European Parliament
2019-2024

TEXTS ADOPTED

P9_TA(2024)0143

Compulsory licensing for crisis management and amending Regulation (EC) No 816/2006

European Parliament legislative resolution of 13 March 2024 on the proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) No 816/2006 (COM(2023)0224 – C9-0151/2023 – 2023/0129(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2023)0224)),

– having regard to Article 294(2) and Articles 114 and 207 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0151/2023),

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

– having regard to the opinion of European Economic and Social Committee of 27 September 2023[1],

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

– having regard to the opinion of the Committee on International Trade,

– having regard to the report of the Committee on Legal Affairs (A9-0042/2024),

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

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1 OJ C, C/2023/865, 08.12.2023, ELI: http://data.europa.eu/eli/C/2023/865/oj.

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

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

P9_TC1-COD(2023)0129

Position of the European Parliament adopted at first reading on 13 March 2024 with a view to the adoption of Regulation (EU) 2024/... of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) No 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[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

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1 OJ C , , p. .
2 OJ C , , p. .

Whereas:

(1) Crises require the setting-up of exceptional, swift, ~~and~~ adequate ***and proportionate*** measures able to provide means to address the consequences of the crisis***, without unnecessarily and disproportionally affecting the rights of citizens or the protection of intellectual property rights of businesses***. In this context, the use of patented products or processes could prove indispensable to address the consequences of a crisis. Voluntary licensing agreements usually suffice to licence the patent rights on these products and allow their supply in the Union territory. Voluntary agreements are the most adequate, quick, and efficient solution to allow the use of patented products~~, including~~ ***and to scale up production*** in crises. Nevertheless, voluntary agreements may not always be available or only under inadequate conditions such as lengthy delivery times. In such cases, compulsory licensing can provide a solution to allow access to patented products, in particular products necessary to tackle the consequences of a crisis. **[Am. 1]**

(2) In the context of the ~~Union~~ crisis or emergency mechanisms ***having a cross-border effect in the Union and involving two or more Member States***, the Union should therefore have the possibility to rely on compulsory licensing ***to adequately respond to the needs commanded by the public interest***. The activation of a crisis or an emergency mode or the declaration of a crisis or a state of emergency addresses obstacles to free movement of goods, services, and persons in crises and shortages of crisis-relevant goods and services. In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can help in lifting any patent-related barriers and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the 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. **[Am. 2]**

(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')[3].

(4) All Member States have implemented compulsory licensing frameworks for patents in their national law. National laws usually allow compulsory licensing on the ground of public interest or in the event of an emergency. However, divergences exist across Member States, as regards the grounds, conditions, and procedures under which a compulsory licence can be granted. This results in a fragmented, suboptimal, and uncoordinated system preventing the Union from effectively relying on compulsory licensing when addressing a cross-border crisis.

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3 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 manufactured under a compulsory licence. Apart from the fact that the issuance of multiple national compulsory licences is a high hurdle for cross-border supply within the single market, it also bears the risk of contradicting and incoherent decisions among Member States. Consequently, the current compulsory licensing framework appears inadequate to address the realities of the internal market and its inherent cross-border supply chains. This suboptimal compulsory licensing framework prevents the Union from relying on an additional instrument when facing crises~~, in particular~~ ***and*** when voluntary agreements are unavailable ~~or inadequate~~***and cannot be reached within four weeks***. At a time where the Union and its Member States are striving to improve their resilience to crises, it is necessary to provide 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. **[Am. 3]**

(6) Therefore, it is necessary to establish a compulsory licence for crisis or emergency management at Union level. Under this system, the Commission should be empowered to grant a compulsory licence that is valid throughout the Union and that allows the manufacturing and distribution of products necessary to address a crisis or emergency in the Union (‘Union compulsory licence’).

(6a) The Commission might only issue a Union compulsory licence for any crisis emergency-related product where the rights-holder, who has been given the opportunity to engage in negotiations with a potential licensee, did not reach an agreement within 4 weeks. **[Am. 4]**

(7) In recent years, the European Union has adopted several crisis mechanisms to improve its resilience to crises or emergencies affecting the Union. The recent mechanisms include the Single Market Emergency Instrument (SMEI) established under Regulation (EU) No XXX/XX [COM(2022) 459] and Regulation (EU) No 2022/2371 under which the Commission may recognise a public health emergency at Union level. In the event of a public health emergency at Union level a framework of measures for ensuring the supply 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 crisis mode and aim at providing the means to address Union emergencies. By allowing the Commission to grant a compulsory licence when a crisis or emergency mode has been activated by a Union legal act, the necessary synergy between the existing crisis mechanisms and a Union wide compulsory licencing scheme is achieved. In such a case, the determination of the existence of a crisis or emergency depends solely on the Union legal act underlying the crisis mechanism and the crisis definition included therein. For the sake of legal certainty, the crisis mechanisms that qualify as Union emergency or extreme urgency measures and that can trigger a Union compulsory licence should be listed in an Annex to this Regulation.

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

(10) Utility model systems protect new technical inventions that do not fulfil the patentability requirements through the granting of an exclusive right to prevent others, for a limited period of time, from commercially exploiting the protected inventions without consent of the right holders. The definition of utility models varies 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. This would allow a compulsory licence on a patent to produce its effect should the crisis-relevant products no longer be protected by a patent while being protected through a supplementary protection certificate after the expiration of the patent. It should also apply to a supplementary protection certificate in isolation where the licence is granted after the expiry of the patent.

(12) The Union compulsory licence should also apply to published patent applications for national patents and for European patents. As the grant of a patent after the publishing of the patent application can take years, targeting only inventions protected by a granted patent could prevent an effective and timely crisis response. In crises, solutions can derive from the latest state-of-the-art technology. Moreover, certain national patent legislations, as well as the European Patent Convention, provide for protection of patent applicants with regard to unconsented use of their inventions and the corresponding possibility for such applicants to licence the use of their patent application rights. In order to ensure that a Union compulsory licence on a published patent application continues to keep its effects once the patent is granted, the Union compulsory licence for published patent applications should extend to the patent once granted to the extent that the crisis-relevant product still falls within the scope of the patent claims.

(13) It should be clarified that this Regulation is without prejudice to Union law on copyright and related rights, including Directives 96/9[4], 2009/24[5] Directives 2001/29/EC[6], 2004/48/EC[7] and (EU) 2019/790[8] of the European Parliament and of the Council, which establish specific rules and procedures that should remain unaffected.

