Council of the European Union

Brussels, 8 May 2025
(OR. en)

8582/25

Interinstitutional File: 2023/0129 (COD)

LIMITE

PI 82
PHARM 62
COMPET 325
MI 282
IND 127
CODEC 542

PUBLIC

NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	Proposal for a Regulation of the European Parliament and the Council on Compulsory Licensing for crisis management and amending Regulation (EC) 816/2006 – Preparation for the trilogue

I. INTRODUCTION

1. On 27 April 2023, the Commission published a legislative package aimed at modernising and further developing patent law in the EU, which builds on the Commission's 2020 Intellectual Property Action Plan[1].

2. The patent package contains six legislative proposals, including the proposal for a Regulation on compulsory licensing for crisis management and amending Regulation 816/2016. The proposal is based on Articles 114 and 207 of the Treaty on the Functioning of the EU ("TFEU").

3. The objective of the proposed Regulation is to introduce a Union compulsory licensing system that can strengthen the resilience of the EU by addressing Union-wide crises that have a cross-border dimension. In situations when voluntary agreements might not be found or

[1] 13354/20.

might not be adequate, the Union compulsory licence would facilitate access to crisis-relevant products that are protected by intellectual property rights.

4. The European Economic and Social Committee adopted an opinion on the proposal on 20 September 2023[2]. The European Data Protection Supervisor (EDPS) provided its opinion on 28 July 2023.

5. The European Parliament adopted its first reading position[3] on the proposal on 13 March 2024, following the adoption of the report on the proposal in the Committee on Legal Affairs (JURI) on 13 February 2024. On 18 November 2024, the European Parliament's JURI Committee re-appointed Mr Adrián Vázquez Lázara (EPP, ES) as rapporteur for the proposal.

6. The Working Party on Intellectual Property started the substantial examination of the Proposal in January 2024, under the Belgian Presidency. The examination took place over eight meetings, from January to May 2024.

7. Following the examination of the text under the Belgian Presidency, the Permanent Representatives Committee adopted the Council's mandate on 26 June 2024[4].

II. INTERINSTITUTIONAL NEGOTIATIONS – STATE OF PLAY

8. The first political trilogue was held under the Hungarian Presidency on 10 December 2024. During this trilogue, the co-legislators presented their respective positions and key political points were identified: additional measures and trade secrets, as well as the scope of the Regulation. The technical level was given a mandate to work on all technical issues and to exchange positions on the political issues identified at the trilogue. The second political trilogue took place on 26 March 2025, and the matter of the advisory/examination procedure was added to the list of political issues. As a result of this trilogue, the technical level was given a broad mandate to work on all issues.

---

[2] 13349/23.
[3] T9-0143/2024.
[4] 11613/24.

9. The Working Party on Intellectual Property discussed the progress in the interinstitutional negotiations on 14 and 31 January, 10 and 28 February, 11 and 28 March, 10 and 28 April, and 8 May 2025.

10. Overall, 17 informal technical meetings took place, all under the Polish Presidency. While considerable progress was made on the technical level and many of the technical issues have been agreed upon, the remaining open political issues require a substantive discussion at the political level.

11. The third political trilogue is scheduled for 21 May 2025. The Presidency's aim is to conclude the negotiation with the Parliament and reach the political agreement at that trilogue.

III. PREPARATION FOR THE THIRD TRILOGUE

12. In view of the upcoming third political trilogue, the Presidency is inviting delegations to reflect on the following issues:

(a) ADDITIONAL MEASURES AND TRADE SECRETS

13. At the second trilogue on 26 March 2025, the Parliament announced that they accepted to delete their amendments related to the obligatory disclosure of trade secrets (rows 128, 137a, 143b, 143c, 143d, 171a, 171b, 171c, 171d, 171e, 171f, 171g, 171h) and proposed to work on this issue on the basis of the text in the initial Commission Proposal and the concept of "good faith" cooperation between the rights-holder and the licensee. The Presidency strongly defended the Council mandate and, following the positions expressed by delegations, expressed that this is not an option.

14. The Presidency also insisted that the provision in Article 2(3) (row 60a), according to which the Regulation does not impose any obligation to disclose trade secrets, stay in the text. The Parliament views this provision as harbouring the danger of being interpreted as prohibiting the voluntary sharing of trade secrets by the rights-holder with the licensee.

15. To address the Parliament's concern, the Presidency suggests devising and introducing new wording that would reflect the notion that this Regulation does not preclude the conclusion of agreements on trade secrets.

16. *With a view to finding a compromise with the Parliament on this core issue, the Presidency invites delegations to indicate whether they could accept such a notion in the text as a landing zone for a final agreement?*

(b) SCOPE

i. Related crisis instruments

17. The Council removed two crisis instruments from the list of crisis instruments triggering the possibility of a Union compulsory licence, namely the Regulation on Security of Gas Supply[5] and the Chips Act[6], as Member States didn't consider the subject matter of these instruments as relevant for the Union compulsory licence (Table 1). Parliament, strongly supported by the Commission, defended the inclusion of these crisis instruments in the scope of the Regulation, arguing that both gas-related technologies and semi-conductors could be crisis-relevant products.

18. In order to alleviate the Council's concerns on the compliance of the inclusion of the Chips Act with the TRIPS Agreement[7], the Commission proposed to include wording clarifying that a Union compulsory licence shall in the case of semi-conductor technology only be for public non-commercial use (proposed in doc. WK 4653/2025).

19. *As a possible landing zone, the Presidency invites delegations to consider whether they could, on the basis of this new wording and in a spirit of compromise, be flexible on the inclusion of the Chips Act in the scope of the Regulation.*

ii. Placement of related crisis instruments in the operative part of the Regulation

20. For the sake of clarity and legal certainty, in the Council mandate the crisis instruments that were in the Commission proposal outlined only in the Annex of the proposed Regulation are now also listed in the operative part of the draft Regulation (Article 2(-1); rows 55a–55d).

---

5 Regulation (EU) 2017/1938 of the European Parliament and of the Council of 25 October 2017 concerning measures to safeguard the security of gas supply and repealing Regulation (EU) No 994/2010 (OJ L 280, 28.10.2017, p. 1–56).

6 Regulation (EU) 2023/1781 of the European Parliament and of the Council of 13 September 2023 establishing a framework of measures for strengthening Europe's semiconductor ecosystem and amending Regulation (EU) 2021/694 (Chips Act) (OJ L 229, 18.9.2023, p. 1–53).

7 Agreement on Trade-Related Aspects of Intellectual Property Rights.

PUBLIC

Both the Parliament and the Commission claim that retaining the placement of the crisis instrument only in the Annex would facilitate amending the list of related crisis instruments without leading to changes in other Articles of the Regulation.

21. *Could the delegations be open to consider listing the related crisis instruments only in the Annex to the Regulation, should this concession be necessary to achieve an overall compromise?*

PUBLIC

iii. Ad hoc advisory body

22. The Council's mandate no longer includes any provisions on the ad hoc advisory body (Article 6; rows 95, 96), and the Presidency has consistently defended this position by referring to the fact that the related crisis instrument within the scope of the Regulation provide for an advisory body. Both the Parliament and the Commission believe the provisions on the ad hoc advisory body should be kept in the text, as a safety net in case a crisis instrument is added in the future that does not provide for an advisory body.

23. *Could the delegations be open to consider maintaining the provisions on the ad hoc advisory body in the Regulation, should this concession be necessary to achieve an overall compromise?*

iv. Evaluation

24. In Article 25 (row 251a) the Parliament made an amendment according to which the Commission shall assess every two years whether the list of crisis instruments in the Annex is up to date. The Parliament remains open on the timeframe in which such an assessment would take place. The Commission suggested a reworded version of this provision (proposed in doc. WK 4653/2025), according to which the Commission shall assess the list of crisis instruments "regularly", without specifying a concrete time frame. The Commission also proposed to report on the assessment to the co-legislators every five years.

25. The Presidency believes this proposal should further be amended to reflect that the assessment of the list does not only aim at including new instruments into the scope of the Regulation but also at assessing whether there is merit in maintaining the present instruments.

26. *Would delegations be open to accepting a regular assessment of the list of related crisis instruments, if the evaluation provision is devised as described above?*

(c) COMITOLOGY

i. Advisory *vs.* Examination procedure

27. In order to ensure a proper involvement of the Member States in the decision of granting, modifying or terminating the Union compulsory licence, the Council has changed the proposed advisory procedure to the examination procedure (Articles 7(9) and 14(6); rows 114s and 178). On this issue the Parliament sided with the Commission, who provided arguments according to which the examination procedure would cause unnecessary delays in circumstances of crisis.

28. The Presidency will continue to strongly defend the use of the examination procedure and shares the delegations' conviction that no flexibility can be shown on this issue.

ii. Non-opinion clause

29. Complementing the use of the examination procedure, the Council's mandate also introduced the non-opinion clause (Article 24(5); row 249a) to ensure that an implementing act cannot be adopted when the comitology committee does not deliver an opinion. The Presidency will continue defending the Council's mandate but believes that showing flexibility on this issue might be needed for a compromise in which the Parliament would show flexibility on the examination procedure.

30. *In the spirit of final compromise, could delegations consider showing flexibility and delete the non-opinion clause for the adoption of the implementing acts in the Compulsory licensing Regulation?*

(d) TIME LIMIT FOR VOLUNTARY AGREEMENTS

31. The Parliament's initial mandate featured a four-week time limit for reaching a voluntary agreement before the Union compulsory licence is issued. Following the position of Member States, the Presidency stressed on many occasions that such a concrete time limit might be too constraining on the rights-holder and the licensee, and the Parliament agreed to give up on the four-week deadline. However, they insist that some kind of a time limit remain, and a drafting solution was devised (proposed as Alternative 1 in doc. WK 5623/2025), according to which one of the general conditions for granting a Union compulsory licence (Article 4) would be that a voluntary agreement could not be achieved within a reasonable timeframe.

32. However, to take into account the concerns of delegations expressed in this context and to make clear that voluntary agreements can be concluded at any time during or after the granting process, the Presidency suggested adding a provision on this matter in Article 7(11) (proposed in doc. WK 5623/2025).

33. The Presidency sees the compromise package on this point as sound and believes it to be acceptable.

34. *Could the delegations agree to such a compromise?*

IV. CONCLUSION

35. In light of the above, the Permanent Representatives Committee is invited **to confirm** the lines preliminarily agreed at the technical level, as indicated in green in the fourth column of the four-column table, contained in the Annex to this note.

36. In addition, the Permanent Representatives Committee is invited **to provide political guidance** to the Presidency on the possible flexibilities mentioned above.

PUBLIC

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 (Text with EEA relevance)
2023/0129(COD)

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
Formula				
1	2023/0129 (COD)	2023/0129 (COD)	2023/0129 (COD)	
Proposal Title				
2	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 (Text with EEA relevance)	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 (Text with EEA relevance)	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 (Text with EEA relevance)	
Formula				
3	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	
Citation 1				
4	Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 207 thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 207 thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 207 thereof,	
Citation 2				

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
5	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	
Citation 3				
6	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,	
Citation 4				
7	Having regard to the opinion of the European Economic and Social Committee[1], _____ 1. OJ C , , p. .	Having regard to the opinion of the European Economic and Social Committee[1], _____ 1. OJ C , , p. .	Having regard to the opinion of the European Economic and Social Committee[1], _____ 1. OJ C , , p. .	
Citation 5				
8	Having regard to the opinion of the Committee of the Regions[1], _____ 1. OJ C , , p. .	Having regard to the opinion of the Committee of the Regions[1], _____ 1. OJ C , , p. .	Having regard to the opinion of the Committee of the Regions[1], _____ 1. OJ C , , p. .	
Citation 6				
9	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	
Formula				
10	Whereas:	Whereas:	Whereas:	
Recital 1				
11	(1) Crises require the setting-up of exceptional, swift, and adequate measures able to provide means to address the consequences of the crisis. In this	(1) Crises require the setting-up of exceptional, swift, and adequate measures able to provide means to address ~~the~~**a crisis or its direct** consequences~~ of the crisis.~~	(1) Crises require the setting-up of exceptional, swift, ~~and~~ adequate ***and proportionate*** measures able to provide means to address the consequences of the	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	context, the use of patented products or processes could prove indispensable to address the consequences of a crisis. Voluntary licensing agreements usually suffice to licence the patent rights on these products and allow their supply in the Union territory. Voluntary agreements are the most adequate, quick, and efficient solution to allow the use of patented products, including in crises. Nevertheless, voluntary agreements may not always be available or only under inadequate conditions such as lengthy delivery times. In such cases, compulsory licensing can provide a solution to allow access to patented products, in particular products necessary to tackle the consequences of a crisis.	~~In this context~~**. To do so**, the use of patented products or processes could prove indispensable~~ to address the consequences of a crisis~~. Voluntary licensing agreements usually suffice to licence the patent rights on these products and allow their supply in the ~~Union~~ territory **of the Union**. Voluntary agreements are the most adequate, quick, and efficient solution to allow the use of patented products, including in crises. Nevertheless, voluntary agreements ~~may~~**might** not always be available or only under inadequate conditions such as lengthy delivery times. In such cases, **a** compulsory ~~licensing~~**licence, which is an authorisation to use an invention protected by intellectual property rights without the consent of the rights-holder,** can provide a solution **of last resort, where voluntary agreements would not be available or where they would not prove adequate,** to allow access to patented products, in particular products necessary to tackle the consequences of a crisis.	crisis, ***without unnecessarily and disproportionally affecting the rights of citizens or the protection of intellectual property rights of businesses***. In this context, the use of patented products or processes could prove indispensable to address the consequences of a crisis. Voluntary licensing agreements usually suffice to licence the patent rights on these products and allow their supply in the Union territory. Voluntary agreements are the most adequate, quick, and efficient solution to allow the use of patented products~~,~~ ~~*including*~~ ***and to scale up production*** in crises. Nevertheless, voluntary agreements may not always be available or only under inadequate conditions such as lengthy delivery times. In such cases, compulsory licensing can provide a solution to allow access to patented products, in particular products necessary to tackle the consequences of a crisis.	
Recital 2				

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
12	(2) In the context of the Union crisis or emergency mechanisms, the Union should therefore have the possibility to rely on compulsory licensing. The activation of a crisis or an emergency mode or the declaration of a crisis or a state of emergency addresses obstacles to free movement of goods, services, and persons in crises and shortages of crisis-relevant goods and services. In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can help in lifting any patent-related barriers and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the Union. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical	(2) In the context of the Union crisis or emergency mechanisms **according to the applicable Union legal act**, the Union should ~~therefore~~ have the possibility to rely on compulsory licensing **in conformity with the framework of the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement')**[1]. The activation of a crisis or an emergency mode or the declaration of a crisis or a state of emergency addresses obstacles to free movement of goods, services, and persons in crises and shortages of crisis-relevant goods and services. ~~In cases~~**As a last resort,** where **adequate, efficient and swift** access to crisis-relevant products and processes **required to manufacture these products, which are** protected by ~~a patent~~**intellectual property rights,** cannot be achieved through **other means, including** voluntary cooperation, compulsory licensing can ~~help in lifting any patent-related barriers and thus ensure~~**allow for the use of an invention protected by intellectual property rights in**	(2) In the context of the ~~Union~~ crisis or emergency mechanisms ***having a cross-border effect in the Union and involving two or more Member States***, the Union should therefore have the possibility to rely on compulsory licensing ***to adequately respond to the needs commanded by the public interest***. The activation of a crisis or an emergency mode or the declaration of a crisis or a state of emergency addresses obstacles to free movement of goods, services, and persons in crises and shortages of crisis-relevant goods and services. In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can help in lifting any patent-related barriers and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the	For EP to come back on this row together with art. 1 row 54 (COM drafting suggestion)

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	products subject to compulsory licencing in the internal market.	the **public interest for the production and** supply of **crisis-relevant** products ~~or services~~ needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of **the** said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the Union. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical products subject to compulsory licencing in the internal market. _____ **1. [1] OJ L 336, 23.12.1994, p. 214**	Union. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical products subject to compulsory licencing in the internal market.	
Recital 3				
13	(3) The possibility of using compulsory licences in situations of national emergency or other circumstances of extreme urgency is explicitly envisaged under the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement')[1]. _____ 1. OJ L 336, 23.12.1994, p. 214	(3) The possibility of using compulsory licences in situations of national emergency or other circumstances of extreme urgency is explicitly envisaged under the ~~Agreement on Trade-Related Aspects of Intellectual Property Rights (~~'TRIPS Agreement~~')~~[1]. **To this end, the present Regulation should establish a scheme for granting a compulsory licence**	(3) The possibility of using compulsory licences in situations of national emergency or other circumstances of extreme urgency is explicitly envisaged under the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement')[1]. _____ 1. OJ L 336, 23.12.1994, p. 214	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		for crisis management at Union level ('Union compulsory licence'). In accordance with the international obligations laid down in the TRIPS Agreement, as a condition for making use of compulsory licensing, efforts should have been made to obtain prior authorisation from the rights-holder on reasonable commercial terms and conditions and such efforts should have not been successful within a reasonable period of time. However, this requirement may be waived in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. The granting process of a Union compulsory licence should be tailored in a way that it ensures the participation of the rights-holders throughout the procedure, with a view to enable and stimulate voluntary agreements. _____ 1. **[1]** OJ L 336, 23.12.1994, p. 214		
Recital 4				

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
14	(4) All Member States have implemented compulsory licensing frameworks for patents in their national law. National laws usually allow compulsory licensing on the ground of public interest or in the event of an emergency. However, divergences exist across Member States, as regards the grounds, conditions, and procedures under which a compulsory licence can be granted. This results in a fragmented, suboptimal, and uncoordinated system preventing the Union from effectively relying on compulsory licensing when addressing a cross-border crisis.	(4) All Member States have implemented compulsory licensing frameworks for patents in their national law. National laws usually allow compulsory licensing on the ground of public interest or in the event of ~~an~~**a crisis or** emergency. However, divergences exist across Member States~~,~~ as regards the grounds, conditions, and procedures under which a compulsory licence can be granted. This results in a fragmented, suboptimal, and uncoordinated system preventing the Union from effectively relying on compulsory licensing ~~when addressing~~**if necessary to address** a cross-border crisis **or emergency**.	(4) All Member States have implemented compulsory licensing frameworks for patents in their national law. National laws usually allow compulsory licensing on the ground of public interest or in the event of an emergency. However, divergences exist across Member States, as regards the grounds, conditions, and procedures under which a compulsory licence can be granted. This results in a fragmented, suboptimal, and uncoordinated system preventing the Union from effectively relying on compulsory licensing when addressing a cross-border crisis.	
Recital 5				
15	(5) National compulsory licensing systems only operate within the national territory. They are designed to meet the needs of the population of the issuing Member State and to satisfy the public interest of that Member State. This limited territorial reach of a national compulsory licensing system is reinforced by the fact that there is no exhaustion of the patent right regarding products	(5) National compulsory licensing systems only operate within the national territory. They are designed to meet the needs of the population of the issuing Member State and to satisfy the public interest of that Member State. This limited territorial reach of a national compulsory licensing system is reinforced by the fact that there is no exhaustion of the patent right regarding products	(5) National compulsory licensing systems only operate within the national territory. They are designed to meet the needs of the population of the issuing Member State and to satisfy the public interest of that Member State. This limited territorial reach of a national compulsory licensing system is reinforced by the fact that there is no exhaustion of the patent right regarding products	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	manufactured under a compulsory licence. Consequently, compulsory licensing schemes do not provide an adequate solution for cross-border manufacturing processes, and therefore there is no functioning internal market for product manufactured under a compulsory licence. Apart from the fact that the issuance of multiple national compulsory licences is a high hurdle for cross-border supply within the single market, it also bears the risk of contradicting and incoherent decisions among Member States. Consequently, the current compulsory licensing framework appears inadequate to address the realities of the internal market and its inherent cross-border supply chains. This suboptimal compulsory licensing framework prevents the Union from relying on an additional instrument when facing crises, in particular when voluntary agreements are unavailable or inadequate. At a time where the Union and its Member States are striving to improve their resilience to crises, it is necessary to provide for an optimal compulsory licensing	manufactured under a compulsory licence. Consequently, compulsory licensing schemes do not provide an adequate solution for cross-border manufacturing processes, and therefore there is no functioning internal market for ~~product~~**products** manufactured under a compulsory licence. Apart from the fact that the issuance of multiple national compulsory licences is a high hurdle for cross-border supply within the ~~single~~**internal** market, it also bears the risk of contradicting and incoherent decisions among Member States. Consequently, the current compulsory licensing framework appears inadequate to address the realities of the internal market and its inherent cross-border supply chains. This suboptimal compulsory licensing framework prevents the Union from relying on an additional instrument when facing crises, ~~in particular when~~**namely when means other than a Union compulsory licence, including** voluntary agreements**, could not adequately, efficiently and swiftly ensure access to crisis-relevant products and processes**	manufactured under a compulsory licence. Consequently, compulsory licensing schemes do not provide an adequate solution for cross-border manufacturing processes, and therefore there is no functioning internal market for product manufactured under a compulsory licence. Apart from the fact that the issuance of multiple national compulsory licences is a high hurdle for cross-border supply within the single market, it also bears the risk of contradicting and incoherent decisions among Member States. Consequently, the current compulsory licensing framework appears inadequate to address the realities of the internal market and its inherent cross-border supply chains. This suboptimal compulsory licensing framework prevents the Union from relying on an additional instrument when facing crises~~, in particular~~ ***and*** when voluntary agreements are unavailable ~~or inadequate~~***and cannot be reached within four weeks***. At a time where the Union and its Member States are striving to improve their resilience to crises, it is necessary to provide	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	system for crisis management that takes the full advantage of the internal market and allows Member States to support one another in crises.	**required to manufacture these products, which are protected by intellectual property rights** ~~are unavailable or inadequate~~. At a time where the Union and its Member States are striving to improve their resilience to crises, it is necessary to provide for an optimal compulsory licensing system for crisis management that takes the full advantage of the internal market and allows Member States to support one another in crises.	for an optimal compulsory licensing system for crisis management that takes the full advantage of the internal market and allows Member States to support one another in crises.	
Recital 6				
16	(6) Therefore, it is necessary to establish a compulsory licence for crisis or emergency management at Union level. Under this system, the Commission should be empowered to grant a compulsory licence that is valid throughout the Union and that allows the manufacturing and distribution of products necessary to address a crisis or emergency in the Union ('Union compulsory licence').	(6) Therefore, it is necessary to establish a compulsory licence for crisis or emergency management at Union level**, that exists in addition to national compulsory licensing systems**. Under ~~this~~**the Union compulsory licensing** system~~,~~ the Commission**, after considering the opinion of the advisory body,** should be empowered to grant**, in the public interest and as an exceptional measure,** a compulsory licence that is valid throughout the Union and that allows the ~~manufacturing and distribution of~~**use of an invention protected by intellectual property rights to**	(6) Therefore, it is necessary to establish a compulsory licence for crisis or emergency management at Union level. Under this system, the Commission should be empowered to grant a compulsory licence that is valid throughout the Union and that allows the manufacturing and distribution of products necessary to address a crisis or emergency in the Union ('Union compulsory licence').	Agreed to put "temporary and non-exclusive" in recital 6 Recital 6 to be discussed further

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		supply products necessary to address a crisis or emergency in the Union ~~('Union compulsory licence')~~.		
Recital 6a				
16a			***(6a) The Commission might only issue a Union compulsory license for any crisis emergency-related product where the rights holder, who has been given the opportunity to engage in negotiations with a potential licensee, did not reach an agreement within 4 weeks.***	
Recital 7				
R 17	(7) In recent years, the European Union has adopted several crisis mechanisms to improve its resilience to crises or emergencies affecting the Union. The recent mechanisms include the Single Market Emergency Instrument (SMEI) established under Regulation (EU) No XXX/XX [COM(2022) 459] and Regulation (EU) No 2022/2371 under which the Commission may recognise a public health emergency at Union level. In the event of a public health emergency at Union level a framework of measures for ensuring the supply	(7) In recent years, the European Union has adopted several crisis mechanisms to improve its resilience to crises or emergencies affecting the Union. The recent mechanisms include the ~~Single~~**Internal** Market Emergency ~~Instrument (SMEI~~**and Resilience Act (IMERA)** established under Regulation (EU) No XXX/XX [COM(2022) 459] ~~and~~ **,**Regulation (EU) ~~No 2022/2371~~**2022/2371 of the European Parliament and of the Council**[1] under which the Commission may recognise a public health emergency at Union	(7) In recent years, the European Union has adopted several crisis mechanisms to improve its resilience to crises or emergencies affecting the Union. The recent mechanisms include the Single Market Emergency Instrument (SMEI) established under Regulation (EU) No XXX/XX [COM(2022) 459] and Regulation (EU) No 2022/2371 under which the Commission may recognise a public health emergency at Union level. In the event of a public health emergency at Union level a framework of measures for ensuring the supply	Trilogue I - 10/12/2024 To be negotiated at political level R

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	of crisis-relevant medical countermeasures might be activated under Regulation (EU) No 2022/2372. Furthermore, in case of a significant shortage of semiconductors due to serious disruptions in their supply, the Commission may activate a crisis stage by means of implementing acts under Regulation (EU) No XXX/XX (Chips Act) [COM(2022) 46].	level~~.~~**, as well as Council Regulation (EU) 2022/2372[2] that,** in the event of a public health emergency at Union level**, provides** a framework of measures for ensuring the supply of crisis-relevant medical countermeasures~~ might be activated under Regulation (EU) No 2022/2372. Furthermore, in case of a significant shortage of semiconductors due to serious disruptions in their supply, the Commission may activate a crisis stage by means of implementing acts under Regulation (EU) No XXX/XX (Chips Act) [COM(2022) 46].~~**..** _____ **1. [1] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26).** **2. [2] Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for**	of crisis-relevant medical countermeasures might be activated under Regulation (EU) No 2022/2372. Furthermore, in case of a significant shortage of semiconductors due to serious disruptions in their supply, the Commission may activate a crisis stage by means of implementing acts under Regulation (EU) No XXX/XX (Chips Act) [COM(2022) 46].	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (OJ L 314, 6.12.2022, p. 64).		
Recital 8				
18	(8) These mechanisms provide for the activation of an emergency or crisis mode and aim at providing the means to address Union emergencies. By allowing the Commission to grant a compulsory licence when a crisis or emergency mode has been activated by a Union legal act, the necessary synergy between the existing crisis mechanisms and a Union wide compulsory licencing scheme is achieved. In such a case, the determination of the existence of a crisis or emergency depends solely on the Union legal act underlying the crisis mechanism and the crisis definition included therein. For the sake of legal certainty, the crisis mechanisms that qualify as Union emergency or extreme urgency measures and that can trigger a Union compulsory licence should be	(8) These mechanisms provide for the activation of ~~an~~**a crisis or** emergency ~~or crisis~~ mode and aim at providing the means to address Union emergencies. By allowing the Commission to grant a **Union** compulsory licence when a crisis or emergency mode has been activated by a Union legal act, the necessary synergy between the ~~existing~~**relevant** crisis mechanisms and a Union wide compulsory licencing scheme is achieved. In such a case, the determination of the existence of a crisis or emergency depends solely on the Union legal act underlying the crisis mechanism and the crisis definition included therein. For the sake of legal certainty, the crisis mechanisms that qualify as Union emergency or extreme urgency measures and that can trigger a Union compulsory licence should	(8) These mechanisms provide for the activation of an emergency or crisis mode and aim at providing the means to address Union emergencies. By allowing the Commission to grant a compulsory licence when a crisis or emergency mode has been activated by a Union legal act, the necessary synergy between the existing crisis mechanisms and a Union wide compulsory licencing scheme is achieved. In such a case, the determination of the existence of a crisis or emergency depends solely on the Union legal act underlying the crisis mechanism and the crisis definition included therein. For the sake of legal certainty, the crisis mechanisms that qualify as Union emergency or extreme urgency measures and that can trigger a Union compulsory licence should be	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	listed in an Annex to this Regulation.	be listed in ~~an Annex to~~ this Regulation.	listed in an Annex to this Regulation.	
Recital 9				
19	(9) To ensure optimal efficiency of the Union compulsory licence as a tool to address crises, it should be made available in respect of a granted patent or utility model, of a published patent application or a supplementary protection certificate. The Union compulsory licence should equally apply to a national patents, European patents and European patents with unitary effect.	(9) To ensure optimal efficiency of the Union compulsory licence as a tool ~~to address~~ **in addressing** crises **or emergencies**, it should be made available in respect of a granted patent or utility model~~, of a published patent application~~ or a supplementary protection certificate**. It should also be available in respect of a published patent application or a published utility model application**. The Union compulsory licence should equally apply to ~~a~~ national patents, European patents and European patents with unitary effect.	(9) To ensure optimal efficiency of the Union compulsory licence as a tool to address crises, it should be made available in respect of a granted patent or utility model, of a published patent application or a supplementary protection certificate. The Union compulsory licence should equally apply to a national patents, European patents and European patents with unitary effect.	
Recital 10				
20	(10) Utility model systems protect new technical inventions that do not fulfil the patentability requirements through the granting of an exclusive right to prevent others, for a limited period of time, from commercially exploiting the protected inventions without consent of the right holders. The definition of utility	(10) Utility model systems ~~protect new~~**offer protection for** technical inventions **under criteria that are, as a general rule, less stringent than those for patents . The owner of a utility model is granted**~~that do not fulfil the patentability requirements through the granting of~~ an exclusive right to prevent others,	(10) Utility model systems protect new technical inventions that do not fulfil the patentability requirements through the granting of an exclusive right to prevent others, for a limited period of time, from commercially exploiting the protected inventions without consent of the right holders. The definition of utility models varies	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	models varies from one country to another, and not all Member States provide for utility model systems. In general, utility models are suited for protecting inventions that make small improvements to, or adaptations of, existing products, or that have a short commercial life. However, similarly to patents, utility models can protect inventions that could prove necessary to address a crisis and should therefore be included in the scope of the Union compulsory licence.	for a limited period of time, from commercially exploiting the protected ~~inventions~~**invention** without consent of the right holders. The definition of utility models varies from one country to another, and not all Member States provide for utility model systems. In general, utility models are suited for protecting inventions that make small improvements to, or adaptations of, existing products, or that have a short commercial life. However, similarly to patents, utility models can protect inventions that could prove necessary to address a crisis and should therefore be included in the scope of the Union compulsory licence.	from one country to another, and not all Member States provide for utility model systems. In general, utility models are suited for protecting inventions that make small improvements to, or adaptations of, existing products, or that have a short commercial life. However, similarly to patents, utility models can protect inventions that could prove necessary to address a crisis and should therefore be included in the scope of the Union compulsory licence.	
Recital 11				
21	(11) A Union compulsory licence for a patent should extend to the supplementary protection certificate where such protection is granted when the patent expires during the duration period of that compulsory licence. This would allow a compulsory licence on a patent to produce its effect should the crisis-relevant products no longer be protected by a patent while being protected through a	(11) A Union compulsory licence for a patent should extend to the supplementary protection certificate where such protection is granted when the patent expires during the duration period of that compulsory licence **and where the supplementary protection certificate covers the crisis-relevant product. The Union compulsory licence should specify, where relevant, such**	(11) A Union compulsory licence for a patent should extend to the supplementary protection certificate where such protection is granted when the patent expires during the duration period of that compulsory licence. This would allow a compulsory licence on a patent to produce its effect should the crisis-relevant products no longer be protected by a patent while being protected through a	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	supplementary protection certificate after the expiration of the patent. It should also apply to a supplementary protection certificate in isolation where the licence is granted after the expiry of the patent.	**extension to the supplementary protection certificate. This extension**~~. This~~ would allow a **Union** compulsory licence on a patent to produce its effect should the crisis-relevant products no longer be protected by a patent while being protected through a supplementary protection certificate after the ~~expiration~~**expiry** of the patent. It should also apply to a supplementary protection certificate in isolation where the licence is granted after the expiry of the patent.	supplementary protection certificate after the expiration of the patent. It should also apply to a supplementary protection certificate in isolation where the licence is granted after the expiry of the patent.	
Recital 12				
22	(12) The Union compulsory licence should also apply to published patent applications for national patents and for European patents. As the grant of a patent after the publishing of the patent application can take years, targeting only inventions protected by a granted patent could prevent an effective and timely crisis response. In crises, solutions can derive from the latest state-of-the-art technology. Moreover, certain national patent legislations, as well as the European Patent Convention, provide for protection	(12) The Union compulsory licence should also apply to published patent applications for national patents and for European patents**, as well as to published utility model applications**. As the grant of a patent after the publishing of the patent application can take years, targeting only inventions protected by a granted patent could prevent an effective and timely crisis response. In crises, solutions can derive from the latest state-of-the-art technology. Moreover, certain national patent legislations, as well	(12) The Union compulsory licence should also apply to published patent applications for national patents and for European patents. As the grant of a patent after the publishing of the patent application can take years, targeting only inventions protected by a granted patent could prevent an effective and timely crisis response. In crises, solutions can derive from the latest state-of-the-art technology. Moreover, certain national patent legislations, as well as the European Patent Convention, provide for protection	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	of patent applicants with regard to unconsented use of their inventions and the corresponding possibility for such applicants to licence the use of their patent application rights. In order to ensure that a Union compulsory licence on a published patent application continues to keep its effects once the patent is granted, the Union compulsory licence for published patent applications should extend to the patent once granted to the extent that the crisis-relevant product still falls within the scope of the patent claims.	as the European Patent Convention, provide for **provisional** protection of patent applicants with regard to unconsented use of their inventions and the corresponding possibility for such applicants to licence the use of their patent application rights. **For similar reasons, it should be ensured that a Union compulsory licence also applies to published utility model applications. This Regulation does not harmonise national legislation regulating provisional protection accorded to published patent applications and utility model applications.** In order to ensure that a Union compulsory licence on a published patent application **or utility model application** continues to keep its effects once the patent **or utility model** is granted, the Union compulsory licence for published patent applications **or utility model applications** should extend to the patent **or utility model** once granted to the extent that the crisis-relevant product still falls within the **final** scope of ~~the patent claims~~**protection of these**	of patent applicants with regard to unconsented use of their inventions and the corresponding possibility for such applicants to licence the use of their patent application rights. In order to ensure that a Union compulsory licence on a published patent application continues to keep its effects once the patent is granted, the Union compulsory licence for published patent applications should extend to the patent once granted to the extent that the crisis-relevant product still falls within the scope of the patent claims.	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		intellectual property rights as granted.		
Recital 13				
R 23	(13) It should be clarified that this Regulation is without prejudice to Union law on copyright and related rights, including Directives 96/9[1], 2009/24[2] Directives 2001/29/EC[3], 2004/48/EC[4] and (EU) 2019/790[5] of the European Parliament and of the Council, which establish specific rules and procedures that should remain unaffected. _____ 1. Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases (OJ L 77, 27.3.1996, p. 20) 2. Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs (OJ L 111, 5.5.2009, p. 16) 3. Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain	(13) It should be clarified that this Regulation is without prejudice to Union law on copyright and related rights, including Directives 96/9[1], 2009/24[2] ~~Directives~~**,** 2001/29/EC[3], 2004/48/EC[4] and (EU) 2019/790[5] of the European Parliament and of the Council, which establish specific rules and procedures that should remain unaffected. **It should also be clarified that this Regulation is without prejudice to Directive (EU) 2016/943 of the European Parliament and the Council[6]. In addition, no provision of this Regulation should be interpreted as imposing any obligation to disclose undisclosed know-how, business information or technological information protected by trade secrets as defined by Directive (EU) 2016/943.** _____ 1. **[1]** Directive 96/9/EC of the European Parliament and of the Council of 11 March	(13) It should be clarified that this Regulation is without prejudice to Union law on copyright and related rights, including Directives 96/9[1], 2009/24[2] Directives 2001/29/EC[3], 2004/48/EC[4] and (EU) 2019/790[5] of the European Parliament and of the Council, which establish specific rules and procedures that should remain unaffected. _____ 1. Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases (OJ L 77, 27.3.1996, p. 20) 2. Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs (OJ L 111, 5.5.2009, p. 16) 3. Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain	Trilogue I - 10/12/2024 To be negotiated at political level

