

ICPHSO International Symposium
Tokyo, Japan
Day 2 Summary
November 15, 2017

Welcome

Yukihiro Noda – Keynote – Director of Consumer Safety Division

I will give an overview of initiatives related to product life cycle, the theme of this symposium.

The Japanese CAA is affiliated with cabinet office, responsibility to prevent harm in daily lives and ensure consumer safety. Other Ministries implement measures to avoid harm and ensure safety for consumers.

The chart on the slides shows the relationship between CAA and its partners. Incident information comes to the CAA from various partners (consumers, local consumer affairs and ministries, and businesses). Incident information is reported in line with the Consumer Safety Act.

The CAA is the hub of incident information.

CAA, after analysing information and disclosing the result, can request further information to prevent occurrence of (further) incidents. Ministries and agencies have rights to implement measures. They only exercise these rights on decision, not request. Sometimes other ministries may not have other legal rights to implement the measures. If the company doesn't follow recommendation measure, then they can issue an order.

Flow of accident information: information that comes in is registered in an accident information databank and available to the public. There are also incidents related to services or facilities.

The databank is open to the public through the CAA website. It gives a concise description about the accident and injury etc. Potential accidents that may occur and product recall information also. Keyword search function is available. It is only in Japanese and is not translated into other languages such as English.

Sometimes information about something that may lead to an accident, there is product recall information. Manufacturer / supplier > consumers – flow of information. Sometimes comes from Ministries or Agencies that have rights to order a recall. Most recalls carried out in Japan are not ordered by ministries or agencies but are initiated by manufacturers or suppliers themselves.

Critical ones are disseminated to consumers by email and tweeting, and also to the OCED global recall website.

As of end of October of this year, 220,000 pieces of accident information are registered in the databank. Some pieces are double counted and therefore there are no stats for a comprehensive overview of the entire set of data.

Administrative agencies, in accordance with consumer safety act, provides the information. In 5 years, on average 1000 fire accidents, 100 falling accidents.

Soft actions other than enforcement:

- Communicate with consumers
- Propose safe products
- Develop safety measures through collaboration.

Protect Kids from Accidents project:

- Aim to reduce unforeseen accidents, not small % of cause of death in children from 0 to 14.
- Handbook
- Accidents are highly ranked as cause of death.
- Conspicuous and frequent patterns. Some can be prevented by parents if safety tips shared with parents.
 - Issue press release
 - Emails / Twitter
 - Benefit is providing information directly, retweets etc.
 - Publish and distribute Handbook for prevention of child accidents.
 - Explains frequent accidents and shows pictures for accident / rescue measure. This is available for download.
- Other ministries and agencies are providing information about this topic. Each body has a channel to communicate the information they need to provide.
 - Messages sometimes disseminated to industry organisations. Tweets are retweeted by other ministries and agencies. This means more opportunity to access information.
- People can access more information at a glance.
 - E.g. just by following tweets.

Propose safer products for consumers:

- E.g. Information on products that are safer, or have specific functionality for care or safety (e.g. toothbrush with stopper)
- Recall information on recall summary site

Collaboration with related industries

- Request suppliers to improve products from safety perspective
- Request industry associations to share accident information with affiliated members
- Promote soft and diverse approaches

Some activities overlap with ICPHSO.

Pinuccia Contino – Keynote – European Commission

Here to make sure that bad things don't happen. Accidents do happen – there is an important community of people who are there to make sure consumers are safe. It will never be said enough how important it is to do this work.

A lot of work and activity goes into trying to prevent accidents. It's not just a question of watching over the market – need to go out and talk to people, anticipate new risks, defend importance of this field in relation to other interests, including within our own institutions.

Safety is a challenge every day.

Resources tend to decrease. Bosses think it's time to put energy elsewhere, and so we must continue to advocate for what is needed to step up product safety in all sectors.

It's harder when things are sold online as there is no physical contact. The commission published a notice in July – important that it is on the radar.

Upcoming challenges are important to highlight why we need product safety to be a focus.

Imagine daily routine in the context of connected devices: the IOT is going to make our life more interesting but also more difficult.

