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**NOTE**

From:	Presidency
To:	Delegations
Subject:	Presidency Flash



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## Technical Harmonisation Working Party (Machinery)

### Presidency Flash

19<sup>th</sup> October 2022

Dear colleagues,

The Czech Presidency would like to invite you to the half-day meeting of the **Working Party on Technical Harmonisation (Attachés)**, which will take place on **Wednesday 19 October 2022 in physical format, starting at 10:00**.

As we are in phase of the intensive discussions with the European Parliament, we would like to ask delegations for the opinion/guidelines on several issues.

First, we would discuss the **compromise wording of Article 5** resulting from the inter-institutional negotiations, which is presented on the following pages.

As for the organisation of the following debate in the Working Party meeting, we intend to proceed according to the **below stated list of topics** based on the new WK 4column document following the Flash, referring to the specific rows of that document and compromise text in the fourth column, as follows:

- Recitals

rows 19 and 24

- Articles

rows 132a, 151, 152 and 152a (matter of scope of the provisions)

- Annex III

rows 540, 565, 567, 593, 599, 611, 625 and 627a (positioning of the provisions in the text), 724 and 725 (scope and content of the term “combined machinery”), 729, 733, 780

If necessary, the other issues might be added after the technical meeting with the European Parliament on 14 October 2022.

**The Czech Presidency Team**



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## Article 5

(rows 167-184a)

Categories of machinery and related products **that may be** subject to specific conformity assessment procedures.

1. Machinery and related products that fall within the categories listed in Annex I, **part A**, shall be subject to the specific conformity assessment procedures, as referred to in Article 21(2) and **those in part B, may be subject to** the specific conformity assessment procedures, as referred to in Article 21(2a).
2. The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend Annex I, after consulting the stakeholders concerned, in view of technical progress and knowledge or new scientific evidence by adding to the list of categories of 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.
3. The inclusion or removal of a category of machinery or related product to Annex I shall rely on the assessment **by the Commission** of the seriousness of the inherent potential risk. That assessment 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 relevant:

- (a') the nature of the hazard inherent to the function of the machinery or related product category, taking into account the intended use and reasonably foreseeable misuse;
- (a) the severity of harm by which a person would be affected, including the degree of reversibility of such harm;
- (b) the number of persons potentially affected by the harm;
- (c) the frequency and the duration of the exposure to the hazard that a person would be subject to in course of the intended use or reasonably foreseeable misuse of the category of machinery or related product;
- (d) the possibilities of avoiding or limiting harm;
- (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 concerns about a category of machinery or related product being listed or not in Annex I.**

- (a) indications of harm that have been caused in the past by machinery or related products which have been used for its intended use or **following** any reasonably foreseeable misuse;



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(ba) information about safety defects detected in the course of market surveillance activities, and possible available material in the information systems administered by the Commission;

(ca) known accidents and serious close calls, including characteristics of these accidents or close calls;

(d) data on accidents or damage to the health caused by the machinery or related product at least for the preceding four years. **In particular information obtained, among others, from the Information and Communication System for Market Surveillance (ICSMS), safeguard clauses, Rapid Alert System (RAPEX), the European Injury Database (EU-IDB), the Eurostat European Statistics on Accidents at Work (ESAW) and the Machinery Administrative Cooperation Group (AdCo).**

4. **a.** A category of machinery or related product which seriousness of its inherent potential risk is established according to paragraph 3 and taking into account data required in paragraph 4, shall be included in Annex I, Part A provided that at least one of the following **conditions** is fulfilled:

(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 including those which could be reduced by particular training or personal protective equipment according to the manufacturer and for which data and information set out in paragraph 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 paragraph 4 which demonstrate **either shortcomings in the relevant harmonised standards or common specifications** or a recurring wrongful application of the relevant harmonised standards or common specifications and for which conducted market surveillance activities have not led to major improvements of the market situation, in a reasonable period of time;

(iv) the degree of uncertainty of the existing risk assessment methods related to new categories of machinery or technologies.

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

2. **a.** A Member State which has concerns about a category of machinery or related product being listed or not 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.



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

By [OJ office: 3 years after the date of entry into force of the Regulation] 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 implementing acts establishing and updating, in view of technological and market development, a template to collect the data and information set out in this Article.

These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 46(3).

The first implementing act shall be adopted not later than twelve months after the entry into force of this Regulation

*Nb. The terminology 'machinery and related products' is still subject to discussion and is to be aligned once an agreement is found.*



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## Recital 15 (row 24)

(15) ~~Since~~ The purpose of this Regulation is to address the risks stemming from the machinery function and not from the transport of goods, persons or animals. Consequently, this Regulation ~~it~~ should not apply to ~~vehicles which only objective is the mere transport of goods or persons on road, by air, on water or on rail networks, regardless of the speed limits. However, machinery mounted on such vehicles or mobile machinery intended for facilitating works such as in construction sites or warehouses e.g. dumpers and forklifts, have a machinery function and should therefore be covered by this Regulation~~ means of transport by air, on water and on rail networks with the exclusion of machinery mounted on these means of transport. The means of transport on road that are not yet included in the scope of a specific Union legislation are regulated by this Regulation with the exception of the risks that may arise from the circulation. of such means of transport on road, and only until such time as those means of transport become the subject of specific Union legislation. This notably means that vehicles including off-road vehicles, e-bikes, e-scooters and other personal mobility devices that are not subject to EU type approval under Regulation (EU) No 167/2013 or Regulation (EU) 168/2013 should be covered by this Regulation.

~~Since agricultural and forestry vehicles tractors and two or three wheel vehicles and quadricycles, and motor vehicles and their trailers, as well as systems, components, separate technical units, parts and equipment designed and constructed or intended for such vehicles, fall within the scope of Regulation (EU) No 167/2013 of the European Parliament and of the Council<sup>1</sup>, Regulation (EU) No 168/2013 of the European Parliament and of the Council<sup>2</sup> or and Regulation (EU) No 168/2013 No 2018/858 of the European Parliament and of the Council<sup>2</sup> [3] respectively, they should be excluded from the scope of this Regulation.~~

The Czech Presidency Team



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