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	aspects of copyright and related rights in the information society (OJ L 167, 22.6.2001, p. 10). 4. Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157, 30.4.2004, p. 45). 5. 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 (OJ L 130, 17.5.2019, p. 92).	1996 on the legal protection of databases (OJ L 77, 27.3.1996, p. 20) 2. **[2]** Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs (OJ L 111, 5.5.2009, p. 16) 3. **[3]** Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society (OJ L 167, 22.6.2001, p. 10). 4. **[4]** Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157, 30.4.2004, p. 45). 5. **[5]** 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	aspects of copyright and related rights in the information society (OJ L 167, 22.6.2001, p. 10). 4. Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157, 30.4.2004, p. 45). 5. 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 (OJ L 130, 17.5.2019, p. 92).	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		Directives 96/9/EC and 2001/29/EC (OJ L 130, 17.5.2019, p. 92). **6. Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1).**		
Recital 13a				
23a		**(13a) The Union crisis or emergency mechanisms provide for dedicated measures aimed at ensuring the supply of products that are critical for tackling a crisis or emergency or their direct impacts, in the territory of the Union. Such measures include, for instance, priority-rated orders for crisis-relevant products, a joint procurement procedure as well as the possibility for the Commission to act as a central purchasing body. Considering that the Union compulsory licencing framework is intended to**		

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		complement the relevant Union crisis or emergency mechanism, the supply and distribution of the crisis-relevant products manufactured under a Union compulsory licence should be carried out within the framework of the specific measures provided for in the relevant crisis or emergency instrument. These measures should set out the details related to manufacturing and distribution of crisis-relevant products. In addition, a Union compulsory licence should not allow for the manufacturing of products that are excluded from the scope of the relevant crisis or emergency mechanism.		
Recital 14				
24	(14) When a compulsory licence has been granted, regulatory data protection may, if still in force, prevent the effective use of the compulsory licence as it impedes the authorisation of generic medicinal products. This would result in serious negative consequences for Union compulsory licences granted to tackle a crisis, as this could hamper access to the medicinal	(14) [1] When a compulsory licence has been granted, regulatory data protection may, if still in force, prevent the effective use of the compulsory licence as it impedes the authorisation of generic medicinal products. This would result in serious negative consequences for Union compulsory licences granted to tackle a crisis, as this could ~~hamper~~**impact** access to the	(14) When a compulsory licence has been granted, regulatory data protection may, if still in force, prevent the effective use of the compulsory licence as it impedes the authorisation of generic medicinal products. This would result in serious negative consequences for Union compulsory licences granted to tackle a crisis, as this could hamper access to the medicinal	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	products needed to address the crisis. For this reason, Union pharmaceutical legislation (cf. Art. 80 para. 4 of Directive (EU) No XXX/XX [COM(2023)192]) provides for the suspension of data exclusivity and market protection when a compulsory licence has been issued to tackle a public health emergency. Such suspension is allowed only in relation to the compulsory licence granted and its beneficiary and must comply with the objectives, the territorial scope, the duration, and the subject-matter of the granted compulsory licence. The suspension means that the data exclusivity and market protection produce no effect in relation to the licensee of the compulsory licence while that licence is in effect. When the compulsory licence ends, the data exclusivity and market protection resume their effect. The suspension should not result in an extension of the original duration of the regulatory data protection.	medicinal products needed to address the crisis. For this reason, Union pharmaceutical legislation (cf. Art. 80 para. 4 of Directive (EU) No XXX/XX [COM(2023)192]) provides for the suspension of data exclusivity and market protection when a compulsory licence has been issued to tackle a public health emergency. Such suspension is allowed only in relation to the compulsory licence granted and its beneficiary and must comply with the objectives, the territorial scope, the duration, and the subject-matter of the granted compulsory licence. The suspension means that the data exclusivity and market protection produce no effect in relation to the licensee of the compulsory licence while that licence is in effect. When the compulsory licence ends, the data exclusivity and market protection resume their effect. The suspension should not result in an extension of the original duration of the regulatory data protection. _____ **1. [1] Recital to be ultimately kept, adapted or**	products needed to address the crisis. For this reason, Union pharmaceutical legislation (cf. Art. 80 para. 4 of Directive (EU) No XXX/XX [COM(2023)192]) provides for the suspension of data exclusivity and market protection when a compulsory licence has been issued to tackle a public health emergency. Such suspension is allowed only in relation to the compulsory licence granted and its beneficiary and must comply with the objectives, the territorial scope, the duration, and the subject-matter of the granted compulsory licence. The suspension means that the data exclusivity and market protection produce no effect in relation to the licensee of the compulsory licence while that licence is in effect. When the compulsory licence ends, the data exclusivity and market protection resume their effect. The suspension should not result in an extension of the original duration of the regulatory data protection.	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		deleted during the negotiations with the European Parliament depending on the progress of the Pharma package.		
Recital 15				
25	(15) In order to ensure as much coherence as possible with existing crisis mechanisms and with other Union legislation, the definition of a 'crisis-relevant product' should be based on the definition adopted in the Single Market Emergency Instrument (SMEI) but should be more general in order to cover products related to different kinds of crises or emergencies.	(15) In order to ensure as much coherence as possible with existing crisis mechanisms ~~and with other Union legislation~~, the definition of a 'crisis-relevant product' should be ~~based on the definition adopted in the Single Market Emergency Instrument (SMEI) but should be more~~**sufficiently** general ~~in order~~**so as** to cover products related to different kinds of ~~crises or emergencies~~**crisis or emergency modes under the respective Union legal acts listed in this Regulation**.	(15) In order to ensure as much coherence as possible with existing crisis mechanisms ***and their requirements pertaining to the public interest*** and with other Union legislation, the definition of a 'crisis-relevant product' should be based on the definition adopted in the Single Market Emergency Instrument (SMEI) but should be more general in order to cover products related to different kinds of crises or emergencies.	Trilogue I - 10/12/2024 "Scope" to be negotiated at political level
Recital 15a				
25a		**(15a) A Union compulsory licence should only be granted when specific conditions are fulfilled. In particular, given the fact that the Union compulsory licensing framework complements the Union crisis or emergency mechanisms, a Union**		

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		compulsory licence should only be granted where a crisis or emergency mode listed in the Annex has been activated or declared. In addition, a Union compulsory licence should only be relied upon in situations in which the use of an invention protected by intellectual property rights is required to supply crisis-relevant products in the territory of the Union. As a further condition, a Union compulsory licence should only be granted as a measure of last resort in the sense that it should only be granted where means other than a Union compulsory licence, including voluntary agreements to use an invention protected by intellectual property rights concerning crisis-relevant products, could not ensure access to these products. The second and third conditions should be evaluated and assessed by the Commission, with the assistance and advice of the competent advisory body, in accordance with the procedure under this Regulation. Finally, it is of utmost importance that rights-holders are given the		

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		opportunity to provide their comments in order to safeguard their rights, as well as to enable the advisory body to obtain all information necessary.		
Recital 16				
26	(16) A Union compulsory licence authorises the use of a protected invention without the consent of the rights-holder. Therefore, it must only be granted exceptionally and under conditions that take into account the interests of the rights-holder. This includes a clear determination of the scope, duration and territorial coverage of the licence. In the context of a Union level crisis mechanism, the crisis mode or emergency mode is activated or declared for a limited period of time. Where a Union compulsory licence is granted within such framework, the duration of the licence shall not extend beyond the duration of the activated or declared crisis or emergency mode. In order to ensure that the compulsory licence fulfils its objective as well as its conditions, the use of the invention should only be authorised to a qualified person able to manufacture the crisis-	(16) A Union compulsory licence authorises the use of a protected invention without the consent of the rights-holder. Therefore, it must only be granted exceptionally and under conditions that take into account the interests of the rights-holder. This includes a clear determination of the scope, duration and territorial coverage of the licence. In the context of a Union level crisis mechanism, the crisis mode or emergency mode is activated or declared for a limited period of time. Where a Union compulsory licence is granted within such framework, the duration of the licence shall not extend beyond the duration of the activated or declared crisis or emergency mode. In order to ensure that the **Union** compulsory licence fulfils its objective as well as its conditions, the use of the invention should only be authorised to a qualified ~~person able~~ **entity that has the capacity**	(16) A Union compulsory licence authorises the use of a protected invention without the consent of the rights-holder. Therefore, it must only be granted exceptionally ***with the purpose of safeguarding the public interest, as a last resort mechanism,*** and under conditions that take into account the interests of the rights-holder. This includes a clear determination of the scope, duration and territorial coverage of the licence ***which are strictly in line with the duration of the crisis and the purpose for which the compulsory licence was granted***. In the context of a Union level crisis mechanism, the crisis mode or emergency mode is activated or declared for a limited period of time. Where a Union compulsory licence is granted within such framework, the duration of the licence shall not extend beyond the duration of the activated or declared crisis or emergency mode	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	relevant product and to pay a reasonable remuneration to the rights-holder.	**to efficiently exploit the protected invention and consequently** to manufacture the crisis-relevant product and to pay ~~a reasonable~~**an adequate** remuneration to the rights-holder. **When selecting potential licensees, the Commission should also take into account criteria such as the price of crisis-relevant products, the licensees' capacity to supply them in necessary quantities, in a timely fashion, with the quality required in the relevant area, and in compliance with all the industrial and sanitary requirements. To that end, potential licensees should provide any information deemed relevant for this purpose in the course of the procedure for granting a Union compulsory licence, as well as information about any changes to their capacity that occurred after the granting of the licence.**	***and in principle should not exceed 12 months, unless a renewal is necessary due to the continued existence of the circumstances that had led to the granting of the licence***. In order to ensure that the compulsory licence fulfils its objective as well as its conditions, the use of the invention should only be authorised to a qualified person able to manufacture the crisis-relevant product and to pay a reasonable remuneration to the rights-holder.	
Recital 17				
27	(17) When considering the granting of a Union compulsory licence, the Commission should, in order to be able to take a well-informed decision, be assisted by	(17) When considering the granting of a Union compulsory licence, the Commission should, in order to be able to take a well-informed decision, be assisted **and**	(17) When considering the granting of a Union compulsory licence, the Commission should, in order to be able to take a well-informed decision, be assisted by	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	an advisory body. The consultation of the advisory body should arise early in the discussions on the need to issue a compulsory licence under the relevant instrument. Discussions on whether there is a need for a Union compulsory licence will often start already in the context of the work of the advisory body involved in the context of the relevant Union crisis or emergency mechanisms. In such case, there is no need for the Commission to convene the advisory body but rather to swiftly indicate that that body also has the competence to assess the need for compulsory licensing at Union level, and the conditions thereof. Clarification as regards the competence of the advisory body should be given early in the process, as soon as concrete consideration of using compulsory licensing at Union level is expressed by the Commission.	**advised** by an advisory body~~. The consultation of the advisory body should arise early in the discussions on the need to issue a compulsory licence under the relevant instrument~~. Discussions on whether there is a need for a Union compulsory licence will often start already in the context of the work of the advisory body involved ~~in the context of~~**under** the relevant Union crisis or emergency mechanisms. ~~In such case, there is no need for~~**These early discussions should already provide** the Commission ~~to convene~~**with information on the lack of supply of crisis-relevant products, available manufacturing capacities, as well as, when possible, initial information on the intellectual property rights and the rights-holders concerned. As part of the early discussions within** the advisory body~~ but rather to swiftly indicate that that body also has the competence to~~**, the Commission should also** assess **whether the specific measures taken under the relevant crisis or emergency mechanism are sufficient to address the lack of supply of**	an advisory body. The consultation of the advisory body should arise early in the discussions on the need to issue a compulsory licence under the relevant instrument. Discussions on whether there is a need for a Union compulsory licence will often start already in the context of the work of the advisory body involved in the context of the relevant Union crisis or emergency mechanisms. In such case, there is no need for the Commission to convene the advisory body but rather to swiftly indicate that that body also has the competence to assess the need for compulsory licensing at Union level, and the conditions thereof. Clarification as regards the competence of the advisory body should be given early in the process, as soon as concrete consideration of using compulsory licensing at Union level is expressed by the Commission.	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		crisis-relevant products. If this is not the case and a Union~~the need for~~ compulsory ~~licensing at Union level, and the conditions thereof. Clarification as regards the competence of~~**licence seems, a priori, necessary,** the advisory body should ~~be given early in the process, as soon as concrete consideration of using~~**provide the Commission with a clearer idea of how products manufactured under the Union** compulsory ~~licensing at Union level is expressed by~~**licence could be adequately delivered via these measures. The preliminary information gathered by the advisory body should help** the Commission **in determining whether to initiate the procedure for granting a Union compulsory licence, as well as the content of the notice to be published for this purpose**.		
Recital 18				
28	(18) The participation of an advisory body aims at guaranteeing a comprehensive, thorough, and concrete assessment of the situation, taking into consideration the individual merits of each situation. It is therefore	(18) The participation of an advisory body aims at guaranteeing a comprehensive, thorough, and concrete assessment of the situation, taking into consideration the individual merits of each situation. It is therefore	(18) The participation of an advisory body aims at guaranteeing a comprehensive, thorough, and concrete assessment of the situation, taking into consideration the individual merits of each situation. It is therefore	Trilogue I - 10/12/2024 "Scope" to be negotiated at political level

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	important that the advisory body has the right composition, expertise, and procedures to support the Commission when deciding on whether to grant a Union compulsory licence and under what conditions. Union crisis mechanisms usually include the setting-up of an advisory body ensuring coordination of action of the Commission and relevant bodies and agencies, the Council and the Member States. In this respect, an advisory group is set up under SMEI. Regulation (EU) No 2022/2371 provides for a Health Crisis Board and under Regulation (EU) No XXX/XX (Chips Act) [COM/2022) 46], the Commission relies on the Semiconductor Board. Those advisory bodies have the right composition, expertise, and procedures to address the crises and emergencies for which they have been set-up. When compulsory licensing is being discussed in the context of such crisis instrument, relying on the advisory body set-up for the specific instrument allows the Commission to be adequately advised and avoid duplication of	important that the advisory body has the right composition, expertise, and procedures to support the Commission when deciding on whether to grant a Union compulsory licence and ~~under what conditions~~**on the content of the compulsory licence**. Union crisis mechanisms usually include the setting-up of an advisory body ensuring coordination of action of the Commission and relevant bodies and agencies, the Council and the Member States. In this respect, an ~~advisory group~~ **Internal Market Emergency and Resilience Board** is set up under ~~SMEI. Regulation (EU) No 2022/2371 provides for~~**IMERA, while Regulations (EU) 2022/2371 and (EU) 2022/2372 provide for a Health Security Committee and** a Health Crisis Board ~~and under Regulation (EU) No XXX/XX (Chips Act) [COM/2022) 46], the Commission relies on the Semiconductor Board~~**respectively**. Those advisory bodies have the right composition, expertise, and procedures to address the crises and emergencies for which they	important that the advisory body has the right composition, expertise, and procedures to support the Commission when deciding on whether to grant a Union compulsory licence and under what conditions. Union crisis mechanisms usually include the setting-up of an advisory body ensuring coordination of action of the Commission and relevant bodies and agencies, the Council and the Member States. In this respect, an advisory group is set up under SMEI. Regulation (EU) No 2022/2371 provides for a Health Crisis Board and under Regulation (EU) No XXX/XX (Chips Act) [COM/2022) 46], the Commission relies on the Semiconductor Board. Those advisory bodies have the right composition, expertise, and procedures to address the crises and emergencies for which they have been set-up. When compulsory licensing is being discussed in the context of such crisis instrument, relying on the advisory body set-up for the specific instrument allows the Commission to be adequately advised and avoid duplication of	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	advisory bodies, leading to incoherences between processes. The competent advisory bodies shall be listed, together with the corresponding crisis mechanisms, in an Annex to this Regulation. In case the Union crisis mechanism does not provide for an advisory body, the Commission should set up an ad hoc advisory body for the granting of the Union (the 'ad hoc advisory body').	have been set-up. When compulsory licensing is being discussed in the context of such crisis instrument, relying on the advisory body set-up for the specific instrument allows the Commission to be adequately advised and avoid duplication of advisory bodies, leading to incoherences between processes. **However, considering the specific role of the advisory body, it should be ensured that the said body draws on additional expertise in intellectual property rights, in particular patents, and in the granting of compulsory licenses.** The competent advisory bodies shall be listed, together with the corresponding crisis mechanisms, in an Annex to this Regulation. ~~In case the Union crisis mechanism does not provide for an advisory body, the Commission should set up an ad hoc advisory body for the granting of the Union (the 'ad hoc advisory body').~~	advisory bodies, leading to incoherences between processes. The competent advisory bodies ~~*shall*~~***should*** be listed, together with the corresponding crisis mechanisms, in an Annex to this Regulation. ***The Commission should ensure that representatives of other crisis-relevant bodies at Union level participate in, and are invited as observers to, the relevant meetings of the advisory body in order to ensure consistency with the measures implemented through other Union mechanisms. It is important that the Commission invites as observers national representatives from all national authorities responsible for issuing compulsory licenses under their national patent laws.*** In case the Union crisis mechanism does not provide for an advisory body, the ~~*Commission should set up an ad hoc*~~ advisory body ~~*for the granting*~~***should be constituted on an ad-hoc basis by the Commission and should be composed of representatives*** of the ~~*Union (the 'ad hoc advisory body')*~~***institutions and bodies of***

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
			the Member States that exercise the competence to grant national compulsory licences under national laws.	
Recital 19				
29	(19) The role of the advisory body is to advise the Commission when discussions arise on the need to rely on compulsory licensing at Union level. It should provide the Commission with a non-binding opinion. Its main tasks include assisting of the Commission in the determination of the necessity to rely on compulsory licensing at Union level, and in the determination of the conditions for such licensing. When the advisory body is already set up, its existing rules of procedure should apply. As regards ad hoc advisory bodies, they should be composed of one representative of each Member State in order to provide the Commission with information and input concerning the situation on the national level, including information on manufacturing capacities, potential licensees and, if applicable, proposals for voluntary solutions. In addition, the advisory body should have the function of collecting and	(19) The role of the advisory body is to **assist and** advise the Commission when discussions arise on the need to rely on **a Union** compulsory ~~licensing at Union level. It~~**licence and its content . To achieve this, the advisory body** should ~~provide the Commission with a non-binding opinion. Its main tasks include assisting of~~**support** the Commission in **taking the necessary steps to identify the intellectual property rights concerned and the rights-holders. To allow for the widest dissemination of information on the initiation**~~the determination~~ of the ~~necessity to rely on~~**procedure for granting a Union** compulsory ~~licensing at Union level~~**licence**, ~~and in the determination of the conditions for such licensing. When~~ the advisory body ~~is already set up, its existing rules of procedure~~ should ~~apply. As regards ad hoc~~**contact the national intellectual property**	(19) The role of the advisory body is to advise the Commission when discussions arise on the need to rely on compulsory licensing at Union level. It should provide the Commission with a non-binding opinion. Its main tasks include assisting of the Commission in the determination of the necessity to rely on compulsory licensing at Union level, and in the determination of the conditions for such licensing. When the advisory body is already set up, its existing rules of procedure should apply. As regards ad hoc advisory bodies, they should be composed of ~~*one representative of each Member State*~~***those representatives of national competent authorities*** in order to provide the Commission with information and input concerning the situation on the national level, including information on manufacturing capacities, potential licensees and~~*,*~~ ~~*if applicable,*~~ proposals for voluntary solutions. In addition,	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	analysing relevant data, as well as ensuring coherence and cooperation with other crisis relevant bodies at Union and national level in order to ensure an adequate, coordinated and coherent crisis reply at Union level.	**offices, the relevant business and industry associations as well as international organisations. The** advisory ~~bodies, they~~**body** should ~~be composed of one representative of each Member State in order to provide~~**draw the attention of these entities to the notice published by** the Commission ~~with information and input concerning the situation~~ on the ~~national level, including~~**initiation of the procedure for granting a Union compulsory licence, containing the relevant** information ~~on manufacturing capacities, potential licensees and, if applicable, proposals for voluntary solutions. In addition~~ **and should encourage its further distribution by any means appropriate. As the Union compulsory licence can only be granted to a licensee having the capacity, including facilities, expertise and supply chains, to manufacture crisis-relevant products efficiently and swiftly**, the advisory body should **assist the Commission in identifying potential licensees and establishing whether they meet this requirement. Rights-holders**	the advisory body should have the function of collecting and analysing relevant data, as well as ensuring coherence and cooperation with other crisis relevant bodies at Union and national level in order to ensure an adequate, coordinated and coherent crisis reply at Union level.	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		and potential licensees should have the ~~function of collecting and analysing~~**opportunity to provide their arguments to the advisory body, which should analyse their written comments and invite them to participate in the** relevant ~~data, as well as ensuring coherence and cooperation with~~**meetings. These meetings should also serve as a forum to explore the possibility of reaching a voluntary agreement, with the Commission and the advisory body serving as facilitators in this respect. Alongside the rights-holders and licensees, it may be useful to invite contributions from other actors, in particular economic operators of the sectors concerned and other relevant entities such as social partners, and representatives of international bodies such as the European Patent Office or the World Health Organization. Given the importance of expediency in managing a crisis, consultations and exchanges with the various actors should be carried out quickly and by means most appropriate to the**		

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		situation. To properly consider all relevant aspects of intellectual property law and, more specifically, compulsory licensing, it is necessary to fully involve the representatives of national intellectual property offices and national authorities responsible for granting compulsory licences in the relevant discussions of the advisory body. Each Member State should designate the most suitable representatives for this. Due to its expertise, the advisory body is the most competent entity to gather and analyse the available crisis information from the Member States and from other crisis relevant bodies at Union and ~~national~~**international** level**. The analysis of this information should provide the Commission with a clearer view of the crisis, its characteristics and the way in which it could evolve,** in order to ~~ensure an adequate, coordinated and coherent crisis reply at~~**tailor the potential** Union **compulsory licence to current and future needs. As crises rarely respect borders, the advisory body**		

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		should engage in cross-border collaboration and cooperation with other crisis-relevant bodies at national, European and international level. **Finally, the advisory body assists the Commission in deciding whether to terminate or modify a granted Union compulsory licence for reasons set out in this Regulation.**		
Recital 19a				
29a		**(19a) A Union compulsory licence should only be granted in the context of a Union crisis or emergency mode. In the context of such mode, the discussions in the advisory body set up under the relevant crisis or emergency mechanism may unveil that the lack of adequate supply of crisis-relevant products results from intellectual property rights or their exercise. In these cases the Commission should have the possibility to initiate the procedure for granting a Union compulsory licence. For reasons of expediency, the Commission should initiate the procedure by publishing a notice on its website. It should publish the said notice in the Official**		

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		Journal of the European Union as soon as possible.		
Recital 19b				
29b		**(19b) The publication of the notice should serve to inform the public that discussions are ongoing as regards the possible granting of a Union compulsory licence. To that end, the notice should include information on the crisis-relevant products for which a lack of adequate supply is considered to exist as well as on the relevant intellectual property rights and the rights-holders, where available. The advisory body should assist the Commission in gathering this information. The notice should also include an invitation to rights-holders, potential licensees and other interested persons to submit their comments to the Commission and the competent advisory body. This should ensure the inclusiveness of the procedure and that all relevant information reaches the advisory body. The notice should also include information on the competent advisory body and the contact**		

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		details for submitting the comments.		
Recital 19c				
29c		**(19c) After publishing the notice, the Commission should request the competent advisory body to provide an opinion on the need for a Union compulsory licence and on its content. The Commission should be entitled to set a time limit for the issuing of the opinion, and this time limit should be reasonable in view of the circumstances of the case and of the crisis.**		
Recital 20				
30	(20) The Commission should grant the Union compulsory licence in the light of the non-binding opinion of the advisory body. Persons, in particular the licensee and the rights-holder, whose interests may be affected by the Union compulsory licence should be given the opportunity to submit their comments. These elements should enable the Commission to consider the individual merits of the situation and determine, on that basis, the adequate conditions of the licence, including an adequate	(20) **. The work performed under this Regulation by the advisory body for the purposes of advising and assisting** the Commission should ~~grant ther~~**result in an opinion including an assessment of the need for a** Union compulsory licence ~~in the light of the non-binding~~**and its content. The** opinion of the advisory body~~. Persons, in particular the licensee and the rights-holder, whose interests may be affected by the~~ **on the granting of a** Union compulsory licence should **not be binding. The**	(20) The Commission should grant the Union compulsory licence in the light of the non-binding opinion of the advisory body. Persons, in particular the licensee and the rights-holder, whose interests may be affected by the Union compulsory licence should be given the opportunity to submit their comments***, within a reasonable timeframe, to the advisory body upon receiving the case file and analyses presented to or conducted by the advisory body, and be provided with any other pertinent information they***	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	remuneration to be paid by the licensee to the rights-holder. To avoid overproduction of products manufactured under a Union compulsory licence, the Commission should also consider any existing compulsory licences at national level.	**opinion should include the above-mentioned assessment that**~~be given the opportunity to submit their comments. These elements~~ should enable the Commission to consider the individual merits of the ~~situation~~**case** and determine, on that basis, the ~~adequate~~ conditions of the **Union compulsory** licence, including ~~an adequate~~**the** remuneration to be paid by the licensee to the rights-holder. ~~To avoid overproduction of products manufactured under a Union compulsory licence, the Commission~~**Furthermore, the opinion** should also ~~consider any existing compulsory licences at national level~~**include an annex containing explanations, arguments, factual elements and results of the analyses conducted, which have been taken into account to carry out the assessments submitted in the opinion**. **The protection of confidential information is of paramount importance and should be preserved throughout the procedure, including when deciding whether and how**	***require for their evaluation of the potential repercussions of a proposed Union compulsory license on their intellectual property rights***. These elements should enable the Commission to consider the individual merits of the situation and determine, on that basis, the adequate conditions of the licence, including an adequate remuneration to be paid by the licensee to the rights-holder. To avoid overproduction of products manufactured under a Union compulsory licence, the Commission should also consider any existing compulsory licences at national level.	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		information should be included in the opinion and the annexes.		
Recital 21				
31	(21) The Commission should guarantee that the rights-holder has the right to be heard before the adoption of the Union compulsory licence. Therefore, the Commission should inform the concerned rights-holder, where possible individually, without undue delay that a Union compulsory licence might be granted. The involvement of the rights-holder should be possible once there are ongoing advanced discussions in the relevant advisory body as regards the granting of a Union compulsory licence.	(21) **After receiving the opinion from the advisory body**~~The Commission should guarantee that the rights-holder has the right to be heard before the adoption of the Union compulsory licence. Therefore~~, the Commission should ~~inform the concerned rights-holder, where possible individually, without undue delay that a Union compulsory licence might be granted. The involvement of the rights-holder should be possible once there are ongoing advanced discussions in the relevant advisory body as regards~~**assess whether to continue the procedure for** the granting of a Union compulsory licence. **Where the Commission, having taken into account the opinion of the advisory body, considers that continuing the procedure is justified, it should inform, as soon as reasonably practicable, the rights-holder, whose interests may be affected by the Union compulsory licence, and the potential licensees. The**	(21) The Commission should guarantee that the rights-holder has the right to be heard before the adoption of the Union compulsory licence. Therefore, the Commission should inform the concerned rights-holder, ~~*where possible*~~ individually, without undue delay that a Union compulsory licence might be granted. The involvement of the rights-holder should be possible once there are ongoing advanced discussions in the relevant advisory body as regards the granting of a Union compulsory licence.	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		Commission should inform them of the envisaged content of the Union compulsory licence and provide a summary of the opinion of the advisory body. In addition, the Commission should invite them to submit comments within a set time limit.		
Recital 21a				
31a		**(21a) Throughout the procedure for the granting of a Union compulsory licence, the concerned rights-holders should be able to provide their comments. The involvement of the rights-holders should be ensured at every relevant step of the granting procedure, from its start, with the publication of the notice and, until its final stages, namely after the advisory body has issued its opinion. This should ensure the protection of the rights-holders' rights and interests and allow for the exploration of ways for reaching voluntary solutions that would adequately, efficiently, and swiftly remedy the lack of adequate supply of crisis-relevant products. Involvement of the rights-holders in the procedure should ensure that**		

