



Machinery Directive 2006/42/EC

Closing of "loopholes" through private contracts¹

What sellers and buyers have to consider

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Practical solutions for the manufacturer in the Single European Market

CE

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Introduction

After more than 15 years, the European Union has decided on a comprehensive amendment of the European Machinery Directive. As of 29.12.2009, the new Machinery Directive 2006/42/EC² was implemented in binding German national law. Corresponding national implementations were enacted at the same time also in all other member states of the EEA as well as in Switzerland and Turkey.³

While earlier demarcation problems between the Machinery Directive and the Low Voltage Directive were reduced and more legal security was gained by the inclusion of "partly completed machinery" in the list of products covered by the scope of the Machinery Directive, a lack of clarity and points of uncertainty can still be observed in practice even one year after the new Machinery Directive came into force when it comes to the implementation of the demands of the Machinery Directive in the procurement process between sellers of machinery on the one hand and the buyers of machinery on the other, as the following examples from a quotation from a machine manufacturer show:

- "A CE mark on the machines supplied by us is not generally covered by the contract. Should you wish for such a mark, this shall require our express written confirmation."
- "A precondition for the supply in exceptional cases of a product not conforming to the EC directives is the signing of an "indemnification declaration" with the following content ..."

With this paper the authors aim to track down public law loopholes in the scope of the Machinery Directive and to give the

² DIRECTIVE 2006/42/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 May 2006 on machinery. The Machinery Directive that has been amended several times in the meantime is available in a consolidated version at "www.maschinenrichtlinie.de" (German text only)

³ See www.maschinenrichtlinie.de under "Geltungsbereich"

contract parties tips for the drafting of contracts with respect to the handling of the subjects governed by and the demands of the Machinery Directive.


Demands on the manufacturer

According to Article 5 of the Machinery Directive, the manufacturer of machinery / partly completed machinery must satisfy the following demands:

- The machine must satisfy the requirements of Annex I of the Machinery Directive

Directive 2006/42/EC
Obligations for manufacturers of machinery
- Article 5 -

- **Satisfying the relevant essential health and safety requirements**
 - e.g. risk assessment
 - e.g. safety integration
 - e.g. marking
- **Keeping the technical file available**
- **Providing the necessary information**
 - e.g. instructions
- **Carrying out the conformity assessment**
 - procedure for normal machinery
 - procedure for Annex-IV-machinery
- **Drawing up the EC declaration of conformity**
- **Attaching the EC declaration of conformity to the machinery**
- **Affixing the CE marking**
- **Applying specific Directives if applicable**

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- The drawing up of a risk assessment is mandatory
- The technical file on the machinery must be available
- The operating instructions (or assembly instructions in the case of partly completed machinery) must accompany the machinery
- The corresponding conformity assessment procedure (or special procedures

- in the case of partly completed machinery) must have been performed
- The EC Declaration of Conformity or declaration of incorporation must be completed and must accompany the machinery
 - The CE mark expressing the conformity of the machinery with all the relevant EC Directives demanding such a marking must be attached to the machine

Note:

Partly completed machinery, by contrast, does not bear a CE mark unless another EC single market directive applicable to the partly completed machinery demands such a mark

- The manufacturer of machinery must have the necessary means to manufacture the machinery "safely"

Note:

"Machinery" in the above sense is used for the sake of simplicity as a generic term for all products in the sense of Article 2 a) to f) of the Machinery Directive, while the term "partly completed machinery" in the sense of Article 2 g) of the Machinery Directive is used separately, see also the corresponding provisions in Article 2 of the Machinery Directive.

Compliance with these requirements is a mandatory precondition for the placing of machinery (or partly completed machinery) on the market. Failure to comply with the preconditions can result in stringent measures being taken by the responsible authorities in accordance with ~~§ 8 (4) GPSG~~; these cannot, however, be covered in more detail in this paper.

In practical application it has been observed, however, that the Machinery Directive leaves considerable scope for interpretation in some area and has loopholes that lead to legal uncertainty in the drafting of contracts. This paper aims to give examples as to how these loopholes can be expediently closed within the context of the contract drafting.

Who is actually the "manufacturer"?

