How to target continuous compliance

Conformity assessment, legal metrology and market surveillance tools for the changing dynamic of digital goods

Regulatory perspective

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European legal framework

Today, almost every modern application comes with an embedded system. From the latest smartphone, smartwatches, and automobiles to sophisticated home security alarms, medical equipment, IoT products, and more, embedded systems exist within millions of simple and complex products around us, enhancing our quality of life.
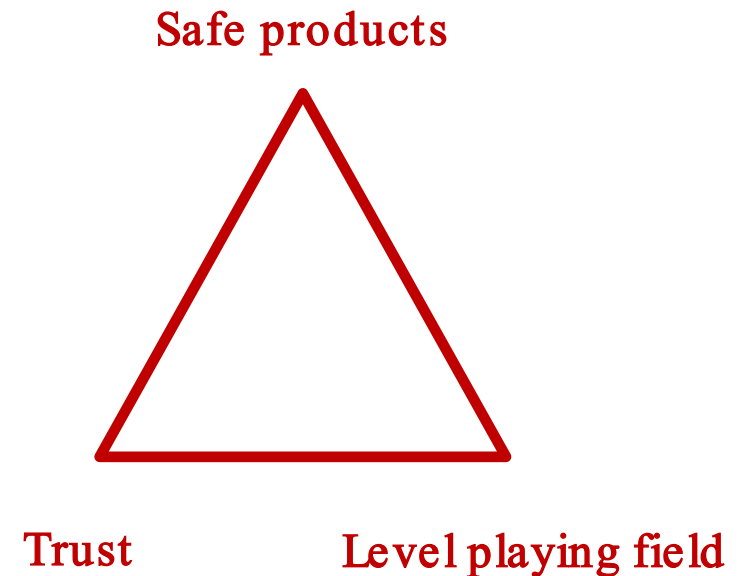
Embedded systems impact our daily life activities, interactions, and tasks—the way we spend our time off, the way we travel, and the way we do business. With diverse applications in communications, transportation, manufacturing, retail, consumer electronics, healthcare, and energy, embedded systems have transformed how we interact with technology in our everyday lives.
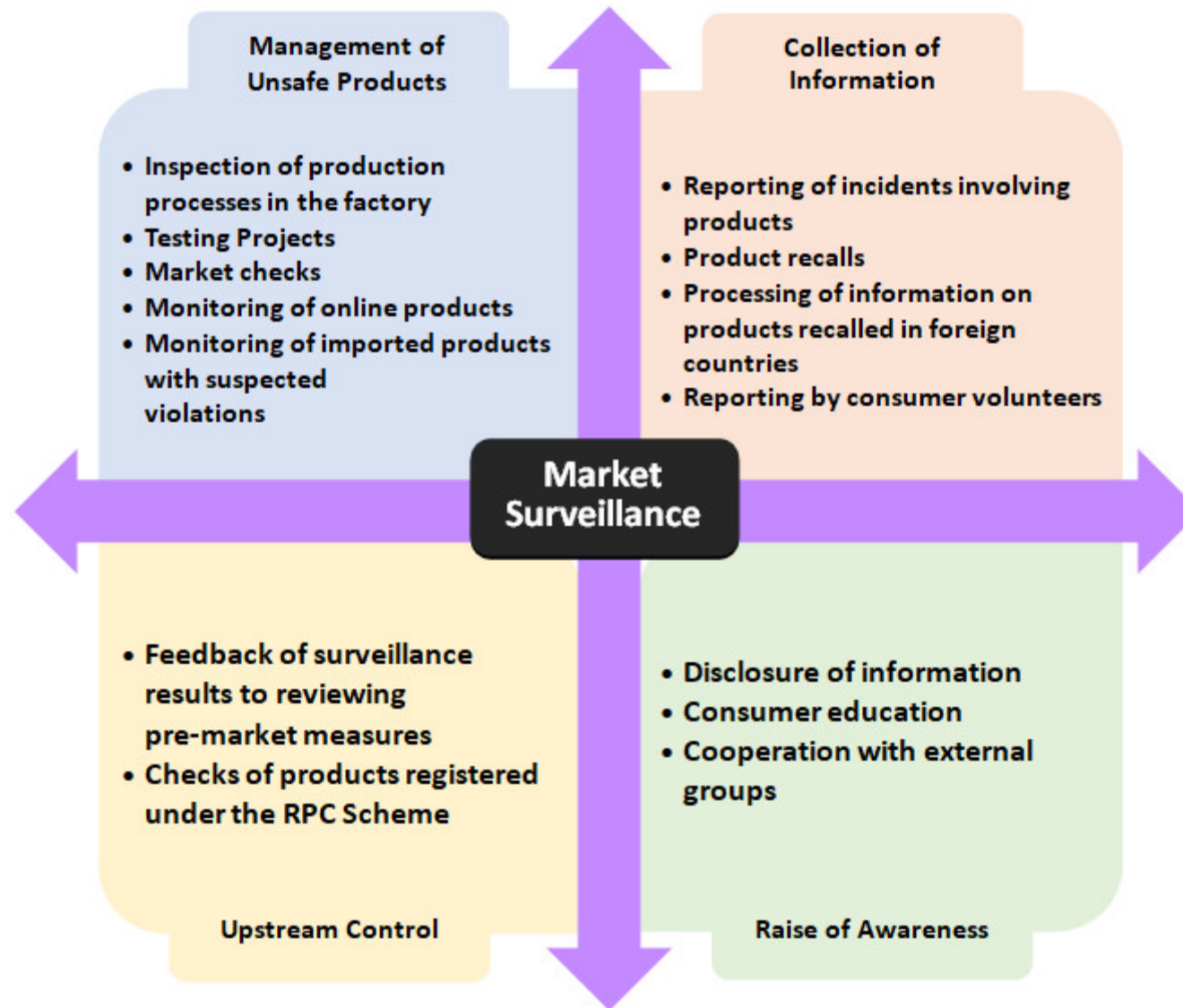
So, what is an embedded system? An embedded system/solution is a computer system—a combination of hardware and software—designed to perform a specific function within a larger mechanical or electrical system. Most embedded systems are based on programmable microcontrollers or processors. Typically, embedded systems have three main components: the hardware, the software, and the real-time operating system.

