

~~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)~~
Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on machinery products

注) 欧州機械規則（提案）は、欧州機械指令を廃止しこれに代わるものとして提案されているものです。2021年5月現在、この提案は最終提案段階であり、まだ正式に発行されたものではありません。

本紙は、機械指令 2006/42/EC（2009/127/EC によって修正）をベースに、機械規則の最終提案版 COM(2021) 202 final, 2021/0105(COD) による変更点を赤色で示したものです。付属書Ⅲ 一般原則（現行の機械指令では、付属書Ⅰ 一般原則に相当）を抜粋しています。

ANNEX Ⅲ**ESSENTIAL HEALTH AND SAFETY REQUIREMENTS RELATING TO THE DESIGN AND CONSTRUCTION OF MACHINERY PRODUCTS****GENERAL PRINCIPLES**

1. The manufacturer of a machinery product or his or her authorised representative ~~must~~ shall ensure that a risk assessment is carried out in order to determine the health and safety requirements, which apply to the machinery product. The machinery product ~~must~~ shall then be designed and constructed to prevent and minimise all relevant risks, taking into account the results of the risk assessment.

By the iterative process of risk assessment and risk reduction referred to ~~above~~ in the first subparagraph, the manufacturer or his or her authorised representative shall:

- (a) determine the limits of the machinery product, which include the intended use and any reasonably foreseeable misuse thereof,
- (b) determine the risks resulting from interactions between machinery in order to achieve the same end that are arranged and controlled so that they function as an integral whole, thus forming a machinery product as defined in Article 3, point (1), point (d);
- (c) identify the hazards that ~~can~~ may be generated by the machinery product and the associated hazardous situations, including hazards that may be generated during the lifecycle of the machinery product that are foreseeable at the time of placing of the machinery product on the market as an intended evolution of its fully or partially evolving behaviour or logic as a result of the machinery product designed to operate with varying levels of autonomy. In this respect, where the machinery product integrates an artificial intelligence system, the machinery risk assessment shall consider the

risk assessment for that artificial intelligence system that has been carried out pursuant to the Regulation ... of the European Parliament and of the Council +++ on a European approach for Artificial Intelligence;

- (d) estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence,
- (e) evaluate the risks, with a view to determining whether risk reduction is required, in accordance with the objective of this ~~Directive~~ Regulation;
- (f) eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b).
2. The obligations laid down by the essential health and safety requirements only apply when the corresponding hazard exists for the machinery **product** in question when it is used under the conditions foreseen by the manufacturer or his **or her** authorised representative or in foreseeable abnormal situations. ~~In any event~~ However, the principles of safety integration ~~referred to established~~ in section 1.1.2 and the obligations concerning marking of machinery **products** and instructions referred to in sections 1.7.3 and 1.7.4 apply **in all cases**.
3. 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 **product must shall**, as far as possible, be designed and constructed with the purpose of approaching ~~these~~ **those** objectives.
4. This Annex is organised ~~in several parts~~ into six chapters. The first ~~one~~ **chapter** is of general scope and applicable to all ~~kinds of~~ machinery **products**. The other ~~parts~~ **chapters** refer to certain ~~kinds~~ **sorts** of more specific hazards. Nevertheless, it is essential to examine the whole of this Annex in order to be sure of meeting all the relevant essential requirements. When **a** machinery **product** is being designed, the requirements of the ~~general part~~ **first chapter** and the requirements of one or more of the other ~~parts~~ **chapters** shall be taken into account, depending on the results of the risk assessment carried out in accordance with point 1 of these General Principles. Essential health and safety requirements for the protection of the environment are applicable only to the machinery **product** referred to in section 2.4.