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		they have the right to be heard before the adoption of the Union compulsory licence and that they are able to propose such voluntary solutions throughout the procedure and therefore render the granting of a Union compulsory licence unnecessary. The Commission should also end the procedure without granting a Union compulsory licence should it appear that there is no need for it. For the sake of transparency, a notice informing of the end of the procedure should be published in the Official Journal of the European Union.		
Recital 22				
32	(22) When informed of advanced discussions as regards the granting of a Union compulsory licence, the rights-holder should have the possibility to propose a voluntary agreement, should the circumstances of the Union crisis or emergency, including the urgency of the situation, allow it. The rights-holder should also be given the opportunity to comment on the need for a Union compulsory licence and on the conditions of	(22) ~~When informed of advanced discussions as regards the granting of a Union compulsory licence, the rights-holder should have the possibility to propose a voluntary agreement, should the circumstances of the Union crisis or emergency, including the urgency of the situation, allow it. The rights-holder should also be given the opportunity to comment on the need for a Union compulsory licence and on the conditions of~~	(22) ~~*When informed of advanced discussions as regards*~~***Considering that voluntary agreements are the most suitable way to deal with patented products or processes in a time of crisis, prior to any decision by the Commission on*** the granting of a Union compulsory licence, the rights-holder should ~~*have the possibility to propose a voluntary*~~***be provided with a reasonable opportunity to negotiate such*** agreement~~.~~***. A time***	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	the licence, including remuneration, should it be granted. To this end, the rights-holder should be allowed to provide the Commission with written or oral comments and any information the rights-holder considers useful to allow the Commission to make a fair, comprehensive, and thorough assessment of the situation. The Commission should allow the rights-holder a reasonable period of time to provide comments and information, considering the situation of the rights-holder and the urgency of the situation. The comments of the rights-holder should, where relevant, be transmitted by the Commission to the competent advisory body. In order for confidential information to be shared with the Commission, the Commission shall ensure a safe environment for the sharing of this information and should take measures to preserve the confidentiality of the documents provided by the rights-holder in the context of that procedure. Once a Union compulsory licence has been granted, the Commission should notify the rights-holder as soon as reasonably practicable.	~~the licence, including remuneration, should it be granted. To this end, the rights-holder should be allowed to provide the Commission with written or oral comments and any information the rights-holder considers useful to allow the Commission to make a fair, comprehensive, and thorough assessment of the situation. The Commission should allow the rights-holder a reasonable period of time to provide comments and information, considering the situation of the rights-holder and the urgency of the situation. The comments of the rights-holder should, where relevant, be transmitted by the Commission to the competent advisory body. In order for confidential information to be shared with the Commission,~~ The Commission shall ensure a safe environment for the sharing of ~~this~~**confidential** information and should take measures to preserve the confidentiality of the documents provided by the rights-holder **and other relevant actors** in the context of ~~that~~**the** procedure~~. Once~~ **for granting** a Union compulsory licence ~~has been granted, the Commission~~	***period of four weeks*** should ~~*the circumstances of the Union crisis or emergency, including*~~***be sufficient to enable good faith and meaningful negotiations, taking into account*** the urgency of the situation~~, allow it~~. The rights-holder should also be given the opportunity to comment on the need for a Union compulsory licence and on the conditions of the licence, including remuneration, should it be granted. To this end, the rights-holder should be allowed to provide the Commission with written or oral comments and any information the rights-holder considers useful to allow the Commission to make a fair, comprehensive, and thorough assessment of the situation. The Commission should allow the rights-holder a reasonable period of time to provide comments and information, considering the ***balance to be struck between the public interest and the*** situation of the rights-holder***, and considering*** ~~*and*~~ the urgency of the situation. The comments of the rights-holder should, where relevant, be transmitted by the Commission to the competent advisory body ***on a***	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		~~should notify the rights-holder as soon as reasonably practicable~~.	***timely basis***. In order for confidential information to be shared with the Commission, the Commission shall ensure a safe environment for the sharing of this information and should take measures to preserve the confidentiality of the documents provided by the rights-holder in the context of that procedure. Once a Union compulsory licence has been granted, the Commission should notify the rights-holder as soon as reasonably practicable.	
Recital 23				
33	(23) The initiation of the compulsory licensing procedure should be publicised, by means of a notice published in the Official Journal of the European Union. This notice should include information on the discussions about the granting of a Union compulsory licence in the context of a Union crisis or emergency mechanism. This notice should also help the Commission in identifying the intellectual property rights concerned, the rights-holders concerned as well as potential licensees.	*deleted*	(23) The initiation of ~~the~~***any*** compulsory licensing procedure should ***first involve the identification of the intellectual property rights concerned, the rights-holders concerned, as well as potential licensees, with the involvement of the national authorities responsible for issuing compulsory licenses under their national patent laws. It should*** be publicised~~,~~ by means of a notice published in the Official Journal of the European Union. ~~*This notice should include information on the discussions about the granting of a Union compulsory licence in the context of a Union crisis or*~~	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
			~~*emergency mechanism. This notice should also help the Commission in identifying the intellectual property rights concerned, the rights-holders concerned as well as potential licensees.*~~	
Recital 24				
34	(24) The Commission should, assisted by the advisory body, make its best efforts to identify in its decision the patent, patent application, supplementary protection certificate and utility model related to the crisis-relevant products, and the rights-holders of those intellectual property rights. In certain circumstances, the identification of intellectual property rights and of their respective rights-holders may require lengthy and complex investigations. In such cases, a complete identification of all intellectual property rights and of their rights-holders may seriously undermine the efficient use of the Union compulsory licence to swiftly tackle the crisis or the emergency. Therefore, where the identification of all those intellectual property rights or rights-holders would significantly delay the granting of the Union	(24) The Commission should~~,~~ ~~assisted by the advisory body, make its best efforts to~~ identify in ~~its decision the patent~~**the implementing act granting a Union compulsory licence the patents and**, **where applicable, published** patent ~~application~~**applications**, **utility models and, where applicable, published utility model applications, and** supplementary protection ~~certificate and utility model~~**certificates** related to the crisis-relevant products, ~~and~~**as well as** the rights-holders of those intellectual property rights. ~~In certain circumstances~~ **It cannot be fully excluded that**, **despite the efforts undertaken by the Commission and the advisory body, further** ~~the identification of intellectual property rights and of their respective rights-holders may require lengthy and complex investigations. In such cases, a~~	(24) The Commission should, assisted by the advisory body, ~~*make its best efforts to*~~ identify in its decision the patent, patent application, supplementary protection certificate and utility model related to the crisis-relevant products, and the rights-holders of those intellectual property rights. In certain circumstances, the identification of intellectual property rights and of their respective rights-holders may require lengthy and complex investigations. ~~*In such cases, a complete identification of all intellectual property rights and of their rights-holders may seriously undermine the efficient use of the Union compulsory licence to swiftly tackle the crisis or the emergency. Therefore, where the identification of all those intellectual property rights or rights-holders would significantly delay the granting of the Union*~~	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	compulsory licence, the Commission should be able to initially only indicate in the licence the non-proprietary name of the product for which it is sought. The Commission should nevertheless identify all applicable and relevant intellectual property rights and their rights-holder as soon as possible and amend the implementing act accordingly. The amended implementing act should also identify any necessary safeguards and remuneration to be paid to each identified rights-holder.	~~complete identification of all~~ intellectual property rights ~~and of their rights-holders may seriously undermine the efficient use of~~**covering the crisis-relevant product referred to in a Union compulsory licence by the non-proprietary name or CN code have been identified only after the licence had been granted and have consequently not been listed therein. As** the Union compulsory licence ~~to swiftly tackle the crisis or the emergency. Therefore, where the identification of all those intellectual property rights or rights-holders would significantly delay the granting of~~**should ensure the adequate and swift supply of crisis-relevant products, the Commission should in this situation modify** the Union compulsory licence~~, the Commission should be able to initially only indicate in the licence the non-proprietary name of the product for which it is sought. The Commission should nevertheless identify all applicable and relevant intellectual property rights and their rights-holder as soon as possible and amend the~~ **by**	~~*compulsory licence,*~~ The Commission should ~~*be able to initially only indicate in the licence the non-proprietary name of the product for which it is sought. The Commission should nevertheless*~~ identify all applicable and relevant intellectual property rights and their rights-holder ~~*as soon as possible and amend the implementing act accordingly. The amended*~~***before granting the compulsory licence. The*** implementing act should ~~*also*~~ identify any necessary safeguards and remuneration to be paid to each identified rights-holder.	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		means of an implementing act**, so as to update the list of the rights and rights-holders. To ensure proportionality between the safeguard of the public interest and the rights and interests of the rights-holders, this modification may have retroactive effect. The retroactive effect of the modification should not prevent the rights-holder from submitting comments on the possibility to reach a voluntary licensing agreement with the licensee and on the amount of remuneration. It should prevent situations such as recalls from the market or destructions of crisis-relevant products due to an incomplete list of rights and rights-holders, where such measures would threaten the supply of crisis-relevant products in the territory of the Union. The modified Union compulsory licence** ~~accordingly. The amended implementing act~~ should also identify any necessary safeguards and remuneration to be paid to each identified rights-holder. **In accordance with Article 297 TFEU, the**		

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		Commission should notify the addressees of the implementing act granting the Union compulsory licence, as well as the implementing act modifying or terminating the Union compulsory licence.		
Recital 25				
35	(25) Where the rights-holder or not all the rights-holders could be identified in a reasonable period of time, the Commission should exceptionally be entitled to grant the Union compulsory licence by referring only to the non-proprietary name of the crisis-relevant product where it is absolutely necessary considering the urgency of the situation. Nevertheless, after the granting of the Union compulsory licence, the Commission should identify, notify and consult the concerned rights-holders as quickly as possible, including by relying on publication measures and on national Intellectual Property Offices.	*deleted*	(25) Where the rights-holder or not all the rights-holders could be identified in a reasonable period of time, the Commission should ~~*exceptionally be entitled to*~~***not*** grant the Union compulsory licence ~~*by referring only to the non-proprietary name of the crisis-relevant product where it is absolutely necessary considering the urgency of the situation*~~. ~~*Nevertheless, after the granting of the Union compulsory licence, the Commission should identify, notify and consult the concerned rights-holders as quickly as possible, including by relying on publication measures and on national Intellectual Property Offices.*~~	
Recital 26				
36	(26) The Union compulsory licence should also include information allowing the	(26) The Union compulsory licence should ~~also~~ include information allowing the	(26) The Union compulsory licence should also include information allowing the	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	identification of the crisis-relevant product for which it is granted, as well as details on the licensee to whom the Union compulsory licence is granted, including details about the description, name or brand of the product; the commodity codes under which the crisis-relevant products are classified, as defined in Council Regulation (EEC) No 2658/87; details on the licensees (and, where applicable, the manufacturers) to whom the compulsory licence is granted, including their name, trade name or registered trade mark, their contact details, their unique identification number in the country where they are established and, where available, their Economic Operators Registration and Identification (EORI) number. Where required under Union legislation, other information should be included, such as a type, reference, model, batch or serial number, or unique identifier of a product passport.	identification of the crisis-relevant product for which it is granted, ~~as well as details on the licensee to whom the Union compulsory licence is granted,~~ including details about the description, name or brand of the product; **where appropriate, the non-proprietary name of the crisis-relevant product and/or** the commodity codes under which the crisis-relevant products are classified, as defined in Council Regulation (EEC) No 2658/87~~;~~[1]**, and** details on the ~~licensees~~**licensee** (and, where applicable, the ~~manufacturers~~**manufacturer**) to whom the compulsory licence is granted, including their name~~,~~ **or** trade name ~~or registered trade mark~~, their contact details, their unique identification number in the country where they are established and, where available, their Economic Operators Registration and Identification (EORI) number. Where required under Union legislation, other information **allowing for the identification of the crisis-relevant products** should be included, such as a type, reference,	identification of the crisis-relevant product for which it is granted, as well as details on the licensee to whom the Union compulsory licence is granted, including details about the description, name or brand of the product; the commodity codes under which the crisis-relevant products are classified, as defined in Council Regulation (EEC) No 2658/87; details on the licensees (and, where applicable, the manufacturers) to whom the compulsory licence is granted, including their name, trade name or registered trade mark, their contact details, their unique identification number in the country where they are established and, where available, their Economic Operators Registration and Identification (EORI) number. Where required under Union legislation, other information should be included, such as a type, reference, model, batch or serial number, or unique identifier of a product passport.	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		model, batch or serial number, or unique identifier of a product passport. _____ **1. [1] Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).**		
Recital 27				
37	(27) The licensee should pay an adequate remuneration to the rights-holder as determined by the Commission. The amount of the remuneration should be determined considering the economic value of the exploitation authorised under the licence to the licensee and to the Member States concerned by the crisis, any public support received by the rights-holder to develop the invention, the degree to which development costs have been amortized as well as humanitarian circumstances relating to the granting of the Union compulsory licence. In addition, the Commission should consider the comments made by the rights-holder and the	(27) The licensee should pay an adequate remuneration to the rights-holder as determined by the Commission. The amount of the **adequate** remuneration should be determined **according to the circumstances of each case,** considering the economic value of the exploitation authorised under the licence to the licensee and to the Member States concerned by the crisis**. To assess such an economic value**, **the Commission should take into account the expected total gross revenue generated by the licensee through the relevant activities under the Union compulsory licence, the hypothetical amount that a reasonable rights-holder**	(27) The licensee should pay an adequate remuneration to the rights-holder as determined by the Commission. The amount of the remuneration should be determined considering ***the total gross revenue generated by the licensee from the pertinent activities governed by the Union compulsory licence,*** the economic value of the exploitation authorised under the licence to the licensee and to the Member States concerned by the crisis, any public support received by the rights-holder to develop the invention, the degree to which development costs have been amortized as well as humanitarian circumstances relating to the granting of the	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	assessment made by the advisory body with regard to the amount of the remuneration. In any case, the remuneration should not exceed 4 % of the total gross revenue generated by the licensee through the acts under the Union compulsory licence. This percentage is the same as the one provided for under Regulation 816/2006. In the event of a compulsory licence granted on the basis of a published patent application that ultimately does not lead to the granting of a patent, the rights-holder would have no ground to receive remuneration under the compulsory licence, as the subject matter for the receipt of the remuneration has not materialised. In such circumstances, the rights-holder should refund the remuneration it received under the compulsory licence.	**would demand and a reasonable licensee would grant under a voluntary agreement, as well as** any public support received by the rights-holder to develop the invention,**. The amount of the remuneration should also take into consideration** the degree to which **research and** development costs have been ~~amortized as well as humanitarian~~**amortised by the rights-holder. This factor should ensure proper remuneration in case where the development costs would not have been appropriately amortised. Depending on the** circumstances **of the case and where relevant, the Commission may also take account of humanitarian grounds** relating to the granting of the Union compulsory licence. In addition, the Commission should consider the comments made by the rights-holder and the assessment made by the advisory body with regard to the amount of the remuneration~~. In any case, the remuneration should not exceed 4 % of the total gross revenue generated by the licensee through the acts under the Union compulsory licence. This~~	Union compulsory licence. ~~*In addition,*~~ The Commission should ***also*** consider the comments made by the rights-holder and the assessment made by the advisory body with regard to the amount of the remuneration. ~~*In any case, the remuneration should not exceed 4 % of the total gross revenue generated by the licensee through the acts under the Union compulsory licence. This percentage is the same as the one provided for under Regulation 816/2006. In the event of a compulsory licence granted on the basis of a published patent application that ultimately does not lead to the granting of a patent, the rights-holder would have no ground to receive remuneration under the compulsory licence, as the subject matter for the receipt of the remuneration has not materialised. In such circumstances, the rights-holder should refund the remuneration it received under the compulsory licence.*~~	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		~~percentage is the same as the one provided for under Regulation 816/2006~~**, taking into consideration general practices and any existing precedents in the relevant field**. In the event of a compulsory licence granted ~~on the basis of~~**with regard to** a published patent application that ultimately does not lead to the granting of a patent, the rights-holder would have no ground to receive remuneration under the **Union** compulsory licence, as the subject matter for ~~the receipt of ther~~**receiving** remuneration has not materialised. In such circumstances, the rights-holder should refund the remuneration ~~it~~ received under the **Union** compulsory licence.		
Recital 28				
G	38	(28) It is imperative that products manufactured under a Union compulsory licence reach only the internal market. The Union compulsory licence should therefore impose clear conditions upon the licensee as regards the activities authorised under the licence, including the territorial reach of those activities. The rights-holder should be able to	(28) It is imperative that products manufactured under a Union compulsory licence reach only the internal market. The Union compulsory licence should therefore impose clear conditions upon the licensee as regards the activities authorised under the licence, including the territorial reach of those activities. The rights-holder should be able to	(28) It is imperative that products manufactured under a Union compulsory licence reach only the internal market. The Union compulsory licence should therefore impose clear conditions upon the licensee as regards the activities authorised under the licence, including the territorial reach of those activities. The rights-holder should be able to	(28) It is imperative that products manufactured under a Union compulsory licence reach only the internal market. The Union compulsory licence should therefore impose clear conditions upon the licensee as regards the activities authorised under the licence, including the territorial reach of those activities. The rights-holder should be able to	G

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	challenge actions and uses of the rights concerned by the Union compulsory licence that do not comply with the conditions of the licence, as infringement of its intellectual property rights in accordance with Directive 2004/48/EC of the European Parliament and of the Council[1]. In order to facilitate monitoring of the distribution of products manufactured under a Union compulsory licence, including controls by customs authorities, the licensee should ensure that such products have special characteristics that make them easily identifiable and distinguishable from the products marketed by the rights-holder. _____ 1. Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157 30.4.2004, p. 45).	challenge actions and uses of the rights concerned by the Union compulsory licence that do not comply with the conditions of the licence, as infringement of its intellectual property rights in accordance with Directive 2004/48/EC of the European Parliament and of the Council[1]. In order to facilitate monitoring of the distribution of products manufactured under a Union compulsory licence, including controls by customs authorities, the licensee should ensure that such products have special characteristics that make them easily identifiable and distinguishable from the products marketed by the rights-holder. _____ 1. **[1]** Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157 30.4.2004, p. 45).	challenge actions and uses of the rights concerned by the Union compulsory licence that do not comply with the conditions of the licence, as infringement of its intellectual property rights in accordance with Directive 2004/48/EC of the European Parliament and of the Council[1]. In order to facilitate monitoring of the distribution of products manufactured under a Union compulsory licence, including controls by customs authorities, the licensee should ensure that such products have special characteristics that make them easily identifiable and distinguishable from the products marketed by the rights-holder. _____ 1. Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (OJ L 157 30.4.2004, p. 45).	challenge actions and uses of the rights concerned by the Union compulsory licence that do not comply with the conditions of the licence, as infringement of its intellectual property rights in accordance with Directive 2004/48/EC of the European Parliament and of the Council[1]. In order to facilitate monitoring of the distribution of products manufactured under a Union compulsory licence, including controls by customs authorities, the licensee should ensure that such products have special characteristics that make them easily identifiable and distinguishable from the products marketed by the rights-holder. ***Besides, the licensee should regularly record the quantities of crisis-relevant products manufactured under the Union compulsory licence. This should make it possible to establish the quantities of crisis-relevant products manufactured in a given timeframe.*** _____ 1. Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				enforcement of intellectual property rights (OJ L 157 30.4.2004, p. 45). Text Origin: Commission Proposal
Recital 29				
39	(29) A Union compulsory licence in the context of a Union crisis or emergency mechanism should only be granted to supply the internal market with crisis-relevant products. Therefore, it should be prohibited to export products manufactured under a Union compulsory licence.	(29) A Union compulsory licence in the context of a Union crisis or emergency mechanism should only be granted to supply the internal market with crisis-relevant products. Therefore, **without prejudice to Regulation (EC) No 816/2006 of the European Parliament and of the Council[1],** it should be prohibited to export products manufactured under a Union compulsory licence. _____ **1. [1] Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (OJ L 157, 9.6.2006, p. 1).**	(29) A Union compulsory licence in the context of a Union crisis or emergency mechanism should only be granted to supply the internal market with crisis-relevant products. Therefore, it should be prohibited to export products manufactured under a Union compulsory licence.	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
Recital 30				
40	(30) Customs authorities should ensure, through a risk analysis approach, that products manufactured under a Union compulsory license are not exported. To identify such products, the main source of information to feed such customs risk-analysis should be the Union compulsory license itself. Information on each implementing act granting or modifying a Union compulsory license should thus be entered in the Electronic Customs Risk Management System (CRMS) referred to in Article 36 of Commission Implementing Regulation (EU) 2015/2447[1]. When customs authorities identify a product that is suspected not to comply with the export prohibition, they should suspend the export of that product and notify the Commission immediately. The Commission should reach a conclusion on the compliance with the export prohibition within 10 working days, but should have the possibility of requiring the customs authorities to maintain the suspension where necessary. To	(30) Customs authorities should ensure, through a risk analysis approach, that products manufactured under a Union compulsory license are not exported. To identify such products, the main source of information to feed such customs risk-analysis should be the Union compulsory license itself. Information on each implementing act granting or modifying a Union compulsory license should thus be entered **by the Commission** in the Electronic Customs Risk Management System (CRMS) referred to in Article 36 of Commission Implementing Regulation (EU) 2015/2447[1]. When customs authorities identify a product that is suspected not to comply with the export prohibition, they should suspend the export of that product and notify the Commission immediately**. The Commission should inform the rights-holder and, where appropriate, the licensee, accordingly**. The Commission should reach a conclusion on the compliance with the export prohibition within 10	(30) Customs authorities should ensure, through a risk analysis approach, that products manufactured under a Union compulsory license are not exported. To identify such products, the main source of information to feed such customs risk-analysis should be the Union compulsory license itself. Information on each implementing act granting or modifying a Union compulsory license should thus be entered in the Electronic Customs Risk Management System (CRMS) referred to in Article 36 of Commission Implementing Regulation (EU) 2015/2447[1]. When customs authorities identify a product that is suspected not to comply with the export prohibition, they should suspend the export of that product and notify the Commission immediately. The Commission should reach a conclusion on the compliance with the export prohibition within 10 working days, but should have the possibility of requiring the customs authorities to maintain the suspension where necessary. To	

Public

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	help its assessment the Commission may consult the relevant rights-holder. Where the Commission concludes that a product does not comply with the export prohibition, customs authorities should refuse its export. _____ 1. Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015 laying down detailed rules for implementing certain provisions of Regulation (EU) No 952/2013 of the European Parliament and of the Council laying down the Union Customs Code (OJ L 343, 29.12.2015, p. 558).	working days, but should have the possibility of requiring the customs authorities to maintain the suspension where necessary. To help its assessment the Commission may consult the relevant rights-holder. Where the Commission concludes that a product does not comply with the export prohibition, customs authorities should refuse its export. _____ 1. **[1]** Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015 laying down detailed rules for implementing certain provisions of Regulation (EU) No 952/2013 of the European Parliament and of the Council laying down the Union Customs Code (OJ L 343, 29.12.2015, p. 558).	help its assessment the Commission may consult the relevant rights-holder. Where the Commission concludes that a product does not comply with the export prohibition, customs authorities should refuse its export. _____ 1. Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015 laying down detailed rules for implementing certain provisions of Regulation (EU) No 952/2013 of the European Parliament and of the Council laying down the Union Customs Code (OJ L 343, 29.12.2015, p. 558).	
Recital 31				
41	(31) The legal validity of the implementing act granting the Union compulsory license, or any subsequent implementing act, should be subject to judicial review.	(31) **Under the provisions of the TFEU, and in particular its Article 263, the**~~The legal~~ validity of ~~the~~ implementing ~~act~~**acts** granting the Union compulsory license **and the adequate remuneration provided therein,**	(31) The legal validity of the implementing act granting the Union compulsory license, or any subsequent implementing act, should be subject to judicial review.	ITM 29 04 Agreed to drop EP mandate 217 a and b and to keep 263 in rec 31

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		as well as the validity of any other~~, or any subsequent~~ implementing ~~act, should be~~**acts pertaining to the Union compulsory license, is** subject to judicial review **by the Court of Justice of the European Union**.		
Recital 32				
42	(32) The relation between the rights-holder and the licensee should be governed by the principle of good faith. The rights-holder and licensee should work towards the success of the Union compulsory licence and collaborate, where necessary, to ensure that the Union compulsory licence effectively and efficiently fulfils its objective. The Commission may act as an enabler in achieving the good-faith cooperation between the rights-holder and the licensee, taking into account interests of all parties. In that respect, the Commission should also be entitled to take additional measures in line with Union law to ensure that the compulsory licence meets its objective and ensure that necessary crisis-relevant goods can be made available in the Union. Such additional measures	(32) **During the procedure for granting a Union compulsory licence and after such licence has been granted the rights-holder and licensee should refrain from actions and omissions that could jeopardize the efficiency of the Union compulsory licensing process. Where applicable, the rights-holder and the licensee should also provide the Commission and the advisory body with the information about the known intellectual property rights, including rights owned by third parties, covering the crisis-relevant products. Information to be provided in**~~The~~ relation **to the Union compulsory licence and its granting process should include, in particular, information on the changes to the status of the relevant intellectual property rights, any**	(32) The relation between the rights-holder and the licensee should be governed by the principle of good faith. The rights-holder and licensee should work towards the success of the Union compulsory licence and collaborate, where necessary, to ensure that the Union compulsory licence effectively and efficiently fulfils its objective. The Commission may act as an enabler in achieving the good-faith cooperation between the rights-holder and the licensee, taking into account interests of all parties. In that respect, the Commission should also be entitled to take additional measures in line with Union law to ensure that the compulsory licence meets its objective and ensure that necessary crisis-relevant goods can be made available in the Union. Such additional measures	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	may include requesting further information which is deemed indispensable to achieve the objective of the compulsory licence. These measures should always include adequate safeguards to ensure the protection of the legitimate interests of all parties.	**pending infringement or invalidity actions in relation to them, as well as the associated voluntary licensing agreements. On request from the rights-holder, licensee or on its own initiative, the Commission should have the possibility to arrange meetings or other exchanges** between the rights-holder and the licensee ~~should be governed by the principle of good faith. The rights-holder and licensee should work towards the success~~**on matters relevant for the fulfilment of the objective** of the Union compulsory licence ~~and collaborate, where necessary, to ensure that the Union compulsory licence effectively and efficiently fulfils its objective~~. The Commission ~~may act as an enabler in achieving the good-faith cooperation between~~**should also have the possibility to share crisis-relevant information with** the rights-holder and the licensee, ~~taking into account interests of all parties. In that respect, the Commission should also be entitled to take additional measures in line with Union law to ensure that the compulsory licence~~	may include requesting further information which is deemed indispensable to achieve the objective of the compulsory licence. These measures should always include adequate safeguards to ensure the protection of the legitimate interests of all parties.	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		~~meets its objective and ensure that necessary~~**including new information on available manufacturing capacities of** crisis-relevant ~~goods can be made available in~~**products in the territory of** the Union.~~ Such additional measures may include requesting further~~ Information ~~which is deemed indispensable to achieve the objective of the compulsory licence. These measures~~**shared during such meetings or exchanges** should ~~always include adequate safeguards to ensure the protection of the legitimate interests of all parties.~~**remain confidential.**		
Recital 32a				
R 42a			***(32a) Where appropriate, the Commission should oblige the rights-holder to disclose the trade secrets which are strictly necessary in order to achieve the purpose of the Union compulsory licence. In such cases, rights holders should receive an adequate remuneration. It is possible that a detailed description of how to carry out the invention might not be sufficient and complete enough to enable the licensee to efficiently***	Trilogue I - 10/12/2024 To be negotiated at political level

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
			use that invention. This could encompass, without being exhaustively limited to, the comprehensive transfer of necessary technology, expertise, data, samples, and reference products essential for production and obtaining market authorisation in collaboration with the licensee, taking into account both the rights-holder and the licensee's interests. In cases where that additional information and know-how is necessary, some of which is an undisclosed trade secret, the disclosure of that necessary trade secret, with a view to only achieving the purpose of exercising the Union compulsory licence pursuant to this Regulation, should be considered to be lawful within the meaning of Article 3(2) and Article 5 of Directive (EU) 2016/943 of the European Parliament and the Council. While this Regulation requires the disclosure of trade secrets only when they are strictly necessary in order to achieve the purpose of the Union compulsory licence, it should be interpreted in such a manner as to preserve the	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
			protection afforded to trade secrets under Directive (EU) 2016/943. The Commission should require the licensee(s) to put in place all appropriate measures reasonably identified by the rights-holder, including contractual, technical and organisational measures, to ensure the confidentiality of trade secrets, in particular vis-à-vis third parties and the protection of the legitimate interests of all parties. To that end, right holders should identify trade secrets prior to the disclosure. Those appropriate measures may consist of model contractual terms, confidentiality agreements, strict access protocols, technical standards and the application of codes of conduct. Where the licensee fails to implement the measures required for preserving the confidentiality of the trade secrets, the Commission should be able to withhold or suspend the disclosure of trade secrets until the situation is corrected by the licensee. Any use, acquisition or disclosure of trade secrets which would not be necessary to fulfil the objective of the Union	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
			compulsory licence or which would go beyond the duration of the Union compulsory license should be considered to be unlawful within the meaning of that Directive.	
Recital 32b				
R 42b			***(32b) This Regulation should guarantee that the Commission has the authority to oblige rights-holders to provide all necessary information to facilitate the rapid and efficient production of critical crisis-related products, such as pharmaceuticals and other health-related items. This information should encompass details about know-how, particularly when it is essential for the effective implementation of compulsory licensing. While patent licensing alone might suffice to enable other manufacturers to quickly produce simple pharmaceuticals, in case of more intricate pharmaceutical products, such as vaccines during a pandemic, it is often insufficient. Where it is essential for the implementation of the compulsory licence, an alternative producer will also require access to know-how.***	Trilogue I - 10/12/2024 To be negotiated at political level

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
Recital 33				
43	(33) In order to respond appropriately to the crisis situations, the Commission should be authorised to review the conditions of the Union compulsory licence and adapt them to changed circumstances. This should include the modification of the compulsory licence to indicate the complete list of rights and rights-holders covered by the compulsory licence, where this complete identification had not be done initially. This should also include the termination of the licence if the circumstances which led to it cease to exist and are unlikely to recur. When deciding on the revision of the Union compulsory licence, the Commission may decide to consult the competent advisory body for that purpose. If the Commission intends to change essential components of the Union compulsory licence, such as its duration or remuneration or if the change itself could be the subject of a separate compulsory licence, it should be required to consult the advisory body.	(33) In order to respond appropriately to the crisis situations, the Commission should be authorised to review the conditions of the Union compulsory licence and adapt them to changed circumstances. ~~This should include the modification of the compulsory licence to indicate the complete~~**Where necessary, the** list of **the** rights and rights-holders covered by the **Union** compulsory licence~~, where this complete identification had not be done initially. This~~ should ~~also include the termination~~**be updated, with retroactive effect where appropriate. Where a published patent application is included in the content** of the **Union compulsory** licence **but such application does not result in a patent or where the final scope of protection of the patent granted based on such application no longer covers the crisis-relevant product, the list of the rights and rights-holders should be updated accordingly.** If the circumstances which led to ~~it~~**the Union compulsory licence**	(33) In order to respond appropriately to the crisis situations, the Commission should be authorised to review the conditions of the Union compulsory licence and adapt them to changed circumstances. This should include the modification of the compulsory licence to indicate the complete list of rights and rights-holders covered by the compulsory licence~~, where this complete identification had not be done initially~~. This should also include the termination of the licence if the circumstances which led to it cease to exist and are unlikely to recur. When deciding on the revision of the Union compulsory licence, the Commission ~~may decide to~~***should*** consult the competent advisory body for that purpose***, as well as the rights-holders and licensees***. If the Commission intends to change essential components of the Union compulsory licence, such as its duration or remuneration or if the change itself could be the subject of a separate compulsory licence,	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		cease to exist and are unlikely to recur**, the licence should be terminated. The Commission should notify the rights-holder and the licensee about the termination of the Union compulsory licence, as well as about its expiry in case the relevant crisis or emergency mode has ended**. When deciding on the revision of the Union compulsory licence, the Commission ~~may decide to~~**should** consult the competent advisory body for that purpose~~. If the Commission intends to change essential components~~ **and duly consider the rights and interests** of the ~~Union compulsory licence, such as its duration or remuneration or if the change itself could be the subject of a separate compulsory licence, it should be required to consult the advisory body~~**rights-holder and the licensee**.	it should be required to consult the advisory body.	
Recital 34				
44	(34) To prevent and stop any misuse of the Union compulsory licence, specific safeguards should be in place to allow the Commission to take action. In addition to the possibility to	(34) ~~To prevent and stop any misuse of the Union compulsory licence, specific safeguards should be in place to allow the Commission to take action.~~ In addition to the possibility to	(34) To prevent and stop any misuse of the Union compulsory licence, specific safeguards should be in place to allow the Commission to take action. In addition to the possibility to	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	terminate the Union compulsory licence, the Commission should be authorised to impose fines and periodic penalty payments on the rights-holder and the licensee in order to enforce the obligations under this Regulation. The penalties should be effective, proportionate and dissuasive.	terminate the Union compulsory licence, the Commission should be authorised to impose fines and periodic penalty payments on the rights-holder and the licensee in order to enforce the obligations under this Regulation. The ~~penalties~~**fines and periodic penalty payments, which can also be applied cumulatively, should aim to safeguard the rights and interests of the rights-holder and the licensee and to guarantee the efficient implementation of the Union compulsory licence. These sanctions** should be effective~~,~~ ~~proportionate~~ and dissuasive**, and they should also be subject to the overarching principles of proportionality and ne bis in idem**.	terminate the Union compulsory licence, the Commission should be authorised to impose fines and periodic penalty payments on the rights-holder and the licensee in order to enforce the obligations under this Regulation. The penalties should be effective, proportionate and dissuasive***, and should not contravene the usual enforcement measures of intellectual property rights as provided by Directive 2004/48/EC***.	
Recital 35				
45	(35) Compliance with the relevant obligations imposed under this Regulation should be enforceable by means of fines and periodic penalty payments. To that end, appropriate levels of fines and periodic penalty payments should be laid down and the imposition of fines and periodic penalty payments should be	(35) ~~Compliance~~**Appropriate levels of fines for non-compliance** with the ~~relevant~~ obligations ~~imposed~~**under this Regulation and of periodic penalty payments to put an end to an infringement of the obligations** under this Regulation should be ~~enforceable by means of fines and periodic penalty~~	(35) Compliance with the relevant obligations imposed under this Regulation should be enforceable by means of fines and periodic penalty payments. To that end, appropriate levels of fines and periodic penalty payments should be laid down and the imposition of fines and periodic penalty payments should be subject to	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	subject to appropriate limitation periods in accordance with the principles of proportionality and ne bis in idem. All decisions taken by the Commission under this Regulation are subject to review by the Court of Justice of the European Union in accordance with the TFEU. The Court of Justice of the European Union should have unlimited jurisdiction in respect of fines and penalty payments in accordance with Article 261 TFEU.	~~payments. To that end, appropriate levels of fines and periodic penalty payments should be~~ laid down**, taking into account any aggravating or mitigating factors. Limitation periods should apply for** ~~and~~ the imposition of fines and periodic penalty payments ~~should be subject to appropriate limitation periods~~**, as well as for their enforcement.** In accordance with ~~the principles of proportionality and ne bis in idem. All decisions taken by~~**Article 297 TFEU,** the Commission ~~under this Regulation are subject to review by the Court of Justice of the European Union in accordance with the TFEU~~**should notify the addressees of its decision on fines and penalties**. The Court of Justice of the European Union should have unlimited jurisdiction in respect of **all decisions taken by the Commission to impose** fines and **periodic** penalty payments in accordance with Article 261 TFEU.	appropriate limitation periods in accordance with the principles of proportionality and ne bis in idem. All decisions taken by the Commission under this Regulation are subject to review by the Court of Justice of the European Union in accordance with the TFEU. The Court of Justice of the European Union should have unlimited jurisdiction in respect of ***the implementing act granting the compulsory licence, as well as the decisions on*** fines and penalty payments in accordance with Article 261 TFEU.	
Recital 36				
46	(36) When a national compulsory licence has been granted for the purpose of	(36) When a national compulsory licence has been granted for the purpose of	(36) When a national compulsory licence has been granted for the purpose of	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	addressing a crisis, the Member State or its competent authority should be required to notify the Commission of the granting of the licence, and of the specific conditions attached to it, since it allows the Commission to get an overview of national compulsory licences in the Member States and to take those compulsory licences into account when considering a Union compulsory licence, and in particular when setting the conditions for such licence.	addressing a crisis **or emergency at national level, which in its nature corresponds to crises or emergencies falling within the scope of the crisis mechanisms listed in this Regulation**, the Member State or its competent authority should be required to ~~notify~~**inform** the Commission of the granting of the licence, and of the specific conditions attached to it, since it allows the Commission to get an overview of national compulsory licences in the Member States and to take those compulsory licences into account when considering **the need to grant** a Union compulsory licence, and in particular when setting the conditions for such licence. **Considering that there are differences between the Member States in terms of authorities responsible for granting compulsory licences at national level, it should remain for the Member States to establish appropriate procedures under their national laws, ensuring that the relevant information is provided to the Commission without undue delay. To ensure efficient**	addressing a crisis, the Member State or its competent authority should be required to notify the Commission of the granting of the licence, and of the specific conditions attached to it, since it allows the Commission to get an overview of national compulsory licences in the Member States and to take those compulsory licences into account when considering a Union compulsory licence, and in particular when setting the conditions for such licence.	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		cooperation, Member States should inform the Commission of the national authority that is responsible for providing information on national compulsory licences issued for the purposes of addressing a crisis or emergency. The Commission should keep a list of the said national authorities and publish it on its website.		
Recital 37				
47	(37) The possibility of a compulsory licence at Union level should not only be available for the supply of the Union market but also under certain conditions for export purposes concerning countries with public health problems, already regulated by Regulation (EC) No 816/2006 of the European Parliament and of the Council[1]. Under that Regulation, the granting of such compulsory licences is decided and performed nationally by the competent authorities of the Member States that have received a corresponding application from a person that intends to manufacture and sell pharmaceutical products covered by a patent or a supplementary protection for	(37) The possibility of a compulsory licence at Union level should not only be available for the supply of the Union market but also under certain conditions for export purposes concerning countries with public health problems, already regulated by Regulation (EC) No 816/2006 ~~of the European Parliament and of the Council~~[1]. Under that Regulation, the granting of such compulsory licences is decided and performed nationally by the competent authorities of the Member States that have received a corresponding application from a person that intends to manufacture and sell pharmaceutical products covered by a patent or a supplementary protection for	(37) The possibility of a compulsory licence at Union level should not only be available for the supply of the Union market but also under certain conditions for export purposes concerning countries with public health problems, already regulated by Regulation (EC) No 816/2006 of the European Parliament and of the Council[1]. Under that Regulation, the granting of such compulsory licences is decided and performed nationally by the competent authorities of the Member States that have received a corresponding application from a person that intends to manufacture and sell pharmaceutical products covered by a patent or a supplementary protection for	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	export to eligible third countries. Regulation (EC) No 816/2006 only allows compulsory licensing covering the manufacturing of products across several Member States through national procedures. In the context of a cross-border manufacturing process different national compulsory licences would be needed. This can lead to a burdensome and lengthy process as this would require the launch of different national procedures with possibly different scope and conditions. In order to achieve the synergies and efficient process as for the Union crisis mechanisms, a Union compulsory licence should also be available, in the context of Regulation (EC) No 816/2006. This will facilitate manufacturing of the relevant products across several Member States and provide Union-level solution in order to avoid a situation where several compulsory licences for the same product in more than one Member States would be required for licensees to manufacture and export the products as planned. Any person considering to apply for a compulsory licence under,	export to eligible third countries. Regulation (EC) No 816/2006 only allows compulsory licensing covering the manufacturing of products across several Member States through national procedures. In the context of a cross-border manufacturing process different national compulsory licences would be needed. This can lead to a burdensome and lengthy process as this would require the launch of different national procedures with possibly different scope and conditions. In order to achieve the synergies and efficient process as for the Union crisis mechanisms, a Union compulsory licence should also be available, in the context of Regulation (EC) No 816/2006. This will facilitate manufacturing of the relevant products across several Member States and provide Union-level solution ~~in order to avoid~~**avoiding** a situation where several compulsory licences for the same product in more than one Member States would be required for licensees to manufacture and export the products as planned. Any person considering to apply for a	export to eligible third countries. Regulation (EC) No 816/2006 only allows compulsory licensing covering the manufacturing of products across several Member States through national procedures. In the context of a cross-border manufacturing process different national compulsory licences would be needed. This can lead to a burdensome and lengthy process as this would require the launch of different national procedures with possibly different scope and conditions. In order to achieve the synergies and efficient process as for the Union crisis mechanisms, a Union compulsory licence should also be available, in the context of Regulation (EC) No 816/2006. This ***should be further facilitated by reviewing the conditions for issuing compulsory licences for export, in order to make them fully in line with the TRIPS Agreement and its full spectrum of flexibilities. The Union compulsory licence*** will facilitate ***the use of this mechanism and all the*** manufacturing of the relevant products across several Member States and provide Union-level	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	for the purposes and within the scope of Regulation (EC) No 816/2006 should have the possibility to request, with a single application, a compulsory licence under that Regulation that is valid throughout the Union, if that person, when relying on national compulsory licencing schemes of the Member States, would otherwise need to apply for multiple compulsory licences for the same crisis-relevant product in more than one Member State in order to realise its intended activities of manufacture and sale for export under Regulation (EC) No 816/2006. Therefore, Regulation (EC) No 816/2006 should be amended accordingly. _____ 1. Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (OJ L 157, 9.6.2006, p. 1).	compulsory licence under~~, for the purposes and within the scope of~~ Regulation (EC) No 816/2006 should have the possibility to request, with a single application, a compulsory licence under that Regulation that is valid throughout the Union, if that person, when relying on national compulsory licencing schemes of the Member States, would otherwise need to apply for multiple compulsory licences for the same crisis-relevant product in more than one Member State in order to realise its intended activities of manufacture and sale for export under Regulation (EC) No 816/2006. **To this end, the applicant should specify the Member States in which the intended activities of manufacture and sale for export of the product to be covered by the Union compulsory licence are to be carried out.** Therefore, Regulation (EC) No 816/2006 should be amended accordingly. _____ ~~1. Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory~~	solution in order to avoid a situation where several compulsory licences for the same product in more than one Member States would be required for licensees to manufacture and export the products as planned. Any person considering to apply for a compulsory licence ~~*under*~~, for the purposes and within the scope of Regulation (EC) No 816/2006 should have the possibility to request, with a single application, a compulsory licence under that Regulation that is valid throughout the Union, if that person, when relying on national compulsory licencing schemes of the Member States, would otherwise need to apply for multiple compulsory licences for the same crisis-relevant product in more than one Member State in order to realise its intended activities of manufacture and sale for export under Regulation (EC) No 816/2006. Therefore, Regulation (EC) No 816/2006 should be amended accordingly. _____ 1. Regulation (EC) No 816/2006 of the European Parliament and of the Council	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		~~licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (OJ L 157, 9.6.2006, p. 1).~~	of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (OJ L 157, 9.6.2006, p. 1).	
Recital 37a				
47a		**(37a) On 1 February 2020, the United Kingdom withdrew from the European Union. The Withdrawal Agreement[1] was concluded between the European Union and the European Atomic Energy Community, on the one part, and the United Kingdom, on the other part. It was approved by Council Decision (EU) 2020/135[2] of 30 January 2020 and entered into force on 1 February 2020. The Withdrawal Agreement provides for a transition period which ended on 31 December 2020. At the end of the transition period, Union law ceased to apply to the United Kingdom, whilst the Protocol on Ireland / Northern Ireland – now referred to as the Windsor Framework[3], which forms an integral part of the Withdrawal Agreement,**		

