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NOTE

De: Présidence
A: Groupe de travail «Harmonisation technique» (Machines)
Sujet: Flash de la Présidence - réunion du mardi 24 mai 2022

Groupe de travail « Harmonisation technique »

Réunion du mardi 24 mai 2022

Chères et chers collègues,

Nous nous retrouverons mardi 24 mai matin afin d'échanger spécifiquement sur la proposition de compromis relative à l'article 5 et l'Annexe I que vous trouverez en Annexe du présent flash.

Afin de tenir compte des grandes réticences de certains Etats membres, ce texte, dans un esprit de compromis, propose :

- De conserver l'ensemble des machines de l'Annexe IV de la directive 2006/42 en Partie B ;
- D'encadrer la collecte des données avec la mise en place d'un formulaire harmonisé qui devra être adopté par acte d'exécution dans les 12 mois de l'entrée en vigueur du règlement ;
- D'ajouter une obligation d'évaluation du contenu par la Commission dans les 3 ans suivant l'entrée en vigueur ;
- De rappeler que l'inscription d'une catégorie de machine en partie A ne doit pas ajouter une charge disproportionnée pour les opérateurs économiques et les consommateurs.
- De reporter l'entrée en application à 36 mois en lieu et place des 30 mois prévus initialement.

Nous nous réjouissons de pouvoir vous retrouver demain !

L'équipe de la Présidence

*Annexe**Considérant 21*

- (21) The evolution of the state of the art in the machinery field sector has an impact on the classification of high-risk machinery or related products listed in Annex I. In view of order to properly reflecting all high-risk machinery or related products presenting a high risk factor, criteria should be established for the assessment by the Commission at the Union level of which machinery products should be included in the list of potentially high-risk machinery or related products subject to a stricter certification procedure.

*Article 5*Potentially High-risk Machinery and related products listed in Annex I

1. Potentially High-risk Machinery and related products listed in Annex I shall be subject to a specific conformity assessment procedure, as referred to in Article 21(2) and 21(2a).
2. The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend Annex I, after consultation with national experts and relevant stakeholders, in view of technical progress and knowledge or new scientific evidence by including in the list of potentially high-risk machinery and related products in Annex I a new category of machinery or related product or withdrawing an existing category of machinery or related product from that list, pursuant to the criteria laid down in paragraphs 3 and 4.

Each delegated act shall be based on an analysis that demonstrates that the amendment of the content of Annex I is not likely to lead to disproportionate burdens on economic operators or consumers, having due regard to the objectives pursued

2.a. A Member State which has concerns about a category of machinery or related product being listed or not listed in Annex I shall immediately inform the Commission of its concerns and provide reasons in support thereof.

The Commission shall thoroughly assess the risks as referred to in paragraph 3 immediately after having been informed by a Member State.

After that assessment the Commission may initiate the procedure laid down in paragraph 2 .

3. A machinery or related product shall be included in the list of potentially high-risk machinery or related products in Annex I if its risk is serious based on the combination of the probability of occurrence of harm and the severity of that harm it presents poses a potential risk to human health or safety taking into account its design and intended purpose.

A machinery or related product shall be withdrawn from the list of potentially high risk machinery or related products in Annex I if it no longer presents poses such risk. The inclusion or removal of a machinery or related product to Annex I shall rely on the assessment of the seriousness of the inherent potential risk. That assessment The risk presented posed by a certain machinery or related product shall be established based on the combination of the probability of occurrence of harm and the severity of that harm.

In determining the probability and severity of harm, the following criteria shall be taken into account, where applicable relevant:

(a') the nature of the hazard inherent to the function of the machinery or related product category type, taking into account the intended use and reasonably foreseeable misuse;

- (a) the severity of harm with by degree to which each affected a person would be affected, including the degree of reversibility of such harm impacted by the harm;
- (b) the number of persons potentially affected by the harm;
- (c) the degree to which potentially affected parties are dependent on the outcome produced by the machinery or related product the frequency and the duration of the exposure to the hazard that a person would be exposed to in course of the intended use or reasonably foreseeable misuse of the category of machinery or related product;
- (d) the degree to which the behavior of the machinery or related product is foreseeable by the potentially affected parties are in a vulnerable position vis-à-vis the end user of the machinery or related product possibilities of avoiding or limiting harm;
- (e) the degree of reversibility of the harm produced by the machinery or related product;
- (f) the degree to which the machinery or related product has been used for its intended use or any reasonably foreseeable misuse a specific purpose;
- (g) indications of harm that have been caused in the past by machinery or related products which have been used for its intended use or any reasonably foreseeable misuse a specific purpose.
- (h) in case of safety components, the likelihood of serious consequences for the safety of the persons exposed in the event of failure.

