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**NOTE**

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| To: | Permanent Representatives Committee |
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| 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<br>– Mandate for negotiations with the European Parliament |

## I. INTRODUCTION

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

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

[1] Doc. 13354/20.

3. A compulsory licence is the possibility for a government, court or other public authority to allow a third party, in justified circumstances, to use an invention that is protected by an intellectual property right without the authorisation of the rights-holder.

4. Currently, Member States have compulsory licensing schemes implemented at national level. However, these schemes can only address national crises, and are unsuitable to tackle EU-wide crises and emergencies.

5. The objective of the proposed Regulation is to introduce a Union compulsory licensing system that can strengthen the resilience of the EU by addressing Union-wide crises that have a cross-border dimension. In situations when voluntary agreements might not be found or might not be adequate, the Union compulsory licence would facilitate access to crisis-relevant products that are protected by intellectual property rights.

6. 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.

7. 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.

## II. WORK CONDUCTED IN COUNCIL PREPARATORY BODIES

8. An initial presentation of the whole patent package, including the Compulsory licensing proposal, was made by the Commission to the Working Party on Intellectual Property on 31 May 2023.

9. The substantial examination of the Compulsory licensing proposal started in January 2024, under the Belgian Presidency, with the objective of obtaining a mandate for negotiations with the European Parliament.

10. The impact assessment accompanying the proposal was examined at the Working Party meeting of 12 January 2024. The majority of delegations welcomed the objectives of the proposal and underlined the importance of strengthening the EU's resilience in times of crisis.

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[2] Doc. 13349/23.
[3] Doc. T9-0143/2024.

However, many delegations noted that significant adjustments of the proposal would be needed, in order to emphasise the exceptional and last resort nature of a Union compulsory licence and to better safeguard the rights of the rights-holders. A few Members States questioned the necessity of regulatory action at EU level in the area of compulsory licensing.

11. The Working Party on Intellectual Property examined the proposal in an intensive pace in eight meetings from January to May 2024, in the course of which the Belgian Presidency proposed four compromise texts.

12. At the Working Party on Intellectual Property (Attachés) meeting on 18 June 2024, broad support from delegations was received on the compromise text set out in doc. 10985/24. To address final concerns expressed by delegations, some minor final adjustments were made in Article 12, as well as in recitals 9, 12, 32 and 39. Additionally, a new point (c) in Article 23 and a new recital 37a have been inserted in the compromise text with a view to achieving compliance with the Windsor Framework. *The text of these amendments has been communicated to delegations by way of WK 8717/2024, WK 8831/2024 and WK 9043/2024*.

13. On this basis, the Presidency considers that the text set out in the Annex to this note strikes an appropriate balance between the various viewpoints expressed throughout the negotiations, without undermining the effect of the proposal, and that it can be forwarded to COREPER for the approval of a negotiating mandate. Changes compared to the Commission proposal are marked in **bold underlined** or ~~strikethrough~~.

## III. MAIN ELEMENTS OF THE COMPROMISE

### *(a) Mechanism of last resort*

14. From the outset of the examination of the proposal, delegations pointed out that the Union compulsory licence should be a mechanism of last resort that is used only when voluntary agreements could not ensure access to crisis-relevant products, and that this aspect needs to be expressed clearly in the text of the draft Regulation.

15. To accommodate delegations' requests, the Presidency introduced additional wording in Articles 1 and 4 to emphasise the last resort nature of the instrument and inserted additional clarifications on the matter in recitals 1, 2 and 15a.

*(b) Scope*

*i. Related crisis instruments*

16. The Union compulsory licence is intended to function as a complement to the EU instruments that are aimed at addressing crises or emergencies within the Internal Market. The Commission proposal referred to five crisis instruments that could trigger the procedure for issuing a Union compulsory licence, namely the Internal Market Emergency and Resilience Act (IMERA), the Regulation on serious cross-border threats to health, the Emergency Framework Regulation, the Chips Act and the Regulation on security of gas supply.

17. While the inclusion of the first three instruments was mostly met with delegations' agreement, discussions at the Working Party brought into question the relevance and usefulness of the Union compulsory licence for products envisaged in the framework of the Chips Act and the Regulation on security of gas supply. Therefore, in the compromise text, these two instruments were removed from the list of crisis instruments triggering the possibility of a Union compulsory licence (see Article 2, recitals 7 and 18).

18. Additionally, for the sake of clarity and legal certainty, the crisis instruments that were previously outlined only in the Annex of the proposed Regulation are now also listed in the operative part of the draft Regulation (Article 2).

*ii. Intellectual property rights covered*

19. As per the Commission proposal, a Union compulsory license can be issued for patents, published patent applications, utility models and supplementary protection certificates.

20. Several delegations expressed reservations with regard to the inclusion of published patent applications in the scope. However, taking into account the provisional protection that they provide and the impact such protection may have on the effectiveness of the Union compulsory licence, as well as the clarifications that their inclusion is TRIPS[4]-compliant, published patent applications were retained in the scope, as reflected in Article 2 and the corresponding recitals.

21. In order to ensure coherence within the text, published utility model applications were added to the scope (see additions in Article 2 and the corresponding recitals).

[4]Agreement on Trade-Related Aspects of Intellectual Property Rights.

22. To address delegations' concerns that a compulsory licence cannot be issued in relation to defence-related products, a new paragraph 3a was added in Article 2 to clarify this issue.

***(c) Definition of "crisis or emergency mode"***

23. According to the Commission proposal, a Union compulsory licence can be granted when a crisis or emergency mode is activated or declared at EU level, as provided for in the respective crisis instruments. However, many delegations were concerned that the link between the references to "crisis or emergency" in the proposal and the respective crisis instruments is not sufficiently clear.

24. In order to take account of these concerns, the Presidency inserted into the compromise text a definition of "crisis or emergency mode" that clearly links the term as it appears in the proposal and the notions of crises or emergencies in the respective crisis instruments (Article 3).

***(d) General conditions for granting a Union compulsory licence***

25. As it was insufficiently clear to delegations which conditions had to be fulfilled in order for the Commission to be able to justify the granting of a compulsory licence, the Presidency has amended Article 4 to specify four fundamental conditions that have to be fulfilled before a Union compulsory license is granted.

***(e) Granting procedure***

26. Delegations generally expressed the view that the process for granting a Union compulsory licence is not sufficiently clear. To streamline the procedure and to ensure better protection of the rights-holder, the core Articles 6 and 7 of the proposal, as well as the corresponding recitals, have been significantly restructured so as to add necessary procedural steps and rearrange the existing steps in a more chronological manner.

***i. Advisory body***

27. The Commission proposal provides that an advisory body, established under the respective crisis instrument, would be responsible for assisting and advising the Commission in the performance of tasks related to the granting of the Union compulsory licence. At the request of Member States, Article 6 and recitals 18 and 19 were amended to ensure and strengthen the

PUBLIC

involvement of national intellectual property experts and authorities responsible for issuing national compulsory licences.

28. Another important amendment involves the deletion of the *ad-hoc* advisory body (former Article 6(5)), which the Commission proposal envisaged for cases in which a crisis instrument would not provide for an advisory body. However, given that all crisis instruments currently listed in the proposal provide for an advisory body, there was broad consensus among delegations that the provision on an *ad-hoc* advisory body was not needed.

