Ministry of Infrastructure and Water Management

Safe-by-Design

Preventing future risks

Safe-by-Design seeks to include safety as a design requirement at the earliest stages of product and process development to prevent possible risks for human health and the environment. The Dutch Ministry of Infrastructure and Water Management is looking for frontrunners to jointly develop the concept of Safe-by-Design.

Identifying risks earlier

Emerging technologies are developing rapidly. New developments in biotechnology, such as the targeted editing of DNA in organisms, offer a range of new possibilities for precision agriculture, medicines and pest control. It may even be possible to design new organisms in the future. Nanotechnologies also offer opportunities for innovation in areas as diverse as healthcare, energy supply, construction and industrial production. Examples include targeted drug delivery to prevent side effects, functional foods with health-promoting properties, and self-cleaning toilets. Technological progress is also leading to a tremendous boost of the rate of innovation in the chemical industry.

Clean, healthy and safe living environment

The Ministry of Infrastructure and Water Management is committed to improving quality of life, access and mobility in a clean, safe and sustainable environment, which everyone experiences as such. State Secretary Ms. Stientje van Veldhoven emphasises that environmental and health risks must be negligible and that new risks are identified and addressed as early as possible. New materials, products and processes must become inherently safe ('safety at the front end'). Safe-by-Design is one of the strategies that the State Secretary intends to follow in order to prevent risks for human health and the environment.

But what are the consequences of all these new technological developments and applications? Their possible unintended consequences are notoriously difficult to foresee. For example, the risks of new nanomaterials and chemical substances that are currently entering the market cannot always be properly assessed. This raises the question whether regulatory risk assessment strategies and methods are able to keep track of technological developments. Sometimes this is not possible, for instance when the available methods are no longer appropriate or simply because there is insufficient knowledge or information to assess the risks. Another aspect

related to such situations is that the actor who introduces a new application on the market has the prime responsibility for the inherent safety of this application. This includes both assessing risks at the earliest possible stage and mitigating or minimising them.

Towards a new safety culture

Increased safety awareness among technologists and product and process developers can contribute to improved safety assurances for new technologies, now and in the future. Including safety as a design requirement at early stages of development enables the early identification of potential risks for human health and the environment. This way the design can be adapted accordingly much earlier in the innovation process. This is the essence of Safe-by-Design.

Safe-by-Design aims to consistently take safety aspects into account when making design choices by finding answers to questions including 'What could go wrong with this design?', 'Which materials and structures are potentially dangerous?', 'How can the design be adapted to prevent the occurrence of risks, for instance by replacing, changing or reducing components?', 'And if things do go wrong, how do we prevent or control adverse effects?'. See the example of SafeChassis in the box on the right. Safe-by-Design also requires a new safety awareness on the part of the management of companies, since they make the investment decisions. A distinct aim of manufacturers must be to design products and processes in such a way that these have no harmful effects on human health or the environment throughout the whole life cycle. In this way, safety becomes an integral part of the entire process of research and innovation, assisting manufacturers to avoid problems that may arise later on in the process. When a new product or process is being developed, vested interests often decrease the willingness to stop the development or to adapt a development at a later stage. Hence it is warranted to asses risks associated to a new development at the earliest possible stages. The history of asbestos use illustrates that despite early warning signals about the health risks of asbestos, a continued use of this material has occurred on a large scale in a wide variety of applications. Regrettably, this resulted in a large number of asbestos victims. Application of the Safe-by-Design approach, might have led to preventive actions being taken by manufacturers and applicants based on these early warnings. This could have prevented or even avoided risks, as opposed to the current situation in which safety mainly depends on legislative frameworks. Particularly with new products, such as nanomaterials and biotechnological products, it is important to aim for a high safety performance in their design in order to prevent risks for human health and the environment once they are in use. The same applies to chemicals. The EU is therefore developing a strategy aimed at creating a non-toxic environment. This implies that toxic substances are replaced as much as possible by non-toxic or less toxic alternatives, which may need to be newly developed. Safe-by-Design could also trigger a new functional design for products or processes avoiding the use of toxic chemical substances.

