 coordinated by the US, also reiterated that information sharing and the harmonization of standards as key points to improve trade and cross border movement of safe consumer products.

Similar outcomes were noticed at the end of a product safety workshop organized by Australia and Malaysia in 2009. Information sharing on product safety incidents can address safety concerns with products at a very early stage and prevent large scale product recall and safety scandals. It supports the efficient movement of goods both within the APEC economies and between other regions.

A safety incidents database would also promote the harmonization of standards and technical regulations and thus contribute to the facilitation of trade liberalisation. Situations where a product is recalled due to safety issues in one member economy and is still being used or sold in other member economies, can be minimised.

An Information Sharing System would further avoid developing member economies from becoming dumping grounds for substandard products due to a lack of safety information.

Malaysia has been working towards this with many APEC economies namely Japan, Korea, Australia and the United States. The Asian Network for Consumer Participation in Standardization was first initiated by Japan and Malaysia in 2006 and 5 successful capacity building workshops for representatives of developing economies in Asia have been organized to date. The workshops focused on enhancing the balance of stakeholder participation in domestic standards development. The last workshop held in March of 2011 concluded that information sharing is the key in sustaining capacity building efforts.

Product safety incidents information sharing will create an impetus to harmonize standards, foster conformity of assessments and technical regulations allowing free movement of goods between and within economies. This form of information sharing will also help in capacity building and better understanding of consumer protection and consequently enhance consumer protection laws. By doing so consumer confidence is strengthened and businesses gain confidence in marketing their products in other regions.

Some developing APEC economies; Viet Nam and Papua New Guinea for example, have just begun implementing consumer protection laws. Still many have laws, but which are not implemented effectively or are weak due to various reasons; among them being lack of technical capacity and access to up to date information.

Regulating unsafe products without imposing barriers to trade requires these economies to assess risks associated with products sold, produced or used within their economies.

One way to do this effectively is by gathering and sharing injury, product safety incident data and product recall information. Analysis of this data provides insight on the level of risks associated with a product and help identify the relevant international safety standards and consequently develop or impose corresponding regulations (if needed).

If incident data and reports are shared among APEC economies, a more harmonised approach towards compliance with standards and laws can be utilized. This will promote freer movement of safe goods and enhance consumer protection across economies.

The sharing of information also promotes the application of best practices in regulatory implementation and management, leveraging on accreditation schemes and initiatives, mutual recognition of test results etc.

#### 2. Scope and Considerations

#### 2.1. Overall Objectives

The portal will assist in promoting shared understanding of product safety issues, increase transparency and promote better alignment of technical requirements and safety standards. This project also supports capacity-building activities, including the exchanging of views and experiences on best practices for implementing good regulatory practices.

#### 2.2. Specific Objectives

To share information among APEC developing economies about product safety incidents reported by consumers and businesses AND Measures taken by regulators (participating economies) – voluntary and mandatory:

- to identify potentially unsafe products (using reports and analysis by APEC PSIISS as one of the sources of information)
- to take measures to minimize risks to consumers due to unsafe product (type of measures determined by participating member economies)
- carry out risk assessment, determine regulatory or voluntary measures (determined by participating member economies)

#### 2.3. Scope

APEC PSIISS applies to general consumer products (regulated and unregulated) AND will exclude:

- Food
- Drugs
- · Pharmaceuticals and
- Medical Devices
- Automobiles and small crafts

(Note: In many developing economies products like toys or electrical and electronic products are not regulated or a regulatory framework may not be harmonized. Economies wishing to use the APEC PSIISS for excluded products may do so with the relevant modifications)