The manufacturer or his authorised representative is responsible for the compliance with the fundamental healthy and safety requirements of Annex I of the Machinery Directive and for the performance of the above measures for establishment / declaration of the "EC conformity" of the machinery. The manufacturer or his authorised representative is also the primary addressee of measures taken by the responsible authorities.

Against this background, the question of who the **manufacturer** of the machinery is in individual cases is of great relevance. While "single source" machinery (in the sense of the design and manufacture of the machinery) generally does not pose a problem (even in the light of the fact that the property of "manufacturer" is not lost by the sub-contracting of work)⁴, a lack of clarity as to the person of the manufacturer can quite conceivably arise in certain cases with "machine plants" (assemblies of machinery in the sense of Article 2 a) 4th indent of the Machinery Directive).

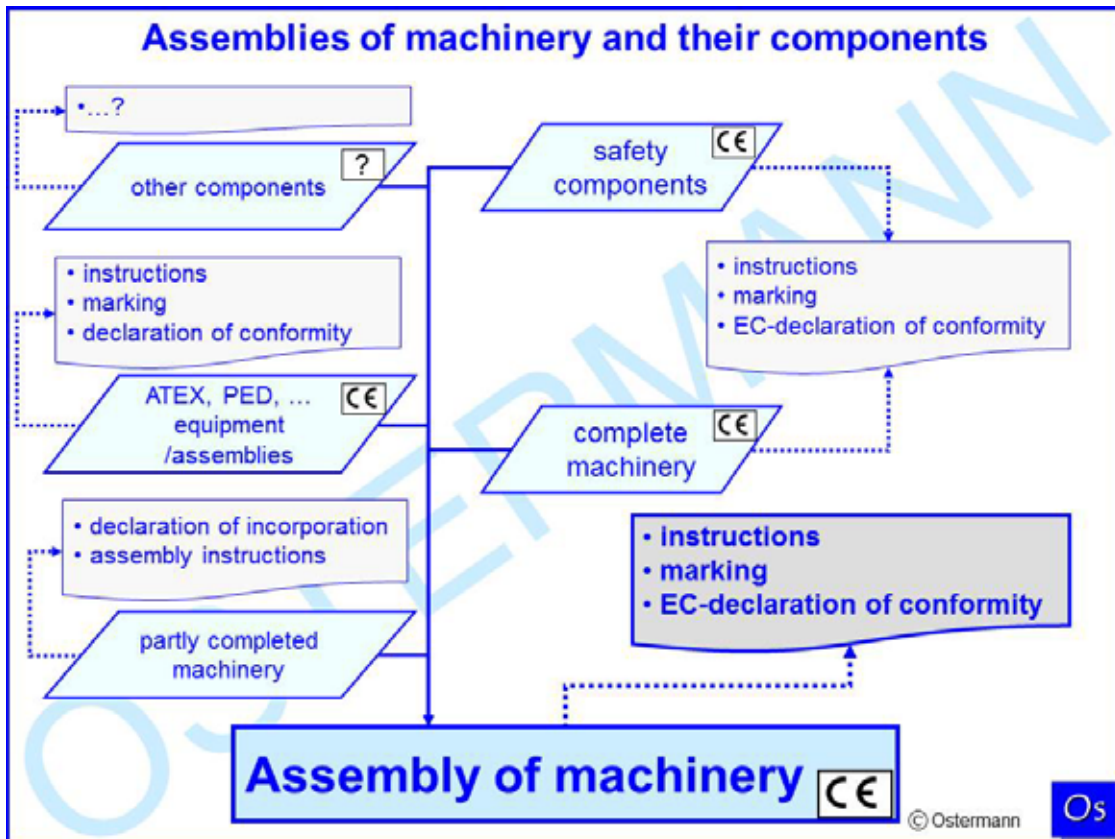
If we look at the definition of the manufacturer as defined in Article 2 i) of the Machinery Directive more closely

"... any natural or legal person who designs and/or manufactures machinery or partly completed machinery covered by this Directive and is responsible for the conformity of the machinery or the partly completed machinery with this Directive with a view to its being placed on the market, under his own name or trademark or for his own use,"

then a broad scope for interpretation becomes obvious, particularly for engineering "assemblies of machinery"⁵ (machinery plants). The manufacturer can then be:

⁴ cf. clause 3.1.1 of the European Commission's "Guide to the Implementation of Directives Based on the New Approach" - Blue Guide <http://www.maschinenrichtlinie.de/fileadmin/dokumente/Binnenmarktleitfaden%20Blueguide.pdf>

⁵ See Machinery Directive, Article 2, paragraph a, fourth indent



- The plant design engineer
- The plant construction engineer
- The person who attaches his name / his trademark to the plant
- The "in-house manufacturer" who manufactures the plant for his own use

„A manufacturer, in the meaning of New Approach, is the person who is responsible for designing and manufacturing a product“

How can this "dilemma" be resolved?