SafeChassis: New, safer microorganisms

The SafeChassis project of Wageningen University & Research applies Safe-by-Design to synthetic biology, a branch of modern biotechnology in which micro-organisms can be radically redesigned. SafeChassis involves researchers working on the optimization of *Pseudonomas putida* to enable this organism to synthesize various products, from biofuels to pharmaceuticals. Potential safety risks are avoided by redesigning this organism in such a way that, for example, it can only survive under controlled conditions.

Safe-by-Design in a Circular Economy

Ruud Balkenende, Professor of Circular Product Design at Delft University of Technology, describes safety as an indispensable element of the circular economy: "Yes, environmental quality is at the core of circular design; and environmental safety is an integral element. First of all, by avoiding risks in the use phase of a product. If something fails abruptly, this not only shortens the life span, but can also create risks for people and the environment. Furthermore, designers need to be aware that the reuse of products containing toxic materials can be difficult. Besides the environmental aspect, safety is therefore also a vital area of attention in circular design." The intended reuse of substances and materials in the circular economy makes Safe-by-Design an essential element of circular design. This point is endorsed by State Secretary Stientje van Veldhoven: "I want [...] to emphasize the prevention of damage by phasing out substances of very high concern, partly because it assists the circular economy".

Wanted: Frontrunners!

By developing safer products and processes, Safe-by-Design clearly provides benefits and advantages for society. However, this safety approach also offers benefits to businesses. With Safe-by-Design, manufacturers can further shape and develop their social responsibility. This offers advantages from both a moral and an economic point of view. It can contribute to reducing the volume of dangerous products being placed on the market, which reduces potential liability for damage or the need for remediation. Based on the principle of 'fail early, fail fast', the pharmaceutical industry tries to detect potential failures in the development of drugs as early as possible, in order to prevent high costs connected to clinical trials of medicines that due to such failures eventually do not lead to introduction on the market. This has turned out to be a profitable strategy.

Safe-by-Design requires a change in attitude and behaviour from all parties involved. In addition to existing laws and regulations, which are mainly aimed at risk management, Dutch safety policy will focus more strongly on the prevention of risks. The Ministry is therefore looking for partners to jointly develop and expand the concept of Safe-by-Design.

Challenges

There are several challenges to be addressed. Safe-by-Design is a specific approach to technological design: it is an iterative, interactive, interdisciplinary process that includes safety – in addition to functionality – as one of the key requirements during the design and development process. This approach requires close collaboration between specialists with specific areas of expertise such as technology, toxicology and process and product development. It also requires new skills in the field of toxicology, design thinking and interdisciplinary collaboration, which, in turn, requires innovative, design-oriented education.

Adequate research is needed to acquire reliable information about potential risks for human health and the environment. Recent explorations of Safe-by-Design in the context of nanotechnology have shown that more technical and scientific knowledge is needed to assess safety at an early stage of product design. For that reason, the Netherlands plays an active role in European initiatives on nanotechnology and Safe-by-Design. Participants in these initiatives focus on the development of validated and standardized test methods for (eco)toxicological research and exposure measurements, and on models and measurement methods for

characterization and testing of nanomaterials. New forms of collaboration between researchers, toxicologists and policy makers are also being investigated. Combining and sharing different measurement methods, qualitative models and databases will make it possible to estimate the possible health and environmental impacts of new materials earlier in the process.

But above all, Safe-by-Design involves a cultural shift. It requires a different mindset, one that focuses more on interdisciplinary collaboration, and on safety as an essential requirement for technological design.

Operationalization of Safe-by-Design

State Secretary Stientje van Veldhoven emphasises the importance of cooperation with companies: "Over the next two years, we will be looking for frontrunner companies – companies that have technology and innovation high on their agenda and are committed to Responsible Research and Innovation. With these companies, I want to initiate joint activities (pilots/ demonstration projects) which are aimed at operationalising Safe-by-Design."

Interested in participating?
Please contact us via
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