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INFORMATION NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 - Outcome of the European Parliament's first reading (Strasbourg, 11 to 14 March 2024)

I. INTRODUCTION

The rapporteur, Adrián VÁZQUEZ LÁZARA (RE, ES), presented a report on the above proposal for a Regulation on behalf of the Committee on Legal Affairs (JURI) which contained 98 amendments (amendments 1 to 98) to the proposal.

In addition, the Greens/EFA group tabled one amendment (amendment 99) and the Committee on International Trade (INTA) tabled nine amendments (amendments 100 to 108).

II. VOTE

When it voted on 13 March 2024, the plenary of the European Parliament adopted amendments 1 to 98 to the proposal for a Regulation. No other amendments were adopted.

The Commission's proposal as thus amended constitutes the Parliament's first-reading position which is contained in its legislative resolution as set out in the Annex hereto.

ANNEX
(13.3.2024)

P9_TA(2024)0143

Compulsory licensing for crisis management and amending Regulation (EC) 816/2006

European Parliament legislative resolution of 13 March 2024 on the proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 (COM(2023)0224 – C9-0151/2023 – 2023/0129(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

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

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

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

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

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

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

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

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

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

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

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

Amendment 1
Proposal for a regulation
Recital 1

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

Amendment 2
Proposal for a regulation
Recital 2

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

Amendment 3
Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) National compulsory licensing systems only operate within the national territory. They are designed to meet the needs of the population of the issuing Member State and to satisfy the public interest of that Member State. This limited territorial reach of a national compulsory licensing system is reinforced by the fact that there is no exhaustion of the patent right regarding products manufactured under a compulsory licence. Consequently, compulsory licensing schemes do not provide an adequate solution for cross-border manufacturing processes, and therefore there is no functioning internal market for product manufactured under a compulsory licence. Apart from the fact that the issuance of multiple national compulsory licences is a high hurdle for cross-border supply within the single market, it also bears the risk of contradicting and incoherent decisions among Member States. Consequently, the current compulsory licensing framework appears inadequate to address the realities of the internal market and its inherent cross-border supply chains. This suboptimal compulsory licensing framework prevents the Union from relying on an additional instrument when facing crises***, in particular*** when voluntary agreements are unavailable ***or inadequate***. At a time where the Union and its Member States are striving to improve their resilience to crises, it is necessary to provide for an optimal compulsory licensing system for crisis management that takes the full advantage of the internal market and allows Member States to support one another in crises.	(5) National compulsory licensing systems only operate within the national territory. They are designed to meet the needs of the population of the issuing Member State and to satisfy the public interest of that Member State. This limited territorial reach of a national compulsory licensing system is reinforced by the fact that there is no exhaustion of the patent right regarding products manufactured under a compulsory licence. Consequently, compulsory licensing schemes do not provide an adequate solution for cross-border manufacturing processes, and therefore there is no functioning internal market for product manufactured under a compulsory licence. Apart from the fact that the issuance of multiple national compulsory licences is a high hurdle for cross-border supply within the single market, it also bears the risk of contradicting and incoherent decisions among Member States. Consequently, the current compulsory licensing framework appears inadequate to address the realities of the internal market and its inherent cross-border supply chains. This suboptimal compulsory licensing framework prevents the Union from relying on an additional instrument when facing crises ***and*** when voluntary agreements are unavailable ***and cannot be reached within four weeks***. At a time where the Union and its Member States are striving to improve their resilience to crises, it is necessary to provide for an optimal compulsory licensing system for crisis management that takes the full advantage of the internal market and allows Member States to support one another in crises.

Amendment 4
Proposal for a regulation
Recital 6 a (new)

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

Amendment 5
Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) In order to ensure as much coherence as possible with existing crisis mechanisms and with other Union legislation, the definition of a 'crisis-relevant product' should be based on the definition adopted in the Single Market Emergency Instrument (SMEI) but should be more general in order to cover products related to different kinds of crises or emergencies.	(15) In order to ensure as much coherence as possible with existing crisis mechanisms ***and their requirements pertaining to the public interest*** and with other Union legislation, the definition of a 'crisis-relevant product' should be based on the definition adopted in the Single Market Emergency Instrument (SMEI) but should be more general in order to cover products related to different kinds of crises or emergencies.

