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NOTE

From:	Presidency
To:	Permanent Representatives Committee
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 - Analysis of the final compromise text with a view to agreement

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 816/2006. 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

[1] 13354/20.

a cross-border dimension. In situations when voluntary agreements might not be found or 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. Based on the examination of the text under the Belgian Presidency, on 26 June 2024 the Permanent Representatives Committee adopted the Council's mandate[4] for interinstitutional negotiations.

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

II. INTERINSTITUTIONAL NEGOTIATIONS – STATE OF PLAY

8. The interinstitutional negotiations started with the first trilogue on 10 December 2024 under the Hungarian Presidency. The second and third trilogues took place under the Polish Presidency, on 26 March and 21 May 2025 respectively. In addition, 21 interinstitutional technical meetings were held. A provisional agreement between the co-legislators was reached at the third trilogue.

9. The Permanent Representatives Committee was informed about the provisional agreement and its core elements on 28 May 2025. The major elements of the compromise text were presented to the Working Party on Intellectual Property on 2 June 2025 and were broadly welcomed by delegations. The compromise reached is also supported by the Commission.

10. With a view to agreement on the Regulation on compulsory licensing for crisis management and amending Regulation 816/2006 in an early second reading between the Council and the European Parliament, the Presidency submits to the Permanent Representatives Committee the outcome of the final trilogue in the form of a consolidated text of the draft Regulation.

III. ANALYSIS OF THE FINAL COMPROMISE TEXT WITH A VIEW TO AGREEMENT

(a) ADDITIONAL MEASURES AND TRADE SECRETS

11. In the trilogue negotiations on the issue of additional measures and trade secrets, the Council managed to achieve its main objective of keeping trade secrets protected and outside of the scope of the Regulation (*Article 2(3)*). The Article on the conduct of the rights-holder and the licensee (*Article 13*) was also agreed based on the Council's mandate, meaning that all provisions that could potentially result in an obligation to disclose trade secrets have been removed from the text.

12. As part of the overall compromise on this point, a clarification was introduced in recital 13 to elaborate that the Regulation does not preclude voluntary conclusion of agreements on trade secrets.

(b) SCOPE

i. Related crisis instruments

13. With a view to ensuring that the competitiveness in the single market stays protected in terms of semiconductors, it was agreed that the Chips Act should be removed from the list of crisis instruments that can trigger the possibility of a Union compulsory licence (*Annex*). However, to ensure that the Commission will take note of this issue in the future, the Parliament stipulated the removal of the instrument from the scope with the mention of semiconductors for medical equipment in the evaluation clause (*Article 25*).

14. Moreover, it was also agreed to remove the Gas Security of Supply Regulation from the said list, as it was agreed that it is not relevant for the objectives of the Regulation on compulsory licensing due to the fact that gas-related technologies take a long time to implement (*Annex*).

ii. Defence-related products

15. Defence-related products were also excluded from the scope of the Regulation, as the co-legislators agreed that the instrument should not tackle issues of national security and defence, a strategic sector for Member States (*Article 2(3a)*).

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

16. As part of the overall compromise, the Council accepted to list the related crisis instruments that can trigger the possibility of a Union compulsory licence in the Annex to the Regulation, as opposed to the operative part of the text.

iv. Ad hoc advisory body

17. The compromise on the issue reflects the Commission proposal and the Parliament's position, it was agreed to retain the provisions on the ad hoc advisory body 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 (*Articles 6(1d) and 6(1e)*). The definition of the competent advisory body was adjusted accordingly (*Article 3(ea)*).

PUBLIC

v. Evaluation

18. In Article 25, the Parliament's position contained 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 Commission suggested a reworded version of this provision, 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.

19. The Council agreed to include the evaluation provision, under the condition that the drafting of the provision is finetuned to reflect that not every assessment would need to result in amendments to the Regulation (meaning that the Commission only *may* propose amendments, rather than saying that it *shall* propose them) (*Article 25*).

20. As part of the compromise on the related crisis instruments, namely the Chips Act, it was agreed to clarify in the Article that the regular evaluation of the list of crisis instruments would give specific regard to the issue of semiconductors for medical equipment (*recital 40a*).

(c) COMITOLOGY

21. After discussions, the Parliament accepted that the implementing acts on the granting, modification and termination of the Union compulsory licence would be adopted via the examination procedure. Council, in turn, agreed to introduce a clarification in recital 38, explaining that the choice of the examination procedure for the adoption of implementing acts is justified by the fact that decisions on a compulsory license have a potentially important impact on the fundamental right to intellectual property (*Articles 7(9), 14(6), 24(2) and (4), recital 38*).

22. Furthermore, the non-opinion clause was retained as per the Council mandate, with a view to ensuring that an implementing act cannot be adopted when the comitology committee does not deliver an opinion (*Articles 24(5)*).

