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## LEGISLATIVE ACTS AND OTHER INSTRUMENTS

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Subject: Position of the Council at first reading with a view to the adoption of a  
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE  
COUNCIL on compulsory licensing for crisis management and amending  
Regulation (EC) No 816/2006

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**REGULATION (EU) 2025/...**  
**OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**of...**

**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<sup>1</sup>,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure<sup>2</sup>,

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<sup>1</sup> OJ C, C/2023/865, 8.12.2023, ELI: <http://data.europa.eu/eli/C/2023/865/oj>.

<sup>2</sup> Position of the European Parliament of 13 March 2024 (not yet published in the Official Journal) and position of the Council at first reading of ... (not yet published in the Official Journal). Position of the European Parliament of ... (not yet published in the Official Journal).

Whereas:

- (1) Crises require the carrying out of exceptional, swift, adequate and proportionate measures capable of providing means to address them or their impact. To do so, the use of patented products or processes could prove indispensable. Voluntary licensing agreements usually suffice to licence the patent rights on those products or processes and to allow their supply in the Union. Voluntary agreements are the most appropriate, quickest, and most efficient solution to allow the use of patented products and processes and to scale up production in crises. Nevertheless, it might not be possible to reach voluntary agreements or such agreements might involve inadequate conditions such as lengthy delivery times. A compulsory licence, which is an authorisation to use an invention protected by intellectual property rights without the consent of the right holder, can provide a solution of last resort, where voluntary agreements would not be achievable or where they would prove inadequate, to allow access to patented products or processes, in particular in respect of products necessary to tackle the impact of a crisis.

- (2) In the context of a Union crisis or emergency mode under a crisis or emergency mechanism provided for in a Union legal act listed in the Annex to this Regulation (a ‘Union crisis or emergency mechanism’), the Union should have the possibility to rely on compulsory licensing, in conformity with the framework of the Agreement on Trade-Related Aspects of Intellectual Property Rights<sup>3</sup> (the ‘TRIPS Agreement’). The declaration of a crisis or emergency mode addresses obstacles to free movement of goods, services, and persons in crises and the lack of adequate supply of crisis-relevant products and services. As a last resort, where adequate and swift access to crisis-relevant products and processes required to manufacture crisis-relevant products, which are covered by intellectual property rights, cannot be achieved through other means, including through the increase of own manufacturing capacities by the right holder or through voluntary cooperation, compulsory licensing can allow the use, in the public interest, of a protected invention for the manufacturing and supply of crisis-relevant products needed to address an ongoing crisis or emergency. It is therefore important, in the context of such crisis or emergency mechanisms, that the Union can rely on an efficient and effective compulsory licensing system at Union level, which is uniformly applicable within the Union. Such a system would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-relevant products subject to compulsory licensing in the internal market.

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<sup>3</sup> OJ L 336, 23.12.1994, p. 214.

- (3) The possibility of using compulsory licences in situations of national emergency or other circumstances of extreme urgency is explicitly provided for under the TRIPS Agreement. In that context, this Regulation should establish a system for granting a compulsory licence for crisis management at Union level (the ‘Union compulsory licence’). In accordance with the international obligations laid down in the TRIPS Agreement, as a condition for making use of compulsory licensing, efforts should have been made to obtain prior authorisation from the right holder on reasonable commercial terms and conditions, and such efforts should prove to have been unsuccessful within a reasonable period of time. However, that requirement could be waived in the case of a national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use. The process for granting a Union compulsory licence should be designed in such a way that it ensures the participation of the right holder throughout the procedure, with a view to enabling and encouraging the conclusion of voluntary agreements.
- (4) All Member States have implemented compulsory licensing frameworks for patents in their national laws. National laws usually allow compulsory licensing on the ground of public interest or in the event of a crisis or emergency. However, divergences exist between Member States as regards the grounds, conditions, and procedures under which a compulsory licence can be granted. Those divergences result in a fragmented, suboptimal, and uncoordinated system preventing the Union from effectively relying on compulsory licensing in cases where it is needed to address a cross-border crisis or emergency.

- (5) National compulsory licensing systems operate only 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. That limited territorial scope of the national compulsory licensing systems is accompanied by the fact that there is no exhaustion of the patent right regarding products manufactured under a compulsory licence. Consequently, those compulsory licensing systems do not provide an adequate solution for cross-border manufacturing processes, and therefore there is no functioning internal market for products manufactured under such compulsory licences. Apart from the fact that the issuance of multiple national compulsory licences is a significant obstacle to cross-border supply within the internal market, it also entails the risk of contradictory and incoherent decisions among Member States. As a result, the current compulsory licensing framework appears inadequate to address the realities of the internal market and its inherent cross-border supply chains. That suboptimal compulsory licensing framework prevents the Union from relying on an additional instrument when facing a crisis or emergency, where means other than a Union compulsory licence, including voluntary agreements, could not be achieved within a reasonable timeframe and could not adequately and swiftly ensure access to crisis-relevant products or to processes required to manufacture those products, which are covered by intellectual property rights. The Union and its Member States are striving to improve their resilience with regard to crises. It is therefore necessary to provide for an optimal compulsory licensing system for crisis management that takes the full advantage of the internal market and allows Member States to support one another in crises.

- (6) Therefore, it is necessary to establish a compulsory licensing system for crisis management at Union level, in addition to the national compulsory licensing systems. Under the Union compulsory licensing system, the Commission, after considering the opinion of the competent advisory body as defined in this Regulation, should be empowered to grant, in the public interest and as an exceptional measure, a temporary and non-exclusive compulsory licence that is valid throughout the Union and that allows the use of a protected invention in order to supply products necessary to address a crisis or emergency in the Union.

- (7) In recent years, the Union has adopted several Union crisis or emergency mechanisms to improve its resilience with regard to crises or emergencies affecting the Union. The recent mechanisms include Regulation (EU) 2022/2371 of the European Parliament and of the Council<sup>4</sup>, under which the Commission can recognise a public health emergency at Union level, Council Regulation (EU) 2022/2372<sup>5</sup>, which, in the event of a public health emergency at Union level, provides a framework of measures for ensuring the supply of crisis-relevant medical countermeasures, and Regulation (EU) 2024/2747 of the European Parliament and of the Council<sup>6</sup> establishing a framework of measures related to an internal market emergency.

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<sup>4</sup> Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26, ELI: <http://data.europa.eu/eli/reg/2022/2371/oj>).

<sup>5</sup> Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (OJ L 314, 6.12.2022, p. 64, ELI: <http://data.europa.eu/eli/reg/2022/2372/oj>).

<sup>6</sup> Regulation (EU) 2024/2747 of the European Parliament and of the Council of 9 October 2024 establishing a framework of measures related to an internal market emergency and to the resilience of the internal market and amending Council Regulation (EC) No 2679/98 (Internal Market Emergency and Resilience Act) (OJ L, 2024/2747, 8.11.2024, ELI: <http://data.europa.eu/eli/reg/2024/2747/oj>).



- (8) Those Union crisis or emergency mechanisms provide for the declaration of a crisis or emergency mode and aim at providing the means to address Union crises or emergencies. By allowing the Commission to grant a Union compulsory licence when a crisis or emergency mode has been declared under a Union legal act, the necessary synergy between the relevant Union crisis or emergency mechanisms and a Union-wide compulsory licensing system can be achieved. In such a case, the determination of the existence of a crisis or emergency will depend solely on the underlying Union legal act and the relevant definition of ‘crisis’ or ‘emergency’ included therein. For the sake of legal certainty, the Union crisis or emergency mechanisms that provide for measures that qualify as emergency or extreme urgency measures at Union level and that can trigger a Union compulsory licence should be listed in the Annex to this Regulation.
- (9) To ensure optimal efficiency of the Union compulsory licence as a tool for addressing crises or emergencies, it should be available in respect of a patent or utility model or a supplementary protection certificate. It should also be available in respect of a published patent application or a published application for a utility model. The Union compulsory licence should apply to the same extent to national patents, European patents and European patents with unitary effect.

- (10) Utility model systems offer protection for technical inventions based on criteria that are, as a general rule, less stringent than those for patents. The owner of a utility model is granted an exclusive right to prevent third parties, for a limited period, from commercially exploiting the protected invention without the consent of the right holder. The concept of ‘utility model’ varies from one Member State to another, and not all Member States have a utility model system. In general, utility models are suitable 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 or emergency, and should therefore be included in the scope of the Union compulsory licence.
- (11) A Union compulsory licence concerning a patent should extend to the supplementary protection certificate where such certificate takes effect after the expiry of the patent, during the duration of that compulsory licence, and where the supplementary protection certificate covers the crisis-relevant product. The Union compulsory licence should specify, where relevant, that it extends to the supplementary protection certificate. That extension would allow a Union compulsory licence concerning a patent to produce its effects where the invention is no longer protected by a patent but is protected by a supplementary protection certificate after the expiry of the patent. It should also apply to a supplementary protection certificate on its own where a Union compulsory 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 well as to published applications for utility models. As the process for granting 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 legislation, as well as the European Patent Convention of 5 October 1973, provide for provisional protection of patent applicants with regard to unauthorised use of their inventions and the corresponding possibility for such applicants to license the use of their rights protected by a patent application. For similar reasons, it should be ensured that a Union compulsory licence also applies to published applications for utility models. This Regulation does not harmonise national legislation governing the provisional protection of published patent applications and published applications for utility models. In order to ensure that a Union compulsory licence concerning a published patent application or a published application for a utility model maintains its effects once the patent or utility model is granted, the Union compulsory licence concerning a published patent application or a published application for a utility model should also extend to the patent or utility model once it has been granted, to the extent that the crisis-relevant product still falls within the final scope of protection of those intellectual property rights.

