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Safe-by-Design – The Early Integration of Safety Aspects in Innovation Processes

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Summary

A number of concepts address safety-relevant issues of innovative materials and products. The Safe-by-Design (SbD) concept is one of these, and aims to take account of these safety issues early on and during the entire product development process. The nano-specific concepts of SbD are intended to address prevailing uncertainties about potential risks to the environment and human health at the beginning stages in the development of new nanomaterials and products. The basic assumption of the SbD concept is that risks can be reduced through the choice of materials, products, tools and technologies, making them as safe as possible. Particular attention is paid to the product development stage, when it is still possible to intervene to control the selection of these factors. In line with the precautionary principle, the early integration of safety in the innovation process is generally seen as desirable.

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Introduction

If there is a potential risk to the environment or human health, it is to be avoided or reduced by means of preventive decisions. This principle – known as the precautionary principle – was laid down by the European Union in a Communication in 2000[1] and is set out in detail in Article 191 of the Treaty on the Functioning of the European Union (TFEU).[2] Hence environment and health policies consider not only known and scientifically provable risks but in addition account is also taken of any lack of scientific certainty. General food law[3] and the EU regulatory framework for chemicals (REACH)[4] for instance refer strongly to the precautionary principle.

Recent years have seen the emergence of the "innovation principle", which can be regarded as the counterpart to the precautionary principle.[5] This still very new concept states that the development of new regulatory strategies or guidelines should include a comprehensive analysis of the effects on innovation. This demand is based on the basic assumption that innovation also includes elements of novelty and experimentation. The aim is a regulatory system in which regulation encourages innovation rather than impeding it. The European Commission uses the term "flexibility by design".[6] Critics warn of the risk that the innovation principle, whose origins lie in the industrial sector,[7] could undermine the precautionary principle and make it easier to circumvent EU safety requirements.[8, 9] Its supporters, on the other hand, refer to Art. 3(3) of the European Union Treaty which lays down: "[The Union] shall promote scientific and technological advance."[10] Hence, depending on point of view, Union law is interpreted to implicitly encompass the innovation principle. The 2021 Regulation on the framework programme for research and innovation, "Horizon Europe" is likely to be the first legislative measure to explicitly contain the innovation principle.[11]

In the field of conflict between safety and innovation, it is above all the manufacturers and producers of nanomaterials or products containing them who find themselves facing a particular challenge. Nanotechnologies are noted for the variety of ways in which they can be used, but where it is very difficult to predict the potential risks and effects. In addition, there are ambiguities in the definition of the term "nano".

This dossier presents an overview of the concepts behind the idea of integrating health or environmental safety considerations in the design of materials, products or processes. The focus is placed on the nano-specific Safe-by-Design (SbD) concept. The conclusion will present an overview of recent national and international projects that have addressed or are addressing SbD in the nano-context.

Safe-by-Design Concepts

There are a number of concepts that use design approaches to aim for increased safety and hence can be qualified as SbD concepts, as well as those that include elements of SbD. The concepts described in this section may differ in their primary objectives – be it enhanced worker safety, better environmental protection, financial savings or the protection of human health – but ultimately they all address the reduction of risks by including safety-relevant considerations in the innovation processes as early as possible and taking account of the entire life cycle of the material or product.

Design for Safety

"Design for Safety" is a systematic approach from the field of engineering. Its purpose is to identify particularly high-risk areas and to minimise both probabilities of occurrence and effects, with systems being analysed through all phases of their life-cycle.[12] A fundamental aspect is that safety must be taken into account in the design itself. The aim is thus to develop an inherently safe design. The four principles of inherently safe design are "minimize", "substitute", "moderate" and "simplify". Thus, it is possible to increase intrinsic safety by reducing hazardous substances, or replacing them with less hazardous materials. If risks are eliminated by changes in design, there is no need for further counter-measures that would increase system complexity. In addition, it is possible to integrate error-tolerance that for instance would guarantee the operation of a system even in the event of partial failures.[13] In practice, the "Design for Safety" principles cannot always be fully realized, in particular in cases where the desired function is in conflict with safety. In such cases, the advantages must be weighed up against the risks involved.

Green Chemistry

In the field of environment protection, thoughts are also being given to developing products and processes with a lower intrinsic risk. For instance, in 2006 the United States Environmental Protection Agency (EPA) drew up the "Green Chemistry Framework", whose aim is to achieve a reduction of the production and use of hazardous substances.[14] Environmental pollution is to be avoided by relying not on post-hoc disposal or treatment (such as safe waste separation and disposal) but rather on the reduction of the causes of pollution. NanoTrust[15] lists a total of 12 Green Chemistry principles, which inter alia require real-time monitoring of synthesis processes or the development of chemicals and products that are degradable and do not accumulate in the environment.

