VDMA-Position

Technical affairs and Standardization

Status: 5 September 2023
On Case C-588/21 P, Public.Resource.Org, Inc, Right to Know CLG v. European Commission
Here conclusions of Advocate General Laila Medina, provisional version

The VDMA represents more than 3,600 German and European companies in the mechanical and plant engineering sector, making it the most important industrial association in Europe. As a platform of 36 sectoral associations, it represents the entire value chain of the capital goods industry - from components to complete plants, from system suppliers to service providers, from communicating machines to self-organizing logistics.

The VDMA finances and staffs the Mechanical Engineering Standards Committee (NAM), which was founded on 11 March 1949. The NAM is responsible for national, European and international standardization work in the field of mechanical engineering. In the same way, the Machine Tools Standards Committee (NWM), with which the NAM cooperates closely, is also affiliated to the VDMA. In the 2022 business year, the NAM managed 15 CEN/TC secretariats and 20 ISO/TC or ISO/SC secretariats. In more than 70 years of practice of the Mechanical Engineering Standards Committee, the close organizational connection of the NAM to the VDMA with its trade associations has proved to be a guarantee for standardization work at a high level of quality.

The VDMA is following Case C-588/21 P with great interest because several fundamental elements of standardization work are affected. As the VDMA has been successfully involved in standardization for many decades, we would like to contribute our expertise regarding standardization and the legal basis. The Advocate General's Opinion relates in particular to harmonized standards, the references of which are to be published in the EU Official Journal so that these standards can be given the presumption of conformity with harmonized standards. The VDMA has therefore taken note of the preliminary version of the Advocate General's opinion. In our view, a number of points need to be corrected. These corrections have a considerable influence on the conclusions. In addition, the legal provisions of the CE marking regulations must also be used as a yardstick for a factually correct consideration and analysis. These provisions were not sufficiently taken into account in the arguments and conclusions. The mere reference to the provisions of the standardization regulation is not sufficient.

The VDMA does not comment on a possible misinterpretation of Regulation No. 1049/2001 or on the legality of the copyright protection of standards.

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Legal basis for the analysis
The VDMA comments on the legal basis of standards under the New Legislative Framework (NLF) including Regulation (EU) No 1025/2012. The NLF successfully continues the New Approach to technical harmonization from 1985. On the basis of the NLF, the rules for CE marking are developed. The model provisions of Decision 768/2008 are regularly applied. The Machinery Directive 2006/42/EC was also revised on the basis of these model provisions. On 29 June 2023, the new Regulation (EU) 2023/1230 was published in the Official Journal of the EU. When assessing whether harmonized standards can be part of Union law or whether their application can be de facto mandatory, the provisions of the CE marking regulations and explanations of those provisions are crucial. On the other hand, relying solely on the provisions of the 2012 Standardization Regulation (Regulation (EU) No 1025/2012) is not sufficient for the assessment.

Harmonized standards are supposed to be part of Union law
The "James Elliott judgment" cited by the Advocate General mentions that standards are supposed to be part of Union law. However, the "James Elliott judgement" is about a case concerning the Construction Products Directive. However, this provision differs significantly from other internal market legislation, as it provides for mandatory application of harmonized standards. No other internal market provision on CE marking of products has such an obligation. The application of standards is always voluntary under the provisions of these other internal market rules. Therefore, the example given by the Advocate General is misleading and cannot make any factual contribution to clarifying the actual question. It should also be made clear that the certification of products must not be mixed with standardization or the application of standards. Certification, when provided for by law, is part of the conformity assessment procedure for which the manufacturer has overall responsibility. The manufacturer shall involve a third party in the conformity assessment procedure if required by law or on a voluntary basis. Furthermore, the type of conformity assessment may not be determined by standards (see decisions of CEN, CENELEC, ISO and IEC). This determination is made exclusively by the legislator - i.e. through provisions in regulations for the marketing of products.

The Conclusion claims that compliance with the essential requirements of Union law (rules on the marketing of products) would in practice be achieved exclusively, or at least in the vast majority of cases, through the application of harmonized standards. It is also claimed that other types of evidence or other measures, such as those shown in the harmonized standards, would be too costly or burdensome for manufacturers to meet the essential requirements of Union law. Furthermore, it is claimed that the application of harmonized standards should be de facto mandatory. However, it is acknowledged that the application of harmonized standards is de jure voluntary.