- (13) It should be clarified that this Regulation is without prejudice to Union law on copyright and related rights, including Directives 96/9/EC<sup>7</sup>, 2001/29/EC<sup>8</sup>, 2004/48/EC<sup>9</sup>, 2009/24/EC<sup>10</sup> and (EU) 2019/790<sup>11</sup> of the European Parliament and of the Council, which establish specific rules and procedures that should remain unaffected. It should also be clarified that this Regulation is without prejudice to Directive (EU) 2016/943 of the European Parliament and the Council<sup>12</sup>. In addition, nothing in this Regulation should be interpreted as imposing any obligation to disclose undisclosed know-how, business information or technological information protected by trade secrets as defined by Directive (EU) 2016/943, or as precluding the voluntary conclusion of agreements on trade secrets.

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<sup>7</sup> 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, ELI: <http://data.europa.eu/eli/dir/1996/9/oj>).

<sup>8</sup> 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, ELI: <http://data.europa.eu/eli/dir/2001/29/oj>).

<sup>9</sup> 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, ELI: <http://data.europa.eu/eli/dir/2004/48/oj>).

<sup>10</sup> 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, ELI: <http://data.europa.eu/eli/dir/2009/24/oj>).

<sup>11</sup> 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, ELI: <http://data.europa.eu/eli/dir/2019/790/oj>).

<sup>12</sup> Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1, ELI: <http://data.europa.eu/eli/dir/2016/943/oj>).

- (14) The Union crisis or emergency mechanisms provide for dedicated measures aimed at ensuring the supply in the Union of products that are critical for tackling a crisis or emergency or their impact. Such measures include, for instance, priority-rated orders for crisis-relevant products, a joint procurement procedure, as well as the possibility for the Commission to act as a central purchasing body. Considering that the Union compulsory licensing system is intended to complement the relevant Union crisis or emergency mechanism, the supply and distribution of the crisis-relevant products manufactured or marketed under a Union compulsory licence should be carried out within the framework of the specific measures provided for in that Union crisis or emergency mechanism. Those measures should set out the details relating to the supply and distribution of crisis-relevant products. In addition, a Union compulsory licence should not permit the manufacturing or marketing of products that are excluded from the scope of the relevant Union crisis or emergency mechanism.

- (15) When a compulsory licence has been granted, regulatory data protection could prevent the effective use of the compulsory licence as it impedes the authorisation of generic medicinal products. That situation would have serious negative consequences for Union compulsory licences granted to tackle a crisis, as it could affect access to medicinal products needed to address the crisis or emergency. For that reason, it is important that the relevant Union law on pharmaceuticals provide for the suspension of data exclusivity and market protection, in particular where a compulsory licence has been granted to tackle a public health emergency. Such suspension should be allowed only in relation to the granted compulsory licence and its beneficiary and should be consistent with the objectives, the territorial scope, the duration, and the subject matter of that compulsory licence. That suspension means that the data exclusivity and market protection have no effect in relation to the licensee under the compulsory licence while that licence is valid. When the compulsory licence expires or is terminated, the data exclusivity and market protection should resume. That suspension should not result in an extension of the original duration of the regulatory data protection.
- (16) Matters relating to product liability in relation to crisis-relevant products manufactured or marketed under a Union compulsory licence should be governed by the relevant Union or national law, as applicable.

- (17) In order to ensure as much coherence as possible with regard to the existing crisis or emergency mechanisms, the definition of ‘crisis-relevant product’ laid down in this Regulation should be sufficiently general to cover products related to various types of crisis or emergency modes under the relevant Union crisis or emergency mechanism.
- (18) A Union compulsory licence should be granted only where specific conditions are fulfilled. In particular, given the fact that the Union compulsory licensing system complements the Union crisis or emergency mechanisms, a Union compulsory licence should be granted only where a crisis or emergency mode listed in the Annex to this Regulation has been declared. Secondly, a Union compulsory licence should be relied upon only in situations in which the use of a protected invention is required to supply crisis-relevant products in the Union. As a third condition, a Union compulsory licence should be granted only as a measure of last resort, in the sense that it should be granted only where means other than a Union compulsory licence, including voluntary agreements to use a protected invention concerning crisis-relevant products, could not be achieved within a reasonable timeframe and could not ensure access to those products. The Commission should, with the assistance and advice of the competent advisory body, evaluate and assess whether the second and third conditions have been fulfilled, in accordance with the procedure laid down in this Regulation. Finally, it is of utmost importance that the right holder be given the opportunity to submit comments during the procedure for granting a Union compulsory licence in order to safeguard the right holder’s rights, as well as to enable the competent advisory body to obtain all the necessary information.

- (19) A Union compulsory licence authorises the use of a protected invention without the consent of the right holder. Therefore, such a licence should be granted only exceptionally and under conditions that take into account the interests of the right holder. For that reason, the scope, duration and territorial coverage of the licence should be clearly determined. In the context of a Union crisis or emergency mechanism, the crisis or emergency mode is declared for a limited period of time. Where a Union compulsory licence is granted within such a framework, the duration of the licence should not extend beyond the duration of the declared crisis or emergency mode. In order to ensure that the Union compulsory licence fulfils its objective as well as the conditions for being granted, the use of the protected invention should be authorised only to a qualified person or entity that has the capacity to exploit the protected invention and consequently to manufacture or market the crisis-relevant product and to pay an adequate remuneration to the right holder. When selecting potential licensees, the Commission should also take into account criteria such as the price of the crisis-relevant products, the potential licensees' capacity to supply crisis-relevant products of the quality required in the relevant field and to supply them in sufficient quantities, in a timely manner and in accordance with all the industrial and sanitary requirements. To that end, the potential licensees should provide any information relevant for that purpose in the course of the procedure for granting a Union compulsory licence, as well as information about any changes to their capacity of supply that occur after the granting of the licence.



- (20) When considering the granting of a Union compulsory licence, the Commission should, in order to be able to take a well-informed decision, be assisted and advised by an advisory body. Discussions on whether there is a need for a Union compulsory licence might often already start in the context of the work of an advisory body involved pursuant to the relevant Union crisis or emergency mechanism. Those early discussions should provide the Commission with information on the lack of adequate supply of crisis-relevant products and available manufacturing capacities, as well as, whenever possible, initial information on the intellectual property rights and the right holders concerned. In the context of the early discussions within the competent advisory body, the Commission should also assess whether the specific measures taken pursuant to the relevant Union crisis or emergency mechanism are sufficient to address the lack of adequate supply of crisis-relevant products. If this is not the case and a Union compulsory licence seems, a priori, necessary, the competent advisory body should provide the Commission with a clearer idea of how products manufactured or marketed under the Union compulsory licence could be adequately delivered. The preliminary information gathered by the competent advisory body should help the Commission in determining whether to initiate the procedure for granting a Union compulsory licence, as well as in establishing the content of the notice to be published for that purpose.

- (21) The aim of an advisory body participating in the Union compulsory licensing process is to guarantee a comprehensive, thorough, and concrete assessment of the situation, taking into consideration the individual merits of each case. It is therefore important that the competent advisory body have the correct composition, expertise, and procedures to support the Commission when deciding on whether to grant a Union compulsory licence and on the content of that licence. Union crisis or emergency mechanisms usually include the setting-up of an advisory body ensuring coordination of action of the Commission and relevant Union bodies and agencies, the Council and the Member States. In that respect, Regulations (EU) 2022/2371 and (EU) 2022/2372 provide for a Health Security Committee and a Health Crisis Board respectively, while an Internal Market Emergency and Resilience Board is set up under Regulation (EU) 2024/2747. Those advisory bodies have the correct composition, expertise, and procedures to address the crises and emergencies for which they have been set up. Where compulsory licensing is being discussed in the context of a Union crisis or emergency mechanism, relying on the advisory body set up under the relevant mechanism allows the Commission to be adequately advised and avoids duplication of advisory bodies that would lead to inconsistencies between processes. However, considering its specific role, it should be ensured that the competent advisory body draws on additional expertise in intellectual property rights, in particular patents, and in the granting of compulsory licences.

The competent advisory bodies should be listed, together with the corresponding Union crisis or emergency mechanisms, in the Annex to this Regulation. Where the Union crisis or emergency mechanism does not provide for an advisory body, the Commission should set up an ad hoc advisory body for the granting of the Union compulsory licence (the ‘ad hoc advisory body’). The ad hoc advisory body set up by the Commission should be composed of one representative of each Member State and should include a representative of the European Parliament as an observer. The rules of procedure of that ad hoc advisory body should include provisions relating to the avoidance of potential conflicts of interest in order to ensure accountability and transparency.