(d) TIME LIMIT FOR VOLUNTARY AGREEMENTS

23. As a compromise between the co-legislators, it was agreed that one of the general conditions for granting a Union compulsory licence would be that a voluntary agreement could not be achieved within a reasonable timeframe (*Articles 4(1)(c), 6(1)(d), 7(2)(c)(i), 14(1a)*).

24. At the request of the Council, a provision was added to clarify that voluntary agreements can be concluded at any time during or after the compulsory licence granting process (*Article 7(11)*).

(e) OTHER ISSUES

i. Amendments to Regulation 816/2006 for export (Article 23)

25. When it comes to Article 23, the Parliament agreed to give up on the numerous amendments they had proposed, and the Council's amendments were agreed upon. In order to accommodate the Parliament's concerns over the use of Regulation 816/2006, it was agreed that the Commission would make a declaration committing the Commission to conduct a full review of Regulation 816/2006 in line with its Article 19.

ii. Remuneration

26. As per the Council mandate, the criteria for determining remuneration were adjusted to emphasise economic value of the relevant activities authorised under the Union compulsory licence, while the criterion of amortisation of research and development costs, as well as the criterion of humanitarian grounds, were moved to the recitals (*recital 27*). As an act of concession to the Parliament, it was agreed that the Article would also mention the criterion of public support received to develop the invention (*Article 9(3)*).

iii. Advance notification

27. The co-legislators agreed to introduce an obligation for the Commission to provide, where appropriate, an advance notification to the licensee of the termination or expiry of the Union compulsory licence, in order to enable an orderly completion of the activities relating to crisis-relevant products under a Union compulsory licence (*Article 14(3a)*).

IV. CONCLUSION

28. The Presidency invites the Committee of Permanent Representatives to analyse and approve the compromise text resulting from the final trilogue, as set out in the Annex to this note, with a view to agreement. This approval would be conditional upon the receipt of a letter from the Chair of the European Parliament's JURI Committee confirming that the European Parliament can accept the text as set out in the Annex to this note and that, should the Council adopt this text as its first-reading position, the European Parliament would not adopt any amendments to it in its second reading.

PUBLIC

ANNEX

2023/0129 (COD)

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)

PUBLIC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 and 207 thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee[5],

Having regard to the opinion of the Committee of the Regions[6],

Acting in accordance with the ordinary legislative procedure,

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5 OJ C , , p. .
6 OJ C , , p. .

Whereas:

(1) Crises require the setting-up of exceptional, swift, [redacted] adequate ***and proportionate*** measures able to provide means to address ***a crisis or its*** consequences. ***To do so***, the use of patented products or processes could prove indispensable [redacted] . Voluntary licensing agreements usually suffice to licence the patent rights on these products and allow their supply in the [redacted] territory ***of the Union***. Voluntary agreements are the most adequate, quick, and efficient solution to allow the use of patented products ***and to scale up production*** in crises. Nevertheless, voluntary agreements ***might*** not always be available or only under inadequate conditions such as lengthy delivery times. In such cases, ***a*** compulsory ***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.

PUBLIC

(2) In the context of the Union crisis or emergency mechanisms ***according to the applicable Union legal act***, the Union should ▌ 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')***[7]. 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. ***As a last resort,*** where ***adequate and swift*** access to crisis-relevant products and processes ***required to manufacture these products, which are*** protected by ***intellectual property rights,*** cannot be achieved through ***other means, including through increase of own production capacities by rights-holders or*** voluntary cooperation, compulsory licensing can ***allow for the use of an invention protected by intellectual property rights in*** the ***public interest for the production and*** supply of ***crisis-relevant*** products ▌ 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.

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[7] ***[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 ▌ 'TRIPS Agreement ▌[8]. ***To this end, the present Regulation should establish a scheme for granting a compulsory licence 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.***

(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 ***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 ***if necessary to address*** a cross-border crisis ***or emergency***.

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[8] ***[1]*** OJ L 336, 23.12.1994, p. 214

(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 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 ***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 ***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, ***namely when means other than a Union compulsory licence, including*** voluntary agreements***, could not be achieved within a reasonable timeframe and could not adequately and swiftly ensure access to crisis-relevant products and processes required to manufacture these products, which are protected by intellectual property rights***. 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.

PUBLIC

(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 ***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 temporary and non-exclusive*** compulsory licence that is valid throughout the Union and that allows the ***use of an invention protected by intellectual property rights to supply*** products necessary to address a crisis or emergency in the 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 ***Internal*** Market Emergency ***and Resilience Act (IMERA***) established under Regulation (EU) No XXX/XX [COM(2022) 459]**,**Regulation (EU) ***2022/2371 of the European Parliament and of the Council***[9] under which the Commission may recognise a public health emergency at Union level***, as well as Council Regulation (EU) 2022/2372***[10] ***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**..**

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9 ***[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).***

10 ***[2] 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 (OJ L 314, 6.12.2022, p. 64).***

(8) These mechanisms provide for the activation of ***a crisis or*** emergency ▌ 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 ***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 be listed in an Annex to this Regulation.