- Imagine waking up in the morning. Connected device alarm clock – will ask coffee machine to start preparing your coffee in half an hour.

- First you go for a short run, your sportswear will measure your blood pressure and pulse, whether you are better or worse.
- Meanwhile, child goes to school. Driverless car, checking your tablet whether the smart watch is telling you that your child is going to school in the normal route. It also says that there is medication going to your elderly patients.
- What if alarm gives strange instruction to coffee machine? 100 not 1 cups – glitch. Maybe kitchen catches fire.
- Whilst running, it starts raining and sportswear interprets the message strangely.
- Driverless car, cloudy day – can't distinguish truck on the street from the sky. Even if you escape an accident, maybe the child's smartwatch is hacked at the same time and could get lost or taken. It also gives your parents an increased amount of medication.

2013: only 1.8 million connected devices around the world. 2020: expected 6bn connected devices.

- What is a product? Are we sure we know what it is? EU legislative framework – defined as “tangible” product. So what is an app? If not a product, what is it? In the IOT story above, most of the problems came from apps. Do we need to develop or interpret the existing framework?
- Liability: who is going to be responsible for what is happening? Who has to pay? We all prefer to avoid the problems, but who will be liable? System like that for cars? New system? AI robots have no personality so cannot take responsibility?
- Do we need a new concept of product safety? Heard Australia bring this up.

Don't have the answers today. One hint: link between cyber security and product safety. Once it is connected, the product can be hacked. First thought is that hack = personal data is at risk, there is potentially a criminal responsibility there. Product safety consequences when there is a cybersecurity breach.

Need more resources and efforts – these show we need to keep working on this. There are also other factors to take into account. Sharing economy, more collaborative society, product flows. All of this changes how products are put on the market, re-put on the market etc.

Challenge is to keep up with technology, keep consumer trust, we want consumers to get what they want and to be happy and safe with that. Continue creating new products. Should not let the most vulnerable consumers down. There are many categories of vulnerable people who are becoming more important – e.g. elderly, not just children.

This is not to scare us, we don't have all the answers but this is a “passionating challenge”. European Union is going to do new deal for consumers. EU has highest politically responsible people are taking these issues seriously, showing to the world.

New deal for consumers will be new sets of initiatives, regulations, enforcement activities and projects and so on. Consumer legislation is currently being reviewed – is it still fit for purpose? Another important point – need better enforcement for consumer protection. Not just IOT challenges, lots of other familiar ones (online sales, vulnerable consumer). Need to work better with national enforcement authorities. This is very ambitious – can't do it alone.

Anticipating future risks.

Upcoming – first quarter of 2018. IOT focussed.

New or enhancing projects to help all stakeholders to become even stronger, more effective and to work better together. E.g. projects to try and help authorities to use big data in order to identify potential dangerous products. Promoting other projects like teaching, bringing together right expertise, how to conduct investigations online.

Stepping up consumer awareness. There can be no empowerment without trust. Consumers can take us for granted, because they don't tend to see the negative effects / the accidents.

Join forces, champion product safety together in an open, inclusive and collaborative way.

Advanced Planning with New Technologies, Protection (Security and Safety) when Conceiving your IOT Device – David Kosnoff, Gail Greatorex, Rick Brenner, Stephen Brown

David Kosnoff

IOT, quality and safety – can't ignore the news. Giant Equifax data breach, 143 million people could be affected. Yahoo (2013) all three billion accounts affected. Cayla, connected doll, recalled in Germany last year.

WHICH: consumer advocate group – UK – warning today (15 November) about connected toys.

Risks are not isolated. UL report

- 70% of IOT devices are vulnerable to attack
- By 2018, 66% of networks will have experienced an IOT breach

In quality world, talk about how all failure modes will be discovered (but question is when and by whom?); in cybersecurity world, talk about how all vulnerabilities will be discovered (but when and by whom?)

Failure Mode and Effects Analysis, Design for x (safety, failure, automation, assembly etc).

Do FMEA early on. Do DFX early on. Train employees on quality and highlight it at every aspect of new product development. Why would this be different in context of cyber security?

