Improving Risk Management with Digital Transformation

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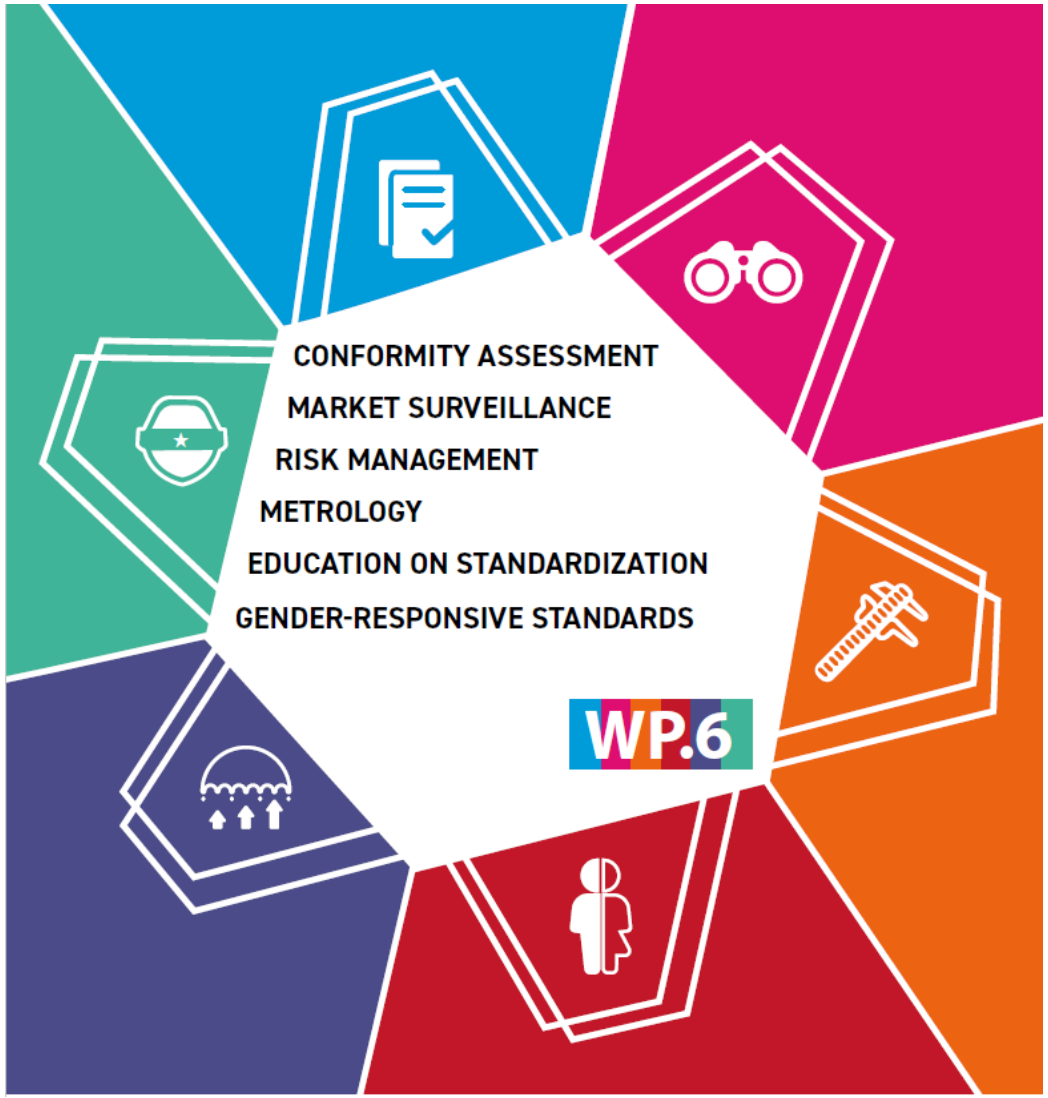
Working Party on Regulatory Cooperation and Standardization Policies



