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NOTE

From: Presidency/General Secretariat of the Council
To: Permanent Representatives Committee

Subject: Proposal for a Regulation of the European Parliament and of the Council
on machinery products
- Preparation for the Trilogue

I. INTRODUCTION

1. On 21 April 2021, the Commission presented a proposal for a Regulation of the European Parliament and of the Council on machinery products.
2. The main objectives of this proposal are to establish a legal framework for the placing on the Union market of safe machinery, to guarantee legal certainty by clarifying the scope and definitions, to clarify the issue of mandatory third-party conformity assessment for certain product categories, as well as to find the right balance between digital and paper documentation.
3. The European Economic and Social Committee delivered its opinion on 22 December 2021.

4. Examination of the proposal at the Council started in the Working Party on Technical Harmonization on 26 April 2021 under the Portuguese Presidency, the examination continued the Slovenian presidency and under the French presidency until the Permanent Representatives Committee adopted the Council's mandate on 22 June 2022.
5. In the European Parliament, the committee responsible is the Committee on the Internal Market and Consumer Protection (IMCO Committee). The IMCO Committee voted on its final report, as well as the decision to enter into interinstitutional negotiations, on 3 May 2022. The Plenary endorsed that decision on 20 May 2022.

II. INTERINSTITUTIONAL NEGOTIATIONS – STATE OF PLAY

6. The opening political trilogue was held under the Czech Presidency on 12 July 2022. The co-legislators presented their views on the main political issues and gave a broad mandate to the subsequent technical meetings to identify and make progress on areas of compromise. So far, eleven interinstitutional technical meetings have been held.
7. The Working Party on Technical Harmonisation was convened to discuss the progress in the interinstitutional technical meetings on 27 September, 19 and 28 October 2022.
8. At the technical level, Articles 1-13, 17, 21, 50-52, Annexes I, II and III, and related recitals have been discussed so far. Although considerable progress has been made in the negotiations and most of the rows regarding these provisions have been preliminary agreed, some provisions could not be agreed and therefore need political guidance for further discussions. Namely, the terminology (Article 2), definitions (Article 3), high-risk machinery and related products (Article 5, Annex I), obligations of economic operators (Articles 10-13), presumption of conformity (Article 17), conformity assessment procedures (Article 21), transitional provisions (Article 50), and entry into force and application (Article 52).
9. The next political trilogue is scheduled for 17 November 2022.

III. PREPARATION FOR THE NEXT TRILOGUE

10. Following the discussion at the Working Party meeting on 28 October 2022, the Presidency has identified a set of key issues where it seems necessary to adjust accordingly the mandate for further negotiations so that compromise solutions can be sought more effectively. These are listed below in order of the individual articles, excluding important issues not yet discussed at technical level. The Presidency would like to invite Coreper to consider the questions below and to express their views on possible areas of flexibility in order to reach a compromise. Discussion in the forthcoming political dialogue will be focused on the political aspects that emerged from the negotiations at the technical level so far. Some of these aspects are expected to be a part of the final compromise package, namely the question of fees for SMEs (Article 21 para 4, recital 24), digital vs. paper documentation (Article 10 para 7 and relevant provisions), transitional provisions (Article 50), dates of application and entry into force (Article 52), “high risk“ machinery (Article 5, Annex I). On these issues, it is necessary to already identify possible flexibilities of the Council towards the Parliament's position in order to be able to negotiate the final compromise package.
11. The Permanent Representatives Committee is therefore invited:
 - to confirm the preliminary agreement reached at the technical level on the part of the text proposal, which is set out in the Annex to this note;
 - to consider the questions below and to express their views on possible areas of flexibility in order to reach a compromise.

1. TERMINOLOGY

- Scope - Article 2(1), Rows: 91 - 98a;

The Council introduced in its mandate the distinction between the three categories of products covered by this Regulation, namely “*machinery*”, “*related products*”, and “*partly completed machinery*”, whereas in the Commission’s proposal the “*partly completed machinery*” was not considered to be a separate category. The aim was to distinguish between different categories of products, which may be subject to different requirements. To make this distinction clear throughout the text of Regulation, the Council also introduced a new terminology (“*machinery*”, “*related products*”, and “*products subject to this Regulation*”). Also the term “*machinery products*” was removed from the text because it did not bring sufficient clarity about the requirements that are applicable to different categories of products and posed translation issues for a number of Member States. The European Parliament accepted, in general, the concept proposed by the Council, i.e. the need to treat “*partly completed machinery*” separately from other categories of products that may be subject to different requirements. A general understanding was reached that the term “*products within the scope of this Regulation*” could be used instead of the term “*products subject to this Regulation*”. The European Parliament, however, opposes the terminology “*machinery*” and “*related products*” introduced by the Council as this terminology seems to make the text unclear as it is repeated many times within the text of the Regulation. The Parliament's compromise proposals, replacing terms “*machinery*” and “*related products*” by new terms “*machines*”, “*complete machines*”, and “*machinery accessories*” were strongly opposed by Member States as such proposals would make the text confusing and cause issues with translations into many national languages.