First: Application of the state of the art
According to the legal provisions of the Machinery Directive, the application of harmonized standards is voluntary. Furthermore, these provisions stipulate that, as a first step, the manufacturer must take protective measures on machinery which must correspond to the state of the art in order to comply with the essential Health and Safety Requirements of Annex I of the Machinery Directive 2006/42/EC, see 2006/42/EC, Annex I, general principles, No. 3). The state of the art is regularly reflected in standards. These can be international standards (ISO or IEC standards), European standards (EN), national standards (e.g. DIN) or harmonized standards (hEN). The state of the art may also be documented in consortium papers. One example is VDMA Standard 13463-4, published in 2009, which contains the state of the art for certain protective measures for agitator vessels and mixers for intended use in potentially explosive atmospheres in accordance with the ATEX Directive.

For pressure equipment covered by the scope of the Pressure Equipment Directive 2014/68/EU, the state of the art for protective measures or the design of pressure equipment is often taken from national specifications, such as the AD-2000 rules from Germany or the CODAP from France. These protective measures are regularly accepted by notified bodies of the EU. Thus, the state of the art contained in these national specifications is also recognized by the experts for pressure equipment for the purpose of fulfilling the essential requirements of Union law.

In the field of surface technology, VDMA Specifications, i.e. consortium papers, have been used by manufacturers for many years in order to be able to take measures that correspond to the state of the art and thus fulfil the regulations for CE marking for these products. The measures described in the VDMA Specifications concern the most diverse types of hazards, such as mechanical, electrical, thermal and fire hazards, to name but a few. For this purpose, we name the following VDMA Specifications:

- VDMA 24389:2012, Blasting technology – Dry-ice blasting equipment
- VDMA 24362:2021, Surface Technology – Obliquely ventilated spray booths
- VDMA 24392:2020, Automatic coating powder supply systems
- VDMA 24393:2020, Surface Technology – Automatic flame treatment booth
- VDMA 24394:2022, Surface Technology – Touch-up stations at paint spray booths for powder coating – Safety requirements
- VDMA 24395:2021, Surface Technology – Flash-off booths
- VDMA 24388:2019, Blasting technology – Fire and explosion protection
- VDMA 24391:2015, Surface Technology – Machinery for plasma surface treatment

Secondly: Application of the presumption of conformity of harmonized standards
After the manufacturer has taken measures which correspond to the state of the art in order to meet the essential requirements of Union law, the presumption of conformity can be

claimed in a second step if the measures taken were taken from harmonized standards. Therefore, the two facts, i.e. the application of the state of the art and the claiming of the presumption of conformity based on the application of harmonized standards, must be strictly separated. It should also be noted that the application of the state of the art has priority over the claim of presumption of conformity. From this point of view, the application of the state of the art is the "duty", the use of a possible presumption of conformity is the "free exercise".

Maintaining international connectivity
Mechanical engineering is very export-oriented, so many standards are developed and published at ISO or IEC level. Many of these standards are also published as EN standards. The references of some of these EN or EN ISO standards are published as harmonized standards in the Official Journal of the EU. In order not to lose international connectivity, the VDMA attaches great importance to the statement that the practice mentioned in this paper must be recognized and that these practices must be maintained.

If harmonized standards were considered to be part of Union law, this could promote the rejection of these standards in regions outside the European Economic Area or even lead directly to rejection there. For with the recognition of these otherwise technical contents of the standards, actors in the above-mentioned regions, including authorities based there, could also infer the recognition of Union law, which, incidentally, would be entirely in line with the Advocate General's presentation. However, this erroneous impression is effectively avoided by the practice that has been in place until today.

Standards are technical content and requirements for which there is also a global need for harmonization due to global markets and supply chains. This global need for harmonization can be achieved gradually through technical standards, as many years of practice have shown. The global harmonization of regulations for the marketing of products, on the other hand, is a hopeless undertaking, not least because of very different legal structures in the individual regions. In addition, the competitiveness of the mechanical engineering industry in the global environment is seriously endangered by the interpretations in the final motions that require correction and would destroy the international connectivity of the standards.

No de facto obligation to apply standards
The Advocate General's submissions argue that there should be a de facto obligation to apply standards. It is argued that the costs of proof for measures that are not based on harmonized standards are disproportionately high. However, this is precisely not the case. For the mechanical engineering industry, the use of alternative solutions, i.e. solutions that are not prescribed by standards, is of fundamental importance. Many customers procure machines for a specific purpose. Such machines are often built as one-offs or produced in small series. Therefore, no standards are available for such machines. The creation of standards for machines of this type would not be economically feasible, and it would come

much too late to fulfil the order. Customers are not willing to wait for machines that could only be designed and built after a standard has been drawn up.

