

**Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011 as regards emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency (Text with EEA relevance)**

2022/0279(COD)

DRAFT [Versions after T4\_Following TM on 12 February]

13-02-2024 at 12h05

|                | Commission Proposal   | EP Mandate  | Council Mandate  | Draft Agreement   |
|----------------|---|---|--|---|
| Formula        |   |   |  |   |
| 1              | 2022/0279 (COD)   | 2022/0279 (COD)   | 2022/0279 (COD)  | 2022/0279 (COD)   |
| Proposal Title |   |   |  |   |
| 2              | Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011 as regards emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency (Text with EEA relevance) | Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009, <u>(EU) 2023/988, (EU) 2023/1230</u> and (EU) No 305/2011 as regards emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to <u>a Single internal</u> market emergency (Text with EEA relevance) | Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) <del>2019/1009 and (EU) No 305/2011</del> <b>No 305/2011 and (EU) 2023/1230</b> as regards emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency (Text with EEA relevance) | <del>Proposal for a</del> REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations <u>(EU) No 305/2011</u> , (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) <del>2019/1009 and (EU) No 305/2011</del> <u>2023/988 and (EU) 2023/1230</u> as regards emergency procedures for the conformity assessment, <u>presumption of conformity</u> , adoption of common specifications and market surveillance due to <u>a Single internal</u> market emergency (Text with EEA relevance) |

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011 as regards emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency (Text with EEA relevance) 2022/0279(COD) 13-02-

2024 at 12h05 1/204

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|            |  |  |  | Text Origin: Council Mandate   |
| Formula    |  |  |  |  |
| 3          | THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,   | THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,   | THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,   | THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,<br><br>Text Origin: Commission Proposal   |
| Citation 1 |  |  |  |  |
| 4          | Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof, | Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof, | Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof, | Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,<br><br>Text Origin: Commission Proposal |
| Citation 2 |  |  |  |  |
| 5          | Having regard to the proposal from the European Commission,  | Having regard to the proposal from the European Commission,  | Having regard to the proposal from the European Commission,  | Having regard to the proposal from the European Commission,<br><br>Text Origin: Commission Proposal  |
| Citation 3 |  |  |  |  |
| 6          | After transmission of the draft legislative act to the national parliaments,                                 | After transmission of the draft legislative act to the national parliaments,                                 | After transmission of the draft legislative act to the national parliaments,                                 | After transmission of the draft legislative act to the national parliaments,   |

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|            |   |   |   | Text Origin: Commission Proposal  |
| Citation 4 |   |   |   |   |
| 7          | Having regard to the opinion of the European Economic and Social Committee <sup>1</sup> ,<br><u>1. OJ C , , p. .</u>  | Having regard to the opinion of the European Economic and Social Committee <sup>1</sup> ,<br><u>1. OJ C , , p. .</u>  | Having regard to the opinion of the European Economic and Social Committee <sup>1</sup> ,<br><u>1. OJ C , , p. .</u>  | Having regard to the opinion of the European Economic and Social Committee <sup>1</sup> ,<br><u>1. OJ C , , p. .</u><br><br>Text Origin: Commission Proposal  |
| Citation 5 |   |   |   |   |
| 8          | Acting in accordance with the ordinary legislative procedure <sup>1</sup> ,<br><u>1. Position of the European Parliament of xxx (not yet published in the Official Journal) and Decision of the Council of xxx.</u> | Acting in accordance with the ordinary legislative procedure <sup>1</sup> ,<br><u>1. Position of the European Parliament of xxx (not yet published in the Official Journal) and Decision of the Council of xxx.</u> | Acting in accordance with the ordinary legislative procedure <sup>1</sup> ,<br><u>1. Position of the European Parliament of xxx (not yet published in the Official Journal) and Decision of the Council of xxx.</u> | Acting in accordance with the ordinary legislative procedure <sup>1</sup> ,<br><u>1. Position of the European Parliament of xxx (not yet published in the Official Journal) and Decision of the Council of xxx.</u><br><br>Text Origin: Commission Proposal |
| Formula    |   |   |   |   |
| 9          | Whereas:  | Whereas:  | Whereas:  | Whereas:<br><br>Text Origin: Commission Proposal  |
| Recital 1  |   |   |   |   |
| 10         |   |   |   |   |

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|           | (1) [insert reference to SMEI Regulation] aims to ensure the normal functioning of the Single Market, including the free movement of goods, services and persons and guarantee the availability of crisis-relevant goods and services and goods and services of strategic importance to citizens, businesses and public authorities during a crisis. | (1) [insert reference to <del>SMEI</del> <u>IMERA</u> Regulation] aims to ensure the normal functioning of the <del>Single</del> <u>internal</u> market, including the free movement of goods, services and persons and <del>guarantee</del> <u>ensure</u> the availability of crisis-relevant goods and services and goods and services of strategic importance to citizens, businesses and public authorities during a crisis. | (1) [insert reference to SMEI Regulation] aims to ensure the normal functioning of the Single Market, including the free movement of goods, services and persons and guarantee the availability of crisis-relevant goods and services and goods and services of strategic importance to citizens, businesses and public authorities during a crisis. | (1) [insert reference to <del>SMEI</del> <u>IMERA</u> Regulation] aims to ensure the normal functioning of the <del>Single</del> <u>internal</u> market, including the free movement of goods, services and persons and <del>guarantee</del> <u>ensure</u> the availability of crisis-relevant goods and services and goods and services of strategic importance to citizens, businesses and public authorities during a crisis. |
| Recital 2 |  |  |  |  |
| 11        | (2) The framework established by [insert reference to SMEI Regulation] lays down measures, which should be deployed in a coherent, transparent, efficient, proportionate and timely manner, so as to prevent, mitigate and minimise the impact on the functioning of the Single Market that a crisis may cause.                                      | (2) The framework established by [insert reference to <del>SMEI</del> <u>IMERA</u> Regulation] lays down measures, which should be deployed in a coherent, transparent, efficient, proportionate and timely manner, so as to prevent, mitigate and minimise the impact <u>a crisis may cause</u> on the functioning of the <del>Single</del> <u>internal</u> market <del>that a crisis may cause</del> .                         | (2) The framework established by [insert reference to SMEI Regulation] lays down measures, which should be deployed in a coherent, transparent, efficient, proportionate and timely manner, so as to prevent, mitigate and minimise the impact on the functioning of the Single Market that a crisis may cause.                                      | (2) The framework established by [insert reference to <del>SMEI</del> <u>IMERA</u> Regulation] lays down measures, which should be deployed in a coherent, transparent, efficient, proportionate and timely manner, so as to prevent, mitigate and minimise the impact on the functioning of the <del>Single</del> <u>internal</u> market that a crisis may cause.   |
| Recital 3 |  |  |  |  |
| 12        | (3) [insert reference to SMEI Regulation] lays down a multi-layered mechanism consisting of contingency planning, vigilance mode and Single Market emergency mode.   | (3) [insert reference to <del>SMEI</del> <u>IMERA</u> Regulation] lays down a multi-layered mechanism consisting of contingency planning, <del>vigilance mode and Single</del> <u>and internal</u> market <del>vigilance and</del> emergency <del>mode</del> <u>modes</u> .  | (3) [insert reference to SMEI Regulation] lays down a multi-layered mechanism consisting of contingency planning, vigilance mode and Single Market emergency mode.   | (3) [insert reference to <del>SMEI</del> <u>IMERA</u> Regulation] lays down a multi-layered mechanism consisting of contingency planning, <del>vigilance mode and Single</del> <u>and internal</u> market <del>vigilance and</del> emergency <del>mode</del> <u>modes</u> .  |

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| Recital 4 |  |  |  |  |
| 13        | (4) [insert reference to SMEI Regulation] lays down rules with the objective of safeguarding the free movement of goods, services and persons in the Single Market and to ensure the availability of goods and services that are particularly important also in times of crisis. [insert reference to SMEI Regulation] applies to both goods and services. | (4) [insert reference to <del>SMEI</del> IMERA Regulation] lays down rules with the objective of safeguarding the free movement of goods, services and persons in the <del>Single</del> internal market and to ensure the availability of goods and services that are particularly important also in times of crisis. [insert reference to <del>SMEI</del> IMERA Regulation] applies to both goods and services. | (4) [insert reference to SMEI Regulation] lays down rules with the objective of safeguarding the free movement of goods, services and persons in the Single Market and to ensure the availability of goods and services that are particularly important also in times of crisis. [insert reference to SMEI Regulation] applies to both goods and services. | (4) [insert reference to <del>SMEI</del> IMERA Regulation] lays down rules with the objective of safeguarding the free movement of goods, services and persons in the <del>Single</del> internal market and to ensure the availability of goods and services that are particularly important also in times of crisis. [insert reference to <del>SMEI</del> IMERA Regulation] applies to both goods and services. |
| Recital 5 |  |  |  |  |
| 14        | (5) In order to complement, ensure consistency and to further enhance the effectiveness of such measures, it is appropriate to ensure that referred to in [insert reference to SMEI Regulation] may be swiftly placed on the Union market in order to contribute to addressing and mitigating the disruptions.   | (5) In order to complement, ensure consistency and to further enhance the effectiveness of such measures, it is appropriate to ensure that <del>crisis-relevant goods</del> referred to in [insert reference to <del>SMEI</del> IMERA Regulation] may be swiftly placed on the <del>Union</del> internal market in order to contribute to addressing and mitigating the disruptions.                             | (5) In order to complement, ensure consistency and to further enhance the effectiveness of such measures, it is appropriate to ensure that referred to in [insert reference to SMEI Regulation] may be swiftly placed on the Union market in order to contribute to addressing and mitigating the disruptions.   | (5) In order to complement, ensure consistency and to further enhance the effectiveness of such measures, it is appropriate to ensure that <del>crisis-relevant goods</del> referred to in [insert reference to <del>SMEI</del> IMERA Regulation] may be swiftly placed on the Union market in order to contribute to addressing and mitigating the disruptions.   |
| Recital 6 |  |  |  |  |
| 15        | (6) A number of Union sectoral legal acts lay down harmonised rules regarding the design, manufacture,   | (6) A number of Union sectoral legal acts lay down harmonised rules regarding the design, manufacture,   | (6) A number of Union sectoral legal acts lay down harmonised rules regarding the design, manufacture,   | (6) A number of Union sectoral legal acts lay down harmonised rules regarding the design, manufacture,   |

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|   | <p>conformity assessment and placing on the market of certain products. Such legal acts include Regulations (EU) 2016/424<sup>1</sup>, (EU) 2016/425<sup>2</sup>, (EU) 2016/426<sup>3</sup>, (EU) 2019/1009<sup>4</sup> and (EU) No 305/2011<sup>5</sup> of the European Parliament and of the Council. Those legal acts are based on the principles of the new approach to technical harmonisation. Moreover, Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2019/1009 are also aligned to the reference provisions laid down by Decision No 768/2008/EC of the European Parliament and of the Council <sup>6</sup>.</p> <p>1. OJ L 81, 31.3.2016, p. 1.<br/>2. OJ L 81, 31.3.2016, p. 51.<br/>3. OJ L 81, 31.3.2016, p. 99.<br/>4. OJ L 170, 25.6.2019, p. 1.<br/>5. OJ L 88, 4.4.2011, p. 5.<br/>6. OJ L 218, 13.8.2008, p. 82.</p> | <p>conformity assessment and placing on the market of certain products. Such legal acts include Regulations (EU) 2016/424<sup>1</sup>, (EU) 2016/425<sup>2</sup>, (EU) 2016/426<sup>3</sup>, (EU) 2019/1009<sup>4</sup>, <u>(EU) 2023/1230<sup>4a</sup></u> and (EU) No 305/2011<sup>5</sup> of the European Parliament and of the Council. Those legal acts are based on the principles of the new approach to technical harmonisation. Moreover, Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, <u>(EU) 2019/1009, (EU) 2023/988<sup>5a</sup> and (EU) 2023/1230</u> <del>and (EU) 2019/1009</del> are also aligned to the reference provisions laid down by Decision No 768/2008/EC of the European Parliament and of the Council <sup>6</sup>. <u>In addition, Regulation (EU) 2023/988 lays down essential rules on the safety of consumer products placed or made available on the market.</u></p> <p>1. OJ L 81, 31.3.2016, p. 1.<br/>2. OJ L 81, 31.3.2016, p. 51.<br/>3. OJ L 81, 31.3.2016, p. 99.<br/>4. OJ L 170, 25.6.2019, p. 1.<br/><u>4a. OJ L 165, 29.6.2023, p. 1</u><br/>5. OJ L 88, 4.4.2011, p. 5.<br/><u>5a. OJ L 135, 23.5.2023, p. 1.</u><br/>6. OJ L 218, 13.8.2008, p. 82.</p> | <p>conformity assessment and placing on the market of certain products. Such legal acts include Regulations (EU) 2016/424<sup>1</sup>, (EU) 2016/425<sup>2</sup>, (EU) 2016/426<sup>3</sup>, <sup>4</sup> (EU) No 305/2011<sup>5</sup> and (EU) No 2023/1230<sup>6</sup> <del>(EU) 2019/1009<sup>4</sup> and (EU) No 305/2011<sup>5</sup></del> of the European Parliament and of the Council. Those legal acts are based on the principles of the new approach to technical harmonisation. Moreover, Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) <del>2019/1009</del> <u>No 2023/1230</u> are also aligned to the reference provisions laid down by Decision No 768/2008/EC of the European Parliament and of the Council<sup>7</sup>. <sup>6</sup>.</p> <p>1. OJ L 81, 31.3.2016, p. 1.<br/>2. OJ L 81, 31.3.2016, p. 51.<br/>3. OJ L 81, 31.3.2016, p. 99.<br/>4. OJ L 170, 25.6.2019, p. 1.<br/>5. OJ L 88, 4.4.2011, p. 5.<br/>6. OJ L 218, 13.8.2008, p. 82 <u>165, 29.6.2023, p 1.</u><br/>7. OJ L 218, 13.8.2008, p. 82.</p> | <p>conformity assessment and placing on the market of certain products. Such legal acts include Regulations (EU) 2016/424<sup>1</sup>, (EU) 2016/425<sup>2</sup>, (EU) 2016/426<sup>3</sup>, <sup>4</sup> <u>(EU) No 305/2011<sup>5</sup> and (EU) No 2023/1230<sup>6</sup></u> <del>(EU) 2019/1009<sup>4</sup> and (EU) No 305/2011<sup>5</sup></del> of the European Parliament and of the Council. Those legal acts are based on the principles of the new approach to technical harmonisation. Moreover, Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) <del>2019/1009</del> <u>No 2023/1230</u> are also aligned to the reference provisions laid down by Decision No 768/2008/EC of the European Parliament and of the Council<sup>7</sup>. <sup>6</sup>.</p> <p>1. OJ L 81, 31.3.2016, p. 1.<br/>2. OJ L 81, 31.3.2016, p. 51.<br/>3. OJ L 81, 31.3.2016, p. 99.<br/>4. OJ L 170, 25.6.2019, p. 1.<br/>5. OJ L 88, 4.4.2011, p. 5.<br/>6. OJ L <del>218, 13.8.2008, p. 82</del> <u>165, 29.6.2023, p 1.</u><br/><u>7. OJ L 218, 13.8.2008, p. 82.</u></p> <p>Text Origin: Council Mandate</p> |
|   | Recital 7  |  |   |  |
| G | 16   |  |   | G  |


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|           | (7) Neither the reference provisions laid down by Decision No 768/2008/EC, nor the specific provisions laid down by the sectoral <del>nion</del> U harmonisation legislation provide for procedures designed to apply in crisis. It is appropriate to introduce targeted adjustments to those Regulations, aimed at preparing and responding to impacts of crises affecting products that have been designated as crisis-relevant goods and covered by those Regulations. | (7) Neither the reference provisions laid down by Decision No 768/2008/EC, nor the specific provisions laid down by the sectoral <del>nion</del> <b>Union</b> harmonisation legislation provide for procedures designed to apply in crisis. It is appropriate to introduce targeted adjustments to those Regulations, aimed at preparing and responding to impacts of crises affecting products that have been designated as crisis-relevant goods and covered by those Regulations.                            | (7) Neither the reference provisions laid down by Decision No 768/2008/EC, nor the specific provisions laid down by the sectoral <del>nion</del> <b>Union</b> harmonisation legislation provide for procedures designed to apply in crisis. It is appropriate to introduce targeted adjustments to those Regulations, aimed at preparing and responding to impacts of crises affecting products that have been designated as crisis-relevant goods and covered by those Regulations.                         | (7) Neither the reference provisions laid down by Decision No 768/2008/EC, nor the specific provisions laid down by the sectoral <del>nion</del> <b>Union</b> harmonisation legislation provide for procedures designed to apply in crisis. It is appropriate to introduce targeted adjustments to those Regulations, aimed at preparing and responding to impacts of crises affecting products that have been designated as crisis-relevant goods and covered by those Regulations.<br><br>Text Origin: EP Mandate                            |
| Recital 8 |   |   |  |  |
| 17        | (8) Experience from the recent crises that have affected the Single Market has shown that the procedures laid down in the sectoral legislation are not designed to cater for the needs of crisis-response scenarios and do not offer the necessary regulatory flexibility. It is therefore appropriate to provide for a legal basis for such crisis-response procedures as a complement to the measures adopted under [insert reference to SMEI Regulation].              | (8) Experience from the recent crises that have affected the <del>Single</del> <b>internal</b> market has shown that the procedures laid down in the sectoral legislation are not designed to cater for the needs of crisis-response scenarios and do not offer the necessary regulatory flexibility. It is therefore appropriate to provide for a legal basis for such crisis-response procedures as a complement to the measures adopted under [insert reference to <del>SMEI</del> <b>IMERA</b> Regulation]. | (8) Experience from the recent crises that have affected the Single Market has shown that the procedures laid down in the sectoral legislation are not designed to cater for the needs of crisis-response scenarios and do not offer the necessary regulatory flexibility. It is therefore appropriate to provide for a legal basis for such crisis-response procedures as a complement to the measures adopted under [ <del>insert reference to SMEI Regulation</del> insert reference to SMEI Regulation]. | (8) Experience from the recent crises that have affected the <del>Single</del> <b>internal</b> market has shown that the procedures laid down in the sectoral legislation are not designed to cater for the needs of crisis-response scenarios and do not offer the necessary regulatory flexibility. It is therefore appropriate to provide for a legal basis for such crisis-response procedures as a complement to the measures adopted under [insert reference to <del>SMEI</del> <b>IMERA</b> Regulation].<br><br>Text Origin: EP Mandate |

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| Recital 8a |   |   |   |   |
| 17a        |   |   |   | <p><u>(8a) Non-harmonised products can also be crisis-relevant goods. Therefore, some of the relevant mechanisms under this Regulation, notably the presumption of safety based on national requirements, national or international standards, could provide an additional avenue to establish the presumption of safety of non-harmonised crisis-relevant goods during the crisis. This would facilitate the placing on the market of non-harmonised crisis-relevant goods in times of crisis.</u></p>   |
| Recital 9  |   |   |   |   |
| 18         | <p>(9) In order to overcome the potential effects of disruptions on the Single Market and in order to ensure that crisis-relevant goods are placed on the market swiftly, it is appropriate to provide for a requirement for the conformity assessment bodies to prioritise the conformity assessment applications of such products over any pending applications concerning products, which have not been designated as crisis-relevant.</p> | <p>(9) In order to overcome the potential effects of disruptions <del>on the Single</del> <u>to the internal</u> market and in order to ensure that crisis-relevant goods are placed on the market swiftly, it is appropriate to provide for a requirement for the conformity assessment bodies to prioritise the conformity assessment applications of such products over any pending applications concerning products, which have not been designated as crisis-relevant.</p> | <p>(9) In order to overcome the potential effects of disruptions on the Single Market and in order to ensure that crisis-relevant goods are placed on the market swiftly, it is appropriate to provide for a requirement for the conformity assessment bodies to prioritise the conformity assessment applications of such products over any pending applications concerning products, which have not been designated as crisis-relevant. <b>In the context of such prioritisation, any potential additional costs charged by the</b></p> | <p>(9) In order to overcome the potential effects of disruptions on the <del>Single</del> <u>internal</u> market and in order to ensure that <u>harmonised</u> crisis-relevant goods are placed on the market swiftly, it is appropriate to provide for a requirement for the conformity assessment bodies to prioritise the conformity assessment applications of such products over any pending applications concerning products, which have not been designated as crisis-relevant. <u>In the context of such prioritisation, no additional disproportionate costs</u></p> |



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|            |                     |            | <p>conformity assessment body to the manufacturer should be proportionate to the direct costs incurred by the conformity assessment bodies in order to put in place the said prioritisation. The notified bodies are encouraged to increase their testing capacities for such products designated as crisis-relevant goods in respect to which they have been notified.</p> | <p><u>may be charged by the conformity assessment body to the manufacturer. All additional costs charged by a conformity assessment body to the manufacturer should be strictly proportionate to the actual additional efforts deployed by the conformity assessment body to implement the prioritisation and should be limited to the period of application of the internal market emergency. The transfer of certain additional and proportionate costs by the conformity assessment bodies to the manufacturers should remain exceptional and should reflect a fair distribution of the costs among all the stakeholders involved in the efforts to contain the disruptions to the functioning of the internal market. The costs associated with conformity assessment should not become a barrier to the entry on the market of prospective new manufacturers, in particular SMEs and should not restrict the emergence of innovative products. Furthermore, the notified bodies are encouraged to increase their testing capacities for such products designated as crisis-relevant goods in respect to which they have been notified.</u></p> |
| Recital 10 |                     |            |   |   |

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| 19         | (10) To that end, emergency procedures should be laid down in Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011. Those procedures should be available only following the activation of the Single Market emergency mode in accordance with [insert reference to SMEI Regulation].   | (10) To that end, emergency procedures should be laid down in Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009, <u>(EU) 2023/988, (EU) 2023/1230</u> and (EU) No 305/2011. Those procedures should be available only following the activation of the <del>Single</del> <u>internal</u> market emergency mode in accordance with [insert reference to <del>SMEI</del> <u>IMERA</u> Regulation].  | (10) To that end, emergency procedures should be laid down in Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No <del>305/2011</del> <u>2023/1230</u> . Those procedures should be available only following the activation of the Single Market emergency mode in accordance with [ <del>insert reference to SMEI Regulation</del> ].   | (10) To that end, emergency procedures should be laid down in Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) <del>2019/1009 and (EU) No 305/2011</del> <u>No 305/2011, (EU) 2023/988 and (EU) 2023/1230</u> . Those procedures should be available only following the activation of the Single Market emergency mode in accordance with [ <del>insert reference to SMEI Regulation</del> ].  |
| Recital 11 |  |  |  |   |
| 20         | (11) Furthermore, in cases where the disruptions might affect the conformity assessment bodies or in cases where the testing capacities for such crisis-relevant products would not be sufficient, it is appropriate to provide for the possibility for the national competent authorities to exceptionally and temporarily authorise the placing on the market of products, which have not undergone the usual conformity assessment procedures required by the respective EU sectoral legislation. | (11) Furthermore, in cases where the disruptions might affect the conformity assessment bodies or in cases where the testing capacities for such crisis-relevant products would not be sufficient, it is appropriate to provide for the possibility for the national competent authorities to exceptionally and temporarily authorise the placing on the market of products, which have not undergone the usual conformity assessment procedures required by the respective <del>EU</del> <u>Union</u> sectoral legislation. <u>The authorisation for products granted exceptionally and temporarily should remain valid for</u> | (11) Furthermore, in cases, <b>for example</b> , where the disruptions might affect the conformity assessment bodies or in cases where the testing capacities for such crisis-relevant products would not be sufficient, it is appropriate to provide for the possibility for the national competent authorities to exceptionally and temporarily authorise the placing on the market of products, which have not undergone the usual conformity assessment procedures required by the respective EU sectoral legislation. | (11) Furthermore, in cases, <u>for example</u> , where the disruptions might affect the conformity assessment bodies or in cases where the testing capacities for such crisis-relevant products would not be sufficient, it is appropriate to provide for the possibility for the national competent authorities to exceptionally and temporarily authorise the placing on the market of products, which have not undergone the usual conformity assessment procedures required by the respective <del>EU</del> <u>Union</u> sectoral <u>harmonisation</u> legislation. |

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|            |   | <p><u>six months after deactivation or expiration of the internal market emergency mode, where it does not does not affect in any way the health, safety and security of consumers. After this period, products should only be made available on the market after receiving an authorisation under the normal authorisation procedure provided for under the applicable rules. Products already granted authorisation exceptionally and temporarily may be re-authorised under the normal authorisation procedure. Nevertheless, products or components already purchased for use, or which are already in use, may continue to be used without new authorisation.</u></p> |    |   |
| Recital 12 |   |  |   |   |
| 21         | <p>(12) As regards products falling within the scope of those Regulations that have been designated as crisis-relevant goods, the national competent authorities should be able, in the context of an ongoing Single Market emergency, to derogate from the obligation to carry out those conformity assessment procedures laid down in those Regulations, in those cases where the involvement of a notified</p> | <p>(12) As regards products falling within the scope of those Regulations that have been designated as crisis-relevant goods, the national competent authorities should be able, in the context of an ongoing <del>Single</del><u>internal</u> market emergency, to derogate from the obligation to carry out those conformity assessment procedures laid down in those Regulations, <del>in those cases</del> where the involvement</p>   | <p>(12) As regards products falling within the scope of those Regulations that have been designated as crisis-relevant goods, the national competent authorities should be able, in the context of an ongoing Single Market emergency, to derogate from the obligation to carry out those conformity assessment procedures laid down in those Regulations, in those cases where the involvement of a notified</p> | <p>(12) As regards products falling within the scope of those <u>harmonisation</u> Regulations that have been designated as crisis-relevant goods, the national competent authorities should be able, in the context of an ongoing <del>Single</del><u>internal</u> market emergency, to derogate from the obligation to carry out those conformity assessment procedures laid down in those Regulations, <del>in those cases</del> where</p> |

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|  | <p>body is mandatory and should be able to issue authorisations for those products, provided that they comply with all the applicable essential safety requirements. Compliance with those substantive requirements may be demonstrated by various means, which may include testing performed by the national authorities of samples provided by the manufacturer having applied for an authorisation. The specific procedures, which were followed to demonstrate the compliance and their results should be clearly described in the authorisation issued by the national competent authority.</p> | <p>of a notified body is mandatory and should be able to issue authorisations for those products, provided that they comply with all the applicable essential safety requirements <u>and that the safety of consumers and end-users is fully assured</u>. Compliance with those substantive requirements may be demonstrated by various means, which may include testing performed by the national authorities of samples provided by the manufacturer having applied for an authorisation. The specific procedures, which were followed to demonstrate the compliance and their results should be clearly described in the authorisation issued by the national competent authority. <u>The principle of mutual recognition should apply to goods placed on the market under that derogation. The competent national authority should keep relevant technical documentation to ensure compliance with applicable rules. Products manufactured during the internal market emergency mode, where derogation from the conformity assessment procedures was authorised, should also be subject to the relevant obligations of traceability provided for in Regulation (EU) 2023/988, in particular those set out in Article</u></p> | <p>body is mandatory and should be able to issue authorisations for those products, provided that they <b>ensure the conformity</b> comply with all the applicable essential safety requirements. Compliance with those substantive requirements may be demonstrated by various means, which may include testing performed by the national authorities of samples provided by the manufacturer having applied for an authorisation. The specific procedures, which were followed to demonstrate the compliance and their results should be clearly described in the authorisation issued by the national competent authority.</p> | <p>the involvement of a notified body is mandatory and should be able to issue authorisations for those products, provided that they <del>comply</del> <u>ensure the conformity</u> with all the applicable essential safety requirements. Compliance with those substantive requirements may be demonstrated by various means, which may include testing performed by the national authorities of samples provided by the manufacturer having applied for an authorisation. The specific procedures, which were followed to demonstrate the compliance and their results should be clearly described in the authorisation issued by the national competent authority.</p> |

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|             |                     | <u>15(5) thereof.</u> |   |  |
| Recital 12a |                     |                       |   |  |
| 21a         |                     |                       | <p>(12a) Since the essential safety requirements harmonised by the existing Regulations remain applicable and the authorisation issued by a national competent authority without the CE marking may occur exceptionally, temporarily and additionally to the conformity assessment procedures laid down in those Regulations, this amending Regulation continues to improve the conditions for the functioning of the internal market. Therefore, this amending Regulation takes into account both the context constituted by the fully harmonised rules stemming from the existing Regulations and the complementary rules stemming from amendments that would be made to them which would not only allow national authorities to recognise authorisations issued in other Member States but would also require the Commission to extend the validity of such national authorisations from the territory of a single Member State to the territory of the Union by means of implementing acts unless</p> | <p><u>(12a) Since the essential safety requirements harmonised by the existing Regulations remain applicable and the authorisation issued by a national competent authority without the CE marking may occur exceptionally, temporarily and additionally to the conformity assessment procedures laid down in those Regulations, this amending Regulation continues to improve the conditions for the functioning of the internal market. Therefore, this amending Regulation takes into account both the context constituted by the fully harmonised rules stemming from the existing Regulations and the complementary rules stemming from amendments that would be made to them which would not only allow national authorities to recognise authorisations issued in other Member States but would also require the Commission to extend the validity of such national authorisations from the territory of a single Member State to the territory of the Union by means of implementing acts unless the requirements set in the</u></p> |

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|  |                     |            | <p>the requirements set in the authorisation do not ensure the conformity with the essential requirements laid down in these Regulations. Such a parallel national authorisation scheme in exceptional times of crisis, in addition to the Union conformity assessment procedure, is justified and proportionate for the achievement of the legitimate objective of protecting health, life and safety. By not providing for an automatic mutual recognition of each national authorisation which is granted on a derogatory basis in times of crisis, this amending Regulation aims to avoid any circumvention or undermining of the CE marking procedure and thereby to maintain consumer confidence in the safety of products bearing the CE marking in the Union market. Therefore these new derogatory rules, insofar as they prohibit the CE marking on the products which have been approved only at national level, should not affect the harmonised product legislation and consumer confidence in the CE marking which can only be affixed where all the harmonised substantive and procedural rules have been respected.</p> | <p><u>authorisation do not ensure the conformity with the essential requirements laid down in these Regulations. Such a parallel national authorisation scheme in exceptional times of crisis, in addition to the Union conformity assessment procedure, is justified and proportionate for the achievement of the legitimate objective of protecting health, life and safety. By not providing for an automatic mutual recognition of each national authorisation which is granted on a derogatory basis in times of crisis, this amending Regulation aims to avoid any circumvention or undermining of the CE marking procedure and thereby to maintain consumer confidence in the safety of products bearing the CE marking in the Union market. Therefore, these new derogatory rules, insofar as they prohibit the CE marking on the products which have been approved only at national level, should not affect the harmonised product legislation and consumer confidence in the CE marking which can only be affixed where all the harmonised substantive and procedural rules have been respected. By providing an additional, parallel avenue for exceptionally placing crisis-relevant</u></p> |

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|  |                     |            |                 | <p><u>goods on the market in the context of an internal market emergency, the derogatory rules enable new manufacturers to swiftly place their products on the market without the need to wait for the finalisation of the normal conformity assessment procedures. Such an accelerated and exceptional placing on the market contributes to the swift increase in the supply of crisis-relevant goods and at the same time provides the manufacturers with a facilitation as it allows them to place initial batches or series of products on the market before the conclusion of the conformity assessment procedures. Once the conformity assessment procedures have been successfully completed, subsequent batches or series of products should be fully compliant with the relevant, applicable rules and thus benefit from free movement. The co-existence during an internal market emergency of an exceptional, derogatory set of rules alongside the existing rules thus makes it possible to transition towards the existing rules, enabling the manufacturers to continue placing their products on the market after the expiry or deactivation of the internal market emergency mode.</u></p> |



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| Recital 12b |                     |            |   |   |
| 21b         |                     |            | <p>(12aa) Where the Commission has extended the validity of an authorisation issued by a Member State by means of an implementing act, the conditions for the placing on the market of the concerned goods set out therein should apply only to those goods placed on the market after the date of entry into force of the said implementing act. All pre-existing authorisations adopted by Member States prior to the entry into force of the Commission implementing act should cease to provide a legal basis for the placing of the goods on the market after the entry into force of the Commission implementing act concerning the same goods and Member States should take the necessary actions to that effect. Goods already placed on the market on the basis of an authorisation adopted by a Member State prior to the adoption of the Commission implementing act are not to be withdrawn or recalled unless specific safety concerns have been identified with respect to such goods which result in corrective or restrictive actions to be taken by the Commission by means of</p> | <p><u>(12b) Where the Commission has extended the validity of an authorisation issued by a Member State by means of an implementing act, the conditions for the placing on the market of the concerned goods set out therein should apply only to those goods placed on the market after the date of entry into force of the said implementing act. That implementing act can provide that the benefit of the free movement is also granted to goods already placed on the market on the basis of pre-existing authorisation. All pre-existing authorisations adopted by Member States prior to the entry into force of the Commission implementing act should cease to provide a legal basis for the placing of the goods on the market after the entry into force of the Commission implementing act concerning the same goods and Member States should take the necessary actions to that effect. Goods already placed on the market on the basis of an authorisation adopted by a Member State prior to the adoption of the Commission implementing act are not to be withdrawn or recalled unless specific safety concerns have been identified with respect to such</u></p> |




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|             |                     |            | another implementing act.  | <u>goods which result in corrective or restrictive actions to be taken by the Commission by means of another implementing act.</u>  |
| Recital 12c |                     |            |  |   |
| 21c         |                     |            | (12b) The validity of all authorisations for the placing on the market of goods designated as crisis-relevant in the context of an active Single Market emergency mode, as referred to in [the SMEI Regulation], should automatically expire on the date of expiry or deactivation of the Single Market emergency mode. However, it should also be possible to issue authorisations with a shorter validity. Once the authorisation has expired, no further placing of crisis-relevant goods on the market should occur on the basis of that authorisation. However, the expiry of an authorisation should not automatically trigger an obligation to withdraw or recall goods which have already been placed on the market on the basis of that authorisation. In cases where the placing on the market has occurred in breach of the conditions laid down in the authorisation or where there are sufficient reasons to believe that | <u>(12c) The validity of all authorisations for the placing on the market of goods designated as crisis-relevant in the context of an active internal market emergency mode, as referred to in the IMERA Regulation, should automatically expire on the date of expiry or deactivation of the internal market emergency mode. However, it should also be possible to issue authorisations with a shorter validity. Once the authorisation has expired, no further placing of crisis-relevant goods on the market should occur on the basis of that authorisation. However, the expiry of an authorisation should not automatically trigger an obligation to withdraw or recall goods which have already been placed on the market on the basis of that authorisation. In cases where the placing on the market has occurred in breach of the conditions laid down in the authorisation or where there are sufficient reasons to believe that the goods covered by</u> |

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|     |                     |            | the goods covered by such authorisation present a risk to the health or safety of persons, the national market surveillance authorities should be entitled to take all the corrective and restrictive measures at their disposal in accordance with the provisions of Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) No 305/2011 and (EU) 2023/1230 and Regulation (EU) 2019/1020. In order to ensure uniform conditions for the implementation of the sectorial emergency procedures, the Commission should be empowered to lay down rules regarding the follow-up actions to be taken and the procedures to be followed with respect to the goods placed on the market in accordance with the relevant sectorial emergency procedures. | <u>such authorisation present a risk to the health or safety of persons, the national market surveillance authorities should be entitled to take all the corrective and restrictive measures at their disposal in accordance with the provisions of Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) No 305/2011, (EU) 2023/1230 and Regulation (EU) 2019/1020. In order to ensure uniform conditions for the implementation of the sectorial emergency procedures, the Commission should be empowered to lay down rules regarding the follow-up actions to be taken and the procedures to be followed with respect to the goods placed on the market in accordance with the relevant sectorial emergency procedures.</u> |
|     | Recital 12d         |            |   |  |
| 21d |                     |            | (12c) In order to ensure timely sharing of information and to allow all Member States to react, it should be ensured that the Commission and the other Member States are immediately informed of any decisions at national level to authorise crisis-   | <u>(12d) In order to ensure timely sharing of information and to allow all Member States to react, it should be ensured that the Commission and the other Member States are immediately informed of any decisions at national level to authorise crisis-relevant goods. The</u>  |