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4 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)

5 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)

6 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).

7 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).

8 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).

(14) When a compulsory licence has been granted, regulatory data protection may, if still in force, prevent the effective use of the compulsory licence as it impedes the authorisation of generic medicinal products. This would result in serious negative consequences for Union compulsory licences granted to tackle a crisis, as this could hamper access to the medicinal 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 their requirements pertaining to the public interest*** and with other Union legislation, the definition of a ‘crisis-relevant product’ should be based on the definition adopted in the Single Market Emergency Instrument (SMEI) but should be more general in order to cover products related to different kinds of crises or emergencies. **[Am. 5]**

(16) A Union compulsory licence authorises the use of a protected invention without the consent of the rights-holder. Therefore, it must only be granted exceptionally ***with the purpose of safeguarding the public interest, as a last resort mechanism,*** and under conditions that take into account the interests of the rights-holder. This includes a clear determination of the scope, duration and territorial coverage of the licence ***which are strictly in line with the duration of the crisis and the purpose for which the compulsory licence was granted***. In the context of a Union level crisis mechanism, the crisis mode or emergency mode is activated or declared for a limited period of time. Where a Union compulsory licence is granted within such framework, the duration of the licence shall not extend beyond the duration of the activated or declared crisis or emergency mode ***and in principle should not exceed 12 months, unless a renewal is necessary due to the continued existence of the circumstances that had led to the granting of the licence***. In order to ensure that the compulsory licence fulfils its objective as well as its conditions, the use of the invention should only be authorised to a qualified person able to manufacture the crisis-relevant product and to pay a reasonable remuneration to the rights-holder. **[Am. 6]**

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

(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. Union crisis mechanisms usually include the setting-up of an advisory body ensuring coordination of action of the Commission and relevant bodies and agencies, the Council and the Member States. In this respect, an advisory group is set up under SMEI. Regulation (EU) 2022/2371 provides for a Health Crisis Board and under Regulation (EU) No XXX/XX (Chips Act) [COM/2022) 46], the Commission relies on the Semiconductor Board. Those advisory bodies have the right composition, expertise, and procedures to address the crises and emergencies for which they have been set-up. When compulsory licensing is being discussed in the context of such crisis instrument, relying on the advisory body set-up for the specific instrument allows the Commission to be adequately advised and avoid duplication of advisory bodies, leading to incoherences between processes. The competent advisory bodies ~~shall~~***should*** be listed, together with the corresponding crisis mechanisms, in an Annex to this Regulation. ***The Commission should ensure that representatives of other crisis-relevant bodies at Union level participate in, and are invited as observers to, the relevant meetings of the advisory body in order to ensure consistency with the measures implemented through other Union mechanisms. It is important that the Commission invites as observers national representatives from all national authorities responsible for issuing compulsory licenses under their national patent laws.*** In case the Union crisis mechanism does not provide for an advisory body, the ~~Commission should set up an ad hoc~~ advisory body ~~for the granting~~***should be constituted on an ad-hoc basis by the***

Commission and should be composed of representatives of the ~~Union (the 'ad hoc advisory body')~~***institutions and bodies of the Member States that exercise the competence to grant national compulsory licences under national laws***. **[Am. 7]**

(19) The role of the advisory body is to advise the Commission when discussions arise on the need to rely on compulsory licensing at Union level. It should provide the Commission with a non-binding opinion. Its main tasks include assisting of the Commission in the determination of the necessity to rely on compulsory licensing at Union level, and in the determination of the conditions for such licensing. When the advisory body is already set up, its existing rules of procedure should apply. As regards ad hoc advisory bodies, they should be composed of ~~one representative of each Member State~~***those representatives of national competent authorities*** in order to provide the Commission with information and input concerning the situation on the national level, including information on manufacturing capacities, potential licensees and~~,~~ ~~if applicable,~~ proposals for voluntary solutions. In addition, 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. **[Am. 8]**

(20) The Commission should grant the Union compulsory licence in the light of the non-binding opinion of the advisory body. Persons, in particular the licensee and the rights-holder, whose interests may be affected by the Union compulsory licence should be given the opportunity to submit their comments***, within a reasonable timeframe, to the advisory body upon receiving the case file and analyses presented to or conducted by the advisory body, and be provided with any other pertinent information they require for their evaluation of the potential repercussions of a proposed Union compulsory licence on their intellectual property rights***. These elements should enable the Commission to consider the individual merits of the situation and determine, on that basis, the adequate conditions of the licence, including an adequate remuneration to be paid by the licensee to the rights-holder. To avoid overproduction of products manufactured under a Union compulsory licence, the Commission should also consider any existing compulsory licences at national level. **[Am. 9]**

(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. **[Am. 10]**

(22) ~~When informed of advanced discussions as regards~~***Considering that voluntary agreements are the most suitable way to deal with patented products or processes in a time of crisis, prior to any decision by the Commission on*** the granting of a Union compulsory licence, the rights-holder should ~~have the possibility to propose a voluntary~~***be provided with a reasonable opportunity to negotiate such*** agreement~~,~~***. A time period of four weeks*** should ~~the circumstances of the Union crisis or emergency, including~~***be sufficient to enable good faith and meaningful negotiations, taking into account*** the urgency of the situation~~, allow it~~. The rights-holder should also be given the opportunity to comment on the need for a Union compulsory licence and on the conditions of the licence, including remuneration, should it be granted. To this end, the rights-holder should be allowed to provide the Commission with written or oral comments and any information the rights-holder considers useful to allow the Commission to make a fair, comprehensive, and thorough assessment of the situation. The Commission should allow the rights-holder a reasonable period of time to provide comments and information, considering the ***balance to be struck between the public interest and the*** situation of the rights-holder***, and considering*** ~~and~~ the urgency of the situation. The comments of the rights-holder should, where relevant, be transmitted by the Commission to the competent advisory body ***on a timely basis***. In order for confidential information to be shared with the Commission, the Commission shall ensure a safe environment for the sharing of this information and should take measures to preserve the confidentiality of the documents provided by the rights-holder in the context of that procedure. Once a Union compulsory licence has been granted, the Commission should notify the rights-holder as soon as reasonably practicable.

