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NOTE

From:	FI Delegation
To:	Working Party on Technical Harmonisation (Machinery)
N° prev. doc.:	WK 7570/2021 INIT, WK 9158/2021 INIT
Subject:	Regulation on Machinery Products - Complementary comments from the Finnish delegation on chapter I and Art 10

Complementary comments from the Finnish delegation on chapter I and Art 10 of the proposal for a regulation on Machinery Products

This paper complements the written comments given earlier by FI delegation, see documents

- WK 7570/2021 INIT released on 8 June 2021 "*FI remarks concerning the overlapping provisions between EC proposal for a regulation on machinery products and market surveillance regulation (EU) 2019/1020*" and
- WK 9158/2021 INIT released on 8 July 2021 "*Regulation on Machinery Products - Written comments by Finland – NLF alignment, scope, definitions, Articles 1, 2, 3, 10, 17, 21, 22, 28, 45, and annexes*"

Finland maintains *a general scrutiny reservation* on the proposal as the reading in the national parliament is still in progress. The comments expressed in this document are therefore preliminary remarks expressed during the thematic discussions and article-by-article reading of the proposal.

Terminology

As to the basic terminology to be used in the Regulation, we can support the suggestion made by Sweden presented in WK 9136/2021 INIT released on 8 July 2021 with the difference that we suggest abandoning the term "machinery product" and instead suggest using the term machine equipment for interchangeable equipment; safety components; lifting accessories; chains, ropes and webbing as well as for removable mechanical transmission devices.

Below you can find your proposal for Art 2(1):

- (1) *This Regulation applies to*
- (a) machinery;*
 - (b) partly completed machinery.*

This Regulation also applies to the following machine equipment:

- (a) interchangeable equipment;*
- (b) safety components;*
- (c) lifting accessories;*
- (d) chains, ropes and webbing;*
- (e) removable mechanical transmission devices.*

As requested by the Sweden in the document WK 9136/2021 INIT, following the changes made to the terminology used in Art 2 for defining the scope of the regulation, the impact of the changes to the terms needs to be carefully examined throughout the text.

Furthermore, we yet consider, that the other option to solve the problems faced with the terminology is to use the wording and categorization proposed in our earlier written comments (doc. WK 9158/2021 INIT released on 8 July 2021), in which we suggested that Art2(1) could be written as follows:

- (1) *This Regulation applies to the following [term to be decided]*
- (a) machinery;*
 - (b) interchangeable equipment;*
 - (c) safety components;*
 - (d) lifting accessories;*
 - (e) chains, ropes and webbing;*
 - (f) removable mechanical transmission devices..*

This regulation also applies to partly completed machinery.

where the “term to be decided” could simply be “**products**”.

Definitions

▪ **Safety components**

The proposed definition in Art 3(3) refers to “machinery” (in the strict sense): “*safety component*’ means a physical or digital component, including software, of machinery... is not necessary in order for the machinery to function...”. In the context of the proposed regulation, this term has narrower meaning than in the current MD. We suggest using the term “machinery” in the broad sense in this definition.

▪ **Substantial modification**

In line with our position expressed in our written comments released on 8 July 2021 (WK 9158/2021 INIT), we have drafted a preliminary proposal for a definition of substantial modification:

Substantial modification is a modification,

- *which significantly changes the original specific application or the intended use of the [term to be decided], or*
- *which significantly affects the safety of the [term to be decided] by creating a new risk or by increasing an existing risk, which must be addressed by designing and constructing new protective measures because the existing protective measures present on the [term to be decided] before the modification are not sufficient.*

For all other comments on definitions, see WK 9158/2021 INIT released on 8 July 2021.

Article 5

In line with our position expressed in our written comments released on 8 July 2021 (WK 9158/2021 INIT), page 4, we have drafted a preliminary proposal for Article 5, taking also into account the fact that attention should be paid to how the criteria set out in Article 5 fit in with safety components listed in Annex I. Safety components do not in themselves (as such) pose a risk, but their failure or malfunction can pose a high risk to the machinery, in which they will be incorporated. In our view, this should be taken into account in the wording of Article 5.

We also prefer the idea (expressed e.g. by DE and DK) of updating the list introduced in Annex I before the adoption of the Regulation.