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|             |                     |            | relevant goods. The Information and Communication System for Market Surveillance (ICSMS) already provides the necessary functions to allow quick notification of administrative decisions and therefore can be used by Member States for this purpose. Moreover, information on all corrective or restrictive measures should also be shared. Pursuant to Regulation (EU) 2019/1020 such information is to be accessible in ICSMS irrespectively whether those measures have to be notified or not in Safety Gate [formerly known as RAPEX] due to the products presenting a serious risk. Double entry will be avoided by means of the data interface between Safety Gate [formerly known as RAPEX] and ICSMS maintained by the Commission in accordance with article 20(5) of Regulation (EU) 2019/1020. | <u>Information and Communication System for Market Surveillance (ICSMS) already provides the necessary functions to allow quick notification of administrative decisions and therefore can be used by Member States for this purpose. Moreover, information on all corrective or restrictive measures should also be shared. Pursuant to Regulation (EU) 2019/1020 such information is to be accessible in ICSMS irrespectively whether those measures have to be notified or not in Safety Gate due to the products presenting a serious risk. Double entry will be avoided by means of the data interface between Safety Gate and ICSMS maintained by the Commission in accordance with article 20(5) of Regulation (EU) 2019/1020.</u> |
| Recital 12e |                     |            |  |   |
| 21e         |                     |            |  | <u>(12e) All authorisations for the placing on the market of crisis-relevant goods issued by Member States should contain at least certain elements which substantiate the assessment of the compliance of</u>  |

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|            |                     |            |                 | <p><u>the good in question with the applicable essential requirements and which allow to ensure traceability. The relevant elements concerning the traceability include specific requirements regarding the labelling, accompanying documents or any additional means of ensuring the identification of the goods concerned and allowing to trace them along the supply chain. In order to ensure uniform and coherent implementation of the traceability requirements across the Union, Commission implementing acts extending the validity of authorisations issued by a Member State should also specify the common traceability requirements. These include the specific arrangements regarding the indication that the product concerned is a ‘crisis-relevant good’. On expiry of the internal market emergency mode, the Commission should be empowered to adopt via implementing acts any necessary adjustments to the traceability requirements for crisis-relevant products that have already been placed on the market on the basis of an authorisation issued by a Member State.</u></p> |
| Recital 13 |                     |            |                 |  |

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| 22         | (13) Where a Single Market emergency entails an exponential increase in the demand for certain products and in order to support the efforts of economic operators to meet such demand, it is appropriate to provide technical references, which may be used by the manufacturers to design and produce crisis-relevant goods, which comply with the applicable essential health and safety requirements.                                      | (13) Where <del>a Single</del> <u>an internal</u> market emergency entails an exponential increase in the demand for certain products and in order to support the efforts of economic operators to meet such demand, it is appropriate to provide technical references, which may be used by the manufacturers to design and produce crisis-relevant goods, which comply with the applicable essential health and safety requirements.  | (13) Where a Single Market emergency entails an exponential increase in the demand for certain products and in order to support the efforts of economic operators to meet such demand, it is appropriate to provide technical references, which may be used by the manufacturers to design and produce crisis-relevant goods, which comply with the applicable essential health and safety requirements.                                      | (13) Where <del>a Single</del> <u>an internal</u> market emergency entails an exponential increase in the demand for certain products and in order to support the efforts of economic operators to meet such demand, it is appropriate to provide technical references, which may be used by the manufacturers to design and produce crisis-relevant goods, which comply with the applicable essential health and safety requirements.<br><br>Text Origin: EP Mandate   |
| Recital 14 |   |   |   |   |
| 23         | (14) A number of sectoral Union harmonisation legislation provide for the possibility for a manufacturer to benefit from a presumption of conformity if their product complies with a harmonised European standard. However, in cases where such standards do not exist or the compliance with them might be rendered excessively difficult by the disruptions caused by the crisis, it is appropriate to provide for alternative mechanisms. | (14) A number of sectoral Union harmonisation legislation provide for the possibility for a manufacturer to benefit from a presumption of conformity if their product complies with a harmonised European standard. <u>Furthermore, the general product safety framework laid down in Regulation (EU) 2023/988 provides for the possibility for a product to benefit from a presumption of conformity with the general product safety requirement if that product conforms with the European standard or parts thereof as far as the risks and risk categories covered by that standard</u> | (14) A number of sectoral Union harmonisation legislation provide for the possibility for a manufacturer to benefit from a presumption of conformity if their product complies with a harmonised European standard. However, in cases where such standards do not exist or the compliance with them might be rendered excessively difficult by the disruptions caused by the crisis, it is appropriate to provide for alternative mechanisms. | (14) A number of sectoral Union harmonisation legislation provide for the possibility for a manufacturer to benefit from a presumption of conformity if their product complies with a harmonised European standard. <u>The Union general product safety framework established by Regulation (EU) 2023/988 also establishes under certain conditions a mechanism of presumption of conformity with the general safety requirement where a product complies with relevant European standards, the references of which have been published in the Official Journal of the European</u> |

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|            |  | <p><u>are concerned, the references of which have been published in the Official Journal of the European Union.</u> However, in cases where such standards do not exist or the compliance with <del>them</del><u>such standards</u> might be rendered excessively difficult <del>by</del><u>as a result of</u> the disruptions caused by the crisis, it is appropriate to provide for alternative mechanisms.</p>  |   | <p><u>Union.</u> However, in cases where such standards do not exist or the compliance with them might be rendered excessively difficult by the disruptions caused by the crisis, it is appropriate to provide for alternative <u>crisis-response</u> mechanisms.</p>  |
| Recital 15 |  |  |  |  |
| 24         | <p>(15) With respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and, (EU) 2019/1009, the competent national authorities should be able to presume that products manufactured in accordance with national or international standards within the meaning of Regulation (EU) No 1025/2012<sup>1</sup> ensuring an equivalent level of protection to that offered by the harmonised European standards comply with the relevant essential health and safety requirements.</p> <p><sup>1</sup> OJ L 316, 14.11.2012, p. 12.</p> | <p>(15) With respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, <u>(EU) 2019/1009</u> <del>and</del>, (EU) <del>2019/1009</del><u>2023/988, and (EU) 2023/1230</u>, the competent national authorities should be able to presume that products manufactured in accordance with national or international standards within the meaning of Regulation (EU) No 1025/2012<sup>1</sup> ensuring an equivalent level of protection to that offered by the harmonised European standards comply with the relevant essential health and safety requirements.</p> <p><sup>1</sup> OJ L 316, 14.11.2012, p. 12.</p> | <p>(15) With respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and, <del>(EU) 2019/1009</del>, (EU) <b>2023/1230</b> the competent national authorities should be able to presume that products manufactured in accordance with <del>national or international</del><b>international, European or national</b> standards within the meaning of Regulation (EU) No 1025/2012<sup>1</sup> <b>identified by the Commission as suitable to reach conformity and</b> ensuring an equivalent level of protection to that offered by the harmonised European standards comply with the relevant essential health and safety requirements.</p> <p><sup>1</sup> OJ L 316, 14.11.2012, p. 12.</p> | <p>(15) With respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and, <del>(EU) 2019/1009</del>, <u>(EU) 2023/1230</u> the competent national authorities should be able to presume that products manufactured in accordance with <u>European or national standards of the Member States, or with relevant</u> <del>or</del> international standards <del>within the meaning of Regulation (EU) No 1025/2012<sup>1</sup></del> <u>developed by a recognised international standardisation body, identified by the Commission as suitable to reach conformity and</u> ensuring an equivalent level of protection to that offered by the harmonised European standards comply with the relevant <u>and applicable</u> essential <del>health and</del></p> |

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|  |                     |            | <div data-bbox="1182 156 1554 518">PUBLIC</div> | <p><del>safety</del><u>requirements. Products placed on the market on the basis of the presumption of conformity established via this emergency mechanism should not be withdrawn automatically simply as a result of the expiry or deactivation of the implementing act listing the European, relevant and applicable international or the national standards of the Member States. In cases where there are concerns regarding the compliance of a harmonised crisis-relevant product placed on the market during an internal market emergency on the basis of a presumption of conformity established via such an implementing act, the market surveillance authorities should be able to take all the necessary corrective and restrictive actions at national level provided for under Regulation (EU) 2019/1020 and under the respective sectorial legislation. After the expiry or withdrawal of the implementing act, compliance with the European, relevant and applicable international or the national standards of the Member States should no longer provide a presumption of conformity with the relevant and applicable essential requirements.</u></p> |



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|             |                     |            |                 | <i>1. OJ L 316, 14.11.2012, p. 12.</i>  |
| Recital 15a |                     |            |                 |   |
| 24a         |                     |            |                 | <p><u>(15a) With respect to Regulation (EU) 2023/988, under the competent national authorities should be able to presume that products manufactured in accordance with European or national standards of the Member States, or with relevant international standards developed by a recognised international standardisation body comply with the general safety requirement. Products placed on the market on the basis of the presumption of conformity established via this emergency mechanism should not be withdrawn automatically simply as a result of the expiry or deactivation of the internal market emergency mode. Where there is evidence that the crisis-relevant non-harmonised product placed on the market during an internal market emergency on the basis of the presumption of conformity established via these emergency procedures is dangerous, the market surveillance authorities should be allowed to take all appropriate measures under Regulation (EU) 2023/988. After</u></p> |



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|            |   |   |   | <u>the expiry or deactivation of the internal market emergency mode a demonstration of compliance with the said European, relevant and applicable international, or national standards of the Member States should no longer provide a presumption of conformity with the general safety requirement.</u>   |
| Recital 16 |   |   |   |   |
| 25         | (16) Furthermore, with respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011, the Commission should have the possibility to adopt by means of implementing acts common specifications, on which the manufacturers may rely in order to benefit from a presumption of conformity with the applicable essential requirements. The implementing act laying down such common specifications should remain applicable for the duration of the Single Market emergency. | (16) Furthermore, with respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009, <u>(EU) 2023/988, (EU) 2023/1230</u> and (EU) No 305/2011, the Commission should have the possibility to adopt by means of implementing acts common specifications, on which the manufacturers may rely in order to benefit from a presumption of conformity with the applicable essential requirements. The implementing act laying down such common specifications should remain applicable for the duration of the <u>Single internal</u> market emergency. | (16) Furthermore, <b>if no such international or European standards are available</b> , with respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) <del>2019/1009 and (EU) No 305/2011</del> <b>No 305/2011 and (EU) 2023/1230</b> , the Commission should have the possibility to adopt by means of implementing acts common specifications, on which the manufacturers may rely in order to benefit from a presumption of conformity with the applicable essential requirements. The implementing act laying down such common specifications should remain applicable for the duration of the Single Market emergency. | (16) Furthermore, with respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, <del>(EU) 2019/1009 and (EU) No 305/2011</del> <u>and (EU) 2023/1230</u> , the Commission should have the possibility to adopt by means of implementing acts common specifications, on which the manufacturers may rely in order to benefit from a presumption of conformity with the applicable essential requirements. The implementing act laying down such common specifications should remain applicable for the duration of the <u>Single internal</u> market emergency. <u>Products placed on the market on the basis of the presumption of conformity established via the demonstration of compliance with these common specifications should not be</u> |

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|    |  |                |                 | <u>withdrawn automatically simply as a result of the expiry or withdrawal of the implementing act laying down the said common specifications. In cases where there are concerns regarding the compliance of a crisis-relevant product placed on the market during an internal market emergency on the basis of the presumption of conformity established via the demonstration of compliance with common specifications, the market surveillance authorities should be able to take all the necessary corrective and restrictive actions at national level provided for under Regulation (EU) 2019/1020 and under the respective sectorial legislation. After the expiry or withdrawal of the implementing act laying down the common specifications a demonstration of compliance with the said common specifications should no longer provide a presumption of conformity with the relevant and applicable essential requirements.</u> |
|    | Recital 17   |                |                 |  |
| 26 | (17) With respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and | <i>deleted</i> | <i>deleted</i>  | <i>deleted</i>   |

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|             | (EU) No 305/2011, in exceptional and duly justified circumstances, notably in order to ensure the interoperability among products or systems, the Commission should be able to adopt by means of implementing acts common specifications laying down mandatory technical specifications, with which the manufacturers will be required to comply. The implementing act laying down such common specifications should remain applicable for the duration of the Single Market emergency. |   | PUBLIC   |  |
| Recital 18  |   |   |  |  |
| 27          | (18) In order to ensure that the level of safety provided by the harmonised products is not compromised, it is necessary to provide for rules for enhanced market surveillance, in particular with respect to goods designated as crisis-relevant and including by enabling closer cooperation and mutual support among the market surveillance authorities.  | (18) In order to ensure that the level of safety provided by the harmonised products <u>or by products under the general safety framework</u> is not compromised, it is necessary to provide for rules for enhanced market surveillance, in particular with respect to goods designated as crisis-relevant and including by enabling closer cooperation and mutual support among the market surveillance authorities. | (18) In order to ensure that the level of safety provided by the harmonised products is not compromised, it is necessary to provide for rules for enhanced market surveillance, in particular with respect to goods designated as crisis-relevant and including by enabling closer cooperation and mutual support among the market surveillance authorities. | (18) In order to ensure that the level of safety provided by the harmonised <u>and non-harmonised</u> products is not compromised, it is necessary to provide for rules for enhanced market surveillance, in particular with respect to goods designated as crisis-relevant and including by enabling closer cooperation and mutual support among the market surveillance authorities. |
| Recital 18a |   |   |  |  |
| 27a         |   |   | (18a) In accordance with the   | <u>(18a) In accordance with the</u>  |

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|            |   |   | relevant provisions of Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) No 305/2011 and (EU) 2023/1230, Member States should lay down rules on penalties applicable to infringements by economic operators and conformity assessment bodies of the provisions of those Regulations including the new provisions introduced by this amending Regulation and ensure that those rules are enforced by the competent national authorities, including the respective notifying authority. | <u>relevant provisions of Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) No 305/2011 and (EU) 2023/1230, Member States should lay down rules on penalties applicable to infringements by economic operators and conformity assessment bodies of the provisions of those Regulations including the new provisions introduced by this amending Regulation and ensure that those rules are enforced by the competent national authorities, including the respective notifying authority.</u> |
| Recital 19 |   |   |   |  |
| 28         | (19) In accordance with its established practice, the Commission would systematically consult the relevant sectoral experts in the context of the early preparation of all draft implementing acts laying down common specifications. | (19) In accordance with its established practice, the Commission would systematically consult the relevant sectoral experts in the context of the early preparation of all draft implementing acts laying down common specifications. | (19) In accordance with its established practice, the Commission would systematically consult the relevant sectoral experts in the context of the early preparation of all draft implementing acts laying down common specifications.   | (19) In accordance with its established practice, the Commission would systematically consult the relevant sectoral experts in the context of the early preparation of all draft implementing acts laying down common specifications.<br><br>Text Origin: Commission Proposal  |
| Recital 20 |   |   |   |  |
| 29         | (20) Regulations (EU) 2016/424,   | (20) Regulations (EU) 2016/424,   | (20) Regulations (EU) 2016/424,   | (20) Regulations (EU) 2016/424,  |

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|                            | (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011 should therefore be amended accordingly,              | (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009, <u>(EU) 2023/988</u> , <u>(EU) 2023/1230</u> and (EU) No 305/2011 should therefore be amended accordingly, | (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011 and (EU) <b>2023/1230</b> should therefore be amended accordingly, | (EU) 2016/425, (EU) 2016/426, (EU) <del>2019/1009 and (EU) No 305/2011</del> <u>No 305/2011, (EU) 2023/988 and (EU) 2023/1230</u> should therefore be amended accordingly.         |
| Recital 21                 |   |  |  |  |
| 30                         | (21) In order for this Regulation to apply from the same date as [SMEI Regulation], its application should be deferred, | (21) In order for this Regulation to apply from the same date as [SMEI <del>IMERA</del> Regulation], its application should be deferred,                 | (21) In order for this Regulation to apply from the same date as [SMEI Regulation], its application should be deferred,              | (21) In order for this Regulation to apply from the same date as [SMEI <del>IMERA</del> Regulation], its application should be deferred,<br><small>Text Origin: EP Mandate</small> |
| Formula                    |   |  |  |  |
| 31                         | HAVE ADOPTED THIS REGULATION:   | HAVE ADOPTED THIS REGULATION:  | HAVE ADOPTED THIS REGULATION:  | HAVE ADOPTED THIS REGULATION:<br><small>Text Origin: Commission Proposal</small>   |
| Article 1                  |   |  |  |  |
| 32                         | Article 1<br>Amendments to Regulation (EU) 2016/424   | Article 1<br>Amendments to Regulation (EU) 2016/424  | Article 1<br>Amendments to Regulation (EU) 2016/424  | Article 1<br>Amendments to Regulation (EU) 2016/424  |
| Article 1, first paragraph |   |  |  |  |
| 33                         | In Regulation (EU) 2016/424, the  | In Regulation (EU) 2016/424, the   | <del>In</del> Regulation (EU) 2016/424, <del>the</del>   | <del>In</del> Regulation (EU) 2016/424, <del>the</del>   |

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|     | following Chapter VIa is inserted:  | following Chapter VIa is inserted: | following Chapter VIa is inserted is amended as follows:  | <del>following Chapter VIa is inserted</del> <u>is amended as follows:</u>   |
|     | Article 1, first paragraph, point (1)                                       |                                    |   |  |
| 33a |   |                                    | (1) In Article 3 the following points are added:  | <u>(1) In Article 3 the following points are added:</u>  |
|     | Article 1, first paragraph, point (1), amending provision, first paragraph  |                                    |   |  |
| 33b |   |                                    | "<br>(28) 'crisis-relevant goods' means 'crisis-relevant goods' within the meaning of Article 3, point (6) of Regulation (EU) .../.... [SMEI Regulation]; | <u>(28) 'crisis-relevant goods' means 'crisis-relevant goods' within the meaning of Article 3, point (6) of Regulation (EU) .../.... [IMERA Regulation];</u>         |
|     | Article 1, first paragraph, point (1), amending provision, second paragraph |                                    |   |  |
| 33c |   |                                    | (29) 'Single Market Emergency' means 'Single Market Emergency' within the meaning of Article 3, point (3) of Regulation (EU) .../... [SMEI Regulation].;  | <u>(29) 'internal market emergency' means 'internal market emergency' within the meaning of Article 3, point (3) of Regulation (EU) .../... [IMERA Regulation].;</u> |
|     | Article 1, first paragraph, point (2)                                       |                                    |   |  |
| 33d |   |                                    | (2) The following Chapter Va is inserted after Chapter V:   | <u>(2) The following Chapter Va is inserted after Chapter V:</u>   |
|     | Article 1, first paragraph, amending provision, Chapter I                   |                                    |   |  |

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| 34   | CHAPTER VIa<br>EMERGENCY PROCEDURES   | CHAPTER VIa<br>EMERGENCY PROCEDURES   | Chapter Va<br><del>CHAPTER VIa</del><br>EMERGENCY PROCEDURES   | <u>Chapter Va</u><br><del>CHAPTER VIa</del><br>EMERGENCY PROCEDURES  |
| Article 1, first paragraph, amending provision, Article                |   |   |  |  |
| 35   | Article 43a<br>Application of emergency<br>procedures   | Article 43a<br>Application of emergency<br>procedures   | Article 43a<br><del>Article 43a</del><br>Application of emergency<br>procedures  | <u>Article 43a</u><br><del>Article 43a</del><br>Application of emergency<br>procedures   |
| Article 1, first paragraph, amending provision, numbered paragraph (1) |   |   |  |  |
| 36   | 1. Articles 43b to 43g shall only<br>apply if the Commission has adopted<br>an implementing act pursuant to<br>Article 23 of [the SMEI Regulation]<br>activating Article 26 of [the SMEI<br>Regulation] with respect to this<br>Regulation. | 1. Articles 43b to 43g <u>of this<br/>Regulation</u> shall only apply if the<br>Commission has adopted an<br>implementing act pursuant to Article<br><del>23 of [the SMEI Regulation]</del><br><del>activating Article 26 of [the<br/>SMEI 14(5) of [the IMERA<br/>Regulation] with respect to this<br/>Regulation.</del> | 1. Articles 43b to 43g shall only<br>apply if the Commission has adopted<br>an implementing act pursuant to<br>Article 23 of [the SMEI Regulation]<br>activating Article 26 of [the SMEI<br>Regulation] with respect to<br><b>subsystems and safety components<br/>covered by this Regulation.</b> | 1. Articles 43b to 43g <u>of this<br/>Regulation</u> shall only apply if the<br>Commission has adopted an<br>implementing act pursuant to Article<br><del>23 of [the SMEI Regulation]</del><br><del>activating Article 26 of [the SMEI<br/>Regulation] with respect to this</del> <u>the<br/>IMERA</u> Regulation. |
| Article 1, first paragraph, amending provision, numbered paragraph (2) |   |   |  |  |
| 37   | 2. Articles 43b to 43g shall apply<br>exclusively to subsystems and safety<br>components, which have been<br>designated as crisis-relevant goods<br>in the implementing act referred to<br>in paragraph 1 of this Article.                  | 2. Articles 43b to 43g shall apply<br>exclusively to subsystems and safety<br>components, which have been<br>designated as crisis-relevant goods<br>in the implementing act referred to<br>in paragraph 1 of this Article.  | 2. Articles 43b to 43g <del>shall</del> apply<br>exclusively to subsystems and safety<br>components, which have been<br>designated as crisis-relevant goods<br><del>in the implementing act referred to<br/>in paragraph 1 of this</del>   | 2. Articles 43b to 43g shall apply<br>exclusively to subsystems and safety<br>components, which have been<br>designated as crisis-relevant goods<br><del>in the implementing act referred to<br/>in paragraph 1 of this</del>  |

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|    |  |  | Article pursuant to Article 14 of [the SMEI Regulation].   | <del>Article</del> pursuant to Article 14(5) of the SMEI/IMERA Regulation.  |
|    | Article 1, first paragraph, amending provision, numbered paragraph (3), first subparagraph   |  |  |   |
| 38 | 3. Articles 43b to 43g, except as regards provisions concerning the powers of the Commission, shall apply during the Single Market emergency mode.   | 3. Articles 43b to 43g, except as regards provisions concerning the powers of the Commission, shall apply during the <del>Single</del> internal market emergency mode. | 3. Articles 43b to 43g, except as regards provisions concerning the powers <del>the power</del> of the Commission in Article 43e(5), shall apply <b>only</b> during the Single Market emergency mode <b>activated in accordance with Article 14 of [the SMEI Regulation]</b> .                                 | 3. Articles 43b to 43g, except as regards <del>provisions concerning the powers</del> the power of the Commission in Article 43e(5), shall apply <u>only</u> during the <del>Single</del> internal market emergency mode <u>activated in accordance with Article 14 of the IMERA Regulation</u> .                               |
|    | Article 1, first paragraph, amending provision, numbered paragraph (3), second subparagraph  |  |  |   |
| 39 | However, Article 43c(2), second subparagraph, and Article 43c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.   | <i>deleted</i>   | However, <del>Article 43c(2), second subparagraph, and</del> Article 43c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.  | However, Article 43 <del>e(2), second subparagraph, and Article 43c(5)</del> shall apply during the <del>Single</del> internal market emergency mode and after its deactivation or expiry.  |
|    | Article 1, first paragraph, amending provision, numbered paragraph (4)   |  |  |   |
| 40 | 4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to subsystems and safety components placed on the market in accordance with Articles 43c to 43f. Those implementing acts shall be adopted in accordance with | <i>deleted</i>   | 4. The Commission <del>shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken</del> may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures to be followed and the specific labelling and traceability | 4. The Commission <del>shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken</del> may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures to be <del>taken</del> followed and the specific labelling and traceability |



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|  | the examination procedure referred to in Article 44(3).  |  | <b>requirements</b> with respect to subsystems and safety components placed on the market in accordance with Articles 43c to <del>43f</del> <b>43e</b> . Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3). | <u>requirements</u> with respect to subsystems and safety components placed on the market in accordance with Articles 43c to <del>43f</del> <b>43e</b> . Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3). |
| Article 1, first paragraph, amending provision, Article                |  |  |  |  |
| 41   | Article 43b<br>Prioritisation of the conformity assessment of crisis-relevant subsystems and safety components   | Article 43b<br>Prioritisation of the conformity assessment of crisis-relevant subsystems and safety components   | <b>Article 43b</b><br><del>Article 43b</del><br>Prioritisation of the conformity assessment of crisis-relevant subsystems and safety components  | <u>Article 43b</u><br><del>Article 43b</del><br>Prioritisation of the conformity assessment of crisis-relevant subsystems and safety components  |
| Article 1, first paragraph, amending provision, numbered paragraph (1) |  |  |  |  |
| 42   | 1. This Article shall apply to all subsystems and safety components designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 18 requiring mandatory involvement of a notified body. | 1. This Article shall apply to all subsystems and safety components designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 18 requiring mandatory involvement of a notified body. | 1. This Article shall apply to all subsystems and safety components designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 18 requiring mandatory involvement of a notified body.                             | 1. This Article shall apply to all subsystems and safety components designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 18 requiring mandatory involvement of a notified body.                             |
| Article 1, first paragraph, amending provision, numbered paragraph (2) |  |  |  |  |
| 43   | 2. The notified bodies shall process all applications for conformity assessment of subsystems and safety components designated as crisis-  | 2. The notified bodies shall <u>ensure all reasonable efforts are made to</u> process all applications for conformity assessment of  | 2. The notified bodies shall process all applications for conformity assessment of subsystems and safety components designated as crisis-  | 2. The notified bodies shall <u>make best efforts to</u> process all applications for conformity assessment of subsystems and safety   |

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|  | relevant goods as a matter of priority.  | subsystems and safety components designated as crisis-relevant goods as a matter of priority.  | relevant goods as a matter of priority, <b>irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 43a.</b> | components designated as crisis-relevant goods as a matter of priority, <u>irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 43a.</u> |
| Article 1, first paragraph, amending provision, numbered paragraph (3) |  |  |  |  |
| 44   | 3. All pending applications for conformity assessment of subsystems and safety components designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of subsystems and safety components, which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of subsystems and safety components designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 43a. | 3. All pending applications for conformity assessment of subsystems and safety components designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of subsystems and safety components, which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of subsystems and safety components designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 43a. | <i>deleted</i>   | <i>deleted</i>   |
| Article 1, first paragraph, amending provision, numbered paragraph (4) |  |  |  |  |
| 45   | 4. The prioritisation of applications for conformity assessment of subsystems and safety components  | 4. The prioritisation of applications for conformity assessment of subsystems and safety components  | 4. The prioritisation of applications for conformity assessment of subsystems and safety components  | 4. The prioritisation of applications for conformity assessment of subsystems and safety components  |

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|  | pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.  | pursuant to paragraph 3 shall not give rise to any <u>extraordinary</u> additional costs for the manufacturers, who have lodged those applications.  | pursuant to paragraph <del>32</del> shall not give rise to any <b>disproportionate</b> additional costs for the manufacturers, who have lodged those applications.   | pursuant to paragraph <del>32</del> shall not give rise to <del>any additional</del> <u>additional disproportionate</u> costs for the manufacturers, who have lodged those applications.   |
| Article 1, first paragraph, amending provision, numbered paragraph (5) |   |  |  |  |
| 46   | 5. The notified bodies shall deploy their best efforts to increase their testing capacities for subsystems and safety components designated as crisis-relevant goods in respect of which they have been notified. | 5. The notified bodies shall <del>deploy</del> <del>their best</del> <u>ensure all reasonable</u> efforts <u>are made</u> to increase their testing capacities for subsystems and safety components designated as crisis-relevant goods in respect of which they have been notified. | <i>deleted</i>   | 5. The notified bodies shall <del>deploy</del> <del>their best</del> <u>make reasonable</u> efforts to increase their testing capacities for subsystems and safety components designated as crisis-relevant goods in respect of which they have been notified. |
| Article 1, first paragraph, amending provision, Article                |   |  |  |  |
| 47   | Article 43c<br>Derogation from the conformity assessment procedures requiring mandatory involvement of a notified body  | Article 43c<br>Derogation from the conformity assessment procedures requiring mandatory involvement of a notified body   | <b>Article 43c</b><br><del>Article 43e</del><br>Derogation from the conformity assessment procedures requiring mandatory involvement of a notified body  | <u>Article 43c</u><br><del>Article 43e</del><br>Derogation from the conformity assessment procedures requiring mandatory involvement of a notified body  |
| Article 1, first paragraph, amending provision, numbered paragraph (1) |   |  |  |  |
| 48   | 1. By way of derogation from Article 18, any competent national authority may authorise, on a duly justified request, the placing on the market or the incorporation into a cableway installation within the      | 1. By way of derogation from Article 18, <del>any the</del> competent national authority, <u>after carrying out a risk assessment</u> , may authorise, on a duly justified request <u>from an economic operator established in its</u>   | 1. By way of derogation from Article 18, any competent national authority may authorise, on a duly justified request, the placing on the market or the incorporation into a cableway installation within the | 1. By way of derogation from Article 18, <del>any competent national authority</del> <u>the Member State</u> may authorise, on a duly justified request <u>from an economic operator</u> , the placing on the market or the                                    |

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|   | territory of the Member State concerned, of a specific subsystem or safety component which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body, referred to in Article 18 have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated. | <u>Member State</u> , the placing on the market or the incorporation into a cableway installation within the territory of <del>the</del> <u>that</u> Member State <del>concerned</del> , of a specific subsystem or safety component which has been designated as <u>a</u> crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body, referred to in Article 18 have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated. | territory of the Member State concerned, of a specific subsystem or safety component which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body, referred to in Article 18 have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated <b>in accordance with procedures referred to in that authorisation.</b> | incorporation into a cableway installation within the territory of the Member State concerned, of a specific subsystem or safety component which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body, referred to in Article 18 have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated <u>in accordance with procedures referred to in that authorisation.</u> |
| Article 1, first paragraph, amending provision, numbered paragraph (1a), first subparagraph |   |  |  |  |
| 48a   |   |  | <b>1a. The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure the conformity with the essential requirements laid down in Annex II to this Regulation, the Commission shall without delay adopt an implementing act extending for a limited period of time the validity of the authorisation granted by a</b>                            | <u><b>1a. The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure the conformity with the essential requirements laid down in Annex II to this Regulation, the Commission shall without delay adopt an implementing act extending the validity of the authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions</b></u>       |

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|     |  |            | Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the specific subsystem or safety component may be placed on the market. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 44(3). | <u>under which the specific subsystem or safety component may be placed on the market. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 44(3).</u>               |
|     | Article 1, first paragraph, amending provision, numbered paragraph (1a), second subparagraph |            |  |  |
| 48b |  |            | The specific subsystem or safety component subject to the extension of validity referred to in the first subparagraph shall bear the information that it is placed on the market as a “crisis-relevant good”. The implementing act referred to in the first subparagraph shall specify the modalities of that information. That information, as well as any labelling, shall be clear, understandable and intelligible and, where relevant, in a language  | <u>The specific subsystem or safety component subject to the extension of validity referred to in the first subparagraph shall bear the information that it is placed on the market as a "crisis-relevant good". The implementing act referred to in the first subparagraph shall specify the modalities of that information. That information, as well as any labelling, shall be clear, understandable and intelligible and, where relevant, in a language which can be easily understood by</u> |

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|  |                     |            | which can be easily understood by consumers and other end-users, as determined by the Member State concerned.  | <u>consumers and other end-users, as determined by the Member State concerned.</u>  |
| Article 1, first paragraph, amending provision, numbered paragraph (1a), third subparagraph  |                     |            |  |   |
| 48c  |                     |            | 1b. On duly justified imperative grounds of urgency relating to the need to preserve the health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 44(4).  | <u>1b On duly justified imperative grounds of urgency relating to the need to preserve the health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 44(4).</u>   |
| Article 1, first paragraph, amending provision, numbered paragraph (1b), first subparagraph  |                     |            |  |   |
| 48d  |                     |            | 1c. As long as an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act. | <u>1b. As long as an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act.</u> |
| Article 1, first paragraph, amending provision, numbered paragraph (1b), second subparagraph |                     |            |  |   |

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| 48e   |   |   | Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.   | <u>Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.</u>  |
| Article 1, first paragraph, amending provision, numbered paragraph (2), first subparagraph  |   |   |  |  |
| 49  | 2. The manufacturer of a subsystem or safety component subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the subsystem or safety component concerned complies with all the applicable essential requirements set out in Annex II and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the national competent authority. | 2. The manufacturer of a subsystem or safety component subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the subsystem or safety component concerned complies with all the applicable essential requirements set out in Annex II and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the national competent authority. | 2. The manufacturer of a subsystem or safety component subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the subsystem or safety component concerned complies with all the applicable essential requirements set out in Annex II and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the <del>national</del> competent <b>national</b> authority. | 2. The manufacturer of a subsystem or safety component subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the subsystem or safety component concerned complies with all the applicable essential requirements set out in Annex II and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the <del>national</del> competent <u>national</u> authority. |
| Article 1, first paragraph, amending provision, numbered paragraph (2), second subparagraph |   |   |  |  |
| 50  | The manufacturer shall also deploy all reasonable measures to ensure that the subsystem or safety component, which has been granted an authorisation pursuant to paragraph 1, does not leave the territory of the Member State, which issued the authorisation.   | <i>deleted</i>  | <i>deleted</i>   | <i>deleted</i>   |



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| Article 1, first paragraph, amending provision, numbered paragraph (3)            |  |   |  |   |
| 51  | 3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the subsystem or safety component may be placed on the market or incorporated into a cableway installation, including: | 3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the subsystem or safety component may be placed on the market or incorporated into a cableway installation, including <u>at least</u> : | 3. Any authorisation issued <del>by a national competent authority</del> pursuant to paragraph 1 shall set out the conditions and requirements under which the subsystem or safety component may be placed on the market or incorporated into a cableway installation, <del>including</del> .<br><b>The authorisations shall at least set out the following:</b> | 3. Any authorisation issued <del>by a national competent authority</del> pursuant to paragraph 1 shall set out the conditions and requirements under which the subsystem or safety component may be placed on the market or incorporated into a cableway installation, <del>including</del> . <u>The authorisations shall at least set out the following:</u> |
| Article 1, first paragraph, amending provision, numbered paragraph (3), point (a) |  |   |  |   |
| 52  | (a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;  | (a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;   | (a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;  | (a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;<br><br>Text Origin: Commission Proposal   |
| Article 1, first paragraph, amending provision, numbered paragraph (3), point (b) |  |   |  |   |
| 53  | (b) specific requirements regarding the traceability of the subsystem or safety component concerned;   | (b) specific requirements regarding the traceability of the subsystem or safety component concerned;  | (b) <b>any</b> specific requirements regarding the traceability of the subsystem or safety component concerned;  | (b) <u>any</u> specific requirements regarding the traceability of the subsystem or safety component concerned;   |
| Article 1, first paragraph, amending provision, numbered paragraph (3), point (c) |  |   |  |   |
| 54  | (c) an end date of validity of the   | (c) an end date of validity of the  | (c) an end date of validity of the   | (c) an end date of validity of the  |



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|  | authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated;   | authorisation, <u>unless otherwise specified</u> , which cannot go beyond the last day of the period for which the <del>Single</del> <u>internal</u> market emergency mode has been activated;  | authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated <b>activated in accordance with Article 14 of [the SMEI Regulation]</b> ;  | authorisation, which cannot go beyond the last day of the period for which the <del>Single</del> <u>internal</u> market emergency mode has been activated <u>in accordance with Article 14 of the IMERA Regulation</u> ;   |
| Article 1, first paragraph, amending provision, numbered paragraph (3), point (d)  |   |   |   |  |
| 55   | (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the subsystem or safety component concerned;  | (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the subsystem or safety component concerned;  | (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the subsystem or safety component concerned;  | (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the subsystem or safety component concerned;   |
| Article 1, first paragraph, amending provision, numbered paragraph (3), point (e)  |   |   |   |  |
| 56   | (e) measures to be taken with respect to the subsystem or safety component concerned upon expiry of the authorisation in order to ensure that the subsystem or safety component concerned is brought back in compliance with all the requirements of this Regulation. | (e) measures to be taken with respect to the subsystem or safety component concerned upon expiry of the authorisation in order to ensure that the subsystem or safety component concerned is brought back in compliance with all the requirements of this Regulation. | (e) measures to be taken with respect to the subsystem or safety component <del>concerned upon expiry of the authorisation in order to ensure that the subsystem or safety component concerned is brought back in compliance with all the requirements of this Regulation</del> <b>placed on the market upon expiry of the Single Market emergency.</b> | (e) measures to be taken <del>with respect to the subsystem or safety component concerned upon expiry of the authorisation in order to ensure that</del> <u>internal market emergency with respect to</u> the subsystem or safety component <del>concerned is brought back in compliance with all the requirements of this Regulation</del> <u>placed on the market.</u> |
| Article 1, first paragraph, amending provision, numbered paragraph (3), point (ea) |   |   |   |  |
| 56a  |   | <u>(ea) labelling requirements, including radio frequency</u>   |   | deleted  |

