New technologies: the testing clause in need of an update

The so-called testing clause, as per Point 6.2.5 of the Product Liability Conditions (*Produkthaftungsbedingungen* – ProdHB), is of increasing importance for emerging technology products. These model policy conditions and risk descriptions for product liability insurance for manufacturers and merchants were drafted by the German Insurance Association (*Gesamtverband der Deutschen Versicherungswirtschaft* – GDV). To the author's knowledge, there is no recent jurisprudence on this clause, which excludes specific risks from insurance coverage according to objective criteria, despite its importance. Nor does the most recent literature bring it up to date in order to align it with technological progress in a disruptive and globalized industrial world.[1] This paper examines possible routes of revision with a focus on auto parts as they move down through the supply chain in the automotive industry.

The testing clause's 2002 version reads[2]:

"This policy does not cover any claims from material damage or financial losses caused by manufactured items whose use or mode of action, in view of their specific intended use, has not been subject to state-of-the-art testing or has otherwise been tested insufficiently. This does not apply to damage to objects that neither function together with the manufactured or supplied items nor are subject to these items' influence."[3]

No definition of „state of the art"

The testing clause requires that manufacturers sufficiently test their products against the benchmark of the technological „state of the art". This testing is target-oriented in that it is geared towards the product's fitness for a specific purpose. The clause sanctions any failure to meet the target, or the product's fitness for purpose, caused by insufficient testing. State-of-the-art measures are anticipated tools that are

[1] Thürmann/Kettler, *Produkthaftpflichtversicherung*, 7th edn., 2019, p. 237 ff; Prölls/Martin, *Versicherungsvertragsgesetz*, 30th edn. 2018, p. 265, 6, marginal numbers 8 ff., p. 1811 ff.

[2] Thürmann/Kettler ibid., p. 240, with an overview of the clause's history.

[3] In a special information brochure on product safety from 2012 (title: *„Innovationen sind der Treibstoff der Kfz-Zulieferindustrie"* – „Innovation is the automotive supplier industry's fuel"), the German insurance company HDI (*Haftpflichtverband der Deutschen Industrie*) presented an alternative wording inspired by the then applicable rules and standards for the automotive industry: „Items which have been developed in compliance with chapter 7.3 of ISO/TS 16949:2009 and the processes of Verification (ISO 9000-3.8.3) and Validation (ISO 9000-3.8.5) therein, the latter applied, carried out and documented according to the state of the art, will also be deemed sufficiently tested." This proposal has not caught on.

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needed in order to meet the target. Their implementation is intended to create certainty that the targets will be met under field conditions.

The term „state of the art“, however, is an indeterminate legal concept and there has been and remains an urgent need for clarification. Currently, its meaning is for the most part derived from Section 3(6) of the German Federal Immission Control Act (*Bundesimmissionsschutzgesetz*, BImSchG)[4]: “State of the art as used herein shall mean the state of development of advanced processes, facilities or modes of operation which is deemed to indicate with overall certainty the practical suitability of a measure to restrict emission levels in the air, water and soil to ensure plant safety, to ensure environmentally sustainable waste disposal or to otherwise avoid or reduce impact on the environment in order to attain a general high level of environmental protection.”[5]

This description – a definition of „state of the art“ is not being provided therein – hardly enables practitioners „to draw on a legal term that is being used elsewhere and thus has been shaped and given concrete meaning.“[6] Also in need of interpretation is the term „sufficiently tested“, which also fails to increase clarity. Critics of the prevailing opinion refer to this ambiguity and suggest the clause might be null and void because it infringes German law on general terms and conditions, especially if used in a contract with a bona-fide insurance holder. This will not be discussed in detail in this paper.[7]

Need for revision and modernization

The clause’s justification lies in the following consideration: where a manufacturer buys insurance cover for its own liability, the insurer cannot be burdened with the incalculable risk of insufficient design and development on the part of the policy holder, as well. The policy exclusion applies both to insurance coverage for settling legitimate claims and legal defense against unjustified claims. Yet, considering how essential liability insurance is for companies, new technological developments also warrant a rethink on what makes the testing clause, as part of an individual bilateral insurance contract, suitable for the modern age.

[4] As last revised on May 17, 2013, Federal Gazette (*Bundesgesetzblatt*, BGBl.) I p. 1274; Thürmann/Kettler, *supra*, p. 241, work with the shorter version of Section 3(6) BImSchG that existed prior to the Act’s revision.

[5] The criteria to make it concrete are listed in the annex to Section 3(6) BImSchG.

[6] Thürmann/Kettler, *supra*, p. 241, however, argue along those lines.

[7] Thürmann in Langheid/Wandt, *Münchner Kommentar zum VVG*, 2nd edn., 2017, p. 310 Produkthaftpflichtversicherung, marginal numbers 296 ff.