Amendment 6
Proposal for a regulation
Recital 16

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

Amendment 7
Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) The participation of an advisory body aims at guaranteeing a comprehensive, thorough, and concrete assessment of the situation, taking into consideration the individual merits of each situation. It is therefore important that the advisory body has the right composition, expertise, and procedures to support the Commission when deciding on whether to grant a Union compulsory licence and under what conditions. Union crisis mechanisms usually include the setting-up of an advisory body ensuring coordination of action of the Commission and relevant bodies and agencies, the Council and the Member States. In this respect, an advisory group is set up under SMEI. Regulation (EU) No 2022/2371 provides for a Health Crisis Board and under Regulation (EU) No XXX/XX (Chips Act) [COM/2022) 46], the Commission relies on the Semiconductor Board. Those advisory bodies have the right composition, expertise, and procedures to address the crises and emergencies for which they have been set-up. When compulsory licensing is being discussed in the context of such crisis instrument, relying on the advisory body set-up for the specific instrument allows the Commission to be adequately advised and avoid duplication of advisory bodies, leading to incoherences between processes. The competent advisory bodies ***shall*** be listed, together with the corresponding crisis mechanisms, in an Annex to this Regulation. In case the Union crisis mechanism does not provide for an advisory body, the ***Commission should set up an ad hoc*** advisory body ***for the granting*** of the ***Union (the 'ad hoc advisory body')***.	(18) The participation of an advisory body aims at guaranteeing a comprehensive, thorough, and concrete assessment of the situation, taking into consideration the individual merits of each situation. It is therefore important that the advisory body has the right composition, expertise, and procedures to support the Commission when deciding on whether to grant a Union compulsory licence and under what conditions. Union crisis mechanisms usually include the setting-up of an advisory body ensuring coordination of action of the Commission and relevant bodies and agencies, the Council and the Member States. In this respect, an advisory group is set up under SMEI. Regulation (EU) No 2022/2371 provides for a Health Crisis Board and under Regulation (EU) No XXX/XX (Chips Act) [COM/2022) 46], the Commission relies on the Semiconductor Board. Those advisory bodies have the right composition, expertise, and procedures to address the crises and emergencies for which they have been set-up. When compulsory licensing is being discussed in the context of such crisis instrument, relying on the advisory body set-up for the specific instrument allows the Commission to be adequately advised and avoid duplication of advisory bodies, leading to incoherences between processes. The competent advisory bodies ***should*** be listed, together with the corresponding crisis mechanisms, in an Annex to this Regulation. ***The Commission should ensure that representatives of other crisis-relevant bodies at Union level participate in, and are invited as observers to, the relevant meetings of the advisory body in order to ensure consistency with the measures implemented through other Union mechanisms. It is important that the Commission invites as observers national***

	representatives from all national authorities responsible for issuing compulsory licenses under their national patent laws. In case the Union crisis mechanism does not provide for an advisory body, the advisory body ***should be constituted on an ad-hoc basis by the Commission and should be composed of representatives*** of the ***institutions and bodies of the Member States that exercise the competence to grant national compulsory licences under national laws***.

Amendment 8
Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) The role of the advisory body is to advise the Commission when discussions arise on the need to rely on compulsory licensing at Union level. It should provide the Commission with a non-binding opinion. Its main tasks include assisting of the Commission in the determination of the necessity to rely on compulsory licensing at Union level, and in the determination of the conditions for such licensing. When the advisory body is already set up, its existing rules of procedure should apply. As regards ad hoc advisory bodies, they should be composed of ***one representative of each Member State*** in order to provide the Commission with information and input concerning the situation on the national level, including information on manufacturing capacities, potential licensees and***, if applicable,*** proposals for voluntary solutions. In addition, the advisory body should have the function of collecting and analysing relevant data, as well as ensuring coherence and cooperation with other crisis relevant bodies at Union and national level in order to ensure an adequate, coordinated and coherent crisis reply at Union level.	(19) The role of the advisory body is to advise the Commission when discussions arise on the need to rely on compulsory licensing at Union level. It should provide the Commission with a non-binding opinion. Its main tasks include assisting of the Commission in the determination of the necessity to rely on compulsory licensing at Union level, and in the determination of the conditions for such licensing. When the advisory body is already set up, its existing rules of procedure should apply. As regards ad hoc advisory bodies, they should be composed of ***those representatives of national competent authorities*** in order to provide the Commission with information and input concerning the situation on the national level, including information on manufacturing capacities, potential licensees and proposals for voluntary solutions. In addition, the advisory body should have the function of collecting and analysing relevant data, as well as ensuring coherence and cooperation with other crisis relevant bodies at Union and national level in order to ensure an adequate, coordinated and coherent crisis reply at Union level.

Amendment 9
Proposal for a regulation
Recital 20

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

Amendment 10
Proposal for a regulation
Recital 21

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

Amendment 11
Proposal for a regulation
Recital 22

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

Amendment 12
Proposal for a regulation
Recital 23

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

Amendment 13
Proposal for a regulation
Recital 24

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

Amendment 14
Proposal for a regulation
Recital 25

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

Amendment 15
Proposal for a regulation
Recital 27

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

Amendment 16
Proposal for a regulation
Recital 32 a (new)

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

measures required for preserving the confidentiality of the trade secrets, the Commission should be able to withhold or suspend the disclosure of trade secrets until the situation is corrected by the licensee. Any use, acquisition or disclosure of trade secrets which would not be necessary to fulfil the objective of the Union compulsory licence or which would go beyond the duration of the Union compulsory license should be considered to be unlawful within the meaning of that Directive.

Amendment 17
Proposal for a regulation
Recital 32 b (new)

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

Amendment 18
Proposal for a regulation
Recital 33

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

Amendment 19
Proposal for a regulation
Recital 34

Text proposed by the Commission	*Amendment*
(34) To prevent and stop any misuse of the Union compulsory licence, specific safeguards should be in place to allow the Commission to take action. In addition to the possibility to terminate the Union compulsory licence, the Commission should be authorised to impose fines and periodic penalty payments on the rights-holder and the licensee in order to enforce the obligations under this Regulation. The penalties should be effective, proportionate and dissuasive.	(34) To prevent and stop any misuse of the Union compulsory licence, specific safeguards should be in place to allow the Commission to take action. In addition to the possibility to terminate the Union compulsory licence, the Commission should be authorised to impose fines and periodic penalty payments on the rights-holder and the licensee in order to enforce the obligations under this Regulation. The penalties should be effective, proportionate and dissuasive***, and should not contravene the usual enforcement measures of intellectual property rights as provided by Directive 2004/48/EC***.