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		became applicable. In accordance with Article 5(4) of the Windsor Framework and point 7 of Annex 2 to the Windsor Framework, Regulation (EC) No 816/2006, as well as legal acts of the Union implementing, amending or replacing that legal act, apply to and in the United Kingdom in respect of Northern Ireland. Considering that the amendments to Regulation (EC) No 816/2006 would be applicable to and in the United Kingdom in respect of Northern Ireland in accordance with the Windsor Framework and that the competent authorities of the United Kingdom should continue exercising their responsibility for issuing compulsory licenses in respect of Northern Ireland, it is appropriate to stipulate that the procedure for granting a Union compulsory licence, and a Union compulsory licence granted under that provision, should not apply to and in the United Kingdom in respect of Northern Ireland. However, the United Kingdom in respect of Northern		

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		Ireland should ensure that the products manufactured under such a license are not reimported into the territory of the Union or Northern Ireland in accordance with Article 13 of Regulation (EC) No 816/2006 and take necessary actions to that end in accordance with Article 14 of that Regulation. **_____** **1. [1] Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (OJ L 29, 31.1.2020, p. 7).** **2. [2] Council Decision (EU) 2020/135 of 30 January 2020 on the conclusion of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (OJ L 29, 31.1.2020, p. 1).** **3. [3] Joint Declaration No 1/2023 of the Union and the United Kingdom in the**		

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		Joint Committee established by the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community of 24 March 2023 (OJ L 102, 17.4.2023, p. 87).		
Recital 38				
48	(38) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the granting, complementing, modification or termination of a Union compulsory license, the determination of the remuneration to be paid to the rights-holder, the procedural rules for the ad hoc advisory body and the characteristics allowing the identification of products produced under a Union compulsory licence. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[1]. The advisory procedure should be used for the adoption of	(38) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the granting, complementing, modification or termination of a Union compulsory license~~, the determination of the remuneration to be paid to the rights-holder, the procedural rules for the ad hoc advisory body and the characteristics allowing the identification of products produced under a Union compulsory licence~~. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[1]. The ~~advisory~~ **examination** procedure should be used for the	(38) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the granting, complementing, modification or termination of a Union compulsory license, the determination***, in the absence of an agreement between the rights-holder and the licensee,*** of the remuneration to be paid to the rights-holder, the procedural rules for the ad hoc advisory body and the characteristics allowing the identification of products produced under a Union compulsory licence. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[1].	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	implementing acts granting, complementing, modifying or terminating a Union compulsory licence, and implementing acts determining the remuneration. The choice of the advisory procedure is justified given that those implementing acts would be adopted in the context of a procedure with considerable participation of the Member States through the consultation of the advisory body. The examination procedure should be used for the adoption of implementing acts establishing procedural rules for the ad hoc advisory body and implementing acts establishing the characteristics allowing the identification of products produced under a Union compulsory licence. _____ 1. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of	adoption of implementing acts granting, complementing, modifying or terminating a Union compulsory licence~~, and implementing acts determining the remuneration. The choice of the advisory procedure is justified given that those implementing acts would be adopted in the context of a procedure with considerable participation of the Member States through the consultation of the advisory body. The examination procedure should be used for the adoption of implementing acts establishing procedural rules for the ad hoc advisory body and implementing acts establishing the characteristics allowing the identification of products produced under a Union compulsory licence.~~**.** _____ 1. **[1]** Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of	The advisory procedure should be used for the adoption of implementing acts granting, complementing, modifying or terminating a Union compulsory licence, and implementing acts determining the remuneration. The choice of the advisory procedure is justified given that those implementing acts would be adopted in the context of a procedure with considerable participation of the Member States through the consultation of the advisory body. The examination procedure should be used for the adoption of implementing acts establishing procedural rules for the ad hoc advisory body and implementing acts establishing the characteristics allowing the identification of products produced under a Union compulsory licence. _____ 1. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	implementing powers (OJ L 55, 28.2.2011, p. 13).	implementing powers (OJ L 55, 28.2.2011, p. 13).	Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).	
Recital 39				
49	(39) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the granting, modification or termination of a Union compulsory licence or the determination of the remuneration, imperative grounds of urgency so require.	(39) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the granting, modification or termination of a Union compulsory licence ~~or the determination of the remuneration~~, imperative grounds of urgency so require. **As regards the granting of a Union compulsory licence, these grounds should relate to the nature and the gravity of the crisis or emergency and to the firmly established finding that voluntary agreements for intellectual property rights concerning crisis-relevant products are unavailable to ensure the supply of these products in the territory of the Union. This should include cases where the rights-holder expressly indicates that it cannot ensure such supply and is unwilling to negotiate voluntary agreements. The same should apply in the case of a**	(39) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the granting, modification or termination of a Union compulsory licence or the determination of the remuneration, imperative grounds of urgency so require.	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		modification of the licence for the purpose of adding further rights-holders. When it comes to the termination of a Union compulsory licence, the grounds should relate to firmly established finding that the licensee is unable to exploit the protected invention in a manner that permits the carry out of the relevant activities of the crisis-relevant products, inter alia, where the licensee expressly indicates this to be the case. When deciding whether to adopt immediately applicable implementing acts, the Commission should take into account the preliminary information gathered by the advisory body and the preliminary exchanges in that body.		
Recital 40				
50	(40) Union compulsory licensing for crisis management is a tool that is only used in exceptional circumstances. The evaluation should therefore be conducted only where a Union compulsory licence has been granted by the Commission. The evaluation report should be	(40) Union compulsory licensing for crisis management is a tool that is only used in exceptional circumstances. The evaluation should therefore be conducted only where a Union compulsory licence has been granted by the Commission. The evaluation report should be	(40) Union compulsory licensing for crisis management is a ***last resort*** tool that is ~~*only*~~ used in exceptional circumstances. The evaluation should therefore be conducted only where a Union compulsory licence has been granted by the Commission. The evaluation report should be	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	submitted by the last day of the third year following the granting of the Union compulsory licence, to allow an adequate and substantiated assessment of this Regulation.	submitted by the last day of the third year following the granting of the **first** Union compulsory licence, to allow an adequate and substantiated assessment of this Regulation.	submitted by the last day of the third year following the granting of the Union compulsory licence, to allow an adequate and substantiated assessment of this Regulation.	
Recital 40a				
R 50a			***(40a) While the Annex is to be updated by any future legislative act in relation to an emergency or crisis mode, the Commission should nevertheless monitor the situation and assess whether the list in the Annex has been properly updated. If it appears that this list is no longer up-to-date, the Commission should assess its consequences. In any event, the Commission should submit its assessment to the European Parliament and the Council accompanied, where appropriate, by legislative proposals to amend the Annex. Although the Commission should carry out this assessment every two years from the date of entry into force of this Regulation, it is expected that, given the rapid changes in current European and global situation, the Commission should carry out that assessment without undue delay in the event***	Trilogue I - 10/12/2024 To be negotiated at political level

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
			of exceptional threats to public safety or to national security.	
Recital 41				
51	(41) Since a period of time is required to ensure that the framework for the proper functioning of the system for Union compulsory licencing is in place, the application of this Regulation should be deferred.	(41) ~~Since a period of time is required to ensure that the framework for the proper functioning of the system for Union compulsory licencing is in place, the application of this Regulation should be deferred.~~	(41) Since a period of time is required to ensure that the framework for the proper functioning of the system for Union compulsory licencing is in place, the application of this Regulation should be deferred.	
Recital 41a				
51a			***(41a) Since the objective of this Regulation, namely to ensure access to crisis-relevant patented products needed to address crises in the internal market, cannot be sufficiently achieved by the Member States because of the fragmentation of compulsory licensing in the Union and the insufficient territorial scope of national compulsory licensing but can rather, by reason of the scale and effects of the necessary solution, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that***	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
			Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.	
Formula				
52	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	
Article 1				
53	Article 1 Subject matter	Article 1 **Objectives and** subject matter	Article 1 Subject matter	
Article 1, first paragraph				
54	This Regulation has the objective to ensure that in crises the Union has access to crisis-relevant products. To this end, this Regulation lays down rules on the procedure and conditions for the granting of a Union compulsory licence of intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States in the context of a Union crisis or emergency mechanism.	~~This Regulation has the objective to ensure that in crises the Union has access to crisis-relevant products. To this end,~~ This Regulation lays down rules on the ~~procedure and~~ conditions **and procedure** for the granting of a Union compulsory licence of intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States ~~in the context of a Union~~**during an activated or declared** crisis or emergency ~~mechanism~~**mode, pursuant to any of the respective Union legal acts listed in Article 2(1a). The Union compulsory licence is granted in the public interest and as a last resort measure when other means, including**	This Regulation has the objective to ensure that ***a temporary and non-exclusive Union compulsory license may be granted to protect the public interest in the context of cross-border crisis or emergency situations in*** ~~*in crises*~~ the Union ~~*has access to crisis-relevant products. To this end,*~~ This Regulation lays down rules on the procedure and conditions for the granting ***as a last resort*** of a Union compulsory licence of intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States in the context of a Union crisis or emergency mechanism. ***To this end, if no prior voluntary agreement has been reached within four weeks between right***	This Regulation has the objective to ensure that ***a Union compulsory license may be granted in the context of a crisis or emergency affecting*** ~~*in crises*~~ the Union ~~*has access to crisis-relevant products*~~. To this end, this Regulation lays down rules on the ~~*procedure and*~~ conditions ***and procedure*** for the granting of a Union compulsory licence of intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States ~~*in the context of a Union*~~ ***during an activated or declared*** crisis or emergency ***mode, pursuant to any of the respective Union legal acts [to be completed after the outcome of the discussions on "scope"- either art***

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		voluntary agreements to use an invention protected by intellectual property rights which concerns crisis-relevant products, could not ensure access to those products.	***holder and licensee, the Commission may grant a Union compulsory license.***	~~*mechanism*~~. ***2(-1) or Annex]".*** ***The Union compulsory licence is granted in the public interest and as a last resort measure when other means, including voluntary agreements to use an invention protected by intellectual property rights which concerns crisis-relevant products, could not ensure access to those products.*** Trilogue I - 10/12/2024 "Scope" to be negotiated at political level "four weeks": agreed to drop it in art. 1 But time limitation to be discussed further where/how time limitation to be incorporated in other article(s) "temporary and non-exclusive": agreed to put in a recital - rec 4 or 16 ? For COM to propose the right place EP would support COM drafting suggestion with small change for consistency with art. 3 (pending outcome of discussions on scope) and provided that "other means" are further explained in a recital

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				COM drafting with EP changes, agreed by CSL What is in brackets ("scope") to be completed after the outcome on political discussions
Article 2				
55	Article 2 Scope	Article 2 Scope	Article 2 Scope	Article 2 Scope Text Origin: Commission Proposal
Article 2(-1)				
R 55a		**-1. This Regulation applies where a crisis or emergency mode, as referred to in Annex to this Regulation, is activated or declared in accordance with any of the following Union legal acts:**		Trilogue I - 10/12/2024 To be negotiated at political level R
Article 2(-1), point (a)				
R 55b		**(a) Regulation XXX/XX of the European Parliament and of the Council[1];** **1. [1] Regulation … of the European Parliament and of the Council of … establishing a framework of measures on emergency and resilience of the internal**		Trilogue I - 10/12/2024 To be negotiated at political level R

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		market (Internal market emergency and resilience act) and amending Council Regulation (EC) No 2679/98 [COM(2022) 459].		
Article 2(-1), point (b)				
R	55c	**(b) Regulation (EU) 2022/2371;**		Trilogue I - 10/12/2024 To be negotiated at political level
Article 2(-1), point (c)				
R	55d	**(c) Council Regulation (EU) 2022/2372.**		Trilogue I - 10/12/2024 To be negotiated at political level
Article 2(1)				
	56	1. This Regulation establishes Union compulsory licensing of the following intellectual property rights in force in one or more Member States:	1. This Regulation establishes Union compulsory licensing of the following intellectual property rights in force in one or more Member States:	1. This Regulation establishes Union compulsory licensing of the following intellectual property rights in force in one or more Member States: Text Origin: Commission Proposal
Article 2(1), point (a)				
G	57	(a) patents, including published patent applications;	(a) patents~~, including~~ **and** published patent applications;	(a) patents~~, *including*~~ ***and*** published patent applications; Text Origin: Council Mandate
Article 2(1), point (b)				

PUBLIC

		Commission Proposal	Council Mandate	EP Mandate	Draft Agreement	
G	58	(b) utility models; or	(b) utility models **and published utility model applications**; or	(b) utility models; or	(b) utility models ***and published utility model applications***; or Text Origin: Council Mandate	G
Article 2(1), point (c)						
G	59	(c) supplementary protection certificates;	(c) supplementary protection certificates~~;~~**.**	(c) supplementary protection certificates;	(c) supplementary protection certificates~~;~~**.** Text Origin: Council Mandate	G
Article 2(2)						
R	60	2. This Regulation is without prejudice to the rules laid down by other Union legal acts regulating copyright and related rights, including Directive 2001/29, Directive 2009/24 and the sui generis rights granted by Directive 96/9/EC on the legal protection of databases.	2. This Regulation is without prejudice to the rules laid down by other Union legal acts regulating copyright and related rights, including Directive 2001/29, Directive 2009/24**,** and the sui generis rights granted by Directive 96/9/EC on the legal protection of databases **and without prejudice to Directive (EU) 2016/943 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure**.	2. This Regulation is without prejudice to the rules laid down by other Union legal acts regulating copyright and related rights, including Directive 2001/29, Directive 2009/24 and the sui generis rights granted by Directive 96/9/EC on the legal protection of databases.	Trilogue I - 10/12/2024 To be negotiated at political level	R
Article 2(3)						

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement	
R	60a		**3. This Regulation does not impose any obligation to disclose trade secrets.**	Trilogue I - 10/12/2024 To be negotiated at political level	R
Article 2(3a)					
R	60b		**3a. This Regulation shall not apply to defence-related products as defined in Article 3 paragraph 1 of Directive 2009/43/EC of the European Parliament and the Council of 6 May 2009 simplifying terms and conditions of transfers of defence-related products within the Community or as defined by national law of Member States in compliance of Union law.**	Trilogue I - 10/12/2024 To be negotiated at political level	R
Article 2(4)					
R	60c		**4. The Union compulsory licence shall be granted pursuant to the conditions and procedure established in this Regulation only for the purpose of carrying out the specific measures related to crisis-relevant products provided for in the respective Union legal acts listed in Article 2(1a), in the framework of an activated or declared crisis or emergency mode listed in the Annex to this Regulation.**	Trilogue I - 10/12/2024 To be negotiated at political level	R

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
Article 3				
61	Article 3 Definitions	Article 3 Definitions	Article 3 Definitions	Article 3 Definitions Text Origin: Commission Proposal
Article 3, first paragraph				
62	For the purposes of this Regulation, the following definitions shall apply:	For the purposes of this Regulation, the following definitions shall apply:	For the purposes of this Regulation, the following definitions shall apply:	For the purposes of this Regulation, the following definitions shall apply: Text Origin: Commission Proposal
Article 3, first paragraph, point (-a)				
62a		**(-a) 'crisis or emergency mode' means a crisis or emergency mode listed in the Annex, which has been activated or declared pursuant to the respective Union legal act listed in Article 2(1a);**	***(-a) 'crisis mode or emergency mode' means a crisis mode or an emergency mode, as applicable, listed in the Annex to this Regulation, which has been activated or declared in the context of a Union crisis or emergency mechanism listed in that Annex in accordance with one of the Union acts listed therein;***	***(-a) "crisis or emergency mode" means a crisis mode or emergency mode listed in the Annex to this Regulation, which has been activated or declared [to be completed after the outcome of the discussions on "scope"- either art. 2(-1) or Annex]"*** Trilogue I - 10/12/2024 "Scope" to be negotiated at political level What is in brackets: related to "scope" - pending agreement on scope
Article 3, first paragraph, point (a)				

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
63	(a) 'crisis-relevant products' means products or processes that are indispensable for responding to a crisis or emergency or for addressing the impacts of a crisis or emergency in the Union;	(a) 'crisis-relevant products' means products ~~or processes~~ that are indispensable for responding to a crisis or emergency or for addressing the **direct** impacts of a crisis or emergency in the Union;	(a) 'crisis-relevant products' means products or processes that are indispensable for responding to a crisis or emergency or for addressing the impacts of a crisis or emergency in the Union ***and for which the granting of a compulsory license is the only means of ensuring the sufficient and timely availability and supply of such products or processes, as determined by the Commission through the guidance of the advisory body in accordance with Article 6***;	(a) 'crisis-relevant products' means products ~~*or processes*~~ that are indispensable for responding to a crisis or emergency or for addressing the impacts of a crisis or emergency in the Union; Text Origin: Council Mandate
Article 3, first paragraph, point (b)				
64	(b) 'relevant activities' means the acts of making, using, offering for sale, selling or importing.	(b) 'relevant activities' means the acts of making, using, offering for sale, selling or importing.	(b) 'relevant activities' means the acts of making, using, offering for sale, selling or importing.	(b) 'relevant activities' means the acts of making, using, offering for sale, selling or importing. Text Origin: Commission Proposal
Article 3, first paragraph, point (c)				
65	(c) 'rights-holder' means a holder of any of the intellectual property rights referred to in Article 2(1);	(c) 'rights-holder' means a holder of any of the intellectual property rights referred to in Article 2(1);	(c) 'rights-holder' means a holder of any of the intellectual property rights referred to in Article 2(1);	(c) 'rights-holder' means a holder of any of the intellectual property rights referred to in Article 2(1); Text Origin: Commission Proposal
Article 3, first paragraph, point (d)				

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
66	(d) 'protected invention' means any invention protected by any of the intellectual property rights referred to in Article 2(1);	(d) 'protected invention' means any invention protected by any of the intellectual property rights referred to in Article 2(1);	(d) 'protected invention' means any invention protected by any of the intellectual property rights referred to in Article 2(1);	(d) 'protected invention' means any invention protected by any of the intellectual property rights referred to in Article 2(1); Text Origin: Commission Proposal
Article 3, first paragraph, point (e)				
67	(e) 'Union compulsory licence' means a compulsory licence granted by the Commission to exploit a protected invention of crisis-relevant products for any of the relevant activities in the Union;	(e) 'Union compulsory licence' means a compulsory licence granted by the Commission to exploit a protected invention ~~of crisis-relevant products for~~**in order to carry out** any of the relevant activities **referred to in Article 3(b) in the territory of**~~in~~ the Union **concerning crisis-relevant products or processes required to manufacture these products**;	(e) 'Union compulsory licence' means a compulsory licence granted by the Commission to exploit a protected invention of crisis-relevant products for any of the relevant activities in the Union;	(e) 'Union compulsory licence' means a compulsory licence granted by the Commission to exploit a protected invention ~~*of crisis-relevant products for*~~***in order to carry out*** any of the relevant activities ***referred to in Article 3(b) in the territory of***~~*in*~~ the Union ***concerning crisis-relevant products or processes required to manufacture these products***; Text Origin: Council Mandate
Article 3, first paragraph, point (ea)				
67a		**(ea) 'competent advisory body' means the advisory body competent for the Union crisis or emergency mechanism as listed in the Annex to this Regulation;**		***(ea) 'competent advisory body' means the advisory body competent for the Union crisis or emergency mechanism as listed in the Annex to this Regulation;***

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				Text Origin: Council Mandate
Article 3, first paragraph, point (f)				
68	(f) 'customs authorities' means customs authorities as defined in Article 5, point (1), of Regulation (EU) No 952/2013 of the European Parliament and of the Council[1]; _____ 1. Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).	(f) 'customs authorities' means customs authorities as defined in Article ~~5, point (1),~~**5(1)** of Regulation (EU) No 952/2013 of the European Parliament and of the Council[1]; _____ 1. **[1]** Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).	(f) 'customs authorities' means customs authorities as defined in Article 5, point (1), of Regulation (EU) No 952/2013 of the European Parliament and of the Council[1]; _____ 1. Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).	(f) 'customs authorities' means customs authorities as defined in Article 5, point (1), of Regulation (EU) No 952/2013 of the European Parliament and of the Council[1]; _____ 1. Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1). Text Origin: Commission Proposal
Article 4				
69	Article 4 Union compulsory licence	Article 4 **General conditions for granting a** Union compulsory licence	Article 4 Union compulsory licence	
Article 4, first paragraph				
70	The Commission may grant a Union compulsory licence where a crisis mode or an emergency mode listed in the Annex to this Regulation has been activated or declared in accordance with one of	The Commission may grant a Union compulsory licence ~~where a crisis mode or an emergency mode listed in the Annex to this Regulation has been activated or declared in accordance with one of~~	The Commission may grant a Union compulsory licence ~~where~~***in the event of*** a crisis mode or an emergency mode ~~listed~~ in ***case no voluntary agreement with a view to ensuring the supply of***	Trilogue I - 10/12/2024 "Scope" to be negotiated at political level To be discussed at a later stage

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	the Union acts listed in that Annex.	~~the Union acts listed in that Annex.~~ **only on the condition that:**	***crisis-relevant products*** ~~*the Annex to this Regulation*~~ has been ~~*activated or declared in accordance with one of the Union acts listed in that Annex*~~***reached between right-holder and the potential licensee within four weeks***.	ITM 24 04 For CSL to come back on "time constraint" in art. 4 For EP to come back on content of art. 4
Article 4, first paragraph, point (a)				
70a		**(a) a crisis mode or an emergency mode listed in the Annex to this Regulation has been activated or declared in accordance with the respective Union legal act listed in Article 2(1a);**		Trilogue I - 10/12/2024 "Scope" to be negotiated at political level To be discussed at a later stage
Article 4, first paragraph, point (b)				
70b		**(b) the Commission has concluded, in accordance with Article 7, that the use of an invention protected by intellectual property rights which concerns crisis-relevant products is required to supply those products in the territory of the Union;**		To come back after discussions on art. 6 and 7
Article 4, first paragraph, point (c)				
70c		**(c) the Commission has concluded, in accordance with Article 7, that means other than a Union compulsory licence,**		To come back after discussions on art. 6 and 7

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		including voluntary agreements to use an invention protected by intellectual property rights which concerns crisis-relevant products, could not ensure access to those products ('measure of last resort');		ITM 24 04 CSL proposal: (c) the Commission has concluded, in accordance with Article 7, that means other than a Union compulsory licence, including voluntary agreements to use an invention protected by intellectual property rights which concerns crisis-relevant products, could not be achieved within a reasonable timeframe and could not ensure access to those products ('measure of last resort'); EP proposal: "(c) the Commission has concluded, in accordance with Article 7, that means other than a Union compulsory licence could not ensure access to the crisis-relevant products concerned and, in particular, that voluntary licensing agreements to use a protected invention relating to such products could not be concluded within a reasonable time limit ('measure of last resort');
Article 4, first paragraph, point (d)				
70d		**(d) the rights-holders concerned were given the opportunity to provide their comments to the competent advisory body and the**		To come back after discussions on art. 6 and 7

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		Commission in accordance with Articles 6 and 7.		
Article 5				
71	Article 5 General conditions of a Union compulsory licence	Article 5 General ~~conditions~~**requirements** of a Union compulsory licence	Article 5 General conditions of a Union compulsory licence	
Article 5(1)				
72	1. The Union compulsory licence shall	1. The Union compulsory licence shall	1. The Union compulsory licence ***that may be granted by the Commission in accordance with Article 4*** shall***, notwithstanding the obligations pursuant to Article 10:***	1. The Union compulsory licence ***that may be granted by the Commission in accordance with Article 4*** shall Text Origin: EP Mandate
Article 5(1), point (a)				
73	(a) be non-exclusive and non-assignable, except with that part of the enterprise or goodwill which enjoys such compulsory licence;	(a) be non-exclusive and non-assignable, except with that part of the enterprise or goodwill which enjoys such compulsory licence;	(a) be non-exclusive and non-assignable, except with that part of the enterprise or goodwill which enjoys such compulsory licence;	(a) be non-exclusive and non-assignable, except with that part of the enterprise or goodwill which enjoys such compulsory licence; Text Origin: Commission Proposal
Article 5(1), point (b)				
74	(b) have a scope and duration that is limited to the purpose for which the compulsory licence is granted and limited to the scope and duration of the crisis or	(b) have a **material** scope and duration that is **strictly** limited to the purpose for which the **Union** compulsory licence is granted and **strictly** limited to the scope and duration of the crisis or emergency	(b) have a ***strict limitation concerning*** scope***, field of use, necessary quantities, and a*** ~~*and*~~ duration that is ~~*limited to the*~~***fully in line with the specific*** purpose for which the compulsory licence	(b) have a ***[material]*** scope and duration that ~~*is*~~***are strictly*** limited to the purpose for which the ***Union*** compulsory licence is granted and ***strictly*** limited to the scope and duration of the crisis or

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement	
	emergency mode in the framework of which it is granted;	mode in the framework of which it is granted;	is ~~granted and limited~~***issued, as well as strictly linked*** to the scope and duration of the crisis or emergency mode ~~in the framework of~~***under*** which it is granted ***within the Union***;	emergency mode in the framework of which it is granted; "Material": in brackets ; to discuss it further / link with TS Text Origin: Council Mandate	
Article 5(1), point (c)					
G	75	(c) be strictly limited to the relevant activities of crisis-relevant products in the Union;	(c) be strictly limited to the relevant activities **that are necessary to ensure the adequate supply** of crisis-relevant products in the Union;	(c) be strictly limited to the relevant ***and properly justified*** activities of crisis-relevant products in the Union;	(c) be strictly limited to the relevant activities ***that are necessary to ensure the adequate supply*** of crisis-relevant products in the Union; Text Origin: Council Mandate	G
Article 5(1), point (d)					
G	76	(d) only be granted against payment of an adequate remuneration to the rights-holder;	(d) only be granted against payment of an adequate remuneration to the rights-holder**, determined in accordance with Article 9**;	(d) only be granted against payment of an adequate remuneration to the rights-holder ***determined in accordance with Article 9***;	(d) only be granted against payment of an adequate remuneration to the rights-holder, ***determined in accordance with Article 9***; Text Origin: Council Mandate	G
Article 5(1), point (e)					
G	77	(e) be limited to the territory of the Union;	(e) be limited to the territory of the Union;	(e) be ***strictly*** limited to the ***precisely defined*** territory of the Union;	(e) be ***strictly*** limited to the territory of the Union;	G