(9) To ensure optimal efficiency of the Union compulsory licence as a tool ***for addressing*** crises ***or emergencies***, it should be made available in respect of a granted patent or utility model ▌ 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 national patents, European patents and European patents with unitary effect.

PUBLIC

(10) Utility model systems ***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*** an exclusive right to prevent others, for a limited period of time, from commercially exploiting the protected ***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.

(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 extension to the supplementary protection certificate. This extension*** 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 ***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.

PUBLIC

(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 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 ***protection of these intellectual property rights as granted***.

PUBLIC

(13) It should be clarified that this Regulation is without prejudice to Union law on copyright and related rights, including Directives 96/9▌, 2009/24, 2001/29/EC▌, 2004/48/EC▌ and (EU) 2019/790▌ 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. 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 or as precluding the voluntary conclusion of agreements on trade secrets.***

(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 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 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.

PUBLIC

(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 ***impact*** access to the medicinal products needed to address the crisis. For this reason, ***the relevant*** Union ***law on pharmaceuticals should provide*** for the suspension of data exclusivity and market protection***, in particular*** 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.

(14a) 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.

(15) In order to ensure as much coherence as possible with existing crisis mechanisms [redacted] , the definition of a 'crisis-relevant product' should be ***sufficiently*** general ***so as*** to cover products related to different kinds of ***crisis or emergency modes under the respective Union legal acts listed in the Annex to this Regulation***.

PUBLIC

(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 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 be achieved within a reasonable timeframe and 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 opportunity to provide their comments in order to safeguard their rights, as well as to enable the advisory body to obtain all information necessary.

PUBLIC

(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 ***or entity that has the capacity to exploit the protected invention and consequently*** to manufacture the crisis-relevant product and to pay ***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.***

PUBLIC

(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 advised*** by an advisory body ▌. 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 ***under*** the relevant Union crisis or emergency mechanisms. ***These early discussions should already provide*** the Commission ***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***, 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 crisis-relevant products. If this is not the case and a Union*** compulsory ***licence seems, a priori, necessary,*** the advisory body should ***provide the Commission with a clearer idea of how products manufactured under the Union*** compulsory ***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***.

PUBLIC

(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 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 ***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 ***Internal Market Emergency and Resilience Board*** is set up under ***IMERA, while Regulations (EU) 2022/2371 and (EU) 2022/2372 provide for a Health Security Committee and*** a Health Crisis Board ***respectively***. 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 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 ***compulsory licence*** (the 'ad hoc advisory body'). ***Ad hoc advisory bodies should be composed of one representative of each Member State and include a representative of the European Parliament as an observer. The rules of procedure of the ad hoc advisory body should include provisions relating to the avoidance of potential conflicts of interest in order to ensure accountability and transparency.***

PUBLIC

(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 ***licence and its content . To achieve this, the advisory body*** should ***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*** of the ***procedure for granting a Union*** compulsory ***licence***, ▌ the advisory body ▌ should ***contact the national intellectual property offices, the relevant business and industry associations as well as international organisations. The*** advisory ***body*** should ***draw the attention of these entities to the notice published by*** the Commission ▌ on the ***initiation of the procedure for granting a Union compulsory licence, containing the relevant*** information ▌ , ***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 adequately and swiftly***, the advisory body should ***assist the Commission in identifying potential licensees and establishing whether they meet this requirement. Rights-holders and potential licensees should*** have the ***opportunity to provide their arguments to the advisory body, which should analyse their written comments and invite them to participate in the*** relevant ***meetings. These meetings should also serve as a forum to explore the possibility of reaching a voluntary agreement within a reasonable timeframe, 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 representatives of the academia and of civil society, 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 situation.***

PUBLIC

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 ***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 ***tailor the potential*** Union ***compulsory licence to current and future needs. As crises rarely respect borders, the advisory body 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.***

(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 Journal of the European Union as soon as possible.

PUBLIC

(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, including on whether voluntary licensing agreements could be concluded within a reasonable timeframe. 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 details for submitting the comments.

(19c) After publishing the notice, the Commission should 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 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.

PUBLIC

(20) ***The work performed under this Regulation by the advisory body for the purposes of advising and assisting*** the Commission should ***result in an opinion including an assessment of the need for a*** Union compulsory licence ***and its content. The*** opinion of the advisory body ***on the granting of a*** Union compulsory licence should ***not be binding. The opinion should include the above-mentioned assessment that*** should enable the Commission to consider the individual merits of the ***case*** and determine, on that basis, the conditions of the ***Union compulsory*** licence, including ***the*** remuneration to be paid by the licensee to the rights-holder. ***Furthermore, the opinion*** should also ***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 information should be included in the opinion and the annexes.***

(21) ***After receiving the opinion from the advisory body***, the Commission should ***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 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, including on whether voluntary licensing agreements have been concluded.***

PUBLIC

(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. In addition, it should be possible to conclude voluntary licensing agreements at any time during the granting procedure or after the granting of a Union compulsory licence. These elements 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 and swiftly remedy the lack of adequate supply of crisis-relevant products. Involvement of the rights-holders in the procedure should ensure that they have the right to be heard before the adoption of the Union compulsory licence and that they are able to reach 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.***

(22) ▌ The Commission shall ensure a safe environment for the sharing of ***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 ***the*** procedure ***for granting*** a Union compulsory licence ▌ .