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|   |  | <u>identification, indicating that the subsystem or safety component was authorised under the internal market emergency mode.</u>   |  |  |
| Article 1, first paragraph, amending provision, numbered paragraph (4)                          |  |   |  |  |
| 57  | 4. By way of derogation from Article 43a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3also after the deactivation or expiry of the Single Market Emergency mode.                              | 4. By way of derogation from Article 43a(3), <del>first subparagraph,</del> where appropriate, the national competent authority may <u>also</u> amend the conditions <del>of the authorisation and requirements</del> referred to in paragraph <del>3also</del> <u>3 of this Article</u> after the deactivation or expiry of the <del>Single</del> <u>internal</u> market emergency mode. | <del>deleted</del>   | <del>deleted</del>   |
| Article 1, first paragraph, amending provision, numbered paragraph (5)                          |  |   |  |  |
| 58  | 5. By way of derogation from Articles 7 and 20, subsystems or safety components, for which an authorisation has been granted in accordance with paragraph 1 of this Article, shall not leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking. | <del>deleted</del>  | 5. By way of derogation from Articles 7, <b>20 and 21</b> <del>and 20,</del> subsystems or safety components, for which an authorisation has been granted in accordance with paragraph 1 <del>of this Article,</del> shall not leave the territory of the Member State which has issued the authorisation <del>and bear the CE marking and Article 7 shall not bear the CE marking</del> <u>apply.</u> | 5. By way of derogation from Articles 7, <u>20 and 21</u> <del>and 20,</del> subsystems or safety components, for which an authorisation has been granted in accordance with paragraph 1 <del>of this Article,</del> shall not <del>leave the territory of the Member State which has issued the authorisation and</del> <u>bear the CE marking and Article 7</u> shall not <del>bear the CE marking</del> <u>apply.</u> |
| Article 1, first paragraph, amending provision, numbered paragraph (5a), numbered paragraph (6) |  |   |  |  |

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| 59  | 6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Regulation with respect to such subsystems or safety components. | 6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Regulation with respect to such subsystems or safety components. <u>The market surveillance authorities shall keep all records related to products authorised under a derogation for a period of 10 years. They shall make those records available to other market surveillance authorities upon request.</u> | <del>65a.</del> The market surveillance authorities of <del>the</del> <b>a</b> Member State, <del>whose competent authority has granted</del> <b>where</b> an authorisation pursuant to paragraph 1, <b>paragraphs 1, 1a and 1c is valid</b> , shall be entitled to take all corrective and restrictive <del>measures</del> <b>actions</b> at national level provided for <b>under Regulation (EU) 2019/1020 and</b> under this Regulation with respect to such subsystems or safety components. | <del>65a.</del> The market surveillance authorities of <del>the</del> <b>a</b> Member State, <del>whose competent authority has granted</del> <b>where</b> an authorisation pursuant to <del>paragraph 1,</del> <b>paragraphs 1, 1a and 1c is valid,</b> shall be entitled to take all corrective and restrictive <del>measures</del> <b>actions</b> at national level provided for <b>under Regulation (EU) 2019/1020 and</b> under this Regulation with respect to such subsystems or safety components. |
| Article 1, first paragraph, amending provision, numbered paragraph (5a), numbered paragraph (6) a |  |   |  |  |
| 59a   |  |   | <b>They shall immediately inform the Commission and the market surveillance authorities of other Member States of these actions.</b>   | <u><b>They shall immediately inform the Commission and the market surveillance authorities of other Member States of these actions.</b></u>  |
| Article 1, first paragraph, amending provision, numbered paragraph (7)                            |  |   |  |  |
| 60  | 7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market of subsystems or safety components in accordance with paragraph 1.   | 7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market <u>or incorporation into a cableway installation</u> of subsystems or safety  | <i>deleted</i>   | <i>deleted</i>   |

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|   |  | components in accordance with paragraph 1.   |   |  |
| Article 1, first paragraph, amending provision, numbered paragraph (8)  |  |  |   |  |
| 61  | 8. The application of Articles 43a to 43g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 18 on the territory of the Member State concerned. | 8. The application of Articles 43a to 43g and the use of the authorisation procedure set out in paragraph 1 of this Article <del>does</del> <u>shall</u> not affect the application of the relevant conformity assessment procedures laid down in Article 18 <del>on the territory of the Member State concerned.</del>  | 8. The application of Articles 43a to 43g and the use of the authorisation procedure set out in paragraph 1 of this Article <del>to 1c</del> does not affect the application of the relevant conformity assessment procedures laid down in Article 18 on the territory of the Member State concerned. | 8. <del>The application of Articles 43a to 43g and</del> The use of the authorisation procedure set out in <del>paragraph 1 of this Article does</del> <u>paragraphs 1 to 1c shall</u> not affect the application of the relevant conformity assessment procedures laid down in Article 18 on the territory of the Member State concerned. |
| Article 1, first paragraph, amending provision, numbered paragraph (8a) |  |  |   |  |
| 61a   |  | <u>8a. Subsystems or safety components subject to derogation under paragraph 1 shall remain valid for six months after deactivation or expiration of the internal market emergency mode. After this period, they shall only be made available on the market after receiving an authorisation under the normal authorisation procedure provided for in this Regulation.</u> |   | deleted<br><br>See COM Recital: to clarify (important point for EP)  |
| Article 1, first paragraph, amending provision, Article                 |  |  |   |  |
| 62  | Article 43d<br>Presumption of conformity based on  | Article 43d<br>Presumption of conformity based on  | deleted   | deleted  |

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|   | national and international standards  | national and international standards  |                 |                 |
| <i>Article 1, first paragraph, amending provision, Article, first paragraph</i>                                 |   |   |                 |                 |
| 63  | Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, their competent authorities consider that subsystems and safety components, which comply with the relevant international standards or any national standards in force in the Member State of manufacture, ensuring the safety level required by the essential requirements set out in Annex II, comply with those essential requirements in either of the following cases: | Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, their competent authorities consider that subsystems and safety components, which comply with the relevant international standards or any national standards in force in the Member State of manufacture, ensuring the safety level required by the essential requirements set out in Annex II, comply with those essential requirements in either of the following cases: | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 1, first paragraph, amending provision, Article, first paragraph, point (a), first subparagraph</i>  |   |   |                 |                 |
| 64  | (a) where no reference to harmonised standards covering the relevant essential requirements set out in Annex II is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;   | (a) where no reference to harmonised standards covering the relevant essential requirements set out in Annex II is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;   | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 1, first paragraph, amending provision, Article, first paragraph, point (a), second subparagraph</i> |   |   |                 |                 |
| 65  | Where   | <i>deleted</i>  | <i>deleted</i>  | <i>deleted</i>  |

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|    | Article 1, first paragraph, amending provision, Article, first paragraph, point (b)  |  |  |  |
| 66 | (b) severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex II to this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012. | (b) <u>where</u> severe disruptions in the functioning of the <del>Single</del> <u>internal</u> market, which were taken into consideration when activating the <del>Single</del> <u>internal</u> market emergency mode in accordance with Article <del>15(4) of [the SMEI]</del> <u>14 of [the IMERA]</u> Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex II to this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012. | deleted  | deleted  |
|    | Article 1, first paragraph, amending provision, Article  |  |  |  |
| 67 | Article 43e<br>Adoption of common specifications conferring a presumption of conformity  | Article 43e<br>Adoption of common specifications conferring a presumption of conformity  | Article 43e<br><del>Article 43e</del><br>Adoption of common specifications conferring a presumption of conformity<br><b>Presumption of conformity based on standards and common specifications</b> | <u>Article 43e</u><br><del>Article 43e</del><br><del>Adoption of common specifications conferring a presumption of conformity</del><br><u>Presumption of conformity based on standards and common specifications</u> |
|    | Article 1, first paragraph, amending provision, numbered paragraph (1)   |  |  |  |

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| 68   | 1. Where subsystems and safety components, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such subsystems and safety components to cover the essential requirements set out in Annex II in either of the following cases: | 1. Where subsystems and safety components, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such subsystems and safety components to cover the essential requirements set out in Annex II in either of the following cases:  | 1. Where subsystems and safety components, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts, <b>listing appropriate standards or</b> establishing common specifications for such subsystems and safety components to cover the essential requirements set out in Annex II in either of the following cases: | 1. Where subsystems and safety components, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts, <u>listing appropriate standards or</u> establishing common specifications for such subsystems and safety components to cover the essential requirements set out in Annex II in either of the following cases:                       |
| Article 1, first paragraph, amending provision, numbered paragraph (1), point (a)  |   |  |  |  |
| 69   | (a) where no reference to harmonised standards covering the relevant essential requirements set out in Annex II is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;   | (a) where <del>no reference to harmonised standards covering the relevant essential requirements set out in Annex II is published in the Official Journal of the European Union in accordance with the</del> <u>European standardisation deliverables addressing a request pursuant to Article 10(1) of</u> Regulation (EU) No 1025/2012 <u>were not adopted</u> ; | (a) <del>where</del> no reference to harmonised standards covering the relevant essential requirements set out in Annex II is published in the <b>Official Journal of the European Union</b> Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;   | (a) <del>where</del> no reference to harmonised standards covering the relevant essential requirements set out in Annex II is published in the <u>Official Journal of the European Union</u> <del>Official Journal of the European Union</del> in accordance with Regulation (EU) No 1025/2012 <u>and no such reference is expected to be published within a reasonable period; or</u> |
| Article 1, first paragraph, amending provision, numbered paragraph (1), point (aa) |   |  |  |  |
| 69a  |   | <u>(aa) where a reference to harmonised standards covering the relevant essential requirements set out in Annex II is not published in the Official Journal of the</u>   |  | deleted  |



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|   |  | <u>European Union in accordance with Regulation (EU) No 1025/2012 and such reference is not expected to be published within a reasonable timeframe during the internal market emergency mode;</u>   |   |  |
|   | Article 1, first paragraph, amending provision, numbered paragraph (1), point (ab) |   |   |  |
| G | 69b  |   |   | deleted  |
|   | Article 1, first paragraph, amending provision, numbered paragraph (1), point (ac) |   |   |  |
| G | 69c  |   |   | deleted  |
|   | Article 1, first paragraph, amending provision, numbered paragraph (1), point (ad) |   |   |  |
| G | 69d  |   |   | deleted  |
|   | Article 1, first paragraph, amending provision, numbered paragraph (1), point (b)  |   |   |  |
| G | 70   | (b) where severe disruptions in the functioning of the Single internal market, which led to the activation of the Single internal market emergency mode in accordance with Article 14 of [the SME IMERA Regulation], significantly restrict the possibilities of manufacturers to | (b) <del>where</del> severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode in accordance with Article 14 of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the | (b) <del>where</del> severe disruptions in the functioning of the Single internal market, which led to the activation of the Single internal market emergency mode in accordance with Article 14 of <del>the SMEI</del> the IMERA Regulation <sup>7</sup> , significantly restrict the possibilities of manufacturers to |

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|  | harmonised standards covering the relevant essential requirements set out in Annex II to this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012. | make use of the harmonised standards covering the relevant essential requirements set out in Annex II to this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012. | harmonised standards covering the relevant essential requirements set out in Annex II to this Regulation and already published in the <b>Official Journal of the European Union</b> Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012. | make use of the harmonised standards covering the relevant essential requirements set out in Annex II <del>to this Regulation</del> and already published in the <b>Official Journal of the European Union</b> <del>Official Journal of the European Union</del> in accordance with Regulation (EU) No 1025/2012.  |
| Article 1, first paragraph, amending provision, numbered paragraph (1a)            |   |   |   |  |
| 70a  |   |   | <b>1a. The implementing acts referred to in paragraph 1 may:</b>  | <u><b>1a. The implementing acts referred to in paragraph 1 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.</b></u> |
| Article 1, first paragraph, amending provision, numbered paragraph (1), point (bb) |   |   |   |  |
| 70b  |   |   | <b>(a) publish the references to relevant applicable international standards that provide presumption of conformity in</b>  | <i>deleted</i>   |

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|   |   |            | accordance with paragraph 3;   |                 |
|   | <i>Article 1, first paragraph, amending provision, numbered paragraph (1), point (bc)</i> |            |  |                 |
| G | 70c   |            | (b) if there is no relevant applicable international standards as referred to in point a of this paragraph that cover the essential requirements set out in Annex II [to this Regulation], publish the references to the European standards that provide presumption of conformity in accordance with paragraph 3;               | <i>deleted</i>  |
|   | <i>Article 1, first paragraph, amending provision, numbered paragraph (1), point (bd)</i> |            |  |                 |
| G | 70d   |            | (c) if there is no relevant applicable international or European standard as referred to in points a and b, that cover the essential requirements set out in Annex II [to this Regulation], establish common specifications established by the Commission that provide presumption of conformity in accordance with paragraph 3; | <i>deleted</i>  |
|   | <i>Article 1, first paragraph, amending provision, numbered paragraph (1), point (be)</i> |            |  |                 |
| G | 70e   |            | (d) if there is no relevant applicable international standard,   | <i>deleted</i>  |

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|  |   |   | European standard or common specifications as referred to in points a, b and c, publish the reference to national standards that provide presumption of conformity in accordance with paragraph 3.   |   |
| Article 1, first paragraph, amending provision, numbered paragraph (2) |   |   |  |   |
| 71   | <p>2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 44(3) and they shall apply to subsystems or safety components placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.</p> | <p>2. The implementing acts referred to in paragraph 1 of this Article shall be adopted <del>following a consultation of the sectoral experts and</del> in accordance with the examination procedure referred to in Article 44(3) and they shall apply to subsystems or safety components placed on the market until the last day of the period for which the <del>Single</del><u>internal</u> market emergency mode remains active. <del>In the early preparation of</del><u>When preparing</u> the draft implementing act establishing the common specification, the Commission shall <del>gather</del><u>take into account</u> the views of <del>relevant bodies or expert groups established under the</del> relevant <del>sectoral Union</del> <u>bodies</u> <del>legislation. Based on that consultation, the Commission</del> <u>and shall prepare the draft implementing act</u> <u>duly consult all relevant stakeholders.</u></p> | <p>2. The implementing acts referred to in paragraph 1 <del>of this Article</del> shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 44(3) and they shall apply to subsystems or safety components placed on the market until the last day of the period for which the Single Market emergency mode remains active. <del>In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act,</del> unless amended or repealed in accordance with paragraph 5.</p> | <p>2. The implementing acts referred to in paragraph 1 <del>of this Article</del> shall be adopted <del>following a consultation of the sectoral experts and</del> in accordance with the examination procedure referred to in Article 44(3) and they shall apply <del>to subsystems or safety components placed on the market</del> until the last day of the period for which the <del>Single</del><u>internal</u> market emergency mode remains active. <del>In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act,</del> <u>unless amended or repealed in accordance with paragraph 5.</u></p> |

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| Article 1, first paragraph, amending provision, numbered paragraph (2a) |   |   |   |  |
| 71a   |   |   | <p>2a. Before preparing the draft implementing act referred to in paragraph 1, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or expert groups established under this Regulation and shall duly consult all relevant stakeholders.</p> <p>based on COM text above, line 72</p> | <p><u>2a. Before preparing the draft implementing act referred to in paragraph 1, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or expert groups established under this Regulation and shall duly consult all relevant stakeholders.</u></p> |
| Article 1, first paragraph, amending provision, numbered paragraph (3)  |   |   |   |  |
| 72  | <p>3. Without prejudice to Article 17, subsystems and safety components which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential requirements set out in Annex II covered by those common specifications or parts thereof.</p> | <p>3. Without prejudice to Article 17, subsystems and safety components which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential requirements set out in Annex II covered by those common specifications or parts thereof.</p> | <p>3. Without prejudice to Article 17, subsystems and safety components which are in conformity with <b>the standards or</b> common specifications adopted pursuant to <del>referred to in</del> paragraph 2 of this <del>Article</del><b>1, or parts thereof</b>, shall be presumed to be in conformity with the essential requirements set out in Annex II covered by those <b>standards</b>, common specifications or parts thereof. <b>The presumption</b></p>  | <p>3. Without prejudice to Article 17, subsystems and safety components which are in conformity with <u>the standards or</u> common specifications <del>adopted pursuant to</del> <u>referred to in</u> paragraph <del>2 of this Article</del><b>1, or parts thereof</b>, shall be presumed to be in conformity with the essential requirements set out in Annex II covered by those <u>standards</u>, common specifications or parts thereof. <u>The presumption of</u></p>   |

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|  |  |  | of conformity provided by the standards or the common specifications referred to in the implementing act referred to in paragraph 1 shall automatically cease to apply on the day the Single Market Emergency mode expires or is deactivated.  | <u>conformity provided by the standards, parts thereof or the common specifications referred to in the implementing act referred to in paragraph 1 can no longer be relied upon from the day the internal market emergency mode expires or is deactivated.</u>  |
| Article 1, first paragraph, amending provision, numbered paragraph (4) |  |  |  |   |
| 73   | 4. By way of derogation from Article 43a(3), first subparagraph, unless there is sufficient reason to believe that the subsystems or safety components covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the subsystems or safety components in compliance with the said common specifications which have been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation]. | 4. By way of derogation from Article 43a(3), <del>first subparagraph,</del> unless there is sufficient reason to believe that the subsystems or safety components covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the subsystems or safety components in compliance with <del>the</del> <u>said those</u> common specifications which have been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the <del>Single</del> <u>internal</u> market emergency mode in accordance with [the <del>SMEI</del> <u>IMERA</u> Regulation]. | 4. By way of derogation from Article 43a(3), first subparagraph, unless there is sufficient reason to believe that the subsystems or safety components covered by the <b>standards or</b> common specifications referred to in paragraph 1 <del>of this Article</del> present a risk to the health or safety of persons, the subsystems or safety components <b>which are in conformity</b> in compliance with the <del>said</del> <b>standards or</b> common specifications <b>and</b> which have been placed on the market shall be deemed compliant with <del>this Regulation</del> <b>the essential requirements set out in Annex II</b> after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 <del>of this Article</del> and after the expiry or deactivation of the Single Market Emergency mode in accordance with <del>[the SMEI</del> <b>the IMERA</b> Regulation]. | 4. By way of derogation from Article 43a(3), <del>first subparagraph,</del> unless there is sufficient reason to believe that the subsystems or safety components covered by the <u>standards or</u> common specifications referred to in paragraph 1 <del>of this Article</del> present a risk to the health or safety of persons, the subsystems or safety components <u>which are in conformity with those standards or in compliance with the said</u> common specifications <u>and</u> which have been placed on the market shall be deemed compliant with <del>this Regulation</del> <b>the essential requirements set out in Annex II</b> after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 <del>of this Article</del> and after the expiry or deactivation of the <del>Single</del> <u>internal</u> market emergency mode in accordance with <del>the</del> <u>SMEI</u> <b>the IMERA</b> Regulation]. |

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|  |   |  | <i>Regulation</i> /[the SMEI Regulation].  |   |
| Article 1, first paragraph, amending provision, numbered paragraph (5) |   |  |  |   |
| 74   | 5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the essential requirements which it aims to cover and which are set out in Annex II, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information and, if appropriate, amend or withdraw the implementing act establishing the common specification in question. | 5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the essential requirements which it aims to cover and which are set out in Annex II, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information <del>and, if appropriate,</del> <u>The Commission may amend, where appropriate, or withdraw</u> the implementing act establishing the common specification in question. | 5. When a Member State considers that a <b>standard or</b> common specification referred to in paragraph 1 does not entirely satisfy the essential requirements <del>which it aims to cover and which are</del> set out in Annex II, it shall inform the Commission thereof <b>by submitting</b> <del>with</del> a detailed explanation <del>and</del> . The Commission shall assess that information <b>detailed explanation</b> and, if appropriate, amend or <del>withdraw</del> <b>repeal</b> the implementing act <b>listing the standard or</b> establishing the common specification in question. | 5. When a Member State considers that a <u>standard or</u> common specification referred to in paragraph 1 does not entirely satisfy the essential requirements <del>which it aims to cover and which are</del> set out in Annex II, it shall inform the Commission thereof <del>with</del> <u>by submitting</u> a detailed explanation <del>and</del> . The Commission shall assess that <del>information and, if</del> <u>detailed explanation and, may, where</u> appropriate, amend or <del>withdraw</del> <u>repeal</u> the implementing act <u>listing the standard or</u> establishing the common specification in question. |
| Article 1, first paragraph, amending provision, Article                |   |  |  |   |
| 75   | Article 43f<br>Adoption of mandatory common specifications  | <i>deleted</i>   | <i>deleted</i>   | <i>deleted</i>  |
| Article 1, first paragraph, amending provision, numbered paragraph (1) |   |  |  |   |
| 76   | 1. In exceptional and duly justified cases, the Commission is empowered to adopt implementing   | <i>deleted</i>   | <i>deleted</i>   | <i>deleted</i>  |



|  | Commission Proposal   | EP Mandate     | Council Mandate | Draft Agreement |
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|  | acts establishing mandatory common specifications to cover the essential requirements set out in Annex II for subsystems or safety components, which have been designated as crisis-relevant goods.   |                |                 |                 |
| Article 1, first paragraph, amending provision, numbered paragraph (2) |   |                |                 |                 |
| 77   | 2. The implementing acts establishing mandatory common specifications, referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 44(3). They shall apply to subsystems or safety components placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act. | <i>deleted</i> | <i>deleted</i>  | <i>deleted</i>  |
| Article 1, first paragraph, amending provision, numbered paragraph (3) |   |                |                 |                 |

|  | Commission Proposal   | EP Mandate  | Council Mandate  | Draft Agreement  |
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| 78   | 3. By way of derogation from Article 43a(3), first subparagraph, unless there is sufficient reason to believe that the subsystems or safety components covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the subsystems or safety components in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation]. | <i>deleted</i>  | <i>deleted</i>   | <i>deleted</i>   |
| Article 1, first paragraph, amending provision, Article                |   |   |  |  |
| 79   | Article 43g<br>Prioritisation of market surveillance activities and mutual assistance among authorities   | Article 43g<br>Prioritisation of market surveillance activities and mutual assistance among authorities | <b>Article 43g</b><br><del>Article 43g</del><br>Prioritisation of market surveillance activities and mutual assistance among authorities | <u><a href="#">Article 43g</a></u><br><del>Article 43g</del><br>Prioritisation of market surveillance activities and mutual assistance among authorities |
| Article 1, first paragraph, amending provision, numbered paragraph (1) |   |   |  |  |
| 80   | 1. Member States shall prioritise the market surveillance activities for  | 1. Member States shall prioritise the market surveillance activities for                                | 1. Member States shall prioritise the market surveillance activities for   | 1. Member States shall prioritise the market surveillance activities for   |

|  | Commission Proposal  | EP Mandate  | Council Mandate  | Draft Agreement   |
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|  | subsystems and safety components designated as crisis-relevant goods.  | subsystems and safety components designated as crisis-relevant goods.   | subsystems and safety components designated as crisis-relevant goods.<br><b>The Commission shall facilitate coordination of these efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.</b>  | subsystems and safety components designated as crisis-relevant goods.<br><u><a href="#">The Commission shall facilitate coordination of these efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.</a></u>   |
| Article 1, first paragraph, amending provision, numbered paragraph (2) |  |   |  |   |
| 81   | 2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for subsystems and safety components designated as crisis-relevant goods. | 2. The market surveillance authorities of the Member States shall <del>deploy their</del> <u>ensure</u> best efforts <u>are made</u> to provide assistance to other market surveillance authorities during <del>a Single</del> <u>an internal</u> market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for subsystems and safety components designated as crisis-relevant goods. | 2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for subsystems and safety components designated as crisis-relevant goods. | 2. The market surveillance authorities of the Member States shall <del>deploy their</del> <u>ensure that</u> best efforts <u>are made</u> to provide assistance to other market surveillance authorities during a <del>Single</del> <u>internal</u> market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for subsystems and safety components designated as crisis-relevant goods. |
| Article 2  |  |   |  |   |
| 82   | Article 2<br>Amendments to Regulation (EU)   | Article 2<br>Amendments to Regulation (EU)  | Article 2<br>Amendments to Regulation (EU)   | Article 2<br>Amendments to Regulation (EU)  |

|   | Commission Proposal   | EP Mandate  | Council Mandate   | Draft Agreement  |
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|   | 2016/425  | 2016/425  | 2016/425  | 2016/425<br><small>Text Origin: Commission Proposal</small>  |
| Article 2, first paragraph  |   |   |   |  |
| 83  | In Regulation (EU) 2016/425, the following Chapter VIa is inserted: | In Regulation (EU) 2016/425, the following Chapter VIa is inserted: | <del>In</del> Regulation (EU) 2016/425, the following Chapter VIa is inserted <b>is amended as follows:</b>   | <del>In</del> Regulation (EU) 2016/425, <del>the following Chapter VIa is inserted</del> <b>is amended as follows:</b><br><small>Text Origin: Council Mandate</small>  |
| Article 2, first paragraph, point (1)                                       |   |   |   |  |
| 83a   |   |   | (1) In Article 3 the following points are added:  | <u>(1) In Article 3 the following points are added:</u><br><small>Text Origin: Council Mandate</small>   |
| Article 2, first paragraph, point (1), amending provision, first paragraph  |   |   |   |  |
| 83b   |   |   | "<br>(19) 'crisis-relevant goods' means 'crisis-relevant goods' within the meaning of Article 3, point (6) of Regulation (EU) .../.... [SMEI Regulation]; | <u>(19) 'crisis-relevant goods' means 'crisis-relevant goods' within the meaning of Article 3, point (6) of Regulation (EU) .../.... [SMEI/IMERA Regulation];</u><br><small>Text Origin: Council Mandate</small> |
| Article 2, first paragraph, point (1), amending provision, second paragraph |   |   |   |  |
| 83c   |   |   | (20) 'Single Market   | <u>(20) 'internal market</u>   |

|  | Commission Proposal                                | EP Mandate   | Council Mandate  | Draft Agreement   |
|--|--|--|--|---|
|  |  |  | Emergency' means 'Single Market Emergency' within the meaning of Article 3, point (3) of Regulation (EU) .../... [SMEI Regulation].; | <u>emergency' means 'internal market emergency' within the meaning of Article 3, point (3) of Regulation (EU) ..../... [IMERA Regulation].;</u><br><br>Text Origin: Council Mandate |
| Article 2, first paragraph, point (2)                                  |  |  |  |   |
| 83d  |  |  | (2) The following Chapter VIa is inserted after Chapter VI:  | <u>(2) The following Chapter VIa is inserted after Chapter VI:</u><br><br>Text Origin: Council Mandate  |
| Article 2, first paragraph, amending provision, Chapter I              |  |  |  |   |
| 84   | CHAPTER VIa<br>EMERGENCY PROCEDURES                | CHAPTER VIa<br>EMERGENCY PROCEDURES                | Chapter VIa<br><del>CHAPTER VIa</del><br>EMERGENCY PROCEDURES  | <u>Chapter VIa</u><br><del>CHAPTER VIa</del><br>EMERGENCY PROCEDURES<br><br>Text Origin: Council Mandate  |
| Article 2, first paragraph, amending provision, Article                |  |  |  |   |
| 85   | Article 41a<br>Application of emergency procedures | Article 41a<br>Application of emergency procedures | Article 41a<br><del>Article 41a</del><br>Application of emergency procedures   | <u>Article 41a</u><br><del>Article 41a</del><br>Application of emergency procedures<br><br>Text Origin: Council Mandate   |
| Article 2, first paragraph, amending provision, numbered paragraph (1) |  |  |  |   |

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| 86  | 1. Articles 41b to 41g shall only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Regulation. | 1. Articles 41b to 41g <u>of this Regulation</u> shall only apply if the Commission has adopted an implementing act pursuant to Article <del>23 of [the SMEI Regulation]</del> <u>activating Article 26 of [the SMEI 14(5) of [the IMERA Regulation] with respect to this Regulation.</u> | 1. Articles 41b to 41g shall only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to <b>PPE covered by this Regulation.</b>  | 1. Articles 41b to 41g <u>of this Regulation</u> shall only apply if the Commission has adopted an implementing act pursuant to Article <del>23 of [the SMEI Regulation]</del> <u>activating Article 26 of [the SMEI Regulation] with respect to this the IMERA Regulation.</u>  |
| Article 2, first paragraph, amending provision, numbered paragraph (2)                      |   |   |  |  |
| 87  | 2. Articles 41b to 41g shall apply exclusively to PPE, which has been designated as crisis-relevant goods in the implementing act referred to in paragraph 1.   | 2. Articles 41b to 41g shall apply exclusively to PPE, which has been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 <u>of this Article.</u>  | 2. Articles 41b to 41g <del>shall</del> apply exclusively to PPE, which has been designated as <del>crisis-relevant goods in the implementing act referred to in paragraph 1</del> <b>a crisis-relevant good pursuant to Article 14 of [the SMEI Regulation].</b>                            | 2. Articles 41b to 41g <del>shall</del> apply exclusively to PPE, which has been designated as crisis-relevant goods <del>in the implementing act referred to in paragraph 1</del> <u>pursuant to Article 14(5) of the IMERA Regulation.</u>   |
| Article 2, first paragraph, amending provision, numbered paragraph (3), first subparagraph  |   |   |  |  |
| 88  | 3. Articles 41b to 41g, except as regards provisions concerning the powers of the Commission, shall apply during the Single Market emergency mode.  | 3. Articles 41b to 41g, except as regards provisions concerning the powers of the Commission, shall apply during the <del>Single</del> <u>internal</u> market emergency mode.   | 3. Articles 41b to 41g, except as regards <del>provisions concerning the powers</del> <b>the power</b> of the Commission <b>in Article 41e(5)</b> , shall apply <b>only</b> during the Single Market emergency mode <b>activated in accordance with Article 14 of [the SMEI Regulation].</b> | 3. Articles 41b to 41g, except as regards <del>provisions concerning the powers</del> <u>the power</u> of the Commission <u>in Article 41e(5)</u> , shall apply <u>only</u> during the <del>Single</del> <u>internal</u> market emergency mode <u>activated in accordance with Article 14 of the IMERA Regulation.</u> |
| Article 2, first paragraph, amending provision, numbered paragraph (3), second subparagraph |   |   |  |  |

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| 89   | However, Article 41c(2), second subparagraph, and Article 41c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.  | <i>deleted</i>  | However, <del>Article 41c(2), second subparagraph, and</del> Article 41c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.   | However, Article 41 <del>e(2), second subparagraph, and Article 41c(5)</del> shall apply during the <del>Single</del> <u>internal</u> market emergency mode and after its deactivation or expiry.  |
| Article 2, first paragraph, amending provision, numbered paragraph (4) |   |   |   |  |
| 90   | 4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to PPE placed on the market in accordance with Articles 41c to 41f. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3). | <i>deleted</i>  | 4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken <b>may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures to be followed and the specific labelling and traceability requirements</b> with respect to PPE placed on the market in accordance with Articles 41c to <del>41f</del> <b>41e</b> . These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3). | 4. The Commission <del>shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions</del> <u>may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures</u> to be <del>taken</del> <u>followed and the specific labelling and traceability requirements</u> with respect to PPE placed on the market in accordance with Articles 41c to <del>41f. These</del> <u>41e. Those</u> implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3). |
| Article 2, first paragraph, amending provision, Article                |   |   |   |  |
| 91   | Article 41b<br>Prioritisation of the conformity assessment of crisis-relevant PPE   | Article 41b<br>Prioritisation of the conformity assessment of crisis-relevant PPE | <b>Article 41b</b><br><del>Article 41b</del><br>Prioritisation of the conformity assessment of crisis-relevant PPE  | <u><b>Article 41b</b></u><br><del>Article 41b</del><br>Prioritisation of the conformity assessment of crisis-relevant PPE<br><br>Text Origin: Council Mandate  |



|    | Commission Proposal  | EP Mandate   | Council Mandate  | Draft Agreement   |
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|    | Article 2, first paragraph, amending provision, numbered paragraph (1)   |  |  |   |
| 92 | 1. This Article shall apply to PPE designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 19 requiring mandatory involvement of a notified body.                  | 1. This Article shall apply to PPE designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 19 requiring mandatory involvement of a notified body.                  | 1. This Article shall apply to PPE designated as a crisis-relevant <del>goods</del> good, which <del>are</del> is subject to conformity assessment procedures in accordance with Article 19 requiring mandatory involvement of a notified body.  | 1. This Article shall apply to PPE designated as <u>a</u> crisis-relevant <del>goods</del> good, which <del>are</del> is subject to conformity assessment procedures in accordance with Article 19 requiring mandatory involvement of a notified body.  |
|    | Article 2, first paragraph, amending provision, numbered paragraph (2)   |  |  |   |
| 93 | 2. The notified bodies shall process all applications for conformity assessment of PPE designated as crisis-relevant goods as a matter of priority.  | 2. The notified bodies shall <u>ensure all reasonable efforts are made to</u> process all applications for conformity assessment of PPE designated as crisis-relevant goods as a matter of priority.                             | 2. The notified bodies shall process all applications for conformity assessment of PPE designated as a crisis-relevant <del>goods</del> good as a matter of priority, <b>irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 41a.</b> | 2. The notified bodies shall <u>make best efforts to</u> process all applications for conformity assessment of PPE designated as <u>a</u> crisis-relevant <del>goods</del> good as a matter of priority, <u>irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 41a.</u> |
|    | Article 2, first paragraph, amending provision, numbered paragraph (3)   |  |  |   |
| 94 | 3. All pending applications for conformity assessment of such PPE shall be processed as a matter of priority, ahead of any other applications for conformity assessment of PPE, which has not been designated as crisis-relevant | 3. All pending applications for conformity assessment of such PPE shall be processed as a matter of priority, ahead of any other applications for conformity assessment of PPE, which has not been designated as crisis-relevant | <i>deleted</i>   | <i>deleted</i>  |

|  | Commission Proposal  | EP Mandate   | Council Mandate  | Draft Agreement   |
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|  | goods. This requirement applie with respect to all applications for conformity assessment of PPE designated as crisis-relevant good, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 41a. | goods. This requirement applie with respect to all applications for conformity assessment of PPE designated as crisis-relevant good, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 41a. | PUBLIC   |   |
| Article 2, first paragraph, amending provision, numbered paragraph (4) |  |  |  |   |
| 95   | 4. The prioritisation of applications for conformity assessment of PPE pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.  | 4. The prioritisation of applications for conformity assessment of PPE pursuant to paragraph 3 shall not give rise to any <u>extraordinary</u> additional costs for the manufacturers, who have lodged those applications.   | 4. The prioritisation of applications for conformity assessment of PPE pursuant to paragraph <del>32</del> shall not give rise to <del>any</del> <b>disproportionate</b> additional costs for the manufacturers, who have lodged those applications. | 4. The prioritisation of applications for conformity assessment of PPE pursuant to paragraph <del>32</del> shall not give rise to <del>any additional</del> <u>additional disproportionate</u> costs for the manufacturers, who have lodged those applications. |
| Article 2, first paragraph, amending provision, numbered paragraph (5) |  |  |  |   |
| 96   | 5. The notified bodies shall deploy their best efforts to increase their testing capacities for PPE designated as crisis-relevant goods in respect to which they have been notified.   | 5. The notified bodies shall <del>deploy</del> <u>their best ensure all reasonable</u> efforts <u>are made</u> to increase their testing capacities for PPE designated as crisis-relevant goods in respect to which they have been notified.                           | <del>deleted</del>   | 5. The notified bodies shall <del>deploy</del> <u>their best make reasonable</u> efforts to increase their testing capacities for PPE designated as crisis-relevant goods in respect <del>to of</del> which they have been notified.                            |
| Article 2, first paragraph, amending provision, Article                |  |  |  |   |
| 97   | Article 41c<br>Derogation from the conformity assessment procedures requiring  | Article 41c<br>Derogation from the conformity assessment procedures requiring  | <b>Article 41c</b><br><del>Article 41e</del><br>Derogation from the conformity   | <u>Article 41c</u><br><del>Article 41e</del><br>Derogation from the conformity  |