Difference between quality and cybersecurity – most products don't have people actively attempting to sabotage, except in cybersecurity world.

There is a lot that's out there. Standards for network / system related security and also for products – can be learned from.

When products are submitted for testing, can go after known threats and known vulnerabilities. There is a lot below the surface. The best FMEA is only as good as the experience of people in the room.

UL 2900 series.

Gartner forecasts 50bn connected devices by 2020.

Smart fish tank left casino vulnerable to hackers. Connected fish tanks, hackers from Finland could access network of the casino and play around with the data for two weeks before discovery.

You're only as strong as your weakest link, and if your weakest link is that you are connected to a network.....

Manufacturing standpoint: potential issues to consider. Not just the physical but the coding.

- Physical
 - Programming chips on the line, if it isn't air gapped, could be infected by malware, and then infected by a virus.
 - Programming errors exposing a backdoor
 - Purchased component with malware embedded

Post launch support:

- Security updates: can you push them out, do they need USB connection, passive / active approach (pull vs push)
- Software vs firmware
- Porting software to new OS versions
- Regulatory agency interactions and notifications
- Plan in event of security breach

Gail Greatorex

“Data is the new electricity”

Can they still make the product safe? New hazard mechanisms and new cohort of designers.

Democratisation of product / software design and development: using software in consumer products.

Fast moving ecosystem – standards won't necessarily pick up. Collaboration needed.

Whole new framework of thinking. Is it a product or a service? What is the definition of a product and product safety in this context?

Security and inter-operability can impact safety.

Silent change? Software controller making unknown change to manufacturer or even consumer?

Benefits to IOT that we should be alert to: consumer messaging and warnings, monitoring the way you're using it and tell you how you are using it wrong.

Interesting data will be collected, may be used for goods. Government or academics could get access to it to get more informed about how people are using the products. Message from locked car if there was a child in the seat for example.

Government agencies need to work with a new cohort of other agencies and lawmakers, designers, consumers, associations, producers, academics.

New skills needed in government due to new hazards. The product life cycle also changes.

Need to look at all the ways IOT devices can act, react and apply some of the same learnings.

Product safety laws need to be preventative not just reactive. To deter people from selling unsafe products. E.g. post sale duty to patch vulnerable software.

IOT has two unique aspects in terms of product safety: global in its nature, unique opportunity to get it right before it really takes off.

Stephen Brown

How to solve some of the problems?

Networking and consumer electronics.

- TV, security systems, streaming devices
- Fridges, washers, vacuums
- Thermostats
- Bulbs, security lighting

Items all subject to any attacks that might occur. What's the process to mitigate risks?

Should be testing almost every day. When adding more feature sets to an item, retest, retest, retest.

Further down the line you go, the more expensive it comes. How do you do this quickly enough – rush to get to market. Testing, patch management etc.

Third party testing is better – you test for what you know you're good at.

- Security controls testing, penetration testing (when, how etc. can it break), vulnerability identification, communications robustness (where might there be a problem and what does that mean for safety?)

If you only test at a components level, you haven't really tested the product.

Questions

- Children's products space and information is very regulated. We are all part of a vulnerable population when discussing connected devices. Need people at the table with a broad set of backgrounds. Post market, should patch them for updates whether legally mandated or not. But for how long? There should be a sunset clause.
- What responsibility does the consumer have for their own behaviour and how do you help that along by providing them with information. How open is the product when first purchased and how likely that other products will be connected to it – need to take responsibility.
- Prohibitively expensive?
- Who is liable? If you become aware of an issue: obligation to remedy. Can you be responsible for all of the downstream effects? Probably would stifle innovation. But moral, if not legal, obligation to remedy?
- Who picks up cost of education of consumer, who ensures the consistency of that? Collaborative approach needed. Would like to see better use of e.g. YouTube, on how to use a product correctly etc.
- Retailer responsibility to do DD on products they sell either in store or online?
- What if it was perfectly safe when you launched, but then 6 months later a new way to hack for example, comes about? If it is widely known, do what is possible to fix. If you become aware by internal means, fix and potentially notify.
- Is mandatory regulation needed? DH says voluntary is faster and usually effective. Challenge is that it is not required, and so if the products can be introduced that don't comply then that's that.

