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Contents

I *Legislative acts*

DECISIONS

- ★ **Decision (EU) 2023/1461 of the European Parliament and of the Council of 12 July 2023 providing macro-financial assistance to the Republic of North Macedonia** 1

II *Non-legislative acts*

REGULATIONS

- ★ **Council Regulation (EU) 2023/1462 of 17 July 2023 amending Regulation (EU) No 36/2012 concerning restrictive measures in view of the situation in Syria** 8
- ★ **Commission Implementing Regulation (EU) 2023/1463 of 10 July 2023 approving a modification of traditional terms in the wine sector in accordance with Article 115(2) of Regulation (EU) No 1308/2013 of the European Parliament and of the Council ('Landwein', 'Qualitätswein', 'Kabinett/Kabinettwein', 'Spätlese/Spätlesewein', 'Auslese/Auslesewein', 'Strohwein', 'Schilfwein', 'Eiswein', 'Ausbruch/Ausbruchwein', 'Trockenbeerenauslese', 'Beerenauslese/Beerenauslesewein')** 10
- ★ **Commission Regulation (EU) 2023/1464 of 14 July 2023 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards formaldehyde and formaldehyde releasers ⁽¹⁾** 12
- ★ **Commission Implementing Regulation (EU) 2023/1465 of 14 July 2023 providing for emergency financial support for the agricultural sectors affected by specific problems impacting on the economic viability of agricultural producers** 21

⁽¹⁾ Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

★ Commission Implementing Regulation (EU) 2023/1466 of 14 July 2023 amending Annexes V, XIV, XV and XIX to Implementing Regulation (EU) 2021/404 as regards the entries for Canada, Namibia, the United Kingdom and the United States in the lists of third countries authorised for the entry into the Union of consignments of poultry, germinal products of poultry, fresh meat of poultry and game birds, meat products of poultry and wild game birds and eggs and egg products ⁽¹⁾	28
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DECISIONS

★ Council Decision (CFSP) 2023/1467 of 14 July 2023 amending Decision 2013/255/CFSP concerning restrictive measures in view of the situation in Syria	41
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RECOMMENDATIONS

★ Commission Recommendation (EU) 2023/1468 of 10 May 2023 on voluntary EU performance requirements for metal detection equipment used in public spaces (outside aviation)	43
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⁽¹⁾ Text with EEA relevance.

I

(Legislative acts)

DECISIONS

DECISION (EU) 2023/1461 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**of 12 July 2023****providing macro-financial assistance to the Republic of North Macedonia**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 212(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure ⁽¹⁾,

Whereas:

- (1) Relations between the Union and the Republic of North Macedonia (North Macedonia) continue to develop within the framework of the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and the former Yugoslav Republic of Macedonia, of the other part ⁽²⁾ (the 'Stabilisation and Association Agreement'). Accession negotiations between the Union and North Macedonia were launched on 19 July 2022.
- (2) The economy of North Macedonia has been significantly affected by the recession in 2020, which was caused by the COVID-19 pandemic, as well as by the recent energy crisis. Those circumstances have contributed to the country's sizeable financing gap, deteriorating external position and growing fiscal needs.
- (3) The government of North Macedonia has demonstrated a strong commitment to implementing further reforms, focusing on key policy areas identified in the Joint Conclusions of the Economic and Financial Dialogue between the EU and the Western Balkans and Turkey of 24 May 2022 and including fundamental areas such as the judiciary, the fight against corruption and organised crime, good governance and the rule of law.
- (4) North Macedonia has successfully completed the macro-financial assistance operation in the context of the COVID-19 pandemic pursuant to Decision (EU) 2020/701 of the European Parliament and of the Council ⁽³⁾, as all reform actions agreed with the Union in the Memorandum of Understanding referred to in that Decision have been carried out.

⁽¹⁾ Position of the European Parliament of 13 June 2023 (not yet published in the Official Journal) and decision of the Council of 10 July 2023.

⁽²⁾ OJ L 84, 20.3.2004, p. 13.

⁽³⁾ Decision (EU) 2020/701 of the European Parliament and of the Council of 25 May 2020 on providing macro-financial assistance to enlargement and neighbourhood partners in the context of the COVID-19 pandemic (OJ L 165, 27.5.2020, p. 31).

- (5) In April 2022, the government of North Macedonia and the International Monetary Fund (IMF) reached a staff-level agreement on a 24-month precautionary and liquidity line for up to EUR 530 000 000, which was officially approved by the IMF Executive Board on 22 November 2022. The IMF programme aims to mitigate the worsening external situation, support fiscal consolidation and accelerate structural reforms in a number of areas, including tax policy and public investment.
- (6) In view of the worsening economic situation and outlook, North Macedonia first requested macro-financial assistance from the Union to complement the IMF programme, in April 2022. However, the Commission put that request on hold because the country's economy was still proving quite resilient at that time and there were some other financing options available to meet the 2022 external financing needs. The government of North Macedonia renewed its request for macro-financial assistance in October 2022.
- (7) Given that North Macedonia is a candidate country and has begun accession negotiations, it is considered eligible to receive macro-financial assistance from the Union.
- (8) The Union's macro-financial assistance to North Macedonia should be an exceptional financial instrument of untied and undesignated balance-of-payments support which aims to address North Macedonia's immediate external financing needs, and it should underpin the implementation of a policy programme containing strong immediate adjustment and structural reform measures designed to improve North Macedonia's balance-of-payments position in the short term.
- (9) Given that there are still significant residual external financing needs in North Macedonia's balance of payments, beyond the needs met by the resources provided by the IMF, the Union's macro-financial assistance to North Macedonia is, in the current exceptional circumstances, considered to be an appropriate response to the country's request for support in stabilising its economy, in conjunction with the IMF programme. The Union's macro-financial assistance would support the economic stabilisation and the structural reform agenda of North Macedonia, supplementing resources made available under the IMF's financial arrangement.
- (10) The Union's macro-financial assistance should aim to support the restoration of a sustainable external financing situation for North Macedonia, thereby supporting its economic and social development.
- (11) The Union's macro-financial assistance is expected to go hand-in-hand with the implementation of budget support operations under the Instrument for Pre-Accession Assistance pursuant to Regulation (EU) 2021/1529 of the European Parliament and of the Council ^(*).
- (12) The determination of the amount of the Union's macro-financial assistance to North Macedonia should be based on a quantitative assessment of the residual external financing needs of North Macedonia and takes into account the country's capacity to finance itself with its own resources, in particular the international reserves at its disposal. The Union's macro-financial assistance to North Macedonia should complement the programmes and resources provided by the IMF and the World Bank. The determination of the amount of the assistance should also take into account expected financial contributions from multilateral donors and the need to ensure fair burden sharing between the Union and other donors, as well as the pre-existing deployment of the Union's other external financing instruments in North Macedonia and the added value of the Union's overall involvement in North Macedonia.
- (13) The Commission should ensure that the Union's macro-financial assistance to North Macedonia is legally and substantially in accordance with the key principles and objectives of the different areas of external action, with the measures taken in respect of those areas, and with other relevant Union policies.

^(*) Regulation (EU) 2021/1529 of the European Parliament and of the Council of 15 September 2021 establishing the Instrument for Pre-Accession assistance (IPA III) (OJ L 330, 20.9.2021, p. 1).

- (14) The Union's macro-financial assistance should support the Union's external policy towards North Macedonia. The Commission and the European External Action Service should work closely together throughout the macro-financial assistance operation in order to coordinate, and ensure the consistency of, Union's external policy.
- (15) The Union's macro-financial assistance should support the commitment of North Macedonia to values shared with the Union, including democracy, the rule of law, good governance, respect for human rights, sustainable development and poverty reduction, as well as its commitment to the principles of open, rule-based and fair trade.
- (16) A precondition for granting the Union's macro-financial assistance should be that North Macedonia respect effective democratic mechanisms, including a multi-party parliamentary system, and the rule of law, and guarantee respect for human rights. In addition, the specific objectives of the Union's macro-financial assistance should strengthen the efficiency, transparency and accountability of the public finance management systems, as well as of the governance and supervision of the financial sector, in North Macedonia and should promote structural reforms that aim to support sustainable and inclusive growth, decent employment creation and fiscal consolidation. The Commission should regularly monitor the North Macedonia's fulfilment of that precondition and the achievement of those objectives.
- (17) In order to ensure that the Union's financial interests linked to its macro-financial assistance are protected efficiently, North Macedonia should take appropriate measures relating to the prevention of, and fight against, fraud, corruption and any other irregularities linked to that assistance. In addition, provision should be made for the Commission to carry out checks, for the Court of Auditors to carry out audits and for the European Public Prosecutor's Office to exercise its competences with regard to the provision of the Union's macro-financial assistance to North Macedonia.
- (18) The release of the Union's macro-financial assistance to North Macedonia is without prejudice to the powers of the European Parliament and the Council as budgetary authority.
- (19) The amounts of the Union's macro-financial assistance to North Macedonia provided in the form of loans should be consistent with the budgetary appropriations provided for in the multiannual financial framework.
- (20) The Union's macro-financial assistance to North Macedonia should be managed by the Commission. In order to ensure that the European Parliament and the Council are able to follow the implementation of this Decision, the Commission should regularly inform them of developments relating to that assistance and provide them with the relevant documents.
- (21) In order to ensure uniform conditions for the implementation of this Decision, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ⁽³⁾.
- (22) The Union's macro-financial assistance to North Macedonia should be subject to economic policy conditions, to be set out in a memorandum of understanding (MoU). In order to ensure uniform conditions of implementation and for reasons of efficiency, the Commission should be empowered to negotiate such conditions with the authorities of North Macedonia under the supervision of the committee of representatives of the Member States in accordance with Regulation (EU) No 182/2011. Under that Regulation, the advisory procedure should, as a general rule, apply in all cases other than as provided for in that Regulation. Considering the potentially significant impact of assistance of more than EUR 90 000 000, it is appropriate that the examination procedure as specified in Regulation (EU) No 182/2011 be used for operations above that threshold. Considering the amount of the Union's macro-financial assistance to North Macedonia, the examination procedure should apply to the adoption of the MoU, and to any reduction, suspension or cancellation of that assistance.

⁽³⁾ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

- (23) Given the limited amount of the financial assistance, namely EUR 100 000 000, its one-off nature, and the desired time frame of the disbursement, a back-to-back funding approach would ensure more flexibility and efficiency of the borrowing operations compared to the diversified funding strategy. Therefore, by way of exception, the Commission should fund the loan instalments on the capital market back-to-back rather than by means of the diversified funding strategy provided for in Article 220a of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ⁽⁶⁾. It is therefore appropriate to fund the macro-financial assistance to North Macedonia through individual financial transactions,

HAVE ADOPTED THIS DECISION:

Article 1

1. The Union shall make macro-financial assistance of a maximum amount of EUR 100 000 000 available to North Macedonia (the 'Union's macro-financial assistance'), with a view to supporting North Macedonia's economic stabilisation and substantive reform agenda. The entire amount of the assistance shall be provided in the form of loans. The release of the Union's macro-financial assistance is subject to the adoption of the Union budget for the relevant year by the European Parliament and the Council. The assistance shall contribute to covering the balance-of-payments needs of North Macedonia as identified in the IMF programme.
2. In order to finance the loan, the Commission shall be empowered, on behalf of the Union, to borrow the necessary funds on the capital markets or from financial institutions and to on-lend the corresponding amounts to North Macedonia under the conditions applicable to the borrowings. The loans shall have a maximum average maturity of 15 years.
3. The release of the Union's macro-financial assistance shall be managed by the Commission in a manner consistent with the agreements or understandings reached between the IMF and North Macedonia, and with the key principles and objectives of economic reforms set out in the Stabilisation and Association Agreement.

The Commission shall regularly inform the European Parliament and the Council of developments regarding the Union's macro-financial assistance, including disbursements thereof, and shall provide those institutions with the relevant documents in due time.

4. The Union's macro-financial assistance shall be made available for a period of two and a half years, starting from the first day after the entry into force of the MoU referred to in Article 3(1).
5. If the financing needs of North Macedonia decrease fundamentally during the period of the disbursement of the Union's macro-financial assistance compared to the initial projections, the Commission, acting in accordance with the examination procedure referred to in Article 7(2), shall reduce the amount of the assistance or suspend or cancel it.

Article 2

1. A precondition for granting the Union's macro-financial assistance shall be that North Macedonia respect effective democratic mechanisms, including a multi-party parliamentary system, and the rule of law, and guarantee respect for human rights.
2. The Commission shall monitor North Macedonia's fulfilment of the precondition set out in paragraph 1 throughout the life-cycle of the Union's macro-financial assistance.
3. Paragraphs 1 and 2 of this Article shall apply in accordance with Council Decision 2010/427/EU ⁽⁷⁾.

⁽⁶⁾ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

⁽⁷⁾ Council Decision 2010/427/EU of 26 July 2010 establishing the organisation and functioning of the European External Action Service (OJ L 201, 3.8.2010, p. 30).

Article 3

1. The Commission, in accordance with the examination procedure referred to in Article 7(2), shall agree with the authorities of North Macedonia on clearly defined economic policy and financial conditions, focusing on structural reforms and sound public finances, to which the Union's macro-financial assistance is to be subject. Those economic policy and financial conditions shall be set out in a memorandum of understanding (MoU) which shall include a time frame for the fulfilment of those conditions. Those economic policy and financial conditions shall be consistent with the agreements or understandings referred to in Article 1(3), including the macro-economic adjustment and structural reform programmes implemented by North Macedonia with the support of the IMF.
2. The conditions referred to in paragraph 1 shall aim, in particular, to enhance the efficiency, transparency and accountability of the public finance management systems in North Macedonia, including for the use of the Union's macro-financial assistance. Progress in mutual market opening, the development of rule-based and fair trade, and other priorities in the context of the Union's external policy shall also be duly taken into account when designing the policy measures. The Commission shall regularly monitor North Macedonia's progress in attaining those objectives.
3. The detailed financial terms of the Union's macro-financial assistance shall be laid down in a loan agreement to be concluded between the Commission and North Macedonia.
4. The Commission shall verify, at regular intervals, that the conditions referred to in Article 4(3) continue to be met, including whether the economic policies of North Macedonia are in accordance with the objectives of the Union's macro-financial assistance. For the purposes of that verification, the Commission shall coordinate closely with the IMF and the World Bank, and, where necessary, with the European Parliament and with the Council.