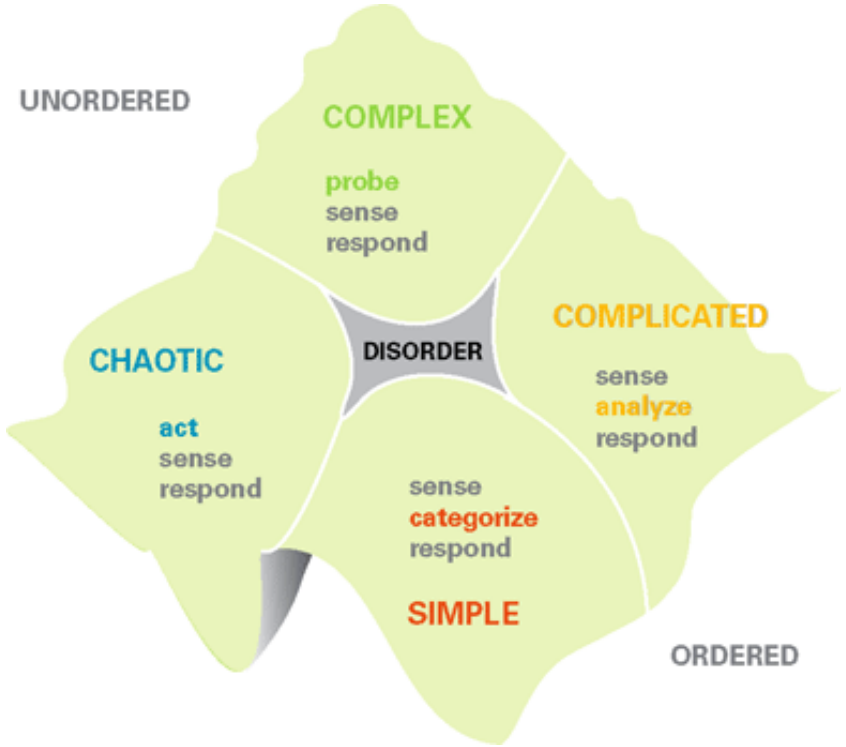
Managing Uncertainty

- For a Standards organisation like WP6, the starting point has to be ISO 31000, which defines *“risk”* as *“the effect of uncertainty on objectives”*.

- Knowledge is fundamental to good risk management – the more we know, the more confident we can be in assessing options.

- Uncertainty, though, is where we don’t know enough. Risk management tries to help make decisions in that situation, i.e. managing uncertainty.

Cynefin



From "A Leader's Guide to Decision-Making", Snowden and Boone, HBR 2007 - https://hbr.org/2007/11/a-leaders-framework-for-decision-making.

Donald Rumsfeld's "known unknowns" came from the State Department applying the Cynefin model of uncertainty, following the 911 disaster.

In the Simple domain, we know all we need to know – the known knowns.
In the Complicated domain, we know what we know but also are aware of what we don't know and need to find out – the known unknowns.
In the Complex domain, we don't know how much we don't know or what we need to find out – the unknown unknowns.

We use knowledge plus causality to predict the future. In the Complex domain, the system adapts to change and is unpredictable – but causality still applies. But we can only understand it in retrospect.

Rumsfeld wanted to know weak signals they had missed that might have allowed them to anticipate Al Quaeda's attack.

Structured and Unstructured Data

Complicated vs Complex

A fast BMW is complicated but a skilled mechanic can dismantle it and rebuild it so that it is exactly as it was.

A rain forest is complex. Change one bit of it and you can never rebuild it as it was.

Structured vs Unstructured Data

Structured data may be huge but it is known knowns or a few known unknowns that may be worked out from what is already known. Unstructured data is full of unknown unknowns and we may not even know where to start. AI may be able to identify the weak signals, recognise patterns and begin to construct predictions. That's risk management. That's managing uncertainty.

Use of AI in Risk Management

- As explained, working with unstructured data has great potential and is the aspect most promoted by B2B companies offering AI services for risk management. It doesn't just do more faster, as AI can with structured data as well, it does what is not feasible without AI.

- AI can also discover new threats and risks. Since it is exploring the unknown, many things become possible.

- AI can also be used to monitor behaviours. The online gambling industry is turning to AI to spot problem gamblers through their patterns of play, as a way of managing the risk of gambling harm. This technology is itself a spin-off from adoption across the financial services industry.

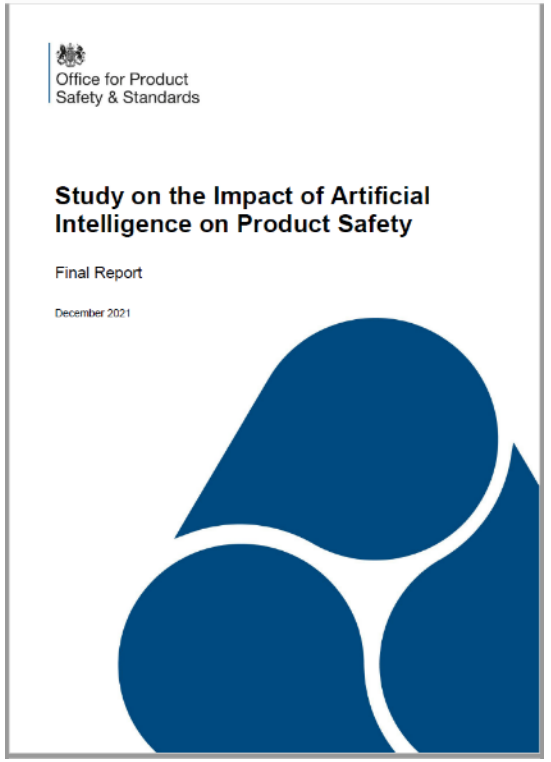
- Cybersecurity is another prime area for AI, often on both sides of the battle.

However, at this stage of development, AI can also create new risks.