- (22) The role of the competent advisory body is to assist and advise the Commission where discussions arise on the need to grant a Union compulsory licence and on its content. To that end, the competent advisory body should support the Commission in taking the necessary steps to identify the intellectual property rights and the right holders concerned. To allow for the widest dissemination of information on the initiation of the procedure for granting a Union compulsory licence, the competent advisory body should contact the national intellectual property offices and the relevant business and industry associations, as well as relevant international organisations. The competent advisory body should draw the attention of such entities to the notice published by the Commission on the initiation of the procedure for granting a Union compulsory licence, containing the relevant information, and should encourage the further dissemination of that notice by any appropriate means. Given that a Union compulsory licence should be granted only to a person or entity having the capacity, including the facilities, expertise and supply chains, to manufacture or market crisis-relevant products adequately and swiftly, the competent advisory body should assist the Commission in identifying potential licensees and establishing whether they meet that requirement. The right holders and potential licensees should have the opportunity to make their views known to the competent advisory body, which should analyse their written comments and invite them to participate in the relevant meetings. Those meetings should also serve as a forum to explore the possibility of reaching a voluntary agreement within a reasonable timeframe. The Commission and the competent advisory body should serve as facilitators in that respect.

It might also be useful to invite other actors to provide contributions, in particular economic operators in the sectors concerned, and other relevant entities, such as representatives of academia and of civil society, social partners, and representatives of international bodies such as the European Patent Office or the World Health Organization. Given the importance of expediency in managing a crisis or emergency, consultations and exchanges with the various actors should be carried out quickly and by the means most appropriate to the situation. In order to consider properly all relevant aspects of intellectual property law and, more specifically, compulsory licensing, it is necessary to fully involve in the relevant discussions within the competent advisory body the national intellectual property offices and other national authorities responsible for granting compulsory licences. Each Member State should designate the most suitable representatives to that end. Given its expertise, the advisory body set up under the relevant Union crisis or emergency mechanism is the most competent entity to gather and analyse the available crisis-related information from the Member States and from other relevant bodies at Union and international level. The analysis of that information should provide the Commission with a clearer view of the situation, its characteristics and the way in which it could evolve, in order to tailor the potential Union compulsory licence to current and future needs. As crises and emergencies rarely remain confined within borders, the competent advisory body should engage in cross-border collaboration and cooperation with other crisis-relevant bodies at Union, national and international level. Finally, the competent advisory body should assist the Commission in deciding whether to modify or terminate a granted Union compulsory licence for reasons set out in this Regulation.

- (23) A Union compulsory licence should be granted only in the context of a Union crisis or emergency mode. In such a context, the discussions within the advisory body set up under the relevant Union crisis or emergency mechanism could reveal that the lack of adequate supply of crisis-relevant products results from intellectual property rights or the exercise thereof. In such cases, the Commission should have the possibility to initiate the procedure for granting a Union compulsory licence. For reasons of expediency, the Commission should initiate the procedure by publishing a notice on its website. It should also publish that notice in the *Official Journal of the European Union* without undue delay.
- (24) The publication of the notice on the initiation of the procedure should serve to inform the public that discussions are ongoing as regards the possible granting of a Union compulsory licence. To that end, the notice should include information on the crisis-relevant products for which a lack of adequate supply is considered to exist, as well as on the relevant intellectual property rights and the right holders, where available. The competent advisory body should assist the Commission in gathering that information. The notice should also include an invitation to the right holders, potential licensees and other interested persons to submit their comments to the Commission and the competent advisory body, including on whether voluntary licensing agreements could be concluded within a reasonable timeframe. That notice should also include information on the competent advisory body and the contact details for submitting the comments. Those rules should ensure that the procedure is inclusive and that all relevant information reaches the competent advisory body.

- (25) After publishing the notice on the initiation of the procedure, the Commission should request the competent advisory body to disseminate it further through appropriate channels and to provide an opinion on the need for a Union compulsory licence and on its content. The Commission should set a time limit for the submission of the opinion. That time limit should be reasonable and appropriate in view of the circumstances of the case and of the urgency of the situation.
- (26) The work performed under this Regulation by the competent advisory body for the purposes of advising and assisting the Commission should result in an opinion, including an assessment of the need for a Union compulsory licence and its content. That opinion should not be binding. The assessment set out in the opinion of the competent advisory body should enable the Commission to consider the individual merits of the case and determine, on that basis, the conditions of the Union compulsory licence, including what would be adequate remuneration to be paid by the licensee to the right holder. That opinion should also include an annex containing explanations, arguments, factual elements and the results of the analysis conducted, which have been taken into account to carry out the assessment submitted in the opinion. The confidentiality of information is of paramount importance and should be preserved throughout the procedure, including when deciding whether and how information should be included in the opinion and the annex thereto.

- (27) After receiving the opinion of the competent advisory body, the Commission should assess whether to continue the procedure for granting a Union compulsory licence. Where the Commission, having taken into account the opinion of the competent advisory body, considers that continuing the procedure is justified, it should inform, as soon as reasonably practicable, any right holder whose interests could be affected by the Union compulsory licence, and the potential licensees. The Commission should inform the right holder and the potential licensees of the envisaged content of the Union compulsory licence and provide a summary of the opinion of the advisory body. In addition, the Commission should invite the right holder and the potential licensees to submit comments within a set time limit, including on whether voluntary licensing agreements have been concluded.



- (28) The right holder concerned should be able to submit comments throughout the procedure for granting a Union compulsory licence. The involvement of the right holder should be ensured at every relevant step of the procedure, from the start, with the publication of the notice, until the final stages of the procedure, including after the competent advisory body has issued its opinion. In addition, it should be possible to conclude voluntary licensing agreements at any time during the procedure or after the granting of a Union compulsory licence. Those elements should ensure that the right holder's rights and interests are protected and make it possible to explore ways of reaching voluntary solutions that would adequately and swiftly remedy the lack of adequate supply of crisis-relevant products in the Union. The right holder should be involved in the procedure in such a manner that the right holder can exercise the right to be heard before the granting of the Union compulsory licence and that a voluntary solution can be reached at any time throughout the procedure, thereby rendering the granting of a Union compulsory licence unnecessary. The Commission should also end the procedure without granting a Union compulsory licence where a Union compulsory licence appears no longer to be necessary. For the sake of transparency, a notice indicating the end of the procedure should be published in the *Official Journal of the European Union*.
- (29) The Commission should ensure that there is a secure environment for the sharing of confidential information and should take measures to preserve the confidentiality of the documents provided by the right holders and other relevant actors in the context of the procedure for granting a Union compulsory licence.

- (30) In the implementing act by which it grants a Union compulsory licence, the Commission should identify the patents and, where applicable, published patent applications, as well as utility models and, where applicable, published applications for utility models, and supplementary protection certificates related to the crisis-relevant products. The Commission should also identify the right holders of those intellectual property rights. It cannot be fully excluded that, despite the efforts undertaken by the Commission and the competent advisory body, further intellectual property rights covering the crisis-relevant product referred to in a Union compulsory licence by its non-proprietary name or Combined Nomenclature (CN) code are identified only after the licence has been granted and therefore are not listed therein. As the Union compulsory licence should ensure the adequate and swift supply of crisis-relevant products, in such a situation, the Commission should modify the Union compulsory licence by means of an implementing act, so as to update the list of intellectual property rights and right holders. To ensure a balance between the safeguarding of the public interest and the rights and interests of right holders, that modification should, where appropriate, have retroactive effect. That retroactive effect should not prevent the right holders from submitting comments on the possibility of reaching a voluntary licensing agreement with the licensees and on the amount of adequate remuneration. It should prevent situations such as recalls from the market or the destruction of crisis-relevant products due to an incomplete list of intellectual property rights and right holders, where such measures would threaten the supply of crisis-relevant products in the Union. The modified Union compulsory licence should also identify any necessary safeguards and adequate remuneration to be paid to each newly identified right holder. In accordance with Article 297 of the Treaty on the Functioning of the European Union (TFEU), the Commission should notify the addressees of the implementing act granting the Union compulsory licence, as well as of the implementing act modifying or terminating the Union compulsory licence.

- (31) The Union compulsory licence should include information enabling the crisis-relevant product in respect of which it is granted to be identified, including details about the description, name or brand of the crisis-relevant product, where appropriate, the non-proprietary name of the crisis-relevant product or the CN code under which the crisis-relevant product is classified, as set out in Annex I to Council Regulation (EEC) No 2658/87<sup>13</sup>, and details on the licensee and, where applicable, the manufacturer, to whom the Union compulsory licence is granted, including their name or trade name, their contact details, their unique identification number in the Member State or third country where they are established and, where available, their Economic Operators Registration and Identification (EORI) number. Where required under Union law, other information enabling the crisis-relevant product to be identified should be included, such as its type, reference, model, batch or serial number, or unique identifier of its product passport.

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<sup>13</sup> Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1, ELI: <http://data.europa.eu/eli/reg/1987/2658/oj>).

- (32) The licensee should pay adequate remuneration to the right holder . The amount of the adequate remuneration should be determined by the Commission having regard to the circumstances of each case, considering the economic value of the exploitation authorised under the Union compulsory licence. To assess that economic value, the Commission should take into account the expected total gross revenue generated by the licensee through the relevant activities under the Union compulsory licence, the hypothetical amount that a reasonable right holder would request and that a reasonable licensee would pay under a voluntary agreement, as well as any public support received by the right holder to develop the invention. The amount of the adequate remuneration should be determined also taking into account the extent to which research and development costs have been amortised by the right holder. That amount should ensure proper remuneration in cases where the development costs have not been appropriately amortised. Depending on the circumstances of the case and where relevant, the Commission should also be able to take into account humanitarian grounds relating to the granting of the Union compulsory licence. In addition, the Commission should consider the comments submitted by the right holder and the assessment made by the competent advisory body with regard to the amount of the adequate remuneration, taking into consideration general practices and any existing precedents in the relevant field. In the case of a Union compulsory licence granted with regard to a published patent application that ultimately does not lead to the granting of a patent, the grounds for the patent applicant to be remunerated in respect of the subject matter of the application will not have come into being. In such circumstances, the right holder should be required to refund the remuneration received under the Union compulsory licence. The same rule should apply *mutatis mutandis* in the case of published applications for utility models.