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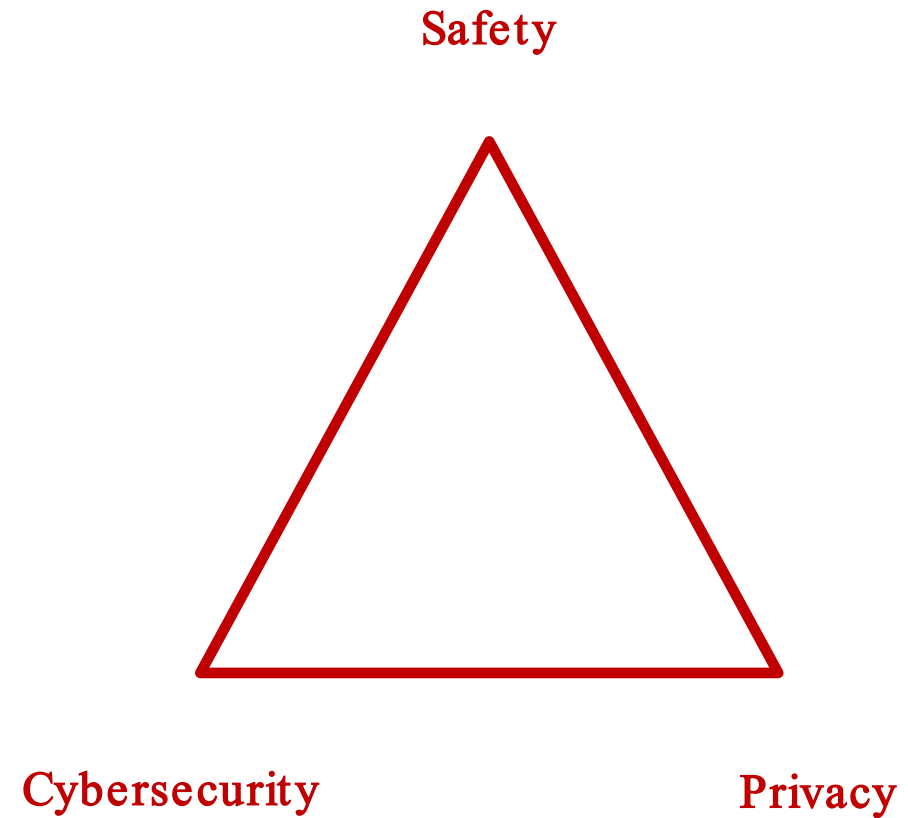
The role of market surveillance authorities

