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*	Consultation procedure
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(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments by Parliament:

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.

EUROPEAN PARLIAMENT

2021–2022 SESSION

Sitting of 11 November 2021

TEXTS ADOPTED

Thursday 11 November 2021

I

(Resolutions, recommendations and opinions)

RESOLUTIONS

EUROPEAN PARLIAMENT

P9_TA(2021)0451

Strengthening democracy, media freedom and pluralism in the EU

European Parliament resolution of 11 November 2021 on strengthening democracy and media freedom and pluralism in the EU: the undue use of actions under civil and criminal law to silence journalists, NGOs and civil society (2021/2036(INI))

(2022/C 205/01)

The European Parliament,

— having regard to the Treaty on European Union (TEU) and in particular Article 2, Article 3, Article 4(3) and Articles 5, 6, 7 and 19 thereof,

— having regard to the Treaty on the Functioning of the European Union (TFEU) and in particular Articles 70, 81, 82, 114 and 352 thereof,

— having regard to the Charter of Fundamental Rights of the European Union ('the Charter') and in particular Articles 11, 12, 15, 20, 47, 48 and 54 thereof,

— having regard to Protocol No 1 on the role of national parliaments in the European Union and Protocol No 2 on the application of the principles of subsidiarity and proportionality, annexed to the TEU and the TFEU,

— having regard to the Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II) ([1]),

— having regard to the Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgements in civil and commercial matters (Brussels I) ([2]),

— having regard to Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law ([3]),

— having regard to Regulation (EU) 2021/692 of the European Parliament and of the Council of 28 April 2021 establishing the Citizens, Equality, Rights and Values Programme and repealing Regulation (EU) No 1381/2013 of the European Parliament and of the Council and Council Regulation (EU) No 390/2014 ([4]),

([1]) OJ L 199, 31.7.2007, p. 40.
([2]) OJ L 351, 20.12.2012, p. 1.
([3]) OJ L 305, 26.11.2019, p. 17.
([4]) OJ L 156, 5.5.2021, p. 1.

— having regard to Regulation (EU) 2021/693 of the European Parliament and of the Council of 28 April 2021 establishing the Justice Programme and repealing Regulation (EU) No 1382/2013 ([5]),

— having regard to the case law of the Court of Justice of the European Union,

— having regard to the communication entitled 'Commission Work Programme 2021 — A Union of vitality in a world of fragility' (COM(2020)0690),

— having regard to the Commission communication entitled 'On the European democracy action plan' (COM(2020)0790),

— having regard to the Commission communication of 5 March 2020 'A Union of Equality: Gender Equality Strategy 2020-2025' COM(2020)0152,

— having regard to the Commission communication of 30 September 2020 entitled '2020 Rule of Law Report — The rule of law situation in the European Union' (COM(2020)0580), and its 27 accompanying country chapters on the rule of law in the Member States (SWD(2020)0300-0326),

— having regard to the Commission communication of 12 November 2020 entitled 'Union of Equality: LGBTIQ Equality Strategy 2020-2025' (COM(2020)0698),

— having regard to the Commission recommendation on ensuring the protection, safety and empowerment of journalists and other media professionals in the European Union (C/2021/6650),

— having regard to the Commission's follow-up to the European Parliament non-legislative resolution of 3 May 2018 on media pluralism and media freedom in the European Union,

— having regard to the report by the European Union Agency for Fundamental Rights entitled 'Challenges facing civil society organisations working on human rights in the EU' published on 17 January 2018, to its bulletins on the fundamental rights implications of the coronavirus pandemic in the EU published in 2020, and to the Agency's other reports, data and tools, in particular the European Union Fundamental Rights Information System (EFRIS),

— having regard to the Universal Declaration of Human Rights and in particular Article 19 thereof,

— having regard to other UN instruments on the protection of human rights and fundamental freedoms, and to the recommendations and reports of the UN Universal Periodic Review, as well as to the case law of the UN Human Rights Treaty Bodies and the special procedures of the Human Rights Council,

— having regard to the UN Declaration on Human Rights Defenders of 8 March 1999,

— having regard to the report of the UN Special Rapporteur on the rights to freedom of peaceful assembly and of association on SLAPPs and FoAA rights,

— having regard to the European Convention for the Protection of Human Rights and Fundamental Freedoms, the European Social Charter, the case law of the European Court of Human Rights and the European Committee of Social Rights, and to the conventions, recommendations, resolutions, opinions and reports of the Council of Europe Parliamentary Assembly, the Committee of Ministers, the Human Rights Commissioner, the European Commission Against Racism and Intolerance, the Steering Committee on Anti-Discrimination, Diversity and Inclusion, the Venice Commission and other bodies of the Council of Europe,

— having regard to the declaration of the Council of Europe of 4 July 2012 on the Desirability of International Standards dealing with Forum Shopping in respect of Defamation, 'Libel Tourism', to Ensure Freedom of Expression,

— having regard to the Council of Europe Recommendation of the Committee of Ministers to Member States of 13 April 2016 on the protection of journalism and safety of journalists and other media actors (CM/Rec(2016)4[1]),

([5]) OJ L 156, 5.5.2021, p. 21.

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— having regard to the recommendation of the Council of Europe of 28 November 2018 on the need to strengthen the protection and promotion of civil society space in Europe (CM/Rec(2018)11),

— having regard to the recommendation of the Council of Europe to Member States of 7 March 2018 on media pluralism and transparency of media ownership (CM/Rec(2018)1),

— having regard to the resolution of the Council of Europe Ministerial Conference of 11 June 2021 on the safety of journalists,

— having regard to the article by the Council of Europe Commissioner for Human Rights entitled 'Human Rights Comment: Time to take action against SLAPPs' published on 27 October 2020,

— having regard to the 2021 annual report by the partner organisations to the Council of Europe Platform to Promote the Protection of Journalism and Safety of Journalists,

— having regard to the recommendations and reports of the Office for Democratic Institutions and Human Rights, the Representative on Freedom of the Media and other bodies of the Organization for Security and Co-operation in Europe (OSCE),

— having regard to the EU-CITZEN Network study entitled 'SLAPP in the EU context' of 29 May 2020 ([6]),

— having regard to the call for an anti-SLAPP directive by a coalition of non-governmental organisations ([7]),

— having regard to the study entitled 'The Use of SLAPPs to Silence Journalists, NGOs and Civil Society' of June 2021 commissioned by the European Parliament Policy Department at the request of the Committee of Legal Affairs,

— having regard to its briefing entitled 'European added value of an EU mechanism on democracy, rule of law and fundamental rights — Preliminary Assessment' of 23 April 2020,

— having regard to its resolution of 21 May 2013 on the EU Charter: standard settings for media freedom across the EU ([8]),

— having regard to its resolution of 25 October 2016 with recommendations to the Commission on the establishment of an EU mechanism on democracy, the rule of law and fundamental rights ([9]),

— having regard to its resolution of 19 April 2018 on the need to establish a European Values Instrument to support civil society organisations which promote fundamental values within the European Union at local and national level ([10]),

— having regard to its resolution of 19 April 2018 on protection of investigative journalists in Europe: the case of Slovak journalist Ján Kuciak and Martina Kušnírová ([11]),

— having regard to its resolution of 3 May 2018 on media pluralism and media freedom in the European Union ([12]),

([6]) https://ec.europa.eu/info/sites/default/files/ad-hoc-literature-review-analysis-key-elements-slapp_en.pdf
([7]) https://rsf.org/en/news/rsf-and-60-other-organisations-call-eu-anti-slapp-directive
([8]) OJ C 55, 12.2.2016, p. 33.
([9]) OJ C 215, 19.6.2018, p. 162.
([10]) OJ C 390, 18.11.2019, p. 117.
([11]) OJ C 390, 18.11.2019, p. 111.
([12]) OJ C 41, 6.2.2020, p. 64.

— having regard to its resolution of 14 November 2018 on the need for a comprehensive EU mechanism for the protection of democracy, the rule of law and fundamental rights ([13]),

— having regard to its resolution of 13 February 2019 on experiencing a backlash in women's rights and gender equality in the EU ([14]),

— having regard to its resolution of 28 March 2019 on the situation of the rule of law and the fight against corruption in the EU, specifically in Malta and Slovakia ([15]),

— having regard to its resolution of 18 December 2019 on the Rule of Law in Malta, after the recent revelations around the murder of Daphne Caruana Galizia ([16]),

— having regard to its resolution of 15 January 2020 on the annual report 2018 on human rights and democracy in the world and the European Union's policy on the matter ([17]),

— having regard to its resolution of 7 October 2020 on the establishment of an EU Mechanism on Democracy, the Rule of Law and Fundamental Rights ([18]),

— having regard to its resolution of 25 November 2020 on Strengthening Media Freedom: the Protection of Journalists in Europe, Hate Speech, Disinformation and the Role of Platforms ([19]),

— having regard to its resolution of 26 November 2020 on the situation of Fundamental Rights in the European Union — Annual Report for the years 2018-2019 ([20]),

— having regard to its resolution of 17 December 2020 on the Multiannual Financial Framework 2021-2027, the Interinstitutional Agreement, the EU Recovery Instrument and the Rule of Law Regulation ([21]),

— having regard to its resolution of 11 March 2021 on the declaration of the EU as an LGBTIQ Freedom Zone ([22]),

— having regard to its resolution of 25 March 2021 on the application of Regulation (EU, Euratom) 2020/2092, the Rule of Law conditionality mechanism ([23]),

— having regard to its resolution of 29 April 2021 on the assassination of Daphne Caruana Galizia and the rule of law in Malta ([24]),

— having regard to its resolution of 19 May 2021 on the effects of climate change on human rights and the role of environmental defenders on this matter ([25]),

— having regard to Rule 54 of its Rules of Procedure,

— having regard to the joint deliberations of the Committee on Legal Affairs and the Committee on Civil Liberties, Justice and Home Affairs under Rule 58 of the Rules of Procedure,

— having regard to the opinion of the Committee on Culture and Education,

— having regard to the report of the Committee on Legal Affairs and the Committee on Civil Liberties, Justice and Home Affairs (A9-0292/2021),

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([13]) OJ C 363, 28.10.2020, p. 45.
([14]) OJ C 449, 23.12.2020, p. 102.
([15]) OJ C 108, 26.3.2021, p. 107.
([16]) OJ C 255, 29.6.2021, p. 22.
([17]) OJ C 388, 13.11.2020, p. 100.
([18]) OJ C 395, 29.9.2021, p. 2.
([19]) OJ C 425, 20.10.2021, p. 28.
([20]) OJ C 425, 20.10.2021, p. 107.
([21]) OJ C 445, 29.10.2021, p. 15.
([22]) Texts adopted, P9_TA(2021)0089.
([23]) Texts adopted, P9_TA(2021)0103.
([24]) Texts adopted, P9_TA(2021)0148.
([25]) Texts adopted, P9_TA(2021)0245.

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A. whereas the rights to freedom of expression, to information and to public participation, are among the cornerstones of democracy; whereas freedom of expression is indispensable for the realisation of the principles of transparency and accountability; whereas public participation by a natural or legal person engaging on a matter of public interest can take a variety of forms; whereas public participation can include the online and offline exercise of public scrutiny and the dissemination of public information, such as journalistic communications, publications or works, including editorial content, communications, publications or works of a political, scientific, academic, artistic nature, commentary or satirical material, including when those concerned are, among others, figures open to public scrutiny, in the context of broader interests in open discussion of political issues; whereas publications which contribute to debates on matters of public interest or general concern enjoy a higher threshold of protection; whereas the limits of acceptable criticism are wider for public figures, especially politicians and state officials;

B. whereas independent impartial, professional and responsible journalism as well as access to pluralistic information are key pillars of democracy; whereas the information, reports, opinions, claims, arguments and other statements by civil society are vital for any democracy to thrive; whereas the shrinking space for civil society in certain countries has become an increasingly worrying issue and may negatively impact democracies; whereas independent and high quality journalism and civil society organisations play a crucial role as guardians of democracy and the rule of law by holding power to account and fighting disinformation and misinformation, as well as foreign political interference and manipulation;

C. whereas in recent years, journalists and media actors in Europe and abroad are increasingly being threatened, physically attacked and assassinated because of their work, particularly when it focuses on the misuse of power, corruption, fundamental rights violations and criminal activities; stresses that the effective exercise of freedom of expression requires a range of positive measures for the protection for journalists, including to protect life and to investigate assassinations, as well as the effective protection of their sources; notes that these threats are not only of a violent nature and that intimidation against journalists also stems from legal, political, socio-cultural and economic pressures;

D. whereas the right to freedom of expression is a fundamental right that must be exercised with sense of duty and responsibility, taking into account people's fundamental right to obtain impartial information as well as the respect for the fundamental right to protect one's reputation ([26]) and privacy; whereas, in cases of a conflict between these rights, all parties must have access to courts if the situation was not resolved amicably;

E. whereas Strategic Lawsuits Against Public Participation (SLAPPs) are lawsuits or other legal actions (e.g. injunctions, asset-freezing) brought forward by private individuals and entities, and also by public officials, public bodies and publicly controlled entities, directed at one or more individuals or groups, using a variety of legal bases mostly in civil and criminal law, as well as the threats of such actions, with the purpose of preventing investigation and reporting on breaches of Union and national law, corruption or other abusive practices or of blocking or otherwise undermining public participation; whereas this has a direct and detrimental impact on democratic participation, societal resilience and dialogue, and runs counter to the values enshrined in Article 2 TEU;

F. whereas public participation includes but is not limited to investigating, speaking out about, reporting or otherwise exposing matters of public interest, inter alia, practices that threaten fundamental rights and freedoms, democracy, the rule of law or good governance, and engaging in advocacy through the exercise of civil liberties such as the freedom of association, freedom of peaceful assembly and freedom of expression and of information;

G. whereas victims of SLAPPs are most commonly sued for expressing critical views on the behaviour, or denouncing the wrongdoing, of private individuals and entities as well as of public officials, public bodies and publicly controlled entities, through online or offline forms of expression, or in retaliation for their involvement in campaigns, court cases,

([26]) Article 10 of the European Convention for the Protection of Human Rights and Fundamental Freedoms.

actions or protests; whereas SLAPPs are commonly characterised by claims that lack any legal merit, are manifestly unfounded, exhibit an imbalance of power and the abuse of rights or of process by the plaintiff making excessive claims in matters in which the defendant is exercising a legally protected right, and therefore using the judicial process for purposes other than genuinely exercising a right;

H. whereas, according to civil society organisations, academics, legal practitioners and victims that work on this topic, SLAPPs are becoming more sophisticated and more effective, with one of the techniques used being multiple lawsuits filed against the same person on the same subject matter, meaning that all of them have to be defended and dealt with simultaneously and in parallel by the same person, which increases costs disproportionally; whereas SLAPPs are often grounded in claims of defamation, libel or slander, which still constitute criminal offences in most Member States, and SLAPP victims find themselves facing criminal charges while being sued for civil liability purportedly arising from the same conduct; whereas SLAPPs often infringe on victims' right to defence recognised by the Charter, possibly also impacting on their right to a fair trial and the presumption of innocence;

I. whereas the lack of a consistent and comprehensive legal and judicial approach within the Union does not allow SLAPP suits to be swiftly identified and efficiently addressed; whereas the level of protection against SLAPP suits remains very fragmented across Member States, frustrating legal certainty and SLAPP victims' right to an effective remedy; whereas one of the main challenges in drafting anti-SLAPP legislation lies in how to address abusive claims, without prejudice to claimants' rights deriving from Member States' constitutions and their obligations under the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights;

J. whereas evidence shows that SLAPPs have become an increasingly widespread practice, as demonstrated by many cases throughout the Union, such as the chilling case of investigative journalist Daphne Caruana Galizia, who was reportedly facing 47 civil and criminal defamation lawsuits (resulting in the freezing of her assets) across multiple jurisdictions on the day of her strongly condemned assassination on 16 October 2017, and the lawsuits her heirs continue to face; whereas other illustrative and alarming cases against independent journalists and media include Realtid Media, which was repeatedly threatened with a lawsuit in a different jurisdiction from where the reporting in question took place, and Gazeta Wyborcza, which continues to be sued by a number of public entities and officials on a regular basis;

K. whereas SLAPPs are frequently used by public authorities or its proxies, such as state-funded media outlets, state-funded NGOs or state-owned companies;

L. whereas SLAPPs can be a tool to reduce media pluralism at the systemic level by exercising a chilling effect on independent media; whereas SLAPPs are deliberately initiated with the intent of making the litigation expensive, protracted and complicated for the defendants, including by intimidating and draining the financial and psychological resources of their targets; whereas SLAPPs not only have a detrimental impact on victims, but also on their families and on broader public participation;

M. whereas reference to SLAPP victims and targets covers journalists, publishers and media organisations, academics, NGOs, civil society and other actors engaging in public participation, such as those working on human rights and environmental issues;

N. whereas SLAPPs within the Union are often cross-border in nature, which results in reporting delays or incomplete information, as illustrated in many cases, often relating to human rights and environmental protection, financial fraud and/or corruption, where they constitute a clear attempt to delay publication of information by halting or discrediting the work of individual journalists and publishing entities, hence depriving citizens of their right to information and impacting media pluralism, freedom and diversity; whereas SLAPPs and SLAPP threats may also be brought against watchdogs within the Union by actors in third countries and before courts in third countries;

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O. whereas domestic SLAPP cases are increasingly used within the Member States with the aim of limiting free speech and the right to information, producing a chilling effect against SLAPP victims by relying on psychologically and financially draining their targets in order to force them to give up on exposing matters of public interest;

P. whereas the lack of direct legislation in any Member State on SLAPPs together with often ambiguous and broad national defamation provisions in this context, as well as harsh penalties, including of a criminal nature, significantly contribute to the growth in the number of these abusive lawsuits and the subsequent intimidation of their targets;

Q. whereas the criminalisation of journalists for their work is a particularly grave issue; whereas criminalised defamation remains in legislation in 23 Member States, in spite of the repeated calls for its abolition by, among other organisations, the UN, the Council of Europe and the OSCE, and prestigious NGOs such as Index on Censorship, the International Press Institute and the Committee to Protect Journalists;

R. whereas soft law measures are a welcome complementary measure to accompany a legislative proposal and the revision of certain private international laws currently in force, but on their own they do not provide full judicial protection;

S. whereas raising awareness on SLAPPs plays a crucial role in creating awareness of this issue among both the public and legal professionals, in particular judges and lawyers;

T. whereas where SLAPP suits are issued by public officials, public bodies or publicly controlled entities such as state-owned companies, they become a tool for exerting political power and the damage to SLAPP victims can be even greater;

Effects on fundamental rights and the rule of law

1. Highlights that SLAPPs are vexatious, a direct attack on the exercise of fundamental rights and freedoms, and aim to silence the diversity of critical public thought and opinion, including through journalistic self-censorship; underlines that fundamental rights and democracy are linked to upholding the rule of law, and that undermining media freedom and public democratic participation, including the freedoms of expression and information, of assembly and of association threatens Union values as enshrined in Article 2 TEU; is of the opinion that SLAPPs are particularly worrying if they are funded directly or indirectly from state budgets and are combined with other indirect and direct state measures against independent media outlets, independent journalism and civil society; welcomes the fact that the Commission's 2020 rule of law report includes SLAPP lawsuits in its assessment of media freedom and pluralism across the Union, and that this report points to concrete measures and best practices for countering them; calls for future annual reports to include a thorough assessment of the legal environment for the media and investigative journalism in particular, and to look more thoroughly at challenges affecting journalists and civil society and the chilling effect that SLAPPs can have on these actors; highlights that SLAPP lawsuits are a threat to a free and pluralist media; calls on the Commission to also issue country-specific recommendations and assess their progress, including on issues concerning the situation of media freedom within the Member States;

2. Expresses concern about the shrinking space for civil society organisations and the threat to journalists who communicate on important matters in the public interest and are critical of powerful members of society, and about the growing use of SLAPPs as a way to silence and intimidate SLAPP victims; encourages Member States to include media literacy and critical thinking in national curricula and to work closely with journalists on this at all levels of society, especially with young people and those vulnerable to misinformation, disinformation and manipulation; welcomes the introduction of new actions to enhance media freedom, quality journalism and media literacy under the cross-sectoral strand of the Creative Europe Programme;

3. Recalls that the Member States' obligation to facilitate the exercise of the rights of freedom of expression, peaceful assembly and association includes the duty to establish and maintain a favourable environment for public participation and public watchdogs; stresses that it is important for all actors engaging in public participation to be able to operate freely and without fear that they may be subjected to any threats, acts of intimidation or violence; highlights that Member States must also guarantee the right of journalists to protect their sources;

Effects on the internal market

4. Emphasises that public participation also has an important role to play in the proper functioning of the internal market, as well as in the enforcement of Union legislation and policies, as it is often through public participation that breaches of Union law, including violations of fundamental rights, corruption and other abusive practices threatening the proper functioning of the internal market, are made known to the public; underlines that protective measures against the practice of SLAPP suits are essential to addressing the risks that this abusive practice poses to the enforcement of EU law and policies;

5. Highlights that the use of SLAPPs has a negative impact on the enjoyment of internal market freedoms by individuals and organisations engaging in public participation and who are vulnerable to such claims, as the lack of the same level of protection against these claims in Member States may discourage them from operating confidently throughout the Union; underlines, moreover, that SLAPPs cases, or the threat of SLAPPs, runs counter to the effective enjoyment of the rights to freedom of establishment and free movement of services, as it has a chilling effect particularly on journalists, who might exercise self-censorship instead of reporting on matters of public interest in other Member States because they run the risk of then facing SLAPPs in different and unknown legal systems;

6. Draws attention to the fact that media pluralism and diversity is at risk when the very existence of small media providers has been affected by the deliberate threat of disproportionate damages by claimants through libel tourism;

7. Considers, in this regard. that by contributing to the enforcement of Union law and preserving the effective functioning of national justice systems and of the common space of judicial cooperation, protection from SLAPPs lawsuits would substantively contribute to the proper functioning of the internal market;

Effects on justice systems

8. Points out that SLAPPs not only severely undermine the right of effective access to justice of SLAPP victims, and thereby the rule of law, but also constitute a misuse of Member States' justice systems and legal frameworks, especially by hampering the ability of Member States to successfully address ongoing common challenges outlined in the Justice Scoreboard, such as the length of proceedings and the quality of justice systems, as well as caseload administration and case backlogs; recalls that a properly functioning and independent justice system delivers judgements without undue delay, and manages judicial resources so as to maximise efficiency, and that this is only possible where judges and judicial bodies perform their duties with complete independence and in an impartial manner, and are not burdened with the handling of unfounded claims that are later on dismissed as abusive and lacking in legal merit; considers that the early dismissal of a SLAPP suit could be based on objective criteria, such as the number and nature of lawsuits or actions brought by the claimant, the choice of jurisdiction and law applicable to the case, or the existence of a clear and burdensome imbalance of power between the claimant and the defendant; stresses therefore that SLAPPs severely hamper the effective access to justice, possibly undermining the right to a fair trial;

9. Stresses that judicial independence is integral to judicial decision-making and is a requirement resulting from the principle of effective legal protection enshrined in Article 19 TEU; is concerned with the efforts of some Member State governments to weaken the separation of powers and the independence of the judiciary, as well as to use SLAPPs to silence critical voices;

10. Stresses that the independence, quality and efficiency of national justice systems are crucial for the achievement of effective justice; underlines that the availability of legal aid and the level of court fees can have a major impact on access to justice; stresses that the Charter has the same legal value as the Treaties; notes that, in accordance with the guidance of the Court of Justice of the European Union, the Charter is applied by Member States' judicial authorities only when implementing Union legal acts, but that it is, however, important for the rights as enshrined in the Charter to always be taken into account in order to foster a common legal, judicial and rule of law culture;

Hate speech

11. Highlights that in recent years hate speech and discrimination in the media, both online and offline, as well as cyber-violence, have become increasingly widespread against journalists, NGOs, academics, rights defenders and other civil society actors, including those defending LGBTIQ rights, gender equality issues, religion or belief, thus threatening media

freedom, freedom of expression information and assembly, as well as public safety; recalls that online hate speech can incite offline violence; recalls the need to promote the Commission's code of conduct on countering illegal hate speech online; emphasises that female journalists face the same pressures as their colleagues for content-related issues. but are more often the victims of sexual violence and harassment;

12. Stresses the importance of common European standards and a coordinated approach for dealing with hate speech, particularly in the online environment;

Current situation in the Union

13. Stresses that SLAPPs are often meritless, frivolous or based on exaggerated and often abusive claims, and that they are not initiated for the purposes of obtaining a favourable judicial outcome but rather to intimidate, professionally discredit, harass, tire out, put psychological pressure on or consume the financial resources of those they target with the ultimate objective of blackmailing and forcing them into silence through the judicial procedure itself; stresses that SLAPPs cause not only a financial burden but also dire psychological consequences for their targets as well as their family members, aggravated by the fact that the latter may also inherit those abusive proceedings upon the target's death; points out that SLAPPs have a great chilling effect, leading to self-censorship, suppressing participation in democratic life, and also discouraging others from reporting on similar issues from entering into these professions or from engaging in relevant associated activities;

14. Points out that litigants that resort to SLAPPs mostly use and abuse criminal defamation laws, civil lawsuits for libel, protection of one's reputation or intellectual property rights such as copyright; notes, however, that a variety of other instruments are also misused to silence public participation, such as labour sanctions (dismissal), criminal charges of tax fraud, tax audit procedures and data protection rules;

15. Deplores the fact that journalists have paid with their own lives for simply doing their jobs and being the guardians of our democracies;

16. Underlines that an imbalance of power between the claimant and the defendant, particularly in terms of financial resources, and unpredictably large damages award claims in matters such as libel are common features of SLAPPs;

17. Stresses, with regard to this problem, that all Member States lack legislation on minimum safeguards which protect people from becoming SLAPP targets and ensure that their fundamental rights are upheld in all Member State jurisdictions; underlines that judicial independence is paramount to preventing members of government, public entities and public authorities from succeeding in bringing SLAPPs against people and organisations legitimately participating in public debate; notes, in this regard, the need for concrete measures towards creating and maintaining a safe environment for journalists and media workers; calls on the Member States to guarantee media pluralism and ensure transparency of media ownership; calls on the Commission and Member States to develop an ambitious, robust and complete legal framework in its future Media Freedom Act; acknowledges that the digital shift has profoundly changed the media landscape; calls on all Member States to swiftly implement Directive 2010/13/EU on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive) ([27]) as revised in 2018 in all its provisions; welcomes the establishment of the European Regulators Group for Audiovisual media services (ERGA) and encourages cooperation between audiovisual regulatory bodies in the internal market, as well as with other regulatory bodies of relevance for online news activities;

18. Is aware that victims or potential victims of SLAPP suits are currently only receiving financial and psychological assistance from other colleagues who have faced similar lawsuits or are knowledgeable about the character and procedure of SLAPP suits, in order to be able to understand and potentially even contest the lawsuit they have been served with; considers nevertheless that, while commendable, such aid is insufficient and that further measures must be put in place;

([27]) OJ L 95, 15.4.2010, p. 1.

19. Commends civil society's important and useful work in raising awareness of the harmful effects of SLAPPs, as well as the support it gives to victims and potential targets of SLAPPs;

20. Is alarmed that the COVID-19 pandemic has had an impact on the whole media sector, in particular through a revenue drop and deteriorating working conditions for journalists, thus potentially increasing their vulnerability to SLAPPs; warns that governments have been using the coronavirus emergency as an excuse to implement restrictive measures limiting the freedom of expression;

SLAPPs at global level

21. Regrets that no Member State has so far enacted targeted legislation to provide protection against SLAPPs; notes however that anti-SLAPP legislation is particularly well-developed in some states of the United States and Canada as well as in Australia; encourages the Commission to analyse anti-SLAPP best practices currently applied outside the EU which could provide valuable inspiration for Union legislative and non-legislative measures on the matter; underlines the importance of a common Union approach committing to the most ambitious legislation and best practices currently in force to discourage the use of SLAPPs in the Union;

Need for legislative action

22. Agrees with the numerous civil society organisations academics, legal practitioners and victims who point to the need for legislative action against the growing problem of SLAPPs; urgently calls, therefore, for the Brussels I and Rome II Regulations to be amended in order to prevent 'libel tourism' or 'forum shopping' by establishing that the court having jurisdiction and the law applicable to criminal or civil lawsuits concerning defamation, reputational damage and protection of an individual's reputation should, in principle, be that of the place in which the defendant is habitually resident; including the introduction of a uniform and predictable applicable law rule for defamation; urgently calls the Commission to present proposals for binding Union legislation on common and effective safeguards for victims of SLAPPs across the Union, including through a directive establishing minimum standards for protection against SLAPPs, respecting rights and principles enshrined in the Charter; argues that without such legislative action, SLAPPs will continue to threaten democracy, the rule of law and the fundamental rights of freedom of expression, association and peaceful assembly and information in the Union; is concerned that if measures only address defamation lawsuits, actions on other civil matters or criminal procedures may still be used at the initiative of claimants based in or outside the Union;

Legal basis

23. Affirms that legislative measures at Union level could be based on Article 81 TFEU (for cross-border civil lawsuits) and Article 82 TFEU (for criminal lawsuits), and separately on Article 114 TFEU to protect public participation, in order to ensure the proper functioning of the internal market by allowing corruption and other abusive practices to be exposed; asserts that the latter measure could also address SLAPPs, understood as lawsuits that are used for purposes other than genuinely asserting or exercising a right seeking to prevent investigation and reporting on breaches of Union law using a similar approach to the one that led to the adoption of Directive (EU) 2019/1937 (the 'Whistleblower Directive'); is of the opinion that the above legal bases could address SLAPPs consisting of both criminal and civil lawsuits, albeit through separate legislative instruments; calls for effective safeguards against SLAPPs throughout the Union on the basis of these Commission proposals together with actions by the Member States for those safeguards to also apply to domestic cases;

General protective rules and civil justice

24. Considers that it is essential to adopt a legislative measure protecting the role of SLAPP victims in preventing, reporting and denouncing breaches of Union law and ensuring the proper functioning of the internal market and full respect for fundamental rights; urges the Commission to present a proposal for legislation that sets out common safeguards for persons investigating and reporting on or otherwise exposing these matters of public interest;

25. Urges the Commission to present a proposal for a measure to address SLAPP cases such as rules for the early dismissal of SLAPPs and other court actions that have the purpose of preventing public participation, which should include appropriate sanctions such as civil penalties or administrative fines, consideration of abusive motives even if the lawsuit or

action is not dismissed, costs and damages suffered by the victim (economic, reputational, psychological or otherwise); stresses that the modalities for applying for an early dismissal should take account of the challenges faced by SLAPP victims, in particular by requiring that the claimant justifies why the action is not abusive, allocating the legal costs of procedures to the claimant and granting legal and financial support to the defendant; strongly encourages Member States to also apply such civil procedure safeguards to domestic SLAPPs cases and not just to cross-border cases; calls on the Commission, further, to address issues giving rise to forum shopping and libel tourism in the forthcoming review of the Brussels I and Rome II Regulations while also taking account of work carried out at The Hague Conference on Private International Law; calls on the Commission, finally, to raise awareness among judges and prosecutors across the Union about SLAPPs, which including the provision of information on the need for early dismissal of such lawsuits, as well as on the proper implementation of the case law of the European Court of Human Rights on defamation;

26. Recalls that the *res judicata* principle prevents SLAPP initiators from bringing other actions related to the same facts and against the same parties; considers that courts should duly take into account the fact that a party has previously initiated SLAPPs (even when the facts and the parties are not exactly the same, but are similar and/or connected) when examining a submission on SLAPPs;

27. Believes that any revision of the relevant rules in the Brussels I Regulation should be properly mirrored by an equivalent revision of the Lugano Convention so as to ensure a cohesive application of international jurisdiction rules in civil and commercial matters beyond the Union and where Union citizens are concerned;

Criminal justice

28. Urges the Commission to address the seriousness of SLAPPs brought through criminal proceedings by presenting a proposal for measures to ensure that defamation, libel and slander, which constitute criminal offences in most Member States, cannot be used for SLAPPs through public or private prosecution; underlines the calls of the Council of Europe and OSCE for the decriminalisation of defamation; invites the Commission to address SLAPP as lawsuits that are used for purposes other than that of genuinely asserting or exercising a right; notes that defendants often face criminal charges while at the same time being sued for civil liability allegedly arising from the same conduct, and invites the Commission to introduce common minimum procedural safeguards against combined SLAPPs;

29. Recalls that inherent to and at the very core of the right to a fair trial under Article 47 of the Charter is the concept of equality of arms between parties in administrative, civil and criminal proceedings; is concerned that the imbalance of power and resources between parties in SLAPPs cases undermines equality of arms, and thus the right to a fair trial;

Legitimate interest of claimants

30. Declares that due and timely process and the balanced protection of legitimate rights such as the right to protect one's reputation, arising from Union law must be ensured by Member State courts and cannot be jeopardised, including the rights which are routinely cited in abusive lawsuits; underlines, therefore, that anti-SLAPP measures should be without prejudice to legitimate court actions and claimants' right of access to justice; defends at the same time that it is necessary to prevent any abusive use of justice systems and those rights in a manner which is manifestly contrary to the legislators' intention when conferring them upon natural or legal persons in order to guarantee the right to a fair trial; considers that to that end, safeguards are needed not only in order to protect the victims of SLAPPs, but also to prevent and sanction the misuse of measures against SLAPPs, e.g. in cases when authoritarian governments weaponise anti-SLAPP clauses to protect their government-organised NGOs against legitimate defamation lawsuits; notes that preventing such abuse is equally necessary for the correct and uniform application of Union law, thereby safeguarding its effectiveness;

Possible soft law measures

31. Underlines the urgent need for a robust fund for supporting victims of SLAPPs and organisations supporting them provided the funds are directly used for legal fees or the provision of legal aid and psychological support; stresses the importance for victims and potential victims of SLAPPs to have easy and accessible information about these types of cases, legal aid and support, including psychological support for victims and their family members;

32. Considers that support for independent bodies that can hear complaints and provide assistance to potential victims of SLAPPs and adequate training of judges and lawyers can substantively contribute to building knowledge and capacity in how to detect and deal with SLAPPs as lawsuits used for purposes other than that of genuinely asserting or exercising a right, and the threat of SLAPPs;

33. Considers it necessary to collect data on SLAPP cases and raise awareness about the nature and detrimental effects of SLAPPs;

34. Welcomes the Commission's recommendation on ensuring the protection, safety and empowerment of journalists and other media professionals in the European Union (C/2021/6650); notes the increasing use of freelancers, particularly young journalists and media workers at the start of their career, to cover high-risk areas and conflict zones; is concerned by the precarious working and deteriorating safety conditions under which freelancers operate in high-risk areas and conflict zones; calls on the Member States to fully implement the Council of Europe recommendation on the protection of journalism and safety of journalists and other media actors;

Complementarity with other instruments and policies

35. Considers that the new anti-SLAPP legislative and non-legislative measures should complement other EU instruments and policies; welcomes the Union Strategy to tackle Organised Crime 2021-2025, and calls for efforts to be stepped up in this regard; notes that legislative and soft law measures cannot be effective in Member States where there are concerns about the independence of the judiciary or the fight against corruption; reiterates, in this regard, the critical need for an EU mechanism on democracy, the rule of law and fundamental rights as proposed by Parliament;

36. Recalls the importance of Regulation (EU, Euratom) 2020/2092 on a general regime of conditionality for the protection of the Union budget, which has applied to all commitment and payment appropriations since 1 January 2021; underlines that the Union's financial interests are to be protected in accordance with EU values and commitments, and that the Commission should use the conditionality mechanism if Member States fail to protect these values; commends in this light the important work of investigative journalists in exposing cases of abuses of EU funds, and emphasises the importance of journalists being able to exercise their profession without being hindered by SLAPPs;

37. Stresses that Union level measures to combat SLAPPs should be complementary and consistent with other available tools, such as the mechanism for the protection of democracy, the rule of law and fundamental rights, policies on combating corruption, and current financial programmes to support civil society and justice systems;

38. Highlights that the fight against corruption is essential for preserving democracy, fundamental rights and rule of law, as corruption, which can take many forms, undermines our values, the proper functioning of states and enables organised crime;

39. Calls on the Commission to strengthen, in the framework of the annual mechanism on democracy, the rule of law and fundamental rights, the regular, inclusive and structured dialogue with national authorities, NGOs, professional associations and other stakeholders in order to protect and support journalists, and other civil society representatives at risk of SLAPPs, prosecution or harassment;

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40. Calls on the Commission to come forward with proposals on the basis of the annex to this resolution;

41. Instructs its President to forward this resolution to the Council and the Commission.

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ANNEX

1. A package of both soft law and hard law

Legislative measures — a package addressing SLAPPs ***including early dismissal mechanisms,*** should include proposals:

— for general rules providing protection against SLAPPs; specific legislation that sets common minimum standards on supporting and deterrent measures providing protection from SLAPPs;

— specifically addressing questions of civil justice; which Member States are strongly encouraged to apply also to domestic cases of SLAPPs, and private international law, including judicial cooperation and forum shopping;

— addressing in particular issues of criminal justice.