***ii. Notice***

29. Building on the views expressed by delegations, the initiation of the procedure for granting a Union compulsory licence was clarified so as to ensure that rights-holders are better informed. In particular, as a first step of the process, the notice initiating the procedure has to be published not only in the *Official Journal of the European Union* as per the Commission proposal, but also on the website of the Commission (Article 7(1)).

30. Furthermore, the content of the notice was elaborated to include, in particular, the available information on the intellectual property rights and rights-holders concerned, as well as an invitation to all parties concerned to submit comments, thereby ensuring their better involvement in the procedure (Article 7(2)).

***iii. Other amendments with regard to the granting procedure***

31. Further changes include the introduction of a provision requiring the Commission to indicate reasons in case its decision on the granting of a Union compulsory licence departs from the opinion of the advisory body (Article 7(8)). Moreover, at the request of numerous delegations, the advisory procedure was replaced with the examination procedure with regard to the implementing acts granting a Union compulsory licence (Article 7(9)).

***(f) Conduct of the rights-holder and licensee***

32. The Commission proposal envisaged that the rights-holder and the licensee should be obliged to act and cooperate in good faith. A large number of delegations, however, saw the concept of "good faith" as somewhat unclear and not suitable in the context of compulsory licensing. Some also expressed fears that such provision might be interpreted as an obligation for the rights-holder to disclose trade secrets, otherwise exposing them to fines and penalties.

33. In order to ensure proper protection of the rights-holder and avoid legal uncertainty, the requirement to cooperate in good faith was not retained in the compromise text, and Article 13 has been reworded to instead specify that the rights-holder and the licensee shall refrain from any actions or omissions that could undermine the Union compulsory licensing process. Furthermore, an example of expected conduct has been introduced in the corresponding recital 32.

***(g) Additional measures***

34. Under the Commission proposal it was suggested that the Commission is entitled to take additional measures to ensure that the Union compulsory licence meets its objective, such as requesting additional information from the rights-holder.

35. A significant number of Member States, however, expressed fears that this requirement might result in an obligation for the rights-holder to disclose trade secrets and know-how.

36. To address these concerns, the possibility to impose additional measures has been removed in the compromise text, resulting in changes to Articles 6, 8, 14, 15, 16 and recital 32. In order to underline this understanding and safeguard the rights of the rights-holder, additional amendments were made in Article 2 and recital 13 to clarify that the Regulation does not impose any obligation to disclose trade secrets.

***(h) Remuneration***

37. The remuneration for the rights-holder whose intellectual property rights are affected by a compulsory licence is a crucial measure counterbalancing this impact. Limiting the remuneration by a cap of 4% on the total gross revenue generated by the licensee, as suggested in the Commission proposal, was strongly opposed by many delegations.

38. Delegations pointed out that the existence of the cap in Regulation (EC) No 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to low and mid-income countries could not equally justify such a cap in the context of a Union compulsory licensing scheme for the internal market.

39. In order to align the compromise text with the arguments provided by delegations, the Presidency removed the 4% cap in Article 9.

PUBLIC

40. Moreover, the compromise text further clarifies the criteria that have to be taken into account when determining the remuneration. Criteria such as humanitarian circumstances and public support to the invention, which were considered by some delegations as too vague for the operative part of the text, were moved to recital 27 so that it is clear that these aspects can serve as guidance, rather than strict criteria. On the other hand, the criterion of economic value of relevant activities authorised under the Union compulsory licence was prioritised, and it was clarified in the compromise text that the Commission should, when determining the remuneration, also consider the opinion of the advisory body and the individual circumstances of each case.

***(i) Fines and penalties***

41. With the removal of the possibility to impose additional measures and of the notion of "good faith cooperation", no obligations remained for the rights-holder that could be subject to fines under Articles 15 and 16. Article 15, as well as recitals 34 and 35, were amended to reflect the deletion of fines for the rights-holder.

42. When it comes to the fines for the licensee for failure to comply with the obligations provided for in the Regulation, the proposal contains a threshold for the maximum fine of 6% of their respective total turnover for the preceding business year.

43. Many delegations challenged this 6% cap, claiming that the Digital Markets Act and the Digital Services Act, on the basis of which the cap was set, would result in fines and penalties that are too high and might therefore pose too big of a burden in times of crises.

44. The Presidency followed this reasoning and established in the compromise text, instead of the maximum percentage, maximum limit for fines of EUR 300 000 or EUR 50 000 in the case of SMEs.

45. Furthermore, Article 16 on periodic penalty payments has been streamlined in order to reflect the changes made in Article 15.

## IV. CONCLUSION

46. The Permanent Representatives Committee is invited to examine and endorse the compromise text as set out in the Annex to this note and to grant a mandate to the Presidency on the basis of that text for negotiations with the European Parliament with a view to reaching an agreement.

47. In accordance with the approach to legislative transparency endorsed by Coreper on 14 July 2020[5], and in full consistency with Regulation (EC) 1049/2001 and the Council's Rules of Procedure, the text of the mandate thus agreed will be made public unless the Permanent Representatives Committee objects.

PUBLIC

[5] Doc. 9493/20.

**ANNEX**

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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)

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[6],

Having regard to the opinion of the Committee of the Regions[7],

Acting in accordance with the ordinary legislative procedure,

Whereas:

[6] OJ C , , p. .
[7] OJ C , , p. .

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

(2) In the context of the Union crisis or emergency mechanisms **according to the applicable Union legal act**, the Union should ~~therefore~~ have the possibility to rely on compulsory licensing **in conformity with the framework of the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement')**[8]. The activation of a crisis or an emergency mode or the declaration of a crisis or a state of emergency addresses obstacles to free movement of goods, services, and persons in crises and shortages of crisis-relevant goods and services. ~~In cases~~ **As a last resort,** where **adequate, efficient and swift** access to crisis-relevant products and processes **required to manufacture these products, which are** protected by ~~a patent~~ **intellectual property rights,** cannot be achieved through **other means, including** voluntary cooperation, compulsory licensing can **allow for the use of an invention protected by intellectual property rights in the public interest** ~~help in lifting any patent-related barriers and thus ensure the~~ **for the production and** supply of **crisis-relevant** products ~~or services~~ needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of **the** said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the Union. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical products subject to compulsory licencing in the internal market.

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**8** ***OJ L 336, 23.12.1994, p. 214***

(3) The possibility of using compulsory licences in situations of national emergency or other circumstances of extreme urgency is explicitly envisaged under the ~~Agreement on Trade-Related Aspects of Intellectual Property Rights (~~'TRIPS Agreement'~~)~~[9]**. 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~~n~~ **crisis or** emergency. However, divergences exist across Member States~~,~~ as regards the grounds, conditions, and procedures under which a compulsory licence can be granted. This results in a fragmented, suboptimal, and uncoordinated system preventing the Union from effectively relying on compulsory licensing ~~when addressing~~ **if necessary to address** a cross-border crisis **or emergency**.