For the question as to who the manufacturer is, the definition of the "manufacturer" in the Machinery Directive essentially focuses on the question as to who bears the "overall responsibility" for the safety of the machine plant:

"[The person who] is responsible for the conformity of the machinery ... with this directive with a view to its being placed on the market"

This is also made clear in the Blue Guide⁶ in section 3.1.1:

At first sight there is a great deal here to suggest that the "main supplier" (= the supplier of the main components of the plant) is the plant manufacturer. This is not necessarily the case, however. It can just as easily be e.g. the engineering office responsible for the plant conformity, particularly if it carries out the detail engineering or safety engineering.

Also conceivable, however, is the erection company that assembles all the plant components "safely" or the control system installer who integrates the plant components into his control system. In many cases the plant operator has also appointed a project manager who "keeps hold of the reins" so that the plant owner as an "in-house manufacturer" can also be considered for the declaration of conformity of the plant as a whole, as he holds the "project or planning sovereignty" with respect to the plant.


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<http://www.maschinenrichtlinie.de/fileadmin/dokumente/Binnenmarktleitfaden%20Blueguide.pdf>

Of relevance to the decision, and hence a question also to be clarified, is who can influence the safety engineering properties during design and construction of the plant up to its placement on the market or putting into service.

In order to avoid discussions and high costs later, the parties involved in a plant project are therefore well advised to give consideration to the question of the overall

If it is not clear who the plant manufacturer is, then it is also not clear who is responsible for drawing up the risk assessment for the plant so that in practice this is – legally inadmissibly – frequently not carried out. Added to that is the fact that safety engineering corrections due to a delay in drawing up the risk assessment generally entail high costs. With the right approach, these costs - caused by a wrong engineering

Sample of an “EC declaration of conformity” according annex II 1 A	
<p>„Original“ or „Translation“</p> <p style="text-align: center;">Declaration of conformity for machinery (2006/42/EC)</p> <p>Hereby the manufacturer ... [business name and full address] declares:</p> <ul style="list-style-type: none"> • The machinery ... [description and identification] <ul style="list-style-type: none"> – fulfils all the relevant provisions of the Directive 2006/42/EC. – fulfils all the relevant provisions of the following other Directives: ... • The following harmonised standards are applied: ... 	<ul style="list-style-type: none"> • Name and address of the person authorised to compile the technical file: ... • If so, name, address and identification number of the notified body involved for: <ul style="list-style-type: none"> – EC type-examination no.: ... or – approval of a full QS-System <p>... [place and date of declaration]</p> <p>... [identity of the signer]</p> <p style="text-align: right;">Signature</p> <p style="text-align: right;">© Ostermann </p>

responsibility at the time of conclusion of the contract. A later clarification after the start of the planning or engineering involves great expense and is furthermore legally inadmissible (cf. Annex I Machinery Directive: „*The machinery must then be designed and constructed taking into account the results of the risk assessment*“).

approach - can be avoided.

Agreement on the person of the plant manufacturer in the contracts between the participating parties is therefore urgently recommended. Agreement could be reached, for example, on the following **contract clause** in the relationship between main supplier and plant owner:

The contract parties are agreed that [name of the company] is manufacturer of the complete plant in the sense of Article 2 lit. i of the Machinery Directive 2006/42/EC and assumes the duties of the manufacturer defined in Article 5 clause 1 of this Directive for the complete plant to be placed onto the market.⁷

Where necessary, contractual cooperation obligations of the other contract party should also be defined. If, for example, the main supplier is the manufacturer of the plant and the plant owner purchases parts of the plant himself, the relationship between manufacturer and plant owner's sub-supplier must also be clarified. The main supplier must, for example, be given the possibility by the plant owner in his contracts with his suppliers to consult these suppliers and, where necessary, to examine the conformity documentation as

the main supplier has no contractual relationship with the plant owner's suppliers.