The Presidency’s intention is to insist on the Council’s mandate as regards the terminology “*machinery*” and “*related products*”.

Q1: Do delegations agree with the Presidency’s intention to insist on the Council’s mandate as regards the terms “machinery” and “related products”?

2. COMMON SPECIFICATIONS

- Definitions - Article 3(23a), Row: 152a;

The Commission proposal includes a provision that empowers the Commission to adopt under the specific circumstances via the implementing acts the “*common specifications*” to cover the essential health and safety requirements set out in Annex III of the Regulation in case no harmonised standards exist. To differentiate the “*common specification*” from the “*technical specification*” adopted according to the Standardisation Regulation (1025/2012) and to define clearly the scope of the Commission empowerment, the Council introduced in its mandate the definition of “*common specification*”. The Parliament strongly opposes the introduction of this definition as, according to the Parliament, the definition should be introduced in horizontal legislation, not in the sectoral one. Furthermore, the Parliament considers the formulation of the definition with reference to the “*technical specifications*” as defined in Regulation (EU) No 1025/2012 on European standardisation to be misleading, because the adoption of such “*technical specifications*” is subject to the procedure established by that Regulation,. In order to find a compromise solution, the new wording of the definition inspired by the definition of “*common specifications*” in Regulation (EU) No 2017/745 (Medical Devices Regulation), which is without specific reference to the Regulation (EU) No 1025/2012, has been discussed but with no conclusive result. If the Parliament continues to insist that no such definition should be introduced in this sectoral legislation, the Presidency suggests removing the definition from Article 3 and clarifying the meaning of the “*common specification*” directly in the respective provision of Article 17.

Q2: In order to find a possible compromise solution, could the delegations agree to show flexibility to the solution based on clarification of the term “common specification” directly in the respective provision of Article 17 if the Parliament insists on not having the specific definition in the Article 3?

Q3: In case of negative answer to the previous question, could delegations support the definition of the “common specification” without the specific reference to Regulation (EU) No 1025/2012 on European standardisation and inspired by the definition provided for in the Medical Devices Regulation?

- Presumption of conformity of machinery products - Article 17, Rows: 248 - 249, 251 - 253a

The Council agreed with the Commission's intention to introduce the empowerment for the Commission to adopt via the implementing acts the "*common specifications*" in case no harmonised standards exist. To ensure that the Commission uses this empowerment only as a fall-back option, the Council introduced in its mandate a clear legal framework as regards the triggering conditions as well as the withdrawal of the common specifications once the reference to the relevant harmonised standard is published in the Official Journal of the European Union. The Parliament agrees, in general, with the Council that the legal framework for this specific Commission's empowerment needs to be clearly specified. The Parliament accepts the Council's position to a considerable extent as regards the triggering conditions, however, suggesting simplifying the text and rewording the respective provisions. The Parliament suggests that the Commission should not be allowed to adopt the common specification "*when the reference to the harmonised standard is expected to be published within a reasonable period*". Some Member States oppose this condition, saying that the term "reasonable period" is not clear enough and provides a lot of room for various interpretations. The Parliament's proposal seems to aim to limit the empowerment of the Commission as it addresses the situations when a harmonised standard is already being prepared by the respective European standardisation organisation (ESO), however, it is evident that it will not be issued within a deadline set by the standardisation request but *within a reasonable period* after this deadline. The Parliament's proposal would prevent the Commission from adopting the implementing acts establishing the common specifications immediately after the deadline was not complied with by the ESO, ensuring that the application of common specifications will only be used as a fall-back option where a harmonised standard is obviously not going to be issued in the nearest future. Given the justification provided by the Parliament, the Presidency suggests showing openness towards this Parliament's proposal.