Breakout Session 4: Techniques for Improving Safety in the product life cycle: David Wroth, Don Huber, Rakesh Vazirani

Rakesh Vazirani

RAPEX form gives information about the risks in the markets. OECD looked at non-compliance rates. How many are still on the market even if banned or recalled. How many don't meet safety standards (88% noncompliance cross border).

What techniques can be used to enhance safety in the "use phases".

Trends: increasing product complexity, multiple legacy systems to integrate, globally dispersed development teams and diverse supply chain / contractor network.

David Wroth

Why do we have products that look like they are for children, but actually are for adults? Why have products with unclear audiences? Innovation means we need product differentiation and this comes in

many different ways. It's one thing, but make it look like something else. We also have a need for nostalgia in some cultures – look back on childhood with fondness.

3D printer – unique hazards. The one on the slide is an open case, no enclosure around heated elements and by having that as an open case, one of the characteristics is that any ultra-fine particles or chemicals are released into the atmosphere. Post processing steps are also very important. Usually plate at the bottom needs to be separated – sharp tool used to do this, cuts to the hand.

Rapid movement of technology from industrial to consumer setting. First mover advantage here. The need to keep cost of product low has limited the number of safety features available on some of the products in the market place.

Techniques to mitigate?

- Early phases of life cycle – ensure we understand regulatory requirements for products around the world.
- Don't just look at standards and regulations in the market where you intend to sell, but take a broader view
 - Look at most stringent, and create your own rules based on those.
 - Can subscribe to a number of bodies / standards
- Understand human factors associated with the product design. Understand the intended user and what the reasonable person is going to look at.
- Ensure congruence between design, functionality and marketing. Understand underlying attractiveness of the products that might be marketed to adults.
- Hazard based safety engineering. We can mitigate, and even eliminate, hazards in the design cycle. If we can't mitigate – go to idea of educating.

Furniture and furniture tip over:

- 300,000 emergency department visits in US, since 2000 more than 500 fatalities.
- This is a significant hazard that needs to be addressed.
- Reasons
 - New dynamics in product designs
 - Large flat screen TVs
 - Changing demographics
 - Size of children – heavier and larger in the US. Some of the ideas of how to protect children go back to anthropologic data that may now be out of date.

Lithium ion battery

- Pushing the limit
- Trying to make smaller and trying to make them power more.

Natural language processing

- Can get deeper understanding of incidents with products than we had before.

Machine learning algorithm

Takeaways

- Traditional product design methods remain the same
- Data science is an important and emerging tool in improving product design
 - Infusing data from multiple sources – means that we can put the pieces together

Don Huber

Share additional techniques that can be used. It may be appropriate to employ or deploy a product integrity process. It's a framework that can be used to cover all necessary areas to ensure product safety: compliance, safety and quality and sustainability.

Compliance requirements:

- Manufacturers license to place a product on the market. When there isn't regulation for a type of product, there is usually a voluntary or industry standard. Retail customer requirements, e.g. Walmart. Company policy on compliance to protect the brand. Consumer expectations – understand and account for these. Set your standard above the requirements – you have breathing space.

Product safety:

- Just because it complies; that doesn't mean it is safe. Other issues need to be taken into account.
- Design hazard reviews – start early in the process, and repeat. Identify and remove potential hazards.
- Risk assessment – extension of hazard analysis. Assess likelihood and severity. It's quantifiable.
- Human factors analysis – how will it be used, will it be used correctly or incorrectly.
- End of life safety – testing regime that does product life testing, when finished with that product life testing and assessing the product there should be no product safety hazards involved.

Product Quality

- Quality management system, supply chain risk management, product parts and traceability, process control and inspections, complaints management.

Sustainability:

- Once you understand your product, once you have identified an issue, work on that.
- Compliance with global regulations and institutional expectations. Mismanagement can mean safety risk.
- Environmental and social code of conduct. Enforce corporate social responsibility code of conduct.
- End of life disposal / recycling – choose product packaging etc. that are sustainable and recyclable.
- Green chemistry – choose materials and substances that are aligned with Green Chemistry guidelines.