- (33) It is imperative that the crisis-relevant products manufactured or marketed under a Union compulsory licence are supplied only within the internal market. The Union compulsory licence should therefore impose upon the licensee clear conditions as regards the activities authorised under the licence, including the territorial scope of those activities. In accordance with Directive 2004/48/EC, the right holder should be able to challenge as infringements of its intellectual property rights actions of the licensee and uses of the intellectual property rights covered by the Union compulsory licence that do not comply with the conditions of the licence. In order to facilitate monitoring of the distribution of crisis-relevant products manufactured or marketed under a Union compulsory licence, including controls by customs authorities, the licensee under a Union compulsory licence should ensure that such products have special characteristics that make them easily identifiable and distinguishable from the products manufactured or marketed by the right holder or other licensees. In addition, the licensee under a Union compulsory licence should regularly record the quantities of crisis-relevant products manufactured or marketed under the Union compulsory licence. Those records should make it possible to establish the quantities of crisis-relevant products so manufactured or marketed during a given period.

- (34) The Commission should be able to consider, as a matter of its internal organisation, entrusting actions relating to cooperation on enforcement as provided for in this Regulation to the European Anti-Fraud Office (OLAF), which has relevant expertise in that regard. Such internal decisions should not affect the continued exercise of the powers conferred upon the Commission or OLAF by other Union legal acts, including Council Regulation (EC) No 515/97<sup>14</sup>.
- (35) A Union compulsory licence in the context of a Union crisis or emergency mechanism should be granted to supply only the internal market with crisis-relevant products. Therefore, without prejudice to Regulation (EC) No 816/2006 of the European Parliament and of the Council<sup>15</sup>, it should be prohibited to export products manufactured or marketed under a Union compulsory licence.

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<sup>14</sup> Council Regulation (EC) No 515/97 of 13 March 1997 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs and agricultural matters (OJ L 82, 22.3.1997, p. 1, ELI: <http://data.europa.eu/eli/reg/1997/515/oj>).

<sup>15</sup> 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, ELI: <http://data.europa.eu/eli/reg/2006/816/oj>).

- (36) Customs authorities should ensure, by applying a risk analysis approach, that crisis-relevant products manufactured or marketed under a Union compulsory licence are not exported. To identify such products, the main source of information for such customs risk-analysis should be the Union compulsory licence itself. Information on each implementing act granting or modifying a Union compulsory licence should thus be entered by the Commission into the electronic customs risk management system referred to in Commission Implementing Regulation (EU) 2015/2447<sup>16</sup>. When customs authorities identify a product that is suspected of not complying with the export prohibition, they should suspend the export of that product and notify the Commission immediately. The Commission should inform the right holder and, where appropriate, the licensee, accordingly. The Commission should reach a conclusion on the compliance with the export prohibition within 10 working days, but should have the possibility of requiring the customs authorities to maintain the suspension where necessary. To help it in its assessment, the Commission should be able to consult the relevant right 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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<sup>16</sup> 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, ELI: [http://data.europa.eu/eli/reg\\_impl/2015/2447/oj](http://data.europa.eu/eli/reg_impl/2015/2447/oj)).

- (37) Pursuant to TFEU, and in particular Article 263 thereof, the validity of implementing acts granting a Union compulsory licence and the adequate remuneration provided for therein, as well as the validity of any other implementing acts pertaining to the Union compulsory license, is subject to judicial review by the Court of Justice of the European Union (the ‘Court’).
- (38) During the procedure for granting a Union compulsory licence, and after such a licence has been granted, the right holder and the licensee should refrain from actions and omissions that could jeopardise the efficiency of the Union compulsory licensing process. Where applicable, the right holder and the licensee should also provide the Commission and the competent advisory body with information about the known intellectual property rights, including rights of third parties, covering the crisis-relevant products. Information to be provided in relation to the Union compulsory licence and the process for its granting should include, in particular, information on the changes to the status of the relevant intellectual property rights, any pending infringement or invalidity actions in relation to them, as well as the associated voluntary licensing agreements. On request from the right holder or the licensee, or on its own initiative, the Commission should have the possibility of arranging meetings or other exchanges between the right holder and the licensee on matters relevant for the fulfilment of the objective of the Union compulsory licence. The Commission should also have the possibility of sharing crisis-relevant information with the right holder and the licensee, including new information on available manufacturing capacities of crisis-relevant products in the Union. Information shared during such meetings or exchanges should be treated confidentially.



- (39) In order to respond appropriately to crisis or emergency situations, the Commission should be empowered to review the conditions of the Union compulsory licence and adapt them to new circumstances. Where necessary, the list of the rights and right holders covered by the Union compulsory licence should be updated, with retroactive effect where appropriate. Where a published patent application or a published application for a utility model is included in the content of the Union compulsory licence but such application does not result in a patent or a utility model or where the scope of protection of the patent or the utility model granted based on such application no longer covers the crisis-relevant product, the list of the rights and right holders should be updated accordingly, without retroactive effect. In addition, that list should be modified without retroactive effect in the case of a transfer or revocation of a right covered by the Union compulsory licence. If the circumstances which led to the Union compulsory licence being granted cease to exist and are unlikely to recur, the Union compulsory licence should be terminated. The Commission should notify the right holder and the licensee of the termination of the Union compulsory licence, as well as of its expiry in the event the relevant crisis or emergency mode has ended. The right holder and the licensee should be notified sufficiently in advance to enable the orderly completion of the activities relating to crisis-relevant products covered by a Union compulsory licence. However, such advance notification should not be required in certain cases, for instance where the licence is terminated due to non-compliance with a licensee's obligation laid down in this Regulation. When deciding on the modification of the Union compulsory licence, the Commission should consult the competent advisory body and duly consider the rights and interests of the right holder and the licensee.

- (40) In addition to the possibility of terminating the Union compulsory licence, the Commission should be authorised to impose fines and periodic penalty payments on the licensee in order to enforce the licensee's obligations laid down in this Regulation. It should be possible to apply fines and periodic penalty payments cumulatively. The aim of fines and periodic penalty payments is to safeguard the rights and interests of the right holder and to guarantee the efficient implementation of the Union compulsory licence. The fines and periodic penalty payments imposed should be effective and dissuasive. They should also be subject to the overarching principles of proportionality and *ne bis in idem*.
- (41) Appropriate levels of fines for non-compliance with the obligations laid down in this Regulation, and of periodic penalty payments to put an end to the non-compliance with such obligations should be set, taking into account any aggravating or mitigating factors. Limitation periods should apply for the imposition of fines and periodic penalty payments, as well as for their enforcement. In accordance with Article 297 TFEU, the Commission should notify the addressees of its decision on fines or periodic penalty payments. In accordance with Article 261 TFEU, the Court should have unlimited jurisdiction in respect of all Commission decisions imposing fines or periodic penalty payments.

- (42) Where a national compulsory licence has been granted for the purposes of addressing a crisis or emergency at national level, which in nature corresponds to a crisis or emergency falling within the scope of a Union crisis or emergency mechanism, the Member State concerned should inform the Commission of the granting of the licence, and of the conditions attached to it. That information would allow the Commission to form an overview of national compulsory licences granted by the Member States and to take them into account when considering the need to grant a Union compulsory licence, and in particular when setting the conditions attached to a Union compulsory licence. Considering that there are differences between the Member States in terms of the authorities responsible for granting compulsory licences at national level, it should remain for the Member States to establish appropriate procedures under their national laws to ensure that the relevant information is provided to the Commission without undue delay. To ensure efficient cooperation, Member States should inform the Commission of the national authority that is responsible for providing information on national compulsory licences granted for the purposes of addressing a crisis or emergency. The Commission should establish a list of those national authorities and publish it on its website.

- (43) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the granting, modification or termination of a Union compulsory license, establishing the rules of procedure of the ad hoc advisory body and establishing the characteristics enabling crisis-relevant products manufactured or marketed under a Union compulsory licence to be identified. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>17</sup>. The examination procedure should be used for the adoption of implementing acts granting, modifying or terminating a Union compulsory licence and establishing the rules of procedure of ad hoc advisory body, and for implementing acts establishing the characteristics enabling of crisis-relevant products manufactured or marketed under a Union compulsory licence to be identified. The choice of the examination procedure for the adoption of such implementing acts is justified by the fact that decisions on a Union compulsory licence have a potentially significant impact on the fundamental right to intellectual property.

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<sup>17</sup> 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, ELI: <http://data.europa.eu/eli/reg/2011/182/oj>).

- (44) The Commission should adopt immediately-applicable implementing acts where, in duly justified cases relating to the granting, modification or termination of a Union compulsory licence, imperative grounds of urgency so require. As regards the granting of a Union compulsory licence, those grounds should relate to the nature and the gravity of the crisis or emergency and to the well-substantiated finding that it is not possible to reach a voluntary agreement to ensure the adequate supply of the crisis-relevant products in the Union. That should include cases where the right holder expressly indicates that it cannot ensure such supply and is unwilling to negotiate voluntary agreements. The same rules should apply in the case of a modification of a Union compulsory licence for the purpose of adding further right holders. In the event of the termination of a Union compulsory licence, those grounds should relate to the well-substantiated finding that the licensee is unable to exploit the protected invention in a manner that permits the licensee to carry out relevant activities concerning the crisis-relevant products, inter alia, where the licensee expressly indicates that to be the case. When deciding whether to adopt immediately-applicable implementing acts, the Commission should take into account the preliminary information gathered by the competent advisory body and the preliminary exchanges within that body.