Non-legislative measures — this package should further include:

— adequate training of judges and legal practitioners on SLAPPs;

— assessment of the interplay between different fields of law, such as national media laws and constitutional laws in this context;

— a specific Union fund to provide support to victims of SLAPPs and their family members, including in terms of financial aid, legal assistance and psychological support;

— support for independent bodies (such as ombudspersons) able to deal with complaints from persons threatened or faced with SLAPP suits, and to provide assistance to them as well as for media self-regulatory bodies;

— a publicly accessible Union register of relevant court decisions;

— a 'one-stop-shop'/support hub supported by dedicated national networks of specialised lawyers, legal practitioners and psychologists, which victims of SLAPPs can contact and where they can receive guidance and easy access to information on and support against SLAPPs, including regarding 'first aid', legal aid, financial and psychological support, including through peer exchange networks.

2. General rules

A legislative proposal for a general protection measure would have the dual aim of protecting, in line with the fundamental rights and principles recognised in particular by the Charter persons investigating, reporting or otherwise exposing matters of public interest concerning breaches of Union law, which includes abusive practices which do not appear to be unlawful but defeat the object or the purpose of the law, and protecting the proper functioning of the internal market.

The legislative measure should also provide:

(a) a clear definition of SLAPPs, including the definition of public participation on a matter of public interest;

(b) rules on confidentiality of investigations and reports, including of information sources;

(c) rules on the prohibition of retaliation and effective and dissuasive penalties against SLAPP actions;

(d) rules preventing the misuse of measures provided against SLAPPs;

(e) support measures, including:

(i) effective assistance, information and practical advice and support provided by a 'one-stop-shop' for 'first aid' to SLAPP victims;

(ii) legal and financial aid;

(f) effective measures to protect against retaliation stemming from imbalances of power between the parties and allowing potential damages suffered to be repaired.

3. Civil procedure

A legislative proposal for a civil procedure measure applicable in SLAPP cases, which Member States are strongly encouraged to apply also to domestic cases, should develop judicial cooperation in civil matters by providing for common rules on SLAPPs arising from claims of civil law and include:

(a) that the claimant in cases concerning public participation shall specify and provide justification as to why the action is not abusive;

(b) that courts shall summarily dismiss abusive lawsuits, at the earliest stage possible, either ex officio or following a request by the defendant based on his or her right to file a motion for early dismissal;

(c) that courts shall consider the abusive element in any final decision;

(d) that third parties may intervene and subrogate to the defendant's rights and obligations, in accordance with national procedural law;

(e) that courts shall consider the public interest and the balance of financial resources between parties when assessing costs and the award of damages;

(f) means to protect victims against SLAPPs brought outside the Union;

(g) the right to the full award of costs;

(h) the right to damages for material and immaterial harm, including economic, reputational, psychological or other damages suffered;

(i) rules on preventing further abusive litigation by a party that filed a SLAPP lawsuit in relation to the same facts, namely by taking into account that circumstance when examining a new case.

A proposal from the Commission, aiming to achieve legal certainty and predictability and following the review of private international law instruments should establish:

(a) a recast of the Brussels I Regulation with an explicit rule that, in defamation claims or other claims based in civil and commercial law which may constitute a SLAPP, the habitual residence of the defendant as the sole forum, having due regard to cases where the victims of defamation are private persons;

(b) that the applicable law is the law of the place to which a publication is directed or, should that place not be possible to identify, the place of editorial control or relevant activity with regard to the public participation.

4. Criminal procedure

A legislative proposal regarding criminal law aspects of SLAPPs, should:

(a) specify that where defamation, libel and slander constitute an offence, they cannot be used for SLAPPs, in particular through private prosecution;

(b) specify provisions to safeguard the rights of individuals so that prosecution cannot be used to silence victims of SLAPPs;

(c) facilitate mutual recognition of judgements and judicial decisions, and police and judicial cooperation in criminal matters;

(d) set common minimum procedural safeguards to protect defendants facing SLAPPs based on combined criminal charges and civil liability actions allegedly arising from the same conduct.

These measures should be complementary to current Commission activities, legislation already adopted and future initiatives.

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P9_TA(2021)0452

The European Education Area: a shared holistic approach

European Parliament resolution of 11 November 2021 on the European Education Area: a shared holistic approach (2020/2243(INI))

(2022/C 205/02)

The European Parliament,

— having regard to Articles 165 and 166 of the Treaty on the Functioning of the European Union,

— having regard to Article 5(3) of the Treaty on European Union and the Protocol (No 2) on the application of the principles of subsidiarity and proportionality,

— having regard to Article 14 of the Charter of Fundamental Rights of the European Union,

— having regard to the first principle of the European Pillar of Social Rights,

— having regard to the UN 2030 Agenda for Sustainable Development, and in particular UN Sustainable Development Goal 4,

— having regard to the Commission communication of 30 September 2020 on achieving the European Education Area by 2025 (COM(2020)0625),

— having regard to the Commission communication of 30 September 2020 entitled 'Digital Education Action Plan 2021-2027: Resetting education and training for the digital age' (COM(2020)0624),

— having regard to the Commission communication of 1 July 2020 on a European Skills Agenda for sustainable competitiveness, social fairness and resilience (COM(2020)0274),

— having regard to the Commission communication of 22 May 2018 entitled 'Building a stronger Europe: the role of youth, education and culture policies' (COM(2018)0268),

— having regard to the Commission communication of 14 November 2017 entitled 'Strengthening European Identity through Education and Culture' (COM(2017)0673),

— having regard to the Council resolution of 26 February 2021 on a strategic framework for European cooperation in education and training towards the European Education Area and beyond (2021-2030) ([1]),

— having regard to the Council conclusions of 17 May 2021 on equity and inclusion in education and training in order to promote educational success for all ([2]) and on the European Universities initiative — Bridging higher education, research, innovation and society: Paving the way for a new dimension in European higher education ([3]),

([1]) OJ C 66, 26.2.2021, p. 1.
([2]) OJ C 221, 10.6.2021, p. 3.
([3]) OJ C 221, 10.6.2021, p. 14.

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— having regard to the Council conclusions of 12 May 2009 on a strategic framework for European cooperation in education and training (ET 2020) ([4]),

— having regard to the Council recommendations of 22 May 2018 on promoting common values, inclusive education, and the European dimension of teaching ([5]) and on key competences for lifelong learning ([6]), of 26 November 2018 on promoting automatic mutual recognition of higher education and upper secondary education and training qualifications and the outcomes of learning periods abroad ([7]), of 22 May 2019 on High-Quality Early Childhood Education and Care Systems ([8]) and on a comprehensive approach to the teaching and learning of languages ([9]), and of 20 December 2012 on the validation of non-formal and informal learning ([10]),

— having regard to the Paris Declaration of 17 March 2015 on promoting citizenship and the common values of freedom, tolerance and non-discrimination through education,

— having regard to the Eurydice report of 24 March 2021 on teachers in Europe: careers, development and well-being, and the studies published by the Policy Department for Structural and Cohesion Policies of its Directorate-General for Internal Policies in October 2020 entitled 'Towards a European Education — Critical perspectives on challenges ahead' and May 2021 entitled 'Education and youth in post-COVID-19 Europe — crisis effects and policy recommendations',

— having regard to the study published by the Policy Department for Structural and Cohesion Policies of its Directorate-General for Internal Policies in February 2021 entitled 'Making the European Education Area a reality: state of affairs, challenges and prospects',

— having regard to the study published by the Policy Department for Structural and Cohesion Policies of its Directorate-General for Internal Policies in May 2018 entitled 'European Identity',

— having regard to its resolution of 25 March 2021 on shaping digital education policy ([11]),

— having regard to its resolution of 11 December 2018 on education in the digital era: challenges, opportunities and lessons for EU policy design ([12]),

— having regard to its resolution of 12 June 2018 on modernisation of education in the EU ([13]),

— having regard to the opinion of the European Committee of the Regions of 19 March 2021 on achieving the European Education Area by 2025 ([14]),

— having regard to Rule 57 of its Rules of Procedure,

— having regard to the opinion of the Committee on Employment and Social Affairs,

— having regard to the report of the Committee on Culture and Education (A9-0291/2021),

A. whereas everyone has the right to education and to have access to vocational and continuing training;

([4]) OJ C 119, 28.5.2009, p. 2.
([5]) OJ C 195, 7.6.2018, p. 1.
([6]) OJ C 189, 4.6.2018, p. 1.
([7]) OJ C 444, 10.12.2018, p. 1.
([8]) OJ C 189, 5.6.2019, p. 4.
([9]) OJ C 189, 5.6.2019, p. 15.
([10]) OJ C 398, 22.12.2012, p. 1.
([11]) Texts adopted, P9_TA(2021)0095.
([12]) OJ C 388, 13.11.2020, p. 2.
([13]) OJ C 28, 27.1.2020, p. 8.
([14]) OJ C 175, 7.5.2021, p. 6.

B. whereas the European integration process, the EU single market and other EU policies have contributed — albeit in a fragmented manner — to the natural development of a European educational space, which is historically underpinned by the traditions of European humanism and fundamental rights and values;

C. whereas the ultimate goal is to establish a bottom-up European Education Area (EEA) with common European policy objectives that guarantee quality, inclusive and accessible education, reinforce the exchange of good practices and ensure an effective framework for European mobility, requiring the removal of existing obstacles, the use of European tools, and the support of policy developments at national and European levels to make education systems fit to address the climate crisis and enable a successful green and digital transformation;

D. whereas education needs to be conceptualised broadly as 'lifelong learning', ranging from pre-primary to tertiary education, including vocational education and training (VET) as well as non-formal and informal education, and aimed at the acquisition of transversal skills to enable everyone to develop their potential personally and professionally, to participate fully in society and to successfully manage the transition into the labour market;

E. whereas the challenges the EU and its Member States are faced with today, including a lack of competitiveness, climate change, the digital transformation of society, various forms of extremism and populism, disinformation, the undermining of evidence-based education and the exacerbation of existing inequalities as a result of the COVID-19 pandemic, may necessitate appropriate and concerted European action;

F. whereas the entire education sector has been negatively impacted by the pandemic, with the existing differences in educational infrastructure, expertise and access to resources within and across Member States and between different levels and types of education having become even more pronounced during the COVID-19 pandemic, primarily as a result of increased inequality, including lack of access to IT infrastructure for people from socioeconomically disadvantaged backgrounds, which has had negative repercussions on access to education;

G. whereas in-person education remains essential in both the intellectual and personal development of the student;

H. whereas Parliament has called on the Member States to prioritise investments in education and training, for instance by allocating at least 10 % of their national recovery and resilience budgets to corresponding policies, and has requested a considerably higher budget for the Erasmus+ programme, considering education spending an investment in our common future ([15]) rather than an expense, in order to deliver a more sustainable, digital and socially cohesive society; whereas Parliament has called for investment in education and training to be a substantial part of the Commission's NextGenerationEU instrument;

I. whereas quality investment in education has a high return, although increased spending alone does not necessarily deliver the desired results; whereas the private average global rate of return for education remains high and stable over the decades ([16]);

J. whereas there is a need for better recognition of the teaching profession, which is going through a crisis, for motivated and competent teachers and trainers, and for more continuous training; whereas there is considerable variation between Member States in teachers' initial education and induction, working conditions, remuneration, appraisal, careers, and continuing professional development; whereas in 2018, only 40,9 % of teachers in the EU went abroad at least once for professional purposes as a student, teacher or both ([17]);

K. whereas progress has been made in building a European Higher Education Area as a result of the long-term efforts of the Bologna Process and using it as a reference to learn from experiences with its implementation; whereas there is a need to promote the European Universities, as they contribute to European excellence and the EU's geopolitical role;

([15]) European Parliament resolution of 25 March 2021 on shaping digital education policy.

([16]) Psacharopoulos, G., Patrinos, H. A., Returns to Investment in Education: A Decennial Review of the Global Literature, World Bank Group, April 2018.

([17]) Eurydice report of 24 March 2021 on teachers in Europe: careers, development and well-being.

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L. whereas there is a lack of recognition of VET as a path of choice and excellence on an equal footing with other educational pathways; whereas many obstacles remain to the mobility of learners, including the long-term mobility of apprentices, notwithstanding the progress made under the Copenhagen process;

M. whereas Member States have not fully achieved the objectives and benchmarks of the Education and Training 2020 framework, in particular the aims of enhancing equitable and quality education, reducing the rate of early leavers from education and training, and bringing the share of 15-year-olds who are under-skilled in reading, mathematics and science below 15 %;

N. whereas high-quality data collection and statistics on education and training are two of the prerequisites to better understand the relevant challenges across the EU and the differences within it and to help to address those differences;

O. whereas digital education and adequate digital skills should be seen as part of future-oriented education, and not as a subset of or alternative to existing learning and teaching methods, while highlighting the importance of in-person learning; whereas well over a third of Europeans (42 %) lack even basic digital skills, with significant disparities within and between the Member States; whereas the Skills Agenda aims to ensure that 70 % of 16 to 74-year-olds have basic digital skills by 2025, an average increase of two percentage points per year compared to an increase of 0,75 percentage points per year between 2015 and 2019;

P. whereas the EEA provides an important opportunity for more international cooperation;

The need for a European Education Area (EEA)

1. Emphasises the importance of quality, affordable and inclusive education that is accessible for everyone throughout life and that the EEA initiative should provide more and better opportunities for learners in the EU to study, train, pursue research and work wherever they are, increase learning mobility, facilitate a sustained and meaningful dialogue with the relevant actors, and cultivate an environment where skills, qualifications, diplomas and degrees are recognised and valued throughout Europe;

2. Underscores that the rate of return to education remains very high and hence more education and training generally correlates strongly to societal and economic growth, greater equality and better living standards for everyone and more professional and personal opportunities on an individual level; highlights, therefore, the inestimable significance of education, training and learning, which should be accessible to all, as the most vitally important aspects for driving societal progress and sustainable economic growth; believes that the EEA can and must play an unparalleled role in improving access to and the quality of education throughout the EU;

3. Stresses the role of the EEA in allowing for a greater and better flow of learners, teachers and knowledge, fostering a sense of European belonging and civic awareness, guaranteeing rights and values, and providing fair and equal opportunities; emphasises the potential of Europe to become a real educational power by drawing on the richness of our diversity and exchanging good practices to address existing and future challenges;

4. Considers that education and culture are key to achieving personal and social advancement and well-being, fostering European citizenship, improving social cohesion, driving job creation and European economic and social prosperity fairly and sustainably, and ensuring that the EU is a globally competitive and resilient player characterised by more entrepreneurship to lead the green and digital transitions;

5. Calls for the numerous opportunities for 'European added value' afforded through education to be seized, especially through mobility and the sharing of best practices, with the Erasmus+ and European Solidarity Corps programmes playing a particularly important role;

6. Calls for a clearer and stronger geopolitical dimension of the EEA in order to enable the EU to make strategic use of its educational power with its closest neighbours and partners;

Bridging institutional and stakeholder approaches

7. Takes note of the variety of visions and approaches on the EEA, which express a common wish to provide fresh impetus to the European project; regards education as a cornerstone for the achievement of the European project, with the EU's role being focused, inter alia, on supporting and coordinating Member States in sharing good practices, encouraging common standards and bridging existing gaps, while educational content and teaching methods remain a national competence; underlines the need for more collaboration on education across Europe and beyond in order to develop common approaches and solutions to common challenges;

8. Appreciates the Commission's efforts to foster an EEA, while noting the need for a more holistic approach which requires meaningful cooperation and coordination between all actors and a diverse range of stakeholders, including the education and training community, parents' associations, social partners, trade unions, youth organisations, youth workers and civil society; calls for more openness towards novel ideas to ensure that the EEA continues to evolve and serves as a stimulus for more and stronger partnerships, including between the public and private sectors, and synergies between stakeholders;

9. Welcomes the Council's response to the Commission's proposals, in particular its focus on the importance of VET and lifelong learning opportunities, which need to be affordable and accessible to everyone, notably in the EU's outermost regions;

10. Welcomes the Commission's commitment to achieving the EEA by 2025; cautions that the Commission's proposals are still mainly a strategic outline rather than a concrete policy roadmap; suggests, therefore, the establishment of clear mid- and long-term priorities with achievable targets and deadlines for the actions that should be adopted, including clearly defined interim deliverables that will constitute the different building blocks of a genuine EEA without unnecessary delays, while taking account of the Member States' fiscal capacities;

11. Emphasises the urgent need to develop a common implementation strategy and roadmap that includes the EU institutions, the Member States and all the relevant stakeholders, including local and regional authorities and civil society, and defines their respective responsibilities and opportunities; insists that the EEA should be clear and accessible and reflect all levels of governance;

Turning vision into reality: common strategic priorities and EU-level targets

12. Stresses the potential of using European policy coordination tools to achieve the common objectives of the EEA, including the open method of coordination and the European Semester; recalls the role of the European Semester for the successful implementation of EU policies in the field of education, while acknowledging that it was originally conceived as a tool for the coordination of economic policies across the EU in order to ensure that governments observe fiscal responsibility;

13. Calls for all EU institutions and Member States to agree on the same vision, priorities, targets and benchmarks regarding the EEA, while acknowledging existing diversities in Europe;

14. Underlines the importance of establishing academic freedom and pedagogical autonomy as core principles of the EEA;

15. Calls for the use of synergies between the EEA, the European Research Area and the European Higher Education Area, as well as between the various EU programmes; calls for the further strengthening of Erasmus+, Horizon Europe, Creative Europe, the European Solidarity Corps, Digital Europe, and the Citizens, Equality, Rights and Values Programme in order to benefit all teachers, educational workers, education providers, youth workers and all learners;

16. Highlights that inclusion should be a central dimension of the EEA and a prerequisite for achieving quality education for all; underlines that no one should be left behind, that every learner has a talent, and that individual differences should be appreciated and valued; underlines that progress on common targets can only be achieved through a more comprehensive approach;

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17. Stresses the importance of placing the learner at the centre of the learning process; underlines the need to ensure that a tailored approach is taken towards vulnerable groups, including people with any kind of disabilities or learning differences, such as those on the autism spectrum or those with high potential, and to foster a whole-school approach to the EEA; invites the Commission to consult all the relevant stakeholders such as student associations, pedagogical support experts, caregivers for learners with special needs, and others, especially when it comes to developing the European Universities and Centres of Vocational Excellence;

18. Warmly welcomes the objectives of the EU's new strategic framework for lifelong learning and training, which was the subject of the Council resolution of 19 February 2021 on a strategic framework for European cooperation in education, as well as the five strategic priorities identified therein, notably the specific proposals to make lifelong apprenticeships and mobility a reality for all;

19. Stresses the importance of improving working conditions and the need for teachers and educators to be adequately remunerated for their work; urges the Member States, in cooperation with the Commission, to invest in the initial education of teachers and trainers, notably by including a European dimension and transnational mobility in their curricula, to cultivate competences and motivation in the education profession, to enhance the recognition of the value that educators bring to society, and to bolster pedagogical autonomy; points to the importance of professionalising early childhood education and care staff in order to properly recognise and value their work, which is indispensable for the education of children;

20. Urges the Member States to foster media and information literacy, critical thinking and a culture of tolerance at all stages of the learning process as a priority and a critical tool for empowering responsible European citizens with the skillsets they need to counter the increasing wave of disinformation and face up to the challenges of the 21st century;

21. Calls for a common framework on the development of digital competences; stresses the need for a common system of recognition, validation and certification of digital skills, qualifications and credentials, to reduce gaps in digital competences across Europe, and for all learners, especially children, to have access to basic digital equipment;

22. Underlines the need to ensure the digitalisation of universities in the EU and reiterates the call for the creation of a European online university platform; calls for the EU to recognise connectivity and digital infrastructure as a right derived from the fundamental right to education;

23. Welcomes the recent changes in the Electronic Platform for Adult Learning in Europe and invites the European Education and Culture Executive Agency to assess how to further increase the visibility, continue the development and strengthen the impact of the adult learning community;

24. Supports the use of quantitative indicators and benchmarks, giving due consideration to the differences between and within the Member States, in order to allow for the continuous comparison and monitoring of Member States' progress towards common objectives and incentivise further policy actions, while reiterating the need for supplementary qualitative indicators and benchmarks and cautioning against overambitious medium-term targets;

25. Highlights the need to improve the quality and increase the frequency of the necessary data collection activities, and to ensure the active monitoring of relevant indicators and benchmarks such as the target set by the European Skills Agenda to achieve 50 % of the adult population participating in learning activities; urges the Commission and the Member States to achieve ambitious targets, such as on the proportion of low achievers and early school leavers, by reducing the first benchmark from 15 % to 10 % and the second from 10 % to 5 %;

26. Calls for closer collaboration between the EU and other organisations and institutions such as UNESCO and the Organisation for Economic Co-operation and Development, and for the active use of and support for existing and future educational research and studies to assist Member States in identifying effective policy reforms; urges the Commission and the Member States to develop common and participatory educational research with a well-defined mandate and budget within the remit of EU competences;

27. Calls on the Member States and the Commission to provide the requisite funding for the establishment, implementation and development of the EEA and the establishment of a dedicated financial instrument in the 2028-2034 multiannual financial framework with a view to developing the EEA further and facilitating the mutual recognition of qualifications; reiterates its call to allocate at least 10 % of the funding under the Recovery and Resilience Facility to education, including digital education, and calls for the Member States to substantially increase public spending in education to above the EU average (4,7 % of GDP in 2019);

28. Encourages the Commission and the Member States to put in place disaster mitigation strategies for the education sector, in partnership and consultation with all stakeholders, and insists on the importance of concerted European action at times of crisis, such as the COVID 19 pandemic;

Sector-specific measures and considerations

29. Underlines the importance of learning foreign languages, and of English in particular; underscores the need for Member States to take action to support the development of linguistic competences at all levels, especially in primary and secondary education, to embrace the Council of Europe's goal of 'plurilingualism' and to achieve the benchmark of all pupils having a sufficient knowledge of at least two other official languages of the EU and its Member States at the end of lower secondary education at the latest;

30. Calls on the Commission to develop tools to allow Member States to implement the Council recommendation on a comprehensive approach to the teaching and learning of languages, and to monitor progress accordingly; calls on the Member States to collect comparable data on language learning; calls on the Commission to provide financial support for schools teaching European language skills, especially the native languages of EU citizens living in other EU countries;

31. Stresses the need for research and innovation to be promoted in education; underlines the importance of an EEA in promoting the understanding, study and research of cutting-edge technologies such as artificial intelligence (AI) and robotics so as to raise awareness of the associated opportunities and challenges in educational settings, including by means of specific undergraduate study programmes across all Member States; is concerned that the EU as a whole does not have a sufficient supply of specialised AI undergraduate programmes;

32. Welcomes the initiative of the European Centres of Vocational Excellence, which provides a structure for the sector at European level; calls for the creation of a European vocational and training area as an integral part of the EEA; asks the Commission and the Member States to work towards the creation of a European apprentices statute; highlights the need for some Member States to address the lack of attractiveness and prestige of VET and dual education systems; stresses that VET systems need to become even more learner-centred and adapted to the changing world of work; reiterates the importance of VET recognition and calls on the Member States to implement the corresponding Council recommendation and the European Skills Agenda properly and in full; underlines the importance of creating flexible and modular pathways to learning to enable learners to combine and build on different learning experiences and opportunities;

33. Stresses the importance of Commission and Member State action in higher education, such as reinforcing the Bologna Process, strengthening the international dimension of the EEA and furthering the European Student Card, including through embracing the synergies offered by existing EU programmes;

34. Urges that the EEA should be a milestone in the recognition of diplomas and qualifications across the EU and calls on the Commission and the Member States to facilitate the expansion of automatic mutual recognition of learning outcomes and study periods abroad, including in VET and through European micro-credentials;

35. Highlights the prominent role of non-formal and informal learning as well as volunteering and stresses the need to recognise their results; calls on the Commission and the Member States to promote soft skills across the EU;

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36. Encourages the Member States to implement the 2018 Council recommendation on key competences for lifelong learning in order to advance progress in all eight key areas such as opportunities for young learners to undertake at least one practical entrepreneurial experience during their education and, in so doing, to improve the recognition of competences gained through non-formal and informal learning so as to increase the flexibility of learning pathways for learners of all ages; calls for the creation of a European framework on civic and social competences that values, promotes and recognises the benefits of practices such as mentoring and the supervision of youth activities;

37. Underlines that following the COVID-19 pandemic, remote learning has become a part of reality for many learners; stresses that in primary and secondary education, remote learning must remain a last resort and be complementary to face-to-face learning, which is key for teaching valuable social skills; underlines that a modern, blended learning approach aimed at school-age students needs to take place predominantly in the classroom and under the guidance of the teacher, who may for pedagogical reasons choose to mix different tools, be they digital (including online) or non-digital, as part of learning tasks ([18]);

38. Calls on the Member States to promote education related to climate change and the ecological transition and to raise awareness of the European Green Deal;

39. Calls on the Commission and the Member States to close the gender gap in education, including in education and careers in science, technology, engineering, the arts and mathematics (STEAM), to fight gender stereotypes and discrimination, and to eradicate bullying, cyber-bullying and other forms of harassment, discrimination and violent misconduct so as to improve cultural, ethnic and gender diversity through the creation and exchange of good practices across Europe;

40. Welcomes the commitment of the Portuguese Presidency of the Council to launch an online platform aimed at facilitating data sharing among the Member States concerning the challenges linked to unemployment faced by young people as a result of the pandemic;

41. Reiterates the significance of massive open online courses (MOOCs) as a necessary element to promote upskilling and reskilling of the workforce in an interactive and accessible manner; believes that the EEA should promote uptake and development of MOOCs and reflect such objectives in the European approach to micro-credentials;

42. Notes that there is currently no single, agreed definition covering the term 'micro-credentials'; considers, therefore, that uniform EU-wide standards need to be defined in order to effectively promote their mutual recognition among the Member States and ensure that employers trust their value;

Governance framework

43. Calls on the Commission and the Member States to establish a concrete European Education Area Strategic Framework 2030 (EEASF 2030) by the end of 2022, including a comprehensive steering, monitoring and evaluation mechanism, in line with UN Sustainable Development Goal 4 to 'ensure inclusive and equitable quality education and promote lifelong learning opportunities for all' and the first principle of the European Pillar of Social Rights; welcomes the proposal for a steering committee for the EEA, laying the groundwork for a structured and systematic governance framework; emphasises the role of the Conference on the Future of Europe to discuss the way forward on the challenges facing European education and on policy development;

44. Urges the Commission and the Member States to commit to the type of participation required from Member States and other levels of government, including local and regional authorities, as well as the EU institutions, and to devise effective multi-level governance arrangements that respect the principle of subsidiarity, while aiming to generate European added value;

45. Seeks clarity on the level of involvement expected from stakeholders, education sectors that have been hitherto underrepresented, and the relevant civil society actors; stresses that the governance framework should involve all relevant stakeholders working in all areas of learning, including youth workers and youth organisations as well as parents' associations;

([18]) See the Commission proposal of 5 August 2021 for a Council recommendation on blended learning for high quality and inclusive primary and secondary education (COM(2021)0455).

46. Calls on the Commission to establish an EEA platform as an interactive public gateway to support Member States and stakeholders in exchanging information and promoting cooperation and the exchange of good practices; believes that such a platform should be adequately funded and available in all official languages of the EU;

47. Emphasises that European censuses, data collection and research on territorial needs and educational practices across the EU are a key priority for the Member States and their education systems;

Towards a greater European dimension in education

48. Underlines the need for a European dimension in education by incorporating a greater and distinct European perspective in educational curricula and teacher training programmes, encompassing all teachers, trainers and learners from both formal and non-formal organisations and the VET sector, and including support from Jean Monnet actions and teacher academies; proposes that these teacher academies be called 'Comenius Teacher Academies'; supports the creation of a common framework for the shaping and development of teacher qualifications across the Member States;

49. Emphasises the need to provide learners with comprehensive knowledge about European history and cultural heritage, both tangible and intangible, and to foster a critical European memory and historical consciousness based on the fundamental values on which the EU is built; calls on the Commission, the Member States and the Council of Europe to cooperate on European history and cultural heritage education across the EU, and highlights the need for targeted funding and initiatives to increase research on European history, as well as the promotion of public history, taking into account the complex nature of the history of our continent;

50. Calls on the Commission and the Member States to create a common framework on learning about the EU throughout all appropriate levels and areas of education; stresses the need to familiarise learners with the European integration process, the institutions and policies of the EU, the rights stemming from EU citizenship, and how to actively participate in the EU's democratic processes;

51. Calls on the Commission and the Member States to develop a comprehensive European strategy and a common framework on citizenship education with a European dimension, including learning about European values — such as human dignity, democracy, the rule of law, human rights and equality — to encourage the exchange of good practices and the development of common pedagogical material and approaches; asks the Commission, in this respect, to explore the establishment of a citizenship education task force to coordinate this task and improve access to European citizenship education in order to foster a European civic culture and a sense of European belonging, complementing local, regional, national and global dimensions;

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52. Instructs its President to forward this resolution to the Council and the Commission.

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P9_TA(2021)0453

An intellectual property action plan to support the EU's recovery and resilience

European Parliament resolution of 11 November 2021 on an intellectual property action plan to support the EU's recovery and resilience (2021/2007(INI))

(2022/C 205/03)

The European Parliament,

— having regard to the Commission communication of 25 November 2020 on a Pharmaceutical Strategy for Europe (COM(2020)0761),

— having regard to the Commission communication of 19 February 2020 on a European strategy for data (COM(2020)0066),

— having regard to the Commission communication of 25 November 2020 entitled 'Making the most of the EU's innovative potential — An intellectual property action plan to support the EU's recovery and resilience' (COM(2020)0760),

— having regard to the Charter of Fundamental Rights of the European Union (the 'Charter'), in particular Article 17(2) thereof,

— having regard to the Agreement on a Unified Patent Court ([1]),

— having regard to the 1995 WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement),

— having regard to the Geneva Act of the Lisbon Agreement on Appellations of Origin and Geographical Indications of the World Intellectual Property Organization (WIPO), which entered into force on 26 February 2020 ([2]),

— having regard to Regulation (EU) 2021/241 of the European Parliament and of the Council of 12 February 2021 establishing the Recovery and Resilience Facility ([3]),

— having regard to Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products ([4]),

— having regard to Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC ([5]),

— having regard to Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use ([6]),

— having regard to Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights ([7]),

([1]) OJ C 175, 20.6.2013, p. 1.
([2]) OJ L 271, 24.10.2019.
([3]) OJ L 57, 18.2.2021, p. 17.
([4]) OJ L 153, 11.6.2019, p. 1.
([5]) OJ L 130, 17.5.2019, p. 92.
([6]) OJ L 136, 30.4.2004, p. 34.
([7]) OJ L 157, 30.4.2004, p. 45.

— having regard to Directive 98/71/EC of the European Parliament and of the Council of 13 October 1998 on the legal protection of designs ([8]),

— having regard to Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs ([9]),

— having regard to the Commission Pharmaceutical Sector Inquiry Report of 2009,

— having regard to joint EPO-EUIPO firm-level analysis report on intellectual property rights and firm performance in the European Union of February 2021,

— having regard to the Commission's evaluation of EU legislation on design protection,

— having regard to the Council conclusions setting the EU's priorities for the fight against serious and organised crime for EMPACT 2022-2025,

— having regard to the in-depth analysis commissioned by the European Parliament entitled 'Standard Essential Patents and the Internet of Things' of January 2019,

— having regard to its resolution of 9 June 2015 on 'Towards a renewed consensus on the enforcement of Intellectual Property Rights: An EU Action Plan' ([10]),

— having regard to its resolution of 20 October 2020 on intellectual property rights for the development of artificial intelligence technologies ([11]),

— having regard to its resolution of 19 May 2021 with recommendations to the Commission on challenges of sports events organisers in the digital environment ([12]),

— having regard to its resolution of 6 October 2015 on the possible extension of geographical indication protection of the European Union to non-agricultural products ([13]),

— having regard to its resolution of 10 July 2020 on the EU's public health strategy post-COVID-19 ([14]),

— having regard to Rule 54 of its Rules of Procedure,

— having regard to the opinions of the Committee on Development, the Committee on the Internal Market and Consumer Protection, the Committee on Agriculture and Rural Development and the Committee on Culture and Education,

— having regard to the report of the Committee on Legal Affairs (A9-0284/2021),

A. whereas balanced protection and enforcement of intellectual property rights (IPR), are very important to the European economy as well as to the EU's recovery and resilience, in particular to the COVID-19 pandemic;

B. whereas the COVID-19 pandemic has shown the importance of IP protection policies since it illustrated the need for effective measures to address the shortage of vaccines against COVID-19, threatened livelihoods and led to an existential loss of revenue for workers in the cultural and creative sectors;

([8]) OJ L 289, 28.10.1998, p. 28.
([9]) OJ L 3, 5.1.2002, p. 1.
([10]) OJ C 407, 4.11.2016, p. 25.
([11]) OJ C 404, 6.10.2021, p. 129.
([12]) Texts adopted, P9_TA(2021)0236.
([13]) OJ C 349, 17.10.2017, p. 2.
([14]) OJ C 371, 15.9.2021, p. 102.

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C. whereas investments in intangibles were significantly less affected by the 2008 economic crisis, thereby showing IP assets' potential for creating economic stability and growth as well as a positive correlation between IPR ownership and quality and stability of employment; whereas studies show that businesses using IPRs grow faster, are more resilient to economic downturns, increase company value and strengthen their position in the single market; whereas these facts also point to the importance of incentivising and helping SMEs protect and own their IPRs;

D. whereas IP registrations slightly increased in the first months of 2021 compared with the same period in 2020; whereas a sustainable and digital post-COVID economic recovery could be based on IPR; whereas during the current COVID-19 pandemic the rapid alert system for dangerous products ('RAPEX') registered an alarming new all-time high number of alerts;

E. whereas intellectual property (IP) registrations are constantly increasing, and the single market remains fragmented as a result of differences in national legislation; whereas there is a continuing need for parallel national validation procedures and litigation for European patents; whereas gaps remain, in particular in enforcement, which can hinder the development of companies, in particular micro, small and medium-sized enterprises (SMEs), limit consumers' access to innovative and safe products, and prevent social challenges from being addressed through innovation;

F. whereas knowledge-intensive industries are a source of growth and prosperity; whereas between 2012 and 2016 they generated almost 30 % of all jobs and almost 45 % of total economic activity (GDP) in the EU, as shown in the 2019 industry-level analysis report by the European Patent Office (EPO) and the EU Intellectual Property Office (EUIPO) ([15]); whereas IPR-intensive industries account for 93 % of total EU exports of goods to the rest of the world;

G. whereas IP is a fundamental right according to Article 17 of the Charter;

H. whereas the development and progress of knowledge-based industries depends to a significant extent on the rules governing IPR, and in particular on ensuring effective protection through efficient legislation on patents, trademarks, designs, copyright and related rights, geographical indications and plant variety protection, as well as through appropriate and harmonised application of the rules on the protection of trade secrets;

I. whereas IP systems contribute to the development of new medicines and IP incentives are important for ensuring effective access to affordable medicines; whereas new medicines must comply with international human rights law, public international law and public health requirements;

J. whereas European innovators are front-runners in green technologies, holding a major proportion of green patents and robust IP portfolios in technologies such as climate change adaptation, carbon capture and storage, and water and waste treatment;

K. whereas there is a need to promote the valorisation and deployment of research and development in Europe, as exemplified by the fact that in the field of AI only a minority of patent applicants worldwide are European, even though a significant percentage of high-value publications on AI come from Europe;

General

1. Supports the Commission in pursuing the aims of its IP action plan of November 2020, as strong, balanced and robust IPR protection at the national, European and international level which allows return on investment is particularly important for the economic and social recovery from and long-term resilience to COVID-19 and other global crises so that the EU can respond to crises in an agile way and in line with the principles of Regulation (EU) 2021/241 establishing the Recovery and Resilience Facility ([16]) and ensures legal certainty and compliance with European legislation, as well as enables the creation of a digital and globally competitive sustainable economy in Europe where innovation also serves the purpose of contributing to the common good of society;

([15]) EPO-EUIPO, *IPR-intensive industries and economic performances in the EU: Industry-level analysis report*, third edition, September 2019.
([16]) OJ L 57, 18.2.2021, p. 17.

