

Nanotechnology Product Liability: Manufacturers in Charge

Worldwide, there is still almost no nano-specific regulation. Nanoproducts have to comply with existing laws and regulations, but this might not be adequate to deal with the specific properties of nanomaterials (see chapter 5 of the Basic Report of the Swiss Actionplan [1]). Since the potential risks of nanomaterials still remain unclear, the manufacturers of nanoproducts must anticipate potential liability cases.

Who will be affected by the scientific uncertainties about the potential hazards of nanomaterials, the consumer or the manufacturer? What do manufacturers have to know about the safety of their products? A recent article in Jusletter gives an overview on the current legal background and identifies possible measures.

The legal situation

According to the Swiss federal court, consumers must be able to rely on minimum product safety standards. Products with an implicit health risk will be claimed faulty and refer to the product liability of the manufacturer. The uncertainties regarding potential negative health effects of nanoproducts therefore remain within the manufacturer's responsibility and must be assessed prior to market launch.

On the other hand, according to product liability laws (PrHG in Switzerland), there are cases when a manufacturer can be exonerated from its liability (compliance with sovereign standards and development risks). However, the compliance with sovereign standards as a reason for discharging the manufacturer from its liability assumes that the norm regulating the risk is adequate. If a legal norm to assess certain risks is obviously insufficient, complying with this norm does not discharge the manufacturer from its liability. According to the current international debate about the adequacy of existing regulations for nanotechnology, this question has yet to be answered.

Referring to the development risk as a reason to discharge from liability implies that the defect of the product could not be recognised according to the state of the art of science and technology at the time when the product was put into circulation. A development risk is regarded as identifiable as soon as *indications* for potential damage by the product exist. The scientific and technical *details* of the damage do not have to be fully clear yet. Since today already a lot of scientific studies prove or do not exclude detrimental effects by nanomaterials, referring to a development risk will probably be difficult for nanomaterial manufacturers.

In contrary to European product liability, in Switzerland the burden of proof generally lies with the claimant. However, the detailed cause of the product defect does not need to be proved. The manufacturer can provide counter-evidence; however, because of the many uncertainties about the effects of nanomaterials, the exact reason for a product defect would probably remain unclear in many cases. The fact that the claimant is not obliged to clarify these uncertainties and the assumption that the manufacturer would probably often fail to provide the necessary counter-evidence means a privileging of the claimant and an additional risk to the manufacturer of nanoproducts.

In principle, product liability for a nanoproduct manufacturer is the same as for any manufacturer of conventional products. However, according to the factors described above (legal distribution of the risks, difficulty to discharge from liability) the risk potential in the nanotechnology sector has to be rated higher. To reduce liability risks, the manufacturer should consider the following measures.

Dealing with uncertainty: Monitoring and product testing are key

Monitoring during the product development phase: The manufacturer should start to continuously monitor the available relevant scientific and technical data already during the product development phase and update the

product according to these findings. The manufacturer should document this process for later use as evidence independently from whether the information influenced product development.

Product tests: The manufacturer should specifically test its nanoproducts in terms of product safety. Therefore, new or adapted test criteria might be necessary to fully take account of the special properties of nanomaterials.

Market introduction: Market introduction should only be carried out if the nanospecific effects of the product are clear and if the risks are known and rated harmless or tolerable. Residual risks should be declared on the product or mentioned in the package leaflet.

Monitoring after market introduction: Risks and properties of nanomaterials will be further clarified. The manufacturer should therefore observe and update its products on the market in response to new safety data available. This process should also be documented and the information should be stored.

Product recall: If the monitoring (after market introduction) leads to the conclusion that the product can not be regarded as safe any more with current scientific knowledge, the manufacturer should consider a product recall at an early stage.

CENARIOS® provides sophisticated monitoring tools

It can be concluded that the the existing uncertainties about the potential risks and the regulation of nanomaterials raise the need for proactive risk assessment and monitoring activities by the industry. Such a system is available with CENARIOS®, [2], the first nanospecific risk management and monitoring system which has been developed by The Innovation Society, St. Gallen and TÜV SÜD Industry Services, Munich. This system incorporates the state of the art of science and technology into a company's risk management system and allows the company to identify and react on nanospecific risks at an early stage in order to prevent liability cases.

The original article which this text bases on was written in German by Dr. jur. Naoki D. Takei and published in Jusletter 5. November 2007. The author of the original article is a lawyer and Corporate Counsel at Novartis International AG. He is a PD for private law at the University of Basel (Switzerland). Original title: „Produkthaftungsrisiken in Zeiten der Nanotechnologie“.

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[1] Basic Report to the Action Plan: <http://www.innovationsgesellschaft.ch/aktionsplan.htm>

[2] CENARIOS® Website: http://www.tuev-sued.de/technische_anlagen/risikomanagement/nanotechnologie