▌

PUBLIC

(24) The Commission should ▌ identify in ***the implementing act granting a Union compulsory licence the patents and***, ***where applicable, published*** patent ***applications***, ***utility models and, where applicable, published utility model applications, and*** supplementary protection ***certificates*** related to the crisis-relevant products, ***as well as*** the rights-holders of those intellectual property rights. ***It cannot be fully excluded that***, ***despite the efforts undertaken by the Commission and the advisory body, further*** intellectual property rights ***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 ***should ensure the adequate and swift supply of crisis-relevant products, the Commission should in this situation modify*** the Union compulsory licence ***by 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 should, where appropriate, 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*** should also identify any necessary safeguards and remuneration to be paid to each identified rights-holder. ***In accordance with Article 297 TFEU, the 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.***

▌

PUBLIC

(26) The Union compulsory licence should ▌ include information allowing the identification of the crisis-relevant product for which it 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[11]***, and*** details on the ***licensee*** (and, where applicable, the ***manufacturer***) to whom the compulsory licence is granted, including their name ***or*** trade name ▌ , 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, model, batch or serial number, or unique identifier of a product passport.

PUBLIC

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11 ***[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).***

(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 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 ***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***, taking into consideration general practices and any existing precedents in the relevant field***. In the event of a compulsory licence granted ***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 ***receiving*** remuneration has not materialised. In such circumstances, the rights-holder should refund the remuneration ▌ received under the ***Union*** compulsory licence.

PUBLIC

(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 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[12]. 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.***

[12] 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).

(28a) The Commission may consider, as a matter of its internal organisation, entrusting actions relating to cooperation on enforcement as foreseen by this Regulation to the European Anti-Fraud Office (OLAF), which possesses relevant expertise in that regard. This should not affect the continued exercise of the powers conferred to the Commission or the European Anti-Fraud Office (OLAF) in other Union legal acts, including Council Regulation (EC) No 515/97 of 13 March 1997 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs or agricultural matters.

(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*[13]*,*** it should be prohibited to export products manufactured under a Union compulsory licence.

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[13] ***[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).***

(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[14]. 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 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.

[14] ***[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).

(31) ***Under the provisions of the TFEU, and in particular its Article 263, the*** validity of ▌ implementing ***acts*** granting the Union compulsory license ***and the adequate remuneration provided therein, as well as the validity of any other*** implementing ***acts pertaining to the Union compulsory license, is*** subject to judicial review ***by the Court of Justice of the European Union***.

(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*** 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 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 ***on matters relevant for the fulfilment of the objective*** of the Union compulsory licence ▌. The Commission ***should also have the possibility to share crisis-relevant information with*** the rights-holder and the licensee, ***including new information on available manufacturing capacities of*** crisis-relevant ***products in the territory of*** the Union. ▌ Information ***shared during such meetings or exchanges*** should ***remain confidential.***

▌

PUBLIC

(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. ***Where necessary, the*** list of ***the*** rights and rights-holders covered by the ***Union*** compulsory licence ▌ should ***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, without retroactive effect. Likewise, the said list should be modified without retroactive effect in case of a transfer or revocation of a right included in the content of the Union compulsory licence.*** If the circumstances which led to ***the Union compulsory licence*** 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. The rights-holder and the licensee should be notified sufficiently in advance to enable an orderly conclusion of the activities relating to crisis-relevant products under a Union compulsory licence. However, such advance notification should not be provided in certain cases, for instance where the licence is terminated due to the breach of licensee's obligations under this Regulation***. When deciding on the revision of the Union compulsory licence, the Commission ***should*** consult the competent advisory body for that purpose ***and duly consider the rights and interests*** of the ***rights-holder and the licensee***.

PUBLIC

(34) ▌ In addition to the possibility to 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 ***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 ▌ and dissuasive***, and they should also be subject to the overarching principles of proportionality and ne bis in idem***.

(35) ***Appropriate levels of fines for non-compliance*** with the ▌ obligations ***under this Regulation and of periodic penalty payments to put an end to an infringement of the obligations*** under this Regulation should be ▌ laid down***, taking into account any aggravating or mitigating factors. Limitation periods should apply for*** the imposition of fines and periodic penalty payments***, as well as for their enforcement.*** In accordance with ***Article 297 TFEU,*** the Commission ***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.