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This includes in particular the question of whether the apparently prevailing opinion may still be applied without restrictions, especially to new, still untested yet widely marketed, technologies. With regard to the latter, the prevailing opinion states that because the clause contains objective exclusion criteria, it is irrelevant why testing was insufficient and "whether the insurance holder or his customer or any third party was responsible for the testing and whether a failure to recognize the need for testing measures, unawareness of the technological possibilities or any other factor was ultimately the reason why testing remained insufficient."[8] As a consequence, the testing clause's applicability in individual cases is largely determined by chance: it depends on where the damage occurs and under what circumstances. When the manufacturer of an automotive part is facing claims from his customers, it also depends on how the insufficiency of the manufacturer's testing is determined *ex post*. This seems questionable because in practice, it will be the upstream supplier who ultimately faces claims within the supply chain (TIER n). Practical experience has shown, too, that with an *ex post* examination, proving causality is impossible because of unknown factors in the downstream supply chain and uncertainty about the circumstances under which the auto part actually failed in the field.

This is particularly true for components and aggregate systems with electronic elements. The vehicle with which the driver pulls out of his garage in the morning is often not identical with the one he parks in there at night: without the driver's knowledge, software updates that may have a direct impact on the electronic architecture of the entire vehicle have been installed through internet-based flashing. Their impact on the electronic components, which are later blamed for a part's failure caused by insufficient testing or for having impacted on other system elements before the flashing, is impossible to determine in retrospect (volatile memory) or insufficiently documented. Under actual practical circumstances, as I will explain in more detail below, the testing clause does not entail any realistic scope for findings that anyone – including the insurer – could prove.

Referring to the fact that the insurer bears the burden of proof when it comes to the exclusion clause's applicability is at best a tactical observation for litigation – it helps neither the insurer nor the insurance holder as both are unlikely to be interested in legal proceedings.[9]

[8] Thürmann in Langheid/Wandt, *Münchner Kommentar zum VVG*, 2nd edn., 2017, p. 310 Produkthaftpflichtversicherung, marginal number 300; Littbarski, *Produkthaftpflichtversicherung*, 2nd edn., 2014, point 6, marginal number 181.

[9] Thürmann/Kettler also point out that, so far, insurers have apparently won every legal dispute revolving around the testing clause, *supra*, p. 238.

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Innovation through new technologies

In a world in which globalized supply chains for virtually all products are increasingly disruptive, one must reflect more deeply with respect to emerging technologies and new manufacturing processes. These supply chains do not fit into the one-to-one model of bilateral contracts of purchase that give rise to specific rights. I leave manufacturers of standalone products out of consideration.

Mid-range cars consist of tens of thousands of individual parts. Development errors or insufficient testing – often equivalent to each other – of an individual product usually only have an impact once the finished vehicle operates in the field. From the point of view of the part manufacturer, considering that his technical evaluation only covers one of numerous individual parts (inclusive of its function and functionality within the vehicle), he must not be over-burdened with the development responsibility for the entire vehicle. It lies solely with the vehicle manufacturer, even if he himself lacks the expertise needed to develop each individual part or aggregate system[10], which is usually the case.

Modern developments and the expectations we hold for products of the future are determined and controlled by algorithms, Artificial Intelligence (AI) and robotics, all of which function on the basis of certain basic assumptions whose foundations have not been determined, and much less proven, beyond doubt. After development has begun, the process continues with the help of algorithms and AI until it reaches a point at which the endless process of AI is halted because there is reason to assume that an acceptable result has been found that makes further considerations of maturity unnecessary. From the insurer's point of view, there seem to be no problems vis-à-vis liability. The coverage of such liability issues, however, remains open.[11]

Complex products such as machines or vehicles are increasingly equipped with components that the vehicle manufacturer uses based on suitability assessments by the buyer, but the parts manufacturer often does not know how (and for what purpose) his products are being used. Having said that, the parts manufacturer does ordinarily know that his products will also be used in the automotive industry and thus at least anticipates this sector's special requirements and conditions.

This is particularly and increasingly true for all products made from new materials or with electronic parts, for electronic control systems, assistance systems and any

[10] According to Article 60(2) of Regulation (EU) 2018/858, European type approval law distinguishes between systems, components, separate technical units, parts and equipment.
[11] Sigulla/Visser "Künstliche Intelligenz und Versicherung", Phi 2018, p. 197 ff.

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other digital implementation that functions and functionalities may have.[12] To put that into context, the automotive industry's demand for semiconductors is growing rapidly. According to studies by the ZVEI (*Zentralverband Elektrotechnik- und Elektronikindustrie* – German Electrical and Electronic Manufacturers' Association), 95 percent of all automotive innovation is driven by semiconductors. Driving this growth are the launch of 5G networks, the next and more interconnected generation of vehicles as well as technologies operating with Artificial Intelligence.