Article 4

1. Subject to the conditions referred to in paragraph 3, the Union's macro-financial assistance shall be made available by the Commission in two equal instalments.
2. The amounts of the Union's macro-financial assistance shall be provisioned, where required, in accordance with Regulation (EU) 2021/947 of the European Parliament and of the Council ⁽⁸⁾.
3. The Commission shall decide on the release of the instalments, subject to the fulfilment of the following conditions:
 - (a) the precondition set out in Article 2(1);
 - (b) a continuous satisfactory track record of implementing a policy programme that contains strong adjustment and structural reform measures supported by a non-precautionary IMF credit arrangement;
 - (c) the satisfactory implementation of the economic policy and financial conditions agreed in the MoU.
4. The release of the second instalment shall not, in principle, take place earlier than three months after the release of the first instalment.
5. Where the conditions referred to in paragraph 3 are not met, the Commission shall temporarily suspend or cancel the disbursement of the Union's macro-financial assistance. In such cases, it shall inform the European Parliament and the Council of the reasons for the suspension or cancellation.
6. The Union's macro-financial assistance shall be disbursed to the National Bank of North Macedonia. Subject to the agreed provisions set out in the MoU, including a confirmation of residual budgetary financing needs, the Union funds may be transferred to the Ministry of Finance of North Macedonia as the final beneficiary.

⁽⁸⁾ Regulation (EU) 2021/947 of the European Parliament and of the Council of 9 June 2021 establishing the Neighbourhood, Development and International Cooperation Instrument – Global Europe, amending and repealing Decision No 466/2014/EU of the European Parliament and of the Council and repealing Regulation (EU) 2017/1601 of the European Parliament and of the Council and Council Regulation (EC, Euratom) No 480/2009 (OJ L 209, 14.6.2021, p. 1).

Article 5

1. The borrowing and lending operations related to the Union's macro-financial assistance shall be carried out in euro using the same value date and shall not involve the Union in the transformation of maturities, or expose the Union to any exchange or interest rate risk, or to any other commercial risk.
2. Where the circumstances permit, and if North Macedonia so requests, the Commission may take the steps necessary to ensure that an early repayment clause is included in the loan terms and conditions and that it is matched by a corresponding clause in the terms and conditions of the borrowing operations.
3. Where circumstances permit an improvement of the interest rate of the loan, and if North Macedonia so requests, the Commission may decide to refinance all or part of its initial borrowings or may restructure the corresponding financial conditions. Refinancing or restructuring operations shall be carried out in accordance with paragraphs 1 and 4 and shall not have the effect of extending the maturity of the borrowings concerned or of increasing the amount of capital outstanding at the date of the refinancing or restructuring.
4. North Macedonia shall bear all costs incurred by the Union which relate to the borrowing and lending operations under this Decision.
5. The Commission shall inform the European Parliament and the Council of developments regarding the operations referred to in paragraphs 2 and 3.

Article 6

1. The Union's macro-financial assistance shall be implemented in accordance with Regulation (EU, Euratom) 2018/1046.
2. The Union's macro-financial assistance shall be implemented under direct management.
3. The loan agreement to be agreed with the authorities of North Macedonia shall contain all of the following provisions:
 - (a) ensuring that North Macedonia regularly checks that financing provided from the general budget of the Union has been properly used, takes appropriate measures to prevent irregularities and fraud and, where necessary, takes legal action to recover any funds provided under this Decision that have been misappropriated;
 - (b) ensuring the protection of the Union's financial interests, in particular providing for specific measures in relation to the prevention of, and fight against, fraud, corruption and any other irregularities affecting the Union's macro-financial assistance, in accordance with Council Regulations (EC, Euratom) No 2988/95 ⁽⁹⁾ and (Euratom, EC) No 2185/96 ⁽¹⁰⁾, Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council ⁽¹¹⁾ and, for those Member States participating in enhanced cooperation regarding the European Public Prosecutor's Office, also in accordance with Council Regulation (EU) 2017/1939 ⁽¹²⁾;
 - (c) expressly authorising the European Anti-Fraud Office to carry out investigations, including on-the-spot checks and inspections including digital forensic operations and interviews;

⁽⁹⁾ Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests (OJ L 312, 23.12.1995, p. 1).

⁽¹⁰⁾ Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

⁽¹¹⁾ Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

⁽¹²⁾ Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office ('the EPPO') (OJ L 283, 31.10.2017, p. 1).

- (d) expressly authorising the Commission or its representatives to carry out checks, including on-the-spot checks and inspections;
- (e) expressly authorising the Commission and the Court of Auditors to perform audits during and after the availability period of the Union's macro-financial assistance, including document audits and on-the-spot audits, such as operational assessments;
- (f) ensuring that the Union is entitled to early repayment of the loan if it has been established that, in relation to the management of the Union's macro-financial assistance, North Macedonia has engaged in any act of fraud or corruption or any other illegal activity detrimental to the financial interests of the Union;
- (g) ensuring that North Macedonia is to bear all costs incurred by the Union that relate to the borrowing and lending operations under this Decision.

4. Before the implementation of the Union's macro-financial assistance, the Commission shall assess, by means of an operational assessment, the soundness of the country's financial arrangements, administrative procedures and internal and external control mechanisms, which are relevant to the assistance.

Article 7

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 8

1. By 30 June of each year, the Commission shall submit to the European Parliament and to the Council a report on the implementation of this Decision in the preceding year, including an evaluation of that implementation. That report shall:
 - (a) examine progress made in implementing the Union's macro-financial assistance;
 - (b) assess the economic situation and prospects of North Macedonia, as well as progress made in implementing the policy measures referred to in Article 3(1);
 - (c) indicate the connection between the economic policy conditions set out in the MoU, the country's ongoing economic and fiscal performance and the Commission's decisions to release the instalments of the Union's macro-financial assistance.
2. Not later than two years after the expiry of the availability period referred to in Article 1(4), the Commission shall submit to the European Parliament and to the Council an ex-post evaluation report, assessing the results and efficiency of the completed Union's macro-financial assistance and the extent to which it has contributed to the aims of the assistance.

Article 9

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

Done at Strasbourg, 12 July 2023.

For the European Parliament
The President
R. METSOLA

For the Council
The President
P. NAVARRO RÍOS

II

(Non-legislative acts)

REGULATIONS

COUNCIL REGULATION (EU) 2023/1462

of 17 July 2023

amending Regulation (EU) No 36/2012 concerning restrictive measures in view of the situation in Syria

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 215 thereof,

Having regard to the joint proposal of the High Representative of the Union for Foreign Affairs and Security Policy and of the European Commission,

Whereas:

- (1) On 18 January 2012, the Council adopted Decision 2013/255/CFSP ⁽¹⁾ and Regulation (EU) No 36/2012 ⁽²⁾ concerning restrictive measures in view of the situation in Syria, pursuant to the adoption of Council conclusions in which the Council condemned the violence and widespread and systematic gross violations of human rights in Syria.
- (2) In view of the deteriorating situation in Syria and the widespread and systematic violations of human rights and international humanitarian law, including the use of chemical weapons against the civilian population, the Council has continued to add names to the lists of persons and entities subject to Union restrictive measures.
- (3) The tragic earthquake of 6 February 2023 has exacerbated the dire conditions and increased the suffering of the Syrian population.
- (4) In its conclusions of 9 February 2023, the European Council reaffirmed the Union's readiness to provide further assistance to alleviate the suffering in all affected regions. It called on all to ensure humanitarian access to the victims of the earthquake in Syria irrespective of where they are and called on the humanitarian community, under the auspices of the United Nations, to ensure the speedy delivery of aid.
- (5) Union restrictive measures, including those adopted in view of the situation in Syria, are not meant to impede the supply of humanitarian aid to persons in need. Trade in the majority of sectors between the Union and Syria – including in food and medicines – is not restricted by the restrictive measures adopted by the Council in view of the situation in Syria. Moreover, as regards individual measures, exceptions are in place to allow for funds and economic resources to be made available to designated persons and entities, where such funds or economic resources are necessary solely for the purpose of providing humanitarian relief in Syria or assistance to the civilian population in Syria. In certain cases, prior authorisation from the relevant national competent authority is necessary.

⁽¹⁾ Council Decision 2013/255/CFSP of 31 May 2013 concerning restrictive measures in view of the situation in Syria (OJ L 147, 1.6.2013, p. 14).

⁽²⁾ Council Regulation (EU) No 36/2012 of 18 January 2012 concerning restrictive measures in view of the situation in Syria and repealing Regulation (EU) No 442/2011 (OJ L 16, 19.1.2012, p. 1).

- (6) On 23 February 2023, the Council adopted Decision (CFSP) 2023/408 ⁽³⁾ and Regulation (EU) 2023/407 ⁽⁴⁾, which introduced an exemption to the freezing of the assets of, and to the restrictions on making funds and economic resources available to, designated natural or legal persons and entities. The Council decided that this exemption should apply to the benefit of international organisations and certain defined categories of actors involved in humanitarian activities and for an initial period of six months, i.e., until 24 August 2023.
- (7) In order to respond to the continuing urgency of the humanitarian crisis in Syria exacerbated by the earthquake and with a view to facilitating the rapid delivery of aid, it is appropriate to prolong this exemption until 24 February 2024.
- (8) The amendments included within this Regulation fall within the scope of the Treaty and therefore regulatory action at the level of the Union is necessary in order to implement them, in particular with a view to ensuring their uniform application in all Member States.
- (9) Regulation (EU) No 36/2012 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

In Article 16a(1) of Regulation (EU) No 36/2012, the date '25 August 2023' is replaced by '24 February 2024'.

Article 2

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

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

Done at Brussels, 17 July 2023.

For the Council
The President
N. CALVIÑO SANTAMARÍA

⁽³⁾ Council Decision (CFSP) 2023/408 of 23 February 2023 amending Decision 2013/255/CFSP concerning restrictive measures in view of the situation in Syria (OJ L 56 I, 23.2.2023, p. 4).

⁽⁴⁾ Council Regulation (EU) 2023/407 of 23 February 2023 amending Regulation (EU) No 36/2012 concerning restrictive measures in view of the situation in Syria (OJ L 56 I, 23.2.2023, p. 1).

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1463

of 10 July 2023

approving a modification of traditional terms in the wine sector in accordance with Article 115(2) of Regulation (EU) No 1308/2013 of the European Parliament and of the Council ('Landwein', 'Qualitätswein', 'Kabinett/Kabinettwein', 'Spätlese/Spätlesewein', 'Auslese/Auslesewein', 'Strohwein', 'Schilfwein', 'Eiswein', 'Ausbruch/Ausbruchwein', 'Trockenbeerenauslese', 'Beerenauslese/Beerenauslesewein')

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ⁽¹⁾, and in particular Article 115(2) thereof,

Whereas:

- (1) In accordance with Article 28(2) and (3) and Article 34 of Commission Delegated Regulation (EU) 2019/33 ⁽²⁾, the Commission has examined the application for the approval of a modification to the traditional terms 'Landwein', 'Qualitätswein', 'Kabinett/Kabinettwein', 'Spätlese/Spätlesewein', 'Auslese/Auslesewein', 'Strohwein', 'Schilfwein', 'Eiswein', 'Ausbruch/Ausbruchwein', 'Trockenbeerenauslese', 'Beerenauslese/Beerenauslesewein' forwarded by Austria and has published it in the *Official Journal of the European Union* ⁽³⁾.
- (2) No statement of objection has been received by the Commission under Article 22 of Commission Implementing Regulation (EU) 2019/34 ⁽⁴⁾.
- (3) In accordance with Article 31(3) of Delegated Regulation (EU) 2019/33, the modification of the traditional terms 'Landwein', 'Qualitätswein', 'Kabinett/Kabinettwein', 'Spätlese/Spätlesewein', 'Auslese/Auslesewein', 'Strohwein', 'Schilfwein', 'Eiswein', 'Ausbruch/Ausbruchwein', 'Trockenbeerenauslese', 'Beerenauslese/Beerenauslesewein' should therefore be approved and entered in the electronic register of protected traditional terms referred to in Article 25 of Implementing Regulation (EU) 2019/34.
- (4) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

The modification of the traditional terms 'Landwein', 'Qualitätswein', 'Kabinett/Kabinettwein', 'Spätlese/Spätlesewein', 'Auslese/Auslesewein', 'Strohwein', 'Schilfwein', 'Eiswein', 'Ausbruch/Ausbruchwein', 'Trockenbeerenauslese', 'Beerenauslese/Beerenauslesewein' published in the *Official Journal of the European Union* is hereby approved.

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ Commission Delegated Regulation (EU) 2019/33 of 17 October 2018 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards applications for protection of designations of origin, geographical indications and traditional terms in the wine sector, the objection procedure, restrictions of use, amendments to product specifications, cancellation of protection, and labelling and presentation (OJ L 9, 11.1.2019, p. 2).

⁽³⁾ OJ C 23, 23.1.2023, p. 22.

⁽⁴⁾ Commission Implementing Regulation (EU) 2019/34 of 17 October 2018 laying down rules for the application of Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards applications for protection of designations of origin, geographical indications and traditional terms in the wine sector, the objection procedure, amendments to product specifications, the register of protected names, cancellation of protection and use of symbols, and of Regulation (EU) No 1306/2013 of the European Parliament and of the Council as regards an appropriate system of checks (OJ L 9, 11.1.2019, p. 46).

Article 2

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

Done at Brussels, 10 July 2023.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION REGULATION (EU) 2023/1464**of 14 July 2023****amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards formaldehyde and formaldehyde releasers****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ⁽¹⁾, and in particular Article 68(1) thereof,

Whereas:

- (1) Formaldehyde is a highly reactive gas at ambient temperature and atmospheric pressure conditions. It is classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽²⁾ as carcinogen category 1B, mutagen category 2, acute toxicant category 3, skin corrosive category 1B and skin sensitiser category 1.
- (2) Formaldehyde is a high-production volume chemical with a wide array of uses. It is also produced endogenously in humans and animals, and it is an essential metabolic intermediate in all cells. Furthermore, 98 % of the formaldehyde manufactured or imported in the Union is used as a chemical intermediate in the production of formaldehyde-based resins, thermoplastics and other chemicals, which are further used in a broad range of applications. Formaldehyde-based resins are used in the production of a wide variety of articles, which, as a result, may release formaldehyde. The primary use of formaldehyde-based resins is in the manufacturing of wood-based panels, where they act as a bonding agent for wood particles. Such resins are also used in the production of other wood-based products like furniture and flooring, and for wallpapers, foams, parts for road vehicles and aircraft, textile and leather products.
- (3) On 20 December 2017 ⁽³⁾, pursuant to Article 69(1) of Regulation (EC) No 1907/2006, the Commission asked the European Chemicals Agency ('the Agency') to prepare a dossier which conforms to the requirements of Annex XV to that Regulation (hereinafter 'the Annex XV dossier'), in order to assess the risk to human health from formaldehyde and formaldehyde-releasing substances in mixtures and articles for consumer uses.
- (4) On 11 March 2019, the Agency (to be known as 'the Dossier Submitter' in the context of submission of a dossier) submitted the Annex XV dossier ⁽⁴⁾, which demonstrated that the risk to human health from formaldehyde released from consumer articles in indoor environments is not adequately controlled under all scenarios, and that action on a Union-wide basis is necessary to address that risk.