[Am. 11]

(23) The initiation of ~~the~~***any*** compulsory licensing procedure should ***first involve the identification of the intellectual property rights concerned, the rights-holders concerned, as well as potential licensees, with the involvement of the national authorities responsible for issuing compulsory licenses under their national patent laws. It should*** be publicised~~,~~ by means of a notice published in the *Official Journal of the European Union*. ~~This notice should include information on the discussions about the granting of a Union compulsory licence in the context of a Union crisis or 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.~~ **[Am. 12]**

(24) The Commission should, assisted by the advisory body, ~~make its best efforts to~~ identify in its decision the patent, patent application, supplementary protection certificate and utility model related to the crisis-relevant products, and the rights-holders of those intellectual property rights. In certain circumstances, the identification of intellectual property rights and of their respective rights-holders may require lengthy and complex investigations. ~~In such cases, a complete identification of all intellectual property rights and of their rights-holders may seriously undermine the efficient use of the Union compulsory licence to swiftly tackle the crisis or the emergency. Therefore, where the identification of all those intellectual property rights or rights-holders would significantly delay the granting of the Union compulsory licence,~~ The Commission should ~~be able to initially only indicate in the licence the non-proprietary name of the product for which it is sought. The Commission should nevertheless~~ identify all applicable and relevant intellectual property rights and their rights-holder ~~as soon as possible and amend the implementing act accordingly. The amended~~***before granting the compulsory licence. The*** implementing act should ~~also~~ identify any necessary safeguards and remuneration to be paid to each identified rights-holder.
[Am. 13]

(25) Where the rights-holder or not all the rights-holders could be identified in a reasonable period of time, the Commission should ~~exceptionally be entitled to~~***not*** grant the Union compulsory licence ~~by referring only to the non-proprietary name of the crisis-relevant product where it is absolutely necessary considering the urgency of the situation. Nevertheless, after the granting of the Union compulsory licence, the Commission should identify, notify and consult the concerned rights-holders as quickly as possible, including by relying on publication measures and on national Intellectual Property Offices.~~ **[Am. 14]**

(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; the commodity codes under which the crisis-relevant products are classified, as defined in Council Regulation (EEC) No 2658/87; details on the licensees (and, where applicable, the manufacturers) to whom the compulsory licence is granted, including their name, trade name or registered trade mark, their contact details, their unique identification number in the country where they are established and, where available, their Economic Operators Registration and Identification (EORI) number. Where required under Union legislation, other information should be included, such as a type, reference, model, batch or serial number, or unique identifier of a product passport.

(27) The licensee should pay an adequate remuneration to the rights-holder as determined by the Commission. The amount of the remuneration should be determined considering ***the total gross revenue generated by the licensee from the pertinent activities governed by the Union compulsory licence,*** the economic value of the exploitation authorised under the licence to the licensee and to the Member States concerned by the crisis, any public support received by the rights-holder to develop the invention, the degree to which development costs have been amortized as well as humanitarian circumstances relating to the granting of the Union compulsory licence. ~~In addition,~~ The Commission should ***also*** consider the comments made by the rights-holder and the assessment made by the advisory body with regard to the amount of the remuneration. ~~In any case, the remuneration should not exceed 4 % of the total gross revenue generated by the licensee through the acts under the Union compulsory licence. This percentage is the same as the one provided for under Regulation 816/2006. In the event of a compulsory licence granted on the basis of a published patent application that ultimately does not lead to the granting of a patent, the rights-holder would have no ground to receive remuneration under the compulsory licence, as the subject matter for the receipt of the remuneration has not materialised. In such circumstances, the rights-holder should refund the remuneration it received under the compulsory licence.~~ **[Am. 15]**

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

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9 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).

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

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10 Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015 laying down detailed rules for implementing certain provisions of Regulation (EU) No 952/2013 of the European Parliament and of the Council laying down the Union Customs Code (OJ L 343, 29.12.2015, p. 558).

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

(32) The relation between the rights-holder and the licensee should be governed by the principle of good faith. The rights-holder and licensee should work towards the success of the Union compulsory licence and collaborate, where necessary, to ensure that the Union compulsory licence effectively and efficiently fulfils its objective. The Commission may act as an enabler in achieving the good-faith cooperation between the rights-holder and the licensee, taking into account interests of all parties. In that respect, the Commission should also be entitled to take additional measures in line with Union law to ensure that the compulsory licence meets its objective and ensure that necessary crisis-relevant goods can be made available in the Union. Such additional measures 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.

(32a) Where appropriate, the Commission should oblige the rights-holder to disclose the trade secrets which are strictly necessary in order to achieve the purpose of the Union compulsory licence. In such cases, rights-holders should receive an adequate remuneration. It is possible that a detailed description of how to carry out the invention might not be sufficient and complete enough to enable the licensee to efficiently use that invention. This could encompass, without being exhaustively limited to, the comprehensive transfer of necessary technology, expertise, data, samples, and reference products essential for production and obtaining market authorisation in collaboration with the licensee, taking into account both the rights-holder and the licensee's interests. In cases where that additional information and know-how is necessary, some of which is an undisclosed trade secret, the disclosure of that necessary trade secret, with a view to only achieving the purpose of exercising the Union compulsory licence pursuant to this Regulation, should be considered to be lawful within the meaning of Article 3(2) and Article 5 of Directive (EU) 2016/943 of the European Parliament and the Council. While this Regulation requires the disclosure of trade secrets only when they are strictly necessary in order to achieve the purpose of the Union compulsory licence, it should be interpreted in such a manner as to preserve the protection afforded to trade secrets under Directive (EU) 2016/943. The Commission should require the licensee(s) to put in place all appropriate measures reasonably identified by the rights-holder, including contractual, technical and organisational measures, to ensure the confidentiality of trade secrets, in particular vis-à-vis third parties and the protection of the legitimate interests of all parties. To that end, right holders should identify trade secrets prior to the disclosure. Those appropriate measures may consist of

model contractual terms, confidentiality agreements, strict access protocols, technical standards and the application of codes of conduct. Where the licensee fails to implement the measures required for preserving the confidentiality of the trade secrets, the Commission should be able to withhold or suspend the disclosure of trade secrets until the situation is corrected by the licensee. Any use, acquisition or disclosure of trade secrets which would not be necessary to fulfil the objective of the Union compulsory licence or which would go beyond the duration of the Union compulsory licence should be considered to be unlawful within the meaning of that Directive. **[Am. 16]**