Amendment 20
Proposal for a regulation
Recital 35

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

Amendment 21
Proposal for a regulation
Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) The possibility of a compulsory licence at Union level should not only be available for the supply of the Union market but also ***under certain conditions*** for export purposes concerning countries with public health problems, already regulated by Regulation (EC) No 816/2006 of the European Parliament and of the Council[11] . Under that Regulation, the granting of such compulsory licences is decided and performed nationally by the competent authorities of the Member States that have received a corresponding application from a person that intends to manufacture and sell pharmaceutical products covered by a patent or a supplementary protection for export to eligible third countries. Regulation (EC) No 816/2006 only allows compulsory licensing covering the manufacturing of products across several Member States through national procedures. In the context of a cross-border manufacturing process different national compulsory licences would be needed. This can lead to a burdensome and lengthy process as this would require the launch of different national procedures with possibly different scope and conditions. In order to achieve the synergies and efficient process as for the Union crisis mechanisms, a Union compulsory licence should also be available, in the context of Regulation (EC) No 816/2006. This will facilitate manufacturing of the relevant products across several Member States and provide Union-level solution in order to avoid a situation where several compulsory licences for the same product in more than one Member States would be required for licensees to manufacture and export the products as planned. Any person considering to apply for a compulsory licence ***under***, for the purposes and within	(37) The possibility of a compulsory licence at Union level should not only be available for the supply of the Union market but also for export purposes concerning countries with public health problems, already regulated by Regulation (EC) No 816/2006 of the European Parliament and of the Council[11]. Under that Regulation, the granting of such compulsory licences is decided and performed nationally by the competent authorities of the Member States that have received a corresponding application from a person that intends to manufacture and sell pharmaceutical products covered by a patent or a supplementary protection for export to eligible third countries. Regulation (EC) No 816/2006 only allows compulsory licensing covering the manufacturing of products across several Member States through national procedures. In the context of a cross-border manufacturing process different national compulsory licences would be needed. This can lead to a burdensome and lengthy process as this would require the launch of different national procedures with possibly different scope and conditions. In order to achieve the synergies and efficient process as for the Union crisis mechanisms, a Union compulsory licence should also be available, in the context of Regulation (EC) No 816/2006. This ***should be further facilitated by reviewing the conditions for issuing compulsory licences for export, in order to make them fully in line with the TRIPS Agreement and its full spectrum of flexibilities. The Union compulsory licence*** will facilitate ***the use of this mechanism and all the*** manufacturing of the relevant products across several Member States and provide Union-level solution in order to avoid a situation where several compulsory licences for the same

the scope of Regulation (EC) No 816/2006 should have the possibility to request, with a single application, a compulsory licence under that Regulation that is valid throughout the Union, if that person, when relying on national compulsory licencing schemes of the Member States, would otherwise need to apply for multiple compulsory licences for the same crisis-relevant product in more than one Member State in order to realise its intended activities of manufacture and sale for export under Regulation (EC) No 816/2006. Therefore, Regulation (EC) No 816/2006 should be amended accordingly.	product in more than one Member States would be required for licensees to manufacture and export the products as planned. Any person considering to apply for a compulsory licence, for the purposes and within the scope of Regulation (EC) No 816/2006 should have the possibility to request, with a single application, a compulsory licence under that Regulation that is valid throughout the Union, if that person, when relying on national compulsory licencing schemes of the Member States, would otherwise need to apply for multiple compulsory licences for the same crisis-relevant product in more than one Member State in order to realise its intended activities of manufacture and sale for export under Regulation (EC) No 816/2006. Therefore, Regulation (EC) No 816/2006 should be amended accordingly.
[11] Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (OJ L 157, 9.6.2006, p. 1).	[11] Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (OJ L 157, 9.6.2006, p. 1).

Amendment 22
Proposal for a regulation
Recital 38

Text proposed by the Commission	*Amendment*
(38) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the granting, complementing, modification or termination of a Union compulsory license, the determination of the remuneration to be paid to the rights-holder, the procedural rules for the ad hoc advisory body and the characteristics allowing the identification of products produced under a Union compulsory licence. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[12] . The advisory procedure should be used for the adoption of implementing acts granting, complementing, modifying or terminating a Union compulsory licence, and implementing acts determining the remuneration. The choice of the advisory procedure is justified given that those implementing acts would be adopted in the context of a procedure with considerable participation of the Member States through the consultation of the advisory body. The examination procedure should be used for the adoption of implementing acts establishing procedural rules for the ad hoc advisory body and implementing acts establishing the characteristics allowing the identification of products produced under a Union compulsory licence.	(38) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the granting, complementing, modification or termination of a Union compulsory license, the determination***, in the absence of an agreement between the rights-holder and the licensee,*** of the remuneration to be paid to the rights-holder, the procedural rules for the ad hoc advisory body and the characteristics allowing the identification of products produced under a Union compulsory licence. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[12] . The advisory procedure should be used for the adoption of implementing acts granting, complementing, modifying or terminating a Union compulsory licence, and implementing acts determining the remuneration. The choice of the advisory procedure is justified given that those implementing acts would be adopted in the context of a procedure with considerable participation of the Member States through the consultation of the advisory body. The examination procedure should be used for the adoption of implementing acts establishing procedural rules for the ad hoc advisory body and implementing acts establishing the characteristics allowing the identification of products produced under a Union compulsory licence.
[12] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).	[12] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Amendment 23
Proposal for a regulation
Recital 40

