

Federal Ministry of Labour and Social Affairs

Product Safety Act / 9th Ordinance on Product Safety (Machinery Ordinance)

Here: Interpretation paper on substantial modification to machinery

– Notice from the Federal Ministry of Labour and Social Affairs of 9 April 2015 – IIIb5-39607-3 –

This interpretation paper is a revised version, taking into account the new Product Safety Act¹ (ProdSG) and the latest findings in risk assessment, of the *Interpretation paper of the Federal Ministry of Labour and Social Affairs and the Länder on the subject of "substantial modification to machinery"*, published by the Federal Ministry of Labour and Social Affairs on 7 September 2000 - IIIc3-39607-3 - Bundesarbeitsblatt 11/2000 p. 35.

This new paper has been worked out by a working group under the leadership of the Federal Ministry of Labour and Social Affairs (BMAS) with participation of the Federal Institute for Occupational Safety and Health (BAuA), the Ministry of Environment, Climate and Energy of the Land of Baden-Württemberg as representative of the Länder for the EC Machinery Directive 2006/42/EC² (MD) in coordination with the market surveillance authorities of the Länder, the German Statutory Accident Insurance (DGUV), individual accident insurance institutions, the German Engineering Federation (VDMA) and the VGB PowerTech e. V. as a professional association for electricity and heat generation. It replaces the old interpretation paper referred to above.

The ProdSG regulates the making available on the market of products. These products include machinery. What requirements must be met by machinery if it is made available on the market results from the ProdSG in conjunction with the Ninth Ordinance to the ProdSG (Machinery Ordinance - 9th ProdSV). The 9th ProdSV and ProdSG transpose the relevant European legislation for machinery, the MD, into national law.

In accordance with § 2 No. 4 of the ProdSG "making available on the market" shall mean "any supply of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge. This definition was adopted verbatim for the ProdSG from the Regulation (EC) No 765/2008³. The "making available on the market" takes the place of the previous term "placing on the market" in the Equipment and Product Safety Act (GPSG), which the ProdSG replaces. There "placing on the market" was

¹ Act on the making available on the market of products (Product Safety Act - ProdSG) of 8 November 2011.

² Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery and amending Directive 95/16/EC (recast)

³ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

defined as "any disposal of a product to another party, regardless of whether the product is new, used, reworked or has been substantially modified [...]."

The ProdSG now includes - in accordance with Regulation (EC) No 765/2008 - the term "making available on the market" and the term "placing on the market". In the new ProdSG the definition of "placing on the market" is now to be understood in accordance with the EC Regulation No 765/2008 only as the **first** making available on the market of a product (§ 2 No. 15).

By adopting the definitions of "making available on the market" and "placing on the market" from the Regulation (EC) No 765/2008, the term "substantially modified product" was omitted. However, the underlying facts have not changed: As in the previous GPSG, also in the new ProdSG a used product that has been modified **substantially** compared to its original condition is to be regarded as a new product. This arises from the applicable European interpretation in No. 2.1 of the "Blue Guide"⁴.

"A product, which has been subject to important changes or overhaul aiming to modify its original performance, purpose or type after it has been put into service, having a significant impact on its compliance with Union harmonisation legislation, may be considered as a new product. This has to be assessed on a case-by-case basis and, in particular, in view of the objective of the legislation and the type of products covered by the legislation in question."

Regarding machinery the Guide of the European Commission to the MD⁵ should also be consulted. This includes the following explanation under § 72:

"The Machinery Directive also applies to machinery based on used machinery that has been transformed or rebuilt so substantially that it can be considered as new machinery. The question arises as to when a transformation of machinery is considered as construction of new machinery subject to the Machinery Directive. It is not possible to give precise criteria for answering this question in each particular case."

This interpretation paper provides assistance in answering this question and with a flowchart shows the procedure for deciding whether a particular case is a substantial modification.