Ecodesign

Ecodesign/ecological design is a concept from the field of environment management, and its aim is to reduce the environmental effects of products over their entire life cycle, an aim to be achieved by means of an appropriate design in the course of product development. The concept has been codified within two ISO standards, ISO 14062:2002[16] and ISO 14006:2011.[17] Within Ecodesign various strategies can be pursued, such as the selection of renewable materials, the reduction of packaging materials, the prolongation of the useful life, an increase of functions or an improvement of recycling capability. In addition to the ecological benefits, the hope is that Ecodesign will also increase worker safety, since it calls for the avoidance of hazardous substances in production. Economic benefits for business have also been demonstrated, for instance through a reduction of operating costs.[18]

Quality by Design

"Quality by Design" is a concept that has long been in use in industrial sectors such as aerospace, the automobile industry, medical technology and the biotechnical and pharmaceutical industries.[19] The introduction of quality tests during the product development process leads to a more efficient fault identification and reduction. The successful application of this approach is dependent on comprehensive knowledge of the material properties, development and production processes involved so that risks can be identified and evaluated.

In the pharmaceutical industry, Quality by Design is implemented via internationally applicable guidelines. The underlying principles are set out in the three ICH guidelines "Pharmaceutical Development" (ICH Q8),[20] "Quality Risk Management" (ICH Q9)[21] and "Pharmaceutical Quality System" (ICH Q10).[22] The entire life cycle is considered in order to identify the toxicity of pharmaceutical products at as early a stage as possible, with a check being made of all critical process parameters with respect to safety, effectiveness and quality.[23]

Guaranteed safety?

Although many approaches claim to develop inherently safe materials, products and processes, statements that postulate complete safety are generally avoided. Hence, the phrase "Safe-by-Design" is often replaced by the term "Safer-by-Design". The problem can be most clearly illustrated using the example of pharmaceutical research and development: Despite intensive optimisation and testing processes, it is not necessarily the case that all possible negative effects of a drug are known when the product is launched on the market.[24] A pharmaceutical product can be withdrawn even many years after official licensing and market launch for safety reasons.[25,26] Even though it is, for instance, possible to identify substances with a low intrinsic risk potential, the simultaneous maximisation of safety and function is a major challenge, and requires laborious optimisation processes involving expensive and time-intensive iterative testing procedures.

Nano-specific "Safe-by-Design"

The term Safe-by-Design is becoming increasingly common in the fields of nanotoxicology and nanosafety research. Safe-by-Design and Safer-by-Design are approaches that include sustainability aspects and the consideration of potential risks as early as possible in the innovation process. The concept has been further developed for the nano-specific context within the EU co-funded "NANoREG" project, a 42-month interdisciplinary research project involving 68 partners from 14 European countries. The aim is to reduce the risks that result from nanotechnology-based industrial and consumer products. Within the NANoREG project, SbD is a voluntary tool that can be used as an aid to industry in the production of nanomaterials, nanoproducts and nano-specific innovation processes.[27]

SbD is regarded as a supplementary application in risk management alongside existing industrial processes that offer a selection of precautionary measures and tools for handling possible risks and uncertainties. The creation of a network of public authorities, industries and science is intended to achieve efficient risk management for artificially produced materials and hence accelerate the licensing process for new nanomaterials and products. In order to build upon existing risk management systems, the development of the nano-specific SbD concept made use of the international standardisation for risk management (ISO 31000:2009),[28] and created a deliberate link to the ISO project management guidelines (ISO 21500:2012).[29]

The NANoREG SbD concept makes use of the Stage-Gate® innovation model as conceptual framework, a process model developed by Robert G. Cooper for innovation and product development.[30] Its starting point is a multi-stage linear innovation process with "stages" constituting product development milestones where the actual innovatory steps take place. Integrated "gates" provide the opportunity for intervention and adjustment, allowing relevant correction measures to be taken. The decision-makers at the gates are referred to as "gatekeepers" and base their decisions on an evaluation of safety-relevant data. To this end, the entire findings of various risk investigations are collected in "safety dossiers".[31]

In practice, it is only with difficulty that regulation and safety research can be combined, and in many cases run parallel to each other. Safe-by-Design is intended to provide an approach at this point to integrate safety as constructively as possible in product development, but to date the NANoREG SbD concept must be seen as difficult to implement, as was determined in the national SbD projects as part of the 4th national invitation of the Nano Environment Health Safety (NanoEHS) programme (see Box 2). The follow-up NANoREG programme – NANoREG 2 – addressed the question of the practical applicability of this concept. A further objective was to establish a link to the regulatory process and industry.