#### 2.4. Beneficiaries

- a) Consumer protection regulators/ authorities in developing APEC economies can look forward to enhancing their knowledge on the best available techniques and tools in gathering and sharing information on product safety incidents and recalls. They will then be able to use the tools or techniques within the context of local conditions and regulatory settings. Standards bodies and regulators will be able to harmonize and develop new standards or make existing standards mandatory based on more credible information. They can also ensure conformity assessment requirements are readily available or accessible. Ultimately this will improve the transparency of regulatory practices among economies.
- **b) Business and Industry** and members of the product supply chain will be able to enhance their understanding on best practices in product safety regulations and compliance and the availability of tools to facilitate compliance with product safety standards. Improving safety standards enables businesses in developing economies to access international market for their products.
  - The supply chain will be able to address the safety concerns at an early stage instead of recalling products which has a huge cost impact to all stakeholders.
- c) Consumers and consumer organizations will benefit from improved product safety standards which are one of the outcomes of the implementation of a product safety information sharing system. The system will be able to indicate products which pose a danger to both local consumers and consumers in importing economies. Consumer organizations may use guidance provided by safety standards to educated consumers on safe use of products.
- **d) All other organisations under APEC member economies** that are working on improving the information sharing system will be able to work to converge information sharing and leverage on each others' work in this area

#### 3. Definitions

#### 3.1. Consumer

Individual member of the general public purchasing or using property, products or services for private purposes

[source: ISO 26000:2010, definition 2.2 (MOD)]

#### 3.2. Consumer Product

Product designed and produced primarily for, but not limited to, personal use, including its components, parts, accessories, instructions and packaging.

#### 3.3. Incident

An event where the use of a consumer product or the product has caused or has the potential to cause injury, death or damage to property

#### Incidents include:

- Near Miss no injury / no damage to property
- Minor not requiring medical treatment / not requiring major repairs to / replacement in properties
- Major / Serious requiring outpatient treatment; and hospitalization/ requiring emergency services

#### 3.4. Risk

Combination of the probability of occurrence of harm and the severity of that harm.

(Source: ISO/IEC Guide 51:1999, definition 3.2)

# 3.5. Safety

Freedom from unacceptable risk.

(Source: ISO/IEC Guide 51:1999, definition 3.1.)

#### 3.6. Domestic Contact Point

single contact centre for each economy which coordinates and monitor activities between APEC PSIISS secretariat and domestic regulators.

# 3.7. Regulators / Domestic Authorities

Domestic authorities which are empowered to enforce laws or has legal missions and specific powers in the field pertaining to consumer product safety

#### APECPSISS: Database Standards (Voluntary / **Consumer Complaints** Database: Mandatory: New / -Analyse Injury / incidents Revision based on IS) -Reports Regulations Businesses who report incidents Regulate product Other sources: hospitals, CSOs Comparative Testing etc Ifregulated Market Surveillance - by product regulators - regulated products RECALLS SHARING (RAPEX/OECD) Risk assessment, determine if the product failed, analyse, test, incidents / complaints, injury reports abuse, mis-use, etc – By regulators Product Recall When products in the marketplace fail to meet safety requirements: And Corrective -In the form of standards recalls / CAs Actions (ex--Technical regulations mfg) -Voluntary standards Leading to health risks to human No Advise / response / acknowledge complainant or businesses on what to do

# 4. Framework and Key Considerations of the APEC PSIISS

Figure 1: Relationship between Incident Report PSIISS and Product Recall

Developing APEC economies and non APEC economies often face difficult situations when a product is being regulated in one economy, whilst it is not in another economy. There are also concerns when one economy recalls a consumer product due to safety issues whilst another economy does not.

Regulators need verifiable information to regulate consumer products and one source of information for the justification are records of safety incidents. Other sources may include:

- Hospital injury data
- Comparative testing
- Fire department reports and
- Death certificates (coroner / pathologist)

Based on the above information, product recall incidents and market surveillance reports from other economies, regulators may find enough justification to regulate a consumer product or otherwise.

Regulating products by imposing mandatory standards without justification, or noncompliance with good regulatory practices may become an unnecessary barrier to trade and the free flow of safe products across borders.