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|   | mandatory involvement of a notified body  | mandatory involvement of a notified body  | assessment procedures requiring mandatory involvement of a notified body  | assessment procedures requiring mandatory involvement of a notified body<br><small>Text Origin: Council Mandate</small>  |
| Article 2, first paragraph, amending provision, numbered paragraph (1)                      |   |   |   |  |
| 98  | 1. By way of derogation from Article 19, any competent national authority may authorise, on a duly justified request, the placing on the market within the territory of the Member State concerned, of a specific PPE which has been designated as crisis-relevant good for which the conformity assessment procedures requiring mandatory involvement of a notified body referred to in that Article have not been carried out by a notified body but for which the compliance with all the applicable essential health and safety requirements has been demonstrated. | 1. By way of derogation from Article 19, <del>any</del> <u>the</u> competent national authority, <u>after carrying out a risk assessment</u> , may authorise, on a duly justified request <u>from an economic operator established in its Member State</u> , the placing on the market within the territory of <del>the</del> <u>that</u> Member State <del>concerned</del> , of a specific PPE which has been designated as crisis-relevant <del>good</del> <u>goods</u> for which the conformity assessment procedures requiring mandatory involvement of a notified body referred to in that Article have not been carried out by a notified body but for which the compliance with all the applicable essential health and safety requirements has been demonstrated. | 1. By way of derogation from Article 19, any competent national authority may authorise, on a duly justified request, the placing on the market within the territory of the Member State concerned, of a specific PPE which has been designated as a crisis-relevant good for which the conformity assessment procedures requiring mandatory involvement of a notified body referred to in that Article have not been carried out <del>by a notified body</del> but for which the compliance with all the applicable essential health and safety requirements has been demonstrated <b>in accordance with procedures referred to in that authorisation.</b> | 1. By way of derogation from Article 19, <del>any competent national authority</del> <u>the Member State</u> may authorise, on a duly justified request <u>from an economic operator</u> , the placing on the market within the territory of the Member State concerned, of a specific PPE which has been designated as <u>a</u> crisis-relevant good for which the conformity assessment procedures requiring mandatory involvement of a notified body referred to in that Article have not been carried out by a notified body but for which the compliance with all the applicable essential health and safety requirements has been demonstrated <u>in accordance with procedures referred to in that authorisation.</u> |
| Article 2, first paragraph, amending provision, numbered paragraph (1a), first subparagraph |   |   |   |  |
| 98a   |   |   | <b>1a. The Member State shall immediately inform the Commission and the other</b>   | <u><b>1a. The Member State shall immediately inform the Commission and the other Member</b></u>  |

|  | Commission Proposal | EP Mandate | Council Mandate  | Draft Agreement  |
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|  |                     |            | <p>Member States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure the conformity with the applicable essential health and safety requirements laid down in Annex II to this Regulation, the Commission shall without delay adopt an implementing act extending for a limited period of time the validity of the authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the specific PPE may be placed on the market. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 44(3).</p> | <p><u>States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure the conformity with the applicable essential health and safety requirements laid down in Annex II to this Regulation, the Commission shall without delay adopt an implementing act extending for a limited period of time the validity of the authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the specific PPE may be placed on the market. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 44(3).</u></p> |
| Article 2, first paragraph, amending provision, numbered paragraph (1a), second subparagraph |                     |            |  |  |
| G 98b  |                     |            | The specific PPE subject to the  | <u>The specific PPE subject to the</u>   |

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|   |                     |            | extension of validity referred to in the first subparagraph shall bear the information that it is placed on the market as a “crisis-relevant good”. The implementing act referred to in the first subparagraph shall specify the modalities of that information. That information, as well as any labelling, shall be clear, understandable and intelligible and, where relevant, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. | <u>extension of validity referred to in the first subparagraph shall bear the information that it is placed on the market as a “crisis-relevant good”. The implementing act referred to in the first subparagraph shall specify the modalities of that information. That information, as well as any labelling, shall be clear, understandable and intelligible and, where relevant, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.</u> |
| Article 2, first paragraph, amending provision, numbered paragraph (1b)                     |                     |            |   |  |
| 98c   |                     |            | 1b. On duly justified imperative grounds of urgency relating to the need to preserve the health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 44(4).   | <u>1b. On duly justified imperative grounds of urgency relating to the need to preserve the health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 44(4).</u>   |
| Article 2, first paragraph, amending provision, numbered paragraph (1c), first subparagraph |                     |            |   |  |
| 98d   |                     |            | 1c. As long as an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a  | <u>1c. As long as an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national</u>   |

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|  |   |   | competent national authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act.  | <u>authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act.</u>  |
| Article 2, first paragraph, amending provision, numbered paragraph (1c), second subparagraph |   |   |  |  |
| 98e  |   |   | Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.   | <u>Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.</u>  |
| Article 2, first paragraph, amending provision, numbered paragraph (2), first subparagraph   |   |   |  |  |
| 99   | 2. The manufacturer of a PPE subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the PPE concerned complies with all the applicable essential health and safety requirements and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the national competent authority. | 2. The manufacturer of a PPE subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the PPE concerned complies with all the applicable essential health and safety requirements and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the national competent authority. | 2. The manufacturer of a PPE subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the PPE concerned complies with all the applicable essential health and safety requirements and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the <del>national</del> competent <b>national</b> authority. | 2. The manufacturer of a PPE subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the PPE concerned complies with all the applicable essential health and safety requirements and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the <del>national</del> competent <u>national</u> authority. |

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| Article 2, first paragraph, amending provision, numbered paragraph (2), second subparagraph |  |  |  |  |
| 100   | The manufacturer shall also deploy all reasonable measures to ensure that the PPE, which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of the Member State, which issued the authorisation. | <i>deleted</i>   | <i>deleted</i>   | <i>deleted</i>   |
| Article 2, first paragraph, amending provision, numbered paragraph (3)                      |  |  |  |  |
| 101   | 3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the PPE may be placed on the market, including:                                      | 3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the PPE may be placed on the market, including <u>at least</u> : | 3. Any authorisation issued <del>by a national competent authority</del> pursuant to paragraph 1 shall set out the conditions and requirements under which the PPE may be placed on the market, <del>including</del> . <b>The authorisations shall at least set out the following:</b> | 3. Any authorisation issued <del>by a national competent authority</del> pursuant to paragraph 1 shall set out the conditions and requirements under which the PPE may be placed on the market, <del>including</del> . <u>The authorisations shall at least set out the following:</u> |
| Article 2, first paragraph, amending provision, numbered paragraph (3), point (a)           |  |  |  |  |
| 102   | (a) a description of the procedures, by means of which the compliance with the applicable essential health and safety requirements was successfully demonstrated;  | (a) a description of the procedures, by means of which the compliance with the applicable essential health and safety requirements was successfully demonstrated;  | (a) a description of the procedures, by means of which the compliance with the applicable essential health and safety requirements was successfully demonstrated;  | (a) a description of the procedures, by means of which the compliance with the applicable essential health and safety requirements was successfully demonstrated;<br><br>Text Origin: Commission Proposal  |
| Article 2, first paragraph, amending provision, numbered paragraph (3), point (b)           |  |  |  |  |



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| 103   | (b) specific requirements regarding the traceability of the PPE concerned;  | (b) specific requirements regarding the traceability of the PPE concerned;   | (b) <b>any</b> specific requirements regarding the traceability of the PPE concerned;  | (b) <u>any</u> specific requirements regarding the traceability of the PPE concerned;   |
| Article 2, first paragraph, amending provision, numbered paragraph (3), point (c) |   |  |  |   |
| 104   | (c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated;  | (c) an end date of validity, <u>unless otherwise specified</u> , of the authorisation, which cannot go beyond the last day of the period for which the <u>Singleinternal</u> market emergency mode has been activated; | (c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated <b>in accordance with Article 14 of [the SMEI Regulation]</b> ;                              | (c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the <u>Singleinternal</u> market emergency mode has been activated <u>in accordance with Article 14 of the IMERA Regulation</u> ;                                 |
| Article 2, first paragraph, amending provision, numbered paragraph (3), point (d) |   |  |  |   |
| 105   | (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the PPE concerned;  | (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the PPE concerned;   | (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the PPE concerned;   | (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the PPE concerned;<br><br>Text Origin: Commission Proposal  |
| Article 2, first paragraph, amending provision, numbered paragraph (3), point (e) |   |  |  |   |
| 106   | (e) measures to be taken with respect to the PPE concerned upon expiry of the authorisation in order to ensure that the PPE concerned is brought back in compliance with all the requirements of this Regulation. | (e) measures to be taken with respect to the PPE concerned upon expiry of the authorisation in order to ensure that the PPE concerned is brought back in compliance with all the requirements of this Regulation.      | (e) measures to be taken with respect to the PPE <b>placed on the market upon expiry of the Single Market emergency</b> <del>concerned upon expiry of the authorisation in order to ensure that the PPE concerned is brought back in compliance with all</del> | (e) measures to be taken <del>with respect to the PPE concerned</del> upon expiry of the <del>authorisation in order to ensure that</del> <u>internal market emergency with respect to</u> the PPE <del>concerned is brought back in compliance with all the requirements</del> |

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|  |  |   | the requirements of this Regulation.   | <del>of this Regulation</del> <u>placed on the market.</u>   |
| Article 2, first paragraph, amending provision, numbered paragraph (3), point (ea) |  |   |  |  |
| 106a   |  | <u>(ea) labelling requirements, including radio frequency identification, indicating that the PPE was authorised under the internal market emergency mode.</u>  |  | deleted  |
| Article 2, first paragraph, amending provision, numbered paragraph (4)             |  |   |  |  |
| 107  | 4. By way of derogation from Article 41a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 of this Article also after the deactivation or expiry of the Single Market Emergency mode. | 4. By way of derogation from Article 41a(3), <del>first subparagraph,</del> where appropriate, the national competent authority may <u>also</u> amend the conditions <del>of the authorisation</del> <u>and requirements</u> referred to in paragraph 3 of this Article also after the deactivation or expiry of the <del>Single</del> <u>internal</u> market emergency mode. | deleted  | deleted  |
| Article 2, first paragraph, amending provision, numbered paragraph (5)             |  |   |  |  |
| 108  | 5. By way of derogation from Articles 7 and 17, PPE, for which an authorisation has been granted in accordance with paragraph 1 of this Article, shall not leave the territory of the Member State which has issued the authorisation and shall not                                      | deleted   | 5. By way of derogation from Articles 7, <b>16</b> and 17, PPE, for which an authorisation has been granted in accordance with paragraph 1 <del>of this Article,</del> shall not <del>leave the territory of the Member State which has issued the</del> | 5. By way of derogation from Articles 7, <u>16</u> and 17, PPE, for which an authorisation has been granted in accordance with paragraph 1 <del>of this Article,</del> shall not <del>leave the territory of the Member State which has issued the</del> |

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|   | bear the CE marking.   |   | <del>authorisation and</del> <b>bear the CE marking and Article 7</b> shall not bear the CE marking <b>apply</b> .  | <del>authorisation and</del> <u>bear the CE marking and Article 7</u> shall not <del>bear the CE marking</del> <u>apply</u> .   |
| Article 2, first paragraph, amending provision, numbered paragraph (5a), numbered paragraph (6)   |  |   |   |   |
| 109   | 6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Regulation with respect to such PPE. | 6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Regulation with respect to such PPE. <u>The market surveillance authorities shall keep all records related to products authorised under a derogation for a period of 10 years. They shall make those records available to other market surveillance authorities upon request.</u> | <del>65a.</del> The market surveillance authorities of the Member State, whose competent authority has granted <del>where</del> an authorisation pursuant to paragraph 1, <b>paragraphs 1, 1a and 1c is valid</b> , shall be entitled to take all corrective and restrictive <del>measures</del> <b>actions</b> at national level provided for <b>under Regulation (EU) 2019/1020 and</b> under this Regulation with respect to such PPE. | <del>65a.</del> The market surveillance authorities of <del>the</del> <u>a</u> Member State, <del>whose competent authority has granted</del> <u>where</u> an authorisation pursuant to <del>paragraph 1,</del> <u>paragraphs 1, 1a and 1c is valid</u> , shall be entitled to take all corrective and restrictive <del>measures</del> <u>actions</u> at national level provided for <u>under Regulation (EU) 2019/1020 and</u> under this Regulation with respect to such PPE. |
| Article 2, first paragraph, amending provision, numbered paragraph (5a), numbered paragraph (6) a |  |   |   |   |
| 109a  |  |   | <b>They shall immediately inform the Commission and the market surveillance authorities of other Member States of these actions.</b>  | <u>They shall immediately inform the Commission and the market surveillance authorities of other Member States of these actions.</u>  |
| Article 2, first paragraph, amending provision, numbered paragraph (7)                            |  |   |   |   |
| 110   | 7. Member States shall inform the  | 7. Member States shall inform the   |   |   |

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|   | Commission and the other Member States of any decision to authorise the placing on the market of PPE in accordance with paragraph 1.   | Commission and the other Member States of any decision to authorise the placing on the market of PPE in accordance with paragraph 1.   | <i>deleted</i>   | <i>deleted</i>   |
| Article 2, first paragraph, amending provision, numbered paragraph (8)  |  |  |  |  |
| 111   | 8. The application of Articles 41a to 41g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 19 on the territory of the Member State concerned. | 8. The application of Articles 41a to 41g and the use of the authorisation procedure set out in paragraph 1 of this Article <del>does</del> <i>shall</i> not affect the application of the relevant conformity assessment procedures laid down in Article 19 <del>on the territory of the Member State concerned.</del>                      | 8. The application of Articles 41a to 41g and the use of the authorisation procedure set out in paragraph 1 of this Article <del>does</del> <i>shall</i> not affect the application of the relevant conformity assessment procedures laid down in Article 19 on the territory of the Member State concerned. | 8. <del>The application of Articles 41a to 41g and</del> The use of the authorisation procedure set out in <del>paragraph 1 of this Article does</del> <i>paragraphs 1 to 1c shall</i> not affect the application of the relevant conformity assessment procedures laid down in Article 19 on the territory of the Member State concerned. |
| Article 2, first paragraph, amending provision, numbered paragraph (8a) |  |  |  |  |
| 111a  |  | <u>8a. PPE subject to derogation under paragraph 1 shall remain valid for six months after deactivation or expiration of the internal market emergency mode. After this period, it shall only be made available on the market after receiving an authorisation under the normal authorisation procedure provided for in this Regulation.</u> |  | <i>deleted</i>   |
| Article 2, first paragraph, amending provision, Article                 |  |  |  |  |
| 112   | Article 41d  | Article 41d  |  |  |

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|  | Presumption of conformity based on national and international standards  | Presumption of conformity based on national and international standards  | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 2, first paragraph, amending provision, Article, first paragraph</i>            |  |  |                 |                 |
| 113  | Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, their competent authorities consider that the PPE, which complies with the relevant international standards or any national standards in force in the Member State of manufacture, ensuring the safety level required by the essential health and safety requirements set out in Annex II, complies with those essential health and safety requirements in either of the following cases: | Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, their competent authorities consider that the PPE, which complies with the relevant international standards or any national standards in force in the Member State of manufacture, ensuring the safety level required by the essential health and safety requirements set out in Annex II, complies with those essential health and safety requirements in either of the following cases: | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 2, first paragraph, amending provision, Article, first paragraph, point (a)</i> |  |  |                 |                 |
| 114  | (a) where no reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex II is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;  | (a) where no reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex II is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;  | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 2, first paragraph, amending provision, Article, first paragraph, point (b)</i> |  |  |                 |                 |

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| 115  | (b) where severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex II to this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012. | (b) where severe disruptions in the functioning of the <del>Single</del> <u>internal</u> market, which were taken into consideration when activating the <del>Single</del> <u>internal</u> market emergency mode in accordance with Article <del>15(4) of [the SMEI]</del> <u>14 of [the IMERA]</u> Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex II to this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012. | deleted  | deleted  |
| Article 2, first paragraph, amending provision, Article                |  |   |  |  |
| 116  | Article 41e<br>Adoption of common specifications conferring a presumption of conformity  | Article 41e<br>Adoption of common specifications conferring a presumption of conformity   | Article 41e<br><del>Article 41e</del><br>Adoption of common specifications conferring a presumption of conformity<br><b>Presumption of conformity based on standards and common specifications</b> | <u>Article 41e</u><br><del>Article 41e</del><br><del>Adoption of common specifications conferring a presumption of conformity</del><br><u>Presumption of conformity based on standards and common specifications</u><br><br>Text Origin: Council Mandate |
| Article 2, first paragraph, amending provision, numbered paragraph (1) |  |   |  |  |
| 117  |  |   |  |  |

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|  | 1. Where PPE, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such PPE to cover the essential health and safety requirements set out in Annex II in either of the following cases: | 1. Where PPE, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such PPE to cover the essential health and safety requirements set out in Annex II in either of the following cases:  | 1. Where PPE, <del>have</del> <b>has</b> been designated as <del>a</del> crisis-relevant <del>goods</del> <b>good</b> , the Commission is empowered to adopt implementing acts, <b>listing appropriate standards</b> or establishing common specifications for such PPE to cover the <b>applicable</b> essential health and safety requirements set out in Annex II in either of the following cases: | 1. Where PPE, <del>have</del> <b>has</b> been designated as <u>a</u> crisis-relevant <del>goods</del> <b>good</b> , the Commission is empowered to adopt implementing acts, <u>listing appropriate standards</u> or establishing common specifications for such PPE to cover the <u>applicable</u> essential health and safety requirements set out in Annex II in either of the following cases:                           |
| Article 2, first paragraph, amending provision, numbered paragraph (1), point (a)  |   |  |   |   |
| 118  | (a) where no reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex II is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;                                   | (a) where <del>no reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex II is published in the Official Journal of the European Union in accordance with</del> <u>the European standardisation deliverables addressing a request pursuant to Article 10(1) of Regulation (EU) No 1025/2012</u> <u>were not adopted</u> ; | (a) <del>where</del> no reference to harmonised standards covering the <del>relevant</del> <b>applicable</b> essential health and safety requirements set out in Annex II is published in the <b>Official Journal of the European Union</b> <del>Official Journal of the European Union</del> in accordance with Regulation (EU) No 1025/2012;  | (a) <del>where</del> no reference to harmonised standards covering the relevant essential <del>health and safety</del> requirements set out in Annex II is published in the <u>Official Journal of the European Union</u> <del>Official Journal of the European Union</del> in accordance with Regulation (EU) No 1025/2012 <u>and no such reference is expected to be published within a reasonable period</u> ; <u>or</u> |
| Article 2, first paragraph, amending provision, numbered paragraph (1), point (aa) |   |  |   |   |
| 118a   |   | <u>(aa) where a reference to harmonised standards covering the relevant essential requirements set out in Annex II is not published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012</u>  |   | <i>deleted</i>  |



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|  |  | <u>and such reference is not expected to be published within a reasonable timeframe during the internal market emergency mode;</u>   |  |   |
| Article 2, first paragraph, amending provision, numbered paragraph (1), point (ab) |  |  |  |   |
| 118b   |  |  |  | deleted   |
| Article 2, first paragraph, amending provision, numbered paragraph (1), point (ac) |  |  |  |   |
| 118c   |  |  |  | deleted   |
| Article 2, first paragraph, amending provision, numbered paragraph (1), point (ad) |  |  |  |   |
| 118d   |  |  |  | deleted   |
| Article 2, first paragraph, amending provision, numbered paragraph (1), point (b)  |  |  |  |   |
| 119  | (b) where severe disruptions in the functioning of the Single Market, which led to the activation Single Market emergency mode significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex II to this Regulation and already | (b) where severe disruptions in the functioning of the <u>Singleinternal</u> market, which led to the activation <u>Singleinternal</u> market emergency mode significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex II to | (b) <del>where</del> severe disruptions in the functioning of the Single Market, which led to the activation Single Market emergency mode significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the <del>relevant</del> <b>applicable</b> essential health and safety requirements set out in Annex II to this Regulation and | (b) <del>where</del> severe disruptions in the functioning of the <u>Singleinternal</u> Market, which led to the activation <u>Singleof the internal</u> Market emergency mode <u>in accordance with Article 14 of [the IMERA Regulation]</u> , significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant |

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|  | published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012. | this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012. | already published in the <i>Official Journal of the European Union</i> in accordance with Regulation (EU) No 1025/2012.                          | <u>applicable</u> essential health and safety requirements set out in Annex II <del>to this Regulation</del> and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.   |
| Article 2, first paragraph, amending provision, numbered paragraph (1a)            |  |  |  |   |
| 119a   |  |  | 1a. The implementing acts referred to in paragraph 1 may:  | <u>1a. The implementing acts referred to in paragraph 1 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.</u> |
| Article 2, first paragraph, amending provision, numbered paragraph (1), point (bb) |  |  |  |   |
| 119b   |  |  | (a) publish the references to relevant applicable international standards that provide presumption of conformity in accordance with paragraph 3; | <i>deleted</i>  |

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|      | <i>Article 2, first paragraph, amending provision, numbered paragraph (1), point (bc)</i> |            |   |                 |
| 119c |   |            | (b) if there is no relevant applicable international standards as referred to in point a of this paragraph that cover the essential requirements set out in Annex II, publish the references to the European standards that provide presumption of conformity in accordance with paragraph 3;               | <i>deleted</i>  |
|      | <i>Article 2, first paragraph, amending provision, numbered paragraph (1), point (bd)</i> |            |   |                 |
| 119d |   |            | (c) if there is no relevant applicable international or European standard as referred to in points a and b, that cover the essential requirements set out in Annex II, establish common specifications established by the Commission that provide presumption of conformity in accordance with paragraph 3; | <i>deleted</i>  |
|      | <i>Article 2, first paragraph, amending provision, numbered paragraph (1), point (be)</i> |            |   |                 |
| 119e |   |            | (d) if there is no relevant applicable international standard, European standard or common specifications as referred to in points a, b and c, publish the reference to national standards that provide presumption of  | <i>deleted</i>  |

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|   |  |   | conformity in accordance with paragraph 3.   |  |
| Article 2, first paragraph, amending provision, numbered paragraph (2)  |  |   |  |  |
| 120   | <p>2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 44(3). They shall remain applicable to PPE placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.</p> | <p>2. The implementing acts referred to in paragraph 1 of this Article shall be adopted <del>following a consultation of the sectoral experts and</del> in accordance with the examination procedure referred to in Article 44(3). They shall remain applicable to PPE placed on the market until the last day of the period for which the <del>Single</del><u>internal</u> market emergency mode remains active. <del>In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under the relevant sectoral Union legislation. Based on that consultation, the Commission</del><u>bodies and</u> shall <del>prepare the draft implementing act</del><u>duly consult all relevant stakeholders</u>.</p> | <p>2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 44(3). They shall remain applicable to PPE placed on the market until the last day of the period for which the Single Market emergency mode remains active. <del>In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act,</del> unless amended or repealed in accordance with paragraph 5.</p> | <p>2. The implementing acts referred to in paragraph <del>1 of this Article</del> <u>shall</u> be adopted <del>following a consultation of the sectoral experts and</del> in accordance with the examination procedure referred to in Article 44(3). <del>and</del> they shall <del>remain applicable to PPE placed on the market</del><u>apply</u> until the last day of the period for which the <del>Single</del><u>internal</u> market emergency mode remains active. <del>In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act,</del> unless amended or repealed in accordance with <u>paragraph 5</u>.</p> |
| Article 2, first paragraph, amending provision, numbered paragraph (2a) |  |   |  |  |
| 120a  |  |   | 2a. Before preparing the draft implementing act referred to in   | <u>2a. Before preparing the draft implementing act referred to in</u>  |

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|  |  |  | <p>paragraph 1, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or expert group established under this Regulation and shall duly consult all relevant stakeholders.</p> <p>COM text from row 120 above</p>  | <p><u>paragraph 1, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or expert groups established under this Regulation and shall duly consult all relevant stakeholders.</u></p>  |
| Article 2, first paragraph, amending provision, numbered paragraph (3) |  |  |   |  |
| 121  | <p>3. Without prejudice to Article 14, PPE which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential health and safety requirements set out in Annex II covered by those common specifications or parts thereof.</p> | <p>3. Without prejudice to Article 14, PPE which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential health and safety requirements set out in Annex II covered by those common specifications or parts thereof.</p> | <p>3. Without prejudice to Article 14, PPE which <del>are</del><b>is</b> in conformity with <b>the standards or</b> common specifications <del>adopted pursuant to</del> <b>referred to in</b> paragraph 2 of this <del>Article</del><b>1</b> , or parts thereof, shall be presumed to be in conformity with the essential health and safety requirements set out in Annex II covered by those <b>standards</b>, common specifications or parts thereof. <b>The presumption of conformity provided by the standards or the common specifications referred to in the implementing act referred to in</b></p> | <p>3. Without prejudice to Article 14, PPE which <del>are</del><b>is</b> in conformity with <u>the standards or</u> common specifications <del>adopted pursuant to</del> <u>referred to in</u> paragraph 2 of this <del>Article</del><b>1, or parts thereof</b>, shall be presumed to be in conformity with the <u>applicable</u> essential health and safety requirements set out in Annex II covered by those <u>standards</u>, common specifications or parts thereof. <u>The presumption of conformity provided by the standards, parts thereof or the common specifications referred to in the implementing act referred to</u></p> |

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|  |  |  | paragraph 1 shall automatically cease to apply on the day the Single Market Emergency mode expires or is deactivated.  | <u>in paragraph 1 can no longer be relied upon from the day the internal market emergency mode expires or is deactivated.</u>  |
| Article 2, first paragraph, amending provision, numbered paragraph (4) |  |  |  |  |
| 122  | 4. By way of derogation from Article 41a(3), first subparagraph, unless there is sufficient reason to believe that the PPE covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the PPE in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation]. | 4. By way of derogation from Article 41a(3), <del>first subparagraph,</del> unless there is sufficient reason to believe that the PPE covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the PPE in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the <del>Single</del> <u>internal</u> market emergency mode in accordance with [the <del>SMEI</del> <u>IMERA</u> Regulation]. | 4. By way of derogation from Article 41a(3), first subparagraph, unless there is sufficient reason to believe that the PPE covered by the <b>standards or</b> common specifications referred to in paragraph 1 of this Article <del>present</del> <b>presents</b> a risk to the health or safety of persons, the PPE <del>in compliance</del> <b>which is in conformity</b> with those <b>standards or</b> common specifications <b>and</b> which has been placed on the market shall be deemed compliant with <del>this Regulation</del> <b>the essential requirements set out in Annex II</b> after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation]. | 4. By way of derogation from Article 41a(3), <del>first subparagraph,</del> unless there is sufficient reason to believe that the PPE covered by the <u>standards or</u> common specifications referred to in paragraph 1 <del>of this Article</del> present a risk to the health or safety of persons, the PPE <u>which is in conformity</u> <del>in compliance</del> with those <u>standards or</u> common specifications <u>and</u> which <del>has</del> <u>have</u> been placed on the market shall be deemed compliant with <del>this Regulation</del> <u>the applicable essential health and safety requirements set out in Annex II</u> after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 <del>of this Article</del> and after the expiry or deactivation of the <del>Single</del> <u>Single/internal</u> market emergency mode in accordance with <del>the SMEI</del> <u>the IMERA</u> Regulation <del>7</del> . |
| Article 2, first paragraph, amending provision, numbered paragraph (5) |  |  |  |  |
| 123  | 5. When a Member State considers   | 5. When a Member State considers   | 5. When a Member State considers   | 5. When a Member State considers   |

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|  | that a common specification referred to in paragraph 1 does not entirely satisfy the essential health and safety requirements which it aims to cover and which are set out in Annex II, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information and, if appropriate, amend or withdraw the implementing act establishing the common specification in question. | that a common specification referred to in paragraph 1 does not entirely satisfy the essential health and safety requirements which it aims to cover and which are set out in Annex II, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information. <u>The Commission may</u> <del>and, if appropriate,</del> amend, <u>where appropriate,</u> <del>or withdraw</del> the implementing act establishing the common specification in question. | that a <b>standard or a</b> common specification referred to in paragraph 1 does not entirely satisfy the <b>applicable</b> essential health and safety requirements <del>which it aims to cover and which are</del> set out in Annex II, it shall inform the Commission thereof <del>with</del> <b>by submitting</b> a detailed explanation and the Commission shall assess that <del>detailed explanation</del> information and, if appropriate, amend or <del>withdraw</del> <b>repeal</b> the implementing act <b>listing the standard or</b> establishing the common specification in question. | that a <u>standard or</u> common specification referred to in paragraph 1 does not entirely satisfy the essential health and safety requirements <del>which it aims to cover and which are</del> set out in Annex II, it shall inform the Commission thereof <del>with</del> <u>by submitting</u> a detailed explanation <del>and</del> . The Commission shall assess that <del>information and, if detailed explanation and, may,</del> <u>where</u> appropriate, amend or <del>withdraw</del> <u>repeal</u> the implementing act <u>listing the standard or</u> establishing the common specification in question. |
| Article 2, first paragraph, amending provision, Article                |  |  |  |  |
| 124  | Article 41f<br>Adoption of mandatory common specifications   | <i>deleted</i>   | <i>deleted</i>   | <i>deleted</i>   |
| Article 2, first paragraph, amending provision, numbered paragraph (1) |  |  |  |  |
| 125  | 1. In duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the essential health and safety requirements set out in Annex II for PPE, which has been designated as crisis-relevant goods.   | <i>deleted</i>   | <i>deleted</i>   | <i>deleted</i>   |



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| <i>Article 2, first paragraph, amending provision, numbered paragraph (2)</i> |  |                |                 |                 |
| 126   | 2. The implementing acts establishing mandatory common specifications, referred to in paragraph 1 of this Article, shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 44(3). They shall apply to PPE placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act. | <i>deleted</i> | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 2, first paragraph, amending provision, numbered paragraph (3)</i> |  |                |                 |                 |
| 127   | 3. By way of derogation from Article 41a(3), first subparagraph, unless there is sufficient reason to believe that the PPE covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the PPE in   | <i>deleted</i> | <i>deleted</i>  | <i>deleted</i>  |

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|  | compliance with those common specifications which has been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation]. |   | PUBLIC  |  |
| Article 2, first paragraph, amending provision, Article                |   |   |   |  |
| 128  | Article 41g<br>Prioritisation of market surveillance activities and mutual assistance among authorities   | Article 41g<br>Prioritisation of market surveillance activities and mutual assistance among authorities           | <b>Article 41g</b><br><del>Article 41g</del><br>Prioritisation of market surveillance activities and mutual assistance among authorities  | <u><a href="#">Article 41g</a></u><br><del>Article 41g</del><br>Prioritisation of market surveillance activities and mutual assistance among authorities<br><br>Text Origin: Council Mandate   |
| Article 2, first paragraph, amending provision, numbered paragraph (1) |   |   |   |  |
| 129  | 1. Member States shall prioritise the market surveillance activities for PPE designated as crisis-relevant goods.   | 1. Member States shall prioritise the market surveillance activities for PPE designated as crisis-relevant goods. | 1. Member States shall prioritise the market surveillance activities for PPE designated as a crisis-relevant goods <b>good. The Commission shall facilitate coordination of these efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.</b> | 1. Member States shall prioritise the market surveillance activities for PPE designated as <u>crisis-relevant goods. <a href="#">The Commission shall facilitate coordination of these efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.</a></u> |

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| Article 2, first paragraph, amending provision, numbered paragraph (2) |   |  |  |   |
| 130  | 2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for PPE designated as crisis-relevant goods. | 2. The market surveillance authorities of the Member States shall <del>deploy their</del> <u>ensure</u> best efforts <u>are made</u> to provide assistance to other market surveillance authorities during <del>a Single</del> <u>an internal</u> market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for PPE designated as crisis-relevant goods. | 2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for PPE designated as a crisis-relevant <del>goods</del> <u>good</u> .’ | 2. The market surveillance authorities of the Member States shall <del>deploy their</del> <u>ensure that</u> best efforts <u>are made</u> to provide assistance to other market surveillance authorities during a <del>Single</del> <u>internal</u> market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for <del>PPE</del> <u>subsystems and safety components</u> designated as crisis-relevant goods. |
| Article 3  |   |  |  |   |
| 131  | Article 3<br>Amendments to Regulation (EU) 2016/426   | Article 3<br>Amendments to Regulation (EU) 2016/426  | Article 3<br>Amendments to Regulation (EU) 2016/426  | Article 3<br>Amendments to Regulation (EU) 2016/426<br><br>Text Origin: Commission Proposal   |
| Article 3, first paragraph   |   |  |  |   |
| 132  | In Regulation (EU) 2016/426, the following Chapter VIa is inserted  | In Regulation (EU) 2016/426, the following Chapter VIa is inserted   | <del>In</del> Regulation (EU) 2016/426, <del>the following Chapter VIa is inserted</del>   | <del>In</del> Regulation (EU) 2016/426, <del>the following Chapter VIa is inserted</del>  |

|   | Commission Proposal | EP Mandate        | Council Mandate   | Draft Agreement   |
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|   | after Chapter VI:   | after Chapter VI: | after Chapter VI is amended as follows:   | <del>after Chapter VI</del> <u>is amended as follows:</u><br>Text Origin: Council Mandate   |
| Article 3, first paragraph, point (1)                                       |                     |                   |   |   |
| 132a  |                     |                   | (1) In Article 2 the following points is are added:   | <u>(1) In Article 2 the following points is are added:</u><br>Text Origin: Council Mandate  |
| Article 3, first paragraph, point (1), amending provision, first paragraph  |                     |                   |   |   |
| 132b  |                     |                   | "<br>(32) 'crisis-relevant goods' means 'crisis-relevant goods' within the meaning of Article 3, point (6) of Regulation (EU) .../.... [SMEI Regulation];     | <u>(32) 'crisis-relevant goods' means 'crisis-relevant goods' within the meaning of Article 3, point (6) of Regulation (EU) .../.... [IMERA Regulation];</u><br>Text Origin: Council Mandate        |
| Article 3, first paragraph, point (1), amending provision, second paragraph |                     |                   |   |   |
| 132c  |                     |                   | (33) 'Single Market Emergency' means 'Single Market Emergency' within the meaning of Article 3, point (3) of Regulation (EU) .../... [SMEI Regulation].;<br>" | <u>(33) 'internal market emergency' means 'internal market emergency' within the meaning of Article 3, point (3) of Regulation (EU) .../... [IMERA Regulation];</u><br>Text Origin: Council Mandate |

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|      | Article 3, first paragraph, point (2)   |  |  |  |
| 132d |   |  | (2) The following Chapter Va is inserted after Chapter V:  | <u>(2) The following Chapter Va is inserted after Chapter V:</u><br>Text Origin: Council Mandate   |
|      | Article 3, first paragraph, amending provision, Chapter I   |  |  |  |
| 133  | CHAPTER VIa<br>EMERGENCY PROCEDURES   | CHAPTER VIa<br>EMERGENCY PROCEDURES  | Chapter Va<br><del>CHAPTER VIa</del><br>EMERGENCY PROCEDURES   | <u>Chapter Va</u><br><del>CHAPTER VIa</del><br>EMERGENCY PROCEDURES<br>Text Origin: Council Mandate  |
|      | Article 3, first paragraph, amending provision, Article   |  |  |  |
| 134  | Article 40a<br>Application of emergency procedures  | Article 40a<br><del>Application of</del> <u>Application of</u><br>emergency procedures   | Article 40a<br><del>Article 40a</del><br><del>Application of</del> <u>Application of</u><br>emergency procedures   | <u>Article 40a</u><br><del>Article 40a</del><br><del>Application of</del> <u>Application of</u><br>emergency procedures<br>Text Origin: Council Mandate  |
|      | Article 3, first paragraph, amending provision, numbered paragraph (1)  |  |  |  |
| 135  | 1. Articles 40b to 40g shall only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Regulation. | 1. Articles 40b to 40g <u>of this Regulation</u> shall only apply if the Commission has adopted an implementing act pursuant to Article <del>23 of [the SMEI</del> <u>14(5) of [the IMERA</u> Regulation] activating Article 26 of [the <del>SMEI</del> <u>IMERA</u> | 1. Articles 40b to 40g shall only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to <b>appliances and fittings covered by</b> | 1. Articles 40b to 40g <u>of this Regulation</u> shall only apply if the Commission has adopted an implementing act pursuant to Article <del>23 of [the SMEI Regulation]</del> <u>activating Article 26 of [the SMEI Regulation]</u> with respect to <b>this the</b> |