⁴ The "Blue Guide" on the implementation of the EU product rules - 2014 - <http://ec.europa.eu/DocsRoom/documents/4942/attachments/1/translations/de/renditions/native>

⁵ Guide to the application of the Machinery Directive 2006/42/EC - 2nd Edition June 2010; <http://www.bmas.de/SharedDocs/Downloads/DE/PDF-Meldungen/leitfaden-maschinenrichtlinie.html>

Interpretation of "substantial modification" in terms of machinery

Of 9 April 2015

Every modification to machinery, whether used or new, which can undermine protection of legal interests of the ProdSG, e. g. by an increase in power, a change in function, a change to the intended use (such as by changing the auxiliary or operating materials and consumables, conversion or changes of safety technology) must be determined regarding its safety-related impact.⁶ This means that in each individual case it must be determined whether new hazards⁷ have resulted from the modification of the (used) machinery or whether an existing risk⁸ has increased. Here we can distinguish three types of cases:

1. There is no new hazard or no increase of an existing risk, so that the machinery can still be considered safe.
2. Although there is a new hazard or an increase in an existing risk, the existing protective measures of the machinery before the modification are still sufficient so that the machinery can still be considered safe.
3. There is a new hazard or an increase in an existing risk and the existing protective measures are not sufficient or suitable.

Additional protective measures are not needed for modified machinery in the case type 1 and 2. Modified machinery of case type 3, however, must be examined further systematically through a risk assessment concerning the question of whether a substantial modification has been made.

It must be determined whether it is possible to bring the modified machinery back to a safe state with simple safeguards. A review must be undertaken to determine whether the simple safeguard eliminates or at least sufficiently minimizes the risk. If this is the case, the modification may usually be considered as non-substantial.

An example of a simple safeguard in the aforementioned sense is a fixed guard. Interlocking movable guards and protective devices are also considered simple safeguards as are protective devices provided they do not interfere significantly in the current safety-related control of the machinery. This means that only signals for whose processing the existing safety control system was designed are linked through these interlocking movable guards or protective devices, or that regardless of the existing safety control system only the safe stopping of the hazardous machine function is affected.

⁶ This may be done, for example, in accordance with the procedures of EN ISO 12100 "Safety of machinery – General principles for design. – Risk assessment and risk reduction".

⁷ MD Annex I Section 1.1.1. a) "hazard" means a potential source of injury or damage to health

⁸ MD Annex I Section 1.1.1. e) "risk" means a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation

The replacement of a machinery's components with identical components or components with identical function and identical level of safety or the installation of safety devices, which lead to an increase of the level of safety of the machine and do not enable any additional features or functions are not considered substantial modifications.

Note:

Regardless of this, the obligation to establish additional protective measures may result from other legislation for the employer, who makes the machinery available to his employees as a work equipment.

In principle, for all modifications to machinery - not only after substantial modifications - a risk assessment must be carried out in accordance with § 3 of the Ordinance on Industrial Safety and Health⁹ (BetrSichV). This is one of the occupational safety and health requirements of the user of a machinery or system as a work equipment. On the basis of the risk assessment, measures, especially technical measures, may be necessary to provide employees with safe work equipment.

It is necessary to examine whether an adjustment of the information about the safe operation of the machinery is required, such as working instructions (cf. § 12 BetrSichV).

Conclusion:

Modifications to machinery/assemblies of machinery¹⁰ can have the following effects:

1. The machinery is safe even after the modification without additional protective measures.
→ There is **no** substantial modification.
2. The machinery is no longer safe after the modification without additional protective measures. The new hazard or the increased risk can be eliminated by simple safeguards, or at least sufficiently minimized.
→ There is **no** substantial modification.
3. The machinery is no longer safe after the modification without additional protective measures and sufficient risk reduction cannot be achieved by simple safeguards.
→ **There is a substantial modification.**

⁹ Ordinance on Industrial Safety and Health - Verordnung über Sicherheit und Gesundheitsschutz bei der Verwendung von Arbeitsmitteln (Betriebssicherheitsverordnung – BetrSichV)

¹⁰ Interpretation paper on „assemblies of machinery“ – Notice from BMAS of 5.5.2011, IIIb5-39607-3 – GMBI. 2011, p. 233 (German only)

In order to determine whether there is a significant change, the following diagram (Fig. 1) may help.