In our proposal (see below) we have left the term “machinery product” untouched, even though that term should be replaced with a better one, according to the decisions that will be made on the subject.

Article 5

Potentially high-risk machinery products

1. Potentially high-risk machinery products listed in Annex I shall be subject to a specific conformity assessment procedure, as referred to in Article 21(2).
2. *The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend Annex I in view of technical progress and knowledge or new scientific evidence by including in the list of potentially high-risk machinery products a new machinery product or withdrawing an existing machinery product from that list, pursuant to the criteria laid down in paragraphs 3 and 4.*
3. *A machinery product shall be included ~~in the list of high-risk machinery products~~ in Annex I if it poses a high risk to human health or safety without appropriate safety measures, or in the case of a safety component, if its malfunction poses such a high risk, taking into account its design and intended purpose. A machinery product shall be withdrawn from the list ~~of high-risk machinery products~~ in Annex I if it no longer poses such risk. The risk posed by a certain machinery 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 shall be taken into account, where applicable:
 - (a) *the degree to which each affected person would be impacted by the harm;*
 - (b) *the number of persons potentially affected;*
 - (c) *the degree to which potentially affected parties are dependent on the outcome produced by the machinery product;*
 - (d) *the degree to which potentially affected parties are in a vulnerable position vis-à-vis the user of the machinery product;*
 - (e) *the degree of reversibility of the harm produced by the machinery product;*
 - (f) *the degree to which the machinery product has been used for a specific purpose;*
 - (g) *indications of harm that have been caused in the past by machinery products which have been used for a specific purpose.**

4. *The Commission may initiate the procedure laid down in paragraph 2 if shall thoroughly assess the criteria laid down in paragraph 3 are fulfilled.*

The procedure laid down in paragraph 2 may be initiated by any of on the basis of available information. In particular the following information shall be communicated to the Commission provided by the Member States when it becomes available to them in connection with market surveillance or as a result of the concerns referred to in the fifth paragraph:

- (a) *an assessment of the risks as referred to in paragraph 3;*
- (b) *a cost-effectiveness analysis known accidents and serious close calls, including characteristics of these accidents or close calls;*

(c) a machinery accident analysis information about safety defects detected in the course of market surveillance, and possible available material in the information systems administered by the Commission;

(d) statistics on accidents caused by the machinery product 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 anticipation justifiable with technical considerations on risks related to new types of machinery.

In addition, the Commission shall regularly analyze information from the Information and Communication System for Market Surveillance (ICSMS) information, safeguard clauses, Rapid Alert System (RAPEX) and the Machinery Administrative Cooperation Group reporting. If the Commission detects a need to initiate the procedure laid down in paragraph 2, the Commission shall consult the Member States before initiating the process.

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

Article 6

Art 6(3) states that "The Commission shall thoroughly assess the risks that require the inclusion of a new safety component in the list of safety components in Annex II or a withdrawal of a safety component from that list." We suggest that Art 6(3) is deleted, as the inclusion of a product to Annex II or exclusion of a product from Annex II is not and should not be based on any kind of risk assessment. Instead, it should solely be based on the assessment whether the definition of a safety component given in Art 3(3) is fulfilled or not.

Article 10

As only some of the obligations set out in Art 10 are applicable to partly completed machinery (PCM), for the sake of clarity, Art 10 should not at all deal with PCM. Therefore, the term(s) used in Art 10 should not include PCM. We consider that the obligations of manufacturers of PCM should be set out in a separate article, which includes the applicable the provisions of Art 10 as well as the provisions set out in the proposed Art 22 (see our preliminary drafting proposal later in this document).

Note! This comment applies also to Art 11-13, as some, but not all, of the requirements set out in those articles are applicable to PCM. However, it would be much clearer to set out those requirements in a separate paragraph/article.

In addition, Art 10 should consistently refer also to manufacturing for own use, i.e. to putting into service of machinery. Putting in to service is referred to in three sentences, but not consistently in the whole Art 10. For example:

Art 10(1): “When placing a *[term to be decided]* on the market *and/or putting it into service*, manufacturers shall ensure that it has been designed and constructed in accordance with the essential health and safety requirements set out in Annex III.”