⁽¹⁾ OJ L 396, 30.12.2006, p. 1.

⁽²⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

⁽³⁾ https://echa.europa.eu/documents/10162/13641/formaldehyde_cion_reqst_axvdossier_en.pdf/11d4a99a-7210-839a-921d-1a9a4129e93e.

⁽⁴⁾ <https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e182439477>.

- (5) The Dossier Submitter assessed the hazard of formaldehyde by considering the effects of the substance on several endpoints, concluding that the risk from inhalation leading to sensory irritation is the most sensitive effect in humans. The Annex XV dossier assessed the risks from inhalation of formaldehyde associated with consumer exposure against the World Health Organization (WHO) Guideline for Indoor Air Quality for formaldehyde (30-minute average concentration based on sensory irritation in humans) ⁽⁵⁾. The Guideline provides for a short-term value (0,1 mg/m³) with a view to preventing detrimental effects on lung function, as well as long-term health effects, including nasopharyngeal cancer. The Dossier Submitter used that value as the level above which humans should not be exposed (derived no-effect level ('DNEL')) and to calculate the proposed emission limit of 0,124 mg/m³.
- (6) Based on available literature and the outcome of the exposure estimation, the Dossier Submitter concluded that human health risks from formaldehyde release from mixtures for consumer use are adequately controlled.
- (7) The Dossier Submitter, therefore, proposed to prohibit the placing on the market of formaldehyde and formaldehyde-releasing substances in articles generating consumer exposure where the formaldehyde releases lead to concentrations exceeding 0,124 mg/m³ in the air of a test chamber. Moreover, the Dossier Submitter specified that, where formaldehyde or formaldehyde-releasing substances were intentionally added during their production, road vehicles and aircraft should not be placed on the market if the formaldehyde measured in their interior exceeds a concentration of 0,1 mg/m³ and if exposure of formaldehyde to consumers can occur in such vehicles and aircraft ⁽⁶⁾.
- (8) The Dossier Submitter's original proposal established EN 717-1 as the standard method to measure in a test chamber the emissions for formaldehyde released from wood-based panels. To clarify that other suitable test methods can also be used and to cover articles other than wood-based panels, the Dossier Submitter replaced the reference to standard EN 717-1 in its proposal by a wider description of conditions and methods. Ambient conditions may have an influence on formaldehyde emissions from articles and, therefore, relevant testing parameters were also listed in the Annex XV dossier.
- (9) On 13 March 2020, the Agency's Committee for Risk Assessment ('RAC') adopted its opinion. In its opinion, RAC considered that the WHO guideline value was not sufficiently protective for the general population and concluded in particular that short-term sensory irritation effects in humans cannot be used to predict long-term effects such as cancer. RAC instead set a DNEL of 0,05 mg/m³ derived from data on chronic effects in animals for the inhalation route and concluded that a limit value of 0,05 mg/m³ for formaldehyde released from articles and for formaldehyde in the interior of road vehicles was needed to control the risk.
- (10) RAC concluded that the risk to passengers from formaldehyde in aircraft is adequately controlled.
- (11) RAC recommended a transitional period of 24 months from the entry into force until the application of the proposed restriction, compared to the 12-month period suggested by the Dossier Submitter, as a longer time was considered necessary to allow for the development of standard analytical methods in all affected sectors. RAC concluded that the proposed restriction, as modified by RAC, is the most appropriate Union-wide measure to address the identified risks to human health arising from consumer exposure to formaldehyde, in terms of its effectiveness in reducing the risk, its practicality, and the manner in which it can be monitored.
- (12) On 17 September 2020, the Agency's Committee for Socio-Economic Analysis ('SEAC') adopted its opinion, concluding on the Dossier Submitter's proposed restriction and the modifications proposed by RAC.

⁽⁵⁾ WHO 2010-WHO Guidelines for Indoor Air quality: Selected Pollutants. Geneva. World Health Organization, p. 103.

⁽⁶⁾ ECHA (2020). Background Document to the Opinion on the Annex XV report proposing restrictions on formaldehyde and formaldehyde releasers.

- (13) In its opinion, SEAC acknowledged that the Dossier Submitter's proposal entails costs in terms of production, sampling, testing and enforcement in the order of tens of millions of euros. However, SEAC concluded that those costs are expected to be limited for the concerned sectors, as most of the articles, including road vehicles, placed on the market in the Union today are already compliant with the proposed limit value. SEAC also concluded that benefits from the Dossier Submitter's proposed restriction would result from restricting the placing on the market of articles emitting high concentrations of formaldehyde, including imports. The restriction would result in reduced adverse health effects related to the irritation of the eyes, upper airways and nasopharyngeal cancer, mainly for individuals living in new dwellings.
- (14) SEAC considered that the benefits deriving from limiting formaldehyde emission from consumer articles indoors and in the interior of road vehicles, as proposed, could be achieved at limited costs for society. Therefore, SEAC concluded that the Dossier Submitter's proposal is the most appropriate Union-wide measure to address the identified risk to human health, in terms of its socioeconomic benefits and its socioeconomic costs, if certain derogations are included and if proposed testing conditions are accepted.
- (15) To provide sufficient time for stakeholders to implement the restriction, SEAC recommended a deferral of 24 months for all sectors as regards the application of the restriction. For trucks and buses, however, SEAC recommended 36 months due to the need to develop standard analytical methods for measuring formaldehyde concentrations in the interior of such vehicles.
- (16) SEAC concluded further that the proposed restriction, as modified by RAC, entails major socioeconomic costs, in the order of tens of billions of euros, in terms of investment in research and development, new technologies, higher production costs, sampling and testing costs, as well as job losses. Furthermore, it potentially has negative effects on recycling sectors and the circular economy. SEAC recognised that, to achieve the limit proposed by RAC, technically feasible alternatives exist for certain applications; however, they require far-reaching technological changes and, in specific cases, the use of less sustainable alternatives.
- (17) SEAC acknowledged that RAC's proposal has potential additional benefits in terms of reduced exposure that may lead to a greater reduction in eye and upper airway irritation and nasopharyngeal cancers compared to the Dossier Submitter's proposal. However, RAC did not quantify the risk reduction associated with lowering the limit value; hence, the magnitude of the additional health benefits remains unknown. Furthermore, as part of its assessment, SEAC carried out an analysis by which it calculated that, given the high socioeconomic costs, the incidence of nasopharyngeal cancer among the population in the Union living in new dwellings would have to be 200 times higher than the actual observed incidence, for the RAC proposal to break even. Taking into account this break-even analysis, the information received from industry during the consultations, and the absence of data or information that would allow the quantification of additional health benefits, SEAC concluded that the restriction based on the limit value proposed by RAC does not appear to be an appropriate measure to address the identified risk in terms of socioeconomic benefits and socioeconomic costs.
- (18) The Forum for Exchange of Information on Enforcement was consulted on the Dossier Submitter's proposal and its recommendations on its implementability and enforceability have been taken into account; it is to be noted that the Forum did not consider the modifications recommended by RAC, as they were presented after the consultation of the Forum.
- (19) On 23 February 2021, the Agency submitted the opinions of RAC and SEAC to the Commission ⁽⁷⁾. The opinions of RAC and SEAC concluded that there is a risk to the health of consumers that is not adequately controlled and that needs to be addressed on a Union-wide basis due to the emissions of formaldehyde from articles into indoor air and from road vehicles into their interior.

⁽⁷⁾ Compiled version prepared by the ECHA secretariat of RAC's opinion (adopted 12 March 2020) and SEAC's opinion (adopted 17 September 2020).
<https://echa.europa.eu/documents/10162/f10b57af-6075-bb34-2b30-4e0651d0b52f>.

- (20) The Commission notes that, while the proposed restriction by the Dossier Submitter as well as the opinions by RAC and SEAC refer to consumers, the assessment underpinning the proposal addresses the risk to the population that could be exposed to formaldehyde in indoor air other than workers, and including persons that are not direct consumers. For the sake of legal clarity, it is, therefore, appropriate to refer to the general public as the population targeted by the restriction.
- (21) The Commission, taking into account the Annex XV dossier as well as the RAC and SEAC opinions, considers that there is an unacceptable risk to human health arising from formaldehyde released from articles, and that a restriction establishing an emission limit for articles emitting formaldehyde to decrease exposure of the general public to formaldehyde via inhalation is the most appropriate Union-wide measure to address the risk.
- (22) Formaldehyde is a substance naturally occurring in living organisms. Moreover, formaldehyde can be released by decomposition of substances naturally present in the materials used to produce an article such as from lignin degradation in solid wood. The Commission agrees with the Dossier Submitter that articles in which formaldehyde is exclusively emitted due to its natural occurrence, or due to the natural occurrence of formaldehyde-releasing substances, in the materials from which the articles are produced, should be exempted from the scope of this restriction.
- (23) The Commission agrees with the Dossier Submitter that the proposed limit value of 0,124 mg/m³ prevents articles that emit high amounts of formaldehyde from being placed on the market in the Union and that it is appropriate to limit exposure to formaldehyde in indoor environments. However, the Commission considers that the risk reduction realised by achieving the WHO Guideline value is modest because of existing voluntary and national emission limits and the fact that the majority of articles placed on the market today are already expected to be compliant with the limit value of 0,124 mg/m³. Furthermore, achieving the WHO guideline value would be insufficient to address the identified risk, taking into account RAC's opinion. Likewise, current interior concentrations in road vehicles mostly comply with the proposed limit value of 0,1 mg/m³.
- (24) The Commission also acknowledges, based on SEAC's conclusions on the socioeconomic assessment, that the limit value of 0,05 mg/m³, as proposed by RAC, would entail major socioeconomic impacts for the Union; and that such a limit value requires, in specific cases, shifting to less sustainable alternatives with negative effects on recycling sectors and the circular economy, in particular in view of the absence of an assessment of the additional health benefits of such a limit compared to the limit proposed by the Dossier Submitter.
- (25) The Commission, therefore, examined the appropriateness of the intermediate limit values of 0,080 mg/m³ and 0,062 mg/m³ that had been partly assessed by SEAC based on input received from stakeholders in the consultations. The Commission concluded that the adoption of such intermediate values would entail a higher protection of human health, in particular that of vulnerable populations, compared to the limit proposed by the Dossier Submitter, while entailing a lower socioeconomic burden and fewer technological challenges than the limit proposed by RAC, particularly if taken in combination with adequate transitional periods and specific derogations.
- (26) The Commission recognises the exponential increase in costs when lowering the limit value, and that the estimated combined costs for industry would be at minimum in the range of hundreds of millions of euros for the limit value of 0,080 mg/m³, compared with billions of euros for the limit value of 0,062 mg/m³. The Commission has further analysed the break-even analysis by SEAC, which calculates that, for the limit value of 0,062 mg/m³ to break even, the incidence of nasopharyngeal cancer among the population in the Union living in new dwellings would have to be 70 times higher than the actual observed incidence, and 30 times higher for the limit value of 0,080 mg/m³. However, the Commission also considers that formaldehyde is a carcinogenic substance, for which the limit value of 0,062 mg/m³ would provide higher health benefits to the population in the Union. The Commission, although recognising that the differences in costs between the two values are significant, considers, in view of the potential additional health benefits, in particular to vulnerable groups such as children, that the higher costs for the lower limit value are justified for articles contributing the most to indoor air quality.

- (27) In its consideration, the Commission takes into account that wood-based panels and articles made of wood-based panels or other wood-based articles, as well as furniture that contains wood or other materials, in which formaldehyde other than naturally occurring formaldehyde is used during their production, are the main emission sources of formaldehyde in indoor air, in particular in newly built homes. Therefore, the Commission considers that a lower emission limit for such articles and such products composed of more than one article ('complex products') that are the largest sources of formaldehyde in indoor air is appropriate and provides for increased protection of the general public, while limiting the socioeconomic costs for those sectors that do not contribute to the same extent to the emissions.
- (28) Likewise, it is appropriate to establish a lower limit for the presence of formaldehyde in the interior of road vehicles where the general public is present to ensure adequate protection in particular of vulnerable populations also in the worst-case scenarios.
- (29) The Commission, therefore, concludes that the most appropriate Union-wide measure to address the risk of formaldehyde in indoor air, and in the interior of road vehicles, is a restriction setting the limit value of 0,062 mg/m³ for furniture and wood-based articles, applied to the whole complex product, as well as in the interior of road vehicles; and of the limit value of 0,080 mg/m³ for all other articles. Moreover, the Commission considers that the concentration of formaldehyde emitted from articles into indoor air should be measured under specific reference conditions to ensure harmonised implementation of this restriction. In certain cases it should also be possible to use other test conditions provided that a scientifically valid correlation of test results is applied.
- (30) In order to mitigate the negative impacts and to lower the costs for the affected sectors, as well as to provide sufficient time for stakeholders to implement the restriction, the Commission considers appropriate a deferral of 36 months for all sectors as regards the application of the restriction. For road vehicles, however, a deferral of 48 months is deemed appropriate due to the long development and marketing time for such vehicles, the high material requirements in the automotive industry, the complex supply chains including original equipment manufacturers, as well as the time needed to implement the standard analytical method for measuring emissions for trucks and buses ⁽⁸⁾.
- (31) As for articles that are exclusively for outdoor use under foreseeable conditions it is expected that consumer exposure takes place outside the exterior wall of buildings, such articles should be excluded from the scope of the restriction. Articles in constructions, that are exclusively used outside the building shell and the vapour barrier and that do not emit formaldehyde into indoor air, should also be excluded from the scope of the restriction, as they do not contribute to exposure to formaldehyde in indoor air.
- (32) Articles that are exclusively for industrial or professional use should not be included in the scope of the restriction, as long as these uses do not lead to exposure of the general public. Furthermore, exposure of industrial and professional workers to formaldehyde is already regulated by Council Directive 98/24/EC ⁽⁹⁾, and Directive 2004/37/EC of the European Parliament and of the Council ⁽¹⁰⁾.
- (33) Formaldehyde emissions from articles are expected to decrease over time due to 'off-gassing' of residual formaldehyde. Therefore, second-hand articles should not be included in the scope of the restriction. Moreover, the Forum for Exchange of Information on Enforcement also recommended a derogation for second-hand articles, as enforcing the restriction with regard to second-hand articles may be difficult.