Furthermore, new protection concepts are regularly used in mechanical engineering that are not yet the subject of standards. Manufacturers must therefore assess these protective concepts against the essential Health and Safety Requirements of Annex I of the Machinery Directive and compare the safety level with comparable protective concepts from standards.

For some types of machines, although they are produced in large series, no machine-specific standards are available. This may be due to various reasons. In such cases, manufacturers must take the measures without the support of standards in order to be able to meet the essential Health and Safety Requirements of Annex I of the Machinery Directive. In some cases where no machine-specific standards are available, so-called type B standards are applied, which cover a specific safety aspect or a specific Health and Safety Requirement of Annex I of the Machinery Directive. However, other Health and Safety Requirements applicable to the machinery are not covered. These requirements are then to be fulfilled by the above-mentioned alternative measures, which are not the subject of a standard.

Market surveillance
The surveillance of the market and of the products placed on the market is the responsibility of the competent authorities in each Member State. Users do not exercise control in this context. If users carry out controls on products, this is indisputably done in their own interest or to protect their own interests. An obligation for users to carry out controls would, moreover, turn the entire legal system upside down, with manufacturer obligations, conformity marking and declaration, and market surveillance as a sovereign task.

In this context, it is also worth recalling the essential elements of the internal market based on Union law. With the conformity marking and the EU Declaration of Conformity, the manufacturer indicates that the product complies with all CE marking provisions applicable to the product. The manufacturer's Declaration of Conformity is based on the conformity assessment procedure, irrespective of whether an external testing body has been involved or not. If market players or users were to fundamentally question or doubt the conformity marking of products, for example, this would be tantamount to questioning the presumption of conformity of the EU conformity marking and, as a result, would also call into question this part of Union law. Only the competent authority may challenge the presumption of conformity of the conformity marking of individual products, in particular where there is an initial suspicion and the technical assessment of independent experts who are not economic operators suggests this conclusion.

Mandate of the European Commission
The standards organizations are not merely vicarious agents of the EU Commission. The creation of a standard is a complex process that requires the involvement of experts and the

sounding out of the interests of stakeholder groups. These complexities and steps cannot begin to be reflected in a standardization mandate. However, these elements are crucial for the quality of the standards. The mandate of the EU Commission can therefore only be seen as a general order for the creation of standards, which is only filled with life through the standardization process and receives the necessary concretization through standardization.

The preparation of standards is regularly industry-driven. This applies both to the content of standards and to the structure of standards series. Neither mandates nor standardization roadmaps or other structural papers can take these important elements into account. Mandate money from the EU Commission does not change the high contribution of industry, which exceeds the financial contributions of the EU Commission many times over. Standardization would be inconceivable without this strong financial commitment from industry. Rather, the mandates show a clear interface between regulations or legislation and standards.

Examination of standards on the way to a harmonized standard
The examination of harmonized standards by the Commission takes place after the standard has been published by the respective standards organization. Therefore, the standards organizations do not prepare draft standards for release by the EU Commission. Rather, so far only the publication of the reference of the standard in the EU Official Journal takes place.

Current efforts by the EU Commission are intended to extend the examination of standards whose references are to be published as harmonized standards in the EU Official Journal and also to involve them in the drafting process. This creates a conflict of interest for persons who are supposed to examine the standards but are more or less involved in the drafting of the standards. Furthermore, the practice of first changes in the review of standards shows that these new procedures lead to considerable problems. A considerable backlog of standards is created whose references cannot be published in the Official Journal for procedural reasons. If further amendments are planned with a view to an even greater depth of review, the situation will become even worse and the congestion in the publication of references will increase.
Already today, there are a number of harmonized standards whose reference is still listed in the EU Official Journal, although the European standards organizations have already published or intend to publish updated versions of these standards. The updated version of a standard regularly also contains updates of measures that can be used to meet the essential requirements of the legislation and that reflect the state of the art at that time.

Consequently, the respective standards of older editions, the references of which are still listed in the EU Official Journal, can no longer reflect the state of the art. If the manufacturer were to focus only on the presumption of conformity when applying a standard, the manufacturer would not be able to comply with the legal provisions by applying these standards, which are no longer up to date. According to the legal provisions on CE marking,

however, the manufacturer must take protective measures that correspond to the state of the art. In the case of machinery, this is regulated by the provisions of Article 5(1) of the Machinery Directive in conjunction with the provisions in Annex I, General Principles, No. 3, which read as follows:

> "The essential health and safety requirements laid down in this Annex are mandatory; However, taking into account the state of the art, it may not be possible to meet the objectives set by them. In that event, the machinery must, as far as possible, be designed and constructed with the purpose of approaching these objectives."