(32b) This Regulation should guarantee that the Commission has the authority to oblige rights-holders to provide all necessary information to facilitate the rapid and efficient production of critical crisis-related products, such as pharmaceuticals and other health-related items. This information should encompass details about know-how, particularly when it is essential for the effective implementation of compulsory licensing. While patent licensing alone might suffice to enable other manufacturers to quickly produce simple pharmaceuticals, in case of more intricate pharmaceutical products, such as vaccines during a pandemic, it is often insufficient. Where it is essential for the implementation of the compulsory licence, an alternative producer will also require access to know-how.
[Am. 17]

(33) In order to respond appropriately to the crisis situations, the Commission should be authorised to review the conditions of the Union compulsory licence and adapt them to changed circumstances. This should include the modification of the compulsory licence to indicate the complete list of rights and rights-holders covered by the compulsory licence~~, where this complete identification had not be done initially~~. This should also include the termination of the licence if the circumstances which led to it cease to exist and are unlikely to recur. When deciding on the revision of the Union compulsory licence, the Commission ~~may decide to~~***should*** consult the competent advisory body for that purpose***, as well as the rights-holders and licensees***. If the Commission intends to change essential components of the Union compulsory licence, such as its duration or remuneration or if the change itself could be the subject of a separate compulsory licence, it should be required to consult the advisory body.
[Am. 18]

(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 penalties should be effective, proportionate and dissuasive***, and should not contravene the usual enforcement measures of intellectual property rights as provided by Directive 2004/48/EC***. **[Am. 19]**

(35) Compliance with the relevant obligations imposed under this Regulation should be enforceable by means of fines and periodic penalty payments. To that end, appropriate levels of fines and periodic penalty payments should be laid down and the imposition of fines and periodic penalty payments should be subject to appropriate limitation periods in accordance with the principles of proportionality and ne bis in idem. All decisions taken by the Commission under this Regulation are subject to review by the Court of Justice of the European Union in accordance with the TFEU. The Court of Justice of the European Union should have unlimited jurisdiction in respect of ***the implementing act granting the compulsory licence, as well as the decisions on*** fines and penalty payments in accordance with Article 261 TFEU. **[Am. 20]**

(36) When a national compulsory licence has been granted for the purpose of addressing a crisis, the Member State or its competent authority should be required to notify the Commission of the granting of the licence, and of the specific conditions attached to it, since it allows the Commission to get an overview of national compulsory licences in the Member States and to take those compulsory licences into account when considering a Union compulsory licence, and in particular when setting the conditions for such licence.

(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[11]. 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 ***should be further facilitated by reviewing the conditions for issuing compulsory licences for export, in order to make them fully in line with the TRIPS Agreement and its full spectrum of flexibilities. The Union compulsory licence*** will facilitate ***the use of this mechanism and all the*** manufacturing of the relevant products across several Member States and provide Union-level solution in order to avoid a situation where several compulsory licences for the same product in more than one Member States would be required for licensees to manufacture and export the products as

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11 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).

planned. Any person considering to apply for a compulsory licence ~~under~~, for the purposes and within the scope of Regulation (EC) No 816/2006 should have the possibility to request, with a single application, a compulsory licence under that Regulation that is valid throughout the Union, if that person, when relying on national compulsory licencing schemes of the Member States, would otherwise need to apply for multiple compulsory licences for the same crisis-relevant product in more than one Member State in order to realise its intended activities of manufacture and sale for export under Regulation (EC) No 816/2006. Therefore, Regulation (EC) No 816/2006 should be amended accordingly. **[Am. 21]**

(38) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the granting, complementing, modification or termination of a Union compulsory license, the determination***, in the absence of an agreement between the rights-holder and the licensee,*** of the remuneration to be paid to the rights-holder, the procedural rules for the ad hoc advisory body and the characteristics allowing the identification of products produced under a Union compulsory licence. Those powers should be exercised in accordance with Regulation(EU) No 182/2011 of the European Parliament and of the Council[12]. The advisory procedure should be used for the adoption of implementing acts granting, complementing, modifying or terminating a Union compulsory licence, and implementing acts determining the remuneration. The choice of the advisory procedure is justified given that those implementing acts would be adopted in the context of a procedure with considerable participation of the Member States through the consultation of the advisory body. The examination procedure should be used for the adoption of implementing acts establishing procedural rules for the ad hoc advisory body and implementing acts establishing the characteristics allowing the identification of products produced under a Union compulsory licence. **[Am. 22]**

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

(39) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the granting, modification or termination of a Union compulsory licence or the determination of the remuneration, imperative grounds of urgency so require.

(40) Union compulsory licensing for crisis management is a ***last resort*** tool that is ~~only~~ used in exceptional circumstances. The evaluation should therefore be conducted only where a Union compulsory licence has been granted by the Commission. The evaluation report should be submitted by the last day of the third year following the granting of the Union compulsory licence, to allow an adequate and substantiated assessment of this Regulation.
[Am. 23]

(40a) While the Annex is to be updated by any future legislative act in relation to an emergency or crisis mode, the Commission should nevertheless monitor the situation and assess whether the list in the Annex has been properly updated. If it appears that this list is no longer up-to-date, the Commission should assess its consequences. In any event, the Commission should submit its assessment to the European Parliament and the Council accompanied, where appropriate, by legislative proposals to amend the Annex. Although the Commission should carry out this assessment every two years from the date of entry into force of this Regulation, it is expected that, given the rapid changes in current European and global situation, the Commission should carry out that assessment without undue delay in the event of exceptional threats to public safety or to national security. **[Am. 24]**

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

(41a) Since the objective of this Regulation, namely to ensure access to crisis-relevant patented products needed to address crises in the internal market, cannot be sufficiently achieved by the Member States because of the fragmentation of compulsory licensing in the Union and the insufficient territorial scope of national compulsory licensing but can rather, by reason of the scale and effects of the necessary solution, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives. **[Am. 25]**

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation has the objective to ensure that ***a temporary and non-exclusive Union compulsory licence may be granted to protect the public interest in the context of cross-border crisis or emergency situations in*** ~~in crises~~ the Union ~~has access to crisis-relevant products~~. ~~To this end,~~ This Regulation lays down rules on the procedure and conditions for the granting ***as a last resort*** of a Union compulsory licence of intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States in the context of a Union crisis or emergency mechanism. ***To this end, if no prior voluntary agreement has been reached within four weeks between right holder and licensee, the Commission may grant a Union compulsory licence.*** **[Am. 26]**

Article 2

Scope

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

   (a) patents, including published patent applications;

   (b) utility models; 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.

