International Symposium Summary
Tokyo, Japan
Day 1 – Breakout Sessions
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Breakout Session 1: chemical management – a strategic approach to product safety in the product life cycle.

Anne Bonhoff

Broad overview: raw material > design / manufacturing > distribution > consumption > end of life > recycling.

When you come to end of life and you say this is the material for the next life cycle. Are those materials safe, especially from a chemical perspective? Recycling is the critical point where we don't know what comes as new material into the new cycle.

Legislation to avoid toxic chemicals coming into the circular economy. REACH does this, and REACH like legislation exists elsewhere too.

Green chemistry: 12 principles – utilisation of a set of principles. What is important for consumers and for product liability? The design phase and to reduce toxicity of the chemicals that could be used in the products. Start at the beginning, know what the toxicity is, link this to the molecular structure – consider the risk reduction by design of the safe chemicals.

When we know from modern techniques that the chemical should have safer properties, go into selective testing. When you look at computation and toxicology – heard about big data already. Need to have big data set and analyse it computationally.

Structure + biological activity based on big data. One great outcome of REACH is how much big data is available – chemicals that need to be registered have biological research behind them. Can predict toxicity of chemicals?

Raymond Lui TUV SUD

It is all about a plan to check in the cycle. Coming about testing up the stream of the supply chain. Trying to address the problem at origin. Are we going to test all chemical parameters, or some kind of risk assessment? Is it possible to do a quantitative, not qualitative risk assessment?

When we talk about testing along the supply chain, it's not just about the raw material or chemicals.

With all the considerations, there are specific goals. Correct implementation of chemical management system. Test in line with that. Now when we form testing, we submit test samples but is this really the way to ensure safety to end consumers? The answer may not be yes.

Need to get a quality process and IT systems to allow monitoring, smart and sensible testing, and KPIs for suppliers. Big data is essential for allowing this – quantitative risk assessments.

What is chemical management?

- Establish quality system
    - Purchasing policy, inventory system, qualified personnel, availability and understanding of MSDS, knowledge of chemical segregation / separation, chemical storage and on site

management, training in chemical management in general, PPE implementation and maintenance, documents about permits and verification on its valid date.

- Implementation of quality system
- Periodic audit for gap implementation and analysis
- Offering of healing plans to close any gap

Chemical Data Management (CDMS): store MSDS RSL and TDS of chemicals with risk assessments, precautionary actions and phase out plans. Also compile testing stats.

CDMS is an intelligent database.

Taka Matsuo – Amazon Japan

Case study to comply with amended Japanese household product legislation. JP approach to Azo Colorants.

- Declaration system
- Additional action – White List
    - Developed by study groups in China and Japan.

2016 – New law to add azo dyes as controlled substances. Promote harmonisation with relevant regulations in other countries. Most big data manufacturers have same difficulties to be compliant due to insufficient testing. Hard to control documents regularly for so many products. How can they find out, additionally to certificates?

Japan Textile Federation – developed guidelines recommending standards to eliminate harmful substances as much as possible.

Need cooperation to adopt declaration system. All stakeholder approach needed.

Current options: comprehensive non-use declaration sheet or other confirmation documents.
Lots of beneficial results from non-use declaration sheet. Can consolidate paper work. Can keep manufacturing sites as confidential information.

White list: easy management of countable dyeing factories. Target groups.

More than 15 bodies have worked on the scheme. Most important point is whether we can trust the listed countries or not? Factory audit by accredited bodies.

Summary: continuous collaboration between authorities, industry bodies and companies has resulted in simple consistent method. Adoption of international standards for analysis helps to comply with newly developed regulatory rules.

Jay Kim – Kim and Chang

Korea is very chemical phobic. Chemical sanitisers. Serious social controversy – provoked changes in the regulatory system and how people approach consumer product safety. It was only sold in Korea, developed in Korea.

Korean government stepped in. The product was in full compliance at the time. Manufacturers also used the chemicals on their perceived low toxicity. They weren't classified as toxic. There were no studies of their inhalational toxicity.

There were some gaps in the system that allowed the type of product to be sold without testing.