Only a few years ago, semiconductors used in the automotive industry were worth USD 100 per car. Today, their value lies at USD 350 and is expected to rise to an average of USD 1,000 by 2025 – a figure that some luxury cars already reach today. E-mobility and the rise of automated driving functions are fuelling this development.[13] Experienced IT specialists are needed to realize the innovation push that lies in these new electronic components, but they are becoming an increasingly rare breed. The automotive industry is "currently among the sectors, in which the search for IT specialists is most intense and happening under particularly high pressure"[14] because of the industry's ever shorter innovation cycles. This discrepancy between available electronic technologies that can be applied in any number of cases and the lack of specialists capable of applying them properly bears development risks that may become virulent after the product has been placed on the market.

This may have serious consequences, as shown by an accident with an Uber car in Arizona.[15]

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[12] The European legislator has now drawn far-reaching conclusions from this situation. The new Directives on contracts for the sale of goods to consumers, Directive 2019/770 (Official Journal of the European Union of 22.5.019 L 136/1) and Directive 2019/771 (Official Journal of the European Union of 22.5.2019 L 136/28), concern goods „with digital elements" and set the benchmark for a comprehensive assessment of compatibility, interoperability, durability and functionality. They explicitly refer to the application of technical standards when assessing a consumer good's objective conformity with the contract. For further details see Helmig, "Die neuen Richtlinien zum europäischen Verbraucherkaufrecht", IWRZ 2019, p. 200 ff.; the English version, "The new Directives on European sale of consumer goods law" is available online: https://www.ra-helmig.de/publications/?L=1

[13] https://www.automobilwoche.de/apps/pbcs.dll/article?AID=/20191206/BCONLINE/191209929/1334/weltweiter-halbleitermarkt-warum-sich-die-automobilindustrie-abkoppelt (acc. 7.12.2019).

[14] Report of the industry association Bitkom in *Automobilwoche* No. 26 of 9.12.2019, p. 8. In addition to this lack of IT specialists, most engineers do not possess sufficient IT knowledge, although they are responsible for implementing the IT specialists' contributions, see *Handelsblatt online*: https://www.handelsblatt.com/politik/oekonomische-bildung/hochschullehre-ingenieuren-fehlen-haeufig-it-kenntnisse/25318246.html (acc. 11.12.2019).

[15] After conducting a comprehensive investigation into the accident, the competent US agency, the National Transportation Safety Board (NTSB), criticized above all the insufficient safety culture regarding the car's technology: „The NTSB determined that the immediate cause of the collision was the failure of the Uber ATG operator to closely monitor the road and the operation of the automated driving system because the operator was visually distracted throughout the trip by a personal cell phone. Contributing to the crash was Uber ATG's inadequate safety risk assessment procedures, ineffective oversight of the vehicle operators and a lack of adequate mechanisms for addressing operators' automation complacency – all consequences of the division's inadequate safety culture,";

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A similar dilemma presents itself when, in light of a specific intended use, the product's life span or durability, or that of its materials, are determined and required by contract or law.[16]

The ambiguity that comes with the terms "durability" and "(normal) life" of a vehicle and its materials cannot be dealt with conclusively at this point. Commission Regulation (EU) 2018/1832 of November 5, 2018, for example, describes those terms within the context of emission control devices.[17] The underlying assumption of the term "durability" is that if the durability of pollution control devices is verified within the time frames or mileage laid down in Article 9 of Regulation 2017/1151, it is also assumed to last for the vehicle's entire life.[18]

It is a crucial characteristic of the testing clause's application that neither Union law nor technical standards nor state-of-the-art science and technology provide reliable methods or procedures that would allow for certainty as to how safety and durability requirements may be met within the context of "durability" and "life".[19] Practitioners have found a way through working with assumptions. In a nutshell, they determine certain test types based on empirical testing and experience and consider the results from this, gathered over a certain period of time, as reliable proof of a vehicle's assumed lifespan and/or a component's durability. To this end, Regulation 2017/1151, for instance, draws on the provisions of UN/ECE Regulation No 83, which assumes a durable lifespan of up to five years or a mileage of 100,000 km if a vehicle, specifically aligned with the test type, meets the testing requirements at the moment of testing. It is impossible to derive any meaningful "state of the art" from this

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https://www.ntsb.gov/news/press-releases/Pages/NR20191119c.aspx. The system that Uber used was unable to detect a pedestrian with a bicycle 5.6 seconds before the fatal accident. Apparently, the safety device "Reflex" was turned off at the time of the collision because it had led to frequent and annoying activation of the breaks (see *Automotive News* of 18.11.2019, p. 36). All over the world there is a lack of clear statutory regulations, which could not have come into existence (yet) as sufficiently safe technologies are still missing.