Article 3

Definitions

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

(-a) ***‘crisis mode or emergency mode’ means a crisis mode or an emergency mode, as applicable, listed in the Annex to this Regulation, which has been activated or declared in the context of a Union crisis or emergency mechanism listed in that Annex in accordance with one of the Union acts listed therein;*** **[Am. 27]**

(a) ‘crisis-relevant products’ means products or processes that are indispensable for responding to a crisis or emergency or for addressing the impacts of a crisis or emergency in the Union ***and for which the granting of a compulsory licence is the only means of ensuring the sufficient and timely availability and supply of such products or processes, as determined by the Commission through the guidance of the advisory body in accordance with Article 6***; **[Am. 28]**

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

(c) ‘rights-holder’ means a holder of any of the intellectual property rights referred to in Article 2(1);

(d) ‘protected invention’ means any invention protected by any of the intellectual property rights referred to in Article 2(1);

(e) ‘Union compulsory licence’ means a compulsory licence granted by the Commission to exploit a protected invention of crisis-relevant products for any of the relevant activities in the Union;

(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[13];

Article 4

Union compulsory licence

The Commission may grant a Union compulsory licence ~~where~~***in the event of*** a crisis mode or an emergency mode ~~listed~~ in ***case no voluntary agreement with a view to ensuring the supply of crisis-relevant products*** ~~the Annex to this Regulation~~ has been ~~activated or declared in accordance with one of the Union acts listed in that Annex~~***reached between right-holder and the potential licensee within four weeks***. **[Am. 29]**

[13] 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 5

General conditions of a Union compulsory licence

1. The Union compulsory licence ***that may be granted by the Commission in accordance with Article 4*** shall***, notwithstanding the obligations pursuant to Article 10:*** **[Am. 30]**

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

(b) have a ***strict limitation concerning*** scope***, field of use, necessary quantities, and a*** ~~and~~ duration that is ~~limited to the~~***fully in line with the specific*** purpose for which the compulsory licence is ~~granted and limited~~***issued, as well as strictly linked*** to the scope and duration of the crisis or emergency mode ~~in the framework of~~***under*** which it is granted ***within the Union***; **[Am. 31]**

(c) be strictly limited to the relevant ***and properly justified*** activities of crisis-relevant products in the Union; **[Am. 32]**

(d) only be granted against payment of an adequate remuneration to the rights-holder ***determined in accordance with Article 9***; **[Am. 33]**

(e) be ***strictly*** limited to the ***precisely defined*** territory of the Union; **[Am. 34]**

(f) only be granted to a person deemed to be in a position to exploit the protected invention in a manner that permits the proper carry out of the relevant activities of the crisis-relevant products and in accordance with the obligations referred to in Article 10.

(fa) clearly state that the licensee is responsible for any liability or warranties related to the production and distribution of crisis-relevant products, excluding the rights-holder from product liability claims. **[Am. 35]**

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.

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.

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***, which is to act in the public interest,*** shall assist and advise the Commission as regards the following tasks: **[Am. 36]**

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

(aa) the assessment of whether the obligation to give the rights-holder an opportunity to engage in negotiations for a voluntary agreement to be reached within four weeks, laid down in Article 4, has been complied with; **[Am. 37]**

(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;

(ba) the determination of crisis-relevant products; **[Am. 38]**

(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 ***stakeholders and*** economic operators, ~~and the~~***including*** industry***, academia and civil society***; **[Am. 39]**

(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.

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

(aa) shall invite representatives of the European Parliament as observers to the relevant meetings of the advisory bodies, where possible under the applicable legal acts referred to in Annex; **[Am. 40]**

(b) may invite representatives of the ~~European Parliament~~***national authorities responsible for issuing compulsory licences under national laws***, representatives of economic operators~~, right holders~~, potential licensees, stakeholder organisations, social partners and experts to attend meetings of the advisory body as observers. **[Am. 41]**

5. In the absence of any existing competent advisory body, the tasks referred to in paragraph 2 shall be performed by an ad hoc advisory body set up by the Commission (the 'ad hoc advisory body'). The Commission shall chair the ad hoc advisory body and ensure its secretariat. ~~Each Member State shall have the right to be represented in~~ The ad hoc advisory body ***shall be composed of representatives of the institutions and bodies of each Member State that exercise the competence to grant national compulsory licences under national law***. **[Am. 42]**

6. The Commission shall adopt an implementing act laying down the rules of procedure for the ad hoc advisory body referred to in paragraph 5. The rules of procedure shall specify that the ad hoc advisory body shall not be set up for a period exceeding the duration of the crisis or emergency. ***The rules of procedure shall specify that the ad hoc advisory body shall enforce stringent safeguards to avoid any potential conflicts of interest, and to ensure accountability and transparency.*** That implementing act shall be adopted in accordance with the examination procedure referred to in Article 24 (3). **[Am. 43]**

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;

(ba) the rights and interests of the rights-holder and the potential licensee; **[Am. 44]**

(bb) existing national compulsory licences reported to the Commission in accordance with Article 22 in order to avoid overlaps or a situation of overproduction; **[Am. 45]**

(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.

2a. The Commission shall take the utmost account of the opinion of the advisory body. Where the Commission does not follow the opinion of the advisory body, it shall explain the reasons for its decision to the advisory body, without prejudice to the Commission's powers under paragraphs 7 and 8 of this Article. **[Am. 46]**

3. Before ***issuing the opinion, the advisory body*** ~~the granting of a Union compulsory licence, the Commission~~ shall give the rights-holder and the licensee an opportunity to comment ***within a reasonable timeframe*** on ~~the following~~: **[Am. 47]**

(a) the possibility to ***promptly*** reach a voluntary licensing agreement with manufacturers on intellectual property rights for the purpose of manufacturing, using and distributing the crisis-relevant products ***and the fulfilment of the conditions referred to in Article 4(1a) for conducting meaningful negotiations for that purpose***; **[Am. 48]**

(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.

4. The Commission shall ***identify and*** notify the rights-holder and the licensee as soon as possible of the fact that a Union compulsory licence may be granted. ~~Wherever the identification of the rights-holders is possible and does not cause significant delay,~~ The Commission shall notify ~~them~~***the rights-holders*** individually. **[Am. 49]**

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.~~ **[Am. 50]**

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.

Article 8

Content of the Union compulsory licence

1. The Union compulsory licence shall specify the following:

(a) the patent, patent application, supplementary protection certificate or utility model for which the licence is granted ~~or, where the identification of those rights would significantly delay the granting of the licence, the non-proprietary name of the products which are to be manufactured under the licence~~; **[Am. 51]**

(b) the right-holder~~, provided they can be identified with reasonable efforts having regard to the circumstances, including the urgency of the situation~~; **[Am. 52]**

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

(1) name, trade name and registered trade mark;

(2) contact details;

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

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

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

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

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

(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.