⁽⁸⁾ 12219-10: Interior air of road vehicles – Part 10: Whole vehicle test chamber – Specification and methods for the determination of volatile organic compounds in cabin interiors – Trucks and buses.

⁽⁹⁾ Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

⁽¹⁰⁾ Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

- (34) The following products are already subject to Union rules on limit values on formaldehyde and should, therefore, not be included in the scope of the restriction: articles within the scope of entry 72 of Annex XVII to Regulation (EC) No 1907/2006, articles that are biocidal products within the scope of Regulation (EU) No 528/2012 of the European Parliament and of the Council ⁽¹¹⁾, devices within the scope of Regulation (EU) 2017/745 of the European Parliament and of the Council ⁽¹²⁾, and personal protective equipment within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council ⁽¹³⁾.
- (35) Commission Regulation (EU) No 10/2011 ⁽¹⁴⁾ establishes a limit value for formaldehyde for plastic materials and articles intended to come into contact with food. Although Union law does not set a specific formaldehyde limit for other materials and articles in contact with food, producers must be able to demonstrate their safety to the competent authorities. The requirements of food contact materials aim to protect human health by addressing the potential migration of substances into food. As, due to those requirements, a significant release of formaldehyde from articles intended to come into contact with food, within the meaning of Regulation (EC) No 1935/2004 of the European Parliament and the Council ⁽¹⁵⁾, into the surrounding atmosphere is highly unlikely, the Commission considers that those articles should not be included in the scope of the restriction.
- (36) The Dossier Submitter, RAC and SEAC proposed a derogation for toys covered by Directive 2009/48/EC of the European Parliament and of the Council ⁽¹⁶⁾ which sets a limit of 0,1 mg/m³ for formaldehyde emissions in resin-bonded wooden toys for children younger than 3 years. However, the Commission considers such a derogation not appropriate because children should not be protected less strictly than any other part of the population. The limit value for formaldehyde emissions into indoor air should therefore apply to toys for children of all ages.
- (37) Regulation (EC) No 1907/2006 should therefore be amended accordingly.
- (38) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133(1) of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

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

⁽¹¹⁾ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

⁽¹²⁾ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

⁽¹³⁾ Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).

⁽¹⁴⁾ Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

⁽¹⁵⁾ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

⁽¹⁶⁾ Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1).

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

Done at Brussels, 14 July 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annex XVII to Regulation (EC) No 1907/2006 is amended as follows:

(1) the following entry is added:

77. Formaldehyde CAS No 50-00-0 EC No 200-001-8 and formaldehyde-releasing substances	1. Shall not be placed on the market in articles, after 6 August 2026, if, under the test conditions specified in Appendix 14, the concentration of formaldehyde released from those articles exceeds: (a) 0,062 mg/m³ for furniture and wood-based articles; (b) 0,080 mg/m³ for articles other than furniture and wood-based articles. The first subparagraph shall not apply to: (a) articles in which formaldehyde or formaldehyde releasing substances are exclusively naturally present in the materials from which the articles are produced; (b) articles that are exclusively for outdoor use under foreseeable conditions; (c) articles in constructions, that are exclusively used outside the building shell and vapour barrier and that do not emit formaldehyde into indoor air; (d) articles exclusively for industrial or professional use unless formaldehyde released from them leads to exposure of the general public under foreseeable conditions of use; (e) articles for which the restriction laid down in entry 72 applies; (f) articles that are biocidal products within the scope of Regulation (EU) No 528/2012 of the European Parliament and of the Council (*); (g) devices within the scope of Regulation (EU) 2017/745; (h) personal protective equipment within the scope of Regulation (EU) 2016/425; (i) articles intended to come into contact directly or indirectly with food within the scope of Regulation (EC) No 1935/2004; (j) second-hand articles. 2. Shall not be placed on the market in road vehicles after 6 August 2027 if, under the test conditions specified in Appendix 14, the concentration of formaldehyde in the interior of those vehicles exceeds 0,062 mg/m³. The first subparagraph shall not apply to: (a) road vehicles exclusively for industrial or professional use unless the concentration of formaldehyde in the interior of those vehicles leads to exposure of the general public under foreseeable conditions of use; (b) second-hand vehicles.
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(*) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).;

(2) the following Appendix 14 is added:

Appendix 14

1. Measurement of formaldehyde released to indoor air from articles referred to in paragraph 1, first subparagraph, of entry 77

The formaldehyde released from articles referred to in paragraph 1, first subparagraph of entry 77 shall be measured in the air of a test chamber under the following cumulative reference conditions:

- (a) the temperature in the test chamber shall be $(23 \pm 0,5) ^\circ\text{C}$;
- (b) the relative humidity in the test chamber shall be $(45 \pm 3) \%$;
- (c) the loading factor, expressed as the ratio of the total surface area of the test piece to the volume of the test chamber, shall be $(1 \pm 0,02) \text{ m}^2/\text{m}^3$. This loading factor corresponds to the testing of wood-based panels; for other material or products, if such a loading factor is clearly not realistic under foreseeable conditions of use, loading factors in accordance with Section 4.2.2 of EN 16516 (*) may be used;
- (d) the air exchange rate in the test chamber shall be $(1 \pm 0,05) \text{ h}^{-1}$;
- (e) an appropriate analytical procedure for measuring the formaldehyde concentration in the test chamber shall be used;
- (f) an appropriate method for sampling of the test pieces shall be used;
- (g) the formaldehyde concentration in the air of the test chamber shall be measured at least twice per day throughout the test with a time interval between two consecutive samplings of 3 hours at a minimum; the measurement shall be repeated until sufficient data are available to determine the steady state concentration;
- (h) the duration of the test shall be sufficiently long to allow the determination of the steady state concentration and shall not exceed 28 days;
- (i) the steady state concentration of formaldehyde measured in the test chamber shall be used to verify the compliance with the limit value of formaldehyde released from articles referred to in paragraph 1, first subparagraph, of entry 77.

If data from a test method using the reference conditions specified above are not available or suitable for the measurement of the formaldehyde released from a specific article, data obtained from a test method using non-reference conditions may be used, where there is a scientifically valid correlation between the results of the test method used and the reference conditions.

2. Measurement of formaldehyde concentration in the interior of vehicles referred to in paragraph 2, first subparagraph, of entry 77

For road vehicles, including trucks and buses, the formaldehyde concentration shall be measured in ambient mode in accordance with the conditions specified in ISO 12219-1 (**) or ISO 12219-10 (***), and the concentration measured shall be used to verify the compliance with the limit value referred to in paragraph 2, first subparagraph, of entry 77.¹.

(*) EN 16516: Construction products – Assessment of release of dangerous substances – Determination of emissions into indoor air.

(**) ISO 12219-1: Interior air of road vehicles – Part 1: Whole vehicle test chamber – Specification and method for the determination of volatile organic compounds in cabin interiors.

(***) ISO 12219-10: Interior air of road vehicles – Part 10: Whole vehicle test chamber – Specification and methods for the determination of volatile organic compounds in cabin interiors – Trucks and buses.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1465**of 14 July 2023****providing for emergency financial support for the agricultural sectors affected by specific problems impacting on the economic viability of agricultural producers**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ⁽¹⁾, and in particular Article 221(1) thereof,

Whereas:

- (1) The Covid-19 pandemic, its impact on food supply chains, and the surge in the prices of energy and agricultural inputs since autumn 2021 have been putting the agricultural sector under pressure. Input prices have increased significantly in all agricultural sectors. Energy and fertiliser costs have surged due to the geo-political and geo-economic developments even before Russia's war of aggression against Ukraine which aggravated the situation and had a further markedly negative impact on market expectations.
- (2) As a result, the share of energy and fertilisers costs in total intermediate consumption had increased significantly in 2022, with the largest increase being observed for field crops and permanent crops farms, in both cases because of their exposure to fertiliser costs. Fertiliser prices are still at historically very high levels. Data suggests that farmers have reacted by reducing their use of fertilisers with, as of yet, uncertain negative consequences on yields and the quality of food and feed products.
- (3) The prices of other inputs for farmers and food chain operators such as for example plant protection products and animal health treatments, machinery and packaging have increased in line with the general inflation.
- (4) Agricultural product prices had also increased in 2022 against the backdrop of the recovery from the Covid-19 pandemic and concerns about sufficient global supplies in the aftermath of Russia's attack on Ukraine. And yet, in certain sectors such as the dairy, wine or fruit and vegetables sectors, these high prices had not been able to compensate for worsening business outcomes due to the higher input costs.
- (5) Recently, prices for most agricultural products such as cereals, oilseeds, dairy products or wine have been falling significantly. In certain Member States and regions, the situation has become particularly difficult as the ratio between input prices and agricultural product prices has deteriorated.
- (6) The increased costs for producers have fuelled high consumer prices for food products across the Union, which has had consequences for the affordability of food. The most recent figures show a persistently high food price inflation for consumers of over 15 % across the Union. In certain Member States, the values reach almost 40 %. There is evidence that high prices have been affecting the level of consumption in certain food sectors, such as meat, wine or fruit and vegetables. Consumers have been shifting demand to less expensive food and away from food such as organic food, wine and food protected by designations of origin and geographical indications. Such demand shifts are liable to negatively impact returns on investment accruing to producers.
- (7) In certain agricultural sectors and in certain Member States this overall scenario of economic difficulty has been compounded by urgent sector-specific challenges.

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

- (8) Recent exceptional regional adverse meteorological events such as drought (Spain, Italy and Portugal) and floods (Italy) have caused significant damage to agricultural producers which endangers their economic viability. While there are indications that such events occur in an overall context of increasing climate-change related risks to agriculture, the intensity of those events has been extraordinary.
- (9) As regards the cereals and oilseeds sector, the extreme weather events hitting various Union producing regions are seriously compromising spring and summer crops, in terms of volume and quality. The sector faces decreasing prices. Compared to last year, cereal prices dropped by about 40 %. This creates problems for farmers, as many had purchased expensive inputs in the recent months and now face market prices for their products that hardly, or in some cases do not, cover their costs. Furthermore, some farmers could not sow their fields due to the low levels of soil-humidity and low availabilities of water for irrigation, which will lead to a drop in production and yields. This is particularly the case in Czechia, Denmark, Ireland, Spain, France, Cyprus, Latvia, Austria, Portugal, Slovenia and Sweden.
- (10) The market situation in the fruit and vegetables sector is very difficult, due to the high inflation affecting consumption, which is estimated to have dropped by at least 10 %, compounded by high energy cost. Energy is an important cost factor in glasshouse production and in the post-harvest logistics. As a result, producers continue to face pressure concerning their margins despite the increase in agricultural prices. The hops sector faces similar challenges. The situation is affecting several Member States, in particular Belgium, Czechia, Germany, Estonia, Ireland, Greece, Croatia, Italy, Cyprus, Latvia, the Netherlands, Slovenia and Finland.
- (11) In the animal sector, the high prices of feed combined with the price of energy and general inflation are causing serious difficulties for producers. Despite overall favourable price levels for beef, pig-meat and poultry, producers face problems in covering their production costs. These are even more pronounced in the dairy sector, since prices have started to decrease significantly from their highs at the end of 2022. Moreover, consumer prices for food products affect consumer demand for quality products, that constitute a large share of the income of farmers in those sectors. The dairy sector in Latvia and Lithuania is in a particularly challenging situation as national milk prices have decreased more than in other Member States. But also in Belgium, Czechia, Germany, Estonia, Greece, Spain, France, Croatia, Italy, Cyprus, Luxembourg, Malta, Austria, Slovenia and Finland, the livestock sectors find themselves in the above-mentioned difficulties.
- (12) The contraction of demand due to inflation, including in export markets, combined with high levels of supply, affect in particular the wine sector in certain regions, especially as regards red and rosé wines. Uncertainty on the wine market has also been fuelled by increased input costs and irregular weather events. Germany, Spain, France, Italy and Portugal are particularly affected by this development.
- (13) It is possible that the temporary crisis distillation measure introduced in Article 2 of Commission Delegated Regulation (EU) 2023/1225 ⁽²⁾ allowing Member States to introduce national support programmes in the wine sector will not suffice to address the situation due to the financial limitation of the programmes. Therefore, Member States should be allowed to use further financial resources to reinforce their budget allocations for the national support programmes in the wine sector with a view to financing further distillation operations subject to the same eligibility requirements and support conditions, with the exception of the implementation deadline which should be adapted for the operations financed under this Regulation. If a Member States chooses to avail of this possibility, the Union financial contribution provided by this Regulation should be available in addition to the financial allocations laid down in Annex VII to Regulation (EU) 2021/2115 of the European Parliament and of the Council ⁽³⁾ for the financial years 2023 and 2024.

⁽²⁾ Commission Delegated Regulation (EU) 2023/1225 of 22 June 2023 on temporary exceptional measures derogating from certain provisions of Regulation (EU) No 1308/2013 of the European Parliament and of the Council to address the market disturbance in the wine sector in certain Member States and derogating from Commission Delegated Regulation (EU) 2016/1149 (OJ L 160, 26.6.2023, p. 12).

⁽³⁾ Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulations (EU) No 1305/2013 and (EU) No 1307/2013 (OJ L 435, 6.12.2021, p. 1).