Market surveillance is the activity carried out by authorities to ensure that products on the market are **conform** to the applicable laws and regulations and **comply** with the existing health and safety requirements.
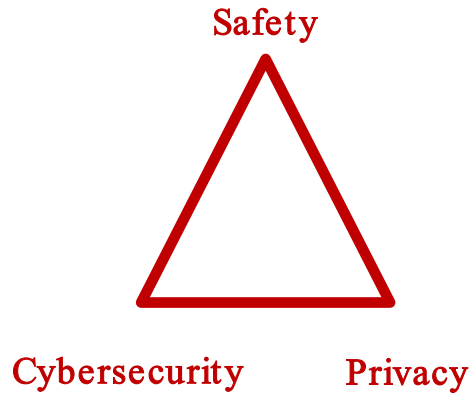It is crucial to keep the market safe and to foster trust among consumers and economic operators. It also helps maintain a level playing field to those companies that comply and thus avoid losing market share to rogue traders.

Safe products

Trust   Level playing field

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Management of Unsafe Products

- Inspection of production processes in the factory
- Testing Projects
- Market checks
- Monitoring of online products
- Monitoring of imported products with suspected violations

Collection of Information

- Reporting of incidents involving products
- Product recalls
- Processing of information on products recalled in foreign countries
- Reporting by consumer volunteers

Market Surveillance

- Feedback of surveillance results to reviewing pre-market measures
- Checks of products registered under the RPC Scheme

Upstream Control

- Disclosure of information
- Consumer education
- Cooperation with external groups

Raise of Awareness

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Embedded Products

Safety

Cybersecurity   **Privacy**

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Safety

Cybersecurity   Privacy

Privacy fears over 'smart' Barbie that can listen to your kids

Campaigners call for ban on Mattel doll that uses voice-recognition technology to respond to children's questions – and send recordings to third parties

📷 Hello Barbie listens to children using cloud-based voice recognition technology, to understand them and talk back. Photograph: Mattel
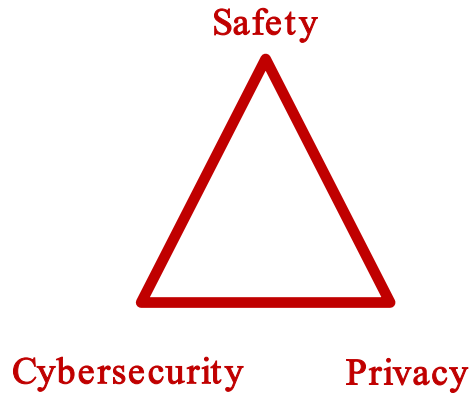
A "smart" Barbie doll that can have "conversations" with children should not go on sale, privacy advocates have said.