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|   |   | Regulation] <del>with respect to this Regulation.</del>  | this Regulation.   | <u>IMERA</u> Regulation.   |
| Article 3, first paragraph, amending provision, numbered paragraph (2)                      |   |  |  |  |
| 136   | 2. Articles 40b to 40g shall apply exclusively to appliances and fittings, which has been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article. | 2. Articles 40b to 40g shall apply exclusively to appliances and fittings, which <del>has</del> <u>have</u> been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article. | 2. Articles 40b to 40g <del>shall</del> apply exclusively to appliances and fittings, which has been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article <b>pursuant to Article 14 of [the SMEI Regulation]</b> .   | 2. Articles 40b to 40g shall apply exclusively to appliances and fittings, which <del>has</del> <u>have</u> been designated as crisis-relevant goods <del>in the implementing act referred to in paragraph 1 of this Article</del> <b>pursuant to Article 14(5) of the IMERA Regulation.</b>   |
| Article 3, first paragraph, amending provision, numbered paragraph (3), first subparagraph  |   |  |  |  |
| 137   | 3. Articles 40b to 40g, except as regards provisions concerning the powers of the Commission, shall apply during the Single Market emergency mode remains active.                                 | 3. Articles 40b to 40g, except as regards provisions concerning the powers of the Commission, shall apply during the <del>Single</del> <u>internal</u> market emergency mode remains active.                             | 3. Articles 40b to 40g, except as regards <del>provisions concerning the powers</del> <b>the power</b> of the Commission <b>in Article 40e(5)</b> , shall apply <b>only</b> during the Single Market emergency mode <b>activated in accordance with Article 14 of [the SMEI Regulation]</b> <del>remains active.</del> | 3. Articles 40b to 40g, except as regards <del>provisions concerning the powers</del> <b>the power</b> of the Commission <b>in Article 40e(5)</b> , shall apply <b>only</b> during the <del>Single</del> <u>internal</u> market emergency mode <del>remains active</del> <b>activated in accordance with Article 14 of the IMERA Regulation.</b> |
| Article 3, first paragraph, amending provision, numbered paragraph (3), second subparagraph |   |  |  |  |
| 138   | However, Article 40c(2), second subparagraph, and Article 40c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.  | <i>deleted</i>   | However, <del>Article 40c(2), second subparagraph, and</del> Article 40c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.  | However, Article 40 <del>e(2), second subparagraph, and Article 40c(5)</del> shall apply during the <del>Single</del> <u>internal</u> market emergency mode and after its deactivation or expiry.  |

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|     | Article 3, first paragraph, amending provision, numbered paragraph (4)  |   |  |  |
| 139 | 4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to appliances and fittings placed on the market in accordance with Articles 40c to 40f. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 42(3). | <i>deleted</i>  | 4. The Commission <del>shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken</del> <b>may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures to be followed and the specific labelling and traceability requirements</b> with respect to appliances and fittings placed on the market in accordance with Articles 40c to <del>40f</del> <b>40e</b> . Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 42(3). | 4. The Commission <del>shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions</del> <b>may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures to be followed and the specific labelling and traceability requirements</b> with respect to appliances and fittings placed on the market in accordance with Articles 40c to <del>40f</del> <b>40e</b> . Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 42(3). |
|     | Article 3, first paragraph, amending provision, Article   |   |  |  |
| 140 | Article 40b<br>Prioritisation of the conformity assessment of crisis-relevant appliances and fittings   | Article 40b<br>Prioritisation of the conformity assessment of crisis-relevant appliances and fittings | <b>Article 40b</b><br><del>Article 40b</del><br>Prioritisation of the conformity assessment of crisis-relevant appliances and fittings   | <u><b>Article 40b</b></u><br><del>Article 40b</del><br>Prioritisation of the conformity assessment of crisis-relevant appliances and fittings<br><br>Text Origin: Council Mandate  |
|     | Article 3, first paragraph, amending provision, numbered paragraph (1)  |   |  |  |
| 141 | 1. This Article shall apply to all  | 1. This Article shall apply to all  | 1. This Article shall apply to all   | 1. This Article shall apply to all   |



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|  | appliances and fittings designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 14 requiring mandatory involvement of a notified body.  | appliances and fittings designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 14 requiring mandatory involvement of a notified body.  | appliances and fittings designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 14 requiring mandatory involvement of a notified body.   | appliances and fittings designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 14 requiring mandatory involvement of a notified body.   |
| Article 3, first paragraph, amending provision, numbered paragraph (2) |   |   |  |  |
| 142  | 2. The notified bodies shall process all applications for conformity assessment of appliances and fittings designated as crisis-relevant goods as a matter of priority.   | 2. The notified bodies shall <u>ensure all reasonable efforts are made to</u> process all applications for conformity assessment of appliances and fittings designated as crisis-relevant goods as a matter of priority.  | 2. The notified bodies shall process all applications for conformity assessment of appliances and fittings designated as crisis-relevant goods as a matter of priority, <b>irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 40a.</b> | 2. The notified bodies shall <u>make best efforts to</u> process all applications for conformity assessment of appliances and fittings designated as crisis-relevant goods as a matter of priority, <u>irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 40a.</u> |
| Article 3, first paragraph, amending provision, numbered paragraph (3) |   |   |  |  |
| 143  | 3. All pending applications for conformity assessment of appliances and fittings designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for appliances and fittings, which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of appliances and fittings designated as crisis- | 3. All pending applications for conformity assessment of appliances and fittings designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for appliances and fittings, which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of appliances and fittings designated as crisis- | <i>deleted</i>   | <i>deleted</i>   |

|  | Commission Proposal   | EP Mandate  | Council Mandate   | Draft Agreement  |
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|  | relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 41a.   | relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 41a.   |   |  |
| Article 3, first paragraph, amending provision, numbered paragraph (4) |   |   |   |  |
| 144  | 4. The prioritisation of applications for conformity assessment of appliances and fittings pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications. | 4. The prioritisation of applications for conformity assessment of appliances and fittings pursuant to paragraph 3 shall not give rise to any <u>extraordinary</u> additional costs for the manufacturers, who have lodged those applications.                              | 4. The prioritisation of applications for conformity assessment of appliances and fittings pursuant to paragraph <del>3</del> 2 shall not give rise to <del>any</del> <b>disproportionate</b> additional costs for the manufacturers, who have lodged those applications. | 4. The prioritisation of applications for conformity assessment of appliances and fittings pursuant to paragraph <del>3</del> 2 shall not give rise to <del>any additional</del> <u>additional disproportionate</u> costs for the manufacturers, who have lodged those applications. |
| Article 3, first paragraph, amending provision, numbered paragraph (5) |   |   |   |  |
| 145  | 5. The notified bodies shall deploy their best efforts to increase their testing capacities for appliances and fittings designated as crisis-relevant goods in respect to which they have been notified.                  | 5. The notified bodies shall <del>deploy</del> <u>ensure all reasonable</u> <del>their best</del> <u>are made</u> efforts to increase their testing capacities for appliances and fittings designated as crisis-relevant goods in respect to which they have been notified. | <i>deleted</i>  | 5. The notified bodies shall <del>deploy</del> <u>make reasonable</u> <del>their best</del> efforts to increase their testing capacities for appliances and fittings designated as crisis-relevant goods in respect <del>to</del> <u>of</u> which they have been notified.           |
| Article 3, first paragraph, amending provision, Article                |   |   |   |  |
| 146  | Article 40c<br>Derogation from conformity assessment procedures requiring mandatory involvement of a notified   | Article 40c<br>Derogation from conformity assessment procedures requiring mandatory involvement of a notified   | <b>Article 40c</b><br><del>Article 40e</del><br>Derogation from conformity assessment procedures requiring  | <u><b>Article 40c</b></u><br><del>Article 40e</del><br>Derogation from conformity assessment procedures requiring  |

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|   | bod  | <del>bod</del> body  | mandatory involvement of a notified<br><del>bod</del> body   | mandatory involvement of a notified<br><del>bod</del> body<br><br>Text Origin: Council Mandate   |
| Article 3, first paragraph, amending provision, numbered paragraph (1)                      |  |  |  |  |
| 147   | 1. By way of derogation from Article 14, any competent national authority may authorise, on a duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of a specific appliance or fitting which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body, referred to in Article 14, have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated. | 1. By way of derogation from Article 14, <del>any</del> <u>the</u> competent national authority, <u>after carrying out a risk assessment</u> , may authorise, on a duly justified request <u>from an economic operator established in its Member State</u> , the placing on the market or putting into service within the territory of <del>the</del> <u>that</u> Member State <del>concerned</del> , of a specific appliance or fitting which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body, referred to in Article 14, have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated. | 1. By way of derogation from Article 14, any competent national authority may authorise, on a duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of a specific appliance or fitting which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body, referred to in Article 14, have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated <b>in accordance with procedures referred to in that authorisation</b> . | 1. By way of derogation from Article 14, <del>any competent national authority</del> <u>the Member State</u> may authorise, on a duly justified request <u>from an economic operator</u> , the placing on the market or <u>the</u> putting into service within the territory of the Member State concerned, of a specific appliance or fitting which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body, referred to in Article 14, have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated <u>in accordance with procedures referred to in that authorisation</u> . |
| Article 3, first paragraph, amending provision, numbered paragraph (1a), first subparagraph |  |  |  |  |
| 147a  |  |  | <b>1a. The Member State shall immediately inform the Commission and the other</b>  | <u>1a. The Member State shall immediately inform the Commission and the other Member</u>   |

|  | Commission Proposal | EP Mandate | Council Mandate   | Draft Agreement  |
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|  |                     |            | <p>Member States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure the conformity with the essential requirements laid down in Annex I to this Regulation, the Commission shall without delay adopt an implementing act extending for a limited period of time the validity of the authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the specific appliance or fitting may be placed on the market. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 42(3).</p> | <p><u>States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure the conformity with the essential requirements laid down in Annex I to this Regulation, the Commission shall without delay adopt an implementing act extending the validity of the authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the specific appliance or fitting may be placed on the market. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 42(3).</u></p> |
| Article 3, first paragraph, amending provision, numbered paragraph (1a), second subparagraph |                     |            |   |  |
| G 147b   |                     |            | <p>The specific appliance or fitting subject to the extension of validity</p>   | <p><u>The specific appliance or fitting subject to the extension of validity</u></p>   |

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|   |                     |            | referred to in the first subparagraph shall bear the information that it is placed on the market as a “crisis-relevant good”. The implementing act referred to in the first subparagraph shall specify the modalities of that information. That information, as well as any labelling, shall be clear, understandable and intelligible and, where relevant, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. | <u>referred to in the first subparagraph shall bear the information that it is placed on the market as a "crisis-relevant good". The implementing act referred to in the first subparagraph shall specify the modalities of that information. That information, as well as any labelling, shall be clear, understandable and intelligible and, where relevant, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.</u> |
| Article 3, first paragraph, amending provision, numbered paragraph (1a), third subparagraph |                     |            |   |  |
| 147c  |                     |            | 1b. On duly justified imperative grounds of urgency relating to the need to preserve the health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(4).   | <u>On duly justified imperative grounds of urgency relating to the need to preserve the health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 42(4).</u>   |
| Article 3, first paragraph, amending provision, numbered paragraph (1b), first subparagraph |                     |            |   |  |
| 147d  |                     |            | 1c. As long as an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national authority in  | <u>1b. As long as an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national authority in one Member State shall</u>   |

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|  |   |   | one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act.  | <u>be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act.</u>   |
| Article 3, first paragraph, amending provision, numbered paragraph (1b), second subparagraph |   |   |  |   |
| 147e   |   |   | Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.   | <u>Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.</u>   |
| Article 3, first paragraph, amending provision, numbered paragraph (2), first subparagraph   |   |   |  |   |
| 148  | 2. The manufacturer of an appliance or a fitting subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the appliance or the fitting concerned complies with all the applicable essential requirements set out in Annex I and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the national competent authority. | 2. The manufacturer of an appliance or a fitting subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the appliance or the fitting concerned complies with all the applicable essential requirements set out in Annex I and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the national competent authority. | 2. The manufacturer of an appliance or a fitting subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the appliance or the fitting concerned complies with all the applicable essential requirements set out in Annex I and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the <del>national</del> competent <b>national</b> authority. | 2. The manufacturer of an appliance or a fitting subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the <u>an</u> appliance or <del>the</del> fitting concerned complies with all the applicable essential requirements set out in Annex I and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the <del>national</del> competent <u>national</u> authority. |

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| Article 3, first paragraph, amending provision, numbered paragraph (2), second subparagraph |   |   |  |  |
| 149   | The manufacturer shall also deploy all reasonable measures to ensure that the appliance or fitting, which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of the Member State, which issued the authorisation. | <i>deleted</i>  | <i>deleted</i>   | <i>deleted</i>   |
| Article 3, first paragraph, amending provision, numbered paragraph (3)                      |   |   |  |  |
| 150   | 3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the appliance or fitting may be placed on the market, including:                                      | 3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the appliance or fitting may be placed on the market <u>or put into service</u> , including <u>at least</u> : | 3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the appliance or fitting may be placed on the market; <del>including.</del> <b>The authorisation shall at least set out the following:</b> | 3. Any authorisation issued <del>by a national competent authority</del> pursuant to paragraph 1 shall set out the conditions and requirements under which the appliance or fitting may be placed on the market; <del>including.</del> <u>The authorisations shall at least set out the following:</u> |
| Article 3, first paragraph, amending provision, numbered paragraph (3), point (a)           |   |   |  |  |
| 151   | (a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;   | (a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;   | (a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;  | (a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;<br><br>Text Origin: Commission Proposal  |
| Article 3, first paragraph, amending provision, numbered paragraph (3), point (b)           |   |   |  |  |
| 152   |   |   |  |  |



|   | Commission Proposal  | EP Mandate  | Council Mandate   | Draft Agreement   |
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|   | (b) specific requirements regarding the traceability of the subsystem or safety component concerned;   | (b) specific requirements regarding the traceability of the subsystem or safety component concerned;  | (b) <b>any</b> specific requirements regarding the traceability of the <del>subsystem or safety component</del> <b>appliance or fitting</b> concerned;  | (b) <u>any</u> specific requirements regarding the traceability of the <del>subsystem or safety component</del> <u>appliance or fitting</u> concerned;  |
| Article 3, first paragraph, amending provision, numbered paragraph (3), point (c) |  |   |   |   |
| 153   | (c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated; | (c) an end date of validity of the authorisation, <u>unless otherwise specified</u> , which cannot go beyond the last day of the period for which the <del>Single</del> <u>internal</u> market emergency mode has been activated; | (c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated; <b>in accordance with Article 14 [the SMEI Regulation]</b> . | (c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the <del>Single</del> <u>internal</u> market emergency mode has been activated <u>in accordance with Article 14 of the IMERA Regulation</u> ; |
| Article 3, first paragraph, amending provision, numbered paragraph (3), point (d) |  |   |   |   |
| 154   | (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the subsystem or safety component concerned;       | (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the subsystem or safety component concerned;  | (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the <del>subsystem or safety component</del> <b>appliance or fitting</b> concerned;                             | (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the <del>subsystem or safety component</del> <u>appliance or fitting</u> concerned;<br><br>Text Origin: Council Mandate                     |
| Article 3, first paragraph, amending provision, numbered paragraph (3), point (e) |  |   |   |   |
| 155   | (e) measures to be taken with respect to the appliance or fitting concerned upon expiry of the authorisation in order to ensure that                               | (e) measures to be taken with respect to the appliance or fitting concerned upon expiry of the authorisation in order to ensure that  | (e) measures to be taken with respect to the appliance or fitting <del>concerned upon expiry of the authorisation in order to ensure that</del>   | (e) measures to be taken <del>with respect to the appliance or fitting concerned upon expiry of the authorisation in order to ensure</del>  |

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|  | the appliance or fitting concerned is brought back in compliance with all the requirements of this Regulation.   | the appliance or fitting concerned is brought back in compliance with all the requirements of this Regulation.   | the appliance or fitting concerned is brought back in compliance with all the requirements of this Regulation placed on the market upon expiry of the Single Market emergency. | <del>that</del> <u>Single/internal market emergency with respect to</u> the appliance or fitting <del>concerned is brought back in compliance with all the requirements of this Regulation</del> <u>placed on the market</u> . |
| Article 3, first paragraph, amending provision, numbered paragraph (3), point (ea) |  |  |  |  |
| 155a   |  | <u>(ea) labelling requirements, including radio frequency identification, indicating that the appliance and fitting was authorised under the internal market emergency mode.</u>   |  | deleted  |
| Article 3, first paragraph, amending provision, numbered paragraph (4)             |  |  |  |  |
| 156  | 4. By way of derogation from Article 40a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 also after the deactivation or expiry of the Single Market Emergency mode. | 4. By way of derogation from Article 40a(3), <del>first subparagraph,</del> where appropriate, the national competent authority may <u>also</u> amend the conditions <del>of the authorisation</del> <u>and requirements</u> referred to in paragraph 3 <del>also of this Article</del> after the deactivation or expiry of the <del>Single</del> <u>internal</u> market emergency mode. | deleted  | deleted  |
| Article 3, first paragraph, amending provision, numbered paragraph (5)             |  |  |  |  |
| 157  | 5. By way of derogation from Articles 6 and 17, appliances or  | deleted  | 5. By way of derogation from Articles 6, <b>16</b> and 17, appliances or   | 5. By way of derogation from Articles 6, <u>16</u> and 17, appliances or   |

|   | Commission Proposal  | EP Mandate  | Council Mandate   | Draft Agreement  |
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|   | fittings, for which an authorisation has been granted in accordance with paragraph 1 of this Article, shall not leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking.  |   | fittings, for which an authorisation has been granted in accordance with paragraph 1 of this Article, shall not leave the territory of the Member State which has issued the authorisation and bear the CE marking and Article 6 shall not bear the CE marking apply.   | fittings, for which an authorisation has been granted in accordance with paragraph 1 <del>of this Article</del> , shall not <del>leave the territory of the Member State which has issued the authorisation and</del> bear the CE marking and Article 6 shall not <del>bear the CE marking</del> apply.  |
| Article 3, first paragraph, amending provision, numbered paragraph (5a), numbered paragraph (6)   |  |   |   |  |
| 158   | 6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1 shall be entitled to take all corrective and restrictive measures at national level provided for under this Regulation with respect to such appliances or fittings. | 6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1 shall be entitled to take all corrective and restrictive measures at national level provided for under this Regulation with respect to such appliances or fittings. <u>The market surveillance authorities shall keep all records related to products authorised under a derogation for a period of 10 years. They shall make those records available to other market surveillance authorities upon request.</u> | <del>6</del> 5a. The market surveillance authorities of the Member State, whose competent authority has granted <del>where</del> an authorisation pursuant to paragraph 1 <del>paragraphs 1, 1a and 1c is valid</del> shall be entitled to take all corrective and restrictive measures actions at national level provided for under Regulation (EU) 2019/1020 and under this Regulation with respect to such appliances or fittings. | <del>6</del> 5a. The market surveillance authorities of the Member State, whose competent authority has granted <del>where</del> an authorisation pursuant to <del>paragraph 1</del> paragraphs 1, 1a and 1c is valid, shall be entitled to take all corrective and restrictive measures actions at national level provided for under Regulation (EU) 2019/1020 and under this Regulation with respect to such appliances or fittings. |
| Article 3, first paragraph, amending provision, numbered paragraph (5a), numbered paragraph (6) a |  |   |   |  |
| 158a  |  |   | They shall immediately inform the Commission and the market surveillance authorities of other   | <u>They shall immediately inform the Commission and the market surveillance authorities of other</u>   |

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|   |  |   | Member States of these actions.  | <u>Member States of these actions.</u>   |
| Article 3, first paragraph, amending provision, numbered paragraph (7)  |  |   |  |  |
| 159   | 7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market of appliances or fittings in accordance with paragraph 1.  | 7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market of appliances or fittings in accordance with paragraph 1.   | deleted  | deleted  |
| Article 3, first paragraph, amending provision, numbered paragraph (8)  |  |   |  |  |
| 160   | 8. The application of Articles 40a to 40g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 14 on the territory of the Member State concerned. | 8. The application of Articles 40a to 40g and the use of the authorisation procedure set out in paragraph 1 of this Article <del>does</del> <u>shall</u> not affect the application of the relevant conformity assessment procedures laid down in Article 14 <del>on the territory of the Member State concerned.</del> | 8. The application of Articles 40a to 40g and the use of the authorisation procedure set out in paragraph 1 of this Article <del>paragraphs 1 to 1c</del> does not affect the application of the relevant conformity assessment procedures laid down in Article 14 on the territory of the Member State concerned. | 8. <del>The application of Articles 40a to 40g and</del> The use of the authorisation procedure set out in <del>paragraph 1 of this Article does</del> <u>paragraphs 1 to 1c shall</u> not affect the application of the relevant conformity assessment procedures laid down in Article 14 on the territory of the Member State concerned. |
| Article 3, first paragraph, amending provision, numbered paragraph (8a) |  |   |  |  |
| 160a  |  | <u>8a. Appliances and fittings subject to derogation under paragraph 1 shall remain valid for six months after deactivation or expiration of the internal market emergency mode. After this period, they shall only be made available on the market after receiving an</u>  |  | deleted  |

|   | Commission Proposal   | EP Mandate  | Council Mandate | Draft Agreement |
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|   |   | <a href="#"><u>authorisation under the normal authorisation procedure provided for in this Regulation.</u></a>  |                 |                 |
| Article 3, first paragraph, amending provision, Article                             |   |   |                 |                 |
| 161   | Article 40d<br>Presumption of conformity based on national and international standards  | Article 40d<br>Presumption of conformity based on national and international standards  | deleted         | deleted         |
| Article 3, first paragraph, amending provision, Article, first paragraph            |   |   |                 |                 |
| 162   | Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market or putting into service, their competent authorities consider that appliances and fittings, which comply with relevant international standards or any national standards in force in the Member State of manufacture, ensuring the safety level required by the essential requirements set out in Annex I, comply with those essential requirements in either of the following cases: | Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market or putting into service, their competent authorities consider that appliances and fittings, which comply with relevant international standards or any national standards in force in the Member State of manufacture, ensuring the safety level required by the essential requirements set out in Annex I, comply with those essential requirements in either of the following cases: | deleted         | deleted         |
| Article 3, first paragraph, amending provision, Article, first paragraph, point (a) |   |   |                 |                 |
| 163   | (a) where no reference to harmonised standards covering the relevant essential safety   | (a) where no reference to harmonised standards covering the relevant essential safety   | deleted         | deleted         |

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|  | requirements set out in Annex I is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;   | requirements set out in Annex I is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;   |   |  |
| <i>Article 3, first paragraph, amending provision, Article, first paragraph, point (b)</i> |   |   |   |  |
| 164  | (b) severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex I to this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012. | (b) <u>where</u> severe disruptions in the functioning of the <del>Single</del> <u>internal</u> market, which were taken into consideration when activating the <del>Single</del> <u>internal</u> market emergency mode in accordance with Article <del>15(4) of [the SMEI]</del> <u>14 of [the IMERA]</u> Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex I to this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012. | <i>deleted</i>  | <i>deleted</i>   |
| <i>Article 3, first paragraph, amending provision, Article</i>                             |   |   |   |  |
| 165  | Article 40e<br>Adoption of common specifications conferring a presumption of conformity   | Article 40e<br>Adoption of common specifications conferring a presumption of conformity   | Article 40e<br><del>Article 40e</del><br>Adoption of common specifications conferring a presumption of conformity | <u>Article 40e</u><br><del>Article 40e</del><br><del>Adoption of common specifications conferring a presumption of conformity</del><br><u>Presumption of</u> |

|  | Commission Proposal   | EP Mandate   | Council Mandate  | Draft Agreement   |
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|  |   |  | conformity based on standards and common specifications  | <u>conformity based on standards and common specifications</u><br>Text Origin: Council Mandate  |
| Article 3, first paragraph, amending provision, numbered paragraph (1)             |   |  |  |   |
| 166  | 1. Where appliances or fittings have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such appliances or fittings to cover the essential requirements set out in Annex I in either of the following cases: | 1. Where appliances or fittings have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such appliances or fittings to cover the essential requirements set out in Annex I in either of the following cases:  | 1. Where appliances or fittings have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts, <b>listing appropriate standards or</b> establishing common specifications for such appliances or fittings to cover the essential requirements set out in Annex I in either of the following cases: | 1. Where appliances or fittings have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts, <u>listing appropriate standards or</u> establishing common specifications for such appliances or fittings to cover the <u>applicable</u> essential requirements set out in Annex I in either of the following cases:  |
| Article 3, first paragraph, amending provision, numbered paragraph (1), point (a)  |   |  |  |   |
| 167  | (a) where no reference to harmonised standards covering the relevant essential requirements set out in Annex I is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;  | (a) where <del>no reference to harmonised standards covering the relevant essential requirements set out in Annex I is published in the Official Journal of the European Union in accordance with the</del> <u>European standardisation deliverables addressing a request pursuant to Article 10(1) of</u> Regulation (EU) No 1025/2012 <u>were not adopted;</u> | (a) <del>where</del> no reference to harmonised standards covering the relevant essential requirements set out in Annex I is published in the <b>Official Journal of the European Union</b> <del>Official Journal of the European Union</del> in accordance with Regulation (EU) No 1025/2012;   | (a) <del>where</del> no reference to harmonised standards covering the relevant essential requirements set out in Annex <del>II</del> <u>II</u> is published in the <u>Official Journal of the European Union</u> <del>Official Journal of the European Union</del> in accordance with Regulation (EU) No 1025/2012 <u>and no such reference is expected to be published within a reasonable period; or</u> |
| Article 3, first paragraph, amending provision, numbered paragraph (1), point (aa) |   |  |  |   |



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| G | 167a   |   |   | deleted  |
|   | Article 3, first paragraph, amending provision, numbered paragraph (1), point (ab) |   |   |  |
| G | 167b   |   |   | deleted  |
|   | Article 3, first paragraph, amending provision, numbered paragraph (1), point (ac) |   |   |  |
| G | 167c   |   |   | deleted  |
|   | Article 3, first paragraph, amending provision, numbered paragraph (1), point (ad) |   |   |  |
| G | 167d   | <u>(aa) where a reference to harmonised standards covering the relevant essential requirements set out in Annex II is not published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 and such reference is not expected to be published within a reasonable timeframe during the internal market emergency mode;</u> |   | deleted  |
|   | Article 3, first paragraph, amending provision, numbered paragraph (1), point (b)  |   |   |  |
| G | 168  | (b) where severe disruptions in the functioning of the Single Market,   | (b) where severe disruptions in the functioning of the Single Market, | (b) <del>where</del> severe disruptions in the functioning of the <del>Single</del> internal |

|  | Commission Proposal  | EP Mandate   | Council Mandate   | Draft Agreement   |
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|  | which led to the activation of the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex I in this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012. | market, which led to the activation of the <del>Single</del> <u>internal</u> market emergency mode in accordance with Article <del>15(4) of [the SMEI]</del> <u>14 of [the IMERA]</u> Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex I in this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012. | which led to the activation of the Single Market emergency mode in accordance with Article <del>15(4)</del> <u>14(4)</u> of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex I in this Regulation and already published in the <del>Official Journal of the European Union</del> <u>Official Journal of the European Union</u> in accordance with Regulation (EU) No 1025/2012. | Market, which led to the activation of the <del>Single</del> <u>internal</u> market emergency mode in accordance with Article <del>15(4) of [the SMEI]</del> <u>14 of the IMERA</u> Regulation <del>],</del> significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant <u>applicable</u> essential requirements set out in Annex I <del>in this Regulation</del> and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012. |
| Article 3, first paragraph, amending provision, numbered paragraph (1a)            |  |  |   |   |
| 168a   |  |  | 1a. The implementing acts referred to in paragraph 1 may:   | <u>(1a) The implementing acts referred to in paragraph 1 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.</u>  |
| Article 3, first paragraph, amending provision, numbered paragraph (1), point (bb) |  |  |   |   |

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| G  | 168b                |            | (a) publish the references to relevant applicable international standards that provide presumption of conformity in accordance with paragraph 3;  | <i>deleted</i>  |
| Article 3, first paragraph, amending provision, numbered paragraph (1), point (bc) |                     |            |   |                 |
| G  | 168c                |            | (b) if there is no relevant applicable international standards as referred to in point a of this paragraph that cover the essential requirements set out in Annex I to this Regulation, publish the references to the European standards that provide presumption of conformity in accordance with paragraph 3;               | <i>deleted</i>  |
| Article 3, first paragraph, amending provision, numbered paragraph (1), point (bd) |                     |            |   |                 |
| G  | 168d                |            | (c) if there is no relevant applicable international or European standard as referred to in points a and b, that cover the essential requirements set out in Annex I to this Regulation, establish common specifications established by the Commission that provide presumption of conformity in accordance with paragraph 3; | <i>deleted</i>  |

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|      | <i>Article 3, first paragraph, amending provision, numbered paragraph (1), point (be)</i>  |   |  |  |
| 168e |  |   | (d) if there is no relevant applicable international standard, European standard or common specifications as referred to in points a, b and c, publish the reference to national standards that provide presumption of conformity in accordance with paragraph 3.  | deleted  |
|      | <i>Article 3, first paragraph, amending provision, numbered paragraph (2)</i>  |   |  |  |
| 169  | 2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 42(3). They shall apply to appliances and fittings placed on the market no longer than until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act. | 2. The implementing acts referred to in paragraph 1 of this Article shall be adopted <del>following a consultation of the sectoral experts and</del> in accordance with the examination procedure referred to in Article 42(3). They shall apply to appliances and fittings placed on the market no longer than until the last day of the period for which the <del>Single</del> <u>internal</u> market emergency mode remains active. <del>In the early preparation of</del> <u>When preparing</u> the draft implementing act establishing the common specification, the Commission shall <del>gather</del> <u>take into account</u> the views of <del>relevant bodies or expert groups established under the</del> relevant <del>sectoral Union legislation. Based on that consultation, the Commission</del> <u>bodies</u> | 2. The implementing acts referred to in paragraph 1 <del>of this Article</del> shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 42(3). They shall apply to appliances and fittings placed on the market no longer than until the last day of the period for which the Single Market emergency mode remains active. <del>In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act,</del> unless amended or repealed in | 2. The implementing acts referred to in paragraph 1 <del>of this Article</del> shall be adopted <del>following a consultation of the sectoral experts and</del> in accordance with the examination procedure referred to in Article 42(3). <del>and</del> they shall apply <del>to appliances and fittings placed on the market no longer than</del> until the last day of the period for which the <del>Single</del> <u>internal</u> market emergency mode remains active. <del>In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation, unless amended or repealed in accordance with paragraph 5. Based on that</del> |

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|   |   | <del>and</del> shall <del>prepare the draft implementing act</del> <u>duly consult all relevant stakeholders</u> .  | accordance with paragraph 5.   | <del>consultation, the Commission shall prepare the draft implementing act.</del>   |
| Article 3, first paragraph, amending provision, numbered paragraph (2a) |   |   |  |   |
| 169a  |   |   | 2a. Before preparing the draft implementing act referred to in paragraph 1, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or expert groups established under the Regulation. | <u>2a. Before preparing the draft implementing act referred to in paragraph 1, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or expert groups established under this Regulation and shall duly consult all relevant stakeholders.</u> |
| Article 3, first paragraph, amending provision, numbered paragraph (3)  |   |   |  |   |
| 170   | 3. Without prejudice to Article 13, appliances or fittings which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential requirements set out in Annex I covered by those common specifications or parts thereof. | 3. Without prejudice to Article 13, appliances or fittings which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential requirements set out in Annex I covered by those common specifications or parts thereof. | 3. Without prejudice to Article 13, appliances or fittings which are in conformity with <b>the standards or</b> common specifications <del>adopted pursuant to</del> <b>referred to in paragraph 2 of this Article 1, or parts thereof,</b> shall be presumed to be in conformity with the essential requirements set out in Annex I covered by those <b>standards,</b>  | 3. Without prejudice to Article 13, appliances or fittings which are in conformity with <u>the standards or</u> common specifications <del>adopted pursuant to</del> <u>referred to in paragraph 2 of this Article 1, or parts thereof,</u> shall be presumed to be in conformity with the <u>applicable</u> essential requirements set out in Annex I covered by those <u>standards.</u>   |

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|  |   |   | common specifications or parts thereof. <b>The presumption of conformity provided by the standards or the common specifications referred to in the implementing act referred to in paragraph 1 shall automatically cease to apply on the date the Single Market Emergency mode expires or is deactivated.</b>   | common specifications or parts thereof. <u>The presumption of conformity provided by the standards, parts thereof or the common specifications referred to in the implementing act referred to in paragraph 1 can no longer be relied upon from the day the internal market emergency mode expires or is deactivated.</u>  |
| Article 3, first paragraph, amending provision, numbered paragraph (4) |   |   |   |  |
| 171  | 4. By way of derogation from Article 40a(3), first subparagraph, unless there is sufficient reason to believe that the appliances or fittings covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the appliances or fittings in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation]. | 4. By way of derogation from Article 40a(3), <del>first subparagraph,</del> unless there is sufficient reason to believe that the appliances or fittings covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the appliances or fittings in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the <del>Single</del> <u>internal</u> market emergency mode in accordance with [the <del>SMEI</del> <u>IMERA</u> Regulation]. | 4. By way of derogation from Article 40a(3), first subparagraph, unless there is sufficient reason to believe that the appliances or fittings covered by the <b>standards or</b> common specifications referred to in paragraph 1 <del>of this Article</del> present a risk to the health or safety of persons, the appliances or fittings <del>in compliance</del> <b>which are in conformity</b> with those <b>standards or</b> common specifications <b>and</b> which have been placed on the market shall be deemed compliant with <b>the essential requirements set out in Annex I</b> to this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 <del>of this Article</del> and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI | 4. By way of derogation from Article 40a(3), <del>first subparagraph,</del> unless there is sufficient reason to believe that the appliances or fittings covered by the <u>standards or</u> common specifications referred to in paragraph 1 <del>of this Article</del> present a risk to the health or safety of persons, the appliances or fittings <del>in compliance</del> <u>which are in conformity</u> <del>in compliance</del> with those <u>standards or</u> common specifications <u>and</u> which have been placed on the market shall be deemed compliant with <del>this Regulation</del> <u>the applicable essential requirements set out in Annex I</u> after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 <del>of this Article</del> and after the expiry or deactivation of the <del>Single</del> <u>internal</u> market emergency mode in accordance with <del>the</del> |

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|  |  |  | Regulation].   | <del>SME</del> <u>the IMERA</u> Regulation <del>7</del> .  |
| Article 3, first paragraph, amending provision, numbered paragraph (5) |  |  |  |  |
| 172  | 5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the essential requirements which it aims to cover and which are set out in Annex I, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information and, if appropriate, amend or withdraw the implementing act establishing the common specification in question. | 5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the essential requirements which it aims to cover and which are set out in Annex I, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information. <u>The Commission may</u> <del>and, if appropriate,</del> amend, <u>where appropriate,</u> <del>or withdraw</del> the implementing act establishing the common specification in question. | 5. When a Member State considers that a <b>standard or</b> common specification referred to in paragraph 1 does not entirely satisfy the essential requirements <del>which it aims to cover and which are</del> set out in Annex I, it shall inform the Commission thereof <del>with</del> <b>by submitting</b> a detailed explanation <del>and</del> . The Commission shall assess that <del>information</del> <b>detailed explanation</b> and, if appropriate, amend or <del>withdraw</del> <b>repeal</b> the implementing act <b>listing the standard or</b> establishing the common specification in question. | 5. When a Member State considers that a <u>standard or</u> common specification referred to in paragraph 1 does not entirely satisfy the <u>applicable</u> essential requirements <del>which it aims to cover and which are</del> set out in Annex I, it shall inform the Commission thereof <del>with</del> <u>by submitting</u> a detailed explanation <del>and</del> . The Commission shall assess that <del>information and, if</del> <u>detailed explanation and, may, where</u> appropriate, amend or <del>withdraw</del> <u>repeal</u> the implementing act <u>listing the standard or</u> establishing the common specification in question. |
| Article 3, first paragraph, amending provision, Article                |  |  |  |  |
| 173  | Article 40f<br>Adoption of mandatory common specifications   | <i>deleted</i>   |  | <i>deleted</i>   |
| Article 3, first paragraph, amending provision, numbered paragraph (1) |  |  |  |  |
| 174  | 1. In duly justified cases, the Commission is empowered to adopt implementing acts establishing  | <i>deleted</i>   |  | <i>deleted</i>   |



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|   | mandatory common specifications to cover the essential requirements set out in Annex I for appliances or fittings, which have been designated as crisis-relevant goods.   |                |                 |                 |
| <i>Article 3, first paragraph, amending provision, numbered paragraph (2)</i> |   |                |                 |                 |
| 175   | 2. The implementing acts establishing mandatory common specifications, referred to in paragraph 1 of this Article, shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 42(3) and they shall apply to appliances or fittings placed on the market at the latest until the last day of the period for which the Single Market emergency remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act. | <i>deleted</i> |                 | <i>deleted</i>  |
| <i>Article 3, first paragraph, amending provision, numbered paragraph (3)</i> |   |                |                 |                 |
| 176   | 3. By way of derogation from  |                |                 |                 |

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|  | Article 40a(3), first subparagraph, unless there is sufficient reason to believe that the appliances or fittings covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the appliances or fittings in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation]. | <i>deleted</i>  | <i>deleted</i>   | <i>deleted</i>  |
| Article 3, first paragraph, amending provision, Article                |  |   |  |   |
| 177  | Article 40g<br>Prioritisation of market surveillance activities and mutual assistance among authorities  | Article 40g<br>Prioritisation of market surveillance activities and mutual assistance among authorities | <b>Article 40g</b><br><del>Article 40g</del><br>Prioritisation of market surveillance activities and mutual assistance among authorities | <u><b>Article 40g</b></u><br><del>Article 40g</del><br>Prioritisation of market surveillance activities and mutual assistance among authorities<br><br>Text Origin: Council Mandate |
| Article 3, first paragraph, amending provision, numbered paragraph (1) |  |   |  |   |
| 178  | 1. The Member States shall prioritise the market surveillance  | 1. The Member States shall prioritise the market surveillance   | 1. The Member States shall prioritise the market surveillance  | 1. <del>The</del> Member States shall prioritise the market surveillance  |