[9] *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 product**s** manufactured under a compulsory licence. Apart from the fact that the issuance of multiple national compulsory licences is a high hurdle for cross-border supply within the ~~single~~ **internal** market, it also bears the risk of contradicting and incoherent decisions among Member States. Consequently, the current compulsory licensing framework appears inadequate to address the realities of the internal market and its inherent cross-border supply chains. This suboptimal compulsory licensing framework prevents the Union from relying on an additional instrument when facing crises, ~~in particular~~ **namely** when **means other than a Union compulsory licence, including** voluntary agreements**, could not adequately, efficiently and swiftly ensure access to crisis-relevant products and processes required to manufacture these products, which are protected by intellectual property rights** ~~are unavailable or inadequate~~. At a time where the Union and its Member States are striving to improve their resilience to crises, it is necessary to provide for an optimal compulsory licensing system for crisis management that takes the full advantage of the internal market and allows Member States to support one another in crises.

(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 th**e**~~is~~ **Union compulsory licensing** system~~,~~ the Commission**, after considering the opinion of the advisory body,** should be empowered to grant**, in the public interest and as an exceptional measure,** a compulsory licence that is valid throughout the Union and that allows the **use of an invention protected by intellectual property rights** ~~manufacturing and distribution of~~ **to supply** products necessary to address a crisis or emergency in the Union ~~('Union compulsory licence')~~.

(7) In recent years, the European Union has adopted several crisis mechanisms to improve its resilience to crises or emergencies affecting the Union. The recent mechanisms include the ~~Single Market Emergency Instrument (SMEI)~~ **Internal Market Emergency and Resilience Act (IMERA)** established under Regulation (EU) No XXX/XX [COM(2022) 459]**,** ~~and~~ Regulation (EU) ~~No~~ 2022/2371 **of the European Parliament and of the Council[10]** under which the Commission may recognise a public health emergency at Union level**, as well as Council Regulation (EU) 2022/2372[11] that,** ~~. I~~**i**n the event of a public health emergency at Union level**, provides** a framework of measures for ensuring the supply of crisis-relevant medical countermeasures**,** ~~, might be activated under Regulation (EU) No 2022/2372~~. ~~Furthermore, in case of a significant shortage of semiconductors due to serious disruptions in their supply, the Commission may activate a crisis stage by means of implementing acts under Regulation (EU) No XXX/XX (Chips Act) [COM(2022) 46].~~

(8) These mechanisms provide for the activation of ~~an emergency or~~ **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 ~~existing~~ **relevant** crisis mechanisms and a Union wide compulsory licencing scheme is achieved. In such a case, the determination of the existence of a crisis or emergency depends solely on the Union legal act underlying the crisis mechanism and the crisis definition included therein. For the sake of legal certainty, the crisis mechanisms that qualify as Union emergency or extreme urgency measures and that can trigger a Union compulsory licence should be listed in ~~an Annex to~~ this Regulation.

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**10** **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).**

**11** **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).**

(9) To ensure optimal efficiency of the Union compulsory licence as a tool ~~to~~ **in** address**ing** crises **or emergencies**, it should be made available in respect of a granted patent or utility model~~, of a published patent application~~ or a supplementary protection certificate. **It should also be available in respect of a published patent application or a published utility model application.** The Union compulsory licence should equally apply to ~~a~~ national patents, European patents and European patents with unitary effect.

(10) Utility model systems **offer** protect**ion for** ~~new~~ technical inventions **under criteria that are, as a general rule, less stringent than those for patents** ~~that do not fulfil the patentability requirements through the~~ **. The owner of a utility model is** grant**ed**~~ing of~~ an exclusive right to prevent others, for a limited period of time, from commercially exploiting the protected invention~~s~~ 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 expir**y**~~ation~~ 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 ~~the patent claims~~ **protection of these intellectual property rights as granted**.

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(13) It should be clarified that this Regulation is without prejudice to Union law on copyright and related rights, including Directives 96/9[12], 2009/24[13], ~~Directives~~ 2001/29/EC[14], 2004/48/EC[15] and (EU) 2019/790[16] 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[17]. 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.**

**(13a) The Union crisis or emergency mechanisms provide for dedicated measures aimed at ensuring the supply of products that are critical for tackling a crisis or emergency or their direct impacts, in the territory of the Union. Such measures include, for instance, priority-rated orders for crisis-relevant products, a joint procurement procedure as well as the possibility for the Commission to act as a central purchasing body. Considering that the Union compulsory licencing framework is intended to 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.**

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12 Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases (*OJ L 77, 27.3.1996, p. 20)*

13 Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs (*OJ L 111, 5.5.2009, p. 16)*

14 Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society (OJ L 167, 22.6.2001, p. 10).

15 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).

16 Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC (OJ L 130, 17.5.2019, p. 92).

17 **Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1).**

(14)[18] When a compulsory licence has been granted, regulatory data protection may, if still in force, prevent the effective use of the compulsory licence as it impedes the authorisation of generic medicinal products. This would result in serious negative consequences for Union compulsory licences granted to tackle a crisis, as this could ~~hamper~~ **impact** access to the medicinal products needed to address the crisis. For this reason, Union pharmaceutical legislation (cf. Art. 80 para. 4 of Directive (EU) No XXX/XX [COM(2023)192]) provides for the suspension of data exclusivity and market protection when a compulsory licence has been issued to tackle a public health emergency. Such suspension is allowed only in relation to the compulsory licence granted and its beneficiary and must comply with the objectives, the territorial scope, the duration, and the subject-matter of the granted compulsory licence. The suspension means that the data exclusivity and market protection produce no effect in relation to the licensee of the compulsory licence while that licence is in effect. When the compulsory licence ends, the data exclusivity and market protection resume their effect. The suspension should not result in an extension of the original duration of the regulatory data protection.

(15) In order to ensure as much coherence as possible with existing crisis mechanisms ~~and with other Union legislation~~, the definition of a 'crisis-relevant product' should be ~~based on the definition adopted in the Single Market Emergency Instrument (SMEI) but should be more~~ **sufficiently** general ~~in order~~**so as** to cover products related to different kinds of cris**is**~~es~~ or ~~emergencies~~ **emergency modes under the respective Union legal acts listed in this Regulation**.

**(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 ensure access**

[18] **Recital to be ultimately kept, adapted or deleted during the negotiations with the European Parliament depending on the progress of the Pharma package.**

**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.**

(16) A Union compulsory licence authorises the use of a protected invention without the consent of the rights-holder. Therefore, it must only be granted exceptionally and under conditions that take into account the interests of the rights-holder. This includes a clear determination of the scope, duration and territorial coverage of the licence. In the context of a Union level crisis mechanism, the crisis mode or emergency mode is activated or declared for a limited period of time. Where a Union compulsory licence is granted within such framework, the duration of the licence shall not extend beyond the duration of the activated or declared crisis or emergency mode. In order to ensure that the **Union** compulsory licence fulfils its objective as well as its conditions, the use of the invention should only be authorised to a qualified ~~person able~~ **entity that has the capacity to efficiently exploit the protected invention and consequently** to manufacture the crisis-relevant product and to pay ~~a reasonable~~ **an adequate** remuneration to the rights-holder. **When selecting potential licensees, the Commission should also take into account criteria such as the price of crisis-relevant products, the licensees' capacity to supply them in necessary quantities, in a timely fashion, with the quality required in the relevant area, and in compliance with all the industrial and sanitary requirements. To that end, potential licensees should provide any information deemed relevant for this purpose in the course of the procedure for granting a Union compulsory licence, as well as information about any changes to their capacity that occurred after the granting of the licence.**