PUBLIC

(36) When a national compulsory licence has been granted for the purpose of 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 ***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 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.***

PUBLIC

(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 ▌. 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 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 ***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 compulsory licence under ▌ 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.

PUBLIC

(37a) On 1 February 2020, the United Kingdom withdrew from the European Union. The Withdrawal Agreement[16] 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[17] 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[18], which forms an integral part of the Withdrawal 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 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.

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16 *[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).*

17 *[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).*

18 *[3] Joint Declaration No 1/2023 of the Union and the United Kingdom in the 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).*

(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, ▌ modification or termination of a Union compulsory license ▌ , 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[19]. The ***examination*** procedure should be used for the adoption of implementing acts granting, ▌ modifying or terminating a Union compulsory licence ***and*** 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. ***The choice of the examination procedure for the adoption of implementing acts is justified by the fact that decisions on a compulsory license have a potentially important impact on the fundamental right to intellectual property.***

[19] 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 implementing powers (OJ L 55, 28.2.2011, p. 13).

(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 ▌, 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 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.***

(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 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.

PUBLIC

(40a) In line with the Union's efforts to enhance its resilience and preparedness to crises, the list of EU crisis instruments able to trigger a compulsory licence should remain up-to-date. To achieve that, the Commission should assess the said list on a regular basis, in particular by taking into consideration new legislative proposals and acts as well as the general objective of enhancing Union's resilience and preparedness to crises. The assessment should take particular regard to the issue of semiconductors for medical equipment. Where appropriate, the Commission should be able to propose amendments to the Annex in order to adapt the list of EU crisis instruments. The Commission should report on its assessment to the European Parliament and the Council, including on legislative proposals aiming at amending the Annex.

▌

(41a) Since the objective of this Regulation, namely to facilitate access to crisis-relevant 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 limited territorial scope of national compulsory licenses but can rather, by reason of their 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 Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

HAVE ADOPTED THIS REGULATION:

PUBLIC

Article 1

***Objectives and* subject matter**

This Regulation has the objective to ensure that ***a Union compulsory license may be granted in the context of a crisis or emergency affecting*** the Union ▌. To this end, this Regulation lays down rules on the 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 ***during an activated or declared*** crisis or emergency ***mode, pursuant to any of the respective Union legal acts listed in the 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.***

PUBLIC

Article 2

Scope

1. This Regulation establishes Union compulsory licensing of the following intellectual property rights in force in one or more Member States:

   (a) patents ***and*** published patent applications;

   (b) utility models ***and published utility model applications***; or

   (c) supplementary protection certificates***.***

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***.

3. This Regulation does not impose any obligation to disclose trade secrets.

PUBLIC

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.

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 in the Annex, in the framework of an activated or declared crisis or emergency mode listed in the Annex to this Regulation.

PUBLIC

Article 3

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(-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 pursuant to the respective Union legal acts listed in the Annex;

(a) 'crisis-relevant products' means products ▌ that are indispensable for responding to a crisis or emergency or for addressing the impacts of a crisis or emergency in the Union;

(b) 'relevant activities' means the acts of making, using, offering for sale, selling or importing.

(c) 'rights-holder' means a holder of 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);

(e) 'Union compulsory licence' means a compulsory licence granted by the Commission to exploit a protected invention ***in order to carry out*** any of the relevant activities ***referred to in Article 3(b) in the territory of*** the Union ***concerning crisis-relevant products or processes required to manufacture these products***;

PUBLIC

(ea) ***'competent advisory body' means the advisory body competent for the Union crisis or emergency mechanism as listed in the Annex to this Regulation; or, where applicable the ad hoc advisory body referred to in Article 6(1)(d);***

(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[20];

PUBLIC

[20] 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).

Article 4

***General conditions for granting a* Union compulsory licence**

The Commission may grant a Union compulsory licence ***only on the condition that:***

(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 the Annex;***

(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;***

(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');***

(d) ***the rights-holders concerned were given the opportunity to provide their comments to the competent advisory body and the Commission in accordance with Articles 6 and 7.***

PUBLIC

Article 5

General *requirements* of a Union compulsory licence

1. The Union compulsory licence ***that may be granted by the Commission in accordance with Article 4*** shall

(a) be non-exclusive and non-assignable, except with that part of the enterprise or goodwill which enjoys such compulsory licence;

(b) have a scope and duration that ***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 emergency mode in the framework of which it is granted;

(c) be strictly limited to the relevant activities ***that are necessary to ensure the adequate supply*** of crisis-relevant products in the Union;

(d) only be granted against payment of an adequate remuneration to the rights-holder***,*** ***determined in accordance with Article 9***;

(e) be ***strictly*** limited to the territory of the Union;

(f) only be granted to a person ***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 ▌

(fa) automatically expire if the crisis or emergency mode has ended.

PUBLIC

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.***

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 such certificate, where the certificate still covers the crisis-relevant product***.