[16] In the automotive industry, specifications usually require a product life span of 300,000 km or 15 years.

[17] Commission Regulation (EU) 2018/1832 of November 5, 2018, amending Directive 2007/46/EC of the European Parliament and of the Council, Commission Regulation (EC) No 692/2008 and Commission Regulation (EU) 2017/1151 for the purpose of improving the emission type approval tests and procedures for light passenger and commercial vehicles, including those for in-service conformity and real-driving emissions and introducing devices for monitoring the consumption of fuel and electric energy; Official Journal of the European Union of 27.11.2018 L 301/1.

[18] The relevant provisions of UN/ECE Resolution No 83, too, suffer from these vague assumptions. In the context of the Type V Test, point 1.2 assumes that the whole vehicle durability test represents an aging test of 160,000 km and this test is to be performed driven on a test track, on the road or on a chassis dynamometer.

[19] For instance by using the Weibull Analysis method (https://www.weibull.com/knowledge/milhdbk.htm) or similar established procedures used in aviation, astronautics and medical engineering.

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because the relevant statutory requirements are not guided by any definition of state of the art.

Innovation is always a projection into the future: with respect to development and use, innovation must first stand the test of reality so that our expectations of products can be confirmed.[20] Pressure from marketing expectations for emerging technologies is not conducive to market maturity. If the product later fails a reality check and gives rise to liability claims, the issue of insurance coverage will always also revolve around whether the testing clause is applicable and the relevant point in time to determine its applicability. [21]

The relevant time factors

What is the relevant point in time to determine (i) the relevant specific intended use; (ii) the state of the art relative to the intended use; (iii) the state of the art at the time when the final product, which is equipped with the part, is placed on the market; (iv) the state of the art in a later liability event?

(i)

The specific intended use is determined through an agreement between the seller

[20] On this issue see: Helmig, "Autonomes Fahren: Konflikt zwischen Basis- und Zukunftstechnologie", Phi 2016, p. 188 ff.; the English version, "Safety expectations for automated and autonomous vehicles: liability arising from basic technology vs. future technology", is available online: https://www.ra-helmig.de/publications/?L=1. This perception is on the rise against the backdrop of experiences with new electric and electronic products: The standard ISO 26262:2018 reflects the current technological state of the art and deals with functional safety of vehicles at the vehicle's system level, without taking into account the entire technological architecture of the whole vehicle. After numerous failures, fatal accidents and successful hacking attacks, more thought is now being put into creating more realistic safety assessments. ISO 26262:2018 is now supplemented and developed further by ISO/PAS 21448:2019 (E) in order to assess the effectiveness of electric and electronic systems that were developed in accordance with ISO 26262:2018 in practice: "The absence of unreasonable risk due to hazards resulting from functional insufficiencies of the intended functionality or by reasonably foreseeable misuse by persons is referred to as the Safety Of The Intended Functionality (SOTIF). This document provides guidance on the applicable design, verification and validation measures needed to achieve the SOTIF. This document does not apply to faults covered by ISO 26262 series or to hazard directly caused by the system technology (e.g. eye damage from a laser sensor). This document is intended to be applied to intended functionality where proper situational awareness is critical to safety, and where that situational awareness is derived from complex sensors and processing algorithms; especially emergency intervention systems (e.g. emergency braking systems) and Advanced Driver Assistance Systems (ADAS) with level 1 and 2 on the OICA/SAE standard J3016 automation scale."

[21] While ISO 26262 is limited to systems, ISO/PAS:2019 "Road vehicles – Safety of the intended functionality" deals with the systems' effectiveness in reality: Is a sensor capable of detecting a given obstacle at all and can it identify the obstacle for the appropriate safety-related response? At present, these questions remain open. ISO 20077:2017 (1 and 2) "Road vehicles – Extended methodology", ISO 20078:2019 (1-3) "Road vehicles – Extended vehicle web services" (connected vehicles) and ISO 20080 "Road vehicle – Information for remote diagnostic support – General requirements, definitions and use cases" all deal with these issues.

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(who is also the insurance holder in our case) and a buyer from the next level in the supply chain.

(ii)

Regarding the state of the art relative to the intended use, the time of the final conclusion of the contract is decisive. The underlying criteria of this state of the art, however, remain uncertain. Any understanding of state of the art that has been determined at a specific point in time comes with an element of the past, from which it continued to develop until the final conclusion of the contract and the agreed intended use. This will be dealt with in more detail below.