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. ~~The consultation of the advisory body should arise early in the discussions on the need to issue a compulsory licence under the relevant instrument.~~ Discussions on whether there is a need for a Union compulsory licence will often start already in the context of the work of the advisory body involved ~~in the context of~~ **under** the relevant Union crisis or emergency mechanisms. **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.** ~~In such case, there is no need for the Commission to convene the advisory body but rather to swiftly indicate that that body also has the competence to assess the need for compulsory licensing at Union level, and the conditions thereof. Clarification as regards the competence of the advisory body should be given early in the process, as soon as concrete consideration of using compulsory licensing at Union level is expressed by the Commission.~~

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 ~~under what conditions~~ **on the content of the compulsory licence**. Union crisis mechanisms usually include the setting-up of an advisory body ensuring coordination of action of the Commission and relevant bodies and agencies, the Council and the Member States. In this respect, an **Internal Market Emergency and Resilience Board** ~~advisory group~~ is set up under ~~SMEI~~ **IMERA**~~.~~**, while** Regulation**s** (EU) ~~No~~ 2022/2371 **and (EU) ~~No~~ 2022/2372** provide~~s~~ for a **Health Security Committee and a** Health Crisis Board **respectively.,** ~~and under Regulation (EU) **2023/1781** No XXX/XX (Chips Act) [COM/2022) 46], the Commission relies on the Semiconductor Board.~~ Those advisory bodies have the right composition, expertise, and procedures to address the crises and emergencies for which they have been set-up. When compulsory licensing is being discussed in the context of such crisis instrument, relying on the advisory body set-up for the specific instrument allows the Commission to be adequately advised and avoid duplication of advisory bodies, leading to incoherences between processes. **However, considering the specific role of the advisory body, it should be ensured that the said body draws on additional expertise in intellectual property rights, in particular patents, and in the granting of compulsory licenses.** The competent advisory bodies shall be listed, together with the corresponding crisis mechanisms, in an Annex to this Regulation. ~~In case the Union crisis mechanism does not provide for an advisory body, the Commission should set up an ad hoc advisory body for the granting of the Union (the 'ad hoc advisory body').~~

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 licens~~ing~~**ce and its content** ~~at Union level~~. **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 efficiently 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, with the Commission and the advisory body serving as facilitators in this respect. Alongside the rights-holders and licensees, it may be useful to invite contributions from other actors, in particular economic operators of the sectors concerned and other relevant entities such as social partners, and representatives of international bodies such as the European Patent Office or the World Health Organization. Given the importance of expediency in managing a crisis, consultations and exchanges with the various actors should be carried out quickly and by means most appropriate to the situation. To properly consider all relevant aspects of intellectual property law and, more specifically, compulsory licensing, it is necessary to fully involve the representatives of national intellectual property offices and national authorities responsible for granting compulsory licences in the relevant discussions of the advisory body. Each Member State should designate the most suitable representatives for this. Due to its expertise, the advisory body is the most competent entity to gather and analyse the available crisis information from the Member States and from other crisis relevant bodies at Union and international level. The analysis of this information should**

PUBLIC

**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.** ~~It should provide the Commission with a non-binding opinion. Its main tasks include assisting of the Commission in the determination of the necessity to rely on compulsory licensing at Union level, and in the determination of the conditions for such licensing. When the advisory body is already set up, its existing rules of procedure should apply. As regards ad hoc advisory bodies, they should be composed of one representative of each Member State in order to provide the Commission with information and input concerning the situation on the national level, including information on manufacturing capacities, potential licensees and, if applicable, proposals for voluntary solutions. In addition, the advisory body should have the function of collecting and analysing relevant data, as well as ensuring coherence and cooperation with other crisis relevant bodies at Union and national level in order to ensure an adequate, coordinated and coherent crisis reply at Union level.~~

**(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. 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 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 Commission should grant the Union compulsory licence in the light of the non-binding opinion of the advisory body. Persons, in particular the licensee and the rights-holder, whose interests may be affected by the Union compulsory licence should be given the opportunity to submit their comments. These elements should enable the Commission to consider the individual merits of the situation and determine, on that basis, the adequate conditions of the licence, including an adequate remuneration to be paid by the licensee to the rights-holder. To avoid overproduction of products manufactured under a Union compulsory licence, the Commission should also consider any existing compulsory licences at national level.~~ **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.**

PUBLIC

(21) ~~The Commission should guarantee that the rights-holder has the right to be heard before the adoption of the Union compulsory licence. Therefore, the Commission should inform the concerned rights-holder, where possible individually, without undue delay that a Union compulsory licence might be granted. The involvement of the rights-holder should be possible once there are ongoing advanced discussions in the relevant advisory body as regards the granting of a Union compulsory licence.~~ **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.**

**(21a) Throughout the procedure for the granting of a Union compulsory licence, the concerned rights-holders should be able to provide their comments. The involvement of the rights-holders should be ensured at every relevant step of the granting procedure, from its start, with the publication of the notice and, until its final stages, namely after the advisory body has issued its opinion. This should ensure the protection of the rights-holders' rights and interests and allow for the exploration of ways for reaching voluntary solutions that would adequately, efficiently, and swiftly remedy the lack of adequate supply of crisis-relevant products. Involvement of the rights-holders in the procedure should ensure that they have the right to be heard before the adoption of the Union compulsory licence and that they are able to propose such voluntary solutions throughout the procedure and therefore render the granting of a Union compulsory licence unnecessary. The Commission should also end the procedure without granting a Union compulsory licence should it appear that there is no need for it. For the sake of transparency, a notice informing of the end of the procedure should be published in the *Official Journal of the European Union*.**

PUBLIC

(22) ~~When informed of advanced discussions as regards the granting of a Union compulsory licence, the rights-holder should have the possibility to propose a voluntary agreement, should the circumstances of the Union crisis or emergency, including the urgency of the situation, allow it. The rights-holder should also be given the opportunity to comment on the need for a Union compulsory licence and on the conditions of the licence, including remuneration, should it be granted. To this end, the rights-holder should be allowed to provide the Commission with written or oral comments and any information the rights-holder considers useful to allow the Commission to make a fair, comprehensive, and thorough assessment of the situation. The Commission should allow the rights-holder a reasonable period of time to provide comments and information, considering the situation of the rights-holder and the urgency of the situation. The comments of the rights-holder should, where relevant, be transmitted by the Commission to the competent advisory body. In order for confidential information to be shared with the Commission, t~~**T**he Commission shall ensure a safe environment for the sharing of ~~this~~ **confidential** information and should take measures to preserve the confidentiality of the documents provided by the rights-holder **and other relevant actors** in the context of the procedure **for granting a Union compulsory licence**. ~~Once a Union compulsory licence has been granted, the Commission should notify the rights-holder as soon as reasonably practicable.~~

(23) ~~The initiation of the compulsory licensing procedure should be publicised, by means of a notice published in the Official Journal of the European Union. This notice should include information on the discussions about the granting of a Union compulsory licence in the context of a Union crisis or emergency mechanism. This notice should also help the Commission in identifying the intellectual property rights concerned, the rights-holders concerned as well as potential licensees.~~