Overly legalistic approach can be problematic on its own. Company did a recall, tried to address the issue. When you have a government finding that is hard to overcome. This means that it activates a review of the issue in the normal sense, but also in unexpected areas e.g. criminal charges.

Aftermath of this problem was how many regulators became involved.

Concluding

- Powerful voice to NGOs and consumers
- Have to comply with all regulations, but this alone may be insufficient.
- More regulatory changes that will create a more stringent system going forward.
- Korea never previously have cumulative damages, but it now does in product liability cases.
- Korean courts have been issuing guidelines to award more damages in these kinds of cases (corporate malfeasance)
- If there is an issue where there is significant issue / harm, overly defensive legalistic approach is too simplistic. Going forward, need proactive not just defensive approach.

Breakout Session 2: product safety standards in Asia

Keith Yung – STC Group - China

- There is a Chinese system in place – national (technical requirements), industrial (coded by name of industry), local (where no industrial standards applicable) or enterprise standards applicable for each product
- There are certain rules and regulations to which the product has to conform.
- National standard will apply to everywhere in China.
- Once the product complies with standards, then there's product certifications that must be required (certification and accreditation administration; ministry of industry and information technology, ASIQ, CQC, certification centre of light industry council).
- Voluntarily certification scheme certification mark.
- After standards and certification also market surveillance (national, province and city authorities), customs etc.
- China compulsory certification – specific products required specific marking (might be related to safety.
- CCC marking can be used for various purposes, including safety – certification body, factory audit, approved CCC testing laboratory.
- Preparation for CCC.
- CCC turnaround times – review of application, acknowledgment of CCC application, type testing, report review and final approval – takes between 1-2 weeks in total.

Brian Oh – Kim and Chang - Korea

- Three main acts:
    - Safety management act and electrical industrial products
    - Framework of product safety
    - Special act on safety of children's products
- Relevant enforcement agencies
    - MOTIE (central agency)
    - KATS (delegated power to KATS)
    - KPSA (performs safety investigations)
- Three systems in safety management act – 1 of 3 processes apply based on harm
    - Safety certification
    - Safety assurance
    - Supplier's assurance of conformity
- Electro-magnetic
- Labelling requirements

- Market monitoring systems by KATS – collects information from various sources, conducts safety inspections, takes administrative actions
- There is a recall process – but there are appellate functions that are never really used
- KPSA – conducts investigations together with KAPS, criminally punishable as high as three years of imprisonment, less than 30,000. Never seen anyone go to jail

Oki Mori NO&T / Tsuneo Matsumoto – NCAC - Japan

- Consumer product safety inspection period.
- Long-term use consumer product safety indications system – aware of risk caused by ageing products.

Breakout Session 3: Standards Development

Martyn Allen – Technical Director (Head Electrotechnical Division), Electrical Safety First
Jeremy Opperer – Senior Manager, Exponent Inc
Jennifer Bohaty-Yelle – Global Product Safety, Compliance (Toysrus)
Toshiuki Kajiya – Compliance, Panasonic Corporation *(via audio translation)*

MA: Standards are invariably out of date; they can take years to develop and a long time to update. They are for the masses and not for the innovators. Neither of these factors should negate their purpose, however.

During the time it takes to promulgate standards, how do we ensure that products are nonetheless safe?

It is notable that many products appear on the market, without any standards applying – including many new technology products.

Unsafe products are not good for business, brand image or consumers.

In the absence of an applicable standard, what obligations are there on producers and suppliers? Are they the same?

JB-Y: Producers and suppliers should share responsibility for products, in absence of a standard. When new product presents itself – there should be a partnership between QA and compliance functions to make sure the right questions are being asked. These economic operators should share responsibility that the products are safe to sell; they must be prepared to answer questions about what due diligence was done.

JO: Irrespective of precise legislation (or indeed existence of any legislation), there is an obligation to put safe products on market. This is heightened in certain jurisdictions (US) owing to litigation hazard. BUT, safety must be addressed, even if there is still some scope as to the identification of potential hazards.

Standards are a way to assess hazards.

What can manufacturers do to satisfy they are compliant in absence of standard?