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				Agreed to put "precisely defined" in a recital Text Origin: EP Mandate
Article 5(1), point (f)				
78	(f) only be granted to a person deemed to be in a position to exploit the protected invention in a manner that permits the proper carry out of the relevant activities of the crisis-relevant products and in accordance with the obligations referred to in Article 10.	(f) only be granted to ~~a person deemed to be in a position to~~**an entity that has the capacity to efficiently and swiftly** exploit the protected invention in a manner that permits the **effective and** proper carry out of the relevant activities of the crisis-relevant products**;** and ~~in accordance with the obligations referred to in Article 10.~~	(f) only be granted to a person deemed to be in a position to exploit the protected invention in a manner that permits the proper carry out of the relevant activities of the crisis-relevant products and in accordance with the obligations referred to in Article 10.	(f) only be granted to a person ~~*deemed to be in a position to*~~***or an entity that has the capacity to swiftly*** exploit the protected invention in a manner that permits the proper carry out of the relevant activities of the crisis-relevant products***;*** and ~~*in accordance with the obligations referred to in Article 10.*~~ Text Origin: Council Mandate
Article 5(1), point (fa)				
78a		**(fa) automatically expire if the crisis or emergency mode has ended.**	***(fa) clearly state that the licensee is responsible for any liability or warranties related to the production and distribution of crisis-relevant products, excluding the rights-holder from product liability claims.***	Agreed to turn (fa) EP in a recital: "Matters relating to product liability in relation to crisis-relevant products manufactured under a Union compulsory licence should be governed by the relevant Union or national law, as applicable". (fa) CSL: EP agrees with automatic expiry but EP insists on keeping

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				transitionnal period as in row 173a - To be considered with art. 14 (3) row 175 and art. 14(4) row 176a
Article 5(2)				
G 79	2. A Union compulsory licence for an invention protected by a published patent application shall cover a patent granted based on that application, provided that the granting of that patent takes place while the Union compulsory licence is valid.	2. A Union compulsory licence for an invention protected by a published patent application shall cover a patent granted based on that application, provided that the granting of that patent takes place while the Union compulsory licence is valid. **This provision shall apply mutatis mutandis to utility model applications.**	2. A Union compulsory licence for an invention protected by a published patent application shall cover a patent granted based on that application, provided that the granting of that patent takes place while the Union compulsory licence is valid.	2. A Union compulsory licence for an invention protected by a published patent application shall cover a patent granted based on that application, provided that the granting of that patent takes place while the Union compulsory licence is valid. ***This provision shall apply mutatis mutandis to utility model applications.*** Text Origin: Council Mandate
Article 5(3)				
G 80	3. A Union compulsory licence for an invention protected by a patent shall cover a supplementary protection certificate issued with reference to that patent, provided that the transition from patent protection to protection conferred by a supplementary protection certificate takes place while the Union compulsory licence is valid.	3. A Union compulsory licence for an invention protected by a patent shall cover a supplementary protection certificate issued with reference to that patent, provided that the transition from patent protection to protection conferred by a supplementary protection certificate takes place while the Union compulsory licence is valid **and provided that such licence specifies that it shall apply to**	3. A Union compulsory licence for an invention protected by a patent shall cover a supplementary protection certificate issued with reference to that patent, provided that the transition from patent protection to protection conferred by a supplementary protection certificate takes place while the Union compulsory licence is valid.	3. A Union compulsory licence for an invention protected by a patent shall cover a supplementary protection certificate issued with reference to that patent, provided that the transition from patent protection to protection conferred by a supplementary protection certificate takes place while the Union compulsory licence is valid ***and provided that such licence specifies that it shall apply to***

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		such certificate, where the certificate still covers the crisis-relevant product.		***such certificate, where the certificate still covers the crisis-relevant product***. Text Origin: Council Mandate
Article 6				
81	Article 6 Advisory body	Article 6 Advisory body	Article 6 Advisory body	Article 6 Advisory body EP agreed with the new structure proposed by the Council Some content still to be discussed further Text Origin: Commission Proposal
Article 6(1)				
82	1. When the Commission considers the granting of a Union compulsory licence, it shall without undue delay consult an advisory body.	1. ~~When the Commission considers the granting of a Union compulsory licence, it shall without undue delay consult an advisory body.~~	1. When the Commission considers the granting of a Union compulsory licence, it shall without undue delay consult an advisory body.	1. ~~*When the Commission considers the granting of a Union compulsory licence, it shall without undue delay consult an advisory body.*~~ EP ok with Council - row 114j
Article 6(2)				
83	2. The advisory body referred to in paragraph 1 shall be the advisory body competent for the Union crisis or emergency	2. ~~The advisory body referred to in paragraph 1 shall be the advisory body competent for the Union crisis or emergency~~	2. The advisory body referred to in paragraph 1 shall be the advisory body competent for the Union crisis or emergency	2. ~~*The advisory body referred to in paragraph 1 shall be the advisory body competent for the Union crisis or emergency*~~

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	mechanism as listed in Annex I to this Regulation (the 'competent advisory body'). For the purposes of the present Regulation, the competent advisory body shall assist and advise the Commission as regards the following tasks:	~~mechanism as listed in Annex I to this Regulation (the 'competent advisory body'). For the purposes of the present Regulation, the competent advisory body shall assist and advise the Commission as regards the following tasks:~~	mechanism as listed in Annex I to this Regulation (the 'competent advisory body'). For the purposes of the present Regulation, the competent advisory body, ***which is to act in the public interest,*** shall assist and advise the Commission as regards the following tasks:	~~*mechanism as listed in Annex I to this Regulation (the 'competent advisory body'). For the purposes of the present Regulation, the competent advisory body shall assist and advise the Commission as regards the following tasks:*~~ EP ok to drop "public interest" as kept in art. 1
Article 6(2), point (a)				
84	(a) the gathering of crisis-relevant information, market intelligence and the analysis of those data;	(a) ~~the gathering of crisis-relevant information, market intelligence and the analysis of those data;~~	(a) the gathering of crisis-relevant information, market intelligence and the analysis of those data;	(a) ~~*the gathering of crisis-relevant information, market intelligence and the analysis of those data;*~~ EP ok but drafting should be clearer in the CSL drafting of row 96h Text Origin: Council Mandate
Article 6(2), point (aa)				
84a			***(aa) the assessment of whether the obligation to give the rights-holder an opportunity to engage in negotiations for a voluntary agreement to be reached within four weeks, laid down in Article 4, has been complied with;***	EP flexible with "four weeks" but insists on keeping the idea of time constraint CSL proposes to come back with drafting proposal on row 96e
Article 6(2), point (b)				

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
85	(b) the analysis of the crisis-relevant information gathered by Member States or the Commission and aggregated data received by other crisis-relevant bodies at Union and international level;	(b) ~~the analysis of the crisis-relevant information gathered by Member States or the Commission and aggregated data received by other crisis-relevant bodies at Union and international level;~~	(b) the analysis of the crisis-relevant information gathered by Member States or the Commission and aggregated data received by other crisis-relevant bodies at Union and international level;	(b) ~~*the analysis of the crisis-relevant information gathered by Member States or the Commission and aggregated data received by other crisis-relevant bodies at Union and international level;*~~ Covered by CSL 96h
Article 6(2), point (ba)				
85a			***(ba) the determination of crisis-relevant products;***	*deleted* *Covered by CSL row 114c*
Article 6(2), point (c)				
86	*(c)* the facilitation of exchanges and sharing of information with other relevant bodies and other crisis-relevant bodies at Union and national level, as well as at international level, where appropriate;	(c) ~~the facilitation of exchanges and sharing of information with other relevant bodies and other crisis-relevant bodies at Union and national level, as well as at international level, where appropriate;~~	(c) the facilitation of exchanges and sharing of information with other relevant bodies and other crisis-relevant bodies at Union and national level, as well as at international level, where appropriate;	(c) ~~*the facilitation of exchanges and sharing of information with other relevant bodies and other crisis-relevant bodies at Union and national level, as well as at international level, where appropriate;*~~ Covered by the CSL row 96i
Article 6(2), point (d)				
87	(d) the identification of the rights protecting the crisis-relevant product;	(d) ~~the identification of the rights protecting the crisis-relevant product;~~	(d) the identification of the rights protecting the crisis-relevant product;	(d) ~~*the identification of the rights protecting the crisis-relevant product;*~~ Covered by CSL row 96b
Article 6(2), point (e)				

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
88	(e) the establishment of whether there is a need to grant a Union compulsory licence;	(e) ~~the establishment of whether there is a need to grant a Union compulsory licence;~~	(e) the establishment of whether there is a need to grant a Union compulsory licence;	(e) ~~*the establishment of whether there is a need to grant a Union compulsory licence;*~~ Covered by CSL row 96j
Article 6(2), point (f)				
89	(f) the identification and consultation of the representatives of right holders or their representatives as well as potential licensees and consulting other economic operators, and the industry;	(f) ~~the identification and consultation of the representatives of right holders or their representatives as well as potential licensees and consulting other economic operators, and the industry;~~	(f) the identification and consultation of the representatives of right holders or their representatives as well as potential licensees and consulting other ***stakeholders and*** economic operators, ~~*and the*~~***including*** industry***, academia and civil society***;	(see also row 96f) Agreed to put academia and civil society in a recital For COM to propose the best place and a drafting ITM 08 04 COM drafting suggestion in rec. 19 Drafting of this addition provisionally agreed, pending discussions on rec. 19
Article 6(2), point (g)				
90	(g) the establishment, if relevant, of whether the criteria for termination or modification of the Union compulsory licence set out in Article 15 have been fulfilled.	(g) ~~the establishment, if relevant, of whether the criteria for termination or modification of the Union compulsory licence set out in Article 15 have been fulfilled.~~	(g) the establishment, if relevant, of whether the criteria for termination or modification of the Union compulsory licence set out in Article 15 have been fulfilled.	(g) ~~*the establishment, if relevant, of whether the criteria for termination or modification of the Union compulsory licence set out in Article 15 have been fulfilled.*~~ Covered by CSL 96k
Article 6(3)				
91	3. The advisory body shall cooperate and coordinate closely,	3. ~~The advisory body shall cooperate and coordinate closely,~~	3. The advisory body shall cooperate and coordinate closely,	3. ~~*The advisory body shall cooperate and coordinate closely,*~~

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	where appropriate, with other relevant crisis-related bodies and with intellectual property offices at Union and national level.	~~where appropriate, with other relevant crisis-related bodies and with intellectual property offices at Union and national level.~~	where appropriate, with other relevant crisis-related bodies and with intellectual property offices at Union and national level.	~~*where appropriate, with other relevant crisis-related bodies and with intellectual property offices at Union and national level.*~~ Covered by 96g, 96i and recital 29
Article 6(4)				
92	4. For the purpose of the present Regulation, the Commission:	4. ~~For the purpose of the present Regulation, the Commission:~~	4. For the purpose of the present Regulation, the Commission:	4. ~~*For the purpose of the present Regulation, the Commission:*~~ Covered by CSL row 96a
Article 6(4), point (a)				
93	(a) shall ensure participation and invite representatives of other crisis-relevant bodies at Union level as observers to the relevant meetings of the advisory body in order to ensure coherence with the measures implemented through other Union mechanisms; and	(a) ~~shall ensure participation and invite representatives of other crisis-relevant bodies at Union level as observers to the relevant meetings of the advisory body in order to ensure coherence with the measures implemented through other Union mechanisms; and~~	(a) shall ensure participation and invite representatives of other crisis-relevant bodies at Union level as observers to the relevant meetings of the advisory body in order to ensure coherence with the measures implemented through other Union mechanisms; and	(a) ~~*shall ensure participation and invite representatives of other crisis-relevant bodies at Union level as observers to the relevant meetings of the advisory body in order to ensure coherence with the measures implemented through other Union mechanisms; and*~~ Covered by CSL row 29 (recital 19)
Article 6(4), point (aa)				
93a			***(aa) shall invite representatives of the European Parliament as observers to the relevant meetings of the advisory bodies, where possible under the applicable legal acts referred to in Annex;***	EP insists on keeping EP representatives; ad hoc AB to be discussed further

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
Article 6(4), point (b)				
94	(b) may invite representatives of the European Parliament, representatives of economic operators, right holders, potential licensees, stakeholder organisations, social partners and experts to attend meetings of the advisory body as observers.	(b) ~~may invite representatives of the European Parliament, representatives of economic operators, right holders, potential licensees, stakeholder organisations, social partners and experts to attend meetings of the advisory body as observers.~~	(b) may invite representatives of the ~~*European Parliament*~~***national authorities responsible for issuing compulsory licences under national laws***, representatives of economic operators~~*, right holders*~~, potential licensees, stakeholder organisations, social partners and experts to attend meetings of the advisory body as observers.	(b) ~~*may invite representatives of the European Parliament, representatives of economic operators, right holders, potential licensees, stakeholder organisations, social partners and experts to attend meetings of the advisory body as observers.*~~ Covered by CSL recital 19 (row 29)and row 96g
Article 6(5)				
95	5. In the absence of any existing competent advisory body, the tasks referred to in paragraph 2 shall be performed by an ad hoc advisory body set up by the Commission (the 'ad hoc advisory body'). The Commission shall chair the ad hoc advisory body and ensure its secretariat. Each Member State shall have the right to be represented in the ad hoc advisory body.	5. ~~In the absence of any existing competent advisory body, the tasks referred to in paragraph 2 shall be performed by an ad hoc advisory body set up by the Commission (the 'ad hoc advisory body'). The Commission shall chair the ad hoc advisory body and ensure its secretariat. Each Member State shall have the right to be represented in the ad hoc advisory body.~~	5. In the absence of any existing competent advisory body, the tasks referred to in paragraph 2 shall be performed by an ad hoc advisory body set up by the Commission (the 'ad hoc advisory body'). The Commission shall chair the ad hoc advisory body and ensure its secretariat. ~~*Each Member State shall have the right to be represented in*~~ The ad hoc advisory body ***shall be composed of representatives of the institutions and bodies of each Member State that exercise the competence to grant national compulsory licences under national law***.	Rows 95 and 96 parked for the moment, pending outcome on the discussions on scope To be discussed after discussions on scope
Article 6(6)				

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
96	6. The Commission shall adopt an implementing act laying down the rules of procedure for the ad hoc advisory body referred to in paragraph 5. The rules of procedure shall specify that the ad hoc advisory body shall not be set up for a period exceeding the duration of the crisis or emergency. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 24 (3).	6. ~~The Commission shall adopt an implementing act laying down the rules of procedure for the ad hoc advisory body referred to in paragraph 5. The rules of procedure shall specify that the ad hoc advisory body shall not be set up for a period exceeding the duration of the crisis or emergency. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 24 (3).~~	6. The Commission shall adopt an implementing act laying down the rules of procedure for the ad hoc advisory body referred to in paragraph 5. The rules of procedure shall specify that the ad hoc advisory body shall not be set up for a period exceeding the duration of the crisis or emergency. ***The rules of procedure shall specify that the ad hoc advisory body shall enforce stringent safeguards to avoid any potential conflicts of interest, and to ensure accountability and transparency.*** That implementing act shall be adopted in accordance with the examination procedure referred to in Article 24 (3).	Rows 95 and 96 parked for the moment, pending outcome on the discussions on scope
Article 6(1)				
G 96a		**1. For the purposes of the present Regulation, the competent advisory body shall assist and advise the Commission in the following tasks:**		***1. For the purposes of the present Regulation, the competent advisory body shall assist and advise the Commission in the following tasks:*** see comments in row 83 and 92 Text Origin: Council Mandate
Article 6(1), point (a)				

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
G 96b		**(a) the identification of the intellectual property rights protecting the crisis-relevant product and the rights-holders;**		***(a) the identification of the intellectual property rights protecting the crisis-relevant product and the rights-holders;*** see comment in row 87 Text Origin: Council Mandate
Article 6(1), point (b)				
G 96c		**(b) the dissemination of the published notice referred to in Article 7(1) through the appropriate channels;**		***(b) the dissemination of the published notice referred to in Article 7(1) through the appropriate channels;*** Agreed to keep it together with COM drafting suggestion in row 114J Text Origin: Council Mandate
Article 6(1), point (c)				
G 96d		**(c) the identification of potential licensees and assessment of whether they have the capacity to efficiently and swiftly exploit the protected invention in a manner that permits the effective and proper carrying out of the relevant activities relating to the crisis-relevant product, in accordance**		***(c) the identification of potential licensees and assessment of whether they have the capacity to swiftly exploit the protected invention in a manner that permits the proper carrying out of the relevant activities relating to the crisis-relevant product, in accordance with the***

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		with the obligations referred to in Article 10;		***obligations referred to in Article 10;*** Text Origin: Council Mandate
Article 6(1), point (d)				
96e		**(d) the gathering of the views of the rights-holders and potential licensees, including on the possibility of voluntary licensing agreements, and, where relevant, through their participation in the discussions of the competent advisory body, as well as the analysis of the comments received in accordance with Article 7(2)(c);**		EP flexible with "four weeks" but insists on keeping the idea of time constraint
Article 6(1), point (e)				
96f		**(e) the gathering of the views, where relevant, of economic operators of the sectors concerned, and of other relevant entities;**		***(e) the gathering of the views, where relevant, of economic operators of the sectors concerned, and of other relevant entities;*** (see also row 89) Agreed to put academia and civil society in a recital For COM to propose the best place and a drafting ITM 08 04

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				COM drafting suggestion in rec. 19 Drafting of this addition provisionally agreed, pending discussions on rec. 19 Text Origin: Council Mandate
Article 6(1), point (f)				
96g		**(f) the gathering of the views of experts from national intellectual property offices and representatives of national authorities responsible for granting national compulsory licences, including by ensuring their participation in the discussions of the competent advisory body where discussions relate to intellectual property;**		***(f) the gathering of the views of experts from national intellectual property offices and representatives of national authorities responsible for granting national compulsory licences, including by ensuring their participation in the discussions of the competent advisory body where discussions relate to intellectual property;*** Text Origin: Council Mandate
Article 6(1), point (g)				
96h		**(g) the gathering and analysis of the crisis-relevant information and market intelligence available, notably in order to take account of the characteristics of the crisis or emergency and how it is expected to evolve, and in order**		***(g) the gathering and analysis of the crisis-relevant information and market intelligence available, in particular in order to take account of:***

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		to take account of the shortage of crisis relevant products and existence of means other than a Union compulsory licence to remedy such shortage;		***(i) the characteristics of the crisis or emergency and how it is expected to evolve;*** ***(ii) the shortage of crisis relevant products;*** ***(iii) the existence of means other than a Union compulsory licence to remedy the shortage of crisis-relevant products.*** Row 100b to be inserted in 96h
Article 6(1), point (h)				
G	96i	**(h) the facilitation of the exchange and sharing of information with other relevant bodies and other crisis-relevant bodies at Union and national level, as well as relevant authorities at international level, where appropriate.**		***(h) the facilitation of the exchange and sharing of information with other relevant bodies and other crisis-relevant bodies at Union and national level, as well as relevant authorities at international level, where appropriate.*** see comment in row 86 and 91 see comments in rows 84, 85 Text Origin: Council Mandate
Article 6(1a.)				
G	96j	**1a. The advisory body shall provide an opinion on the need for a Union compulsory licence**		***1a. The advisory body shall provide an opinion on the need for a Union compulsory licence***

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		and on its content in compliance with Article 7(3).		***and on its content in compliance with Article 7(3).*** see comment in row 88 Text Origin: Council Mandate
Article 6(1b.)				
G 96k		**1b. The advisory body shall provide views on whether the Union compulsory license should be terminated or modified, in accordance with Article 14.**		***1b. The advisory body shall provide views on whether the Union compulsory license should be terminated or modified, in accordance with Article 14.*** see comment in row 90 Text Origin: Council Mandate
Article 7				
97	Article 7 Procedure for granting a Union compulsory licence	Article 7 Procedure for granting a Union compulsory licence	Article 7 Procedure for granting a Union compulsory licence	Article 7 Procedure for granting a Union compulsory licence EP agreed with the new structure proposed by the Council Some content still to be discussed further Text Origin: Commission Proposal
Article 7(1)				

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
98	1. The competent or, where relevant ad hoc, advisory body referred to in Article 6 shall provide the Commission with an opinion without undue delay. That opinion shall be issued in accordance with the rules of procedure of the advisory body and shall contain an assessment of the need for a Union compulsory licence and the conditions for such licence. The opinion shall take account of the following:	1. ~~The competent or, where relevant ad hoc, advisory body referred to in Article 6 shall provide the Commission with an opinion without undue delay. That opinion shall be issued in accordance with the rules of procedure of the advisory body and shall contain an assessment of the need for a Union compulsory licence and the conditions for such licence. The opinion shall take account of the following:~~	1. The competent or, where relevant ad hoc, advisory body referred to in Article 6 shall provide the Commission with an opinion without undue delay. That opinion shall be issued in accordance with the rules of procedure of the advisory body and shall contain an assessment of the need for a Union compulsory licence and the conditions for such licence. The opinion shall take account of the following:	Covered by CSL row 114l, with the caveat that EP insists on keeping the "ad hoc advisory body" ("or, where relevant ad hoc").
Article 7(1), point (a)				
99	(a) the nature of the crisis or emergency;	(a) ~~the nature of the crisis or emergency;~~	(a) the nature of the crisis or emergency;	See row 84
Article 7(1), point (b)				
100	(b) the scope of the crisis or emergency and how it is expected to evolve;	(b) ~~the scope of the crisis or emergency and how it is expected to evolve;~~	(b) the scope of the crisis or emergency and how it is expected to evolve;	See row 84
Article 7(1), point (ba)				
100a			***(ba) the rights and interests of the rights-holder and the potential licensee;***	*deleted* *Covered by CSL row 114r*
Article 7(1), point (bb)				
100b			***(bb) existing national compulsory licences reported to the Commission in accordance with Article 22 in order to avoid***	***(bb) existing national compulsory licences reported to the Commission in accordance with Article 22 ;***

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
			overlaps or a situation of overproduction;	CSL agrees to keep it , stopping after art. 22 To be inserted in 96h Text Origin: EP Mandate
Article 7(1), point (c)				
101	(c) the shortage of crisis-relevant products and the existence of other means than a Union compulsory licence that could adequately and swiftly remedy such shortage.	(c) ~~the shortage of crisis-relevant products and the existence of other means than a Union compulsory licence that could adequately and swiftly remedy such shortage.~~	(c) the shortage of crisis-relevant products and the existence of other means than a Union compulsory licence that could adequately and swiftly remedy such shortage.	See row 84
Article 7(2)				
102	2. The opinion of the advisory body shall not be binding on the Commission. The Commission may set a time limit for the advisory body to submit its opinion. The time limit shall be reasonable and appropriate to the circumstances of the situation, taking particular account of the urgency of the matter.	2. ~~The opinion of the advisory body shall not be binding on the Commission. The Commission may set a time limit for the advisory body to submit its opinion. The time limit shall be reasonable and appropriate to the circumstances of the situation, taking particular account of the urgency of the matter.~~	2. The opinion of the advisory body shall not be binding on the Commission. The Commission may set a time limit for the advisory body to submit its opinion. The time limit shall be reasonable and appropriate to the circumstances of the situation, taking particular account of the urgency of the matter.	2. ~~*The opinion of the advisory body shall not be binding on the Commission. The Commission may set a time limit for the advisory body to submit its opinion. The time limit shall be reasonable and appropriate to the circumstances of the situation, taking particular account of the urgency of the matter.*~~ Covered by CSL row 114m and 114j
Article 7(2a)				
102a			***2a. The Commission shall take the utmost account of the opinion of the advisory body.***	*deleted*

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
			Where the Commission does not follow the opinion of the advisory body, it shall explain the reasons for its decision to the advisory body, without prejudice to the Commission's powers under paragraphs 7 and 8 of this Article.	*Covered by CSL row 114r*
Article 7(3)				
103	*3.* Before the granting of a Union compulsory licence, the Commission shall give the rights-holder and the licensee an opportunity to comment on the following:	3. ~~Before the granting of a Union compulsory licence, the Commission shall give the rights-holder and the licensee an opportunity to comment on the following:~~	3. Before ***issuing the opinion, the advisory body*** ~~*the granting of a Union compulsory licence, the Commission*~~ shall give the rights-holder and the licensee an opportunity to comment ***within a reasonable timeframe*** on ~~*the following*~~:	Covered by CSL row 114e, 114b, 114q, 114n - to be discussed further
Article 7(3), point (a)				
104	(a) the possibility to reach a voluntary licensing agreement with manufacturers on intellectual property rights for the purpose of manufacturing, using and distributing the crisis-relevant products;	(a) ~~the possibility to reach a voluntary licensing agreement with manufacturers on intellectual property rights for the purpose of manufacturing, using and distributing the crisis-relevant products;~~	(a) the possibility to ***promptly*** reach a voluntary licensing agreement with manufacturers on intellectual property rights for the purpose of manufacturing, using and distributing the crisis-relevant products ***and the fulfilment of the conditions referred to in Article 4(1a) for conducting meaningful negotiations for that purpose***;	To be discussed further with row 84a
Article 7(3), point (b)				
105	(b) the need to grant the Union compulsory licence;	(b) ~~the need to grant the Union compulsory licence;~~	(b) the need to grant the Union compulsory licence;	(b) ~~*the need to grant the Union compulsory licence;*~~

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				Covered by CSL row 114g
Article 7(3), point (c)				
106	(c) the conditions under which the Commission intends to grant the Union compulsory licence, including the amount of the remuneration.	(c) ~~the conditions under which the Commission intends to grant the Union compulsory licence, including the amount of the remuneration.~~	(c) the conditions under which the Commission intends to grant the Union compulsory licence, including the amount of the remuneration.	(c) ~~*the conditions under which the Commission intends to grant the Union compulsory licence, including the amount of the remuneration.*~~ Covered by CSL row 114h
Article 7(4)				
107	4. The Commission shall notify the rights-holder and the licensee as soon as possible of the fact that a Union compulsory licence may be granted. Wherever the identification of the rights-holders is possible and does not cause significant delay, the Commission shall notify them individually.	4. ~~The Commission shall notify the rights-holder and the licensee as soon as possible of the fact that a Union compulsory licence may be granted. Wherever the identification of the rights-holders is possible and does not cause significant delay, the Commission shall notify them individually.~~	4. The Commission shall ***identify and*** notify the rights-holder and the licensee as soon as possible of the fact that a Union compulsory licence may be granted. ~~*Wherever the identification of the rights-holders is possible and does not cause significant delay,*~~ The Commission shall notify ~~*them*~~***the rights-holders*** individually.	EP insists to keep "identify" To be discussed further with other articles closely linked
Article 7(5)				
108	5. When the Commission considers the granting of a Union compulsory licence, it shall without undue delay publish a notice to inform the public about the initiation of the procedure under this article. This notice shall also include, where already	5. ~~When the Commission considers the granting of a Union compulsory licence, it shall without undue delay publish a notice to inform the public about the initiation of the procedure under this article. This notice shall also include, where already~~	5. When the Commission considers the granting of a Union compulsory licence, it shall without undue delay publish a notice to inform the public about the initiation of the procedure under this article. This notice shall also include, where already	Covered by CSL row 114a and 114k, as redrafted

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	available and relevant, information on the subject of the compulsory licence and an invitation to submit comments in accordance with paragraph 3. The notice shall be published in the Official Journal of the European Union.	~~available and relevant, information on the subject of the compulsory licence and an invitation to submit comments in accordance with paragraph 3. The notice shall be published in the Official Journal of the European Union.~~	available and relevant, information on the subject of the compulsory licence and an invitation to submit comments in accordance with paragraph 3. The notice shall be published in the Official Journal of the European Union.	
Article 7(6)				
109	6. When assessing whether a Union compulsory licence is to be granted, the Commission shall consider the following:	6. ~~When assessing whether a Union compulsory licence is to be granted, the Commission shall consider the following:~~	*deleted*	6. ~~*When assessing whether a Union compulsory licence is to be granted, the Commission shall consider the following:*~~ Covered by CSL row 114n
Article 7(6), point (a)				
110	(a) the opinion referred to in paragraph 2;	(a) ~~the opinion referred to in paragraph 2;~~	*deleted*	(a) ~~*the opinion referred to in paragraph 2;*~~ Covered by CSL
Article 7(6), point (b)				
111	(b) the rights and interests of the rights-holder and the licensee;	(b) ~~the rights and interests of the rights-holder and the licensee;~~	*deleted*	(b) ~~*the rights and interests of the rights-holder and the licensee;*~~ Covered by CSL
Article 7(6), point (c)				
112	(c) existing national compulsory licences reported to the Commission in accordance with Article 22.	(c) ~~existing national compulsory licences reported to the Commission in accordance with Article 22.~~	*deleted*	*Please see row 100b*
Article 7(7)				

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
113	*7.* Where the Commission finds that the requirements for a Union compulsory licence are met, the Commission shall grant it by means of an implementing act. The implementing act shall be adopted in accordance with the advisory procedure referred to in Article 24(2). On duly justified imperative grounds of urgency relating to the impacts of the crisis, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 24(4). In case of procedure under Article 24(4), the implementing act shall remain in force for a period not exceeding 12 months.	7. ~~Where the Commission finds that the requirements for a Union compulsory licence are met, the Commission shall grant it by means of an implementing act. The implementing act shall be adopted in accordance with the advisory procedure referred to in Article 24(2). On duly justified imperative grounds of urgency relating to the impacts of the crisis, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 24(4). In case of procedure under Article 24(4), the implementing act shall remain in force for a period not exceeding 12 months.~~	7. Where the Commission finds that the requirements for a Union compulsory licence are met, the Commission shall grant it by means of an implementing act. The implementing act shall be adopted in accordance with the advisory procedure referred to in Article 24(2). On duly justified imperative grounds of urgency relating to the impacts of the crisis, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 24(4). In case of procedure under Article 24(4), the implementing act shall remain in force for a period not exceeding 12 months.	Covered by 114r but 114s to be discussed further
Article 7(8)				
114	8. When adopting the implementing act, the Commission shall ensure the protection of confidential information. While respecting the confidentiality of the information, the Commission shall ensure that any information relied on for the purpose of its decision is disclosed to an extent that allows to understand the facts and considerations that led up to	8. ~~When adopting the implementing act, the Commission shall ensure the protection of confidential information. While respecting the confidentiality of the information, the Commission shall ensure that any information relied on for the purpose of its decision is disclosed to an extent that allows to understand the facts and considerations that led up to~~	8. When adopting the implementing act, the Commission shall ensure the protection of confidential information. While respecting the confidentiality of the information, the Commission shall ensure that any information relied on for the purpose of its decision is disclosed to an extent that allows to understand the facts and considerations that led up to	8. ~~*When adopting the implementing act, the Commission shall ensure the protection of confidential information. While respecting the confidentiality of the information, the Commission shall ensure that any information relied on for the purpose of its decision is disclosed to an extent that allows to understand the facts and considerations that led up to*~~

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	the adoption of the implementing act.	~~the adoption of the implementing act.~~	the adoption of the implementing act.	~~*the adoption of the implementing act.*~~ Covered by CSL row 114u and rec. 22 (row 32)
Article 7(1)				
114a		**1. Where the Commission, in the context of a crisis or emergency mode and on the basis of preliminary information gathered in that framework, including on the lack of supply of crisis-relevant products, available manufacturing capacity and on the intellectual property rights and rights-holders concerned, considers that the use of an invention protected by intellectual property rights which concerns crisis-relevant products, is required to supply those products in the territory of the Union, it may initiate the procedure for the granting of a Union compulsory licence by publishing a notice on the website of the Commission.**		***1. Where the Commission, in the context of a crisis or emergency mode and on the basis of preliminary information gathered in that framework, considers that the use of an invention protected by intellectual property rights which concerns crisis-relevant products, is required to supply those products in the territory of the Union, it may initiate the procedure for the granting of a Union compulsory licence by publishing a notice on the website of the Commission.*** ***The preliminary information referred to in the first subparagraph shall include information on the following:*** ***(a) the lack of supply of crisis-relevant products;*** ***(b) available manufacturing capacity;*** ***(c) the intellectual property rights and rights-holders concerned.***

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
Article 7(2)				
G 114b		**2. The notice referred to in paragraph 1 shall include:**		***2. The notice referred to in paragraph 1 shall include:*** Text Origin: Council Mandate
Article 7(2), point (a)				
G 114c		**(a) information about the crisis-relevant products for which a lack of adequate supply is considered to exist;**		***(a) information about the crisis-relevant products for which a lack of adequate supply is considered to exist;*** see comment in row 85 Text Origin: Council Mandate
Article 7(2), point (b)				
G 114d		**(b) where already available, information about the intellectual property rights and rights-holders concerned;**		
Article 7(2), point (c)				
G 114e		**(c) an invitation to rights-holders, potential licensees and other persons with an interest to submit comments to the Commission and the competent advisory body on the envisaged Union compulsory license, in particular on the following:**		***(b) an invitation to rights-holders, potential licensees and other persons with an interest to submit comments to the Commission and the competent advisory body on the envisaged Union compulsory license, in particular on the following:***

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				Text Origin: Council Mandate
Article 7(2), point (c)(i)				
114f		**(i) the possibility to reach a voluntary licensing agreement with manufacturers on intellectual property rights for the purpose of relevant activities relating to the crisis-relevant products;**		
Article 7(2), point (c)(ii)				
G 114g		**(ii) the need to grant a Union compulsory licence;**		***(i) the need to grant a Union compulsory licence;*** see comment in row 105 Text Origin: Council Mandate
Article 7(2), point (c)(iii)				
G 114h		**(iii) the possible content of the Union compulsory licence, including the amount of remuneration;**		***(ii) the possible content of the Union compulsory licence, including the amount of remuneration;*** see comment in row 106 Text Origin: Council Mandate
Article 7(2), point (d)				

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
114i		**(d) information about the relevant competent advisory body.**		***(c) information about the relevant competent advisory body.*** Text Origin: Council Mandate
Article 7(3)				
114j		**3. Upon the publication of the notice on the website of the Commission, the Commission shall request the competent advisory body to provide an opinion on the need for a Union compulsory licence and its content. The Commission shall set a time limit for the competent advisory body to submit its opinion. The time limit shall be reasonable and appropriate to the circumstances of the situation, taking particular account of the urgency of the matter. Where justified, the Commission may indicate a new time limit for the submission of the opinion.**		***3. Upon the publication of the notice on the website of the Commission, the Commission shall request the competent advisory body to disseminate it further through appropriate channels and to provide an opinion on the need for a Union compulsory licence and its content. The Commission shall set a time limit for the competent advisory body to submit its opinion. The time limit shall be reasonable and appropriate to the circumstances of the situation, taking particular account of the urgency of the matter. Where justified, the Commission may indicate a new time limit for the submission of the opinion.*** Agreed to take on board COM drafting suggestion on "to disseminate it further through appropriate channels"