Billed as the world's first "interactive doll", the toy uses voice recognition technology similar to that employed by Apple's Siri and Google's Now digital assistants to understand what a child is saying to Barbie and respond.
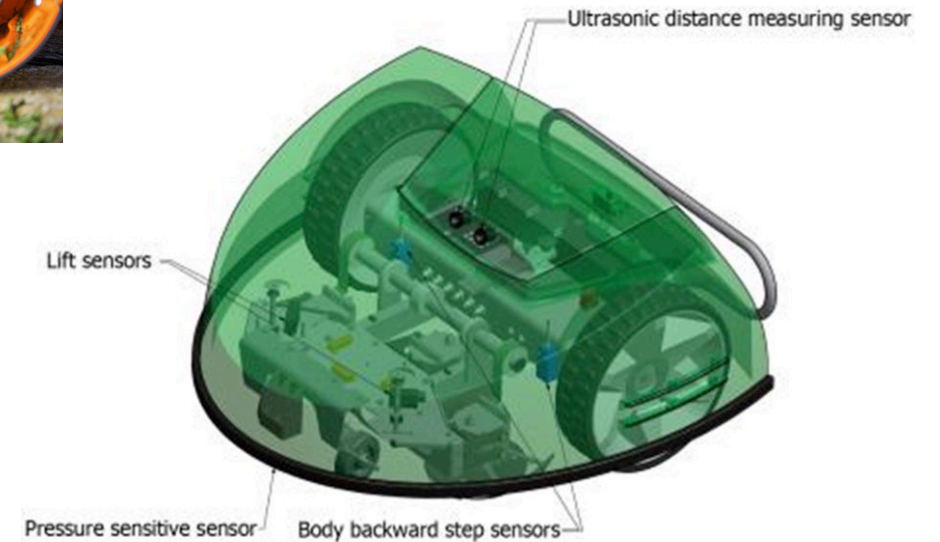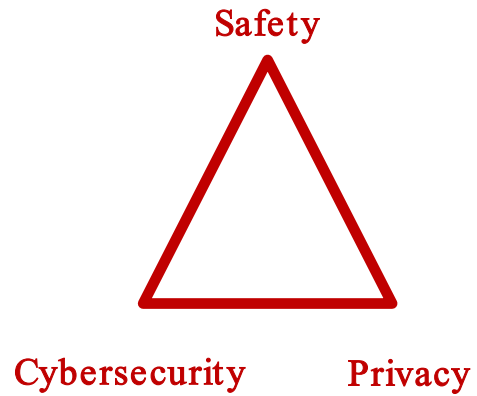
However, privacy advocates are worried about the use of voice recognition technology that sends recordings of children to third-party companies for processing, potentially revealing his or her intimate thoughts and details.

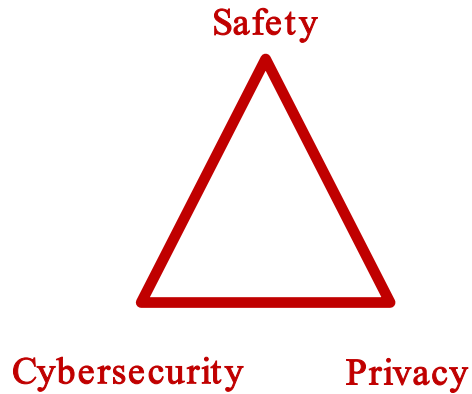"If I had a young child, I would be very concerned that my child's intimate

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Safety

Cybersecurity   Privacy

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Safety

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Ultrasonic distance measuring sensor

Lift sensors

Pressure sensitive sensor   Body backward step sensors

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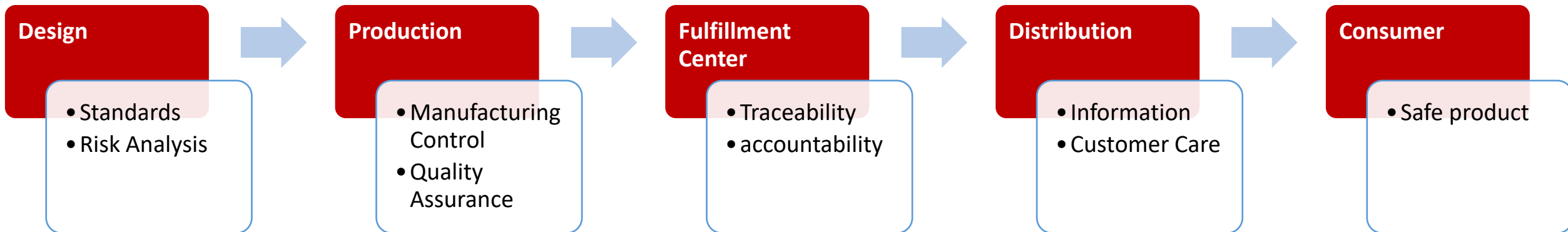FOD Economie, K.M.O., Middenstand en Energie