2. Acknowledges that IPR protection encourages creative, inventive and innovative activity, thus allowing the largest number of people to benefit from this activity; notes that this activity makes it possible for inventors, innovators and authors to obtain compensation for their creative endeavours; calls on the Commission to continue supporting European companies' ability to innovate on the basis of a comprehensive IP regime in order to maintain effective protection for their R&D investments, secure fair returns through licensing, continue developing open technology standards that support competition and choice and ensure the participation of EU industry in the development of key technologies at global level;

SMEs and IP-protection

3. Highlights that IPRs have many benefits for small and medium-sized enterprises (SMEs) and micro-enterprises; underlines that IPR-intensive industries offer better quality jobs with better working conditions and higher remuneration; notes that SMEs that own IPRs generate up to 68 % higher revenue per employee and pay wages that are 20 % higher than those in SMEs that do not; is therefore concerned that many SMEs have difficulties in determining their own IP strategy and managing their IPRs; welcomes, therefore, IP vouchers, the IP Scan and other Commission and EUIPO initiatives to support simple registration procedures and low administrative fees for micro-enterprises and SMEs and to help them make the most of their IP; asks the Commission, the European Patent Office (EPO) and the EUIPO to consider extending these initiatives to all kinds of IP assets and to identify further measures to promote the benefits of IPR registration for the development of SME activities;

4. Is convinced that support for SMEs, including financial and non-financial measures, is the right way to provide them with better knowledge and to facilitate their access to IPRs and that the Union's financial and legal instruments are of the utmost importance in this regard; calls on the Commission and the EUIPO, therefore, to continue implementing IP management support measures for SMEs and micro-enterprises during the economic recovery, including the provision of one-stop shop access to information and related services and advice about IP; stresses that this support will help to leverage and promote all national and regional initiatives of members of the European Union Intellectual Property Network (EUIPN);

5. Is concerned that even though intangibles are some of the most valuable assets, only a few European SMEs are aware of this and benefit from their IP when trying to obtain finance; welcomes, therefore, the announced European IP Information Centre as one of many measures that will ensure that Europe capitalises further on the value of the knowledge our companies constantly create, develop and share, and that they are equipped with the necessary tools and information or manage these assets more actively; stresses that utility models provide fast and low-cost protection for technical inventions and are very attractive for SMEs; encourages the Member States that are not yet offering this tool, therefore, to establish it and calls on the Commission to consider the possibility of introducing EU-level utility model protection, which is currently not available;

Unitary Patent package

6. Stresses that the unitary patent package (UPP), which includes the European patent with unitary effect (unitary patent) and the Unified Patent Court (UPC), aims at making patent protection more efficient, as well as making dispute settlement across Europe comprehensible, by avoiding parallel procedures in Member States, and less costly, by reducing legal costs, as well as more accessible and efficient, thereby enhancing legal certainty; asks the participating Member States which have not yet done so, therefore, to move forward on the ratification of the Protocol to the Agreement on a Unified Patent Court on provisional application (PPA), as soon as possible, or to declare by other means that they are bound by the PPA in order to allow the rapid entry into operation of the UPP;

7. Stresses that the unitary patent is an additional option in parallel to national patents and encourages the Member States that are not yet participating in enhanced cooperation for the creation of unitary patent protection and/or have not yet acceded to the UPC Agreement, to continue the process that will lead to full participation; recalls that innovative SMEs benefit from a consistent European patent system, and underlines that the UPC Agreement and its Rules of Procedure represent a carefully balanced solution reflecting the Union's fundamental principles of proportionality, flexibility, fairness and equity; takes note of the fee reductions and the reimbursement of fees for SMEs in the framework of the UPC Rules of Procedure;

8. Welcomes the one-stop-shop alternative dispute resolution system to be established under Article 35 of the UPC Agreement, which does not interfere with current national systems, so that parties' right to justice is not undermined; asks the Member States to enable the quick roll-out of the patent arbitration and mediation centre, and calls on the Commission to assess whether the centre could, in the medium or long term, deal with all IP disputes; welcomes Member States' efforts to find appropriate solutions to deal with the effects deriving from Brexit;

Supplementary protection certificates

9. Stresses that the supplementary protection certificate (SPC) regime within the EU, while of great practical relevance, suffers from fragmented implementation across the Member States; urges the Commission to issue guidelines for the Member States and to address this fragmentation, including by legislative proposals based on an exhaustive impact assessment;

10. Acknowledges that the UPP does not provide for a unitary SPC title and calls on the Member States to support the establishment of such a title as a logical extension of unitary patent protection;

11. Asks the Commission, in the absence of a unitary SPC title, to ensure coherence between the upcoming unitary patent and current SPC regimes within the EU by clarifying that national SPCs may be granted by national patent offices on the basis of a unitary patent;

12. Welcomes the fact that the Commission wants to assess the potential impact of a proposal for a unitary SPC; notes that the introduction of a unitary SPC title with suspensory condition depending on the formal decision at national level could even happen before the entry into force of the unitary patent, and suggests therefore that consideration be given to extending the EPO's mandate, so that examination of SPC applications could be carried out on the basis of unified rules;

13. Points out that inefficiencies in SPC granting procedures hamper innovators and producers to the detriment of equitable patient access to treatments and that a level playing field for makers of generics and biosimilars in the Union is essential; highlights, therefore, that abuses of divisional patent applications and patent linkage have to be effectively addressed; recalls that innovation should meet the most urgent needs of society and that timely supplies of medicines, including generics and biosimilars, should be promoted in this context, as well as affordability and swift availability; stresses that a possible revision of the so-called Bolar exemption, which allows trials on patented products to be conducted to support generic and biosimilar marketing authorisation applications without being regarded as infringements of patent rights or SPCs for medicinal products, as well as effective and immediate market entry after the expiration of patent rights and SPCs, can only take place after a comprehensive impact assessment;

14. Underlines the important role played by public investments in R&D, and calls on the Commission and the Member States to ensure that the results of publicly financed R&D in the pharmaceutical sector are transparent, so that patenting and licensing conditions guarantee a public health return on public investments;

Standard essential patents

15. Acknowledges that information on the existence, scope and relevance of standard essential patents (SEPs) is important for fair licensing negotiations allowing the potential user of standards to identify the scale of their exposure to SEPs and possible licensors; notes that although good faith negotiations between willing parties occur in most cases, SEPs are often litigated; suggests that the Commission looks into possible incentives for negotiation that avoid litigation as it would avoid the accompanying dispute costs and reduce other related problems;

16. Stresses that many patent applications declared potentially essential in standards development organisations during the standard setting process may eventually not be essential to the standard as finally adopted or after the granting of the patent, and that an appropriate, truly independent and transparent scrutiny mechanism would enhance transparency and increase legal certainty; welcomes in this regard the pilot study for essentiality assessment of SEPs ([17]);

([17]) European Commission Joint Research Centre, *Pilot study for Essentiality Assessment of Standard Essential Patents,* 2020.

17. Asks the Commission to further investigate, together with the relevant actors, the requirements for an independent, neutral and transparent system of third party essentiality checks by identifying the demand for, assessing the impact of and defining the role that resources such as emerging technologies like AI and related technologies and/or technical expertise contributed by the EPO could play in that context, and to use the knowledge gained as input for the legislative initiative on SEP envisaged for the beginning of 2022 based on appropriate impact assessments;

18. Acknowledges the importance of a balanced licensing system for SEPs and insists on the importance of stable, efficient and fair rules for this; underlines that 'fair, reasonable and non-discriminatory terms' (FRAND) are vague legal terms that include legal uncertainty, and calls on the Commission to monitor industry developments and provide more clarity on various aspects of FRAND as well as case law and including through designating an observatory (competence centre) for this purpose; recalls Parliament's previous call for the Commission to publish annual reports evidencing actual cases of non-compliance with FRAND and so-called patent 'hold-ups' and patent 'hold-outs';

19. Emphasises the importance of increasing the transparency of Standards Development Organisation (SDO) databases and calls on SDOs to update their declaration system and databases; highlights in this context Article 9(1)(c) of Regulation (EU) No 1257/2012 ([18]) which provides that the EPO has the task of receiving and registering licensing commitments undertaken by the proprietor of a unitary patent in international standardisation bodies; calls on the Commission to continue observing the conduct of third country companies in international standardisation bodies which, together with recent decisions by foreign courts, places European companies at a significant disadvantage by undermining the competitiveness of the European market;

20. Notes the importance of transparency and the need to proactively provide necessary information in advance when licensing standard essential patents on FRAND terms in a way that will ensure a fair outcome of good faith negotiations between parties; highlights that the question of whether a SEP holder may choose the level of licensing in a supply chain or whether any company in the value chain must have access to a licence is not clarified yet, and therefore asks the Commission to cooperate with the relevant stakeholders in order to find an approach to this issue and to address it;

21. Highlights the value of existing industry-led voluntary initiatives to facilitate SEP licensing for the internet of things, such as licensing pools, which bring together the vast majority of European and international cellular technology developers;

Geographical indications

22. Recalls that around 3 300 products are protected by the EU as geographical indications (GIs) and that the yearly value of all these products has increased to over EUR 75 billion, and therefore welcomes the initiatives and actions to strengthen, modernise, streamline and better enforce the system of GIs for agricultural products, food, wines and spirits in order to make it more precise and effective, since they contribute to creating and protecting quality jobs, to the promotion of social, environmental and economic sustainability in rural areas, and to fostering European cultural diversity;

23. Considers that the issue of overburdening producers with administration in connection with the registration, amendment and management of GIs and traditional specialities guaranteed (TSG) product specifications should be at the heart of future discussions; recalls that the procedures for amending the specifications for GIs have been simplified and streamlined for wine and agri-food products as part of the review of the common agricultural policy reform, and that this approach should be strengthened in the future;

24. Recalls that farm-saved seeds are estimated to account for over 80 % of farmers' total seed requirements in some African countries; calls for the EU to support IPRs regimes that enhance the development of locally adapted seed varieties and farm-saved seeds, in line with the provisions of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and Article 19 of the UN Declaration on the Rights of Peasants and Other People Working in Rural Areas;

([18]) Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection (OJ L 361, 31.12.2012, p. 1).

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25. Considers it essential to protect IPRs in a way that promotes research and innovation, in particular with the aim of introducing more resilient agricultural varieties to cope with climate change, achieve sustainable and agro-ecological farming models that are protective of natural resources and respectful of the potential of non-protected reproductive and heterogeneous material in the organic sector; stresses that protection of plant variety rights is essential and requires a strong and enforceable protection system in the EU and highlights therefore the important role of the Community plant variety rights systems and the International Union for the Protection of New Varieties of Plants; points out that IPRs must also contribute to food security and the resilience and competitiveness of the EU agri-food model;

26. Stresses that further efforts should be made to increase transparency on the status and patentability of biological material; points out that breeders should be provided with adequate access to information on the biological material they will use in the plant breeding process; stresses that the Commission should implement new methods for effective consultation and exchange of information; opposes any patenting of live animals;

27. Believes that the recognition of GIs for non-agricultural products is relevant to the priorities of EU programmes being developed, including those of the industrial strategy, through the development of short supply chains, as well as the Green Deal by fostering locally-made products with greater traceability and transparency on the origin of the product and manufacturing processes used;

28. Supports the Commission in its initiative to establish, on the basis of a thorough impact assessment, an efficient and transparent EU *sui generis* protection of geographical indications (GIs) for non-agricultural products, which identify a product as originating in the territory of a Member State or a region or locality in that territory, where a given quality, reputation or other characteristic of the product is essentially attributable to its geographical origin, in order to align with, inter alia, the Geneva Act of the Lisbon Agreement on Appellations of Origin and Geographical Indications, which the EU has signed and which includes the possibility of protecting GIs for both agricultural and non-agricultural products; expects the Commission to propose legislation on this as soon as possible and by the end of 2021 at the latest;

29. Emphasises that the introduction of an EU *sui generis* protection system of GIs for non-agricultural products should aim to bring benefits to consumers, by facilitating knowledge of the authenticity product indications, have a positive economic impact on micro-enterprises and SMEs by encouraging competitiveness, and have a general impact on employment, development and tourism in rural and less developed areas, which could in particular help the EU's recovery after the COVID-19 crisis; believes that such *sui generis* protection of non-agricultural GIs would also facilitate access to third country markets through EU trade agreements; considers, however, that the system must envisage necessary safeguards, including effective and transparent application and opposition mechanisms;

30. Takes note of the fact that current EU trade mark protection does not allow producers to certify the link between quality and geographical origin, and that some Member States have already established national *sui generis* protection systems for GIs for non-agricultural products, owing to the lack of a harmonised protection system, leading to fragmentation on the market place and legal uncertainty, and also generating impacts to the detriment of producers; takes the view that harmonised protection at Union level would create the necessary legal certainty for all players along with guaranteed prevention of IPR violations for manufactured and artisanal products so that the EU can better protect its interests at international level;

31. Suggests assigning the EUIPO the responsibility for establishing a register for non-agricultural GIs in order to ensure their uniform examination and protection throughout the Union;

Revision of the EU legislation on design protection

32. Stresses that the current design protection system at EU level was established 20 years ago and should be revised; welcomes therefore the Commission's willingness to modernise Union legislation on design protection in order to better support the transition to the digital, sustainable and green economy; calls on the Commission on the one hand to update the registration procedure to allow for new forms of design, such as graphical user interfaces, virtual and animated designs, fonts and icons, and those relevant following new developments and technologies to be protected in an easy and less burdensome way, and on the other hand to further harmonise the application and invalidation procedures in the Member States;

33. Notes that design protection for parts used for the repair of complex products is only partially harmonised; points out that some Member States have already introduced a 'spare parts exception' or 'repair clause' into their legislation, allowing for component parts of complex products to be manufactured and sold without infringing IPRs; notes that this creates fragmentation in the internal market and legal uncertainty; calls on the Commission, therefore, to include a 'repair clause' in its future proposal, which will contribute to support the transition towards a more sustainable and greener economy and avoid distortions of competition;

34. Believes that the EU design protection system should be aligned with the EU trademark system in order to allow for design holders to prevent design infringing goods to enter into the EU's customs territory, since rights attached to trademarks are enforceable against infringing goods transiting though the EU, while those attached to design are not; calls on the Commission to close this gap in the revision of the design legislation and make it possible for brand owners to put a stop to design counterfeits transiting through the EU;

35. Is convinced that design protection should be offered in a uniform way throughout the single market and suggests that the Commission thinks about aligning the Design Directive and the Community Design Regulation with a view to creating a greater legal certainty;

Fighting IPR infringements

36. Points out that counterfeit goods, such as, for example, counterfeit medicines or fake personal protective equipment or masks in the context of health crisis like the COVID-19 pandemic pose serious threats to the health and safety of EU citizens and can cause serious harm to public health; argues that although market surveillance activities aim to protect general public interests, while counterfeit products relate to the protection of private IPRs, there is a close relation between counterfeit products and risks to health and safety of consumers;

37. Highlights that in 2016 up to 6,8 % of EU imports, or a value of EUR 121 billion, were fake goods, and that their availability on the single market caused direct sales losses worth EUR 50 billion and approximately 416 000 direct job losses for the period 2013-2017 ([19]); points out that IPR infringement entails a low level of risk in terms of both the likelihood of detection and the sanction if detected; urges the Member States, together with the Commission, customs authorities, the EU Agency for Law Enforcement Cooperation (Europol), Interpol, and law enforcement authorities to coordinate strategies and to develop effective and dissuasive sanctions particularly in order to limit the amount of hazardous products made available to the public and to fight counterfeiting and piracy especially when it is connected to organised crime;

38. Regrets the significant use of the internet for the distribution of counterfeit products, infringing content and IPR-infringing services, with significant adverse effects for EU manufacturing industry as well as for the creative, cultural and sport sectors; welcomes the Commission proposal for a Digital Services Act; highlights the fact that the 'know your business customer' principle and the trusted flaggers system, would contribute enormously to the fight against counterfeiting and that AI and blockchain could play an important role in tackling counterfeit and pirated goods available online as well as contributing to enhanced enforcement of IPR in the whole supply chain; supports, therefore, the use of new technologies to combat IP infringements and welcomes evidence-based publications produced by the EUIPO Observatory in this respect;

39. Recognises the high potential of blockchain technologies for the registration and protection of IPRs; stresses that blockchain systems can help secure the supply chain through traceability, ensuring safety and securing every step against the dangers of counterfeiting at each level of the supply chain; notes, in particular with regard to the registration of IPRs, the need for intellectual property offices (IPOs) to adopt technical standards for their blockchain solutions in order to allow interoperability; underlines that AI and related technologies used for the registration procedure for granting IPRs cannot be a substitute for human review carried out on a case-by-case basis in order to ensure the quality and fairness of decisions;

([19]) EUIPO, *2020 Status Report on IPR infringement*: average annual figures, 2013-2017.

40. Points out the link between IP crime and organised and serious international crime; welcomes, therefore, the Council's decision to put IP infringements back on the list of EU crime priorities in the framework of the European Multidisciplinary Platform Against Criminal Threats (EMPACT) for the forthcoming cycle 2022-2025, and asks the Council to maintain them on that list and to enhance cross-border cooperation between national authorities, the EUIPO, Europol, the EU Agency for Criminal Justice Cooperation (Eurojust) and the European Anti-Fraud Office (OLAF);

41. Welcomes the fact that the Commission intends to come up with a EU toolbox against counterfeiting in order to ameliorate cooperation between rights holders, public authorities, law enforcement authorities at national and EU level, and intermediaries by further clarifying roles and responsibilities, with the aim of facilitating effective information and data sharing between key actors, promoting the use of new tools and the tackling of counterfeiting activities; calls on the Commission to take concrete actions to monitor wilful infringement of IPRs, including where infringement is used in bad faith as a deliberate commercial strategy, and to push for greater control and cross-border cooperation between customs agencies as part of the fight against the import of counterfeit products; calls the Commission to consider creating a similar EU toolbox to fight against other IPR infringements;

42. Stresses that long-term education on IP in schools, on counterfeiting and piracy would also be necessary in order to change the willingness to consume IPR-infringing goods and services; calls on the Member States, therefore, to cooperate with EUIPO in order to launch awareness campaigns, including in the field of 3D printing; recalls that 3D printing technology may raise some specific legal concerns regarding all areas of IP law, such as copyright, patents, designs, three-dimensional trademarks and geographical indications;

43. Calls on the Commission to continue protecting IPRs and promoting enforcement in non-EU countries, including through an increase in funding for targeted EU technical cooperation programmes and capacity building, such as the three ongoing IP Key cooperation programmes with China, South-East Asia and Latin America and the joint partnership with the African continent to promote better generation and management of IP, and by supporting IP regimes that enhance local agricultural development; encourages, in this context, the Commission, on the basis of the EU's experience, to assist policymakers and enforcement authorities and provide them with knowledge and guidelines for improving their capacity to tackle IPR infringements, and to promote feasible solutions, which could significantly reduce costs and simplify the procedures for obtaining, maintaining and enforcing the protection of IPRs, as well as to provide information to rights holders about the changing infringement landscape and the supply of counterfeit goods;

New challenges for IP policy-making

44. Highlights that IP protection related to AI technologies is important and should be duly considered, and that even though current rules on the protection of computer-implemented inventions by patents may cover AI technologies, there is a need for clear criteria for the protection of inventions generated with the assistance of AI technologies; asks the Commission, therefore, in cooperation with the EPO and EUIPO, to provide legal certainty on this subject and to follow the issue closely at international level in the WIPO;

45. Encourages the Member States to transpose the provisions of the Copyright Directive without delay and in a manner which reflects the agreement struck by the co-legislators to improve the protection it provides, and to allow exceptions such as access to online education and digitised cultural heritage; calls on the Commission to monitor buy-out contracts to ensure fair remuneration of creators based on copyright or authors' rights; underlines that the lack of harmonisation of rules on authorship and copyright ownership can lead to divergent national solutions for AI-assisted works;

46. Underlines that, despite a high level of harmonisation of IP rights across Europe, there is still a lack of efficient cross-border enforcement of these rights in the EU;

47. Welcomes the Commission's announcement that it will review the Database Directive in order to facilitate data access and use while safeguarding legitimate interests; points out that unnecessary barriers still hamper research and that robust data spaces have to be further developed in order to enable researchers to find scientific solutions, including under exceptional time constraints; highlights in this respect the role of limitations and exceptions to exclusive rights;

48. Regrets the fact that the Commission's 2016 study on patent assertion entities (PAE) in Europe ([20]) did not provide a clear answer to the question of whether some PAE's business models, consisting of acquiring patents from third parties and seeking to generate revenue by asserting them against alleged infringers by misusing litigation asymmetries abuse loopholes in current legislation, and therefore constitute a problem that should be tackled; encourages the Commission to continue to monitor this issue and carry out a corresponding in-depth study;

49. Welcomes the efforts of all Member States to make sure that the courts take the principle of proportionality into consideration when dealing with injunction cases;

50. Notes that IPR protection is key to incentivising research and production of innovative products and processes, including new medicines, but is convinced that to fight global health emergencies, address the accessibility of certain medical products, and allow life-saving interventions in the public interest voluntary pooling of patents, compulsory licensing and flexibilities provided for in the WTO TRIPS Agreement are important; calls on the Commission, therefore, to analyse and explore possible options for ensuring effectiveness and better coordination of compulsory licensing in the EU, taking into account cases in which it has been used in the Union, the reasons for its use, the conditions under which it was granted, its economic consequences and whether it achieved the desired effect;

51. Stresses that a more equitable distribution of vaccines around the globe is essential for effectively combating the spread of COVID-19 and its mutations, and the need to support global access to COVID-19 vaccines; notes that the lack of access to affordable vaccines is still a major challenge in developing countries; supports; therefore; the Commission and the Member States in their efforts to push non-EU countries to lift current export bans and to step up the donation of vaccines; calls on the Commission and the Member States to further increase their efforts to support technology transfer and voluntary licensing of IPRs in order to enhance global access to affordable COVID-19-related medical products, to address global production constraints and supply shortages, and to thereby treat endemic or pandemic infectious diseases in the world population;

52. Welcomes the fact that least developed countries already enjoy a waiver, granted until 1 January 2033, on the implementation of TRIPS provisions on pharmaceuticals; urges the Commission, therefore, in cooperation with the WTO, to follow through on its promise to engage in active and constructive text-based negotiations at the WTO in order to work on incentivising and supporting the scaling up of vaccine production capacities in developing countries and incentivising voluntary and rapid pooling of IPR in times of crisis as well as voluntary licensing agreements, and to launch a dialogue on current obstacles to voluntary licensing and how to overcome them;

53. Suggests that an IP coordinator be established at European level in order to ensure a holistic and coordinated approach to EU IP policy and enhance cooperation between the different national IP authorities, Commission Directorates-General and other bodies in charge of IPR, such as the EPO, EUIPO, WIPO and other relevant actors; the IP coordinator could further promote the fight against IPR infringements at the highest political level and take on other duties related to IPR if necessary;

54. Defends the idea that promotion of better IP management in the research and innovation community is needed in order to materialise Europe's excellent research into innovation that are beneficial to its citizens and businesses; stresses that, in this context, publicly funded IP must be used in a fair and effective manner, and that results achieved with EU funds should be used to improve the EU's economy for all;

([20]) European Commission Joint Research Centre, *Patent Assertion Entities in Europe: Their impact on innovation and knowledge transfer in ICT markets,* 2016.

55. Recalls that IPR-intensive industries generate the bulk of EU trade activities and that also protecting and enforcing IPRs in third countries is essential; welcomes the Commission's commitment to seek robust protection for IP in future free trade agreements; asks the Commission to call for IPRs enforcement to be addressed at the World Trade Organization (WTO) and WIPO;

56. Recalls that one of the main challenges for developing countries is to move up the global value chain through economic diversification, which requires fair and pro-development global trade rules;

57. Encourages developing countries to strengthen regional value chains and intra-regional trade and investments in health and health-related areas, in particular through collective R&D efforts in medical research and regional pooling of resources; notes with concern that, according to the Global Trade Alert, by 21 March 2020, 54 governments had introduced export curbs on key medical supplies since the beginning of that year; stresses that regional trade pacts should be used to prevent export bans on key products in times of global and regional shortages, as in the case of the ongoing pandemic crisis;

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58. Instructs its President to forward this resolution to the Council and the Commission.

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P9_TA(2021)0454

Statute and funding of European political parties and foundations

European Parliament resolution of 11 November 2021 on the application of Regulation (EU, Euratom) No 1141/2014 on the statute and funding of European political parties and European political foundations (2021/2018(INI))

(2022/C 205/04)

The European Parliament,

— having regard to Articles 2 and 10(4) of the Treaty on European Union (TEU),

— having regard to Articles 224 and 325 of the Treaty on the Functioning of the European Union (TFEU),

— having regard to Regulation (EU, Euratom) No 1141/2014 of the European Parliament and of the Council of 22 October 2014 on the statute and funding of European political parties and European political foundations [1] (hereinafter 'the Regulation'), as amended by Regulation (EU, Euratom) 2018/673 of the European Parliament and of the Council of 3 May 2018 [2] and Regulation (EU, Euratom) 2019/493 of the European Parliament and of the Council of 25 March 2019 [3], and in particular Article 38(1) thereof,

— having regard to 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 [4] (the Financial Regulation),

— having consulted the Authority for European Political Parties and European Political Foundations (hereinafter 'the Authority') and its annual activity reports,

— having regard to the report of the Secretary-General of the European Parliament to the Bureau of 19 April 2021 on the funding of European political parties and European political foundations, at European level,

— having regard to Rule 54 of its Rules of Procedure,

— having regard to the opinion of the Committee on Budgetary Control,

— having regard to the report of the Committee on Constitutional Affairs (A9-0294/2021),

A. whereas strong political parties and foundations at EU level are essential for the development of a truly EU public sphere;

B. whereas European political parties should play a more central role in the European elections process and contribute to forming EU political awareness and expressing the will of EU citizens; whereas political diversity is essential for public discourse and for expressing citizens' choices;

C. whereas parties cannot be considered as non-partisan entities in the course of political competition and whereas their financing cannot be reduced to apolitical expenses;

D. whereas European political foundations have a mandate which encompasses raising political awareness of and contributing to the debate on EU policy issues and the process of European integration, and within this framework they also develop offerings that are not exclusively directed at the members or voters of a particular party, but are open to everyone on the same terms;

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(1) OJ L 317, 4.11.2014, p. 1.
(2) OJ L 114 I, 4.5.2018, p. 1.
(3) OJ L 85 I, 27.3.2019, p. 7.
(4) OJ L 193, 30.7.2018, p. 1.

E. whereas European political parties and foundations should cooperate with their national member parties and partners in order to support them in bringing the Union and its policies closer to citizens and to enhance democratic legitimacy;

F. whereas European political parties should cooperate with their corresponding national counterparts to facilitate interactive participation on EU issues;

G. whereas in order to continue to be aware of and to give expression to the will of Union citizens, it is essential that the role and functioning of European political parties and foundations are not limited to issues of exclusively European relevance at Union level; whereas those European political parties and foundations should be allowed to use their funds in order to finance any activity which contributes to informing EU citizens and increasing awareness on issues related to EU policies;

H. whereas sufficient financial means are a prerequisite for European political parties and foundations to assume their tasks, while full transparency and accountability ought to be a condition for receiving public funds from the Union budget;

I. whereas European political parties and foundations can play a role in promoting EU policies on neighbouring countries under the common foreign and security policy and as part of the external relations of the Union; whereas they should therefore be open to membership by parties or individuals from these countries and be allowed to receive contributions from them, provided that full transparency and compliance with Article 325 TFEU and the Union's rules regarding the fight against fraud and corruption is ensured;

J. whereas it should be possible for European political parties and foundations to have additional categories of revenue other than contributions and donations;

K. whereas an alignment of the co-financing rate for European political parties with the level imposed on political foundations would prevent the accumulation of debt;

L. whereas the system for administrative control of expenditure should be simplified, with due respect for transparency and proper use of public funds, and the requirement to submit accounts according to the International Financial Reporting Standards should be dropped because it does not correspond to the nature of European political parties and foundations, and represents an unnecessary time-consuming and costly burden;

M. whereas an alignment of the carry-over period for European political foundations with the requirements imposed on political parties would avoid a second layer audit and therefore significantly reduce the administrative burden on foundations;

Evaluation of the application of the Regulation

1. Recalls that Regulation (EU, Euratom) No 1141/2014 on the statute and funding of European political parties and foundations is the legal framework establishing their rights and obligations; highlights that the funding awarded under the Regulation is part of the general budget of the European Union and should therefore be implemented in accordance with the Financial Regulation, with an emphasis on the general principle of sound financial management;

2. Notes that 2018 was the first year of implementation of the Regulation; welcomes the 2019 annual activity report presented by the Authority; takes note of the main activities and challenges encountered during 2019; notes that the Authority performed its first review of the accounts of European political parties and foundations in the context of the 2019 European elections, ensuring compliance with the Regulation, while the Directorate-General for Finance of the European Parliament ensured compliance with the Financial Regulation; welcomes the fact that the Authority did not have to impose sanctions on any European political party or foundation in 2019; takes note, additionally, of the fact that the Authority intervened in proceedings before the Court of Justice of the European Union's General Court, and liaised with Member States to set up a network of national contact points and data protection authorities;

3. Recalls that Article 38 of the Regulation requires Parliament to adopt a report on the application of the Regulation by the end of 2021 and the Commission to present a report on the same matter six months after that, which must be accompanied by a legislative proposal to amend the Regulation; notes that the Commission's roadmap includes tightening the financial and enforcement rules, reducing the administrative burden, enhancing transparency, and strengthening the genuine electoral representation of EU citizens; points out, furthermore, the importance of addressing the risk of foreign interference and the infringement of data protection rules;

4. Welcomes the announcement by the Commission of a new European democracy action plan, including a legislative proposal to ensure greater transparency on paid political advertising and a review of the legislation on the financing of European political parties and foundations; reiterates its proposal to amend the Regulation, as expressed in its resolution of 26 November 2020 on stocktaking of European elections ([5]), with regard to participation in European elections, transparency of funding and the prohibition of donations from private and public bodies from non-EU countries;

5. Acknowledges that the Regulation has improved the status of European political parties and foundations in comparison with the previous legal framework established by Regulation (EC) No 2004/2003 ([6]), notably by recognising that those entities have Union legal personality and by setting up the independent Authority;

6. Recognises the role of the Authority, which has assumed the tasks entrusted to it under the Regulation;

7. Notes, however, that a number of administrative and political obstacles are still preventing European political parties and foundations from achieving their full potential as active and visible players in European democracy, both at European level and in the EU Member States;

8. Underlines the importance of the registration of European political parties and foundations, since it requires compliance with all conditions of the Regulation, in particular respect for the values of the Union enshrined in Article 2 TEU, and makes eligibility for funding from the Union budget conditional upon such compliance, as well as the need to ensure full transparency;

9. Believes, in this regard, that the Regulation should be amended to clarify that respect for EU fundamental values should apply to both the European political party itself and its member parties;

10. Welcomes the reinforcement of the provisions on monitoring respect by European political parties and foundations for the fundamental values of the Union and for the procedure for dealing with infringements, including sanctions and recovery of funds;

11. Considers that the latest amendment of the Regulation, which introduced sanctions for infringements of data protection rules, was a useful first step but should be further strengthened;

12. Considers that the current system for verifying respect for rules on the use of contributions and grants needs to be improved in terms of clarity, efficiency and speed;

13. Considers that making European political parties and foundations subject to EU and national rules, which are laid down in different legal instruments, is a source of confusion and legal uncertainty; proposes, therefore, to harmonise further and strengthen the rules governing European political parties and foundations to ensure a comprehensive EU legal framework for European political parties and foundations addressing, in particular, conditions for registration, structure and operations, visibility and transparency, and sanctions;

14. Underlines that the funding of European political parties and foundations must be transparent, must be subject to Article 325 TFEU, must not be open to abuse and must exclusively support political programmes and activities in line with the founding principles of the Union expressed in Article 2 TEU;

([5]) OJ C 425, 20.10.2021, p. 98.

([6]) Regulation (EC) No 2004/2003 of the European Parliament and of the Council of 4 November 2003 on the regulations governing political parties at European level and the rules regarding their funding (OJ L 297, 15.11.2003, p. 1).