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				Text Origin: Council Mandate
Article 7(4)				
114k		**4. Without undue delay, the Commission shall publish the notice referred to in paragraph 1 in the *Official Journal of the European Union*.**		***4. Without undue delay, the Commission shall publish the notice referred to in paragraph 1 in the Official Journal of the European Union.*** Text Origin: Council Mandate
Article 7(5)				
114l		**5. The competent advisory body shall issue an opinion in accordance with paragraph 3. The opinion shall be issued in accordance with the rules of procedure of the competent advisory body. It shall contain an assessment of the need for a Union compulsory licence and its content. The results of the tasks shall be annexed to the opinion.**		EP: row 98 covered by CSL row 114l, with the caveat that EP insists on keeping the "ad hoc advisory body" ("or, where relevant ad hoc").
Article 7(6)				
114m		**6. The opinion of the competent advisory body shall not be binding on the Commission.**		***6. The opinion of the competent advisory body shall not be binding on the Commission.*** see comment in row 102

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				Text Origin: Council Mandate
Article 7(7)				
G 114n		**7. After receiving the opinion of the competent advisory body, the Commission shall assess whether continuing the procedure for granting a Union compulsory licence is justified. If this is the case, the Commission shall inform the concerned rights-holders and potential licensees individually, as soon as reasonably practicable, about the fact that a Union compulsory licence may be granted. In doing so, the Commission shall provide them with:**		***7. After receiving the opinion of the competent advisory body, the Commission shall assess whether continuing the procedure for granting a Union compulsory licence is justified. If this is the case, the Commission shall inform the concerned rights-holders and potential licensees individually, as soon as reasonably practicable, about the fact that a Union compulsory licence may be granted. In doing so, the Commission shall provide them with:*** Text Origin: Council Mandate
Article 7(7), point (a)				
G 114o		**(a) the envisaged content of the Union compulsory licence;**		***(a) the envisaged content of the Union compulsory licence;*** Text Origin: Council Mandate
Article 7(7), point (b)				

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
G 114p		**(b) a summary of the opinion of the competent advisory body;**		***(b) a summary of the opinion of the competent advisory body;*** Text Origin: Council Mandate
Article 7(7), point (c)				
Y 114q		**(c) the invitation to submit their comments within a time limit set by the Commission.**		***(c) the invitation to submit their comments within a time limit set by the Commission.*** EP agrees Time limitation for voluntary agreements to be possibly discussed further in this context Text Origin: Council Mandate
Article 7(8)				
G 114r		**8. When, after considering the opinion of the competent advisory body and any comments received in accordance with paragraph 8(c), as well as taking into account the public interest and the rights and interests of the rights-holders and potential licensees, the Commission concludes that the conditions referred to in Article 4 are met, it shall grant the Union compulsory licence by**		***8. When, after considering the opinion of the competent advisory body and any comments received in accordance with paragraph 8(c), as well as taking into account the public interest and the rights and interests of the rights-holders and potential licensees, the Commission concludes that the conditions referred to in Article 4 are met, it shall grant the Union compulsory licence by means of an***

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		means of an implementing act. Where the Commission's decision to grant the Union compulsory licence is not aligned with the opinion of the competent advisory body, the implementing act shall include the reasons for departing from the opinion.		***implementing act. Where the Commission's decision to grant the Union compulsory licence is not aligned with the opinion of the competent advisory body, the implementing act shall include the reasons for departing from the opinion.*** see comments in rows 100a, 102a, 113 Text Origin: Council Mandate
Article 7(9)				
114s		**9. The implementing act referred to in paragraph 8 shall be adopted in accordance with the examination procedure referred to in Article 24(3). On duly justified imperative grounds of urgency relating to the impacts of the crisis, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 24(4).**		CSL insists on examination procedure To be discussed at political level
Article 7(10)				
114t		**10. When, based on the opinion of the competent**		***10. When, based on the opinion of the competent advisory***

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		advisory body and taking into account the rights and interests of the rights-holders and the licensee, the Commission comes to the conclusion that the conditions referred to in Article 4 are not met, the Commission shall publish in the *Official Journal of the European Union* a notice informing the public about the end of the procedure initiated under Article 7(1).		***body and taking into account the rights and interests of the rights-holders and the licensee, the Commission comes to the conclusion that the conditions referred to in Article 4 are not met, the Commission shall publish in the Official Journal of the European Union a notice informing the public about the end of the procedure initiated under Article 7(1).*** EP agrees Text Origin: Council Mandate
Article 7(11)				
114u		**11. Throughout the procedure for granting a Union compulsory licence, the Commission and the competent advisory body shall ensure the protection of confidential information. While respecting the confidentiality of the information, the Commission and the competent advisory body shall ensure that any information relied on for the purpose of the Commission's decision is disclosed to an extent**		***11. Throughout the procedure for granting a Union compulsory licence, the Commission and the competent advisory body shall ensure the protection of confidential information. While respecting the confidentiality of the information, the Commission and the competent advisory body shall ensure that any information relied on for the purpose of the Commission's decision is disclosed to an extent that allows***

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		that allows to understand the facts and considerations that led up to the adoption of the implementing act.		***to understand the facts and considerations that led up to the adoption of the implementing act.*** see comment in row 114 EP: row 98 is covered by CSL row 114l, with the caveat that EP insists on keeping the "ad hoc advisory body" ("or, where relevant ad hoc"). Text Origin: Council Mandate
Article 8				
115	Article 8 Content of the Union compulsory licence	Article 8 Content of the Union compulsory licence	Article 8 Content of the Union compulsory licence	Article 8 Content of the Union compulsory licence Text Origin: Commission Proposal
Article 8(1)				
116	1. The Union compulsory licence shall specify the following:	1. The Union compulsory licence shall specify the following:	1. The Union compulsory licence shall specify the following:	1. The Union compulsory licence shall specify the following: Text Origin: Commission Proposal
Article 8(1), point (a)				
G 117	(a) the patent, patent application, supplementary protection certificate or utility	(a) the patent, **published** patent application, supplementary protection certificate or utility	(a) the patent, patent application, supplementary protection certificate or utility	(a) the patent, ***published*** patent application, supplementary protection certificate or utility G

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	model for which the licence is granted or, where the identification of those rights would significantly delay the granting of the licence, the non-proprietary name of the products which are to be manufactured under the licence;	model **or published utility model application** for which the licence is granted**;** ~~or, where the identification of those rights would significantly delay the granting of the licence, the non-proprietary name of the products which are to be manufactured under the licence;~~	model for which the licence is granted ~~*or, where the identification of those rights would significantly delay the granting of the licence, the non-proprietary name of the products which are to be manufactured under the licence*~~;	model ***or published utility model application*** for which the licence is granted***;*** ~~*or, where the identification of those rights would significantly delay the granting of the licence, the non-proprietary name of the products which are to be manufactured under the licence;*~~ Ok to put "published utility model application" here for consistency But the rest of the deleted text is to be discussed further with art. 14 Text Origin: Council Mandate
Article 8(1), point (b)				
G 118	(b) the right-holder, provided they can be identified with reasonable efforts having regard to the circumstances, including the urgency of the situation;	(b) the ~~right-holder, provided they can be identified with reasonable efforts having regard to the circumstances, including the urgency of the situation~~**rights-holder**;	(b) the right-holder~~, *provided they can be identified with reasonable efforts having regard to the circumstances, including the urgency of the situation*~~;	(b) the ~~*right-holder, provided they can be identified with reasonable efforts having regard to the circumstances, including the urgency of the situation*~~***rights-holder***; To be discussed further with art. 14 Text Origin: Council Mandate
Article 8(1), point (c)				

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
119	(c) the licensee, in particular the following information:	(c) the licensee, in particular the following information:	(c) the licensee, in particular the following information:	(c) the licensee, in particular the following information: Text Origin: Commission Proposal
Article 8(1), point (c)(1)				
120	(1) name, trade name and registered trade mark;	(1) name~~,~~ **and** trade name ~~and registered trade mark~~;	(1) name, trade name and registered trade mark;	(1) name~~,~~ ***and*** trade name ~~*and registered trade mark*~~; Text Origin: Council Mandate
Article 8(1), point (c)(2)				
121	(2) contact details;	(2) contact details;	(2) contact details;	(2) contact details; Text Origin: Commission Proposal
Article 8(1), point (c)(3)				
122	(3) unique identification number in the country where the licensee is established;	(3) unique identification number in the country where the licensee is established;	(3) unique identification number in the country where the licensee is established;	(3) unique identification number in the country where the licensee is established; Text Origin: Commission Proposal
Article 8(1), point (c)(4)				
123	(4) where available, the Economic Operators Registration and Identification (EORI) number;	(4) where available, the Economic Operators Registration and Identification (EORI) number;	(4) where available, the Economic Operators Registration and Identification (EORI) number;	(4) where available, the Economic Operators Registration and Identification (EORI) number;

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				Text Origin: Commission Proposal
Article 8(1), point (d)				
124	(d) the duration for which the Union compulsory licence is granted;	(d) the duration for which the Union compulsory licence is granted;	(d) the duration for which the Union compulsory licence is granted;	(d) the duration for which the Union compulsory licence is granted; Text Origin: Commission Proposal
Article 8(1), point (e)				
125	(e) the remuneration to be paid to the rights-holder determined in accordance with Article 9;	(e) the remuneration to be paid to the rights-holder determined in accordance with Article 9;	(e) the remuneration to be paid to the rights-holder determined in accordance with Article 9;	(e) the remuneration to be paid to the rights-holder determined in accordance with Article 9; Text Origin: Commission Proposal
Article 8(1), point (f)				
126	(f) the non-proprietary name of the crisis-relevant product which is to be manufactured under the Union compulsory licence and its commodity code (CN code) under which the crisis-relevant product is classified, as defined in Council Regulation (EEC) No 2658/87;	(f) **where appropriate,** the non-proprietary name of the crisis-relevant product which is to be manufactured under the Union compulsory licence ~~and~~**and/or** its commodity code (CN code) under which the crisis-relevant product is classified, as defined in Council Regulation (EEC) No 2658/87;	(f) the non-proprietary name of the crisis-relevant product which is to be manufactured under the Union compulsory licence and its commodity code (CN code) under which the crisis-relevant product is classified, as defined in Council Regulation (EEC) No 2658/87;	(f) ***where appropriate,*** the non-proprietary name of the crisis-relevant product which is to be manufactured under the Union compulsory licence ~~*and*~~***and/or*** its commodity code (CN code) under which the crisis-relevant product is classified, as defined in Council Regulation (EEC) No 2658/87; To be discussed further with art. 14

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				Text Origin: Council Mandate
Article 8(1), point (g)				
127	(g) the details referred to in Article 10(1)(c), (d) and (e) allowing the identification of the crisis-relevant product manufactured under the Union compulsory licence and, where applicable, any other specific requirement under Union legislation applicable to the crisis-relevant products and allowing its identification.	(g) the details referred to in Article 10(1)(c), (d) and (e) allowing the identification of the crisis-relevant product manufactured under the Union compulsory licence and, where applicable, any other specific requirement under Union legislation applicable to the crisis-relevant products and allowing its identification~~.~~**;**	(g) the details referred to in Article 10(1)(c), (d) and (e) allowing the identification of the crisis-relevant product manufactured under the Union compulsory licence and, where applicable, any other specific requirement under Union legislation applicable to the crisis-relevant products and allowing its identification.	(g) the details referred to in Article 10(1)(c), (d) and (e) allowing the identification of the crisis-relevant product manufactured under the Union compulsory licence and, where applicable, any other specific requirement under Union legislation applicable to the crisis-relevant products and allowing its identification. Text Origin: Commission Proposal
Article 8(1), point (ga)				
G 127a		**(ga) where feasible, the maximum number of crisis-relevant products to be manufactured under the Union compulsory licence.**		***(ga) the maximum number of crisis-relevant products to be manufactured under the Union compulsory licence.*** Text Origin: Council Mandate
Article 8(1), point (h)				
R 128	(h) measures complementing the compulsory licence, which are necessary to achieve the objective of the compulsory licence.	*deleted*	(h) measures complementing the compulsory licence, ~~*which are*~~***as referred to in Article 13a, including, where strictly***	Trilogue I - 10/12/2024 To be negotiated at political level

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
			necessary to achieve the objective of the compulsory licence***, the obligation for the rights-holder to disclose trade secrets to the licensee when the conditions provided for in Article 13a (2) and (3) are fulfilled***.	
Article 8(2)				
129	2. By way of derogation from paragraph 1, point (e), the Commission may determine the remuneration after the granting of the licence, by way of an implementing act, where that determination requires, further investigation and consultation. This implementing act shall be adopted in accordance with the rules referred to in Article 7(6) (a) and (b), 7(7) and 7(8).	*deleted*	*2.* By way of derogation from paragraph 1, point (e), the Commission may determine the remuneration after the granting of the licence, by way of an implementing act, where that determination requires, further investigation and consultation. This implementing act shall be adopted in accordance with the rules referred to in Article 7(6) (a) and (b), 7(7) and 7(8).	To be discussed with art. 9
Article 9				
130	Article 9 Remuneration	Article 9 Remuneration	Article 9 Remuneration	Article 9 Remuneration Text Origin: Commission Proposal
Article 9(1)				
G 131	1. The licensee shall pay an adequate remuneration to the rights-holder. The amount of the	1. The licensee shall pay an adequate remuneration to the rights-holder. The amount of the	1. The licensee shall pay an adequate remuneration to the rights-holder. The amount of the	1. The licensee shall pay an adequate remuneration to the rights-holder. The amount of the G

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	remuneration shall be determined by the Commission and specified in the Union compulsory licence.	remuneration shall be determined by the Commission and specified in the Union compulsory licence.	remuneration shall be determined by the Commission and specified in the Union compulsory licence.	remuneration ***and the timeframe within which the remuneration is to be paid*** shall be determined by the Commission and specified in the Union compulsory licence. Text Origin: Commission Proposal
Article 9(1a)				
131a			***1a. The rights-holder shall receive the remuneration within a pre-established timeframe as agreed with the Commission.***	Agreed to put EP addition in art. 9(1) row 131 Text Origin: EP Mandate
Article 9(2)				
132	2. The remuneration shall not exceed 4 % of total gross revenue generated by the licensee through the relevant activities under the Union compulsory licence.	*deleted*	2. The remuneration shall ~~not exceed 4 % of~~***be determined based on the*** total gross revenue generated by the licensee ~~through the relevant~~***from the pertinent*** activities ~~under~~***governed by*** the Union compulsory licence.	2. ~~The remuneration shall not exceed 4 % of total gross revenue generated by the licensee through the relevant activities under the Union compulsory licence.~~ agreed to delete Text Origin: Commission Proposal
Article 9(3)				

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
133	3. When determining the remuneration, the Commission shall consider the following:	3. When determining the **adequate** remuneration, the Commission shall ~~consider the following:~~**take into account the economic value of relevant activities authorised under the Union compulsory licence as well as the circumstances of each case. It shall also take into account the opinion of the competent advisory body and any comments received under Article 7(7).**	3. When determining the remuneration, the Commission shall consider the following:	
Article 9(3), point (a)				
134	(a) the economic value of the relevant activities authorised under the Union compulsory licence.	*deleted*	*(a)* the economic value of the relevant activities authorised under the Union compulsory licence.	EP would like to keep the criteria as in the COM proposal (rows 134 to 137)
Article 9(3), point (b)				
135	(b) whether the rights-holder has received public support to develop the invention.	*deleted*	*(b)* whether the rights-holder has received public support to develop the invention.	EP would like to keep the criteria as in the COM proposal (rows 134 to 137)
Article 9(3), point (c)				
136	(c) the degree to which development costs have been amortized by the rights-holder.	*deleted*	*(c)* the degree to which development costs have been amortized by the rights-holder.	EP would like to keep the criteria as in the COM proposal (rows 134 to 137)
Article 9(3), point (d)				
137	(d) where relevant, the humanitarian circumstances relating to the granting of the Union compulsory licence.	*deleted*	*(d)* where relevant, the humanitarian circumstances relating to the granting of the Union compulsory licence.	EP would like to keep the criteria as in the COM proposal (rows 134 to 137)

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
Article 9(3), point (da)				
R 137a			***(da) the possible disclosure of trade secrets pursuant to Article 13a(2) and (3) and the relevant limitations to the protection of trade secrets according to Directive (EU) 2016/94; that disclosure shall give rise to adequate compensation for the rights-holder.***	Trilogue I - 10/12/2024 To be negotiated at political level
Article 9(4)				
G 138	4. If the published patent application for which a compulsory licence has been granted does not subsequently lead to the granting of a patent, the rights-holder shall refund the remuneration paid under this article to the licensee.	4. If the published patent application for which a **Union** compulsory licence has been granted does not subsequently lead to the granting of a patent, the rights-holder shall refund the remuneration paid under this article to the licensee. **This provision shall apply mutatis mutandis to utility model applications.**	4. If the published patent application for which a compulsory licence has been granted does not subsequently lead to the granting of a patent, the rights-holder shall refund the remuneration paid under this article to the licensee.	4. If the published patent application for which a ***Union*** compulsory licence has been granted does not subsequently lead to the granting of a patent, the rights-holder shall refund the remuneration paid under this article to the licensee. ***This provision shall apply mutatis mutandis to utility model applications.*** Text Origin: Council Mandate
Article 10				
139	Article 10 Obligations to be fulfilled by the licensee	Article 10 Obligations to be fulfilled by the licensee	Article 10 Obligations to be fulfilled by the licensee	Article 10 Obligations to be fulfilled by the licensee

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				Text Origin: Commission Proposal
Article 10(1), first subparagraph				
140	1. The licensee shall be authorised to exploit the protected invention covered by the Union compulsory license only under the following obligations:	1. The licensee shall be authorised to exploit the protected invention covered by the Union compulsory ~~license~~**licence** only under the following obligations:	1. The licensee shall be authorised to exploit the protected invention covered by the Union compulsory license only under the following obligations:	1. The licensee shall be authorised to exploit the protected invention covered by the Union compulsory ~~*license*~~***licence*** only under the following obligations: Text Origin: Council Mandate
Article 10(1), first subparagraph, point (a)				
141	(a) the number of crisis-relevant products manufactured under the Unioncompulsory licence does not exceed what is necessary to meet the needs of the Union;	(a) the number of crisis-relevant products manufactured under the Union compulsory licence does not exceed ~~what is necessary to meet the needs of the Union~~**the maximum number determined in accordance with Article 8(1)(ga)**;	(a) the number of crisis-relevant products manufactured under the Union compulsory licence does not exceed ***the defined quantities and*** what is necessary to meet the needs of the Union;	(a) the number of crisis-relevant products manufactured under the Union compulsory licence does not exceed ~~*what is necessary to meet the needs of the Union*~~***the maximum number determined in accordance with Article 8(1)(ga)***; Text Origin: Council Mandate
Article 10(1), first subparagraph, point (b)				
142	(b) the relevant activities are carried out solely for the supply of the crisis-relevant products in the Union market;	(b) the relevant activities are carried out solely for the supply of the crisis-relevant products in the Union market;	(b) the relevant activities are carried out solely for the supply of the crisis-relevant products in the Union market;	(b) the relevant activities are carried out solely for the supply of the crisis-relevant products in the Union market;

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				Text Origin: Commission Proposal
Article 10(1), first subparagraph, point (c)				
143	(c) the products manufactured under the Union compulsory licence are clearly identified, through specific labelling or marking, as being manufactured and marketed pursuant to this Regulation.	(c) the products manufactured under the Union compulsory licence are clearly identified, through specific labelling or marking, as being manufactured and marketed pursuant to this Regulation.	(c) the products manufactured under the Union compulsory licence are clearly identified, through specific labelling or marking, as being manufactured and marketed pursuant to this Regulation.	(c) the products manufactured under the Union compulsory licence are clearly identified, through specific labelling or marking, as being manufactured and marketed pursuant to this Regulation. Text Origin: Commission Proposal
Article 10(1), first subparagraph, point (ca)				
G 143a			***(ca) a detailed account of the products produced under the Union compulsory licence;***	***(ca) the quantities of crisis-relevant products manufactured under the Union compulsory licence are regularly recorded;*** G
Article 10(1), first subparagraph, point (cb)				
R 143b			***(cb) treat the information acquired in relation to the Union compulsory licence with utmost confidentiality, refraining, in particular, from making trade secrets available to a third party without the consent of the Commission, which should inform and consult the rights-holder in this regard;***	Trilogue I - 10/12/2024 To be negotiated at political level R
Article 10(1), first subparagraph, point (cc)				

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement	
R	143c		***(cc) implement all necessary measures to preserve the confidentiality of the rights-holder's trade secrets, as ordered by the Commission pursuant to Article 13a(3);***	Trilogue I - 10/12/2024 To be negotiated at political level	R
Article 10(1), first subparagraph, point (cd)					
R	143d		***(cd) do not use trade secrets disclosed pursuant to Article 13a(2) beyond the duration of the Union compulsory licence or for any other purpose than those considered as lawful uses under Article 13a(2);***	Trilogue I - 10/12/2024 To be negotiated at political level	R
Article 10(1), first subparagraph, point (d)					
	144	(d) the products manufactured under the Union compulsory licence can be distinguished from products manufactured and marketed by the rights-holder or under a voluntary licence granted by the rights-holder by way of special packaging, colouring or shaping, provided that such distinction is feasible and does not have a significant impact on the price of the products;	(d) the products manufactured under the Union compulsory licence can be distinguished from products manufactured and marketed by the rights-holder or under a voluntary licence granted by the rights-holder by way of special packaging, colouring or shaping, provided that such distinction is feasible and does not have a significant impact on the price of the products;	(d) the products manufactured under the Union compulsory licence can be distinguished from products manufactured and marketed by the rights-holder or under a voluntary licence granted by the rights-holder by way of special packaging, colouring or shaping, provided that such distinction is feasible and does not have a significant impact on the price of the products; Text Origin: Commission Proposal	
Article 10(1), first subparagraph, point (e)					

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
145	(e) the packaging of the products manufactured under the Union compulsory licence and any associated marking or leaflet indicate that the products are subject to a Union compulsory licence under this Regulation and specify clearly that the products are exclusively for distribution in the Union and are not to be exported.	(e) the packaging of the products manufactured under the Union compulsory licence and any associated marking or leaflet indicate that the products are subject to a Union compulsory licence under this Regulation and specify clearly that the products are exclusively for distribution in the Union and are not to be exported.	(e) the packaging of the products manufactured under the Union compulsory licence and any associated marking or leaflet indicate that the products are subject to a Union compulsory licence under this Regulation and specify clearly that the products are exclusively for distribution in the Union and are not to be exported.	(e) the packaging of the products manufactured under the Union compulsory licence and any associated marking or leaflet indicate that the products are subject to a Union compulsory licence under this Regulation and specify clearly that the products are exclusively for distribution in the Union and are not to be exported. Text Origin: Commission Proposal
Article 10(1), first subparagraph, point (f)				
146	(f) before the marketing of the products manufactured under the Union compulsory licence, the licensee shall make available on a website the following information:	(f) before the marketing of the products manufactured under the Union compulsory licence, the licensee shall make available on a website the following information:	(f) before the marketing of the products manufactured under the Union compulsory licence, the licensee shall make available on a website the following information:	(f) before the marketing of the products manufactured under the Union compulsory licence, the licensee shall make available on a website the following information: Text Origin: Commission Proposal
Article 10(1), first subparagraph, point (f)(1)				
147	(1) the quantities of the products manufactured under the Union compulsory licence per Member State of manufacturing;	(1) the quantities of the products manufactured under the Union compulsory licence per Member State of manufacturing;	(1) the quantities of the products manufactured under the Union compulsory licence per Member State of manufacturing;	(1) the quantities of the products manufactured under the Union compulsory licence per Member State of manufacturing; Text Origin: Commission Proposal

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
Article 10(1), first subparagraph, point (f)(2)				
148	(2) the quantities of the products supplied under the Union compulsory licence per Member State of supply;	(2) the quantities of the products supplied under the Union compulsory licence per Member State of supply;	(2) the quantities of the products supplied under the Union compulsory licence per Member State of supply;	(2) the quantities of the products supplied under the Union compulsory licence per Member State of supply; Text Origin: Commission Proposal
Article 10(1), first subparagraph, point (f)(3)				
149	(3) the distinguishing features of the products under the Union compulsory licence.	(3) the distinguishing features of the products under the Union compulsory licence.	(3) the distinguishing features of the products under the Union compulsory licence.	(3) the distinguishing features of the products under the Union compulsory licence. Text Origin: Commission Proposal
Article 10(1), second subparagraph				
150	The address of the website shall be communicated to the Commission. The Commission shall communicate the address of the website to the Member States.	The address of the website shall be communicated to the Commission. The Commission shall communicate the address of the website to the Member States.	The address of the website shall be communicated to the Commission. The Commission shall communicate the address of the website to the Member States.	The address of the website shall be communicated to the Commission. The Commission shall communicate the address of the website to the Member States. Text Origin: Commission Proposal
Article 10(2)				
151	2. In the event of a failure by the licensee to fulfil the obligations laid down in paragraph 1 of this Article the Commission may:	2. In the event of a failure by the licensee to fulfil the obligations laid down in paragraph 1 of this Article the Commission may:	2. In the event of a failure by the licensee to fulfil the obligations laid down in paragraph 1 of this Article the Commission may:	2. In the event of a failure by the licensee to fulfil the obligations laid down in paragraph 1 of this Article the Commission may:

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				Text Origin: Commission Proposal
Article 10(2), point (a)				
152	(a) terminate the Union compulsory licence in accordance with Article 14(3); or	(a) terminate the Union compulsory licence in accordance with Article 14(3);~~or~~	(a) ***immediately*** terminate the Union compulsory licence in accordance with Article 14(3); or	(a) terminate the Union compulsory licence in accordance with Article 14(3);~~or~~ Text Origin: Council Mandate
Article 10(2), point (b)				
153	(b) impose fines or periodic penalties on the licensee in accordance with Articles 15 and 16.	(b) impose fines or periodic penalties on the licensee in accordance with Articles 15 and 16.	(b) impose fines ~~or~~***and*** periodic penalties on the licensee in accordance with Articles 15 and 16.	(b) impose fines or periodic penalties on the licensee in accordance with Articles 15 and 16. Text Origin: Commission Proposal
Article 10(3)				
154	3. The European Anti-Fraud Office (OLAF) in cooperation with the relevant national authorities of the Member States may, at the request of the rights-holder or on its own initiative, request access to books and records kept by the licensee, for the purpose of checking whether the content and the conditions of the Union compulsory licence, and	3. The European Anti-Fraud Office (OLAF) in cooperation with the relevant national authorities of the Member States may, at the request of the rights-holder or on its own initiative, request access to books and records kept by the licensee, for the purpose of checking whether the content ~~and the conditions~~ of the Union compulsory licence, and	3. The European Anti-Fraud Office (OLAF) in cooperation with the relevant national authorities of the Member States may, at the request of the rights-holder or on its own initiative***, and on the basis of sufficient elements of proof of misuse***, request access to books and records kept by the licensee, for the purpose of checking whether the content and	3. The European Anti-Fraud Office (OLAF) in cooperation with the relevant national authorities of the Member States may, at the request of the rights-holder or on its own initiative, request access to books and records kept by the licensee, for the purpose of checking whether the content ~~and the conditions~~ of the Union compulsory licence, and

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	in general the provisions of this Regulation, have been complied with.	in general the provisions of this Regulation, have been complied with.	the conditions of the Union compulsory licence, and in general the provisions of this Regulation, have been complied with.	in general the provisions of this Regulation, have been complied with. Agreed to put EP addition in a recital For COM to come back with a drafting Text Origin: Council Mandate
Article 10(4)				
155	4. The Commission is empowered to adopt implementing acts establishing rules for the specific labelling or marking referred to in paragraph 1, point (c), and for the packaging, colouring and shaping referred to in point (d) as well as rules for their use and, where relevant, their positioning on the product. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 24(2).	4. The Commission is empowered to adopt implementing acts establishing rules for the specific labelling or marking referred to in paragraph 1, point (c), and for the packaging, colouring and shaping referred to in point (d) as well as rules for their use and, where relevant, their positioning on the product. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article ~~24(2)~~**24(3)**.	4. The Commission is empowered to adopt implementing acts establishing rules for the specific labelling or marking referred to in paragraph 1, point (c), and for the packaging, colouring and shaping referred to in point (d) as well as rules for their use and, where relevant, their positioning on the product. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 24(2).	
Article 11				
156	Article 11 Prohibition of export	Article 11 Prohibition of export	Article 11 Prohibition of export	Article 11 Prohibition of export Text Origin: Commission Proposal
Article 11, first paragraph				

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
157	The export of products manufactured under a Union compulsory licence is prohibited.	The export of products manufactured under a Union compulsory licence is prohibited. **This provision is without prejudice to Regulation (EC) No 816/2006.**	The export of products manufactured under a Union compulsory licence is prohibited.	The export of products manufactured under a Union compulsory licence is prohibited. ***This provision is without prejudice to Regulation (EC) No 816/2006.*** Text Origin: Council Mandate
Article 12				
158	Article 12 Customs control	Article 12 Customs control	Article 12 Customs control	Article 12 Customs control Text Origin: Commission Proposal
Article 12(1)				
159	1. The application of this article is without prejudice to other Union legal acts governing the export of products, in particular Articles 46, 47 and 267 of Regulation (EU) No 952/2013[1]. _____ 1. REGULATION (EU) No 952/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 October 2013 laying down the Union Customs Code.	1. The application of this article is without prejudice to other Union legal acts governing the export of products, in particular Articles 46, 47 and 267 of Regulation (EU) No 952/2013[1]. _____ 1. REGULATION (EU) No 952/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 October 2013 laying down the Union Customs Code.	1. The application of this article is without prejudice to other Union legal acts governing the export of products, in particular Articles 46, 47 and 267 of Regulation (EU) No 952/2013[1]. _____ 1. REGULATION (EU) No 952/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 October 2013 laying down the Union Customs Code.	1. The application of this article is without prejudice to other Union legal acts governing the export of products, in particular Articles 46, 47 and 267 of Regulation (EU) No 952/2013[1]. _____ 1. REGULATION (EU) No 952/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 October 2013 laying down the Union Customs Code.