PUBLIC

Article 6

Advisory body

1. For the purposes of the present Regulation, the competent advisory body shall assist and advise the Commission in the following tasks:

(a) the identification of the intellectual property rights protecting the crisis-relevant product and the rights-holders;

(b) the dissemination of the published notice referred to in Article 7(1) through the appropriate channels;

(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 obligations referred to in Article 10;

(d) the gathering of the views of the rights-holders and potential licensees, including on the possibility to conclude voluntary licensing agreements within a reasonable timeframe, 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);

PUBLIC

(e) the gathering of the views, where relevant, of economic operators of the sectors concerned, and of other relevant entities;

(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;

(g) the gathering and analysis of the crisis-relevant information, including on the existing national compulsory licences reported to the Commission in accordance with Article 22, and market intelligence available, in particular in order to take account of: (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.

(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.

PUBLIC

1a. The chair of the advisory body shall invite a representative of the European Parliament as observer to the relevant meetings of the advisory body, where possible under the applicable legal acts referred to in Annex.

1b. The competent advisory body shall provide an opinion on the need for a Union compulsory licence and on its content in compliance with Article 7(3).

1c. The competent advisory body shall provide views on whether the Union compulsory license should be terminated or modified, in accordance with Article 14.

1d. In the absence of any existing competent advisory body, the tasks referred to in paragraph 1 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. The chair of the ad hoc advisory body shall invite a representative of the European Parliament as observer to the relevant meetings of the ad hoc advisory body.

1e. 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).

PUBLIC

Article 7

Procedure for granting a Union compulsory licence

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.

2. The notice referred to in paragraph 1 shall include:

(a) information about the crisis-relevant products for which a lack of adequate supply is considered to exist;

(b) where already available, information about the intellectual property rights and rights-holders concerned;

PUBLIC

(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:

(i) the possibility to reach, within a reasonable timeframe, a voluntary licensing agreement with manufacturers on intellectual property rights for the purpose of relevant activities relating to the crisis-relevant products;

(ii) the need to grant a Union compulsory licence;

(iii) the possible content of the Union compulsory licence, including the amount of remuneration;

(d) information about the relevant competent advisory body.

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.

PUBLIC

4. Without undue delay, the Commission shall publish the notice referred to in paragraph 1 in the Official Journal of the European Union.

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.

6. The opinion of the competent advisory body shall not be binding on the Commission.

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:

(a) the envisaged content of the Union compulsory licence;

(b) a summary of the opinion of the competent advisory body;

(c) the invitation to submit their comments and a time limit for doing so, including comments on whether voluntary licensing agreements have been concluded.

PUBLIC

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 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.

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).

10. When, based on the opinion of the competent 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).

PUBLIC

11. Without prejudice to paragraph 8, voluntary licensing agreements may be concluded at any time during or after the procedure set out in this Article.

12. 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 to understand the facts and considerations that led up to the adoption of the implementing act.

PUBLIC

Article 8

Content of the Union compulsory licence

1. The Union compulsory licence shall specify the following:

(a) the patent, ***published*** patent application, supplementary protection certificate or utility model ***or published utility model application*** for which the licence is granted***;***

(b) the ***rights-holder***;

(c) the licensee, in particular the following information:

(1) name ***and*** trade name [redacted] ;

(2) contact details;

(3) unique identification number in the country where the licensee is established;

(4) where available, the Economic Operators Registration and Identification (EORI) number;

(d) the duration for which the Union compulsory licence is granted;

(e) the remuneration to be paid to the rights-holder determined in accordance with Article 9;

PUBLIC

(f) ***where appropriate,*** the non-proprietary name of the crisis-relevant product which is to be manufactured under the Union compulsory licence ***and/or*** its commodity code (CN code) under which the crisis-relevant product is classified, as defined in Council Regulation (EEC) No 2658/87;

(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.

(ga) the maximum number of crisis-relevant products to be manufactured under the Union compulsory licence.

▌

PUBLIC

Article 9

Remuneration

1. The licensee shall pay an adequate remuneration to the rights-holder. The amount of the 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.

[redacted]

3. When determining the ***adequate*** remuneration, the Commission shall ***take into account the economic value of relevant activities authorised under the Union compulsory licence as well as the circumstances of each case such as public support received to develop the invention. It shall also take into account the opinion of the competent advisory body and any comments received under Article 7(7).***

[redacted]

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.***

PUBLIC

Article 10

Obligations to be fulfilled by the licensee

1. The licensee shall be authorised to exploit the protected invention covered by the Union compulsory ***licence*** only under the following obligations:

(a) the number of crisis-relevant products manufactured under the Union compulsory licence does not exceed ***the maximum number determined in accordance with Article 8(1)(ga)***;

(b) the relevant activities are carried out solely for the supply of the crisis-relevant products in the Union market;

(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.

(ca) the quantities of crisis-relevant products manufactured under the Union compulsory licence are regularly recorded;

PUBLIC

(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;

(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.