(h) measures complementing the compulsory licence, ~~which are~~***as referred to in Article 13a, including, where strictly*** necessary to achieve the objective of the compulsory licence***, the obligation for the rights-holder to disclose trade secrets to the licensee when the conditions provided for in Article 13a (2) and (3) are fulfilled***. **[Am. 53]**

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).

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.

1a. The rights-holder shall receive the remuneration within a pre-established timeframe as agreed with the Commission. **[Am. 54]**

2. The remuneration shall ~~not exceed 4 % of~~***be determined based on the*** total gross revenue generated by the licensee ~~through the relevant~~***from the pertinent*** activities ~~under~~***governed by*** the Union compulsory licence. **[Am. 55]**

3. When determining the remuneration, the Commission shall 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.

(da) the possible disclosure of trade secrets pursuant to Article 13a(2) and (3) and the relevant limitations to the protection of trade secrets according to Directive (EU) 2016/943; that disclosure shall give rise to adequate compensation for the rights-holder. **[Am. 56]**

4. If the published patent application for which a compulsory licence has been granted does not subsequently lead to the granting of a patent, the rights-holder shall refund the remuneration paid under this article to the licensee.

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 license only under the following obligations:

(a) the number of crisis-relevant products manufactured under the Union compulsory licence does not exceed ***the defined quantities and*** what is necessary to meet the needs of the Union; **[Am. 57]**

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

(c) the products manufactured under the Union compulsory licence are clearly identified, through specific labelling or marking, as being manufactured and marketed pursuant to this Regulation.

(ca) a detailed account of the products produced under the Union compulsory license; **[Am. 58]**

(cb) treat the information acquired in relation to the Union compulsory licence with utmost confidentiality, refraining, in particular, from making trade secrets available to a third party without the consent of the Commission, which should inform and consult the rights-holder in this regard; **[Am. 59]**

(cc) implement all necessary measures to preserve the confidentiality of the rights-holder's trade secrets, as ordered by the Commission pursuant to Article 13a(3); **[Am. 60]**

(cd) do not use trade secrets disclosed pursuant to Article 13a(2) beyond the duration of the Union compulsory licence or for any other purpose than those considered as lawful uses under Article 13a(2); **[Am. 61]**

(d) the products manufactured under the Union compulsory licence can be distinguished from products manufactured and marketed by the rights-holder or under a voluntary licence granted by the rights-holder by way of special packaging, colouring or shaping, provided that such distinction is feasible and does not have a significant impact on the price of the products;

(e) the packaging of the products manufactured under the Union compulsory licence and any associated marking or leaflet indicate that the products are subject to a Union compulsory licence under this Regulation and specify clearly that the products are exclusively for distribution in the Union and are not to be exported.

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

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

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

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

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

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) ***immediately*** terminate the Union compulsory licence in accordance with Article 14(3); or **[Am. 62]**

(b) impose fines ~~or~~***and*** periodic penalties on the licensee in accordance with Articles 15 and 16. **[Am. 63]**

3. The European Anti-Fraud Office (OLAF) in cooperation with the relevant national authorities of the Member States may, at the request of the rights-holder or on its own initiative***, and on the basis of sufficient elements of proof of misuse***, request access to books and records kept by the licensee, for the purpose of checking whether the content and the conditions of the Union compulsory licence, and in general the provisions of this Regulation, have been complied with. **[Am. 64]**

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

Article 11

Prohibition of export

The export of products manufactured under a Union compulsory licence is prohibited.

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[14].

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

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

3. Where customs authorities identify a product that may fall under the prohibition laid down in Article 11, they shall suspend its export. Customs authorities shall immediately notify the Commission of the suspension and provide it with all relevant information to enable it to establish whether the product was manufactured under a Union compulsory license. To assess whether the suspended products correspond to the Union compulsory license, the Commission may consult the relevant rights-holder.

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

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

Article 13

Relations between rights-holder and licensee

1. The relations between the rights-holder and the licensee who has been granted a Union compulsory license shall act and cooperate with each other in good faith when performing rights and obligations under this Regulation.

2. In compliance with the good faith obligation, the rights-holder and the licensee shall make their best efforts to fulfil the objective of the Union compulsory licence, taking into account each other's interests ***as well as the public interest***. **[Am. 65]**

Article 13a

Additional measures complementing the Union compulsory licence

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

2. Where strictly necessary, the Commission shall request the disclosure of the rights-holder's trade secrets to the licensee to the extent required to provide him with the necessary know-how to achieve the objective for which the Union compulsory licence is granted under this Regulation. The lawful uses of the trade secrets by the licensee shall be strictly limited to the manufacturing of the crisis-relevant products in view of fulfilling the objective for which the Union compulsory licence has been granted.

3. Where the rights-holder is requested to disclose his trade secrets in accordance with paragraph 3, the Commission shall, prior to the disclosure of trade secrets, order the licensee to put in place all appropriate technical and organisational measures that the rights-holder reasonably identifies as necessary to preserve the confidentiality of trade secrets, in particular in relation to third parties, including, as appropriate, the use of model contractual terms, confidentiality agreements, strict access protocols, technical standards or the application of codes of conduct. If the licensee fails to implement the necessary measures required by the Commission, the Commission may withhold or, as the case may be, suspend the disclosure of trade secrets until the situation is corrected by the licensee.

4. Appropriate remuneration to the rights-holders in compensation for the disclosure of their trade secrets shall be granted in accordance with Directive (EU) 2016/943.

5. Where the Commission considers adopting additional measures as referred to in paragraphs 1 and 2, it shall consult the advisory body referred to in Article 6.

6. The implementing acts referred to in paragraphs 1 and 2 shall be adopted in accordance with the rules referred to in Article 7(6), points (a) and (b), and Article 7(7) and (8).
[Am. 66]

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 the complete list of rights and rights-holders covered by the compulsory licence.

~~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.~~ **[Am. 67]**

3. A Union compulsory licence may 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 where the licensee fails to comply with the obligations laid down in this Regulation.