PUBLIC

(24) The Commission should~~, assisted by the advisory body, make its best efforts to~~ identify in **the implementing act granting a Union compulsory licence**~~its decision~~ the patent**s and**, **where applicable, published** patent application**s**, **utility models and, where applicable, published utility model applications, and** supplementary protection certificate**s** ~~and utility model~~ related to the crisis-relevant products, ~~and~~**as well as** the rights-holders of those intellectual property rights. ~~In certain circumstances, the identification of intellectual property rights and of their respective rights-holders may require lengthy and complex investigations. In such cases, a complete identification of all intellectual property rights and of their rights-holders may seriously undermine the efficient use of the Union compulsory licence to swiftly tackle the crisis or the emergency. Therefore, where the identification of all those intellectual property rights or rights-holders would significantly delay the granting of the Union compulsory licence, the Commission should be able to initially only indicate in the licence the non-proprietary name of the product for which it is sought. The Commission should nevertheless identify all applicable and relevant intellectual property rights and their rights-holder as soon as possible and amend the implementing act accordingly.~~ **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 may have retroactive effect. The retroactive effect of the modification should not prevent the rights-holder from submitting comments on the possibility to reach a voluntary licensing agreement with the licensee and on the amount of remuneration. It should prevent situations such as recalls from the market or destructions of crisis-relevant products due to an incomplete list of rights and rights-holders, where such measures would threaten the supply of crisis-relevant products in the territory of the Union.** ~~The amended implementing act~~ **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**

PUBLIC

**implementing act granting the Union compulsory licence, as well as the implementing act modifying or terminating the Union compulsory licence.**

(25) ~~Where the rights-holder or not all the rights-holders could be identified in a reasonable period of time, the Commission should exceptionally be entitled to grant the Union compulsory licence by referring only to the non-proprietary name of the crisis-relevant product where it is absolutely necessary considering the urgency of the situation. Nevertheless, after the granting of the Union compulsory licence, the Commission should identify, notify and consult the concerned rights-holders as quickly as possible, including by relying on publication measures and on national Intellectual Property Offices.~~

(26) The Union compulsory licence should ~~also~~ include information allowing the identification of the crisis-relevant product for which it is granted, ~~as well as details on the licensee to whom the Union compulsory licence is granted,~~ including details about the description, name or brand of the product; **where appropriate, the non-proprietary name of the crisis-relevant product and/or** the commodity codes under which the crisis-relevant products are classified, as defined in Council Regulation (EEC) No 2658/87[19]**,** ~~;~~ **and** details on the licensees ~~(~~ (and, where applicable, the manufacturers~~)~~) to whom the compulsory licence is granted, including their name~~;~~ **or** trade name ~~or registered trade mark~~, their contact details, their unique identification number in the country where they are established and, where available, their Economic Operators Registration and Identification (EORI) number. Where required under Union legislation, other information **allowing for the identification of the crisis-relevant products** should be included, such as a type, reference, model, batch or serial number, or unique identifier of a product passport.

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[19] **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 amounts 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 degree to which development costs have been amortized as well as humanitarian circumstances relating to the granting of the Union compulsory licence~~. **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 developments 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 any case, the remuneration should not exceed 4 % of the total gross revenue generated by the licensee through the acts under the Union compulsory licence. This percentage is the same as the one provided for under Regulation 816/2006.~~ In the event of a compulsory licence granted ~~on the basis of~~ **with regard to** a published patent application that ultimately does not lead to the granting of a patent, the rights-holder would have no ground to receive remuneration under the **Union** compulsory licence, as the subject matter for ~~the receipt of the~~ **receiving** remuneration has not materialised. In such circumstances, the rights-holder should refund the remuneration ~~it~~ received under the **Union** compulsory licence.

(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[20]. 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.

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

PUBLIC

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20 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).

21 **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[22]. 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.

(31) ~~The legal validity of the implementing act granting the Union compulsory license, or any subsequent implementing act, should be subject to judicial review.~~ **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.**

[22] 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).

(32) ~~The relation between the rights-holder and the licensee~~**During the procedure for granting a Union compulsory licence and after such licence has been granted** ~~should be governed by the principle of good faith. T~~**t**he rights-holder and licensee should ~~work towards the success of the Union compulsory licence and collaborate, where necessary, to ensure that the Union compulsory licence effectively and efficiently fulfils its objective.~~ **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.** ~~The Commission may act as an enabler in achieving the good-faith cooperation between the rights-holder and the licensee, taking into account interests of all parties.~~ **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.** ~~In that respect, the Commission should also be entitled to take additional measures in line with Union law to ensure that the compulsory licence meets its objective and ensure that necessary crisis-relevant goods can be made available in the Union. Such additional measures may include requesting further information which is deemed indispensable to achieve the objective of the compulsory licence. These measures should always include adequate safeguards to ensure the protection of the legitimate interests of all parties.~~

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. ~~This should include the modification of the compulsory licence to indicate the complete~~ **Where necessary, the** list of **the** rights and rights-holders covered by the **Union** compulsory licence **should be updated, with retroactive effect where appropriate.** ~~where this complete identification had not be done initially.~~ **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.** ~~This should also include the termination of the licence i~~**I**f the circumstances which led to ~~it~~ **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.** When deciding on the revision of the Union compulsory licence, the Commission ~~may decide to~~ **should** consult the competent advisory body for that purpose **and duly consider the rights and interests of the rights-holder and the licensee**. ~~If the Commission intends to change essential components of the Union compulsory licence, such as its duration or remuneration or if the change itself could be the subject of a separate compulsory licence, it should be required to consult the advisory body.~~

(34) ~~To prevent and stop any misuse of the Union compulsory licence, specific safeguards should be in place to allow the Commission to take action.~~ In addition to the possibility to 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.** The**se** ~~penalties~~ **sanctions** should be effective~~, proportionate~~ and dissuasive**, and they should also be subject to the overarching principles of proportionality and *ne bis in idem***.

PUBLIC

(35) ~~Compliance with the relevant obligations imposed under this Regulation should be enforceable by means of fines and periodic penalty payments. To that end, a~~**A**ppropriate 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.** ~~and the~~ **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.** ~~should be subject to appropriate limitation periods in accordance with the principles of proportionality and *ne bis in idem*. All decisions taken by the Commission under this Regulation are subject to review by the Court of Justice of the European Union in accordance with the TFEU.~~ The Court of Justice of the European Union should have unlimited jurisdiction in respect of **all decisions taken by the Commission to impose** fines and **periodic** penalty payments in accordance with Article 261 TFEU.

(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 ~~notify~~ **inform** the Commission of the granting of the licence, and of the specific conditions attached to it, since it allows the Commission to get an overview of national compulsory licences in the Member States and to take those compulsory licences into account when considering **the need to grant** a Union compulsory licence, and in particular when setting the conditions for such licence. **Considering that there are differences between the Member States in terms of authorities responsible for granting compulsory licences at national level, it should remain for the Member States to establish appropriate procedures under their national laws, ensuring that the relevant information is provided to the Commission without undue delay. To ensure efficient 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.**

(37) The possibility of a compulsory licence at Union level should not only be available for the supply of the Union market but also under certain conditions for export purposes concerning countries with public health problems, already regulated by Regulation (EC) No 816/2006~~ of the European Parliament and of the Council~~[23]. 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~~ in order to~~ avoid**ing** a situation where several compulsory licences for the same product in more than one Member States would be required for licensees to manufacture and export the products as planned. Any person considering to apply for a compulsory licence under~~, for the purposes and within the scope of~~ Regulation (EC) No 816/2006 should have the possibility to request, with a single application, a compulsory licence under that Regulation that is valid throughout the Union, if that person, when relying on national compulsory licencing schemes of the Member States, would otherwise need to apply for multiple compulsory licences for the same crisis-relevant product in more than one Member State in order to realise its intended activities of manufacture and sale for export under Regulation (EC) No 816/2006. **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.