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

Amendment 24
Proposal for a regulation
Recital 40 a (new)

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

Amendment 25
Proposal for a regulation
Recital 41 a (new)

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

Amendment 26
Proposal for a regulation
Article 1 – paragraph 1

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

Amendment 27
Proposal for a regulation
Article 3 – paragraph 1 – point -a (new)

Text proposed by the Commission	*Amendment*
	(-a) 'crisis mode or emergency mode' means a crisis mode or an emergency mode, as applicable, listed in the Annex to this Regulation, which has been activated or declared in the context of a Union crisis or emergency mechanism listed in that Annex in accordance with one of the Union acts listed therein;

Amendment 28
Proposal for a regulation
Article 3 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) 'crisis-relevant products' means products or processes that are indispensable for responding to a crisis or emergency or for addressing the impacts of a crisis or emergency in the Union;	(a) 'crisis-relevant products' means products or processes that are indispensable for responding to a crisis or emergency or for addressing the impacts of a crisis or emergency in the Union ***and for which the granting of a compulsory license is the only means of ensuring the sufficient and timely availability and supply of such products or processes, as determined by the Commission through the guidance of the advisory body in accordance with Article 6;***

Amendment 29
Proposal for a regulation
Article 4 – paragraph 1

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

Amendment 30
Proposal for a regulation
Article 5 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The Union compulsory licence shall	1. The Union compulsory license ***that may be granted by the Commission in accordance with Article 4*** shall***, notwithstanding the obligations pursuant to Article 10:***

Amendment 31
Proposal for a regulation
Article 5 – paragraph 1 – point b

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

Amendment 32
Proposal for a regulation
Article 5 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) be strictly limited to the relevant activities of crisis-relevant products in the Union;	(c) be strictly limited to the relevant ***and properly justified*** activities of crisis-relevant products in the Union;

Amendment 33
Proposal for a regulation
Article 5 – paragraph 1 – point d

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

Amendment 34
Proposal for a regulation
Article 5 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) be limited to the territory of the Union;	(e) be ***strictly*** limited to the ***precisely defined*** territory of the Union;

Amendment 35
Proposal for a regulation
Article 5 – paragraph 1 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) clearly state that the licensee is responsible for any liability or warranties related to the production and distribution of crisis-relevant products, excluding the rights-holder from product liability claims.

Amendment 36
Proposal for a regulation
Article 6 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. The advisory body referred to in paragraph 1 shall be the advisory body competent for the Union crisis or emergency mechanism as listed in Annex I to this Regulation (the 'competent advisory body'). For the purposes of the present Regulation, the competent advisory body shall assist and advise the Commission as regards the following tasks:	2. The advisory body referred to in paragraph 1 shall be the advisory body competent for the Union crisis or emergency mechanism as listed in Annex I to this Regulation (the 'competent advisory body'). For the purposes of the present Regulation, the competent advisory body***, which is to act in the public interest,*** shall assist and advise the Commission as regards the following tasks:

Amendment 37
Proposal for a regulation
Article 6 – paragraph 2 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) the assessment of whether the obligation to give the rights-holder an opportunity to engage in negotiations for a voluntary agreement to be reached within four weeks, laid down in Article 4, has been complied with;

Amendment 38
Proposal for a regulation
Article 6 – paragraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) the determination of crisis-relevant products;

Amendment 39
Proposal for a regulation
Article 6 – paragraph 2 – point f

Text proposed by the Commission	*Amendment*
(f) the identification and consultation of the representatives of right holders or their representatives as well as potential licensees and consulting other economic operators, ***and the*** industry;	(f) the identification and consultation of the representatives of right holders or their representatives as well as potential licensees and consulting other ***stakeholders and*** economic operators, ***including*** industry***, academia and civil society***;

Amendment 40
Proposal for a regulation
Article 6 – paragraph 4 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) shall invite representatives of the European Parliament as observers to the relevant meetings of the advisory bodies, where possible under the applicable legal acts referred to in Annex;

Amendment 41
Proposal for a regulation
Article 6 – paragraph 4 – point b

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

Amendment 42
Proposal for a regulation
Article 6 – paragraph 5

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

Amendment 43
Proposal for a regulation
Article 6 – paragraph 6

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

Amendment 44
Proposal for a regulation
Article 7 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) the rights and interests of the rights-holder and the potential licensee;

Amendment 45
Proposal for a regulation
Article 7 – paragraph 1 – point b b (new)

Text proposed by the Commission	*Amendment*
	(bb) existing national compulsory licences reported to the Commission in accordance with Article 22 in order to avoid overlaps or a situation of overproduction;