Application in the Product Safety Sector

The UK's Product Safety Regulator, OPSS, commissioned a study of the impact of AI on product safety, which reported in December 2021. The direct benefits identified were not extensive but did show broad potential:

- Data collection and analysis at the production stage can improve design and assembly, including building in predictive maintenance.
- The use of a "digital twin" allows aircraft engines to be monitored in real time but can also teach machines to detect failures and quality issues on the assembly line and allows the discovery of "rare events".
- For Market Surveillance, analysis of Amazon's product reviews is being used in the US to identify products to be recalled.
- Products can be tailored to specific customers through co-creation.
- Some smart IoT sensors and meters can provide tailored advice on domestic energy use.



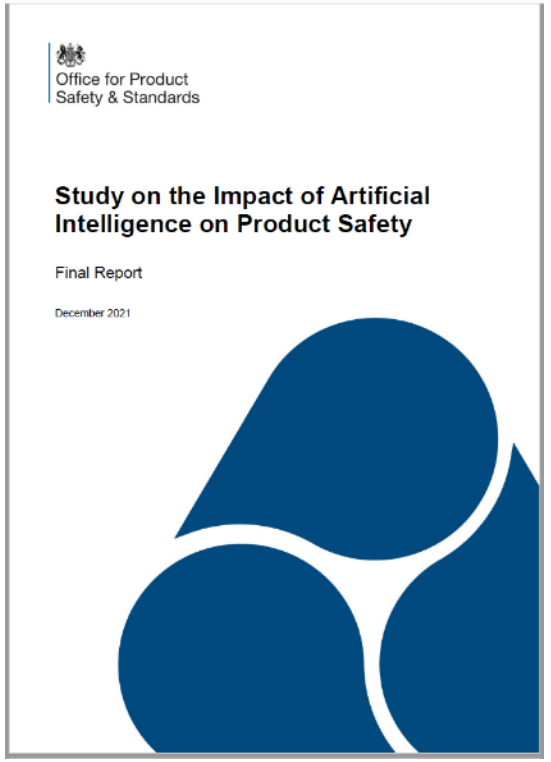
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1077630/impact-of-ai-on-product-safety.pdf.

Application in the Product Safety Sector 2

But the study also looked at problems facing the product safety sector arising from AI in its current state of development:

- **Mutability**: Machine learning allows the product to change, which presents challenges in maintaining control. Even if its development is "frozen" on placing on the market, third party suppliers may provide upgrades (which also confuses the identity of the "producer").
- **Autonomy**: The capability of human intervention in the mutating product varies according to design, including the level of difficulty of accessing the decision-making of the product.
- **Discrimination**: Bias in AI design remains an issue that can lead to harm
- **Privacy**: What may have seemed innocent data about a person's daily life could build a profile of behaviour that may prejudice the person.

As with any powerful tool, its use may be beneficial or damaging.



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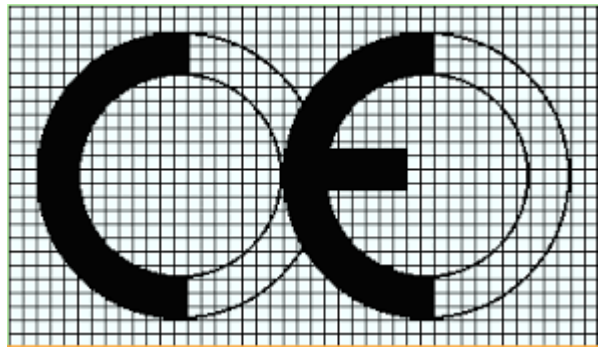
The changing environment of product safety



The basic concepts of the EU product safety / liability regime are 40 years old and no longer fit for purpose. These include – “product”, “producer”, “harm” and “market”. The Commission has recently produced a draft Product Liability Directive that re-writes the concepts, coming on top of the extensive revision of the product safety regime under Reg (EU) 2019/1020.

The digital and green transformations underpin the need for change. A “product” was essentially linear and never changed: with AI, it can learn and mutate. The Circular Economy requires it to change, rather than become waste. A “producer” of a product may be a third party software provider whose software alters the product after placing on the market. “Harm” can now be immaterial, such as data loss or privacy invasion, as well as material. The “market” is increasingly online, with fulfilment centres beginning to replace retail stores. The line between products and services is being blurred.

Although this is stated in the EU context, the issues apply globally.

Finding and Dealing with Dangerous Products

The upside of these changes is that the an online market is susceptible to data gathering and data analysis. The example of analysing Amazon's product reviews is a great illustration of what may become typical of Market Surveillance in the future. Inspectors checking store shelves for products without the CE mark is no longer the way to go (if it ever really was).

The Single Window in trade is another opportunity to capture data on the flow of products and UNECE's Recommendation V and its joint publication with ICT on a Guide for Border Agencies managing risk should contribute to more efficient use of risk management.

There is also great potential for revitalising Market Surveillance through cross-border collaboration in monitoring the online market, as stressed by Reg (EU) 2019/1020. MS authorities in different countries can share resources by segmenting the market amongst them for monitoring.

So, the main contribution of AI to risk management for product safety remains the capacity to analyse masses of structured and unstructured data. It could be a game-changer.

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მადლობთ 감사합니다
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Tak skal du have Diolch
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Thank you

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