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				Text Origin: Commission Proposal
Article 12(2)				
160	2. Customs authorities shall rely on the Union compulsory license and modifications thereof to identify products that may fall under the prohibition laid down in Article 11. For that purpose, risk information as regards each Union compulsory licence and any modification thereof shall be entered in the relevant customs risk management system. Customs authorities shall take such risk information into consideration when they carry out controls on products placed under the customs procedure 'export' in accordance with Articles 46 and 47 of Regulation (EU) No 952/2013.	2. Customs authorities shall rely on the Union compulsory license and modifications thereof to identify products that may fall under the prohibition laid down in Article 11. For that purpose, **the Commission shall enter** risk information as regards each Union compulsory licence and any modification thereof ~~shall be entered~~ in the ~~relevant~~**Union** customs risk management system. Customs authorities shall take such risk information into consideration when they carry out controls on products placed under the customs procedure 'export' in accordance with Articles 46 and 47 of Regulation (EU) No 952/2013.	2. Customs authorities shall rely on the Union compulsory license and modifications thereof to identify products that may fall under the prohibition laid down in Article 11. For that purpose, risk information as regards each Union compulsory licence and any modification thereof shall be entered in the relevant customs risk management system. Customs authorities shall take such risk information into consideration when they carry out controls on products placed under the customs procedure 'export' in accordance with Articles 46 and 47 of Regulation (EU) No 952/2013.	2. Customs authorities shall rely on the Union compulsory license and modifications thereof to identify products that may fall under the prohibition laid down in Article 11. For that purpose, ***the Commission shall enter*** risk information as regards each Union compulsory licence and any modification thereof ~~*shall be entered*~~ in the ~~*relevant*~~***Union*** customs risk management system. Customs authorities shall take such risk information into consideration when they carry out controls on products placed under the customs procedure 'export' in accordance with Articles 46 and 47 of Regulation (EU) No 952/2013. Text Origin: Council Mandate
Article 12(3)				
161	3. Where customs authorities identify a product that may fall under the prohibition laid down in Article 11, they shall suspend its	3. Where customs authorities identify a product that may fall under the prohibition laid down in Article 11, they shall suspend its	3. Where customs authorities identify a product that may fall under the prohibition laid down in Article 11, they shall suspend its	3. Where customs authorities identify a product that may fall under the prohibition laid down in Article 11, they shall suspend its

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	export. Customs authorities shall immediately notify the Commission of the suspension and provide it with all relevant information to enable it to establish whether the product was manufactured under a Union compulsory license. To assess whether the suspended products correspond to the Union compulsory license, the Commission may consult the relevant rights-holder.	export. Customs authorities shall immediately notify the Commission of the suspension and provide it with all relevant information to enable it to establish whether the product was manufactured under a Union compulsory ~~license~~**licence**. **The Commission shall inform the rights-holder and, where appropriate, the licensee. The Commission may consult the relevant rights-holder** to assess whether the suspended products correspond to the Union compulsory license~~, the Commission may consult the relevant rights-holder~~.	export. Customs authorities shall immediately notify the Commission of the suspension and provide it with all relevant information to enable it to establish whether the product was manufactured under a Union compulsory license. To assess whether the suspended products correspond to the Union compulsory license, the Commission may consult the relevant rights-holder.	export. Customs authorities shall immediately notify the Commission of the suspension and provide it with all relevant information to enable it to establish whether the product was manufactured under a Union compulsory ~~*license*~~***licence***. ***The Commission shall inform the rights-holder and, where appropriate, the licensee. The Commission may consult the relevant rights-holder*** to assess whether the suspended products correspond to the Union compulsory license~~*, the Commission may consult the relevant rights-holder*~~. Text Origin: Council Mandate
Article 12(4)				
162	4. Where the export of a product has been suspended in accordance with paragraph 3, the product shall be released for export provided that all the other requirements and formalities under Union or national law relating to such export have been fulfilled, and either of the following conditions is fulfilled:	4. Where the export of a product has been suspended in accordance with paragraph 3, the product shall be released for export provided that all the other requirements and formalities under Union or national law relating to such export have been fulfilled, and either of the following conditions is fulfilled:	4. Where the export of a product has been suspended in accordance with paragraph 3, the product shall be released for export provided that all the other requirements and formalities under Union or national law relating to such export have been fulfilled, and either of the following conditions is fulfilled:	4. Where the export of a product has been suspended in accordance with paragraph 3, the product shall be released for export provided that all the other requirements and formalities under Union or national law relating to such export have been fulfilled, and either of the following conditions is fulfilled:

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				Text Origin: Commission Proposal
Article 12(4), point (a)				
163	(a) the Commission has not requested the customs authorities to maintain the suspension within 10 working days after it was notified thereof;	(a) the Commission has not requested the customs authorities to maintain the suspension within 10 working days after it was notified thereof;	(a) the Commission has not requested the customs authorities to maintain the suspension within 10 working days after it was notified thereof;	(a) the Commission has not requested the customs authorities to maintain the suspension within 10 working days after it was notified thereof; Text Origin: Commission Proposal
Article 12(4), point (b)				
164	(b) the Commission has informed the customs authorities that the product is not manufactured under a Union compulsory licence.	(b) the Commission has informed the customs authorities that the product is not manufactured under a Union compulsory licence.	(b) the Commission has informed the customs authorities that the product is not manufactured under a Union compulsory licence.	(b) the Commission has informed the customs authorities that the product is not manufactured under a Union compulsory licence. Text Origin: Commission Proposal
Article 12(5)				
G 165	5. Where the Commission concludes that a product manufactured under a Union compulsory licence does not comply with the prohibition laid down in Article 11, customs authorities shall not authorise its release for export. The	5. Where the Commission concludes that a product manufactured under a Union compulsory licence does not comply with the prohibition laid down in Article 11, customs authorities shall not authorise its release for export. The	5. Where the Commission concludes that a product manufactured under a Union compulsory licence does not comply with the prohibition laid down in Article 11, customs authorities shall not authorise its release for export. The	5. Where the Commission concludes that a product manufactured under a Union compulsory licence does not comply with the prohibition laid down in Article 11, customs authorities shall not authorise its release for export. The G

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	Commission shall inform the concerned rights-holder of such non-compliance.	Commission shall inform **customs authorities and** the concerned rights-holder of such non-compliance.	Commission shall inform the concerned rights-holder of such non-compliance.	Commission shall inform ***customs authorities and*** the concerned rights-holder of such non-compliance. Text Origin: Council Mandate
Article 12(6)				
166	6. Where the release for export of a product has not been authorised:	6. Where the release for export of a product has not been authorised:	6. Where the release for export of a product has not been authorised:	6. Where the release for export of a product has not been authorised: Text Origin: Commission Proposal
Article 12(6), point (a)				
167	(a) where appropriate in view of the crisis or emergency context, the Commission may require customs authorities to oblige the exporter to take specific actions at their own costs, including supplying them to designated Member States, if need be, after rendering them compliant with Union law.	(a) where appropriate in view of the crisis or emergency ~~context~~**mode**, the Commission may require**, via** customs authorities ~~to oblige~~**,** the exporter to take specific actions at their own costs, including supplying them to designated Member States, if need be, after rendering them compliant with Union law.	(a) where appropriate in view of the crisis or emergency context, the Commission may require customs authorities to oblige the exporter to take specific actions at their own costs, including supplying them to designated Member States, if need be, after rendering them compliant with Union law.	(a) where appropriate in view of the crisis or emergency ~~*context*~~***mode***, the Commission may require***, via*** customs authorities ~~*to oblige*~~***,*** the exporter to take specific actions at their own costs, including supplying them to designated Member States, if need be, after rendering them compliant with Union law. Text Origin: Council Mandate
Article 12(6), point (b)				

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
G 168	(b) in all other cases, customs authorities may take any necessary measure to ensure that the product concerned is disposed of in accordance with national law consistent with Union law. Articles 197 and 198 of Regulation (EU) No 952/2013 shall apply accordingly.	(b) in all other cases~~, customs authorities may take any necessary measure to ensure that~~ the product concerned ~~is~~**may be** disposed of in accordance with national law consistent with Union law. Articles 197 and 198 of Regulation (EU) No 952/2013 shall apply accordingly.	(b) in all other cases, customs authorities may take any necessary measure to ensure that the product concerned is disposed of in accordance with national law consistent with Union law. Articles 197 and 198 of Regulation (EU) No 952/2013 shall apply accordingly.	(b) in all other cases~~, customs authorities may take any necessary measure to ensure that~~ the product concerned ~~is~~***may be*** disposed of in accordance with national law consistent with Union law. Articles 197 and 198 of Regulation (EU) No 952/2013 shall apply accordingly. Text Origin: Council Mandate G
Article 13				
169	Article 13 Relations between rights-holder and licensee	Article 13 ~~Relations between~~**Conduct of the** rights-holder and licensee	Article 13 Relations between rights-holder and licensee	
Article 13(1)				
R 170	1. The relations between the rights-holder and the licensee who has been granted a Union compulsory license shall act and cooperate with each other in good faith when performing rights and obligations under this Regulation.	1. **When exercising the rights or performing the obligations under this Regulation,**~~The relations between~~ the rights-holder and the licensee ~~who has been granted as~~**shall refrain from any actions or omissions that could undermine the** Union compulsory ~~license shall act and cooperate with each other in good faith when performing rights and obligations under this Regulation~~**licensing process**.	1. The relations between the rights-holder and the licensee who has been granted a Union compulsory license shall act and cooperate with each other in good faith when performing rights and obligations under this Regulation.	Trilogue I - 10/12/2024 To be negotiated at political level R

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement	
Article 13(2)					
R	171	2. In compliance with the good faith obligation, the rights-holder and the licensee shall make their best efforts to fulfil the objective of the Union compulsory licence, taking into account each other's interests.	*deleted*	2. In compliance with the good faith obligation, the rights-holder and the licensee shall make their best efforts to fulfil the objective of the Union compulsory licence, taking into account each other's interests ***as well as the public interest***.	Trilogue I - 10/12/2024 To be negotiated at political level	R
Article 13a						
R	171a			***Article 13a Additional measures complementing the Union compulsory licence***	Trilogue I - 10/12/2024 To be negotiated at political level	R
Article 13a(1)						
R	171b			***1. Where necessary, the Commission shall decide, upon a reasoned request from the rights-holder or the licensee, or on its own initiative, on additional measures complementing the Union compulsory licence to ensure it achieves its objective as well as to facilitate and ensure the good collaboration between the rights-holder and the licensee.***	Trilogue I - 10/12/2024 To be negotiated at political level	R
Article 13a(2)						
R	171c			***2. Where strictly necessary, the Commission shall request the disclosure of the rights-holder's trade secrets to the licensee to the***	Trilogue I - 10/12/2024 To be negotiated at political level	R

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
			extent required to provide him with the necessary know-how to achieve the objective for which the Union compulsory licence is granted under this Regulation. The lawful uses of the trade secrets by the licensee shall be strictly limited to the manufacturing of the crisis-relevant products in view of fulfilling the objective for which the Union compulsory licence has been granted.	
Article 13a(3), first subparagraph				
R	171d		***3. Where the rights-holder is requested to disclose his trade secrets in accordance with paragraph 3, the Commission shall, prior to the disclosure of trade secrets, order the licensee to put in place all appropriate technical and organisational measures that the rights-holder reasonably identifies as necessary to preserve the confidentiality of trade secrets, in particular in relation to third parties, including, as appropriate, the use of model contractual terms, confidentiality agreements, strict access protocols, technical standards or the application of codes of conduct.***	Trilogue I - 10/12/2024 To be negotiated at political level

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
Article 13a(3), second subparagraph				
R 171e			***If the licensee fails to implement the necessary measures required by the Commission, the Commission may withhold or, as the case may be, suspend the disclosure of trade secrets until the situation is corrected by the licensee.***	Trilogue I - 10/12/2024 To be negotiated at political level
Article 13a(4)				
R 171f			***4. Appropriate remuneration to the rights-holders in compensation for the disclosure of their trade secrets shall be granted in accordance with Directive (EU) 2016/943.***	Trilogue I - 10/12/2024 To be negotiated at political level
Article 13a(5)				
R 171g			***5. Where the Commission considers adopting additional measures as referred to in paragraphs 1 and 2, it shall consult the advisory body referred to in Article 6.***	Trilogue I - 10/12/2024 To be negotiated at political level
Article 13a(6)				
R 171h			***6. The implementing acts referred to in paragraphs 1 and 2 shall be adopted in accordance with the rules referred to in Article 7(6), points (a) and (b), and Article 7(7) and (8).***	Trilogue I - 10/12/2024 To be negotiated at political level

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
Article 14				
172	Article 14 Review and termination of the Union compulsory licence	Article 14 Review and termination of the Union compulsory licence	Article 14 Review and termination of the Union compulsory licence	
Article 14(1)				
173	1. The Commission shall review the Union compulsory licence upon reasoned request by the rights-holder or the licensee or on its own initiative and shall, where needed, modify the specifications referred to in Article 8 by means of an implementing act. Where necessary, the Union compulsory licence shall be modified to indicate the complete list of rights and rights-holders covered by the compulsory licence.	1. The Commission shall review the Union compulsory licence upon reasoned request by the rights-holder or the licensee or on its own initiative and shall, where needed, modify the specifications referred to in Article 8 by means of an implementing act. Where necessary, the Union compulsory licence shall be modified to ~~indicate the complete~~**update the** list of rights and rights-holders covered by the compulsory licence**, and this modification may have a retroactive effect**.	1. The Commission shall review the Union compulsory licence upon reasoned request by the rights-holder or the licensee or on its own initiative and shall, where needed, modify the specifications referred to in Article 8 by means of an implementing act. Where necessary, the Union compulsory licence shall be modified to indicate the complete list of rights and rights-holders covered by the compulsory licence.	1. The Commission shall review the Union compulsory licence upon reasoned request by the rights-holder or the licensee or on its own initiative and shall, where needed, modify the specifications referred to in Article 8 by means of an implementing act. ~~*Where necessary*~~***Without prejudice to the Commission's obligation to identify the rights and the rightsholders before granting the Union compulsory license, [in accordance with [para 1 (a) and (c) in art. 6/task of identifying RH - to be checked by LL]***, the Union compulsory licence shall***, where necessary,*** be modified to ~~*indicate the complete*~~***update the*** list of rights and rights-holders covered by the compulsory licence***, and this modification shall, where appropriate, have a retroactive effect.”*** Text agreed For LL to check correct cross-ref to article

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
Article 14(1a)				
173a		**1a. Where the Commission considers updating the list of rights and rights-holders covered by the Union compulsory licence, it shall inform the rights-holders concerned and invite them to submit comments on the possibility to reach a voluntary licensing agreement with the licensee and on the amount of remuneration.**		Consistency with row 173
Article 14(2)				
174	2. Where necessary, the Commission shall decide upon reasoned request by the rights-holder or the licensee or on its own initiative on additional measures complementing the Union compulsory licence to ensure it achieves its objective as well as to facilitate and ensure the good collaboration between the rights-holder and the licensee.	*deleted*	*deleted*	*Trilogue I - 10/12/2024* *To be negotiated at political level*
Article 14(3)				
175	*3.* A Union compulsory licence may be terminated by the Commission by means of an implementing act where the circumstances which led to it	3. A Union compulsory licence ~~may~~**shall** be terminated by the Commission by means of an implementing act where the circumstances which led to it	3. A Union compulsory licence may be terminated by the Commission by means of an implementing act where the circumstances which led to it	3. A Union compulsory licence ~~*may*~~***shall*** be terminated by the Commission by means of an implementing act where the circumstances which led to it

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	cease to exist and are unlikely to recur or where the licensee fails to comply with the obligations laid down in this Regulation.	cease to exist and are unlikely to recur**, or may be terminated** ~~or~~ where the licensee fails to comply with the obligations laid down in this Regulation.	cease to exist and are unlikely to recur or where the licensee fails to comply with the obligations laid down in this Regulation.	cease to exist and are unlikely to recur***, or may be terminated*** ~~or~~ where the licensee fails to comply with the obligations laid down in this Regulation. To be considered with Art. 5(1) (fa) CSL, row 78a and with art. 14 (4) row 176a Text Origin: Council Mandate
Article 14(3a)				
175a		**3a. The Commission shall notify the rights-holder and the licensee of the termination or expiry of the Union compulsory licence.**		Text Origin: Council Mandate
Article 14(4)				
176	4. When the Commission considers modifying, adopting additional measures as referred to in paragraph 2, or terminating the Union compulsory licence, it may consult the advisory body referred to in Article 6.	4. When the Commission considers modifying~~, adopting additional measures as referred to in paragraph 2,~~ or terminating the Union compulsory licence, it ~~may~~**shall** consult the **competent** advisory body ~~referred to in Article 6~~.	4. When the Commission considers modifying~~, adopting additional measures as referred to in paragraph 2~~, or terminating the Union compulsory licence, it ~~may~~***shall*** consult the advisory body referred to in Article 6 ***as well as the rights-holders and licensees***.	Trilogue I - 10/12/2024 To be negotiated at political level
Article 14(4a)				
176a			***4a. When considering terminating the Union***	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
			compulsory licence, the Commission shall ensure that a sufficient transitional period is put in place.	To be considered with Art. 5(1) (fa) CSL, row 78a and with art. 14 (3) row 175
Article 14(5)				
177	5. When terminating the Union compulsory licence, the Commission may require that the licensee, within a reasonable period of time, arrange for any goods in its possession, custody, power or control to be redirected or otherwise disposed of in the manner determined by the Commission in consultation with the rights-holder and at the expense of the licensee.	5. When ~~terminating the~~**a** Union compulsory licence **is terminated or expires in accordance with Article 5(1)(h)**, the Commission may require that the licensee, within a reasonable period of time, arrange for any goods in its possession, custody, power or control to be redirected or otherwise disposed of in the manner determined by the Commission in consultation with the rights-holder and **the licensee and** at the expense of the licensee.	5. When terminating the Union compulsory licence, the Commission may require that the licensee, within a reasonable period of time, arrange for any goods in its possession, custody, power or control to be redirected or otherwise disposed of in the manner determined by the Commission in consultation with the rights-holder and at the expense of the licensee.	
Article 14(6)				
178	6. The implementing acts referred to in paragraph 1, 2 and 3 shall be adopted in accordance with the rules referred to in Article 7(6) (a) and (b), 7(7) and 7(8).	6. The implementing acts referred to in paragraph 1~~, 2~~ and 3 shall be adopted in accordance with the ~~rules~~**examination procedure** referred to in Article ~~7(6) (a) and (b), 7(7) and 7(8)~~**24(3). On duly justified imperative grounds of urgency relating to the impacts of the crisis, the Commission shall adopt immediately applicable implementing acts in accordance**	6. The implementing acts referred to in paragraph 1~~, 2~~ and 3 shall be adopted in accordance with the rules referred to in Article 7(6) (a) and (b), 7(7) and 7(8).	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		with the procedure referred to in Article 24(4). When adopting the implementing act the Commission shall ensure the protection of confidential information and shall duly consider the rights and interests of the rights-holder and the licensee.		
Article 15				
179	Article 15 Fines	Article 15 Fines	Article 15 Fines	Article 15 Fines Text Origin: Commission Proposal
Article 15(1)				
180	1. The Commission may by decision impose on the licensee or the rights-holder fines not exceeding 6 % of their respective total turnover in the preceding business year where, intentionally or negligently:	1. The Commission may by decision impose ~~on~~**fines if** the licensee ~~or the rights-holder fines not exceeding 6 % of their respective total turnover in the preceding business year where, intentionally or negligently:~~**fails to comply with its obligations under Article 9(1), Article 10(1) or Article 11.**	1. The Commission may by decision impose on the licensee or the rights-holder fines not exceeding 6 % of their respective total turnover in the preceding business year where, intentionally or negligently:	To be discussed further together with art. 16
Article 15(1), point (a)				
181	(a) the licensee fails to comply with its obligations under Article 9(1) or Article 10(1);	*deleted*	*(a)* the licensee fails to comply with its obligations under Article 9(1) or Article 10(1);	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
Article 15(1), point (b)				
182	(b) the rights-holder or the licensee fail to comply with the principle of good faith and cooperation referred to in Article 13; or	*deleted*	*(b)* the rights-holder or the licensee fail to comply with the principle of good faith and cooperation referred to in Article 13; or	To be discussed after outcome of discussions on trade secrets
Article 15(1), point (c)				
183	(c) the rights-holder or the licensee fail to comply with any obligation resulting from the additional measures complementing the Union compulsory licence as referred to in Articles 8(1)(h) and 14(2), as specified in the relevant implementing act.	*deleted*	(c) the rights-holder or the licensee fail to comply with any obligation resulting from the additional measures complementing the Union compulsory licence as referred to in Articles 8(1)(h) and ~~*14(2)*~~ ***Article 13a(1) and (2)***, as specified in the relevant implementing act.	To be discussed after outcome of discussions on trade secrets
Article 15(1), point (ca)				
183a			***(ca) the licensee does not comply with the prohibition referred in Article 11;***	To be discussed together with art. 11 Text Origin: EP Mandate
Article 15(1a)				
183b		**1a. Fines imposed in accordance with paragraph 1 shall not exceed EUR 300 000. Where the undertaking concerned is an SME, the fines**		

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		imposed shall not exceed EUR 50 000.		
Article 15(2)				
184	2. In fixing the amount of the fine, regard shall be had to the gravity, to the recurrence of the infringement and to the duration of the infringement.	2. In fixing the amount of the fine, regard shall be ~~had~~**given** to the ~~gravity, to the recurrence of the infringement and to the duration of the infringement.~~**following:**	2. In fixing the amount of the fine, regard shall be had to the gravity, to the recurrence of the infringement and to the duration of the infringement.	
Article 15(2), point (a)				
184a		**(a) nature, gravity and duration of the infringement;**		
Article 15(2), point (b)				
184b		**(b) the intentional or negligent character of the infringement;**		
Article 15(2), point (c)				
184c		**(c) any other aggravating or mitigating factor applicable to the circumstances of the case, such as actions taken to mitigate the damages, the financial benefits gained, or losses avoided, directly or indirectly, from the infringement.**		
Article 16				
185	Article 16 Periodic penalty payments	Article 16 Periodic penalty payments	Article 16 Periodic penalty payments	Article 16 Periodic penalty payments

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				To be discussed further with art. 15 Text Origin: Commission Proposal
Article 16(1)				
186	1. The Commission may, by decision, impose on the licensee or the rights-holder periodic penalty payments not exceeding 5 % of their respective average daily turnover in the preceding business year per day and calculated from the date appointed by the decision, in order to compel:	1. The Commission may, by decision, impose on the licensee ~~or the rights-holder~~ periodic penalty payments ~~not exceeding 5 % of their respective average daily turnover in the preceding business year per day and~~**for each working day** calculated from the date ~~appointed by~~**determined in** the decision, in order to compel~~:~~ **it to put an end to an infringement of its obligations under Article 9(1), Article 10(1) or Article 11.**	1. The Commission may, by decision, impose on the licensee or the rights-holder periodic penalty payments not exceeding 5 % of their respective average daily turnover in the preceding business year per day and calculated from the date appointed by the decision, in order to compel:	
Article 16(1), point (a)				
187	(a) the licensee to put an end to an infringement of its obligations under Article 10(1);	*deleted*	*(a)* the licensee to put an end to an infringement of its obligations under Article 10(1);	
Article 16(1), point (b)				
188	(b) the licensee and the rights-holder to put an end to the infringement of Article 13; or	*deleted*	*(b)* the licensee and the rights-holder to put an end to the infringement of Article 13; or	To be discussed after outcome of discussions on trade secrets
Article 16(1), point (c)				
189	(c) the rights-holder or the licensee to comply with any obligation resulting from the	*deleted*	(c) the rights-holder or the licensee to comply with any obligation resulting from the	To be discussed after outcome of discussions on trade secrets

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	additional measures complementing the Union compulsory licence as referred to in Articles 8(1)(h) and 14(2), as specified in the relevant implementing act.		additional measures complementing the Union compulsory licence as referred to in Articles 8(1)(h) and ~~14(2)~~***Article 13a(1) and (2)***, as specified in the relevant implementing act.	
Article 16(1), point (ca)				
189a			***(ca) the licensee to put an end to an infringement of the prohibition referred in Article 11;***	To be discussed together with art. 11
Article 16(1a)				
189b		**1a. Periodic penalty payments imposed in accordance with paragraph 1 shall not exceed 1.5% of the average daily turnover of the undertaking concerned in the preceding financial year. Where the undertaking concerned is an SME, the periodic payment shall not exceed 0.5% of the average daily turnover in the preceding financial year.**		
Article 16(2)				
190	2. Where the licensee or the rights-holder have satisfied the obligation which the periodic penalty payment was intended to enforce, the Commission may fix the definitive amount of the	2. **Article 15(2) shall apply mutatis mutandis.** Where the licensee ~~or the rights-holder have~~**has** satisfied the obligation which the periodic penalty payment was intended to enforce,	2. Where the licensee or the rights-holder have satisfied the obligation which the periodic penalty payment was intended to enforce, the Commission may fix the definitive amount of the	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	periodic penalty payment at a figure lower than that which would arise under the original decision.	the Commission may fix the definitive amount of the periodic penalty payment at a figure lower than that which would arise under the original decision.	periodic penalty payment at a figure lower than that which would arise under the original decision.	
Article 17				
191	Article 17 Limitation period for the imposition of fines and periodic penalty payments	Article 17 Limitation period for the imposition of fines and periodic penalty payments	Article 17 Limitation period for the imposition of fines and periodic penalty payments	Article 17 Limitation period for the imposition of fines and periodic penalty payments Text Origin: Commission Proposal
Article 17(1)				
192	1. The powers conferred on the Commission by Articles 15 and 16 shall be subject to a limitation period of five years.	1. The powers conferred on the Commission by Articles 15 and 16 shall be subject to a limitation period of five years.	1. The powers conferred on the Commission by Articles 15 and 16 shall be subject to a limitation period of five years.	1. The powers conferred on the Commission by Articles 15 and 16 shall be subject to a limitation period of five years. Text Origin: Commission Proposal
Article 17(2)				
G 193	2. Time shall begin to run on the day on which the infringement is committed. However, in the case of continuing or repeated infringements, time shall begin to run on the day on which the infringement ceases.	2. ~~Time~~**The limitation period** shall begin to run on the day on which the infringement is committed. However, in the case of continuing or repeated infringements, ~~time~~**the limitation period** shall begin to run on the	2. Time shall begin to run on the day on which the infringement is committed. However, in the case of continuing or repeated infringements, time shall begin to run on the day on which the infringement ceases.	2. ~~*Time*~~***The limitation period*** shall begin to run on the day on which the infringement is committed. However, in the case of continuing or repeated infringements, ~~*time*~~***the limitation period*** shall begin to run on the G

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		day on which the infringement ceases.		day on which the infringement ceases. Text Origin: Council Mandate
Article 17(3)				
194	3. Any action taken by the Commission or by a competent authority of the Member States for the purpose of the investigation or proceedings in respect of an infringement shall interrupt the limitation period for the imposition of fines or periodic penalty payments.	3. Any action taken by the Commission or by a competent authority of the Member States for the purpose of the investigation or proceedings in respect of an infringement shall interrupt the limitation period for the imposition of fines or periodic penalty payments.	3. Any action taken by the Commission or by a competent authority of the Member States for the purpose of the investigation or proceedings in respect of an infringement shall interrupt the limitation period for the imposition of fines or periodic penalty payments.	3. Any action taken by the Commission or by a competent authority of the Member States for the purpose of the investigation or proceedings in respect of an infringement shall interrupt the limitation period for the imposition of fines or periodic penalty payments. Text Origin: Commission Proposal
Article 17(4)				
195	4. Each interruption shall start time running afresh. However, the limitation period for the imposition of fines or periodic penalty payments shall expire at the latest on the day on which a period equal to twice the limitation period has elapsed without the Commission having imposed a fine or a periodic penalty payment. That period shall be extended by the time during which the	4. Each interruption shall start time running afresh. However, the limitation period for the imposition of fines or periodic penalty payments shall expire at the latest on the day on which a period equal to twice the limitation period has elapsed without the Commission having imposed a fine or a periodic penalty payment. That period shall be extended by the time during which the	4. Each interruption shall start time running afresh. However, the limitation period for the imposition of fines or periodic penalty payments shall expire at the latest on the day on which a period equal to twice the limitation period has elapsed without the Commission having imposed a fine or a periodic penalty payment. That period shall be extended by the time during which the	4. Each interruption shall start time running afresh. However, the limitation period for the imposition of fines or periodic penalty payments shall expire at the latest on the day on which a period equal to twice the limitation period has elapsed without the Commission having imposed a fine or a periodic penalty payment. That period shall be extended by the time during which the

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	limitation period has been suspended pursuant to paragraph 5.	limitation period has been suspended pursuant to paragraph 5.	limitation period has been suspended pursuant to paragraph 5.	limitation period has been suspended pursuant to paragraph 5. Text Origin: Commission Proposal
Article 17(5)				
196	5. The limitation period for the imposition of fines or periodic penalty payments shall be suspended for as long as the decision of the Commission is the subject of proceedings pending before the Court of Justice of the European Union.	5. The limitation period for the imposition of fines or periodic penalty payments shall be suspended for as long as the decision of the Commission is the subject of proceedings pending before the Court of Justice of the European Union.	5. The limitation period for the imposition of fines or periodic penalty payments shall be suspended for as long as the decision of the Commission is the subject of proceedings pending before the Court of Justice of the European Union.	5. The limitation period for the imposition of fines or periodic penalty payments shall be suspended for as long as the decision of the Commission is the subject of proceedings pending before the Court of Justice of the European Union. Text Origin: Commission Proposal
Article 18				
197	Article 18 Limitation period for the enforcement of fines and periodic penalty payments	Article 18 Limitation period for the enforcement of fines and periodic penalty payments	Article 18 Limitation period for the enforcement of fines and periodic penalty payments	Article 18 Limitation period for the enforcement of fines and periodic penalty payments Text Origin: Commission Proposal
Article 18(1)				
198	1. The power of the Commission to enforce decisions taken pursuant to Articles 15 and	1. The power of the Commission to enforce decisions taken pursuant to Articles 15 and	1. The power of the Commission to enforce decisions taken pursuant to Articles 15 and	1. The power of the Commission to enforce decisions taken pursuant to Articles 15 and

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	16 shall be subject to a limitation period of five years.	16 shall be subject to a limitation period of five years.	16 shall be subject to a limitation period of five years.	16 shall be subject to a limitation period of five years. Text Origin: Commission Proposal
Article 18(2)				
199	2. Time shall begin to run on the day on which the decision becomes final.	2. ~~Time~~**The limitation period** shall begin to run on the day on which the decision becomes final.	2. Time shall begin to run on the day on which the decision becomes final.	2. ~~*Time*~~***The limitation period*** shall begin to run on the day on which the decision becomes final. Text Origin: Council Mandate
Article 18(3)				
200	3. The limitation period for the enforcement of penalties shall be interrupted:	3. The limitation period for the enforcement of penalties shall be interrupted:	3. The limitation period for the enforcement of penalties shall be interrupted:	3. The limitation period for the enforcement of penalties shall be interrupted: Text Origin: Commission Proposal
Article 18(3), point (a)				
201	(a) by notification of a decision varying the original amount of the fine or periodic penalty payment or refusing an application for variation;	(a) by notification of a decision varying the original amount of the fine or periodic penalty payment or refusing an application for variation;	(a) by notification of a decision varying the original amount of the fine or periodic penalty payment or refusing an application for variation;	(a) by notification of a decision varying the original amount of the fine or periodic penalty payment or refusing an application for variation; Text Origin: Commission Proposal
Article 18(3), point (b)				

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
202	(b) by any action of the Commission, or of a Member State acting at the request of the Commission, designed to enforce payment of the fine or periodic penalty payment.	(b) by any action of the Commission, or of a Member State acting at the request of the Commission, designed to enforce payment of the fine or periodic penalty payment.	(b) by any action of the Commission, or of a Member State acting at the request of the Commission, designed to enforce payment of the fine or periodic penalty payment.	(b) by any action of the Commission, or of a Member State acting at the request of the Commission, designed to enforce payment of the fine or periodic penalty payment. Text Origin: Commission Proposal
Article 18(4)				
203	4. Each interruption shall start time running afresh.	4. Each interruption shall start time running afresh.	4. Each interruption shall start time running afresh.	4. Each interruption shall start time running afresh. Text Origin: Commission Proposal
Article 18(5)				
204	5. The limitation period for the enforcement of penalties shall be suspended for so long as:	5. The limitation period for the enforcement of penalties shall be suspended for so long as:	5. The limitation period for the enforcement of penalties shall be suspended for so long as:	5. The limitation period for the enforcement of penalties shall be suspended for so long as: Text Origin: Commission Proposal
Article 18(5), point (a)				
205	(a) time to pay is allowed;	(a) time to pay is allowed;	(a) time to pay is allowed;	(a) time to pay is allowed; Text Origin: Commission Proposal
Article 18(5), point (b)				

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
206	(b) enforcement of payment is suspended pursuant to a decision of the Court of Justice of the European Union or to a decision of a national court.	(b) enforcement of payment is suspended pursuant to a decision of the Court of Justice of the European Union or to a decision of a national court.	(b) enforcement of payment is suspended pursuant to a decision of the Court of Justice of the European Union or to a decision of a national court.	(b) enforcement of payment is suspended pursuant to a decision of the Court of Justice of the European Union or to a decision of a national court. Text Origin: Commission Proposal
Article 19				
207	Article 19 Right to be heard and access to the file	Article 19 Right to be heard and access to the file **in the procedure of fines and penalties**	Article 19 Right to be heard and access to the file	Article 19 Right to be heard and access to the file ***in the procedure of fines and periodic penalties*** Text Origin: Council Mandate
Article 19(1)				
208	1. Before adopting a decision pursuant to Article 15 or 16, the Commission shall give the licensee or the rights-holder the opportunity of being heard on the alleged infringement which is to be made subject to a fine or periodic penalty payments.	1. Before adopting a decision pursuant to Article 15 or 16, the Commission shall give the licensee ~~or the rights-holder~~ the opportunity of being heard on the alleged infringement which is to be made subject to a fine or periodic penalty payments.	1. Before adopting a decision pursuant to Article 15 or 16, the Commission shall give the licensee or the rights-holder the opportunity of being heard ***and fully involved in the procedure*** on the alleged infringement which is to be made subject to a fine or periodic penalty payments.	EP agrees to delete its addition
Article 19(2)				
209	2. The licensee or the rights-holder may submit its observations on the alleged infringement within	2. The licensee ~~or the rights-holder~~ may submit its observations on the alleged infringement within	2. The licensee or the rights-holder may submit its observations on the alleged infringement within	Agreed to keep CSL addition

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	a reasonable period set by the Commission, which may not be less than 14 days.	a reasonable period set by the Commission, which may not be less than 14 days **and is calculated from the notification of the invitation to submit observations**.	a reasonable period set by the Commission, which may not be less than 14 days.	
Article 19(2a)				
209a			***2a. The Commission shall reply to the observations made by the licensee or the right holder and in case of a rejection of the observations, it shall provide a justification within a reasonable period of time which shall not exceed 7 days.***	EP ok to drop it Text Origin: EP Mandate
Article 19(3)				
210	3. The Commission shall base its decisions only on objections on which the parties concerned have been able to comment.	3. The Commission shall base its decisions **pursuant to Article 15 or 16** only on objections on which the parties concerned have been able to comment.	3. The Commission shall base its decisions only on objections on which the parties concerned have been able to comment.	3. The Commission shall base its decisions ***pursuant to Article 15 or 16*** only on objections on which the parties concerned have been able to comment. Text Origin: Council Mandate
Article 19(4)				
211	4. The rights of defence of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the Commission's file under the	4. The rights of defence of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the Commission's file under the	4. The rights of defence of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the Commission's file under the	4. The rights of defence of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the Commission's file under the

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	terms of a negotiated disclosure, subject to the legitimate interest of the licensee or the rights-holder or other person concerned in the protection of their commercially sensitive information and trade secrets. The Commission shall have the power to adopt decisions setting out such terms of disclosure in case of disagreement between the parties. The right of access to the file of the Commission shall not extend to confidential information and internal documents of the Commission, other competent authorities or other public authorities of the Member States. In particular, the right of access shall not extend to correspondence between the Commission and those authorities. Nothing in this paragraph shall prevent the Commission from disclosing and using information necessary to prove an infringement.	terms of a negotiated disclosure, subject to the legitimate interest of the licensee or the rights-holder or other person concerned in the protection of their commercially sensitive information and trade secrets. The Commission shall have the power to adopt decisions setting out such terms of disclosure in case of disagreement between the parties. The right of access to the file of the Commission shall not extend to confidential information and internal documents of the Commission, other competent authorities or other public authorities of the Member States. In particular, the right of access shall not extend to correspondence between the Commission and those authorities. Nothing in this paragraph shall prevent the Commission from disclosing and using information necessary to prove an infringement.	terms of a negotiated disclosure, subject to the legitimate interest of the licensee or the rights-holder or other person concerned in the protection of their commercially sensitive information and trade secrets ***fully in line with existing legislation on the protection of data and trade secrets***. The Commission shall have the power to adopt decisions setting out such terms of disclosure, in case of disagreement between the parties. The right of access to the file of the Commission shall not extend to confidential information and internal documents of the Commission, other competent authorities or other public authorities of the Member States. In particular, the right of access shall not extend to correspondence between the Commission and those authorities. Nothing in this paragraph shall prevent the Commission from disclosing and using information necessary to prove an infringement.	terms of a negotiated disclosure, subject to the legitimate interest of the licensee or the rights-holder or other person concerned in the protection of their commercially sensitive information and trade secrets. The Commission shall have the power to adopt decisions setting out such terms of disclosure in case of disagreement between the parties. The right of access to the file of the Commission shall not extend to confidential information and internal documents of the Commission, other competent authorities or other public authorities of the Member States. In particular, the right of access shall not extend to correspondence between the Commission and those authorities. Nothing in this paragraph shall prevent the Commission from disclosing and using information necessary to prove an infringement. Text Origin: Commission Proposal
Article 19(5)				
212	5. If the Commission considers it necessary, it may also	5. If the Commission considers it necessary, it may also	5. If the Commission considers it necessary, it may also	5. If the Commission considers it necessary, it may also