Amendment 46
Proposal for a regulation
Article 7 – paragraph 2 a (new)

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

Amendment 47
Proposal for a regulation
Article 7 – paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
3. Before ***the granting of a Union compulsory licence, the Commission*** shall give the rights-holder and the licensee an opportunity to comment on ***the following***:	3. Before ***issuing the opinion, the advisory body*** shall give the rights-holder and the licensee an opportunity to comment ***within a reasonable timeframe*** on:

Amendment 48
Proposal for a regulation
Article 7 – paragraph 3 – point a

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

Amendment 49
Proposal for a regulation
Article 7 – paragraph 4

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

Amendment 50
Proposal for a regulation
Article 7 – paragraph 6

Text proposed by the Commission	*Amendment*
6. When assessing whether a Union compulsory licence is to be granted, the Commission shall consider the following:	***deleted***
(a) the opinion referred to in paragraph 2;	
(b) the rights and interests of the rights-holder and the licensee;	
(c) existing national compulsory licences reported to the Commission in accordance with Article 22.	

Amendment 51
Proposal for a regulation
Article 8 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the patent, patent application, supplementary protection certificate or utility model for which the licence is granted ***or, where the identification of those rights would significantly delay the granting of the licence, the non-proprietary name of the products which are to be manufactured under the licence***;	(a) the patent, patent application, supplementary protection certificate or utility model for which the licence is granted;

Amendment 52
Proposal for a regulation
Article 8 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the right-holder***, provided they can be identified with reasonable efforts having regard to the circumstances, including the urgency of the situation***;	(b) the right-holder;

Amendment 53
Proposal for a regulation
Article 8 – paragraph 1 – point h

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

Amendment 54
Proposal for a regulation
Article 9 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The rights-holder shall receive the remuneration within a pre-established timeframe as agreed with the Commission.

Amendment 55
Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The remuneration shall ***not exceed 4 % of*** total gross revenue generated by the licensee ***through the relevant*** activities ***under*** the Union compulsory licence.	2. The remuneration shall ***be determined based on the*** total gross revenue generated by the licensee ***from the pertinent*** activities ***governed by*** the Union compulsory licence.

Amendment 56
Proposal for a regulation
Article 9 – paragraph 3 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) the possible disclosure of trade secrets pursuant to Article 13a(2) and (3) and the relevant limitations to the protection of trade secrets according to Directive (EU) 2016/94; that disclosure shall give rise to adequate compensation for the rights-holder.

Amendment 57
Proposal for a regulation
Article 10 – paragraph 1 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the number of crisis-relevant products manufactured under the Union compulsory licence does not exceed what is necessary to meet the needs of the Union;	(a) the number of crisis-relevant products manufactured under the Union compulsory licence does not exceed ***the defined quantities and*** what is necessary to meet the needs of the Union;

Amendment 58
Proposal for a regulation
Article 10 – paragraph 1 – subparagraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) a detailed account of the products produced under the Union compulsory licence;

Amendment 59
Proposal for a regulation
Article 10 – paragraph 1 – subparagraph 1 – point c b (new)

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

Amendment 60
Proposal for a regulation
Article 10 – paragraph 1 – subparagraph 1 – point c c (new)

Text proposed by the Commission	*Amendment*
	(cc) implement all necessary measures to preserve the confidentiality of the rights-holder's trade secrets, as ordered by the Commission pursuant to Article 13a(3);

Amendment 61
Proposal for a regulation
Article 10 – paragraph 1 – subparagraph 1 – point c d (new)

Text proposed by the Commission	*Amendment*
	(cd) do not use trade secrets disclosed pursuant to Article 13a(2) beyond the duration of the Union compulsory licence or for any other purpose than those considered as lawful uses under Article 13a(2);

Amendment 62
Proposal for a regulation
Article 10 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) terminate the Union compulsory licence in accordance with Article 14(3); or	(a) ***immediately*** terminate the Union compulsory licence in accordance with Article 14(3); or

Amendment 63
Proposal for a regulation
Article 10 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) impose fines ***or*** periodic penalties on the licensee in accordance with Articles 15 and 16.	(b) impose fines ***and*** periodic penalties on the licensee in accordance with Articles 15 and 16.

Amendment 64
Proposal for a regulation
Article 10 – paragraph 3

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

Amendment 65
Proposal for a regulation
Article 13 – paragraph 2

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

Amendment 66
Proposal for a regulation
Article 13 a (new)

Text proposed by the Commission	*Amendment*
	Article 13a
	Additional measures complementing the Union compulsory licence
	1. Where necessary, the Commission shall decide, upon a reasoned request from the rights-holder or the licensee, or on its own initiative, on additional measures complementing the Union compulsory licence to ensure it achieves its objective as well as to facilitate and ensure the good collaboration between the rights-holder and the licensee.
	2. Where strictly necessary, the Commission shall request the disclosure of the rights-holder's trade secrets to the licensee to the extent required to provide him with the necessary know-how to achieve the objective for which the Union compulsory licence is granted under this Regulation. The lawful uses of the trade secrets by the licensee shall be strictly limited to the manufacturing of the crisis-relevant products in view of fulfilling the objective for which the Union compulsory licence has been granted.
	3. Where the rights-holder is requested to disclose his trade secrets in accordance with paragraph 3, the Commission shall, prior to the disclosure of trade secrets, order the licensee to put in place all appropriate technical and organisational measures that the rights-holder reasonably identifies as necessary to preserve the confidentiality of trade secrets, in particular in relation to third parties, including, as appropriate, the use of model contractual terms, confidentiality agreements, strict access protocols, technical standards or the application of codes of conduct.
	If the licensee fails to implement the necessary measures required by the Commission, the Commission may withhold or, as the case may be, suspend the disclosure of trade secrets until the situation is corrected by the licensee.