SbD projects at EU level

Following the NANoREG project, further projects alongside NANoREG 2 have taken up the topic of SbD at the EU level or focused on the earliest possible inclusion of safety in the innovation process for nanomaterials, products and processes. With the exception of NANoREG and NanoMile, which are funded within the seventh EU research framework programme, all the projects fall under the EU Horizon 2020 programme. Box 1 provides an overview of the basic details of each project.

NANoREG

The project starting point is the limited understanding of safety aspects of synthetic nanomaterials along the value-creation chain, which also endangers innovatory and commercial potential. The aim was to reduce the risks that derived from nanotechnology-based industrial and consumer products. To this end, the Safe-by-Design concept was developed as a voluntary tool for self-regulation and self-testing of synthetically made nanoproducts and nano-specific innovation processes. The project is seen as a pan-European approach with 68 partners from 14 different countries of Europe.[32]

NANoREG 2

The "Safe Innovation Approach" (SIA) was developed as part of the EU funded NANoREG 2 project, linking the SbD concept with the "regulatory preparedness" approach. Regulatory preparedness describes the timely perception of innovations by the regulatory authority in order to determine whether the existing legislation covers all safety aspects. A basic factor in SIA is that innovators and regulators develop a high degree of awareness for safety issues and that a greater interaction with industry is required.[33,34]

ProSafe

The project's aim is to encourage the implementation of Safe-by-Design. Amongst other things, there should also be an increase in the acceptance of the SbD concept in order to ensure its inclusion in industrial nano-specific innovation processes. The ProSafe project is affiliated with the NANoREG and NANoREG 2 projects.[35]

NanoGenTools

The project is developing new methods to identify risks in connection with nanomaterials in order to ensure consumer safety. The aim is to establish cross-sector synergies between leading nanosafety research centres and industry. It combines approaches from the fields of genomics (toxicogenomics), proteomics, biophysics, chemistry, bioinformatics and chemoinformatics in order to develop "in vitro high throughput (HTS) assays".[36]

NanoMile

This project was dedicated to acquiring a detailed understanding of the interaction between synthetic nanomaterials and living systems. A number of test systems were used, from bio-fluids to multi-cellular organisms, animals and humans. One focal point was the development of in-silico tools to predict risks.[37]

Box 1:
EU projects on Safe-by-Design and the early integration of safety in innovation processes

Project title	Funding programme	Coordinator	Term	Project budget	Homepage
NANoREG A Common European Approach to the Regulatory Testing of Nanomaterials	FP7	Ministerie van Infrastructuur en Waterstaat, Netherlands	1.3.2013-28.2.2017	€ 49.586 mill. of which € 10 mill. EU funding	www.nanoreg.eu
NANoREG 2 Development and Implementation of Grouping and Safe-by-Design Approaches Within Regulatory Frameworks	Horizon 2020	Institut National de l'Environnement Industriel et des Risques (INERIS), France	1.9.2015-31.8.2018	€ 11.933 mill. of which € 9.995 mill. EU funding	www.nanoreg2.eu
ProSafe Promoting the Implementation of Safe by Design	Horizon 2020	Ministerie van Infrastructuur en Waterstaat, Netherlands	1.02.2015-30.04.2017	€ 3.095 mill. of which € 2.512 mill. EU funding	n/a
NanoGenTools	Horizon 2020	Universidad de Burgos, Spain	1.01.2016-31.12.2019	€ 706.500 of which € 706.500 EU funding	www3.ubu.es/nanogentools/
NanoMile Engineered Nanomaterial Mechanisms of Interactions With Living Systems and the Environment: a Universal Framework for Safe Nanotechnology	FP7	The University of Birmingham, Great Britain	1.03.2013-28.02.2017	€ 12.965 mill. of which € 9.625 mill. EU funding	http://nanomile.eu-vri.eu/
NanoFase Nanomaterial Fate and Speciation in the Environment	Horizon 2020	Natural Environment Research Council, Great Britain	1.09.2015-31.08.2019	€ 11.297 mill. of which € 9.954 mill. EU funding	www.nanofase.eu/
EC4SafeNano European Centre for Risk Management and Safe Innovation in Nanomaterials & Nanotechnologies	Horizon 2020	Institut National de l'Environnement Industriel et des Risques (INERIS), France	1.11.2016-31.10.2019	€ 1.999 mill. of which € 1.999 mill. EU funding	www.ec4safenano.eu
caLIBRAte Performance Testing, Calibration and Implementation of a Next Generation System-of-Systems Risk Governance Framework for Nanomaterials	Horizon 2020	Det Nationale Forskningscenter for Arbejdsmiljø, Denmark	1.05.2016-31.10.2019	€ 9.828 mill. of which € 7.999 mill. EU funding	www.nanocalibrate.eu/home