~~23~~ ~~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).~~

**(37a) On 1 February 2020, the United Kingdom withdrew from the European Union. The Withdrawal Agreement[24] 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[25] 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[26], 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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**[24] 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).**

**[25] 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).**

**[26] 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, complementing, modification or termination of a Union compulsory license~~, the determination of the remuneration to be paid to the rights-holder, the procedural rules for the ad hoc advisory body and the characteristics allowing the identification of products produced under a Union compulsory licence~~. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[27]. The **examination** ~~advisory~~ procedure should be used for the adoption of implementing acts granting, complementing, modifying or terminating a Union compulsory licence**.**~~, and implementing acts determining the remuneration. The choice of the advisory procedure is justified given that those implementing acts would be adopted in the context of a procedure with considerable participation of the Member States through the consultation of the advisory body. The examination procedure should be used for the adoption of implementing acts establishing procedural rules for the ad hoc advisory body and implementing acts establishing the characteristics allowing the identification of products produced under a Union compulsory licence.~~

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

[27] 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).

**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 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.

(41) ~~Since a period of time is required to ensure that the framework for the proper functioning of the system for Union compulsory licencing is in place, the application of this Regulation.~~

PUBLIC

HAVE ADOPTED THIS REGULATION:

*Article 1*

***Objectives and ~~S~~subject matter***

~~This Regulation has the objective to ensure that in crises the Union has access to crisis-relevant products. To this end,~~ t**T**his Regulation lays down rules on the ~~procedure and~~ conditions **and procedure** for the granting of a Union compulsory licence of intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States ~~in the context of a Union~~ **during an activated or declared** crisis or emergency ~~mechanism~~ **mode, pursuant to any of the respective Union legal acts listed in Article 2(1a). The Union compulsory licence is granted in the public interest and as a last resort measure when other means, including 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***

**1a. This Regulation applies where a crisis or emergency mode, as referred to in Annex to this Regulation, is activated or declared in accordance with any of the following Union legal acts:**

**(a) Regulation XXX/XX of the European Parliament and of the Council[28];**

**(b) Regulation (EU) 2022/2371;**

**(c) Council Regulation (EU) 2022/2372.**

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

(a) patents **and**~~, including~~ 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.**

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**28** **Regulation … of the European Parliament and of the Council of … 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].**

**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 Article 2(1a), 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 or emergency mode listed in the Annex, which has been activated or declared pursuant to the respective Union legal act listed in Article 2(1a);**

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

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

(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** ~~of~~ crisis-relevant products **or processes required to manufacture these products** ~~for any of the relevant activities in the Union~~;

**(ea)** **'competent advisory body' means the advisory body competent for the Union crisis or emergency mechanism as listed in the Annex to this Regulation;**

(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[29];

[29] 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 ~~where a crisis mode or an emergency mode listed in the Annex to this Regulation has been activated or declared in accordance with one of the Union acts listed in that Annex.~~ **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 Article 2(1a);**

**(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 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 ~~conditions~~ requirements of a Union compulsory licence***

1. The Union compulsory licence 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 **material** scope and duration that is **strictly** limited to the purpose for which the **Union** compulsory licence is granted and **strictly** limited to the scope and duration of the crisis or emergency 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 limited to the territory of the Union;

(f) only be granted to a**n** ~~person~~ **entity** ~~deemed to be in a position~~**that has the capacity** to **efficiently and swiftly** exploit the protected invention in a manner that permits the **effective and** proper carry out of the relevant activities of the crisis-relevant products ~~and in accordance with the obligations referred to in Article 10.~~**; and**

**(h) 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. ~~When the Commission considers the granting of a Union compulsory licence, it shall without undue delay consult an advisory body.~~

2. ~~The advisory body referred to in paragraph 1 shall be the advisory body competent for the Union crisis or emergency mechanism as listed in Annex I to this Regulation (the 'competent advisory body'). For the purposes of the present Regulation, the competent advisory body shall assist and advise the Commission as regards the following tasks:~~

   (a) ~~the gathering of crisis-relevant information, market intelligence and the analysis of those data;~~

   (b) ~~the analysis of the crisis-relevant information gathered by Member States or the Commission and aggregated data received by other crisis-relevant bodies at Union and international level;~~

   (c) ~~the facilitation of exchanges and sharing of information with other relevant bodies and other crisis-relevant bodies at Union and national level, as well as at international level, where appropriate;~~

   (d) ~~the identification of the rights protecting the crisis-relevant product;~~

   (e) ~~the establishment of whether there is a need to grant a Union compulsory licence;~~

   (f) ~~the identification and consultation of the representatives of right holders or their representatives as well as potential licensees and consulting other economic operators, and the industry;~~

   (g) ~~the establishment, if relevant, of whether the criteria for termination or modification of the Union compulsory licence set out in Article 15 have been fulfilled.~~

PUBLIC

3. The advisory body shall cooperate and coordinate closely, where appropriate, with other relevant crisis-related bodies and with intellectual property offices at Union and national level.

4. For the purpose of the present Regulation, the Commission:

(a) shall ensure participation and invite representatives of other crisis-relevant bodies at Union level as observers to the relevant meetings of the advisory body in order to ensure coherence with the measures implemented through other Union mechanisms; and

(b) may invite representatives of the European Parliament, representatives of economic operators, right holders, potential licensees, stakeholder organisations, social partners and experts to attend meetings of the advisory body as observers.

5. In the absence of any existing competent advisory body, the tasks referred to in paragraph 2 shall be performed by an ad hoc advisory body set up by the Commission (the 'ad hoc advisory body'). The Commission shall chair the ad hoc advisory body and ensure its secretariat. Each Member State shall have the right to be represented in the ad hoc advisory body.

6. The Commission shall adopt an implementing act laying down the rules of procedure for the ad hoc advisory body referred to in paragraph 5. The rules of procedure shall specify that the ad hoc advisory body shall not be set up for a period exceeding the duration of the crisis or emergency. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 24 (3).

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 efficiently and swiftly exploit the protected invention in a manner that permits the effective and proper carrying out of the relevant activities relating to the crisis-relevant product, in accordance 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 of voluntary licensing agreements, and, where relevant, through their participation in the discussions of the competent advisory body, as well as the analysis of the comments received in accordance with Article 7(2)(c);**

**(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;**

PUBLIC

**(g) the gathering and analysis of the crisis-relevant information and market intelligence available, notably in order to take account of the characteristics of the crisis or emergency and how it is expected to evolve, and in order to take account of the shortage of crisis relevant products and existence of means other than a Union compulsory licence to remedy such shortage;**

**(h) the facilitation of the exchange~~s~~ 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.**

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

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

PUBLIC

*Article 7*

***Procedure for granting a Union compulsory licence***

1. The competent or, where relevant ad hoc, advisory body referred to in Article 6 shall provide the Commission with an opinion without undue delay. That opinion shall be issued in accordance with the rules of procedure of the advisory body and shall contain an assessment of the need for a Union compulsory licence and the conditions for such licence. The opinion shall take account of the following:

   (a) the nature of the crisis or emergency;

   (b) the scope of the crisis or emergency and how it is expected to evolve;

   (c) the shortage of crisis-relevant products and the existence of other means than a Union compulsory licence that could adequately and swiftly remedy such shortage.