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|  | activities for appliances and fittings designated as crisis-relevant goods.   | activities for appliances and fittings designated as crisis-relevant goods.  | activities for appliances and fittings designated as crisis-relevant goods.<br><b>The Commission shall facilitate coordination of these efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.</b>   | activities for <del>appliances</del> <u>appliance</u> and fittings designated as crisis-relevant goods. <u>The Commission shall facilitate coordination of these efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.</u>   |
| Article 3, first paragraph, amending provision, numbered paragraph (2) |   |  |   |  |
| 179  | 2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for appliances and fittings designated as crisis-relevant goods. | 2. The market surveillance authorities of the Member States shall <del>deploy their</del> <u>ensure</u> best efforts <u>are made</u> to provide assistance to other market surveillance authorities during <del>a Single</del> <u>an internal</u> market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for appliances and fittings designated as crisis-relevant goods. | 2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for appliances and fittings designated as crisis-relevant goods. | 2. The market surveillance authorities of the Member States shall <del>deploy their</del> <u>ensure that</u> best efforts <u>are made</u> to provide assistance to other market surveillance authorities during <del>a</del> <del>Single</del> <u>an internal</u> market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for appliances and fittings designated as crisis-relevant goods. |
| Article 4  |   |  |   |  |
| 180  | Article 4<br>Amendments to Regulation (EU) 2019/1009  | Article 4<br>Amendments to Regulation (EU) 2019/1009   | <i>deleted</i>  | <i>deleted</i>   |

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|     |   |   |                 |                 |
|     | <i>Article 4, first paragraph</i>   |   |                 |                 |
| 181 | In Regulation (EU) 2019/1009, the following Chapter Va is inserted:   | In Regulation (EU) 2019/1009, the following Chapter Va is inserted:   | <i>deleted</i>  | <i>deleted</i>  |
|     | <i>Article 4, first paragraph, amending provision, first paragraph</i>  |   |                 |                 |
| 182 | CHAPTER VIa<br>EMERGENCY PROCEDURES   | CHAPTER VIa<br>EMERGENCY PROCEDURES   | <i>deleted</i>  | <i>deleted</i>  |
|     | <i>Article 4, first paragraph, amending provision, second paragraph</i>   |   |                 |                 |
| 183 | Article 41a<br>Application of emergency procedures  | Article 41a<br>Application of emergency procedures  | <i>deleted</i>  | <i>deleted</i>  |
|     | <i>Article 4, first paragraph, amending provision, numbered paragraph (1)</i>   |   |                 |                 |
| 184 | 1. Articles 41b to 41g shall only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Regulation. | 1. Articles 41b to 41g <u>of this Regulation</u> shall only apply if the Commission has adopted an implementing act pursuant to Article <del>23 of [the SMEI Regulation]</del> <u>activating Article 26 of [the SMEI 14(5) of [the IMERA Regulation]]</u> <del>with respect to this Regulation.</del> | <i>deleted</i>  | <i>deleted</i>  |
|     | <i>Article 4, first paragraph, amending provision, numbered paragraph (2)</i>   |   |                 |                 |
| 185 |   |   |                 |                 |

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|   | 2. Articles 41b to 41g shall apply exclusively to fertilising products, which has been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.  | 2. Articles 41b to 41g shall apply exclusively to fertilising products, which <del>has</del> <u>have</u> been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article. | <i>deleted</i>  | <i>deleted</i>  |
| Article 4, first paragraph, amending provision, numbered paragraph (3), first subparagraph  |   |   |                 |                 |
| 186   | 3. Articles 41b to 41g, except as regards provisions concerning the powers of the Commission, shall apply during the Single Market emergency mode.  | 3. Articles 41b to 41g, except as regards provisions concerning the powers of the Commission, shall apply during the <del>Single</del> <u>internal</u> market emergency mode.   | <i>deleted</i>  | <i>deleted</i>  |
| Article 4, first paragraph, amending provision, numbered paragraph (3), second subparagraph |   |   |                 |                 |
| 187   | However, Article 41c(2), second subparagraph, and Article 41c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.  | <i>deleted</i>  | <i>deleted</i>  | <i>deleted</i>  |
| Article 4, first paragraph, amending provision, numbered paragraph (4)                      |   |   |                 |                 |
| 188   | 4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to fertilising products placed on the market in accordance with Articles 41c to 41f. Those implementing acts shall be adopted | <i>deleted</i>  | <i>deleted</i>  | <i>deleted</i>  |

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|   | in accordance with the examination procedure referred to in Article 45(3).   |  |                 |                 |
| <i>Article 4, first paragraph, amending provision, seventh paragraph</i>      |  |  |                 |                 |
| 189   | Article 41b<br>Prioritisation of the conformity assessment of crisis-relevant fertilising products   | Article 41b<br>Prioritisation of the conformity assessment of crisis-relevant fertilising products   | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 4, first paragraph, amending provision, numbered paragraph (1)</i> |  |  |                 |                 |
| 190   | 1. This Article shall apply to fertilising products designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 15 requiring mandatory involvement of a notified body. | 1. This Article shall apply to fertilising products designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 15 requiring mandatory involvement of a notified body. | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 4, first paragraph, amending provision, numbered paragraph (2)</i> |  |  |                 |                 |
| 191   | 2. The notified bodies shall process all applications for conformity assessment of fertilising products designated as crisis-relevant goods as a matter of priority.   | 2. The notified bodies shall <u>ensure all reasonable efforts are made to</u> process all applications for conformity assessment of fertilising products designated as crisis-relevant goods as a matter of priority.            | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 4, first paragraph, amending provision, numbered paragraph (3)</i> |  |  |                 |                 |

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| 192  | 3. All pending applications for conformity assessment of fertilising products designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of fertilising products, which have not been designated as crisis-relevant goods. This requirement is applicable with respect to all applications for conformity assessment of fertilising products designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 41a. | 3. All pending applications for conformity assessment of fertilising products designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of fertilising products, which have not been designated as crisis-relevant goods. This requirement is applicable with respect to all applications for conformity assessment of fertilising products designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 41a. | <i>deleted</i>  | <i>deleted</i>  |
| Article 4, first paragraph, amending provision, numbered paragraph (4) |  |  |                 |                 |
| 193  | 4. The prioritisation of applications for conformity assessment of fertilising products pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.   | 4. The prioritisation of applications for conformity assessment of fertilising products pursuant to paragraph 3 shall not give rise to any <u>extraordinary</u> additional costs for the manufacturers, who have lodged those applications.  | <i>deleted</i>  | <i>deleted</i>  |
| Article 4, first paragraph, amending provision, numbered paragraph (5) |  |  |                 |                 |
| 194  | 5. The notified bodies shall deploy their best efforts to increase their   | 5. The notified bodies shall <del>deploy</del> <u>ensure all reasonable</u>  | <i>deleted</i>  | <i>deleted</i>  |



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|  | testing capacities for fertilising products designated as crisis-relevant goods in respect of which they have been notified.   | efforts <u>are made</u> to increase their testing capacities for fertilising products designated as crisis-relevant goods in respect of which they have been notified.  |                 |                 |
| Article 4, first paragraph, amending provision, thirteenth paragraph   |  |   |                 |                 |
| 195  | Article 41c<br>Derogation from the conformity assessment procedures requiring mandatory involvement of a notified body   | Article 41c<br>Derogation from the conformity assessment procedures requiring mandatory involvement of a notified body  | deleted         | deleted         |
| Article 4, first paragraph, amending provision, numbered paragraph (1) |  |   |                 |                 |
| 196  | 1. By way of derogation from Article 15, any competent national authority may authorise, on a duly justified request, the placing on the market within the territory of the Member State concerned, of a specific fertilising product which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body referred to in Article 15 have not been carried out by a notified body but for which the compliance with the requirements set out in Annexes I and II has been demonstrated. | 1. By way of derogation from Article 15, <del>any</del> <u>the</u> competent national authority, <u>after carrying out a risk assessment</u> , may authorise, on a duly justified request <u>from an economic operator established in its Member State</u> , the placing on the market within the territory of <del>the</del> <u>that</u> Member State <del>concerned</del> , of a specific fertilising product which has been designated as <u>a</u> crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body referred to in Article 15 have not been carried out by a notified body but for which the compliance with the requirements set out in | deleted         | deleted         |

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|  |  | Annexes I and II has been demonstrated.  |                 |                 |
| <i>Article 4, first paragraph, amending provision, numbered paragraph (2), first subparagraph</i>  |  |  |                 |                 |
| 197  | 2. The manufacturer of a fertilising product subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the fertilising product concerned complies with the requirements set out in Annexes I and II and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the national competent authority. | 2. The manufacturer of a fertilising product subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the fertilising product concerned complies with the requirements set out in Annexes I and II and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the national competent authority. | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 4, first paragraph, amending provision, numbered paragraph (2), second subparagraph</i> |  |  |                 |                 |
| 198  | The manufacturer shall also deploy all reasonable measures to ensure that the fertilising product, which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of the Member State, which issued the authorisation.   | <i>deleted</i>   | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 4, first paragraph, amending provision, numbered paragraph (3)</i>                      |  |  |                 |                 |
| 199  | 3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements  | 3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements  | <i>deleted</i>  | <i>deleted</i>  |

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|  | under which the fertilising products may be placed on the market, including:   | under which the fertilising products may be placed on the market, including <u>at least</u> :   |                 |                 |
| <i>Article 4, first paragraph, amending provision, numbered paragraph (3), point (a)</i> |  |   |                 |                 |
| 200  | (a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;                        | (a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;   | deleted         | deleted         |
| <i>Article 4, first paragraph, amending provision, numbered paragraph (3), point (b)</i> |  |   |                 |                 |
| 201  | (b) specific requirements regarding the traceability of the fertilising product concerned;   | (b) specific requirements regarding the traceability of the fertilising product concerned;  | deleted         | deleted         |
| <i>Article 4, first paragraph, amending provision, numbered paragraph (3), point (c)</i> |  |   |                 |                 |
| 202  | (c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated; | (c) an end date of validity of the authorisation, <u>unless otherwise specified</u> , which cannot go beyond the last day of the period for which the <del>Single</del> <u>internal</u> market emergency mode has been activated; | deleted         | deleted         |
| <i>Article 4, first paragraph, amending provision, numbered paragraph (3), point (d)</i> |  |   |                 |                 |
| 203  | (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the fertilising                                    | (d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the fertilising   | deleted         | deleted         |

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|  | product;   | product;  |                 |                 |
| Article 4, first paragraph, amending provision, numbered paragraph (3), point (e)  |  |   |                 |                 |
| 204  | (e) measures to be taken with respect to the fertilising product concerned upon expiry of the authorisation in order to ensure that the fertilising product concerned is brought back in compliance with all the requirements of this Regulation.  | (e) measures to be taken with respect to the fertilising product concerned upon expiry of the authorisation in order to ensure that the fertilising product concerned is brought back in compliance with all the requirements of this Regulation.   | deleted         | deleted         |
| Article 4, first paragraph, amending provision, numbered paragraph (3), point (ea) |  |   |                 |                 |
| 204a   |  | <u>(ea) labelling requirements, including radio frequency identification, indicating that the fertilising product was authorised under the internal market emergency mode.</u>  |                 |                 |
| Article 4, first paragraph, amending provision, numbered paragraph (4)             |  |   |                 |                 |
| 205  | 4. By way of derogation from Article 41a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3 of this Article also after the deactivation or expiry of the Single Market Emergency mode. | 4. By way of derogation from Article 41a(3), <del>first subparagraph,</del> where appropriate, the national competent authority may <u>also</u> amend the conditions <del>of the authorisation</del> <u>and requirements</u> referred to in paragraph <del>3 of this Article</del> <u>3 of this Article</u> also after the deactivation or expiry of the <del>Single</del> <u>internal</u> market emergency | deleted         | deleted         |

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|  |   | mode.   |                 |                 |
| Article 4, first paragraph, amending provision, numbered paragraph (5) |   |   |                 |                 |
| 206  | 5. By way of derogation from Articles 3 and 18, fertilising products, for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking.                      | <i>deleted</i>  | <i>deleted</i>  | <i>deleted</i>  |
| Article 4, first paragraph, amending provision, numbered paragraph (6) |   |   |                 |                 |
| 207  | 6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Regulation with respect to such fertilising products. | 6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Regulation with respect to such fertilising products.<br><u><a href="#">The market surveillance authorities shall keep all records related to products authorised under a derogation for a period of 10 years. They shall make those records available to other market surveillance authorities upon request.</a></u> | <i>deleted</i>  | <i>deleted</i>  |

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| <i>Article 4, first paragraph, amending provision, numbered paragraph (7)</i>  |  |   |                 |                 |
| 208  | 7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market of fertilising products in accordance with paragraph 1.  | 7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market of fertilising products in accordance with paragraph 1.   | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 4, first paragraph, amending provision, numbered paragraph (8)</i>  |  |   |                 |                 |
| 209  | 8. The application of Articles 41a to 41g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 15 on the territory of the Member State concerned. | 8. The application of Articles 41a to 41g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 15 <del>on the territory of the Member State concerned.</del>   | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 4, first paragraph, amending provision, numbered paragraph (8a)</i> |  |   |                 |                 |
| 209a   |  | <u>8a. Fertilising products subject to derogation under paragraph 1 shall remain valid for six months after deactivation or expiration of the internal market emergency mode. After this period, they shall only be made available on the market after receiving an authorisation under the normal authorisation procedure provided for in this Regulation.</u> |                 | <i>deleted</i>  |


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| <i>Article 4, first paragraph, amending provision, twenty-second paragraph</i> |   |  |                 |                 |
| 210  | Article 41d<br>Presumption of conformity based on national and international standards  | Article 41d<br>Presumption of conformity based on national and international standards   | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 4, first paragraph, amending provision, twenty-third paragraph</i>  |   |  |                 |                 |
| 211  | Where severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation] significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant requirements set out in Annex I, II or III or tests referred to in Article 13(2) of this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012, the Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, their competent authorities consider as complying with requirements set out in Annex I, II or III of this Regulation fertilising products which comply with relevant international standards or any relevant national standards in force | <del>Where severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation] significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant requirements set out in Annex I, II or III or tests referred to in Article 13(2) of this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012,</del> the Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, their competent authorities consider as complying with requirements set out in Annex I, II or III of this Regulation fertilising products which comply with relevant international standards or any relevant national standards in force in the Member State of manufacture, | <i>deleted</i>  | <i>deleted</i>  |




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|   | in the Member State of manufacture, ensuring a safety level equivalent to that required by the requirements set out in Annex I, II or III. | ensuring a safety level equivalent to that required by the requirements set out in Annex I, II or III-; <u>in either of the following cases:</u>  |                 |                 |
| Article 4, first paragraph, amending provision, twenty-third paragraph, point (a) |  |   |                 |                 |
| 211a  |  | <u>(a) where a reference to harmonised standards covering the relevant essential requirements set out in Annex I, II or III or tests referred to in Article 13(2) of this Regulation is not published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;</u>  |                 | deleted         |
| Article 4, first paragraph, amending provision, twenty-third paragraph, point (b) |  |   |                 |                 |
| 211b  |  | <u>(b) where severe disruptions in the functioning of the internal market, which were taken into consideration when activating the internal market emergency mode in accordance with Article 14 of [the IMERA Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant requirements set out in Annex I, II or III or tests referred to in Article 13(2) of this Regulation and already published in the Official Journal of the</u> |                 | deleted         |

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|   |   | <a href="#"><u>European Union in accordance with Regulation (EU) No 1025/2012.</u></a>   |                 |                 |
| Article 4, first paragraph, amending provision, twenty-fourth paragraph |   |  |                 |                 |
| 212   | Article 41e<br>Adoption of common specifications conferring a presumption of conformity   | Article 41e<br>Adoption of common specifications conferring a presumption of conformity  | deleted         | deleted         |
| Article 4, first paragraph, amending provision, numbered paragraph (1)  |   |  |                 |                 |
| 213   | 1. Where EU fertilising products, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such EU fertilising products for the requirements set out in Annex I, II or III or tests referred to in Article 13(2) where severe disruptions in the functioning of the Single Market, which led to the activation of [were taken into consideration when] the Single Market emergency mode significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant requirements set out in Annex I, II or III or tests referred to in Article 13(2) of this Regulation and already published in the Official | 1. Where EU fertilising products, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such EU fertilising products for the requirements set out in Annex I, II or III or tests referred to in Article 13(2) <del>where severe disruptions in the functioning of the Single Market, which led to the activation of [were taken into consideration when] the Single Market emergency mode significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant requirements set out in Annex I, II or III or tests referred to in Article 13(2)</del> of this Regulation and already published in the Official | deleted         | deleted         |

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|   | Journal of the European Union in accordance with Regulation (EU) No 1025/2012. | <del>Journal of the European Union in accordance with Regulation (EU) No 1025/2012.</del>   |                 |                 |
| Article 4, first paragraph, amending provision, numbered paragraph (1), point (a) |  |   |                 |                 |
| 213a  |  | <u>(a) where the European standardisation deliverables addressing a request pursuant to Article 10(1) of Regulation (EU) No 1025/2012 were not adopted;</u>   |                 | deleted         |
| Article 4, first paragraph, amending provision, numbered paragraph (1), point (b) |  |   |                 |                 |
| 213b  |  | <u>(b) where a reference to harmonised standards covering the relevant essential requirements set out in Annex I, II or III or tests referred to in Article 13(2) of this Regulation is not published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 and such reference is not expected to be published within a reasonable timeframe during the internal market emergency mode;</u> |                 | deleted         |
| Article 4, first paragraph, amending provision, numbered paragraph (1), point (c) |  |   |                 |                 |
| 213c  |  | <u>(c) where severe disruptions in the functioning of the internal market, which led to the activation of the</u>   |                 | deleted         |

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|  |  | <u>internal market emergency mode in accordance with Article 14 of [the IMERA Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant requirements set out in Annex I, II or III or tests referred to in Article 13(2) of this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.</u>  |  |                 |
| Article 4, first paragraph, amending provision, numbered paragraph (2) |  |  |   |                 |
| 214  | 2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 45(3). They shall apply to EUfertilising products placed on the market until the last day of the period for which the Single Market emergency mode remains active in accordance with [the SMEI Regulation]. In the early preparation of the draft implementing acts establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under | 2. The implementing acts referred to in paragraph 1 of this Article shall be adopted <del>following a consultation of the sectoral experts and</del> in accordance with the examination procedure referred to in Article 45(3). They shall apply to <del>EUfertilising</del> <u>EU fertilising</u> products placed on the market until the last day of the period for which the <del>Single</del> <u>internal</u> market emergency mode remains active <del>in accordance with [the SMEI Regulation]. In the early preparation of.</del> <u>When preparing</u> the draft implementing <del>acts</del> <u>act</u> establishing the common specification, the Commission shall <del>gather</del> <u>take into account</u> the views of | <i>deleted</i>  | <i>deleted</i>  |

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|  | relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.   | <del>the</del> relevant bodies <del>or expert groups established under</del> <u>and shall duly consult all</u> relevant <del>sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act</del> <u>stakeholders</u> .  |                 |                 |
| Article 4, first paragraph, amending provision, numbered paragraph (3) |   |   |                 |                 |
| 215  | 3. Without prejudice to Article 13, EU fertilising products which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the requirements set out in Annex I, II or III [or tests referred to in Article 13(2)] covered by those common specifications or parts thereof. | 3. Without prejudice to Article 13, EU fertilising products which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the requirements set out in Annex I, II or III [or tests referred to in Article 13(2)] covered by those common specifications or parts thereof. | <i>deleted</i>  | <i>deleted</i>  |
| Article 4, first paragraph, amending provision, numbered paragraph (4) |   |   |                 |                 |
| 216  | 4. By way of derogation from Article 41a(3), first subparagraph, unless there is sufficient reason to believe that the fertilising products covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the fertilising products in compliance with those common                   | 4. By way of derogation from Article 41a(3), <del>first subparagraph,</del> unless there is sufficient reason to believe that the fertilising products covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the fertilising products in compliance with those common        | <i>deleted</i>  | <i>deleted</i>  |

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|  | specifications which have been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation].  | specifications which have been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the <del>Single</del> <u>internal</u> market emergency mode in accordance with [the <del>SMEI</del> <u>IMERA</u> Regulation].  |  |                 |
| Article 4, first paragraph, amending provision, numbered paragraph (5) |  |   |   |                 |
| 217  | 5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the requirements set out in Annexes I and II, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information and, if appropriate, amend or withdraw the implementing act establishing the common specification in question. | 5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the requirements set out in Annexes I and II, it shall inform the Commission thereof with a detailed <del>explanation and</del> <u>explanation and</u> the Commission shall assess that information. <u>The Commission may and, if appropriate, amend, where appropriate, or withdraw</u> the implementing act establishing the common specification in question. | <i>deleted</i>  | <i>deleted</i>  |
| Article 4, first paragraph, amending provision, thirtieth paragraph    |  |   |   |                 |
| 218  | Article 41f<br>Adoption of mandatory common specifications   | <i>deleted</i>  | <i>deleted</i>  | <i>deleted</i>  |


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| <i>Article 4, first paragraph, amending provision, numbered paragraph (1)</i> |  |                |                 |                 |
| 219   | 1. In duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications for EU fertilising products to cover the requirements set out in Annexes I and II which have been designated as crisis-relevant goods.   | <i>deleted</i> | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 4, first paragraph, amending provision, numbered paragraph (2)</i> |  |                |                 |                 |
| 220   | 2. The implementing acts referred to in paragraph 1 shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 45(3) and they shall apply to EU fertilising products placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act. | <i>deleted</i> | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 4, first paragraph, amending provision, numbered paragraph (3)</i> |  |                |                 |                 |





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| 221   | 3. By way of derogation from Article 41a(3), first subparagraph, unless there is sufficient reason to believe that the EU fertilising products covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the fertilising products in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation]. | <i>deleted</i>  | <i>deleted</i>  | <i>deleted</i>  |
| Article 4, first paragraph, amending provision, thirty-fourth paragraph |  |   |                 |                 |
| 222   | Article 41g<br>Prioritisation of market surveillance activities and mutual assistance among authorities  | Article 41g<br>Prioritisation of market surveillance activities and mutual assistance among authorities     | <i>deleted</i>  | <i>deleted</i>  |
| Article 4, first paragraph, amending provision, numbered paragraph (1)  |  |   |                 |                 |
| 223   | 1. Member States shall prioritise the market surveillance activities for fertilising products designated as  | 1. Member States shall prioritise the market surveillance activities for fertilising products designated as | <i>deleted</i>  | <i>deleted</i>  |


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|  | crisis-relevant goods.   | crisis-relevant goods.  |                 |  |
| Article 4, first paragraph, amending provision, numbered paragraph (2) |  |   |                 |  |
| 224  | 2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for fertilising products designated as crisis-relevant goods. | 2. The market surveillance authorities of the Member States shall <del>deploy their</del> <u>ensure</u> best efforts <u>are made</u> to provide assistance to other market surveillance authorities during <del>a Single</del> <u>an internal</u> market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for fertilising products designated as crisis-relevant goods. | deleted         | deleted  |
| Article 4a   |  |   |                 |  |
| 224a   |  | <u>Article 4a</u><br><u>Amendments to Regulation (EU) 2023/988</u>  |                 | <u>Article 4a</u><br><u>Amendments to Regulation (EU) 2023/988</u> |
| Article 4a, first paragraph  |  |   |                 |  |
| 224b   |  | <u>Regulation (EU) 2023/988 is amended as follows:</u>  |                 | <u>Regulation (EU) 2023/988 is amended as follows:</u>             |
| Article 4a, first paragraph, point (1)                                 |  |   |                 |  |

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| G   | 224c                | <u><i>(1) In Article 2(1), point (b) is replaced by the following:</i></u>  |                 | <u><i>(1) In Article 2(1), point (b) is replaced by the following:</i></u>   |
| Article 4a, first paragraph, point (1), amending provision, first paragraph |                     |   |                 |  |
| G   | 224d                |   |                 | <u><i>(b) Chapter IIa, Chapter III, Section 1, Chapters V and VII and Chapters IX to XI do not apply.</i></u>  |
| Article 4a, first paragraph, point (2)                                      |                     |   |                 |  |
| G   | 224e                |   |                 | <u><i>(2) The following chapter is inserted:</i></u>   |
| Article 4a, first paragraph, point (2), amending provision, chapter i       |                     |   |                 |  |
| G   | 224f                | <u><i>“(b) Chapter IIa, Chapter III, Section 1, Chapters V and VII and Chapters IX to XI do not apply.”</i></u>   |                 | <u><i>Chapter IIa</i></u><br><u><i>EMERGENCY PROCEDURES</i></u>  |
| Article 4a, first paragraph, point (2), amending provision, article         |                     |   |                 |  |
| G   | 224g                | <u><i>(2) The following chapter is inserted:</i></u><br><u><i>‘CHAPTER IIa</i></u><br><u><i>EMERGENCY PROCEDURES</i></u><br><u><i>Article 8a</i></u><br><u><i>Activation of the emergency procedures, relationship with other</i></u> |                 | <u><i>Article 8a</i></u><br><u><i>Activation of the emergency procedures, relationship with other provisions of this Regulation and deactivation</i></u> |


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|  |                     | <p><u>provisions of this Regulation and deactivation</u></p> <p><u>1. Articles 8b to 8d shall only apply if the Commission has adopted an implementing act pursuant to Article 14(5) of [the IMERA Regulation].</u></p> <p><u>2. Articles 8b to 8d shall only apply to products which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.</u></p> <p><u>3. Articles 8b to 8d shall apply during the internal market emergency mode, except with respect to provisions concerning the powers of the Commission.</u></p> <p><u>Article 8b</u></p> <p><u>Presumption of safety based on national and international standards</u></p> <p><u>Member States shall take all appropriate measures to ensure that, for the purpose of placing products on the market, their competent authorities consider that the products which comply with the relevant international standards or any national standards in force in the Member State of manufacture, and which ensure the safety level required by this Regulation, meet the general safety requirement laid down in this Regulation as far as the risks and risk categories covered by those standards are</u></p> |  |                 |

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|  |                     | <p><u>concerned in any of the following cases:</u></p> <p><u>(a) where a reference to European standards is not published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;</u></p> <p><u>(b) where severe disruptions to the functioning of the internal market, which were taken into consideration when the internal market emergency mode was activated in accordance with Article 14 of [the IMERA Regulation], significantly restrict the possibility for manufacturers to make use of the European standards already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.</u></p> <p><u>Article 8c</u></p> <p><u>Adoption of common specifications enabling a presumption of safety for the risks and aspects covered by common specifications</u></p> <p><u>1. With respect to products covered by this Regulation that have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common technical specifications in either of the following cases:</u></p> <p><u>(a) where no specific safety requirements in accordance with</u></p> |  |                 |

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|  |                     | <p><u>Article 7 paragraph 2 have been adopted;</u></p> <p><u>(b) where the European standardisation deliverables addressing a request pursuant to Article 10(1) of Regulation No 1025/2012 were not adopted;</u></p> <p><u>(c) where a reference to European standards is not published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 and such reference is not expected to be published within a reasonable timeframe during the internal market emergency mode;</u></p> <p><u>(d) where severe disruptions in the functioning of the internal market, which were taken into consideration when the internal market emergency mode was activated in accordance with Article 14 of [the IMERA Regulation], significantly restrict the possibility for manufacturers to make use of the European standards covering the relevant essential safety requirements already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.</u></p> <p><u>2. The implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article</u></p> |  |                 |

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|  |                     | <p><u>46(3) and they shall remain applicable at the latest until the last day of the period for which the internal market emergency mode has been activated in accordance with Article 14 of [the IMERA Regulation].</u></p> <p><u>3. When preparing the draft implementing act establishing the common specification, the Commission shall take into account the views of the Consumer Safety Network, referred to in Article 30 and shall duly consult relevant stakeholders.</u></p> <p><u>4. Products covered by this Regulation which are in conformity with common specifications adopted pursuant to paragraph 1 of this Article shall be presumed to be in conformity with the general safety requirement laid down in Article 5 for the risks and risk categories covered by those common specifications or parts thereof.</u></p> <p><u>5. Products covered by this Regulation, which comply with the common specifications adopted pursuant to paragraph 1 and have been placed on the market, shall not be affected by the subsequent expiry or withdrawal of an implementing act adopted pursuant to paragraph 2, which has laid down those common specifications.</u></p> |  |                 |



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|  |                     | <p><u>unless there is sufficient reason to believe that goods covered by those common specifications present a risk to the health or safety of persons.</u></p> <p><u>6. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the general safety requirement laid down in Article 5, it shall inform the Commission thereof with a detailed explanation and the Commission shall consider that information. The Commission may amend, where appropriate, amend the implementing act establishing the common specification in question.</u></p> <p><u>Article 8d</u></p> <p><u>Prioritisation of market surveillance activities and mutual assistance among authorities</u></p> <p><u>1. Member States shall prioritise market surveillance activities for products covered by this Regulation, which have been designated as crisis-relevant goods.</u></p> <p><u>2. The market surveillance authorities of the Member States shall ensure best efforts are made to provide assistance to other market surveillance authorities during an internal market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of</u></p> |  |                 |

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|   |                     | <u>market surveillance authorities requesting assistance or by providing logistical support, such as reinforcement of the testing capacity for products covered by this Regulation which have been designated as crisis-relevant goods.</u> |                 |   |
| Article 4a, first paragraph, point (2), amending provision, article, first paragraph  |                     |   |                 |   |
| 224h  |                     |   |                 | <u>1. Articles 8b to 8d shall only apply if the Commission has adopted an implementing act pursuant to Article 14(5) of the IMERA Regulation.</u>   |
| Article 4a, first paragraph, point (2), amending provision, article, second paragraph |                     |   |                 |   |
| 224i  |                     |   |                 | <u>2. Articles 8b to 8d shall only apply to products covered by this Regulation which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.</u> |
| Article 4a, first paragraph, point (2), amending provision, article, third paragraph  |                     |   |                 |   |
| 224j  |                     |   |                 | <u>3. Articles 8b to 8d shall apply during the internal market emergency mode activated by a measure adopted in line with Article 14(5) of IMERA Regulation, except with respect to provisions</u>          |

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|      |  |            |                 | <u>concerning the powers of the Commission.</u>  |
|      | Article 4a, first paragraph, point (2), amending provision, article                  |            |                 |  |
| 224k |  |            |                 | <u>Article 8b</u><br><u>Presumption of conformity with the general safety requirement in the context of an internal market emergency</u>   |
|      | Article 4a, first paragraph, point (2), amending provision, article, first paragraph |            |                 |  |
| 224l |  |            |                 | <u>1. In addition to the presumption of conformity laid down in Article 7 of this Regulation, where severe disruptions to the functioning of the internal market, which were taken into consideration when the internal market emergency mode was activated in accordance with Article 14 of the IMERA Regulation, significantly restrict the possibility for manufacturers to make use of the relevant European standards already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012, it shall be considered, for the purpose of placing products on the market, that the presumption of conformity with the general safety requirement laid down in Article 5 may also be</u> |

|   | Commission Proposal | EP Mandate | Council Mandate | Draft Agreement  |
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|   |                     |            |                 | <u>established if the product conforms to national requirements, as regards the risks and risk categories covered by health and safety requirements laid down in the national law of the Member State in which it is made available on the market, provided that such law is in compliance with Union law.</u>   |
| Article 4a, first paragraph, point (2), amending provision, article, second paragraph |                     |            |                 |  |
| 224m  |                     |            |                 | <u>2. In addition to the cases where the presumption of conformity with the general safety requirement laid down in Article 5 applies under paragraph 1 and Article 7(1), Member States shall take all appropriate measures to ensure that, for the purpose of placing or making available of products on the market, their competent authorities consider that the products which comply with the relevant European standards other than those the references of which have been published in the Official Journal of the European Union in accordance with Article 10(7) of Regulation (EU) No 1025/2012, the relevant international standards developed by a recognised international standardisation body as defined by Article 2(9) of Regulation (EU) 1025/2012, and relevant national</u> |


|   | Commission Proposal   | EP Mandate | Council Mandate | Draft Agreement  |
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|   |   |            |                 | <u>standards developed by a national standardisation body as defined by Article 2(10) of Regulation (EU) 1025/2012, are presumed to meet the general safety requirement laid down in this Regulation as far as the risks and risk categories covered by those standards are concerned unless such standards are not adequate in view of the other elements of Articles 6 and 8 of this Regulation.</u> |
|   | Article 4a, first paragraph, point (2), amending provision, article, third paragraph            |            |                 |  |
| G | 224n  |            |                 | <u>3. Article 7(3) applies in the presumption of conformity established in accordance with this Article.</u>   |
|   | Article 4a, first paragraph, point (2), amending provision, article                             |            |                 |  |
| G | 224o  |            |                 | <i>deleted</i>   |
|   | Article 4a, first paragraph, point (2), amending provision, article, first paragraph            |            |                 |  |
| G | 224p  |            |                 | <i>deleted</i>   |
|   | Article 4a, first paragraph, point (2), amending provision, article, first paragraph, point (a) |            |                 |  |
| G | 224q  |            |                 |  |


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|   |  |            |                 | <i>deleted</i>  |
|   | <i>Article 4a, first paragraph, point (2), amending provision, article, first paragraph, point (b)</i> |            |                 |                 |
| G | 224r   |            |                 | <i>deleted</i>  |
|   | <i>Article 4a, first paragraph, point (2), amending provision, article, first paragraph, point (c)</i> |            |                 |                 |
| G | 224s   |            |                 | <i>deleted</i>  |
|   | <i>Article 4a, first paragraph, point (2), amending provision, article, first paragraph, point (d)</i> |            |                 |                 |
| G | 224t   |            |                 | <i>deleted</i>  |
|   | <i>Article 4a, first paragraph, point (2), amending provision, article, second paragraph</i>           |            |                 |                 |
| G | 224u   |            |                 | <i>deleted</i>  |
|   | <i>Article 4a, first paragraph, point (2), amending provision, article, third paragraph</i>            |            |                 |                 |
| G | 224v   |            |                 | <i>deleted</i>  |
|   | <i>Article 4a, first paragraph, point (2), amending provision, article, fourth paragraph</i>           |            |                 |                 |
| G | 224w   |            |                 |                 |


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|   |   |            |                 | <i>deleted</i>   |
|   | <i>Article 4a, first paragraph, point (2), amending provision, article, fifth paragraph</i>   |            |                 |  |
| G | 224x  |            |                 | <i>deleted</i>   |
|   | <i>Article 4a, first paragraph, point (2), amending provision, article, sixth paragraph</i>   |            |                 |  |
| G | 224y  |            |                 | <i>deleted</i>   |
|   | <i>Article 4a, first paragraph, point (2), amending provision, article, seventh paragraph</i> |            |                 |  |
| G | 224z  |            |                 | <i>deleted</i>   |
|   | <i>Article 4a, first paragraph, point (2), amending provision, article</i>                    |            |                 |  |
| G | 224aa   |            |                 | <u><a href="#">Article 8d</a></u><br><u><a href="#">Prioritisation of market surveillance activities and mutual assistance among authorities</a></u> |
|   | <i>Article 4a, first paragraph, point (2), amending provision, article, first paragraph</i>   |            |                 |  |
| G | 224ab   |            |                 | <u><a href="#">1. Member States shall prioritise market surveillance activities for products covered by this Regulation, which have been</a></u>     |





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|   |   |  |                 | <u>designated as crisis-relevant goods.</u>   |
|   | Article 4a, first paragraph, point (2), amending provision, article, second paragraph |  |                 |   |
| G | 224ac   |  |                 | <u>2. The market surveillance authorities of the Member States shall ensure best efforts are made to provide assistance to other market surveillance authorities during an internal market emergency.</u> |
|   | Article 4b  |  |                 |   |
| G | 224ad   | <u>Article 4b</u><br><u>Amendments to Regulation (EU)</u><br><u>2023/1230</u>  |                 | deleted   |
|   | Article 4b, first paragraph   |  |                 |   |
| G | 224ae   | <u>In Regulation (EU)2023/1230, the following chapter is inserted:</u>   |                 | deleted   |
|   | Article 4b, first paragraph, amending provision, first paragraph                      |  |                 |   |
| G | 224af   | <u>'CHAPTER VIa</u><br><u>EMERGENCY PROCEDURES</u><br><u>Article 46a</u><br><u>Application of emergency</u><br><u>procedures</u><br><u>1. Articles 46b to 46f of this</u><br><u>Regulation shall only apply if the</u> |                 | deleted   |