- (45) The possibility of granting a compulsory licence at Union level should not be available only with regard to the internal market. It should also be possible, under certain conditions, to grant a Union compulsory licence for the purposes of export to countries with public health problems, which is a matter already regulated by Regulation (EC) No 816/2006. Under Regulation (EC) No 816/2006, the granting of such compulsory licences is decided upon and carried out at national level by the competent authorities of the Member States acting on a corresponding application from a person that intends to manufacture and sell pharmaceutical products covered by a patent or a supplementary protection certificate for export to eligible third countries. Regulation (EC) No 816/2006 allows only compulsory licensing covering the manufacturing of products across several Member States through national procedures. In the context of a cross-border manufacturing process, national compulsory licences granted in more than one Member State would be needed. That could lead to a burdensome and lengthy process as it would require initiating a number of national procedures with potentially a different scope and different conditions. In order to achieve the same synergies and efficient process as provided for by this Regulation for the Union crisis or emergency mechanisms, a Union compulsory licence should also be available in the context of Regulation (EC) No 816/2006. That possibility would facilitate the manufacturing of the relevant product across several Member States, and provide a Union-level solution, thus avoiding a situation where compulsory licences in more than one Member State would be required in order for a licensee to be able to manufacture and sell for export the relevant product as planned.

Any person intending to apply for a compulsory licence under Regulation (EC) No 816/2006 should have the possibility of requesting, with a single application, a compulsory licence under that Regulation that is valid throughout the Union, where that person, if relying on the national compulsory licensing systems of the Member States, would need to apply for several compulsory licences for the same product in more than one Member State in order to carry out its intended activities of manufacture and sale for export. To that end, the applicant should specify the Member States in which the intended activities of manufacture and sale for export of the product to be covered by the Union compulsory licence are to be carried out. Regulation (EC) No 816/2006 should therefore be amended accordingly.

- (46) On 1 February 2020, the United Kingdom of Great Britain and Northern Ireland (the ‘United Kingdom’) withdrew from the Union. The Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community<sup>18</sup> (the ‘Withdrawal Agreement’) was concluded between the Union and the European Atomic Energy Community, of the one part, and the United Kingdom, of the other part.

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<sup>18</sup> OJ L 29, 31.1.2020, p. 7, ELI: [http://data.europa.eu/eli/treaty/withd\\_2020/sign](http://data.europa.eu/eli/treaty/withd_2020/sign).

It was approved by Council Decision (EU) 2020/135<sup>19</sup> on 30 January 2020, and entered into force on 1 February 2020. The Withdrawal Agreement provided for a transition period which ended on 31 December 2020. At the end of the transition period, Union law ceased to apply to the United Kingdom, whilst the Protocol on Ireland / Northern Ireland (the ‘Windsor Framework’), which forms an integral part of the Withdrawal Agreement, became applicable. In accordance with Article 5(4) of the Windsor Framework and point 7 of Annex 2 to the Windsor Framework, Regulation (EC) No 816/2006, as well as legal acts of the Union implementing, amending or replacing that legal act, apply to and in the United Kingdom in respect of Northern Ireland. Considering that the amendments to Regulation (EC) No 816/2006 would be applicable to and in the United Kingdom in respect of Northern Ireland in accordance with the Windsor Framework and that the competent authorities of the United Kingdom should continue to exercise their responsibility for issuing compulsory licenses in respect of Northern Ireland, it is appropriate to stipulate that the procedure for granting a Union compulsory licence, and a Union compulsory licence granted under that Regulation, should not apply to or in the United Kingdom in respect of Northern Ireland. However, the United Kingdom in respect of Northern Ireland should ensure that the products manufactured under such a licence are not reimported into the territory of the Union or Northern Ireland, in accordance with Article 13 of Regulation (EC) No 816/2006, and should take necessary actions to that end in accordance with Article 14 of that Regulation.

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<sup>19</sup> Council Decision (EU) 2020/135 of 30 January 2020 on the conclusion of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (OJ L 29, 31.1.2020, p. 1, ELI: <http://data.europa.eu/eli/dec/2020/135/oj>).



- (47) This Regulation provides for a tool of last resort that is to be used only in exceptional circumstances. The application of this Regulation should be evaluated by the Commission. However, such an evaluation should be carried out only if one or more Union compulsory licences have been granted by the Commission. The Commission should submit its evaluation report to the European Parliament, the Council and the European Economic and Social Committee by the last day of the third year following the granting of the first Union compulsory licence, to allow for an adequate and substantiated analysis.
- (48) In line with the Union's efforts to enhance its preparedness for and resilience against crises, the list of Union crisis or emergency mechanisms capable of triggering a Union compulsory licence should be kept up to date. To that end, the Commission should assess that list on a regular basis, in particular by taking into consideration new legislative acts or proposals, as well as the general objective of enhancing the Union's preparedness for and resilience against crises. The assessments should be carried out having particular regard to semiconductors for medical equipment. Where appropriate, the Commission should be able to propose amendments to the Annex, in order to adapt the list of Union crisis or emergency mechanisms. The Commission should report on its assessments to the European Parliament and to the Council, including on any legislative proposals for amending the Annex.

- (49) Since the objective of this Regulation, namely to facilitate access to crisis-relevant products needed to address crises or emergencies in the Union, cannot be sufficiently achieved by the Member States because of the fragmented nature of the existing compulsory licensing framework in the Union and the limited territorial scope of national compulsory licenses, 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 that objective,

HAVE ADOPTED THIS REGULATION:

## *Article 1*

### *Objective and subject matter*

This Regulation has the objective of ensuring that a Union compulsory licence may be granted in the context of a crisis or emergency affecting the Union. To that end, this Regulation lays down rules on the conditions and the procedure for granting a Union compulsory licence for intellectual property rights that are necessary for the supply of crisis-relevant products to the Member States in the context of a crisis or emergency mode which has been declared pursuant to a crisis or emergency mechanism provided for in a Union legal act listed in the Annex (a ‘Union crisis or emergency mechanism’). This Regulation provides that a Union compulsory licence is granted in the public interest and as a measure of last resort where other means, including voluntary agreements to use a protected invention that concerns crisis-relevant products, could not ensure access to those products.

## *Article 2*

### *Scope*

1. This Regulation establishes Union compulsory licensing of the following intellectual property rights in force in one or more Member States:
  - (a) patents and published patent applications;
  - (b) utility models and published applications for 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 Directives 2001/29/EC and 2009/24/EC. This Regulation is also without prejudice to the *sui generis* rights granted by Directive 96/9/EC and to Directive (EU) 2016/943.
3. This Regulation does not impose any obligation to disclose trade secrets.
4. This Regulation does not apply to defence-related products as defined in Article 3, point 1, of Directive 2009/43/EC of the European Parliament and of the Council<sup>20</sup>, or as defined by national law of Member States, in compliance with Union law.
5. The Union compulsory licence shall be granted in accordance with the conditions and the procedure established in this Regulation. The Union compulsory licence shall be granted only for the purpose of carrying out the specific measures related to crisis-relevant products provided for in the relevant Union crisis or emergency mechanism and in the context of a declared crisis or emergency mode.

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<sup>20</sup> Directive 2009/43/EC of the European Parliament and of the Council of 6 May 2009 simplifying terms and conditions of transfers of defence-related products within the Community (OJ L 146, 10.6.2009, p. 1, ELI: <http://data.europa.eu/eli/dir/2009/43/oj>).

*Article 3*  
*Definitions*

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

- (1) ‘Union compulsory licence’ means a compulsory licence granted by the Commission to exploit a protected invention in order to carry out in the Union relevant activities concerning crisis-relevant products or processes required to manufacture those products;
- (2) ‘crisis or emergency mode’ means a crisis or emergency mode listed in the Annex, which has been declared pursuant to a Union crisis or emergency mechanism;
- (3) ‘crisis-relevant product’ means a product that is indispensable for responding to a crisis or emergency in the Union, or for addressing the impact of a crisis or emergency in the Union;
- (4) ‘relevant activities’ means the act of manufacturing, namely making, or the act of marketing, namely using, offering for sale, selling or importing;
- (5) ‘right holder’ means the holder or holders of any of the intellectual property rights referred to in Article 2(1);
- (6) ‘protected invention’ means any invention protected by any of the intellectual property rights referred to in Article 2(1);

- (7) ‘competent advisory body’ means the advisory body competent under a Union crisis or emergency mechanism as listed in the Annex or, where applicable, the ad hoc advisory body referred to in Article 6(5);
- (8) ‘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<sup>21</sup>.

#### *Article 4*

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

The Commission may grant a Union compulsory licence only if all of the following conditions are fulfilled:

- (a) a crisis or emergency mode has been declared pursuant to the relevant Union crisis or emergency mechanism;
- (b) the Commission has concluded, in accordance with Article 7, that the use of a protected invention which concerns crisis-relevant products is required in order to supply those products in the Union;

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<sup>21</sup> 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, ELI: <http://data.europa.eu/eli/reg/2013/952/oj>).