#### 4.1. Incident Information Flow

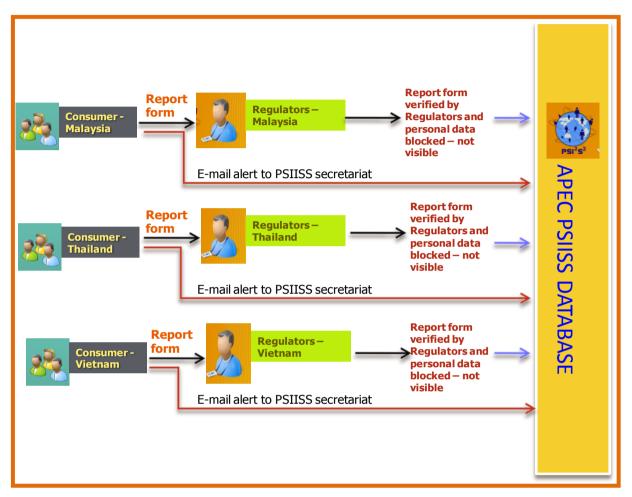


Figure 2 Incident Information Flow in the APEC PSIISS Part -1

The figure above shows the flow of the incident information, which is briefly explained as follows:

- i. Consumers submit the incident report.
- ii. An email alert will be sent to the APEC PSIISS secretariat that a new incident report has been submitted. At the same time an alert goes to the relevant regulators in the participating economy.
- iii. Regulators will log on to view the completed incident report form.
- iv. Regulators need to verify the incident report form. Failing which, the mandatory information for the APEC PSIISS will NOT be submitted to the APEC PSIISS for tabulating and sharing.
- v. Upon verification by regulators, the incident report form will be submitted to the APEC PSIISS database. The form will neither have the personal data of the incident reporter nor that of the victim/s.

- vi. Incident information will be tabulated and two reports generated:
  - a. General report for all participating economies and interested stakeholders and general public
  - b. Economy incident report compilation (only for participating economies).

NOTE: this is to address concerns that SMEs which make up 99% of all business entities may not be able to manage bad publicity for incidents which may be falsely reported.

vii. Regulators will determine actions taken on incidents depending on its nature, types of injuries caused, number of victims and its severity among others

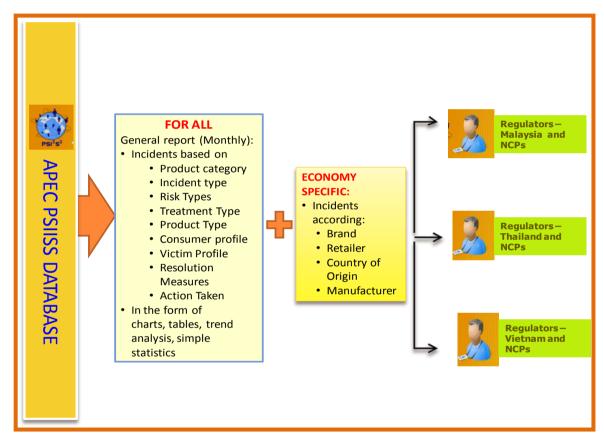


Figure 3 Incident Information Flow in the APEC PSIISS Part - 2

#### 4.2. Confidential Business Information and Personal Data / Information

To be considered confidential business information (CBI) under any relevant laws in a specific economy, data/information should generally fulfill the following criteria:

- not be publicly available;
- measures are taken that are reasonable, to ensure that it remains not publicly available; and
- the CBI has actual or potential economic value to the person or their competitors and its disclosure would result in financial loss to the businesses.

The disclosure of personal information must comply with the disclosure provisions defined in the relevant economy's regulations.

#### 4.3. Key Features of the APEC PSIISS

The APEC PSIISS will be hosted as a secure site (i.e https). It is primarily to share safety incident information. Information from the APEC PSIISS is by no means to be used for litigation and liability suits of any kind.

It is not a product recall information site thus will not share brand names. Product recall information is public information whereas safety incidents which may or may not lead to recalls are not public information.

Graphs and tables generated by the APEC PSIISS are not statistically accurate as population density, the level of exposure, etc to unsafe products will not be considered by the APEC PSIISS.