Three aspects become clear through these cases from practice:

1) The first obligation of the manufacturer is to take protective measures to meet the essential requirements of Union law. In doing so, the manufacturer can apply norms or standards or take measures which the manufacturer has chosen alternatively and which also ensure the required level of protection. Only then is it a question of claiming the presumption of conformity in the case of the application of a harmonized standard.
2) Harmonized standards are not part of Union law, as the manufacturer can also take the state of the art for taking measures from standards that are not harmonized standards or the manufacturer takes the state of the art from standards, i.e. consortium documents, that are not standards that have been drawn up with the consensus of all social groups.
3) The depth of examination intended by the EU Commission for harmonized standards is clearly too great. Therefore, the tried and tested examination practice should be returned to in order to be able to effectively avoid the aforementioned congestion in the publication of the references of harmonized standards. Moreover, the funds currently set aside for a period of four years for the examination of harmonized standards by HAS- consultants will be used up prematurely if the intended depth of examination is to be implemented. This will then inevitably lead to an interruption of the publication of references in the Official Journal, as was felt in the period 04/2022 to 07/2023. The difficulties of the intended practice on the depth of examination, which can already be observed, also show that neither the EU Commission nor other EU institutions are technically and personnel-wise in a position to examine standards in the desired depth. The resulting problems, such as the jams in publication and the premature consumption of budgetary resources, should be noted in order to draw the necessary conclusions.

Formal objection

It is precisely the formal objection that proves that standards are not part of Union law. Union law and in particular the rules on the marketing of products are drawn up in the ordinary legislative procedure (co-decision procedure), in which the Council and Parliament are involved to discuss and amend the EU Commission's proposal. This differs significantly from

the standardization process, including the Commission’s mandate. The mandate is regularly drawn up after the rule has entered into force. This shows the clear separation between the law and the standards.

When Member States or the Commission raise a formal objection, they are not satisfied with the content of the harmonized standard against which the formal objection is to be opened, despite the mandate and despite the Commission's examination. If standards were part of the regulations, the formal objection would intervene in the legislative procedure afterwards, without involving all institutions that are usually involved in the ordinary legislative procedure. Formal objections are regularly raised without the involvement of the European Parliament. Furthermore, formal objections are raised in some cases because market surveillance checks reveal defects in the products covered by the harmonized standard, even though the manufacturer has taken all the measures that are the subject of the standard. In other cases, formal objections are raised by representatives of the Member States who were also involved in the standardization work, whose proposed amendments were not taken into account as they felt they should have been. Practice in the case of formal objections shows that this procedure is also influenced by findings from enforcement and in some cases even by individual wishes of acting persons. The provisions of the EU's ordinary legislative procedure (co-decision procedure) can certainly not be applied here. For this reason, too, the proven legal principles should continue to apply unchallenged, according to which harmonized standards are not part of Union law.

Common Specifications
The VDMA was very surprised to discover the mention of "common specifications" based on implementing acts in the final proposals. This planned type of technical specification is rejected by the VDMA as it undermines the tried and tested system of standardization and standards. Furthermore, standardization has functioned exceptionally well in mechanical engineering for many years. Therefore, the VDMA does not see any need for this new type of technical specification. Since they compete with harmonized standards, they undermine a tried and tested system, even if the EU Commission assures that Common Specifications are to be understood exclusively as a "fall-back option". Since standardization in mechanical engineering has been carried out successfully for many years and no significant deficiencies can be observed, we see no need for such a “fall-back option".

Furthermore, there is no practical experience with Common Specifications so far. Currently there is not a single Common Specification. Therefore, we consider the reference to this planned type of technical specification to be premature and, moreover, superfluous. It remains to be seen whether there will ever be such Common Specifications. The experts who are capable of drafting such papers and who could also reflect the individual interest groups in the drafting of such documents are already actively involved in standardization bodies, and the majority of them have been working in these standardization bodies for many years. Furthermore, it is doubtful whether the EU Commission will ever be able to finance the

preparation of such documents due to limited budgetary resources. As already explained, the current examination practice is already causing some problems with financing. The planned examination practice with increased audit depth would considerably exacerbate these problems. Therefore, the question of available budgetary means for the preparation of Common Specifications is not only legitimate, but of high relevance for an implementation in practice. Rather, we see the budget resources better invested in the area of publication of the references of harmonized standards and examination practice at a reasonable depth of testing.

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