(f) before the marketing of the products manufactured under the Union compulsory licence, the licensee shall make available on a website the following information:

(1) the quantities of the products manufactured under the Union compulsory licence per Member State of manufacturing;

(2) the quantities of the products supplied under the Union compulsory licence per Member State of supply;

(3) the distinguishing features of the products under the Union compulsory licence.

The address of the website shall be communicated to the Commission. The Commission shall communicate the address of the website to the Member States.

PUBLIC

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:

(a) terminate the Union compulsory licence in accordance with Article 14(3); ▌

(b) impose fines or periodic penalties on the licensee in accordance with Articles 15 and 16.

3. ***Where there is sufficient suspicion that the licensee has failed to fulfil the obligations laid down in paragraph 1, the Commission*** in cooperation with the relevant national authorities of the Member States may, ***based on information from the latter or*** the rights-holder ▌ , request access to books and records kept by the licensee ***that is necessary***for the purpose of checking ***compliance with the afore-mentioned obligations in paragraph 1.***

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(3)***.

PUBLIC

Article 11

Prohibition of export

The export of products manufactured under a Union compulsory licence is prohibited. ***This provision is without prejudice to Regulation (EC) No 816/2006.***

Article 12

Customs control

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[21].

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 ▌ in the ***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.

[21] REGULATION (EU) No 952/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 October 2013 laying down the Union Customs Code.

3. Where customs authorities identify a product that may fall under the prohibition laid down in Article 11, they shall suspend its 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 ***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 ▌ .

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:

   (a) the Commission has not requested the customs authorities to maintain the suspension within 10 working days after it was notified thereof;

   (b) the Commission has informed the customs authorities that the product is not manufactured under a Union compulsory licence.

PUBLIC

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 Commission shall inform ***customs authorities and*** the concerned rights-holder of such non-compliance.

6. Where the release for export of a product has not been authorised:

(a) where appropriate in view of the crisis or emergency ***mode***, the Commission may require***, via*** customs authorities**,** 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.

(b) in all other cases ▌ the product concerned ***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.

PUBLIC

Article 13

***Conduct of the* rights-holder and licensee**

1. ***When exercising the rights or performing the obligations under this Regulation,*** the rights-holder and the licensee ***shall refrain from any actions or omissions that could undermine the*** Union compulsory ***licensing process***.

Article 14

Review and termination of the Union 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. ***Without prejudice to the Commission's obligation to identify the rights and the rightsholders before granting the Union compulsory license, in accordance with article 8***, the Union compulsory licence shall***, where necessary,*** be modified to ***update the*** list of rights and rights-holders covered by the compulsory licence***, and this modification shall, where appropriate, have a retroactive effect***.***"***

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, within a reasonable timeframe, a voluntary licensing agreement with the licensee and on the amount of remuneration.

PUBLIC

3. A Union compulsory licence ***shall*** be terminated by the Commission by means of an implementing act where the circumstances which led to it cease to exist and are unlikely to recur***, or may be terminated*** where the licensee fails to comply with the obligations laid down in this Regulation.

3a. The Commission shall notify the rights-holder and the licensee of the termination or expiry of the Union compulsory licence. Where appropriate, advance notification shall be provided to enable an orderly completion by the licensee of the activities relating to crisis-relevant products under a Union compulsory licence.

4. When the Commission considers modifying ▌ or terminating the Union compulsory licence, it ***shall*** consult the ***competent*** advisory body ▌ .

▌

PUBLIC

5. When ***a*** Union compulsory licence ***is terminated or expires in accordance with Article 5(1)(fa)***, 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.

6. The implementing acts referred to in paragraph 1 ▌ and 3 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). 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***.

PUBLIC

Article 15

Fines

1. The Commission may by decision impose ***fines where*** the licensee [redacted] intentionally or negligently ***fails to comply with its obligations under Article 9(1), Article 10(1) or Article 11.***

[redacted]

1a. Fines imposed in accordance with paragraph 1 shall not exceed EUR 300 000. Where the undertaking concerned is an SME, the fines imposed shall not exceed EUR 50 000.

2. In fixing the amount of the fine, regard shall be had to the ***nature,*** gravity, ***duration and*** recurrence of the infringement ***as well as 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.

[redacted]

PUBLIC

Article 16

Periodic penalty payments

1. The Commission may, by decision, impose on the licensee ▌ periodic penalty payments ***for each working day*** calculated from the date ***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.***

▌

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.

2. ***Article 15(2) shall apply mutatis mutandis.*** Where the licensee ***has*** satisfied the obligation which the periodic penalty payment was intended to enforce, 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.

PUBLIC

Article 17

Limitation period for the imposition of fines and periodic penalty payments

1. The powers conferred on the Commission by Articles 15 and 16 shall be subject to a limitation period of five years.

2. ***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, ***the limitation period*** shall begin to run on the day on which the infringement ceases.