# 5. Consumer Incident Reporting Module

#### 5.1. APEC PSIISS Incident Information

#### 5.1.1. Types of incidents:

Table 1: Types of Incidents and Description

Incident Types	Description
Death	A consumer product has resulted in the death of person/s OR is suspected to have resulted in the death of person/s
Serious Injuries	A consumer product has resulted in physical injury which requires hospitalization and/or surgery. Examples of such injuries include acute poisoning, allergic reactions, unconsciousness etc.
Minor Injuries: requiring outpatient treatment	A consumer product has resulted in physical injury which requires outpatient treatment at clinics or hospitals.  Examples of such injuries include lacerations, cuts, bruises etc.
Minor Injuries: NOT requiring treatment	A consumer product has resulted in physical injury which requires some form of minor home treatment or minor first aid.
Property damage	A consumer product has resulted in damage to property
Near Misses	A consumer product with the potential to cause injury or property damage (injury or damage has not happened, but almost happened).

# 5.1.2. Risk Type [NOTE: include risk to property]

Table 2: Types of Risks and Description

Risk Type	Description
No Injury	
Amputation	removal of a limb or body part.
Bleeding	release of blood from the vascular system as a result of damage to a blood vessel
Break, Fracture	a complete or incomplete break in a bone resulting from the application of excessive force
Bruising, Scratches	discoloration and actual hemorrhage at the site of injury,
Burn	injury to tissues caused by the contact with heat, flame, chemicals, electricity, or radiation
Choking	inability to breathe because the trachea is blocked, constricted, or swollen shut
Concussion	injury to the brain, produced by a violent blow and followed by a temporary or prolonged loss of function
Cut	Self explanatory (terms are deemed obvious)
Dental Injury	fractures, avulsions, and luxations along with lip and oral mucosal lacerations, jaw fractures, TMJ cartilage injuries
Skin or Eye Irritation/Rash	inflammation of the skin / eye and itchiness
Dislocation	displacement of a bone from a joint
Drowning	suffocation and death resulting from filling of the lungs with water or other substance
Electric Shock	shock caused by electric current passing through the body
Foreign Object Stuck in / on the body	
Internal Organ Injury	
Lack of Oxygen	Self explanatory (terms are deemed
Nerve Damage	( obvious)
Object Inhaled	
Object Swallowed	
Poisoning	any substance interferes with normal body functions after it is swallowed, inhaled, injected, or absorbed
Puncture	Injury that is deeper than it is wide, produced by a narrow pointed object
Sever Bruising	Self explanatory (terms are deemed obvious)
Skin Tear, Nail Detachment	Self explanatory (terms are deemed obvious)
Strain/Sprain	an injury to a joint, with possible rupture of some of the ligaments or tendons but without dislocation or fracture
Suffocation	an interruption in breathing with oxygen deprivation, usually caused by an obstruction in the airways
Strangulation	puts external pressure on the trachea causing another form of choking

#### 5.1.3. Body Part Injured [property]

Refers to parts of the victim/s (or affected persons') body affected by the incident (or potentially affected in the case of near misses)

#### 5.1.4. Incident Location

Information on Incident location may help regulator to determine environment prior to incident and classify incident according to appropriate classification.

#### 5.1.5. Treatment [property]

- First Aid given at incident location such as a plaster, CPR, ointment application, medication etc.
- Outpatient Treatment person affected needs medical attention but is not hospitalised.
- Hospitalised person affected need to be admitted for medical treatment or observation.
- Poison Control Centre in some economies there are poison control centres and persons affected may be referred to such centres for treatment.

#### 5.1.6. Did You Make Any Changes To The Product

Person affected or person making report on behalf them may know if the product suspected to have caused the incident, was modified in some way.

#### 5.1.7. Action taken

This information would allow for the regulators to investigate the product which is suspected to have caused the safety incident, and update other PSIISS users on action taken in a specific economy.

#### 5.1.8. Economy

This is one of the mandatory fields to be filled in to ensure that the incident report is submitted to the relevant domestic contact point

#### 5.2. APEC PSIISS Product Information

#### 5.2.1. Product Type:

The list of product types is not exhaustive. It is expected that the reference to product types will be populated and a harmonized reference may be developed with other initiatives such as the OECD recall pools to ensure consistent reference across economies / jurisdictions / languages and cultures.