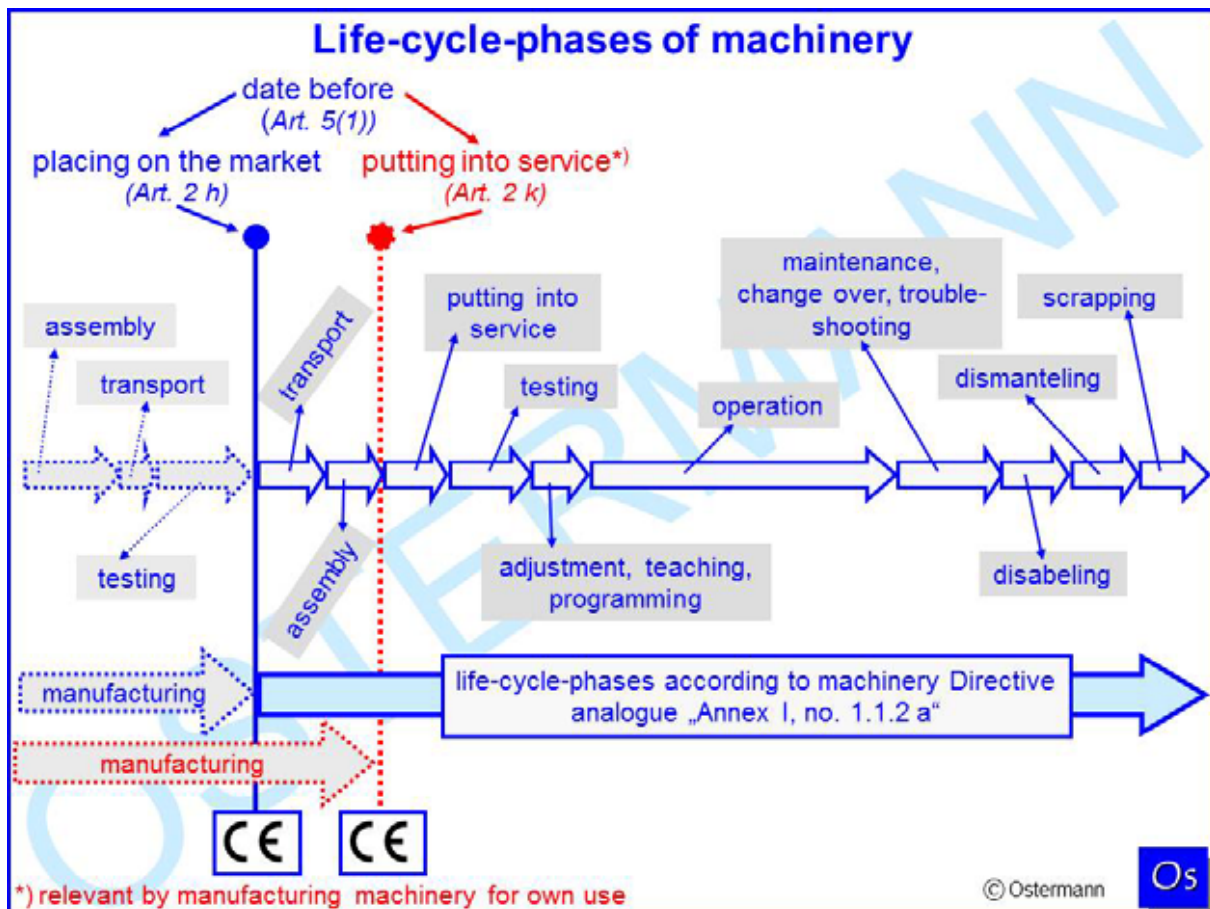
What has actually to be supplied?

The machinery manufacturer's public law scope of supply is described in Article 5 of the Machinery Directive.

It states that together with the machinery, the following must be handed over to the buyer:

- The EC Declaration of Conformity in accordance with Annex II part 1 Section A
- The necessary information (Annex I, No. 1.7 Machinery Directive), such as the operating instructions (Annex I, No. 1.7.4 Machinery Directive)

In addition, the technical file must be available for examination / inspection by the responsible market supervisory authorities (Article 5(1) b in conjunction with Annex VII part A No. 2 Machinery Directive).