Q4: Do delegations agree with the Presidency's suggestion to show the flexibility to move towards the Parliament's position as regards the triggering condition for adoption of implementing act establishing common specification when the harmonised standard requested by the Commission has not been delivered within the deadline set in the standardisation request but the delivery is expected within a reasonable period?

- Presumption of conformity of machinery products - Article 17, Rows 254a – 256

In its mandate, the Council emphasized the role of common specifications as a fall-back option by suggesting that “*the implementing act shall be repealed when references to a harmonised standard are published in the Official Journal of the EU*”. The position of the Parliament regarding this provision is very close to the Council’s mandate. However, the Parliament mentions that “*the relevant technical specification shall no longer apply*”. At the technical level, the compromise text has been discussed stating that the Commission shall “*assess whether to repeal implementing acts*” when references to a harmonised standard are published in the Official Journal of the EU. Many Member States opposed that wording, saying it undermines common specifications' "*fall-back option*" nature. The aim of the proposed text, however, is to ensure the Commission's ability to assess whether the harmonized standard has an added value in terms of reflecting the technological development and justifies repealing the common specifications. The Presidency suggests considering the compromise solution in this regard.

Q5: Do delegations agree with the Presidency’s suggestion to show some flexibility towards the compromise solution that gives the Commission a level of discretion to assess whether to repeal implementing acts setting out the common specifications when references to a harmonised standard are published in the Official Journal of the EU.

3. SME FEES

- Conformity assessment procedures - Article 21(4), recital 24, Article 36(2), Rows: 278, 33, 369

Regarding the issue of the specific conditions for SMEs, all three institutions agree in general with the provision that the notified bodies should not impose disproportionate burdens on SMEs. However, the positions of the institutions differ as regards the way how the specific interests and needs of SMEs should be taken into account and how to regulate this aspect. While the Parliament and the Commission insist on maintaining the respective provision introducing the obligation of notified bodies to take into account the specific interests and needs of SMEs when setting the fees for conformity assessment in the normative part of the text, the Council considers that this cannot be an obligation for the notified bodies in the text of Article 21(4) but only a recommendation in recital 24.

The Member States also oppose the Parliament's suggestion in the text of the recital 24 that notified bodies should "simplify and facilitate procedures", because conformity assessment modules are clearly defined by Decision No 768/2008/EC and also set out in the Annexes of this proposal, and do not offer any possibility for simplification. In order to find a possible compromise solution, the Presidency suggests accepting the Parliament's position in Article 21(4), where the explicit obligation to reduce the fees proportionately for SMEs has been deleted, while insisting on the Council's mandate on recital 24.

Q6: Do delegations agree with the Presidency's suggestion to show a degree of flexibility towards the Parliament by accepting the wording of Article 21 para 4 as proposed by the Parliament provided that the Parliament considers its position on recital 24 and reflects the Council's position on this recital?

4. DIGITAL VS. PAPER DOCUMENTATION

- Obligations of manufacturers - Article 10(7), Rows: 206a - 206g;

The Council specified in its mandate that the manufacturer has the option of providing the instructions in digital form, whereby it must be ensured that the user can request the instructions in paper form free of charge at the time of purchase or within 6 months after the purchase. This is due to concerns by some Member States that a digital form of the instructions may not be sufficient in certain situations. The Parliament does not agree with the possibility to request the paper instruction later than at the time of purchase as this provision would be very difficult for the manufacturer to comply with in practice. Compromise text that includes the possibility to provide the instruction in paper form at the place of the purchase or later by mail has been discussed at the technical level. Several Member States expressed reservations towards this text saying that it would result in larger engagement of the distributors as they would have to inform the purchaser about the fact that the paper instruction is not included in the packaging and upon request provide the paper form of the instructions. Moreover, many Member States do not agree with the Parliament, which, at the same time, insists on deletion of the obligation for manufacturers to provide the safety information in paper format in the case of machinery intended for non-professional users. Furthermore, the Parliament suggested that manufacturers shall make the digital instructions accessible online not less than 15 years after the placing on the market of the machinery which is contrary to standard NLF period of 10 years. In order to find possible compromise, the Presidency suggests showing the flexibility towards the Parliament's proposal regarding the paper format of the instructions provided that provision concerning the safety instructions as well as and the ten year period for accessibility of digital instructions will be maintained.

Q7: In order to find possible compromise solutions would delegations agree to show of flexibility regarding the Parliament's amendments as listed above, while maintaining the obligation to provide the safety instructions in paper format when the machinery is intended for non-professional users and the ten year period for accessibility of digital instructions online?