#### 5.2.2. Product Categories

See 5.2.1 above

#### 5.2.3. Product Pictures:

It is desirable to upload pictures of products. However the file size should be limited (e.g. not more than 2mb) in consideration of the APEC PSIISS or any similar systems' server capacity.

#### 5.2.4. Company, Producer/Manufacturer, Distributor, Importer, Retailer

It is desirable that the incident reporter provides the above information, however this is not always available. Regulators who are responding to the incident report in the participating economy may need to investigate further to gather information about the producer or importer, etc of the affected product/s.

#### 5.2.5. Incident Pictures:

It is desirable to upload pictures indicating the incident (i.e type of injury etc). However the file size should be limited (eg not more than 2mb) in consideration of the APEC PSIISS or any similar systems' server capacity.

#### 5.2.6. Country of Origin

Again it is desirable that incident reporter provides the above information, but this is not always available. Regulators who are responding to the incident report in the participating economy may need to investigate further to gather information.

#### 5.2.7. Expiry Date

The above is applicable for products with a shelf life such as some household chemicals: organic solvents, natural air fresheners etc.

#### 5.3. APEC PSIISS Reporter Information

- 5.3.1. Surname
- 5.3.2. Given Name

#### 5.3.3. Contact Number

The above information is pertinent to the economy and its designated regulators. In many economies with best practices on privacy / personal data sharing, names and contact details are not allowed to be shared across borders without prior consent from (in this case) incident reporter. The PSIISS is designed not to share the personal information of a reporter within the system. The system is designed to extract only mandatory fields related to the incident and the product.

Specific procedures to protect personal data will be administered by the participating economy and its relevant regulators and domestic contact points.

5.3.4. Person Affected By The Incident: (Please Stated The Others Victims if more Than 1) - If More than 5 Please Stated How Many Affected

The above is required by the APEC PSIISS to generate useful reports and information sharing among participating economies.

#### 5.3.5. Relationship With Person Affected

The above information is required to assist in ensuring that incident reports are not filed to sabotage a competitor's brands or products. This information can also assist in developing effective consumer education programmes to promote incident reporting among consumers.

# 6. Business Reporting Module

In many developed economies, businesses are required by law to report product safety incidents as soon as they become aware of it or them. Economies like the United States of America and Japan have laws which include a time limit by which reports should be notified to regulators.

Incidents reports by businesses or others are regarded as helpful in serving as an early warning system for the detection of health or safety issues with the purpose of reducing the number of unsafe or potentially unsafe consumer products in their respective markets.

The inputs required for business reporting incidents are similar to consumer reporting module with the addition of the following.

Businesses are required to register with the APEC PSIISS to obtain approval, followed by username and ID to be able to use the business incident reporting system. The approval process may take 5 working days as confirmation or verification from relevant regulators MAYBE required.

#### 6.1.SKU

Stock Keeping Unit or SKU is a number or string of alpha and numeric characters that uniquely identify a product. Also referred to as are part numbers, product numbers, or product identifiers (such as UPC or GTIN). Regulators may need to know the SKUs from retailers / distributors (for example) in case of a product recall.

#### 6.2. HS Code

The HS code which is developed by the World Customs Organisation (WCO) is a tariff nomenclature and is an internationally standardized system of names and numbers for classifying traded products.

#### 6.3. Applicable Safety Specification

This refers to the relevant standards or specifications which a product must or should comply with to ensure that the product is safe or pose minimum risk to consumers. Example ISO 8124-3:2010 - Safety of toys -- Part 3: Migration of certain elements or MS 1-1 Protective Helmets and Visors for Vehicle Users — Specification Part 1- Protective Helmets

#### 7. Regulators' Module

Regulators are able to sort incident information according to the relevant fields they feel are necessary and conduct analysis as required to inform product safety policies, revise standards, develop new standards or for market surveillance activities.