TK: (translation). In Panasonic, we have launched thousands of products in the past 100 years. Over this time, we have collated lots of market incident data and built a mechanism which enables us still to bring innovative products to market.

More than 50 years ago, a Panasonic gas appliance product caused a fatal accident – a death attributable to gas toxicity. This was the first severe accident at Panasonic. Until then, design of products had simply been in line with public safety standards. However, Panasonic learnt in that accident that these standards had not prevented the fatal accident and so the decision was taken to start the process of developing Panasonic Corporation Safety Standards – an in-house safety framework. This is common to all Panasonic products – whether truly innovative or not.

We analyse a huge number of events and incidents in developing these in-house standards.

Traditional public safety standards will ordinarily triangulate between the uses of product; scope of product; and time and length to derive an appropriate standard.

Panasonic Safety Standards go wider – incorporating foreseeable and unforeseeable risks; based upon known issues and past accidents.

In a new development, Panasonic deploys risk assessments.

By way of example, take a service robot used for nursing care. There is presently an ISO standard for robot, but no ISO standard for nursing care and certainly no standard for robots for nursing care. ISO standards therefore cannot be applied. Therefore we performed a risk assessment and came up with an in-house robotic standard. Panasonic's standard has subsequently become the entry standard for international service standard.

JBY: good example in recent years = hover board. Real challenge to make sure you are on right side of the line and performing to a higher standard than any emerging public standard. All stakeholders have a vested interest in a successful deployment.

JO: If no existing standard, but expertise to create internal standards, you can work to your advantage as the first mover.

Sometimes an existing standard that does not go far enough is harder to work with – example given of a toy where a 2 year old could exceed the torque.

To the extent there are gaps in any standard, these represent organisational risks.

<u>Role of Test Labs in getting to market</u>

JO: background at Intertek, now Exponent. Intertek: follow standards where possible. Develop in-house procedures with the business.

JBY: for retailer, if presented with new product and no standard – partner with the labs before launch to minimise risk and understand and which products are related.

TK: Panasonic has in-house labs dedicated to testing. Deep knowledge about safety. Equivalent to external lab tests.

JO: From experience, many instances of accredited labs in private business. Draw from widest experience – even if you would not normally find in that particular labs.

<u>What should you do whilst risk assessment work being carried out?</u>

JBY – look for test reports and standards used to rely on testing. Safety and risks assessment. Be prepared to turn over your own risk assessments.

JO: former client would have a test: could you "Press ready" within 2 hours? Expect that the press would be there in a short time span and understand what the high-level, technical response on the genesis of product is. Different for each company, but collate high level information so you have a response.

TK: In various places, I have seen seminars regarding compliance – especially SMEs - on how to be ready to respond. Not a black and white question.

MA – all about market surveillance and effective communication.

Enforcement: use standard as a check list; if fails, then a conversation to be had. If no standard, what do the enforcement authorities do?

Audience response from Jan Deconinck, Advisor General Consumer Safety at FOD Economie / SPF Economie / FPS Economy

Product without prior issue – carry out a risk analysis to see if safe enough. This will be a different assessment to that of the manufacturer. We look to prove in one case that a product is not safe; rather than saying safe in all these cases. Manufacturer must show that it is safe.

Could use standards from other countries.

QUESTIONS FROM FLOOR:

(Gail Greatorex) MSDS - Material Safety Data Sheet – how does this compare to a due diligence safety assessment?

JBY - Part of the same pack but MSDS has more specificity. MSDS part of the technical file. No higher status than any other. This is from a retailer operator's perspective where no higher priority is given to MSDS.

(Jan Deconinck) To JO: you mentioned the deficient standard for toys – and that a 2 year old could exceed the torque set out in standard. What do you do with the information about such deficiency?

JO – where we have found that standards have not gone far enough to capture enough safety, we work with the brands to take that information forward. Many gaps we find are raised.

(Jan) noted that EU has safeguard clause – national authorities can raise a matter, if they suspect insufficient coverage or not fit for purpose. We will then take up with the standard authorities.

Perspective from Innovative Product Manufacturers – Safety Journey in Product Lifecycle

Pelagio Payumo – Oculus

Even with VR – use what's already out there, don't reinvent product safety process or testing.