⁷ See www.maschinenrichtlinie.de on the subject "Responsible persons / plant manufacturer"

What does this mean with respect to the **risk assessment**?

Under public law the buyer of machinery (including machine plants) / partly completed machinery has no right to demand the handover of the seller's risk assessment. It is intended as part of the technical file only for examination by the authorities.

In individual cases, e.g. with complex plants where the plant owner as "in-house manufacturer" has to evaluate the CE conformity of given interfaces or in situations where existing plants are modified, however, it is quite understandable that the buyer demands the handover of the risk assessment of machinery / partly completed machinery.

This can only be agreed upon by private law within the scope of the supply contract. In view of the private autonomy, the contract parties have the possibility to define the subject of supplies and services.

Example of a **contract clause**:

"The documents to be handed over by the Seller shall also include the risk assessment in accordance with the General Principles of Annex I of the Machinery Directive 2006/42/EC for the machinery / partly completed machinery to be supplied."

Without such an "agreement on condition", however, the buyer has no entitlement to claim the handover of the risk assessment.

Alternatively it can be agreed, for example, that the machinery owner / buyer can examine the manufacturer's / seller's risk assessment at his company premises instead of the handover. In both cases agreement on an obligation to confidential handling of the manufacturer's technical solutions is justified, as it is unquestionable that this constitutes know-how of the manufacturer / seller that is not yet in the public domain and is therefore worthy of protection.

When does the conformity documentation have to be handed over?

The Machinery Directive prescribes in Article 5 (1) that the EC declaration of conformity must be handed over to the owner / user together with the machinery when it is placed on the market or put into service. While the time of placement onto the market or putting into service of individual machines generally raises no questions, this is often seen as a complex process of long duration in the case of machine plants, as the "trial operation" by the plant manufacturer is regularly carried out after the end of the erection work, i.e. the machine plant is adjusted, run in, etc.

The trial operation by the plant manufacturer is, however, regularly characterised in that the machine plant does not yet satisfy the demands of the Machinery Directive in all respects, in particular Annex I, as e.g. guards have not yet been fitted, covers have to be removed again, etc. An issue of the EC declaration of conformity and the attachment of the CE marking is not yet admissible at this point, so that this does not represent a "placement on the market". This trial operation consequently takes place on a machine plant that is still in the manufacturing phase. The trial operation at this time is therefore subject to the occupational safety provisions under the responsibility of the plant manufacturer. The machine plant must satisfy the protection goals of Annex I Machinery Directive only at the time of placement on the market or of putting into service. Like with a single machine this is a "point in time" and not a "period of time".

There is therefore a need for clarification of the "safety-related", i.e. the point at which the plant manufacturer's trial operation has been concluded, the machine plant satisfies the public law requirements such as the Machinery Directive and the machine plant can be placed on the market or put into service. Private law measures can be taken here, e.g. in the form of a commissioning protocol to be signed by both contract parties in which the owner / buyer not only confirms that e.g. the mechanical function

of the machine plant is assured or e.g. the production over a 24-hour period of operation has been successfully demonstrated, but also that the machine plant satisfies the public law requirements of the Machinery Directive ("CE acceptance"). From this point in time, the owner / buyer is responsible in accordance with Article 4(2) of the Directive 2009/104/EC for ensuring that this safety level is not infringed during the further operation of the machine plant.

Example of a **contract clause** in the commissioning protocol:

"With the commissioning of the subject of supply, it shall be placed at the Buyer's disposal for the first time for its intended use. The Buyer confirms that at this time the subject of supply satisfies the safety and health protection requirements of the Machinery Directive 2006/42/EC and of the other relevant European directives of the Community and therefore functions and can be operated safely."

This does not preclude the necessity for further contractual provisions, e.g. on the quality of the machine plant over and above this "safety-related transfer of perils". The "CE acceptance" must therefore not necessarily constitute a "quality acceptance" at the same time. This can and will as a rule take place later, e.g. when the product-specific performance values of the machine plant have been demonstrated, e.g. in the form of test or guarantee runs. The advantage of such a split acceptance is that after the "CE acceptance", the owner can produce with the plant from a public law point of view because it is "safe".