	4. Appropriate remuneration to the rights-holders in compensation for the disclosure of their trade secrets shall be granted in accordance with Directive (EU) 2016/943.
	5. Where the Commission considers adopting additional measures as referred to in paragraphs 1 and 2, it shall consult the advisory body referred to in Article 6.
	6. The implementing acts referred to in paragraphs 1 and 2 shall be adopted in accordance with the rules referred to in Article 7(6), points (a) and (b), and Article 7(7) and (8).

Amendment 67
Proposal for a regulation
Article 14 – paragraph 2

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

Amendment 68
Proposal for a regulation
Article 14 – paragraph 4

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

Amendment 69
Proposal for a regulation
Article 14 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. When considering terminating the Union compulsory licence, the Commission shall ensure that a sufficient transitional period is put in place.

Amendment 70
Proposal for a regulation
Article 14 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The implementing acts referred to in paragraph 1***, 2*** and 3 shall be adopted in accordance with the rules referred to in Article 7(6) (a) and (b), 7(7) and 7(8).	6. The implementing acts referred to in paragraph 1 and 3 shall be adopted in accordance with the rules referred to in Article 7(6) (a) and (b), 7(7) and 7(8).

Amendment 71
Proposal for a regulation
Article 15 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the rights-holder or the licensee fail to comply with any obligation resulting from the additional measures complementing the Union compulsory licence as referred to in Articles 8(1)(h) and ***14(2)***, as specified in the relevant implementing act.	(c) the rights-holder or the licensee fail to comply with any obligation resulting from the additional measures complementing the Union compulsory licence as referred to in Articles 8(1)(h) and ***Article 13a(1) and (2)***, as specified in the relevant implementing act.

Amendment 72
Proposal for a regulation
Article 15 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) the licensee does not comply with the prohibition referred in Article 11;

Amendment 73
Proposal for a regulation
Article 16 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the rights-holder or the licensee to comply with any obligation resulting from the additional measures complementing the Union compulsory licence as referred to in Articles 8(1)(h) and ***14(2)***, as specified in the relevant implementing act.	(c) the rights-holder or the licensee to comply with any obligation resulting from the additional measures complementing the Union compulsory licence as referred to in Articles 8(1)(h) and ***Article 13a(1) and (2)***, as specified in the relevant implementing act.

Amendment 74
Proposal for a regulation
Article 16 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) the licensee to put an end to an infringement of the prohibition referred in Article 11;

Amendment 75
Proposal for a regulation
Article 19 – paragraph 1

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

Amendment 76
Proposal for a regulation
Article 19 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Commission shall reply to the observations made by the licensee or the right holder and in case of a rejection of the observations, it shall provide a justification within a reasonable period of time which shall not exceed 7 days.

Amendment 77
Proposal for a regulation
Article 19 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The rights of defence of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the Commission's file under the terms of a negotiated disclosure, subject to the legitimate interest of the licensee or the rights-holder or other person concerned in the protection of their commercially sensitive information and trade secrets. The Commission shall have the power to adopt decisions setting out such terms of disclosure in case of disagreement between the parties. The right of access to the file of the Commission shall not extend to confidential information and internal documents of the Commission, other competent authorities or other public authorities of the Member States. In particular, the right of access shall not extend to correspondence between the Commission and those authorities. Nothing in this paragraph shall prevent the Commission from disclosing and using information necessary to prove an infringement.	4. The rights of defence of the parties concerned shall be fully respected in the proceedings. They shall be entitled to have access to the Commission's file under the terms of a negotiated disclosure, subject to the legitimate interest of the licensee or the rights-holder or other person concerned in the protection of their commercially sensitive information and trade secrets ***fully in line with existing legislation on the protection of data and trade secrets***. The Commission shall have the power to adopt decisions setting out such terms of disclosure***,*** in case of disagreement between the parties. The right of access to the file of the Commission shall not extend to confidential information and internal documents of the Commission, other competent authorities or other public authorities of the Member States. In particular, the right of access shall not extend to correspondence between the Commission and those authorities. Nothing in this paragraph shall prevent the Commission from disclosing and using information necessary to prove an infringement.

Amendment 78
Proposal for a regulation
Article 21 – paragraph 1

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

Amendment 79
Proposal for a regulation
Article 21 – paragraph 1 – point 1 (new)

Text proposed by the Commission	*Amendment*
	(1) has granted a compulsory licence. It may cancel or amend its terms and conditions;

Amendment 80
Proposal for a regulation
Article 21 – paragraph 1 – point 2 (new)

Text proposed by the Commission	*Amendment*
	(2) has imposed fines or periodic penalty payments. It may cancel, reduce or increase the fine or periodic penalty payment imposed.