4. When applying the criteria laid down in paragraph 3-the Commission may consider any of the following elements that shall be provided by the Member States in connection with market surveillance or as a result of the concerns referred to in the paragraph 2.a:

- (a) an assessment of the risks as referred to in paragraph 3; indications of harm that have been caused in the past by machinery or related products which have been used for its intended use or any reasonably foreseeable misuse a specific purpose;
- (b) a cost-effectiveness analysis;

- (ba) information about safety defects detected in the course of market surveillance, and possible available material in the information systems administered by the Commission;
- (c) a machinery accident analysis;
- (ca) known accidents and serious close calls, including characteristics of these accidents or close call;
- (d) statistics data on accidents or damage to the health caused by the machinery or related product at least for the preceding four years based, in particular information obtained from the Information and Communication System for Market Surveillance (ICSMS) information, safeguard clauses, Rapid Alert System (RAPEX) and the Machinery Administrative Cooperation Group reporting.
- (da) anticipation justifiable by technical considerations on risks related to new types of machinery.

4a. A category of machinery or related product which seriousness of its inherent potential risk is established according to §3 and taking into account data required in §4, shall be included in Annex I, Part A on the basis of at least one an overall assessment of the following criteria:

- (i) Lack of harmonised standards or common specifications covering all the relevant essential health and safety requirements;
- (ii) Existence of residual risks due to shortcomings of the protective measures adopted for which data and information set out in § 4 demonstrate the recurrence of similar serious or fatal accidents or damage to health in relation with these residual risks;
- (iii) data and information set out in §4 which demonstrate a recurring wrongfud application of the relevant harmonised standards or common specifications;
- (iv) in the case of new types of machinery or related products, the anticipation justifiable by technical considerations of inherent and unknown risk. The degree of uncertainty of the potential risk related to new categories of machinery or technologies.

Any other machinery or related product which seriousness of its inherent potential risk is established according to §3 and taking into account data required in §4, shall be included in Annex I, Part B.

5. A Member State which has concerns about a category of machinery or related product being listed or not listed in Annex I shall immediately inform the Commission of its concerns and provide reasons in support thereof.

By [2 years after the date of the entry into force of the Regulation], and every 5 years thereafter, Member States shall provide, if available, the information referred to in paragraph 4 for any category of machinery or related products which ought to be included in or excluded from the annex.

By [OJ office: 3 years after the date of entry into force] and every 5 years thereafter, the Commission shall carry out a review of the content of Annex I in view of the criteria set out in this article and shall submit a report to the European Parliament and to the Council.

6. **The Commission is empowered to adopt an implementing act establishing a template to collect the data and information set out in this article.**

Such implementing act shall be adopted not later than twelve months after the entry into force of this regulation.

This implementing act shall be adopted in accordance with the examination procedure referred to in article 46(3).

Article 21

Conformity assessment procedures for machinery and related products

1. ~~T~~he manufacturer **of machinery or a related product**, shall apply one of the procedures for assessment of conformity referred to in paragraphs 2, **2a** and 3.
2. Where the machinery **or related** product is ~~a high risk machinery product~~ listed in Annex I **part A**, the manufacturer ~~or~~ shall apply one of the following procedures:
 - (a) EU type-examination procedure (module B) ~~provided for~~ **set out** in Annex VII, followed by conformity to type based on internal production control (module C) set out in Annex VIII;
 - (b) Conformity based on full quality assurance (module H) set out in Annex IX;
(c) Conformity based on unit verification (module G) set out in Annex IXa.

2a. Where the machinery or related product is listed in Annex I part B, the manufacturer shall apply one of the following procedures:

- (a) Conformity with the internal production control procedure (module A) set out in Annex VI;**
- (b) EU type-examination procedure (module B) set out in Annex VII, followed by conformity to type based on internal production control (module C) set out in Annex VIII;**
- (c) Conformity based on full quality assurance (module H) set out in Annex IX;**
- (d) Conformity based on unit verification (module G) set out in Annex IXa.**

If a manufacturer applies the internal production control procedure referred to in point (a), he or she shall have designed and constructed the machinery or related product in accordance with the harmonised standards or common specifications specific for that category of machinery or related product covering all the relevant essential health and safety requirements.