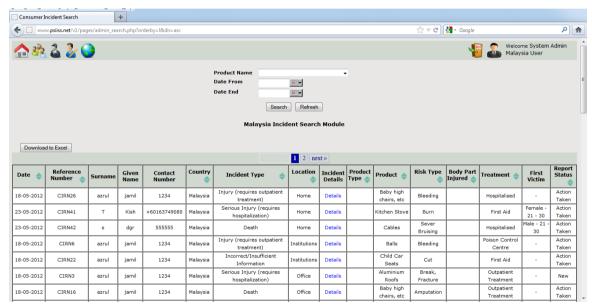


Figure 4: View of Regulators Page

#### 7.1. Storage of PSIISS data

Complete PSIISS incident report form will be stored in the relevant regulators local database.

PSIISS incident report minus personal information will be stored in the APEC PSIISS database storage.

#### 8. Terms of Reference

The following terms of reference is to facilitate implementation of the APEC PSIISS during its full run and for the purpose of guiding operational arrangement between participating economies and APEC PSIISS Secretariat.

#### 8.1. Role of APEC PSIISS Secretariat

The APEC PSIISS secretariat who is also the project overseer (PO) will manage the PSIISS portal. The following are the roles of the APEC PSIISS Secretariat:

- i. Develop and maintain the portal
- ii. Manage security aspects of the portal
- iii. Manage access to the portal
- iv. Develop, facilitate use, revise and update guidance document (in consultation with participating economy) on the use of the portal
- v. Report progress to APEC SCSC
- vi. Provide analysis of incidents and prepare monthly report for participating economies and APEC secretariat
- vii. Prepare and publish weekly summary of incident notifications
- viii. Provide technical advice to PSIISS users namely regulators and Domestic Contact Points
- ix. Update information in the portal on regular basis
- x. The cost of translating the PSIISS to the relevant language of the participating economies will be borne by PO/APEC PSIISS secretariat **BUT ONLY** during the project period and a maximum of two other languages than English language.
- xi. Regulators with local security system and infrastructure for the PSIISS shall ensure proper functioning of the system and infrastructure. APEC PSIISS secretariat will not bear any responsibilities for loss of data for such systems.

#### 8.2. Role of Domestic Contact Points

- i. Domestic contact points are generally APEC SCSC contact points who will be point of contact for enquiries and information to manage PSIISS at local level (respective participating economies)
- ii. Domestic Contact Points (NCP) will update the regulators in the participating economies on updates in the APEC PSIISS (other than incident alerts such as reports, news, capacity building opportunities etc).
- iii. NCP and regulators interested to establish local level management of PSIISS shall bear the cost of establishing local level security and infrastructure support for the PSIISS. Cost to modify the PSIISS to suit local conditions and regulatory system shall be borne by the relevant economy/ies.

- iv. Cost of having the PSIISS made available in native languages of the participating economies will be borne by the participating economy after the project period November 2012.
- v. NCPs will facilitate proper functioning of the PSIISS as intended by ensuring regulators respond to incident reports promptly especially in verifying incident report.

Note: If regulators do not verify the incident report PSIISS portal will not be able to include the incident report for analysis. However, PSIISS will be able to record number of reports made via an e-mail alert to the PO.

# 8.3. Role of Regulators

- i. Relevant regulators to verify incident reports received.
- ii. Relevant regulators should respond to action taken in relation to the reported incidents
- iii. Relevant regulators may (depending on the economy regulations) choose to contact the incident reporter if necessary
- iv. Relevant regulators may choose to analyse their respective economy's incident reports or obtain the reports from the PSIISS secretariat on a predetermined frequency.
- v. Regulators with local security system and infrastructure for the PSIISS shall ensure proper functioning of the infrastructure. APEC PSIISS secretariat **will not bear** any responsibilities for loss of data for such systems or any cost implications thereof.
- vi. In the event that relevant regulators' web or IT administrator need to consult in person with the APEC PSIISS secretariat, cost of travel to the economy will be borne by the regulators or domestic contact point of the particular economy which ever applicable.
- vii. Regulators may (depending on the economy regulations) choose to apply relevant risk assessment tools to assess risk of the products involved in an incident report.
- viii. Relevant regulators will report discrepancies related to the functioning of the PSIISS portal to PSIISS secretariat the soonest possible for prompt action by the secretariat.