Points of particular note for partly completed machinery

1. Declaration of incorporation instead of EC declaration of conformity

Since 29.12.2009, certain manufacturer's obligations in accordance with Article 5 (2) and Article 13 Machinery Directive apply also to "partly completed machinery" as defined in Article 2 g) Machinery Directive.

In particular a special procedure (not a conformity assessment procedure) in accordance with Article 13 in conjunction with Annex VII B Machinery Directive has to be carried out which includes also the drawing up of a risk assessment. The declaration of incorporation in accordance with Annex II Part 1 Section B Machinery Directive to be drawn up and handed over to the buyer, however, requires the manufacturer only to indicate which fundamental requirements of the Machinery Directive in the sense of the protective goals of Annex I Machinery Directive are applied and fulfilled. The manufacturer of the partly completed machinery can therefore limit himself in the declaration of incorporation to individual safety and health protection requirements which **in his view** are applicable to the partly completed machinery.

For the buyer, however, who integrates the partly completed machinery into a complete machine, or assembles it together with other machinery or partly completed machinery, it is often important that the manufacturer of the partly completed machinery confirms that this conforms to **all** the safety and health protection requirements in the sense of Annex I Machinery Directive relevant and applicable to the partly completed machinery up to the interfaces indicated in the documentation.

This can be achieved in that the manufacturer of the partly completed machinery undertakes contractually to issue an "**extended declaration of incorporation**"⁸ in which he certifies precisely this statement.

In this way the buyer who installs this partly completed machinery in the final machine / plant receives a high degree of legal security.

⁸ See www.maschinenrichtlinie.de "Erweiterte Einbauerklärung"

Sample of an „Extended declaration of incorporation“ based on Annex II 1 B	
<p>„Original“ or „Translation“</p> <p style="text-align: center;">Extended declaration of incorporation for partly completed machinery (PCM) (Directive 2006/42/EC)</p> <p>Hereby the manufacturer [<i>business name and full address</i>] declares:</p> <ul style="list-style-type: none"> • The PCM [<i>details according Annex II 1 B no. 3</i>] fulfils the following applied provisions of Annex I of the Directive 2006/42/EC: <ul style="list-style-type: none"> • General Principle no. 1 • no. 1.1.2, 1.1.3, <p>All relevant provisions of Annex I of the Directive above are applied and fulfilled up to the interfaces described in the attached</p> <ul style="list-style-type: none"> <input type="checkbox"/> instructions <input type="checkbox"/> data sheets <input type="checkbox"/> technical documents <ul style="list-style-type: none"> • The following harmonised standards are applied [completely or partly] 	<ul style="list-style-type: none"> • The partial-instructions are drawn up and will accompany the PCM. • The relevant technical documentation according Annex VII B is compiled. • The relevant technical documentation will be transposed to the national authorities on reasoned request. <i>[mention method of transmission]</i> • The conformity of the PCM with the provisions of the following further Directives: ... • Name and address of the person authorised to compile the relevant technical documentation: ... <p>Where appropriate* putting into service of the PCM is prohibited, until the final machinery into which it is to be incorporated has been declared in conformity with the provisions of the Directive above.</p> <p>... <i>[place and date of declaration]</i></p> <p>... <i>[Signature and identity of the signer]</i></p> <p><small>*) that means, only when the final machinery is subject to the Machinery Directive</small></p>

2. Assembly instructions instead of operating instructions

According to the procedure for partly completed machinery described in Article 13 Machinery Directive, the manufacturer must ensure that assembly instructions in accordance with Annex VI Machinery Directive are drawn up and that these are included with the partly completed machinery. According to Annex VI Machinery Directive, the assembly instructions for partly completed machinery must contain a description of the conditions which must be met with a view to correct incorporation of the partly completed machinery into the final machinery, so as not to compromise safety and health of persons.

These are therefore installation or assembly instructions for the owner/buyer.

The question must be permitted at this point as to where the stipulations for the intended use of the partly completed machinery (this is by no means exhausted by the simple installation in final machi-

nery, as the partly completed machinery also has to fulfil certain functions) or even the reasonably foreseeable misuse of the partly completed machinery are contained, and in particular what risks exist during the use of the partly completed machinery - *after installation* - and how users can protect themselves against these risks.