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Problems identified

15. Recalls that the Regulation requires national member parties to display the logo, political programme and website link of their European party of affiliation on their websites 'in a clearly visible and user-friendly manner' as a condition for the European political party to access funds; is concerned that according to European Democracy Consulting's Logos project, national member parties overwhelmingly fail to properly implement the Regulation's display requirement, as only 15 % of them display the logo in a clear and user-friendly manner;

16. Underlines the need to make the definition of indirect funding from European political parties and foundations to national counterparts and members more precise and simpler in order to avoid hampering their required cooperation in promoting and explaining EU policies, as well as their engagement with EU citizens;

17. Stresses that the ban on financing referendum campaigns on EU issues goes against the purpose of European political parties and foundations;

18. Highlights that funding of European political parties and foundations is inherently linked to registration criteria listed in the Regulation; acknowledges the need to ensure that registration and membership criteria provide for inclusive and genuine representation of political parties that are active at EU level, while avoiding hindering the democratic representation of smaller political parties at the same level; recalls the debates held in Parliament's Committee on Constitutional Affairs regarding the threshold for registration and citizen support; notes that, following Brexit, there is an increased need to revise different categories of party membership and the collection of membership fees; suggests, therefore, a revision of the registration requirements and representational criteria, including a reflection on direct citizens' membership;

19. Regrets the narrow interpretation of the concept of membership established by case law, the lack of clear definitions of modalities of membership of European political parties and the lack of differentiated levels of affiliation to European political foundations in the Regulation, which do not allow for flexibility in the internal organisation of European political parties and foundations, especially as regards associate members and partners of European political foundations, including those from former Member States and other European countries; is concerned that this narrow interpretation has the effect of preventing, without good reason, European political parties from receiving financial contributions from such members; considers that the modalities of membership and affiliation to European political foundations, as well as research partnerships with them, should likewise be clarified;

20. Considers that the prohibition of cross-party and cross-foundation membership should be clarified and extended;

21. Underlines that the categories of revenue are defined too narrowly in the Regulation and in particular do not take into account other possible legally acquired own resources;

22. Stresses that the co-financing level imposed, in particular on European political parties, has proved very difficult to achieve;

23. Considers that the requirement for the accounts of European political parties and European political foundations to be set up both in accordance with the national audit standards of the Member State in which they are based and in accordance with International Financial Reporting Standards adds no value and entails unnecessary costs and time delays;

24. Laments that a flawed design in the Regulation limits European political parties in truly fulfilling their role as modern political parties connecting citizens to the political system as they are unknown to citizens due to limited individual membership and their limited role in influencing policymaking and shaping public agendas, and thus do not trigger anywhere near the same level of activist mobilisation that national and regional parties are able to muster;

25. Points out that the Authority has limited powers with regard to verifying whether a European political party or foundation is in breach of the EU's shared values and has never triggered the complex values compliance procedure thus far; calls for the set-up of the Authority to be strengthened in order to be able to better monitor all criteria laid down in the Regulation, including respect for Union values and the democratic governance of European political parties and compliance with relevant rules and the implementation of sanctions, as well as to ensure its complete autonomy and neutrality;

26. Notes with concern that several existing transnational political parties active in EU politics and represented in the European Parliament are not permitted to register officially as European political parties due to disproportionate requirements laid down in the Regulation which hinder the democratic representation of smaller political parties at the EU level;

Proposals for improvements

27. Considers that a clear set of rules and conditions should be established for the joint organisation and co-financing of activities concerning EU issues by European political parties and foundations and their members; considers that for such joint activities, the display of the European political party's logo alongside that of the national member party should be required;

28. Underlines that no rule should prevent the participation of representatives and staffers of political parties in events of European political foundations, which is justified by their very nature;

29. Calls on the Commission to provide clear requirements and detailed guidelines related to the visibility of the European political party of affiliation in order to ensure enforcement of Article 18(2)(a) of the Regulation on displaying European political parties' logos alongside the logos of national or regional parties;

30. Highlights that the first review of the accounts identified possible improvements, particularly regarding the level of detail and comparability of the requested information provided by European parties and foundations; welcomes the introduction of templates in 2020 to facilitate the process; notes that in 2019, most of the financial resources of European political parties and foundations were spent on personnel, meetings and gathering information;

31. Is of the opinion that sound financial management and transparency require strict rules defining the eligibility of expenditure; asks for the creation of explicit provisions for activities undertaken with larger international organisations and partners from outside the EU as well as detailed rules for personnel and meeting costs, especially in terms of ceilings and tender procedures;

32. Calls for the prohibition on financing referendum campaigns to be lifted to allow European political parties to finance referendum campaigns that are related to the implementation of the TEU or the TFEU;

33. Insists that different categories of membership for parties, foundations and research partnerships with foundations be recognised, that the affiliation of members from member states of the Council of Europe and other European countries be allowed, that a category of research partners be created for foundations, and that European political parties and foundations be authorised to legally collect membership fees on the basis of a general contribution order applicable equally to all their members;

34. Underlines the need for a definition of members in order to have legal certainty on the different types of membership, the members' relationship with the European political party they adhere to and the requirements they have to meet;

35. Proposes that the scope of the prohibition on cross-party membership be extended to the members of national and regional parliaments and assemblies;

36. Supports the creation of further categories of revenue in order to cover all sources of income of political parties and political foundations, rather than just contributions and donations, such as creating a new category of 'other own resources' which includes contributions from joint activities, sales of publications, participation fees for conferences or workshops or other activities directly linked to political action;

37. Advocates the lowering of the required own resources rate for political parties to 5 % instead of 10 % to align it with the rate applicable to foundations;

38. Advocates the extension of the carry-over period for foundations to the entire following year (N+1), aligning it with the period applicable to parties;

39. Asks for the obligation for European political parties and foundations to submit their annual financial statements on the basis of the International Financial Reporting Standards, in addition to the Generally Accepted Accounting Principles, to be abolished;

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40. Recalls the role of further instances of financial control within their respective mandates, namely the European Court of Auditors, the European Anti-Fraud Office and the European Public Prosecutor's Office; notes, in the context of audit and control, the importance of submitting the expenditure of European political parties not only to an internal audit system and the judgement of their members, but also to an external auditor, public authorities and public scrutiny;

41. Proposes that the expenditure of European political parties and foundations be subject to a self-control mechanism, accompanied by an internal audit system, and subject to oversight by an external auditor and the European Court of Auditors and to public oversight;

42. Recommends using a harmonised timeframe for reporting and the controls carried out by European political parties, the Authority and Parliament respectively, in order to avoid having to recalculate the final amounts of funding, while taking into account the deadlines imposed by the relevant rules;

43. Advocates an increase in the transparency of the financing of European political parties and foundations by creating an obligation for Parliament to publish the annual financial statements it receives in a user-friendly manner; underlines that the information covering the registration and financial situation of European political parties and foundations should, to the greatest extent possible, be made publicly available and be complete and up-to-date;

44. Is of the opinion that the information published by Parliament and the Authority should be presented in open and machine-readable formats in a user-friendly manner;

45. Is of the opinion that strengthened scrutiny by the Authority of reported aggregate donations totalling more than EUR 3 000 would make substantial/significant external influences on European political parties more transparent; believes that the Authority should focus such scrutiny on cases where it observes significant and sudden increases in the aggregate number of small donations;

46. Is, moreover, of the opinion that in order to strengthen the transparency of funding, donations by the same donor to a European political party, its national member parties and their regional substructures should be subject to publication by the Authority; is furthermore of the opinion that suitable instruments must be in place by the financial year 2027 at the latest to ensure that donations are not made to legally independent entities which are part of the same European political party in order to circumvent transparency rules, which together would exceed the transparency limits;

47. Advocates ensuring that, by the calendar year 2027, any donation made by a donor to a European political party is equal under tax law to donations made to national political parties in the donor's respective country of residence;

48. Supports the idea of increasing the importance of the own resources of European political parties when calculating the amount financed by the Union;

49. Believes, for the sake of legal certainty and clarity, that all provisions applicable to European political parties and foundations, including those that are currently part of the Financial Regulation, should be brought together in a single Union legal act, namely Regulation (EU, Euratom) No 1141/2014;

50. Is of the opinion that the rules on eligibility of expenditure are too narrow and that European political parties and foundations should be allowed to finance any activity that is not only organised as an internal event but is also open to the general public and which contributes to increasing EU political awareness and giving expression to the will of Union citizens;

51. Proposes that a genuine EU legal status and an EU legal personality for European political parties and foundations be established by setting minimum conditions for the structure and functioning of European political parties and foundations, while at the same time rendering them more independent from national law;

52. Stresses, in particular, the need to include measures to ensure that European political parties are not classified as foreign legal entities under national law in the Member States;

53. Insists that European political parties and their members must have a democratic structure and respect the values on which the Union is founded and must observe democratic procedures and transparency when selecting their party leaders and candidates for elections and also hold a democratic vote for the adoption of their internal rules and political programme;

54. Urges the Commission to review the Regulation with a view to updating the rules on registration, financing, political and electoral campaigning and membership in order to make European political parties the mouthpiece for citizens in EU politics and policymaking and to bring EU citizens closer to EU decision-making;

55. Calls in particular for the review of the Regulation to ease registration conditions under Article 3 thereof and open membership to all EU citizens in order to provide for a more inclusive representation of political parties active at the EU level;

56. Is of the opinion that the hybrid status of the Authority should be clarified, and its structure redefined, and that the possibility for an administrative appeal to the Authority's decisions should also be provided, given that under the current Regulation, complainants can only appeal to the Court of Justice of the European Union;

57. Proposes that a clear distinction between deregistration as a last resort measure and financial sanctions be established and that the coherence of the financial sanctions regime be enhanced;

58. Considers that the coherence and legal certainty of certain provisions of the Regulation need to be enhanced, that the reasons for deregistration need to be further developed and clarified, that a common set of rules for the publication, entry into force and effect of deregistration decisions is necessary and that the rules on recovery need to be clarified;

59. Considers it necessary to make the financing rules of European political parties and their foundations compatible with a pan-European constituency campaign at the European elections;

60. Recommends that the Commission strengthen the provisions on data protection by including references to the offences defined in Articles 3 to 6 of Directive 2013/40/EU on attacks against information systems ([7]); welcomes the fact that the Authority has established a network of national data protection authorities to render the new verification procedure fully operational;

61. Calls on the Commission to take due account of these proposals when drafting and putting forward its proposal for a regulation amending Regulation (EU, Euratom) No 1141/2014;

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62. Instructs its President to forward this resolution to the Council and the Commission.

([7]) OJ L 218, 14.8.2013, p. 8.

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The first anniversary of the de facto abortion ban in Poland

European Parliament resolution of 11 November 2021 on the first anniversary of the de facto abortion ban in Poland (2021/2925(RSP))

(2022/C 205/05)

The European Parliament,

— having regard to the Treaty on European Union (TEU), and, in particular, Articles 2 and 7(1) thereof,

— having regard to the European Convention on Human Rights (ECHR) of 4 November 1950 and the related case law of the European Court of Human Rights (ECtHR),

— having regard to the Universal Declaration on Human Rights, and, in particular, Articles 18 and 19 thereof,

— having regard to the Charter of Fundamental Rights of the European Union ('the Charter') and, in particular, Articles 1, 2, 3, 6, 7, 10, 11, 21, 23, 35 and 45 thereof,

— having regard to the Constitution of the Republic of Poland,

— having regard to the UN International Covenant on Economic, Social and Cultural Rights of 16 December 1966 and the UN International Covenant on Civil and Political Rights of 16 December 1966,

— having regard to the UN Convention on the Elimination of All Forms of Discrimination against Women of 18 December 1979, and to its General Recommendations No 21 (1994), No 24 (1999), No 28 (2010), No 33 (2015) and No 35 (2017),

— having regard to the Beijing Platform for Action and the outcomes of its review conferences,

— having regard to the 1994 International Conference on Population and Development (ICPD) in Cairo, its Programme of Action, and the outcomes of its review conferences, in particular the Nairobi Summit on ICPD+25 and its commitments to strive for the 'three zeros' objective, zero unmet need for family planning information and services, zero preventable maternal deaths and zero sexual and gender-based violence and harmful practices against women and girls,

— having regard to the UN Sustainable Development Goals agreed in 2015, in particular goals 3 and 5,

— having regard to the World Health Organization Regional Office for Europe's Action Plan for Sexual and Reproductive Health: Towards achieving the 2030 Agenda for Sustainable Development in Europe — leaving no one behind,

— having regard to the UN Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment of 10 December 1984,

— having regard to the Council of Europe Convention on preventing and combating violence against women and domestic violence ('the Istanbul Convention'), which entered into force on 1 August 2014,

— having regard to its resolution of 28 November 2019 on the EU's accession to the Istanbul Convention and other measures to combat gender-based violence [1],

[1] OJ C 232, 16.6.2021, p. 48.

— having regard to the issue paper of the Council of Europe's Commissioner for Human Rights of 4 December 2017 entitled 'Women's sexual and reproductive health and rights in Europe',

— having regard to UNESCO's 2018 International Technical Guidance on Sexuality Education,

— having regard to its previous resolutions on Poland, in particular those of 15 November 2017 on the situation of the rule of law and democracy in Poland ([2]) and of 17 September 2020 on the proposal for a Council decision on the determination of a clear risk of a serious breach by the Republic of Poland of the rule of law ([3]),

— having regard to the four infringement procedures launched by the Commission against Poland in relation to the reform of the Polish judicial system and to the proposal for a Council decision of 20 December 2017 on the determination of a clear risk of a serious breach by the Republic of Poland of the rule of law (COM(2017)0835),

— having regard to its resolution of 1 March 2018 on the Commission's decision to activate Article 7(1) TEU as regards the situation in Poland ([4]),

— having regard to its resolution of 14 November 2019 on the criminalisation of sexual education in Poland ([5]),

— having regard to its resolution of 13 February 2019 on experiencing a backlash in women's rights and gender equality in the EU ([6]),

— having regard to its resolution of 26 November 2020 on the de facto ban on the right to abortion in Poland ([7]),

— having particular regard to its resolution of 24 June 2021 on the situation of sexual and reproductive health and rights in the EU, in the frame of women's health ([8]),

— having regard to the 2021 European Abortion Policies Atlas, which ranks 52 European countries and territories by assigning scores for their legal frameworks to access safe abortion care,

— having particular regard to its resolutions of 16 September 2021 on media freedom and further deterioration of the rule of law in Poland ([9]) and of 21 October 2021 on the rule of law crisis in Poland and the primacy of EU law ([10]),

— having regard to Rule 132(2) of its Rules of Procedure,

A. whereas the Union is founded on the values of respect for human dignity, freedom, democracy, equality, justice, the rule of law, respect for human rights and non-discrimination, as set out in Article 2 TEU; whereas all Member States have assumed obligations and duties under international law and the EU Treaties to respect, guarantee and fulfil fundamental rights;

B. whereas according to the Charter, the ECHR and the case law of the ECtHR, and the jurisprudence of the UN treaty bodies, sexual and reproductive health and rights (SRHR) are related to multiple human rights, such as the right to life, the right to access healthcare, freedom from inhuman or degrading treatment, and respect for bodily integrity, privacy

([2]) OJ C 356, 4.10.2018, p. 44.
([3]) OJ C 385, 22.9.2021, p. 317.
([4]) OJ C 129, 5.4.2019, p. 13.
([5]) OJ C 208, 1.6.2021, p. 24.
([6]) OJ C 449, 23.12.2020, p. 102.
([7]) OJ C 425, 20.10.2021, p. 147.
([8]) Texts adopted, P9_TA(2021)0314.
([9]) Texts adopted, P9_TA(2021)0395.
([10]) Texts adopted, P9_TA(2021)0439.

and personal autonomy; whereas these human rights are also enshrined in the Polish Constitution; whereas the Member States are legally obliged to uphold and protect human rights in accordance with their constitutions, the EU Treaties and the Charter, as well as international law;

C. whereas delaying and denying access to abortion constitutes a form of gender-based violence; whereas access to abortion care is essential for social and economic equality; whereas several human rights bodies ([11]) have asserted that the denial of safe abortion may amount to torture or cruel, inhuman and degrading treatment, and unsafe abortions that lead to death in the context of abortion bans should be understood as 'gender-arbitrary killings, only suffered by women, as a result of discrimination enshrined in law';

D. whereas one year ago, on 22 October 2020, the illegitimate Polish Constitutional Tribunal ruled unconstitutional the provision of the 1993 Act on Family Planning, Protection of the Human Foetus and Conditions for Termination of Pregnancy that allowed for abortion in cases where a prenatal test or other medical considerations had indicated a high probability of a severe and irreversible foetal defect or an incurable illness that threatened the foetus's life; whereas this entailed a de facto abortion ban, as the vast majority of the legal abortions performed in Poland were based on the aforementioned ground;

E. whereas the erosion of the rule of law in Poland has led to violations of human rights, including SRHR; whereas the de facto abortion ban in Poland is a clear attack on the rule of law and fundamental rights, and restricts the realisation of SRHR in Poland, following the many attacks against the rule of law in recent years;

F. whereas the Committee of Ministers of the Council of Europe has expressed repeated concerns regarding Poland's failure to implement the ECtHR's judgments for over 13 years in several cases ([12]) in which the Court found that Poland had violated human rights as a result of its failures to ensure the accessibility of legal abortion in practice;

G. whereas previous attempts to restrict SRHR were initially halted in 2016, 2018 and 2020 as a result of mass opposition from Polish citizens, as expressed in the 'Black Friday' marches, which were strongly supported by Members of the European Parliament from different political groups;

H. whereas as a response to the ruling further restricting access to abortion, unprecedented protests have again taken place across Poland, including in small towns and villages, and around the world, and were again organised during October 2021 in over 20 cities across Poland to mark the one-year anniversary of the de facto ban; whereas the protests began in opposition to the serious restriction that undermines Polish women's fundamental SRHR but evolved into protests opposing further violations of the rule of law and against the government responsible for these violations; whereas the use of excessive and disproportionate force against protesters by law enforcement officers has been well documented;

I. whereas, in spite of the unprecedented demonstrations, the ruling was officially published on 27 January 2021 and therefore the de facto ban on abortion became a reality for women in Poland, leading to the expansion of unsafe abortions and forcing women to travel to seek an abortion abroad, thereby undermining women's health and rights, their sexual and bodily autonomy and integrity, and putting their lives at risk;

J. whereas a 30-year-old pregnant woman named Izabela died of septic shock on 22 September 2021 because her doctors did not perform a life-saving abortion, waiting instead for the foetus to die because of the restrictions on legal abortions and the chilling effect of these on doctors in Poland; whereas her death triggered protests in several Polish cities and on social media under the slogan 'Not One More';

([11]) The Committee on the Elimination of Discrimination against Women, the Human Rights Committee, the Special Rapporteur on torture and other forms of cruel, inhuman and degrading treatment or punishment, and the Special rapporteur on extrajudicial, summary or arbitrary executions (Information Series on Sexual and Reproductive Health and Rights of the UN High Commissioner for Human Rights, Abortion, 2020).

([12]) Tysiąc v. Poland (2007), R.R. v. Poland (2011), and P. and S. v. Poland (2012).

K. whereas according to media reports, another woman named Anna, who was in her fifth month of pregnancy, died of septic shock on 14 June 2021 after doctors forced her to deliver a stillborn baby despite suspected sepsis;

L. whereas since the ruling, many Polish women have been forced to ask for help through initiatives such as Abortion Without Borders and organisations based in other Member States in order to have access to their SRHR, especially to abortion services; whereas the organisation of abortion procedures rests on the shoulders of women's rights organisations and informal groups, and depends on money raised from donations;

M. whereas over the past 12 months, Abortion Without Borders groups have helped 34 000 people ([13]) from Poland to access abortion; whereas these numbers are only a fraction of the total number of Polish women needing support in accessing abortion care;

N. whereas as a result of legal restrictions and of stigmatisation, there is a lack of reliable data on abortion incidence in many Member States, as well as on the context in which the abortions are carried out; whereas accurate, regularly updated and anonymous data on abortion from all Member States are vital to understanding SRHR needs and securing the rights of women;

O. whereas according to the data gathered by the Federation for Women and Family Planning (FEDERA), over the last 10 months only 300 women accessed abortion services in Polish hospitals on the grounds of a threat to life and health; whereas the ruling further stigmatises SRHR and disproportionately affects women and pregnant persons who lack the financial means to fund medical abortion or abortions abroad, as well as those who lack access to information technologies;

P. whereas only a few hospitals in Poland perform abortions for fear of litigation; whereas women often refrain from using their services out of fear of cumbersome, purposefully delayed procedures and referrals; whereas the path of accessing the right to legal abortion on mental health grounds is increasingly being attempted by women who experience severe mental health conditions as a result of not receiving any State institutional assistance in accessing legal abortion services in Poland; whereas in July 2021 the ECHtR announced its intention to address the complaints of Polish women concerning violations of their rights safeguarded by the ECHR ([14]);

Q. whereas according to the 2020 European Contraception Atlas ([15]), even prior to the ruling Poland had one of the most restrictive policies regarding access to contraceptive supplies, family planning, counselling and the provision of online information; whereas Poland is one of the few countries that requires a prescription for emergency contraception, which is often denied by doctors on the grounds of personal beliefs;

R. whereas on the basis of the Polish criminal code, anyone who terminates another person's pregnancy, or aids or abets a pregnant person in terminating their pregnancy in violation of the provisions of the law, faces criminal liability, including imprisonment; whereas as a result of the existing legal provisions, social stigma, fear and pressure from their peers and the medical authorities, doctors in Poland prefer not to be associated with abortion procedures, and this was already the case even when abortion was still legal; whereas apart from the widely used conscience clause, some doctors create additional non-statutory obstacles, such as unnecessary medical examinations, psychological consultations or additional consultations with experts, or limit women's rights to prenatal tests and information, which should be guaranteed for all under the public health scheme; whereas an individual's personal beliefs concerning abortion are not allowed to interfere with a patient's right to full access to healthcare and services provided under the law;

([13]) https://www.asn.org.uk/press-release-abortion-without-borders-helps-more-than-17000-with-abortion-in-six-months-after-polish-constitutional-court-ruling/

([14]) https://en.federa.org.pl/womens-collective-complaint-in-the-echr/

([15]) https://www.epfweb.org/european-contraception-atlas#:~:text=On%2012%20November%202020%2C%20MEPs,on%20access%20to%20modern%20contraception

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S. whereas access to gynaecological care in Poland is highly restricted and in some regions almost impossible, resulting in a high number of unintended pregnancies, poor reproductive health, a high prevalence of cervical cancer and insufficient access to contraception; whereas according to the Supreme Audit Office, in 2018 only 2 % of pregnant women living in rural areas in Poland underwent all standard tests that are necessary during pregnancy; whereas LGBTI + people's access to sexual and reproductive healthcare is highly restricted, as are their rights; whereas trans and non-binary people requiring gynaecological care face discrimination in medical settings and are often denied access to care; whereas age-appropriate sexuality and relationship education in Polish schools is neither obligatory, nor is it comprehensive and evidence-based, and attempts are being made to prohibit it altogether;

T. whereas there has been an increase in the number of worrying threats and hate campaigns targeting women human rights defenders (WHRDs) in Poland for supporting women's rights, the right to abortion and the Women's Strike movement which has been at the forefront of mass protests against the restrictions on access to legal abortion; whereas these threats are disturbing reminders of the escalating risks to WHRDs in the country;

U. whereas WHRDs have been collecting signatures for a bill, as a part of the civic initiative prepared by FEDERA entitled 'Legal Abortion. No compromises', which would reverse the abortion ban and allow for the safe termination of a pregnancy up to 12th week without the patient being asked to give a reason, and in exceptional cases after the 12th week; whereas in September 2021, the Pro-Right to Life Foundation submitted a bill to the Polish Parliament entitled 'Stop abortion 2021' (Stop Aborcji), which would completely prohibit the access to abortion and criminalise it, with penalties of up to 25 years in prison;

V. whereas the Polish Parliament's acts on the Constitutional Tribunal, adopted on 22 December 2015 and 22 July 2016, as well as the package of three acts adopted at the end of 2016, seriously undermined the Constitutional Tribunal's independence and legitimacy; whereas the acts of 22 December 2015 and of 22 July 2016 were declared unconstitutional by the Constitutional Tribunal on 9 March and 11 August 2016, respectively; whereas those judgments were neither published nor implemented at the time by the Polish authorities; whereas the constitutionality of Polish laws can no longer be effectively guaranteed in Poland since the entry into force of the aforementioned legislative changes ([16]) and thus the legality of the ruling of 22 October 2020 is questionable;

W. whereas on 7 October 2021, the same illegitimate 'Constitutional Tribunal' presented its decision in case K 3/21, adopted with two dissenting opinions, on the request initiated by the Polish Prime Minister on 29 March 2021, finding the provisions of the TEU incompatible with the Polish Constitution on multiple grounds; whereas this decision is an attack on the European community of values and laws as a whole, undermining the primacy of EU law as one of its cornerstone principles in accordance with well-established case law of the Court of Justice of the European Union;

X. whereas the ruling of 22 October 2020 reverses the acquired rights of Polish women, as prior to its implementation, abortion in Poland was legal in three cases, which means that Polish women are in a worse legal position now than they were when Poland joined the EU in 2004; stresses that the constitutionality of the three existing exceptions had not been questioned by the Constitutional Tribunal until the PiS-led government took control of the tribunal and the justice system more broadly;

Y. whereas a fundamentalist organisation, Ordo Iuris, which is closely linked to the ruling coalition, has been a driving force behind the campaigns which are undermining human rights and gender equality in Poland, including the attempts to ban abortion, the calls for Poland's withdrawal from the Istanbul Convention and the calls for the creation of so-called LGBTI-free zones; whereas cultural and religious values in Poland are therefore being abused as reasons to impede the full realisation of women's rights, equality for women and their right to make decisions about their own bodies;

([16]) Venice Commission Opinion of 14 and 15 October 2016 on the Act on the Constitutional Tribunal, paragraph 128; UN Human Rights Committee, Concluding observations on the seventh periodic report of Poland, 23 November 2016, paragraphs 7 and 8; Commission Recommendation (EU) 2017/1520 of 26 July 2017 regarding the rule of law in Poland (OJ L 228, 2.9.2017, p. 19).

Z. whereas the Venice Commission of the Council of Europe, the ECtHR, Parliament and the Commission have expressed serious concerns regarding the rule of law, including the legitimacy, independence and effectiveness of the Constitutional Tribunal; whereas the Commission triggered an Article 7(1) procedure following the 2015 reforms of the justice system in Poland;

1. Reiterates its strong condemnation of the illegitimate Constitutional Tribunal's ruling of 22 October 2020 that imposes a near-total ban on abortion and of this blatant attack on SRHR in Poland; calls on the Polish Government to swiftly and fully guarantee access to and the provision of abortion services, to provide safe, legal, free and high-quality abortion services, and to make them accessible to all women and girls; calls on the Polish authorities to respect, fulfil and promote women's human rights to life, health and equality, as well as their freedom from discrimination, violence and torture or cruel, inhuman and degrading treatment;

2. Strongly regrets the absence during the year that has elapsed of any initiative or proposal aimed at lifting the de facto abortion ban and the numerous restrictions on access to SRHR in the country; reiterates that the de facto abortion ban is putting women's health and lives at risk and has already led to the death of at least one woman; recalls that universal access to healthcare and SRHR are fundamental human rights;

3. Stands in solidarity with Polish women, activists and with the brave individuals and organisations who continue to help women to access abortion care when they need it, as it is their body, their choice; deeply regrets the entry into force of the ruling, in spite of the mass demonstrations in favour of legal access to abortion; supports all women and human rights defenders who are continuing to protest tirelessly against these grave restrictions on their fundamental freedoms and rights; notes that the protestors are demanding not only the annulment of the illegitimate Constitutional Tribunal's ruling, but also the right to free, legal and safe access to abortion and respect for bodily autonomy and integrity; highlights the expressions of support for, and interest in, the cause of the Polish protesters from many Member States and worldwide;

4. Stresses that restricting or banning the right to abortion by no means reduces the need for abortions, but results in women having to seek unsafe abortions, to travel abroad in order to obtain abortions or to carry their pregnancy to term against their will, including in cases of fatal or severe foetal impairment; stresses further that this is a violation of human rights and a form of gender-based violence affecting women's and girls' rights to life, physical and mental integrity, equality, non-discrimination and health;

5. Is deeply concerned about the fact that thousands of women have to travel to access a health service as essential as abortion; emphasises that cross-border abortion services are not a viable option, especially for those living in poverty, facing intersectional discrimination and in vulnerable situations; is perturbed by the fact that travelling abroad puts women's health, life and well-being at risk; stresses the importance of post-abortion care, especially for women who experience complications from an incomplete or unsafe abortion;

6. Strongly condemns all legislative proposals or restrictions that aim to further prohibit, criminalise and limit access to safe and legal abortion in Poland; reminds the Polish Parliament and authorities that measures to restrict SRHR are contrary to the principle of non-retrogression under international human rights law and urges them to ensure the full realisation of SRHR;

7. Condemns the increasingly hostile and violent environment for WHRDs in Poland, and calls on the Polish authorities to guarantee WHRDs' right to express themselves publicly, including when they oppose government policy, without fear of repercussions or threats; calls on the Polish authorities to urgently protect the WHRDs who have been targeted, to investigate the threats against them and to hold those responsible to account; urges the Polish Government to counter the abusive misinformation campaigns targeting WHRDs; stresses that many WHRDs in Poland are now facing criminal charges for their role in the protests against the bill as a result of the COVID-19 restrictions imposed at that time; urges the Polish Government to refrain from bringing politically motivated criminal charges against WHRDs;

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8. Strongly condemns the excessive and disproportionate use of force and violence against protesters, including activists and women's rights organisations, by the law enforcement authorities and by non-state actors such as far-right nationalist groups; calls on the Polish authorities to ensure that those who attack protesters are held accountable for their actions;

9. Condemns the hostile rhetoric used by Polish government officials against WHRDs and other critics of government policies, and urges the Commission to address this and support the activists both politically and financially;

10. Calls on the Polish Government to ensure the participation of women and girls in the drafting of laws and policies that affect their lives, including SRHR and abortion, and that they are able to access justice and remedies when their rights are violated;

11. Calls on the Council and the Commission to provide adequate funding for national and local civil society organisations in order to foster grassroots support for democracy, the rule of law and fundamental rights in Member States, including Poland; urges the Commission to provide immediate and direct support for programmes and Polish civil society organisations working to ensure that SRHR are protected; calls on the Commission and the Member States to support SRHR awareness-raising and training courses through funding programmes; welcomes the support provided by certain Member States in assisting civil society organisations helping Polish women realise their SRHR and encourages others to do the same; calls on the Member States to cooperate more effectively in order to facilitate cross-border access to abortion, for example by granting Polish women access to free and safe abortion within national healthcare systems;

12. Insists that performing an abortion should not be included in the criminal code in any way, shape or form, as this has a chilling effect on doctors who, as a consequence, refrain from providing SRH services out of fear of criminal sanctions and thus limit the healthcare available to women and girls; is alarmed that, as a result of this situation, doctors tend to prioritise saving the foetus rather than the woman's life; calls on the Polish Government to ensure that 'not one more' woman in Poland dies because of this restrictive law and to entirely decriminalise abortion and remove anything related to abortion from criminal law, in order to ensure that doctors agree to perform abortions in practice within the legal boundaries of national law, and to ensure that the information it provides on access to abortion and other sexual and reproductive rights is unbiased and evidence-based;

13. Recalls that the unjustified excess of restrictions on access to safe abortion resulting from the aforementioned ruling of the illegitimate Constitutional Tribunal fails to protect the inherent and inalienable rights and dignity of women, as it breaches the Charter, the ECHR, the case law of the ECtHR, numerous international conventions to which Poland is a signatory, as well as the Constitution of the Republic of Poland; reiterates its call on the Polish authorities to fully implement the judgments handed down by the ECtHR in the cases brought against Poland, in which it has ruled that restricting access to lawful abortion violates the human rights of women;

14. Stresses that unhindered and timely access to reproductive health services and respect for women's reproductive autonomy and decision-making is critical to protecting women's human rights and gender equality; underlines that the UN experts ([17]) have stressed that 'women's human rights are fundamental rights that cannot be subordinated to cultural, religious or political considerations', and that 'the influence of ideologically and religiously motivated interference in public health matters has been particularly detrimental to the health and well-being of women and girls';

15. Is deeply concerned about the use of the conscience clause, which is a denial of medical care based on personal beliefs; regrets that, following the amendment to the 'Act on doctors and dentists professions', doctors and health facilities are not obliged to indicate an alternative facility or practitioner in the event of a denial of abortion and other SRH services owing to personal beliefs; notes that following the ruling of the illegitimate Constitutional Tribunal of 22 October 2020, the practical use of the conscience clause is in itself limited as a result of the lack of access to abortion on the grounds of

([17]) Working Group on discrimination against women and girls, 14 September 2021, available at: https://www.ohchr.org/FR/NewsEvents/Pages/DisplayNews.aspx?NewsID=27457&LangID=E

foetal condition; deplores that the way in which this clause is framed under Polish law does not envisage any appeals procedure against the abusive use of the conscience clause; regrets the fact that gynaecologists frequently invoke it incorrectly when asked to prescribe contraceptives, thereby also in effect restricting access to contraception in Poland; notes that this mechanism of denying medical care based on personal beliefs also hinders access to prenatal screening, which is not only a violation of the right to information on the condition of a foetus, but also obstructs successful treatment either during pregnancy or immediately afterwards; calls on the Polish Government to regulate refusals to provide SRH services by healthcare providers in a manner that does not deny access to SRHR, and urges the Polish Government to adopt the necessary reforms to introduce the obligation to refer a patient to an alternative practitioner and an appeals procedure against the abusive use of the conscience clause;

16. Urges the Polish authorities to repeal the law limiting access to the emergency contraceptive pill, and to finance, develop and promote the full range of contraceptives, including male contraception;

17. Condemns the Polish Government's abuse of the judicial system and of its legislative powers in order to instrumentalise and politicise the lives and health of women and LGBTI+ persons, leading both to their oppression and to discrimination against them;

18. Reiterates its deep concerns expressed in its resolutions over the attempts to criminalise the dissemination of sexuality and relationship education in Poland and calls on the Commission and the Member States, including Poland, to make sure that students of all ages and sexual orientations receive age-appropriate and evidence-based comprehensive sexuality and relationship education, which is key to building young peoples' skills to form healthy, equal, nurturing and safe relationships, free from discrimination, coercion and violence; highlights that only education, information, universal access to contraception, the eradication of sexual violence and shared responsibility for contraception between women and men can reduce misinformation and the number of unintended pregnancies;

19. Strongly condemns the decision by the Polish Minister of Justice to officially begin Poland's withdrawal from the Istanbul Convention, which in itself already is and, if followed through, would further be a serious setback with regard to gender equality, women's rights and the fight against gender-based violence; urges the Polish authorities to reverse this decision and ensure the effective and practical implementation of the Convention; calls on the Council to urgently conclude the EU's ratification of the Istanbul Convention;

20. Recalls that women's rights are fundamental human rights and that the EU institutions and the Member States are legally obliged to uphold and protect them in accordance with the Treaties and the Charter, as well as international law;

21. Calls on the Council to address this matter and other allegations of violations of fundamental rights in Poland by expanding the scope of its hearings on the situation in Poland, in accordance with Article 7(1) TEU;

22. Calls on the Polish Government to comply with the ruling from the ECtHR, which declares the composition of the Constitutional Court unlawful ([18]); reiterates its calls on the Commission to carry out a thorough assessment of the composition of the illegitimate Constitutional Tribunal; underlines that the ruling on abortion is yet another example of the political takeover of the judiciary and the systemic collapse of the rule of law in Poland, and that the EU institutions are under an obligation to act accordingly;

23. Calls on the Commission to support the Member States in guaranteeing universal access to SRHR, including access to safe and legal abortion for all citizens;

([18]) CASE OF XERO FLOR w POLSCE sp. z o.o. v. POLAND, available at: https://hudoc.echr.coe.int/eng?i=001-210065

24. Calls on the Commission and the Council to safeguard the right to health and ensure that women and girls in Poland are not left behind, by taking decisive action and countering any legislative proposals or restrictions on accessing healthcare services coming from Poland, including abortion care;

25. Calls on the Commissioners for Health and Food Safety, for Equality and for Democracy and Demography to facilitate and promote the protection of SRHR in Poland as a vital part of achieving the right to health, safety and gender equality;

26. Calls on the Commission to take concrete steps to protect SRHR in the EU more generally, starting with the establishment of an EU Special Envoy on SRHR and the addition of a designated chapter on the 'State of play of SRHR' in the EU Annual Report on Human Rights and Democracy;

27. Calls on the Commission to adopt guidelines for Member States in order to ensure equal access to SRHR goods and services in line with EU law and the jurisprudence of the ECtHR;

28. Reminds the Commission that it should propose a comprehensive directive on preventing and combating gender-based violence in all its forms, including violations of SRHR;

29. Instructs its President to forward this resolution to the Commission and the Council, the President, Government and Parliament of Poland and the governments and parliaments of the Member States.

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II

(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN PARLIAMENT

P9_TA(2021)0443

Request for the waiver of the immunity of Fulvio Martusciello

European Parliament decision of 11 November 2021 on the request for waiver of the immunity of Fulvio Martusciello (2021/2049(IMM))

(2022/C 205/06)

The European Parliament,

— having regard to the request for waiver of the immunity of Fulvio Martusciello, submitted on 31 March 2021 by the Federal Public Service for Foreign Affairs of the Kingdom of Belgium, and announced in plenary on 26 April 2021,

— having heard Fulvio Martusciello in accordance with Rule 9(6) of its Rules of Procedure,

— having regard to Articles 8 and 9 of Protocol No 7 on the Privileges and Immunities of the European Union, and Article 6(2) of the Act of 20 September 1976 concerning the election of the members of the European Parliament by direct universal suffrage,

— having regard to the judgments of the Court of Justice of the European Union of 21 October 2008, 19 March 2010, 6 September 2011, 17 January 2013 and 19 December 2019 [1],

— having regard to Rule 5(2), Rule 6(1) and Rule 9 of its Rules of Procedure,

— having regard to the report of the Committee on Legal Affairs (A9-0302/2021),

A. whereas the Prosecutor General at the Brussels Court of Appeal has requested the waiver of the immunity of Fulvio Martusciello, Member of the European Parliament elected for Italy, in connection with a speeding offence in breach of Article 11.2(1)(a) of the Royal Decree of 1 December 1975 laying down general regulations on road traffic police and the use of public roads and Article 29(3) of the Law of 16 March 1968 on road traffic police;

B. whereas on 25 November 2020, as part of an anti-speeding campaign, the traffic police intercepted a vehicle on the E411 motorway that was recorded as travelling at 179 km/h in a 120 km/h zone;

[1] Judgment of the Court of Justice of 21 October 2008, *Marra* v *De Gregorio and Clemente*, C-200/07 and C-201/07, ECLI:EU:C:2008:579; judgment of the General Court of 19 March 2010, *Gollnisch* v *Parliament*, T-42/06, ECLI:EU:T:2010:102; judgment of the Court of Justice of 6 September 2011, *Patriciello*, C-163/10, ECLI:EU:C:2011:543; judgment of the General Court of 17 January 2013, *Gollnisch* v *Parliament*, T-346/11 and T-347/11, ECLI:EU:T:2013:23. judgment of the Court of Justice of 19 December 2019, *Junqueras Vies*, C-502/19, ECLI:EU:C:2019:1115.