Art 10(2), 1st paragraph: “Before placing a *[term to be decided]*-~~machinery product~~ on the market *and/or putting it into service*, manufacturers shall draw up the technical documentation referred to in Annex IV (‘technical documentation’) and carry out the relevant conformity assessment procedures referred to in Article 21 ~~or Article 22~~ or have them carried out.”

Art 10(3) refers to the source code or programmed logic included in the technical documentation. Mentioning them here and in several other sections and articles of the proposal separately creates great confusion. We therefore suggest that for the sake of clarity, the 2nd sentence of Art 10(3) should be deleted, as well as all other points in the proposal that refer to this.

As to Art 10(8), in case digital documentation will be accepted as being the only form of document delivery, the *retention period of digitally available DoC* should be determined. The retention period should be considerably long covering at least the expected life time of the machinery.

Obligations of manufacturers of partly completed machinery

Here is our preliminary proposal for a separate article setting out the obligations of manufacturers of PCM (the proposal includes requirements set out in Art 22 as well as applicable requirements set out in Art 10 of the EC proposal):

Article X: Obligations of manufacturers of partly completed machinery

1. *The manufacturer of partly completed machinery or the manufacturer’s authorised representative shall, before placing partly completed machinery on the market, ensure that the following documents are drawn up:*

(a) the relevant technical documentation that satisfies the requirements laid down in Annex IV, part B;

(b) assembly instructions that satisfy the requirements laid down in Annex X;

(c) the EU declaration of incorporation that has the model structure set out in Annex V.

2. *The assembly instructions and the EU declaration of incorporation shall accompany the partly completed machinery until it is incorporated into the final machinery and shall afterwards form part of the technical file for that machinery. Manufacturers shall either provide these documents with the partly completed machinery in paper or in digital form or include in a document accompanying the partly completed machinery the internet address at which these documents can be accessed.*

3. *Manufacturers shall keep the relevant technical documentation and the EU declaration of incorporation at the disposal of the market surveillance authorities for ten years after the partly completed machinery has been placed on the market. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation*

necessary to demonstrate the conformity of the partly completed machinery with the essential health and safety requirements applied and attested, in a language determined by that authority.

4. Manufacturers shall ensure that the partly completed machinery which they place on the market bears a type, batch or serial number or other element allowing its identification. Manufacturers shall also indicate their name, registered trade name or registered trade mark, the postal address and the email address at which they can be contacted on the partly completed machinery. The contact details shall be in a language or languages determined by the Member State in which the partly completed machinery is placed on the market.

5. Manufacturers shall ensure that procedures are in place for partly completed machinery that are part of a series production to remain in conformity with this Regulation and with the essential health and safety requirements applied and attested.

6. Manufacturers who consider or have a reason to believe that a partly completed machinery, which they have placed on the market is not in conformity with the health and safety requirements applied and attested, shall immediately take any corrective measures necessary to bring the partly completed machinery into conformity with the requirements applied and attested, to withdraw it or to recall it, as appropriate.

Language requirements in Art 10-13

There are inconsistencies in the language requirements of contact details and other information on machinery, instructions and documentation included in the technical file. For example, as to user instructions, the requirements are written in the same way for manufacturers in art 10(7) and importers in art 12(4), but not for distributors in art 13(2).

- Art 10(7): *Manufacturers shall ensure that the machinery products are accompanied by the instructions and information set out in section 1.7 of Annex III in a language which can be easily understood by end-users, **as determined by the Member State concerned.***
- Art 12(4): *Importers shall ensure that the machinery product is accompanied by the instructions and information set out in section 1.7 of Annex III in a language which can be easily understood by end-users, **as determined by the Member State concerned.***
- Art 13(2): *(b) the machinery product is accompanied by the required documents and by the instructions and information set out in section 1.7 of Annex III in a language which can be easily understood by end-users **in the Member State in which the machinery product is to be made available on the market;***

This would obviously cause confusion, so we consider that the language requirements should be re-examined throughout the text of the proposal and written in a uniform way throughout the text by using the wording "*as determined by the Member State concerned*" (as e.g. in Art 10(7) and 12(4)).