- (c) the Commission has concluded, in accordance with Article 7, that means other than a Union compulsory licence, including voluntary agreements to use a protected invention which concerns crisis-relevant products, could not be achieved within a reasonable timeframe and could not ensure access to those products ('measure of last resort');
- (d) the right holder concerned was given the opportunity to submit comments to the Commission and the competent advisory body in accordance with Articles 6 and 7.

### *Article 5*

#### *General requirements concerning a Union compulsory licence*

1. The Union compulsory licence shall:
  - (a) be non-exclusive and non-assignable, except with that part of the enterprise or goodwill which enjoys the Union compulsory licence;
  - (b) have a scope and duration that are strictly limited to the purpose for which the Union compulsory licence is granted and to the scope and duration of the crisis or emergency mode in the framework of which it is granted;
  - (c) be strictly limited to the relevant activities that are necessary to ensure the adequate supply of crisis-relevant products in the Union;
  - (d) be granted only against payment of an adequate remuneration to the right holder, as determined in accordance with Article 9;

- (e) be strictly limited to the Union;
  - (f) be granted only to a person or an entity that has the capacity to exploit swiftly the protected invention in a manner that permits the proper carrying out of relevant activities concerning the crisis-relevant products; and
  - (g) automatically expire if the crisis or emergency mode ends.
2. A Union compulsory licence for an invention protected by a published patent application shall also cover a patent granted based on that application, provided that the patent is granted while the Union compulsory licence is valid. This paragraph shall apply *mutatis mutandis* to published applications for utility models.
3. A Union compulsory licence for an invention protected by a patent shall cover a supplementary protection certificate issued with reference to that patent, where that certificate continues to cover the crisis-relevant product, provided that:
- (a) the transition from patent protection to protection conferred by a supplementary protection certificate takes place while the Union compulsory licence is valid, and
  - (b) the Union compulsory licence specifies that it applies to such supplementary protection certificate.



*Article 6*  
*Competent advisory body*

1. For the purposes of this Regulation, the competent advisory body shall assist and advise the Commission in the following tasks:
  - (a) identifying the intellectual property rights covering the crisis-relevant product, and identifying the corresponding right holder;
  - (b) disseminating the notice published in accordance with Article 7(1) through appropriate channels;
  - (c) identifying potential licensees and assessing whether they have the capacity to exploit swiftly the protected invention in a manner that permits the proper carrying-out of relevant activities concerning the crisis-relevant product, in accordance with the obligations referred to in Article 10;
  - (d) gathering the views of the right holder and potential licensees, including on whether voluntary licensing agreements can be concluded within a reasonable timeframe and, where relevant, by ensuring the participation of the right holder and potential licensees in the discussions within the competent advisory body, as well as analysing comments received, in accordance with Article 7(2), point (c);
  - (e) gathering the views, where relevant, of economic operators in the sectors concerned, and of other relevant entities;

- (f) gathering the views of experts from national intellectual property offices and the views of national authorities responsible for granting national compulsory licences, including by ensuring their participation in the discussions within the competent advisory body where those discussions concern intellectual property rights;
- (g) gathering and analysing crisis-relevant information, including on the existing national compulsory licences reported to the Commission in accordance with Article 22, and the market intelligence available, in particular in order to take account of:
  - (i) the characteristics of the crisis or emergency and how it is expected to evolve;
  - (ii) the lack of adequate supply of crisis-relevant products in the Union;
  - (iii) the existence of means other than a Union compulsory licence to remedy the lack of adequate supply of crisis-relevant products in the Union.
- (h) facilitating the exchange and sharing of information with other relevant bodies and other crisis-relevant bodies at Union and national level, as well as with relevant bodies at international level, where appropriate.

2. The chair of the competent advisory body shall invite a representative of the European Parliament to the relevant meetings of the competent advisory body as an observer, where possible under the applicable Union crisis or emergency mechanism.

3. The competent advisory body shall provide an opinion on the need for a Union compulsory licence and on the content of the licence, in accordance with Article 7(4).
4. The competent advisory body shall provide views on whether the Union compulsory licence should be modified or terminated, in accordance with Article 14.
5. Where there is no advisory body referred to in the Annex, the competent advisory body shall be 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 provide its secretariat. Each Member State shall have the right to be represented in the ad hoc advisory body. The chair of the ad hoc advisory body shall invite a representative of the European Parliament as an observer to the relevant meetings of the ad hoc advisory body.
6. The Commission shall, by means of an implementing act, lay down the rules of procedure of the ad hoc advisory body referred to in paragraph 5 of this Article. The rules of procedure shall specify that the ad hoc advisory body is to be set up for a period not exceeding the duration of the crisis or emergency. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 23(2).

## Article 7

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

1. Where the Commission, in the context of a declared crisis or emergency mode and on the basis of preliminary information gathered under the relevant Union crisis or emergency mechanism, considers that the use of a protected invention which concerns crisis-relevant products is required to ensure the adequate supply of those products in the Union, it may initiate the procedure for granting a Union compulsory licence by publishing a notice on its website.

The preliminary information referred to in the first subparagraph shall include information on the following:

- (a) the lack of adequate supply of crisis-relevant products;
- (b) the available manufacturing capacities;
- (c) the intellectual property rights and the right holder concerned.

The Commission shall publish the notice referred to in the first subparagraph in the *Official Journal of the European Union* without undue delay.

2. The notice referred to in paragraph 1 shall include:
  - (a) information about the crisis-relevant products in respect of which the Commission considers that there is lack of adequate supply;

- (b) the information about the intellectual property rights and right holder concerned gathered at the time of the publication of the notice;
  - (c) an invitation to the right holder, to potential licensees and to other persons with an interest to submit comments to the Commission and the competent advisory body on the envisaged Union compulsory licence, in particular on the following:
    - (i) whether voluntary licensing agreements can be concluded with potential licensees, within a reasonable timeframe, on intellectual property rights for the purpose of carrying out relevant activities concerning the crisis-relevant products;
    - (ii) the need to grant a Union compulsory licence;
    - (iii) the envisaged content of the Union compulsory licence, including on the amount of the remuneration;
  - (d) information about the competent advisory body.
3. Upon the publication of the notice on its website, the Commission shall request the competent advisory body to disseminate the notice further through appropriate channels and to provide an opinion containing an assessment of the need for a Union compulsory licence and of the envisaged content of such licence.

The Commission shall set a time limit for the submission of that opinion. That time limit shall be reasonable and appropriate to the circumstances of the case, taking particular account of the urgency of the situation.

Where justified, the Commission may set a new time limit for the submission of the opinion referred to in the first subparagraph.

4. The competent advisory body shall provide the opinion referred to in paragraph 3 of this Article in accordance with its rules of procedure. The opinion shall contain an assessment of the need for a Union compulsory licence and of the envisaged content of such licence. The information on the outcome of the tasks performed in accordance with Article 6 shall be annexed to the opinion.
5. The opinion of the competent advisory body shall not be binding on the Commission.
6. After receiving the opinion of the competent advisory body, the Commission shall assess whether continuing the procedure for granting a Union compulsory licence is justified. If continuing the procedure is justified, the Commission shall inform the right holder and potential licensees concerned individually, as soon as reasonably practicable, of the fact that it is considering granting a Union compulsory licence. The Commission shall provide them with:
  - (a) the envisaged content of the Union compulsory licence;

- (b) a summary of the opinion of the competent advisory body;
- (c) an invitation to submit their comments and a time limit for doing so, including comments on whether a voluntary licensing agreement has been concluded.

7. Where, after considering the opinion of the competent advisory body and any comments received in accordance with paragraph 6, point (c), of this Article, as well as taking into account the public interest and the rights and interests of the right holder and the potential licensees, the Commission concludes that the conditions referred to in Article 4 are met, it shall grant the Union compulsory licence by means of an implementing act. Where the Commission's decision to grant the Union compulsory licence departs from the opinion of the competent advisory body, that implementing act shall indicate the Commission's reasons for departing from that opinion.
8. The implementing act referred to in paragraph 7 of this Article shall be adopted in accordance with the examination procedure referred to in Article 23(2).

On duly justified imperative grounds of urgency relating to the impact of the crisis or emergency, the Commission shall adopt an immediately applicable implementing act in accordance with the procedure referred to in Article 23(3).

9. Where, based on the opinion of the competent advisory body and taking into account the rights and interests of the right holder and the potential licensees, the Commission comes to the conclusion that the conditions referred to in Article 4 are not met, the Commission shall publish in the *Official Journal of the European Union* a notice informing the public that the procedure initiated under paragraph 1 of this Article has ended.
10. Throughout the procedure for granting a Union compulsory licence, the Commission and the competent advisory body shall ensure that confidential information is protected.

While respecting the confidentiality of the information, the Commission and the competent advisory body shall ensure that any information relied on for the purposes of the Commission's implementing act referred to in paragraph 7 is disclosed to an extent that allows an understanding of the facts and considerations that led to the adoption of that implementing act.

11. Without prejudice to paragraph 7, voluntary licensing agreements may be concluded at any time during or after the procedure for granting a Union compulsory licence set out in this Article.