Where the machinery or related product is listed in Annex I part B and has not been manufactured in accordance with the harmonized standards or common specifications specific for that category of machinery or related product and provided that those standards covering all the relevant essential health and safety requirements, the manufacturer shall apply one of the procedures referred to in paragraph 2a (b),(c) or (d).

3. Where the machinery **or related** product is ~~a high risk machinery product~~ listed in Annex I, the manufacturer ~~or~~ the manufacturer's authorised representative and the person who has

~~made a substantial modification to the machinery product shall apply the internal production control procedure (module A) set out in Annex VI.~~

4. ~~Notified bodies shall take into account the specific interests and needs of small and medium sized enterprises when setting the fees for conformity assessment and reduce those fees proportionately to their specific interests and needs.~~

ANNEX I

HIGH-RISK CATEGORIES OF MACHINERY OR RELATED PRODUCTS TO WHICH ONE OF THE PROCEDURES REFERRED TO IN ARTICLE 21 (2) AND (2A) SHALL BE APPLIED

Part A Categories of machinery or related products to which the procedures referred to in Article 21 (2) shall be applied

18. Portable cartridge-operated fixing and other impact machinery.
24. Software ~~Safety components—with fully or partially self-evolving behaviour—using machine learning approaches or logic Systems~~ ensuring safety functions, ~~including AI systems~~
25. Machinery embedding AI-Systems ~~with fully or partially self-evolving behaviour using machine learning approaches~~ ensuring safety functions ~~that have not been placed independently on the market, in respect only to those systems.~~

Part B Categories of machinery or related products to which one of the procedures referred to in Article 21 (2a) shall be applied:

- 1. Circular saws (single- or multi-blade) for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:**
 - 1.1. sawing machinery with fixed blade(s) during cutting, having a fixed bed or support with manual feed of the workpiece or with a demountable power feed;**
 - 1.2. sawing machinery with fixed blade(s) during cutting, having a manually operated reciprocating saw-bench or carriage;**
 - 1.3. sawing machinery with fixed blade(s) during cutting, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading;**
 - 1.4. sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with manual loading and/or unloading.**
- 2. Hand-fed surface planing machinery for woodworking.**
- 3. Thicknessers for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.**
- 4. Band-saws with manual loading and/or unloading for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:**
 - 4.1. sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or support for the workpiece;**
 - 4.2. sawing machinery with blade(s) assembled on a carriage with reciprocating motion.**
- 5. Combined machinery of the types referred to in points 1 to 4 and in point 7 for working with wood and material with similar physical characteristics.**
- 6. Hand-fed tenoning machinery with several tool holders for woodworking.**
- 7. Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical characteristics.**
- 8. Portable chainsaws for woodworking.**

9. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.
10. Injection or compression plastics-moulding machinery with manual loading or unloading.
11. Injection or compression rubber-moulding machinery with manual loading or unloading.
12. Machinery for underground working of the following types:
 - 12.1. locomotives and brake-vans;
 - 12.2. hydraulic-powered roof supports.
13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.
14. Removable mechanical transmission devices including their guards.
15. Guards for removable mechanical transmission devices.
16. Vehicle servicing lift machinery or related products.
17. Devices for the machinery or related producting lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres
19. Protective devices designed to detect the presence of persons.
20. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9 of Part A, 10 and 11 of Part B.
21. Logic units to ensure safety functions.
22. Roll-over protective structures (ROPS).
23. Falling-object protective structures (FOPS).

*Article 52****Entry into force and application***

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from ~~... [30 36 months after the date of entry into force of this Regulation]~~, **with the exception of:**

- a) **articles 24 to 40 and article 46, which shall apply from [6 months following the entry into force of this Regulation]**
- b) **article 48(1) which shall apply from [29 35 months following the entry into force of this Regulation]**
- c) **Article 5(2) to (6) and article 45, which shall apply from 6 months following the entry into force of this Regulation]**

This Regulation shall be binding in its entirety and directly applicable in all Member States.