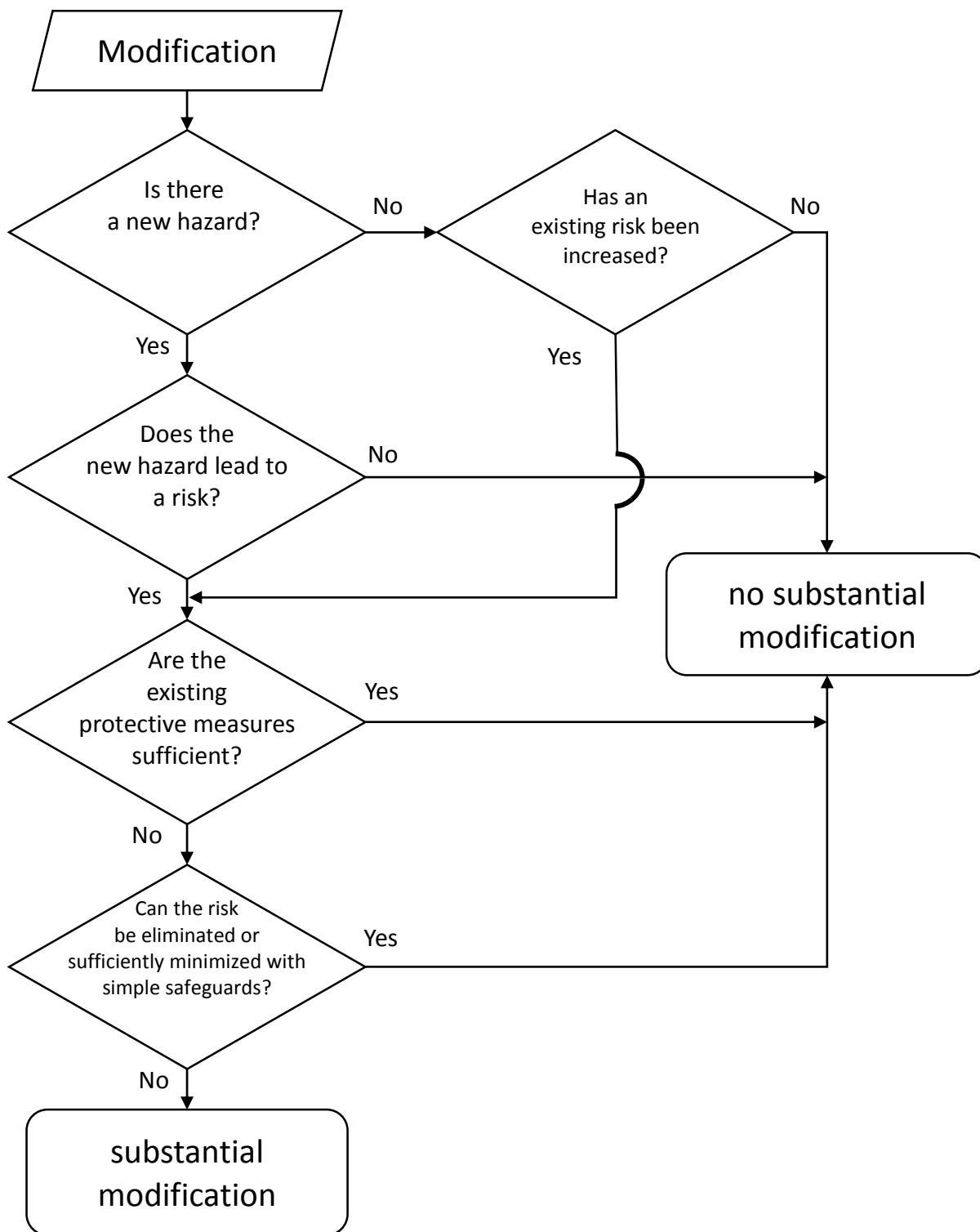


Fig. 1: Decision steps - substantial modification to machinery

Substantially modified machinery

Substantially modified machinery is treated as new machinery. The provisions of the ProdSG and the 9th ProdSV are applicable in their entirety. This means that the person who is responsible for the substantial modification, is to be considered the manufacturer and has therefore to fulfil the manufacturer's obligations pursuant ProdSG and the 9th ProdSV. In accordance with this, the manufacturer must ensure that the substantially modified machinery meets the essential health and safety requirements in Annex I of the MD. The manufacturer carries out the appropriate conformity assessment procedures for the substantially modified machinery and in particular compiles the prescribed technical file, with which the implementation of the conformity assessment procedure can be demonstrated. Furthermore, the manufacturer provides the instructions and if necessary provides the substantially modified machinery with warnings of residual risks that cannot be further minimized with technical protective measures because of the state of the art. Finally, the manufacturer, draws up the EC declaration of conformity, attaches this and affixes the CE marking to the substantially modified machinery.

Assemblies of machinery

For modification to an assembly of machinery, the above principles apply.

If a modification affects only a part of an assembly of machinery (for example, a complex production line or integrated manufacturing system) it must be determined to what extent this will affect the assembly (system as a whole). If this modification itself is considered substantial and its impact on the assembly is as well, this is a case of substantial modification in an assembly of machinery.