- (14) The still very high input prices, the fall in prices for agricultural products, as well as the problems affecting certain sectors and Member States are liable to cause liquidity problems for agricultural producers. Member States have been resorting to state aid measures under Union state aid rules to try to tackle the situation.
- (15) The Commission decided upon two agricultural emergency support packages benefitting certain Member States to compensate farmers in the most affected sectors of cereals and oilseeds: Commission Implementing Regulations (EU) 2023/739 ⁽⁴⁾ and (EU) 2023/1343 ⁽⁵⁾ aimed at addressing the negative effects caused by the pressure on prices in the said sectors. The present third emergency support package concerns farmers in other Member States who suffer from specific problems impacting on the viability of agricultural production.
- (16) An exceptional measure should therefore be adopted to contribute to addressing the specific problems identified and to forestalling a rapid deterioration of production in those Member States that have not been beneficiaries of the two recent agricultural support packages laid down by Implementing Regulations (EU) 2023/739 and (EU) 2023/1343.
- (17) The difficulties mentioned constitute specific problems within the meaning of Article 221 of Regulation (EU) No 1308/2013. They cannot be readily addressed by measures taken pursuant to Articles 219 or 220 of that Regulation. The situation is not specifically linked to an existing particular market disturbance or a precise threat thereof. It is not linked either to measures that would combat the spread of animal diseases or the loss of consumer confidence due to public, animal or plant health risks.
- (18) The amounts available to the beneficiary Member States should be determined, taking into account in particular their respective weight in the Union's agricultural sector, on the basis of the net ceilings for direct payments set out in Annex III to Regulation (EU) No 1307/2013 of the European Parliament and of the Council ⁽⁶⁾. The amounts for Spain, Italy and Portugal should take into account that these countries are the main Member States affected by the exceptional adverse meteorological events. The amounts for Latvia and Lithuania should take into account that these countries face a particularly challenging situation in the dairy sector.
- (19) The beneficiary Member States should distribute the aid through the most effective channels on the basis of objective and non-discriminatory criteria that take account of the extent of the difficulties and economic damages faced by the farmers concerned. They should ensure that farmers are the ultimate beneficiaries of the aid and avoid any distortions of the market or of competition.
- (20) As the amounts allocated to the beneficiary Member States would address the economic difficulties faced by farmers only partially, these Member States should be allowed to grant additional national support to producers, under the conditions and within the time limits set by this Regulation.
- (21) In order to give the beneficiary Member States the flexibility to distribute the aid as circumstances of the farmers concerned require, they should be allowed to cumulate it with other support financed by the European Agricultural Guarantee Fund and the European Agricultural Fund for Rural Development without overcompensating the farmers.
- (22) In order to avoid overcompensation, the beneficiary Member States should take into account the support granted under other national or Union support instruments or private schemes to respond to the economic losses concerned.

⁽⁴⁾ Commission Implementing Regulation (EU) 2023/739 of 4 April 2023 providing for an emergency support measure for the cereal and oilseed sectors in Bulgaria, Poland and Romania (OJ L 96, 5.4.2023, p. 80).

⁽⁵⁾ Commission Implementing Regulation (EU) 2023/1343 of 30 June 2023 providing for an emergency support measure for the cereal and oilseed sectors in Bulgaria, Hungary, Poland, Romania and Slovakia (OJ L 168, 3.7.2023, p. 22).

⁽⁶⁾ Regulation (EU) No 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 637/2008 and Council Regulation (EC) No 73/2009 (OJ L 347, 20.12.2013, p. 608).

- (23) As the Union aid is fixed in euro, it is necessary, in order to ensure a uniform and simultaneous application, to fix a date for the conversion of the amount allocated to Member States not having adopted the euro as their national currencies, as it is the case for Czechia, Denmark and Sweden. Since this Regulation does not provide for a deadline for the submission of the applications for aid, it is appropriate to consider, for the purposes of Article 30(3) of Commission Delegated Regulation (EU) 2022/127 ⁽⁷⁾, the date of entry into force of this Regulation as the operative event for the exchange rate regarding the amounts set out in this Regulation.
- (24) For budgetary reasons, the Union should finance the expenditure incurred by the beneficiary Member States only where such expenditure is made by a certain eligibility date. The support for this exceptional measure should therefore be paid by 31 January 2024.
- (25) The beneficiary Member States should communicate to the Commission detailed information about the implementation of this Regulation, to enable the Union to monitor the efficiency of the measure introduced by this Regulation.
- (26) In order to ensure that farmers receive aid as soon as possible, the beneficiary Member States should be enabled to implement this Regulation without delay. Therefore, this Regulation should enter into force on the day following that of its publication in the *Official Journal of the European Union*.
- (27) The measure provided for in this Regulation is in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

1. Union aid of a total amount of EUR 330 000 000 shall be available to Belgium, Czechia, Denmark, Germany, Estonia, Ireland, Greece, Spain, France, Croatia, Italy, Cyprus, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Austria, Portugal, Slovenia, Finland and Sweden, to provide exceptional support to farmers subject to the conditions set out in this Regulation.
2. The Member States referred to in paragraph 1 shall use the amounts referred to in Article 3 for measures aiming to compensate farmers in the most affected sectors such as the animal, fruit and vegetables, wine, cereals and oilseeds sectors, for the economic losses impacting on the viability of agricultural producers.
3. The measures shall be taken on the basis of objective and non-discriminatory criteria that take account of the economic losses borne by the affected farmers and ensure that the resulting payments do not cause any market or competition distortion.
4. Member States shall ensure that, when farmers are not the direct beneficiaries of the payments of the Union aid, the economic benefit of the Union aid is passed on to them in full.
5. Expenditure borne by the Member States referred to in paragraph 1 in relation to the payments for the measures referred to in paragraph 2 shall only be eligible for Union aid if those payments have been made by 31 January 2024.
6. For the purposes of Article 30(3) of Delegated Regulation (EU) 2022/127, the operative event for the exchange rate as regards the amounts set out in Article 3(1) of this Regulation shall be the date of entry into force of this Regulation.
7. Measures under this Regulation may be cumulated with other support financed by the European Agricultural Guarantee Fund and the European Agricultural Fund for Rural Development.

⁽⁷⁾ Commission Delegated Regulation (EU) 2022/127 of 7 December 2021 supplementing Regulation (EU) 2021/2116 of the European Parliament and of the Council with rules on paying agencies and other bodies, financial management, clearance of accounts, securities and use of euro (OJ L 20, 31.1.2022, p. 95).

Article 2

1. Member States referred in Article 1(1) implementing national support programmes in the wine sector may also use their financial allocations laid down in Article 3(1) of this Regulation for the purpose of financing the temporary crisis distillation measure as provided for in Article 2 of Delegated Regulation (EU) 2023/1225 in accordance with the same requirements and conditions as those provided for therein, with the exception of Article 1(2) and Article 6, first subparagraph, thereof.
2. Distillation operations financed under this Regulation may be implemented later than 15 October 2023. In this case, Articles 39 to 54 of Regulation (EU) No 1308/2013 as well as Articles 4(1), point (b), Article 5, Article 7(3), Article 17, Articles 40 to 43 and Articles 51, 52, 54, 59, 63 and 65 of Regulation (EU) No 1306/2013 of the European Parliament and of the Council ⁽⁸⁾ shall continue to apply to these operations and payments made in their respect. Similarly, Articles 1 and 2, Article 43, Articles 48 to 54 and Article 56 of Commission Delegated Regulation (EU) 2016/1149 ⁽⁹⁾, Articles 1, 2 and 3, Articles 19 to 23, Articles 25 to 31, Article 32(1), second subparagraph, and Articles 33 to 40 of Commission Implementing Regulation (EU) 2016/1150 ⁽¹⁰⁾ shall continue to apply *mutatis mutandis*. In addition, Article 5, Article 11(1), second subparagraph, and Articles 12 and 13 of Commission Delegated Regulation (EU) No 907/2014 ⁽¹¹⁾ shall continue to apply to expenditure incurred and payments made for these distillation operations.
3. Distillation operations financed under this Regulation shall be implemented sufficiently in advance to enable payments in accordance with the eligibility date for payments referred to in Article 1(5).
4. Member States may grant additional national support for distillation operations financed under this Regulation up to a maximum of 200 % in line with the additional national support referred to in Article 3(2).
5. The Union financial support paid for distillation operations financed in accordance with paragraph 1 shall be deemed Union financial contribution for the financial year in which the payments by Member States are made.

Article 3

1. The Union expenditure incurred in accordance with Articles 1 and 2 shall not exceed a total amount of:
 - (a) EUR 3 912 118 for Belgium;
 - (b) EUR 6 862 150 for Czechia;
 - (c) EUR 6 352 520 for Denmark;
 - (d) EUR 35 767 119 for Germany;
 - (e) EUR 1 722 597 for Estonia;
 - (f) EUR 9 529 841 for Ireland;
 - (g) EUR 15 773 591 for Greece;
 - (h) EUR 81 082 911 for Spain;
 - (i) EUR 53 100 820 for France;

⁽⁸⁾ Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 (OJ L 347, 20.12.2013, p. 549).

⁽⁹⁾ Commission Delegated Regulation (EU) 2016/1149 of 15 April 2016 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards the national support programmes in the wine sector and amending Commission Regulation (EC) No 555/2008 (OJ L 190, 15.7.2016, p. 1).

⁽¹⁰⁾ Commission Implementing Regulation (EU) 2016/1150 of 15 April 2016 laying down rules for the application of Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards the national support programmes in the wine sector (OJ L 190, 15.7.2016, p. 23).

⁽¹¹⁾ Commission Delegated Regulation (EU) No 907/2014 of 11 March 2014 supplementing Regulation (EU) No 1306/2013 of the European Parliament and of the Council with regard to paying agencies and other bodies, financial management, clearance of accounts, securities and use of euro (OJ L 255, 28.8.2014, p. 18).

- (j) EUR 3 371 029 for Croatia;
- (k) EUR 60 547 380 for Italy;
- (l) EUR 574 358 for Cyprus;
- (m) EUR 6 796 780 for Latvia;
- (n) EUR 10 660 962 for Lithuania;
- (o) EUR 462 680 for Luxembourg;
- (p) EUR 240 896 for Malta;
- (q) EUR 4 995 081 for Netherlands;
- (r) EUR 5 529 091 for Austria;
- (s) EUR 11 619 548 for Portugal;
- (t) EUR 1 234 202 for Slovenia;
- (u) EUR 4 269 959 for Finland;
- (v) EUR 5 594 367 for Sweden.

2. The Member States referred to in Article 1(1) may grant additional national support for the measures taken under Article 1(2) up to a maximum of 200 % of the corresponding amount set out in paragraph 1 of this Article, on the basis of objective and non-discriminatory criteria, provided that the resulting payments do not cause any market or competition distortion, or overcompensation.

3. The Member States referred to in Article 1(1) and those using their financial allocations for the purpose of financing the temporary crisis distillation measure referred to in Article 2(1), shall pay the additional support referred to in paragraph 2 of this Article and in Article 2(4), respectively, by 31 January 2024.

Article 4

In order to avoid overcompensation, when granting support under this Regulation, the Member States referred to in Article 1(1) shall take into account the support granted under other national or Union support instruments or private schemes to respond to the economic losses concerned.

Article 5

1. Without delay and no later than 30 September 2023, the Member States referred to in Article 1(1) shall notify the Commission of the following in relation to measures implemented under Article 1:

- (a) a description of the measures to be taken;
- (b) the criteria used to determine the methods for granting the aid and the rationale for distributing the aid across farmers;
- (c) the intended impact of the measures in view of compensating farmers for economic losses;
- (d) the actions taken to verify that the intended impact of the measures is reached;
- (e) the actions taken to avoid distortion of competition and overcompensation;
- (f) the forecast for payments of the Union expenditure broken-down per month until 31 January 2024;
- (g) the level of additional support granted pursuant to Article 3(2);
- (h) the actions taken to control the eligibility of farmers and to protect the financial interests of the Union.

2. No later than 15 June 2024, the Member States referred to in Articles 1(1) and 2(1) shall notify the Commission of the total amounts paid per measure, when applicable, broken down by Union aid and additional national aid, the number and type of beneficiaries and the assessment of the effectiveness of the measure.

Article 6

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

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

Done at Brussels, 14 July 2023.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1466**of 14 July 2023****amending Annexes V, XIV, XV and XIX to Implementing Regulation (EU) 2021/404 as regards the entries for Canada, Namibia, the United Kingdom and the United States in the lists of third countries authorised for the entry into the Union of consignments of poultry, germinal products of poultry, fresh meat of poultry and game birds, meat products of poultry and wild game birds and eggs and egg products****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ⁽¹⁾, and in particular Articles 230(1) and 232(1) and (3) thereof.

Whereas:

- (1) Regulation (EU) 2016/429 provides that consignments of animals, germinal products and products of animal origin must come from a third country or territory, or zone or compartment thereof, listed in accordance with Article 230(1) of that Regulation in order to enter the Union.
- (2) Commission Delegated Regulation (EU) 2020/692 ⁽²⁾ lays down the animal health requirements that consignments of certain species and categories of animals, germinal products and products of animal origin, from third countries or territories, or zones thereof, or compartments thereof in the case of aquaculture animals, must comply with in order to enter the Union.
- (3) Commission Implementing Regulation (EU) 2021/404 ⁽³⁾ establishes the lists of third countries, or territories, or zones or compartments thereof, from which the entry into the Union of the species and categories of animals, germinal products and products of animal origin falling within the scope of Delegated Regulation (EU) 2020/692 is permitted.
- (4) More particularly, Annexes V and XIV to Implementing Regulation (EU) 2021/404 set out the lists of third countries, or territories, or zones thereof authorised for the entry into the Union, respectively, of consignments of poultry, germinal products of poultry, and of fresh meat of poultry and game birds.
- (5) The United Kingdom has notified the Commission of two outbreaks of highly pathogenic avian influenza (HPAI) in poultry in the county of Cumbria, England (1), and in the county of Aberdeenshire, Scotland (1), which were confirmed respectively on 2 and 9 July 2023 by laboratory analysis (RT-PCR).
- (6) Following that recent outbreak of HPAI, the veterinary authorities of the United Kingdom established a restricted zone of at least 10 km around the affected establishments and implemented a stamping-out policy in order to control the presence of HPAI and limit the spread of that disease.

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).

⁽³⁾ Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and of the Council (OJ L 114, 31.3.2021, p. 1).