(iii)

If one were inclined to follow the prevailing opinion, i.e. that it is irrelevant when, where, how and by whom insufficient testing was detected, one might also look at the state of the art at the time when the buyer places the product on the market after having integrated the part.[22] This option must be ruled out, in my opinion, when determining the testing clause's applicability because it would burden the insurance holder as initial seller with incalculable risks created through the buyer's processing and use of the part, although the insurance holder does not participate in these processes.

(iv)

This problem presents itself even more strikingly when the testing's insufficiency is only detected in the field after the final product, developed in a coordinated downstream supply chain, has been marketed, and thus with a considerable time gap between the detection and the final conclusion of the contract. Between the time of the conclusion of the contract between the seller (insurance holder) and the buyer and the actual event that must be assessed in light of the testing clause lie several technological development steps, because every supply chain level usually comes with the next level of processing or applying the product for the next level thereafter. Any expert witness, who was asked before a court to determine the technological state of the art at the time when the final contract on the contested product was concluded, would draw on his current expertise at the time of the objection against covering the damage. The insurance holder thus faces the risk that new technological advancements will feed into this *ex post* determination of what the state of the art was at the time when the contract was concluded, although they had not existed at that time. This is an inevitable consequence of the fact that it is not only

[22] In this context, the product's defectiveness will play an important role, too, if the final manufacturer promotes the product with advertisements depicting uses beyond the part's specific intended use and, therefore, issues regarding the sufficiency of the testing arise at a basic level with respect to potential ways of using the product.

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objective facts that count when determining the state of the art, but also subjective assessments.

Ultimately, the state of the art at the time of the conclusion of the contract between the insurance holder and the buyer is the relevant factor, but it is hardly possible to determine it with certainty in retrospect.

What is „specific intended use"?

According to the Federal Court of Justice's (*Bundesgerichtshof* – BGH) jurisprudence, only „the envisaged type of use" is relevant when determining a product's specific use that is agreed in the bilateral contract between seller and buyer and according to Section 434(1) sentence 2, number 1 of the German Civil Code (*Bürgerliches Gesetzbuch* – BGB).[23] This BGH jurisprudence leads to a "fitness for purpose dilemma" concerning the testing clause's inherent notion that sufficient testing will ensure with certainty that the predefined targets will be met.

Following this logic, the feature "the use specified in the contract" in Section 434(1) sentence 2, number 1 BGB would not aim at "the *specific features* of the purchased thing, which the buyer imagines it will have, but at whether the thing is suited for what the buyer wants to *use* it for (type of use) and whether this is *discernible* for the seller."[24] The BGH thus deems the seller's perception and cognizance the decisive factor, i.e. how he, the seller, could and was allowed to understand the buyer's description of the product's intended use. Accordingly, from the BGH's point of view, any inadequacy in the buyer's description of the specific intended use is to the disadvantage of the buyer.[25]

The dilemma: In practice, as the case before the BGH has shown, the industrial world hardly makes a razor-sharp distinction between "feature" and "use" and – as I will address below – this distinction cannot be found in the relevant rules and regulations. Nonetheless, the parties perform the contract of sale. The dissent in the legal sense, however, remains. To the author's knowledge, there is no point of reference for the assumption that the term "use", which has been a part of the testing clause since 1973, is and has been understood as encompassing the BGH's distinction from its 2019 judgment between the *use discernible* for the seller (type of use) and the *specific features* of the thing purchased from the buyer's perspective.[26]

[23] BGH, judgment of 20.3.2019, VIII ZR 231/18, marginal number 29, NJW 2019, p. 1937, 1938.
[24] BGH, judgment of 20.3.2019, VIII ZR 231/18, marginal number 29, NJW 2019, p. 1937, 1938.
[25] Palandt/Ellenberger, *BGB*, 78th edn., 2019, § 133 BGB, marginal number 9.
[26] Thürmann/Kettler, *supra*, do not address this issue, probably because the new edition of their book was already in print when the judgment was handed down. The judgment quoted by them (Fourth

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The new BGH jurisprudence, however, is now essential to the application of the testing clause.

A very simplified practical example:

The manufacturer is a so called system supplier[27] and supplies a plastic product. The buyer's specifications state that the product's specific purpose is its use in an exhaust gas system[28] and provide critical levels that the buyer assumes. The specifications impose testing obligations on the supplier and expressly state that the tests specified by the vehicle manufacturer are not binding and do not relieve the supplier from his development responsibility as a system supplier. The plastic product itself is a passive component and does not have any steering or control function within the exhaust gas system. The manufacturer of this passive plastic component is not in a position to assess the part's fitness for purpose under the operating conditions of the next system level, i.e. the emission control unit requiring type-approval, and under real in-service conditions of the entire vehicle because he lacks the necessary testing capabilities.