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C. whereas the driver of that vehicle was identified by the police as Fulvio Martusciello, who stated that he was a Member of the European Parliament; whereas on 15 December 2020 Fulvio Martusciello was sent a copy of the police report by the Walloon Brabant Public Prosecutor, asking him to submit any comments, and in response did not contest the speeding offence;

D. whereas Parliament cannot assume the role of a court, and whereas, in a waiver of immunity procedure, a Member cannot be regarded as a defendant ([2]);

E. whereas the alleged offence has no direct or obvious bearing on the performance by Fulvio Martusciello of his duties as a Member of the European Parliament, and nor does it constitute an opinion expressed or a vote cast in the performance of those duties within the meaning of Article 8 of Protocol No 7 on the Privileges and Immunities of the European Union;

F. whereas Article 9 of Protocol No 7 on the Privileges and Immunities of the European Union states:

'During the sessions of the European Parliament, its Members shall enjoy:

(a) in the territory of their own State, the immunities accorded to members of their parliament;

(b) in the territory of any other Member State, immunity from any measure of detention and from legal proceedings.

Immunity shall likewise apply to Members while they are travelling to and from the place of meeting of the European Parliament.

Immunity cannot be claimed when a Member is found in the act of committing an offence and shall not prevent the European Parliament from exercising its right to waive the immunity of one of its Members.';

G. whereas, in this case, Parliament has found no evidence of *fumus persecutionis*, i.e. facts which suggest that the intention underlying the legal proceedings in question is to undermine the Member's political activity as a Member of the European Parliament;

1. Decides to waive the immunity of Fulvio Martusciello;

2. Instructs its President to forward this decision and the report of its committee responsible immediately to the competent authority of the Kingdom of Belgium and to Fulvio Martusciello.

([2]) Judgment of the General Court of 30 April 2019, *Briois* v *Parliament*, T-214/18, ECLI:EU:T:2019:266.

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P9_TA(2021)0444

Request for the waiver of the immunity of Harald Vilimsky

European Parliament decision of 11 November 2021 on the request for waiver of the immunity of Harald Vilimsky (2021/2073(IMM))

(2022/C 205/07)

The European Parliament,

— having regard to the request for waiver of the immunity of Harald Vilimsky, submitted by the Public Prosecutor's Office in Vienna and transmitted on 7 May 2021 by the Head of the Permanent Representation of Austria to the EU in connection with criminal proceedings, and announced in plenary on 20 May 2021,

— having heard Harald Vilimsky in accordance with Rule 9(6) of its Rules of Procedure,

— having regard to Articles 8 and 9 of Protocol No 7 on the Privileges and Immunities of the European Union, and Article 6(2) of the Act of 20 September 1976 concerning the election of the members of the European Parliament by direct universal suffrage,

— having regard to the judgments of the Court of Justice of the European Union of 21 October 2008, 19 March 2010, 6 September 2011, 17 January 2013 and 19 December 2019 [1],

— having regard to Article 57(2) and (3) of the Austrian Constitution,

— having regard to Rule 5(2), Rule 6(1) and Rule 9 of its Rules of Procedure,

— having regard to the report of the Committee on Legal Affairs (A9-0303/2021),

A. whereas the Vienna Public Prosecutor's Office has requested the waiver of the immunity of Harald Vilimsky, Member of the European Parliament, in order to initiate criminal prosecution proceedings in connection with the offence of embezzlement under Section 153(1) and (3), first instance, and the offence of involvement in misappropriation of funds under Sections 12, second alternative, and 133(1) and (2), first instance, and misuse of funds under Section 153b(1), (2) and (3) of the Austrian Criminal Code;

B. whereas Harald Vilimsky served as finance officer of the Austrian Freedom Party (FPÖ) National Assembly group from 27 October 2006 to 23 October 2019; whereas he was elected to the European Parliament as result of the European Parliament elections held in May 2019;

C. whereas from 1 October 2011 to 13 August 2019, Harald Vilimsky allegedly abused his authority to avail himself of bank accounts belonging to the parliamentary group of the FPÖ in the Austrian National Assembly, by arranging for the payment of bills by means of regular transfers from the FPÖ National Assembly group's account for mobile phone services used for entirely private ends by a third party, resulting in a financial loss to the FPÖ National Assembly group;

D. whereas he allegedly used the funds granted to the FPÖ National Assembly group for purposes beyond the scope of those defined in Section 1 of the Austrian Parliamentary Groups Funding Act 1985 (KlubFG), and whereas he allegedly did so in full knowledge of the fact that the services paid were non-party-related;

E. whereas the alleged offence does not concern opinions expressed or votes cast in the performance of the duties of the Member of the European Parliament for the purposes of Article 8 of Protocol No 7 on the Privileges and Immunities of the European Union;

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[1] Judgment of the Court of Justice of 21 October 2008, *Marra* v *De Gregorio and Clemente*, C 200/07 and C-201/07, EU:C:2008:579; judgment of the General Court of 19 March 2010, *Gollnisch* v *Parliament*, T-42/06, EU:T:2010:102; judgment of the Court of Justice of 6 September 2011, *Patriciello*, C 163/10, EU:C:2011:543; judgment of the General Court of 17 January 2013, *Gollnisch* v *Parliament*, T-346/11 and T-347/11, EU:T:2013:23; judgment of the Court of Justice of 19 December 2019, *Junqueras Vies*, C-502/19, EU:C:2019:1115.

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F. whereas Article 9 of Protocol No 7 on the Privileges and Immunities of the European Union states that Members of the European Parliament enjoy, in the territory of their own state, the immunities accorded to members of the parliament of that state;

G. whereas Article 57(2) and (3) of the Austrian Constitution states:

'2. The members of the National Council may on the ground of a criminal offense — the case of apprehension in the act of committing a crime excepted — be arrested only with the consent of the National Council. Likewise, searches of houses of members of the National Council require the consent of the National Council.

3. Otherwise members of the National Council may only be officially prosecuted on account of a punishable act, with the consent of the National Council, if it has obviously no connection with the official activity of the deputy in question. However, the agency (Behörde) must seek a ruling from the National Council concerning the existence of such a connection if the deputy concerned or a third of the members of the Standing Committee [which is] entrusted with these matters, demands it. In the case of such a demand, any official prosecuting action must immediately cease or be terminated.';

H. whereas Parliament cannot assume the role of a court, and whereas, in a waiver of immunity procedure, a Member cannot be regarded as a defendant ([2]);

I. whereas the purpose of parliamentary immunity is to protect Parliament and its Members from legal proceedings in relation to activities carried out in the performance of their parliamentary duties and which cannot be separated from those duties;

J. whereas in this case, Parliament has found no evidence of *fumus persecutionis*, i.e. factual elements which indicate that the intention underlying the legal proceeding may be to damage a Member's political activity and thus the European Parliament;

1. Decides to waive the immunity of Harald Vilimsky;

2. Instructs its President to forward this decision and the report of its committee responsible immediately to the competent authority of the Republic of Austria and to Harald Vilimsky.

([2]) Judgment of the General Court of 30 April 2019, *Briois* v *Parliament*, T-214/18, EU:T:2019:266.

Thursday 11 November 2021

P9_TA(2021)0445

Request for the waiver of the immunity of Nils Ušakovs

European Parliament decision of 11 November 2021 on the request for waiver of the immunity of Nils Ušakovs (2020/2239(IMM))

(2022/C 205/08)

The European Parliament,

— having regard to the request for waiver of the immunity of Nils Ušakovs, dated 23 October 2020 and transmitted by the General Prosecutor of the Republic of Latvia in connection with criminal proceedings to be initiated in the Republic of Latvia and announced in plenary on 13 November 2020,

— having heard Nils Ušakovs in accordance with Rule 9(6) of its Rules of Procedure,

— having regard to Articles 8 and 9 of Protocol No 7 on the Privileges and Immunities of the European Union, and Article 6(2) of the Act of 20 September 1976 concerning the election of the members of the European Parliament by direct universal suffrage,

— having regard to the judgments of the Court of Justice of the European Union of 21 October 2008, 19 March 2010, 6 September 2011, 17 January 2013 and 19 December 2019 [1],

— having regard to Articles 29 and 30 of the Latvian Constitution,

— having regard to Rule 5(2), Rule 6(1) and Rule 9 of its Rules of Procedure,

— having regard to the report of the Committee on Legal Affairs (A9-0304/2021),

A. whereas the Prosecutor at the Division for Investigation of Especially Serious Cases in the Criminal Justice Department of the General Prosecutor's Office in Riga has requested the waiver of the immunity of Nils Ušakovs, Member of the European Parliament, in order to initiate criminal proceedings against him in connection with the infringement of the prohibition on the circulation of devices modified for special clandestine operations;

B. whereas on 30 January 2019, during an authorised search of the office of Nils Ušakovs as Chairman of Riga City Council, in connection with other criminal proceedings, a device primarily intended for use as a means of clandestine video and audio recording, especially designed and used for special clandestine operations, was found;

C. whereas by keeping the device in his office at the Riga City Council premises, Mr Ušakovs allegedly infringed the prohibition laid down in Article 5^1, paragraph 1, of the Law on the circulation of goods of strategic importance banning natural persons from acquiring or keeping equipment, devices or tools or components thereof that have been specially designed or modified for special clandestine operations included in the Republic of Latvia's national list of goods and services of strategic importance; whereas by his actions, Mr Ušakovs allegedly committed a crime under Article 237^1, paragraph 2, of the Latvian Criminal Code;

D. whereas Nils Ušakovs was elected to the European Parliament as result of the European Parliament elections held in May 2019;

E. whereas the alleged offence does not concern opinions expressed or votes cast by Nils Ušakovs in the performance of his duties within the meaning of Article 8 of Protocol No 7 on the Privileges and Immunities of the European Union;

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[1] Judgment of the Court of Justice of 21 October 2008, *Marra* v *De Gregorio and Clemente*, C 200/07 and C-201/07, ECLI:EU:C:2008:579; judgment of the General Court of 19 March 2010, *Gollnisch* v *Parliament*, T-42/06, ECLI:EU:T:2010:102; judgment of the Court of Justice of 6 September 2011, *Patriciello*, C 163/10, ECLI: EU:C:2011:543; judgment of the General Court of 17 January 2013, *Gollnisch* v *Parliament*, T-346/11 and T-347/11, ECLI:EU:T:2013:23; judgment of the Court of Justice of 19 December 2019, *Junqueras Vies*, C-502/19, ECLI:EU:C:2019:1115.

F. whereas Article 9 of Protocol No 7 on the Privileges and Immunities of the European Union states that Members of the European Parliament enjoy, in the territory of their own state, the immunities accorded to members of the parliament of that state;

G. whereas Article 29 and Article 30 of the Latvian Constitution provide that:

'Article 29

Members of the Saeima shall not be arrested, nor shall their premises be searched, nor shall their personal liberty be restricted in any way without the consent of the Saeima. (…)

Article 30

Without the consent of the Saeima, criminal prosecution may not be commenced against its member.';

H. whereas Parliament cannot assume the role of a court, and whereas, in a waiver of immunity procedure, a Member cannot be regarded as a defendant ([2]);

I. whereas the purpose of parliamentary immunity is to protect Parliament and its Members from legal proceedings in relation to activities carried out in the performance of their parliamentary duties and which cannot be separated from those duties;

J. whereas in this case, Parliament has found no evidence of *fumus persecutionis*, i.e. factual elements which indicate that the intention underlying the legal proceeding may be to damage a Member's political activity and thus the European Parliament;

1. Decides to waive the immunity of Nils Ušakovs;

2. Instructs its President to forward this decision and the report of its committee responsible immediately to the competent authority of the Republic of Latvia and to Nils Ušakovs.

([2]) Judgment of the General Court of 30 April 2019, *Briois* v *Parliament*, T-214/18, ECLI:EU:T:2019:266.

Thursday 11 November 2021

III

(Preparatory acts)

EUROPEAN PARLIAMENT

P9_TA(2021)0446

Disclosure of income tax information by certain undertakings and branches ***II

European Parliament legislative resolution of 11 November 2021 on the Council position at first reading with a view to the adoption of a directive of the European Parliament and of the Council amending Directive 2013/34/EU as regards disclosure of income tax information by certain undertakings and branches (09722/1/2021 — C9-0371/2021 — 2016/0107(COD))

(Ordinary legislative procedure: second reading)

(2022/C 205/09)

The European Parliament,

— having regard to the Council position at first reading (09722/1/2021 — C9-0371/2021),

— having regard to the statement of the Council's reasons for its position at first reading,

— having regard to the reasoned opinions submitted within the framework of Protocol 2 on the application of the principles of subsidiarity and proportionality, by the Irish Houses of the Oireachtas and the Swedish Parliament, asserting that the draft legislative act does not comply with the principle of subsidiarity,

— having regard to the opinion of the European Economic and Social Committee of 21 September 2016 [1],

— having regard to its position at first reading [2] on the Commission proposal to Parliament and the Council (COM(2016)0198),

— having regard to Article 294(7) of the Treaty on the Functioning of the European Union,

— having regard to the provisional agreement approved by the committees responsible under Rule 74(4) of its Rules of Procedure,

— having regard to Rule 67 of its Rules of Procedure,

— having regard to the recommendation for second reading of the Committee on Economic and Monetary Affairs and the Committee on Legal Affairs (A9-0305/2021),

1. Approves the Council position at first reading;

2. Notes that the act is adopted in accordance with the Council position;

3. Instructs its President to sign the act with the President of the Council, in accordance with Article 297(1) of the Treaty on the Functioning of the European Union;

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[1] OJ C 487, 28.12.2016, p. 62.
[2] OJ C 108, 26.3.2021, p. 623.

4. Instructs its Secretary-General to sign the act, once it has been verified that all the procedures have been duly completed, and, in agreement with the Secretary-General of the Council, to arrange for its publication in the *Official Journal of the European Union*;

5. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Thursday 11 November 2021

P9_TA(2021)0447

European Partnership on Metrology ***I

European Parliament legislative resolution of 11 November 2021 on the proposal for a decision of the European Parliament and of the Council on the participation of the Union in the European Partnership on Metrology jointly undertaken by several Member States (COM(2021)0089 — C9-0083/2021 — 2021/0049(COD))

(Ordinary legislative procedure: first reading)

(2022/C 205/10)

The European Parliament,

— having regard to the Commission proposal to Parliament and the Council (COM(2021)0089),

— having regard to Article 294(2), Article 185 and the second paragraph of Article 188 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0083/2021),

— having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

— having regard to the opinion of the European Economic and Social Committee [1],

— having regard to the provisional agreement approved by the committee responsible under Rule 74(4) of its Rules of Procedure and the undertaking given by the Council representative by letter of 8 October 2021 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

— having regard to Rule 59 of its Rules of Procedure,

— having regard to the report of the Committee on Industry, Research and Energy (A9-0242/2021),

1. Adopts its position at first reading hereinafter set out;

2. Takes note of the statement by the Commission annexed to this resolution;

3. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

4. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P9_TC1-COD(2021)0049

Position of the European Parliament adopted at first reading on 11 November 2021 with a view to the adoption of Decision (EU) 2021/… of the European Parliament and of the Council on the participation of the Union in the European Partnership on Metrology jointly undertaken by several Member States

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Decision (EU) 2021/2084.)

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[1] OJ C 341, 24.8.2021, p. 34.

ANNEX TO THE LEGISLATIVE RESOLUTION

Statement by the Commission

In order to help Member States in strengthening synergies between Horizon Europe and Cohesion Policy, the Commission will develop guidelines focused on the opportunities that the alternative, combined and cumulative funding and transfer of resources provide.

Thursday 11 November 2021

P9_TA(2021)0448

European Union Agency for Asylum ***I

European Parliament legislative resolution of 11 November 2021 on the proposal for a regulation of the European Parliament and of the Council on the European Union Agency for Asylum and repealing Regulation (EU) No 439/2010 (COM(2016)0271 — C8-0174/2016 — 2016/0131(COD))

(Ordinary legislative procedure: first reading)

(2022/C 205/11)

The European Parliament,

— having regard to the Commission proposal to Parliament and the Council (COM(2016)0271) and the amendments to the proposal (COM(2018)0633),

— having regard to Article 294(2) and Article 78(1) and (2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C8-0174/2016),

— having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

— having regard to the provisional agreement approved by the committee responsible under Rule 74(4) of its Rules of Procedure and the undertaking given by the Council representative by letter of 30 June 2021 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

— having regard to Rules 59 of its Rules of Procedure,

— having regard to the opinions of the Committee on Foreign Affairs and the Committee on Budgets,

— having regard to the report of the Committee on Civil Liberties, Justice and Home Affairs (A8-0392/2016),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P9_TC1-COD(2016)0131

Position of the European Parliament adopted at first reading on 11 November 2021 with a view to the adoption of Regulation (EU) 2021/… of the European Parliament and of the Council on the European Union Agency for Asylum and repealing Regulation (EU) No 439/2010

(As an agreement was reached between Parliament and Council, Parliament's position corresponds to the final legislative act, Regulation (EU) 2021/2303.)

Thursday 11 November 2021

P9_TA(2021)0449

Serious cross-border threats to health ***I

Amendments adopted by the European Parliament on 14 September and 11 November 2021 on the proposal for a regulation of the European Parliament and of the Council on serious cross-border threats to health repealing Decision No 1082/2013/EU (COM(2020)0727 — C9-0367/2020 — 2020/0322(COD)) [1]

(Ordinary legislative procedure: first reading)

(2022/C 205/12)

Amendment 1

Proposal for a regulation

Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) The health provisions of the Treaties are still largely under-used in terms of the purposes they were designed to achieve. This Regulation should therefore be aimed at making the best possible use of such health provisions, in order to demonstrate the strength of the Union's health policy, while preserving the normal functioning of the single market in the event serious cross-border threats to health arise.

[1] The matter was referred back for interinstitutional negotiations to the committee responsible, pursuant to Rule 59(4), fourth subparagraph (A9-0247/2021).

Thursday 11 November 2021

Amendments 2 and 244

Proposal for a regulation

Recital 2

Text proposed by the Commission	*Amendment*
(2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate adequate Union-wide preparedness and response to all cross-border threats to health, the legal framework for epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, as set out in Decision No 1082/2013/EU, needs to be broadened with regard to additional reporting requirements and analysis on health systems indicators, and cooperation ***by*** Member States ***with*** the European Centre for Disease Prevention and Control (ECDC). Moreover, in order to ensure effective Union response to novel cross-border threats to health, the legal framework to combat serious cross-border threats to health should enable to immediately adopt case definitions for the surveillance of novel threats and should provide for the establishment of a network of EU reference laboratories and a network to support monitoring of disease outbreaks that are relevant to substances of human origin. The capacity for contact tracing should be strengthened via the creation of an automated system, using modern technologies.	(2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate adequate Union-wide ***prevention of,*** preparedness and response to all cross-border threats to health***, including zoonotic-related threats***, the legal framework for epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, as set out in Decision No 1082/2013/EU, needs to be broadened with regard to additional reporting requirements and analysis on health systems indicators, and cooperation ***between*** Member States ***and Union agencies, particularly*** the European Centre for Disease Prevention and Control (ECDC***), the Health Emergency Preparedness and Response Authority (HERA), the European Medicines Agency (EMA), and international organisations, in particular the World Health Organization (WHO***). Moreover, in order to ensure effective Union response to novel cross- border threats to health, the legal framework to combat serious cross-border threats to health should enable to immediately adopt case definitions for the surveillance of novel threats and should provide for the establishment of a network of EU reference laboratories and a network to support monitoring of disease outbreaks that are relevant to substances of human origin. The capacity for contact tracing should be strengthened via the creation of an automated system, using modern technologies***, while respecting Regulation (EU) 2016/679 of the European Parliament and of the Council ('GDPR')*** [1a].

[1a] ***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).***

Thursday 11 November 2021

Amendment 245

Proposal for a regulation

Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) The HERA was set up to strengthen the Union's ability to prevent, detect and rapidly respond to cross-border health threats, by ensuring the supply of crisis-relevant medical countermeasures, including through their monitoring, procurement and purchase, by activating emergency research and innovation plans, providing emergency funding and financing, and by taking measures concerning the production, availability and supply of such key medical countermeasures.

Amendment 246

Proposal for a regulation

Recital 2 b (new)

Text proposed by the Commission	*Amendment*
	(2b) All such public investments in research, development, manufacturing, production, procurement, stockpiling, supply and distribution of medical countermeasures should be transparent.

Amendment 3

Proposal for a regulation

Recital 3

Text proposed by the Commission	*Amendment*
(3) An important role in the coordination of preparedness and response planning for serious cross-border threats to health is being played by the Health Security Committee (HSC), as formally established by Decision No 1082/2013/EU. This Committee should be given additional responsibilities with regard to the adoption of guidance and opinions to better support Member States in the prevention and control of serious cross-border threats to health.	(3) An important role in the coordination of ***prevention,*** preparedness and response planning for serious cross-border threats to health is being played by the Health Security Committee (HSC), as formally established by Decision No 1082/2013/EU. This Committee should be given additional responsibilities with regard to the adoption of guidance and opinions to better support Member States in the prevention and control of serious cross-border threats to health, ***and support better coordination between Member States to address those threats. Representatives designated by the European Parliament should be able to participate in the HSC as observers.***

Thursday 11 November 2021

Amendment 247

Proposal for a regulation

Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) In order to avoid duplication of efforts and to have coherence in decision-making at Union level, the HSC should closely cooperate with the HERA Board, established under the Commission Decision of 16 September 2021, the Health Crisis Board, established under a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, and other relevant Union agencies and bodies, to ensure that effective preparedness and response mechanisms are in place for health emergencies.

Amendment 4

Proposal for a regulation

Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) Prevention and promotion strategies concern all sectoral policies including fiscal, commercial, economic, agro-environmental, educational, housing, cultural and relating to social assistance. 'Health in all Policies' should be a principle of all public policies. An instrument already used at the national level to assess the health impact of the different sectoral policies is the so-called Health Test. A Health impact assessment should be undertaken for all programmes managed by the Union.

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Amendment 5

Proposal for a regulation

Recital 5

Text proposed by the Commission	*Amendment*
(5) This Regulation should apply without prejudice to other binding measures concerning specific activities or quality and safety standards for certain goods, which provide for special obligations and tools for monitoring, early warning and combatting specific threats of a cross-border nature. Those measures include, in particular, relevant Union legislation in the area of common safety concerns in public health matters, covering goods such as pharmaceutical products, medical devices and foodstuffs, substances of human origin (blood, tissues and cells, organs), and exposure to ionising radiation.	(5) This Regulation should apply without prejudice to other binding measures concerning specific activities or quality and safety standards for certain goods, which provide for special obligations and tools for monitoring, early warning and combatting specific threats of a cross-border nature***, such as the International Health Regulations (IHR) of the World Health Organization (WHO)***. Those measures include, in particular, relevant Union legislation in the area of common safety concerns in public health ***and environmental*** matters, covering goods such as pharmaceutical products, medical devices***, in vitro diagnostic medical devices,*** and foodstuffs, substances of human origin (blood***, plasma***, tissues and cells, organs), and exposure to ionising radiation.

Amendment 242

Proposal for a regulation

Recital 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) The over-exploitation of wildlife and other natural resources and the accelerated loss of biodiversity pose a risk to human health. As the health of humans, animals and the environment are inextricably linked, it is crucial to respect the principles of the 'One Health' approach to address current and emerging crises.

Thursday 11 November 2021

Amendment 6

Proposal for a regulation

Recital 6

Text proposed by the Commission	*Amendment*
(6) The protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System ('EWRS') set up by Decision No 2119/98/EC.	(6) ***In line with the 'One Health' and 'Health in all policies' approaches,*** the protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities***. The Union should support Member States in reducing health inequalities, within and between Member States, in achieving universal health coverage and in addressing the challenges of vulnerable groups. The Union should also urge Member States to implement the health-specific country-specific recommendations and support Member States in strengthening the resilience, responsiveness and readiness of healthcare systems to address future challenges, including pandemics***. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States***, and all relevant stakeholders, such as health professionals, patient associations, industry and supply chain actors***, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. ***Those mechanisms should look for synergies between Union and national measures, while seeking to avoid duplicating measures undertaken in the context of the WHO framework.*** In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System ('EWRS') set up by Decision No 2119/98/EC.

Thursday 11 November 2021

Amendment 7

Proposal for a regulation

Recital 7

Text proposed by the Commission	*Amendment*
(7) Preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States' preparedness and response plans so as to ensure they are compatible within the regional level structures. To support Member States in this endeavour, targeted training and ***knowledge exchange activities*** for healthcare staff and public health staff ***should be provided*** knowledge and necessary skills ***should be provided by the Commission and Union Agencies***. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation. Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.	(7) ***Prevention,*** preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States' ***prevention,*** preparedness and response plans so as to ensure they are compatible within the regional level structures. ***The plans should be implemented through interregional crisis anticipation planning with particular attention paid to cross-border regions to enhance their health cooperation. Where appropriate, regional authorities should participate in the drawing up of these plans.*** To support Member States in this endeavour, ***the Commission and Union agencies should provide*** targeted training and ***facilitate the sharing of best practices*** for healthcare staff and public health staff ***to improve their*** knowledge and ***ensure*** necessary skills. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should ***include recommendations for policy interventions related to mitigating the impact of communicable diseases on health services and care, including on major non-communicable diseases (NCDs). The plans should*** be coordinated, be functional and updated, and have sufficient resources for their operationalisation***. Specific considerations should be given to border regions, where joint cross-border exercises should be promoted and health practitioners encouraged to gain familiarity with the public health systems in neighbouring countries***. Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.

Thursday 11 November 2021

Amendment 8

Proposal for a regulation

Recital 8

Text proposed by the Commission	*Amendment*
(8) To this end, Member States should provide the Commission with an update on the latest situation with regard to their preparedness and response planning and implementation at national level. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the context of the International Health Regulations (IHR) ([15]). In turn, the Commission should report to the European Parliament and to the Council on the state of play and progress with preparedness, response planning and implementation at Union level, including on corrective actions, every ***2 years*** to ensure that national preparedness and response plans are adequate. In order to support the assessment of these plans, EU audits in Member States should be conducted, in coordination with the ECDC and Union agencies. Such planning should include in particular adequate preparedness of critical sectors of society, such as energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared gender-sensitive public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between health and veterinary sectors for preparedness and response planning.	(8) To this end, Member States should provide the Commission with an update on the latest situation with regard to their ***prevention,*** preparedness and response planning and implementation at national level***, and regional level where applicable***. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the context of the International Health Regulations (IHR) ([15])***. Access to timely and complete data is a precondition for rapid risk assessments and crisis mitigation. To avoid duplication of efforts and diverging recommendations, standardised definitions, where possible, and fluid information exchanges should take place between Union agencies, the WHO and national agencies***. In turn, the Commission should report to the European Parliament and to the Council on the state of play and progress with ***prevention,*** preparedness, response planning and implementation at Union level, including on corrective actions, every ***year*** to ensure that national preparedness and response plans are adequate. In order to support the assessment of these plans, EU audits in Member States should be conducted, in coordination with the ECDC and Union agencies. Such planning should include in particular adequate preparedness of critical ***long-term healthcare and critical*** sectors of society, such as ***agriculture,*** energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared gender-sensitive public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between health and veterinary sectors for preparedness and response planning.

([15]) World Health Organization. International Health Regulation (IHR, 2005) https://www.who.int/publications/i/item/9789241580496

([15]) World Health Organization. International Health Regulation (IHR, 2005) https://www.who.int/publications/i/item/9789241580496

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Amendment 9

Proposal for a regulation

Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for further firmer action at Union level to support cooperation and coordination among the Member States, in particular between neighbouring border regions. The national plans of Member States sharing a border with at least one other Member State should therefore include plans to improve the preparedness for, prevention of and response to health crises in border areas in neighbouring regions, including through mandatory cross-border training for healthcare staff and coordination exercises for the medical transfer of patients. The Commission should regularly report on the state of play of cross-border crisis preparation in neighbouring regions.

Amendment 10

Proposal for a regulation

Recital 8 b (new)

Text proposed by the Commission	*Amendment*
	(8b) The role of frontline health professionals has also become apparent during the pandemic as they have been key to ensuring access to medicine and continuity of care, providing moral support and being a source of trusted information against false information. For future emergencies, it is necessary to strengthen the knowledge of health professionals by laying down rules to provide training for workers in the fields of health care and public health. It is also necessary to integrate them through their professional organisations in the definition of public health policies as well as in the digital transformation in order to improve the quality and efficiency of health systems and ensure their sustainability for the health, social and territorial cohesion work they carry out.

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Amendment 11

Proposal for a regulation

Recital 8 c (new)

Text proposed by the Commission	*Amendment*
	(8c) Health literacy plays a fundamental role in preventing and mitigating the impact of cross-border threats and contributing to a better understanding on the part of the population of the countermeasures and risk assessment of different threats. Respiratory etiquette, correct hand washing, avoiding unnecessary close contact with anyone with flu-like symptoms, and avoiding unprotected contact with wild animals should be part of health education campaigns to improve the population's behaviour, based on the latest available evidence.

Amendments 12 and 248

Proposal for a regulation

Recital 8 d (new)

Text proposed by the Commission	*Amendment*
	(8d) Building on lessons learnt from the COVID-19 pandemic, this Regulation should create a more robust mandate for coordination at Union level. The declaration of a Union emergency situation would trigger increased coordination and allow for timely development, stockpiling and joint procurement of medical countermeasures, under the umbrella of the HERA.

Amendment 13

Proposal for a regulation

Recital 8 e (new)

Text proposed by the Commission	*Amendment*
	(8e) This Regulation also ensures coordinated action at Union level, in order to ensure that the internal market functions properly, and to ensure that basic supplies, including medicines, medical products and personal protective equipment (PPE) circulate freely.

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Amendment 14

Proposal for a regulation

Recital 8 f (new)

Text proposed by the Commission	*Amendment*
	(8f) Health logistics mechanisms should meet the specific legal requirements of Directive 2001/83/EC of the European Parliament and of the Council ([1a]) and Regulation (EU) 2017/745 of the European Parliament and of the Council ([1b]).

([1a]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. (OJ L 311, 28.11.2001, p. 67).

([1b]) 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).

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Amendments 15 and 249

Proposal for a regulation

Recital 9

Text proposed by the Commission	*Amendment*
(9) As serious cross-border threats to health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU. The Commission should ensure coordination and information exchange between the entities organizing any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council ([16]) .	(9) As serious cross-border threats to health are not limited to Union borders, ***the Union should adopt a coordinated approach, characterised by solidarity and responsibility, in combatting such threats. The*** joint procurement of medical countermeasures should***, therefore,*** be extended to include European Free Trade Association States and Union candidate countries, ***the Principality of Andorra, the Principality of Monaco, the Republic of San Marino and the Vatican City State,*** in accordance with the applicable Union legislation***. Joint procurement of medical countermeasures would strengthen the negotiating position of participating countries, improve the security of supply and ensure equitable access to medical countermeasures. Joint procurement procedures, including purchases coordinated by the HERA and related emergency funding programmes, such as rescEU, should abide by high standards of transparency, including in relation to the disclosure of the amounts ordered by and delivered to each participating country and details of their liabilities***. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU. The ***exclusivity clause should entail that countries participating in the joint procurement procedure do not negotiate and sign parallel contracts with producers, and define clear consequences for those that do. The*** Commission should ensure coordination and information exchange between the entities organizing ***and participating in*** any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the ***framework of measures adopted under a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, and the*** strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council ([16])***. The Member States should ensure***

([16]) Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924).

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Text proposed by the Commission	*Amendment*
	a sufficient reserve of critical medical products to counter the risk of shortages of critical products.

([16]) Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism (OJ L 347, 20.12.2013, p. 924).

Amendment 16

Proposal for a regulation

Recital 9 a (new)

Text proposed by the Commission	*Amendment*
	(9a) Joint procurement should be based on shared responsibilities and a fair approach with rights and obligations for all parties involved. Clear commitments should be provided and respected, with manufacturers delivering the agreed production levels and the authorities purchasing their agreed reserved volumes.

Amendment 17

Proposal for a regulation

Recital 9 b (new)

Text proposed by the Commission	*Amendment*
	(9b) In times of crisis, temporary measures should be introduced by the Commission to mitigate shortages and facilitate the circulation of medicines between Member States, including the acceptance of different packaging formats, a reuse procedure to enable marketing authorisation holders to obtain approval in another Member State, extending the validity of good manufacturing practices certificates, longer expiry periods, and the use of veterinary medicinal products. The Commission should strictly monitor the use of such measures, to ensure that patient safety is not compromised and to keep medicines available in the event of difficulties or shortages.

Amendment 18

Proposal for a regulation

Recital 9 c (new)

Text proposed by the Commission	*Amendment*
	(9c) Joint procurement should be carried out in a transparent, timely and effective way. In this respect, clear and transparent stages for the process, scope, tender, specifications, timelines and formalities should be defined. A preliminary consultation phase, subject to adequate safeguards against conflict of interest and asymmetry of information, involving relevant actors should be guaranteed, as well as two-way communication throughout the procedure.

Amendment 19

Proposal for a regulation

Recital 9 d (new)

Text proposed by the Commission	*Amendment*
	(9d) The Commission should pay special attention to ensuring that joint procurement of medical countermeasures within the meaning of Article 12 also includes procurement of orphan drugs.

Amendment 20

Proposal for a regulation

Recital 9 e (new)

Text proposed by the Commission	*Amendment*
	(9e) If joint procurement is deployed, the awarding process should take into account qualitative criteria, such as the ability of the manufacturer to ensure security of supply during a health crisis, as well as price.

Amendment 21

Proposal for a regulation

Recital 9 f (new)

Text proposed by the Commission	*Amendment*
	(9f) In order to achieve transparency, the European Parliament should scrutinise contracts concluded under the Joint Procurement Procedure. The Commission should provide to the Parliament complete, timely and accurate information on the ongoing negotiations and give access to the tender documents as well as to the contracts concluded.

Amendment 22

Proposal for a regulation

Recital 9 g (new)

Text proposed by the Commission	*Amendment*
	(9g) Where a joint procurement procedure has not been used to purchase medical countermeasures, the Commission should encourage Member States to exchange information on pricing and delivery dates of medical countermeasures, to provide an increased level of transparency and thus allow Member States to access and negotiate medical countermeasures in more equitable conditions.

Amendment 23

Proposal for a regulation

Recital 9 h (new)

Text proposed by the Commission	*Amendment*
	(9h) In times of crisis, other mechanisms should be used to enable global response and crises mitigation. Such mechanisms could, for example, include a Union export control mechanism, enhanced cooperation agreements on the production of medical countermeasures, pre-allocating part of the Union joint procurement, and both voluntary and compulsory technology know-how pools and licensing agreements between companies, which should facilitate access to counter-measures for people, including those in Eastern Partnership and low- and middle-income countries.

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Amendment 24

Proposal for a regulation

Recital 10

Text proposed by the Commission	*Amendment*
(10) Unlike for communicable diseases, the surveillance of which at Union level is carried out on a permanent basis by the ECDC, other potentially serious cross-border threats to health do not currently necessitate monitoring by EU Agencies. A risk-based approach, whereby monitoring is carried out by Member States and available information is exchanged through EWRS, is therefore more appropriate for such threats.	(10) Unlike for communicable diseases, the surveillance of which at Union level is carried out on a permanent basis by the ECDC, other potentially serious cross-border threats to health do not currently necessitate monitoring by EU Agencies. A risk-based approach, whereby monitoring is carried out by Member States and available information is exchanged through EWRS, is therefore more appropriate for such threats. ***Nevertheless, the ECDC should have the ability to monitor the impact of communicable diseases on major non-communicable diseases, including mental diseases, assessing the continuity of screening, diagnosis, monitoring, treatment and care in the healthcare system, in coordination with existing data sets, tools and registers.***

Amendments 25 and 250

Proposal for a regulation

Recital 11

Text proposed by the Commission	*Amendment*
(11) The Commission should strengthen cooperation and activities with the Member States, the ECDC, the European Medicines Agency ('EMA'), other Union Agencies, research infrastructures and the WHO to improve the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance.	(11) The Commission***, in particular the HERA,*** should strengthen cooperation and activities with the Member States, the ECDC, the European Medicines Agency('EMA'), other Union Agencies ***or bodies***, research infrastructures and the WHO to improve***, through the One Health approach,*** the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance***, and other major non-communicable diseases***. ***During health crises, particular attention should be paid to the continuity of screening, diagnosis, monitoring, treatment and care for other diseases and conditions, and to the mental health implications of the crisis and psychosocial needs of the population.***

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Amendment 26

Proposal for a regulation

Recital 12

Text proposed by the Commission	*Amendment*
(12) In case of cross-border health threats due to a communicable disease, the blood and transplant services in the Member States can provide a means for rapid testing of the donor population and assessing exposure to and immunity from the disease in the general population. These services in return are dependent on rapid risk assessments by the ECDC to safeguard patients, in need of a therapy from a substance of human origin, from a transmission of such communicable disease. Such risk assessment serves then as basis to allow for the appropriate adaptation of measures setting standards for quality and safety of such substances of human origin. The ECDC should therefore set up and operate a network of national blood and transplant services and their authorities to serve this dual purpose.	(12) In case of cross-border health threats due to a communicable disease, the blood and transplant services***, pharmacies and other licensed health care establishments*** in the Member States can provide a means for rapid testing of the donor population and assessing exposure to and immunity from the disease in the general population. These services in return are dependent on rapid risk assessments by the ECDC to safeguard patients, in need of a therapy from a substance of human origin or ***undergoing a process of medically assisted reproduction*** from a transmission of such communicable disease. Such risk assessment serves then as basis to allow for the appropriate adaptation of measures setting standards for quality and safety of such substances of human origin. The ECDC should therefore set up and operate a network of national blood and transplant services and their authorities***, as well as pharmacy services and other licensed health services and establishments,*** to serve this dual purpose.