- (7) The United Kingdom has submitted information to the Commission on the epidemiological situation on its territory and the measures taken to prevent the further spread of HPAI.
- (8) That information has been evaluated by the Commission. The Commission considers that, in view of the animal health situation in the area under restrictions established by the veterinary authorities of the United Kingdom, the entry into the Union of consignments of poultry, germinal products of poultry, and fresh meat of poultry and game birds from those areas should be suspended, in order to protect the animal health status of the Union.
- (9) Canada, the United Kingdom and the United States have provided updated information in relation to epidemiological situations on their territories as regards HPAI that gave rise to the suspension of the entry of certain products into the Union, as set out in Annexes V and XIV to Implementing Regulation (EU) 2021/404.
- (10) In particular, Canada has submitted updated information on the epidemiological situation on its territory in relation to 32 outbreaks of HPAI in poultry establishments in the provinces of Alberta (6), British Columbia (11), Nova Scotia (1), Ontario (2), Quebec (6) and Saskatchewan (6) which were confirmed between 14 April 2022 and 6 May 2023.
- (11) In addition, the United Kingdom has submitted updated information on the epidemiological situation on its territory in relation to three outbreaks of HPAI in poultry establishments in the counties of Lincolnshire (2) and East Sussex (1) in England, the United Kingdom, which were confirmed between 17 May 2023 and 25 May 2023.
- (12) Moreover, the United States has submitted updated information on the epidemiological situation on its territory in relation to three outbreaks of HPAI in poultry establishments in the states North Dakota, South Dakota and Tennessee, which were confirmed between 5 January 2023 and 19 April 2023.
- (13) Canada, the United Kingdom and the United States have also submitted information on the measures that were taken to prevent the further spread of HPAI. In particular, following those outbreaks of that disease, Canada, the United Kingdom and the United States have implemented a stamping-out policy in order to control and limit the spread of that disease, and they have also completed the requisite cleaning and disinfection following the implementation of the stamping-out policy on the infected poultry establishments on their territories.
- (14) The Commission has evaluated the information submitted by Canada, the United Kingdom and the United States. The Commission considers that Canada, the United Kingdom and the United States have provided appropriate guarantees that the animal health situation that gave rise to the suspensions, no longer represents a threat to animal or public health within the Union, and that, consequently, the entry into the Union of poultry commodities from the concerned zones of Canada, the United Kingdom and the United States from which entry into the Union had been suspended, should be reauthorised.
- (15) Annexes V and XIV to Implementing Regulation (EU) 2021/404 should therefore be amended to take account of the current epidemiological situation as regards HPAI in Canada, the United Kingdom and the United States.
- (16) In addition, as it has not exported for many years and do not plan any export to the Union poultry and germinal products thereof, fresh meat of ratites, meat products from poultry and game birds and eggs and egg products, Namibia has requested to be removed from the list of third countries authorised for the entry into the Union of those commodities set out in Annexes V, XIV, XV and XIX to Implementing Regulation (EU) 2021/404. Therefore, those Annexes should be amended accordingly.

- (17) Commission Implementing Regulation (EU) 2023/1226 ⁽⁴⁾ amended Annexes V and XIV to Implementing Regulation (EU) 2021/404 by setting an opening date for the previously closed zone CA-2.187, in the entries for Canada. An error has been detected in the row for that zone in Part 1 to Annex V which should be corrected. That Annex should therefore be corrected accordingly.
- (18) Taking into account the current epidemiological situation in Canada, the United Kingdom and the United States as regards HPAI and the request by Namibia, the amendments to be made to Annexes V, XV, XIV and XIX to Implementing Regulation (EU) 2021/404 by this Regulation should take effect as a matter of urgency.
- (19) The correction of the entry for Canada in the row for the zone CA-2.187 in Part 1 of Annex V to Implementing Regulation (EU) 2021/404 should apply from the date of application of Implementing Regulation (EU) 2023/1226.
- (20) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Implementing Regulation (EU) 2021/404

Annexes V, XIV, XV and XIX to Implementing Regulation (EU) 2021/404 are amended in accordance with Part I of the Annex to this Regulation.

Article 2

Correction to Implementing Regulation (EU) 2021/404

Annex V to Implementing Regulation (EU) 2021/404 is corrected in accordance with the Part II of the Annex to this Regulation.

Article 3

Entry into force and applicability

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*. However, Part II of the Annex shall apply from 27 June 2023.

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

Done at Brussels, 14 July 2023.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁴⁾ Commission Implementing Regulation (EU) 2023/1226 of 22 June 2023 amending Annexes V, XIV and XV to Implementing Regulation (EU) 2021/404 as regards the entries for Canada, Chile and the United Kingdom in the lists of third countries authorised for the entry into the Union of consignments of poultry, germinal products of poultry and fresh meat of poultry and game birds (OJ L 160, 26.6.2023, p. 19).

ANNEX

PART I

AMENDMENTS TO IMPLEMENTING REGULATION (EU) 2021/404

Annexes V and XIV to Implementing Regulation (EU) 2021/404 are amended as follows:

(1) Annex V is amended as follows:

(a) in Part 1, Section B is amended as follows:

(i) in the entry for Canada, the row for the zone CA-2.22 is replaced by the following:

‘CA Canada	CA-2.22	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		14.4.2022	30.6.2023’
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(ii) in the entry for Canada, the rows for the zones CA-2.48 and CA-2.49 are replaced by the following:

‘CA Canada	CA-2.48	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		29.4.2022	30.6.2023
	CA-2.49		N, P1		2.5.2022	30.6.2023’

(iii) in the entry for Canada, the row for the zone CA-2.55 is replaced by the following:

‘CA Canada	CA-2.55	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		3.5.2022	30.6.2023’
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(iv) in the entry for Canada, the row for the zone CA-2.58 is replaced by the following:

‘CA Canada	CA-2.58	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		5.5.2022	30.6.2023’
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(v) in the entry for Canada, the row for the zone CA-2.60 is replaced by the following:

‘CA Canada	CA-2.60	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		10.5.2022	30.6.2023’
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(vi) in the entry for Canada, the rows for the zones CA-2.62 and CA-2.63 are replaced by the following:

‘CA Canada	CA-2.62	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		12.5.2022	30.6.2023
	CA-2.63		N, P1		13.5.2022	30.6.2023’

(vii) in the entry for Canada, the rows for the zones CA-2.66 and CA-2.67 are replaced by the following:

'CA Canada	CA-2.66	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		22.5.2022	30.6.2023
	CA-2.67		N, P1		26.5.2022	30.6.2023'

(viii) in the entry for Canada, the rows for the zones CA-2.69 and CA-2.70 are replaced by the following:

'CA Canada	CA-2.69	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		4.6.2022	30.6.2023
	CA-2.70		N, P1		4.6.2022	30.6.2023'

(ix) in the entry for Canada, the rows for the zones CA-2.72 and CA-2.73 are replaced by the following:

'CA Canada	CA-2.72	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		15.6.2022	30.6.2023
	CA-2.73		N, P1		18.6.2022	30.6.2023'

(x) in the entry for Canada, the row for the zone CA-2.97 is replaced by the following:

'CA Canada	CA-2.97	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		21.9.2022	30.6.2023'
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(xi) in the entry for Canada, the row for the zone CA-2.101 is replaced by the following:

'CA Canada	CA-2.101	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		26.9.2022	30.6.2023'
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(xii) in the entry for Canada, the row for the zone CA-2.104 is replaced by the following:

'CA Canada	CA-2.104	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		28.9.2022	30.6.2023'
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(xiii) in the entry for Canada, the row for the zone CA-2.114 is replaced by the following:

'CA Canada	CA-2.114	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		27.9.2022	2.7.2023'
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(xiv) in the entry for Canada, the row for the zone CA-2.116 is replaced by the following:

'CA Canada	CA-2.116	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		30.9.2022	30.6.2023'
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(xv) in the entry for Canada, the row for the zone CA-2.126 is replaced by the following:

'CA Canada	CA-2.126	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		13.10.2022	30.6.2023'
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(xvi) in the entry for Canada, the row for the zone CA-2.138 is replaced by the following:

'CA Canada	CA-2.138	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		26.10.2022	30.6.2023'
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(xvii) in the entry for Canada, the row for the zone CA-2.157 is replaced by the following:

'CA Canada	CA-2.157	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		23.11.2022	30.6.2023'
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(xviii) in the entry for Canada, the rows for the zones CA-2.168, CA-2.169 and CA-2.170 are replaced by the following:

'CA Canada	CA-2.168	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		23.12.2022	30.6.2023
	CA-2.169		N, P1		29.12.2022	30.6.2023
	CA-2.170		N, P1		5.1.2023	30.6.2023'

(xix) in the entry for Canada, the row for the zone CA-2.175 is replaced by the following:

'CA Canada	CA-2.175	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		3.3.2023	30.6.2023'
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(xx) in the entry for Canada, the row for the zone CA-2.179 is replaced by the following:

'CA Canada	CA-2.179	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		3.4.2023	6.7.2023'
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(xxi) in the entry for Canada, the row for the zone CA-2.182 is replaced by the following:

'CA Canada	CA-2.182	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		13.4.2023	30.6.2023'
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(xxii) in the entry for Canada, the rows for the zones CA-2.184 and CA-2.185 are replaced by the following:

'CA Canada	CA-2.184	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		17.4.2023	7.7.2023
	CA-2.185				19.4.2023	30.6.2023'

(xxiii) in the entry for Canada, the row for the zone CA-2.188 is replaced by the following:

'CA Canada	CA-2.188	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		28.4.2023	30.6.2023'
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(xxiv) in the entry for Canada, the row for the zone CA-2.190 is replaced by the following:

'CA Canada	CA-2.190	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		6.5.2023	30.6.2023'
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(xxv) the entry for Namibia is deleted;

(xxvi) in the entry for the United Kingdom, the rows for the zones GB-2.303, GB-2.304 and GB-2.305 are replaced by the following:

'GB United King- dom	GB-2.303	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		16.5.2023	28.6.2023
	GB-2.304		N, P1		18.5.2023	26.6.2023
	GB-2.305		N, P1		24.5.2023	28.6.2023'

(xxvii) in the entry for the United Kingdom, the following rows for the zones GB-2.306 and GB-2.307 are added after the row for the zone GB-2.305:

'GB United King- dom	GB-2.306	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		2.7.2023	
	GB-2.307				9.7.2023'	

(xxviii) in the entry for the United States, the row for the zone US-2.399 is replaced by the following:

'US United States	US-2.399	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		5.1.2023	10.6.2023'
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(xxix) in the entry for the United States, the row for the zone US-2.403 is replaced by the following:

'US United States	US-2.403	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		20.1.2023	12.6.2023'
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(xxx) in the entry for the United States, the row for the zone US-2.455 is replaced by the following:

'US United States	US-2.455	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		19.4.2023	18.6.2023'
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(b) in Part 2, in the entry for the United Kingdom, the following description of the zones GB-2.306 and GB-2.307 is added after the description of the zone GB-2.305:

'United Kingdom	GB-2.306	near Bootle, Copeland, Cumbria, England, GB The area contained with a circle of a radius of 10 km, centered on WGS84 dec, coordinates Lat: N54.27 and Long: W3.38
	GB-2.307	near Banff, Aberdeenshire, Scotland, GB The area contained with a circle of a radius of 10 km, centred on WGS84 dec, coordinates Lat: N57.64 and Long: W2.57'

(2) in Annex XIV, in Part 1, Section B is amended as follows:

(i) in the entry for Canada, the rows for the zone CA-2.22 are replaced by the following:

'CA Canada	CA-2.22	POU, RAT	N, P1		14.4.2022	30.6.2023
		GBM	P1		14.4.2022	30.6.2023'

(ii) in the entry for Canada, the rows for the zones CA-2.48 and CA-2.49 are replaced by the following:

'CA Canada	CA-2.48	POU, RAT	N, P1		29.4.2022	30.6.2023
		GBM	P1		29.4.2022	30.6.2023
	CA-2.49	POU, RAT	N, P1		2.5.2022	30.6.2023
		GBM	P1		2.5.2022	30.6.2023'

(iii) in the entry for Canada, the rows for the zone CA-2.55 are replaced by the following:

'CA Canada	CA-2.55	POU, RAT	N, P1		3.5.2022	30.6.2023
		GBM	P1		3.5.2022	30.6.2023'

(iv) in the entry for Canada, the rows for the zone CA-2.58 are replaced by the following:

'CA Canada	CA-2.58	POU, RAT	N, P1		5.5.2022	30.6.2023
		GBM	P1		5.5.2022	30.6.2023'

(v) in the entry for Canada, the rows for the zone CA-2.60 are replaced by the following:

'CA Canada	CA-2.60	POU, RAT	N, P1		10.5.2022	30.6.2023
		GBM	P1		10.5.2022	30.6.2023'

(vi) in the entry for Canada, the rows for the zones CA-2.62 and CA-2.63 are replaced by the following:

'CA Canada	CA-2.62	POU, RAT	N, P1		12.5.2022	30.6.2023
		GBM	P1		12.5.2022	30.6.2023
	CA-2.63	POU, RAT	N, P1		13.5.2022	30.6.2023
		GBM	P1		13.5.2022	30.6.2023'

(vii) in the entry for Canada, the rows for the zones CA-2.66 and CA-2.67 are replaced by the following:

'CA Canada	CA-2.66	POU, RAT	N, P1		22.5.2022	30.6.2023
		GBM	P1		22.5.2022	30.6.2023
	CA-2.67	POU, RAT	N, P1		26.5.2022	30.6.2023
		GBM	P1		26.5.2022	30.6.2023'

(viii) in the entry for Canada, the rows for the zones CA-2.69 and CA-2.70 are replaced by the following:

'CA Canada	CA-2.69	POU, RAT	N, P1		4.6.2022	30.6.2023
		GBM	P1		4.6.2022	30.6.2023
	CA-2.70	POU, RAT	N, P1		4.6.2022	30.6.2023
		GBM	P1		4.6.2022	30.6.2023'

(ix) in the entry for Canada, the rows for the zones CA-2.72 and CA-2.73 are replaced by the following:

'CA Canada	CA-2.72	POU, RAT	N, P1		15.6.2022	30.6.2023
		GBM	P1		15.6.2022	30.6.2023
	CA-2.73	POU, RAT	N, P1		18.6.2022	30.6.2023
		GBM	P1		18.6.2022	30.6.2023'

(x) in the entry for Canada, the rows for the zone CA-2.97 are replaced by the following:

'CA Canada	CA-2.97	POU, RAT	N, P1		21.9.2022	30.6.2023
		GBM	P1		21.9.2022	30.6.2023'

(xi) in the entry for Canada, the rows for the zone CA-2.101 are replaced by the following:

'CA Canada	CA-2.101	POU, RAT	N, P1		26.9.2022	30.6.2023
		GBM	P1		26.9.2022	30.6.2023'

(xii) in the entry for Canada, the rows for the zone CA-2.104 are replaced by the following:

'CA Canada	CA-2.104	POU, RAT	N, P1		28.9.2022	30.6.2023
		GBM	P1		28.9.2022	30.6.2023'

(xiii) in the entry for Canada, the rows for the zone CA-2.114 are replaced by the following:

'CA Canada	CA-2.114	POU, RAT	N, P1		27.9.2022	2.7.2023
		GBM	P1		27.9.2022	2.7.2023'

(xiv) in the entry for Canada, the rows for the zone CA-2.116 are replaced by the following:

'CA Canada	CA-2.116	POU, RAT	N, P1		30.9.2022	30.6.2023
		GBM	P1		30.9.2022	30.6.2023'

(xv) in the entry for Canada, the rows for the zone CA-2.126 are replaced by the following:

'CA Canada	CA-2.126	POU, RAT	N, P1		13.10.2022	30.6.2023
		GBM	P1		13.10.2022	30.6.2023'

(xvi) in the entry for Canada, the rows for the zone CA-2.138 are replaced by the following:

'CA Canada	CA-2.138	POU, RAT	N, P1		26.10.2022	30.6.2023
		GBM	P1		26.10.2022	30.6.2023'

(xvii) in the entry for Canada, the rows for the zone CA-2.157 are replaced by the following:

'CA Canada	CA-2.157	POU, RAT	N, P1		23.11.2022	30.6.2023
		GBM	P1		23.11.2022	30.6.2023'

(xviii) in the entry for Canada, the rows for the zones CA-2.168, CA-2.169 and CA-2.170 are replaced by the following:

'CA Canada	CA-2.168	POU, RAT	N, P1		23.12.2022	30.6.2023
		GBM	P1		23.12.2022	30.6.2023
	CA-2.169	POU, RAT	N, P1		29.12.2022	30.6.2023
		GBM	P1		29.12.2022	30.6.2023
	CA-2.170	POU, RAT	N, P1		5.1.2023	30.6.2023
		GBM	P1		5.1.2023	30.6.2023'

(xix) in the entry for Canada, the rows for the zone CA-2.175 are replaced by the following:

'CA Canada	CA-2.175	POU, RAT	N, P1		3.3.2023	30.6.2023
		GBM	P1		3.3.2023	30.6.2023'

(xx) in the entry for Canada, the rows for the zone CA-2.179 are replaced by the following:

'CA Canada	CA-2.179	POU, RAT	N, P1		3.4.2023	6.7.2023
		GBM	P1		3.4.2023	6.7.2023'

(xxi) in the entry for Canada, the rows for the zone CA-2.182 are replaced by the following:

'CA Canada	CA-2.182	POU, RAT	N, P1		13.4.2023	30.6.2023
		GBM	P1		13.4.2023	30.6.2023'

(xxii) in the entry for Canada, the rows for the zones CA-2.184 and CA-2.185 are replaced by the following:

'CA Canada	CA-2.184	POU, RAT	N, P1		17.4.2023	7.7.2023
		GBM	P1		17.4.2023	7.7.2023
	CA-2.185	POU, RAT	N, P1		19.4.2023	30.6.2023
		GBM	P1		19.4.2023	30.6.2023'

(xxiii) in the entry for Canada, the rows for the zone CA-2.188 are replaced by the following:

'CA Canada	CA-2.188	POU, RAT	N, P1		28.4.2023	30.6.2023
		GBM	P1		28.4.2023	30.6.2023'

(xxiv) in the entry for Canada, the rows for the zone CA-2.190 are replaced by the following:

'CA Canada	CA-2.190	POU, RAT	N, P1		6.5.2023	30.6.2023
		GBM	P1		6.5.2023	30.6.2023'

(xxv) the entry for Namibia is deleted;

(xxvi) in the entry for the United Kingdom, the rows for the zones GB-2.303, GB-2.304 and GB-2.305 are replaced by the following:

'GB United King- dom	GB-2.303	POU, RAT	N, P1		16.5.2023	28.6.2023
		GBM	P1		16.5.2023	28.6.2023
	GB-2.304	POU, RAT	N, P1		18.5.2023	26.6.2023
		GBM	P1		18.5.2023	26.6.2023
	GB-2.305	POU, RAT	N, P1		24.5.2023	28.6.2023
		GBM	P1		24.5.2023	28.6.2023'

(xxvii) in the entry for the United Kingdom, the following rows for the zones GB-2.306 and GB-2.307 are added after the row for the zone GB-2.305:

'GB United King- dom	GB-2.306	POU, RAT	N, P1		2.7.2023	
		GBM	P1		2.7.2023	
	GB-2.307	POU, RAT	N, P1		9.7.2023	
		GBM	P1		9.7.2023'	

(xxviii) in the entry for the United States, the rows for the zone US-2.399 are replaced by the following:

'US United States	US-2.399	POU, RAT	N, P1		5.1.2023	10.6.2023
		GBM	P1		5.1.2023	10.6.2023'

(xxix) in the entry for the United States, the rows for the zone US-2.403 are replaced by the following:

'US United States	US-2.403	POU, RAT	N, P1		20.1.2023	12.6.2023
		GBM	P1		20.1.2023	12.6.2023'

(xxx) in the entry for the United States, the rows for the zone US-2.455 are replaced by the following:

'US United States	US-2.455	POU, RAT	N, P1		19.4.2023	18.6.2023
		GBM	P1		19.4.2023	18.6.2023'

- (3) Annex XV is amended as follows:
- (a) in Part 1, in Section A, the entry for Namibia is replaced by the following:

NA Namibia	NA-0	B	B	B	B	B	B	B	Not authorised	Not authorised	Not authorised	MPST	
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- (b) in Part 1, in Section B, the entry for Namibia is replaced by the following:

NA Namibia	NA-0	Not authorised	Not authorised	Not authorised	Not authorised	Not authorised	Not authorised	Not authorised	Not authorised	Not authorised	Not authorised	MPST	
	NA-1	E	E	Not authorised	Not authorised	Not authorised	Not authorised	Not authorised	Not authorised	Not authorised	Not authorised	MPST	

- (4) in Annex XIX, in Part 1, the entry for Namibia is deleted.

PART II

CORRECTION TO IMPLEMENTING REGULATION (EU) 2021/404

In Part 1 of Section B to Annex V, in the entry for Canada, the row for the zone CA-2.187 is replaced by the following:

CA Canada	CA-2.187	BPP, BPR, DOC, DOR, SP, SR, POU-LT20, HEP, HER, HE-LT20	N, P1		18.4.2023	14.6.2023
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DECISIONS

COUNCIL DECISION (CFSP) 2023/1467

of 14 July 2023

amending Decision 2013/255/CFSP concerning restrictive measures in view of the situation in Syria

The Council of the European Union,

Having regard to the Treaty on European Union, and in particular Article 29 thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 31 May 2013, the Council adopted Decision 2013/255/CFSP ⁽¹⁾.
- (2) The Council remains deeply concerned about the situation in Syria. After more than a decade, the conflict in Syria is far from over and remains a source of suffering and instability. The tragic earthquake of 6 February 2023 further increases the suffering of the Syrian population.
- (3) In its conclusions of 9 February 2023, the European Council extended its deepest condolences to the victims of the tragic earthquake of 6 February 2023 and expressed its solidarity with the people of Türkiye and Syria. The European Council reaffirmed the Union's readiness to provide further assistance to alleviate the suffering in all affected regions. It called on all to ensure humanitarian access to the victims of the earthquake in Syria irrespective of where they are and called the humanitarian community, under the auspices of the United Nations, to ensure the speedy delivery of aid.
- (4) In its conclusions of 20 May 2021 on the 'Communication from the Commission to the European Parliament and the Council on the EU's humanitarian action: new challenges, same principles', the Council reaffirmed its commitment to avoid and where unavoidable, mitigate to the maximum extent any potential unintended negative impacts of Union restrictive measures on principled humanitarian action. The Council reiterated that the Union restrictive measures comply with all obligations under international law, in particular international human rights law, international humanitarian law and international refugee law. It underlined the importance of fully adhering to humanitarian principles and international humanitarian law in the Union sanctions policy, including through the consistent inclusion of humanitarian exceptions in restrictive measures regimes where relevant, and by ensuring that an effective framework is in place for the use of such exceptions by humanitarian organisations.
- (5) The Council recalls that the Union restrictive measures, including those adopted in view of the situation in Syria, are not meant to stand in the way nor impede the supply of humanitarian aid, including medical assistance. The majority of sectors – including food, medicines, and medical equipment – are not targeted by the restrictive measures adopted in view of the situation in Syria. Moreover, as regards individual measures, exceptions are already in place that allow for funds and economic resources to be made available to designated persons and entities, where such funds or economic resources are necessary solely for the purpose of providing humanitarian relief in Syria or assistance to the civilian population in Syria. In certain cases, prior authorisation from the relevant national competent authority is necessary.

⁽¹⁾ Council Decision 2013/255/CFSP of 31 May 2013 concerning restrictive measures in view of the situation in Syria (OJ L 147, 1.6.2013, p. 14).

- (6) On 23 February 2023, the Council adopted Decision (CFSP) 2023/408 ⁽²⁾, which introduced an exemption to the freezing of the assets of, and to the restrictions on making funds and economic resources available to, designated natural or legal persons and entities, to the benefit of international organisations and certain defined categories of actors involved in humanitarian activities. The Council decided that this exemption, which does not require prior authorisation from the relevant national competent authority, should have applied for an initial period of six months, i.e. until 24 August 2023.
- (7) In view of the gravity of the humanitarian crisis in Syria, and with a view to facilitating the speedy delivery of aid, it is appropriate to prolong this exemption until 24 February 2024.
- (8) Further action by the Union is necessary to implement certain measures in this Decision.
- (9) Decision 2013/255/CFSP should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

In Article 28a(1) of Decision 2013/255/CFSP, the date '24 August 2023' is replaced by '24 February 2024'.

Article 2

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

Done at Brussels, 14 July 2023.

For the Council
The President
N. CALVIÑO SANTAMARÍA

⁽²⁾ Council Decision (CFSP) 2023/408 of 23 February 2023 amending Decision 2013/255/CFSP concerning restrictive measures in view of the situation in Syria (OJ L 56 I, 23.2.2023, p. 4).

RECOMMENDATIONS

COMMISSION RECOMMENDATION (EU) 2023/1468

of 10 May 2023

on voluntary EU performance requirements for metal detection equipment used in public spaces (outside aviation)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

- (1) Except for the field of civil aviation, Union law does not provide, at present, for harmonised performance requirements for metal detection equipment used for detection in public spaces. Such requirements differ between Member States, leading to uneven and not always sufficiently high levels of protection against security threats for the general public. Terrorists and other criminals may exploit the resulting vulnerabilities, including to stage attacks or conduct other criminal activities in Member States with a lower level of security in public spaces.
- (2) Terrorist attacks committed across the Union in recent years have predominantly taken place in public spaces, targeting members of the general public. In order to contribute to a sufficiently high level of protection against security threats in public spaces across the Union, voluntary performance requirements for metal detection equipment should be set out at Union level.
- (3) The detection equipment, including metal detection equipment, used in the field of civil aviation is subject to detailed requirements laid down in Commission Implementing Decision C(2015) 8005 ⁽¹⁾. Those requirements are well defined and offer a high level of protection in the field of civil aviation security. Therefore, that field should not be covered by this Recommendation. In addition, in the interest of clarity, it should be clarified that this Recommendation should not affect acts of Union law regulating safety aspects of metal detection equipment.
- (4) In the Counter-Terrorism Agenda for the EU ⁽²⁾, the Commission committed to support the development of voluntary EU requirements for detection technologies to ensure that they detect the threats which need to be detected while preserving the mobility of people. In pursuit of that commitment, the Commission established the Technical Working Group on detection performance requirements, composed of Member State experts, manufacturers and officials from a number of Commission services, and asked it to assist in developing voluntary EU performance requirements for metal detection equipment at Union level. This Recommendation, and in particular the voluntary requirements contained therein relating to product documentation and metal detection performance, is based on the preparatory work conducted by that working group.
- (5) Member States should therefore use the voluntary EU performance requirements in public procurement of metal detection equipment intended to be used in public spaces.
- (6) Member States should not be required to procure or use certain particular metal detection equipment in public spaces. The decisions on which metal detection equipment to procure or use in a given public space should continue to be taken exclusively by Member States, in accordance with Union law. The voluntary EU performance requirements should be used in the context of Member States' procurement activities to contribute to achieving a high level of detection performance by metal detection equipment used by Member States in public spaces across the Union.

⁽¹⁾ Commission Implementing Decision C(2015) 8005 laying down detailed measures for the implementation of the common basic standards on aviation security containing information, as referred to in point (a) of Article 18 of Regulation (EC) No 300/2008.

⁽²⁾ Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions. A Counter-Terrorism Agenda for the EU: Anticipate, Prevent, Protect, Respond (COM(2020) 795 final).

- (7) The voluntary EU performance requirements should set out several standards corresponding to different types of application of the metal detection equipment covered. The lowest standard concerns such equipment with lower sensitivity which is intended for application in mass transit or large gathering areas, where especially dangerous weapons need to be detected but where high throughput of persons and their items and low nuisance alarm rates are required. The highest standard concerns such equipment with higher sensitivity, which is intended for application where even the smallest threats need to be detected, and where a low throughput rate can be accommodated.
- (8) The voluntary EU performance requirements should not be understood as being intended to replace national performance standards for metal detection equipment, where such national standards exist. In particular, Member States should remain free to apply, in accordance with Union law, more stringent performance requirements for metal detection equipment used in public spaces.
- (9) This Recommendation should indirectly incentivise manufacturers to comply with the requirements in future production of metal detection equipment. Member States should therefore require in the procurement document for the metal detection equipment to be used for security-threat detection in public spaces that the tenderers include in the tender the product documentation and the declaration of conformity based on the manufacturer's own methodology to demonstrate the conformity of the metal detection equipment with the voluntary performance requirements contained in this Recommendation.
- (10) The use of metal detection equipment in public spaces may pose challenges from the viewpoint of the rights to protection of privacy and personal data. It is of crucial importance in relation to all activities connected to such use, including the procurement and operation of the equipment and any subsequent processing activities, to limit the intrusiveness as much as possible and, in any event, to act in compliance with Union law, in particular Regulation (EU) 2016/679 of the European Parliament and the Council ^(*), Directive 2016/680 of the European Parliament and of the Council ^(*) and the Charter of Fundamental Rights of the European Union.
- (11) Bearing in mind in particular the relevant technological developments in the area of security-threat detection, the voluntary performance requirements for metal detection equipment should be subject to review and adjustments where necessary. The Commission, with the assistance of the technical working group on detection performance requirements, will therefore closely follow technological and other relevant developments and regularly assess the need for adjustments of this Recommendation.
- (12) In the interest of effectiveness and transparency and, in particular, in view of the importance of addressing the security threats identified as soon as possible, Member States should be encouraged to give effect to this Recommendation and submit a report on their implementing measures to the Commission within a reasonable timeframe.
- (13) On the basis of those reports and any other relevant information, after a suitable time period, the progress made in giving effect to this Recommendation should be assessed, with a view, inter alia, to assessing whether Union legal acts with binding force on this subject matter are necessary,

HAS ADOPTED THIS RECOMMENDATION:

1. For the purposes of this Recommendation, the following definitions apply:
 - (a) 'metal detection equipment' means devices, consisting of either hand-held metal detectors or walk-through metal detectors, designed to detect the presence of metals on persons or items as part of physical security controls to detect objects of interest which may be used to cause security threats, such as explosive devices, firearms and sharp objects;

^(*) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC ('General Data Protection Regulation') (OJ L 119, 4.5.2016, p. 1).