5. TRANSITIONAL PROVISIONS, ENTRY INTO FORCE AND APPLICATION

- Transitional provisions - Article 50 para 2, Rows: 463;

The Council mandate specifies the deadline by which the EC type-examination certificates and approval decisions issued under the existing legislation (Directive 2006/42/EC) shall remain valid. The Parliament suggests to state that the above mentioned documents shall remain valid until they expire. The proposals of both institutions are identical in substance as the certificates and approval decisions are issued for a period of 5 years, which is the same as 60 months after the date of application of the Regulation according to deadline set out in the Council mandate (if they do not expire earlier). In order to find possible compromise the Presidency suggests accepting Parliament's position for Article 50(2).

Q8: Do delegations agree with the Presidency's suggestion to show a degree of flexibility towards the Parliament by accepting the wording of Article 50 para 2 as proposed by the Parliament?

- Entry into force and application - Article 52, Rows: 472 - 472d;

Regarding the provision of application, both the Parliament and the Council agreed that the period should be longer than the 30 months suggested by the Commission. Some Member States prefer an earlier application of Regulation suggestion a parallel application of the Regulation and the existing Directive. However, most Member States prefer the Regulation to apply from no less than 36 months after its entry into force, as proposed by the Council's mandate. The Council also introduced some exceptions regarding the provisions on notified bodies, sanctions and the Commission's empowerment to adopt delegated and implementing acts set in Article 5, which are supposed to enter into application sooner than the rest of the text. The Parliament proposes the date of application to be 48 months after the entry into force.

Q9: Could delegations, in the spirit of compromise, show some flexibility towards the Parliament's position provided that the exceptions set by the Council's mandate are reflected?

6. HIGH-RISK MACHINERY PRODUCTS

- High-risk machinery products - Article 5, Rows: 167 - 184a;

The Council specified in its mandate the procedure and criteria for amending Annex I (lists of categories of machinery or related products to which specific conformity assessment procedures shall be applied). Although Parliament has generally accepted most of the changes proposed by the Council, it proposes certain specific elements to be adjusted. Namely, the deletion of the explicit reference to consultation of Member States' experts before adopting delegated acts to amend Annex I, the listing of existing databases and information systems collecting data on accidents or damage to the health caused by the machinery or related products, introducing delegated powers to the Commission to establish a methodology for collecting and communicating required data.

As the Parliament indicated that the provisions of Article are of crucial importance for them, the Presidency suggests showing a degree of openness towards a compromise while stressing that this compromise must provide a clear and feasible legal framework for the amendment of Annex I and respective obligation for the Member States to provide relevant data.

Q10: Do delegations insist on explicit mention of consultation with national experts of the Member States before adopting the delegated acts amending Annex I despite the provisions of Article 45 para 3?

Q11: Could delegations agree to show a certain degree of flexibility concerning the indicative listing of databases and information systems collecting data on accidents or damage to the health caused by the machinery or related products provided that the list is introduced by the words "among others" or other relevant words?

Q12: Do delegations agree with the Presidency's suggestion not to insist on mentioning "if available" as regards the obligation for the Member States to provide the Commission with the respective information, provided that the Commission confirms that the obligation is fulfilled if the Member State communicates that there is no information on the accidents or damage to the health caused by respective machinery or related product on its territory?

Q13: Do delegations agree with establishment of a methodology for collecting and communicating required data instead of the development of a template?

Q14: In case of positive answer to the previous question could delegations agree with the establishment of the methodology by the delegated act?

- High-risk machinery products – Annex I, Rows: 477 – 510b

Even though the discussion at the technical level on the content of Annex I has been very limited, the Parliament expressed its strong opinion on maintaining the proposed number of categories of machinery and related products in Annex I, part A. Regarding the fact that the Parliament strongly links the possible future agreement on Article 5 with the wording of Annex I, the Presidency suggests considering both of these topics together to find compromise solution. Therefore, the Presidency asks the Member States to indicate possible flexibility for the extension of the number of categories of machinery and related products in Annex I, part A, if already possible at this stage, to gain clearer understanding of room for manoeuvre as regards the compromise on Article 5.

Q15: Could delegations indicate flexibility for the extension of the number of categories of machinery and related products in Annex I, part A?

IV. CONCLUSIONS

12. The Permanent Representatives Committee is invited to reflect on the abovementioned questions and to express their views on possible areas of flexibility as regards moving towards the position of the European Parliament during the meeting of the Permanent Representatives Committee.