Amendments 27 and 251

Proposal for a regulation

Recital 12 a (new)

Text proposed by the Commission	*Amendment*
	(12a) In order to improve early preparedness for, and response to, the emergence of cross-border health threats, it is crucial to enable continuous and rapid access to data on the availability of the necessary medical counter measures. Therefore, a network of Member States' services providing up-to-date information on national strategic stockpiles and the availability of medical countermeasures, stockpiles of medical products, essential health products and diagnostic tests should be established, operated and coordinated at Union level by the HERA. Strengthening coordination and exchange of information with Member States on strategic stockpiles and medical countermeasures available is necessary to enhance the collection, modelling and use of prospective data that allow early alert notifications in the Union.

Thursday 11 November 2021

Amendment 28

Proposal for a regulation

Recital 13

Text proposed by the Commission	*Amendment*
(13) A system enabling the notification at Union level of alerts related to serious cross-border threats to health has been put in place by Decision No 2119/98/EC in order to ensure that competent public health authorities in Member States and the Commission are duly informed in a timely manner. All serious cross-border threats to health covered by this Regulation are covered by the EWRS. The operation of the EWRS should remain within the remit of the ECDC. The notification of an alert should be required only where the scale and severity of the threat concerned are or could become so significant that they affect or could affect more than one Member State and require or could require a coordinated response at the Union level. To avoid duplication and ensure coordination across Union alert systems, the Commission and ECDC should ensure that alert notifications under the EWRS and other rapid alert systems at Union level are linked to each ***other to*** the extent possible so that the competent authorities of the Member States can avoid as much as possible notifying the same alert through different systems at Union level and can benefit from receiving all-hazard alerts from a single coordinated source.	(13) A system enabling the notification at Union level of alerts related to serious cross-border threats to health has been put in place by Decision No 2119/98/EC in order to ensure that competent public health authorities in Member States and the Commission are duly informed in a timely manner. All serious cross-border threats to health covered by this Regulation are covered by the EWRS. The operation of the EWRS should remain within the remit of the ECDC. The notification of an alert should be required only where the scale and severity of the threat concerned are or could become so significant that they affect or could affect more than one Member State and require or could require a coordinated response at the Union level. To avoid duplication and ensure coordination across Union alert systems, the Commission and ECDC should ensure that alert notifications under the EWRS and other rapid alert systems at Union level are ***fully interoperable and, subject to human oversight, automatically*** linked to each ***other to*** the extent possible so that the competent authorities of the Member States can avoid as much as possible notifying the same alert through different systems at Union level and can benefit from receiving all-hazard alerts from a single coordinated source.

Thursday 11 November 2021

Amendment 29

Proposal for a regulation

Recital 14

Text proposed by the Commission	*Amendment*
(14) In order to ensure that the assessment of risks to public health at the Union level from serious cross-border threats to health is consistent as well as comprehensive from a public health perspective, the available scientific expertise should be mobilised in a coordinated manner, through appropriate channels or structures depending on the type of threat concerned. That assessment of risks to public health should be developed by means of a fully transparent process and should be based on principles of excellence, independence, impartiality and transparency. The involvement of Union agencies in these risk assessments needs to be broadened according to their speciality in order to ensure an all hazard approach, via a permanent network of agencies and relevant Commission services to support the preparation of risk assessments.	(14) In order to ensure that the assessment of risks to public health at the Union level from serious cross-border threats to health is consistent as well as comprehensive from a public health perspective, the available scientific expertise should be mobilised in a coordinated ***and multidisciplinary*** manner, through appropriate channels or structures depending on the type of threat concerned. That assessment of risks to public health should be developed by means of a fully transparent process and should be based on principles of excellence, independence, impartiality and transparency. The involvement of Union agencies ***and bodies*** in these risk assessments needs to be broadened according to their speciality in order to ensure an all hazard approach, via a permanent network of agencies and relevant Commission services to support the preparation of risk assessments. ***In order to achieve a sufficient degree of expertise and effectiveness, the financial and human resources of Union agencies and bodies should be increased.***

Amendments 30 and 252

Proposal for a regulation

Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) Member States, the Commission, in particular the HERA, and Union agencies, while applying the One Health approach, should identify recognised public health organisations and experts, both in the area of communicable and major non-communicable diseases, and other relevant stakeholders across sectors, available to assist in Union responses to health threats. Such experts and stakeholders, including civil society organisations, should be structurally engaged throughout all crisis response activities and contribute to the decision-making processes. National authorities should also consult and involve representatives of patient organisations and national social partners in the healthcare and social services sector in the implementation of this regulation where appropriate. It is essential that there be full compliance with transparency and conflict of interest rules for stakeholder engagement.

Amendment 31

Proposal for a regulation

Recital 14 b (new)

Text proposed by the Commission	*Amendment*
	(14b) Green lanes should only be considered as an appropriate tool for pandemic situations of a declared public health emergency where they are aimed at ensuring that essential goods, medical countermeasures and cross border workers circulate freely and safely within the internal market. The creation of green lanes in such situations should not affect the relevant treaty provisions or legislation regulating border controls.

Amendment 32

Proposal for a regulation

Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) The Commission should ensure that, at the time of the declaration of a state of emergency, the number of accommodation facilities in hospitals in the Member States, as well as the number of available accommodation units in intensive care units in the Member States, are known, for the purpose of cross-border movement of patients.

Amendment 33

Proposal for a regulation

Recital 16 a (new)

Text proposed by the Commission	*Amendment*
	(16a) Regular dialogue and exchange of information between authorities, industry, relevant entities of the pharmaceutical supply chain, healthcare professionals' and patients' organisations should also be ensured, in order to start early discussions about expected potential serious cross-border threats to health in the market, by way of sharing information about expected supply constraints or raising specific clinical needs, thereby allowing better coordination, synergies and appropriate reaction when needed.

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Amendment 34

Proposal for a regulation

Recital 17

Text proposed by the Commission	*Amendment*
(17) Inconsistent communication with the public and stakeholders such as healthcare professionals can have a negative impact on the effectiveness of the response from a public health perspective as well as on economic operators. The coordination of the response within the HSC, assisted by relevant subgroups, should, therefore, encompass rapid information exchange concerning communication messages and strategies and addressing communication challenges with a view to coordinating risk and crisis communication, based on robust and independent evaluation of public health risks, to be adapted to national needs and circumstances. Such exchanges of information are intended to facilitate the monitoring of the clarity and coherence of messages to the public and to healthcare professionals. Given the cross-sectoral nature of this type of crises, coordination should also be ensured with other relevant constituencies, such as the Union Civil Protection Mechanism established by Decision (EU) 2019/420 of the European Parliament and of the Council ([17]) .	(17) Inconsistent communication with the public and stakeholders such as healthcare ***and public health*** professionals can have a negative impact on the effectiveness of the response from a public health perspective as well as on economic operators. The coordination of the response within the HSC, assisted by relevant subgroups, should, therefore, encompass rapid information exchange concerning communication messages and strategies and addressing communication challenges with a view to coordinating risk and crisis communication, based on ***holistic,*** robust and independent evaluation of public health risks, to be adapted to national ***and regional*** needs and circumstances***. In those Member States with regions having health competences, those regions should provide this information***. Such exchanges of information are intended to facilitate the monitoring of the clarity and coherence of messages to the public and to healthcare professionals***. Following its recommendations to Member States and healthcare professionals, the ECDC should broaden its communication activity to include the general public by establishing and managing an online portal to share verified information and fight against disinformation***. Given the cross-sectoral nature of this type of crises, coordination should also be ensured with other relevant constituencies, such as the Union Civil Protection Mechanism established by Decision (EU) 2019/420 of the European Parliament and of the Council ([17]).
([17]) Decision (EU) 2019/420 of the European Parliament and of the Council of 13 March 2019 amending Decision No 1313/2013/EU on a Union Civil Protection Mechanism (OJ L 77 I, 20.3.2019, p. 1).	([17]) Decision (EU) 2019/420 of the European Parliament and of the Council of 13 March 2019 amending Decision No 1313/2013/EU on a Union Civil Protection Mechanism (OJ L 77 I, 20.3.2019, p. 1).

Thursday 11 November 2021

Amendments 35 and 253

Proposal for a regulation

Recital 18

Text proposed by the Commission	*Amendment*
(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, and of other Union bodies or agencies as observers. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as 'EU Health Task Force'.	(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, ***representatives of health and care workers, including nurses and medical doctors, and representatives of civil society,*** selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, ***of the HERA*** and of other Union bodies or agencies as observers***. All members of the Advisory Committee should provide declarations of interest. The advisory committee should work in close cooperation with national advisory bodies***. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, ***Union export control mechanisms,*** flexible mechanisms to develop, procure, manage and deploy medical countermeasures ***through the HERA*** as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as 'EU Health Task Force'. ***The recognition of a public health emergency may trigger the activation of the framework set out in a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level. That framework should remain operational for an initial period of 6 months, renewable as long as the public health emergency exists.***

Thursday 11 November 2021

Amendment 36

Proposal for a regulation

Recital 20

Text proposed by the Commission	*Amendment*
(20) The occurrence of an event that corresponds to serious cross-border threats to health and is likely to have Union-wide consequences should require the Member States concerned to take particular control or contact-tracing measures in a coordinated manner in order to identify people already contaminated and those persons exposed to risk. Such cooperation could require the exchange of personal data through the system, including sensitive information related to health and information about confirmed or suspected human cases of the disease, between those Member States directly involved in the contact-tracing measures. The exchange of personal data concerning health by the Member States has to comply with Article 9(2)(i) of Regulation (EU) 2016/679 of the European Parliament and of the Council ([18]).	(20) The occurrence of an event that corresponds to serious cross-border threats to health and is likely to have Union-wide consequences should require the Member States ***concerned or potentially*** concerned to take particular control or contact-tracing measures in a co-ordinated manner in order to identify people already contaminated and those persons exposed to risk. Such cooperation could require the exchange of personal data through the system, including sensitive information related to health and information about confirmed or suspected human cases of the disease ***or infection***, between those Member States directly involved in the contact-tracing measures. The exchange of personal data concerning health by the Member States has to comply with Article 9(2)(i) of Regulation (EU) 2016/679 of the European Parliament and of the Council ([18]).
([18]) 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).	([18]) 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).

Thursday 11 November 2021

Amendment 37

Proposal for a regulation

Recital 21

Text proposed by the Commission	*Amendment*
(21) Cooperation with third countries and international organisations in the field of public health should be fostered. It is particularly important to ensure the exchange of information with the WHO on the measures taken pursuant to this Regulation. This reinforced cooperation is also required to contribute to EU's commitment to strengthening support to health systems and reinforcing partners' preparedness and response capacity. The Union could benefit from concluding international cooperation agreements with third countries or international organisations, including the WHO, to foster the exchange of relevant information from monitoring and alerting systems on serious cross-border threats to health. Within the limits of the Union's competences, such agreements could include, where appropriate, the participation of such third countries or international organisations in the relevant epidemiological surveillance monitoring network and the EWRS, exchange of good practice in the areas of preparedness and response capacity and planning, public health risk-assessment and collaboration on response coordination, including the research response.	(21) Cooperation with third countries and international organisations in the field of public health should be fostered. It is particularly important to ensure the exchange of information with the WHO on the measures taken pursuant to this Regulation. This reinforced cooperation is also required to contribute to EU's commitment to strengthening support to health systems and reinforcing partners' preparedness and response capacity. The Union could benefit from concluding international cooperation agreements with third countries or international organisations, including the WHO, to foster the exchange of relevant information from monitoring and alerting systems on serious cross-border threats to health. Within the limits of the Union's competences, such agreements could include, where appropriate, the participation of such third countries or international organisations in the relevant epidemiological surveillance monitoring network***, such as the European Surveillance System (TESSy),*** and the EWRS, exchange of good practice in the areas of preparedness and response capacity and planning, public health risk-assessment and collaboration on response coordination, including the research response. ***The Commission and the Member States should actively work towards the establishment of a WHO framework convention on pandemic preparedness and response, which should lay down principles and priorities for pandemic preparedness and response. Such a framework convention should facilitate the implementation of the International Health Regulations (2005) ([1a]) and should support the strengthening of the international health framework and the improvement of cooperation with regard to early detection, prevention, response and resilience in respect of future pandemics.***

([1a]) World Health Organisation International Health Regulations (2005) Third Edition available at https://www.who.int/publications/i/item/9789241580496

Thursday 11 November 2021

Amendment 38

Proposal for a regulation

Recital 22

Text proposed by the Commission	*Amendment*
(22) The processing of personal data for the purpose of implementing this Regulation should comply with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 of the European Parliament and of the Council ([19]). In particular, the operation of the EWRS should provide for specific safeguards for the safe and lawful exchange of personal data for the purpose of contact tracing measures implemented by Member States at national level. In this regard, the EWRS includes a messaging function in which personal data, including contact and health data, can be communicated to relevant authorities involved in contact tracing measures.	(22) ***Due to the sensitive nature of health data, Member States, the Commission and Union agencies should safeguard and guarantee that their processing operations respect the data protection principles in accordance with Article 5 of the GDPR.*** The processing of personal data for the purpose of implementing this Regulation should comply with the GDPR and Regulation (EU) 2018/1725 of the European Parliament and of the Council ([19]). In particular, the operation of the EWRS should provide for specific safeguards for the safe and lawful exchange of personal data for the purpose of contact tracing measures implemented by Member States at national level. In this regard, the EWRS includes a messaging function in which personal data, including contact and health data, can be communicated to relevant authorities involved in contact tracing***. Regulation (EU) 2018/1725 of the European Parliament and of the Council should be strictly respected and appropriate technical and organisational security*** measures***, in accordance with that Regulation, should be put in place***.

([19]) Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

Thursday 11 November 2021

Amendment 39

Proposal for a regulation

Recital 25

Text proposed by the Commission	*Amendment*
(25) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt implementing acts in relation to: templates to be used when providing the information on preparedness and response planning; organisation of the training activities for health care and public health staff; the establishment and update of a list of communicable diseases and related special health issues subject to the network of epidemiological surveillance ***and the procedures for the operation of such a network; the adoption of case definitions for those communicable diseases and special health issues covered by the epidemiological surveillance network and, where necessary, for other serious cross-border threats to health subject to ad hoc monitoring; the procedures for the operation of the EWRS; the functioning of the surveillance platform***; the designation of EU reference laboratories to provide support to national reference laboratories; the procedures for the information exchange on and the coordination of the responses of the Member States; the recognition of situations of public health emergency at Union level and the termination of such a recognition and procedures necessary to ensure that the operation of the EWRS and the processing of data are in accordance with the data protection legislation.	(25) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt implementing acts in relation to: templates to be used when providing the information on preparedness and response planning; organisation of the training activities for health care and public health staff; the establishment and update of a list of communicable diseases and related special health issues subject to the ***procedures for the operation of the*** network of epidemiological surveillance; the designation of EU reference laboratories to provide support to national ***and regional*** reference laboratories; the procedures for the information exchange on and the coordination of the responses of the Member States; the recognition of situations of public health emergency at Union level and the termination of such a recognition and procedures necessary to ensure that the operation of the EWRS and the processing of data are in accordance with the data protection legislation.

Thursday 11 November 2021

Amendment 40

Proposal for a regulation

Recital 28

Text proposed by the Commission	*Amendment*
(28) In order to ascertain the state of implementation of the national preparedness plans and their coherence with the Union plan, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission ***in respect of*** procedures, standards and criteria for the audits aimed at the assessment of preparedness and response planning at national level. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016 ([21]). In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.	(28) ***In order to supplement certain aspects of this Regulation and*** to ascertain the state of implementation of the national ***and regional*** preparedness plans and their coherence with the Union plan, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission ***in respect of: the establishment and updating of a list of communicable diseases and related special health issues subject to the network of epidemiological surveillance; the adoption of case definitions for those communicable diseases and special health issues covered by the epidemiological surveillance network and, where necessary, for other serious cross-border threats to health that are the subject of ad hoc monitoring; the requirements necessary to ensure the compliance of the operation of the EWRS and the processing of data with the relevant Regulations; the establishment and updating of a list of relevant health data to be automatically collected by a digital platform, subject to human oversight; the functioning of the surveillance platform; and the*** procedures, standards and criteria for the audits aimed at the assessment of preparedness and response planning at national ***and regional*** level. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016 ([21]). In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

([21]) OJ L 123, 12.5.2016, p. 1.

([21]) OJ L 123, 12.5.2016, p. 1

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Amendment 41

Proposal for a regulation

Recital 28 a (new)

Text proposed by the Commission	*Amendment*
	(28a) In respect of the establishment and updating of a list of communicable diseases and related special health issues subject to the network of epidemiological surveillance and the procedures for the operation of such a network, the adoption of case definitions for those communicable diseases and special health issues covered by the epidemiological surveillance network and the case definitions to be used for ad hoc monitoring, the Commission should adopt delegated acts under the urgency procedure where duly justified imperative grounds of urgency related to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread between the Member States so require.

Amendment 42

Proposal for a regulation

Article 1 — paragraph 1 — point c

Text proposed by the Commission	*Amendment*
(c) joint procurement of medical countermeasures;	(c) joint procurement***, management and deployment*** of medical countermeasures;

Amendment 254

Proposal for a regulation

Article 1 — paragraph 1 — point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) emergency research and innovation plans, including clinical trial networks and innovation platforms;

Amendment 43

Proposal for a regulation

Article 1 — paragraph 2 — point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) a network of national strategic stockpiles and available medical countermeasures;

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Amendment 44

Proposal for a regulation

Article 1 — paragraph 3

Text proposed by the Commission	*Amendment*
3. The implementation of this Regulation shall be supported by funding from relevant Union programmes and instruments.	3. ***In keeping with the 'One Health' and 'Health in all policies' approaches,*** the implementation of this Regulation shall be supported by funding from relevant Union programmes and instruments. ***The strengthened Union health framework addressing serious cross-border health threats shall work in synergy with and in a manner that is complementary to other Union policies and funds, such as actions implemented under the EU4Health programme, the European Structural and Investment Funds (ESIF), Horizon Europe, the Digital Europe Programme, rescEU reserve, the European Social Fund Plus (ESF+), the Emergency Support Instrument (ESI) and the Single Market Programme (SMP).***

Amendment 45

Proposal for a regulation

Article 1 — paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. This Regulation shall ensure that in future health emergencies, the detection of, health interventions concerning and treatment of other serious diseases are not halted.

Amendment 46

Proposal for a regulation

Article 1 — paragraph 3 b (new)

Text proposed by the Commission	*Amendment*
	3b. This Regulation shall be implemented with full respect for the dignity and fundamental rights and freedoms of persons.

Amendment 243

Proposal for a regulation

Article 2 — paragraph 1 — point a — point i

Text proposed by the Commission	*Amendment*
(i) communicable diseases;	(i) communicable diseases***, including those of zoonotic origin***;

Amendment 47

Proposal for a regulation

Article 2 — paragraph 2

Text proposed by the Commission	*Amendment*
2. This Regulation shall also apply to the epidemiological surveillance of communicable diseases ***and of*** related special health issues.	2. This Regulation shall also apply to the epidemiological surveillance of communicable diseases***, the monitoring of the impact of such diseases on major non-communicable diseases and on*** related special health issues***, such as mental health, and the impact on deferred screening, diagnosis, monitoring, treatment and care for other diseases and conditions***.

Amendment 48

Proposal for a regulation

Article 2 — paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. This Regulation shall promote the implementation of the International Health Regulations, reduce administrative burden and duplication of resources, and strengthen the gaps exposed during the COVID-19 pandemic in the prevention of, preparedness for and response to public health threats.

Amendment 49

Proposal for a regulation

Article 2 — paragraph 4

Text proposed by the Commission	*Amendment*
4. In exceptional emergency situations, a Member State or the Commission may request the coordination of response within the HSC as referred to in Article 21, for serious cross-border threats to health other than those referred to in Article 2(1), if it is considered that public health measures taken previously have proven insufficient to ensure a high level of protection of human health.	4. In exceptional emergency situations, a Member State or the Commission may request the coordination of response within the HSC as referred to in Article 21, for serious cross-border threats to health other than those referred to in Article 2(1), ***especially in relation to major non-communicable diseases,*** if it is considered that public health measures taken previously have proven insufficient to ensure a high level of protection of human health.

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Amendment 50

Proposal for a regulation

Article 2 — paragraph 5

Text proposed by the Commission	*Amendment*
5. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the mechanisms and structures established under this Regulation and similar mechanisms and structures established at Union level or under the Euratom Treaty whose activities are relevant for preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health.	5. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the mechanisms and structures established under this Regulation and similar mechanisms and structures established at ***international level,*** Union level or under the Euratom Treaty whose activities are relevant for preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health.

Amendment 51

Proposal for a regulation

Article 2 — paragraph 6

Text proposed by the Commission	*Amendment*
6. Member States shall retain the right to maintain or introduce additional arrangements, procedures and measures for their national systems in the fields covered by this Regulation, including arrangements provided for in existing or future bilateral or multilateral agreements or conventions, on condition that such additional arrangements, procedures and measures do not impair the application of this Regulation.	6. Member States shall retain the right to maintain or introduce additional arrangements, procedures and measures for their national systems in the fields covered by this Regulation, including arrangements provided for in existing or future bilateral or multilateral agreements or conventions, on condition that such additional arrangements, procedures and measures do not impair the application of this Regulation. ***The Union shall call for the establishment of a WHO framework convention on pandemic preparedness and response. That convention shall be such as to facilitate the implementation of the International Health Regulation (2005) ([1a]) and resolve the weaknesses of that Regulation, identified during the COVID-19 crisis.***

([1a]) World Health Organization. International Health Regulation (IHR, 2005) https://www.who.int/ihr/publications/9789241596664/en/

Amendment 52

Proposal for a regulation

Article 2 — paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. This Regulation shall also apply, where appropriate, to regional competent authorities, systems and programmes in the fields covered by this Regulation.

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Amendment 255

Proposal for a regulation

Article 3 — paragraph 1 — point - 1 (new)

Text proposed by the Commission	*Amendment*
	(-1) 'public health emergency' means a public health emergency at Union level recognised by the Commission based on an opinion of the Advisory Committee in accordance with Article 23 of this Regulation;

Amendment 53

Proposal for a regulation

Article 3 — paragraph 1 — point 3

Text proposed by the Commission	*Amendment*
(3) 'contact tracing' means measures ***implemented in order to trace*** persons who have been exposed to a source of a serious cross-border threat to health, and who are in danger of ***developing*** or have developed a disease, through manual or other technological means;	(3) 'contact tracing' means measures ***to identify, assess and manage*** persons who have been exposed to a source of a serious cross-border threat to health, and who are in danger of ***being infected or being infectious*** or who have developed a ***communicable*** disease, through manual or other technological means***, with the sole objective of rapidly identifying potentially newly infected persons who may have come into contact with existing cases, in order to reduce further onward transmission***;

Amendment 54

Proposal for a regulation

Article 3 — paragraph 1 — point 4

Text proposed by the Commission	*Amendment*
(4) 'epidemiological surveillance' means the systematic collection, recording, analysis, interpretation and dissemination of data and analysis on communicable diseases and related special health issues;	(4) 'epidemiological surveillance' means the systematic collection, recording, analysis, interpretation and dissemination of data and analysis on communicable diseases***, the monitoring of the impact of such diseases on major non-communicable diseases, such as those relating to mental health,*** and ***on*** related special health issues;

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Amendment 55

Proposal for a regulation

Article 3 — paragraph 1 — point 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) 'One Health approach' means a multisectoral approach which recognises that human health is connected to animal health and to the environment, and that actions to tackle threats to health must take into account those three dimensions;

Amendment 56

Proposal for a regulation

Article 3 — paragraph 1 — point 5 b (new)

Text proposed by the Commission	*Amendment*
	(5b) 'Health in All Policies' means an approach to the development, implementation and review of public policies, regardless of the sector, whereby the health implications of decisions are taken into account, and which seeks to achieve synergies and to avoid harmful health impacts being caused by such policies, in order to improve the health of the population and health equity;

Amendment 57

Proposal for a regulation

Article 3 — paragraph 1 — point 7 a (new)

Text proposed by the Commission	*Amendment*
	(7a) 'major non-communicable disease' means a disease as defined in point (4a) of Article 2 of Regulation (EU) [ECDC regulation, correct reference to be inserted];

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Amendment 58

Proposal for a regulation

Article 3 — paragraph 1 — point 8

Text proposed by the Commission	*Amendment*
(8) 'medical countermeasure' means medicinal products for human use and medical devices as defined in Directive 2001/83/EC of the European Parliament and of the Council ([23]) and in Regulation (EU) 2017/745 of the European Parliament and of the Council ([24]) or other goods or services for the ***for the*** purpose of preparedness and response to a serious cross-border threat to health.	(8) 'medical countermeasure' means medicinal products for human use and medical devices as defined in Directive 2001/83/EC of the European Parliament and of the Council[23] ([23]) and in Regulation (EU) 2017/745 of the European Parliament and of the Council ([24]) or other goods or services for the purpose ***of facilitating diagnosis and treatment in the framework*** of preparedness and response to a serious cross-border threat to health.

([23]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

([24]) 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).

Amendment 59

Proposal for a regulation

Article 3 — paragraph 1 — point 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) 'International Health Regulations' mean the International Health Regulations adopted by the World Health Organization in 2005;

Amendment 60

Proposal for a regulation

Article 3 — paragraph 1 — point 8 b (new)

Text proposed by the Commission	*Amendment*
	(8b) 'medical device' means both a medical device as defined in point (1) of Article 2 of Regulation (EU) 2017/745, read in conjunction with point (2) of Article 1 and point (a) of Article 1(6) of that Regulation, and an in vitro diagnostic medical device as defined in point (2) of Article 2 of Regulation (EU) 2017/746;

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Amendment 61

Proposal for a regulation

Article 3 — paragraph 1 — point 8 c (new)

Text proposed by the Commission	*Amendment*
	(8c) 'green lanes' means passable and safe transit corridors that preserve supply chains in the event of a declared public health emergency at Union level in a pandemic situation by ensuring that essential goods, medical countermeasures and cross border workers can circulate freely and safely within the internal market, while fully respecting Article 77 (2)(e) TFEU.

Amendment 62

Proposal for a regulation

Article 4 — paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Representatives of relevant Union agencies shall participate in HSC meetings as observers.

Amendment 63

Proposal for a regulation

Article 4 — paragraph 2 — point b

Text proposed by the Commission	*Amendment*
(b) coordination in liaison with the Commission of the preparedness and response planning of the Member States in accordance with Article 10;	(b) coordination in liaison with the Commission ***and relevant Union agencies*** of the ***prevention,*** preparedness and response planning of the Member States in accordance with Article 10;

Amendment 64

Proposal for a regulation

Article 4 — paragraph 2 — point c

Text proposed by the Commission	*Amendment*
(c) coordination in liaison with the Commission of the risk and crisis communication and responses of the Member States to serious cross-border threats to health, in accordance with Article 21;	(c) coordination in liaison with the Commission ***and relevant Union agencies*** of the risk and crisis communication and responses of the Member States to serious cross-border threats to health, in accordance with Article 21;

Amendment 65

Proposal for a regulation

Article 4 — paragraph 2 — point d a (new)

Text proposed by the Commission	*Amendment*
	(da) adoption, on an annual basis, of an action programme to clearly set its priorities and objectives at the high level working group and the technical working group levels.

Amendment 66

Proposal for a regulation

Article 4 — paragraph 4

Text proposed by the Commission	*Amendment*
4. The HSC shall be chaired by a representative of the Commission. The HSC shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State.	4. The HSC shall be chaired by a representative of the Commission ***without the right to vote***. The HSC shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State.

Amendment 67

Proposal for a regulation

Article 4 — paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. Members of the HSC and the Commission shall ensure thorough consultation with relevant Union agencies, public health experts, international organisations and stakeholders, including healthcare professionals.

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Amendment 68

Proposal for a regulation

Article 4 — paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7a. The European Parliament shall designate representatives to participate in the Health Security Committee ('HSC') as observers.

Amendment 69

Proposal for a regulation

Article 4 — paragraph 7 b (new)

Text proposed by the Commission	*Amendment*
	7b. The list of members of the HSC at both the political and technical levels shall be made public on the Commission and Council websites. Members of the Committee shall have no financial or other interests that could affect their impartiality. They shall act in the public interest and in an independent manner and make an annual declaration of their financial interests. All direct interests which could relate to the medical or another relevant sector shall be entered in a register held by the Commission and be accessible to the public, upon request.

Amendment 70

Proposal for a regulation

Article 4 — paragraph 7 c (new)

Text proposed by the Commission	*Amendment*
	7c. The rules of procedure, guidance, agendas and minutes of the meetings of the HSC shall be published on the Commission's web-portal.

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Amendment 256

Proposal for a regulation

Article 4 — paragraph 7 d (new)

Text proposed by the Commission	*Amendment*
	7d. The HSC shall act in cooperation with the board of HERA established under the Commission decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority, and the Health Crisis Board (HCB) to be established under a Council regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level. The coordination between those bodies shall ensure the participation of all relevant stakeholders, including healthcare professionals' organisations, patients' associations, and industry and supply chain actors with recognised experience in disciplines related to the HSC, HCB and to the work of the HERA. The provisions related to conflict of interests and transparency, as provided for in paragraphs 7b and 7c, shall apply in relation to this paragraph also. The Commission shall invite a representative of the European Parliament to serve as an active member of the HCB.

Amendment 71

Proposal for a regulation

Chapter II — title

Text proposed by the Commission	*Amendment*
II PREPAREDNESS AND RESPONSE PLANNING	II ***PREVENTION,*** PREPAREDNESS AND RESPONSE PLANNING

Amendment 72

Proposal for a regulation

Article 5 — title

Text proposed by the Commission	*Amendment*
Union preparedness and response plan	Union ***prevention,*** preparedness and response plan

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Amendment 73

Proposal for a regulation

Article 5 — paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission, in cooperation with Member States and the relevant Union agencies, shall establish a Union health crisis and pandemic plan ('the Union preparedness and response plan') to promote effective and coordinated response to cross-border health threats at Union level.	1. The Commission, in cooperation with Member States and the relevant Union agencies ***and taking into account the WHO framework***, shall establish a Union health crisis and pandemic plan ('the Union ***prevention***, preparedness and response plan') to promote effective and coordinated response to cross-border health threats at Union level.

Amendment 74

Proposal for a regulation

Article 5 — paragraph 2

Text proposed by the Commission	*Amendment*
2. The Union preparedness and response plan shall complement the national preparedness and response plans established in accordance with Article 6.	2. The Union ***prevention,*** preparedness and response plan shall complement the national preparedness and response plans established in accordance with Article 6.

Amendment 75

Proposal for a regulation

Article 5 — paragraph 3 — introductory part

Text proposed by the Commission	*Amendment*
3. The Union preparedness and response plan shall, in particular, include arrangements for governance, capacities and resources for:	3. The Union ***prevention,*** preparedness and response plan shall, in particular, include arrangements for governance, capacities and resources for:

Amendment 257

Proposal for a regulation

Article 5 — paragraph 3 — point a

Text proposed by the Commission	*Amendment*
(a) the timely cooperation between the Commission, the Member States and the Union agencies;	(a) the timely cooperation between the Commission, the Member States and the Union agencies ***and bodies***;

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Amendment 258

Proposal for a regulation

Article 5 — paragraph 3 — point b

Text proposed by the Commission	*Amendment*
(b) the secure exchange of information between the Commission, Union agencies and the Member States;	(b) the secure exchange of information between the Commission, Union agencies and ***bodies and*** the Member States;

Amendment 76

Proposal for a regulation

Article 5 — paragraph 3 — point c

Text proposed by the Commission	*Amendment*
(c) the epidemiological surveillance and monitoring;	(c) the epidemiological surveillance and monitoring***, as well as the impact of communicable diseases on major non-communicable diseases***;

Amendment 77

Proposal for a regulation

Article 5 — paragraph 3 — point e

Text proposed by the Commission	*Amendment*
(e) the risk and crisis communication;	(e) the risk and crisis communication***, aimed at health professionals and at citizens***;

Amendment 78

Proposal for a regulation

Article 5 — paragraph 3 — point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) the mapping of the production capacities of medical products in the Union as a whole;

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Amendment 79

Proposal for a regulation

Article 5 — paragraph 3 — point f b (new)

Text proposed by the Commission	*Amendment*
	(fb) the establishment of a Union stock of critical medicinal products, medical countermeasures and personal protective equipment as part of the rescEU emergency reserve;

Amendment 259

Proposal for a regulation

Article 5 — paragraph 3 — point f c (new)

Text proposed by the Commission	*Amendment*
	(fc) the implementation of the provisions of the plan relating to emergency research and innovation aspects;

Amendment 80

Proposal for a regulation

Article 5 — paragraph 3 — point g a (new)

Text proposed by the Commission	*Amendment*
	(ga) the criteria for activating and deactivating the actions;

Amendment 81

Proposal for a regulation

Article 5 — paragraph 3 — point g b (new)

Text proposed by the Commission	*Amendment*
	(gb) ensuring that healthcare services, including the screening, diagnosis, monitoring, treatment and care for other diseases and conditions, are provided without disruption during health emergencies;

Amendment 82

Proposal for a regulation

Article 5 — paragraph 3 — point g c (new)

Text proposed by the Commission	*Amendment*
	(gc) ensuring that national health systems are inclusive and provide equal access to health and related services, and that quality treatments are available without delays;

Amendment 83

Proposal for a regulation

Article 5 — paragraph 3 — point g d (new)

Text proposed by the Commission	*Amendment*
	(gd) an adequate and needs-oriented staffing level;

Amendment 84

Proposal for a regulation

Article 5 — paragraph 3 — point g e (new)

Text proposed by the Commission	*Amendment*
	(ge) monitoring whether adequate risk assessments, preparedness plans and training courses are foreseen for health and social care professionals.

Amendment 85

Proposal for a regulation

Article 5 — paragraph 4

Text proposed by the Commission	*Amendment*
4. The Union preparedness and response plan shall include interregional preparedness ***elements*** to establish coherent, multi-sectoral, cross-border public health measures, in particular considering capacities for testing, contact tracing, laboratories, and specialised treatment or intensive care across neighbouring regions. The plans shall include preparedness and response means to address the situation of those citizens with higher risks.	4. The Union ***prevention,*** preparedness and response plan shall include ***cross-border and*** interregional preparedness ***plans*** to establish coherent, multi-sectoral, cross-border public health measures, in particular considering capacities for testing, contact tracing, laboratories, ***training of healthcare staff*** and specialised treatment or intensive care across neighbouring regions. The plans shall include preparedness and response means to address the situation of those citizens with higher risks.

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Amendment 86

Proposal for a regulation

Article 5 — paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The Union preparedness and response plan shall also provide for measures to ensure that the single market functions normally in the event serious cross-border threats to health arise.

Amendment 87

Proposal for a regulation

Article 5 — paragraph 5

Text proposed by the Commission	*Amendment*
5. In order to ensure the operation of the Union preparedness and response plan, the Commission shall conduct stress tests, exercises and in-action and after-action reviews with Member States, and update the plan as necessary.	5. In order to ensure the operation of the Union ***prevention,*** preparedness and response plan, the Commission shall conduct stress tests, exercises and in-action and after-action reviews with Member States, and update the plan as necessary. ***The prevention, preparedness and response plan shall take into account health systems data and relevant data to be collected at national or regional level.***

Amendment 88

Proposal for a regulation

Article 5 — paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. In order to respond to public health emergencies, the European Commission may issue recommendations, based on Union health systems data, on the minimum resources needed, in relation, among other things, to each Member State's population, for the provision of baseline universal health coverage of adequate quality, including on the option of pooling resources at Union level.