Under the actual in-service operating conditions of the exhaust gas system the plastic product then fails in the field after the start of production (SOP) for systemic reasons, not because of its quality: from the vehicle manufacturer's point of view, the product has proven unfit for its specific intended use in the vehicle, which was not discernible to the supplier. The insurer then considers invoking the testing clause, arguing the plastic product's unfitness according to the vehicle manufacturer's opinion indicates insufficient testing. In practice, this conflict is the rule. Generally speaking, this is true not just for plastic components, but also for electric and electronic components.

State-of-the-art testing in rules and regulations

There is no generally applicable product- or usage-specific technological state of the art. There are only standards for defined products. In some cases, these standards

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Panel of the BGH, judgment of 9.1.1991, VersR 1991, p. 414 – liquid gas facility) does not mention this distinction.

[27] This term is primarily used in the automotive industry, usually by customers at the next processing level, in order to attribute development responsibility in liability recourse cases revolving around the entire system, which is equipped with the part, and thus to attribute responsibility that, at the time when the order was placed, the supplier originally did not have and could not have assumed.

[28] „Pollution control devices" as components of a vehicle that control and/or limit exhaust and evaporative emissions, see UN/EC 83, Official Journal of the European Union of 15.2.2019 L 45, point 2.12.

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have become part of statutory regulations.[29] Over the course of decades, the industry developed globally applicable standards for development and production processes in order to create compatibility, certainty and reliability in cooperative global supply networks. The processes set out in these standards can serve as a source for determining the state of the art: its meaning is always guided by development and production processes and follows an essentially easy pattern of questions: What is the solid foundation of any given assumption, for example, for the assumption that certain safety requirements have been met? Based on how reliable a set of conditions were the necessary data (that is, necessary according to the target, i.e. the specific intended use) selected from a complex environment? How are the conclusions, based on results from the data selected in accordance with the target definition, but drawn from the development results, verified and validated? What are the documented and reliable production requirements to ensure the safety goal is met and what mechanisms are in place to ensure the production result fulfills its purpose in view of the specific intended use?

DIN EN ISO 9001:2015

DIN EN ISO 9001:2015 is a prominent example.[30] Pursuant to Recital 42 of Regulation 2018/858[31], this standard is "one of the cornerstones of the EU type-approval system."[32]

The standard takes as its basis the downstream supply chain. It imposes shared responsibility for the final product on all participants of the supply chain, relative to their own level of production, when it states that every participant must take into account the "interaction"[33] of the various steps taken in the supply chain.

[29] Basis for Regulation (EU) 1025/2012 of 25.10.2012 on European standardisation, Official Journal of the European Union of 14.11.2012 L 316/12.

[30] „Quality management systems – Requirements". Compliance with this harmonized standard is a precondition for a vehicle's fitness to get type approval („conformity of production"), as currently determined by Annex X to Directive 2007/46/EC, then, as from September 15, 2020, Annex II to the then-applicable Type Approval Regulation.

[31] Official Journal of the European Union of 14.6.2018 L 151.

[32] By comparison with the now applicable ISO 9001:2015, its predecessor ISO 9001:2008 was less abstract. The same is true for the predecessor of IATF 16949. Since the basic principles have not changed in the revisions, reading the old versions greatly facilitates understanding these standards.

[33] In this paper, the term "interaction" refers to the process-oriented approach of DIN EN ISO 9000:2015 (chapter 4.4.1), a standard for quality management systems applicable in the EU that will be examined in more detail later in this paper. Point 3.4.1 (Note 2) of DIN EN ISO 9000:2015 defines: "Inputs to a process are generally the outputs of other processes and outputs of a process are generally the inputs to other processes." It is the various technical processes within a supply chain (within which the success of any given process depends on the outcome of the previous process) that interact with each other. Legally, the requirement to take into account the interaction between different processes is directly connected to the intended use specified in the contract.

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The “process approach” of the standard thus considers “processes in terms of added value” pursuant to Point 0.3.1 lit. b). According to Chapter 8.2.3.1, the organization (in our case the insurance holder as supplier) “shall ensure that it has the ability to meet the requirements for products and services to be offered to customers.” In order to do so, the supplier is required to review and assess: “a) requirements by the customer, including the requirements for delivery and post-delivery activities; b) requirements not (sic!) stated by the customer[34], but necessary for the specified or intended use, when known (sic!); […] d) statutory and regulatory requirements applicable to the products and services[35].” These customer requirements “shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements”, for instance in requirement specifications or any other specification.