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.

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 limitation period has been suspended pursuant to paragraph 5.

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.

PUBLIC

Article 18

Limitation period for the enforcement of fines and periodic penalty payments

1. The power of the Commission to enforce decisions taken pursuant to Articles 15 and 16 shall be subject to a limitation period of five years.

2. ***The limitation period*** shall begin to run on the day on which the decision becomes final.

3. The limitation period for the enforcement of penalties shall be interrupted:

   (a) by notification of a decision varying the original amount of the fine or periodic penalty payment or refusing an application for variation;

   (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.

4. Each interruption shall start time running afresh.

5. The limitation period for the enforcement of penalties shall be suspended for so long as:

   (a) time to pay is allowed;

   (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.

PUBLIC

Article 19

Right to be heard and access to the file *in the procedure of fines and periodic penalties*

1. Before adopting a decision pursuant to Article 15 or 16, the Commission shall give the licensee ▌ the opportunity of being heard on the alleged infringement which is to be made subject to a fine or periodic penalty payments.

2. The licensee ▌ may submit its observations on the alleged infringement within 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***.

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.

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 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.

PUBLIC

5. If the Commission considers it necessary, it may also 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.

Article 20

Publication of decisions *on fines and periodic penalties*

1. **.** The Commission shall publish ***in the Official Journal of the European Union*** the decisions it adopts pursuant to Articles ***15 and*** 16. Such publication shall state the main content of the decision, including any fines or penalties imposed ***and, when duly justified, the names of the parties***.

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***.

Article 21

Review *of the fines or periodic penalty payments* by the Court of Justice of the European Union

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.

PUBLIC

Article 22

Reporting on national compulsory licences

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 the Annex***, the Member State shall ***inform*** the Commission of the granting of the licence ***without undue delay. Article 2(3a) shall apply mutatis mutandis***. The information provided shall include the following:

(a) the purpose of the national compulsory licence and its legal basis in national law;

(b) the name and address of the licensee;

(c) the products concerned and, to the extent possible, the concerned intellectual property rights and rights-holders;

(d) the remuneration to be paid to the rights-holder;

(e) the quantity of products to be supplied under the licence;

(f) the duration of the licence.

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.***

PUBLIC

Article 23

Amendments to Regulation (EC) No 816/2006

Regulation (EC) No 816/2006 is amended as follows:

▌

‘(a) The following Article 18a is inserted:

“Article 18a

Union compulsory licence

1. ***By derogation from Article 1, second subparagraph, and from Articles 2(4) and 3*** 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 product in more than one Member State.

2. Any person may submit an application for a compulsory licence under paragraph 1. ***By derogation from Article 6(1) and (2), the application shall be submitted to the Commission.*** The application shall fulfil the requirements laid down in Article ***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 and 12 shall apply mutatis mutandis.***

▌

PUBLIC

3. The compulsory licence ***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.

▌

5. The Commission is empowered to adopt implementing acts in order to:

(a) grant a compulsory licence ***referred to in paragraph 1***;

(b) reject the application for a compulsory licence ***referred to in paragraph 2, Article 11 shall apply mutatis mutandis***;

(c) ***modify*** or terminate the compulsory licence ***granted pursuant to point (a). Article 16 and Article 5(c) shall apply mutatis mutandis.***

Those implementing acts shall be adopted in accordance with the ***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).***""***

PUBLIC

(b) The following Article 18b is inserted:

"Article 18b Committee Procedure

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.

2. 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 8 of Regulation (EU) No 182/2011, in conjunction with Article ***5*** thereof, shall apply.

4. 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."

PUBLIC

(c) The following Article 18c is inserted:

'Article 18c

Applicability to and in the United Kingdom in respect of Northern Ireland

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 Northern Ireland in accordance with Article 13 and take necessary actions to that end in accordance with Article 14.'

PUBLIC

Article 24

Committee Procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

▌

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article ***5*** thereof, shall apply.

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.

PUBLIC

Article 25

Evaluation

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.

1.a. The Commission shall regularly, and for the first time by 31 December 2027, assess whether the list in the Annex is up-to-date, including with particular regard to the issue of semiconductors for medical equipment and may, where appropriate, submit proposals to amend the said Annex. Every five years after the date of entry into force of this Regulation, the Commission shall report on the assessments carried out to the European Parliament and the Council.

PUBLIC

Article 26

Entry into force

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

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

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

PUBLIC

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Annex - Crisis or emergency modes and competent advisory bodies are listed below:

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 ***framework of measures on emergency and resilience of the internal market (Internal*** market emergency ***and resilience act) and amending*** Council Regulation (EC) ***No 2679/98*** [COM(2022) 459]	***Internal*** Market emergency mode activated by means of a Council implementing act [Article 14 of Regulation XXX/XX] [COM(2022) 459]	***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]

[redacted]	[redacted]	[redacted]

PUBLIC