Safety

Cybersecurity   Privacy

Smart Electric Toothbrush, Sonic Power Toothbrush with Interactive Live Tracking App for Adults (Black)

Conformity Assessment Flow

Legislation		Standards		Tests		Conformity Assessment		Manufacturer
• Essential Requirements	→	• Assumption of conformity	→	• Test report • Fail/Pass Requirements	→	• CAB • Accreditation • Notified bodies	→	• Declaration of Conformity • Technical File

Market Surveillance Flow

Design
- Standards
- Risk Analysis

Production
- Manufacturing Control
- Quality Assurance

Fulfillment Center
- Traceability
- accountability

Distribution
- Information
- Customer Care

Consumer
- Safe product

Pre-Market Surveillance
+
Post-Market Surveillance

Design
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Production
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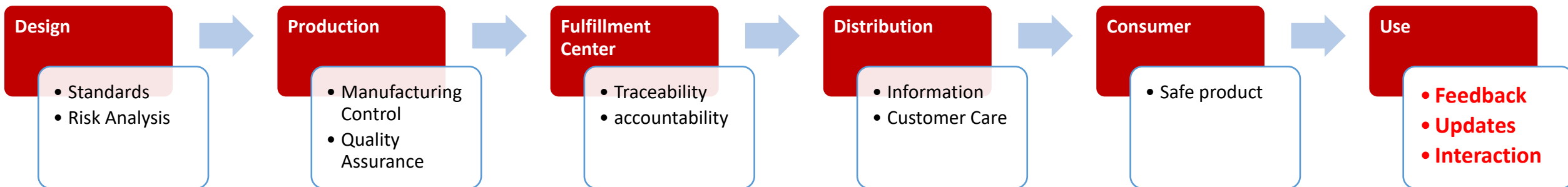
Use
- **Feedback**
- **Updates**
- **Interaction**
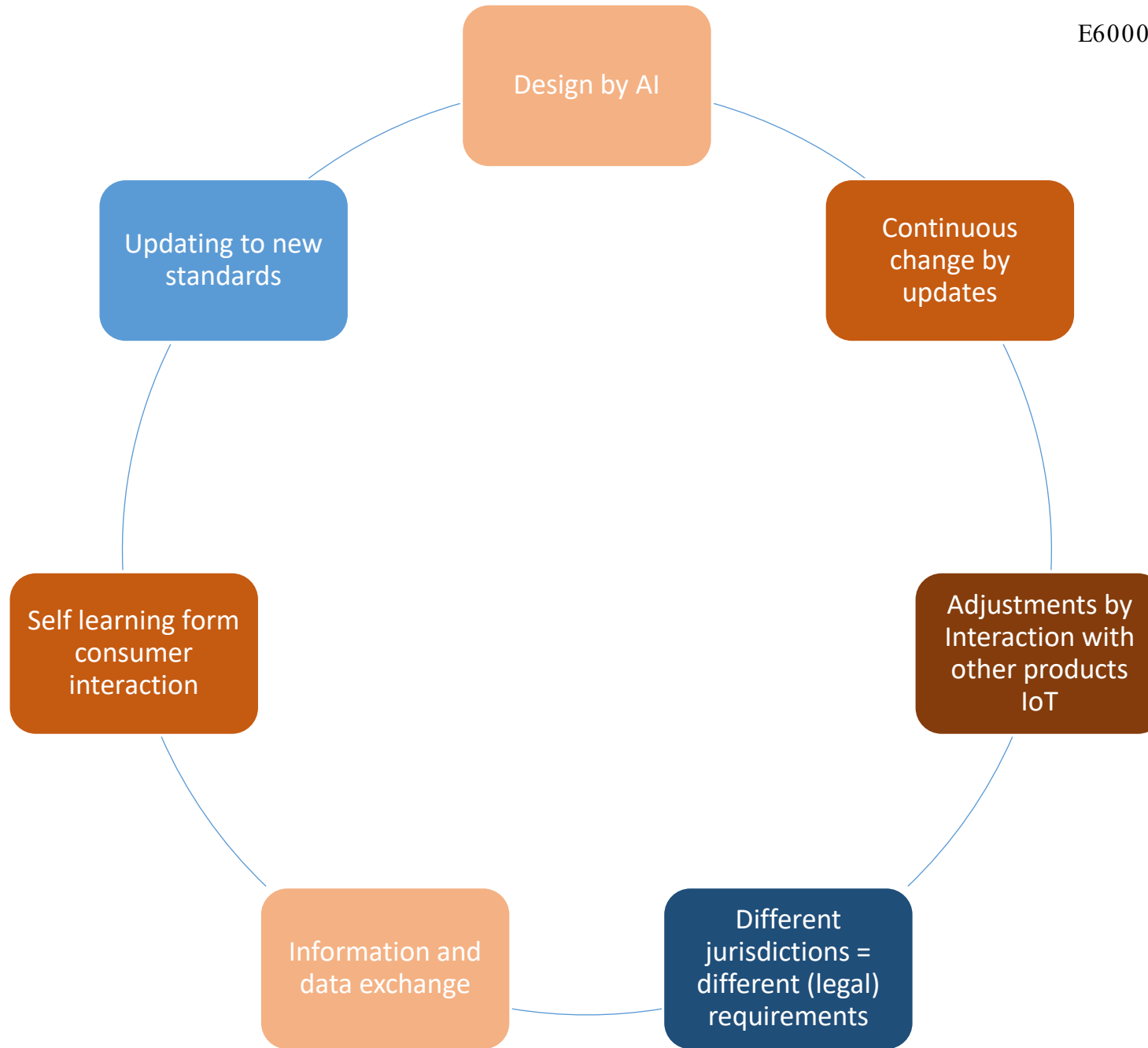
Do we need post-market surveillance ? *(Medical Devices)*