Amendment 89

Proposal for a regulation

Article 5 — paragraph 5 b (new)

Text proposed by the Commission	*Amendment*
	5b. The reviews and any subsequent adjustments to the plan shall be published to increase the transparency of the process of prevention, preparedness and response planning.

Amendment 90

Proposal for a regulation

Article 6 — title

Text proposed by the Commission	*Amendment*
National preparedness and response plans	National ***prevention,*** preparedness and response plans

Amendments 91 and 260

Proposal for a regulation

Article 6 — paragraph 1

Text proposed by the Commission	*Amendment*
1. When preparing national preparedness and response plans each Member State shall coordinate with the Commission in order to reach consistency with the Union preparedness and response plan, ***also*** inform without delay the Commission and the HSC of any substantial revision of the national plan.	1. When preparing national ***prevention,*** preparedness and response plans each Member State shall ***consult patients' organisations, healthcare professionals' organisations, industry and supply chain stakeholders, and national social partners,*** coordinate with the Commission***, in particular with the HERA,*** in order to reach consistency with the Union ***prevention,*** preparedness and response plan, ***which shall be in accordance with arrangements for governance, capacities and resources referred to in Article 5(3), including with regard to national stockpiling requirements and the management of Union strategic reserves, and*** inform without delay the Commission***, the HCB*** and the HSC of any substantial revision of the national plan.

Amendment 92

Proposal for a regulation

Article 6 — paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. National prevention, preparedness and response plans shall include arrangements for governance and information on capacities and resources referred to in Article 5(3).

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Amendment 93

Proposal for a regulation

Article 7 — title

Text proposed by the Commission	*Amendment*
Reporting on preparedness and response planning	Reporting on ***prevention,*** preparedness and response planning

Amendments 94 and 261

Proposal for a regulation

Article 7 — paragraph 1 — subparagraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ***by the end of November 2021*** and every 2 years thereafter provide the Commission with ***a*** report on their preparedness and response planning and implementation at national level.	1. Member States shall ***within 6 months of the entry into force of this regulation*** and every 2 years thereafter provide the Commission ***and relevant Union agencies and bodies*** with ***an updated*** report on their ***prevention,*** preparedness and response planning and implementation at national level ***and, where appropriate, regional and cross-border levels***.

Amendment 95

Proposal for a regulation

Article 7 — paragraph 1 — subparagraph 2 — introductory part

Text proposed by the Commission	*Amendment*
That report shall cover the following:	That report ***shall be succinct, based on common indicators, give an overview of the actions implemented in the Member States, and*** shall cover the following:

Amendment 96

Proposal for a regulation

Article 7 — paragraph 1 — subparagraph 2 — point a

Text proposed by the Commission	*Amendment*
(a) identification of, and update on the status of the implementation of the capacity standards for preparedness and response planning as determined at national level for the health sector, as provided to the WHO in accordance with the IHR;	(a) identification of, and update on the status of the implementation of the capacity standards for ***prevention,*** preparedness and response planning as determined at national ***and, where appropriate, regional*** level for the health sector, as provided to the WHO in accordance with the IHR;

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Amendment 97

Proposal for a regulation

Article 7 — paragraph 1 — subparagraph 2 — point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) a description of the measures or arrangements aimed at ensuring interoperability between the health sector and other sectors that are critical in the case of an emergency;

Amendment 98

Proposal for a regulation

Article 7 — paragraph 1 — subparagraph 2 — point a b (new)

Text proposed by the Commission	*Amendment*
	(ab) a description of the business continuity plans, measures or arrangements aimed at ensuring the continuous delivery of critical services and products;

Amendment 99

Proposal for a regulation

Article 7 — paragraph 1 — subparagraph 2 — point b

Text proposed by the Commission	*Amendment*
(b) elements of emergency preparedness, in particular:	(b) ***an update, if needed, on the*** elements of emergency ***prevention,*** preparedness ***and response***, in particular:

Amendment 100

Proposal for a regulation

Article 7 — paragraph 1 — subparagraph 2 — point b — point i

Text proposed by the Commission	*Amendment*
(i) governance: including national policies and legislation that integrate emergency preparedness; plans for emergency preparedness, response and recovery coordination mechanisms;	(i) governance: including national ***and, if appropriate, regional*** policies and legislation that integrate emergency ***prevention and*** preparedness; plans for emergency ***prevention,*** preparedness, response and recovery coordination mechanisms ***at national and, where relevant, regional and cross-border levels***; ***continuity of critical long-term healthcare;***

Thursday 11 November 2021

Amendment 101

Proposal for a regulation

Article 7 — paragraph 1 — subparagraph 2 — point b — point ii

Text proposed by the Commission	*Amendment*
(ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; surveillance and early warning, information management; access to diagnostic services during emergencies; basic and safe gender-sensitive health and emergency services; risk communications; research development and evaluations to inform and accelerate emergency preparedness;	(ii) capacities: including assessments of risks and capacities to determine priorities for emergency preparedness; surveillance and early warning, information management; ***the capacities to produce medicinal products; stocks of medical countermeasures, including personal protective equipment of the highest quality; equitable*** access to diagnostic services ***and tools, and medical products*** during emergencies; ***information relevant for the internal market and Union strategic reserves of medical products; equitable, high-quality,*** basic and safe gender-sensitive health and emergency services ***that take account of the needs of populations at higher risk; continuity of screening, diagnosis, monitoring and treatment for care in relation to other diseases and conditions, in particular critical long-term healthcare***; risk communications; research development and evaluations to inform and accelerate emergency preparedness;

Amendment 102

Proposal for a regulation

Article 7 — paragraph 1 — subparagraph 2 — point b — point iii

Text proposed by the Commission	*Amendment*
(iii) resources: including financial resources for emergency preparedness and contingency funding for response; logistics mechanisms and essential supplies for health; ***and*** dedicated, trained and equipped human resources for emergencies; ***and***	(iii) resources: including financial resources for emergency preparedness and contingency funding for response; logistics mechanisms and essential supplies for health; ***measures to ensure continuity of critical long-term healthcare; and health and social services with an adequate number of*** dedicated, trained and equipped human resources for emergencies;

Amendment 103

Proposal for a regulation

Article 7 — paragraph 1 — subparagraph 2 — point b — point iii a (new)

Text proposed by the Commission	*Amendment*
	(iiia) strategic stockpile: each Member State shall provide information on the number and availability of medical countermeasures and other essential medicinal products and critical medical devices for the control of the threats set out in Article 2(1), as well as the capacity for their safekeeping and storage. In order to have a greater response capacity, storage shall be carried out in the premises closest to and most accessible for the population centres, without compromising the accessibility of those products for people in remote, rural and outermost regions, which meet the necessary requirements to provide the service in accordance with the regulations applicable to medicinal products, medical devices ([1b]) and other medical countermeasures; and
	([1b]) 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).

Amendment 104

Proposal for a regulation

Article 7 — paragraph 1 — subparagraph 2 — point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) the consultation with relevant partners that has taken place to ensure risk assessments, prevention, preparedness and response plans and implementation are broadly shared and supported and in line with applicable labour legislation and collective agreements;

Amendment 105

Proposal for a regulation

Article 7 — paragraph 1 — subparagraph 2 — point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) gaps found in the implementation and any necessary actions that will be taken by the Member States to improve their preparedness and response capacity.

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Amendment 106

Proposal for a regulation

Article 7 — paragraph 1 — subparagraph 3

Text proposed by the Commission	*Amendment*
The report shall include***, whenever relevant***, interregional preparedness and response elements ***in line with the Union and national plans, covering in particular the existing capacities, resources*** and coordination mechanisms ***across neighbouring regions***.	***For Member States sharing a land border with at least one other Member State,*** the report shall include ***cross-border***, interregional ***and intersectoral prevention,*** preparedness and response ***plans with neighbouring regions including coordination mechanisms for all*** elements ***listed in points (a), (b) and (c), cross-border training and sharing of best practices for healthcare staff and public health staff*** and coordination mechanisms ***for the medical transfer of patients. Union or national entities that are engaged in stockpiling of medical products shall engage with the Commission and Member States in reporting of stocks that are available and taken into account in both Union and national preparedness and response planning.***

Amendment 107

Proposal for a regulation

Article 7 — paragraph 1 — subparagraph 3 a (new)

Text proposed by the Commission	*Amendment*
	The report shall also include, as far as feasible, information on the impact of communicable diseases on major non-communicable diseases.

Amendment 108

Proposal for a regulation

Article 7 — paragraph 1 — subparagraph 3 b (new)

Text proposed by the Commission	*Amendment*
	The latest available version of the prevention, preparedness and response plans shall be attached to the report.

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Amendment 262

Proposal for a regulation

Article 7 — paragraph 2 — subparagraph 1

Text proposed by the Commission	*Amendment*
2. The Commission shall make the information received in accordance with paragraph 1 available to the HSC in a report prepared in cooperation with the ECDC and other relevant Union agencies and bodies every 2 years.	2. The Commission shall make the information received in accordance with paragraph 1 available to the HSC in a report prepared in cooperation with the ECDC and other relevant Union agencies and bodies every 2 years. ***For the purpose of drawing up the report, the HERA shall assess the availability of crisis-relevant medical countermeasures, the production capacity for and the existing stockpiles of such countermeasures and the risk of disruption in supply chains in the framework of the national preparedness and response planning, taking into account information obtained pursuant to Regulation (EU) …/… [OJ: Please insert the number of the Regulation on EMA [ISC/2020/12532]] and in particular Articles XX [Article numbers to be confirmed after adoption] thereof, concerning the monitoring and mitigation of shortages of critical medicinal products, medical devices and in vitro diagnostic medical devices.***

Amendment 109

Proposal for a regulation

Article 7 — paragraph 2 — subparagraph 4

Text proposed by the Commission	*Amendment*
The recommendations of the report shall be published on ***at the website*** of the Commission.	The recommendations of the report shall be published on ***the websites*** of the Commission ***and the ECDC***.

Amendment 110

Proposal for a regulation

Article 8 — title

Text proposed by the Commission	*Amendment*
Auditing on preparedness and response planning	Auditing on ***prevention,*** preparedness and response planning

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Amendment 111

Proposal for a regulation

Article 8 — paragraph 1

Text proposed by the Commission	*Amendment*
1. Every ***3*** years, the ECDC shall conduct audits in the Member States aimed at ascertaining the state of implementation of the national plans and their coherence with the Union plan. Such audits shall be implemented with the relevant Union agencies, aiming at the assessment of preparedness and response planning at national level with regard to the information referred to in Article 7(1).	1. Every ***2*** years, the ECDC shall conduct audits in the Member States aimed at ascertaining the state of implementation of the national plans and their coherence with the Union plan. Such audits shall be ***based on a set of indicators and*** implemented ***in cooperation*** with the relevant Union agencies, aiming at the assessment of ***prevention,*** preparedness and response planning at national level with regard to the information referred to in Article 7(1)..

Amendment 112

Proposal for a regulation

Article 8 — paragraph 2 — subparagraph 1

Text proposed by the Commission	*Amendment*
2. Member ***States*** shall present an action plan addressing the proposed recommendations of the audit and the corresponding corrective actions and milestones.	2. ***In the event the audit identifies deficiencies, the*** Member ***State*** shall***, within six months of receipt of its conclusions,*** present an action plan addressing the proposed recommendations of the audit and ***setting out*** the corresponding corrective actions and milestones.

Amendment 113

Proposal for a regulation

Article 8 — paragraph 2 — subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	If a Member State decides not to follow a recommendation, it shall state its reasons for doing so.

Amendment 114

Proposal for a regulation

Article 9 — title

Text proposed by the Commission	*Amendment*
Commission report on preparedness planning	Commission report on ***prevention,*** preparedness planning

Amendment 115

Proposal for a regulation

Article 9 — paragraph 1

Text proposed by the Commission	*Amendment*
1. On the basis of the information provided by the Member States in accordance with Article 7, and of the results of the audits referred to in Article 8, the Commission shall by July 2022 and every 2 years afterwards, transmit to the European Parliament and to the Council a report on the state of play and progress on preparedness and response planning at Union level.	1. On the basis of the information provided by the Member States in accordance with Article 7, and of the results of the audits referred to in Article 8, the Commission shall by July 2022 and every 2 years afterwards, transmit to the European Parliament and to the Council a report on the state of play and progress on ***prevention,*** preparedness and response planning at Union level.

Amendment 116

Proposal for a regulation

Article 9 — paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The Commission report shall include the state of cross-border preparedness and response planning in neighbouring regions.

Amendment 117

Proposal for a regulation

Article 9 — paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission may adopt recommendations on preparedness and response planning addressed to Member States based on the report referred to in paragraph 1.	2. The Commission may adopt recommendations on ***prevention,*** preparedness and response planning addressed to Member States based on the report referred to in paragraph 1. ***Those recommendations may cover, inter alia, the minimum resources needed to respond to public health emergencies in relation to, among other things, population size, and they shall be developed on the basis of good practice and policy assessments.***

Amendment 118

Proposal for a regulation

Article 10 — title

Text proposed by the Commission	*Amendment*
Coordination of preparedness and response planning in the HSC	Coordination of ***prevention,*** preparedness and response planning in the HSC

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Amendments 119 and 263

Proposal for a regulation

Article 10 — paragraph 1 — subparagraph 1

Text proposed by the Commission	*Amendment*
1. The Commission and the Member States shall work together within the HSC to coordinate their efforts to develop, strengthen and maintain their capacities for the monitoring, early warning and assessment of, and response to serious cross-border threats to health.	1. The Commission***, relevant Union agencies and bodies, including the HERA,*** and the Member States shall work together within the HSC to coordinate their efforts to develop, strengthen and maintain their capacities for the monitoring, ***prevention,*** early warning and assessment of, and response to serious cross-border threats to health.

Amendment 120

Proposal for a regulation

Article 10 — paragraph 1 — subparagraph 2 — point a

Text proposed by the Commission	*Amendment*
(a) sharing best practice and experience in preparedness and response planning;	(a) sharing best practice and experience in ***prevention,*** preparedness and response planning;

Amendment 121

Proposal for a regulation

Article 10 — paragraph 1 — subparagraph 2 — point b

Text proposed by the Commission	*Amendment*
(b) promoting the interoperability of national preparedness planning and the intersectoral dimension of preparedness and response planning at Union level;	(b) promoting the interoperability of national ***prevention,*** preparedness planning and the intersectoral dimension of ***prevention,*** preparedness and response planning at Union level;

Amendment 122

Proposal for a regulation

Article 10 — paragraph 1 — subparagraph 2 — point e

Text proposed by the Commission	*Amendment*
(e) monitoring progress, identifying gaps and actions to strengthen preparedness and response planning, including in the field of research, at national and at Union levels.	(e) monitoring progress, identifying gaps and actions to strengthen ***prevention,*** preparedness and response planning, including in the field of research, at ***regional,*** national and at Union levels;

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Amendment 123

Proposal for a regulation

Article 10 — paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The Commission and the Member States shall, where appropriate, conduct a dialogue with stakeholders, including health and care workers' organisations, industry and supply chain stakeholders, and patient and consumer organisations. That dialogue shall include regular exchanges of information between authorities, industry and relevant actors in the pharmaceutical supply chain to identify expected supply constraints so as to allow better coordination, development of synergies and appropriate responses.

Amendment 124

Proposal for a regulation

Article 11 — paragraph 1 — subparagraph 1

Text proposed by the Commission	*Amendment*
1. The Commission may organise training activities for healthcare staff and public health staff in the Member States, including preparedness capacities under the International Health Regulations.	1. The Commission may organise training activities***, supported by the relevant Union agencies, in close cooperation with medical associations and patient organisations,*** for healthcare ***staff, social service*** staff and public health staff in the Member States ***in particular interdisciplinary One Health training***, including preparedness capacities under the International Health Regulations.

Amendment 125

Proposal for a regulation

Article 11 — paragraph 1 — subparagraph 2

Text proposed by the Commission	*Amendment*
The Commission shall organise those activities in cooperation with the Member States concerned.	The Commission shall organise those activities in cooperation with the Member States concerned ***or potentially concerned, and in coordination, where possible, with the WHO to avoid duplication of activities, including preparedness capacities under the International Health Regulations***.

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Amendment 126

Proposal for a regulation

Article 11 — paragraph 1 — subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	In cross-border regions, joint cross-border training and sharing of best practices for healthcare staff and public health staff shall be promoted and familiarity with public health systems shall be mandatory.

Amendment 127

Proposal for a regulation

Article 11 — paragraph 1 — subparagraph 2 b (new)

Text proposed by the Commission	*Amendment*
	The Commission shall use the fullest potential of distance learning to broaden the number of trainees.

Amendment 128

Proposal for a regulation

Article 11 — paragraph 2

Text proposed by the Commission	*Amendment*
2. The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with knowledge and skills necessary in particular to develop and implement the national preparedness plans referred to in Article 6, implement activities to strengthen crisis preparedness and surveillance capacities including the use of digital tools.	2. The training activities referred to in paragraph 1 shall aim to provide staff referred to in that paragraph with knowledge and skills necessary in particular to develop and implement the national preparedness plans referred to in Article 6, implement activities to strengthen crisis preparedness and surveillance capacities including the use of digital tools***, ensure the continuity of critical long-term healthcare services and be consistent with the One Health approach***.

Amendment 129

Proposal for a regulation

Article 11 — paragraph 3

Text proposed by the Commission	*Amendment*
3. The training activities referred to in paragraph 1 may be open to staff of the competent authorities of third countries and may be organised outside the Union.	3. The training activities referred to in paragraph 1 may be open to staff of the competent authorities of third countries and may be organised outside the Union ***in coordination, where possible, with ECDC activities in this area***.

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Amendment 130

Proposal for a regulation

Article 11 — paragraph 5

Text proposed by the Commission	*Amendment*
5. The Commission may support organising programmes, in cooperation with the Member States, for the exchange of healthcare staff and public health staff between two or more Member States and for the temporary secondment of staff from one Member State to the other.	5. The Commission may support organising programmes, in cooperation with the Member States, for the exchange of healthcare staff and public health staff between two or more Member States and for the temporary secondment of staff from one Member State to the other. ***In organising those programmes, account shall be taken of the contribution made by professional health organisations in each of the Member States.***

Amendments 131 and 264

Proposal for a regulation

Article 12 — paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission and any Member States ***which so desire*** may engage in a joint procurement procedure conducted pursuant to Article 165(2) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ([29]) with a view to the advance purchase of medical countermeasures for serious cross-border threats to health.	1. The Commission***, in particular with the HERA,*** and any Member States may engage in a joint procurement procedure ***as contracting parties*** conducted pursuant to Article 165(2) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ([29]) with a view to the advance purchase of medical countermeasures for serious cross-border threats to health ***within a reasonable time frame***.

([29]) 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).

Amendment 132

Proposal for a regulation

Article 12 — paragraph 2 — point a

Text proposed by the Commission	*Amendment*
(a) participation in the joint procurement procedure shall be open to all Members States, European Free Trade Association (EFTA) States ***and*** Union candidate countries in accordance with Article 165(2) of Regulation (EU, Euratom) 2018/1046;	(a) participation in the joint procurement procedure shall be open to all Members States, European Free Trade Association (EFTA) States, Union candidate countries in accordance with Article 165(2) of Regulation (EU, Euratom) 2018/1046***, and to the Principality of Andorra, the Principality of Monaco, the Republic of San Marino and the Vatican City State***;

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Amendment 133

Proposal for a regulation

Article 12 — paragraph 2 — point c

Text proposed by the Commission	*Amendment*
(c) ***Member States, EFTA States and Union candidate*** countries participating in a joint procurement shall procure the medical countermeasure in question through that procedure and not through other channels, and shall not run parallel negotiation processes for that product;	(c) countries participating in a joint procurement shall procure the medical countermeasure in question through that procedure and not through other channels, and shall not run parallel negotiation processes for that product ***from that moment onwards. Countries that engage in parallel negotiation processes from that moment onwards shall be excluded from the group of participating countries, irrespective of whether those processes have reached the signature stage***;

Amendment 134

Proposal for a regulation

Article 12 — paragraph 2 — point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) the joint procurement shall define clear procedural steps for the process, scope, tender specifications and timelines, and it shall require all parties to deliver and respect clear commitments, including manufacturers delivering agreed production quantities and authorities purchasing agreed reserved volumes. The precise amounts ordered by and provided to each participating country and details of their liabilities shall be disclosed;

Amendment 135

Proposal for a regulation

Article 12 — paragraph 2 — point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) A high degree of transparency shall be applied to all joint procurement activities and related purchase agreements. The European Court of Auditors shall have full access to all relevant documents to provide accurate annual scrutiny of signed contracts and the public investment involved;

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Amendment 136

Proposal for a regulation

Article 12 — paragraph 2 — point c c (new)

Text proposed by the Commission	*Amendment*
	(cc) if joint procurement is deployed, qualitative criteria shall be considered in the award process, in addition to cost. Such criteria shall also take into consideration, for example, the ability of the manufacturer to ensure security of supply during a health crisis;

Amendment 137

Proposal for a regulation

Article 12 — paragraph 2 — point c d (new)

Text proposed by the Commission	*Amendment*
	(cd) the joint procurement shall be conducted in such a way so as to strengthen the purchasing power of participating countries, improve the security of supply and ensure equitable access to medical countermeasures against serious cross-border threats to health;

Amendment 265

Proposal for a regulation

Article 12 — paragraph 2 — point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) when joint procurement is performed under Article 7 of a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (ISC/2020/12524), the Commission shall have the right to require the licensing, under fair and reasonable conditions, of intellectual property and know-how pertaining to such countermeasures, if an economic operator abandons their development effort or is unable to ensure the sufficient and timely delivery of such countermeasures under the terms of the agreement concluded. Further conditions and procedures relating to the exercise of that right may be set out in the specific agreements with economic operators;

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Amendment 266

Proposal for a regulation

Article 12 — paragraph 2 — point e b (new)

Text proposed by the Commission	*Amendment*
	(eb) to ensure transparency as regards the expenditure of public funds, when joint procurement is performed under Article 7 of a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level [ISC/2020/12524], the Commission shall in a timely manner make publicly available the contracts and agreements established with economic operators at least stipulating the following:
	(i) the delivery schedule of the good or service;
	(ii) terms of liabilities and indemnifications;
	(iii) where relevant, the quantity and number of manufacturing locations.

Amendment 138

Proposal for a regulation

Article 12 — paragraph 3 — introductory part

Text proposed by the Commission	*Amendment*
3. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the entities organizing any action, including, but not limited to joint procurement procedures, stockpiling and donation of medical countermeasures under different mechanisms established at Union level, in particular under:	3. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the entities organizing ***and participating in*** any action, including, but not limited to joint procurement procedures, ***development,*** stockpiling ***in facilities that meet the specific legal requirements for the storage of medical countermeasures and having the greatest proximity to and accessibility for the greatest number of population centres, without compromising the accessibility of those products for people in remote, rural and outermost regions, distribution*** and donation of medical countermeasures***, which shall be of benefit to low- and middle-income countries,*** under different mechanisms established at Union level, in particular under:

Amendment 139

Proposal for a regulation

Article 12 — paragraph 3 — point a

Text proposed by the Commission	*Amendment*
(a) stockpiling under the rescEU referred to in Article ***12*** of Decision No 1313/2013/EU;	(a) stockpiling under the rescEU referred to in Article ***23*** of Decision No 1313/2013/EU;

Amendments 140 and 267

Proposal for a regulation

Article 12 — paragraph 3 — point f

Text proposed by the Commission	*Amendment*
(f) other instruments supporting biomedical research and development at Union level for enhanced capacity and readiness to respond to cross-border threats and emergencies.	(f) other ***programmes and*** instruments supporting biomedical research and development at Union level for enhanced capacity and readiness to respond to cross-border threats and emergencies ***such as a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level [ISC/2020/12524]***.

Amendment 141

Proposal for a regulation

Article 12 — paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Participating countries shall ensure that there is adequate stockpiling and distribution of procured medical countermeasures. The main details and characteristics of that stockpiling and distribution shall be set out in national plans.

Amendment 142

Proposal for a regulation

Article 12 — paragraph 3 b (new)

Text proposed by the Commission	*Amendment*
	3b. In accordance with the principle of transparency, the Commission shall regularly inform the European Parliament about negotiations concerning the joint procurement of medical countermeasures.

Amendment 143

Proposal for a regulation

Article 12 — paragraph 3 c (new)

Text proposed by the Commission	*Amendment*
	3c. The European Parliament reserves at all times the right to scrutinize, under existing confidentiality rules, the uncensored content of all contracts concluded in proceedings under this Article.

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Amendment 144

Proposal for a regulation

Article 12 — paragraph 3 d (new)

Text proposed by the Commission	*Amendment*
	3d. The Commission and Member States shall provide up-to-date, accessible and clear information to consumers on their rights and duties regarding jointly procured medical countermeasures, including details on liability for damages, and access to legal protection and to consumer representation.

Amendment 145

Proposal for a regulation

Article 12 — paragraph 3 e (new)

Text proposed by the Commission	*Amendment*
	3e. Where the joint procurement procedure for medical countermeasures to cross-border threats to health is not applied, the Commission shall encourage Member States to exchange information on pricing and delivery dates for medical countermeasures.

Amendments 146 and 268

Proposal for a regulation

Article 13 — paragraph 1

Text proposed by the Commission	*Amendment*
1. The network for the epidemiological surveillance of the communicable diseases and of the related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1) shall ensure a permanent communication between the Commission, the ECDC, and the competent authorities responsible at national level for epidemiological surveillance.	1. The network for the epidemiological surveillance of the communicable diseases***, including communicable diseases of zoonotic origin,*** and of the related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1) shall ensure a permanent communication between the Commission, ***in particular the HERA,*** the ECDC, and the competent authorities responsible at national level for epidemiological surveillance.

Amendment 147

Proposal for a regulation

Article 13 — paragraph 2 — point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) monitor the impact of communicable diseases on the continuity of screening, diagnosis, monitoring, treatment and care for other diseases and conditions;

Amendment 148

Proposal for a regulation

Article 13 — paragraph 2 — point b b (new)

Text proposed by the Commission	*Amendment*
	(bb) monitor the impact of communicable diseases on mental health;

Amendment 149

Proposal for a regulation

Article 13 — paragraph 2 — point d

Text proposed by the Commission	*Amendment*
(d) identify risk factors for disease transmission, population groups at risk and in need of targeted prevention measures;	(d) identify ***and monitor*** risk factors for disease transmission, population groups at risk and in need of targeted prevention measures;

Amendment 150

Proposal for a regulation

Article 13 — paragraph 2 — point e

Text proposed by the Commission	*Amendment*
(e) contribute to the assessment of the burden of communicable diseases on the population using such data as disease prevalence, complications, hospitalisation ***and*** mortality;	(e) contribute to the assessment of the burden of communicable diseases ***on health systems and care delivery and*** on the population using such data as disease prevalence, complications, hospitalisation, mortality***, the mental health impact, deferred screening, diagnosis, monitoring, treatment and care for other diseases and conditions and their social and economic impact***;

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Amendment 151

Proposal for a regulation

Article 13 — paragraph 2 — point h a (new)

Text proposed by the Commission	*Amendment*
	(ha) identify any weaknesses in the global supply chain involved in the production and manufacturing of medical countermeasures needed for the prevention, diagnosis, treatment and follow up of communicable diseases, and make plans to mitigate such weaknesses. Other mechanisms, such as a Union export control mechanism, regulatory flexibility, cooperation agreements, compulsory or voluntary licensing agreements between companies, may enable the Union to facilitate access to counter-measures for its citizens and residents as well as for people from the Eastern Partnership countries and low and middle-income countries;

Amendment 152

Proposal for a regulation

Article 13 — paragraph 3 — point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) information on the availability of medical countermeasures needed for the prevention, diagnosis, treatment and follow up of the disease.

Amendment 153

Proposal for a regulation

Article 13 — paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The information communicated by Member States referred to in point (a) of paragraph 3 shall be reported at least at NUTS II level to the European Surveillance System (TESSy) or another platform, on a timely basis determined in accordance with Article 7.

Amendment 154

Proposal for a regulation

Article 13 — paragraph 6 — subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	The ECDC shall support the Member States to ensure the collection and sharing of data in times of health crisis and the integrated operation of the network for the epidemiological surveillance of communicable diseases and of the related special health issues referred to in points (i) and (ii) of point (a) of Article 2(1). The ECDC shall, where appropriate, also make available its expertise in that domain to third countries.

Amendment 155

Proposal for a regulation

Article 13 — paragraph 9 — subparagraph 1 — introductory part

Text proposed by the Commission	*Amendment*
9. The Commission shall***, by means of implementing*** acts, establish and update:	9. The Commission shall ***adopt delegated*** acts ***in accordance with Article 28 concerning the establishment and*** update ***of***:

Amendment 156

Proposal for a regulation

Article 13 — paragraph 9 — subparagraph 1 — point c

Text proposed by the Commission	*Amendment*
(c) procedures for the operation of the epidemiological surveillance network as developed pursuant to Article 5 of Regulation (EU) …/… [OJ: Please insert the number of Regulation ECDC [ISC/2020/ 12527]].	***deleted***

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Amendment 157

Proposal for a regulation

Article 13 — paragraph 9 a (new)

Text proposed by the Commission	*Amendment*
	9a. Where duly justified imperative grounds of urgency related to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread between Member States so require, the procedure provided for in Article 28a shall apply to delegated acts adopted pursuant to this Article.

Amendment 158

Proposal for a regulation

Article 13 — paragraph 9 b (new)

Text proposed by the Commission	*Amendment*
	9b. The Commission shall, by means of implementing acts, establish and update procedures for the operation of the epidemiological surveillance network developed pursuant to Article 5 of Regulation (EU) …/… [OJ: Please insert the number of Regulation ECDC [ISC/2020/12527]].

Amendment 159

Proposal for a regulation

Article 13 — paragraph 10

Text proposed by the Commission	*Amendment*
10. On duly justified imperative grounds of urgency related to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread among the Member States, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 27(3) for the adoption ***of case definitions,*** procedures ***and indicators*** for surveillance in Member States in the case of a threat referred to in points (i) and (ii) of point (a) of Article 2 (1). ***The indicators mentioned above shall also support the assessment of capacity for diagnosis, prevention and treatment.***	10. On duly justified imperative grounds of urgency related to the severity or novelty of a serious cross-border threat to health or to the rapidity of its spread among the Member States, the Commission may adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 27(3) for the adoption procedures for surveillance in Member States in the case of a threat referred to in points (i) and (ii) of point (a) of Article 2(1).

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Amendment 160

Proposal for a regulation

Article 14 — paragraph 1

Text proposed by the Commission	*Amendment*
1. The ECDC shall ensure the ***further*** development of the digital platform through which data are managed and automatically exchanged, to establish integrated and interoperable surveillance systems enabling real-time surveillance where appropriate, for the purpose of supporting communicable disease prevention and control.	1. The ECDC shall ensure the ***continued*** development of the digital platform ***after having conducted a data protection impact assessment and having mitigated any risks to the rights and freedoms of the data subjects,*** through which data are managed and automatically exchanged, to establish integrated and interoperable surveillance systems enabling real-time surveillance where appropriate, , for the purpose of supporting communicable disease prevention and control. ***It shall ensure there is human oversight of the digital platform and include specific measures for minimising risks that may emerge from the transfer of biases or incomplete data from multiple sources, as well as establish procedures for data quality review. Digital platforms and applications supporting epidemiological surveillance at Union and Member State level shall be implemented in compliance with the principle of data protection by design pursuant to Article 27(1) of Regulation (EU) 2018/1725.***

Amendment 161

Proposal for a regulation

Article 14 — paragraph 2 — point a

Text proposed by the Commission	*Amendment*
(a) enable the automated collection of surveillance and laboratory data, make use of ***information from*** electronic health records, media monitoring, and apply artificial intelligence for data validation, analysis and automated reporting;	(a) enable the automated collection of surveillance and laboratory data, make use of ***relevant health data from a previously defined and authorised list from*** electronic health records ***and health databases***, media monitoring, and apply artificial intelligence for data validation, analysis and ***statistical*** reporting ***in accordance with Article 22 GDPR***;

Amendment 162

Proposal for a regulation

Article 14 — paragraph 2 — point b

Text proposed by the Commission	*Amendment*
(b) allow for the computerised handling and exchange of information, data and documents.	(b) allow for the computerised processing and exchange of information, data and documents, ***taking into account Union law concerning the protection of personal data;***

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Amendment 163

Proposal for a regulation

Article 14 — paragraph 2 — point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) allow for automated notification on EWRS when communicable diseases rise above warning thresholds, as referred to in point (a) of Article 13(2). The notification shall be validated by the competent health authority.

Amendment 164

Proposal for a regulation

Article 14 — paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States are responsible for ensuring that the integrated surveillance system is fed on a regular basis with timely ***and*** complete information, data and documents transmitted and exchanged through the digital platform.	3. Member States are responsible for ensuring that the integrated surveillance system is fed on a regular basis with timely, complete ***and accurate*** information, data and documents transmitted and exchanged through the digital platform. ***The Member States shall promote the automation of this process between the national and the Union surveillance system.***

Amendment 165

Proposal for a regulation

Article 14 — paragraph 5

Text proposed by the Commission	*Amendment*
5. For epidemiological purposes, ECDC shall also have access to relevant health data accessed or made available through digital infrastructures enabling the use of health data for research, policy making and regulatory purposes.	5. For epidemiological ***surveillance*** purposes, ECDC shall also have access to relevant health data accessed or made available through digital infrastructures enabling the use of health data for research, policy making and regulatory purposes. ***The access to the health data shall be proportionate to specific and concrete purposes that shall have been defined previously by ECDC.***

Amendment 166

Proposal for a regulation

Article 14 — paragraph 6 — introductory part

Text proposed by the Commission	*Amendment*
6. The Commission shall adopt ***implementing*** acts ***for*** the functioning of the surveillance platform ***which lay*** down:	6. ***The Commission, following the carrying out of a consultation procedure as set out in Article 42(2) of Regulation (EU) 2018/1725,*** shall adopt ***delegated*** acts ***in accordance with Article 28 concerning*** the functioning of the surveillance platform ***laying*** down:

Amendment 167

Proposal for a regulation

Article 14 — paragraph 6 — point a

Text proposed by the Commission	*Amendment*
(a) the technical specifications of the platform, including the electronic data exchange mechanism for exchanges with existing national systems, identification of applicable standards, definition of message structures, data dictionaries, exchange of protocols and procedures;	(a) the technical specifications of the platform, including the electronic data exchange mechanism for exchanges with existing ***international and*** national systems, identification of applicable standards, definition of message structures, data dictionaries, exchange of protocols and procedures;

Amendment 168

Proposal for a regulation

Article 14 — paragraph 6 — point c

Text proposed by the Commission	*Amendment*
(c) contingency arrangements to be applied in the event of unavailability of any of the functionalities of the platform;	(c) contingency arrangements ***and secure data backups*** to be applied in the event of unavailability of any of the functionalities of the platform;

Amendment 169

Proposal for a regulation

Article 14 — paragraph 6 — point d

Text proposed by the Commission	*Amendment*
(d) the cases where, and the conditions under which the ***third countries and*** international organisations concerned may be granted partial access to the functionalities of the platform and the practical arrangements of such access;	(d) the cases where, and the conditions under which the international organisations concerned may be granted partial access to the functionalities of the platform and the practical arrangements of such access, ***in full compliance with Regulations (EU) 2018/1725 and (EU) 2016/679 and Directive (EU) 2016/680;***

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Amendment 170

Proposal for a regulation

Article 14 — paragraph 6 — point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) ensure standardisation of the infrastructure for storage, processing and analysis of data.

Amendment 171

Proposal for a regulation

Article 14 — paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. Digital platforms and applications supporting epidemiological surveillance at Union and Member State level shall be implemented in compliance with the principle of data protection by design pursuant to Article 27(1) of Regulation (EU) 2018/1725.