*Article 8*  
*Content of the Union compulsory licence*

The Commission shall specify in the Union compulsory licence the following:

- (a) the intellectual property rights, namely the patent, published patent application, supplementary protection certificate, utility model or published application for a utility model in respect of which the Union compulsory licence is granted;
- (b) the right holder;
- (c) the licensee, in particular the following information:
  - (i) name and trade name;
  - (ii) contact details;
  - (iii) unique identification number in the country where the licensee is established;
  - (iv) where available, the Economic Operators Registration and Identification (EORI) number;
- (d) the duration for which the Union compulsory licence is granted;

- (e) the remuneration to be paid to the right holder and the timeframe within which it is to be paid, as determined in accordance with Article 9;
- (f) where appropriate, the non-proprietary name of the crisis-relevant product which is to be manufactured or marketed under the Union compulsory licence or the Combined Nomenclature (CN) code under which the crisis-relevant product is classified, as set out in Annex I to Regulation (EEC) No 2658/87;
- (g) the details referred to in Article 10(1), points (c), (e) and (f), which make it possible to identify the crisis-relevant product manufactured or marketed under the Union compulsory licence and, where applicable, any other specific requirement under the Union legislation applicable to the crisis-relevant product and making its identification possible; and
- (h) the maximum quantity of the crisis-relevant products to be manufactured or marketed under the Union compulsory licence.

#### *Article 9*

##### *Remuneration*

1. The licensee shall pay an adequate remuneration to the right holder. The Commission shall determine the amount of that remuneration and the timeframe within which it is to be paid.

2. When determining the amount of the adequate remuneration, the Commission shall take into account the economic value of the relevant activities authorised under the Union compulsory licence, as well as the circumstances of each case, such as any public support received to develop the protected invention. The Commission shall also take into account the opinion of the competent advisory body and any comments received under Article 7(6), point (c).
3. If a published patent application in respect of which a Union compulsory licence has been granted does not lead to the granting of a patent, the right holder shall refund to the licensee the remuneration paid under this Article.

This paragraph shall apply *mutatis mutandis* to published applications for utility models.

#### *Article 10*

##### *Obligations of the licensee*

1. The licensee shall be authorised to exploit the protected invention covered by the Union compulsory licence only where the licensee complies with the following obligations:
  - (a) the licensee shall ensure that the quantity of the crisis-relevant products manufactured or marketed under the Union compulsory licence does not exceed the maximum quantity determined in accordance with Article 8, point (h);

- (b) the licensee shall carry out relevant activities concerning the crisis-relevant products solely for ensuring the adequate supply of the crisis-relevant products in the Union;
- (c) the licensee shall ensure that the crisis-relevant products manufactured or marketed under the Union compulsory licence are clearly identified, through specific labelling or marking, as being manufactured or marketed pursuant to a Union compulsory licence granted under this Regulation;
- (d) the licensee shall keep regular records of the quantities of crisis-relevant products manufactured or marketed under the Union compulsory licence;
- (e) the licensee shall ensure that the crisis-relevant products manufactured or marketed under the Union compulsory licence can be distinguished from products manufactured or marketed by the right holder or under a voluntary licence granted by the right holder by means of special packaging, colouring or shaping, unless such distinction is not feasible or has a significant impact on the price of the crisis-relevant products;
- (f) the licensee shall ensure that the packaging of the crisis-relevant products manufactured or marketed under the Union compulsory licence and any associated marking or leaflet indicate that those products are subject to a Union compulsory licence granted under this Regulation and specify clearly that they are exclusively for distribution in the Union and are not to be exported;

- (g) before marketing the crisis-relevant products covered by the Union compulsory licence, the licensee shall make available on a website the following information:
  - (i) the quantities of the crisis-relevant products manufactured under the Union compulsory licence per Member State of manufacturing;
  - (ii) the quantities of the crisis-relevant products to be supplied under the Union compulsory licence per Member State of destination;
  - (iii) the distinguishing features of the crisis-relevant products covered by the Union compulsory licence.

The licensee shall communicate the address of the website referred to in point (g) 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 any of the obligations laid down in paragraph 1 of this Article, the Commission may:
  - (a) terminate the Union compulsory licence in accordance with Article 14(3);
  - (b) impose fines or periodic penalty payments on the licensee in accordance with Article 15 or 16.

3. Where there are sufficient grounds to suspect that the licensee has failed to fulfil the obligations laid down in paragraph 1, the Commission, in cooperation with the relevant national authorities of the Member States, may, based on information from those authorities or from the right holder, request access to books and records kept by the licensee as necessary for the purpose of checking compliance with the licensee's obligations laid down in paragraph 1.
4. The Commission shall, by means of implementing acts, establish rules for the specific labelling or marking referred to in paragraph 1, point (c), of this Article, and for the packaging, colouring and shaping referred to in paragraph 1, point (e), of this Article, as well as rules for their use and, where relevant, their positioning on the crisis-relevant products. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 23(2).

#### *Article 11*

#### *Prohibition of export*

The export of products manufactured or marketed under a Union compulsory licence shall be prohibited.

This Article is without prejudice to Regulation (EC) No 816/2006.

*Article 12*  
*Customs control*

1. 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.
2. Customs authorities shall rely on the Union compulsory licence and on any modifications thereto to identify products that could fall under the prohibition laid down in Article 11 of this Regulation. For that purpose, the Commission shall enter risk information, as regards each Union compulsory licence and any modification thereto into the Union electronic customs risk management system, referred to in Article 36 of Implementing Regulation (EU) 2015/2447. Customs authorities shall take such risk information into consideration when they carry out controls on products placed under the customs procedure ‘export’ in accordance with Articles 46 and 47 of Regulation (EU) No 952/2013.
3. Where customs authorities identify a product that could 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 or marketed under a Union compulsory licence. The Commission shall inform the right holder and, where appropriate, the licensee. The Commission may consult the right holder to assess whether the product is covered by a Union compulsory licence.

4. Where the export of a product has been suspended in accordance with paragraph 3, that 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 where either of the following conditions is fulfilled:
- (a) the Commission has not requested the customs authorities to maintain the suspension within 10 working days of it being notified thereof;
  - (b) the Commission has informed the customs authorities that the product is not manufactured or marketed under a Union compulsory licence.
5. Where the Commission concludes that the export of a product manufactured or marketed under a Union compulsory licence does not comply with the prohibition laid down in Article 11, the customs authorities shall not authorise the release for export of that product. The Commission shall inform the customs authorities and the right holder concerned of such non-compliance.
6. Where the release for export of a product has not been authorised, the Commission may, where appropriate in view of the declared crisis or emergency mode, require, through the customs authorities, the exporter to take specific actions at its own expense, including supplying the product to designated Member States, if need be, after rendering it compliant with Union law.



In all other cases, the product concerned may be disposed of in accordance with national law, in compliance with Union law. In such cases, Articles 197 and 198 of Regulation (EU) No 952/2013 shall apply accordingly.

### *Article 13*

#### *Conduct of the right holder and the licensee*

When exercising the rights or performing the obligations laid down in this Regulation, the right holder and the licensee shall refrain from any actions or omissions that could undermine the Union compulsory licensing process.

### *Article 14*

#### *Review and termination of the Union compulsory licence*

1. The Commission shall review the Union compulsory licence upon a reasoned request by the right holder or the licensee, or on its own initiative, and shall, where necessary, modify the content of the licence as referred to in Article 8 by means of an implementing act.

Without prejudice to the Commission's obligation laid down in Article 8, points (a) and (b), to identify the intellectual property rights and the right holders before granting the Union compulsory licence, the Commission shall modify the Union compulsory licence, where necessary, to update the list of intellectual property rights and right holders covered by the Union compulsory licence. That modification shall, where appropriate, have a retroactive effect.

2. Where the Commission is considering updating the list of rights and right holders covered by the Union compulsory licence, it shall inform the right holders concerned and invite them to submit comments on the possibility of reaching, within a reasonable timeframe, a voluntary licensing agreement with the licensee, as well as comments on the amount of the adequate remuneration.
3. The Commission shall terminate a Union compulsory licence by means of an implementing act where the circumstances which led to it being granted cease to exist and are unlikely to recur.

The Commission may terminate a Union compulsory licence by means of an implementing act where the licensee fails to comply with the obligations laid down in this Regulation.

4. Where a Union compulsory licence is terminated in accordance with paragraph 3 of this Article or where it expires in accordance with Article 5(1), point (g), the Commission shall notify the right holder and the licensee accordingly. Where appropriate, advance notification shall be provided to enable the orderly completion by the licensee of the activities relating to the crisis-relevant products covered by the Union compulsory licence.
5. Where the Commission is considering modifying or terminating a Union compulsory licence, it shall consult the competent advisory body.

6. Where a Union compulsory licence is terminated in accordance with paragraph 3 of this Article or where it expires in accordance with Article 5(1), point (g), the Commission may require that the licensee, within a reasonable period of time, arrange for any crisis-relevant products in its possession, custody, power or control to be redirected or otherwise disposed of, at the expense of the licensee and in the manner determined by the Commission in consultation with the right holder and the licensee.
7. The implementing acts referred to in paragraphs 1 and 3 of this Article shall be adopted in accordance with the examination procedure referred to in Article 23(2).

On duly justified imperative grounds of urgency relating to the impact of the crisis or emergency, the Commission shall adopt immediately-applicable implementing acts in accordance with the procedure referred to in Article 23(3).

When adopting the implementing acts referred to in paragraphs 1 and 3 of this Article the Commission shall ensure that confidential information is protected and shall duly consider the rights and interests of the right holder and the licensee.