^(*) Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, p. 89).

- (b) 'metal detection performance requirements' mean the technical specifications to be met by metal detection equipment, in particular as regards the results to be achieved during its operation;
 - (c) 'product documentation' means the documentation provided either on paper or in electronic form, or both, containing information on the metal detection equipment performance requirements;
 - (d) 'public spaces' mean any physical place that is accessible to the public, regardless of whether certain conditions for access may apply;
 - (e) 'self-declaration of conformity' means a declaration of conformity with the metal detection performance requirements that is issued by the manufacturer based on the manufacturer's own methodology;
2. Member States should require in the procurement document for metal detection equipment to be used for security-threat detection in public spaces, except in the field of aviation, that the tenderer include in the tender the product documentation meeting the requirements set out in Section 2 of the Annex.
 3. Member States should ensure that the metal detection equipment that they procure for the use of security-threat detection in public spaces comply with the metal detection performance requirements set out in Section 3 of the Annex, except when procuring such equipment for the use in the field of civil aviation.
 4. Member States should require in the procurement document for metal detection equipment to be used for security-threat detection in public spaces that the tenderer include in the tender a declaration of conformity with the performance requirements that is issued by the manufacturer, based on the manufacturer's own methodology.
 5. By 10 May 2024, Member States should take the necessary measures, in accordance with Union law, to give effect to this Recommendation.
 6. Member States should report to the Commission on their implementing measures by 10 November 2024.

Done at Brussels, 10 May 2023

For the Commission
Ylva JOHANSSON
Member of the Commission

ANNEX

Product documentation and metal detection equipment performance requirements**SECTION 1: DEFINITIONS**

For the purposes of this Annex, the following definitions apply:

- (1) 'active implantable medical device (AIMD)' means electrically powered medical devices, which can be implanted, worn, or both, and which typically employ electronic circuitry, for human physiological monitoring or to deliver medical treatment or therapy, such as drugs or electrical stimulation;
- (2) 'concept of operations (CONOPS)' means a document describing the characteristics of the equipment and the procedure or procedures for the correct operating thereof;
- (3) 'detector plane' means an imaginary plane (two-dimensional surface) that passes through the centre of the sensor region of the hand-held metal detector or walk-through metal detector that is parallel to the plane of the sensing element of the handheld metal detector or to the portal of the walk-through metal detector, and that bisects the sensor region into two symmetric halves;
- (4) 'divesture procedure' means a procedure regulating the practice that requires items, including both big objects, such as purses, bags, backpacks and other types of luggage, and smaller objects, such as watches, spectacles, belts and jewellery, that people carry with them to be removed and inspected separately, such as through X-rays;
- (5) 'hand-held metal detector (HHMD)' means a portable piece of metal detection equipment designed to be held in the hands of the person operating it, typically held by one hand;
- (6) 'improvised explosive device (IED)' means a bomb or similar explosive device constructed and deployed in ways other than in conventional military action;
- (7) 'measurement plane' means an imaginary plane (two-dimensional surface) over which the handheld metal detector or walk-through metal detector is tested, which is parallel to the detector plane and is referenced from the detector plane;
- (8) 'nuisance alarm rate (NAR)' means the rate of false alarm, that is, the rate of alarms on innocuous metal items calculated over the number of people that have transited the detection area of a walk-through metal detector;
- (9) 'throughput rate' means the maximum number of people and their items that can be screened per unit of time, typically one hour, and still have the detector correctly alarm on any appropriately-sized metal objects according to the security standard set;
- (10) 'test object' means an object that is used to test the performance of a handheld metal detector or walk-through metal detector, simulating the electromagnetic properties of an objects of interest which may be used to cause security threat, such as a weapon or an item that can be used to neutralise security devices;
- (11) 'security standard' means a standard that defines the set of all security threats that need to be detected, with the reference threat targets being representative of the set;
- (12) 'walk-through metal detector (WTMD)' means a stationary piece of metal detection equipment, typically permanently fixed in a particular location and constructed in an archway form;
- (13) 'mechanical interference' means effect caused on the performance of metal detector equipment by nearby stationary or moving metal structures or objects;
- (14) 'NIJ Standard 0601.02' means National Institute of Justice Standard 0601.02, published in Nicholas G. Paulter Jr., *Walk-Through Metal Detectors for Use in Concealed Weapon and Contraband Detection – NIJ Standard 0601.02*, U.S. Department of Justice, Office Justice Programs, National Institute of Justice, 2003;
- (15) 'NIJ Standard 0602.02' means National Institute of Justice Standard 0602.02, published in Nicholas G. Paulter Jr., *Hand-Held Metal Detectors for Use in Concealed Weapon and Contraband Detection – NIJ Standard 0602.02*, U.S. Department of Justice, Office Justice Programs, National Institute of Justice, 2003.

SECTION 2: PRODUCT DOCUMENTATION

The product documentation should comply with the following requirements, which apply in respect of both hand-held metal detectors (HHMD) and walk-through metal detectors (WTMD) unless otherwise indicated:

2.1. Physical dimensions of metal detection equipment

The overall size of the HHMD should be expressed as length (L) x width (W) x height (H) in millimetres (mm).

The passageway interior size and the overall exterior size of the WTMD should be expressed as length (L) x width (W) x height (H) in millimetres (mm).

2.2. Weight of metal detection equipment

The overall weight of the HHMD (including the battery) and of the WTMD should be expressed in grams (g) and kilograms (kg), respectively.

2.3. Power supply

Indication on power supply should include, where applicable, information on voltage of alternating current (VAC), frequency (Hz), current in amperes (A), and power in watt (W).

Tolerance should be expressed in percentage (%).

2.4. Battery

It should be indicated if a backup power supply (i.e. a battery) for the WTMD is included. If so, battery lifetime should be expressed in hours (h).

The HHMD should include a low battery level indicator. Battery lifetime should be expressed in hours (h);

2.5. IP rating

The Ingress Protection (IP) rating according to EN 60529 should be reported.

2.6. Operating environment

Operating temperature should be expressed in degree Celsius (°C).

Storage temperature should be expressed in degree Celsius (°C).

Humidity should be expressed in range in % (non-condensing).

Information should be provided concerning the measures required to avoid adverse electromagnetic interference, such as the recommended unit-to-unit distance in metres (m).

2.7. Zonal/positional alarms (for WTMD)

Information on the number of detection zones and their position under the portal of the WTMD should be provided as part of the product documentation.

2.8. Requirements for CE marking

The product documentation should contain information demonstrating compliance of the metal detection equipment with EU CE marking requirements. It is the responsibility of manufacturers to determine which rules apply for their products. Relevant provisions can include, for example:

- (a) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ⁽¹⁾;

⁽¹⁾ OJ L 174, 1.7.2011, p. 88.

- (b) Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC ⁽³⁾;
- (c) Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility ⁽³⁾;
- (d) Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits ⁽⁴⁾.

2.9. General safety requirements

The product documentation should contain information demonstrating that all reference standards and norms ensuring that the metal detection equipment can be used safely, both for the persons screened and for the persons operating the equipment, are complied with. Those reference standards and norms include the following, in the latest approved edition thereof:

- (a) Standards for active implantable medical devices (AIMDs)
 - EN 50527-1: Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices – Part 1: General
 - EN 50527-2-x: Procedure for the assessment of the exposure to electromagnetic fields of workers bearing active implantable medical devices
 - Part 2.1: Specific assessment for workers with cardiac pacemakers
 - Part 2.2: Specific assessment for workers with cardioverter defibrillators (ICDs)
 - Part 2.3: Specific assessment for workers with implantable neurostimulators
 - EN ISO 14708-X: Implants for surgery – Active implantable medical devices
 - Part 2: Cardiac pacemakers
 - Part 3: Implantable neurostimulators
 - Part 4: Implantable infusions pumps
 - Part 5: Circulatory support devices
 - Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)
 - Part 7: Particular requirements for cochlear and auditory brainstem implant systems
- (b) Standards for human exposure:
 - EN 50364: Product standard for human exposure to electromagnetic fields from devices operating in the frequency range 0 Hz to 300 GHz, used in Electronic Article Surveillance (EAS), Radio Frequency Identification (RFID) and similar application
 - 1999/519/EC Council Recommendation of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz)
 - 2013/35/EU Directive on the minimum health and safety requirements regarding the exposure of workers to the risk arising from physical agent (electromagnetic fields)

2.10. Concept of operations

Concept of operations (CONOPS) should be provided as part of the product documentation. If different CONOPS are associated with different security standards, this should be clearly stated.

⁽³⁾ OJ L 153, 22.5.2014, p. 62.

⁽³⁾ OJ L 96, 29.3.2014, p. 79.

⁽⁴⁾ OJ L 96, 29.3.2014, p. 357.

SECTION 3: METAL DETECTION PERFORMANCE REQUIREMENTS

The metal detection equipment should meet the following metal detection performance requirements:

3.1. Security standards

The metal detection equipment should be set to the appropriate security standards among the following five standards:

3.1.1. *Standard 1 (for WTMD)*

This standard is intended for application where dangerous weapons need to be detected but where high throughput and low nuisance alarm rates are required. Applications include mass transit and large gathering areas.

Threat targets belonging to this category should include automatic rifles, machine guns and pressure cooker IEDs, such as assault rifles (with or without magazine), AK47, Beretta M12, Colt AR-15, pipe bomb housing (80 x 300) mm, and 4-liter stainless steel and aluminium pressure cookers IED, and similar sized objects.

Test objects simulating very large objects of interest should be used for this category. Divesture procedures should not be required and suitcases, bags or backpacks could be carried.

3.1.2. *Standard 2 (for WTMD)*

Threat targets belonging to this category should be medium-size handguns (e.g. Glock 17), and similar sized objects.

Test objects simulating large objects of interest should be used for this category, including full-size handguns as described by section 4.6, security level 2, test piece AM7, of the National Institute of Law Enforcement and Criminal Justice (NILECJ) standard for 'walk through metal detector for use in weapon detection,' (NILECJ-STD-0601.00).

Divesture procedures should not be required and small bags or backpacks could be carried.

3.1.3. *Standard 3*

Threat targets belonging to this category should be small handguns, from compact to pocket size firearms, and similar sized objects.

Test objects simulating medium-sized objects of interest should be used for this category, including handguns constructed of ferromagnetic or non-ferromagnetic metal as described in section 5.1 of NIJ Standard 0601.02 or NIJ Standard 0602.02. Replicas and mechanical drawings are included in NIJ Standard 0601.02 and NIJ Standard 0602.02.

Divesture procedures should be required. All metal items should be divested except wallets, watches, belts, shoes and small jewellery.

3.1.4. *Standard 4*

Threat targets belonging to this category should be knives having blade lengths exceeding 7,5 cm, and similar sized objects.

Test objects simulating small objects of interest should be used for this category, including knives having blade lengths exceeding 7,5 cm constructed of ferromagnetic or non-ferromagnetic metal as described in section 5,2 of NIJ Standard 0601.02 or NIJ Standard 0602.02. Replicas and mechanical drawings are included in NIJ Standard 0601.02 and NIJ Standard 0602.02.

Divesture procedures should be required. All metal items should be divested, except small watches, and small belts.

3.1.5. *Standard 5*

Threat items belonging to this category should be small weapons and include for example, stainless steel knives, handcuff keys, screwdriver bit, small calibre round, and similar sized objects.

Test objects simulating very small objects of interest should be used for this category, including small weapons concealed on a person that are constructed of either ferromagnetic or non-ferromagnetic metal as described in section 5.3 of NIJ Standard 0601.02 or NIJ Standard 0602.02. Replicas and mechanical drawings are included in NIJ Standard 0601.02 and in NIJ Standard 0602.02

Divestiture procedures should be required. All metallic items should be divested.

3.2. Detection sensitivity

The metal detection equipment should detect objects of interest which may be used to cause security threats, carried on a person or in a bag that is worn, carried, or pulled along, independently of their orientation, trajectory and transit, or moving speed.

The detection sensitivity of that equipment may vary according to the standard fulfilled by the equipment described in section 3.1 of this Annex. Standard 1 requires equipment with the lowest sensitivity, while standard 5 requires equipment with the highest sensitivity.

3.2.1. Orientation and moving speed (for HHMD)

The HHMD should detect the test object representative for a particular security standard positioned in the appropriate measurement plane(s) for each allowed orientation by moving the detector at a speed between 0,05 and 2,0 m/s, as described in NIJ Standard-0602.02.

3.2.2. Orientation, trajectory and transit speed (for WTMD)

The minimum set of orthogonal orientations that should be used for testing a WTMD's sensitivity is described in ASTM International 'Standard Practice for Performance Evaluation of In-Plant Walk-Through Metal Detectors' C1309 – 97(2021).

The WTMD should detect the test object representative for a particular security standard at certain trajectory positions as described in NIJ Standard-0601.02.

All positions where the test object, due to its size and orientation, does not completely fit with the detector portal or that causes any portion of the test object to extend above the maximum height of the detection areas should be skipped.

The average transit speed of the test object when tested should be the normal walking pace (0,5 m/s – 1,3 m/s).

3.3. Repeatability

Detection repeatability should be ensured by the manufacturer's quality system and by testing different units of metal detection equipment in a subset of positions.

3.4. Metal discrimination (for WTMD)

Metal discrimination specifications for WTMD should require that the WTMD alarms on the appropriate object and not on an innocuous object. Discrimination should be evaluated by testing the WTMD in a real environment once the detection performances have been validated for the specific security standard. Appropriate divestiture procedures could be required according to the security standard under evaluation. In order to assess discrimination, the alarm/total transits ratio on a number of people passing through the WTMD should be counted. The number of people that is required for this statistical survey should be at least one thousand.

3.5. Throughput and nuisance alarm rate (for WTMD)

The WTMD screening time per person should be lower than 2 seconds. The nuisance alarm rate (NAR) should be below 5 % following the divestiture procedures described in section 3.1 of this Annex.

3.6. Mechanical interference

The detector should not alarm when it is adjusted to find the appropriately-sized test object.

3.7. Multiple metal objects interference (for WTMD)

For WTMD, the presence of metal objects other than the threat targets described by the selected security standard should not affect the detection of a threat item as it is passing through the portal.

3.8. Audible and visual alarms

The metal detection equipment should be provided with an audible and a visual alarm. The audible alarm should be noticeable at a range of 1 meter for HHMD and at a range of 2 meters for WTMD. A visual indicator should show for the HHMD that it is in operation and for the WTMD the strength of the signal detected.

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