Amendment 172

Proposal for a regulation

Article 15 — paragraph 1

Text proposed by the Commission	*Amendment*
1. In the area of public health or for specific areas of public health relevant for the implementation of this Regulation or of the national plans referred to in Article 6, the Commission may, by means of implementing acts, designate EU reference laboratories to provide support to national reference laboratories to promote good practice and alignment by Member States on ***a voluntary basis on*** diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases by Member States.	1. In the area of public health or for specific areas of public health relevant for the implementation of this Regulation or of the national plans referred to in Article 6, the Commission may, by means of implementing acts, designate EU reference laboratories to provide support to national reference laboratories to promote good practice and alignment by Member States on diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases by Member States.

Amendment 173

Proposal for a regulation

Article 15 — paragraph 2 — point f

Text proposed by the Commission	*Amendment*
(f) monitoring, alert and support in outbreak response and	(f) monitoring, alert and support in outbreak response***, in particular for emerging pathogens;*** and

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Amendment 174

Proposal for a regulation

Article 15 — paragraph 3

Text proposed by the Commission	*Amendment*
3. The network of EU reference laboratories shall be operated and coordinated by the ECDC.	3. The network of EU reference laboratories shall be operated and coordinated by the ECDC, ***in cooperation with WHO network laboratories to avoid duplication of activities. The governance structure of the network shall cover cooperation and coordination with existing national and regional reference laboratories and networks***.

Amendment 175

Proposal for a regulation

Article 15 — paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. The laboratories referred to in paragraph 1 shall contribute to sharing good practices and to improving the epidemiological surveillance referred to in Article 13.

Amendment 176

Proposal for a regulation

Article 15 — paragraph 4

Text proposed by the Commission	*Amendment*
4. The designations provided for in paragraph 1 shall follow a public selection process, be limited in time, with a minimum period of 5 years, and be reviewed regularly. Designations shall establish the responsibilities and tasks of the designated laboratories.	4. The designations provided for in paragraph 1 shall follow a public selection process, be limited in time, with a minimum period of 5 years, and be reviewed regularly. ***The Commission shall consult the Member States and the ECDC to elaborate the terms of reference and the criteria of the designation process.*** Designations shall establish the responsibilities and tasks of the designated laboratories. ***Laboratory consortia shall be eligible for designation.***

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Amendment 177

Proposal for a regulation

Article 15 — paragraph 5 — point a

Text proposed by the Commission	*Amendment*
(a) be impartial, free from any conflict of interest, and in particular not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as EU reference laboratories;	(a) be impartial, free from any conflict of interest, and in particular not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as EU reference laboratories. ***Particular attention shall be paid to proprietary tests and methods that may be the property of laboratories***;

Amendment 178

Proposal for a regulation

Article 17 — paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The European Surveillance System (TESSy) shall be used for ad hoc monitoring of a serious cross-border threat to health referred to in point (iii) of point (a) of Article 2(1) and in points (b), (c) and (d) of Article 2(1).

Amendment 179

Proposal for a regulation

Article 17 — paragraph 3 — subparagraph 1

Text proposed by the Commission	*Amendment*
The Commission shall, ***by means of implementing acts,*** adopt, where necessary, the case definitions to be used for ad hoc monitoring, in order to ensure the comparability and compatibility at Union level of the collected data.	The Commission shall adopt, where necessary, ***delegated acts in accordance with Article 28*** concerning the case definitions to be used for ad hoc monitoring, in order to ensure the comparability and compatibility at Union level of the collected data.

Amendment 180

Proposal for a regulation

Article 17 — paragraph 3 — subparagraph 2

Text proposed by the Commission	*Amendment*
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).	***deleted***

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Amendment 181

Proposal for a regulation

Article 17 — paragraph 3 — subparagraph 3

Text proposed by the Commission	*Amendment*
On duly justified imperative grounds of urgency related to the severity of a serious cross-border threat to health or to the rapidity of its spread between the Member States, the ***Commission may adopt or update the case definitions referred to in the first subparagraph through immediately applicable implementing acts in accordance with the procedure referred to in Article 27(3).***	***Where*** duly justified imperative grounds of urgency related to the severity ***or novelty*** of a serious cross-border threat to health or to the rapidity of its spread between the Member States ***so require,*** the ***procedure provided for in Article 28a shall apply to delegated acts adopted pursuant to this Article.***

Amendment 182

Proposal for a regulation

Article 18 — paragraph 1

Text proposed by the Commission	*Amendment*
1. The EWRS shall enable the Commission and the competent authorities responsible at national level to be in permanent communication for the purposes of preparedness, early warning and response, alerting, assessing public health risks and determining the measures that may be required to protect public health.	1. The EWRS shall enable the Commission***, the ECDC,*** and the competent authorities responsible at national level to be in permanent communication for the purposes of preparedness, early warning and response, alerting, assessing public health risks and determining the measures that may be required to protect public health.

Amendment 183

Proposal for a regulation

Article 18 — paragraph 2 — subparagraph 1 — introductory part

Text proposed by the Commission	*Amendment*
The management and use of the EWRS involve the exchange of personal data in specific cases where the relevant legal instruments so provide. This includes:	The management and ***operational*** use of the EWRS involve the exchange of personal data in specific cases where the relevant legal instruments so provide. This includes:

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Amendment 184

Proposal for a regulation

Article 18 — paragraph 2 — subparagraph 2

Text proposed by the Commission	*Amendment*
The ECDC shall continuously update the EWRS allowing for the use of modern technologies, such as digital mobile applications, artificial intelligence models, space enabled applications, or other technologies for automated contact tracing, building upon the contact tracing technologies developed by the Member States.	The ECDC shall continuously update the EWRS allowing for the use of modern technologies, such as digital mobile applications, artificial intelligence models, space enabled applications, or other technologies for automated contact tracing, building upon the contact tracing technologies developed by the Member States ***or by the Union, used for the sole purpose of fighting the pandemic and proven to be adequate, necessary and proportionate, and in full compliance with Regulation (EU) 2016/679 and Directive 2002/58/EC.***

Amendment 185

Proposal for a regulation

Article 18 — paragraph 2 — subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	To ensure data quality and consistency, the EWRS shall implement robust, accurate and interoperable data processes with Member States. The ECDC shall coordinate with Member States throughout such data exchange processes, from assessing the data requirements, transmission and collection, to up to date actualisation and interpretation, ensuring strong collaboration between the Commission, the ECDC and national and regional competent bodies.

Amendment 186

Proposal for a regulation

Article 18 — paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The ECDC shall develop and improve the EWRS, to augment the automation of information collection and analysis, upgrade the categorisation of notifications, reduce open text communication, reduce the administrative burden and improve the standardisation of the notifications.

Amendment 187

Proposal for a regulation

Article 18 — paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. The EWRS shall be improved to reduce the burden of bureaucracy and duplications of notification. The EWRS shall allow the national competent authorities to notify the WHO of events that may constitute public health emergencies of international concern in accordance with Article 6 of the IHR, and shall integrate this information in the EWRS system, in order to automatically notify an alert in the EWRS.

Amendment 188

Proposal for a regulation

Article 18 — paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission shall, by means of implementing acts, adopt procedures concerning the information exchange with other rapid alert systems at Union level, including exchange of personal data, in order to ensure the proper functioning of the EWRS and to avoid overlap of activities or conflicting actions with existing structures and mechanisms for preparedness, monitoring, early warning and combating serious cross-border threats to health.	4. The Commission shall, by means of implementing acts, adopt procedures concerning the information exchange with other rapid alert systems at Union ***and international*** level, including exchange of personal data, in order to ensure the proper functioning of the EWRS and to avoid overlap of activities or conflicting actions with existing structures and mechanisms for preparedness, monitoring, early warning and combating serious cross-border threats to health.

Amendment 189

Proposal for a regulation

Article 18 — paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The EWRS shall be able to automatically collect information from other important databases, such as those comprising environmental data, climate data, water irrigation data and other data relevant to serious cross-border threats to health, that could facilitate understanding and mitigate the risk of potential health threats.

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Amendment 190

Proposal for a regulation

Article 19 — paragraph 2

Text proposed by the Commission	*Amendment*
2. Where the national competent authorities notify the WHO of events that may constitute public health emergencies of international concern in accordance with Article 6 of the IHR, ***they*** shall ***at the latest*** simultaneously ***notify an alert*** in the EWRS, provided that the threat concerned falls within those referred to in Article 2(1) of this Regulation.	2. Where the national competent authorities notify the WHO of events that may constitute public health emergencies of international concern in accordance with Article 6 of the IHR, ***as referred to in Article 18(2b), an alert*** shall ***be*** simultaneously ***notified*** in the EWRS, provided that the threat concerned falls within those referred to in Article 2(1) of this Regulation.

Amendment 191

Proposal for a regulation

Article 19 — paragraph 3 — point f

Text proposed by the Commission	*Amendment*
(f) public health risks;	(f) public health risks***, especially for vulnerable groups, including, as far as possible, their impact on major non-communicable diseases***;

Amendment 192

Proposal for a regulation

Article 19 — paragraph 3 — point h

Text proposed by the Commission	*Amendment*
(h) measures other than public health measures;	(h) ***multisectoral*** measures other than public health measures;

Amendment 193

Proposal for a regulation

Article 19 — paragraph 3 — point i a (new)

Text proposed by the Commission	*Amendment*
	(ia) the existing and potential production sites, with the sole aim of allowing the Union to map the strategic production capacities for the Union as a whole;

Amendment 194

Proposal for a regulation

Article 19 — paragraph 3 — point j

Text proposed by the Commission	*Amendment*
(j) requests and offers for cross-border emergency assistance;	(j) requests and offers for cross-border emergency assistance***, such as the medical transfer of patients or provision of healthcare staff by one Member State to another, in particular in cross-border areas in neighbouring regions***;

Amendment 195

Proposal for a regulation

Article 19 — paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The Member State shall update the information referred to in paragraph 3 as new data become available.

Amendment 196

Proposal for a regulation

Article 20 — paragraph 1 — introductory part

Text proposed by the Commission	*Amendment*
1. Where an alert is notified pursuant to Article 19, the Commission shall, where necessary for the coordination of the response at Union level or upon request of the HSC referred to in Article 21 or on its own initiative, make promptly available to the national competent authorities and to the HSC, through the EWRS, a risk assessment of the potential severity of the threat to public health, including possible public health measures. That risk assessment shall be carried out by:	1. Where an alert is notified pursuant to Article 19, the Commission shall, where necessary for the coordination of the response at Union level or upon request of the HSC referred to in Article 21 or on its own initiative, make promptly available to the national competent authorities and to the HSC, through the EWRS, a risk assessment of the potential severity of the threat to public health, including possible public health measures***, including a risk assessment of the mental health of the affected population***. That risk assessment shall be carried out by:

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Amendment 269

Proposal for a regulation

Article 20 — paragraph 1 — point -a (new)

Text proposed by the Commission	*Amendment*
	(-a) the HERA in accordance with Article 2(2) (a) of the Commission Decision of 16 September 2021. The assessment by the HERA shall be carried out in such a way as to allow a decision to be taken on the activation of the emergency framework as set out in Article 3 of a Council Regulation on a framework for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level, and on which measures as set out in Articles 5 to 11 and Article 13 of that Regulation it is appropriate to activate;

Amendment 197

Proposal for a regulation

Article 20 — paragraph 1 — point a

Text proposed by the Commission	*Amendment*
(a) the ECDC in accordance with Article 8a of Regulation (EU) …/… [OJ: Please insert the number of Regulation ECDC [ISC/2020/12527]] in the case of a threat referred to in ***points (i) and (ii) of*** point (a) of Article 2(1) including substances of human origin: blood, organs, tissues and cells potentially impacted by communicable diseases; or point (d) of Article 2(1); and/or	(a) the ECDC in accordance with Article 8a of Regulation (EU) …/… [OJ: Please insert the number of Regulation ECDC [ISC/2020/12527]] in the case of a threat referred to in point (a) of Article 2(1) including substances of human origin: ***such as*** blood, organs, tissues and cells potentially impacted by communicable diseases; or point (d) of Article 2(1); and/or

Amendment 198

Proposal for a regulation

Article 20 — paragraph 1 — point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) the European Medicines Agency (EMA), in accordance with Article 1 of Regulation (EU) 2021/… [insert the number of revised EMA regulation 2020/0321(COD)], in the case of a threat linked to a defective medical product or in the event a threat is becoming more severe as a result of a shortage of medical products for human use or medical devices; and/or

Amendment 199

Proposal for a regulation

Article 20 — paragraph 1 — point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) Union or national entities engaged in stockpiling of medical products.

Amendment 200

Proposal for a regulation

Article 20 — paragraph 2

Text proposed by the Commission	*Amendment*
2. At the request of the agency or body carrying out the risk assessment within its mandate, the agencies and bodies referred to in paragraph 1 shall, without undue delay, provide any relevant information data at their disposal.	2. At the request of the agency or body carrying out the risk assessment within its mandate, the agencies and bodies referred to in paragraph 1 shall, without undue delay, provide any relevant information data ***and expertise*** at their disposal. ***When delivering its risk assessment, the agency or body shall be designated as the 'lead' agency in accordance with paragraph 3 . The agency or body shall ensure that it takes note of any information or expertise obtained from other agencies or bodies referred to in paragraph 1.***

Amendment 201

Proposal for a regulation

Article 20 — paragraph 3 — subparagraph 1

Text proposed by the Commission	*Amendment*
Where the risk assessment needed is totally or partially outside the mandates of the agencies referred to in paragraph 1, and it is considered necessary for the coordination of the response at Union level, the Commission shall, upon request of the HSC or its own initiative, provide an ad hoc risk assessment.	Where the risk assessment needed is totally or partially outside the mandates of the agencies referred to in paragraph 1, and it is considered necessary for the coordination of the response at Union level, the Commission shall, upon request of the HSC or its own initiative, provide an ad hoc risk assessment. ***Where the risk assessment needed falls under the mandate of several of the agencies referred to in paragraph 1, the Commission shall designate a lead agency to be in charge of carrying out the risk assessment, in collaboration with the other agencies concerned, and set a deadline for the submission of the assessment by that agency.***

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Amendment 202

Proposal for a regulation

Article 20 — paragraph 3 — subparagraph 2

Text proposed by the Commission	*Amendment*
The Commission shall make the risk assessment available to the national competent authorities promptly through the EWRS, and, if appropriate, through linked alerts systems. Where the risk assessment is to be made public, the national competent authorities shall receive it prior to its publication.	The Commission shall make the risk assessment available to the national competent authorities promptly through the EWRS, and, if appropriate, through linked alerts systems. Where the risk assessment is to be made public, the national competent authorities shall receive it prior to its publication ***through the EWRS and the HSC***.

Amendment 203

Proposal for a regulation

Article 20 — paragraph 3 — subparagraph 3

Text proposed by the Commission	*Amendment*
The risk assessment shall take into account, if available, relevant information provided by other entities, in particular by the WHO in the case of a public health emergency of international concern.	The risk assessment shall take into account, if available, relevant information provided by ***public health experts and*** other entities, in particular by the WHO in the case of a public health emergency of international concern.

Amendment 270

Proposal for a regulation

Article 21 — paragraph 1 — introductory part

Text proposed by the Commission	*Amendment*
1. Following an alert notification pursuant to Article 19, on a request from the Commission or a Member State and on the basis of the available information, including the information referred to in Article 19 and the risk assessments referred to in Article 20, Member States shall coordinate within the HSC and in liaison with the Commission:	1. Following an alert notification pursuant to Article 19, on a request from the Commission or a Member State and on the basis of the available information, including the information referred to in Article 19 and the risk assessments referred to in Article 20, Member States shall coordinate within the HSC and in liaison with the Commission ***in particular with the HERA***:

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Amendment 204

Proposal for a regulation

Article 21 — paragraph 1 — point b

Text proposed by the Commission	*Amendment*
(b) risk and crisis communication, to be adapted to Member State needs and circumstances, aimed at providing consistent and coordinated information in the Union to the public ***and*** to healthcare professionals;	(b) risk and crisis communication, to be adapted to Member State needs and circumstances, aimed at providing consistent and coordinated information in the Union to the public, to healthcare professionals ***and public health professionals***;

Amendment 205

Proposal for a regulation

Article 21 — paragraph 1 — point c

Text proposed by the Commission	*Amendment*
(c) adoption of opinions and guidance, including on specific response measures for the Member States for the prevention and control of a serious cross-border threat to health.	(c) adoption of opinions and guidance, including on specific response measures for the Member States for the prevention and control of a serious cross-border threat to health***, including coordination of response measures***.

Amendment 206

Proposal for a regulation

Article 21 — paragraph 1 — point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) national travel restrictions and other cross-border restrictions on movement and the gathering of people, as well as quarantine requirements and supervision of quarantines following cross-border travel.

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Amendments 207 and 271

Proposal for a regulation

Article 21 — paragraph 2

Text proposed by the Commission	*Amendment*
2. Where a Member State intends to adopt public health measures to combat a serious cross-border threat to health, it shall, before adopting those measures, inform ***and*** consult the other Member States ***and*** the Commission on the nature, purpose and scope of the measures, unless the need to protect public health is so urgent that the immediate adoption of the measures is necessary.	2. Where a Member State intends to adopt public health measures to combat a serious cross-border threat to health, it shall, before adopting ***or ceasing*** those measures, inform, consult ***and coordinate with*** the other Member States***, in particular neighbouring Member States,*** the Commission***, in particular the HERA, the HCB and the Health Security Committee*** on the nature, purpose and scope of the measures, unless the need to protect public health is so urgent that the immediate adoption of the measures is necessary.

Amendments 208 and 272

Proposal for a regulation

Article 21 — paragraph 3

Text proposed by the Commission	*Amendment*
3. Where a Member State has to adopt, as a matter of urgency, public health measures in response to the appearance or resurgence of a serious cross-border threat to health, it shall, immediately upon adoption, inform the other Member States ***and*** the Commission on the nature, purpose and scope of those measures.	3. Where a Member State has to adopt, as a matter of urgency, public health measures in response to the appearance or resurgence of a serious cross-border threat to health, it shall, immediately upon adoption, inform the other Member States***, relevant regional authorities,*** the Commission***, in particular the HERA, the HCB and the Health Security Committee*** on the nature, purpose and scope of those measures ***especially in cross-border regions***.

Amendment 209

Proposal for a regulation

Article 21 — paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. In the event of a serious cross-border threat to health overwhelming national response capacities in a Member State, that Member State may also request assistance from other Member States through the ERCC provided for in Decision No 1313/2013/EU of the European Parliament and of the Council ([1a]).

([1a]) Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism.

Amendment 273

Proposal for a regulation

Article 22 — paragraph 2 — point a

Text proposed by the Commission	*Amendment*
(a) be based on in particular recommendations of the ECDC in particular, other relevant agencies or bodies, or the Advisory Committee referred to in Article 24;	(a) be based on in particular recommendations of the ECDC ***and the HERA*** in particular, other relevant agencies or bodies, or the Advisory Committee referred to in Article 24;

Amendment 210

Proposal for a regulation

Article 22 — paragraph 2 — point c

Text proposed by the Commission	*Amendment*
(c) be proportionate to the public health risks related to the threat in question, avoiding in particular any unnecessary restriction to the free movement of persons, of goods and of services.	(c) be ***necessary, suitable and*** proportionate to the public health risks related to the threat in question, avoiding in particular any unnecessary restriction to the free movement of persons, of goods and of services***, and to the rights, freedoms and principles enshrined in the Charter of Fundamental Rights of the European Union, and promote coordination of measures between Member States;***

Amendment 211

Proposal for a regulation

Article 22 — paragraph 2 — point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) be time limited, and cease as soon as one of the applicable conditions set out in points (a), (b) and (c) is no longer met;

Amendment 212

Proposal for a regulation

Article 22 — paragraph 2 — point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) take into account the need for an internal market that functions normally, in particular the existence of green lanes for free circulation of food and medical counter-measures.

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Amendment 213

Proposal for a regulation

Article 23 — paragraph 3

Text proposed by the Commission	*Amendment*
3. Before recognising a situation of public health emergency at Union level, the Commission ***should*** liaise with the WHO in order to share the Commission's analysis of the situation of the outbreak and to inform the WHO of its intention to adopt such a decision.	3. Before recognising a situation of public health emergency at Union level, the Commission ***shall*** liaise with the WHO in order to share the Commission's analysis of the situation of the outbreak and to inform the WHO of its intention to adopt such a decision.

Amendment 214

Proposal for a regulation

Article 23 — paragraph 4 — subparagraph 2

Text proposed by the Commission	*Amendment*
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article ***27(2)***.	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article ***27(3)***.

Amendment 274

Proposal for a regulation

Article 23 — paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Following the recognition of public health emergency, the Council, upon the proposal of the Commission, may adopt a regulation activating the emergency framework where that is appropriate to the economic situation, pursuant to Article 3 of a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level. Where the emergency framework is activated, the HCB shall be set up to coordinate action by the Council, the Commission, the relevant Union agencies and bodies, and Member States to ensure the supply and access of medical countermeasures. In such situations, pursuant to the Joint Declaration on budgetary scrutiny of new proposals based on Article 122 TFEU, a Joint Committee consisting of representatives of the European Parliament and of the Council shall be established.

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Amendment 215

Proposal for a regulation

Article 24 — paragraph 1 — introductory part

Text proposed by the Commission	*Amendment*
1. For the purpose of the formal recognition of a public health emergency at Union level, the Commission shall establish an Advisory Committee on public health emergencies ('Advisory Committee') which, at the request of the Commission, shall advise the Commission by providing its views on:	1. For the purpose of the formal recognition of a public health emergency at Union level, the Commission***, with the consultation of the Health Security Committee*** shall establish an Advisory Committee on public health emergencies ('Advisory Committee') which, at the request of the Commission ***or the Health Security Committee***, shall advise the Commission ***and the Health Security Committee*** by providing its views on:

Amendment 216

Proposal for a regulation

Article 24 — paragraph 1 — point c — point ii

Text proposed by the Commission	*Amendment*
(ii) identification and mitigation of significant gaps, inconsistencies or inadequacies in measures taken or to be taken to contain and manage the specific threat and overcome its impact, including in clinical management and treatment, ***non-pharmaceutical countermeasures*** and public health research needs;	(ii) identification and mitigation of significant gaps, inconsistencies or inadequacies in measures taken or to be taken to contain and manage the specific threat and overcome its impact, including in clinical management and treatment, and public health research needs;

Amendment 217

Proposal for a regulation

Article 24 — paragraph 1 — point c — point ii a (new)

Text proposed by the Commission	*Amendment*
	(iia) in consultation with EMA pursuant to Regulation (EU) …/… [OJ: Please insert the number of EMA Regulation], the stability of supply chains and production capacity of medical supply chains involved in the production and manufacturing of medical countermeasures needed for the diagnosis, treatment and follow-up of the disease concerned;

Thursday 11 November 2021

Amendment 218

Proposal for a regulation

Article 24 — paragraph 2

Text proposed by the Commission	*Amendment*
2. The Advisory Committee shall be composed of independent experts, selected by the Commission according to the fields of expertise and experience most relevant to the specific threat that is occurring. The Committee should have multidisciplinary membership so it can advise on biomedical, behavioural, social, economic, cultural and international aspects. The representatives of the ECDC and of the EMA ***participate as observers*** in the Advisory Committee. The representatives of other Union bodies or agencies relevant to the specific threat shall participate as observers in this Committee as necessary. The Commission may invite experts with specific expertise with respect to a subject matter on the agenda to take part in the work of the Advisory Committee on an ad-hoc basis.	2. The Advisory Committee shall be composed of independent experts***, representatives of health and care workers and civil society representatives***, selected by the Commission according to the fields of expertise and experience most relevant to the specific threat that is occurring. The Committee should have multidisciplinary membership so it can advise on ***sanitary,*** biomedical, behavioural, social, economic, ***research, development, manufacturing,*** cultural***, transport*** and international aspects. The representatives of the ECDC and of the EMA ***shall take an active part*** in the Advisory Committee. The representatives of other Union bodies or agencies relevant to the specific threat shall participate as observers in this Committee as necessary. The Commission ***or the Health Security Committee*** may invite experts ***and stakeholders*** with specific expertise with respect to a subject matter on the agenda to take part in the work of the Advisory Committee on an ad-hoc basis. ***The Commission shall publish the names of the experts selected to form part of the Advisory Committee and details of the professional and/or scientific backgrounds that justify their appointment.***

Amendment 219

Proposal for a regulation

Article 24 — paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Commission shall publish on its website the list of members of the Advisory Committee and the qualifications supporting their appointment. A geographical balance of the membership shall be ensured whenever possible. The members shall act in the public interest and in an independent manner. They shall make declarations of interest and of commitments. Such declarations shall include any activity, position, circumstances or other facts potentially involving a direct or indirect interest, in order to make it possible to identify interests which might be considered prejudicial to those experts' independence.

Thursday 11 November 2021

Amendment 275

Proposal for a regulation

Article 24 — paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. The Advisory Committee shall act in cooperation with the HCB and the HERA Advisory Forum established under the Commission Decision of 16 September 2021. Representatives of the HERA Advisory Forum shall participate as observers on the Advisory Committee. The coordination between those bodies shall ensure that there is participation by all relevant stakeholders, including healthcare professionals' organisations, patients' associations, and industry and supply chain actors with recognised experience in disciplines related to providing advice on response to health emergencies and to the work of the HERA.

Amendment 220

Proposal for a regulation

Article 24 — paragraph 3

Text proposed by the Commission	*Amendment*
3. The Advisory Committee shall meet whenever the situation requires, on a request from the Commission or a Member State.	3. The Advisory Committee shall meet whenever the situation requires, on a request from the Commission***, the Health Security Committee*** or a Member State.

Amendment 221

Proposal for a regulation

Article 24 — paragraph 6

Text proposed by the Commission	*Amendment*
6. The Advisory Committee shall establish its rules of procedure including on the rules for the declaration and termination of an emergency situation, and adoption of recommendations and voting. The rules of procedures shall enter into force after receiving a favourable opinion from the Commission.	6. The Advisory Committee shall establish its rules of procedure including on the rules for the declaration and termination of an emergency situation, and adoption of recommendations and voting. The rules of procedures shall enter into force after receiving a favourable opinion from the Commission ***and the Health Security Committee***.

Amendment 222

Proposal for a regulation

Article 24 — paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. The minutes of the Advisory Committee shall be public.

Thursday 11 November 2021

Amendment 223

Proposal for a regulation

Article 24 — paragraph 6 b (new)

Text proposed by the Commission	*Amendment*
	6b. The advisory committee shall work in close cooperation with national advisory bodies.

Amendments 224 and 276

Proposal for a regulation

Article 25 — paragraph 1 — point b

Text proposed by the Commission	*Amendment*
(b) ***mechanisms*** to monitor shortages of, ***develop, procure, manage and deploy*** medical countermeasures;	(b) ***measures, pursuant to a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level,*** to monitor shortages of, ***the development, the manufacture, the procurement, actions taken to ensure security of supply, the management, the storage, the distribution and the deployment of*** medical countermeasures;

Amendment 225

Proposal for a regulation

Article 25 — paragraph 1 — point c

Text proposed by the Commission	*Amendment*
(c) activation of support from the ECDC as referred to in Regulation (EU) …/… [OJ: Please insert the number of Regulation ECDC [ISC/2020/12527]] to mobilise and deploy the EU Health Task Force.	(c) activation of support from the ECDC as referred to in Regulation (EU) …/… [OJ: Please insert the number of Regulation ECDC [ISC/2020/12527]] to mobilise and deploy the EU Health Task Force ***and in particular the establishment of a list of accommodation facilities in intensive care units in the Member States for the purpose of potential cross-border relocation of patients;***

Amendment 226

Proposal for a regulation

Article 25 — paragraph 1 — point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) a Union export control mechanism with the aim of enabling the Union to guarantee timely and effective access to counter-measures;

Amendment 227

Proposal for a regulation

Article 25 — paragraph 1 — point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) green lanes referred to in Article 25a of this Regulation, in exceptional cases.

Amendment 228

Proposal for a regulation

Article 25 a (new)

Text proposed by the Commission	*Amendment*
	Article 25a
	Green lanes
	1. After recognising a public health emergency for a pandemic situation under Article 23(1), the Commission shall, in the case of border restrictions, establish green lanes to ensure that essential goods, medical countermeasures and cross border workers can move freely within the internal market.
	2. The Commission is empowered to adopt delegated acts to supplement this Regulation with provisions on the establishment of the green lanes referred to in paragraph 1.
	3. A Member State may only prohibit or restrict exports of medical countermeasures in cases defined in Article 36 TFEU during a public health emergency at Union level, on condition that it obtains prior authorisation from the Commission.
	4. The Commission shall decide on the request for prior authorisation within five days of the request. If the Commission takes no decision within this period, the authorisation shall be deemed granted.

Thursday 11 November 2021

Amendment 229

Proposal for a regulation

Article 26 — paragraph 1

Text proposed by the Commission	*Amendment*
1. The EWRS shall include a selective messaging functionality allowing personal data, including contact and health data, to be communicated only to national competent authorities involved in the contact tracing measures concerned. That selective messaging functionality shall be designed ***and*** operated so as to ensure safe and lawful processing of personal data and to link with contact tracing systems at Union level.	1. The EWRS shall include a selective messaging functionality allowing personal data, including contact and health data, to be communicated only to national competent authorities involved in the contact tracing measures concerned. That selective messaging functionality shall be designed ***with respect for the principle of data minimisation and data protection by design and by default, and shall be*** operated so as to ensure safe and lawful processing of personal data and to link with contact tracing systems at Union level.

Amendment 230

Proposal for a regulation

Article 26 — paragraph 5

Text proposed by the Commission	*Amendment*
5. Personal data may also be exchanged in the context of automated contact tracing, using contact tracing applications.	5. Personal data may also be exchanged in the context of automated contact tracing, using contact tracing applications***, in full compliance with Regulation (EU) 2016/679 of the European Parliament and of the Council ('GDPR')*** [1a]
	[1a] 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).

Amendment 231

Proposal for a regulation

Article 26 — paragraph 6 — subparagraph 1 — introductory part

Text proposed by the Commission	*Amendment*
6. ***The*** Commission shall***, by means of implementing acts,*** adopt:	6. ***Following a prior consultation procedure as set out in Article 42(2) of Regulation (EU) 2018/1725, the*** Commission shall adopt ***delegated acts in accordance with Article 28 concerning***:

Amendment 232

Proposal for a regulation

Article 26 — paragraph 6 — subparagraph 1 — point b

Text proposed by the Commission	*Amendment*
(b) procedures for the interlinking of the EWRS with contact tracing systems at Union level;	(b) procedures for the interlinking of the EWRS with contact tracing systems at Union level ***and international level;***

Amendment 233

Proposal for a regulation

Article 26 — paragraph 6 — subparagraph 1 — point d

Text proposed by the Commission	*Amendment*
(d) the modalities for processing automated contract tracing applications and interoperability of these applications, as well as the cases where, and the conditions under which, the third countries may be granted access to contract tracing interoperability and the practical arrangements for such access.	(d) the modalities for processing automated contract tracing applications and interoperability of these applications, as well as the cases where, and the conditions under which, the third countries may be granted access to contract tracing interoperability and the practical arrangements for such access, ***in full compliance with the EUDPR and applicable case law of the Court of Justice;***

Amendment 234

Proposal for a regulation

Article 26 — paragraph 6 — subparagraph 1 — point d a (new)

Text proposed by the Commission	*Amendment*
	(da) a detailed description of the roles of the actors involved in the processing of personal data through the proposed IT tools and systems.

Amendment 235

Proposal for a regulation

Article 26 — paragraph 6 — subparagraph 2

Text proposed by the Commission	*Amendment*
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).	***deleted***

Thursday 11 November 2021

Amendment 236

Proposal for a regulation

Article 28 — paragraph 2

Text proposed by the Commission	*Amendment*
2. The power to adopt delegated acts referred to in ***Article*** 8 (3) shall be conferred on the Commission for an indeterminate period of time from … [date of entry into force of the basic legislative act or any other date set by the co-legislators].	2. The power to adopt delegated acts referred to in ***Articles*** 8 (3), ***13(9), 14(6), 17(3), 25a(2), and 26(6)*** shall be conferred on the Commission for a ***for a period of five years from … [date of entry into force of the basic legislative act or any other date set by the co-legislators]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.***

Amendment 237

Proposal for a regulation

Article 28 — paragraph 3

Text proposed by the Commission	*Amendment*
3. The delegation of power referred to in ***Article*** 8(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	3. The delegation of power referred to in ***Articles*** 8(3), ***13(9), 14(6), 17(3), 25a(2) and 26(6)*** may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

Amendment 238

Proposal for a regulation

Article 28 — paragraph 6

Text proposed by the Commission	*Amendment*
6. A delegated act adopted pursuant to ***Article*** 8(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.	6. A delegated act adopted pursuant to ***Articles*** 8(3), ***13(9), 14(6), 17(3), 25a(2) and 26(6)*** shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Thursday 11 November 2021

Amendment 239

Proposal for a regulation

Article 28 a (new)

Text proposed by the Commission	*Amendment*
	Article 28a
	Urgency procedure
	1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.
	2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 28(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

Amendments 240 and 277

Proposal for a regulation

Article 29 — paragraph 1

Text proposed by the Commission	*Amendment*
By 2025 and every 5 years thereafter the Commission shall carry out an evaluation of this Regulation and present a report on the main findings to the European Parliament and the Council. The evaluation shall be conducted in accordance with the Commission's better regulation guidelines. The evaluation shall include, in particular, an assessment of the operation of the EWRS and the epidemiological surveillance network, as well as the coordination of the response with the HSC.	By 2025 and every 5 years thereafter the Commission shall carry out an evaluation of this Regulation and present a report on the main findings to the European Parliament and the Council. The evaluation shall be conducted in accordance with the Commission's better regulation guidelines. The evaluation shall include, in particular, an assessment of the operation of the EWRS and the epidemiological surveillance network, as well as the coordination of the response with the HSC***, the HERA and the impact of the Regulation on the proper functioning of the single market when serious cross-border threats to health arise. By 2023 and every 2 years thereafter, the Commission shall carry out an in-depth review of the implementation of the operations of HERA, including its structure, governance, funding and human resources. Those reviews shall address, in particular, any need to modify HERA's structure, including but not limited to the possibility of upgrading HERA to a standalone agency, the mandate of HERA and the financial implications of any such modification. The Commission shall report to the European Parliament and to the Council on the findings of the reviews. Those findings shall be made public. The reviews shall be accompanied, where appropriate, by a legislative proposal to address the issues referred to in this paragraph, in full respect of the role of the European Parliament as co-legislator.***

Thursday 11 November 2021

Amendment 241

Proposal for a regulation

Article 29 — paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Based on the evaluation referred to in the previous paragraph, the Commission shall, where appropriate, submit a legislative proposal to amend this Regulation.

Thursday 11 November 2021

P9_TA(2021)0450

EU/Australia Agreement: modification of concessions on all the tariff-rate quotas included in the EU Schedule CLXXV ***

European Parliament legislative resolution of 11 November 2021 on the draft Council decision on the conclusion, on behalf of the Union, of the Agreement in the form of an Exchange of Letters between the European Union and the Commonwealth of Australia pursuant to Article XXVIII of the General Agreement on Tariffs and Trade (GATT) 1994 relating to the modification of concessions on all the tariff-rate quotas included in the EU Schedule CLXXV as a consequence of the United Kingdom's withdrawal from the European Union (06102/2021 — C9-0376/2021 — 2021/0029(NLE))

(Consent)

(2022/C 205/13)

The European Parliament,

— having regard to the draft Council decision (06102/2021),

— having regard to the draft Agreement in the form of an exchange of letters between the European Union and the Commonwealth of Australia pursuant to Article XXVIII of the General Agreement on Tariffs and Trade (GATT) 1994 relating to the modification of concessions on all the tariff-rate quotas included in the EU Schedule CLXXV as a consequence of the United Kingdom's withdrawal from the European Union (06103/2021),

— having regard to the request for consent submitted by the Council in accordance with Article 207(4), first subparagraph, and Article 218(6), second subparagraph, point (a)(v) of the Treaty on the Functioning of the European Union (C9-0376/2021),

— having regard to Rule 105(1) and (4), and Rule 114(7) of its Rules of Procedure,

— having regard to the letter from the Committee on Agriculture and Rural Development,

— having regard to the recommendation of the Committee on International Trade (A9-0306/2021),

1. Gives its consent to the conclusion of the agreement;

2. Instructs its President to forward its position to the Council, the Commission and the governments and parliaments of the Member States and of the Commonwealth of Australia.

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