Are you lagging, developing, performing, or leading? It's a curve of whether your risk management strategy is reactive / proactive. Save money by investing in sound product integrity programme.

Hope we won't be talking about traditional hazards in the future, things that are preventable and foreseeable. Expect we will be talking about continuing discussion of cybersecurity and IOT, convergence of issues around these new technologies.

Natural language processing is a general topic that includes sentiment analysis (social media) and other machine learning techniques that include things like bag of word processing. Concept is the same but applying to a new data set.

Marathon with a lot of sprints (/ "surges").

Breakout Session 5: Beyond Written Warnings: New and Engaging Methods for Effective User Instructions in Virtual Reality: Matthew Dickman, Matt Howsare, Nancy Cowles

Matt Howsare – Mintz Levin

- Warnings – present, visible and understandable. Serve a purpose and can be effective in certain circumstances
- Traditional format of warnings: words signalling caution and pictograms
- Is there an overload of written warnings currently?
- IoT presents challenges and opportunities for warnings
 - Challenges: new risks
 - Opportunities: novel ways to warn
- Potentially interact in different ways, suitable based on novel technology

Matt Dickman – Oculus

- Informing consumers with warnings.
- Products: 3 and 6 degrees freedom with VR sets is the difference between models, one model in collaboration with Sony.
- Where do we warn? In VR full wrap around view, in product, on packaging.
- Areas for development to consider:
 - On-box: traditional warning leveraged but use consumer, use “read all safety warnings”
 - In software.
 - On the website – also referenced elsewhere.
 - Animated warnings (e.g. airline safety videos).
- The goal is to provide necessary info to change user’s behaviour
 - Where the warnings where consumer can find them.
 - Users know when to use.
 - Choice of content.

Nancy Cowles – Kids in Danger

- Warnings are to change behaviour to keep someone safe.
- Over warned products not read by consumers.
- Some warnings needed to drive purchasing decision (e.g. infant choking) – needs to be on packaging.
- Usage patterns has engaged as has use of warnings.
- Don’t look at warnings for familiar products – because think we know how to use it.
- Video instructions of how to use.
 - E.g. warning on problems
- Apps on screen.
- Warnings for connected products.

Q: Point of sale warranty (on packaging) online sales where don’t see on sites before sale?

- Nancy: Online sale supposed to reflect on-package warnings.
- Matt D: Need to make it more obvious (some platforms have different sections).

Q: Use of imagery in warnings to get aesthetic with packaging – novel symbols that require knowledge

- Matt D: Problem with localisation for video.
- Nancy: Important but need to invest to get good symbols.
- Matt H: If want to get it right need to get focus group.

Q: Non-manufacturer videos made where instructions/warnings inadequate

- Matt H: Liability always where insufficient warnings. Took issues with consumer videos and do your own. Can’t compel others to take down own video.
- Nancy: Need to keep an eye out about what is out there about products

Takashi Tatsumi – Keynote – NITE

NITE has been participating in ICPHSO since 2005. Why did it take such a long time?

- Insufficient awareness of ICPHSO in Japan
- Shortage of effort to spread ICPHSO
- This is an epoch-making event for product safety in Japan

1928: Export Silk Fabrics Inspection Institute, direct ancestor of NITE, was established.

2001 (April) – NITE was established. NITE has changed a lot in its long history.

Background of foundation of NITE. Serious accidents from June and July 2000.

- Poisoning of milk by major food company
- Concealment of accidents and defects information to avoid recall by leading automobile company
- 2004 – boy died in a revolving door
- 2005: fatal accidents from CO poisoning from oil fan heaters

NITE was ordered by METI to investigate the deaths from the oil fan heaters.

2007: Consumer Products Safety Act

Slide on serious accident report and notification system.

Change in number of accidents shown by data collected by NITE. In 2007, NITE collected 7298 pieces of information – 60% increase since the previous year. Important as this is the year that the law was brought in. After 2007, the number of reports stayed high compared to previous years. As a result of the increase, many staff members from NITE were transferred to the product safety division.