Post-market surveillance is a set of activities conducted by manufacturers, to collect and evaluate experience gained from *medical devices* that have been placed on the market, and to identify the need to take any action.

Post-market surveillance is a crucial tool to ensure that *medical devices* continue to be safe and well-performing and to ensure actions are undertaken if the risk of continued use of the *medical devices* outweighs the benefit.

The evaluation of post-market surveillance experiences can also highlight opportunities to improve the *medical devices.*

Do we need post-market surveillance ? *(Legal metrology)*

Post-market surveillance in the field of *legal metrology* involves ongoing monitoring and assessment of measuring instruments and devices after they have been placed on the market. The objective is to ensure that these instruments continue to comply with legal requirements and standards, providing accurate and reliable measurements.

Inspection and Verification: Regulatory authorities conduct regular inspections and verifications of measuring instruments already in use.

Do we need post-market surveillance ? *(Embedded products)*

Post-market surveillance is a set of activities conducted by

- <u>manufacturers</u>, to collect and evaluate experience gained from *embedded products* that have been placed on the market, and to identify the need to take any action;

- <u>regulatory authorities</u> to inspect and verify *embedded products* already in use.

Post-market surveillance is a crucial tool to ensure that *embedded products* continue to be safe and well-performing and to ensure actions are undertaken if the risk of continued use of the *embedded products* outweighs the benefit.
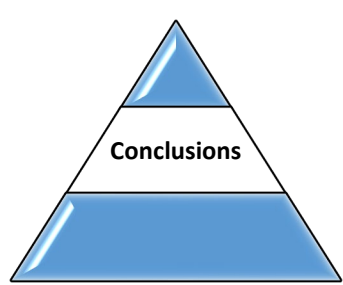
Embedded products : Risks

Conclusions

Security Vulnerabilities

- **Data Privacy Concerns:** Many embedded products collect and transmit personal data. If these devices are not properly secured, there is a risk of unauthorized access and data breaches, leading to privacy violations.
- **Cyberattacks:** Embedded products can be susceptible to hacking and other cyber threats. If compromised, these devices could be used to gain unauthorized access to other connected devices or even cause physical harm.