2. The opinion of the advisory body shall not be binding on the Commission. The Commission may set a time limit for the advisory body to submit its opinion. The time limit shall be reasonable and appropriate to the circumstances of the situation, taking particular account of the urgency of the matter.

3. Before the granting of a Union compulsory licence, the Commission shall give the rights-holder and the licensee an opportunity to comment on the following:

   (a) the possibility to reach a voluntary licensing agreement with manufacturers on intellectual property rights for the purpose of manufacturing, using and distributing the crisis-relevant products;

   (b) the need to grant the Union compulsory licence;

   (c) the conditions under which the Commission intends to grant the Union compulsory licence, including the amount of the remuneration.

PUBLIC

~~4. The Commission shall notify the rights-holder and the licensee as soon as possible of the fact that a Union compulsory licence may be granted. Wherever the identification of the rights-holders is possible and does not cause significant delay, the Commission shall notify them individually.~~

~~5. When the Commission considers the granting of a Union compulsory licence, it shall without undue delay publish a notice to inform the public about the initiation of the procedure under this article. This notice shall also include, where already available and relevant, information on the subject of the compulsory licence and an invitation to submit comments in accordance with paragraph 3. The notice shall be published in the Official Journal of the European Union.~~

~~6. When assessing whether a Union compulsory licence is to be granted, the Commission shall consider the following:~~

~~(a) the opinion referred to in paragraph 2;~~

~~(b) the rights and interests of the rights-holder and the licensee;~~

~~(c) existing national compulsory licences reported to the Commission in accordance with Article 22.~~

~~7. Where the Commission finds that the requirements for a Union compulsory licence are met, the Commission shall grant it by means of an implementing act. The implementing act shall be adopted in accordance with the advisory procedure referred to in Article 24(2). On duly justified imperative grounds of urgency relating to the impacts of the crisis, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 24(4). In case of procedure under Article 24(4), the implementing act shall remain in force for a period not exceeding 12 months.~~

~~8. When adopting the implementing act, the Commission shall ensure the protection of confidential information. While respecting the confidentiality of the information, the Commission shall ensure that any information relied on for the purpose of its decision is disclosed to an extent that allows to understand the facts and considerations that led up to the adoption of the implementing act.~~

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, including on the lack of supply of crisis-relevant products, available manufacturing capacity and on the intellectual property rights and rights-holders concerned, considers that the use of an invention protected by intellectual property rights, which concerns crisis-relevant products, is required to supply those products in the territory of the Union, it may initiate the procedure for the granting of a Union compulsory licence by publishing a notice on the website of the Commission.**

**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;**

**(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 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 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.**

**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 within a time limit set by the Commission.**

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 9 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).**

**11**. **Throughout the procedure for granting a Union compulsory licence, the Commission and the competent advisory body shall ensure the protection of confidential information. While respecting the confidentiality of the information, the Commission and the competent advisory body shall ensure that any information relied on for the purpose of the Commission's decision is disclosed to an extent that allows 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 ~~or, where the identification of those rights would significantly delay the granting of the licence, the non-proprietary name of the products which are to be manufactured under the licence~~;

(b) the right**s**-holder~~, provided they can be identified with reasonable efforts having regard to the circumstances, including the urgency of the situation~~;

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

(~~1~~**i**) name~~,~~ **and** trade name ~~and registered trade mark~~;

(~~2~~**ii**) contact details;

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

(~~4~~ **iv**) 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;

(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;

PUBLIC

(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) where feasible, the maximum number of crisis-relevant products to be manufactured under the Union compulsory licence.**

(h) ~~measures complementing the compulsory licence, which are necessary to achieve the objective of the compulsory licence.~~

2. ~~By way of derogation from paragraph 1, point (e), the Commission may determine the remuneration after the granting of the licence, by way of an implementing act, where that determination requires, further investigation and consultation. This implementing act shall be adopted in accordance with the rules referred to in Article 7(6) (a) and (b), 7(7) and 7(8).~~

PUBLIC

*Article 9*

***Remuneration***

1. The licensee shall pay an adequate remuneration to the rights-holder. The amount of the remuneration shall be determined by the Commission and specified in the Union compulsory licence.

2. ~~The remuneration shall not exceed 4 % of total gross revenue generated by the licensee through the relevant activities under the Union compulsory licence.~~

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. It shall also take into account the opinion of the competent advisory body and any comments received under Article 7(87).** ~~consider the following:~~

   ~~(a) the economic value of the relevant activities authorised under the Union compulsory licence.~~

   ~~(b) whether the rights-holder has received public support to develop the invention.~~

   ~~(c) the degree to which development costs have been amortized by the rights-holder.~~

   ~~(d) where relevant, the humanitarian circumstances relating to the granting of the Union compulsory licence.~~

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 licen**c**~~s~~e only under the following obligations:

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

   (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;

   (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.

PUBLIC

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

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

(~~3~~**ii**) 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.

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); ~~or~~

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

3. The European Anti-Fraud Office (OLAF) in cooperation with the relevant national authorities of the Member States may, at the request of the rights-holder or on its own initiative, request access to books and records kept by the licensee, for the purpose of checking whether the content ~~and the conditions~~ of the Union compulsory licence, and in general the provisions of this Regulation, have been complied with.

4. The Commission is empowered to adopt implementing acts establishing rules for the specific labelling or marking referred to in paragraph 1, point (c), and for the packaging, colouring and shaping referred to in point (d) as well as rules for their use and, where relevant, their positioning on the product. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 24(~~2~~**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[30].

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

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.** T**he Commission may consult the relevant rights-holder** to assess whether the suspended products correspond to the Union compulsory license~~, the Commission may consult the relevant rights-holder~~.

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

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.

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 ~~context~~ **mode**, the Commission may require**, via** customs authorities**,** ~~, to oblige~~ the exporter to take specific actions at their own costs, including supplying them to designated Member States, if need be, after rendering them compliant with Union law.

   (b) in all other cases~~, customs authorities may take any necessary measure to ensure that~~ the product concerned ~~is~~ **may be** disposed of in accordance with national law consistent with Union law. Articles 197 and 198 of Regulation (EU) No 952/2013 shall apply accordingly.