Amendment 81
Proposal for a regulation
Article 22 – paragraph 1 – introductory part

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

Amendment 82
Proposal for a regulation
Article 23 – paragraph 1 – point -a (new)
Regulation (EC) No 816/2006
Article 6 – paragraph 2

Present text	*Amendment*
	(-a) Article 6(2) is replaced by the following:
2. If the person applying for a compulsory licence is submitting applications to authorities ***in more than one country*** for the same product, he shall indicate that fact in each application, together with details of the quantities and importing countries concerned.	***2.*** If the person applying for a compulsory licence is submitting multiple applications to authorities for the same product, he shall indicate that fact in each application, together with details of the quantities and importing countries concerned.

Amendment 83
Proposal for a regulation
Article 23 – paragraph 1 – point -a a (new)
Regulation (EC) No 816/2006
Article 6 – paragraph 3 – point c

Present text	*Amendment*
	(-aa) Point (c) of Article 6(3) is replaced by the following:
(c) the amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence;	(c) the ***expected*** amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence;

Amendment 84
Proposal for a regulation
Article 23 – paragraph 1 – point -a b (new)
Regulation (EC) No 816/2006
Article 6 – paragraph 3 – point e

Present text	*Amendment*
	(-ab) Point (e) of Article 6(3) is replaced by the following:
(e) where applicable, evidence of prior negotiation with the rights-holder pursuant to Article 9	(e) where applicable, evidence of ***efforts of*** prior negotiation with the rights-holder pursuant to Article 9***;***

Amendment 85
Proposal for a regulation
Article 23 – paragraph 1 – point -a c (new)
Regulation (EC) No 816/2006
Article 6 – paragraph 3 – point f

Present text	*Amendment*
	(-ac) Point (f) of Article 6(3) is replaced by the following:
(f) evidence of a specific request from: (i) authorised representatives of the importing country or countries; or (ii) a non-governmental organisation acting with the formal authorisation of one or more importing countries; or (iii) UN bodies or other international health organisations acting with the formal authorisation of one or more importing countries, indicating the quantity of product required.	(f) evidence of a specific request from: (i) authorised representatives of the importing country or countries; or (ii) a non-governmental organisation acting with the formal authorisation of one or more importing countries; or (iii) UN bodies or other international health organisations acting with the formal authorisation of one or more importing countries, indicating the ***expected*** quantity of product required.

Amendment 86
Proposal for a regulation
Article 23 – paragraph 1 – point -a d (new)
Regulation (EC) No 816/2006
Article 7

Present text	*Amendment*
	(-ad) Article 7 is replaced by the following:
Article 7 Rights of the rights-holder	Article 7 Rights of the rights-holder
The competent authority shall notify the rights-holder without delay of the application for a compulsory licence. Before the grant of the compulsory licence, the competent authority ***shall*** give the rights-holder an opportunity to comment on the application and to provide the competent authority with any relevant information regarding the application.	The competent authority shall notify the rights-holder without delay of the application for a compulsory licence. Before the grant of the compulsory licence, the competent authority ***may*** give the rights-holder an opportunity to comment on the application and to provide the competent authority with any relevant information regarding the application.

Amendment 87
Proposal for a regulation
Article 23 – paragraph 1 – point -a e (new)
Regulation (EC) No 816/2006
Article 9 – paragraph 1

Present text	*Amendment*
	(-ae) Article 9(1) is replaced by the following:
1. The applicant shall provide evidence to ***satisfy*** the competent authority that he has made efforts to obtain authorisation from the rights-holder and that such efforts have not been successful within a period of thirty days before submitting the application**.**	1. The applicant shall provide evidence to the competent authority that he has made efforts to obtain authorisation from the rights-holder and that such efforts have not been successful within a period of thirty days before submitting the application.

Amendment 88
Proposal for a regulation
Article 23 – paragraph 1 – point -a f (new)
Regulation (EC) No 816/2006
Article 10 – paragraph 1

Present text	*Amendment*
	(-af) Article 10(1) is replaced by the following:
1. The licence granted shall be non-assignable, except with that part of the enterprise or ***goodwill which enjoys*** the licence, and non-exclusive. It shall contain the specific conditions set out in paragraphs 2 to 9 to be fulfilled by the licensee.	1. The licence granted shall be non-assignable, except with that part of the enterprise or ***organisation that makes use of*** the licence, and non-exclusive. It shall contain the specific conditions set out in paragraphs 2 to 9 to be fulfilled by the licensee***.***

Amendment 89
Proposal for a regulation
Article 23 – paragraph 1 – point -a g (new)
Regulation (EC) No 816/2006
Article 10 – paragraph 2

Present text	*Amendment*
	(-ag) Article 10(2) is replaced by the following:
2. The amount of product(s) manufactured under the licence shall not exceed what is necessary to meet the needs of the importing country or countries cited in the application, taking into account the amount of product(s) manufactured under other compulsory licences granted elsewhere.	2. The ***expected*** amount of product(s) manufactured under the licence shall not exceed what is necessary to meet the needs of the importing country or countries cited in the application, taking into account the amount of product(s) manufactured under other compulsory licences granted elsewhere.