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|  |                     | <p><u><i>Commission has adopted an implementing act pursuant to Article 14(5) of [the IMERA Regulation].</i></u></p> <p><u><i>2. Articles 46b to 46f shall apply exclusively to machinery which has been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.</i></u></p> <p><u><i>3. Articles 46b to 46f shall apply during the internal market emergency mode, except with respect to provisions concerning the powers of the Commission.</i></u></p> <p><u><i>Article 46b</i></u></p> <p><u><i>Prioritisation of the conformity assessment of crisis-relevant machinery</i></u></p> <p><u><i>1. This Article shall apply to machinery designated as crisis-relevant goods, which is subject to conformity assessment procedures in accordance with Article 21, requiring mandatory involvement of a notified body.</i></u></p> <p><u><i>2. The notified bodies shall ensure all reasonable efforts are made to process all applications for a conformity assessment of machinery designated as crisis-relevant goods, as a matter of priority.</i></u></p> <p><u><i>3. All pending applications for a conformity assessment of machinery designated as crisis-</i></u></p> |  |                 |


|  | Commission Proposal | EP Mandate  | Council Mandate   | Draft Agreement |
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|  |                     | <p><u>relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of machinery which has not been designated as crisis-relevant goods. This priority requirement shall apply to all applications for conformity assessments of machinery designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 46a.</u></p> <p><u>4. The prioritisation of applications for a conformity assessment of machinery pursuant to paragraphs 2 and 3 shall not give rise to any extraordinary additional costs for the manufacturers who have lodged those applications.</u></p> <p><u>5. The notified bodies shall ensure all reasonable efforts are made to increase their testing capacities for machinery designated as crisis-relevant goods in respect of which they have been notified.</u></p> <p><u>Article 46c</u></p> <p><u>Derogation from third party conformity assessment procedures requiring mandatory involvement of a notified body</u></p> <p><u>1. By way of derogation from Article 21, the competent national authority, after carrying out a risk assessment, may authorise, on a</u></p> |  |                 |

|  | Commission Proposal | EP Mandate   | Council Mandate   | Draft Agreement |
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|  |                     | <p><u>duly justified request from an economic operator established in its Member State, the placing on the market or putting into service within the territory of that Member State, of specific machinery which has been designated as crisis-relevant goods and for which the conformity assessment procedures requiring mandatory involvement of a notified body referred to in Article 21 have not been carried out by a notified body but for which the compliance with all the applicable essential health and safety requirements has been demonstrated.</u></p> <p><u>2. The manufacturer of machinery, subject to the authorisation procedure referred to in paragraph 1, shall declare on his sole responsibility that the machinery concerned complies with all the applicable essential health and safety requirements set out in Annex III and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the national competent authority.</u></p> <p><u>3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the machinery may be placed on the market or put into</u></p> |  |                 |


|  | Commission Proposal | EP Mandate   | Council Mandate   | Draft Agreement |
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|  |                     | <p><u>service, including at least:</u></p> <p><u>(a) a description of the procedures, by means of which the compliance with the applicable essential health and safety requirements of this Regulation was successfully demonstrated;</u></p> <p><u>(b) specific requirements regarding the traceability of the machinery concerned;</u></p> <p><u>(c) an end date of validity of the authorisation, unless otherwise specified, which cannot go beyond the last day of the period for which the internal market emergency mode has been activated;</u></p> <p><u>(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the machinery concerned;</u></p> <p><u>(e) measures to be taken with respect to the machinery concerned upon expiry of the authorisation in order to ensure that the machinery concerned is brought back in compliance with all the requirements of this Regulation;</u></p> <p><u>(f) labelling requirements, including radio frequency identification, indicating that the machinery was authorised under the internal market emergency mode.</u></p> <p><u>4. By way of derogation from Article 46(3), where appropriate,</u></p> |  |                 |


|  | Commission Proposal | EP Mandate  | Council Mandate   | Draft Agreement |
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|  |                     | <p><u>the national competent authority may also amend the conditions and requirements referred to in paragraph 3 of this Article after the deactivation or expiry of the internal market emergency mode.</u></p> <p><u>5. The market surveillance authorities of the Member State whose competent authority has granted an authorisation pursuant to paragraph 1 shall be entitled to take all corrective and restrictive measures at national level provided for under this Regulation with respect to such machinery. The market surveillance authorities shall keep all records related to products authorised under a derogation for a period of 10 years. They shall make those records available to other market surveillance authorities upon request.</u></p> <p><u>6. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of machinery in accordance with paragraph 1.</u></p> <p><u>7. The application of Articles 46a to 46g and the use of the authorisation procedure set out in paragraph 1 of this Article shall not affect the application of the relevant conformity assessment procedures laid down in Article 21.</u></p> |  |                 |


|  | Commission Proposal | EP Mandate   | Council Mandate   | Draft Agreement |
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|  |                     | <p><u>8. Machinery subject to derogation under paragraph 1 shall remain valid for six months after deactivation or expiration of the internal market emergency mode. After this period, they shall only be made available on the market after receiving an authorisation under the normal authorisation procedure provided for in this Regulation.</u></p> <p><u>Article 46d</u></p> <p><u>Presumption of conformity based on national and international standards</u></p> <p><u>Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market or putting into service, their competent authorities consider that the machinery which complies with the relevant international standards or any national standards in force in the Member State of manufacture, ensuring the safety level required by the essential health and safety requirements set out in Annex III to this Regulation, complies with those essential health and safety requirements in either of the following cases:</u></p> <p><u>a) where a reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex III to this Regulation is not published in the Official Journal of the</u></p> |  |                 |

|  | Commission Proposal | EP Mandate  | Council Mandate   | Draft Agreement |
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|  |                     | <p><u>European Union in accordance with Regulation (EU) No 1025/2012;</u></p> <p><u>b) where severe disruptions in the functioning of the internal market, which were taken into consideration when the internal market emergency mode was activated in accordance with Article 14 of [the IMERA Regulation] significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex III to this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.</u></p> <p><u>Article 46e</u></p> <p><u>Adoption of common specifications conferring a presumption of conformity</u></p> <p><u>1. Where machinery has been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such machinery to cover the essential health and safety requirements set out in Annex III to this Regulation, in either of the following cases:</u></p> <p><u>a) where the European standardisation deliverables</u></p> |  |                 |



|  | Commission Proposal | EP Mandate   | Council Mandate   | Draft Agreement |
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|  |                     | <p><u>addressing a request pursuant to Article 10(1) of Regulation No 1025/2012 were not adopted;</u></p> <p><u>b) where a reference to harmonised standards covering the relevant essential requirements set out in Annex III is not published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 and such reference is not expected to be published within a reasonable timeframe during the internal market emergency mode;</u></p> <p><u>c) where severe disruptions in the functioning of the internal market, which led to the activation the internal market emergency mode in accordance with Article 14 of [the IMERA Regulation], significantly restrict the possibility for manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex III to this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.</u></p> <p><u>2. The implementing acts referred to in paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 48(3). They shall apply to machinery placed on the market</u></p> |  |                 |

|  | Commission Proposal | EP Mandate  | Council Mandate   | Draft Agreement |
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|  |                     | <p><u>until the last day of the period for which the internal market emergency mode remains active. When preparing the draft-implementing act establishing the common specification, the Commission shall take into account the views of the relevant bodies and shall duly consult all relevant stakeholders.</u></p> <p><u>3. Without prejudice to Article 17, machinery which is in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III covered by those common specifications or parts thereof.</u></p> <p><u>4. By way of derogation from Article 46a(3), unless there is sufficient reason to believe that the machinery covered by the common specifications referred to in paragraph 1 of this Article presents a risk to the health or safety of persons, the machinery in compliance with those common specifications which has been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or</u></p> |  |                 |

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|  |                     | <p><u>deactivation of the internal market emergency mode in accordance with [the IMERA Regulation].</u></p> <p><u>5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the essential health and safety requirements which it aims to cover and which are set out in Annex III, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information. The Commission may amend, where appropriate, the implementing act establishing the common specification in question.</u></p> <p><u>Article 46f</u></p> <p><u>Prioritisation of market surveillance activities and mutual assistance among authorities</u></p> <p><u>1. Member States shall prioritise the market surveillance activities for machinery, designated as crisis-relevant goods.</u></p> <p><u>2. The market surveillance authorities of the Member States shall ensure best efforts are made to provide assistance to other market surveillance authorities during an internal market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by</u></p> |  |                 |

|   | Commission Proposal                                    | EP Mandate  | Council Mandate   | Draft Agreement   |
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|   |  | <u>providing logistical support such as reinforcement of the testing capacity for machinery designated as crisis-relevant goods.'</u> |   |   |
| Article 5   |  |   |   |   |
| 225   | Article 5<br>Amendments to Regulation (EU) No 305/2011 | Article 5<br>Amendments to Regulation (EU) No 305/2011  | Article 5<br>Amendments to Regulation (EU) No 305/2011          | Article 5<br>Amendments to Regulation (EU) No 305/2011<br><br>Text Origin: Commission Proposal    |
| Article 5, first paragraph  |  |   |   |   |
| 226   | In Regulation (EU) 305/2011 is amended as follows:     | In Regulation (EU) 305/2011 is amended as follows:  | <del>In</del> Regulation (EU) 305/2011 is amended as follows:   | <del>In</del> Regulation (EU) 305/2011 is amended as follows:<br><br>Text Origin: Council Mandate |
| Article 5, first paragraph, point (-1)                                      |  |   |   |   |
| 226a  |  |   | (-1) In Article 2 the following points is are added:            | <u>(-1) In Article 2 the following points is are added:</u><br><br>Text Origin: Council Mandate   |
| Article 5, first paragraph, point (-1), amending provision, first paragraph |  |   |   |   |
| 226b  |  |   | "<br>(29) 'crisis-relevant goods' means 'crisis-relevant goods' | '<br><u>(29) 'crisis-relevant goods' means 'crisis-relevant goods' within the</u>                 |

|  | Commission Proposal                          | EP Mandate                                   | Council Mandate  | Draft Agreement  |
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|  |  |  | within the meaning of Article 3, point (6) of Regulation (EU) .../.... [SMEI Regulation];  | <u>meaning of Article 3, point (6) of Regulation (EU) .../.... [IMERA Regulation];</u><br><br>Text Origin: Council Mandate   |
| Article 5, first paragraph, point (-1), amending provision, second paragraph |  |  |  |  |
| 226c   |  |  | (30) ‘Single Market Emergency’ means ‘Single Market Emergency’ within the meaning of Article 3, point (3) of Regulation (EU) .../... [SMEI Regulation].; | <u>(30) ‘internal market emergency’ means ‘internal market emergency’ within the meaning of Article 3, point (3) of Regulation (EU) .../... [IMERA Regulation].;</u><br><br>Text Origin: Council Mandate |
| Article 5, first paragraph, point (1)  |  |  |  |  |
| 227  | (1) the following Chapter VIIIa is inserted: | (1) the following Chapter VIIIa is inserted: | (1) The following Chapter VIIIa is inserted <b>after Chapter VIII</b> :  | (1) The following Chapter VIIIa is inserted <u>after Chapter VIII</u> :<br><br>Text Origin: Council Mandate  |
| Article 5, first paragraph, point (1), amending provision, Chapter I         |  |  |  |  |
| 228  | ‘<br>CHAPTER VIIIa<br>EMERGENCY PROCEDURES   | ‘<br>CHAPTER VIIIa<br>EMERGENCY PROCEDURES   | ‘<br><b>Chapter VIIIa</b><br><del>CHAPTER VIIIa</del><br>EMERGENCY PROCEDURES  | ‘<br><u>Chapter VIIIa</u><br><del>CHAPTER VIIIa</del><br>EMERGENCY PROCEDURES<br><br>Text Origin: Council Mandate  |
| Article 5, first paragraph, point (1), amending provision, Article           |  |  |  |  |

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| 229   | Article 59a   | Article 59a   | <i>deleted</i>  | <i>deleted</i>  |
| Article 5, first paragraph, point (1), amending provision, Article                |   |   |   |   |
| 230   | Application of emergency procedures   | Application of emergency procedures   | Article 59a<br>Application of emergency procedures  | <u>Article 59a</u><br>Application of emergency procedures<br><br>Text Origin: Council Mandate   |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (1) |   |   |   |   |
| 231   | 1. Articles 59b to 59f shall only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Regulation. | 1. Articles 59b to 59f <u>of this Article</u> shall only apply if the Commission has adopted an implementing act pursuant to Article <del>23 of [the SMEI Regulation]</del> <u>activating Article 26 of [the SMEI Regulation]</u> <del>with respect to this Regulation.</del> | 1. Articles 59b to 59f shall only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to <b>construction products covered by</b> this Regulation.             | 1. Articles 59b to 59f <u>of this Regulation</u> shall only apply if the Commission has adopted an implementing act pursuant to Article <del>23 of [the SMEI Regulation]</del> <u>activating Article 26 of [the SMEI Regulation]</u> <del>with respect to this</del> <u>the IMERA Regulation.</u> |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (2) |   |   |   |   |
| 232   | 2. Articles 59b to 59f shall apply exclusively to construction products, which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.                          | 2. Articles 59b to 59f shall apply exclusively to construction products, which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.  | 2. Articles 59b to 59f <del>shall</del> apply exclusively to construction products, which have been designated as crisis-relevant goods <del>in the implementing act referred to in paragraph 1 of this Article</del> <b>pursuant to Article 14 of [the SMEI Regulation].</b> | 2. Articles 59b to 59f shall apply exclusively to construction products, which have been designated as crisis-relevant goods <del>in the implementing act referred to in paragraph 1 of this Article</del> <u>pursuant to Article 14(5) of the IMERA Regulation.</u>                              |

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|     | Article 5, first paragraph, point (1), amending provision, numbered paragraph (3), first subparagraph   |   |  |  |
| 233 | 3. Articles 59b to 59f, except as regards provisions concerning the powers of the Commission, shall apply during the Single Market emergency mode.  | 3. Articles 59b to 59f, except as regards provisions concerning the powers of the Commission, shall apply during the <del>Single</del> <u>internal</u> market emergency mode. | 3. Articles 59b to 59f, except as regards <del>provisions concerning the powers</del> <b>the power</b> of the Commission <b>in Article 59d(5)</b> , shall apply <b>only</b> during the Single Market emergency mode <b>activated in accordance with Article 14 of [the SMEI Regulation]</b> .  | 3. Articles 59b to 59f, except as regards <del>provisions concerning the powers</del> <u>the power</u> of the Commission <u>in Article 59d(5)</u> , shall apply <u>only</u> during the <del>Single</del> <u>internal</u> market emergency mode <u>activated in accordance with Article 14 of the IMERA Regulation</u> .  |
|     | Article 5, first paragraph, point (1), amending provision, numbered paragraph (3), second subparagraph  |   |  |  |
| 234 | However, Article 59c(2), second subparagraph, and Article 59c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.  | <i>deleted</i>  | <i>deleted</i>   | However, Article 59 <del>c(2), second subparagraph, and Article 59c(5)</del> shall apply during the <del>Single</del> <u>internal</u> market emergency mode and after its deactivation or expiry.  |
|     | Article 5, first paragraph, point (1), amending provision, numbered paragraph (4)   |   |  |  |
| 235 | 4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to construction products placed on the market in accordance with Articles 59b to 59f. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 64(2a) | <i>deleted</i>  | 4. The Commission <del>shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken</del> <b>may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures to be followed and the specific labelling and traceability requirements</b> with respect to construction products placed on the | 4. The Commission <del>shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken</del> <u>may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures to be followed and the specific labelling and traceability requirements</u> with respect to construction products placed on the |

|   | Commission Proposal   | EP Mandate  | Council Mandate   | Draft Agreement   |
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|   |   |   | market in accordance with Articles 59b to 59f. <del>59d</del> These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 64(2a)-.   | market in accordance with Articles 59b to <del>59f. These</del> <u>59d. Those</u> implementing acts shall be adopted in accordance with the examination procedure referred to in Article 64(2a)-.   |
| Article 5, first paragraph, point (1), amending provision, eighth paragraph       |   |   |   |   |
| 236   | Article 59b   | Article 59b   | <i>deleted</i>  | <i>deleted</i>  |
| Article 5, first paragraph, point (1), amending provision, Article                |   |   |   |   |
| 237   | Prioritisation of the assessment and verification of constancy of performance of crisis-relevant construction products  | Prioritisation of the assessment and verification of constancy of performance of crisis-relevant construction products  | <b>Article 59b</b><br>Prioritisation of the assessment and verification of constancy of performance of crisis-relevant construction products  | <u><b>Article 59b</b></u><br>Prioritisation of the assessment and verification of constancy of performance of crisis-relevant construction products<br><br>Text Origin: Council Mandate   |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (1) |   |   |   |   |
| 238   | 1. This Article shall apply to construction products designated as crisis-relevant goods, which are subject to third party tasks of notified bodies related to the assessment and verification of constancy of performance, in accordance with Article 28(1). | 1. This Article shall apply to construction products designated as crisis-relevant goods, which are subject to third party tasks of notified bodies related to the assessment and verification of constancy of performance, in accordance with Article 28(1). | 1. This Article shall apply to construction products designated as crisis-relevant goods, which are subject to third party tasks of notified bodies related to the assessment and verification of constancy of performance, in accordance with Article 28(1). | 1. This Article shall apply to construction products designated as crisis-relevant goods, which are subject to third party tasks of notified bodies related to the assessment and verification of constancy of performance, in accordance with Article 28(1). |



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| Article 5, first paragraph, point (1), amending provision, numbered paragraph (2) |   |   |   |   |
| 239   | 2. The notified bodies shall process requests for third party tasks related to the assessment and verification of constancy of performance of construction products designated as crisis-relevant goods as a matter of priority.  | 2. The notified bodies shall <u>ensure all reasonable efforts are made to</u> process requests for third party tasks related to the assessment and verification of constancy of performance of construction products designated as crisis-relevant goods as a matter of priority.   | 2. The notified bodies shall process requests for third party tasks related to the assessment and verification of constancy of performance of construction products designated as crisis-relevant goods as a matter of priority, <b>irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 59a.</b> | 2. The notified bodies shall <u>make best efforts to</u> process requests for third party tasks related to the assessment and verification of constancy of performance of construction products designated as crisis-relevant goods as a matter of priority, <u>irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 59a.</u> |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (3) |   |   |   |   |
| 240   | 3. All pending applications for the performance of third party tasks related to the assessment and verification of constancy of performance of construction products designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications regarding construction products, which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for third party tasks related to the assessment and verification of constancy of performance of construction products designated as crisis-relevant goods, irrespective of | 3. All pending applications for the performance of third party tasks related to the assessment and verification of constancy of performance of construction products designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications regarding construction products, which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for third party tasks related to the assessment and verification of constancy of performance of construction products designated as crisis-relevant goods, irrespective of | <i>deleted</i>  | <i>deleted</i>  |

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|   | whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 59a.   | whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 59a.   |   |   |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (4) |   |   |   |   |
| 241   | 4. The prioritisation of applications for third party tasks related to the assessment and verification of constancy of performance of construction products pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers who have lodged those applications. | 4. The prioritisation of applications for third party tasks related to the assessment and verification of constancy of performance of construction products pursuant to paragraph 3 shall not give rise to any <u>extraordinary</u> additional costs for the <del>manufacturers who</del> <u>manufacturers, who</u> have lodged those applications. | 4. The prioritisation of applications for third party tasks related to the assessment and verification of constancy of performance of construction products pursuant to paragraph <del>3</del> 2 shall not give rise to <del>any</del> <b>disproportionate</b> additional costs for the <del>manufacturers who</del> <b>manufacturers who</b> have lodged those applications. | 4. The prioritisation of applications for third party tasks related to the assessment and verification of constancy of performance of construction products pursuant to paragraph <del>3</del> 2 shall not give rise to <del>any additional</del> <u>additional disproportionate</u> costs for the <del>manufacturers who</del> <u>manufacturers, who</u> have lodged those applications. |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (5) |   |   |   |   |
| 242   | 5. The notified bodies shall deploy their best efforts to increase their respective assessment and verification capacities regarding construction products designated as crisis-relevant goods.   | 5. The notified bodies shall <del>deploy</del> <u>ensure all reasonable</u> <del>their best</del> <u>are made</u> efforts to increase their respective assessment and verification capacities regarding construction products designated as crisis-relevant goods.  | <i>deleted</i>  | 5. The notified bodies shall <del>deploy</del> <u>make reasonable</u> <del>their best</del> efforts to increase their respective assessment and verification capacities regarding construction products designated as crisis-relevant goods.  |
| Article 5, first paragraph, point (1), amending provision, Article                |   |   |   |   |
| 243   | Article 59c<br>Derogation from the third party assessment procedures for  | Article 59c<br>Derogation from the third party assessment procedures for  | <i>deleted</i>  | <i>deleted</i>  |

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|   | assessment and verification of constancy of performance   | assessment and verification of constancy of performance   |                 |                 |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (1)                     |   |   |                 |                 |
| 244   | 1. By way of derogation from Article 28(1), the competent national authority may exceptionally authorise, on a duly justified request, the placing on the market within the territory of the Member State concerned, of a specific construction product which has been designated as crisis-relevant good for which the required third-party assessment and verification of constancy of performance procedures referred to in that Article have not been carried out by a notified body. | 1. By way of derogation from Article 28(1), the competent national authority, <u>after carrying out a risk assessment,</u> <del>may</del> exceptionally authorise, on a duly justified request <u>from an economic operator established in its Member State,</u> the placing on the market within the territory of <del>the</del> <u>that</u> Member State <del>concerned,</del> of a specific construction product which has been designated as crisis-relevant good for which the required third-party assessment and verification of constancy of performance procedures referred to in <del>that Article</del> <u>Article 28(1)</u> have not been carried out by a notified body. | deleted         | deleted         |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (2), first subparagraph |   |   |                 |                 |
| 245   | 2. The manufacturer of a construction product subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the construction product concerned achieves the declared performance and shall be responsible for the fulfilment of all the procedures for  | 2. The manufacturer of a construction product subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the construction product concerned achieves the declared performance and shall be responsible for the fulfilment of all the procedures for  | deleted         | deleted         |

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|   | the assessment and verification of constancy of performance indicated by the national competent authority.  | the assessment and verification of constancy of performance indicated by the national competent authority.   |                 |                 |
| <i>Article 5, first paragraph, point (1), amending provision, numbered paragraph (2), second subparagraph</i> |   |  |                 |                 |
| 246   | The manufacturer shall also deploy all reasonable measures to ensure that the construction product, which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of the Member State, which issued the authorisation. | <i>deleted</i>   | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 5, first paragraph, point (1), amending provision, numbered paragraph (3)</i>                      |   |  |                 |                 |
| 247   | 3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the construction products may be placed on the market, including:                                     | 3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the construction products may be placed on the market, including <u>at least</u> : | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 5, first paragraph, point (1), amending provision, numbered paragraph (3), point (a)</i>           |   |  |                 |                 |
| 248   | (a) a description of the procedures, to be followed in order to demonstrate that the construction product achieves the declared performance and complies with this Regulation, as applicable;   | (a) a description of the procedures, to be followed in order to demonstrate that the construction product achieves the declared performance and complies with this Regulation, as applicable;                                      | <i>deleted</i>  | <i>deleted</i>  |

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| <i>Article 5, first paragraph, point (1), amending provision, numbered paragraph (3), point (b)</i> |  |  |                 |                 |
| 249   | (b) the specific requirements regarding the safety as well as the traceability, including labelling, of the concerned construction product;  | (b) the specific requirements regarding the safety as well as the traceability, including labelling, of the concerned construction product;  | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 5, first paragraph, point (1), amending provision, numbered paragraph (3), point (c)</i> |  |  |                 |                 |
| 250   | (c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated;   | (c) an end date of validity, <u>unless otherwise specified</u> , of the authorisation, which cannot go beyond the last day of the period for which the <del>Single</del> <u>internal</u> market emergency mode has been activated; | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 5, first paragraph, point (1), amending provision, numbered paragraph (3), point (d)</i> |  |  |                 |                 |
| 251   | (d) any specific requirements regarding the continuous performance of third party tasks related to the assessment and verification of constancy of performance with respect to the concerned construction product; | (d) any specific requirements regarding the continuous performance of third party tasks related to the assessment and verification of constancy of performance with respect to the concerned construction product;                 | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 5, first paragraph, point (1), amending provision, numbered paragraph (3), point (e)</i> |  |  |                 |                 |
| 252   | (e) measures to be taken with respect to the construction product concerned upon expiry of the authorisation in order to ensure that the construction product concerned  | (e) measures to be taken with respect to the construction product concerned upon expiry of the authorisation in order to ensure that the construction product concerned  | <i>deleted</i>  | <i>deleted</i>  |

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|   | is brought back in compliance with all the requirements of this Regulation.  | is brought back in compliance with all the requirements of this Regulation.  |                 |                 |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (3), point (ea) |  |  |                 |                 |
| 252a  |  | <u>(ea) labelling requirements, including radio frequency identification, indicating that the construction product was authorised under the internal market emergency mode.</u>  |                 | deleted         |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (4)             |  |  |                 |                 |
| 253   | 4. By way of derogation from Article 54a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation issued referred to in paragraph 3 of this Article, also after the deactivation or expiry of the Single Market Emergency mode. | 4. By way of derogation from Article 54a(3), <del>first subparagraph,</del> where appropriate, the national competent authority may <u>also</u> amend the conditions <del>of the authorisation issued</del> <u>and requirements</u> referred to in paragraph 3 of this Article, <del>also</del> after the deactivation or expiry of the <del>Single</del> <u>internal</u> market emergency mode. | deleted         | deleted         |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (5)             |  |  |                 |                 |
| 254   | 5. Construction products, for which an authorisation has been granted in accordance with paragraph 1 of this Article shall not leave the territory of the Member State which has issued  | deleted  | deleted         | deleted         |

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|   | the authorisation and shall not bear the CE marking.   |   |                 |                 |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (6) |  |   |                 |                 |
| 255   | 6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Regulation with respect to such construction products. | 6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Regulation with respect to such construction products. <u>The market surveillance authorities shall keep all records related to products authorised under a derogation for a period of 10 years. They shall make those records available to other market surveillance authorities upon request.</u> | deleted         | deleted         |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (7) |  |   |                 |                 |
| 256   | 7. Member States shall inform the Commission s of any decision to authorise the placing on the market of construction products in accordance with paragraph 1.   | 7. Member States shall inform the Commission s of any decision to authorise the placing on the market of construction products in accordance with paragraph 1.  | deleted         | deleted         |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (8) |  |   |                 |                 |
| 257   |  |   |                 |                 |

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|  | 8. The application of Articles 59a to 59f and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant procedures for the assessment and verification of constancy of performance required by Article 28 on the territory of the Member State concerned. | 8. The application of Articles 59a to 59f and the use of the authorisation procedure set out in paragraph 1 of this Article <del>does</del> <i>shall</i> not affect the application of the relevant procedures for the assessment and verification of constancy of performance required by Article 28 <i>on the territory of the Member State concerned.</i>     | <i>deleted</i>  | <i>deleted</i>   |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (8a) |   |  |   |  |
| 257a   |   | <u>8a. Construction products subject to derogation under paragraph 1 shall remain valid for six months after deactivation or expiration of the internal market emergency mode. After this period, they shall only be made available on the market after receiving an authorisation under the normal authorisation procedure provided for in this Regulation.</u> |   | <i>deleted</i>   |
| Article 5, first paragraph, point (1), amending provision, Article                 |   |  |   |  |
| 258  | Article 59d<br>Adoption of common specifications enabling performance assessment  | Article 59d<br>Adoption of common specifications enabling performance assessment   | Article 59d<br><del>Article 59d</del><br>Adoption of common specifications enabling performance assessment<br>Assessment and declaration of performance based on standards and common | <u>Article 59d</u><br><del>Article 59d</del><br><del>Adoption of common specifications enabling performance assessment</del><br><u>Assessment and declaration of performance based on standards and common</u> |



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|  |   |   | specifications   | <u>specifications</u><br>Text Origin: Council Mandate   |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (1)            |   |   |  |   |
| 259  | 1. Where construction products, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications to cover the methods and the criteria for assessing the performance of those products in relation to their essential characteristics in either of the following cases: | 1. Where construction products, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications to cover the methods and the criteria for assessing the performance of those products in relation to their essential characteristics in either of the following cases:   | 1. Where construction products, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts, <b>listing appropriate standards</b> or establishing common specifications to cover the methods and the criteria for assessing the performance of those products in relation to their essential characteristics in either of the following cases: | 1. Where construction products, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts, <u>listing appropriate standards</u> or establishing common specifications to cover the methods and the criteria for assessing the performance of those products in relation to their essential characteristics in either of the following cases:  |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (1), point (a) |   |   |  |   |
| 260  | (a) where no reference to harmonised standards covering the relevant methods and criteria for assessing the performance of those products in relation to their essential characteristics is published in the Official Journal of the European Union in accordance with Article 17(5);   | (a) where <del>no reference to harmonised standards covering the relevant methods and criteria for assessing the performance of those products in relation to their essential characteristics is published in the Official Journal of the European Union in accordance with Article 17(5)</del> <u>the European standardisation deliverables addressing a request pursuant to Article 10(1) of Regulation (EU) No 1025/2012 were not adopted;</u> | (a) <del>where</del> no reference to harmonised standards covering the relevant methods and criteria for assessing the performance of those products in relation to their essential characteristics is published in the <b>Official Journal of the European Union</b> in accordance with Article 17(5);  | (a) <del>where</del> no reference to harmonised standards covering the relevant <del>methods and criteria for assessing the performance of those products in relation to their essential characteristics</del> <u>essential requirements set out in Annex II</u> is published in the <u>Official Journal of the European Union</u> in accordance with <del>Article 17(5)</del> <u>Regulation (EU) No 1025/2012 and no such reference is</u> |

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|   |   |   |   | <u>expected to be published within a reasonable period; or</u>   |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (1), point (aa) |   |   |   |  |
| 260a  |   | <u>(aa) where a reference to harmonised standards covering the relevant essential requirements set out in Annex II is not published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 and such reference is not expected to be published within a reasonable timeframe during the internal market emergency mode;</u>   |   | deleted  |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (1), point (b)  |   |   |   |  |
| 261   | (b) where the severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode significantly restrict the possibilities of manufacturers to make use of the harmonised standards, providing the relevant methods and criteria for assessing the performance of those product in relation to their essential characteristics, and already published in the Official Journal of the European Union in accordance with Article 17(5). | (b) where the severe disruptions in the functioning of the <del>Single</del> internal market, which led to the activation of the <del>Single</del> internal market emergency mode <u>in accordance with Article 14 of [the IMERA Regulation]</u> , significantly restrict the possibilities of manufacturers to make use of the harmonised standards, providing the relevant methods and criteria for assessing the performance of those product in relation to their essential characteristics, and already published in the Official Journal of | (b) <del>where</del> the severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode significantly restrict the possibilities of manufacturers to make use of the harmonised standards, providing the relevant methods and criteria for assessing the performance of those product in relation to their essential characteristics, and already published in the <b>Official Journal of the European Union</b> in accordance with Article 17(5). | (b) <del>where the</del> severe disruptions in the functioning of the <del>Single</del> internal market, which led to the activation of the <del>Single</del> internal market emergency mode <u>in accordance with Article 14 of the IMERA Regulation</u> , significantly restrict the possibilities of manufacturers to make use of the harmonised standards, providing the relevant methods and criteria for assessing the performance of those product in relation to their essential characteristics, and already published in the Official Journal of |

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|      |   | the European Union in accordance with <del>Article 17(5)</del> <a href="#">Regulation (EU) No 1025/2012</a> . |  | the European Union in accordance with <del>Article 17(5)</del> <a href="#">Regulation (EU) No 1025/2012</a> .   |
|      | Article 5, first paragraph, point (1), amending provision, numbered paragraph (1), point (ba) |   |  |   |
| 261a |   |   | 1a. The implementing acts referred to in paragraph 1 may:  | <u>1a. The implementing acts referred to in paragraph 1 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.</u> |
|      | Article 5, first paragraph, point (1), amending provision, numbered paragraph (1), point (bb) |   |  |   |
| 261b |   |   | (a) publish the references to relevant applicable international standards that include assessment methods for the declaration of performance in accordance with paragraph 3; | <i>deleted</i>  |
|      | Article 5, first paragraph, point (1), amending provision, numbered paragraph (1), point (bc) |   |  |   |
| 261c |   |   |  |   |

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|   |                     |            | (b) if there are no relevant applicable international standards as referred to in point a of this paragraph published in the Official Journal of the European Union in accordance with Article 17(5) of this Regulation that cover the essential characteristics referred in paragraph 1, publish the references to the European standards that include assessment methods for the declaration of performance in accordance with paragraph 3;                               | <i>deleted</i>  |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (1), point (bd) |                     |            |   |                 |
| 261d  |                     |            | (c) if there is no relevant applicable international or European standard as referred to in points a and b of this paragraph published in the Official Journal of the European Union in accordance with Article 17(5) of this Regulation that cover the essential characteristics referred in paragraph 1, establish common specifications established by the Commission that include assessment methods for the declaration of performance in accordance with paragraph 3; | <i>deleted</i>  |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (1), point (be) |                     |            |   |                 |

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| 261e  |  |  | (d) if there is no relevant applicable international standard, European standard or common specifications as referred to in points a, b and c, publish the reference to national standards that include assessment methods for the declaration of performance in accordance with paragraph 3.   | deleted   |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (2) |  |  |   |   |
| 262   | 2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the Standing Committee on Construction and in accordance with the examination procedure referred to in Article 64(2a). They shall apply to construction products placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act. | 2. The implementing acts referred to in paragraph 1 of this Article shall be adopted <del>following a consultation of the Standing Committee on Construction and</del> in accordance with the examination procedure referred to in Article 64(2a). They shall apply to construction products placed on the market until the last day of the period for which the <del>Single</del> <u>internal</u> market emergency mode remains active. <del>In the early preparation of</del> <u>When preparing</u> the draft implementing act establishing the common specification, the Commission shall <del>gather</del> <u>take into account</u> the views of relevant bodies <del>or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission</del> <u>and shall prepare the draft implementing act</u> <u>duly consult</u> | 2. The implementing acts referred to in paragraph 1 <del>of this Article</del> shall be adopted following a consultation of the Standing Committee on Construction and in accordance with the examination procedure referred to in Article 64(2a). They shall apply <del>to construction products placed on the market</del> until the last day of the period for which the Single Market emergency mode remains active. <del>In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act,</del> unless amended or repealed in | 2. The implementing acts referred to in paragraph 1 <del>of this Article</del> shall be adopted <del>following a consultation of the Standing Committee on Construction and</del> in accordance with the examination procedure referred to in Article 64(2a); <u>and</u> they shall apply <del>to construction products placed on the market</del> until the last day of the period for which the <del>Single</del> <u>internal</u> market emergency mode remains active. <del>In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act,</del> <u>unless amended or repealed in</u> |

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|      |   | <u>all relevant stakeholders.</u>   | accordance with paragraph 5.   | <u>accordance with paragraph 5.</u>   |
|      | Article 5, first paragraph, point (1), amending provision, numbered paragraph (2a)  |   |  |   |
| 262a |   |   | 2a. Before preparing the draft implementing act referred to in paragraph 1, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or expert groups established under this Regulation and shall duly consult all relevant stakeholders. | <u>2a. Before preparing the draft implementing act referred to in paragraph 1, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or expert groups established under this Regulation and shall duly consult all relevant stakeholders.</u> |
|      | Article 5, first paragraph, point (1), amending provision, numbered paragraph (3)   |   |  |   |
| 263  | 3. Without prejudice to Articles 4 and 6, the methods and the criteria provided in the common specifications adopted pursuant to paragraph 1 of this Article, may be used for assessing and declaring the performance of construction products covered by those common specifications in relation to their essential characteristics. | 3. Without prejudice to Articles 4 and 6, the methods and the criteria provided in the common specifications adopted pursuant to paragraph 1 of this Article, may be used for assessing and declaring the performance of construction products covered by those common specifications in relation to their essential characteristics. | 3. Without prejudice to Articles 4 and 6, the methods and the criteria provided in the <b>standards and</b> common specifications <b>referred to in</b> adopted pursuant to paragraph 1 of this Article, <b>or parts thereof</b> , may be used for assessing and declaring the performance of construction products covered by those <b>standards or</b> common specifications in relation to their  | 3. Without prejudice to Articles 4 and 6, the methods and the criteria provided in the <u>standards or</u> common specifications <del>adopted pursuant to</del> <u>referred to in</u> paragraph 1, <del>or parts thereof of this Article</del> , may be used for assessing and declaring the performance of construction products covered by those <u>standards or</u> common specifications in relation to their   |