PUBLIC

*Article 13*

***~~Relations between~~ Conduct of the rights-holder and licensee***

1. ~~he relations between the rights-holder and the licensee who has been granted a Union compulsory license shall act and cooperate with each other in good faith w~~When ~~performing~~ **exercising the** rights ~~and~~ **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.**

2. ~~In compliance with the good faith obligation, the rights-holder and the licensee shall make their best efforts to fulfil the objective of the Union compulsory licence, taking into account each other's interests.~~

*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. Where necessary, the Union compulsory licence shall be modified to ~~indicate~~ **update** the ~~complete~~ list of rights and rights-holders covered by the compulsory licence~~.~~**, and this modification may 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 a voluntary licensing agreement with the licensee and on the amount of remuneration.**

2. ~~Where necessary, the Commission shall decide upon reasoned request by the rights-holder or the licensee or on its own initiative on additional measures complementing the Union compulsory licence to ensure it achieves its objective as well as to facilitate and ensure the good collaboration between the rights-holder and the licensee.~~

3. A Union compulsory licence ~~may~~ **shall** be terminated by the Commission by means of an implementing act where the circumstances which led to it 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.**

4. When the Commission considers modifying~~, adopting additional measures as referred to in paragraph 2,~~ or terminating the Union compulsory licence, it ~~may~~ **shall** consult the **competent** advisory body ~~referred to in Article 6~~.

5. When ~~terminating the~~ **a** Union compulsory licence **is terminated or expires in accordance with Article 5(1)(h)**, the Commission may require that the licensee, within a reasonable period of time, arrange for any goods in its possession, custody, power or control to be redirected or otherwise disposed of in the manner determined by the Commission in consultation with the rights-holder **and the licensee** and at the expense of the licensee.

6. The implementing acts referred to in paragraph 1, 2 and 3 shall be adopted in accordance with the ~~rules~~ **examination procedure** referred to in Article ~~7(6) (a) and (b), 7(7) and 7(8)~~ **24(3)**. **On duly justified imperative grounds of urgency relating to the impacts of the crisis, the Commission shall adopt immediately applicable implementing acts in accordance 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** ~~on~~ **if** the licensee **fails to comply with its obligations under Article 9(1), Article 10(1) or Article 11.** ~~or the rights-holder fines not exceeding 6 % of their respective total turnover in the preceding business year where, intentionally or negligently:~~

   ~~(a) the licensee fails to comply with its obligations under Article 9(1), or Article 10(1);~~

   ~~(b) the rights-holder or the licensee fail to comply with the principle of good faith and cooperation referred to in Article 13; or~~

   ~~(c) the rights-holder or the licensee fail to comply with any obligation resulting from the additional measures complementing the Union compulsory licence as referred to in Articles 8(1)(h) and 14(2), as specified in the relevant implementing act.~~

**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~~ **given** to the **following:**

   **(a)** **nature,** gravity~~, to the recurrence of the infringement~~ and ~~to the~~ duration of the infringement**;**

   **(b) the intentional or negligent character of the infringement;**

   **(c) any other aggravating or mitigating factor applicable to the circumstances of the case, such as actions taken to mitigate the damages, the financial benefits gained, or losses avoided, directly or indirectly, from the infringement**.

PUBLIC

*Article 16*

***Periodic penalty payments***

1. The Commission may, by decision, impose on the licensee ~~or the rights-holder~~ periodic penalty payments ~~not exceeding 5 % of their respective average daily turnover in the preceding business year per day and~~ **for each working day** calculated from the date ~~appointed by~~**determined in** the decision, in order to compel **it to put an end to an infringement of its obligations under Article 9(1), Article 10(1) or Article 11.** ~~:~~

   ~~(a) the licensee to put an end to an infringement of its obligations under Article 10(1);~~

   ~~(b) the licensee and the rights-holder to put an end to the infringement of Article 13; or~~

   ~~(c) the rights-holder or the licensee to comply with any obligation resulting from the additional measures complementing the Union compulsory licence as referred to in Articles 8(1)(h) and 14(2), as specified in the relevant implementing act.~~

**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 ~~or the rights-holder~~ ha**s**~~ve~~ 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.

*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. ~~Time~~ **The limitation period** shall begin to run on the day on which the infringement is committed. However, in the case of continuing or repeated infringements, ~~time~~ **the limitation period** shall begin to run on the 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. ~~Time~~**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 penalties***

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

2. The licensee ~~or the rights-holder~~ 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.

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.

PUBLIC

*Article 20*

***Publication of decisions on fines and penalties***

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

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 Article 2(1a)**, the Member State shall ~~notify~~ **inform** the Commission of the granting of the licence ~~and of the specific conditions attached to it~~ **without undue delay**. **Article 2(~~4~~3a) shall apply *mutatis mutandis*.** The information provided shall **also** 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, first subparagraph,** ~~T~~**t**he 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. 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 shall apply *mutatis mutandis***.

3. The compulsory licence ~~granted in accordance with~~ **referred to in** paragraph 1 shall be subject to the conditions set out in Article 10 and shall specify that it is applicable to the whole territory of the Union.

4. ~~In the event of an application referred to in paragraph 2 under this Article, the competent authority referred to in Articles 1 to 11, 16 and 17 shall be the Commission.~~

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

Those implementing acts shall be adopted in accordance with the ~~advisory~~ **examination** procedure referred to in Article 18b (2). On duly justified imperative grounds of urgency relating to the impacts of the public health problems, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 18b(3)."

(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 ~~4~~ **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 ~~4~~ **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.**

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**(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."**

*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.

2. ~~Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.~~

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

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

*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.

*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

**ANNEX - Crisis or emergency modes referred to in Article 4 and competent advisory bodies as referred to in Article 6~~(2)~~ 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 ~~Single Market Emergency Instrument and repealing Council Regulation (EC) 2679/98~~ **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] | ~~**Single**~~ **Internal Market emergency mode** activated by means of a Council implementing act [Article 14 of Regulation XXX/XX] [COM(2022) 459] | ~~**Advisory Group**~~**Internal Market Emergency and Resilience Board** [Article 4 of Regulation XXX/XX] [COM(2022) 459] |
| 2. Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU | **Public health emergency at Union level** formally recognized by means of a Commission implementing act [Article 23 of Regulation (EU) 2022/2371] | **Health Security Committee** [Article 4 of Regulation (EU) 2022/2371] |

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| | | |
|---|---|---|
| 3. Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level | **Emergency framework** activated by the adoption of a Council Regulation [Article 3 of Regulation (EU) 2022/2372] | **The Health Crisis Board** [Article 5 of Regulation (EU) 2022/2372] |
| 4. ~~Regulation XXX/XX~~ **~~(EU) 2023/1781~~** ~~establishing a framework of measures for strengthening Europe's semiconductor ecosystem~~ **~~and amending Regulation (EU) 2021/694 (Chips Act)~~**~~[COM(2022) 46]~~ | **~~Crisis stage~~** ~~activated by a Commission~~ **~~Council~~** ~~implementing act [Article 18~~ **~~23~~** ~~of Regulation XXX/XXX] [COM(2022) 46]~~ **~~2023/1781~~** | **~~European Semiconductor Board~~** ~~[Article 23~~**~~8~~** ~~of Regulation XXX/XXX~~**~~2023/1781~~**~~] [COM(2022) 46]~~ |
| 5. ~~Regulation (EU) 2017/1938 of the European Parliament and of the Council of 25 October 2017 concerning measures to safeguard the security of gas supply and repealing Regulation (EU) No 994/2010~~ | **~~Union emergency~~** ~~declared by the Commission [Article 12 of Regulation (EU) 2017/1938]~~ | **~~Gas Coordination Group~~** ~~[Article 4 of Regulation (EU) 2017/1938]~~ |

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