An aside:

These requirements will become immensely important: with Regulation (EU) 2019/2144 of November 27, 2019, the EU legislator has supplemented the new Type Approval Regulation (EU) 2018/858 and expanded it to essential components of new technologies.[36] Regulation 2019/2144 sets out strict requirements, particularly concerning “advanced vehicle systems for all motor vehicle categories” (Article 6) and advanced emergency braking systems (Article 7). Article 4 of this Regulation, which will apply from July 6, 2022, reinforces the reversal of the burden of proof that has already been introduced by the Type Approval Regulation 2018/858: pursuant to this provision, manufacturers will now have to demonstrate “that all new vehicles that are placed on the market, registered or entered into service, and all new systems, components, and separate technical units that are placed on the market or entered into service, are type-approved in accordance with the requirements of this Regulation and of the delegated acts and implementing acts adopted pursuant to it.”

[34] This requirement of the standard deviates from the BGH’s opinion as expressed in its judgment of March 20, 2019, (VIII ZR 231/18, marginal number 29, NJW 2019, p. 1937, 1938), according to which the decisive factor is supposed to be the seller’s understanding of the buyer’s intended use of the product. The standard requires the supplier enquire comprehensively about the intended use because the supplier, for the most part, possesses greater expertise on the details of his product. In practice, there is usually no congruent obligation to respond on the part of the buyer – and the standard does not explicitly require a response either. With the wording “when known”, the standard inconsistently accepts the possibility that a product’s intended use and the system into which it will be incorporated will not match.

[35] For example, Regulation 661/2009 of 13.7.2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor, Official Journal of the European Union of 31.7.2009 L 200/1; German Product Safety Act (*Produktsicherheitsgesetz*) etc.

[36] Official Journal of the European Union of 16.12.2019 L 325. Regulation (EC) 661/2009 is thus repealed as from July 6, 2022.

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According to Article 4(4), manufacturers must "ensure that vehicles are designed, constructed and assembled so as to minimise the risk of injury to vehicle occupants and vulnerable road users."

Manufacturers must ensure compliance with all delegated acts pursuant to the Regulation and with all procedures and technical specifications laid down by implementing acts adopted pursuant to it, including protection against cyber attacks. This poses a problem and to a great extent explains why the Regulation will take effect so late: from January 5, 2020, the Commission must draft the implementing acts that are supposed to apply from July 6, 2022. Yet, the Commission can hardly be said to have the technical ability to spell out all the requirements vis-à-vis procedures and technical specifications (which do not automatically fall within the scope of European harmonized standards). In addition to the expert panels set up by the Commission, it will rely on borrowing expertise from the industry. A race to meet targets is to be expected. The ambitious statutory provisions must be met with equivalent technical development results that are fit for type approval. From today's point of view, there is hardly any room left for the testing clause. There are more and better reasons to believe that clause 6.2.4 (deviation from written agreements, including those on procedures and processes) will come to the fore. Manufacturers and suppliers of advanced systems will have to focus on this.

Chapter 8.3 regulates the design and development process of manufactured items. This process must already ensure the conditions required for realizing the intended use. To this end, Chapter 8.3.2 lit. c) requires the organization consider "the required design and development verification and validation activities" during development planning.[37] Chapter 8.3.4 supplements these requirements and lays down "Design and development controls". The supplier is thus required to coordinate control processes with the customer and ensure that, "c) verification activities are conducted to ensure that the design and development outputs meet the input requirements" (i.e. the agreed specific intended use, author's note), and that "d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use". Chapter 8.3.5 on "Design and development outputs" requires the supplier ensure that the design and development

[37] According to DIN EN ISO 9000:2015, Chapter 3.8.12, Verification means "confirmation, through the provision of objective evidence, that specified requirements have been fulfilled", and thus evidence by the supplier that all requirement specifications have been fulfilled. As per DIN EN ISO 9000:2015, Chapter 3.8.13, Validation means "confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled", and thus evidence by the customer that the requirement specifications have been fulfilled. These standard terms also describe the aforementioned mutual communication process between supplier and customer, whereby both sides confirm the product's compatibility in terms of function (at supplier level) and functionality (at customer level). Any deviations lead to the conclusion that the specified intended use has not been achieved.

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outputs “d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.”

Drawing on established and agreed product development processes to elucidate the meaning of the term “state of the art” in light of a product’s specific intended use at the bilateral level between supplier and customer, the term thus contains at least two elements with legal relevance: (i) the specifications, which must be as precise as possible and targeted towards achieving compatibility of all technological parameters; and (ii) the determination of identical testing methods, procedures and instruments according to methods that are acknowledged by the relevant standards, for instance statistical process control (SPC) or the Failure Mode and Effects Analysis (FMEA). The resulting data can – ideally – generate key figures for End of Line (EOL) tests that, if they are documented, can provide the customer with verifiable certainty that the delivered products conform to the specific intended usage requirements as agreed in the contract. Processes that are coordinated along those lines are generally suited to avoid the “fitness for purpose dilemma” that the courts have left open, but only if the strict distinction that the cited jurisprudence makes between features and use (type of use) is adjusted to match reality and the targets within a downstream supply chain.