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	hear other natural or legal persons. Applications to be heard on the part of such persons shall, where they show a sufficient interest, be granted.	hear other natural or legal persons. Applications to be heard on the part of such persons shall, where they show a sufficient interest, be granted.	hear other natural or legal persons. Applications to be heard on the part of such persons shall, where they show a sufficient interest, be granted.	hear other natural or legal persons. Applications to be heard on the part of such persons shall, where they show a sufficient interest, be granted. Text Origin: Commission Proposal
Article 20				
G 213	Article 20 Publication of decisions	Article 20 Publication of decisions **on fines and penalties**	Article 20 Publication of decisions	Article 20 Publication of decisions ***on fines and periodic penalties*** Text Origin: Council Mandate
Article 20(1)				
G 214	1. The Commission shall publish the decisions it adopts pursuant to Article 15 and Articles 16. Such publication shall state the names of the parties and the main content of the decision, including any fines or penalties imposed.	1. The Commission shall publish **in the Official Journal of the European Union** the decisions it adopts pursuant to ~~Article 15 and~~ Articles **15 and** 16. Such publication shall state ~~the names of the parties and~~ the main content of the decision, including any fines or penalties imposed.	1. The Commission shall publish the decisions it adopts pursuant to Article 15 and Articles 16. Such publication shall state the names of the parties and the main content of the decision, including any fines or penalties imposed.	1. . The Commission shall publish ***in the Official Journal of the European Union*** the decisions it adopts pursuant to ~~*Article 15 and*~~ Articles ***15 and*** 16. Such publication shall state ~~*the names of the parties and*~~ the main content of the decision, including any fines or penalties imposed ***and, when duly justified, the names of the parties***. Text Origin: Council Mandate

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
Article 20(2)				
215	2. The publication shall have regard to the rights and legitimate interests of the licensee, the rights-holder or any third parties in the protection of their confidential information.	2. The publication shall have regard to the rights and legitimate interests of the licensee, the rights-holder or any third parties in the protection of their confidential information **and shall comply with Union law on the protection of personal data**.	2. The publication shall have regard to the rights and legitimate interests of the licensee, the rights-holder or any third parties in the protection of their confidential information.	2. The publication shall have regard to the rights and legitimate interests of the licensee, the rights-holder or any third parties in the protection of their confidential information ***and shall comply with Union law on the protection of personal data***. Text Origin: Council Mandate
Article 21				
216	Article 21 Review by the Court of Justice of the European Union	Article 21 Review **of the fines or periodic penalty payments** by the Court of Justice of the European Union	Article 21 Review by the Court of Justice of the European Union	
Article 21, first paragraph				
217	In accordance with Article 261 TFEU, the Court of Justice of the European Union has unlimited jurisdiction to review decisions by which the Commission has imposed fines or periodic penalty payments. It may cancel, reduce or increase the fine or periodic penalty payment imposed.	In accordance with Article 261 TFEU, the Court of Justice of the European Union has unlimited jurisdiction to review decisions by which the Commission has imposed fines or periodic penalty payments. It may cancel, reduce or increase the fine or periodic penalty payment imposed.	In accordance with Article 261 ***and 263*** TFEU, the Court of Justice of the European Union has unlimited jurisdiction to review decisions by which the Commission ~~*has imposed fines or periodic penalty payments. It may cancel, reduce or increase the fine or periodic penalty payment imposed.*~~***:***	In accordance with Article 261 TFEU, the Court of Justice of the European Union has unlimited jurisdiction to review decisions by which the Commission has imposed fines or periodic penalty payments. It may cancel, reduce or increase the fine or periodic penalty payment imposed. EP suggestion: going back to COM proposal (row 217) while adding a second paragraph as follows:

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				"This Article is without prejudice to judicial review by the Court of Justice of the European Union in accordance with Article 263 TFEU of acts of the Commission by which it has granted a compulsory licence including the terms and conditions thereof". To be discussed further ITM 29 04 Agreed to drop EP mandate 217 a and b and to keep 263 in rec 31 Text Origin: Commission Proposal
Article 21, first paragraph, point (1)				
217a			***(1) has granted a compulsory licence. It may cancel or amend its terms and conditions;***	
Article 21, first paragraph, point (2)				
217b			***(2) has imposed fines or periodic penalty payments. It may cancel, reduce or increase the fine or periodic penalty payment imposed.***	
Article 22				
218	Article 22 Reporting on national compulsory licences	Article 22 Reporting on national compulsory licences	Article 22 Reporting on national compulsory licences	Article 22 Reporting on national compulsory licences

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				Text Origin: Commission Proposal
Article 22, first paragraph				
219	When a national compulsory licence has been granted for the purpose of addressing a national crisis or emergency, the Member State shall notify the Commission of the granting of the licence and of the specific conditions attached to it. The information provided shall include the following:	**1.** When a national compulsory licence has been granted for the purpose of addressing a national crisis or emergency **corresponding in nature to crises or emergencies falling within the scope of the Union acts listed in Article 2(1a)**, the Member State shall ~~notify~~**inform** the Commission of the granting of the licence ~~and of the specific conditions attached to it~~ **without undue delay. Article 2(3a) shall apply mutatis mutandis**. The information provided shall **also** include the following:	When a national compulsory licence has been granted ***for the public interest or*** for the purpose of addressing a national crisis or emergency, the Member State shall notify the Commission of the granting of the licence and of the specific conditions attached to ~~*it.*~~ ~~*The*~~***it. The*** information provided shall include the following:	Art. 2 (3a) is red - political topic. Scope - political topic. Agreed to delete "public interest" and "also" For EP to come back (notably on possibility to align the scope of reporting of national CL to the one of the UCL)
Article 22, first paragraph, point (a)				
220	(a) the purpose of the national compulsory licence and its legal basis in national law;	(a) the purpose of the national compulsory licence and its legal basis in national law;	(a) the purpose of the national compulsory licence and its legal basis in national law;	(a) the purpose of the national compulsory licence and its legal basis in national law; Text Origin: Commission Proposal
Article 22, first paragraph, point (b)				

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
221	(b) the name and address of the licensee;	(b) the name and address of the licensee;	(b) the name and address of the licensee;	(b) the name and address of the licensee; Text Origin: Commission Proposal
Article 22, first paragraph, point (c)				
222	(c) the products concerned and, to the extent possible, the concerned intellectual property rights and rights-holders;	(c) the products concerned and, to the extent possible, the concerned intellectual property rights and rights-holders;	(c) the products concerned and, to the extent possible, the concerned intellectual property rights and rights-holders;	(c) the products concerned and, to the extent possible, the concerned intellectual property rights and rights-holders; Text Origin: Commission Proposal
Article 22, first paragraph, point (d)				
223	(d) the remuneration to be paid to the rights-holder;	(d) the remuneration to be paid to the rights-holder;	(d) the remuneration to be paid to the rights-holder;	(d) the remuneration to be paid to the rights-holder; Text Origin: Commission Proposal
Article 22, first paragraph, point (e)				
224	(e) the quantity of products to be supplied under the licence;	(e) the quantity of products to be supplied under the licence;	(e) the quantity of products to be supplied under the licence;	(e) the quantity of products to be supplied under the licence; Text Origin: Commission Proposal
Article 22, first paragraph, point (f)				
225	(f) the duration of the licence.	(f) the duration of the licence.	(f) the duration of the licence.	(f) the duration of the licence.

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
				Text Origin: Commission Proposal
Article 22(2)				
225a		**2. Member States shall inform the Commission of the national authority tasked with providing information under paragraph 1. The Commission shall publish the list of national authorities on its website.**		
Article 23				
226	Article 23 Amendments to Regulation (EC) No 816/2006	Article 23 Amendments to Regulation (EC) No 816/2006	Article 23 Amendments to Regulation (EC) No 816/2006	Article 23 Amendments to Regulation (EC) No 816/2006 Text Origin: Commission Proposal
Article 23, first paragraph				
227	Regulation (EC) No 816/2006 is amended as follows:	Regulation (EC) No 816/2006 is amended as follows:	Regulation (EC) No 816/2006 is amended as follows:	Regulation (EC) No 816/2006 is amended as follows: Text Origin: Commission Proposal
Article 23, first paragraph, point (1)				
227a			***(-a) Article 6(2) is replaced by the following:***	
Article 23, first paragraph, point (-a), amending provision, numbered paragraph (2)				
227b			‘	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
			2. If the person applying for a compulsory licence is submitting multiple applications to authorities for the same product, he shall indicate that fact in each application, together with details of the quantities and importing countries concerned. ,	
Article 23, first paragraph, point (-aa)				
227c			***(-aa) Point (c) of Article 6(3) is replaced by the following:***	
Article 23, first paragraph, point (-aa), amending provision, point (c)				
227d			‘ ***(c) the expected amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence;*** ,	
Article 23, first paragraph, point (-ab)				
227e			***(-ab) Point (e) of Article 6(3) is replaced by the following:***	
Article 23, first paragraph, point (-ab), amending provision, point (e)				
227f			‘ ***(e) where applicable, evidence of efforts of prior negotiation with the rights-holder pursuant to Article 9;***	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
			’	
Article 23, first paragraph, point (-ac)				
227g			***(-ac) Point (f) of Article 6(3) is replaced by the following:***	
Article 23, first paragraph, point (-ac), amending provision, point (f)				
227h			‘ ***(f) evidence of a specific request from:***	
Article 23, first paragraph, point (-ac), amending provision, point (f)(i)				
227i			***(i) authorised representatives of the importing country or countries; or***	
Article 23, first paragraph, point (-ac), amending provision, point (f)(ii)				
227j			***(ii) a non-governmental organisation acting with the formal authorisation of one or more importing countries; or***	
Article 23, first paragraph, point (-ac), amending provision, point (f)(iii)				
227k			***(iii) UN bodies or other international health organisations acting with the formal authorisation of one or more importing countries,***	
Article 23, first paragraph, point (4), amending provision, point (a), second subparagraph				
227l			***indicating the expected quantity of product required.*** ’	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
Article 23, first paragraph, point (-ad)				
227m			***(-ad) Article 7 is replaced by the following:***	
Article 23, first paragraph, point (-ad), amending provision, article 7				
227n			***Article 7*** ‘ ***Rights of the rights-holder***	
Article 23, first paragraph, point (-ad), amending provision, article 7, first paragraph				
227o			***The competent authority shall notify the rights-holder without delay of the application for a compulsory licence. Before the grant of the compulsory licence, the competent authority may give the rights-holder an opportunity to comment on the application and to provide the competent authority with any relevant information regarding the application.*** ’	
Article 23, first paragraph, point (-ae)				
227p			***(-ae) Article 9(1) is replaced by the following:***	
Article 23, first paragraph, point (-ae), amending provision, first paragraph				
227q			‘	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
			1. The applicant shall provide evidence to the competent authority that he has made efforts to obtain authorisation from the rights-holder and that such efforts have not been successful within a period of thirty days before submitting the application. '	
Article 23, first paragraph, point (-af)				
227r			***(-af) Article 10(1) is replaced by the following:***	
Article 23, first paragraph, point (-af), amending provision, first paragraph				
227s			‘ ***1. The licence granted shall be non-assignable, except with that part of the enterprise or organisation that makes use of the licence, and non-exclusive. It shall contain the specific conditions set out in paragraphs 2 to 9 to be fulfilled by the licensee.*** '	
Article 23, first paragraph, point (-ag)				
227t			***(-ag) Article 10(2) is replaced by the following:***	
Article 23, first paragraph, point (-ag), amending provision, second paragraph				
227u			‘	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
			2. The expected amount of product(s) manufactured under the licence shall not exceed what is necessary to meet the needs of the importing country or countries cited in the application, taking into account the amount of product(s) manufactured under other compulsory licences granted elsewhere. ,	
Article 23, first paragraph, point (-ah)				
227v			***(-ah) Article 10(8) is replaced by the following:***	
Article 23, first paragraph, point (-ah), amending provision, eighth paragraph				
227w			‘ ***8. The competent authority may, on its own initiative, if national law allows the competent authority to act on its own initiative, request from the licensee proof of exportation of the product, through a declaration of exportation, certified by the customs authority concerned, and proof of importation from one of the bodies referred to in Article 6(3)(f).*** ,	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
Article 23, first paragraph, point (a)				
228	(a) The following Article 18a is inserted:	(a) The following Article 18a is inserted:	(a) The following Article 18a is inserted:	(a) The following Article 18a is inserted: Text Origin: Commission Proposal
Article 23, first paragraph, point (a), amending provision, first paragraph				
229	“ Article 18a	“ Article 18a	“ Article 18a	“ Article 18a Text Origin: Commission Proposal
Article 23, first paragraph, point (a), amending provision, second paragraph				
230	Union compulsory licence	Union compulsory licence	Union compulsory licence	Union compulsory licence ” Text Origin: Commission Proposal
Article 23, first paragraph, point (a), amending provision, numbered paragraph (1)				
231	1. The Commission may grant a compulsory licence where the activities of manufacture and sale for export spread across different Member States and would therefore require compulsory licences for the same product in more than one Member State.	1. **By derogation from Article 1, first subparagraph,** the Commission may grant a compulsory licence **applicable to the whole territory of the Union** where the activities of manufacture and sale for export spread across different Member States and would therefore require compulsory licences for the same	1. The Commission may ***also*** grant a compulsory licence ~~*where the activities of*~~***of patents relating to the*** manufacture ~~*and sale*~~***of pharmaceutical products*** for export ~~*spread across different Member States and would therefore require compulsory licences for the same product in more than one Member State*~~***to***	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		product in more than one Member State.	***countries with public health problems***.	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (2)				
232	2. Any person may submit an application for a compulsory licence under paragraph 1. The application shall fulfil the requirements laid down in Article 6 (3) and shall specify the Member States to be covered by the compulsory licence.	2. Any person may submit an application for a compulsory licence under paragraph 1. The application shall fulfil the requirements laid down in Article ~~6 (3)~~**6(3)(a) to (f)** and shall specify the Member States **in which the activities of manufacture and sale for export of the product** to be covered by the compulsory licence **are to be carried out**. **Articles 7 to 9 shall apply mutatis mutandis.**	2. Any person may submit an application for a compulsory licence under paragraph 1. The application shall ~~*fulfil the requirements laid down in Article 6 (3) and shall specify the Member States to be covered by the compulsory licence.*~~***contain the following information:***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (2), point (a)				
232a			***(a) the name and contact details of the applicant and of any agent or representative whom the applicant has appointed to act for him before the competent authority;***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (2), point (b)				
232b			***(b) the non-proprietary name of the pharmaceutical product or products which the applicant intends to manufacture and sell for export under the compulsory licence;***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (2), point (c)				

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
232c			***(c) the expected amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence;***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (2), point (d)				
232d			***(d) the importing country or countries;***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (2), point (e)				
232e			***(e) where applicable, evidence of efforts of prior negotiation with the rights-holder pursuant to Article 9;***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (2), point (f)				
232f			***(f) evidence of a specific request from***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (2), point (f)(i)				
232g			***(i) authorised representatives of the importing country or countries; or***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (2), point (f)(ii)				
232h			***(ii) a non-governmental organisation acting with the formal authorisation of one or more importing countries; or***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (2), point (f)(iii)				
232i			***(iii) UN bodies or other international health organisations acting with the***	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
			formal authorisation of one or more importing countries.	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (3)				
233	3. The compulsory licence granted in accordance with paragraph 1 shall be subject to the conditions set out in Article 10 and shall specify that it is applicable to the whole territory of the Union.	3. The compulsory licence ~~granted in accordance with~~**referred to in** paragraph 1 shall be subject to the conditions set out in Article 10 and shall specify that it is applicable to the whole territory of the Union.	3. The compulsory licence granted in accordance with paragraph 1 ~~*shall be subject to the conditions set out in Article 10 and*~~ shall specify that it is applicable to the whole territory of the Union~~.~~ ***and shall be subject to the following conditions:***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (3), point (a)				
233a			***(a) the licence granted shall be non-assignable, except with that part of the enterprise or organisation that makes use of the licence, and non-exclusive. It shall contain the specific conditions as set out in this paragraph;***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (3), point (b)				
233b			***(b) the expected amount of product(s) manufactured under the licence shall not exceed what is necessary to meet the needs of the importing country or countries cited in the application, taking into account the amount of product(s) manufactured under other compulsory licences granted elsewhere;***	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
Article 23, first paragraph, point (a), amending provision, numbered paragraph (3), point (c)				
233c			***(c) the duration of the licence shall be indicated;***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (3), point (d)				
233d			***(d) the licence shall be strictly limited to all acts necessary for the purpose of manufacturing the product in question for export and distribution in the country or countries cited in the application. No product made or imported under the compulsory licence shall be offered for sale or put on the market in any country other than that cited in the application, except where an importing country avails itself of the possibilities under subparagraph 6(i) of the Decision to export to fellow members of a regional trade agreement that share the health problem in question;***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (3), point (e)				
233e			***(e) products made under the licence shall be clearly identified, through specific labelling or marking, as being produced pursuant to this Regulation. The products shall be distinguished from those made by the rights-***	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
			holder through special packaging or special colouring or shaping, provided that such distinction is feasible and does not have a significant impact on the price. The packaging and any associated literature shall bear an indication that the product is subject to a compulsory licence under this Regulation, giving the name of the competent authority and any identifying reference number, and specifying clearly that the product is exclusively for export to and distribution in the importing country or countries concerned. Details of the product characteristics shall be made available to the customs authorities of the Member States;	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (3), point (f), first subparagraph				
233f			***(f) before shipment to the importing country or countries cited in the application, the licensee shall post on a website the following information;***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (3), point (f), first subparagraph, point (i)				
233g			***(i) the quantities being supplied under the licence and the importing countries to which they are supplied,***	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
Article 23, first paragraph, point (a), amending provision, numbered paragraph (3), point (f), first subparagraph, point (ii)				
233h			***(ii) the distinguishing features of the product or products concerned.***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (3), point (f), second subparagraph				
233i			***The website address shall be communicated to the competent authority;***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (3), point (g)				
233j			***(g) if the product(s) covered by the compulsory licence are patented in the importing countries cited in the application, the product(s) shall only be exported if those countries have issued a compulsory licence for the import, sale or distribution of the products;***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (3), point (h)				
233k			***(h) the competent authority may, on its own initiative, if national law allows the competent authority to act on its own initiative, request from the licensee proof of exportation of the product in the form of a declaration of exportation certified by the customs authority concerned, and proof of importation from one of the***	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
			bodies referred to in Article 18a(2), point (e);	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (3), point (i)				
233l			***(i) the licensee shall be responsible for the payment of adequate remuneration to the rights-holder as determined by the competent authority as follows:***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (3), point (i)(i)				
233m			***(i) in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use, the remuneration shall be a maximum of 4 % of the total price to be paid by the importing country or on its behalf,***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (3), point (i)(ii)				
233n			***(ii) in all other cases, the remuneration shall be determined taking into account the economic value of the use authorised under the licence to the importing country or countries concerned, as well as humanitarian or non-commercial circumstances relating to the issue of the licence;***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (3), point (j), first subparagraph				

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
233o			***(i) the licence conditions are without prejudice to the method of distribution in the importing country.***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (3), point (j), second subparagraph				
233p			***Distribution may be carried out for example by any of the bodies listed in Article 18a (2), point (f), and on commercial or non-commercial terms including completely without charge.***	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (4)				
234	4. In the event of an application referred to in paragraph 2 under this Article, the competent authority referred to in Articles 1 to 11, 16 and 17 shall be the Commission.	*deleted*	*4.* In the event of an application referred to in paragraph 2 under this Article, the competent authority referred to in Articles 1 to 11, 16 and 17 shall be the Commission.	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (5)				
235	5. The Commission is empowered to adopt implementing acts in order to:	5. The Commission is empowered to adopt implementing acts in order to:	5. The Commission is empowered to adopt implementing acts in order to:	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (5), point (a)				
236	(a) grant a compulsory licence;	(a) grant a compulsory licence **referred to in paragraph 1**;	(a) grant a compulsory licence;	
Article 23, first paragraph, point (a), amending provision, numbered paragraph (5), point (b)				
237	(b) reject the application for a compulsory licence;	(b) reject the application for a compulsory licence **referred to in**	(b) reject the application for a compulsory licence;	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		paragraph 2, Article 11 shall apply mutatis mutandis;		
Article 23, first paragraph, point (a), amending provision, numbered paragraph (5), point (c)				
238	(c) amend or terminate the compulsory licence.	(c) ~~amend~~**modify** or terminate the compulsory licence **granted pursuant to point (a). Article 16 shall apply mutatis mutandis.**~~.~~	(c) amend or terminate the compulsory licence.	
Article 23, first paragraph, point (a), amending provision, eighth paragraph				
239	Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 18b (2). On duly justified imperative grounds of urgency relating to the impacts of the public health problems, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 18b (3). ”	Those implementing acts shall be adopted in accordance with the ~~advisory~~**examination** procedure referred to in Article 18b (2). On duly justified imperative grounds of urgency relating to the impacts of the public health problems, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 18b ~~(~~3~~)~~.**”** ”	Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 18b (2). On duly justified imperative grounds of urgency relating to ~~*the impacts of the*~~ public health problems, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 18b (3). ”	
Article 23, first paragraph, point (b)				
240	(b) The following Article 18b is inserted:	(b) The following Article 18b is inserted:	(b) The following Article 18b is inserted:	(b) The following Article 18b is inserted: Text Origin: Commission Proposal
Article 23, first paragraph, point (b), amending provision, first paragraph				
241	“	“	“	“

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	Article 18b Committee Procedure	Article 18b Committee Procedure	Article 18b Committee Procedure	Article 18b Committee Procedure ” Text Origin: Commission Proposal
Article 23, first paragraph, point (b), amending provision, numbered paragraph (1)				
242	1. The Commission shall be assisted by a committee (‘the Compulsory Licensing Committee’). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	1. The Commission shall be assisted by a committee (‘the Compulsory Licensing Committee’). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	1. The Commission shall be assisted by a committee (‘the Compulsory Licensing Committee’). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	
Article 23, first paragraph, point (b), amending provision, numbered paragraph (2)				
243	2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article **45** of Regulation (EU) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.	
Article 23, first paragraph, point (b), amending provision, numbered paragraph (3)				
244	3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 thereof, shall apply. ”	3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article **45** thereof, shall apply.	3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 thereof, shall apply. ”	
Article 23, first paragraph, point (b), amending provision, numbered paragraph (4)				
244a		**4. Where the committee delivers no opinion, the**		

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		Commission shall not adopt the draft implementing act and Article 5(4), third subparagraph, of Regulation (EU) No 182/2011 shall apply. ”		
Article 23, first paragraph, point (c)				
244b		**(c) The following Article 18c is inserted:**		
Article 23, first paragraph b, amending provision, article				
244c		**Article 18c** ‘ **Applicability to and in the United Kingdom in respect of Northern Ireland**		
Article 23, first paragraph b, amending provision, article, first paragraph				
244d		**The procedure for granting a Union compulsory licence under Article 18a, and a Union compulsory licence granted under that provision, shall not apply to and in the United Kingdom in respect of Northern Ireland. The United Kingdom in respect of Northern Ireland shall ensure that the products manufactured under a license granted in accordance with Article 18a are not imported into the territory of the Union or**		

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
		Northern Ireland in accordance with Article 13 and take necessary actions to that end in accordance with Article 14. ,		
Article 24				
245	Article 24 Committee Procedure	Article 24 Committee Procedure	Article 24 Committee Procedure	Article 24 Committee Procedure Text Origin: Commission Proposal
Article 24(1)				
246	1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	Text Origin: Commission Proposal
Article 24(2)				
247	2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.	*deleted*	*2.* Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.	Examination procedure/advisory procedure to be brought at political level
Article 24(3)				
248	3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	
Article 24(4)				

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
249	4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 thereof, shall apply.	4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article **45** thereof, shall apply.	4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 thereof, shall apply.	
Article 24(5)				
249a		**5. Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and Article 5(4), third subparagraph, of Regulation (EU) No 182/2011 shall apply.**		Examination procedure/advisory procedure to be brought at political level
Article 25				
250	Article 25 Evaluation	Article 25 Evaluation	Article 25 Evaluation	Article 25 Evaluation Text Origin: Commission Proposal
Article 25, first paragraph				
251	The Commission shall, by the last day of the third year following the granting of the Union compulsory licence in accordance with Article 7, present an evaluation report to the Council, the European Parliament and the European Economic and Social Committee on the application of this Regulation.	The Commission shall, by the last day of the third year following the granting of the **first** Union compulsory licence in accordance with Article 7, present an evaluation report to the Council, the European Parliament and the European Economic and Social Committee on the application of this Regulation.	The Commission shall, by the last day of the third year following the granting of the Union compulsory licence in accordance with Article 7, present an evaluation report to the Council, the European Parliament and the European Economic and Social Committee on the application of this Regulation.	

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
Article 25, first paragraph a				
251a			***By ... [two years after the date of entry into force of this Regulation] and every two years thereafter, the Commission shall assess whether the list in the Annex is up-to-date in light of the adoption of future legislative acts in relation to an emergency or crisis mode. If the list of the Annex is no longer up-to-date, the Commission shall assess its consequences. The Commission shall submit its assessment to the European Parliament and the Council, accompanied, where appropriate, by legislative proposals to amend the Annex.***	Trilogue I - 10/12/2024 To be negotiated at political level
Article 25, first paragraph b				
251b			***In case of exceptional threats to public safety or to national security, the Commission shall carry out the assessment pursuant to paragraph 1a without undue delay.***	Trilogue I - 10/12/2024 To be negotiated at political level
Article 26				
252	Article 26 Entry into force	Article 26 Entry into force	Article 26 Entry into force ***and application***	EP agrees to delete
Article 26, first paragraph				
253	This Regulation shall enter into force on the day following that of	This Regulation shall enter into force on the day following that of	This Regulation shall enter into force on the day following that of	

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
	its publication in the Official Journal of the European Union.	its publication in the Official Journal of the European Union.	its publication in the Official Journal of the European Union.	
Article 26, second paragraph				
254	This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States.	
Article 26, second paragraph a				
254a			***It shall apply from [the first day of the month following the period of twelve months after the date of entry into force].***	EP agrees to delete Text Origin: EP Mandate
Formula				
255	Done at Brussels,	Done at Brussels,	Done at Brussels,	Done at Brussels, Text Origin: Commission Proposal
Formula				
256	For the European Parliament	For the European Parliament	For the European Parliament	For the European Parliament Text Origin: Commission Proposal
Formula				
257	The President	The President	The President	The President Text Origin: Commission Proposal

PUBLIC

	Commission Proposal	Council Mandate	EP Mandate	Draft Agreement
Formula				
258	For the Council	For the Council	For the Council	For the Council Text Origin: Commission Proposal
Formula				
259	The President	The President	The President	The President Text Origin: Commission Proposal
Annex	Crisis or emergency modes referred to in Article 4 and competent advisory bodies as referred to in Article 62 are listed below:			
260	Annex - Crisis or emergency modes referred to in Article 4 and competent advisory bodies as referred to in Article 6(2) are listed below:	Annex - Crisis or emergency modes referred to in Article 4 and competent advisory bodies as referred to in Article 6(2) are listed below:	Annex - Crisis or emergency modes referred to in Article 4 and competent advisory bodies as referred to in Article 6(2) are listed below:	
Annex	Crisis or emergency modes referred to in Article 4 and competent advisory bodies as referred to in Article 62 are listed below:, Table 1			
261	Table 1	Table 1	Table 1	

PUBLIC

PUBLIC

Commission Proposal Table 1

Union crisis or emergency mechanism	Crisis mode or emergency mode	Competent Advisory Body
1. Regulation XXX/XX of the European Parliament and of the Council establishing a Single Market Emergency Instrument and repealing Council Regulation (EC) 2679/98 [COM(2022) 459]	Single Market emergency mode activated by means of a Council implementing act [Article 14 of Regulation XXX/XX] [COM(2022) 459]	Advisory Group [Article 4 of Regulation XXX/XX] [COM(2022) 459]
2. Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU	Public health emergency at Union level formally recognized by means of a Commission implementing act [Article 23 of Regulation (EU) 2022/2371]	Health Security Committee [Article 4 of Regulation (EU) 2022/2371]
3. Council Regulation (EU) 2022/2372 of 24 October 2022 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	Emergency framework activated by the adoption of a Council Regulation [Article 3 of Regulation (EU) 2022/2372]	The Health Crisis Board [Article 5 of Regulation (EU) 2022/2372]
4. Regulation XXX/XX establishing a framework of measures for strengthening Europe's semiconductor ecosystem [COM(2022) 46]	Crisis stage activated by a Commission implementing act [Article 18 of Regulation XXX/XXX] [COM(2022) 46]	European Semiconductor Board [Article 23 of Regulation XXX/XXX] [COM(2022) 46]
5. Regulation (EU) 2017/1938 of the European Parliament and of the Council of 25 October 2017 concerning measures to safeguard	Union emergency declared by the Commission [Article 12 of Regulation (EU) 2017/1938]	Gas Coordination Group [Article 4 of Regulation (EU) 2017/1938]

the security of gas supply and repealing Regulation (EU) No 994/2010		

PUBLIC

PUBLIC

Council Mandate Table 1

Union crisis or emergency mechanism	Crisis mode or emergency mode	Competent Advisory Body
1. Regulation XXX/XX of the European Parliament and of the Council establishing a ~~Single~~**framework of measures on emergency and resilience of the internal market (Internal** market emergency ~~Instrument and repealing~~**and resilience act) and amending** Council Regulation (EC) ~~2679/98~~**No 2679/98** [COM(2022) 459]	~~Single~~**Internal** Market emergency mode activated by means of a Council implementing act [Article 14 of Regulation XXX/XX] [COM(2022) 459]	~~Advisory Group~~**Internal Market Emergency and Resilience Board** [Article 4 of Regulation XXX/XX] [COM(2022) 459]
2. Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU	Public health emergency at Union level formally recognized by means of a Commission implementing act [Article 23 of Regulation (EU) 2022/2371]	Health Security Committee [Article 4 of Regulation (EU) 2022/2371]
3. Council Regulation (EU) 2022/2372 of 24 October 2022 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	Emergency framework activated by the adoption of a Council Regulation [Article 3 of Regulation (EU) 2022/2372]	The Health Crisis Board [Article 5 of Regulation (EU) 2022/2372]
~~4. Regulation XXX/XX establishing a framework of measures for strengthening Europe's semiconductor ecosystem [COM(2022) 46]~~	~~Crisis stage activated by a Commission implementing act [Article 18 of Regulation XXX/XXX] [COM(2022) 46]~~	~~European Semiconductor Board [Article 23 of Regulation XXX/XXX] [COM(2022) 46]~~

~~5. Regulation (EU) 2017/1938 of the European Parliament and of the Council of 25 October 2017 concerning measures to safeguard the security of gas supply and repealing Regulation (EU) No 994/2010~~	~~Union emergency declared by the Commission [Article 12 of Regulation (EU) 2017/1938]~~	~~Gas Coordination Group [Article 4 of Regulation (EU) 2017/1938]~~

PUBLIC

EP Mandate Table 1

PUBLIC

Union crisis or emergency mechanism	Crisis mode or emergency mode	Competent Advisory Body
1. Regulation XXX/XX of the European Parliament and of the Council establishing a Single Market Emergency Instrument and repealing Council Regulation (EC) 2679/98 [COM(2022) 459]	Single Market emergency mode activated by means of a Council implementing act [Article 14 of Regulation XXX/XX] [COM(2022) 459]	Advisory Group [Article 4 of Regulation XXX/XX] [COM(2022) 459]
2. Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU	Public health emergency at Union level formally recognized by means of a Commission implementing act [Article 23 of Regulation (EU) 2022/2371]	Health Security Committee [Article 4 of Regulation (EU) 2022/2371]
3. Council Regulation (EU) 2022/2372 of 24 October 2022 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	Emergency framework activated by the adoption of a Council Regulation [Article 3 of Regulation (EU) 2022/2372]	The Health Crisis Board [Article 5 of Regulation (EU) 2022/2372]
4. Regulation XXX/XX establishing a framework of measures for strengthening Europe's semiconductor ecosystem [COM(2022) 46]	Crisis stage activated by a Commission implementing act [Article 18 of Regulation XXX/XXX] [COM(2022) 46]	European Semiconductor Board [Article 23 of Regulation XXX/XXX] [COM(2022) 46]
5. Regulation (EU) 2017/1938 of the European Parliament and of the Council of 25 October 2017 concerning measures to safeguard the security of gas supply and repealing Regulation (EU) No 994/2010	Union emergency declared by the Commission [Article 12 of Regulation (EU) 2017/1938]	Gas Coordination Group [Article 4 of Regulation (EU) 2017/1938]

PUBLIC