Project title	Funding programme	Coordinator	Term	Project budget	Homepage
SafeNanoKap Applicability of the "Safe-by-Design" Concept – Case Study Development of Nanomaterials for Coffee Capsules	Nano-EHS	University of Natural Resources and Life Sciences, Vienna – Institute of Waste Management	1.3.2017-28.2.2018	79,905 €	www.oeaw.ac.at/ita/projekte/safenanokap/ueberblick/
SbD-AT Relevance and Added Value for Austrian Companies	Nano-EHS	Brimatech Services GmbH	1.01.2017-31.12.2017	80,000 €	www.bionanonet.at/projects/sbd-at
Nano EHS SWOT SbD Nano EHS Strengths/Weaknesses Analysis "Safe-by-Design"	Nano-EHS	Austrian Institute of Technology	1.03.2017-28.02.2018	n/a	www.ait.ac.at/ueber-das-ait/center/center-for-innovation-systems-policy/nano-swot-sbd/

***Box 2:** National Safe-by-Design projects*

NanoFase

An integrated exposure assessment framework is being developed containing methods, parameter values, models and guidelines. The intention is to create a flexible multimedia model for risk assessment of differing scales and complexities. In this way, the project is aimed at making a contribution to Safe-by-Design by identifying connections between material properties of synthetic nanomaterials and their environment.[38]

EC4SafeNano

The EC4SafeNano project's aim is to set up an independent scientifically sound centre. This centre ("hub") is to be linked with various networks and thus will act at the interface between research institutions, industry, regulatory authorities and civil society. The aim is to increase communication between science and industry.[39]

caLIBRAte

The aim of calibrate is to develop an adaptable and overriding state-of-the-art risk governance system for the assessment and management of nano-specific risks for human health and environment.[40] The framework is a system of systems combining a number of models and methods. The existing risk governance tools handled within caLIBRAte are the Swiss Precautionary Matrix, SimpleBox4Nano,[41] StoffenmanagerNano,[42] Licara Nanoscan, GuideNano,[43] Nanosafer CB, CB Nanotool[44] and SUNDs.[45]

SbD projects at national level

The 4th national invitation to tender of the Nano Environment Health Safety (Nano-EHS) programme funded three projects on the topic of the assessment and monitoring of the sustained implementation and verification of the NANoREG Safe-by-Design concept. Box 2 presents an overview of the relevant project details.

SafeNanoKap

Within SafeNanoKap the applicability of the SbD concept was played out on the basis of a theoretical example – the development of coffee capsules made of plastic with nanoscale additives. A Life-Cycle-Mapping was carried out of the selected product example in order to identify the possible risks and environmental effects of nanomaterials in plastics and to show the strengths and weaknesses of the concept. In addition, expert assessments were gathered.[46]

SbD-AT

The SbD-AT project considered various aspects of the possible implementation of Safe-by-Design concepts in industrial innovation processes, including possible barriers from the point of view of industry. The study identified and analysed perceived advantages and disadvantages, risk awareness and acceptance barriers of the SbD concept from the point of view of experts and that of potential users.[47]

Nano EHS SWOT

The aim of this project was to determine and assess the extent to which the SbD concept can serve to ensure the development of safe nanomaterials and products in industry. The project's focus was on Austrian industrial downstream users of chemical substances with synthetic nanomaterials.[48]

Conclusion

The early integration of safety aspects in innovation processes through design approaches is often seen as an effective way to reduce risks for health and the environment and simultaneously to save financial and time resources. The field of synthetic nanomaterials and nanoproducts has seen the development of the Safe-by-Design concept, which has precisely this objective. In recent years, many projects have been dedicated to the SbD concept per se and to its practical implementation in industry. Alongside the strengths of the concept, such as the early addressing of safety-relevant issues, currently, however, a number of challenges concerning practical applicability have been identified. The voluntary nature of the utilization increases the users' outlay in money and time without any visible added benefit for the enterprise. Currently, therefore, the nano-specific SbD concept must be considered as difficult to implement, although the effort to include safety as early as possible in the innovation process is generally very positively received.

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