In practice, the necessary process discipline, based on transactional technical communication, is rarely observed. This is essentially the reason behind increasing recall numbers and the ensuing liability cases. The European legislator has recognized this shortcoming and reacted to it. The existence of an effective quality management system in accordance with DIN EN ISO 9001:2008 (“conformity of production”) has been a prerequisite for vehicle manufacturers in order to even be allowed to produce vehicles fit for type-approval since Directive 2007/46/EC establishing a framework for the approval of motor vehicles entered into force in 2007.

As from September 1, 2020, the new Type-Approval Regulation (EU) 2018/858[38] will replace this Directive. In Article 31, the new Regulation adopts the requirement of a quality management system in accordance with DIN EN ISO 9001:2015 (Annex IV) with an extended scope.

As a consequence, Article 60 codifies the required communication process of the quality management system with its state-of-the-art processes (“Information intended for manufacturers”):

“1. Manufacturers of vehicles shall make available to the manufacturers of systems, components, separate technical units, parts or equipment all particulars that are

[38] Official Journal of the European Union of 14.6.2018 L 151.

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necessary for EU type-approval of systems, components or separate technical units or to obtain the authorisation referred to in Article 55(1). […]

2. Manufacturers of systems, components, separate technical units, parts or equipment shall provide the manufacturer of vehicles with all detailed information on the restrictions that apply to their type-approvals and that are either referred to in Article 29(3) or imposed by a regulatory act listed in Annex II."

General proposed definition for "state of the art"

For the purposes of the testing clause, state of the art – if one were inclined to use the term at all – could be defined as follows:

State of the art shall mean the determination, documented according to statutorily stipulated or contractually agreed rules and regulations produced by recognized standardizing organizations, of specific development and production processes for a product, whose parameters simulate the actual operating conditions of the product realistically in view of its specific intended use as per statutory provisions. The same meaning of state of the art shall apply to modifications and adjustments of the product and to its specific intended use.

This wording puts the testing clause in more concrete terms. It is clear and transparent for every insurance holder. The indeterminate legal concept of "insufficient" testing does not need to be included, because compliance with the processes set out in the rules and regulations already encompasses the scope and depth of sufficient testing.

This is why, in my opinion, insurance contracts can do without the testing clause when the insurance holder is a supplier for products with a complex downstream supply chain. As a result, the insurer could no longer object to providing coverage based on insufficient testing. This does not create any disadvantage, because the insurer could invoke an exclusion that, in my view, is far more effective: the exclusion pursuant to Point 6.2.4 ProdHB ("Deliberate deviation from provisions or instructions/conditions"). The technical rules and regulations of, for instance, DIN EN ISO 9001:2015 or ISO 26262 almost always form an integral part of the contracts between manufacturers and their suppliers. They are industrial standards and, as far as DIN EN ISO 9001:2015 is concerned, statutorily binding according to Annex IV to Regulation (EU) 2018/858. Any violation of these standards can lead to an exclusion of coverage according to Point 6.2.4 ProdHB. The insurer's burden of proof is facilitated because the insurance holder, but in this case also the claimant, must prove the existence of the entire relevant process documentation, which is (or at

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least should be) available to them anyway.[39] This approach will increase manufacturers' and suppliers' process discipline, which should lead to fewer liability cases as a result.

If the actors involved in the development process wish to invoke the relevant rules and regulations, then they are compelled to comply with the necessary process discipline on the whole and to document their compliance in a way that is comprehensible and reliable to independent third parties. DIN EN ISO 9001:2015 explicitly requires (in Chapter 1 "Scope", Note 2) statutory and regulatory requirements be considered as legal requirements. In Chapter 4.3, the standard prevents any party from selectively invoking it: "Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction."

Conclusions:

1.
The term "state of the art", as used in the currently applicable testing clause, needs to be put in more concrete terms by including a product-specific reference to rules and regulations produced by recognized standardizing organizations which are statutorily applicable or which are agreed-on by the contracting parties.

2.
The testing clause is not necessary, at least not with respect to parts in a complex and disruptive downstream supply chain.

3.
The insurer's interest to not cover insufficiently developed or manufactured products is effectively protected through the exclusion of coverage according to Point 6.2.4 ProdHB.

Translated from German into English by

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Quotes from German courts, legislation, literature etc.
have been freely translated by the translator.

[39] Thürmann/Kettler, *supra*, p. 236, provide an appropriate and classic example: An insurer rightly invoked exclusion of coverage because the insurance holder failed to notify his customer, in deviation of the agreed conditions (in this case in particular VDA 2), of a modification he had carried out on a capacitor that had proven defective.

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