Strictly speaking, this information does not form part of the assembly instructions. The buyer is therefore neither informed about the intended use of the partly completed machinery, nor does he receive information on (residual) risks which can arise during such an intended use or reasonably foreseeable misuse of the partly completed machinery. The conclusions drawn by the EU Commission on the stipulations in the assembly instructions in § 390 of the EU Guide to the Machinery Directive⁹ therefore go too far, even if this would be desirable for the practical application.

⁹ Guide to Application of the Machinery Directive 2006/42/EC, 2nd Edition June 2010

But the manufacturer of the partly completed machinery exposes himself to product liability law risks if he limits the documentation to be supplied with the partly completed machinery to the requirements of Annex VI Machinery Directive. Both the manufacturer liability under tort law in accordance with § 823 (1) German Civil Code (BGB), and the liability of the manufacturer under the German Product Liability Act (§ 3 (1) lit. a) ProdHG which is based on the Council Directive 85/374/EEC) sanction faulty or the lack of operating instructions or instructions for use and / or a lack of warnings against potentially hazardous properties of a product (keyword: "faulty instruction")¹⁰.

The contract parties to the purchase of partly completed machinery are therefore well advised to also include the point "operating instructions" in their contract documents. See also the "extended declaration of incorporation" mentioned above.

The assessment of the contract conformity of the supply

We should expressly point out once again here:

The CE marking on machinery / plants makes no statement about the (agreed) quality of a product. The CE marking has to fulfil a different function, namely that of assuring the freedom of the movement of goods within the European single market. Thus it is like an "European-single-market-passport" for goods and not a quality symbol with respect to safety.

The assessment of the agreed condition / quality of a product, and hence the contract conformity of the supply, is performed purely under private law. If the purchase is e.g. a commercial transaction for both parties, the buyer must ensure in accordance with § 377 German Commercial Code (HGB) that the goods are examined for visible defects immediately on arrival in his "domain", and

that notice of any defects discovered is given immediately.

Failure to meet this obligation regularly results in the loss of the rights with respect to material defects, at least as far as the defects not discovered or not reported are concerned (the question as to what extent the buyer can assign this obligation to the seller is not the subject of this paper).

In the case of contracts for work (which is regularly the case for contracts for the construction of a complex machinery plant tailored individually to the needs of the owner / buyer), the ordering party has to accept the work manufactured by the contractor:

(§ 640 BGB)

"Acceptance" means here the receipt of the manufactured work and its recognition as being in conformity with the contract.

In the case of contracts for the purchase of (individual) machine or partly completed machinery, however, it is recommended that tests for the proof of the agreed quality are also agreed. This can be achieved contractually through the terms for the acceptance of the goods / services. In the case of long-term supply relationships it is recommended – also in the light of minimising the product liability risks – that "quality assurance agreements" are concluded.

A quality assurance agreement is to be understood as quality assurance measures contractually agreed with a supplier in which i.a. the following points can be defined in concrete terms:

- Quality goals for the individual parts / components
- Proof of quality by the supplier, such as e.g. quality control measures to be performed, presentation of test certificates, etc.
- Quality assurance
- Exchange of quality data
- Demands on the supplier's quality management systems

¹⁰ See www.maschinenrichtlinie.de under the heading "Produkthaftung" (Product liability)

- Testing and inspection rights of the accepting party
- Liability provisions for joint and several liability towards a damaged party

The commercially biased conditions of purchase are thus expanded to include aspects necessary to ensure the demanded quality of the products, and this serves to establish the legal security between the parties involved.

Conclusion

The Machinery Directive 2006/42/EC imperfectly governs the demands on the manufacturer with respect to the placement on the market / putting into service of machinery or partly completed machinery. The Machinery Directive

continues to have considerable scope for interpretation and loopholes that lead to a lack of clarity and to uncertainty in the procurement process for machinery / partly completed machinery and which the contract parties have to consider or close during the drafting of their contracts.

The points outlined above on the drafting of contracts are intended to give sellers and buyers of machinery or partly completed machinery legal security in the handling of the Machinery Directive in contracts. At the same time, the knowledge of the loopholes in the Machinery Directive can help the contract parties to avoid annoyance, time and costs.