Amendment 90
Proposal for a regulation
Article 23 – paragraph 1 – point -a h (new)
Regulation (EC) No 816/2006
Article 10 – paragraph 8

Present text	*Amendment*
	(-ah) Article 10(8) is replaced by the following:
8. The competent authority may ***at the request of the rightsholder or*** on its own initiative, if national law allows the competent authority to act on its own initiative, request ***access to books and records kept by*** the licensee, ***for the sole purpose of checking whether the terms of the licence, and in particular those relating to the final destination of the products, have been met. The books and records shall include*** proof of exportation of the product, through a declaration of exportation certified by the customs authority concerned, and proof of importation from one of the bodies referred to in Article 6(3)(f).	8. The competent authority may, on its own initiative***,*** if national law allows the competent authority to act on its own initiative***, request from*** the licensee proof of exportation of the product, through a declaration of exportation, certified by the customs authority concerned, and proof of importation from one of the bodies referred to in Article 6(3)(f).

Amendment 91
Proposal for a regulation
Article 23 – paragraph 1 – point a
Regulation (EC) No 816/2006
Article 18a – paragraph 1

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

Amendment 92
Proposal for a regulation
Article 23 – paragraph 1 – point a
Regulation (EC) No 816/2006
Article 18a – paragraph 2

Text proposed by the Commission	*Amendment*
2. Any person may submit an application for a compulsory licence under paragraph 1. ***The application shall fulfil the requirements laid down in Article 6 (3) and shall specify the Member States to be covered by the compulsory licence.***	2. Any person may submit an application for a compulsory licence under paragraph 1. ***The application shall contain the following information:***
	(a) the name and contact details of the applicant and of any agent or representative whom the applicant has appointed to act for him before the competent authority;
	(b) the non-proprietary name of the pharmaceutical product or products which the applicant intends to manufacture and sell for export under the compulsory licence;
	(c) the expected amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence;
	(d) the importing country or countries;
	(e) where applicable, evidence of efforts of prior negotiation with the rights-holder pursuant to Article 9;
	(f) evidence of a specific request from:
	(i) authorised representatives of the importing country or countries; or
	(ii) a non-governmental organisation acting with the formal authorisation of one or more importing countries; or
	(iii) UN bodies or other international health organisations acting with the formal authorisation of one or more importing countries.

Amendment 93
Proposal for a regulation
Article 23 – paragraph 1 – point a
Regulation (EC) No 816/2006
Article 18a – paragraph 3

Text proposed by the Commissiont	*Amendment*
3. The compulsory licence granted in accordance with paragraph 1 ***shall be subject to the conditions set out in Article 10 and*** shall specify that it is applicable to the whole territory of the Union.	3. The compulsory licence granted in accordance with paragraph 1 shall specify that it is applicable to the whole territory of the Union ***and shall be subject to the following conditions:***
	(a) the licence granted shall be non-assignable, except with that part of the enterprise or organisation that makes use of the licence, and non-exclusive. It shall contain the specific conditions as set out in this paragraph;
	(b) the expected amount of product(s) manufactured under the licence shall not exceed what is necessary to meet the needs of the importing country or countries cited in the application, taking into account the amount of product(s) manufactured under other compulsory licences granted elsewhere;
	(c) the duration of the licence shall be indicated;
	(d) the licence shall be strictly limited to all acts necessary for the purpose of manufacturing the product in question for export and distribution in the country or countries cited in the application. No product made or imported under the compulsory licence shall be offered for sale or put on the market in any country other than that cited in the application, except where an importing country avails itself of the possibilities under subparagraph 6(i) of the Decision to export to fellow members of a regional trade agreement that share the health problem in question;
	(e) products made under the licence shall be clearly identified, through specific labelling or marking, as being produced pursuant to this Regulation. The products shall be distinguished from those made by the rights-holder through special packaging or special colouring or shaping, provided that such distinction is feasible and does not have a significant impact on the price. The packaging and any associated literature shall bear an indication that the product is subject to a compulsory licence under this Regulation, giving the name of the competent authority and any identifying reference number, and specifying clearly that the product is exclusively for export to and distribution in

the importing country or countries concerned. Details of the product characteristics shall be made available to the customs authorities of the Member States;

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

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

(ii) the distinguishing features of the product or products concerned.

The website address shall be communicated to the competent authority;

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

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

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

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

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

(j) the licence conditions are without prejudice to the method of distribution in the importing country.

Distribution may be carried out for example by any of the bodies listed in Article 18a (2), point (f), and on commercial or non-commercial terms including completely without charge.

Amendment 94
Proposal for a regulation
Article 23 – paragraph 1 – point a
Regulation No 816/2006/EC
Article 18a – paragraph 5 – subparagraph 2

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

Amendment 95
Proposal for a regulation
Article 25 – paragraph 1 a (new)

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

Amendment 96
Proposal for a regulation
Article 25 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	In case of exceptional threats to public safety or to national security, the Commission shall carry out the assessment pursuant to paragraph 1a without undue delay.

Amendment 97
Proposal for a regulation
Article 26 – title

Text proposed by the Commission	*Amendment*
Entry into force	Entry into force ***and application***

Amendment 98
Proposal for a regulation
Article 26 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	It shall apply from [the first day of the month following the period of twelve months after the date of entry into force].