If you don't need it in your design, don't include it. E.g. LED lights
If you don't need it to be sharp, don't make it be sharp.
If it can short, it will short.
If it can break, it will break (glass isn't the only thing that breaks)
Software bugs can and will happen
Material and parts selection matters – to the environment, users and product end of life.
If it is a new, untested, uncertified material – it needs to get tested and validated.

Step 2: implement independent protections. Design them into your product, looks like it is part of the product but really it is protecting the consumer. E.g. foam and insulations. Visual cues can be used to give on screen warnings.
If you are providing a functionality to help with the safety or functioning of your product, make sure you identify that issue and notify the consumer.

Third and last level of controlling hazards – warning and instruction manuals. On product warnings, manuals with dos and don'ts, additional ways to show warnings e.g. in set up (agree / acknowledge) or first use.

Escalation is important – what does safety escalation look like. Consumer gives report of issue – where does it go? Verification process – cross-functional between legal, CS and product safety, quality and user research.

Anthea Davies – Hogan Lovells

The thing with consumer products is that they don't last forever. Important to plan for this.

Two scenarios: Planned end of life and unplanned.

- Pre-market issues – think about design and development, start talking about "the end"
- On-market – it's in the hands of consumers, it encompasses repair or after-sales service.
- Planned end – planned obsolescence, defined number of uses, advances in technology.

Natural and foreseeable vs. intervening event that cuts life of the product short.

What to think about?

- How long do you intend product to last?
    - What are you intending to charge?
- Useful life?
    - How do you ensure safety beyond intended design life? Consumers won't just stop.
    - Should there be indicators on a product for how long it should last.
- Product failure?
    - Safety glass fails in a way that doesn't result in huge shards of glass. Designed to fail in a safe way.
- Repair?
- Disposal, destruction, reuse?

European Parliament: 4 July 2017 – resolution on longer lifetime for products. See IPLR article. Aimed at encouraging product longevity. Three key factors

- Upgradeability of products
    - Modular designs or software updates?
- Durability
    - Minimum criteria?
- Reparability
    - Availability of spare parts?
    - Non-proprietary repairs?

Unexpected end:

- Design fault, manufacturing fault, unintended or unforeseeable use etc.
- Prompts question about safety….. Recall?

Innovation = new risks AND new opportunities (push notifications, automatic updates, social media). Technology can be used to help.

Keep an eye out for this – it is a hot topic. Innovative technology is a shield and a sword.

Jeremy Opperer Exponent

A hazard might be something that injures brand too. Hazard doesn't equal risk. Risk is about the probability of the hazard causing a risk. Risk management for innovative products requires identifying the hazards that people could be exposed to, and then designing them out.

Innovative products:

- LED Lightbulb: bug zapper capability. This was recalled because the LED lightbulb component could detach and expose hazardous electrical components. The issue that resulted in the recall was something that was understood – common.

- The wheel: mechanics in a wheel for – could be added to an e-bike. There was a mechanical problem with the hub that meant it could fall off. Again, risk and hazard here is something that is well understood.

- E-cigarette: lithium ion technology – familiar issues.

Even when developing new products, can look to familiar hazards and risks. When looking to bring new products to markets, look to see what other information is out there.

Key points:
- Review historical data
- Look at sub-components
- Who is the consumer
- Identify potential hazards
- Gather data
- Remember risk equation

Questions
- Impact of putting an unsafe product on the market (intentionally or not) – for the first product placed on the market
    - PP – for VR, there was an attempt in the 1990s. When Oculus was launched, one is stigma of previous versions of VR, and the other is the stigma of VR itself. Cost aspect – got to be high quality if it's expensive.
    - Media coverage means it is on the mind of regulators.
    - Start-up – if it goes well, great, they can get bought out, and if not – oh well, out of the game anyway. They didn't have a brand to protect, they just wanted to move quickly. If it is an established company, then it's different. Innovation is often in start-ups.
    - Setting expectations in marketing materials.

Closing remarks

- Leadership of Japan and role of Japan within product safety. Right that we should start with a keynote speech from Wada – data and trends in Japan and for the Japanese regulatory.