#### **ANNEX**

# A - 1 APEC PSIISS Data / Flow Chart

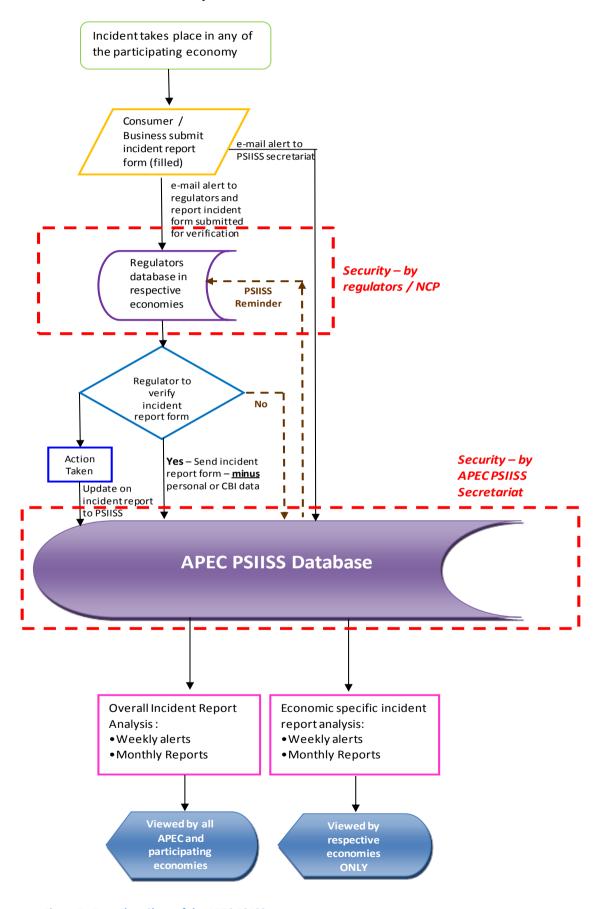
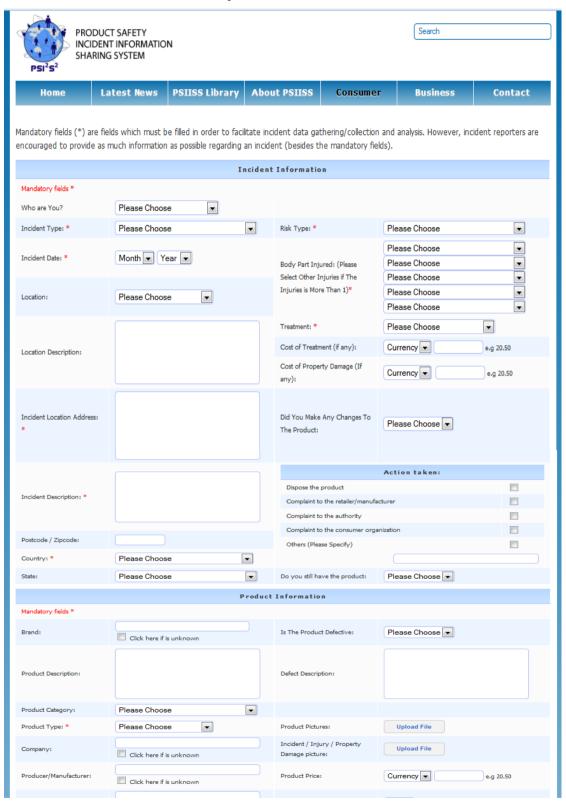


Figure 5: Data Flow Chart of the APEC PSIISS

#### A - 2 Consumer Incident Report Form



**Figure 6: Online Consumer Incident Report Form** 

APEC Project: CTI 36 2011A (SCSC)

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