## *Article 15*

### *Fines*

1. The Commission may, by means of a decision, impose fines where the licensee, intentionally or negligently, fails to comply with its obligations laid down in Article 9(1), Article 10(1) or Article 11.
2. The fine imposed in accordance with paragraph 1 shall not exceed EUR 300 000. Where the licensee is a micro, small or medium-sized enterprise (SME) as defined in Article 2 of the Annex to Commission Recommendation 2003/361/EC<sup>22</sup>, the fine shall not exceed EUR 50 000.
3. In fixing the amount of the fine, regard shall be had to the nature, gravity, duration and any recurrence of the infringement, as well as to any other aggravating or mitigating factor applicable to the circumstances of the case, such as actions taken to mitigate the harm, and the financial benefits gained from, or losses avoided through, the infringement, directly or indirectly.

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<sup>22</sup> Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: <http://data.europa.eu/eli/reco/2003/361/oj>).

## Article 16

### *Periodic penalty payments*

1. The Commission may, by means of a decision, impose on the licensee a periodic penalty payment for each working day calculated from the date determined in that decision, in order to compel the licensee to put an end to the non-compliance with the obligations laid down in Article 9(1), Article 10(1) or Article 11.
2. The periodic penalty payment imposed in accordance with paragraph 1 shall not exceed 1,5 % of the average daily turnover of the licensee in the preceding financial year. Where the licensee is an SME, the periodic penalty payment shall not exceed 0,5 % of its average daily turnover in the preceding financial year.
3. Article 15(3) shall apply *mutatis mutandis*.
4. Where the licensee has satisfied the obligation which the periodic penalty payment was intended to enforce, the Commission may fix the definitive amount of the periodic penalty payment at a figure lower than that which would arise under the original decision.

## Article 17

### *Limitation period for the imposition of fines and periodic penalty payments*

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

2. The limitation period referred to in paragraph 1 shall begin to run on the day on which the infringement is committed. However, in the case of continuing or repeated infringements, the limitation period shall begin to run on the day on which the infringement ceases.
3. Any action taken by the Commission or by a competent authority of a Member State for the purpose of an investigation or of proceedings in respect of an infringement shall interrupt the limitation period for the imposition of fines or periodic penalty payments.  
  
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 4.
4. 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 (the ‘Court’).

### *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 Article 15 or 16 shall be subject to a limitation period of five years.

2. The limitation period referred to in paragraph 1 shall begin to run on the day on which the decision becomes final.
3. The limitation period for the enforcement of fines and periodic penalty payments shall be interrupted:
  - (a) by notification of a decision modifying the original amount of the fine or periodic penalty payment or refusing an application for the modification of that amount;
  - (b) by any action of the Commission, or of a Member State, acting at the request of the Commission, intended to enforce payment of the fine or periodic penalty payment.

Each interruption shall start time running afresh.

4. The limitation period for the enforcement of fines and periodic penalty payments shall be suspended for so long as:
  - (a) time to pay is allowed;
  - (b) the enforcement of the payment is suspended pursuant to a decision of the Court or pursuant to a decision of a national court.

## *Article 19*

### *Right to be heard and access to the file in the procedure for imposing fines or periodic penalty payments*

1. Before adopting a decision pursuant to Article 15 or 16, the Commission shall give the licensee the opportunity to be heard on the alleged infringement.
2. The licensee may submit observations on the alleged infringement within a reasonable period set by the Commission. That period shall not be less than 14 days from the notification of the invitation to submit observations.
3. The Commission shall base its decision pursuant to Article 15 or 16 only on arguments on which the parties concerned have been given an opportunity to comment.
4. The rights of defence of the parties 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 right holder or of the licensee, or of any other person concerned in the protection of their commercially sensitive information and trade secrets. The Commission shall have the power to adopt decisions setting out such terms of a negotiated disclosure in the event of disagreement between the parties.



The right of access to the Commission's file referred to in the first subparagraph shall not extend to confidential information and internal documents of the Commission, of other competent authorities or of public authorities of the Member States. In particular, the right of access shall not extend to correspondence between the Commission and those authorities.

Nothing in this paragraph shall prevent the Commission from disclosing and using information necessary to prove an infringement.

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

## *Article 20*

### *Publication of decisions on fines and periodic penalty payments*

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

2. The publication referred to in paragraph 1 shall have regard to the rights and legitimate interests of the right holder, of the licensee or of any third parties in the protection of their confidential information, and shall comply with Union law on the protection of personal data.

#### *Article 21*

##### *Review of fines or periodic penalty payments by the Court*

In accordance with Article 261 TFEU, the Court has unlimited jurisdiction to review Commission decisions imposing fines or periodic penalty payments. The Court may cancel, reduce or increase the fine or periodic penalty payment imposed.

#### *Article 22*

##### *Reporting on national compulsory licences*

1. Where a national compulsory licence has been granted for the purpose of addressing a national crisis or emergency corresponding in nature to a crisis or emergency falling within the scope of a Union crisis or emergency mechanism, the Member State concerned shall inform the Commission of the granting of the licence without undue delay. The information to be provided shall include the following:
  - (a) the purpose of the national compulsory licence and its legal basis in national law;
  - (b) the name and address of the licensee;

- (c) the products concerned and, to the extent possible, the intellectual property rights and the right holder concerned;
- (d) the remuneration to be paid to the right holder;
- (e) the quantity of products to be supplied under the licence;
- (f) the duration of the licence.

Article 2(4) shall apply *mutatis mutandis*.

2. Member States shall inform the Commission of the national authority tasked with providing the information under paragraph 1. The Commission shall publish the list of those national authorities on its website.

### *Article 23*

#### *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 5 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.
4. Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and Article 5(4), third subparagraph, of Regulation (EU) No 182/2011 shall apply.

#### *Article 24*

#### *Amendments to Regulation (EC) No 816/2006*

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

- (1) the following article is inserted:

##### *‘Article 18a*

##### *Union compulsory licence*

1. By way of derogation from Article 1, second subparagraph, and from Article 2, point (4), and Article 3 the Commission may grant a compulsory licence applicable to the whole of the Union where the activities of manufacture and sale for export are spread across different Member States and would therefore require compulsory licences for the same product in more than one Member State.

2. Any person may submit an application for a Union compulsory licence referred to in paragraph 1 of this Article. By way of derogation from Article 6(1) and (2), that application shall be submitted to the Commission. The application shall fulfil the requirements laid down in Article 6(3), points (a) to (f), and shall specify the Member States in which the activities of manufacture and sale for export of the product to be covered by the Union compulsory licence are to be carried out.

Articles 7, 8, 9 and 12 shall apply *mutatis mutandis*.

3. The Union compulsory licence referred to in paragraph 1 of this Article shall be subject to the conditions set out in Article 10 and shall specify that it is applicable to the whole of the Union.
4. The Commission shall, by means of an implementing act:
  - (a) grant a Union compulsory licence referred to in paragraph 1;
  - (b) reject an application for a Union compulsory licence submitted pursuant to paragraph 2;
  - (c) modify or terminate the Union compulsory licence granted pursuant to point (a).

In cases referred to in point (b) of the first subparagraph, Article 11 shall apply *mutatis mutandis*.

In cases referred to in point (c) of the first subparagraph, Article 5, point (c), and Article 16 shall apply *mutatis mutandis*.

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 18b(2).

On duly justified imperative grounds of urgency relating to the impact of the public health problems to be addressed, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 18b(3).’;

(2) the following article is inserted:

‘Article 18b

*Committee procedure*

1. The Commission shall be assisted by a committee (the “Compulsory Licensing Committee”). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

4. Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and Article 5(4), third subparagraph, of Regulation (EU) No 182/2011 shall apply.’;

(3) the following article is inserted:

*‘Article 18c*

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

The procedure for granting a Union compulsory licence under Article 18a, and a Union compulsory licence granted under that Article, shall not apply to and in the United Kingdom in respect of Northern Ireland. The United Kingdom in respect of Northern Ireland shall ensure that the products manufactured under such a licence are not imported into the Union or Northern Ireland in accordance with Article 13, and shall take the necessary actions to that end in accordance with Article 14.’.

*Article 25*

*Evaluation*

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

The Commission shall regularly, and for the first time by 31 December 2027, assess whether the list in the Annex is up to date, including, in particular, in relation to semiconductors for medical equipment. It may, where appropriate, submit proposals to amend the Annex.

Every five years from ... [the date of entry into force of this Regulation], the Commission shall report on the assessments carried out pursuant to the second paragraph to the European Parliament and the Council.

#### *Article 26*

##### *Entry into force*

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

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

Done at ...,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*

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## ANNEX

List of Union crisis or emergency mechanisms, crisis or emergency modes and advisory bodies

Union crisis or emergency mechanism	Crisis or emergency mode	Advisory body
1. Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU	Public health emergency at Union level formally recognised by means of a Commission implementing act (Article 23 of Regulation (EU) 2022/2371)	Health Security Committee (Article 4 of Regulation (EU) 2022/2371)
2. Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level	Emergency framework activated by means of a Council Regulation (Article 3 of Regulation (EU) 2022/2372)	Health Crisis Board (Article 5 of Regulation (EU) 2022/2372)
3. Regulation (EU) 2024/2747 of the European Parliament and of the Council of 9 October 2024 establishing a framework of measures related to an internal market emergency and to the resilience of the internal market and amending Council Regulation (EC) No 2679/98 (Internal Market Emergency and Resilience Act)	Internal Market emergency mode activated by means of a Council implementing act (Article 18 of Regulation (EU) 2024/2747)	Internal Market Emergency and Resilience Board (Article 4 of Regulation (EU) 2024/2747)