4. When the Commission considers modifying~~, adopting additional measures as referred to in paragraph 2~~, or terminating the Union compulsory licence, it ~~may~~***shall*** consult the advisory body referred to in Article 6 ***as well as the rights-holders and licensees***. **[Am. 68]**

4a. When considering terminating the Union compulsory licence, the Commission shall ensure that a sufficient transitional period is put in place. **[Am. 69]**

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

6. The implementing acts referred to in paragraph 1~~, 2~~ and 3 shall be adopted in accordance with the rules referred to in Article 7(6) (a) and (b), 7(7) and 7(8). **[Am. 70]**

Article 15

Fines

1. The Commission may by decision impose on the licensee or the rights-holder fines not exceeding 6 % of their respective total turnover in the preceding business year where, intentionally or negligently:

   (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)~~***Article 13a(1) and (2)***, as specified in the relevant implementing act. **[Am. 71]**

(ca) the licensee does not comply with the prohibition referred in Article 11; **[Am. 72]**

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

Article 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 calculated from the date appointed by the decision, in order to compel:

(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)~~***Article 13a(1) and (2)***, as specified in the relevant implementing act. **[Am. 73]**

(ca) the licensee to put an end to an infringement of the prohibition referred in Article 11; **[Am. 74]**

2. Where the licensee or the rights-holder have satisfied the obligation which the periodic penalty payment was intended to enforce, the Commission may fix the definitive amount of the 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 shall begin to run on the day on which the infringement is committed. However, in the case of continuing or repeated infringements, time shall begin to run on the day on which the infringement ceases.

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.

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 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.

Article 19

Right to be heard and access to the file

1. Before adopting a decision pursuant to Article 15 or 16, the Commission shall give the licensee or the rights-holder the opportunity of being heard ***and fully involved in the procedure*** on the alleged infringement which is to be made subject to a fine or periodic penalty payments. **[Am. 75]**

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.

2a. The Commission shall reply to the observations made by the licensee or the rights-holder and in case of a rejection of the observations, it shall provide a justification within a reasonable period of time which shall not exceed 7 days. **[Am. 76]**

3. The Commission shall base its decisions 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 ***fully in line with existing legislation on the protection of data and trade secrets***. The Commission shall have the power to adopt decisions setting out such terms of disclosure**,** in case of disagreement between the parties. The right of access to the file of the Commission shall not extend to confidential information and internal documents of the Commission, other competent authorities or other public authorities of the Member States. In particular, the right of access shall not extend to correspondence between the Commission and those authorities. Nothing in this paragraph shall prevent the Commission from disclosing and using information necessary to prove an infringement. **[Am. 77]**

5. If the Commission considers it necessary, it may also hear other natural or legal persons. Applications to be heard on the part of such persons shall, where they show a sufficient interest, be granted.

Article 20

Publication of decisions

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

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.

Article 21

Review by the Court of Justice of the European Union

In accordance with Article 261 ***and 263*** TFEU, the Court of Justice of the European Union has unlimited jurisdiction to review decisions by which the Commission ~~has imposed fines or periodic penalty payments. It may cancel, reduce or increase the fine or periodic penalty payment imposed.~~***:***

[Am. 78]

(1) has granted a compulsory licence. It may cancel or amend its terms and conditions; **[Am. 79]**

(2) has imposed fines or periodic penalty payments. It may cancel, reduce or increase the fine or periodic penalty payment imposed. **[Am. 80]**

Article 22

Reporting on national compulsory licences

When a national compulsory licence has been granted ***for the public interest or*** for the purpose of addressing a national crisis or emergency, the Member State shall notify the Commission of the granting of the licence and of the specific conditions attached to ~~it. The~~***it.The*** information provided shall include the following: **[Am. 81]**

(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.

Article 23

Amendments to Regulation (EC) No 816/2006

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

(-a) Article 6(2) is replaced by the following:

"***(2) If the person applying for a compulsory licence is submitting multiple applications to authorities for the same product, he shall indicate that fact in each application, together with details of the quantities and importing countries concerned.***" **[Am. 82]**

(-aa) Point (c) of Article 6(3) is replaced by the following:

"***(c) the expected amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence;***" **[Am. 83]**

(-ab) Point (e) of Article 6(3) is replaced by the following:

"(e) where applicable, evidence of efforts of prior negotiation with the rights-holder pursuant to Article 9;" **[Am. 84]**

(-ac) Point (f) of Article 6(3) is replaced by the following:

"(f) evidence of a specific request from:

(i) authorised representatives of the importing country or countries; or

(ii) a non-governmental organisation acting with the formal authorisation of one or more importing countries; or

(iii) UN bodies or other international health organisations acting with the formal authorisation of one or more importing countries, indicating the expected quantity of product required." **[Am. 85]**

(-ad) Article 7 is replaced by the following:

*"**Article 7***

Rights of the rights-holder

***The competent authority shall notify the rights-holder without delay of the application for a compulsory licence. Before the grant of the compulsory licence, the competent authority may give the rights-holder an opportunity to comment on the application and to provide the competent authority with any relevant information regarding the application.*" [Am. 86]**

(-ae) Article 9(1) is replaced by the following:

*"**1. The applicant shall provide evidence to the competent authority that he has made efforts to obtain authorisation from the rights-holder and that such efforts have not been successful within a period of thirty days before submitting the application.*" [Am. 87]**

(-af) Article 10(1) is replaced by the following:

*"**1. The licence granted shall be non-assignable, except with that part of the enterprise or organisation that makes use of the licence, and non-exclusive. It shall contain the specific conditions set out in paragraphs 2 to 9 to be fulfilled by the licensee.*" [Am. 88]**

(-ag) Article 10(2) is replaced by the following:

"2. The expected amount of product(s) manufactured under the licence shall not exceed what is necessary to meet the needs of the importing country or countries cited in the application, taking into account the amount of product(s) manufactured under other compulsory licences granted elsewhere." **[Am. 89]**

(-ah) Article 10(8) is replaced by the following:

"8. The competent authority may, on its own initiative, if national law allows the competent authority to act on its own initiative, request from the licensee proof of exportation of the product, through a declaration of exportation, certified by the customs authority concerned, and proof of importation from one of the bodies referred to in Article 6(3)(f)." **[Am. 90]**

(a) The following Article 18a is inserted:

“Article 18a

Union compulsory licence

1. The Commission may ***also*** grant a compulsory licence ~~where the activities of~~***of patents relating to the*** manufacture ~~and sale~~***of pharmaceutical products*** for export ~~spread across different Member States and would therefore require compulsory licences for the same product in more than one Member State~~***to countries with public health problems***. **[Am. 91]**