NITE expanded product safety activities, including analysing accident information to detect the trend of accidents and to use the results to prevent future product accidents. Until then, consumers were thought to be the problem of faults. People thought the best way to prevent accidents would be to call consumer's attention to how to use products, and no other way. This is not the case.

2003: 40% of accidents caused by human error, 32% by design, production deterioration, installation, 23% by unknown cause, 4% for reasons not attributable to the product.

Effort to decrease accidents due to human error:

- Problems common to products that led consumers to make mistakes
- Human error accidents could be effectively prevented by a slight improvement on products
- Handbook for Prevention of Accidents Arising from Improper Use or Human Error"

Expanded also by establishing Office of Accident Risk Information Analysis, additionally – international cooperation.

In 2005, when Japan first participated in ICPHSO, the concept of "safety" was different – Japanese wanted no damage at all, often misunderstood. Not so effective.

NITE made efforts to spread risk assessments in the product safety field. How do we assess risk? Defined "safety, hazard, risk and risk assessment". Three ways: essential safety design, protective devices, provision of information to consumers.

2000-2013: share of imported product accidents increased, now almost 50%. NITE realised that efforts were needed to cooperate internationally. Domestic efforts are not the solution.

NITE appointed staff to be in charge of international affairs in order to collect overseas information. Agreements with e.g. CPSC, CAIQ.

NITE hold a press conference every month to provide information about particular products at a particular time. In 2016, taken up 167 times via TV, 155 times in newspapers, 39 times in magazines.

Recent accident trends in Japan

- Fires associated with lithium ion batteries
- Silent change

Product accident forecasting system – two systems (i) manufacturers and (ii) distribution companies. May publish a system next year.

NITE outlook:

- What new can NITE do for product safety?
- What can NITE contribute for AI, IOT?
- Sharing information both domestically and overseas is very important
- NITE will try to make a significant contribution towards ICPHSO's activities.

Plenary Session 9: International Regulators Panel: Our Decisions as Products of Process

Feature of ICPHSO now. Four jurisdictions represented.

Geoff Barrett – Health Canada

Fortunate to have a vehicle / venue like ICPHSO. Can engage with counterparts and discussion with industry stakeholders. Use ICPHSO at Health Canada to share and describe.

Consumer Product Safety Programme

- Risk assessment group
- Risk management group
- Regional offices that are often the points of contact

Risk assessment framework: how do we go about this? Risk based approach – look at hazard characteristics, exposure, and likelihood, to then frame the character of the risk. Triage or screening first, then more rigorous risk assessments.

Decision making process: engagement with international counterparts, seeing continued non-compliance, information pushed through mandatory incident reports and other assessment activity (including information with companies coming to say we are seeing these results...). This informs what tool is used – there is a suite of pools. Average of 300 recalls a year, 90%+ are probably voluntary. All actions tend to entail outreach and education.

Instrument Choice Process: risk assessment process is upfront, rare circumstances where action is needed quickly, over 15 product committees, cross section of staff.

Any related hazards or products? Toolbox is not only filled with big regulatory mallets. Only 33 regulations in Canada to deal with consumer product safety issues. Most options are voluntary, or engagement with other departments or government.

Many decisions rely on an explicit process. Critical that they are transparent as possible about what that process looks like. May not like the decision, but critically important that you understand how it's been arrived at.

George Borlase – CPSC

Agree with all comments from Health Canada.

Regulators are risk managers – that's their role in consumer product safety.

Pace of innovation as mentioned in my presentation yesterday.

CPSC Risk Management Process is available online. Mandatory regulations are just one tool to manage risk.

Feedback – begins and ends with data collection. Comparing risk to acceptability criteria? Whose criteria? Societies. It is for the consumer and society – what is the amount of risk they are willing to take.

Goldilocks = not too much, not too little. The solution is difficult to find.

There comes a time where it is no longer a technical decision, but a policy and political decision.

The last step of evaluating the results is the most difficult – assessing the effect of any actions taken. Is it enough, does more need to be done? Comes back to data.

Need to maintain public trust and need data. Interconnected element of the job. Don't want to add chemicals that decrease cancer risk whilst reducing fire risk.