Physical Safety Hazards

- **Malfunction and Accidents:** Embedded products, especially those used in critical systems like medical devices or autonomous vehicles, can pose serious risks if they malfunction. Malfunctions may lead to accidents and physical harm to users.

Lack of Regulatory Standards

- **Inconsistent Regulations:** The rapid development of embedded products has often outpaced the creation of comprehensive regulatory frameworks. In some cases, there might be a lack of standardized safety regulations, making it challenging to ensure that all products meet the same safety standards.

## AI and continuous coonetivity

- **Pre – market :** Unclear ownership and decisions on design
- **Post-market changes :** Products continue to change and are being adapted by intended updates and interaction with consumers and other products.

Obsolescence and Lack of Updates

- **End-of-Life Issues:** As technology evolves, manufacturers may stop providing updates or support for older embedded products. This can leave users with devices that are vulnerable to security threats and lacking essential maintenance.

Dependency on Connectivity

- **Network Reliability:** Many embedded products rely on continuous connectivity to function properly. If the network experiences issues or disruptions, it can impact the performance and safety of these devices.
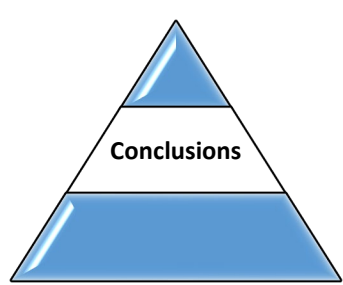
Conclusions

In conclusion, let us approach these challenges with a spirit of solidarity. The pursuit of consumer safety requires international cooperation, a commitment to rigorous standards, and an unwavering dedication to innovation that prioritizes the well-being of our citizens. Together, we can navigate the complexities of embedded products, ensuring a safer and more interconnected future for all.

- Ursula von der Leyen

In conclusion, let us embark on a journey of collaboration and innovation. By navigating these challenges with a spirit of unity, we can collectively contribute to a future where embedded products not only enrich our lives but also stand as paragons of consumer safety and well-being.

- Charles Michel

In conclusion, it's a wild ride out here in the tech cosmos. We've got to be laser-focused on cybersecurity, have a meticulous eye on quality control, find the Goldilocks zone for regulations, keep the updates flowing like liquid oxygen, and build networks that can handle the warp speed of innovation. It's not just about safety; it's about making sure we're light-years ahead in the tech universe. Rockets away!

Let it be known, dear mortals, that in the pursuit of embedded wonders, one must tread with the lantern of skepticism, casting light upon the shadows that threaten the purity of consumer safety. Seek not in the glow of innovation alone, but in the simplicity of true utility, for therein lies the path to enlightenment.

- Diogenes

In addressing these risks, let our actions be guided by the principles of truth, love, and compassion. As we embrace technological advancements, let us remember that the well-being of individuals and the harmony of the Earth are inseparable from our journey toward a just and peaceful world.

- Ghandi

Embedded products : Risks

Hacking and Privacy

- Bad actors might try to sneak into your devices and steal your personal information. It's like someone breaking into your diary – not cool.

Things Not Working Right:

- Sometimes, these devices might go haywire, causing accidents or not working as they should. It's like your toaster suddenly deciding to play music instead of toasting bread.

No Clear Rules

- Imagine if there were no clear rules for using these products. It could lead to chaos. We need simple and fair rules, like traffic rules on the road.

Not Keeping Up

- Just like you update your apps on your phone, these products need updates too. If they don't get them, they might become outdated and not as safe

Dependence on Connections.

- These products often need the internet to work. If the internet goes down, they might not work properly. It's like needing electricity to use your TV – no power, no show.

In a nutshell, we need to make sure these products are protected from bad guys, work properly, have clear rules, get regular updates, and don't rely too much on the internet. It's all about keeping things simple and safe for everyone.

- Jan Deconinck ?

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