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|   |   |   | essential characteristics.<br><b>Declaration of performance based on the standards or the common specifications referred to in the implementing act referred to in paragraph 1 shall automatically cease to apply on the day the Single Market Emergency mode expires or is deactivated.</b>   | essential characteristics. <u>Declaration of performance based on the standards or the common specifications referred to in the implementing act referred to in paragraph 1 shall automatically cease to apply on the day the internal market emergency mode expires or is deactivated.</u>   |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (4) |   |   |  |   |
| 264   | 4. By way of derogation from Article 59a(3), first subparagraph, declaration of performance in compliance with the common specifications referred to in paragraph 1 of this Article regarding construction products which have been placed on the market shall not be affected by the subsequent expiry or repeal of the implementing act, which has laid down those common specifications, unless there is sufficient reason to believe that construction products covered by those common specifications present a risk or do not achieve the declared performance. | 4. By way of derogation from Article 59a(3), first subparagraph, declaration of performance in compliance with the common specifications referred to in paragraph 1 of this Article regarding construction products which have been placed on the market shall not be affected by the subsequent expiry or repeal of the implementing act, which has laid down those common specifications, unless there is sufficient reason to believe that construction products covered by those common specifications present a risk or do not achieve the declared performance. | 4. By way of derogation from Article 59a(3), first subparagraph, <del>declaration of performance in compliance with the</del> <b>unless there is sufficient reason to believe that construction products covered by those standards or common specifications referred to in paragraph 1 of this Article regarding</b> <b>present a risk to the health and safety or fail to achieve the declared performance, declaration of performance of</b> construction products which have been placed on the market <del>shall not be affected by the subsequent expiry or repeal of the implementing act, which has laid down those common specifications, unless there is sufficient reason to believe that</del> <b>construction products covered by those common specifications present a risk or do not achieve the declared</b> | 4. By way of derogation from Article 59a(3), <del>first subparagraph, declaration of performance in compliance with the</del> <b>unless there is sufficient reason to believe that construction products covered by the standards or common specifications referred to in paragraph 1</b> <b>present a risk to the health or safety of persons or fail to achieve the declared performance, the declaration of performance of</b> <del>this Article regarding</del> construction products which have been placed on the market <del>shall not be affected by the subsequent expiry or repeal of the implementing act, which has laid down those common specifications, unless there is sufficient reason to believe that construction products covered by those common specifications present a risk or do not achieve the declared</del> |



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|   |   |  | performance in compliance with the standards or common specifications referred to in paragraph 1 shall remain valid after the expiry or repeal of the implementing act adopted pursuant to paragraph 2 and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation].   | <del>performance</del> <u>in compliance with the standards or common specifications referred to in paragraph 1 shall remain valid after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 and after the expiry or deactivation of the internal market emergency mode in accordance with the IMERA Regulation.</u>  |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (5) |   |  |   |  |
| 265   | 5. When a Member State considers that a common specification referred to in paragraph 1 is incorrect in terms of criteria and methods for the assessment of performance in relation to essential characteristics, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information and, if appropriate, amend or withdraw the implementing act establishing the common specification in question | 5. When a Member State considers that a common specification referred to in paragraph 1 is incorrect in terms of criteria and methods for the assessment of performance in relation to essential characteristics, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information. <u>The Commission may</u> <del>and, if appropriate,</del> amend, <u>where appropriate,</u> <del>or withdraw</del> the implementing act establishing the common specification in question. | 5. When a Member State considers that a <b>standard or</b> common specification referred to in paragraph 1 is incorrect in terms of criteria and methods for the assessment of performance in relation to essential characteristics, it shall inform the Commission thereof <del>with</del> <u>by submitting</u> a detailed explanation and the Commission shall assess that information <del>and</del> <b>detailed explanation</b> and, if appropriate, amend or <del>withdraw</del> <b>repeal</b> the implementing <del>act</del> <b>listing the standard or</b> establishing the common specification in question. | 5. When a Member State considers that a <u>standard or</u> common specification referred to in paragraph 1 is incorrect in terms of criteria and methods for the assessment of performance in relation to essential characteristics, it shall inform the Commission thereof <del>with</del> <u>by submitting</u> a detailed explanation <del>and</del> . The Commission shall assess that <del>information and, if</del> <u>detailed explanation and, may, where</u> appropriate, amend or <del>withdraw</del> <u>repeal</u> the implementing <del>act</del> <u>listing the standard or</u> establishing the common specification in question. |
| Article 5, first paragraph, point (1), amending provision, Article                |   |  |   |  |
| 266   |   |  |   |  |



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|  | Article 59e<br>Adoption of mandatory common specifications  | <i>deleted</i> | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 5, first paragraph, point (1), amending provision, numbered paragraph (1)</i> |   |                |                 |                 |
| 267  | 1. In duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the methods and the criteria for assessing the performance of construction products which have been designated as crisis-relevant goods.   | <i>deleted</i> | <i>deleted</i>  | <i>deleted</i>  |
| <i>Article 5, first paragraph, point (1), amending provision, numbered paragraph (2)</i> |   |                |                 |                 |
| 268  | 2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the Standing Committee on Construction and in accordance with the examination procedure referred to in Article 64(2a). They shall apply to construction products placed on the market until the last day of the period for which the Single Market emergency remains active. In the early preparation of the draft implementing acts establishing the common specifications, the Commission shall gather the views of relevant bodies or expert groups | <i>deleted</i> | <i>deleted</i>  | <i>deleted</i>  |

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|  | established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.   |   |  |  |
| <i>Article 5, first paragraph, point (1), amending provision, numbered paragraph (3)</i> |   |   |  |  |
| 269  | 3. By way of derogation from Article 59a(3), first subparagraph, unless there is sufficient reason to believe that the construction products covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the construction products in compliance with those common specifications which have been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation]. | <i>deleted</i>  | <i>deleted</i>   | <i>deleted</i>   |
| <i>Article 5, first paragraph, point (1), amending provision, Article</i>                |   |   |  |  |
| 270  | Article 59f<br>Prioritisation of market surveillance activities and mutual assistance among authorities   | Article 59f<br>Prioritisation of market surveillance activities and mutual assistance among authorities | <b>Article 59f</b><br><del>Article 59f</del><br>Prioritisation of market surveillance activities and mutual assistance | <b>Article 59f</b><br><del>Article 59f</del><br>Prioritisation of market surveillance activities and mutual assistance |

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|   |   |  | among authorities   | among authorities<br>Text Origin: Council Mandate  |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (1) |   |  |   |  |
| 271   | 1. Member States shall prioritise the market surveillance activities for construction products designated as crisis-relevant goods.   | 1. Member States shall prioritise the market surveillance activities for construction products designated as crisis-relevant goods.  | 1. Member States shall prioritise the market surveillance activities for construction products designated as crisis-relevant goods. <b>The Commission shall facilitate coordination of these efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.</b>  | 1. Member States shall prioritise the market surveillance activities for construction products designated as crisis-relevant goods. <u>The Commission shall facilitate coordination of these efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.</u>   |
| Article 5, first paragraph, point (1), amending provision, numbered paragraph (2) |   |  |   |  |
| 272   | 2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for construction products designated as crisis-relevant goods. | 2. The market surveillance authorities of the Member States shall <del>deploy their</del> <u>ensure</u> best efforts <u>are made</u> to provide assistance to other market surveillance authorities during <del>a Single</del> <u>an internal</u> market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for construction products designated as crisis-relevant goods. | 2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for construction products designated as crisis-relevant goods. | 2. The market surveillance authorities of the Member States shall <del>deploy their</del> <u>ensure that</u> best efforts <u>are made</u> to provide assistance to other market surveillance authorities during a <del>Single</del> <u>internal</u> market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for construction products designated |

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|      |  |  |  | as crisis-relevant goods.  |
|      | Article 5, first paragraph, point (2)  |  |  |  |
| 273  | (2) In Article 64, the following paragraph 2a is inserted:   | (2) In Article 64, the following paragraph 2a is inserted:   | (2) In Article 64, the following paragraph 2a is inserted:   | (2) In Article 64, the following paragraph 2a is inserted:<br><br>Text Origin: Commission Proposal   |
|      | Article 5, first paragraph, point (2), amending provision, first paragraph                           |  |  |  |
| 274  | 2a. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply. | 2a. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply. | 2a. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply. | 2a. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.<br><br>Text Origin: Commission Proposal |
|      | Article 5a   |  |  |  |
| 274a |  |  | <b>Article 5a</b><br><b>Amendments to Regulation (EU)</b><br><b>2023/1230</b>                        | <u><b>Article 5a</b></u><br><u><b>Amendments to Regulation (EU)</b></u><br><u><b>2023/1230</b></u><br><br>Text Origin: Council Mandate       |
|      | Article 5a, first paragraph  |  |  |  |
| 274b |  |  | <b>Regulation (EU) 2023/1230 is amended as follows:</b>  | <u><b>Regulation (EU) 2023/1230 is amended as follows:</b></u>   |

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|  |                     |            |   | Text Origin: Council Mandate  |
| Article 5a, first paragraph, point (1)                                       |                     |            |   |   |
| 274c   |                     |            | (1) In Article 3 the following points is are added:   | <u>(1) In Article 3 the following points are added:</u><br>Text Origin: Council Mandate   |
| Article 5a, first paragraph, point (1), amending provision, first paragraph  |                     |            |   |   |
| 274d   |                     |            | "<br>(37) 'crisis-relevant goods' means 'crisis-relevant goods' within the meaning of Article 3, point (6) of Regulation (EU) .../.... [SMEI Regulation]; | <u>(37) 'crisis-relevant goods' means 'crisis-relevant goods' within the meaning of Article 3, point (6) of Regulation (EU) .../.... [IMERA Regulation];</u><br>Text Origin: Council Mandate        |
| Article 5a, first paragraph, point (1), amending provision, second paragraph |                     |            |   |   |
| 274e   |                     |            | (38) 'Single Market Emergency' means 'Single Market Emergency' within the meaning of Article 3, point (3) of Regulation (EU) .../... [SMEI Regulation].;  | <u>(38) 'internal market emergency' means 'internal market emergency' within the meaning of Article 3, point (3) of Regulation (EU) .../... [IMERA Regulation];</u><br>Text Origin: Council Mandate |
| Article 5a, first paragraph, point (2)                                       |                     |            |   |   |
| 274f   |                     |            |   |   |

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|  |                     |            | (2) The following Chapter IVa is inserted after Chapter IV:   | <u>(2) The following Chapter IVa is inserted after Chapter IV:</u><br>Text Origin: Council Mandate  |
| Article 5a, first paragraph, point (2), amending provision, chapter i  |                     |            |   |   |
| 274g   |                     |            | Chapter IVa<br>"EMERGENCY PROCEDURES"   | <u>Chapter IVa</u><br><u>EMERGENCY PROCEDURES</u><br>Text Origin: Council Mandate   |
| Article 5a, first paragraph, point (2), amending provision, article    |                     |            |   |   |
| 274h   |                     |            | Article 25a<br>Application of emergency procedures  | <u>Article 25a</u><br><u>Application of emergency procedures</u><br>Text Origin: Council Mandate  |
| Article 5a, first paragraph, point (2), amending provision, article(1) |                     |            |   |   |
| 274i   |                     |            | 1. Articles 25b to 25e shall only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to machinery and related products covered by this Regulation. | <u>1. Articles 25b to 25e of this Regulation shall only apply if the Commission has adopted an implementing act pursuant to Article 26 of the IMERA Regulation.</u> |
| Article 5a, first paragraph, point (2), amending provision, article(2) |                     |            |   |   |

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| 274j   |                     |            | 2. Articles 25b to 25e apply exclusively to machinery and related products, which have been designated as crisis-relevant goods pursuant to Article 14 of [the SMEI Regulation].                                    | <u>2. Articles 25b to 25e apply exclusively to machinery and related products, which have been designated as crisis-relevant goods pursuant to Article 14(5) of the IMERA Regulation.</u>                                   |
| Article 5a, first paragraph, point (2), amending provision, article(3) |                     |            |   |   |
| 274k   |                     |            | 3. Articles 25b to 25e, except as regards the power of the Commission in Article 25d(5), shall apply only during the Single Market emergency mode activated in accordance with Article 14 of [the SMEI Regulation]. | <u>3. Articles 25b to 25e, except as regards the power of the Commission in Article 25d(5), shall apply only during the internal market emergency mode activated in accordance with Article 14 of the IMERA Regulation.</u> |
| Article 5a, first paragraph, point (2), amending provision, article(4) |                     |            |   |   |
| 274l   |                     |            | However, Article 25c(4) shall apply during the Single Market emergency mode and after its deactivation or expiry.   | <u>4. However, Article 25c(4) shall apply during the internal market emergency mode and after its deactivation or expiry.</u>   |
| Article 5a, first paragraph, point (2), amending provision, article(5) |                     |            |   |   |
| 274m   |                     |            | 4. The Commission may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures to be followed and the specific labelling and traceability requirements with              | <u>5. The Commission may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures to be followed and the specific labelling and traceability requirements with</u>               |

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|  |                     |            | respect to machinery and related products placed on the market or put into service in accordance with Articles 25c to 25d. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(3).                 | <u>respect to machinery and related products placed on the market or put into service in accordance with Articles 25c to 25d. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(3).</u>                 |
| Article 5a, first paragraph, point (2), amending provision, article    |                     |            |  |   |
| G  | 274n                |            | <b>Article 25b</b><br>Prioritisation of the conformity assessment of crisis-relevant machinery and related products  | <u><b>Article 25b</b></u><br><u>Prioritisation of the conformity assessment of crisis-relevant machinery and related products</u><br><br>Text Origin: Council Mandate   |
| Article 5a, first paragraph, point (2), amending provision, article(1) |                     |            |  |   |
| G  | 274o                |            | <b>1. This Article shall apply to all types of machinery and related products designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 25 requiring mandatory involvement of a notified body.</b> | <u><b>1. This Article shall apply to all types of machinery and related products designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 25 requiring mandatory involvement of a notified body.</b></u> |
| Article 5a, first paragraph, point (2), amending provision, article(2) |                     |            |  |   |
| G  | 274p                |            | <b>2. The notified bodies shall process all applications for</b>   | <u><b>2. The notified bodies shall make best efforts to process all</b></u>   |



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|  |                     |            | conformity assessment of machinery and related products designated as crisis-relevant goods as a matter of priority, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 25a. | <u>applications for conformity assessment of machinery and related products designated as crisis-relevant goods as a matter of priority, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 25a.</u> |
| Article 5a, first paragraph, point (2), amending provision, article(3) |                     |            |  |  |
| 274q   |                     |            | 3. The prioritisation of applications for conformity assessment of machinery and related products pursuant to paragraph 2 shall not give rise to disproportionate additional costs for the manufacturers, who have lodged those applications.          | <u>3. The prioritisation of applications for conformity assessment of machinery and related products pursuant to paragraph 2 shall not give rise to additional disproportionate additional costs for the manufacturers, who have lodged those applications.</u>                |
| Article 5a, first paragraph, point (2), amending provision, article(4) |                     |            |  |  |
| 274r   |                     |            |  | <u>4. The notified bodies shall make reasonable efforts to increase their testing capacities for machinery and related products designated as crisis-relevant goods in respect of which they have been notified.</u>   |
| Article 5a, first paragraph, point (2), amending provision, article    |                     |            |  |  |
| 274s   |                     |            | Article 25c  | <u>Article 25c</u>   |

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|  |                     |            | Derogation from conformity assessment procedures requiring mandatory involvement of a notified body  | <u>Derogation from conformity assessment procedures requiring mandatory involvement of a notified body</u><br><br>Text Origin: Council Mandate   |
| Article 5a, first paragraph, point (2), amending provision, article(1) |                     |            |  |  |
| 274t   |                     |            | 1. By way of derogation from Article 25, any competent national authority may authorise, on a duly justified request, the placing on the market or putting into service within the territory of the Member State concerned, of specific machinery and related products which have been designated as crisis-relevant goods and for which the conformity assessment procedures requiring the mandatory involvement of a notified body, referred to in Article 25, have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated in accordance with procedures referred to in that authorisation. | <u>1. By way of derogation from Article 25, any competent national authority may authorise, on a duly justified request from an economic operator, the placing on the market or putting into service within the territory of the Member State concerned, of specific machinery or related products which have been designated as crisis-relevant goods and for which the conformity assessment procedures requiring the mandatory involvement of a notified body, referred to in Article 25, have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated in accordance with procedures referred to in that authorisation.</u> |
| Article 5a, first paragraph, point (2), amending provision, article(2) |                     |            |  |  |
| 274u   |                     |            | 1b. On duly justified imperative   | <u>1b. On duly justified imperative</u>  |

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|  |                     |            | grounds of urgency relating to the need to preserve the health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 48(4).   | <u>grounds of urgency relating to the need to preserve the health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 48(4).</u>   |
| Article 5a, first paragraph, point (2), amending provision, article(3) |                     |            |  |   |
| 274v   |                     |            | 2. The manufacturer of machinery or the related products subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the machinery or the related products concerned comply with all the applicable essential requirements set out in Annex III and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the competent national authority. | <u>2. The manufacturer of machinery or the related products subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the machinery or the related products concerned comply with all the applicable essential requirements set out in Annex III and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the competent national authority.</u> |
| Article 5a, first paragraph, point (2), amending provision, article(4) |                     |            |  |   |
| 274w   |                     |            | 3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the machinery or the related products may be placed on the market or   | <u>3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the machinery or the related products may be placed on the market or put into service. The</u>   |

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|         |   |            | put into service. The authorisation shall at least set out the following:  | <u>authorisation shall at least set out the following:</u>  |
|         | Article 5a, first paragraph, point (2), amending provision, article(4), point (a) |            |  |   |
| G 274x  |   |            | (a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;  | <u>(a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;</u>  |
|         | Article 5a, first paragraph, point (2), amending provision, article(4), point (b) |            |  |   |
| G 274y  |   |            | (b) any specific requirements regarding the traceability of the machinery and the related products concerned;  | <u>(b) any specific requirements regarding the traceability of the machinery and the related products concerned;</u>  |
|         | Article 5a, first paragraph, point (2), amending provision, article(4), point (c) |            |  |   |
| G 274z  |   |            | (c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated in accordance with Article 14 [the SMEI Regulation]; | <u>(c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the internal market emergency mode has been activated in accordance with Article 14 of the IMERA Regulation;</u> |
|         | Article 5a, first paragraph, point (2), amending provision, article(4), point (d) |            |  |   |
| G 274aa |   |            | (d) any specific requirements regarding the need to ensure the   | <u>(d) any specific requirements regarding the need to ensure the</u>   |

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|         |   |            | continuous conformity assessment with respect to the machinery and the related products concerned;   | <u>continuous conformity assessment with respect to the machinery and the related products concerned;</u>   |
|         | Article 5a, first paragraph, point (2), amending provision, article(4), point (e) |            |  |   |
| G 274ab |   |            | (e) measures to be taken with respect to the machinery or the related products placed on the market upon expiry of the Single Market emergency.  | <u>(e) measures to be taken with respect to the machinery or the related products placed on the market upon expiry of the internal market emergency.</u>  |
|         | Article 5a, first paragraph, point (2), amending provision, article(5)            |            |  |   |
| G 274ac |   |            | 4. By way of derogation from Articles 4, 23 and 24, machinery or the related products, for which an authorisation has been granted in accordance with paragraph 1 shall not bear the CE marking and Article 4 shall not apply.   | <u>4. By way of derogation from Articles 4, 23 and 24, machinery or the related products, for which an authorisation has been granted in accordance with paragraph 1 shall not bear the CE marking and Article 4 shall not apply.</u>   |
|         | Article 5a, first paragraph, point (2), amending provision, article(6)            |            |  |   |
| G 274ad |   |            | 6. The use of the authorisation procedure set out in paragraphs 1 to 1c does not affect the application of the relevant conformity assessment procedures laid down in Article 25 on the territory of the Member State concerned. | <u>6. The use of the authorisation procedure set out in paragraphs 1 to 1c does not affect the application of the relevant conformity assessment procedures laid down in Article 25 on the territory of the Member State concerned.</u> |

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|       | Article 5a, first paragraph, point (2), amending provision, article(7), first subparagraph |            |   |  |
| 274ae |  |            | <p>1a. The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure the conformity with the essential requirements laid down in Annex III to this Regulation, the Commission shall without delay adopt an implementing act extending for a limited period of time the validity of the authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the specific machinery or the related products may be placed on the market or put into service. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 48(3).</p> | <p><u>2. The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure the conformity with the applicable essential requirements laid down in Annex III to this Regulation, the Commission shall without delay adopt an implementing act extending for a limited period of time the validity of the authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the specific machinery or the related products may be placed on the market or put into service. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 48(3).</u></p> |

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|       |   |            |  |   |
|       | Article 5a, first paragraph, point (2), amending provision, article(7), second subparagraph |            |  |   |
| 274af |   |            | <p>The specific machinery or the related products subject to the extension of validity referred to in the first subparagraph shall bear the information that they are placed on the market or put into service as a “crisis-relevant goods”. The implementing act referred to in the first subparagraph shall specify the modalities of that information. That information, as well as any labelling, shall be clear, understandable and intelligible and, where relevant, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.</p> | <p><u>The specific machinery or the related products subject to the extension of validity referred to in the first subparagraph shall bear the information that they are placed on the market or put into service as a “crisis-relevant goods”. The implementing act referred to in the first subparagraph shall specify the modalities of that information. That information, as well as any labelling, shall be clear, understandable and intelligible and, where relevant, in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.</u></p> |
|       | Article 5a, first paragraph, point (2), amending provision, article(8), first subparagraph  |            |  |   |
| 274ag |   |            | <p>1c. As long as an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member</p>   | <p><u>1c. As long as an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national</u></p>   |



|   | Commission Proposal | EP Mandate | Council Mandate  | Draft Agreement   |
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|   |                     |            | States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act.   | <u>authorities have recognised the validity of that authorisation before the adoption of the said implementing act.</u>   |
| Article 5a, first paragraph, point (2), amending provision, article(8), second subparagraph |                     |            |  |   |
| 274ah   |                     |            | Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.   | <u>Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.</u>   |
| Article 5a, first paragraph, point (2), amending provision, article(9), first subparagraph  |                     |            |  |   |
| 274ai   |                     |            | 5. The market surveillance authorities of a Member State, where an authorisation pursuant to paragraphs 1, 1a and 1c is valid shall be entitled to take all corrective and restrictive actions at national level provided for under Regulation (EU) 2019/1020 and under this Regulation with respect to such machinery and the related products. | <u>5. The market surveillance authorities of a Member State, where an authorisation pursuant to paragraphs 1, 1a and 1c is valid shall be entitled to take all corrective and restrictive actions at national level provided for under Regulation (EU) 2019/1020 and under this Regulation with respect to such machinery and the related products.</u> |
| Article 5a, first paragraph, point (2), amending provision, article(9), second subparagraph |                     |            |  |   |
| 274aj   |                     |            | They shall immediately inform the Commission and the market surveillance authorities of other  | <u>They shall immediately inform the Commission and the market surveillance authorities of other</u>  |



|       | Commission Proposal   | EP Mandate | Council Mandate   | Draft Agreement   |
|-------|---|------------|---|---|
|       |   |            | Member States of these actions.   | <u>Member States of these actions.</u>  |
|       | Article 5a, first paragraph, point (2), amending provision, article               |            |   |   |
| 274ak |   |            | Article 25d<br>Presumption of conformity based on standards and common specifications   | <u>Article 25d</u><br><u>Presumption of conformity based on standards and common specifications</u><br><br>Text Origin: Council Mandate   |
|       | Article 5a, first paragraph, point (2), amending provision, article(1)            |            |   |   |
| 274al |   |            | 1. Where machinery or the related products have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts, listing appropriate standards or establishing common specifications for such machinery or the related products to cover the essential requirements set out in Annex III in either of the following cases: | <u>1. Where machinery or the related products have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts, listing appropriate standards or establishing common specifications for such machinery or the related products to cover the applicable essential requirements set out in Annex III in either of the following cases:</u> |
|       | Article 5a, first paragraph, point (2), amending provision, article(1), point (a) |            |   |   |
| 274am |   |            | (a) no reference to harmonised standards covering the relevant essential requirements set out in Annex III is published in the Official Journal of the European   | <u>(a) no reference to harmonised standards covering the relevant essential requirements set out in Annex II is published in the Official Journal of the European</u>   |

|   | Commission Proposal  | EP Mandate | Council Mandate  | Draft Agreement   |
|---|--|------------|--|---|
|   |  |            | Union in accordance with Regulation (EU) No 1025/2012;   | <u>Union in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period; or</u> |
|   | Article 5a, first paragraph, point (2), amending provision, article(1), point (aa) |            |  |   |
| G | 274an  |            |  | deleted   |
|   | Article 5a, first paragraph, point (2), amending provision, article(1), point (ab) |            |  |   |
| G | 274ao  |            |  | deleted   |
|   | Article 5a, first paragraph, point (2), amending provision, article(1), point (ac) |            |  |   |
| G | 274ap  |            |  | deleted   |
|   | Article 5a, first paragraph, point (2), amending provision, article(1), point (ad) |            |  |   |
| G | 274aq  |            |  | deleted   |
|   | Article 5a, first paragraph, point (2), amending provision, article(1), point (b)  |            |  |   |
| G | 274ar  |            | (b) severe disruptions in the functioning of the Single Market, which led to the activation of the | <u>(b) severe disruptions in the functioning of the internal market, which led to the activation of the</u>                                   |

|   | Commission Proposal | EP Mandate | Council Mandate  | Draft Agreement   |
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|   |                     |            | Single Market emergency mode in accordance with Article 14 of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex I in this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012. | <u>internal market emergency mode in accordance with Article 14 of the IMERA Regulation, significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant applicable essential requirements set out in Annex I in this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.</u>   |
| Article 5a, first paragraph, point (2), amending provision, article(2)            |                     |            |  |   |
| 274as   |                     |            | 1a. The implementing acts referred to in paragraph 1 may:  | <u>1a. The implementing acts referred to in paragraph 1 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international or national standards or, if there is no relevant applicable European, international or national standard, may establish common specifications.</u> |
| Article 5a, first paragraph, point (2), amending provision, article(2), point (a) |                     |            |  |   |
| 274at   |                     |            |  |   |

|   | Commission Proposal | EP Mandate | Council Mandate   | Draft Agreement |
|---|---------------------|------------|---|-----------------|
|   |                     |            | (a) publish the references to relevant applicable international standards that provide presumption of conformity in accordance with paragraph 3;  | <i>deleted</i>  |
| Article 5a, first paragraph, point (2), amending provision, article(2), point (b) |                     |            |   |                 |
| 274au   |                     |            | (b) if there is no relevant applicable international standards as referred to in point a of this paragraph that cover the essential requirements set out in Annex III to this Regulation, publish the references to the European standards that provide presumption of conformity in accordance with paragraph 3;               | <i>deleted</i>  |
| Article 5a, first paragraph, point (2), amending provision, article(2), point (c) |                     |            |   |                 |
| 274av   |                     |            | (c) if there is no relevant applicable international or European standard as referred to in points a and b, that cover the essential requirements set out in Annex III to this Regulation, establish common specifications established by the Commission that provide presumption of conformity in accordance with paragraph 3; | <i>deleted</i>  |
| Article 5a, first paragraph, point (2), amending provision, article(2), point (d) |                     |            |   |                 |

|  | Commission Proposal | EP Mandate | Council Mandate   | Draft Agreement  |
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| 274aw  |                     |            | (d) if there is no relevant applicable international standard, European standard or common specifications as referred to in points a, b and c, publish the reference to national standards that provide presumption of conformity in accordance with paragraph 3.   | <i>deleted</i>   |
| Article 5a, first paragraph, point (2), amending provision, article(3) |                     |            |   |  |
| 274ax  |                     |            | 2. The implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 48(3). They shall apply until the last day of the period for which the Single Market emergency mode remains active, unless amended or repealed in accordance with paragraph 5. | <u>2. The implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 48(3). They shall apply until the last day of the period for which the Single Market emergency mode remains active, unless amended or repealed in accordance with paragraph 5.</u> |
| Article 5a, first paragraph, point (2), amending provision, article(4) |                     |            |   |  |
| 274ay  |                     |            | 2a. Before preparing the draft implementing act referred to in paragraph 1, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have   | <u>2a Before preparing the draft implementing act referred to in paragraph 1, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the</u>   |

|  | Commission Proposal | EP Mandate | Council Mandate  | Draft Agreement   |
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|  |                     |            | been fulfilled. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or expert group established under the Regulation.  | <u><i>draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or expert group established under the Regulation.</i></u>  |
| Article 5a, first paragraph, point (2), amending provision, article(5) |                     |            |  |   |
| 274az  |                     |            | 3. Without prejudice to Article 20, machinery and the related products which are in conformity with the standards or common specifications referred to in paragraph 1, or parts thereof, shall be presumed to be in conformity with the essential requirements set out in Annex III covered by those standards, common specifications or parts thereof. The presumption of conformity provided by the standards or the common specifications referred to in the implementing act referred to in paragraph 1 shall automatically cease to apply on the date the Single Market Emergency mode expires or is deactivated. | <u><i>3. Without prejudice to Article 20, machinery and the related products which are in conformity with the standards or common specifications referred to in paragraph 1, or parts thereof, shall be presumed to be in conformity with the applicable essential requirements set out in Annex III covered by those standards, common specifications or parts thereof. The presumption of conformity provided by the standards or the common specifications referred to in the implementing act referred to in paragraph 1 shall automatically cease to apply on the date the internal market emergency mode expires or is deactivated.</i></u> |
| Article 5a, first paragraph, point (2), amending provision, article(6) |                     |            |  |   |
| 274ba  |                     |            | 4. By way of derogation from Article 25a(3), first subparagraph,   | <u><i>4. By way of derogation from Article 25a(3), first subparagraph,</i></u>  |

|  | Commission Proposal | EP Mandate | Council Mandate  | Draft Agreement   |
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|  |                     |            | <p>unless there is sufficient reason to believe that the machinery and the related products covered by the standards or common specifications referred to in paragraph 1 present a risk to the health or safety of persons, the machinery and the related products which are in conformity with those standards or common specifications and which have been placed on the market or put into service shall be deemed compliant with the essential requirements set out in Annex III to this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation].</p> | <p><u>unless there is sufficient reason to believe that the machinery and the related products covered by the standards or common specifications referred to in paragraph 1 present a risk to the health or safety of persons, the machinery and the related products which are in conformity with those standards or common specifications and which have been placed on the market or put into service shall be deemed compliant with the applicable essential requirements set out in Annex III to this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 and after the expiry or deactivation of the internal market emergency mode in accordance with the IMERA Regulation.</u></p> |
| Article 5a, first paragraph, point (2), amending provision, article(7) |                     |            |  |   |
| 274bb  |                     |            | <p>5. When a Member State considers that a standard or common specification referred to in paragraph 1 does not entirely satisfy the essential requirements set out in Annex III, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and, if</p>   | <p><u>5. When a Member State considers that a standard or common specification referred to in paragraph 1 does not entirely satisfy the applicable essential requirements set out in Annex III, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation</u></p>  |

|       | Commission Proposal  | EP Mandate | Council Mandate  | Draft Agreement   |
|-------|--|------------|--|---|
|       |  |            | appropriate, amend or repeal the implementing act listing the standard or establishing the common specification in question.   | <u>and, if appropriate, amend or repeal the implementing act listing the standard or establishing the common specification in question.</u>   |
|       | Article 5a, first paragraph, point (2), amending provision, article    |            |  |   |
| 274bc |  |            | Article 25e<br>Prioritisation of market surveillance activities and mutual assistance among authorities  | <u>Article 25e</u><br><u>Prioritisation of market surveillance activities and mutual assistance among authorities</u><br><br>Text Origin: Council Mandate   |
|       | Article 5a, first paragraph, point (2), amending provision, article(1) |            |  |   |
| 274bd |  |            | 1. The Member States shall prioritise the market surveillance activities for machinery and the related products designated as crisis-relevant goods. The Commission shall facilitate coordination of these efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020. | <u>1. The Member States shall prioritise the market surveillance activities for machinery and the related products designated as crisis-relevant goods. The Commission shall facilitate coordination of these efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.</u> |
|       | Article 5a, first paragraph, point (2), amending provision, article(2) |            |  |   |
| 274be |  |            | 2. The market surveillance authorities of the Member States shall deploy their best efforts to   | <u>2. The market surveillance authorities of the Member States shall deploy their best efforts to</u>   |



|                             | Commission Proposal  | EP Mandate   | Council Mandate   | Draft Agreement   |
|-----------------------------|--|--|---|---|
|                             |  |  | provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for machinery and the related products designated as crisis-relevant goods. | <u>provide assistance to other market surveillance authorities during an internal market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for machinery and the related products designated as crisis-relevant goods.</u> |
| Article 6                   |  |  |   |   |
| 275                         | Article 6<br>Entry into force  | Article 6<br>Entry into force  | Article 6<br>Entry into force   | Article 6<br>Entry into force<br><br>Text Origin: Commission Proposal   |
| Article 6, first paragraph  |  |  |   |   |
| 276                         | This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. | This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. | This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.  | This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.<br><br>Text Origin: Commission Proposal  |
| Article 6, second paragraph |  |  |   |   |

|                            | Commission Proposal  | EP Mandate   | Council Mandate  | Draft Agreement   |
|----------------------------|--|--|--|---|
| 277                        | It shall apply from [OP- please insert the date identical to that of the entry into application of the SMEI Regulation]. | It shall apply from [OP- please insert the date identical to <del>that of the entry</del> <u>into the date of</u> application of the <del>SMEI</del> <u>IMERA</u> Regulation]. | It shall apply from [ <del>OP- please insert the date identical to that of the entry into application of the SMEI Regulation</del> <u>OP- please insert the date identical to that of the entry into application of the SMEI Regulation</u> ]. | It shall apply from [ <u>OP- please insert the date identical to that of the entry into application of the IMERA Regulation</u> <del>OP- please insert the date identical to that of the entry into application of the SMEI Regulation</del> ]. |
| Article 6, third paragraph |  |  |  |   |
| 278                        | This Regulation shall be binding in its entirety and directly applicable in all Member States.                           | This Regulation shall be binding in its entirety and directly applicable in all Member States.   | This Regulation shall be binding in its entirety and directly applicable in all Member States.   | This Regulation shall be binding in its entirety and directly applicable in all Member States.  |
| Formula                    |  |  |  |   |
| 279                        | Done at Brussels,  | Done at Brussels,  | Done at Brussels,  | Done at Brussels,<br>Text Origin: Commission Proposal   |
| Formula                    |  |  |  |   |
| 280                        | For the European Parliament  | For the European Parliament  | For the European Parliament  | For the European Parliament<br>Text Origin: Commission Proposal   |
| Formula                    |  |  |  |   |
| 281                        | The President  | The President  | The President  | The President<br>Text Origin: Commission  |

|     | Commission Proposal | EP Mandate      | Council Mandate | Draft Agreement                                   |
|-----|---------------------|-----------------|-----------------|---|
|     |                     |                 |                 | Proposal  |
|     | Formula             |                 |                 |   |
| 282 | For the Council     | For the Council | For the Council | For the Council<br>Text Origin: Council Mandate   |
|     | Formula             |                 |                 |   |
| 283 | The President       | The President   |                 | The President<br>Text Origin: Commission Proposal |

Brussels, 13 February 2024

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**Interinstitutional files:**

**2022/0279 (COD)**

**2022/0280 (COD)**

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**WK 2309/2024 REV 1**

**LIMITE**

**MI**

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**IND**

**CONSOM**

**CODEC**

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**NOTE**

|          |   |
|----------|---|
| From:    | Presidency  |
| To:      | Working Party on Competitiveness and Growth (Internal Market - Attachés)<br>Working Party on Technical Harmonisation (SMEI Omnibus)<br>Working Party on Competitiveness and Growth (Internal Market)  |
| Subject: | Proposal for a regulation of the European Parliament and of the Council amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011 as regards emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency<br>- 4-column table |

Delegations find attached the latest version of the 4-column table, reflecting the outcome of the latest technical meeting.

Compared to WK 2309/2024 INIT, the following lines were changed: 2, 21b, 69-69d, 118-118d, 167-167d, 260-260a, 274am-274aq.

Only technical changes (change of colour, correction of punctuation or cross-reference, deletion of a comment) were made to lines: 18, 21a-21e, 24, 25, 37, 87, 224h, 224j, 232, 274j, 274ad, 252.