Not just hazards that are interconnected.

Regulators work is never done.

Pinuccia Contino – European Commission

How to eat an elephant piece by piece.

- EU in the centre and then the current member states around the sides.
- Product safety at EU level is based on four fundamental principles. Strict rules. Protect, flourish, level playing field
 - Only safe products can be placed on the markets – future proof principles (devil is in the detail)
 - Enforcement action taken if this is not the case.
 - When dangerous products are detected.
 - Commission / member states
 - Legislation and tools.
 - EU institutions collectively initiate and adopt regulations and directives
 - One about market surveillance
 - Then around 50 directives
 - 25% of existing products – GPSD – safety net
 - Delegated to co-regulation process, safety standards agreed by industry, consumers – give a presumption of safety when published on official journal of EU.
 - Harmonised product legislation
 - Sector by sector
 - Safety requirements are already included.
 - If there's a problem, enforcement actors are in the Member States. National authorities do the assessment, management etc. of risk. They test. They investigate etc.
 - Globally they act with same goal and to ensure the same thing.
 - RAPEX
 - Dangerous non-food products

- Whenever an MS takes a measure against a product, they send a notification, then share with all other MS so they can also do what is necessary in respect of the product, then they publish it on the webpage so all actors are informed.
- Without this, the single market wouldn't exist from product safety point of view.
- RAPEX system, enshrined in GPSD, makes single market a reality.
- Once a year – March – RAPEX annual report (stats and results).
 - Important to draw attention to the work.

Mr Wada - METI

Risk assessment against accidents in consumer products.

METI oversees. CAA is newly established.

NITE corrects 200 cases a year and does individual investigations on each.

Globalisation trends. Newly emerging issues due to supply chains expanding all over the globe.

Different surveillance, skipped inspections required by clients, even faking data. That corrupts the trust in capability in government authorities. Accident reporting systems may contribute to the raised awareness of product safety issues. If non-serious accidents are reported, then recalls may be requested.

Some years ago, a risk assessment handbook was created and published.

Health Canada – often have to provide an explanation for softer responses. E.g. why haven't you conducted a full recall? Acknowledge that it is a shared responsibility, regulatory approach isn't always the best approach. Also consumer has important role to play. What happens when request comes politically (not just from media or consumers)? What is the process in that case? This is the value of having a clear and defined process. Companies also work with both regulators. Consistency also happens in the delivery.

CPSC – looking at societal acceptance of risk. Spike of outrage is a blind spot of what we thought people would expect and what they actually do.

EC – alignment of the way MS works, role of commission is more the role of a facilitator and/or catalyst. Don't have kind of responsibilities that MS authorities have, but have the privileged position of being able to see discrepancies of e.g. interpretations of risks, or upcoming challenges etc. goal is to be proactive. Lots of resources (2.5m euros per year) in doing joint market surveillance with MS – can identify product categories etc. or other horizontal issues.

CPSC – specific outreach. Working with a company, created a set of 10 exercises for kids that teach them about consumer product safety and they get a certificate / safety star.

METI – meetings with e.g. education ministry to discuss accidents with children.

EC – awareness raising campaign for online selling, particularly targets parents. Another project in the pipeline "Safe House" – raise awareness of consumers of dangers in the house. Also important to cooperate with consumer organisations.

Health Canada – information sharing has always come from a bilateral standpoint. That has been the work around to now, versus much more substantial changes to privacy / protection of information. This is a challenge from a legislative and legal standpoint. Common terminology and definitions is also a problem. Tremendous amount of resource. Are we defining hazards in the same way?

EC – in EU, common data database (like the one in the US and Japan). Costs a lot for all 28 MS, don't have the resources for it. Data always hits the wall on resources.

Plenary Session 10: Risk Tolerance in Perspective: Measuring and Assessing Risk in Societies

Junichi Ikeda

Frame as broadly as possible: issues for consideration:

1. What is the mechanism of risk perception and what factors may affect this mechanism
 - a. This may affect the risk assessment
 - b. Lots of new products e.g. drones and 3d printers – we react in the same way to risks from new and familiar products
2. Risk communication in product safety regime
 - a. Question is what information should be communicated in order to secure better safety?
 - i. Systems are provided for in almost all legal system to communicate risks to the public. E.g. labelling requirements, manufacturer / importer reporting obligation to the authority.
 - ii. No product that is absolutely free from risk – what matters is whether the product is free from risk that is not acceptable or tolerable.
3. What aspect of tolerable risk may vary depending on societies and what aspects are consistent or the same amongst all societies?