2. Any person may submit an application for a compulsory licence under paragraph 1. The application shall ~~fulfil the requirements laid down in Article 6 (3) and shall specify the Member States to be covered by the compulsory licence.~~***contain the following information:***

(a) the name and contact details of the applicant and of any agent or representative whom the applicant has appointed to act for him before the competent authority;

(b) the non-proprietary name of the pharmaceutical product or products which the applicant intends to manufacture and sell for export under the compulsory licence;

(c) the expected amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence;

(d) the importing country or countries;

(e) where applicable, evidence of efforts of prior negotiation with the rights-holder pursuant to Article 9;

(f) evidence of a specific request from

(i) authorised representatives of the importing country or countries; or

(ii) a non-governmental organisation acting with the formal authorisation of one or more importing countries; or

(iii) UN bodies or other international health organisations acting with the formal authorisation of one or more importing countries. **[Am. 92]**

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

(a) the licence granted shall be non-assignable, except with that part of the enterprise or organisation that makes use of the licence, and non-exclusive. It shall contain the specific conditions as set out in this paragraph;

(b) the expected amount of product(s) manufactured under the licence shall not exceed what is necessary to meet the needs of the importing country or countries cited in the application, taking into account the amount of product(s) manufactured under other compulsory licences granted elsewhere;

(c) the duration of the licence shall be indicated;

(d) the licence shall be strictly limited to all acts necessary for the purpose of manufacturing the product in question for export and distribution in the country or countries cited in the application. No product made or imported under the compulsory licence shall be offered for sale or put on the market in any country other than that cited in the application, except where an importing country avails itself of the possibilities under subparagraph 6(i) of the Decision to export to fellow members of a regional trade agreement that share the health problem in question;

(e) products made under the licence shall be clearly identified, through specific labelling or marking, as being produced pursuant to this Regulation. The products shall be distinguished from those made by the rights-holder through special packaging or special colouring or shaping, provided that such distinction is feasible and does not have a significant impact on the price. The packaging and any associated literature shall bear an indication that the product is subject to a compulsory licence under this Regulation, giving the name of the competent authority and any identifying reference number, and specifying clearly that the product is exclusively for export to and distribution in the importing country or countries concerned. Details of the product characteristics shall be made available to the customs authorities of the Member States;

(f) before shipment to the importing country or countries cited in the application, the licensee shall post on a website the following information;

(i) the quantities being supplied under the licence and the importing countries to which they are supplied,

(ii) the distinguishing features of the product or products concerned. The website address shall be communicated to the competent authority;

(g) if the product(s) covered by the compulsory licence are patented in the importing countries cited in the application, the product(s) shall only be exported if those countries have issued a compulsory licence for the import, sale or distribution of the products;

(h) the competent authority may, on its own initiative, if national law allows the competent authority to act on its own initiative, request from the licensee proof of exportation of the product in the form of a declaration of exportation certified by the customs authority concerned, and proof of importation from one of the bodies referred to in Article 18a(2), point (e);

(i) the licensee shall be responsible for the payment of adequate remuneration to the rights-holder as determined by the competent authority as follows:

(i) in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use, the remuneration shall be a maximum of 4 % of the total price to be paid by the importing country or on its behalf,

(ii) in all other cases, the remuneration shall be determined taking into account the economic value of the use authorised under the licence to the importing country or countries concerned, as well as humanitarian or non-commercial circumstances relating to the issue of the licence;

(j) the licence conditions are without prejudice to the method of distribution in the importing country. Distribution may be carried out for example by any of the bodies listed in Article 18a (2), point (f), and on commercial or non-commercial terms including completely without charge. **[Am. 93]**

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.

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

   (a) grant a compulsory licence;

   (b) reject the application for a compulsory licence;

   (c) amend or terminate the compulsory licence.

Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 18b (2). On duly justified imperative grounds of urgency relating to ~~the impacts of the~~ public health problems, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 18b (3).” **[Am. 94]**

(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 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 thereof, shall apply.”

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 thereof, shall apply.

Article 25
Evaluation

The Commission shall, by the last day of the third year following the granting of the Union compulsory licence in accordance with Article 7, present an evaluation report to the Council, the European Parliament and the European Economic and Social Committee on the application of this Regulation.

By … [two years after the date of entry into force of this Regulation] and every two years thereafter, the Commission shall assess whether the list in the Annex is up-to-date in light of the adoption of future legislative acts in relation to an emergency or crisis mode. If the list of the Annex is no longer up-to-date, the Commission shall assess its consequences. The Commission shall submit its assessment to the European Parliament and the Council, accompanied, where appropriate, by legislative proposals to amend the Annex. **[Am. 95]**

In case of exceptional threats to public safety or to national security, the Commission shall carry out the assessment pursuant to paragraph 1a without undue delay. **[Am. 96]**

Article 26

Entry into force ***and application*** **[Am. 97]**

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.

It shall apply from [the first day of the month following the period of twelve months after the date of entry into force]. **[Am. 98]**

Done at …,

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

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 [COM(2022) 459]	Single Market emergency mode activated by means of a Council implementing act [Article 14 of Regulation XXX/XX] [COM(2022) 459]	Advisory Group [Article 4 of Regulation XXX/XX] [COM(2022) 459]
2. Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU	Public health emergency at Union level formally recognized by means of a Commission implementing act [Article 23 of Regulation (EU) 2022/2371]	Health Security Committee [Article 4 of Regulation (EU) 2022/2371]
3. Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the	Emergency framework activated by the adoption of a Council Regulation [Article 3 of Regulation (EU)	The Health Crisis Board [Article 5 of Regulation (EU) 2022/2372]

Union crisis or emergency mechanism	Crisis mode or emergency mode	Competent Advisory Body
event of a public health emergency at Union level	2022/2372]	
4. Regulation XXX/XX establishing a framework of measures for strengthening Europe's semiconductor ecosystem [COM(2022) 46]	Crisis stage activated by a Commission implementing act [Article 18 of Regulation XXX/XXX] [COM(2022) 46]	European Semiconductor Board [Article 23 of Regulation XXX/XXX] [COM(2022) 46]
5. Regulation (EU) 2017/1938 of the European Parliament and of the Council of 25 October 2017 concerning measures to safeguard the security of gas supply and repealing Regulation (EU) No 994/2010	Union emergency declared by the Commission [Article 12 of Regulation (EU) 2017/1938]	Gas Coordination Group [Article 4 of Regulation (EU) 2017/1938]