David Ropeik – International consultant and author

The definition of risk: the chance that something bad might happen. This isn't what it means to you as a person. This is why the definition matters.

The chance of a risk can be measured and understood. This is the first half of the definition. The second part is that something bad happens – that depends on how you feel. This is world about feelings, not facts – bad depends. People don't look at risk the same way regulators do.

Chance (probability) can be factually studied and minimised. Bad is a feeling. Riskiness is about emotions. A sure way to fail in a conversation about risk is to say "here are the facts, stupid, calm down".... This misses the point. Any information that suggests, even as politely as it is offered, here are the facts as you know them – now make a decision – that ignores their feelings. It is risk communication that ignores their feelings.

We think we are smarter than we are. The brain makes quick judgments to keep us alive.

Studies can explain how the brain works when it comes to danger: the subconscious does this. The brain is wired to sense danger and send out a fight or flight response. Then rationality. Brain is hard wired to think first and think second. It uses many tricks to do this.

Reason and rationality are conscious.

Nancy Cowles – Kids in Danger

Some things appear to be risky and yet people can use it safely and decide their own risk level and tolerance.

Cultural differences in risk:

- Some perceptions or risk are the same no matter where we are
- Cultural norms may affect risk perception
- Social structure may affect risk taking – can you afford to get injured?

- Might explain why manufacturers and companies may not see the risk than an individual consumer may see – this is why it's important to get lots of viewpoints.

Kids in Danger – about giving tools to parents.

1 in 200 children who slept in the cot died. That level of risks in planes would not be accepted.

Consumers aren't engineers, can't see hidden risks.

How do consumers assess risk – visual review, past use, media and peers, instructions and warnings?

How should companies assess product risk?

- Real world use vs intended use
- What are the environmental factors and developmental stages of the user that might impact use of the product
- Risk patterns of similar products
- Observation

Ken Yoshida – UL – senior human factors specialist

Usability & risk

- Usability: characteristic of the user interface that facilitates use and thereby establishes effectiveness, efficiency, and user satisfaction in the intended use environment
- Products that have poor usability might be difficult to use and error prone resulting in poor user experience
- A poor user experience can lead to perception of risk

A good user interface is a must – goal = safe, effective, usable and satisfying device

- Anything the user interacts with (packaging, controls, manual etc.)

A safe and effective device relies on high quality user interaction.

Who is to blame?

- Common belief: user misused device in spite of manufacturers warning
- Reality: manufacturer acknowledged the risk by issuing a warning but failed to alter the design.

Anticipate user errors. It is natural for people to make mistakes. Use errors are often linked to user interface design shortcomings. Mitigate risks associated with errors through good user interface design.

Usability engineering, like risk management, is iterative.

Iterative process improves product usability > reduces the likelihood of use-errors > improves user experience > reduces the perception of risk > can improve product safety.

Questions

1. DR: information alone has very little impact on how we use the product. We want the product to do something for us. It's there because lawyers say.
2. Risks imposed on us make us more concerned.
3. If we can understand why people behave the way they do, we can predict when they will and won't be afraid. Giving people a sense of control means they will take more risk.
4. In four states where hands free driving only was brought in, the number of accidents increase.
 - a. People want the benefit of the risk in some cases.
 - b. We can predict how they will behave and then predict the risk.

Furniture instability: dressers that didn't tip over. Latent hazards that parents are generally not aware of. Doesn't make sense to them that a tall, stable, piece of furniture would tip under the weight of a small child. Should anchor them. Those that met the standard went far above it. But some furniture tipped at under 20 pounds (8 or 9 month old baby). It doesn't make sense with what they know and therefore doesn't make sense to consumers. We are more worried about risks that could happen to us, than other people.